PART FIVE

CONTROLLING RISK – THE CURRENT METHODS AND AN ALTERNATIVE PARADIGM

CHAPTER TWELVE

PERCEPTION, DECISION MAKING IN UNCERTAINTY AND CONTROL OF HEALTH RISKS

12.1 Health hazards and effects and their control

12.1.1 Perception of the problem

12.1.1.1 Relativity and perception

In Part 2.0 and Appendix 1 the way the general pattern of human disease and how its prevention was perceived was seen to shift in the USA in the 1920s and 1930s. By the mid 1930s infectious diseases such as TB, while still seems as important causes of morbidity and mortality in the working population, were being displaced in the league table by others such as silicosis. And the character of the diseases of occupation was also changing. While acute poisonings and deaths still occurred their prevalence, by the 1930s, had fallen away. Exposures in the work environment caused or exacerbated chronic degenerative diseases and these effects became visible because the acute effects of workplace exposures were coming under control and infectious diseases were becoming less important causes of death.

The sanitary engineers in the USA could see that their engineering, preventative approach to control of infectious hazards worked. Indeed, at the time when sanitary engineering came into being, it was the only option available, and that it worked has been well demonstrated. McKeown examined the fall in death rate from 1841, when records were first kept to 1971 and the results of his analysis are shown in Figure 12.1. McKEOWN (1979). He estimated that "... 86% of the total reduction of the death rate from the beginning of the eighteenth century to the present day was attributable to the decline of infections." Moreover, "it is unlikely that treatment had any appreciable effect on the outcome of the diseases before the use of intravenous therapy in the 1930s, by which time 95% of the improvement had occurred. For the main explanation of the fall in mortality ..." we must look to the hygienic measures which reduce exposure..." and better nutrition resulting in populations which are more resistant when infection occurs. While McKeown brought this understanding to a wide public audience in recent years the basic tenets were clearly understood and espoused by powerful sanitary engineers at the turn of the century in the USA such as Whipple and Wilmslow.

Some sanitary engineers became concerned with health hazards in the workplace and wished to apply the same preventative approach. Non-medical IHs followed in this tradition. In the USA at least in the 1920s and 1930s the perception of the problems of occupational health hazards and effects changed.

Due partly to actual changes in disease patterns and prevalence, partly to the perception of professionals such as Hayhurst and Bloomfield and partly to the growth of the new professions, non-medical IH and IT. These last two, in the shape of key individuals like Bloomfield, Patty, Smyth (Junior) and Hatch appreciated the change, saw the future for their professions and seized the time. How this came about has already been examined; that it took almost two decades longer in the UK is due in part to the slow and halting development of IH (and IT) in this country.

Figure 12.1 Decline in mortality-death rates (standardised to 1901 population) England and Wales, (taken from McKeown, (1979)).

Against this backcloth of actual and perceived change other changes were occurring in industry. Some data have already been quoted and more recent data confirm the explosive growth of the US chemical industry starting in the 1920s (see Figure 12.2 taken from CORN (1983)). A similar but perhaps slightly muted growth occurred in the UK. For professionals and others in the 1920s and 1930s not only were the causes of morbidity and mortality changing but the growth of the chemical industry and the more widespread use of new chemicals reinforced the belief, particularly amongst IHs and ITs that control of exposure to these agents was the biggest challenge facing the occupational health professions. Bloomfield, Patty and a few others were quite explicitly on this point.

Figure 12.2 growth in US population and chemical production (taken from CORN (1983)).

In addition to these quantifiable charges there were and there continues to be changes in the way aetiologies and effects are seen. One such shift in view was the examined earlier in chapter "5" when a number of factors combined to create a challenge to the OEL paradigm.

The environment in which the various occupational health professional species operated was changing in the 1920s and 1930s and this change was perceived and broadcast by certain professional species particularly IH and IT and a few far sighted individuals in other professions. Perceptions changed most in those professional species which had most to gain from the changing environment. A general argument could be made that the perception of a profession in a changing environment is mediated by the degree to which that species is in a position to address that change – whether the change is occurring within the environmental range of the professional species.

The pattern of health hazards and effects in and out of the workplace has changed over this century and went through a particularly important shift in the present context in the 1920s and 1930s. But the picture was and will be painted differently depending upon the professional species holding the brush.

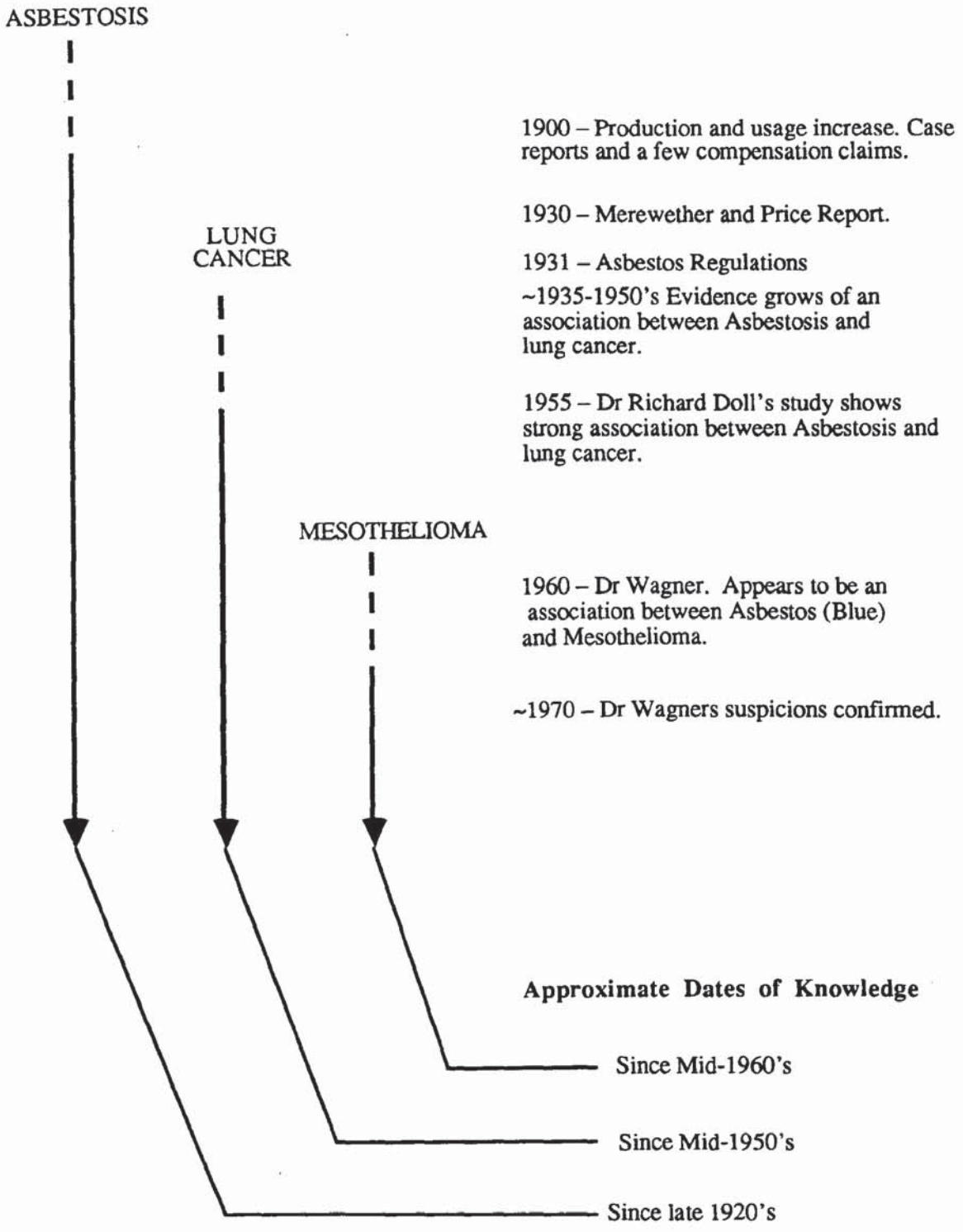

Figure 12.3 Evolution in the perception of the main asbestos-related diseases

Moving trigonometric points on the map of morbidity and mortality create a changing and relative backcloth and professional, species – bound views, add to this relativity.

12.1.1.2 Examples of changes in perception of risk

The example of asbestos is one of the best illustrations of the changes this century in perception of occupational health risk. Figure 12.3 summarises the evolution of our understanding of the health effects which asbestos could cause. The pattern is the same each time: case reports followed by increasingly secure evidence through confirmation, general acceptance and preventative action which took decades for each disease.

In the first two decades of this century it became clear that asbestos exposure caused a lung disease but the disease was not exactly the same as silicosis. Also, many afflicted contracted TB and it was felt by some that asbestos dust merely weakened the lungs and laid them open to the TB bacillus. By the time Merewether and Price published their investigation the term "asbestosis" had been coined and it was recognised as a separate and specific disease associated with exposure to asbestos dust. However, almost from the start of the enforcement of the 1931 Asbestos Regulations and the associated compensation scheme the picture began to change. Individual case reports suggested a link between asbestos exposure, asbestosis and lung cancer as early as 1934 and by the 1940s the connection was regarded as strong by some including Wyers who worked for Turner and Newalls' (UK) and the FI by 1947. Wyers's work is both interesting and apocryphal. He was concerned with the effectiveness of the 1931 regulations in preventing asbestosis but also examined other asbestos related diseases. He concluded "... evidence already accumulated seems to favour a causal connection between asbestosis and pulmonary cancer and humanitarian motive may decide the public conscience not to wait for scientific proof before insisting on more stringent safeguards against dust inhalation." WYERS (1946).

A little later he suggests that, "the result that asbestos can cause cancer is a plain warning to use to the full such engineering wit as is available to suppress dust, whereby asbestosis certainly will be abolished and perhaps some cases of cancer prevented." Ibid.

In the conclusions he summarises his view of how the asbestos related disease has changed:

"As a result of legislation (1931 Asbestos Regulations) biological changes have occurred in the disease itself. The original type of acute disease which killed in a year or two after an exposure of a few months, has given place to a disease which is protracted and consequent on many years of exposure." Two sentences on he summarises his view and asks an astute and with the wisdom of hindsight a horribly accurate question: "If the acute disease has merged into the chronic, is the chronic disease merging into the neoplastic?" Ibid.

A year after Wyers submitted his MD thesis the FI published its own parallel study confirming that people with asbestosis had an increased incidence of lung cancer. However the link was not regarded as definitive until Doll's study, DOLL (1955). Even so the Medical Review Committee, already quoted, in 1967 could only hope that controls applied to deal with asbestosis would reduce the lung cancer risk and the BOHS side stepped the issue by pleading that there was no decent dose-response data. It was not until the later 1970s/early 1980s that the problem of lung cancer caused by asbestos exposure was clearly addressed. Wyers was right, "the chronic disease had merged into the neoplastic." but wrong about the "public conscience", it did wait for the scientific proof before..." insisting on more stringent safeguards", it waited close on four decades. The learning curve as regards mesothelioma was more compressed and because of public concern in the USA and the UK in the 1970s and 1980s preventative action was more rapid. Russell, in his essay "Asbestos – a failure?" summarises the position by the late 1960s and the problem this posed for the inspectorate:

"The relevance of this information to the inspector in the field took some time to sink in. Asbestos had suddenly ceased to be a fibrosis risk roughly on a par with the silica risks of potteries or steel foundries and had become a material requiring the highest possible standards of industrial hygiene. It required a considerable jump in inspector thinking to adopt the urgency now necessary in the approach to asbestos problems." RUSSELL (1983).

Apart from his contention that the knowledge that, asbestos was carcinogenic as well as fibrogenic, was "suddenly" revealed this quotation captures neatly the problem that faced industry, enforcing authorities and the professions in the field.

Asbestos illustrates the way perception of occupational health hazards have changed in the US and UK this century. At first its effects were bound up with infectious hazards such as TB. Then its more acute effects were differentiated – the fairly rapid onset of asbestosis, and this was regarded as the only health effect that required prevention until the 1950s when lung cancer became added to the list. With asbestos there were not truly acute effects and the first health effect noticed was not related to the other effects revealed later. With other substances the focus changed from acute to chronic effects but these two effects were still related, lead and its effects being a good example. At the turn of the century there were upwards of 2,000 reported cases of lead poisoning in the UK which resulted in significant numbers of deaths due mainly to lead encephalopathy. Nowadays acute lead poisoning is a rarity in the UK but the concern is still with the effects of low level lead exposure on the nervous system and the CNS. There are other examples of both types of relationship, see Figure 12.4, and the process continues. The process consists of a mixture of controls applied reducing the more acute effects, revealing the chronic and latent , resulting in an alternation in our perception of the health effects a substance can cause. It is salutary to recall that there is a large element of perception in this equation, that the substances revealed to have additional unsuspected health effects or effects at lower levels than was appreciated have been inducing the full range of health effects ever since they were first used.

Figure 12.4 Changes in hazard perception

Substance	Early perceptions	Later perceptions
Mineral oil (by inhalation)	Irritation	Irritation and asthma
Mercury	Acute CNS damage	Chronic CNS damage
Wood dust	Irritation	Irritation, allergy and nasal cancer (hardwood dust)
Benzene	Narcosis and acute haematological effects	Leukaemia
vinyl chloride monomer	Narcosis	Angiosarcoma
Formaldehyde	Irritation	Irritation, allergy and cancer (?).

12.1.1.3 Change in perception of adequate control

It would be easy to tidy up history and argue that as perceptions of the health effects a particular substance caused were clarified, and were seen to be more serious than had been appreciated, then the controls applied to reduce exposure became more stringent. From the analysis in the earlier parts of this work this is clearly not the case or at best is partially the case. Benzene and lead are good examples of how perception of risk and perception of adequate control interact.

On benzene, Winslow's committee decided in 1926 that 100ppm was the lowest level that could practicably be obtained with rubber coating, the most difficult process to control. The National Safety Council's (NSC) Working Party (chaired by Winslow) was also clear that there were known serious health effects including death for some at this level of exposure. The NSC's practicable level of 100ppm became transmuted into an OEL of 100ppm by Sayers and Dallavale and Cook in the USA, Browning in the UK and many others. By a process of substitution, recommended by the NSC, and better controls, benzene exposure was reduced and the quoted OEL fell to 30ppm by the 1940s. Benzene was known for its chronic toxicity and it probably came as no surprise to many involved in the field to learn that benzene also caused leukaemia. The pressure to reduce exposure still further increased. In 1926 100ppm was a practicable limit determined by the capabilities of the then current control technology. Once benzene had been singled out as a "toxic substance" there was an interaction between perception of risk and adequate control. Sometimes perception of risk pushed control and at other times control led, in the sense that exposure were brought considerably below the contemporary OEL. This would appear to be the position nowadays with benzene. Exposures are kept below 1ppm

for most jobs (see CONCAWE (1986)) and yet the OEL remains at 10ppm in the UK, FBR and until recently the USA.

Lead illustrates a slightly different pattern of interaction. In 1912 Legge proposed a limit of 0.2mg/m3 to prevent "... the onset of chronic plumbism..." but the concern at the time was with exposure way above this level. The control methods could not reduce exposure sufficiently and in a sense public and professional perceptions of lead and its typical health effects became defined and perceived by the capabilities of the control technology. It took several decades for lead substitutes, process changes and reliable, effective, routinely applied control technology to make headway. As this mix of controls was applied recorded lead poisonings plummeted (see WILLIAMS (1983)). The problem is now one of chronic effects, effects which existed before but did not occupy centre stage and were hardly perceived except by visionaries such as Legge.

Similar stories could be told for silica and cotton dust and many other substances. Though the pattern varies from substance to substance there are common and identifiable elements. One of these elements is that control standards tend to become fossilised with or without the help of an equally fossilised 'safe OEL'. The temptation of academic consultants, enforcing authorities and industry is to go along with the demands of what Drinker called the "practical men", who wanted to know what the safe level was and therefore when enough control had been applied. And time and again the perception of the problem has been fitted in with the capabilities of the then current control technology or the control technology and its concomitant exposures have tended to define what health effects were 'tolerable' or 'acceptable' or even normal and immutable. Even though Drinker felt compelled to offer the "practical men" an achievable limit for silica dust of 20mppcf he also felt ambivalent and knew that this limit would not prevent silicosis. It would offer some protection and he was in effect making his peace with what he judged to be the most practicable control technology at the time. By doing so he defined the risk as being acceptable and the control technology as being adequate.

The interaction between perception of risk, practicability and adequacy of control is a fundamental reality of OEL setting. Yet it is not made explicit in the OEL paradigm. It is a fundamental and fatal contradiction which any alternative paradigm must reconcile and accommodate.

12.1.2 Present perceptions

12.1.2.1 The size of the risk

"The available national statistics relating to industrial diseases are of little help as a means of monitoring current situations or in the identification of newly emerging hazard.." p.137 GREAT BRITAIN (1972a) "Robens Report'

A general analysis of occupational mortality in the UK suggested that 12% of cancers, 32% of circulatory disease and 28% of respiratory disease were related to work, FOX and ADELSTEIN (1978). Overall, including accidents this paper suggested that about 18,000 deaths per year were work related. Whereas another estimate based on a Finnish report puts the figure at around 8,000 deaths per year ,GEE (1986).

In 1975 the WHO estimated that work related cancer represented less than 1% of the total. In 1977 OSHA put the figure at between 1 and 5%. In 1978 OSHA released a report based on work done at the NCI and NIOSH which claimed that between 21 and 38% of cancer was occupationally related (see BRIDBORD et al (1978)). The study, in retrospect was fatally flawed and a more considered estimate requested by the US Congress's office of Technology Assessment, was published by Doll and Peto in 1981. Their estimated "The proportion of cancer deaths that we have tentatively attributed to occupational causes is ... about 4% of all cancer deaths". DOLL and PETO (1981). Translated to the UK that represents 130,000 x 0.04 = 5,200 cancer deaths per year.

The 4% risk is not spread evenly across the UK workforce, it is located principally in the lower two social classes which do the majority of manual work. And within these two social classes the risk is located in certain industries and jobs within those industries. The risk for those "at risk" groups may well be 10+%.

However, if one turns to the official UK data based on DHSS death benefit claims a different picture emerges, Table 12.1. It is clear that the current data grossly underestimate the true toll of occupationally related mortality. A graphic example is obtained by comparing the DHSS claim statistics for mesothelioma with the national data for this disease. Assuming that most of the mesothelioma is caused by asbestos exposure at work one can calculate the degree of under reporting of this disease, Table 12.2. Up to the mid-1970s the DHSS scheme only accounted for a small proportion of the actual cases. More recently the proportion of the total has increased to 40%. This is mainly due to greater public and medical consciousness and must also be aided by a knowledge of the total size of the problem. With most other diseases, barring the pneumoconioses, there are no national estimates of the approximate proportion of work related ill health by type of disease. The amount of work related lung cancer or asthma or bronchitis is unknown. And the DHSS compensation scheme which recognises a connection

between exposure in a certain trade or to a certain substance is so closely drawn as to be of very limited use for estimating the size of the work related proportion.

Table 12.1 Social Security act industrial death benefit figures (1972-1986)

Late	Number of Deaths
1972	771
1973	705
1974	706
1975	777
1976	690
1977	751
1978	736
1979	778
1980	763
1981	756
1982	782
1983	780
1984	676
1985	931
1986	874

Table 12.2 Under reporting of mesothelioma*

Year	Mesothelioma on death Certificate (1)	Mesothelioma death benefit (2)	Proportion $(\frac{(2)}{(1)} \times 100)\%$
1968	154	27	18
1969	159	22	14
1970	192	18	9
1971	178	24	13
1972	211	22	10
1973	223	28	13
1974	245	41	17
1975	271	78	29
1976	315	94	30
1977	336	109	32
1978	390	109	28
1979	434	128	30
1980	458	108	24
1981	472	175	37
1982	504	190	38
1983	573	201	35
1984	622	245	39
1985	615	279	45
1986	695	265	38

* Based on HSE (1989b).

Mesothelioma is a rare disease strongly associated with exposure to asbestos and yet until recently DHSS figures grossly underestimated the size of the problem. With relatively common diseases such as lung cancer, asthma and bronchitis the occupational connection is even less likely to be made.

12.1.2.2 The shape of the problem

Getting to grips with the effect of occupation, particularly the effect of chemical exposure in the workplace is difficult. Assessing the potential effects of chemical usage might be thought to be an easier task. Mendeloff quotes the US National Research Council which estimates that roughly 53,000 chemicals are in regular use and almost 1,700 are added to this total each year, MENDELOFF (1988). The Organisation for Economic Co-operation and Development (OECD) take a slightly different view: "the total number of existing chemicals is enormous. Among the five million entities listed by the chemical Abstracts Service Registry, more than 80,000 chemical are produced commercially." OECD (1986). However Mendeloff also point out that figures like these are deceptive. Worker exposure is unlikely to have increased at the same rate as the earlier figures from Corn and Gerarde would suggest. Thus, for instance, sulphuric acid is by far the leading single chemical in production by volume, representing 5% of the total, yet 96 OSHA inspections between 1979 and 1981 found only 9 workers exposed above the PEL. Tonnage or volume or crude numbers cannot be used to give a good estimate of likely increase or decrease in exposure. Additional knowledge on the process involved, the physical form of the substance and other factors are required. There is no simple method of determining whether the position is getting better or worse. Mendeloff concludes that: "... in view of the increase in the total number of chemicals and the uncertainty about their toxicity ... we do not know whether the **combined** threat from all toxic exposures is declining." Ibid (Emphasis in the original).

This author argued that OSHA should go for less strict but more extensive standards. He acknowledged that his "... policy prescription may not be attractive if the world is characterised by a few hazards for which large reduction in exposure will bring major benefits and many hazards for which even moderate reductions would bring little benefit." Ibid.

Later he argues that it is highly unlikely that the world of toxic chemicals at work is characterised by a few recognisable bad actors amongst a cast of innocent thousands. With this view the current author agrees. It seems more likely that the stage is populated by some clearly bad actors plus many more bad to middlingly bad yet unrecognised actors. There is also the problem of attributing blame where exposure is complex and where exposure to no one substance appears excessive and yet health effects are identified as is the case for rubber fume and dust or steel foundry fume exposure, picking out the "bad actors" from amongst a soup of chemical species becomes under these circumstances, an almost impossible if not a fruitless task. Even so, for the majority of circumstances where exposure is not so complex there is still the problem of identifying unrevealed bad to middlingly-bad actors.

12.1.2.3 Identifying hazardous substances

Figure 12.5 illustrates the information which exists and is needed to assess the health hazards of various categories of chemical substance. The figure is taken from stratified NAS study initiated in 1980. The NAS committee found that for only 36% of pesticide ingredients, 39% of pharmaceutical compounds and 20% of food additions was there even minimal data. For these same three categories there was no toxicity information at all in 38%, 56% and 46% of cases. For "chemicals in commerce" the position was even worse, for some 80% there was no toxicity data, for 20% there was some data and for 10% there was enough data for a "partial health hazard assessment." Interestingly and perhaps going against what one might immediately assume information was no more abundant for high compared with low production volume chemicals. The NAS analysis is based on extrapolation from a small sample to the "entire universe of chemicals" but even taking the 90% upper confidence limit from the study this still means that for only 30% of "chemicals in commerce" is there minimal toxicity information. One author summed up the implications of this study thus:

"For the process of standard-setting the implications of findings such as (those of the NAS) are sobering to put it mildly". SCHRECKER (1986).

Figure 12.5 Availability of information for health hazard assessment (taken from NAS (1984))

Another difficulty that standard setters face is the inherent insensitivity of animal experiment. This was well illustrated by the results of the so called "megamouse" experiments, in which over 24,000 mice were used to examine 2-acetylaminofluorene (2-AAF), a known carcinogen. The objective of the study was to discover the effective dosage which would produce a 1% tumour incidence and enable the research workers "... to study the shape of the dose response curve with precision about one order of magnitude greater than generally obtained by amount carcinogenesis screening studies." CAIRNS (1980). 2-AAF was found to cause bladder cancer with a steep curved dose-response curve and liver cancer with a much flatter linear dose-response curve. The study ran over the entire lifetime of the mice and found that bladder cancers occurred considerably before liver cancers yet the latter, at low dosages, had killed more mice by the end of the experiments. On the question of sensitivity one of the team summarised the position:

"For animals sacrificed at 18 months, liver tumours were observed in 5.8% of the animals at the highest dosage level tested. Had a typical number of 50 animals been used, and had the study been terminated at 18 months ... liver tumours would have gone undetected. Thus, the tumour end point which posed the greatest risk at low doses would have been overlooked. In fact, even bladder tumours would not

have been detected by 18 months with 50 animals except at the highest dosage of 150ppm. The results indicate the need to conduct mouse studies for more than 18 months." GAYLOR (1980).

Before the megamouse experiments animal based carcinogenesis in studies tended to sacrifice at 18 months and some used only 2 dose levels. It was also proposed by others that dose levels should be more realistic, closer to equivalent human exposure levels. After the megamouse experiments it was clear that dosing and observation should continue when using mice past 18 months, and generally for the major part of the test animals life span. The tests also demonstrated that several dose levels should be used; that the No Observed Effect Level (NOEL) was highly dependent on the size of the test population and length of follow up and high dose levels were essential and defensible in order to increase the sensitivity of the tests, at least for substances with a similar action to 2-AAF. And even so the tests were concerned with identifying the ED01 - the dose which would produce a 1% tumour incidence - a completely unacceptable rate in a human population. The tests confirmed that a lot of earlier animal based carcinogens studies were insensitive and a significant number were flawed in other ways.

If the toxicological data are not available in the right quantity or, in some cases, of the right quality perhaps epidemiological studies of exposed human populations exist to fill the gap.

Volumes 1-20 of the IARC monographs reviewed 442 chemicals, groups of chemicals and industrial processes. Of these there were 142 chemicals or groups of chemicals with "sufficient evidence" of carcinogenicity in animals. Ten were judged by IARC to be carcinogenic in animals and humans. A group based at Mount Sinai School of Medicine reviewed the remaining 132 and determined that in 21 cases there was adequate epidemiological evidence to make a judgement KARSTADT et al (1981). Of the 111 cases left 75 related to substances or groups of substances used in the USA. Letters were sent to suppliers and it was determined that 23 out of the 75 were under some sort of epidemiological review, 8 of the 23 were considered to be "completed epidemiological studies". Of the others not under any kind of review various reasons were offered including:

1. Insufficient time lapse since first exposure.
2. Small workforce.
3. Tracing difficulties.
4. Small usage or little/no exposure.
5. Miscellaneous – mainly "chemicals ... did not pose health hazards".

Some of these reasons were judged to be valid and others perhaps surmountable. However, the authors conclude:

"Given the obstacles to performance of ... studies, it is unlikely that many of the remaining chemicals could be studied by epidemiological techniques .... In these circumstances, animal data represent the best available information ..." Ibid.

The evidence from this study suggests that epidemiological studies are unlikely to fill the gaps where the toxicological data are missing. Indeed epidemiology cannot be used in certain circumstances (eg. 1 and 2 above) and toxicological assessment is the only method for assessing human risk. And epidemiology shares a similar statistical limitation to animal tests and that relates to statistical power, which two authors recently defined thus: "... power quantifies the ability of a particular study to detect an excess risk that truly exists". BEAUMONT and BRESCOW (1981).

The power to detect a risk increases as the number of expected deaths increases which in turn is "determined by the size of the exposed population and the size of the relative risk. There is a tradeoff with a large, well defined, population a study can have high power (80-40%) and detect a relatively small increase in risk. Conversely a study population can be relatively small and yet the power of the study can be maintained if the risk is high. What causes confusion is where the study population is quite small, the relative risk of interest is also small and thus the power of the study is low (though with a group of studies the position can be improved by combining and careful comparisons - see ibid).

In 1980 OSHA, as part of its generic policy on cancer stipulated that "the group of exposed subjects (should be) large enough for an increase in cancer incidence of 50% above that in unexposed controls to have been detected at any of the predicted sites." (Quoted in HAINES and SHANNON (1983)).

Two authors recently applied these criteria which are essentially concerned with statistical power to 33 occupational mortality studies publish in Journal of Occupational Medicine and British Journal of Industrial Medicine between 1979 and 1980. They found, "... that a large proportion of SMR studies have a low probability of detecting ... an increase in the incidence of disease or of cancer at predicted sites of 50% above that among unexposed subjects." HAINES and SHANNON (1983).

Yet they also point out that the OSHA criterion are not without their problems: "it is often argued that confounding variables could account for increases of up to this magnitude (50%)" and that "... for some causes of death, such increases are not usually detectable by epidemiological methods." And they put their finger on a real problem for regulators: "on the other hand, true increases of 50% in cancer risk could translate into large numbers of cases among workers exposed to widely used agents." Ibid. For instance if 100,000 people were significantly exposed to asbestos and this exposure increased their relative risk of contracting lung cancer by 50% (ie. from 10/100 to 15/100) this would equate to an increase in early deaths from 10,000 to 15,000.

Doll and Peto summarised the position of the conscientious epidemiologist:

"Unless epidemiologists have studied reasonably large well-defined groups of people who have been heavily exposed to a particular substance for two or three decades without apparent effect, than can offer no guarantee that continued exposure to moderate levels will, in the long run, be without material risk. For this reason, restrictions on occupational or public exposure to various substances often have to be based on indirect inference from laboratory studies of the agent being examined, without any direct evidence concerning its actual effect upon humans. DOLL and PETO (1981).

The evidence would suggest that perception of the size of the work related morbidity and mortality problem is, and always has been a fragmentary underestimate. Also the evidence of potential for harm from toxicological and epidemiological studies in the 1940's and 1950's would have been even less than is available nowadays. Past studies in the 1940's, 1950's and 1960's were less sophisticated and sensitive and were, and still are, the basis of many TLVs.

The underestimate of the size of the problem led to complacency especially in the UK where national statistics seemed to indicate that the problem was under control or at least its shape and size were understood.

The lack of understanding of the shape of the problem meant that certain effects drew disproportionate attention. Wyers was right when he foresaw asbestos diseases changing, "... the chronic disease (pneumoconiosis) merging into the neoplastic" WYERS (1946) but for many, bolstered by the national statistics which only registered asbestosis, the problem had not changed. This capturing of peoples vision by the available statistics is perhaps natural, however it has prevented or slowed preventative action and distorted the perceptions of people working in all organisations concerned with the problem.

For the great majority of chemicals in commercial use there are inadequate data for risk assessment.

Those who prefer human evidence when making a judgement are faced with a number of inter-related problems, apart from the moral and ethical questions of allowing exposures to continue which may prove a significant risk. Firstly there is the lack of epidemiological studies which Karstadt and co-workers study demonstrated. Secondly there is the impossibility of performing studies, for instance where a substance is newly introduced or the exposed population is relatively small and/or is widely and sparsely scattered. And thirdly there is the low power of many studies to detect significant risks. In many instances the epidemiology has not been done, or that that has been is insensitive or it is not possible to conduct meaningful studies. In these circumstances, particularly the latter, the only way of making a risk assessment is via the use of toxicological testing. And, here we come full circle to the position that there are toxicological data for altogether far more substances than there are epidemiological data, there is still a great lack of knowledge. And this is even without considering the questions raised by the megamouse study and other critiques of current routine testing regimes.

Identification of substances hazardous to human health has always been difficult. This sub-section throws some light on current perceptions, as characterised by the author. But it also reflects some light

back onto the past, the era of TLV setting and the practice of the ACGIH and other OEL setting committees.

12.1.3 Risk, cost and practicability

12.1.3.1 Is there any difference between reasonably practicable and practicable?

In the UK the phrase "as far as is reasonably practicable" (AFARP) is used repeatedly in modern post Health and Safety at Work Act legislation. It is supposed to mean that the employing organisation or inspector balances the risks to health (or safety) against the costs of control. In theory, if the risk of exposure is found to be higher than was previously thought or the cost of control falls then the risk versus cost balance point moves and the exposure to a health (or safety) risk falls. Although other countries may not use the specific phrase AFARP in their legislation most, if not all, use the concept in setting health and safety standards including OEL's, for instance (they make use the term cost-benefit).

The phrase "as far as is practicable" (AFAP) in the UK has more force in law and is supposed to signify a more absolute duty. Broadly speaking it would appear to be equivalent to the USA's "as far as is technically feasible". It is regarded by enforcing authorities such as the FI as easier to enforce an AFAP duty compared to an AFARP, in that there is much less argument over what the organisation or individual should do, the judgement is more open and shut – there is less potential legal argument.

But in the context of OELs is there really a great difference between AFARP and AFAP? The answer is, NO not often because there are very few, if any, examples where AFAP is not in fact a graded form of AFARP. Almost always judging AFAP involves a judgement on the size and the type of risk being controlled because practicability or technical feasibility are elastic concepts. In any particular circumstance there are grades of practicability which get harder to attain as the control technology is pushed further and further. Which grade is chosen depends on how important it is to control the risk and this, in turn, depends upon perception of the size and quality of risk. Although the balancing of cost with risk is not as overt as with AFARP it is still present. Even Winslow's grinding dust OEL examined in Part 3 was not based purely on practicability – if there had been no judgement on risk and that it was in some way significant, Winslow and his colleagues would not have bothered to consider control measures. He may not have had any quantitative data but he had enough belief that a health hazard existed and that control should be improved to embark and complete his research project. The risk, to his mind, must have been big enough.

12.1.3.2 "It's the same the whole world over..."

"... explaining that she was always willing to accept half a loaf rather than no bread, she agreed to a standard for benzene that was considered unacceptably high by two colleagues, on the grounds that the standard could be realised practically while a more rigid standard would be rejected, and we should be left with no standard at all." (Alice Hamilton – quoted by SICHERMAN (1984)).

Following on from the important point made in the last sub-section it is worth reiterating that in the judgement of AFARP and as the paradigm demands a single OEL number, the practicability of control, for certain processes, weighs heavily and anchors the definition of AFARP to a narrow range of numbers. The anchoring effect of practicability has been seen again and again in this thesis in a range of guises:

(i) In Winslow's early forays into standard setting.

(ii) When Drinker was selecting a permissible level of dust for silica.

(iii) In the process of the ACGIH and very clearly in the process of ACTS when setting Control Limits (now Maximum Exposure Levels).

A great deal of effort is put into setting single number OELs by many countries and several international bodies. Yet, for the same substance, they tend to arrive at the same or a similar number – Why?

Partly because one committees decision anchors the other to a certain limited range of numbers – the ACGIH, DFG, ACTS, OSHA and the Swedish Commission cannot and do not move too far apart. And when a new substance is considered, because it is found to be carcinogenic in a variety of short term tests, it is considered in the light of substances with similar effects and similar physico-chemical properties and by reference to the OELs set for such substances. The mutual anchoring of expert, and indeed non-expert, committees and the past judgement of such committees is a very real effect. But for the majority of OELs which are, as discussed earlier, reasonably practicable, the element of practicability exerts the greatest anchoring effect. It is possible to assert this based on the previous analysis and the mechanism would appear to be based on how risk and practicability are perceived. In the mind of the OEL setting committee, those that set reasonably practicable OELs, the assessment of risk is always far more vague and less tangible than the assessment of practicability and cost – a point that will be returned to shortly.

The discussion of the apparent differences between AFARP and AFAP can be extended to another related and pertinent area and that is the apparent differences in philosophy and approach when developing and applying performance and specification standards.

12.1.3.3 USA compared with UK – real or imagined differences?

There has been and continues to be a debate about performance and specification standards - which works best and which is politically and economically preferable. The two types of standard are defined as follows:

Performance standards are, as the name implies, a set of goals or objectives, often quantitative, which the regulated body or organisation is supposed to meet. True performance standards say nothing about how they should be met – OELs are a form of performance standard.

Specification standards are far more complex and often specify in considerable detail exactly what the regulated body should do.

Performance standards are said to appeal to governments in federal countries (see BRICKMAN et al 1982) that wish to control exposure but for political and economic reasons do not wish to, and are not able to, intervene in industry's workings in a direct way. They appeal because they appear to represent the least interventionist, most hands-off method of control. They are supposed to suit market economies and allow, and even encourage, innovation in control methods. The US Federal Government is often described as favouring such standards and OSHA and ACGIH OELs certainly appear to fit the bill. In contrast European countries such as the UK and the FDR were said to favour detailed specification standards. There is truth in these views though they are a gross simplification. Various US states have developed and used very detailed specification standards as has OSHA, and the FDR and more recently, the UK have both developed OELs. The UK since the HSW Act and especially in the 1980s has moved very strongly in the direction of general enabling, performance based regulations. The picture is not black and white. But then neither are performance and specification standards when applied to control of chemical exposure in the workplace. The perception that pure performance standards exist which are non-intervention and pure specification standards exist which are very interventionist is a fiction certainly as regards OELs. It is clear from the analysis of OEL standard setting that there is no absolute separation of performance and specification standards, in fact the two are invariably intimately linked.

TLVs and MAKs in fact most OELs in the West (and many in the East) are balances between risk, practicability and cost. As was described in Chapter 9 (9.2.4.1), the focus is usually on the balance as regards one process, often in one industry. The debate revolves around the practicability of control within a certain, relatively narrow, range of exposures. It is resolved in what becomes well tramped territory and well worn arguments. The styrene OEL examined in Chapter 11 is a good example. Application of good general ventilation and some form of push-pull exhaust ventilation would control

exposure down to the 25-50ppm range in all circumstances except where people had to work inside boat hulls. In effect the performance standard (OEL) became restricted to numbers ≥ 25ppm due to the limitations of the control technology applied to GPP boat building. At this point it is useful to consider how the OEL (25-50ppm or 100ppm in the case of the UK) will be monitored or enforced. Company or consulting IHs and state inspectors, such as the UK FI, will examine the process, the control technology, its state of repair etc. and compare what they see with what they know, from previous studies and guidance, should be in place to keep exposure below 25ppm or 50ppm or 100ppm. Sometimes air sampling will be conducted but in a sense this is icing on the cake if the relationship between control technology and exposure is well understood and characterised. The IH or enforcing authorities are using a specification standard approach to police a performance standard. Indeed the performance standard (OEL) is strongly influenced by arguments about practicability, often very detailed arguments about how well a particular set of control technologies will work on a certain process. The performance standard sometimes pushes the control technology and therefore the eventual specification standard ("technology forcing" as it is called in the USA) but more often than not the practicalities of control anchor the performance standard (OEL).

This reality is overt and public in the case of ACTS and implicit, and more so nowadays explicit, in the case of ACGIH.

There is a strong practical argument in the public and private sectors amongst enforcing, advising and auditing agencies, for translating performance standards into specification standards. In the UK in particularly, (but also clearly present in OSHA and NIOSH rule-making policy), as has already been pointed out the whole ethos of the FI was and largely still is specification standard orientated: Is it GRP boat building? Yes; Is there adequate general and exhaust ventilation? Yes; Is PPE, of a certain type, supplied and correctly worn for in-hull work? Yes. Decision = control deemed to be adequate. This specification approach is far less time consuming, from the inspectors or auditors point of view, than the measurement and process and data evaluation followed by control recommendations path which a performance standard would imply.

Enforcement, consulting and auditing authorities not only want standards, which are reasonably practicable, a point already made, but they want standards which are policable. The pressure from such bodies to translate performance standards into specification standards is nigh on overwhelming and it is not too difficult given that the performance standard pedigree contains a large if not dominant element of specification standard in the first place.

There are very important lessons to be drawn from this discussion which will be picked up in the next chapter but this is a useful point at which to consider an interesting and pertinent question: Has the US system, with its emphasis on performance standards, led to safer working conditions than the UK

system with its emphasis (in the past at least) on specification standards? This question itself leads to the more general question: Are performance standards better than specification standards do they result in safer working conditions?

A general answer to the first question is almost impossible to give because the answer varies depending on whether one compares the UK and the USA as a whole or, individual states.

On the face of it, if US OELs were enforced and companies followed the ACGIH dictums ...

"Enlightened industrial hygiene practice inclines towards controlling exposures below the limit rather than maintenance at the limit" ACGIH (1964).

Changed to the following in 1969:

"In spite of the fact that serious injury is 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 (1969).

Such companies would have achieved lower levels of exposure than will have occurred by the piece meal UK application of Section 47 or Section 63 of the Factories Acts 1937 or 1961, in the case of those reasonably practicable OELs which "forced" the control technology as applied to the crucial "Type 1" processes (see Chapter 9).

A good example which illustrates the apparent difference between the US and UK approaches is the control of silica and other dust exposure at grinding, polishing and cutting processes. In the UK, grinding and polishing operations were surveyed across the metal working industries, MACKLIN and MIDDLETON (1923). The effectiveness of various control methods was measured using particle counts. However, unlike Winslow and his committee who performed similar work a few years earlier the UK investigator and the FI felt no need to set a practicable OEL for reasons already explored.

Instead their work became the technical background to the Grinding of Metals Regulations (1925). The FI enforced the good practice as identified by Macklin and Middleton.

In the late 1920's Bloomfield adopted a similar approach in a survey of the granite cutting industry BLOOMFIELD (1929). In this case however, based on a PHS survey and a tentative permissible dust level, various processes were identified as unsafe and for which no effective dust control could be found within the industry. Research was commissioned into the problem processes and various solutions were developed, HATCH et al (1930). Bloomfield had a benchmark with which to identify processes where dust exposure was "too high". This did not happen in the UK, Macklin and Middleton's survey simply identified the best methods but made no judgement on whether they were good enough. The UK at this time relied wholly on specification standards whereas the USA used both

specification standards coupled performance standards (which themselves contained a strong element of specification). In the 1920's, 30's and 40's the USA's use of industry wide surveys of practically achievable air contaminant levels coupled with apparent performance standards (OELs) was an advance on the UK approach. Without OELs, imperfect as they were and still are, the UK was stuck in the past, a point that Harvey was very well aware of. The point at issue was whether the US approach was in practice more successful. In the case of stonemasons and silicosis it possibly was although Hatch and co-workers research was not put into full practice until the 1940's. Silicosis was not prevented but it was much reduced, HOSEY et al (1957). The US PHS, based on Bloomfield's, Hatch's and other work developed clear specification standards for individual machines and processes and published their recommendations. By the 1940's all that the UK FI could offer was an A5 size sheet which suggested that precautions might be required at certain operations and warned that wetting the stone did not necessarily prevent dust formation. No practical guidance was given.

Returning to the title of this sub-section one can say that there are differences between the US and UK approaches. The US, nominally at least, favour performance standards in the shape of OELs. They fitted in the political culture of an avowedly capitalist country. However it is also clear that OELs were and are tied to specification or practical controls for certain processes and some OELs were and still are transplanted into explicit specification standards. This is part of what Morton Corn means when he argues that standards nowadays are far more than just OEL numbers. The UK in contrast started at the other end as it were – all standards to reduce exposure to air contaminants were specification standards or were written in specification terms, for instance Sections 47 and 63 of the 1937 and 1961 Factories Acts. No OELs were routinely used until the 1960s, the Inspector's (Factory or Chemical) approach would be to run through a list of questions: Is this a process which should be controlled? If yes, the next question was; does control look adequate? Adequate as defined by specification in Regulations or adequate as laid out in internal guidance or negotiated with the industry. Control was almost, though not always, exhaust ventilation and the inspector, once he or she had determined ventilation should be applied would ask subsidiary questions: – What is the state of the ventilation? Has it been tested and maintained? Where are the inspection certificates? If the process was not on the list and did not emit air contaminants which were visible or caused clearly recognisable short-term effects then no control would be asked for by the UK FI or applied voluntarily by the company (unless it followed ACGIH TLVs). From the 1960s onwards the UK FI and now HSE has tried to combine both specification and performance standard approaches. Nowadays I would argue that in the UK the process has gone too far and entered surrealist realms. The baby that was specification standards has been thrown out with the bathwater labelled "old fashioned, burdensome regulations'.

Before moving on to consider other general issues it is interesting to return to the question – have working conditions in the USA been better than in the UK? There is no simple answer and any answer one can give depends on other factors in addition to the use or non-use of OELs. Harvey after his study

leave in the USA described the scene as follows: "The American had all the knowledge and none of the means of enforcing it", HARVEY (1986). This is an exaggeration; in the large companies TLVs were followed and the ACGIH dictum was probably applied.

Harvey's own observations to the Chief Inspector would appear to confirm this, "in some factories, for instance, of the better run companies, the standard ventilation and protection for the workpeople concerned is of the highest order..." p. 10, HARVEY (1953). In some States, for instance New York and Massachusetts there was comprehensive legislation and competent enforcing authorities. But as Harvey also observed on his return, "while there is an immense effort through insurance companies, private organisations, such as the National Safety Council and the Federal Bureau of Labour Standards, there is not much doubt that control of accident hazards does not reach very far down into the smaller manufacturing units." p5, HARVEY (1953). The UK with a national enforcing authority applying specification standards probably resulted in better conditions than in the USA in medium to small workplaces. However, this would only apply to those processes which were regulated where the air contaminant was clearly visible or for substances with recognisable short term effects. While a large proportion of TLVs are based on such effects not all are and Harvey and Luxon both confirm that measurement and comparison with the TLV did, when introduced, produce some surprises.

Returning to the discussion of performance and specification standards it is clear that pure examples of the latter have existed but the former always contains an element of specification in it. With this in mind it is instructive to compare the specification and performance approaches to regulation compare the advantages and disadvantages of the, Table 12.3.

The points drawn out in this sub-section will be incorporated in the next chapter which outlines an alternative paradigm and standard setting practice.

Table 12.3 A comparison of specification and performance approaches

	Specification	Performance
1.	Guidance is clear and practical but regulations can be long winded and complex. Danger of missing a process or use.	Guidance is simple and all encompassing.
2.	A large and continuing effort is required by the regulating authority to develop standards.	Far less time and effort to produce than specification standards once number is chosen. Once set revision should, in theory, be a simple process.
3.	Can stifle innovation in control and fossilize technology.	In theory should not stifle innovation in control but as many are not "technology forcing" they do in fact stifle as much as specification standards. If set at "technology forcing" levels can stimulate innovations in production and control; can, in theory, also allow the identification of processes which cannot be adequately controlled by current technology. For reasonably practicable OELs the number is pinned by the practicability of control for a small number of processes or by one process.
4.	Some control exercised in those cases where air contaminant is visible and/or has recognisable short-term effects.	No pressure to improve control on those processes where exposure is normally below the OEL.
5.	Audit/inspection is relatively easy and quick, and this facilitates and stimulates control even in small or medium sized companies.	Audit/inspection is much more time consuming and delayed. Only routinely viable for large companies.

12.1.4 Soft versus hard facts – risk versus cost

In Part 3 an attempt was made to flesh out the OEL paradigm and its interpretation by examining work of key individuals. In each case when Stokinger, Hatch, Drinker or Smyth were defending the paradigm especially in the turbulent 1960s they all felt forced back onto the need to demonstrate risk by means of "hard facts" (HATCH 1972). In the case of Hatch whose model went a good way to, temporarily at least, resolving the paradigm crisis the demand for "hard facts" pushed the decision making process away from the region of "sub-clinical toxicology" in which Hatch claimed standard setters operated into the "medical" region, (see Chapter 9, sub-section 9.4.4.1). Later in this thesis it became clear this is the region in which most OEL setting committees operate most of the time.

From a separate source the effect of pressure on standard setters corroborates this analysis. Via an analysis of carcinogenic potency and strength of evidence, using the IARC hierarchy, Mendeloff shows using multiple regression that OSHA places more emphasis on human evidence of harm compared to ACGIH which is more responsive to animal evidence. Mendeloff sees this result as due to OSHA's need to have "sufficient" evidence of human carcinogenicity before it dares to start the rule-making process. OSHA like Stokinger, Hatch and others feel more comfortable with hard facts – hard human facts. One other conclusion of Mendeloff's analysis is: "The great emphasis on human evidence and the belittling of animal evidence have important implications for underregulation because the list of undisputed human carcinogens continues to be dwarfed by the list of substances for which the evidence of a cancer threat to humans is more equivocal" MENDELOFF (1988).

This quote leads to another piece of corroborative evidence concerning "hard facts" OEL setting and epidemiology and that concerns IARC.

Nicholson examined the epidemiological evidence behind the 18 substances for which IARC judged the evidence of a causal relationship with cancer as "sufficient". He examined the relative risks in each epidemiological study for the 18 substances or processes NICHOLSON (1984), They broke down as follows:

Table 12.4 IARC Group 1* Compounds

Agent or Process	Relative Risk**
9	50–500
8	5–50
1	~2

* Causally associated with human cancer

** Site specific

For the human evidence on most substances or processes to be judged to be "sufficient", to be accepted as "hard facts", the relative risks have to be large.

Because the statistical power of studies is related to the size of the study populations which are often limited in size by practical constraints only substances or processes achieving sufficient power, where

the relative risks are high, are taken seriously when the pressure is on. And yet here is the dilemma again which was considered earlier in this chapter and which Nicholson describes:

"Any plausible frequency distribution of the relative risks of site specific human occupational cancers would certainly have a large number of points with relative risks less than 5, were they to be known. In terms of accepted human carcinogens, we have clearly identified only the 'tip of the iceberg'" Ibid.

When an OEL standard setting committee is deliberating, costs, practicability for specific processes, current exposures from these processes and their widespread use and economic importance are all hard, inescapable facts. All the way through this thesis these facts have haunted the standard setting process and all the standard setters we have met have felt the need to come to some accommodation with them. The general effect of this process has already been examined – the way practicability intrudes and anchors the determination of reasonable practicability. This effect is worth exploring in a little detail because it touches the heart of the OEL setting process and informs the alternative arrangements for standard setting in the next chapter.

Larry Mazzuchelli wrote the first draft of the NIOSH criteria document on styrene. He had an interesting way of describing the process – it was not a review of the literature it was telling the story, describing human experience with that substance:

"It's a very curious data set. If you sit down and look at the molecule you'd expect it to do all sorts of nasty things and do these things very clearly. Instead the effects you see for styrene are very subtle and very hard to document except for acute irritation" MAZZUCKELLI (1984).

When the observations of a UK GP who had a patient who "changed" according to his wife, whenever he had been making GRP boats were related, Mazzuckelli's response was, "I have no trouble believing that ... One of the reasons we had trouble teasing out what was going on here is because you see a bunch of apparently diverse effects." Ibid. Including clear signs of CNS and PNS, depressions.

Mazzuckelli was particularly concerned about the CNS effects which he took to be real "EEG changes at ~50ppm argue for a much lower standard than 50. That tells me that you should be somewhere around; at a maximum of 25ppm," Ibid.

He believed that self selection had probably undermined the usefulness of the limited epidemiology on styrene and masked the chronic effects. Also he felt that many organic solvents probably had CNS effects at levels lower than current OELs; that evidence was getting stronger. But he had a problem, "You can't publish a document which says that NIOSH has a gut feeling that solvents are quite a bit more hazardous than was previously thought." Ibid.

On the question of the OEL number chosen by NIOSH for styrene (50 ppm, 10 hour TWA) the interview ran as follows:

MP: "When you went for 50 how far do you feel constrained by the exposures as occurring now?"

LM: "Oh, I don't feel constrained by them at all".

MP: "Well you could have chosen 10."

LM: "If I were to have the data I would have said 5. It's up to those guys (the industry using styrene) to get there."

MP: "But it wasn't 10 and it wasn't 5 it was 50."

LM: "That's right, that's because I didn't have the data to push it hard enough. I couldn't convince people. The arguments cannot be made strongly enough in these (the Criteria Document), although they could be made."

MP: "So, on the health side although you had a gut feeling you couldn't demonstrate it."

LM: "Right."

Mazzuckelli's candid description of how he viewed the potential harmfulness of styrene is very instructive. He works for NIOSH, an organisation whose remit amongst other things, is to do research and make recommendations on prudent public health policy and "to make these recommendations based on health, free from economic considerations." Ibid. Yet one sees in the dialogue the dilemma of a man who clearly believes/feels (as did Stokinger tentatively at least in 1967 when styrene was put on the NIC list) that the evidence points to styrene having subtle but manifest CNS and PNS effects. Yet he is constrained by the exposure data, by conditions in plants and the limits of the current control technology. When cut free of these constraints he goes for levels of 5-10 ppm _ but he had to be consciously pushed. His reading of the evidence suggested prudent public health policy would ask for styrene exposure in the range 5-10ppm, lower perhaps if a "safety factor" were applied. But the evidence was too soft – the "argument could not be made strong enough." The hard evidence of practicability won the day. It is clear from this thesis that the hard evidence of practicability always wins the day unless the evidence of harm is overwhelming and based on evidence of harm in human populations and such evidence is very rare. The optimistic project of early industrial toxicologists and hygienists has been and still is dramatically undermined.

Part of the problem stems from the arrangement of the decision making process. OSHA, ACTS and other OEL setting committees setting reasonably practicable OELs consider judgements on health

effects, exposure and practicability of control together. It is simply not possible to compartmentalise ones mind at one moment only considering health effects and at the next moment practicability and cost. The latter always impinges on the former even in these individuals who try to set health based OELs, who work for organisations which are mandated to work "free from economic considerations." like Mazzuckelli. But what happens if a strict effort is made to rigidly separate the two decision making processes? Via a small experiment it is possible to get some idea of the effect that cutting free from considerations of practicability would have on the OEL setting process.

12.1.4.1 The knowledgeable test panel

To perform the test I required a group of knowledgeable people who could assess toxicological and epidemiological evidence but were not involved in OEL standard setting or belonged to an organisation that was. The University of Birmingham's Department of Biochemistry runs an MSc in Toxicology. Via Dr K Chipman, the course tutor, a group of 10 postgraduate students on the MSc course agreed to take part in an exercise.

Four substances were chosen:

Carbon disulphide
Styrene
Trichlorethylene
Cadmium

They were chosen for various reasons:

(i) All four had been considered by the ACTS.

(ii) They were not, as far as could be attained, "high profile" substances like benzene or lead on which the candidates might have had strong preconceived views.

(iii) For three at least there was little human evidence of carcinogencity.

(iv) There was good summary documentation available.

Candidates were asked to assess two substances. They were provided with extracts from NIOSH Criteria Documents and HSE Toxicity Reviews. Care was taken to delete any reference to OELs in the UK, USA or any other country. At a briefing meeting at which the purpose of the exercise was explained each candidate was presented with the documentation for the substances, a set of instructions

and a list of questions, Table 12.5. The results of the exercise are summarised in Table 12.6. Only the 8 hour TWA OELs are listed together with extracts from the assessment sheets. The TWA, 8 hour/work shift numerical results are listed in Table 12.7.

Table 12.5 TOXICOLOGICAL ASSESSMENT EXERCISE:
Setting health based Occupational Exposure Limits (OELs).

INTRODUCTION

In this exercise I would like you to assess the potential health effects of two substances used widely in industry. All the information you require is contained in the documents supplied, which consist of extracts from Health and Safety Executive (HSE) Toxicity Reviews and the US National Institute of Occupational Safety and Health (NIOSH) Criteria Documents or Current Intelligence Bulletins.

The aim of the exercise is to set OEL's to protect against the health effects that may potentially be caused by the substances that you have been asked to evaluate.

The objective in assessing the evidence and choosing an exposure limit is to consider only the health effects of the materials under scrutiny. The question of the practicability of your chosen standard(s) is not relevant in this exercise.

I am interested not only in the OEL(s) that you select but also in the process by which you, as knowledgeable experts, arrive at your decisions. There are no right answers to this exercise.

It is very important, if the exercise is to be a success, that you strictly observe two conditions:

1. Do not confer with your colleagues. I am interested in the judgements of each of you as individuals and not on your collective wisdom.

2. However tempted, do not look up past or current OEL's in this or other countries. To do so would invalidate this exercise which relies on the assessor approaching the task with a fresh mind.

INSTRUCTIONS

1. Please use the answer sheets provided. If you require more space use additional sheets of A4 paper and staple them to the answer sheets.

2. Please answer the questions in order of presentation.

3. Please return the 2 sets of answer sheets and the reference material to me at the Institute of Occupational Health by

Thank you for participating in this exercise. I will circulate the results and my evaluation for your information and interest.

Mark Piney (Occupational Hygienist)

ASSESSMENT EXERCISE.

1. What are the potential human health effects of exposure to the substance you have assessed?

2. What numerical Occupational Exposure Limit or Limits would you choose to protect against the acute and chronic effects of the substance you have been asked to assess?
(It is normal practice to specify a short term limit to protect against acute effects and a longer term, often the length of a work shift, to protect against chronic effects. Adopt this convention if you wish but do not feel bound by it).

3. What health effects will the OEL'(s) you have chosen protect against?

4. How sure are you of the numerical limit or limits that you chose in answer to Question 2?

AND

5. What evidence weighed most heavily in your decisions?

6. If you cannot make a decision on a numerical Limit please summarise why. Also please say what policy you would suggest being adopted towards the material.

7. Please comment on the quality of the information, and the interpretations made in, the reference material with which you have been supplied.

8. Finally, if you have any further observations or insights to make as a result of the assessment exercise please feel free to make them below.

Replies were received from 8 participants providing 16 assessments in all. Despite the small numbers there is clearly a variety of view points. For one, the fact that styrene metabolism involves the formation of an epoxide suggests that styrene may be a carcinogen. While another is more concerned with styrene's possible reproductive effects. One person used animal data and a "safety factor" of 100 to arrive at a numerical limit while another divided up the exposed population into "average" and "sensitive".

As to the numerical limits chosen – again, there is a range but all the numbers are lower than the current Control Limits. The fact that a substance is a proven or potential carcinogen seems to cause the biggest differences – compare the cadmium and styrene results with those for carbon disulphide and trichlorethylene.

Table 12.6 Health based OELs – Results of knowledgable test panel exercise

Substance	8h TWA	Health effects against which protection is offered	Confidence in numerical limit	Most weighty evidence
1. Carbon disulphide	0.1ppm	"All effects"	Not sure because evidence is contradictory	Human evidence. Protection from reproductive hazards would require a x10 safety factor.
2. Carbon disulphide	2ppm	Neurotoxic and atherosclerotic	"Probably fairly reliable" as based on human evidence.	Human evidence – animal data only used to support conclusions.
3. Carbon disulphide	5ppm	"All effects in most workers"	"... very high probability of success."	"... thereis no substitute for good human epidemiological data."
4. Carbon disulphide	2ppm	All effects.	"... a fairly reasonable safety margin."	–
5. Trichloroethylene	50ppm	All effects including most CNS effects.	Confident apart from "... certain individuals would maybe more sensitive than the average person."	Behavioural changes at low concentrations and CNS effects.
6. Trichlorethylene	10ppm	All except "the more minor CNS depressant effects"	"No permanent neurological damage" – though concerned "that there maybe permanent behavioural damage".	Human evidence.
7. Trichlorethylene	5-10ppm	All general CNS effects	"I feel fairly confident in setting a low TLV-TWA value, in view of the wide variety and harmfulness of the effects seen. Though this value may be impractical to enforce."	All types of evidence including the large population potentially exposed.
8. Trichlorethylene	≤10 ppm	All effects	–	–
9. Cadmium	0.04μg/m^3	Pulmonary effects including lung cancer.	Doubt over "safety factors" in animal-man extrapolation used 100 "as 100 is often used" and "it seemed reasonable to assume an epigenetic mechanism."	Animal for "quantitative estimation and human reports to identify important effects."

10. Cadmium	1µg/m3	All toxic effects except cancer.	Sufficient safety margin except for carcinogenic risk.	Carcinogenic effects.
11. Cadmium	2µg/m3	All effects	Problems when considering no effect levels for carcinogens.	Human evidence.
12. Cadmium	0.02µg/m3	All reported effects.	Quite sure	Human evidence - 5µg/m3 ÷ 100 = 0.05µg/m3. Adopted "conservative estimate of no effect level."
13. Styrene	1ppm	All effects	Some doubts if compound is found to be carcinogenic.	Hepatotoxicity.
14. Styrene	10ppm + low as feasible	Irritancy and neurological effects.	"Evidence for the neurological and irritancy effects are quite straight forward" More doubt about evidence of carcinogenicity "especially since an epoxide is produced."	Human and animal evidence.
15. Styrene	3-7ppm	All effects	Problems with exposure data - "much of the data conflicts."	Human evidence.
16. Styrene	<1ppm	All effects.	Fairly confident - some doubts concerning female reproductive effects.	Human evidence (effects down to 5ppm implied "safety factor" of 5).

Table 12.7 Numerical limits chosen by knowledgeable text panel

	CADMIUM	CARBON DISULPHIDE	TRICHLORO-ETHYLENE	STYRENE
	0.04μg/m3	0.1ppm	50.0ppm	1.0ppm
	1.0	2.0	10.0	10.0*
	2.0	5.0	≤10.0	3.0-7.0
	0.02	2.0	5.0	≤1.0
Average =	0.8mg/m3	2.3ppm	19ppm	3.75-4.75ppm
Current UK Control Limit	50mg/m3	10ppm	100ppm	100ppm
Ratio of Control Limit to average Health Based OEL	63:1	4.3:1	5.25:1	27-21

*Limit to protect against neurological effects and irritation – but possibly not carcinogenicity.

What do the results of this exercise show? They show that:

(i) a group charged with setting a health based OEL can do so, if explicitly, asked not to consider practicality.

(ii) health-based OELs will be lower than current reasonably practicable OELs – sometime much lower. Many will not be practicable.

(iii) It is not possible to eliminate information which will indirectly give the assessors a measure of the practicability of their chosen OELs. The exposure data in epidemiological surveys act as surrogates for practicability. There is a clear tendency in some of the analyses to choose an OEL figure from within the exposures reported in epidemiological studies. Such exposure ranges tend to anchor the decision making process. This would appear to be inevitable unless an OEL standard setting committee were to explicitly addressed the problem and to adopt formal procedures to mitigate it.

(iv) As regards styrene, there is a degree of agreement between the Knowledgeable Test Panel and Mazzuckelli's 5-10 ppm choice, if practicability was not such a concern, and/or the neurological evidence were stronger.

(v) Wagner's and others fear that if standard setting were cut free from consideration of practicality it would descend into the realms of femptograms appear, at least on this evidence, be unfounded.

(vi) There was a marked reluctance in some assessments to set health based OELs without reference to practicality or benefit. The exercise was done but done with reluctance.

12.1.4.2 The Dutch Method

In the late 1970's the Dutch discussed and implemented a three tier OEL setting system, see ZIELHUIS and NOTTEN (1979). Dr Balemans described the arrangements as follows:

"Procedure for setting MAC values in the Netherlands

In the first phase the working Group of Experts (WGD), an advising group of the Labour Inspectorate in which medico-biological experts from research institutes, industry, Labour Inspectorate and other government departments participate, produces a recommended value, exclusively based on health aspects. These health-based recommended values are the outcome of a well considered scientific judgement by the group. Evaluations repot and recommended value are published by the Labour Inspectorate.

In the second phase the Commission on Occupational Exposure Limits for harmful substances of the Arbocouncil, an advisory authority of the Minister of Social Affairs and Employment (under which the Labour Inspectorate falls) for matters concerning occupational circumstances, are the Minister about the socio-economic and/or technical aspects of the proposed value. This commission has a tripartite membership: Union representatives of employers and of employees, the Government (Labour Inspectorate). The WGD is represented in an advisory capacity in the Commission. The advice of the Commission, like that of the WGD, is public.

Finally, in the third phase the Director General of Labour establishes the MAC value." BALEMANS (1987).

Between 1977 and 1985 the WGD made 33 recommendations with the following results: 19 Dutch MACS were modified (usually TWAs were converted into ceiling values); 5 MACs were kept the same; 8 MACs – additional STEL values were adopted and 1 new MAC was adopted.

In three cases the NMC (the tripartite committee) has not adapted the WGD value – on toluene diisocyanate (TDI), because of an on-going study, on lead and cadmium "because of the socio-economic consequences for small industries." NOORDAM (1987).

The Department of Labour has adopted all the NMCs recommended MAC values.

The Dutch system is a great improvement on the old compromise methods of other OEL setting committees but it does appear to be constrained by similar forces and concerns as were evident in the thinking of Mazzuckelli at NIOSH. The WGD committee only operates on ground where the evidence of health effects is strong. Unlike the knowledgeable expert exercise none (apart from 2) of the WGDs recommended OELs were impractical – almost all could be adopted by the NMC and made into reasonably practicable OELs. Why is this? Because of the reasons already explored in the discussion of NIOSH's styrene criteria document and REL. Because of a conservative attitude to proof. Proof of harm must be based on scientific proof and this must be beyond all reasonable doubt. There is little room for decisions based on the balance of probabilities – that is not hard enough evidence. But there is a more fundamental reason and that is that although the Dutch method is an improvement it has not broken with the OEL paradigm. All tiers in the OEL setting organisation feel constrained to set a single number OEL. It is this knowledge which constrains the WGD committee to work in the exposure region delimited by "hard facts". To do otherwise and behave as the knowledgeable group did would be to risk rejection of most of the 'health based' OELs put forward to the NMC. The absolute imperative to set a single number OEL is central to the OEL paradigm. The Dutch while they have improved the standard setting process by trying to separate what the NAS called "risk assessment" from "risk management" they did not or perhaps could not go as far as rejecting the paradigm to which all OEL setters in the West have worked for the last 50 years.

12.1.4.3 Setting health based OELs

The "soft facts" on health effects have to be overwhelming to resist the force of the "hard facts" of practicability and result in "technology forcing" OELs. The difficulty of arriving at such health-based OELs given the role and position of groups setting OELs has been examined. But part of the reason that setting such OELs is difficult relates to the availability and the form of evidence on which decisions are based. On the questions of availability of evidence: the concrete evidence of harm rarely exists to set against the very real and very concrete evidence of practicality and cost. Current evaluations cited at the start of the chapter indicate the size of the problem of this missing knowledge. The evidence for or against the existence of harmful effects does not exist because no systematic research has been done or because, in some cases, for instance epidemiology the research is not possible or because the harm, if it occurs, does not present itself in an easily identifiable or quantifiable form. Styrene and its effects would appear to come into the latter category.

The question of availability shades into the question of form. The evidence of harm is rarely complete or absolute. The existence of a risk is always couched in terms of probability as is the size of the risk. Different risks are regarded more or less seriously. Such equivocal, probabilistic evidence is set against the reality of exposures as measured now, control possibilities, costs and numbers exposed. And it is important to remember that whatever the state of the evidence on potential harm the evidence on

practicability almost always exists. Indeed it is clear from the earlier analysis of OELs particularly TLVs that the evidence of practicability coupled with what can only be described as a feeling for the degree of risk was the primary basis by which a significant number of OEL were chosen.

These differences in forms of evidence and the fact that the evidence of health effects is usually not available in adequate breadth or depth mean that evidence of harm may remain only suggestive for many years if not decades. In any regime concerned to set health based OELs such evidence must be taken seriously. People like Mazzuckelli and the members of the DUTCH WGD should be allowed and encouraged to follow their professional intuitive feelings and set OELs to prevent all health effects which are currently known or suspected.

No OEL setting organisation is currently organised to do this though a range of organisations now claim to set health based OELs which by implication, and sometimes by written definition, are 'safe' exposure levels. Such organisations include the WHO, NIOSH, the West German DFG for its MAKs, the Dutch WGD first tier committee more recently the HSE's ACTS for its OESs and most recently the European Community where Technical Progress Committee is preparing to set health based "indicative exposure limits". HSEIB (1989). In the case of the WHO, DFG and HSE their claims are demonstrably not true, most of the OEL numbers chosen by these organisations are the same as or in some cases higher than the ACGIH and this organisation was and is in the business of setting reasonably practicable OELs. The Dutch WGD Committee and NIOSH are less immediately concerned with the practicability of their OELs, NIOSH OELs tend to be significantly lower than the ACGIH (no Dutch WGD figures are publicly available for comparison), though this factor very clearly intrudes. Their OELs maybe "technology forcing", and push the limits towards the strict end of the spectrum of reasonable practicability, but they rarely part company with practicability. This is understandable, for both organisations work indirectly for state enforcing authorities. Such authorities do not want OELs which mean that large swathes of industry are always out of compliance. In a sense we are back in territory already discovered in the analysis of TLVs (17.4.4.1). There we saw how the health-based definition of TLVs not only inhibited the development of truly health based TLVs but it also inhibited the development of truly reasonably practicable TLVs. If an organisation claims that an OEL is health based when it in fact is reasonably practicable then it causes confusion and inhibits the development of both types of standard. This inhibition has clearly occurred in the case of TLVs and is occurring in a similar way with the OELs which various organisations claim to be strictly health-based.

Another part of the mechanism by which practicability is accommodated in health based OELs has been explored in this sub-section. What conclusions can be drawn? Some already have been identified at the end of the Knowledgeable Expert Panel exercise. This exercise, Mazzuckelli's attitude to the styrene OEL and the Dutch method all indicate that if truly health based OEL are to be set then the process must be made more relaxed and the soft facts of harm or potential harm must be allowed to count for more

than they do under the current OEL setting regimes. How could this come about? One part of the solution is crystal clear; the decision making on the hard facts of practicability has got to be separated from the decision making on the soft facts concerned with health effects. OEL definitions and in fact the OEL paradigm have got to change before a change of outlook of the individuals and organisations involved in OEL setting can occur. At present it is clear particularly from Mazzuckelli's interview and the test exercise that even when people are instructed to ignore practicability they find it very difficult if not impossible to do. People are conscious of the implications of their decisions for industry. Mazzuckelli in particular knows that he has not got to defend his decision in terms of public health protection (adopting a x 10 safety factor would be perfectly defensible) but has to be able to put up concrete evidence of harm against the hard facts of practicability and the knowledge that the industries affected will try to undermine his case. Even though the postgraduate students were not in this position some took on board this constraint, so deeply ingrained is the belief that health must be protected but a standard must also be practicable. Simply changing a committees name or remit, for instance, to consider only the scientific and toxicological evidence will not influence this powerful, almost unconscious constraint: a more fundamental change in OEL setting is required. The almost unconscious ground rules to which standard setters whether official or unofficial (as in the case of the knowledgeable experts) work are learnt as individuals learn and are imbued with the OEL paradigm during their professional training. If the standard setting process is to change in a fundamental way it is the paradigm which needs changing.

12.1.5 Science, professions and OELs

This thesis set out to plot the development of a paradigm. The paradigm which the professions of IH an IT in particular developed and to which they work. Many other professions owe allegiance to the paradigm and it has gained acceptance amongst a large range of client groups. At the outset I was unsure as to whether IH and IT had created a scientific or professional paradigm. It seemed likely, given the analytical framework developed in Part 2 that the OEL paradigm would contain elements of both. Indeed this turned out to be the case and this explains why the question, Is the process of setting OEL scientific?, results in such a confusing answer. The answer is yes it is a scientific process in that the OEL paradigm is a scientific paradigm but no in that the OEL paradigm is also a professional paradigm. This mixed quality of the paradigm has allowed IH, IT and the other subscribing professions to engage in a scientific dialogue with nature, ie to undertake what to all intents and purposes looks like "normal science". At the same time other factors, including cost, practicability and the status and admissibility of evidence on health effects, have intruded into this process via the professional facet of the paradigm. Again and again in this thesis we have seen how confusion arises when the standard setters or users emphasise the scientific facet and either directly or by implication argue that this subsumes all the other factors. This has been the steadfast line of the ACGIH. Others have explicitly accepted that economic and social factors are involved in the process. But the confusion

is compounded when attempts are made to divide the decision making process into scientific and non-scientific compartments as if they could be hermetically sealed.

The various interpretations of the key individuals examined in Part 3 on the OEL paradigm; the workings of the TLV Committee; the almost mystical role of "experience" in the standard setting; the work of Fran Lynn on the connection between allegiance and choice of scientific theory and the discussion of perception and health based OELs in this chapter all argue against the possibility of a neat and tidy division of OEL standard setting into scientific and non-scientific compartments. In fact, given the dual nature of the paradigm, it is not surprising that the scientific, social, economic and political factors interact, overlap and coalesce in complex ways. Trying to isolate the scientific from the non-scientific in any absolute fashion in the product of professional groups working to a dual scientific/professional paradigm is just about doomed to failure.

If this is the case then why does the fiction persist that this absolute separation can be performed? The short answer is because it is in the interests of the professions and other organisations involved to do so. As described earlier in the TLV discussion (Chapter 10) to be able to label a decision as a scientific decision has enormous symbolic significance particularly in 20th century Western secular society. This also explains why the professions examined in this thesis cling so strongly to the claim that science and only science rules their thinking and deliberations.

Having said this it is also clear from the analysis of recent developments in the UK that when a committee has no coherent professional/scientific paradigm its decision making soon becomes incoherent and bizarre. A coherent professional/scientific paradigm is needed as is input from a variety of professions. A problem, evident in this thesis is that all professions play to and emphasise their own special strengths and define, indeed over-define the OEL standard setting process with their own peculiar vision. This is not to say that a professional vision of the problem and its solution is not often correct or at least a better solution than offered by another profession. The problem comes when the vision is incomplete and self-servicing and, because of the professions power, excludes other and necessary alternatives.

The IH process based vision was clearly an improvement as earlier medical-IH views but in crystalising the OEL paradigm the profession made unrealistic claims. The paradigm was essential for the coherent growth of the profession – it is now a barrier to change.

CHAPTER THIRTEEN

SOME FINAL CONCLUSIONS AND AN ALTERNATIVE PARADIGM

13.1 Introduction

This thesis is divided into five Parts and 13 Chapters. It does not have as was emphasised in Chapter 1.0 what might be called the traditional structure whereby all discussion and conclusions are saved until the end. As each part unfolds questions arise and issues are discussed. Conclusions are drawn in each Part of the thesis.

While an attempt is made in this Chapter and the next to simplify some of the main conclusions of this thesis inevitably such condensation causes distortion. The interested reader who wants more detail and argument should locate the more discursive chapters in each Part via the contents pages and sub-headings.

13.2 Summary

As part of the analytical framework developed in Part 2 of this thesis it was argued that the widespread production and use of OELs was due to the professions of IH and IT in the USA. The development of these two professions especially IH was examined. The connection between the remit which the profession evolved and the paradigm it crystalised, with IT, was laid bare. The OEL paradigm as a popular and widely used paradigm is a product of these two professions.

The term paradigm was explicitly taken from the work of Thomas Kuhn and his use and understanding of the term were summarised in Part Two. The thesis continued by examining the nature of applied scientific professions and developed a framework with which it was hoped one could eliminate the behaviour of these professions and in particular the actions and process of OEL standard setting committees. The framework treated IH and IT as professions, like any other applied scientific professions, in which people were at one and the same time professional scientists and scientific professionals. The major difference between these two being that the latter explicitly had clients.

At this point the OEL paradigm was considered. A working definition was developed and the different interpretation of key individual IHs/ITs in the USA were examined. Although the process was somewhat artificial and interpretations obviously differed it became clear that a shared paradigm did exist. This reality became clearest in the writings of Stokinger and Hatch in the mid-1960's and early 1970s when they mounted a spirited paradigm defense against attacks from environmental scientists and campaigners and the implicit criticism of the Eastern Bloc OEL

standard setting approach. The bare bones of the OEL paradigm became most visible at this point; a phenomenon Kuhn has pointed to in other contexts for other paradigm crises.

By tracing the origins of the professions, particularly IH, which forged, promulgated and defended the paradigm and examining the writings of key individuals it was possible to show how social, economic and technical factors became embedded in the OEL paradigm. The mission and the needs of the professions of IH and IT and their clients made such influences almost inevitable. It was clear from the writings examined that different individuals at different times were aware of these influences but they were rarely accorded much space in their writings. The intention has never been to argue that such factors do not have a place in OEL standard setting, quite the opposite. The problem comes from the dual professional/scientific nature of IH and IT and the fact that this is rarely acknowledged. Instead a certain objective scientific image is projected by the professions and their clients onto the professions and their workings and products including OELs. The confusion and contradictions that this has generated became clear in the analysis of the OEL paradigm, the evolution of the ACGIH TLV definition and prefaces, and the OELs developed in the UK. Virtually all the OELs produced by such groups have been what would be described nowadays as reasonably practicable OELs.

Exactly how technical and economic factors influenced the OEL setting process was explored by examining the process of the ACGIH TLV Committee since it was set up and by analysing the Committee Minutes from 1962 to 1984. A similar approach was taken to the development and use of OELs in the UK: the important organisations and individuals were identified, the development of the IH profession was examined as was the process of the OEL setting committees. Unlike the USA the IH profession in the UK has never had the same power and status. Even so for a short while through the late 1960s and early 1970s it dominated the OEL setting process and paradigm interpretation in the UK at least.

The ACGIH has been the key organisation and its TLV Committee the most influential OEL setting committee in the Western, perhaps the whole world. An examination of the process of the ACGIH TLV Committee was therefore crucial to an understanding of the how the OEL paradigm was interpreted in practice. The social, economic and technical factors implicit, and occasionally explicit, in the writings of key individuals were far more stark in the process of the TLV Committee. How these factors came to be considered, the mechanisms by which they were introduced and how they effected the committee's actions were examined in some detail.

In the UK the explicit process and reasoning of the BOHS Hygiene Standards Committee gave an illuminating insight into the workings of the TLV Committee and other OEL setting committees. The examination of the workings of the ACTS illustrated in some detail the influences and factors which go to determine a reasonably practicable OEL.

While the ACGIH TLV Committee is the key to understanding how the OEL paradigm has been interpreted in practice, other committees such as the BOHS and the ACTS illuminated parts of the TLV Committee process which were opaque and could only be inferred.

13.2.1 Does the analytical framework work?

The answer, the author believes is – yes the analytical framework does work where the focus is on the behaviour of applied scientific groups such as IH and IT. In understanding the development and behaviour of IH and the shape of the OEL paradigm, the dual nature of applied scientists and the ecological metaphor of professional behaviour has great explanatory power. The framework focuses on the formation, reproduction and position of specific scientific/professional groups and is not distracted into discussion of supposed differences in philosophy between different OEL setting committees or countries. This is the great advantage of the framework developed and applied in this thesis. It has kept the analysis of OELs grounded in the behaviour and priorities of groups who have forged, propounded, used, benefited and defended them.

How then does the framework fair when applied to committees where IH is not dominant or to countries where IH hardly exists. The answer is – quite well. The OEL paradigm has been accepted by far more scientific/professional groups than IH and IT. Although no IH profession exists in France, this has not prevented the use of TLVs by engineers and others. However it has inhibited the formal State acceptance of OELs until recently. On the question of non-professional OEL committees such as the ACTS the OEL paradigm still has considerable influence. However it has been interpreted by non-believers as it were and, as the analysis has shown, the ACTS has drifted in rather strange and aberrant waters.

The concept of paradigms and professions working to such paradigms also seems to "work". The creation of the TLV, the message of single number OELs and the careful definition of TLVs are all outward manifestations of the OEL paradigm. While it is difficult to encompass a paradigm the Working Definition of five tenets has been a useful tool. Even though it is not a complete description it, or something like it, was certainly defended by the IH and IT groups in the 1960's. It is important to remember a quality of paradigms which Kuhn ascribed: that they allow "normal science" to proceed "when the theory isn't there". Puzzle solving, a normal science activity can still proceed: it is clear from the analysis of practical standard setting and the section on the lack of information on substance specific health effects in the last chapter, that in many, if not most instances the basic information on which to set OELs is not there. But this has not prevented the setting of OELs – the OEL paradigm has seen to that. It contains everything needed for the standard setter to believe in the correctness of his or her process: Exemplary past examples (eg. silica and lead); simple and all encompassing theoretical models (Hatch's model and Selye's theory of homeostasis); apparently promising definitions which do not change much and a strong symbolism comprised of the single number OEL itself, certain phrases (eg. "nearly all people...")

a continuity of process (particularly ACGIH) and a continual reiteration of the scientific status of the process and product.

While the OEL paradigm is not a Kuhnian paradigm pure and simple, the applied nature of the professions involved see to that, it bears many of the hallmarks and functions of a scientific paradigm.

As this is the last chapter of the thesis another interesting question can be asked and that is: Does the analytical framework help in explaining what is happening and predicting what, might or could happen?

13.2.2 What future the OEL paradigm?

In a real sense the OEL paradigm is a paradigm from times past. A time when gross exposures were relatively common. A time when such workplace conditions were clearly a factor, if not the major factor causing a disease. A time in which the majority of the scientific community believed homeostasis applied to all toxic effects and thresholds existed for all toxic substances.

The OEL paradigm, one tenet of which was the existence of thresholds of effect, legitimated amongst other things the single number OEL and in turn the single number OEL came to legitimate the OEL paradigm.

Once the belief in thresholds for all toxic substances is questioned and the process of OEL setting clearly does not aim to identify a level below the threshold of effect and, in many instances, cannot identify such a number for lack of information or because other factors demand a higher figure, then the raison d'etre for the single number OEL crumbles. While some standard setting committees have reorientated their approach to substances which would appear to have no thresholds of effect, and many would now extend this view to more than just carcinogens, they have not taken account of the implications of what is in effect a paradigm shift.

If thresholds do not exist, cannot be identified or cannot be contemplated because the levels implied are impractical, then a large part of the legitimation for setting single number OELs crumbles.

13.2.3 IH and the OEL paradigm

OELs were and are a vital part of an IHs day to day work. Members of the profession have had most to lose from an incorrect or mistaken interpretation of the paradigm and the meaning of OELs. This was clear from the analysis of the ACGIH TLV Committee. At annual meetings regular attempts were made to correct misinterpretations, or misuses of TLVs, even though a lot of

this confusion was inherent in the TLV definition, the way the TLV was portrayed, and the OEL paradigm. Still the ACGIH saw itself as the guardian of the interpretation of the TLV and, because of the success of TLVs, the OEL paradigm. When the paradigm came under attack in the 1960s and 1970s it was Stokinger, chair of the TLV Committee and other individuals affiliated to the ACGIH, who came to the paradigms defence. Although other professions have used OELs and contributed to their production OELs have never had the central importance that they have had and still have for IH.

As has been shown, as time went by other countries adopted TLVs and some eventually set up their own OEL setting committees. This occurred where either a small IH profession or an equivalent professional group existed. As these independent national initiatives matured, variation in paradigm interpretation occurred. Even so, until recently the ACGIH and the writings of Stokinger and Hatch dominated the field. More recently the position has changed. In the UK the IH profession have lost control of the OEL setting process and with it control of OEL paradigm interpretation. In France there are now recommended OELs but have no IH profession. In the FDR there is no IH profession but there is a long-standing IT profession. As the process of EC harmonisation continues there will be a harmonisation of EC OELs in some shape or form. It is very unlikely that the IH profession in Europe will control this process. Not only is there now no one coherent dominating professional group to interpret the OEL paradigm there is no one group to defend it since the US IH hegemony has waned.

The OEL paradigm never really recovered from the criticism and attacks made in the 1960s and interestingly it is probably these same forces which may, in the near future, completely undermine it – the conservationist and green movements which Stokinger referred to as the "non-toxicological" hordes. The hordes are approaching if they are not already at the gates and it is time to stop trying to defend the old paradigm and look to a new one. The analytical framework developed in this thesis helps our understanding of the process which is occurring and predicts that whatever form the new paradigm takes it will be the product of a variety of groups, principally applied scientific professions but not solely. Any new paradigm must explicitly accommodate the social factors involved in setting OELs.

In the process of developing an alternative paradigm it is productive to reflect upon the problems and contradiction embedded in the old paradigm. As part of this process and to concentrate the mind on OELs it is useful to consider some of the effects of OELs and influences which impinge on their production. Some of the effects listed below could be regarded as negative and some could be regarded as positive. Which is which will depend upon the individuals viewpoint. Also some effects do not fit into a positive/negative classification. The following list of effects is based on the assumption that most OELs are reasonably practicable. The effects of OELs:

(i) They enable processes and industries to proceed or continue within certain constraints. They may facilitate the use of certain substances or processes.

(ii) Their routine use reinforced and maintains the OEL paradigm and the professions and clients which have allegiance to, or use, the paradigm.

(iii) They limit debate to the discussion of single numbers. The complex range of effects a substance might have have all got to be compressed and mapped onto one number. This restricts the view of a substance and its health effects to one dimension. It encourages an over simple view of a complex world.

(iv) Given their reasonably practicable nature for all processes and uses they:

(a) Inhibit the production of truly health based OELs

(b) Inhibit the identification and promulgation of exposure levels at processes and for uses which are practicable or reasonably practicable but which operate below the OEL.

(v) They exert restrictions on the uncontrolled use of substances with OELs for some processes.

(vi) 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".

(vii) They concentrate attention on substances on OEL lists.

(viii) They deflect attention away from substances which are not on OEL lists.

The influences on OEL production are many and various and again, as with the consideration of the effect of OELs, listing them is a useful exercise before considering alternative methods of OEL production.

13.2.4 Factors which can influence the setting of OELs

1. The capabilities of current control technologies and methods.

2. The costs of control.

3. The current exposure levels for certain industries and/or processes.

4. The health effects at current exposure levels and the evidence of health effects below these levels.

5. The evidence of health effects and its authority – large scale epidemiological survey evidence or animal/short term test data with no human corroboratory evidence.

6. The perceptions, by the standard setters, of the seriousness of the health effects. These are affected by a variety of factors including:

   (i) the type of disease or health effect;

   (ii) the comparative importance of other causes of the same disease or health effect;

   (iii) the number of people effected;

   (iv) the type of population effected for instance, employees or public or both.

7. The importance of the material or process being considered to industry. For instance, less conflict would occur over an OEL which affected small scale use of a substance in one industrial sector of minor importance compared with if it were used on a large scale within many industrial sectors.

8. The development, technical sophistication and financial position of the industries effected (WILLIAMS 1982).

9. The relative balance of effects of a proposed OEL between different industrial sectors, (Ibid)

10. The relative organisational ability and political power of the various groups involved in the OEL setting process.

11. Occasionally the symbolic nature of the substance can be important. For instance the long running arguments over the benzene OEL in the USA and the EC took on a far wider, symbolic nature than the properties of the substance would suggest necessary. Such substances became symbolic battlegrounds fought over between employers and employees organisations and the regulatory authorities.

13.3 Argument for an alternative paradigm

The theoretical models behind OELs, the definitions given to OELs, the way the OELs are projected and described by producers and users all imply that health effects are the main concern of standard setters. Practicability is not considered and anyway it is perfectly possible to protect health and not over-engineer and require unnecessary expense. The general OEL paradigm which all the professions involved work to, and lean on, in times of crisis promises that this is so. The practical reality of OEL standard setting is very different. Any alternative paradigm must address and answer this mismatch between image and reality. The current view can be described as follows:

1. The number of people whose health is affected by occupational exposure to chemicals at work is grossly underestimated by current national statistics.

Few estimates of the amount of work-related morbidity and mortality by disease exist and those that do are very general. Unlike accident statistics, particularly those for mortality and serious injury, health statistics provide a very poor picture of the size of the problem and little feedback on the effectiveness of regulation or OELs.

The UK national statistics used by the FI gave and still paint a distorted picture. They gave and give little clue as to the size and shape of the actual problem. The confidence that people such as Luxon placed in UK statistics was misplaced. His belief and that of others in the 1950s and 1960s that work-related health problems were more or less understood was mistaken. In reality professionals in the field, doctors, hygienists and others have been flying blind or at best partially sighted.

2. There are upwards of 50,000 chemicals in regular commercial use.

3. The number of substances for which there are comprehensive toxicological data is small.

4. The number of substances for which there is good epidemiology with sufficient power to identify a significant relative risk is even smaller.

5. There are fundamental problems which limit the application of epidemiological methods to populations exposed to a significant number of chemicals.

6. Following from (5) and because of the emphasis placed on human evidence out of 414 suspected or potential carcinogenic substances identified by IARC only 18 are regarded as proven.

7. No standard setting committee uses a systematic method for selecting substances, for instance a system of ranking by numbers exposed, potential health effects and likelihood of health effects occurring. There is a widespread belief that OEL lists, particularly the TLV list, cover the "most toxic" substances.

8. Almost all the OELs set are "reasonably practicable" – based on some form of cost-benefit. Health effects will and do occur at or below OEL exposure levels.

9. In those countries where the emphasis is on the use of performance standards such as OELs, the use of reasonably practicable OELs will have inhibited the control of exposure of substances with OELs for processes and industries where exposure is normally below the OEL.

10. Over emphasis on exposure to hazardous substances as being the principle cause of a set of health effects has and does produce a distorted view of the relationship between environmental influences, human behaviour and ill health. The OEL paradigm and the division of the field amongst various professional groups reinforce this substance-orientated focus. The multi-factor view of work related health effects is lost in the process.

The single number OEL, with the implication that it represents a homeostatic balance point, a threshold, a "safe" exposure level is no longer tenable. Neither is the position that OELs have been set by recourse to some form of scientific method or that decision making can be divided into simple scientific and non-scientific compartments. The process of setting OELs and the predictable and identifiable influences on the process undermine so simple a division of labour.

13.3.1 An alternative paradigm

"Mandatory requirements are usually minimum requirements, or representative of the worst permissible conditions. From one viewpoint such requirements are a necessary aid to code administration for dealing with recalcitrants; from another viewpoint, they tend to stifle progress and freeze endeavour at the established minimum." YANT (1948).

At the start of their training all HSE inspectors and scientists attend an eight-day introductory course. Part of this course covers the development of standards using noise and noise induced hearing loss (NIHL) as an example. One of the questions put to the syndicate groups is, "What is the role of standards in the prevention of occupational deafness?"

I have sometimes argued in the case of noise, strictly no standards are necessary to see how the groups respond. The dose response relationship for noise and NIHL is well defined and one

could simply ask that employers assess the reasonable practicability of noise control given the risk at different levels of exposure. Most people in the introductory groups while prepared to entertain the argument do not accept it as practical. The overwhelming view was that people need standards. I have used these session to try out the ideas developed in this thesis. The overall response of all the groups can be summarised as follows:

Standards are a good thing in that they provide a numerical target for machine, process designers and employers to aim at. But such targets have got to be achievable otherwise people will give up trying to attain them. But this, in the case of noise and many chemical OELs, immediately raises problems. Achievable standards while useful as goals are not necessarily safe standards – and this is certainly the case with noise. The reasonably practicable level in the UK has been 90dB(A) (over 8 hours) since 1972 but this is by no means a safe level, nor is it achievable with current technology for some processes: It is a classic reasonably practicable OEL, technology forcing in some sectors.

It is, as Yant pointed out four decades ago an example of a "Mandatory requirements .... representative of the worst permissible conditions." Ibid. The problems with it are, as various syndicate groups concluded, that people will work up to 90dB(A) and not down as far as is practicable; some will regard it as a safe level; for those processes where far lower levels can be achieved there will be no incentive to try. Interestingly some syndicate groups, without much prompting came up with some potential solutions. For instance:

(i) To make the OEL a moving target: in the case of noise – 90dB(A) now, and say 85dB(A) in 10 years time.

(ii) To vary the OEL in different industries or processes while retaining an overall top limit, though some thought this would be impractical.

(iii) Less popular was the idea of setting a target limit and a practical limit.

Other ideas to reduce exposure to noise were examined, with some prompting, in the syndicate exercise which did not necessarily rely on OELs. But the exercise was of particular interest in this context because once the current limit of 90dB(A) was accepted as a reasonably practicable compromise at which exposure a very significant number of people would suffer significant hearing loss, many groups were prepared to accept or spontaneously started to discuss phased limits, or target limits or occasionally, process or industry based targets. The syndicates were run for people working in an organisation concerned with practical enforcement issues. It is therefore of particular interest that once the idea that only one OEL number is allowed loses its grip other options become practicable.

13.3.2 A mechanisms for producing sets of OELs

Henschler (Chair of the West German MAK Commission) is concerned that governments may break with single number OELs and adopt a different approach: "One approach in this direction is not to keep exposure levels as high as tolerable but as low as technically and economically possible; **this is equivalent to the funeral of conventional standards."** HENSCHLER (1984), (Author's emphasis).

The process of setting OELs should be divided into two phases: Phase 1 - the identification of a health based OEL and Phase 2 the identification of reasonably practicable OELs and an overall operational OEL. The two phase nature of the process is similar but not the same as the Dutch scheme. The method builds on the model of the work environment outlined in chapter 9. It would work as follows:

13.3.2.1 Health-Based Limits (HBL)

In Phase 1 a committee would arrive at their best estimate of a Health Based Limit (HBL).

Many, if not most, of these limits would not be attainable across all industry and processes using current technology. HBLs would be target OELs, exposure levels to which industry would aspire. This committee would be separate from the one that was concerned with Phase 2. It would only concern itself with evidence on health effects and its remit would formally specify that questions of practicability and cost were not to be considered. This will be difficult given the behaviour of the Knowledgeable Expert Panel, Mazzuckelli and the various standard setting committees discussed in this thesis. Nevertheless the attempt should be made: with time ground rules could be developed for just how HBLs should be set in different circumstances. One could anticipate that substances would be classified according to their known or possible health effects for instance:

With substances which only appeared to have simple irritant effects a safety factor of say 10 could be applied to the lowest known level of effect. A certain wariness even here is necessary as not all irritants turn out to be simple in their effects, (see STEENLAND et al (1988) and AMDUR (1985).

For substances with more serious effects a safety factor of 50 might be appropriate.

For substances with potential carcinogenic effects a range of safety factors could be applied depending in size, for instance, on the strength of the evidence. This approach could be modified where risk assessment and extrapolation was possible together with some limiting minimum level of risk.

If there was insufficient evidence on which to set a numerical HBL then the criteria of as far as technically achievable could be applied.

Whatever system were to be developed, the committee could operate free to decide on and experiment with a variety of methods and approaches, secure in the knowledge that practicability was not its concern and that there was no intention of trying to enforce the HBLs wholesale in the near future. The committee would be free to express its doubts and write down exactly what its HBLs were based on, what health effects they should protect against and where the evidence was thin and what they had done to compensate or allow for this.

Quite how static HBLs would be is difficult to predict. For substances which do not appear to have cumulative, chronic or latent effects its possible that the HBLs will remain static for long periods. Also, in these cases some, if not all, process based RPEL may with time approach and reach the HBLs. For substances with vaguer and less well documented effects the HBLs are likely to fall with time.

13.3.2.1.1 Health Based Zones (HBZ)

Whether HBL is the right name for health based standards is open to question. It may be better to signify by name, and in practice that the process of determining the safe levels of exposure is uncertain by for instance calling such standards Health Based Zones (HBZs). This would move the committee and its projected message away from the idea of dividing lines and identifiable "safe levels" once and for all. As most of the HBLs/HBZs will not be achievable by all of industry within the medium term the fact that HBZs represent a fuzzy goal to aim at does not matter.

Phase 2 is far less controversial and there is potential for speeding up this phase of the standard setting process, even to the point of semi-automation. This aspect will be expanded upon once the phase is described.

13.3.2.2 Operational Exposure Limits (OpELs)

It is the assumption of the author that each HBL will not be attainable by certain industries or processes and in some cases by all industries and processes. Phase 2 is concerned with setting an Operational Exposure Limit (OpEL) and a set of Reasonable Practicable Exposure Limits (RPEL). The name OpEL is proposed so that these OELs cannot be construed as safe or static. The approach is explained by reference to the model of the work environment detailed in Chapter 9, Figure 9.4; it expands on this model. The routine for setting the top OpEL would be more or less the same each time. The thinking would go as follows:

Which industrial sector or processes result in the highest exposures?

Is it a small number of sub-processes or does it involve a small number of people or does it involve a relatively large number of people but for a short period of time? If YES then the use of RPE could be allowed for a specified time while methods of improving control were developed and tested.

If a large number of people are affected by the top exposure process or industry then it could be exempted compliance with the OpEL for a certain period and control and implementation could be phased in. There are several examples of phased-in OELs and regulations in the UK and USA* .

By adopting this flexible approach the top exposure limit allowed would be "technology forcing" on the industry or processes with the highest exposures. By this means and in the example shown in Figure 9.4 the OpEL might be fixed at what the best 40% of Process 1 can achieve. This would have an effect on a significant number of Process 2 operations but would not touch process 3 and 4. There is a need to set RPELs for each process.

13.3.2.3 Reasonably Practicable Exposure Limits (RPELs)

It is part of the dogma, part of the paradigm of IH, that if sampling results are grouped by process, and the categories of job or process are correctly chosen, then the sampling results will be distributed lognomally. This is not always the case but it is common and is a fair approximation. But this statistical entity, while it describes the work environment it provides no information on why the data are distributed lognomally. It is a fair assumption that the results at the bottom end of the distributions are from processes which are:

1. Small
2. Emit or release small amounts of contaminant
3. Are well controlled
4. Or a combination of factors including 1-3.

Styrene exposure is a good example. The exposure data at the top end of the distribution comes from the GRP boat building industry whereas that from the bottom comes from processes which use GRP on a small scale under ventilation. The logic applied to setting the OpEL could be applied to setting each RPEL. In-hull work where the highest exposures occur could be exempted for a defined period and the use of PPE sanctioned. This process would in effect chop off the tail of the lognomal distribution and allow the committee to set an RPEL in the well controlled region

* In West Germany, "TRKs are based on the 80th percentile of industrial exposures" MORRIS (1986). The apparent logic being "... that if 80% of the industry can achieve that extent of control and survive economically so can the other 20%. Ibid. This approach is blind and rigid and takes no account of the patterns of large/small, badly controlled/well controlled or open/closed processes within the parent distribution. Points further explored in the text.

Figure 13.1. Distribution of rubber fume (CSM) sampling results for the four processes causing the majority of exposure.

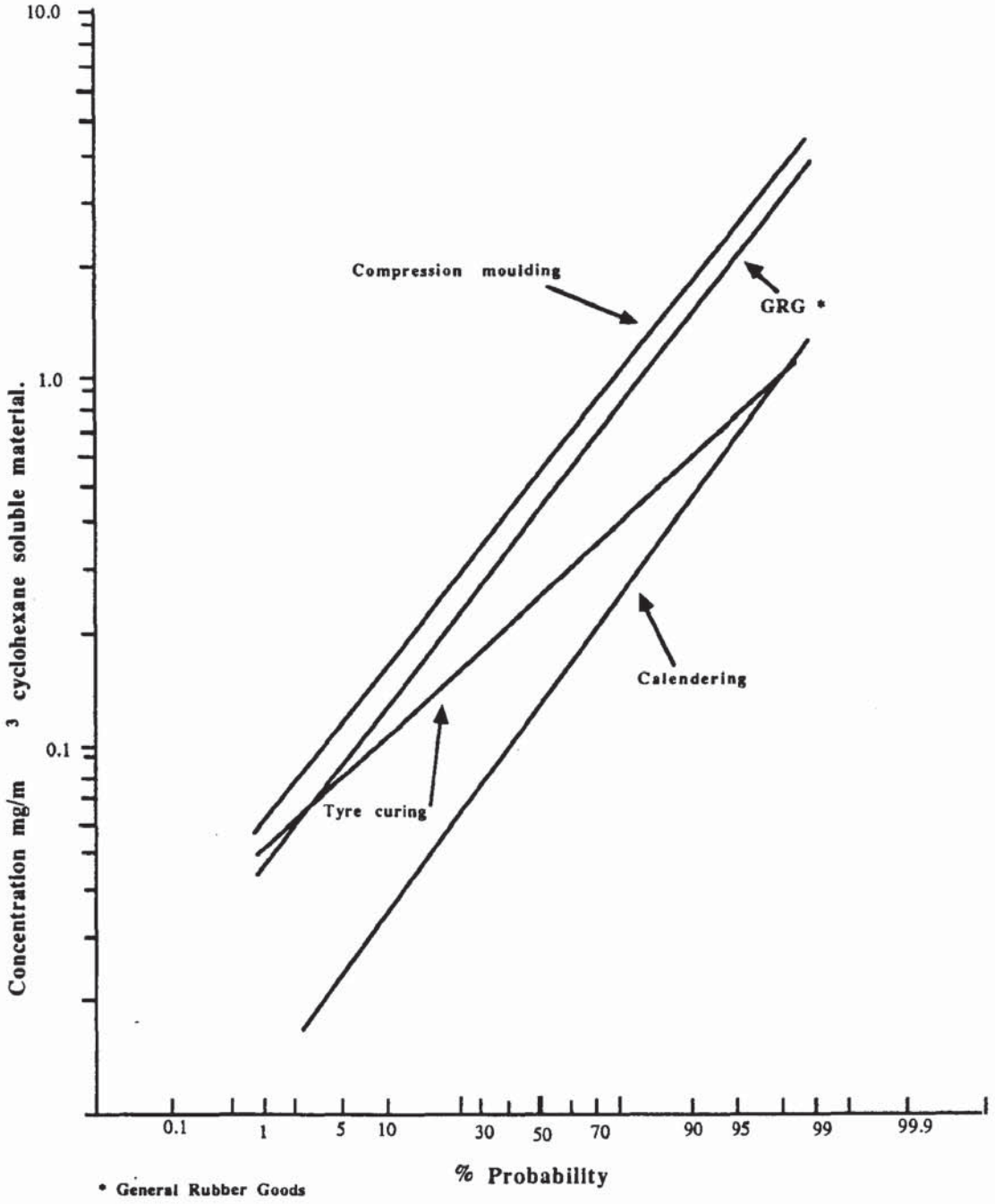

Figure 13.1 Distribution of rubber fume* sampling data for the processes which cause the majority of workplace exposure.

*** (Cyclohexane soluble material)**

of the distribution for processes 2, 3 and 4. It would be tempting, once the top exposure process in the distribution has been stripped out and the data re-plotted to chose the 50th percentile as the RPEL. This would be appropriate if there was no additional information on why the data were distributed as they were. However, if a more analytical approach were to be adopted then instead of simply collecting exposure data, other information on the process and controls applied could also be collected and collated. It would then be possible to identify well-controlled and uncontrolled regions of the distribution. Indeed it would probably be necessary to sub-divide the crude process categories. At present when setting Control Limits now called MELs ACTS has the data to undertake part of this process. The data comes from HSE and industry surveys and an example, based on industry work co-ordinated by the BRMA is shown in Figure 13.1. The distributions involving processes which result in the majority exposures in the rubber industry are plotted. In this instance one could simply chose the 50th percentile for each category (0.6mg/m^3 compression moulding, 0.5mg/m^3 for General Rubber Goods, 0.20mg/m^3 for Tyre curing and 0.1mg/m^3 for calendering. In the case of compression moulding the distribution could certainly be broken down, without too much additional work, into sub-categories and the OpEL set in the way described. And similar sub-divisions of the other three process categories could also be performed. At present, because there is no concern to set numerical RPELs, no such an attempt is made. The rubber fume Control Limit of 0.75 mg^3/m^3 was determined by General Rubber Goods and there is no reason why, apart from a general exhortation, other processes should apply better controls.

The process of setting RPELs is not dependent on having a neat set of lognomal distributions. It could be attempted with far cruder data as long as there was a good understanding of the relationship between the processes causing exposure and the exposure data.

Setting RPELs will necessarily be a developmental process and certain individual RPELs will become refined with time. The proposal will need refinement, further study and pilot application. RPELs will be crude for some processes and perhaps Reasonably Practicable Exposure Bands (RPEB) would be more appropriate than a single number. Also, the committee would probably not be able to set them all at once – which would be no bad thing, it would reinforce the developmental nature of the project. Finally it is not necessarily the case that the OpEL is required, it maybe that an HBL and a set of RPELs would do. The danger is that the OpEL would become the target to attain, as happens now, and not the HBL. Perhaps OpELs should be retained temporarily over the period when the set of RPELs are developed?

What are the advantages of the method outlined?

1. The main advantage is that it faces the realities of work place exposure and the impossibility of setting a single number OEL which protects health and is at the same time practicable.

2. It addresses the reality of OEL standard setting; the unequal struggle between the soft facts on health effects and the hard facts of practicability and cost.

3. It also faces four square the uncertainty of decision making on toxic substances. It makes no pretence that the field is understood with any exactitude. In this sense it is more honest than most of the current OEL standard setting regimes.

4. The HBL introduces a continual pressure into the system to improve control. It is the force which motivates organisations to improve control and lower the RPELs towards the HBL. Without the HBLs the motivation to improve an RPELs disappears. Without the RPELs the phrase "as far as is reasonably practicable" is vague, debatable and unenforceable.

5. The proposal is dynamic and not static as is the current system. The HBL will be refined with time and may fall or rise as knowledge and understanding of the action of different substances increase. Similarly the RPELs will change as process and control technology changes. The system HBLs and RPELs would introduce innovative pressure to develop more cost effective methods of attaining the limits, and eventually with some processes, attaining the HBL.

6. HBLs are more easily altered in the light of new evidence in that they have no immediate effect on the RPELs actually enforced.

7. Sets of RPELs are an improvement on the present system because they represent realistic and agreed targets to aim for in the short/medium term. Coupled to the HBL they will encourage innovation in control. They are practical and draw upon and extend the usefulness of information much of which is already available to the ACTS.

The process of arriving at RPELs could involve, in the UK, IACs, hygienists and process engineers, trade union safety committees and representatives and the people exposed who work with understanding the processes. As such the proposal is far more open, involving and democratic than the current system.

8. Finally, the proposals combine the advantages of performance and specification standards. The HBLs are the performance part of the proposal and as such they are clear and unambiguous unlike current OELs. And the set of RPELs will be closely tied to types of processes, products and control methods. As such, employers will know what is required of them and enforcing or auditing agencies will have a far easier task assessing compliance with the stricture to reduce exposure AFARP.

13.3.3 What are the objections to the proposed method?

13.3.3.1 With the method proposed industry does not know where it is

In the run up to the transmutation of Control and Recommended Limits into MELs and OESs both the CBI and HSE made much play of the need for industry to have fixed targets to work. Both parties seemed to have convinced themselves that this was a coherent and legitimate demand. In my opinion it is not. Fixed and certain targets of the type proposed by the CBI and HSE are not possible or realistic in occupational health as in many other areas of life for the simple reason that our knowledge and understanding is neither complete or static. Also it is not as if industry is not used to trying to hit moving targets as markets evolve and production techniques develop. All that the proposal implies is that HBLs and RPELs become built into the planning process along with other changing factors in production. In these new proposals, industry is not being asked to jump into a bottomless pit and has targets and phased, practical deadlines to work to.

13.3.3.2 The proposal is too complicated

Yes it is and no it is not. There are more numbers involved but these, once the old paradigm is rejected, and the new one accepted become intuitively obvious quite quickly. Setting up formal and agreed procedures for determining HBLs and RPELs will take time. However, once the systems are set up they should be able to function much more rapidly and openly than the current system. On the question of RPELs, the trade unions will not feel so twitchy about one OEL covering all processes. There should far less trench war-fare between employers and employees representatives and less disagreement about where a particular RPEL lies for a specific process. Once care is taken to link exposure data to process and control information the process of identifying at least the region of an RPEL could almost be automatic using a decision flowchart. Even if agreement on an exact HBL is difficult, identifying RPELs can still proceed on the assumption that the HBL is lower than exposures currently being achieved. Once the RPEL setting process is finalised and explicit there will be large scope for industry to "do it itself". The idea of self-regulation so central to the HSW Act and COSHH would become more of a reality.

13.3.3.3 What about the current OELs – what will happen to them?

They will assume the status of OpELs, (and this is probably the best reason for keeping OpELs in the medium term). By doing this the reasonably practicable nature of such single number OELs is made clear and the process of identifying HBLs and RPELs can start. It may be a painful process but it is necessary.

13.3.3.4 The proposal is unfair, some people will be put at greater risk than others

In the late 1970s in the USA the Reagan Republican administration, in a similar vein to the UK Conservative government, was concerned to reduce the regulatory burden on industry. As part of the process the Council on Wages and Price Stability (CWPS) commissioned a regular number of studies of regulatory effectiveness for various US government agencies including OSHA. One of these studies covered OSHA's rule making on the acrylonitrile OEL. The CWPS was concerned with cost effective regulation and was composed mainly of economists. One of their conclusions in response to a similar statement to that made above, was that "the advantage of using a cost-effectiveness approach is that more protection (risk reduction) can be achieved for a given expenditure of societies resources .... a cost effective approach will maximise gains." CWPS (1978).

On the direct question of equal risk the made the clear statement that "... as long as the feasibility of risk reduction methods vary, workers will be exposed to differing amounts of excess risk." Ibid. This is also the conclusion of the work environment model depicted in figure 9.4 and the UK ACA when it developed and coined the term "control limit". In this case the ACA stepped back from the logic of its own arguments but the CWPS did not: it went on to recommend a standard of 1.0ppm for all sectors apart from acrylic fibre production where it recommended 0.2ppm based on cost effectiveness arguments.

Interestingly the FI medical committee which reviewed the state of knowledge on asbestos went further than the ACA and was explicitly in favour of differential process specific standards, (and also the idea of a progressively reducing goal or target) as outlined in chapter 11, section 11.1.

The proposal is not unfair, it is honest and it 'tells it like it is'. It is this admission of the inevitable differential risk that workers are subjected to that proponents of uniform standards do not like or do not wish to acknowledge. A clear appreciation of the work environment and a basic cost effective control analysis sweep away the disingenuousness of such arguments.

13.3.3.5 The proposal is so new that it will never gain acceptance

If the contradictions and confusions identified in the introduction to this thesis and found during the analysis are real and correct then the OEL paradigm is heading for a crisis if it has not already arrived. If this is the case then it may not be a question of newness being a factor against the proposal, it could count as a point in its favour – a way out of the current indefensible impasse.

Almost since the crystallisation of the OEL paradigm the idea of a single number OEL has been under attack. Exposure bands and dual standards were proposed in the 1950's and the separation of health based OELs from feasible OELs was floated by Samuels in the 1970s.

The idea of phasing in standards is also not new HSE "permitted exemptions to general control limits" for dust control on planars when the Woodworking Machinery Regulations were introduced in 1974. The acrylonitrile control limit was phased in in 1979; a two year lead in period was allowed. A 0.75 mg/m^3 rubber fume Control Limit was introduced in 1987 with the agreement that this would be lowered to 0.6mg/m3 within four years.

The cost effectiveness argument of economists have been given credence and more widespread audiences for over a decade. In a paper reviewing the evidence Viscusi concluded "In instances in which there are wide variations in compliance costs, it is often desirable to establish several standards reflecting the differences in the relative costs per unit benefit achieved" VISCUSI (1982).

Finally the Dutch three-tier, two-committee arrangement has been functioning since the early 1980s. The specific details of the method of setting an HBL and a set of RPELs may be new but many of the ideas behind the proposals have been around for some time.

13.3.3.6 HBL/Zs will make employers liable because a proportion will always be out of compliance

This is probably the major objection to the proposal. The idea of HBL/Zs will probably meet far more resistance than RPELs. Insurance companies and governments in particular will not like HBL/Zs as they imply that RPELs are not safe, except where they are within or below the HBL/Z. What counter arguments are there and what adjustments in vision will be necessary?

The most cogent argument is that the alternative paradigm and the proposals deal with the actual reality of the workplace. The OEL paradigm hid and confused this reality. The alternative will require people to confront some unpalatable truths and develop a more mature understanding of chemical exposure, OELs and risk. The easy option of claiming and believing that OELs were safe, or nearly safe, is not now available. All parties involved, employers, inspectorates, workers, and governments, if the analysis and arguments in this research are accepted, have got to face a more complicated but perhaps more believable view of the work environment. There are no easy black and white, safe - unsafe options.

On the question of liability, this can be split into two questions – one concerns liability for causing illness or disease, the other concerns infringement of legal limits.

On claims: exposure above the HBL/Z does not automatically make an employer liable. An individual or group still has to demonstrate a logical connection between the illness or disease they have and exposure in the workplace. If there is a plausible connection then exposure above the HBL/Z will make the claim easier, and this is correct. At present claims that exposures were below reasonably practicable OELs deflect legitimate claims and prevent connections being made.

On non-compliance: the potential problem is more imaginary than real. It all depends on the legal status of HBL/Zs. They would be published, in all probability, as advisory levels which manufacturers, occupiers, designers and suppliers should be aware of and at which they should be aiming. They need not be enforceable limits to have a downward pull on the RPELs. They would, as they are intended to, prevent the claim that the appropriate RPEL had been reached and that no more control effort was needed.

13.3.4 HSEs precautionary policy

In 1983 HSE published a series of essays on the 150th anniversary of the foundation of the UK FI. One reviewed the debacle over asbestos and concluded with some observations on the way HSE now approached IH problems very much in line with the Precautionary Policy on Toxic Substances" published four years earlier, HSE (1974).

".... inspectors are now adopting the stance that because of the uncertainty of health risks the level of contamination of the workplace by hazardous materials should be kept as low as is reasonably practicable. If it is reasonably practicable to achieve with any substantial margin any current standard of hygiene then a still lower standard will be sought by inspectors. It is to be hoped that in this way any material such as asbestos which is initially thought to be a limited risk but subsequently found to be a serious risk will already be controlled to as low standard as is reasonably attainable. RUSSELL (1983).

There is no way with the current commitment to single number OELs, of putting the policy explicitly described by Russell into practice.

The proposals in this subsection would go a long way to making the precautionary policies espoused by HSE (until recently), other enforcing authorities and various professional groups real, practical and attainable goals. Unlike Henschler, I believe it is time the single number OEL was given a decent burial.

13.4 Identifying Hazardous Substances

13.4.1 Evidence of harm

In 1955 Sterner the Chief Medical Officer of Kodak candidly gave his view of how TLVs were arrived at. He described the process as follows:

"The concept that man in his occupational environment is the subject of a continuing industrial hygiene experiment may seem absurd, or at least novel. Certainly the workman in the plant, particularly if environmental factors are reasonably well controlled, does not usually consider himself an experimental subject. When one reflects however, on the history of threshold limits it becomes apparent that many of our present standards have resulted from just a succession of experimental events.

A pattern which has been repeated many times, begins with the introduction of a new industrial substance and an apparent assumption that it will be innocuous under the conditions of use. If injurious effects are observed in the exposed workmen, an effort is made to reduce the exposure. Then follows another trial period at this reduced level. If injury is again noted, a still further reduction is made, and so through a series of step-wise trials until a set of conditions is reached which is acceptable." STERNER (1955)

He appears to view the approach as inevitable and his fatalism was probably shared by many at the time. A group that did not agree that this was an adequate way of identifying harmful substances or processes were the IHs and ITs. As has been shown these two groups, starting from their earliest days as struggling professional entities gave each other complementary and mutual support. The idealism and hope can be seen in their early statements. Lehman, who with his colleague Flury and Zernik, were lent on so much by the early US IHs, pointed out that, "Not until injuries to health appear, which is often much too late, are investigations on the indispensable hygienic hypotheses and principles carried out" LEHMAN and FLURY (1938).

At the time human experiments, using volunteers were encouraged but Lehman understood and argued for prolonged animal experiments, he summed up his position thus, "we sacrifice animals in order to protect and save human lives." Ibid.

Interestingly, prefiguring actual regulations by close on 40 years he stated, "A law prohibiting the use of new chemical substances before they have been scientifically tested for toxicity would be desirable." Ibid.

Similar and very clear statements of belief and hope were made by the US ASA MAC Committee in 1944 in the "American War Standard" document on styrene:

"There has not been sufficient experience with human exposure to evaluate the response of man to this compound. This standard, therefore, has been established on animal experimentation. **It is hoped that by so doing it will be possible to present, in large measure at least, the unfortunate and unnecessary exposure of humans which is usually considered necessary to evaluate the toxic response in man.**" ASA (1944). (Author's emphasis)

Four years later, Patty, having surveyed the development and consolidation of IH could say:

"Industrial hygiene procedures have largely passed through the period of enquiry into the causes of ill health and now devote their energies to anticipating and avoiding harmful situations before they have time to cause injury." PATTY (1948).

The attitude and hopes of the early IHs and ITs could not be further from the fatalism of Sterner prepared to watch and sanction what has been, rather belatedly, called the "generation game", (one generation to be exposed, one generation for the harm to be realised and one generation for adequate controls to be instigated).

There is a need, in any alternative paradigm, to recapture the early optimism of some of the leading IHs and ITs. Implicitly in this process toxicological evidence is given more weight and some form of action is taken whether the epidemiology is negative and the toxicology is positive or indeed vice versa. Early visionary IHs and ITs looked to the time when "exposure of humans ..." would not be "...considered necessary to evaluate toxic response in man." The dominating effect of putting such evidence up against the hard facts of practicality has driven OEL setters back to the human evidence which, as has been shown, is often weak, non-existent or impossible to obtain.

Decoupling the setting of HBLs from RPELs would aid this process – it would allow the debate about how to use animal and other toxicological evidence to take place in less fraught circumstances. The needs and pressures of practicability could be kept at bay. At present they haunt the debate and polarise it.

13.4.2 Attitudes to evidence and uncertainty

"OSHA cannot let workers suffer while it awaits the Godot of scientific certainty" (Judge J S Wright quoted in SCHRECKER (1986)).

"In a rational scheme of public health measures, the possibility of serious harm can warrant protective action. We should not wait for the toxicological equivalent of the smoking gun" MENDELOFF (1988).

Such statements are correct in that they call for action to be taken in the face of uncertain evidence. Given that the relationship between exposure and health effects is always uncertain the question becomes one of how much uncertainty OEL setters are prepared to tolerate; what standard of proof it is appropriate to demand.

Richard Bates describes the attitude contemporary scientists might take to John Snow one of the founders of modern epidemiology. He brought an epidemic of cholera to an end in London 1854.

"John Snow, the hero of the story, studied the habits of the victims and found that almost all obtained their water from the well on Broad Street. Swift action was taken; the pump was closed down and the epidemic rapidly subsided. This action was taken before there was a clear understanding that the disease was caused by exposure to the bacterium *Vibrio cholera*. One can imagine the reaction that might occur today if it were proposed to close down the pump on the basis of evidence of the kind obtained by John Snow. Many scientists would point out that it had not been conclusively demonstrated that the water was the cause of the disease. They would be troubled because of the lack of satisfactory theoretical knowledge to explain how the water could have caused the disease. Furthermore, other habits of those who had become ill had not been adequately investigated, so it would not be possible to rule out other causes of the disease. These

scientists would have been correct. Others would have pointed out that some members of the community who drank from the Broad Street well had not succumbed to cholera. Thus, even if there was something wrong with the water, there must be other factors involved, and if these could be controlled, they would not have to be concerned about the water. These conclusions are also correct. Some who consumed water from the Broad Street well would have objected to closing it because it was inconvenient to get their water elsewhere or because the taste of water from other wells was not as agreeable. Finally, if the pump had been owned by an individual who sold the water, he would certainly have protested against closing down his business on the basis of inconclusive evidence of hazard." BATES (1979).

We will return to the John Snow story but before doing so it is worth considering what people, especially scientists, mean by the phrase "standard of proof".

Schrecker reviews the idea and points out what others have identified before: that the common law standard of proof is "on the balance of probabilities" and the criminal law standard of proof is more severe, because a false positive has such serious consequences, and is defined as "beyond reasonable doubt". He argues that scientists tend to adopt the latter approach limiting the chances of false positives, for instance, by choosing quite stringent ($p = 0.05$) or very stringent ($p = 0.01$) levels of statistical significance. There is a direct trade-off between the level of statistical significance chosen and statistical power. The higher the significance the lower the power to detect a certain level of excess risk. Schrecker goes on to point out that "... standards of proof demanded by scientists, as scientists, may be thoroughly inappropriate when applied to science policy questions. In such situations ... what is at issue should be the relative consequences of the two types of error" (false positive or false negative) SCHRECKER (1986). As an example of the policy effects of rigid insistence on a high level of statistical significance he cites ANSI which excluded all epidemiological studies on microwaves from consideration by use of such criteria. Steneck (quoted in Schrecker) describes this type of behaviour as "the demand for this type of rigour is not the necessary product of science – it is the result of embracing a philosophy of science." STENECK (quoted in Ibid). It is applied by HSE in its Toxicity Reviews without any apparent consciousness that the consequences of adopting "the scientifically rigourous position" (eg. high levels of statistical significance and watertight study design) is not a neutral decision. Statements such as "no product should be banned on the basis of a scientific prediction of an adverse effect, but only on the basis of solid evidence..." PAGE (quoted in Ibid). ".... implicitly attach a very high value to the benefits derived from the products' sale or use". Steneck strikes a neat metaphor for the approach which insists on the highest level of proof when defining the boundary between safe and dangerous. He likens it to the assumption that "... when one is walking along the edge of a cliff, the best way to keep from falling is to know exactly where the edge is.... if all the twists and turns were (known) one would not fall." He counters the view, "it is difficult not to point out that one could also avoid falling by not walking so close to the edge. STENECK (Ibid).

Schrecker goes on to argue, and I agree with him, that decision making on whether a substance or process causes, or helps to cause, a health effect should be judged on the basis of a standard of

proof more akin to common law than criminal law and insistence on only scientific evidence of a rigidly defined kind is implicitly a policy decision. However Schrecker's argument is too simple in two ways. The cliff metaphor has a certain appeal but it implies firstly that an edge as such exists and that given enough research it could be precisely located. Neither assumptions are correct. First no "edge" probably exists for many substances and secondly it seems unlikely that, given the amount of research required, an edge with all the twists and turns could be defined. Standard setters have to live with, and admit publicly that they live in, a world of pervasive and chronic uncertainty.

The second argument which is too simple concerns Schrecker's definition: "'A standard of proof' is simply a decision as to how much evidence will be taken as sufficient to support a particular hypothesis," Ibid. It is not. Firstly because what is and is not regarded as 'evidence' is crucially dependent on the level of proof adopted and secondly decision making is never a simple question of evidence supporting a hypothesis. Mazzuckelli's intellectual feelings about styrene and its health effects could not be described as a hypothesis. It is more that the pattern of evidence points, in his mind, to styrene being more toxic than the apparently rigourous scientific evidence would allow. In his mind he holds a set of hypotheses, a network which together represent the model which makes most sense. Some parts of the evidence and the hypotheses will be vague and incomplete but they fit into a broad sweep picture. At some point Mazzuckelli has to say to himself, as did John Snow before him: I have to make a decision based on a network of inter-related hypotheses of more or less certainty together with evidence of varying quality and levels of proof. We are back in the realms of paradigms, the entities which help paradigm followers operate when the theory and the empirical data are not there. The current OEL paradigm undermines attempts to set HBLs because of the contradictions at its heart. One way the reasonably practicable OELs derived by the OEL paradigm followers have been maintained is by the mechanisms described in this subsection.

A new paradigm which explicitly supported the separate setting of HBLs and RPELs would not hamstring and distort the setting of HBLs as currently occurs. It would allow people to act on tentative models, which did not exclude useful evidence on the basis of, for instance, arbitrary definitions of statistical significance, and which painted the best picture possible on the balance of probabilities. It would also support people to be explicit about the lack of knowledge and their doubts on the precision of the models. It would not, however, prevent RPELs being set. Thus for instance it would encourage standard setting for the 414 substances/processes identified by IARC as possible carcinogens – HBLs and perhaps more importantly RPELs could be identified now. An alternative paradigm would allow and encourage action on tentative evidence to reduce exposure AFARP for all processes releasing suspect substances. It would encourage action by its more relaxed attitude to what might constitute evidence and reduce the number of times we discover to late "... the toxicological equivalent of the smoking gun."

13.5.3 A precautionary policy on toxic substances

13.5.3.1 Health based limits

How HBLs might be set is not the subject of this thesis. What one can say is that the proposal for setting an HBL together with a family of RPELs should enable truly health-based OELs to be set. As almost all past OELs are in fact reasonably practicable OELs the call to set internationally agreed HBLs has met with a confused and contradictory response, with some claiming they already set HBLs and with very few openly describing exactly how, what are called socio-economic factors, are incorporated in and actual effect their OELs. In all cases either practicability is included as an important factor in setting OELs or it lurks as an unmentioned guest at the party – present but not on the guest list. It has its effect in this case by reinforcing the perceived need for hard evidence on health effects and excessive standards of proof. In the process the evidential base is diminished in quantity and quality. If the question of practicability can be divorced from the questions of where a HBL might lie then there should be a much better chance of getting international agreement on HBLs. No country would be required to comply with the HBL in the short term and representatives could relax and work on ways to discuss and resolve their differences. With the reduction in tension between the two world power blocs it may even be possible to resolve East-West differences and agree worldwide HBLs (or indeed HBZs).

13.5.3.2 Performance and Specification Standards/ Approaches

Current OELs contain a strong element of specification standard in that the capability of the control technology and methods applied to the process which causes the highest exposures determines the range in which the OEL can be set.

The standard setting method outlined will result in the more wholesale adoption of this approach, not simply to Process 1 type process (see figure 9.4) but to all processes emitting a particular contaminant or substance.

The method combines the best of the performance and specification approaches. Designers know where they are aiming and inspectors or auditors of workplaces know rapidly whether a process is probably meeting its RPEL. But we should not loose sight of the advantages of the UK system over the US – the Section 63 (Factories Act 1961) approach which specifies that whenever a contaminant is injurious or offensive or given off in quantity, it should be controlled. There is much to commend this general precautionary approach to reducing exposure to any contaminant, whether it has an OEL or not, AFARP, especially if it is offensive or possibly injurious. Such an approach can be applied quickly, well before HBL/RPELs are set and, as the UK/US comparison indicated it has probably resulted in significantly better conditions in small enterprises in the UK

compared to the USA. At another level it is applied common sense. If there are thousands of chemicals in use with little information as to their effects, and no OELs of any kind, a general duty to apply basic control measures makes eminent sense. It also represents in a tacit way an admission of the depth of our own ignorance.

13.6 Priority Setting

The US NAS estimate there are 50,000 chemicals in commercial use and the OECD estimate there to be 80,000. At least several hundred are added to this total each year.

The analysis of the TLV Committee minutes showed that although the committee considered various systematic ways of selecting substances for consideration it has never actually put a scheme into practice. Many believe that the TLV list represents the most hazardous substances used in the workplace which have the greatest public health impact – it does not. There is no such list and given the number of chemicals in use, and the lack of basic data with which to compile such a list, the task is daunting. As there is no systematic basis for selection substances are selected in an ad hoc manner on the basis of available information and individual and organisational interest. Different substances, groups of substances or processes take centre stage at different times. This is partly determined by research and funding interests, but these themselves tend to come out of the ad hoc interest of OEL committees, enforcing authorities and others. The system feeds on itself and it rewards those who do nothing but the bare minimum and do not sponsor additional or exploratory research.

There are at least two organisations trying to address the problem. NIOSH is attempting to use its National Occupational Hazard Survey (NOHS) and Registry of Toxic Effects of Chemical Substances (RTECS) databases to rank-order exposure agents, industries or occupations. These rank orderings, it is hoped, will help in the "selection, testing and evaluation of chemical compounds", VENABLE (1986), (see also PEDERSEN et al (1983)). The OECD has also addressed the problem and described a system for selecting chemicals but I am not sure, how far the method has actually been applied (see OECD (1984). The attempt needs to be made and given the size of the task and international nature of the problems there are good reasons for an international approach, funded by many countries.

There is also a need to use the data currently generated at least for rank ordering chemicals. Various proposals have been made as regards the animal and other data on carcinogenisis and mutagenesis (see ALLEN et al (1988a) and ALLEN et al (1988b)) but there is a need to extend the approach. Prediction of likely irritation now appears possible for some substances LEUNG and PAUSTENBACH (1988) but there is much work to be done on other effects, (see NELSON (1987) for a review of the subject).

A different paradigm which laid greater emphasis on the need to use what data and models we have could stimulate work in the area of selection. It could also stimulate policy makers to face the very difficult problem of what to do once selection and rank ordering of carcinogens, mutagens etc. has taken place. At least HBL/Zs would allow more space for different options to be considered.

13.7 Participation, form and function of OEL setting committees

In the discussion in the last chapter particularly when health-based OELs were considered it was argued that a committee that set reasonably practicable OELs could not set health-based limits/zones. Even for those people who are supposed to, or are instructed to, ignore practicability and cost it is difficult for them not to consider the implications of their decisions. As long as the OEL standard setting system deems it necessary to choose one number, the impossible task of considering health at the same time as practicability will continue. An approach to setting health-based OELs (Phase 1) was considered earlier, this sub-section is concerned with the committee that would do this work. As it has never been done before, under the conditions outlined in the alternative paradigm, there are no exemplary models to learn from. The NIOSH REL team probably comes closest but even here, as was discussed and demonstrated in chapter 12, there is concern with practicability of the proposed OEL and control measures. The health-based OEL committee will be called Committee 1 in this sub-section. What will participants in this committee need to know? There will be a need for people who have a good grounding in toxicology, epidemiology, chemistry and biology. Also some people will need enough knowledge of IH to understand the limitations and pitfalls of exposure measurement and estimation and likewise some will need enough medical knowledge to understand where variable diagnosis could be important. It could be argued quite strongly that it would be better, from the point of view of excluding as much as possible concerns with practicability, if industrial hygienists, toxicologists and physicians were excluded from Committee 1. Such people are so imbued with the OEL paradigm most, at least initially, would not be able to approach setting health-based OELs without reference to practicability and perhaps more importantly, old ideas concerning standards of proof (beyond reasonable doubt) together with firm views on what constituted evidence. However, this view forgets what can happen to a scientific group when a paradigm shifts. In these circumstances many in the old group undergo a shift of vision. It may be that this could happen with industrial hygienists, toxicologists and physicians but it is more likely, because of the braking effect of clients needs, that many cannot make the jump to the new paradigm.

It would be tempting to conclude at this point that Committee 1 should be staffed only by scientific experts who consider the scientific evidence of harm and decide upon HBL/Zs. It is perhaps tempting but it is wrong and goes against the grain of the analysis in this thesis. Knowledgeable scientists are required on Committee 1 and in addition, the committee should contain some intelligent and well briefed assessors, lay assessors. These people would act as the Committee's

conscience, asking the difficult questions – how sure are you that the safety factor is large enough? What doubts do you have on the evidence? What happens if you apply a less stringent criteria of "significance" to the studies under review? How big could the risk be without these studies being able to detect it? What are you not sure of? They would also act to specifically exclude explicit and implicit questions of practicability.

Committee 1 will not consider the thorny question of RPELs and how fast industry should proceed towards the HBL/Zs. The latter are very likely to vary with the development and technological sophistication of the country. Given that Committee 1 is setting target HBL/Zs for which there will be no intention of trying to apply willy-nilly there should be scope for international collaboration. Members could be drawn from many countries and resources, knowledge and experienced pooled.

How would the committee proceed?

It would work in an open fashion and it would do so for two reasons. Firstly for the reason made explicitly, and I think correctly, by Castleman and Zeim (Chapter 9). They argued that the deliberations of committees that set exposure standards for others should, in a democratic society, be open to debate, question and analysis. Secondly, and for a more functional reason, the Committee's process should be open because the committee is venturing into uncharted territory. It will be trying to do something no committee has attempted (in the West at least) and it will need as much help as it can get. The committee could start by convening a series of fora to debate openly the question of how to set health based OELs. Once a methodology had been developed it would then be converted into a set of formal procedures. Because of the number of substances in use, under no formal control, there will be a need for the committee to develop systems for proceeding rapidly. It would seem inevitable that the committee will need to explore the development of generic approaches to chemicals with similar effects, as has been attempted by OSHA for potential carcinogens.

Committee 2, which produces the sets of RPELs (Phase 2) needs different information and people with different knowledge and skills. This committee will need people who understand how processes cause exposure and understand the limitation of different methods of exposure control. Such people would include government and industry based IHs and others involved in process design and control. To speed up the process it would be useful if the committee could agree to apply a standard procedure in the setting of RPELs (including the OpEL) as described earlier (13.2.2). The Committee could usefully hear representations from industry, probably via its research and trade associations. It should also hear from those exposed. The current systems of representation are too hit or miss and do not result in people feeling involved in the process by which their exposure levels, and the concomitant risk will be determined.

As most RPELs will be greater than the HBL there will be a need to develop policies by which lower RPELs are phased in and there will be a continuing need to develop better and more cost-effective methods of control. There will also need to disseminate and apply this information as efficiently and widely as possible. The current systems can best be described as lackadaisical, (see PINEY et al (1988)).

Committee's 1 and 2 will need a secretariat and a research arm sufficiently large and qualified to help them undertake the tasks described. Given the resource implications such a scheme would probably only be viable on a continental scale.

13.7.1 RPELs specification and enforcement

The current reasonably practicable OELs are realisable, with some effort on the part of "Type 1" processes, by all of industry. Indeed this was one of the essential features which made them so attractive to professions such as IH, and their clients. One of the conclusions of this thesis are that reasonably practicable OELs need to be far more carefully defined and monitored. HBL/Zs provide the goals and the motivation that there is a continuing need to do better. However as there are so many substances with no OELs there is a need as Russell reminds us to keep exposure to all chemical substances under some control (see 13.3.4). It follows that any system of regulation which aims to reduce the risk due to exposure to chemicals in the workplace in applying the new paradigm would develop HBL/Zs and RPELs and, at the same time would apply a general specification approach similar to, but perhaps updated, Section 63 of the UK Factories Act 1961. Control of substances which are irritant, offensive or generally cause complaints should not have to wait on the setting of OELs. Under the new paradigm the assumption is made that there are significant numbers of middlingly-bad actors in the large universe of chemicals used in industry. This precautionary approach would mean that exposure to any substance which causes effects in exposed human population should be treated with suspicion. Exposure should be reduced in such cases to a level at which no effects are reported. Section 63 in the 1961 Factories Act and Section 47 in the 1937 Act before it were, in effect, acknowledging our profound ignorance of the effects of many substances at work. These Sections prefigured by decades the explicit precautionary policy adopted by HSE in the late 1970s.

RPELs will be based on and will generate fairly exact descriptions of the types of control methods inspectors or auditors will expect to see in workplaces. However unlike old specification standards RPELs will be dynamic and allow innovation in control methods. Where there are no OELs and yet there is cause for concern a general specifications approach should be applied.

The alternative paradigm takes the best bits from both the performance and specification approaches. It presents industry with numerical and attainable goals which encourage innovation and yet allows rapid audit and inspection of the workplace, one of the principle advantages of the

specification approach. It also encourages the application of controls in cases of doubt where exposed populations report problems. Such, enforcing and auditing organisations should not find it too difficult to adapt to the use of RPELs. In the context of the UK it would require that a new up-dated version of Section 63 should be inserted in the COSHH Regulations 1988.

13.8 Professionals and the alternative paradigm

This thesis has traced the development of IH in the USA the profession which, with IT, forged the OEL paradigm and sold OELs to other professions and a variety of clients. The paradigm came out of the IH profession's and clients priorities and beliefs and it supported day-to-day professional life. The IH profession expanded to fill a niche which was expanding, of which it was conscious and for which it was well adapted, especially once an alliance was forged with IT. This professional evolutionary process occurred nowhere else – there was something special about environment in the USA in the 1920's – 1940's, an area that was examined in Parts 2 and 3. The description and justification of HBL/Zs and RPELs together with the alternative paradigm beg the question of which groups or professions are likely to support or be converted to it. Having identified the dilemma I cannot offer a simple answer. Alternative paradigms do not require the existence of new professions. Paradigm shifts can occur in which the large majority in a profession or a number of professions adopt the new paradigm. The alternative paradigm outlined offers challenges and opportunities for all the professions involved in OELs. It does though imply a different training for new entrants into the professions, a different vision of their respective roles and a different relationship between these professions, the society in which they exist and the clients which they serve.

If the OEL paradigm is indeed in chronic crisis and the social environment is also changing in a similar but more profound way to the 1960s, then large scale acceptance of an alternative paradigm becomes possible. In these circumstances either the professions, particularly IH and IT, with most allegiance to the OEL paradigm will need to adapt or, as happened in an incomplete way in the USA, a new profession will evolve. It will draw on and add to traditions in current professions and do as IH did, crystalise and promulgate the new paradigm.

13.8.1 Professions and clients

No science is homogeneous in the sense that there are camps or factions within any scientific group, (see HULL (1988)). Sciences, particularly applied sciences are not insulated from societal priorities, powerful clients and controversies. These influences are imported into the science, into the paradigm, from the society in which the science is practiced. They become part of the paradigm and its interpretation and they may then be projected back onto society. Even this description is problematic in that it implies that scientific groups are separate from society. In some ways this is a fair description of professionals – they do try to isolate themselves and claim

special knowledge, insight and skills and scientists develop their worldview, working to their paradigm and interacting most strongly amongst themselves. But it is also a false and misleading description in that no one is born an IH or an IT or a scientist. They come to those subjects after a long socialisation process and they bring this, together with socialisation they have received as professionals, to their day-to-day practice. And this latter, as has been discussed is itself shaped by clients needs and priorities.

In the context of this thesis the alternative paradigm will demand as rational and ethical behaviour as the professions involved can muster. For IH, IT and the other applied scientific professions involved there will be a greater need than ever to keep clients implicit and explicit demands at arms length especially those working in industry. This certainly applies to those involved in Committee 1 business but it also applies to Committee 2 which will require honest appraisals of just how low RPELs can be pushed without distorted and special partisan pleading.

Lynn's work, examined in chapter 9, shows how clients and organisational culture may influence theory selection and Castleman and Ziem mount a determined assault on the neutrality of ACGIH TLV Committee's process and imply that any contact with industry employed professionals necessarily distorts the Committees work. And certainly, in the USA at least, the separate formation of the ACGIH and AIHA, would suggest that there was a belief that different IH's with different clients had different and sometime irreconcilable priorities. An important question arises in the context of the proposed alternative paradigm:
How does one foster a self-critical, questioning professional culture which does not become dominated by one set of clients needs and priorities?

All professions have codes of ethics which are policed with more or less vigour. Almost if not all such codes are couched in idealistic terms, exhorting the profession to put, in the case of IH, the health of the workforce as first priority for instance. The reality of day-to-day professional life is not taken account of in such codes. The most consistent way to ensure sustained ethical behaviour, it could be argued, will occur if a person is driven internally to so behave. But no person is an island and most people take their cues from the organisational culture and its priorities. A person takes his or her bearings as to whether he or she is behaving correctly from the immediate professional context. Some people, whether by accident of personality or history, can and do stand back from the context in which they work and can see or feel when they are drifting into dangerous ethical or moral waters, because of the organisational environment and culture with its own priorities, which they inhabit. How does an applied scientific profession like IH or IT maintain an understanding of industries special problems yet at the same time not become morally anaesthetised by the work context and culture?

An openness in the decision making process would certainly help as would regular and open contact with alternative reference groups. This is an argument for greater professional pluralism,

but it does not address the question of day-to-day behaviour. This day to day reality would become very different if there was no direct connection between the IH, IT or industrial physician and their employer, if such professionals were employed by a third and independent party. The exact arrangements are outside the scope of this work but this research, especially the discussion of the influences on applied scientists, indicates that the question of clients will not go away, and will need sustained attention.

13.9 Working definition of an alternative OEL paradigm

In Part 3 a working definition of the OEL paradigm was given and used as a yardstick to gauge the various individual interpretations of the paradigm.

In retrospect the OEL paradigm is seen to be hugely optimistic and, to the degree that practicability and other factors intervene, flawed. The mark II version in chapter 9 at the end of the ACGIH TLV analysis is a much more accurate, if rather prosaic, representation of the paradigm to which hygienists and others have actually been working (9.4.4.1).

We are now in a position to describe some of the tenets of an alternative paradigm.

13.9.1 Introduction

The alternative paradigm keeps faith with the old paradigm in the sense that it is process oriented. It is by controlling or, in some cases eliminating, processes that health effects produced by chemical substances (and indeed other hazards at work) are prevented. Also the alternative paradigm would help rekindle the early optimism of IH and ITs. The person who wrote the footnote in the ASA styrene MAC document in 1944 was correct, and I too look forward to the time when, "exposure of humans" would not be "... considered necessary to evaluate toxic response in man". ASA (1944).

13.9.2 Some tenets of an alternative paradigm

1. Our ignorance concerning exposure to most chemical substances in the workplace and the health effects they may cause is profound.

2. A significant number of the 50,000+ substances in routine use are capable, sometimes in conjunction with other factors, of life shortening of life quality reducing health effects.

3. The techniques available for identifying such substances, although much improved in recent years, are relatively insensitive and imprecise. More importantly, they are not used

routinely in a sustained and wide ranging fashion. Most chemical exposures go unexamined, their effects unmonitored and unrevealed.

4. Given our ignorance, and the potential effects on human populations exposed, the level of proof which should be applied in decisions concerning chemical substances or processes at work (and in the wider community) should not be some arbitrary, restricted and high level often prefaced by the word 'scientific'. The inevitable and profound uncertainty in this area, coupled with the cautious message of history requires decisions to be made on more relaxed standards of proof – on the balance of probabilities. If there is any erring to do it should be in favour of stricter control of the chemical or process involved.

5. A practical effect of this approach should be to apply or improve exposure control wherever and whenever there is evidence of potential harm. This control should be at least AFARP and should be applied to all processes using or emitting substances. The level of exposure which AFARP control measures will bring about will vary from process to process. These are the facts of life and will be made explicit.

6. Groups concerned to identify exposure levels which have no or minimal health effects should be separate from groups concerned with AFARP or AFAP exposure levels. They should develop formal and, where possible, generic rules for rapidly setting HBL/Zs. The overly cautious case by case approach is too slow given the size of the problem we face.

7. A conscious attempt will be made not to impose over-arching models in an attempt to encompass all exposure response relationships. The complexity and subtlety of such relationships properly requires a variety of interlinked models to explain the variety of dose response relationships that are known to exist.

8. The standard setting process of the health-based and reasonably practicable OEL committees/groups will be open, public and explicit.

9. The setting of such limits is the province of people drawn from a variety of backgrounds. It cannot and should not be delegated only to professional experts.

10. The alternative paradigm demands a different perspective and behaviour from the various professional groups that are currently involved.

11. Because of the potential size of the problem faced it is imperative that both health-based and reasonably practicable standard setting proceed as fast as possible. Do-it-yourself standard setting sponsored by industry and others should be encouraged and facilitated.

Such efforts could then be incorporated by national or international organisations if the process and the products were judged to be in-line with the alternative paradigm.

12. RPELs should be accompanied by details of the control measures applied to processes to which the RPELs apply. The performance and specification approaches should be explicitly linked. The specification approaches should not be incorporated in regulations but should be in the form of databases of solutions which can be added to or deleted. In this way control methods would not become fossilised and control innovation would be encouraged. As control ideas and methods improved and were applied so the RPELs would fall towards the HBL/Z.

13. The strategy adopted in the alternative paradigm does not rely solely on OELs for control. It combines the strengths of the performance and specification approaches. If work environment emissions give rise to what Sections 47 and 63 of the 1937 and 1961 Factories Acts described as "likely to be injurious or offensive" then improved control should be applied until the emissions are judged, by those exposed, to be adequate. Where there are no OELs for control guidance or targets, and this will be the case in many instances, then control of exposure which is causing, or has the potential to cause, health effects should not have to wait on the creation of OELs. The spirit behind Sections 47 and 63 should not be lost. This two pronged strategy is essential for any meaningful precautionary approach to toxic substances at work.

13.9.3 What chance for the alternative paradigm?

The alternative paradigm will require different standard setting procedures some aspects of which have been explored. But more than this it will require a different outlook on the control of toxic substances at work. As with all paradigm changes it will require a gestalt shift in the thinking and vision of the followers of the old paradigm. With applied scientific professions this is particularly difficult because of the clients such professions have. The inertia built into the system is large. What then are the chances of the alternative paradigm? The old OEL paradigm has survived for so long because of the symbiotic relationship between the professions who espouse it and the clients who like and use it. Without the power of the clients, it is my contention that, the OEL paradigm would have gone into crisis years ago. IH and IT have much to gain from the alternative paradigm bu' do the clients? The answer is that some do and some don't. Using the list identified in Chapter 2 the likely reaction of clients might go as follows:

Academia – Yes – it opens up possibilities for research both theoretical, how to set HBL/Zs, and applied, how to apply control to a large variety of processes.

Private/Public companies – Yes/no – the alternative would defuse conflict over "safe levels" and RPELs and associated specification control measures could make negotiations less adversarial. But there could be the worry that people were working with 'unsafe' processes.

Union – Yes/No - the alternative paradigm would result in better conditions but RPELs would require official acceptance of the reality of the work environment.

Government – Yes/No – the alternative paradigm is a defendable approach but HBL/Zs could be problematic in that they might appear that governments were sanctioning 'unsafe' levels of exposure.

Insurance companies – No - of all the identifiable clients insurance companies (and that arm of the State which deals with compensation) would be most whole-heartedly against the alternative paradigm. They were the private organisations in the USA with most enthusiasm for OELs (see Chapter 5) and saw them as a way of controlling risk and limiting claims. They would not like the proposed alternative as it provides no screen against claims and identifies risk at levels considerably lower than current OELs.

Which way the clients jump will depend on how long the contradictions in the current OEL paradigm can be shored up, how the opposing forces in the clients identified manoeuvre, and perhaps most importantly how much influence forces outside 'the client' change the environment in which they operate. The environmental movement was one of the major factors in the 1960s which pushed the OEL paradigm into crisis, and it has always been incongruous that acceptable levels of environmental exposure are usually far lower than corresponding OELs. With the greening of politics it may not be too long before the contradiction once again becomes unacceptable. The pressure will then be on to act. At this point an alternative and defensible paradigm may be more attractive to some at least of the clients. Once one breaks rank the rest will have to follow or else be left in the position of defending the indefensible. The approaches taken by OEL setters in Holland and claimed by the EC are perhaps the first signs of movement. Thus the choices of the alternative paradigm, or something like it, gaining widespread acceptance are improving even though not all the clients of the old paradigm will be converted.

13.10 Concluding comments

In considering the development of chemical exposure limits for the workplace this thesis has developed an analytical framework with which to consider the evolution and paradigms of applied scientific professions. The history of the development of IH in particular showed how the priorities of this profession, and indirectly its clients, became incorporated in the OEL paradigm. The symbolic message projected by single number OELs and the content of the paradigm have been examined in detail as has the practice of OEL setting. Along the way national differences

have become clear and have illuminated the process of OEL setting and the discussion of controlling chemical exposure. An attempt has been made to use and build on the paradigm idea of Kuhn and this attempt and the historical approach adopted is a thread running throughout the analysis. The last two chapters consider the paradigm, professions and our current knowledge and offer an alternative paradigm which explicitly admits the difficulties, and separates the practice of setting HBL/Zs and RPELs. Whatever the future holds for OELs it is clear from this research it will be intimately bound up with the applied scientific professions/professional scientists of IH, IT and industrial medicine, their clients and the wider demands of the society in which they operate.

13.11 Further work

In its travels the analysis in this research has walked past a number of research avenues which could profitably be explored.

The analytical framework for looking at the development of applied science based professions could usefully be applied to other similar professions to IH and IT.

There is a need for more research along the lines of Lynn to gain a better understanding of how social and political attitudes become incorporated into the outlook of such professions. The analytical framework developed perhaps helps open the door to this possibility.

The focus in this research has been principally on IH and its evolution. (This was a legitimate compromise as IH was the main profession which developed and promulgated the OEL paradigm), However, more work needs to be done on IT and industrial medicine whose influence is undoubtedly greater than has been allowed for in this research.

Approaching such professions from another angle, there is a real need for sociologists and philosophers of science to turn their gaze on and examine the workings of applied sciences. For too long they have concentrated on the big sciences of physics and chemistry and biology and avoided the issues which inevitably surround research into applied scientific professions.

There is also much practical work to be done on the identification of RPELs and exactly what formal procedures would be viable for Committee 1 in the setting of HBL/Zs.

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APPENDICES

APPENDIX ONE

1.0 The Foundation and Evolution of Industrial Hygiene

This appendix contains a lengthy description and analysis of the evolution of the profession of non-medical industrial hygiene. It was written at the start of my doctoral research before the final analytical framework was developed, see chapter 2. It is included because of its intrinsic interest, and because it supports the points and conclusions made in chapter 3.

Specifically, the approach taken throughout is to plot the growth of non-medical IH as a profession, using the criteria outlined in the early sub-sections. In the light of the final analytical framework this approach is limited. It concentrates too much on the internal working and strength of the professions involved and focuses too much on the ecological rivalry between medical and non-medical IHs. While this rivalry has occurred it offers a partial explanation for the growth of the non-medical IH profession.

The Appendix is included because of its intrinsic interest and because it shows how the analytical framework eventually developed. It should be read from the point of view that it represents an analysis based on a partial and exploratory framework.

1.2 Introduction

In the author's opinion, the most coherent view of the development and evolution of IH can be gained by looking back at the way the subject was forged into its modern form, and by seeing the process by which this took place as a series of steps on the way to the development of an autonomous profession. This approach makes IH the principle focus of attention and all other potentially important developments are only mentioned where they impinge on the development of IH as a subject and profession.

1.3 Professions

There is a large social science literature which addresses the formation, function and workings of professions. Few authors have applied the insights gained by this research to the field of the occupational health and safety professions. Just after the Health and Safety at Work Act was promulgated and the Health and Safety Commission and Executive were set up, Atherley and Hale considered how occupational health and safety could become a coherent, recognised profession in the UK ATHERLEY & HALE (1975). Although they address the question of professionalisation of the whole health and safety field, much of their work is applicable and relevant to occupational hygiene. Using the insights of other authors, principally Johnson and Millerson, they concluded that "Without control there is no possibility for the evolution of a clear and recognisable body which can pursue any of the aims we have identified ..." Ibid. Those aims being the six elements common to a professional group namely:

1 Power
2 Competence
3 Moral precepts
4 Voice
5 Advancement of vocation
6 Service to individual practitioners

The first three were identified as being attractive not only to the aspiring professional but, more importantly, to potential clients. The authors then went on to address how "occupational control" could be gained by considering Millerson's "obstacles to professionalisation" of which there are eight:

1 Insufficient internal or external pressure to form an organisation.

2 Underdevelopment of subject matter and/or practical technique.

3 Great variation in quality of service provided; training received by practitioners; level of study; type of employment; social origins.

4 Rivalry between occupations and organisations.

5 Small number of practitioners.

6 Geographical isolation.

7 Underdeveloped governmental, industrial or commercial structure.

8 Absence of enterprising individuals.

Each "obstacle" will now be assessed in turn.

1 Pressures for development of a profession

It was considered that generally, amongst important and influential groups including the CBI, TUC and HSE, there was not a recognition of the need for a strong health and safety profession, ie. there was little or lukewarm pressure for professionalisation. The authors saw this as partly due to "the lack of any coherent technical framework for considering health and safety".

2 Lack of recognised subject area

The authors identified the "historical split between the engineering aspects of safety and the medical aspect of industrial disease", together with large numbers of diverse groups laying claim to the field as an unresolved problem. They identified the generalist, analogous to the general practitioner in medicine, as the controlling figure the profession required, "binding together the diverse specialisms" and put forward the outline of a coherent subject area.

3 Diversity of jobs, people and services

The level of employment and the qualifications of people employed ranged across the spectrum and did inhibit the cohering of a profession.

4 Rivalry of organisations

Two kinds of rivalry were identified; that coming from the established professions of medicine, engineering and chemistry and that coming from the newer occupations such as the ergonomists. To counter the first was a matter of projecting the single discipline approach as inadequate. To reduce the second the authors proposed negotiation over spheres of influence.

5 and 6 Small numbers and isolation of practitioners

If too small, (which they define as less than 100 members) an aspiring profession may not have a large enough "voice" and members may be tempted to join other larger, more assertive professions which can represent their interests.

7 Underdeveloped governmental, industrial or commercial structure

The field of occupational health and safety has seen to fulfil these criteria (in 1974).

8 Absence of enterprising individuals

The authors "did not presume to" comment on this factor but, as will be discussed later, it may have been an important factor in the growth of industrial hygiene in the USA and the lack of growth of occupational hygiene* as a coherent subject in the UK.

9 Client

Unlike the professions of law and medicine, exactly who is the primary client of the occupational health and safety professional is problematic. The authors argued that this issue needed to be decided and favoured a definition leaning towards the individual employees and the public as being the "clients" of the health and safety professional. They felt that the "profession" would need the support of the state to maintain such a position.

In summary then, for the health and safety practitioners, including the industrial hygienists, to become professionals there has to be a demand for their particular mix of skills; the subject has to be coherent and not successfully claimed by old professionals; rivalry between competing groups needs to be minimised, there must be enough people to create a viable size organisation and enough enterprising individuals; industry needs to be complex enough to warrant specialised professional services, and finally the profession must define who it serves.

Ten years after the Atherley and Hale paper, Hale et al (1986) again reviewed the position of the health and safety professions in Britain. In this work Millerson's eight obstacles to professionalisation were condensed into four summary characteristics and these criteria were applied to the UK occupational hygiene profession. The author's also developed an original approach to a method of viewing the development of the various health and safety professions. An "ecological analogy" is used to try and capture the complexity of the problem which faces the various competing professional and pseudo-professional groups". The authors coin the term "The Ecology of Professions" and describe the way professional species compete. The approach is quoted in some detail because it will be used in later sections, together with Millerson's criterion, to analyse the evolution of non-medical IH. Hale et al (1986) describe the ecological rules which govern professions thus:

"Professions can usefully compared to biological species struggling to survive in an environment filled with competing species of varying size and specialization. The driving forces and constraints for biological species competing for ecological niches are the battles for food and reproductive success; in professions they are the battles for membership for food and reproductive success; in professions they are the battles for membership and control of the knowledge base as they compete for jobs (occupational niches) in the health and safety environment. The environment is a changing one, so there are evolutionary pressures which affect long-term survival. When a new niche is created by a change in the environment (eg. a change in technology or social concern) established species may try to claim the niche as their own or adapt into it. If more than one do so, they will battle for its ownership. Engineering and medicine in particular have done so in relation to the niche called occupational health and safety. However, professions which fit an occupational niche perfectly at one stage may, if they do not grow and adapt with it, find themselves displaced and superseded by more flexible, vigorous species prepared to fit themselves to those changing conditions.

An imperative of ecology is an appropriate degree of adaptation of fit a defined niche. For professions we would define it in terms of meeting the needs of employing organizations in the most cost-effective way. Industry defines its needs in health and safety within the constraints and pressures of statutory requirements and public and state attitudes. This introduces an essential difference between the ecology of biological species and that of professions, namely the niche that the latter are competing for has a subjective as well as an objective element. Industry may not accurately perceive the extent of its problems and their priorities. In particular, it may have its own way of dividing up the field of health and safety into several, perhaps ill-considered, niches. These may be based upon more traditional views of the field and may be strongly influenced by the views held by the existing professional groups.

Powerful and dominant professional species will always try to impose their own subjective view of the niche (adapting the niche to themselves and not themselves to the niche). Thus, the medical profession will always emphasize individual factors, medical examination and diagnosis, engineers will emphasize technical failures and automating the man out of the system (Hale, 1985), while personal managers emphasize selection, training and discipline. For traditional professions this is where their interest lies. To adapt themselves well to the real niche would be difficult for a large, established and well-defined body. It would involve radical changes to training programmes and might even threaten its adaptation to the more important niches at the centre of its ecological range. While it would be possible for a small group from any of these bodies to evolve into the niche, this might only be at the cost of their ability to interbreed with (ie. to retain recognition by and pursue careers in) the central stock. This would be the case, for example, if occupational physicians seriously set out to learn environmental control technology, an endeavour which would involve them in learning basic engineering principles." HALE, PINEY AND ALESBURY (1986) p 6/7

1.4 Early Developments in Industrial Hygiene

1.4.1 Definitions of Industrial Hygiene (IH)

One of the problems any investigator dealing with the development of industrial hygiene (IH) faces is that the definition of IH has changed over time. Thus, when different authors refer to IH, especially when describing early developments in preventive public health, they often mean different things. Some authors are referring to the cleanliness of the workers or workplace, others expand the definition to encompass all prophylactic measures to combat disease in the community and at work and refer to the work of "hygienists". Yet others define the term IH in a more contemporary fashion as a subject concerned with the recognition, evaluation and control of hazards to health (and safety) in the workplace, and hygienists as the people who carry out this work. This makes interpretation of early developments difficult and to make sense of the early literature, the author will concentrate on those figures who used or prefigured the more modern definition of IH and IH's, ie. as a subject and group of people concerned with the recognition, evaluation and control of health hazards at work.

In doing so the author assumes that there is a fundamental difference in the world views of industrial physicians or early medical IH's and non-medical IH's. The development of these world views is described and analysed in the text, however so that the basis of the following analysis is clear the approaches of the industrial physician/medical IH and the non-medical IH to occupational health are summarised below.

1.4.1.1 The Doctors' Approach

All doctors are initially trained as clinicians to diagnose and treat diseases. They have a very broad training which covers to a greater or lesser extent all branches of medicine from gynaecology to ophthalmology. Their focus certainly in the early 1900's was the individual patient.

Later in the text the work that early industrial doctors did will be described in some detail. Of relevance at this point is that most employers and employees expected early industrial doctors to provide general medical services calling upon their general, clinical medical skills. There was little scope or time to devote to preventative actions and where this occurred the emphasis tended to be on individuals and individual behaviour.

Thus the basic world view of the newly trained doctor was and is focussed on the diagnosis and treatment of disease in individual patients. More recently specialist training programmes and the development of epidemiology and the change in perceptions this has brought about have led to a more population based approach to occupational disease. However, these changes can be best described as a process of unlearning or reorientation away from the clinical medical world view. A doctors training, even a present day specialist in industrial medicine, best fits him/her to recognise industrial disease. Evaluation and control involve skills which are not control to medical courses day to day or practice, and these areas are usually left to other scientific specialities include non-medical IH.

1.4.1.2 The (non-medical) Industrial Hygienist Approach

Non-medical industrial hygiene (IH) was developed by engineers and chemists working in the public sector in the USA. Given this background the approach of the non-medical IH to occupational health is biased towards measurement and engineering. It is processed based and assessment and control of the process are expected to prevent occupational disease in working populations. Recognition of disease is left to the doctors although recognition of the potential for disease is done by non-medical IH's in conjunction with toxicologists, physiologists or other in the biological sciences. Non-medical IH's have never been a self contained professional group in that they do not possess clinical diagnostic skills. This, as will be shown later has been a problem for the developments of the profession but it had and still has the advantage that non-medical IH's were not and are not asked to provide general medical services. A summary definition of occupational hygiene (UK equivalent of industrial hygiene) is given below and gives the flavour of the non-medical IH's process or systems based approach to occupational health. "Occupational hygiene is that applied science devoted to the Recognition, Evaluation and Control to acceptable standards of physical, chemical and biological factors arising in or from the workplace which may adversely affect the health or well

being of those at work or those who may be affected by the work of others. Together with Occupational Medicine it forms the general activity known as "Occupational Health".

IOH (1980)

"The achievement of these objectives requires a contribution from many disciplines. Toxicology, physiology and medicine are involved in the recognition of hazards and in the setting of proper standards for the use in their control. Physics and chemistry are applied in the evaluation of existing conditions for comparison with the standards. Along with a basic understanding of the technology involved in the processes and operations, control of the occupational environment - with its attendant benefits of greater safety and increased comfort, morale and efficiency - requires the application of mechanical, chemical and ventilation engineering. Some occupational problems may also require an understanding of specialised aspects of certain other subjects, such as architecture, psychology, or mining engineering; and thus an interdisciplinary approach is essential".

BOHS (1980)

"Those trained in the discipline may work as a member of a team including medical and safety officers and *provide a unique perspective to the work operations* and offer specialised solutions to many problems (authors emphasis).

IOH (1980)

1.4.1 Early IH History

Teleky in 1948, in his history of factory and mine hygiene attempted to summarise the early development of the subject in Europe and North America TELEKY (1948). He took a relatively modern definition of IH and applied it to early authors, mainly but not all medical doctors. (Although this definition "slips" at some points, so, for instance he refers when describing early factory legislation to "IH legislation").

The early references on IH are principally concerned with the effects of the work environments of mines, initially, metal mines and later coal mines. These are environments where some kind of rudimentary IH measures were required simply to allow work to proceed uninterrupted. The early history of IH is the history of mine hygiene.

The later editors of "On the Poisonous and Noxious Vapours of Fumes of Metals" described the publication as "the first publication in the literature that deals specifically with industrial hygiene". KOELSCH and ZOEPFL (1927). It was written by Ulrich Ellenberg in 1437 but not published until 1534 and took the form of a leaflet for goldsmiths and other metal workers which described how to protect themselves against the effects of silver, mercury and lead fumes. TELEKY (1948). Later, Agricola published a more extensive work on mine hygiene in which he describes how mines may be ventilated and how "loose veils" may be used by miners to protect themselves from airborne dust. AGRICOLA (1556). Coalmining activity slowly increased throughout the 16th and 17th Centuries. Mines were taken further and deeper underground from one main shaft. Methane explosions in coal mines became a regular occurrence in the 17th Century and mine ventilation was a major engineering concern in industrialising countries, thus between 1516 and 1688 over 317 patents concerning mine ventilation were lodged in England alone. TELEKY (1948)

Paracelsus's (Theophaetus von Hohenhein*) book: "Phthisis and Other Diseases of Miners" published in 1567 was very influential and several other German authors addressed the same subject following the original authors approach PARACELSUS (1567). However, neither he nor his followers dealt with the prevention of the diseases they described by IH methods though they did recommend the use of various drugs which were supposed to have some prophylactic action. However, at about the same date (1656) another German physician, Samuel Stockhausen, did call for preventative measures in mines and explicitly criticised the approach of Paracelsus. He wrote: "Prophylaxis rather than remedies should be used so that fogs, fumes, vapours and metal dust be avoided and the miners try to preserve their strength". STOCKHAUSEN (1656)

It was at about this time (late 17th Century) that similar concerns were voiced in England concerning the effects of work on health which were published in the transactions of the Royal Society. TELEKY (1948)

At the turn of the 17th Century Bernardo Ramazzini* published his "De Morbis artificum diatriba (Treatise on the Diseases of Artisaus) RAMAZZINI (1700). Although this book presents wide ranging and perceptive descriptions of the link between certain trades and certain diseases it concentrates on the clinical aspects of the diseases and hardly touches on preventative IH measures. Again, as with Paracelsus, Ramazzini recommends prophylactic medicaments. However, despite this limitation Teleky considers that: " ... in describing the working conditions of the individual trades and the damages caused by them, Ramazzini laid the foundation of industrial hygiene and the basis of prophylaxis". TELEKY (1948). Although this claim ignores the earlier work, particularly of the German investigators, it is perhaps fair in that the "Treatise" is very thorough and wide ranging, made many original connections between occupation and disease, and was reprinted many times and translated into several other languages. A number of these translations enlarged and improved on Ramazzini's earlier work ACKERMAN (1780).

The political economy of various European countries evolved over the 16th and 17th Centuries away from a feudal mode of organisation towards a capitalist form. This was accompanied by the development of the factory system and a range of philosophical, scientific and technical innovations. The process occurred unevenly and England led the way for the greater part of the 18th and 19th Century. Steam power meant that factories were not tied to certain geographical locations where water power was present. The factory system coupled with the use of steam power and the capitalist mode of production concentrated people in work rooms for long periods. At the same time discoveries in the science of chemistry and their application to production methods and the formation of new products meant that factory workers were exposed in a concentrated way to novel hazards, never before experienced on a mass scale. By this process the links between certain occupations and particular patterns of disease became clearer for investigators.

The thinking of certain individuals on how processes and work methods could be changed to reduce the risk in certain trades also became clearer. The basic principles of IH evolved during this period and were codified. Teleky identifies Patissier as the first person to describe IH, preventive principles in some detail, though interestingly this author, like many before him, acknowledged the seminal work of Ramazzini PATISSIER (1822). His work, published in Paris in 1882, will be quoted from Teleky's account in some detail because it represents the first known codification of what are recognisable IH preventative principles.

"For the control of industrial damages he recommends:

1 Prohibition of dangerous trades, or, if that is not possible, the exclusive use in them of criminals sentenced to death;

2 Diminution of dangers by substituting machines for hand work;

3 Installation of public baths;

4 If the complete prevention of injury is impossible, the aged and the ill persons should be cared for by mutual insurance.

He also mentions that, as protection against noxious gases, workers should wear over mouth and nose a sponge soaked in certain liquids, depending on the vapours against which they are to protect the wearer. He recommends for certain purposes other respirators but adds that all such respirators are a nuisance for the worker and should not be used regularly. 'We therefore have to look for simple and cheap devices which do not bother the working man and are independent of his volition'. (A plea which echoes down the years to the present day industrial hygienists).As such a device he recommends D'Arcet's 'forneau d'appel'.

D'Arcet, a tester in the Paris mint, saw three of his seven colleagues die from the effects of nitrous fumes. Seeking a means to draw off the vapours, he introduced the pipe of a special furnace into the chimney of the work shop, which by its heat caused a dilution of the air and so

* Regarded by many as the "Father of Occupational Medicine".

furnace into the chimney of the work shop, which by its heat caused a dilution of the air and so a draft strong enough to carry the fumes out with it. For his invention he won a prize of 3,000 Fr placed by a manufacturer of gilded bronzes at the disposal of the Academic Royale des Sciences de France. Besides D'Arcet's "forneau d'appel", Patissier recommended that gilders should wear impermeable gloves and working clothes, and that work clothes and street clothes should be stored in separate lockers. In accordance with the custom in Paris factories of this kind, mirror makers should cover mirrors only one day a week and do other work during the rest of the week. Patissier also speaks very extensively of the sewer workers, who are endangered by "mitte" (ammonia vapours), "plomb" (hydrogen bisulfid), and "gas azote" (lack of oxygen); he recommends various measures for their protection. In summary, we may say that Patissier's book is the first to offer a modern outlook on industrial hygiene; his acute observations and remarks should be - but are not always even today - recognized by everyone". TELEKY (1948).

A seminal figure, for the English speaking world, who published some 10 years after Patissier (in 1831) was Charles Turner Thackrah, THACKRAH (1831) He qualified as a surgeon and apothecary in 1816 and returned to Leeds, his home town, to be the town's surgeon caring for poor-law patients in the slums. Meiklejohn, who reviewed the literature on Thackrah's life and work MEIKLEJOHN (1957) considered that although "Such appointments were poorly paid ... they presented unrivalled opportunities for the study of disease in relation to vicious social conditions. Such experience could not fail to influence his outlook and his life's work", Ibid. He knew of the work of Ramazzini and Patissier and makes reference to them in his book. Other British authors had drawn the attention of the medical profession to the diseases of specific trades but Thackrah's book was the most comprehensive work. He also had a more extensive vision of the role of the doctor:

" ... We find volumes on the symptoms, character and treatment of diseases, but rarely a line on the causes as produced by employment and habits, and this line is as frequently erroneous as correct ... A study of medicine, moreover, which disregards the prevention of diseases, limits its utility and its honours. It would strip the profession of its noblest attribute, that of benevolence; and exhibit our practice as influenced more by personal and pecuniary motives, than by an anxiety to relieve human suffering and promote human happiness" THACKRAH (1831)

The book was well received by the medical press and rapidly sold out. (A second enlarged edition was published in 1832 just after Thackrah's death). It was cited by Michael Thomas Sadler, MP when introducing the second reading of the Bill for regulating the labour of children and young persons in factories. He spoke on 16th March 1832 and quoted extensively from Thackrah's work MEIKLEJOHN (1957)

Although Thackrah's description of the causes of diseases in certain trades are perceptive he did not address the question of prevention in any great detail apart from general comments on the need for personal hygiene and the use of "currents of air" to carry away dust. His work was influential but Patissier must be credited with the first recorded exposition on preventative IH principles.

Although the early ideas, which went on to inform industrial medicine and hygiene were developed by individuals in Europe IH only gained significant organisational support in the USA. It evolved in specific US institutions and took on a peculiarly American form. To understand how IH evolved it is necessary to trace the development of these institutions.

1.5 Public Health and the Development of Industrial Hygiene in the USA

The first recorded industrial work place in the United States was a glass-bottle factory established in Jamestown, Vermont in 1607 to produce glass baubles and trinkets for trade with the native Indians, KLEM ET AL (1950). The concerns of the early settlers at the time were not for the hazards of the "dangerous trades". Industry based on the factory system and capitalist economic relationships was yet to develop. However there was an occupational group, whose health was important to early settlers and later to the newly formed United States - the merchant seamen. In 1783 the war of independence against Great Britain ended and in 1788 after a lengthy convention the Constitution of the United States was ratified by a majority of the 13 states. When the United States (US) became a nation state the vast majority of people "lived on farms and plantations or in small villages", NEVINS and COMMANGER (1981). Within a few years though immigrants, mainly from the old world poured into the country where land was relatively cheap and labour in demand. The foundations of

manufacturing industry were laid though none of the initial enterprises were large or could be described as mills or factories on the English model, Ibid. The US also became a significant maritime merchant trading power, second only to Britain. The health and welfare of merchant seamen was important for the economic prosperity of the new nation and for the defence of US. All 13 of the initial states were on the Atlantic seaboard and open to attack from the sea.

1.5.1 The United States Marine Hospital Service

Williams describes in some detail the background behind the establishment of this institution, WILLIAMS (1950).

After the destruction of the Spanish Armada in 1588 there was widespread support in England for some benefit to be made available for the seamen of the victorious fleet.

The Royal Navy opened Greenwich Hospital near London followed by a hospital at the Chatham Dockyards known as the "Chatham Chest". These hospitals were supported by deducting sixpence per month from the seamen's wages. In 1729 an Act of Parliament instructed that seamen from the American colonies should also pay a tax of sixpence per month towards the upkeep of the English maritime hospitals. A move that cannot have endeared King George III to the Colonialists.

The English approach to seamen's welfare was taken up by local states and cities in the USA including Virginia (1708), Boston (1742), New York (1768) and North Carolina (1790). These local initiatives were useful examples of what could be done and the hospitals were a source of political pressure when Congress came to deliberate on the welfare of seamen. This occurred early on and the first session of the first Congress on 20 July 1789 set up a committee to devise "bills providing for the establishment of hospitals for sick and disabled seamen". It took some years for the different needs of the various states to be reconciled and the Act setting up the Marine Hospital Service (MHS) was not agreed until the fifth congress on 16 July 1798. Initially the money collected from seamen in one state was only to be spent in that state. This rule was repealed to allow expenditure in adjacent states and then finally, in 1802, the Service became a truly federal structure and the monies collected could be spent where the Service saw fit.

This pattern of local state or district initiatives followed by eventually country-wide federal laws covering the same issues has been repeated many times over in the history of factory welfare legislation in the USA.

The Service was initially concerned solely with the health and welfare of seamen and their relatives. But with the increasing rate of immigration into the US as industry grew there was increasing concern about the "importation of yellow fever and small pox from foreign countries", Ibid. The most obvious Federal institution to organise and supervise quarantine at ports was the MHS and in 1875 a Dr Woodworth of the MHS set out how this was to be done. A Quarantine Act was passed in 1878. The role of the MHS as the federal organisation responsible for quarantine, an important arm of public health policy, was consolidated. There had also been independent developments on this front in individual states.

After two epidemics of cholera in England (1831 and 1849; a third followed in 1854) a Royal Commission was appointed to deliberate and advise on preventive measures: "... comprehensive sanitary acts were adopted, a general board of health was established and medical officers of health were appointed", RAVENAL (1921). In the USA individual states and cities appointed people to oversee and undertake public health measures. Some were medically qualified and formed Boards of Health which gained considerable executive power later in the century. Others were called "Health Workers" who according to Stephen Smith (the first president of the American Public Health Association - APHA) "were generally saloon keepers", SMITH (1921). These developments were spurred on by developments in England and surveys published in individual states perhaps the most well known and influential of which was the "Report on the Sanitary Conditions of Massachusetts" written by Lemuel Shattuck, a layman, and published in 1850. By the mid-1860's enough local state institutions had been created so that individual doctors employed in public health began to consider the need for a national forum. In 1872, the APHA was formed and the MHS helped organise and staff this new body. The two decades preceding this date had seen the beginning of scientific developments which were to revolutionise preventative public health measures. In 1857 Pasteur published his first paper on lactic acid fermentation and demonstrated that fermentation was caused by microscopic living organisms. In 1865, using methods based on

his discoveries he could control a bacterial disease amongst silk moths. In 1869, Lister, a pupil of Pasteur's, reported good survival rates for surgical amputatees using antiseptic surgical practices. The germ theory of disease, antiseptic techniques, pasteurisation and the epidemiological work of such figures as John Snow in the UK laid the theoretical and practical foundations of public health. Both the MHS and the APHA changed dramatically in the next three decades. Public health was no longer the province solely of the medical practitioner; bacteriologists, chemists and sanitary engineers were employed and membership of the APHA was opened up to include these groups WILLIAMS (1950).

It was not until 1902 that the Federal government accepted overall responsibility for co-ordinating public health activities. Again it was the needs of maintaining strict quarantine measures that stimulated the Government to create a State organisation. The name of the Service was changed to the Public Health and Marine Hospital Service (PH&MHS on 1 July 1902). The needs to control the entry of diseases via immigrants, and spread of infectious diseases within the USA continued to press. Rather than adopt a passive stance the PH&MHS perceived the need to perform active "field investigations and studies" Ibid on a local and nationwide basis. This more active approach required the agreement of Congress. After an initial failure in 1911, a bill allowing a more active investigative role was passed on 12 August 1912. It also changed the name of the PH&MHS to the shorter, and by now more appropriate, Public Health Service (PHS).

The Federal industrial hygiene (IH) effort grew principally out of the PHS which was to take the lead in the national IH arena from the early 1920s. However, other Federal and local state initiatives were also important and stimulated interest in the field. Before continuing with the development of IH at Federal level, in particular in the PHS, the picture at local level needs to be sketched.

1.5.2 Local Public Health and IH Activity

1.5.2.1 Introduction

The US industrialised later than the UK and other European countries. When industry developed it did so in the most populace eastern states such as Massachusetts, Vermont, Connecticut and Ohio. Areas where most people lived and where coal, iron and other metal ores were located and relatively easily extracted from the ground. As mentioned earlier (see Early Developments in Industrial Hygiene) the development and refinement of the factory systems of production had a dramatic and deleterious effect on working peoples' health. The factory system forced certain groups of people to specialise in certain types of work. They worked all day and if the process they worked on released toxic substances into the air they were exposed all day. As the advantages of this division of labour were realised by more factory owners it was applied ever more intensely . Spurred on, in the early 20th Century, by exponents of this method of production such as FW Taylor.

The Factory system concentrated people in one place and the division of labour concentrated people in one job. By this process, and the effects of the mechanisation of production, certain groups became highly exposed to poisons which before may have been used on occasions by relatively skilled workers as they manufactured a whole product.

Table 1.1
Early Developments in Factory Welfare in the USA (1836-1920)
(Based on Klem et al).

1836	Massachusetts passes first child-labour law. Children < 15 to receive 3 month schooling per year.
1837	First paper to appear in the USA on industrial medicine. Written by BW McReady (New York) and relied heavily on Thackrah's book (published in 1831).
1840	President Van Buren orders that hours of work on Government naval yards be 10 hours or less.
1842	Law amended and tightened. No child < 12 to work > 10 hours/day.
1842	Connecticut enacted a 10-hour law for children under 14 working in cotton and woollen mills.
1847	New Hampshire passes a 10 hour law.
1848	Pennsylvania is the first state to pass a law forbidding child labour. It applied to children under 12 in the textile industry.

1851 New Jersey followed suit applying a child labour law to all children in manufacturing industry under 10.

1852 Massachusetts passes the first safety law which applied to steam machines.

1857 First disability and death benefit pension fund established for New York city policemen.

1860 First paper on industrial toxicology published on mercurialism in hatters by J Addison.

1867 Massachusetts established a police force to enforce the child-labour law. The Cigar Makers Union institutes the first benefit system in the USA, for its members.

1868 First Federal law regarding hours of work is passed. It limited the working day to 8 hours for all labourers, workmen and mechanics employed by or on behalf of the Government. (Apparently it was not very effective and was improved in 1892).

1869 First State Bureau of Labour Statistics established in Massachusetts.

1870 The Iron Moulders Union institute a national benefit scheme.

1874 The first law limiting the hours of work of women in enacted by Massachusetts state.

1880 Massachusetts passes a law instructing that hours of work notices be posted in all work rooms where the 10 hours law applied.

1882 North Pacific Railways established the first employee sponsored mutual benefit association providing medical care and other benefits.

1884 Federal Bureau of Labour created in the Department of Interior.

1885 Alabama enacts the first Employer's Liability Law.

1886 Massachusetts passes an accident-reporting law.

1887 Massachusetts enacts an Employers Liability law.

1890 Massachusetts forbids the employment of women after 10.00pm.

1893 California requires a weekly day of rest for women workers.

1898 US Supreme Court rules that the health of the labourer as producer is of similar benefit as the health of the consumer and that the protection of labour becomes a public purpose.

1902 First official industrial hygiene survey made by Dr CFL Doehring for the Department of Labour.

1903 Illinois enacts an 8-hour day for children under 16.

1904 National Child Labour Committee formed to investigate and educate public opinion.

1905 Dr CEA Winslow gives the first lectures in industrial hygiene to courses in the Department of Biology and Public Health at MIT.

1906 University of Pennsylvania starts a diploma course in public health with significant emphasis on IH.

American Association of Labour Legislation (AALL) organised with JB Andrews as secretary.

1907 Hours of Service Act passed for telegraph and signal workers.

1908 Congress passes industrial injury compensation act for certain Federal employees (extended in 1916 to cover all Federal civilian employees).

Supreme Court upholds Oregon's 10-hour law for when workers as a health measure.

Illinois sets up a Commission on Occupational Disease. (Investigators include Alice Hamilton and E Hayhurst).

First Federal census mortality reports specific to occupation published.

1909 New York State insists all compressed air workers should be declared fit for work by a physician paid for by the employer.

1910 New York passes a compulsory employers liability law. (It was declared invalid in 1911 but made constitutional again in 1914).

Department of Labour publishes "Phosphorus Poisoning in the Match Industry in the US" by JB Andrews (which led to a prohibitive Federal tax on yellow phosphorus matches.

Alice Hamilton asked by Department of Labour to extend her survey of lead poisoning, in Illinois, countrywide.

US Bureau of Mines created in the Department of Interior.

AALL sponsors the first national conference on industrial diseases.

1911 Hamilton report on lead poisoning in the USA published.

Illinois requires monthly medical examinations of people working with lead, zinc, arsenic, brass, mercury and phosphorus.

Nine states enact workmen compensation acts (Washington, California, Nevada, Ohio, Illinois, Kentucky, Kansas, Massachusetts and New Hampshire).
Massachusetts forbids employment of women 2 weeks before and 4 weeks after the birth of a child.
Compulsory reporting of occupational disease instituted in California, Connecticut, Illinois, Michigan, New York and Wisconsin, based on a draft document written by the AALL.
"Kissing shuttles" banned in Massachusetts in an effort to prevent the transmission of tuberculosis.
American Museum of Safety established in New York (including an IH department).

1912 Massachusetts extends workmen's compensation act to include some occupational diseases.
Federal US Children's Bureau established.
"Fatigue and Efficiency: A Study in Industry" by Josephine Goldmark published.

1913 New York and Ohio establish industrial hygiene agencies employing doctors and engineers.
Ohio and Pennsylvania pass lead laws requiring medical certificates and notification of "leaded" workers.
National Council for Industrial Safety established (became National Safety Council in 1915).
International Ladies Garment Workers Union establish the first union medical care plan.
First statewide IH survey conducted in Ohio by Dr Emery Hayhurst (published in 1915).
US Bureau of Mines uses PHS personnel to conduct special health studies.

1914 Office of Industrial Hygiene and Sanitation (OIH&S) established in the US PHS (in the Division of Scientific Research).
APHA establishes an Industrial Hygiene section (President, G Kober, Vice-President, Alice Hamilton).
First US PHS field investigation of an industrial hygiene problem: Pulmonary diseases amongst miners (Lanza and Higgins). The first time (in the USA) when group chest X rays were used.
Conference Board of Industrial Physicians established.
PHS-OIH&S begins to receive periodic sickness benefit reports from ~ 250 associations (first survey results published in 1919).

1915 California 8 hour women's work day upheld by Supreme Court.
American Medical Association holds the first IH and medicine symposium.
American Association of Industrial Physicians and Surgeons formed.
Walsh Commission on Industrial Relations publish on 11 volume report into labour unrest, including an analysis of sickness prevalence amongst "representative occupations".

1917 Hawaii enacts occupational disease compensation legislation.
Working Conditions Service established co-operatively between the Department of Labour and the USPHS-OIH&S (disbanded after WW 1 in 1920).

1918 California enacts occupational disease compensation legislation.
Harvard establishes the first degree course in IH. Open to medical and non-medical students alike.

1919 Journal of Industrial Hygiene established, based at Harvard.
Cincinnati Medical School starts a 1 year diploma in industrial medicine.

As in the UK the effects of poisons at work were not the main priority of reformers in the USA at first. They were more concerned with the employment of women and children, a reduction in the length of the working day* , nutrition and the prevention of infectious diseases. Massachusetts passed the first child-labour law in 1836. It provided that every child

* Though this was in itself seen by some as a prophylactic measure as people were exposed to poisons for a shorter length of time and had longer away from work to recover. Some reformers in the early 20th Century campaigning for a 10 hour day referred to the "Hygienic day" for this reason.

employed under the age of 15 received at least 3 months schooling during the year, and was amended in 1842 to forbid children under 12 years of age from working more than 10 hours a day, KLEM et al (1950). A resume of further developments in factory welfare in the USA is given in Table 1.0. A number of general points can be drawn up examining the chronology of events outlined in Table Appendix 1.1:

1 The pattern is similar to the development of factory welfare concerns and legislation that occurred in the UK and other European countries. Firstly there was a struggle to enact legislation (at state and federal level) initially concerning the employment of children, then hours of work starting with women. These concerns at first only apply to certain types or hours of work (eg. hours at which women can start and finish work) but are then extended gradually to other trades. Then came the problem of supervising and enforcing the laws which had been enacted. In the UK this was one of the principle factors which led to the creation of the Factory Inspectorate. In the US it was a major factor in the creation of the state Bureaux of Labour. Various reforming and union organisations campaigned for factory welfare laws and their enforcement.

2 Developments were patchy across the US. Massachussetts appears to have taken the lead.

3 Only when several states passed legislation covering the same concern (eg. child labour) did the Federal state take action. This action usually only related to federal state employees or subcontractors.

1.5.2.2 Bureau of Labour Statistics

The first Bureau was created in 1869 in Massachusetts brought about according to Kober "as a consequence of agitation by a workers organisation, the Order of the Knight of St Crispin".[39] There was also pressure to create a federal organisation and an Office of Labor was created in 1871 though its status was uncertain until 1884 when it became the Bureau of Labor in the Department of the Interior.* The Commissioner of Labor was charged with controlling " ... information upon the subject of labor, its relation to capital, the hours of labor, and the earnings of labouring men and women, and also upon the means of promoting their material, social, intellectual and moral prosperity". In the meantime various individual states had followed Massachusetts and established their own Bureaux (Pennsylvania, 1872; Kentucky and Texas, 1876; Ohio, 1877; New Jersey, 1878; Illinois and Indiana, 1879; New York and Michigan in 1883). By 1899 there were 30 such Bureaux. Their duties were to collect data on labour practices and conditions and enforce and administer any labor laws which existed. The federal Bureau was supposed to encourage a uniformity of laws and regulations.

Certain states saw the need for some form of factory inspection and located this activity in their Bureaux. In New York inspections began in 1886 and by 1906 the Chief inspector had come to the conclusion that expert "scientific knowledge was indispensable to the proper experience of the function of the Bureau of Factory Inspection". In 1907 a doctor was appointed and the following year it was decided that a competent engineer was needed, "to pass upon plans for ventilation, proposed as a result of orders issued by the Department", TELEKY (1948). By 1912 a chemist and mechanical engineer had been appointed. In 1911 a Factory Investigating Commission was set up which reported the same year and regularly ever year thereafter up to 1915. It identified a host of problems including "the lack of sufficient number of inspectors, especially inspectors having scientific and technical training" Ibid and recommended the creation of a Division of Industrial Hygiene for the control of occupational diseases and industrial accidents. The Division was duly created in 1913 and employed, in 1914, 4 doctors, 1 chemist, 1 mechanical and 1 civil engineer and a fire prevention expert. The Division grew steadily in size and expertise and by 1924 had started its own publication, the "Industrial Hygiene Bulletin". Massachusetts set up a similar department employing a similar range of people. There was a recognition by this time, amongst some state government, Labour Bureaux that IH was broader in definition than preventative medicine and the skills that were required extended further than those possessed by a medical physician. This broader definition does not appear to have been accepted within the newly created Public Health Service. The PHS was named as such in 1912 having been before then the Public Health and Marine Hospital Service.

1.5.3 Industrial Hygiene in the Public Health Service

A year after the New York Division of IH was created the Office of IH and Sanitation (Office of IH&S) was set up in the PHS headed by Dr JW Schereschensky. IH was defined differently in the PHS as compared with the state Bureaux and was mainly done by doctors until after the first World War. The difference between the approach to IH of the two institutions can probably be explained by reference to their functions and the relative strength and dominance of the medical profession.

At the turn of the century the Public Health and Marine Hospital Service (PH&MHS) was concerned with enforcing quarantine at US ports. Its main concern was infectious and parasitic diseases, principally amongst immigrants. Although bacteriologists and sanitary engineers were employed the Service was still dominated by the medical profession and the medical view of prevention. When the Office of IH&S was created the PHS was concerned with the spread of diseases causing organisms and had a medical world view. The impetus which led to the creation of the Office reinforced this orientation. When the Bureau of Mines was created in early 1910 it was charged by the Congressional Act among other things to "make diligent investigations of the methods of mining, especially in relation to the safety of miners" DOYLE (1977). Within months the Bureau involved the PH&MHS's Hygienic Laboratory in blood analysis of victims of a mine gas explosion, Ibid. Possibly stimulated by this initial successful contact, Otis (Director of the Hygienic Laboratory) suggested to the Secretary of the Interior that there should be further co-operation between the two bodies. However his suggestion concerns only the examination of miners for hookworm "that might readily be transmitted from mines of other countries to the US or from one mining region to another within the US", Ibid rather than gas explosions or dust hazards. The suggestion was well received and the Secretary of the Interior painted a vivid picture of the dangers of diseased aliens, "at least 50% are of foreign birth and are unfamiliar with the English language or American customs", ... " distributing those diseases owing to their migratory habit", when he wrote to the Treasury. Apart from hookworm the major concern seems to have been tuberculosis. Thus the problem of the "quarantining" of alien miners working at mines in the US was the main impetus for the creation of the PHS's Office of IH and Sanitation. The co-operation with the Bureau of Mines added another string to the bow of the Service. Industrial Hygiene as practiced in the Bureaux of Labor Statistics was different from that practiced in the PHS. The Bureaux employed doctors and other scientific specialists and were concerned to enforce legislation and inspect and survey a wide range of workplaces and processes. The doctors in the Bureaux, while in charge, would bow to the greater knowledge of the chemist, when it came to atmospheric measurement, and the engineer when it came to ventilation and process control. The PHS's Office of IH&S initially reflected the Services concern with infectious and parasitic diseases, especially amongst immigrant mining communities. Lung disease caused by coal and rock dust was also investigated Ibid, but probably represented a small percentage of the effort expended by the staff of the Office. Unlike the Bureaux, the Office had no enforcement function and was not responsible for making or enforcing preventative actions. Thus the Office of IH&S started as medically oriented and dominated body whose function was purely advisory and whose main initial focus was on the diseases of miners. Its Hygienic Laboratory "was concerned entirely with biological investigations and had no laboratory facilities for environmental testing", Ibid. Doyle summarised the picture of IH in the PHS during its early first phase as follows: "Until the outbreak of World War I, the entire staff of the Office of IH&S consisted of about 12 commissioned medical officers and some clerical assistants". Ibid.

1.5.3.1 The Department of Labour and the Public Health Service

The initial development of IH towards the speciality it eventually became occurred in Bureaux of Labour, mainly the Massachusetts and New York Bureaux. Thus, in 1905 a state survey of potential hazards was published in Massachusetts which was supplemented in 1907 by a report written by Dr WC Hanson illustrated with 90 photographs and dust samples which demonstrate that "many of the insanitary surroundings and injurious factors in the leading industries are due to neglect of perfect ventilation, and hence are to a great extent avoidable" KOBER (1921). The Federal Bureau also initiated studies covering the manufacture of white lead, paint and fertilizers. A Dr CFW Doehring published the results in 1903* which makes this the earliest federal IH publication, KOBER (1921). Also, in 1908, a Dr J Andrews (secretary of the American Association for Labor Legislation) was asked to investigate phosphorous necrosis in the match industry. His study and the resulting public outcry was followed in 1912 by the Esk Law imposing a high tax on white phosphorous matches. In 1910 Dr Alice Hamilton was asked by C O'Neill, the federal Bureau's Commissioner of

Labor, to extend her study of lead workers in Illinois to a country wide survey. And in 1911 the federal Bureau published a treatise by the English physician Thomas Oliver, on industrial lead poisoning, TELEKY (1948).

The evolution of IH started in Bureaux of Labor both at state and federal level. It was not until the start of the first World War that the PHS's Office of IH&S started to pose a serious institutional challenge. On 1 July 1918 the president consolidated the PHS's role as the co-ordinating body overseeing public health activity in the war industries. "All sanitary or public health activities carried on by any executive bureau, agency, or office, specially created for or concerned in the prosecution of the existing war shall be exercised under the control of the Secretary of the Treasury" (Quote from the Executive Order), MOCK (1919). The order designated the US PHS as the bureau of the Treasury Department responsible for this work. This, and the claim that the PHS could lay to the field of medical research as compared to the Department of Labour meant that at the federal level at least the PHS around 1920 supplanted the Department as the body responsible for IH research. It must have been an unequal institutional struggle. The PHS was one of the oldest institutions in the US state and it was run by the most powerful of professions, the doctors. The Department of Labour was created (out of the Department of Commerce and Labour) in 1913, it was run by lay administrators and employed very few doctors. Although the PHS Office of IH&S started late in the day and was almost solely concerned with medical diagnosis in the first few years of its existence, health protection in the minds of the federal government was almost certainly seen as the province of the medical profession. Despite the innovative work of the Bureaux of Labour in expanding the definition and practice of IH in the first two decades of the twentieth century, when it came to a contest for control of the area at federal level, the institutional political and professional influence of the PHS was overwhelming. After the armistice the PHS took over field surveys from the Bureau of Labour Statistics (in the Department of Labour) SICHERMAN (1984).

1.5.4 IH Publications in the USA

Thackrah's book aroused the interest of the Medical Society of New York. In 1836 the Society proposed as the subject of one of its annual prize essays: "The Influence of Trades, Professions and Occupations in the United States on the Production of Diseases". Dr BW McReady won with his booklet which drew heavily on Thackrah's work. For many years this was the only US publication in the field, TELEKY (1948). As Boards of Health were appointed in various states and doctors and others concerned with public health noted the diseases of certain trades further publications on IH were produced. Teleky identifies a chapter on "Hygiene and Occupation" by a Sanitary Inspector, Robert S Tracy, in a volume entitled "On Hygiene and Public Health", published in 1879, as particularly perceptive and original. Despite these home grown efforts, the European authors still dominated the study of industrial health up to at least 1910 and possibly up to 1920. The works of UK Factory Inspectorate doctors such as Legge, Collis and Oliver were widely quoted and read in the US as were the reports of the two English sanitary commissions in 1843-1845 and 1869-1871. Alice Hamilton, a pioneer worker in the field, regarded by many as the grandmother of US occupational medicine, cites as one of the three seminal influences which caused her to specialise in industrial medicine the reading of Thomas Oliver's comprehensive tome "Dangerous Trades" (published in 1902), and other works in the "European literature" . The other two influences which she identified as important were a 'muckraking' article on work and health in a Boston newspaper and the fact that she lived in a working class district in a "community house" which helped the local people SICHERMAN (1984).

As courses in public health developed in universities and colleges so the number of publications dealing with this area and IH, as part of the public health field, increased.

1.5.5 IH Courses

(Note to reader: I have not done so yet but I intend to examine a couple of the standard reference texts on public health and IH to help contrast early and later definitions of IH).

The first recorded courses in IH were given by Dr CEA Winslow in the Department of Biology and Public Health at Massachusetts Institute of Technology (MIT) from 1905 onwards, KOOBER (1921).

The Harvard Medical School (established in 1910) together with MIT ran a course in public health which contained a significant element of IH. In 1918 the Departments of Physiology

(under Dr Edsall) and Engineering (under Dr Winslow) at Harvard established in the first degree course in IH in the world, SICHERMAN (1984). Kober (1921) provides a partial list of the course contents. Subjects included: "Applied physiology of industry; methods of air analysis; industrial toxicology; vital statistics; industrial sanitation; preventative medicine and hygiene; industrial health administration; employment management; workmen's compensation and the legal aspects of industrial disease; nutrition; industrial surgery; orthopedic surgery and industrial medicine", KOBER (1921). These areas were covered in the first year. The second year was devoted to a field research project. The course was open to doctors and other suitable, non-medically qualified, candidates. Judging by the course contents, the fact that the Physiology Department was based in the Medical School and the initial orientation of IH towards a rather medical definition, most of the early students were almost certainly doctors. This position changed in the mid-late 1920's and will be discussed later in this section.

Other courses and colleges listed by Kober (1921) included:

(i) A course in IH and preventative medicine was started in 1915 in the Department of Public Health at Ohio State University (under Dr E Hayhurst).

(ii) A School of Hygiene and Public Health was opened in October 1918 at Johns Hopkins University in Baltimore.

(iii) The Rush Medical College at Chicago University offered a "clinical and conference" course to medical students and the Department of Hygiene and Bacteriology offered a course on the dangerous trades which sociology students could attend.

(iv) The Medical Department of Pennsylvania University offered a doctorate course to medically qualified candidates in 1906. There was, apparently, "considerable emphasis on IH, including inspection of industrial plants; service in first aid stations and emergency hospitals in some of the larger plants and the occupational disease clinic of the University Hospital".

(v) Yale Medical School offered students in public health opportunities to specialise in IH and continue into research work in the area, from 1917.

(vi) Cincinnati University medical school offered a one year medical certificate in public health in industrial medicine in 1919.

Other places offering graduate courses in public health, listed in the Journal of the American Medical Association (13 August 1921) include: University of Wisconsin (1910), University of Michigan (1913), Detroit College of Medicine and Surgery (1913), University of California (1915) and the Albany Medical College (1920). Hayhurst provided Kober with a list of a further 13 colleges and universities that by 1921 offered courses in public health, which were presumed to "give attention to IH".

By 1921, when Kober reviewed the area, there were at least 25 courses in public health which covered IH in more or less detail, some of which offered specialised courses in the subject area. IH was viewed as a distinct entity and a legitimate part of many public health courses.

1.5.6 Industrial Hygiene Research - Pre 1920

An idea of what IH consisted of can be formed from an examination of the publications produced by the early institutions and individuals who worked in the field. Table 2 based on Kober's "History of IH", Ibid lists a selection of pre-1920 research work in IH.

Almost all the research work was concerned with examining the health of various groups of workers. In a number of cases the concern is with the spread of infectious diseases. The titles/subject areas do not suggest that any exposure measurements were attempted or control methods investigated.

The picture that emerges is that IH, up to 1920, was practiced by doctors and consisted, in the main, of the examination and medical supervision of groups of workers. There were exceptions, thus, for instance, Alice Hamilton, as early as 1912 published a lengthy work on lead poisoning in the potteries (the first IH publication of the new Bureau of Labour) HAMILTON (1912) which discusses preventative measures in detail. Though, even in this work, no airborne lead measurements were attempted and recommendations on ventilation are

in general terms. This latter point is perhaps not surprising in that almost no systematic scientific work on local exhaust ventilation (LEV) design was done until the 1920's. This fact is well illustrated by reference to a chapter in a book edited by Parvenal in 1921 on the history of US public health, RAVENAL (1921)entitled "What Fifty Years have done for Ventilation" (author: Palmer GT, former Chief of NY Commission on Ventilation). There is not one reference to LEV in this review, the whole emphasis is on general ventilation to control odour and regulate room temperature. Though LEV was used on a small scale its design was strictly by trial and error.

3.7 Professional, Federal and Campaigning Organisations

Various organisations were set up to provide professional support and co-ordinate the development of industrial medicine and IH from 1905 onwards (see Table Appendix 1.3). These activities were in their turn supported by various non-official bodies which campaigned for improved working conditions and greater interest in the field of occupational health. Over the same period three federal organisations were created which were to have a lasting influence on IH; The Department of Labor, the Public Health Service and the Bureau of Mines. The organisations listed in Table 3 were created in the 8 years between 1906 and 1914, a short space of time. Some of them represent the culmination of political and institutional pressure from individual states, trade unions and reforming groups. The Department of Labour, and probably also the Bureau of Mines come under this category. Others represent internal initiatives within professional groups (eg. the IH Section of the APHA) while the American Association for Labor Legislation (AALL) was a reforming lobby group which drew support from trade unions, individual government officials, professionals

Table Appendix 1.2

Early Industrial Hygiene Research Work and Research Institutes - Pre-1920 (based on Kober 1921)

1	University of California - skin disease amongst fruit packers.
2	New York Department of Physiology - industrial fatigue.
3	University of Iona - Health hazards in the pearl button industry.
4	Stanford Junior University - Strength tests and the effects of tobacco on mental and physical work.
5	Henry Phipps Institute (Philadelphia) - Health of garment workers.
6	Memorial Research Laboratory (Pittsburgh) - Prevention of epidemic influenza; unresolved pneumonia associated with severe anthracosis, TNT poisoning.
7	Mellon Institute (Pittsburgh) - Researchers in industrial medicine.
8	National Lamp Workers (Ohio) - Physiology and psychology of illumination.
9	Carnegie Institution - on the effect of temperature, alcohol and under-nutrition on skilled muscular performance.
10	The Houghton Research Staff (Philadelphia) - Skin sores and boils amongst metal workers.
11	The National Industrial Conference Board - hours of work as related to output and health of workers.
12	The Carnegie Foundation - Special medical sanitary and health problems due to immigrant employees.
13	Lanza AJ and Childs SB - Miners consumption. (PHS).
14	Neal PA and Flinn RH - Chronic Manganese poisoning in an ore crushing mill. Bureau of Labour.

and politicians. It is noteworthy that so many bodies were created in such a short period. They all, to a greater or lesser extent, promoted IH. By 1914 IH had achieved sufficient status that its promotion could now take institutional form. Just what were the underlying reasons for this increase in professional, educational, and governmental interest is difficult to identify, though the turmoil in the late 19th century after the civil war probably inhibited developments.

Certainly the turn of the century in the USA was a period of some political and labour turmoil. (This is my feeling for the period but I have more reading to do on this point - any guidance would be appreciated). The old ideology of laissez-faire was being questioned by organised labour and reforming groups. Individual reformers argued that it was the concern of the state (both local and federal) to intervene and regulate the relationship between capital and labour in the interests of the health, economic and physical, of both. These views, at least as far as

labour was concerned, were reinforced by the researches of physicians and physiologists into industrial fatigue.

Apart from the social and ideological shifts scientific developments had laid a secure foundation on which to plan public health policy. By the turn of the century it was accepted that many diseases were caused by microorganisms and parasites and that poor nutrition weakened peoples resistance to infection and probably also their ability to withstand toxic insults. Preventative measures were available which had been tested and found to work. Sanitary engineering, good, clean, nutritious food, together with adequate housing, public education and medical supervision were the recognised basis of an effective preventative public health programme. Eventually industrial hygiene became seen in the 1920's by proponents and practitioners of public health as this preventative approach applied to the work environment. Which underlying and which immediate factors were the most important in the institutional recognition of IH is difficult to judge and is not the focus of this research.

Table Appendix 1.3
Professional, Federal and Other Organisations Associated with IH- Pre 1920 (in chronological order).

1906	*American Association for Labor Legislation (AALL) (Pressure group).
1910	*Bureau of Mines created in the Department of Interior. (Federal).
1913	*National Council for Industrial Safety* (later, in 1915, renamed the National Safety Council (information and publicity organisation).
1914	*Office of Sanitation and IH created within the PHS. (Federal). *Department of Labour created to guide and co-ordinate state Bureaux and take federal initiatives. (Federal). *Industrial Hygiene section established within the APHA. (Professional). Conference Board of Industrial Physicians in Industrial Practice. (Professional).
1916	*American Association of Industrial Physicians and Surgeons formed. (Professional).

* According to Mock (1919) the pressure for the creation of this organisation came from the Association of Iron and Steel Electrical Engineers and the Co-operative Safety Congress.

1.6 Industrial Hygiene Pre-1920

The year 1920 can be seen as a watershed for a certain type or definition of IH. The subject had been widely recognised as a legitimate part of public health courses by this time and the first BSc in the subject was started at Harvard in 1919. Most of the practitioners of IH were still physicians though and when the PHS was confirmed as the federal IH field research institute at the end of the war this consolidated medical dominance over the subject area, at least at national level. During World War I IH gained temporary federal government support and the PHS Office of IH and Sanitation was, according to Doyle "... assigned responsibility for sanitation and surgical services in the US's explosive plants ... The only preventative effort appeared to be sanitation and inoculations for smallpox and typhoid fever". Studies of TNT and other causes of poisoning were conducted in ordnance plants and by the Office of IH & S and work was done on industrial fatigue and its effect on production, but Doyle, who worked in the Division of IH (in its various forms) within the PHS for many years, is frank about their effect on morbidity and mortality: "These studies (of TNT poisoning etc) had very little impact on controlling occupational diseases. Although the exact number of deaths from TNT poisoning is not known, it is believed that the mortality rate from TNT poisoning was greater than the battle mortality rate among American troops", DOYLE (1977). Medical supervision coupled with personal hygiene and immunisation was certainly in the case of TNT, demonstrably not controlling poisoning. The medical IH practiced within the PHS Office of IH & S was not sufficient when it came to prevention. The field had to be opened up to non-medical practitioners.

After the War interest in IH and industrial medicine waned. Industrial medicine was still a small, low grade speciality in medicine and Alice Hamilton: "feared that at the war's end the medical profession might cease to take an interest in industrial diseases, she later concluded that the war had at last made industrial medicine respectable" SICHERMAN (1984). A

slump occurred in the attendance at the IH Section of the APHA annual conference. Hayhurst in his review of the first 20 years of the IH Section attributes this to two causes:

1 "... to the fact that Government and convention everywhere were, and still are, devoting time and energies to extending accommodations in the shape of rehabilitation and occasionally compensation ... instead of devoting resources to prevention".

2 " ... because public health workers were not looking upon the health of the worker or of the workplace as part of their genuine programs!", HAYHURST (1934).

He attributed the latter cause to the fact that workplace health activities were covered in many states "in other than health departments", and goes on to say that, "This is the Gordian knot then to be cut in America: Industrial Hygiene under other than medical and health supervision", Ibid.

By the early 1920s IH had gained a foothold in academic institutions. Despite being a low status medical speciality it survived and grew in stature, a large stimulus being the needs of the "industrial army" supplying munitions, which Mock regarded as the major reason for the increased status of industrial medicine and surgery his view was that: "... as the months went by the principles of industrial medicine and surgery came to be recognised as essential in procuring maximum production. From a speciality known only to a few ... it rapidly became a measure in the national preparedness program. Today (1919) the language of the industrial physician is spoken familiarly by thousands of physicians and lay men", MOCK (19119). Some of this "language" will surely have included the words "industrial hygiene". The PHS became the main IH research organisation at federal level but control at local level appears to have resided, if Hayhurst's complaint is accurate, in state Bureaus of Labor.

Mock, in the first paper in the newly created "Journal of Industrial Hygiene" (May 1919) summarised the change in attitude to industrial medicine and hygiene which took place amongst state administrations in the years leading up to World War I"

"The report of the Department of Commerce and Labor for 1909 and a study of the various labor laws showed that only twenty-one states had acts bearing directly upon the subject of factory and workshop sanitation. Eight of these states, however, limited their vision of the subject to this order, 'All the work shops must have proper ventilation and proper sanitary conditions', but none of them made specific recommendations as to what constituted 'proper'. Six of the twenty-one states designated the amount of air space per person and made a few specific requirements covering sanitary conditions. At least five were very specific in their requirements for the removal of injurious gases or dusts; two provided for the cleansing of the interior of the work shops; and one only had a law against overcrowding factories and work-rooms. In eight years since this study was made practically every state in the Union has enacted laws seeking to improve the working conditions of employees. In that short period thirty-seven of our states have enactments on employees' compensation; recently a few have included occupational diseases under the causes for compensation. Today, at least eight states are considering laws for workmen's insurance against sickness and an equal number for the rehabilitation of disabled workmen" Ibid.

1.6.1 The Position of Medical Industrial Hygiene by 1920

Non-medical IH did not exist in any coherent form by 1920 although various individuals practiced some aspects. Medical IH's had made some gains and the degree of their success will be assessed against the criteria previously described in the section entitled *Millerson's Criteria.*

For convenience Millerson's eight obstacles to professionalism are reproduced below:

Millerson's Eight Obstacles to Professionalisation

1 Insufficient internal or external pressure to form an organisation.
2 Underdevelopment of subject matter and/or practical technique.
3 Great variation in quality of service provided; training received by practitioners; level of study; type of employment; social origins.
4 Rivalry between occupations and organisations.

5 Small numbers of practitioners.
6 Geographical isolation.
7 Underdeveloped governmental, industrial or commercial structure.
8 Absence of enterprising individuals.

Taking each "obstacle" in turn medical IH by 1920 had faired as follows:

1 The APHA IH Section was created in 1914 and was the most important form for people who practiced IH. It could be seen as the beginnings of a professional organisation but it never in fact behaved as such and was always subsumed within the few larger public health orientation of the APHA.

2 The subject was still evolving and trying to forge a separate identity from general public health. It was restrained in the degree by which it could move into non-medical areas as most IH practitioners before 1920 were doctors. Although the practice of IH was restrained in its breadth the contents of a few courses were not and prefigure later developments. The Harvard MSc syllabus looks remarkably modern in outline. This difference between course contents and actual practice is considered again when the progress of the non-medical IH's by 1940 is analysed.

3 There was little control over the contents, quality or duration of training courses. They varied from postgraduate and thorough to low level and shallow.

4 There may have been rivalry between the National Safety Council and the APHA IH Section over certain areas in the health and safety environment probably those concerned with safety and efficiency. Given that IH was regarded at the time as a medical subject this almost certainly left the IH field open to the APHA. There was rivalry of a different character between the PHS Office of IH and Sanitation and the state Bureaus set up by the Department of Labor. Both Hayhurst and Doyle refer to it and Hamilton alludes to it and it continues to the present day in the shape of disagreements between NIOSH and OSHA. Disagreements and rivalry over which body should control IH and how IH should be defined must surely have occurred between the PHS and the Department of Labor pre-1920, but there is little documentary evidence. As has been shown earlier, the Bureaux of Labor, eg. New York and Massachusetts, employed engineers and chemists in teams which were referred to as IH Units. In doing so they prefigured later developments in the PHS but in the pre-1920's such a definition must have grated with the entirely medical definition and orientation of the Office of IH and Sanitation. Until the question of definition was sorted out and stable IH would find it difficult to progress and grow into a profession.

5&6 The numbers of medical IH's were small and they were spread across the industrialised states. Though the subject received welcome attention as a result of the first World War and the numbers employed by the PHS grow temporarily, nationwide medical IH's were few and far between. Small concentrations existed in certain large cities which serviced industrialized states.

7 From the late nineteenth century onwards the local and federal state interviewed increasingly in industrial relations. A significant step on the road to a more interventionalist role was the creation of the Department of Labor (1913) and the Bureau of Mines (1910). IH was able to gain some support and influence in the Department and collaborative work between the PHS and the Bureau was the starting point for IH in the PHS. Although the local and federal state structure which might have stimulated and supported IH was underdeveloped, that there was helped IH to make a start.

As for the state of industry, mining, steel making and, in the 20th century, the mass production of cars and all the associated processes presented more than enough opportunities for intervention by the medical IH. However it was with the growth of the oil and chemical industry that the need, or at least the perceived need, for IH, both medical and then non-medical, grew. (My feeling is that the chemical industry really didn't take off in terms of numbers of products and quantity of chemicals in use, until well into the 20th century - I've more work to do on this).

8 Whether there was an absence of enterprising individuals is difficult to determine, there were certainly some innovative, determined and persistent individuals. Hamilton, Hayhurst, Lanza, Sayers, Kober and McCord all started practicing or trained in medical IH before 1920 and continued well into the 1940's and some into the 1950's. All held senior positions in the local or federal state IH apparatus or published and popularised the subject.

Of the eight obstacles to professionalisation which Millerson lists the "absence of enterprising individuals" was probably not a significant impediment to the growth of medical IH profession.

Using Millerson's approach various problem areas for the developing medical IH profession have been identified. The position and fundamental problems facing the profession are best appreciated in total by reference to the ecology of professions.

1.6.2 Ecology of Professions

Medical IH was constrained in its development by a number of factors which were connected with the medical profession from which the subject originally evolved. Firstly most practitioners were constrained by the medical approach to occupational health. The focus for recognising and treating problems tended to start and end with the individual worker. Though it has to be said in some individuals such as Alice Hamilton this view had changed and Hamilton in particular looked in a qualitative way at least at possible changes as well as looking at the workforce. She was almost certainly in the minority amongst her medical IH colleagues.

A second constraint which reduced the amount of time which medical IH's could devote to what would now be recognised as IH was the variety of other calls upon the medical IH's time. Apart from chemical and physical health hazards the medical IH could be called upon and would be interested in control of infectious and parasitic diseases, nutrition, pre- and post-employment medicals and general medical services. Only those employed by local and federal state organisations were in a position to specialise.

A third and perhaps principle factor was the need to maintain contact and at least tacit support from the central stock of the medical profession. This constrained the medical IH's in how far they could move away from their roots and presented them with a dilemma because the objective needs of the chemical hazards workers faced and which required control was for people with medical, engineering and chemical skills. Medical IH's did not have the last two sets of skills and could not obtain them without evolving into a non-medical species.

Medical IH was evolutionarily stuck as it could not evolve into an autonomous speciality being too constrained by traditional medical and public health priorities and, if it tried to and was successful it would loose its medical identity. Another fitter species was feeling its way in the various state Bureaus of Labor and would grow to fill an expanded version of the occupational niche which the medical IH's at one time claimed.

1.7 Industrial Hygiene Post 1920

1.7.1 Industrial Hygiene in the Public Health Service

The PHS took command of IH activity at a federal level during World War I and, Doyle (1977) sums up the effect of the small group of medically based hygienists up to this date: "Whether these early studies (of the PHS Office of IH and Sanitation) resulted in any significant reduction in mortality is a debatable question. In these early days the desire to correct adverse environmental conditions was present, but two essential factors, technological and legal mechanisms, were absent". He does not expand on the details of what was "absent" but certainly IH preventative engineering principles were in their infancy and there was no federal factory welfare legislation relating to control of exposure to noxious substances in the workplace at this time.

In the early 1920s a series of joint studies with the Bureau of Mines were started, to evaluate the potential hazards to the workforce and the public of what was eventually called the Holland Tunnel, underneath the Hudson river. The PHS called upon the Bureau's ventilation engineering expertise. In 1922 the new head of the Office of IH and Sanitation, Dr Lewis R Thompson, recruited two engineers from the Bureau, John Bloomfield and

Leonard Greenburg. They were the first sanitary engineers to be taken onto the staff of the Office and they and the other engineers that joined them had a tremendous impact on the type and health of work that the Office could undertake. In effect they expanded the practical definition of IH away from the narrow medical version to cover measurement and control, moving in the same direction taken by various Bureaus of Labor previously, and starting down the road towards what would be recognised nowadays as modern IH.

Greenburg's primary responsibility was research and he together with GW Smith of the US Bureau of Mines developed, at Yale University, what was to become the PHS's standard dust sampling device; the Greenburg-Smith impinger, GREENBURG and BLOOMFIELD (1932). It was first used in the field in the mid-1920's in the Vermont Granite study and replaced the standard method of measurement used up until this time; the Sugar-Tube Method developed for sampling rock dust in early days of the Bureau of Mines, KATZ and LONGFELLOW (1921).

Bloomfield devoted more of his time to field investigations and the assessment of environmental conditions including the early Vermont Granite study. Local doctors in the Barre area of Vermont had known that workers who cut and polished granite suffered a peculiar form of lung disease; usually incorrectly diagnosed as tuberculosis or sometimes "stone cutters phthisis". In reality a large percentage of stone cutters were suffering from silicosis. Over the 1920's as more studies were conducted into the effects of dusty trades, the association between siliceous dust exposure and silicosis became stronger, better understood and more widely recognised. Thompson, head of the Office had studied a polymelitis outbreak on New York and was an early epidemiologist. He, together with E Sydenstriker, a statistician and Bloomfield, designed a series of long-term dust studies into the pathological effect of silica, marble, asbestos and coal dusts. The Vermont study was the first time that environmental conditions were assessed in a planned and relatively accurate way, at the same time as the health of those exposed together with their work history were investigated. This was only possible because a variety of skills and techniques were brought to bear or were developed for occasion. Early PHS doctors working for the Office had experimented in using field X-ray units to assess lung damage. Greenburg and Smith had developed a sampler which would trap the fine particles which caused silicosis and Bloomfield understood the physics of aerosols (such was then known) and was developing his ideas on IH sampling strategies. The Vermont study drew together the experience of earlier "field investigations", but was qualitatively different in that the population assessed was large and a successful attempt was made to relate the degree of harm (silicosis) to the cumulative dust exposure of workers in different classes of work. Based on this research, which was published in 1929, the PHS estimated that the presumed safe limit for exposure to granite dust lay somewhere between 9 and 20 MPPCF (millions of particles per cubic foot of air) in the size range of 10 micrometers or less, for dust containing 35% free silica or less, RUSSELL et al (1929). The risk, for granite cutters, because of the intensity of dust exposure was high; for workers with 15 or more years exposure there was a 100% incidence of silicosis. Apart from considering where the "safe limit" of exposure might lie, the sanitary engineer in the investigative team (Bloomfield) made detailed recommendations on the control of dust, particularly in the highest exposure job categories, BLOOMFIELD (1929). The approach adopted in the granite shed studies of thorough medical examinations and perhaps X-rays, or other medical tests, coupled with environmental measurements and examination of the control possibilities, was to become the model for other studies conducted by the PHS. At about the same time as the Vermont research the exposure and health of anthracite coal mines in Pennsylvania was examined. Roughly a quarter were found to be suffering from "anthracosilicosis" and the PHS recommended 25 MPPCF as a "safe level of exposure" DOYLE (1977). Combining a standard measure of health effect with an assessment of past and present exposure enabled these investigations to set recommended levels of airborne dust exposure with some idea, if crude, of the risk incurred at the levels recommended.

Other cross-industry studies were started by the Office of IH and Sanitation including: an assessment of health hazards in brass foundries (early 1920's); a major assessment of the likely risk of tetra-ethyl lead in petrol (1925); exposure to radium amongst dial painters (1928); heat stress in steel foundry workers (1928); air pollution from car exhausts (1927) and pioneering studies on industrial dermatitis (late 1920s onwards). The latter work was lead by Dr L Schwartz whose efforts lead to a separate Office of Dermatoses Investigations being set up in the PHS in late 1931.

Table Appendix 1.4 lists the PHS publications on industrial hygiene from 1914-1943 and gives some idea of the type of work and interests of the Office of IH and Sanitation (in its various form) over these important decades for IH. The list needs to be approached with care in that the time between a study being finished and appearing in print evidently varies. Thus some of the Vermont Granite study work appeared soon after it was completed, in 1929, whereas other interpretations and analysis of the data had to wait until 1934. A major factor according to both Doyle and Bloomfield was the competing demands of other work on the time of a small group of people in an under funded department (until 1936). It was only in the early 1930s when the depression really bit into the budget for field investigations (and presumably employers were more reluctant to participate in studies because of increased competition for commercial survival) that office staff were able to write up a lot of their earlier work and summarise the general principles of IH they had learnt and developed. Thus although much less field work was done in the early 1930s the IH publication rate of the PHS increased, or at least remained constant.

Early IH Research in Universities

The sugar-tube dust sampler was developed by the Bureau of Mines soon after it was set up in 1910. This was superseded by a more cumbersome device, the Palmer wet spray collector, again developed internally by engineers within the Bureau. The PHS started employing non-medical personnel after the first World War and often placed them in a University department. They were paid and employed by the PHS but were based at universities, thus Bloomfield and Greenburg were both placed at Yale in the Department. This arrangement was mutually beneficial in that the University department gained access to PHS personnel and field studies, while the PHS people could use the University facilities and work with scientists on collaborative projects. In this way the PHS people were not working in isolation away from their peers but also, concomitantly, university research staff were kept in direct contact with practical problems in the workplace. There would appear to have been significant movements of personnel between the PHS and State IH Bureaus and certain universities and visa versa. Thus Hatch started his IH career at Harvard moved to New York Bureau of IH.

It was, for example, the fruitful collaboration with Smith a scientist at Yale which led to the Greenburg-Smith impinger. Some University departments undertook their own IH research into areas which were to be fundamental to development of IH, particularly IH control measures. It must have been evident to early sanitary engineers that methods of exposure control were crude or non-existent. Local exhaust ventilation (LEV) the main engineering method for contaminant control was up until the late 1920s, still designed by simple rules of thumb such as the need to keep the total sum of the branch duct transverse sectional areas equivalent to the main duct transverse sectional area. Ventilation research, such as was performed, up until the early 1920s was concerned with general ventilation of workplaces to control humidity, heat and odour. In the early 1920s research started into air-conditioning and more exact, objective measures of human thermal comfort but it was not until the School of Public Health at Harvard, in the shape of Theodore Hatch, turned its attention to contaminant control that any fundamental work was done on LEV. The need for such work was evident to the early IH engineers, see for instance Bloomfield (1929), and they almost certainly communicated their concerns to the university research staff. Hatch had started as a lecturer in statistics and IH on the Harvard courses in 1928. In 1929 he recruited a postgraduate sanitary engineering research student, who had just completed his engineering degree. The student was Dallavalle, and his research was into the prediction of centre-line velocity in front of various sizes and aspect ratios of captor hood. Some of the work was published in 1929 and Dallavalle submitted his thesis in 1930. His research and the later work of another sanitary engineer at Harvard, Leslie Silverman, in the 1930s laid the empirical foundations of predictable LEV design on which other hygienists built.

1.7.2 The Sanitary Engineer and Industrial Hygiene

In the early 1930s the terms sanitary engineer and industrial hygienist could be used interchangeably when referring to non-medical hygienists. The evolution of a separate IH grouping did not take place until the mid-late 1930's.* When sanitary engineers were

*The term Sanitary Engineer was still used to designate a non-medical industrial hygienist in the PHS throughout the 1950s and well into the 1960s.

recruited into the PHS Office of IH and sanitation in the early 1920s there was no such problem of definition.

A sanitary engineer was a civil engineer, trained in some aspects of public health, who was concerned with the provision of clean water, milk and to an extent food, the treatment and safe disposal of sewage and the control of the spread of infectious diseases. Such an engineer would accomplish his (they were almost certainly all men) task by careful design of sewage pipes and farms, dams and water distribution systems, milking parlours and pasteurisation/sterilization units and drainage of for instance mosquito infested land. The control of infectious diseases was, to the sanitary engineer, primarily a matter of good public health engineering. This conviction would be reinforced by the fact that these techniques had been shown to work and had demonstrably improved public health. The attitude that some sanitary engineers of great influence brought to the subject was almost evangelical. George Whipple (Professor of Sanitary Engineering at Harvard University) had a grand vision of the possible beneficial effects of sanitary engineering in all areas of society, including the workplace. Speaking on "Human Health and the American Engineer" at Johns Hopkins University in November 1918 he had the following to say about the role of engineering:

"The year 1918 has shown that it is possible to do things, and that, I believe, is going to be America's contribution to the health problem of the world - the spirit of accomplishment. That constructive spirit, that instinct for planning, for utilizing resources, for looking ahead, for organisation, for doing large things in large ways is what we mean when we use the word engineering.

I do not say that the coming era is to be that of the engineer, because we often use this word in a technical way, and the engineer personally will be no more important than the men of the other professions, but in the larger sense the coming era is to be the one of dynamics, of engineering achievement in relation to the health and the comfort of the common people". p76

About sanitation and the sanitary engineer:

"The spirit of achievement is broad in the land.

This spirit had included sanitation. We have known for many years that mosquitoes could be conquered by drainage, oiling and other measures, but this year we have gone ahead and done this work and driven out mosquitoes. The regions of the cantonments and the great factories have in fact been safeguarded from malaria. We have long known and we have talked much about city planning and housing, but this year we have gone ahead and laid out the new cities and built the new houses on scientific principles." p77

"The sanitary engineer is called upon to ventilate buildings, install proper plumbing, provide for the removal of garbage, for cleaning the streets, for designing works to get rid of factory wastes. *In short, a sanitary* engineer is he, who, trained fundamentally in the science and art of engineering, has also been taught *the principles of public health. Knowing the science of* public health, he practices the art of the engineer". p78

About the role of sanitary engineering in public health and the professional division of labour:

"I now find myself urging the study of engineering science - or certain parts of it - by health officers, and physicians. There is one science of public health but there are four arts to be practiced. While the science is something to be held in common, the arts of the engineer, the health officer, the doctor, the physical director, and the preparer of vaccines and sere are obviously distinct. No one can successfully practice more than one of these arts, because the detailed knowledge required is too great ... The lines of cleavage of the public health arts are already becoming distinct. Sanitary engineering has always been distinctly marked from the others, but it is only recently that the distinction between medical practice and public health administration has been recognized. The establishment of this new school at Johns Hopkins, and the Schools of Public Health at Harvard University and the Massachusetts Institute of Technology, at Yale and elsewhere have given the movement for special instruction in public health a great push forward. The time is not far distant when no one can become a public health executive unless he holds a degree or a certificate in public health ...

And finally on democracy and the future:

"The engineer has a unique opportunity to be a great social force in the new democracy, to bring about harmony between work and the worker, to make work beneficent. The engineer is the planner of cities, the designer of factories, the builder of roads and railways, the distributor of power, the digger of mines, the operator of all sorts of industries. What has he planned and built and operated for? Chiefly for product. He ought not to be criticized for that. It is a major element in the problem, and he has been content to consider that as his particular work. *But the engineer has greater opportunities than almost anyone else to make working conditions and living conditions better for the worker.*" (Authors emphasis) p81/82

Whipple had a belief in the potential for good of engineering in particular, sanitary engineering. This subject was one of the four planks of public health (the others being science, medical specialities and vaccine production) and was seen, by him, as on a par with and distinct from "medical practice". In this context he celebrates the foundation of various schools of public health which cater for medical and non-medical students and the creation within the army and PHS of separate Sanitary Corps which, in the case of the PHS had equal rating with the medical section. He quite evidently in the final quotation has a grand vision of the role of the engineer in producing better living and working conditions.

Whipple influenced generations of sanitary engineering students, certainly Hatch himself was influenced by a man with a similar vision of the need for engineers to take some responsibility for the creation of industrialized society; a Professor Craig at the University of Maine. Hatch got his undergraduate degree in engineering at Maine while Craig was Professor of Civil Engineering. Apparently Craig himself graduated as an engineer in Scotland and got his first job working as an engineer in the South African gold mines. He worked there long enough to witness what Hatch referred to as the "horrible slaughter" of Cornish tin miners (who had been encouraged to come and open up the underground working of gold mines) and native blacks. Dry drilling through rock with a high silica content resulted in an average life expectancy of less than 5 years. Though Craig eventually became a bridge engineer, according to Hatch: "he carried (his South African experience) in his mind ... he had the feeling that engineering could do a lot of damage to our society as well as good and he carried that thought down through the years", HATCH (1984). Although Maine had a relatively small engineering school a disproportionate number of undergraduates went up to Harvard to the School of Public Health to study sanitary engineering influenced by the ideas of Craig.

The need to apply sanitary engineering techniques to the control of health hazards in the workplace was conscious according to Hatch. It was Whipple, professor of the School of Engineering at Harvard, and Cecil Drinker, Professor of Physiology at the School of Public Health in the same university who ... "had gotten together with the idea of doing a programme ... to train people and at the start they emphasised engineering and the need to do for industry what the sanitary engineers were doing for the community". Hatch (1984) the postgraduate degree had the support of David Edsall, Dean of the Medical Faculty, who had had a longstanding interest in industrial medicine which interest he used to describe, according to Alice Hamilton, as his "hobby". Sicherman (1984). Whipple himself had been involved earlier in joint Harvard and MIT diploma course for health officers which started in 1909 and almost certainly developed his ideas on the contents of the future postgraduate course and the sort of students who should be allowed to attend. Given his background and publicly professional views on preventative occupational health he is almost certain to have insisted that the course which started in 1918, was open to suitably qualified medical and non-medical students.

The few sanitary engineers recruited in the 1920's brought with them a different outlook to problem solving from the doctors in the PHS. Control to the sanitary engineer meant engineering control achieved by changing the process or, more probably, by applying ventilation. In diagnosing and quantifying the problem the approach would be process rather than person oriented. The approach to measurements would be examine and quantify process parameters and airborne levels of contaminant. The sanitary engineers brought with them the belief that health hazards in the workplace could be designed out or dealt with by engineering means and they had the research and engineering skills to develop the practical techniques to achieve these ends. In the next decade they changed the face of industrial hygiene.

The change in perception, content and practice of IH has to be set against a background of the disease pattern in the early 1900's and in particular medical and public health professional's perceptions of what constituted occupational disease and how it ranked in importance with other public health concerns.

Emery Hayhurst worked in the Ohio State Department of Health from its formation in 1914 for over two decades. He was a contemporary of Alice Hamilton's and worked closely with George Kober, the first president of the IH Section of the APHA; Hayhurst being the Sections first Secretary. By 1925 Ohio state had had an occupational disease reporting and compensation scheme for some 12 years. In a paper to the APHA Hayhurst received the results of the scheme, Hayhurst (1925). The biggest cause of reported occupational poisoning was lead the largest proportion of reports coming from battery manufacture. Dermatitis was the most reported and compensated condition by far and away the most reports coming from the rubber industry. The author felt sure that the figures were a gross under-representation of the true picture as the total number of disease cases report was almost the same as the claims for compensation under the recognised list of occupational diseases produced by the state. As Hayhurst commented this fact shows; "... either that the vast majority of occupational diseases reported ... are compensable or that physicians have been reporting only those occupational diseases which are compensable and omitting others". Further he points out that many self-employed workers like house painters will not be covered by the state scheme and are less likely to claim. Also, that "men engaged in industry and whose daily wages are vital to their families will often continue to work under conditions of personal health which would very properly impel clerical and professional employees to stop work". These factors and the ignorance of occupational disease diagnosis within the general medical profession were the reasons given by Hayhurst for believing that the figures he presented were an underestimate of the magnitude of the problem and very much a partial picture. He also believed that the main "occupational disease" at the time was tuberculosis (TB) and that TB was "more important than accidents" in shortening the lives of the working classes and that sickness caused far more lost time than accidents. TB was a general public health concern and Hayhurst was making a plea to a public health audience for prevention of infection in the workplace to be taken more seriously. However, even allowing for the under-reporting and special pleading the picture of occupational disease that emerges is that of acute poisonings with infectious diseases like TB still looming large.

Nine years later Hayhurst returned to the theme of occupational disease when he addressed the APHA, IH Section at its quarter centenary meeting as its President, Hayhurst (1934). There is a distinct change is his view. TB still rates a mention as the incidence is higher in the working population in Ohio compared to the general population (2nd most common cause of death amongst male workers as compared 7th amongst men in the working population). Acute poisonings still occurred and lead still takes pride of place. However silicosis is now fare more widely recognised and the scale of the "pneumoconiosis" is beginning to be realised. Hayhurst summarised his view in 1934 thus:

"At the present time the greatest morbidity and mortality is not associated with childhood any more, but with chronic degenerative diseases which appear in adult life, and are particularly rampant in the industrial working classes". HAYHURST (1934).

He will almost certainly have included TB as a "chronic degenerative disease" alongside silicosis but it is noticeable how this view is changing from a concern with acute poisonings to the prevention of chronic disease. The early work of Kehoe and ? at the Kettering Institute had demonstrated to slow accumulation of lead in the body and the insidious onset of silicosis was widely recognised. This change of focus from the prevention of acute to chronic conditions occurred steadily amongst IH's during the 1930's as infectious disease incidence fell due largely to public health measures and the scale of the chronic effect of working conditions began to be realised.

1.7.3 Early Toxicology

Apart from a few sanitary engineers, the PHS and Bureau of Mines employed a small number of physiological chemists in the late 1920's such as von Oettingen in the PHS and FA Patty in the Bureau. Those individuals, some of whom were medically qualified and used animal toxicology test methods. There was evidently a perceived need to test chemicals on animal species to assess their relative toxicity.

There were no guidelines on test methods in existence and early experiments had to devise their own protocols and choose the most appropriate test species. Alongside the few individuals working on the PHS were an even smaller number of people acting as consultants to industry. Of these individuals the two Henry Smyth's (Senior and Junior) were the most productive and influential examples. According to H Symth (Junior) when his father got his medical degree in 1897 there was little graduate training in medicine in the USA. His father therefore went to Vienna, studied under Craft Eblug and returned as a trained pathologist. After general practice he trained in public health at the University of Pennsylvania. For his thesis he studied the beating of the embryonic chicken heart, ACGIH (1984). Smyth senior ran an IH consulting practice for a number of years and in the early 1920's took on his son who was trained in chemical engineering to set up a chemical laboratory in the basement at home. As part of their business they tested disinfectants for the toxic effects using methods derived by Smyth Senior. When interviewed recently Smyth Junior said that he regarded this part of their consultancy work as "applied biology" but that he now considered that "some of it was experimental toxicology" Smyth (1984). His father was a self-taught early toxicologist and he learnt from his father. There were few other people to turn to at the time. The Smyth's continued consulting in "applied biology" and IH throughout the 1920's and in the early 1930's (~ 1932) were contacted by Dr George Gunman, a friend of Smyth senior, and medical officer for Dupont. They were asked to test the toxicity of a new plasticer which was to be added to cellophane, a relatively new and important Dupont product. This work continued for a year and more contacts concerned with product safety were made with Dupont. By 1935, with consumer product safety more in the public eye and the usefulness of a toxicological testing demonstrated Dupont decided to set up its own in-house toxicology laboratory. About the same time other large companies followed suit including Kodak, Dow and Union Carbide. The Smyth's acted as consultants for Dupont and Union Carbide and maintained their toxicology and IH consultancy work throughout the 1930's, 40's and 50's. Smyth senior came to regard himself as an IH first and a doctor second and Smyth junior was competent in both IH and toxicology. He went on to become a charter member of the American Industrial Hygiene Association (AIHA) and its executive secretary for over a decade. His name and research work is intimately linked with the development of IH and early standard setting and will crop up again in the next chapter.

According to COLES (1983) interest in consumer safety started in the US Department of Agriculture over issues of food adulteration in the early 1900's. The first US Food and Drugs Act was passed in 1906. Concern over the toxic effects of anti-veneral drugs such as Solvarsen used in the first World War increased concern over drug safety. And the voluntary withdrawal of tetra-ethyl lead in 1925 by the Ethyl Corporation, under pressure from the Office of IH and Sanitation in the PHS, prompted the creation of the first industrial toxicology laboratory in 1929 the Kettering Laboratory in Cincinnati. Joseph Aub was the first director and the main subject of research was the toxicology of lead; the work was financed by the Ethyl Corporation. Product and drug safety concerns increased slowly in importance in the minds of public health officials, senior industry managers and the public. The issue of drug safety received widespread publicity when a drug called Elincir of sulphanilimide killed over 100 people in the southern states in the early 1930's. This incident, the general increase in awareness and the Social Security Act led to the formation of the Division of Pharmacology, in the newly created Food and Drugs Administration (FDA), in 1935. The new Division was charged with the routine assay of drugs, the development of techniques to improve bioassay and to establish safe levels of food additives necessary for production, presentation, storage and transportation, Coles (1983). It recruited a variety of young postgraduates from different disciplines and in the next few years devised and set the standards by which toxicity testing was to be done. This included the use of LD_{50} test which was first put forward by Trevan i 1927 and was further refined throughout the 1930's and 1940's. It derives from the works of RA Fisher, Chief biostatistician at Rothampsted and later the UK Medical Research Council. The FDA took to its heart the statistical approach by seconding Chester Bliss to the Division in 1938 and 1939 as he had trained in biostatistics under Fisher and had worked on refining the LD_{50} test himself, Ibid.

In a similar manner to IH, toxicology in the 1930's was a young discipline developing from its roots in medical pharmacology, physiology and biochemistry. Like IH it was an eclectic species calling upon bits of the older and new scientific specialities. As will be demonstrated a little later there is a strong connection between early toxicology and early non-medical IH.

Table Appendix 1.4 gives some indication of the interests of the workers in the PHS Office of IH and S. The number of publications rose in the 1930's compared with the 1920's; also

the subjects changed. In the 1920's the focus was on certain trades which were known to be dangerous and early on work on industrial fatigue was published. By the late 1920's toxicological evaluations of individual organic compounds appear reporting the work of the proto-toxicologists by the PHS and the Bureau of Mines. The paranite test animal appears to have been the guinea pig and tests reports on a variety of different organic compounds are listed in Table and were conducted throughout the 1930's. Apart from the toxicology the main changes in subject matter in the early 1930's were reports on dust measurement, using the techniques and equipment developed by the sanitary engineers and chemists, and reports of the joint medical and sanitary engineer surveys started in the late 1920's. The impact of the various non-medical personnel on the type and breadth of work undertaken by the Office can be clearly seen in the PHS publications.

1.7.4 The Gauley Bridge Disaster

The definition of IH was expanding slowly and non-medical personnel, in small numbers, had been taken on by the PHS and the Bureau of Mines. Knowledge of diseases of the lung caused by dust had probably spread to the medical profession in general and they were certainly the focus of the industrial physician. By the early 1930's the link between exposure to siliceous dust exposure and silicosis had been demonstrated and individual workers had started to apply for compensation in those states which had passed compensation laws. However, the potential hazard of gross over exposure to siliceous dust had not penetrated the public mind until news of the Gauley Bridge disaster was widely reported in 1934.

In the early 1930's the construction of a water diversion tunnel was started near Gauley Bridge in West Virginia. It was built under the Hawk's Nest mountain and was driven through rock with a high silica content with no dust suppression or other protective measures being applied in the process. A large percentage of workers developed an acute and rapidly fatal form of silicosis. Once discovered the silicosis epidemic and the contractors negligence were widely reported. The Secretary of Labor called the first ever National Silicosis Conference. It was held in April 1936, the etiology of the disease was examined, control measures were enumerated and further research was called for. However national legislation was not forthcoming, according to DOYLE (1977), "in part because of the prevailing philosophy of the era that health and safety was a state responsibility and that the federal government should not intervene". Although federal action did not result, individual states with sizable mining industries added silicosis to their lists of compensatable diseases and some set hygienic limits for dust exposure. The derivation of these limits is dealt with in more detail in the next chapter. From the early 1930's, the importance of compensation claims for industrial diseases increased in the minds of employers and more importantly, their insurance carriers as basic state schemes led to much more costly common law (if this is the appropriate term?) claims. The need to cope with an ever increasing number of compensation claims was the primary reason for the creation of the first organisation set up specifically to promote IH; it was initially called the Air Hygiene Foundation (AHF). The AHF was set up in 1937 and had a strong association with the Mellon Institute at Pittsburgh University. Both the Institute and the AHF were funded privately by industry. The former was one of the first of many such industry-university research institutes. The AHF had an affiliation structure whereby companies paid to join the Foundation and sponsor research fellow at the Institute and was, in a sense like, a trade association. Its main initial concern was to co-ordinate industries response to compensation claims, in particular for silicosis to sponsor scientific research into silicosis and in the first few years was concerned more with air pollution than IH. Within a year to so it changed track and became far more involved with IH. In 1939 it changed its name to the Industrial Hygiene Foundation (IHF).

Federal and state interest in and support for IH, in its newly evolving form, increased from the mid 1930's and the definition of the field was transformed at an ever increasing pace. Franklin Delano Roosevelt was elected as President in 1900 on the basis of his New Deal programme to haul the USA out of the Depression. As part of this programme the Social Security Act was enacted in 1935. This released federal state funds some of which were channelled in the PHS and the Office of IH and Sanitation. The money was used to increase the Office's staff and research activities but perhaps the decision with the most far reaching effects was the support given to a new entity, the States Relations Branch. John Bloomfield (a sanitary engineer) was appointed to head the Branch. When he started in 1935 only 4 states had IH programmes. He recruited several new staff including doctors and additional sanitary engineers and chemists; amongst them we Victoria Trasko, William Gafafer and Richard Page all of whom went on to make important individual contributions and stayed in IH in the PHS for many years. Money was made available to states that wished to set up an

IH programme and take part in a PHS survey of IH needs and Bloomfield and his new staff set about training and equipping these new units and beginning an exhaustive IH survey of industry. This was the first large scale IH survey which attempted amongst other things to assess chemical exposure in terms of the type of exposure and the size of the populations exposed. Fifteen states accepted Bloomfields invitation ad took part in the survey. Also in 1935 the Committee on Industrial Sanitation was set up within the APHA because; "along with the older activities including sanitation of water, milk, sewage etc. The protection of the worker from harmful environmental conditions associated with his work **must be recognised as a public health engineering problem** of major importance ..." APHA Engineering Section (1940). Different non-medical groups were beginning to lay tentative claims to a professional influence on conditions in the workplace.

A further stimulus to the whole field of occupational health, including IH, was the Walsh-Healy Public Contracts Act passed in 1936. It established labor standards for government contracts in excess of $10,000. According to Doyle (1977) it was through the influence of the Division of Labor Standards, itself only created in the Department of Labor in 1934, that health and safety requirements were included in these standards.

Having been in the doldrums from the late 1920's IH activity in state labor and health departments began to flower. But the evolutionary changes which had occurred in the subject and in the type of individuals who undertook IH were evident in the fruit of this expansion. The people who did IH work were as likely to have a scientific or engineering background as to be medically qualified.

1.7.5 The Foundation of the NCGIH and AIHA

The PHS and the Department of Labor held regular training and planning meetings for state personnel from 1936 onwards. In 1937 at one such meeting in Washington all the directors of state IH programmes were called together. They decided at the meeting that there was a need for a rational organisation for governmental IH's, to represent their interests, co-ordinate their activities and give them a voice separate from the industrial doctors and other professions who laid claim to the area of industrial health. At the second meeting of this group, in 1938, the National (later to become the American) Conference of Governmental Industrial Hygienists (NCGIH) was formed basing its constitution on the Conference of Sanitary Engineers.

"The first annual conference of Governmental Industrial Hygienists was called to order by the Chairman, Dr AS Gray, in the auditorium of the US PHS, Washington DC, at 9.30am on 27 June 1938" (p 1). ACGIH (1938).

The objectives of the Conference were:

" ... to promote industrial hygiene and sanitation in all its aspects and phases; to co-ordinate industrial hygiene and sanitation activities of official federal, state, local and territorial organisations; to encourage the interchange of experience among industrial hygiene workers in such official organisations; to collect and make accessible to all industrial hygiene workers such information and data as may be of assistance to them in the proper fulfilment of their duties" (pii) ACGIH (1938).

At the first meeting the NCGIH consisted of 55 Members and 16 Associates and after expenses the Treasurer reported that the Conference had $25 in its coffers. Nine committees were set up include the Committee on Technical Standards, chaired by Theodore Hatch with four members including Dr LT Fairhall. In the next few years this Committee evolved and together with the Ventilation Committee became the next productive and influential within the Conference and indeed within IH.

One year later the American Industrial Hygiene Association (AIHA) was formed by IH's working for industry, a few IH consultants and some IH's based at colleges. One of its main aims was to raise the status of the profession and it, like the NCGIH, acted as a forum, representing the interests of IH's.

1.8 Interim Assessment of IH's Progress

In 1938 Bloomfield then chairman of the IH Section of the APHA reviewed the development of IH up to that date. BLOOMFIELD (1938). The number of states with IH programmes

had increased from 4 in 1935 to 26 and employed between them 32 doctors, 55 engineers, 37 technicians and 39 clerical staff. These were still relatively small numbers considering their task was to cover the needs of around 36 million workers but it was a great improvement on the early 1930's. Also it meant that some of the research work done by the PHS and others was more likely to be applied in industry as Bloomfield admits "very little application of these findings was in practice in the states" in the early 1920's and early 1930's. Expenditure on state IH activity had risen, as a result of the Social Security Act from $10,000 to $75,000 in the 3 years since 1935. But considering the size of the per capita budget expended on other public health activities Bloomfield considered that "we (IH's) are still only at the beginning". He describes the state programmes which apparently were concerned chiefly with evaluation and control and not with field epidemiology or medical surveillance. This was possible because; "the relationship between specific occupational diseases and environments is often evident, and tangible benefits of control practice are readily demonstrable", ie. IH's/sanitary engineers could operate independently of the industrial physician to control occupationally induced ill health. They would do so by changing to process or work methods and/or applying exhaust ventilation. Successful control would be judged by direct assessment of the work environment. The IH's would have looked to and used early hygiene standards in this process. Interestingly Bloomfield echoes the words of Hayhurst in his views of which diseases IH should concentrate on; " ... the greatest opportunity today for a substantial saving of life appears to be in the field of chronic diseases and the class offering this opportunity is the industrial population". He emphasises gross under reporting of industrially induced diseases and recommended that absenteeism and its causes should be studied. His guess was that this would reveal the true cost of occupational diseases.

A year later, at the quarter centenary of the IH section of the APHA, Bloomfield continued in this vein emphasising his view that: "Today, it is sound economics to prevent rather than to compensate for occupational diseases", Bloomfield (1939). He was also able to give the preliminary results of the IH survey he had initiated in 1935, which were published in 1940 The survey covered $1\frac{1}{2}$ million workers in 15 states employed at 17,000 factories and exposed "to various materials and conditions of public health significance". Using this sample he was able to roughly estimate how many workers were exposed to which known hazardous substances. Thus, $1\frac{1}{2}$ million were thought to be exposed to carbon monoxide, 3/4 million to lead and its compounds and around 1 million to silica dust. Of the people in the sample exposed to silica dust about 14% were provided with local exhaust ventilation. These data and those produced by similar smaller surveys conducted in individual states were used by IH's and others to justify increased expenditure on IH at state and federal level. Though growing, Bloomfield in 1939, still felt that: "Industrial hygiene, as a special field in public health, is relatively in its infancy".

Up to this point I have considered the development of IH mainly in terms of the allegiances of the people who practiced it or called themselves IH's and the organisations that fostered IH. An appraisal of the IH publications of the PHS has given a clue to the change in interests of those working in the Office of IH and Sanitation within the PHS. However, many others contributed to the IH literature and the principle forum from 1919 onwards was the Journal of Industrial Hygiene (JIH). The contents of the JIH have been analysed in order to gain some relatively objective insights into how IH as a subject changed from 1920-1940. The analysis also shows the change in the type of author who was involved in the field over this period, see Appendix 2.

Table Appendix 1.4
US Public Health Service Publications on Industrial Hygiene

1914

1918 Methods for field study of industrial fatigue. PHR 33. 349 -

1919 Dust hazards in the abrasives industry. PHR 34. 1171 -

Studies of the Medical and Surgical Care of Industrial Workers. PHB 99.

1920 Studies in industrial physiology. Fatigue in relation to working capacity - a comparison of an eight-hour plant with a ten-hour plant. PHD 106.

Mercury fulminate as a skin irritant. Hygienic Lab Bulletin No 126.

Importance of tellurium as a health hazard in industry PHR 35, 939 -

Trinitrotouluene poisoning; its nature, diagnosis and prevention. Hygienic Laboratory Bull No 126

1921 The physiology of fatigue: Physcio-chemical manifestations of fatigue in the blood. PHB 117

Industrial dermatosis among printers. PHR 36, 979 -

1925 Health hazards of brass foundries. PHB 157.

1926 The use of tetraethyl lead gasoline in its relation to public health. PHB 163.

1927 Toxic effects of ethylene dibromide. PHR 42, 370 -

1928 The health of workers in dusty trades: Health of workers in a Portland Cement Plant. PHB 176.

Health hazards in chromium plating. PHR 43. 2330 -

Changes in the regulations proposed for tetraethyle lead gasoline. PHR 43, 3147 -

Benzol poisoning as a possible hazard in chemical laboratories. PHR 43, 1895 -

Problem of automobile exhaust gas in streets and repair shops of large cities. PHR 43, 750 -

1929 A study of the efficiency of dust-removal systems in granite-cutting plants. PHR 44. 2505 -

The health of workers in dusty trades II Exposure to siliceous dust (granite industry). PHB 187

Effect of repeated daily exposure ... to automobile exhaust gas. PHD 186.

Physiological response attending exposure to vapours of methyl bromide, methyl chloride, ethyl bromide, and ethyl chloride. PHB 185

1930 Acute response of guinea-pigs to vapours of some new commercial organic compounds. "Cellosolve" PHR 45, 1459 -

Ethylene oxide, PHR 45, 1832 -

Vinyl chloride, PHR 45, 1963 -

Ethylene dichloride, PHR 45, 225 -

Ethyl benzene, PHR 45, 1241 -

1932 Frequency of pneumonia among iron and steel workers. PHB 202.

The impinger dust sampling apparatus as used by the US PHS. PHR 47, 12-

1933 Exposure to dust in coal mining. PHB 208.

Exposure to dust in textile plant (in Health of Workers in Dusty Trades). PHB 208.

Zinc in relation to general and industrial hygiene. PHR 48, 955 -

Acute response of guinea pigs to dichloro-ethyl-ether. PHR, 48, 3189 -

Lead poisoning in a storage battery plant. PHB 205.

The health of workers in a textile plant. PHB 207.

Preliminary surveys of the industrial environment. PHR 48, 44 -

1934 Skin hazards in American industry PHB 215.

Effect of inhaling marble dust as observed in Vermont marble finishers. PHR 49. 724 -

Acute response of guinea pigs .. to hexanone. PHR 51, 624 -

The potential problems of industrial hygiene in a typical industrial area in the United States. PHB 216.

1935 The determination and control of industrial dust. PHB 217

The effects of exposure to dust in two Georgia talc mills and mines. PHR 50. 131 -

Anthraco-silicosis among hand coal miners. PHB 221.

Acute response of guinea pigs ... to butanone. PHR 50, 1217 -

1936 Skin hazards in American industry. PHB 229.

Toxic and resinant properties of selenium oxychloride. PHR 52, 1217 -

Benzol poisoning as an industrial hazard. PHR 41, 1516 -

Review of carbon monoxide poisoning. PHB 195.

Acute response of guinea pigs to vapours of some new commercial organic compounds; amyl acetate. PHR 51, 811 -

n-butyl acetate. PHR 51, 1229 -

methyl formate. PHR 51, 1329 -

Rentanone. PHR 51, 392 -

Calcium cyanide dust in ship fumigation. PHR 51, 139 -

1937 A study of dust control methods in an asbestos fabricating plant. PHR 52, 1713 -

Occupational and environmental analysis of the cement, clay and pottery industries. PHB 238.

Control of chronic acid mists from plating tanks. PHR 52. 172 -

A study of chronic mercurialism in the Hatter's Fur-cutting industry. PHD 234.

Evaluation of the industrial hygiene problems of a state. PHB 236.

1938 A study of asbestosis in the asbestos textile industry. PHB 241.

Acute response of guinea pigs to the inhalation of methyl isobutyl ketone. PHR 53, 292 -

Evaluation of the industrial hygiene problem of the State of Utah.

Metal fume fever and its prevention. PHR 53, 1080 -

1939 Disabling mortality and mortality in white and negro male employees in the slaughter and meat packing industry. 1930-1934. PHR 54 -

Skin hazards in American industry. PHB 249.

Silicosis and lead poisoning among pottery workers. PHB 244.

Acute response of guinea pigs to the inhalation of dimethyl ketone (acetone) vapour in air. PHR 54, 944 -

Dermatitis and coexisting fungous infections among plate printers. PHB 246.

Evaluation of odour nuisance in the manufacture of kraft paper. PHR 54, 35 -

1940 A preliminary survey of the industrial hygiene problem in the United States. Bulletin No 259. Bloomfield and Trasko.

Causes of disabling morbidity among industrial workers 1921-1938. PHR 55.

Disabling morbidity among male and female industrial workers during 1938 and 1939. PHR 55.

Clothing for protection against occupational skin irritants. PHR 55. 1158 -

Pneumoconiosis among mica and Regmatite workers. PHB 250.

The relative toxicity of lead and some of its compounds. PHB 253.

Chronic manganese poisoning in an ore-crushing mill. PHB 247.

Toxicity and potential dangers of aliphatic and aromatic hydrocarbons. PHB 255.

1941 Dermatitis from cutting oils. PHR 56. 1947 -

Occupational and related dermatoses. PHB 266.

Soft Coal Miners health and working environment. PHB 270.

Health of Workers in Dusty Trades VII Restudy of a group of granite workers. PHB 269.

Fatigue and hours of service in Interstate truck drivers. PHB 265.

A study of the effect of lead arsenate exposure on ? and consumers of sprayed fruit. PHB 267.

Mercurialism and its control in the felt hat industry. PHB 263.

The toxicity and dangers of nitrous fumes. PHB 272.

Hydrogen sulfide - its toxicity and potential dangers. PHR 56, 684 -

Benzene - its toxicity and potential dangers. PHR 56, 514 -

Carbon disulfide; its toxicity and potential dangers. PHR 56, 574 -

Carbon monoxide; its toxicity and potential dangers. PHR 56, 421 -

The aromatic amino and nitro compounds - their toxicity and potential dangers. PHB 271.

Control of the lead hazard in the storage battery industry. PHB 262.

1942 Frequency and duration of disabilities causing absence from work among the employees of a public utility. 1938-41. PHR 57. 625 -

Chloracne from cutting oils. PHR 57. 1747 -

Health and working environment of non-ferrous metal miners. PHB 277.

Cadmium poisoning. PHR 57. 601 -

A medical study of men exposed to measured amounts of carbon monoxide in the Holland tunnel for 13 years. PHB 278.

The toxicity and potential dangers of toluene. PHB 279.

1943 Sickness absenteeism among male and female industrial workers. 1933-1942 inclusive. PHR 58.

A practical plan for the treatment of superficial fungus infections. PHR 58.

Studies on strains of aerobacter cloacae responsible for acute illness among workers using low-grade stained cotton. PHR 58. 1165 -

Toxicity of lead azide. PHR 58, 607 -

A soap which indicates the presence of mercury fulminate. PHR 58, 1183 -

Notes on the pathology of experimental trinitro toluene poisoning. PHR 58. 1436

Disabling morbidity among industrial workers, third quarter of 1942, with a note on the occurrence of the respiratory diseases 1933-42. PHR 58, 232 -

1944 The patch test. PHR

The aliphatic alcohols; their toxicity and potential dangers in relation to their fate in metabolism. PHB 281.

1945 Toxicity and potential dangers of penta-erthitoltetranitrate. PHB 282.

PHR = Public Health Report (a single volume was produced each year. Page number follows volume number.

PHB = Public Health Bulletin.

1.9 Industrial Doctors and Medical Industrial Hygienists

McCord (1947) one of the earlier medical IH's gives a colourful description of the position of the doctor interested in practicing in industry in the early 1920's:

"In early days, more of ire than tolerance was held for physicians who aligned themselves with industry for the purposes of the protection of the health of workers and who called themselves 'industrial physicians'. Privately such physicians were sometimes labelled 'renegades', 'degenerates'. For use in public there was created the disapprobative term 'contract physician'. This term had a little nastiness in it and could be used in public with just the proper inflection to indicate that much more might be said on the subject did not courtesy intervene. **In those days to enter the field of industrial health conservation carried with it the penalty of being shorn of a few of the outer garments of medical respectability", McCORD (1946) (Author's emphasis).**

To be a company doctor in the early years of the 20th Century was not a glamorous or sought after medical speciality. As indicated earlier Alice Hamilton felt there was a good chance after the artificial stimulus of World War I that the medical profession would loose interest in the subject completely. As it turned out she was being too pessimistic. Slowly more industrial physicians were employed by companies especially once states started passing compensation laws. A few went for training in industrial medicine and/or IH most probably did not. Apart from those doctors employed in the PHS, the Bureau of Mines, local state Boards of Health and a few of the larger companies the main activity of industrial physicians right through the 1920's and 1930's was "medical care and emergency treatment of occupational accidents", (p 15) DOYLE (1977). Selby, industrial physician for General Motors and later employed in the Division of Industrial Hygiene, described the early attitude of companies to the "medical services":

"It was regarded by industry very much as a railroad would regard a wrecking crew - something to clear away the wreckage - and as such it was not in high esteem, merely tolerated, SELBY (1940).

By the 1930's some physicians would have seen the need to expand the scope of their activities and some did, McCord and Selby included. They became involved with what nowadays would be called hygiene audits and worked with sanitary engineers in "field surveys". In such surveys the doctors would assess the current health of the work force and the engineer would make environmental measurements and assess the process and the possibilities of control. The early doctors who had received specialist training and worked for the local or federal state or large companies regarded themselves as IH's and referred to themselves as such. Certainly McCord did so well into the 1940's and Selby, in 1940, argued that "industrial traumatic surgery has evolved into industrial hygiene", Selby (1940). However the industrial physicians journal "Industrial Medicine", founded in 1931 12 years after the JIH, dealt mainly with general medicine applied to factory workers, diagnosis of various conditions and surgery applied to industrial injuries. In 1947 the journal changed its name to "Industrial Medicine and Surgery" reflecting the interests of the majority of practicing industrial physicians. As was shown in the last section even those less concerned with such issues as traumatic surgery who published in the JIH were principally concerned with diagnosis and the identification of occupationally related diseases. It was the rare individual who moved into the newer areas of quantitative environmental evaluation, the details of control and concern with the chronic effects which could follow from longterm exposure to airborne contaminants. This latter area became an important focus for the non-medical IH and initially a very few medical colleagues. Most medical IH's and probably all industrial physicians at the time would agree with McCord's views on the non-existence of carbon monoxide poisoning. Reminiscing on his work in the 1920's and 1930's he says:

"In retrospect, the lack of knowledge of trade diseases at that period was appalling. My own ignorance was teeming" ... "My particular contribution to futility was long months spent in an effort to put a substantial basis for a non-existent disease - chronic carbon monoxide poisoning" ...

From the very nature of the action of carbon monoxide no chronic poisoning may arise", McCORD (1947).

Considering the orientation and interests of industrial physicians and medical IH's in the 1930's prompts the question of why their interests and orientation should be as described. Was it due solely to all doctors' common professional training and ethos, ie. the concern with; diagnosis of acute diseases in individuals, curative medicine and in the public health arena, infectious and parasitic diseases. Or was it due to the day to day experience of medical IH's and industrial physicians? The answer, in the authors opinion, is that it was due to both, the one reinforcing the other. Another key factor would have been the strong gravitational pull of the main professional species of medicine on the small and low status sub-species; industrial medicine and hygiene.

The orientation a doctor got and still gets from his or her training has been described earlier and is called for the sake of brevity the "medical world view". This "view" can of course change and in the case of industrial physicians and medical IH's did change over the decades 1920-1940. However, as will be analysed in more detail later, the rate of change of the doctors world view was slow compared to the non-medical IH. Partly this was due to the orientation of medical training but it was reinforced by the role of the doctor in the workplace and his or her day to day responsibilities.

The role of the industrial physician in the 1920's, the 1930's, and in a modified manner for three or more decades thereafter involved a number of discrete areas of work including:

(i) The supply of general medical services often concerning ill health not connected with the workplace.

(ii) The identification, treatment and organisation of the prevention of infectious and parasitic diseases.

(iii) Supplying advice on nutrition.

(iv) Treating accident cases which, in the larger company might include surgical operations.

(v) Being concerned with the effects of physical and chemical factors on the health of the workforce and, in the case of the medical IH, making recommendations on preventative action.

The list could be increased in length but even as it is it indicates that industrial physicians had a variety of responsibilities between which they would have to divide their time. Only a few medical IH's concentrated on the effects of the work environment on health and even they were mainly concerned with the recognition of diseases and their medical evaluation (see Analysis of the JIH) in Appendix 2. The companies that hired doctors and nurses almost certainly viewed them as employed to treat cases of accidents and disease that occurred. It took many years to convince employers, local state authorities and probably the bulk of the industrial physicians themselves that medical personnel also had a role to play in prevention. There is a limit to how far a sub group of a professional species can adapt away from the main species niche before the sub group becomes an isolated and separate new species. This need for a change of emphasis, a reorientation of "world view", dogged the more visionary leaders of medical IH even within the PHS. Thus Doyle (1977) recounts that:

"In 1957 this was the subject of a memorandum from Dr Magnuson to the Chief, Bureau of State Services, in which he state that there was a need for public health agencies to shift from an emphasis on microbiology to a detailed consideration of microchemical factors. It was suggested that any future realignment of occupational health activities at the federal level should foster the concept of environmental emphasis *and lesser emphasis on promotion of personal health services for workers*", p 23 (authors emphasis).

Another source of inertia which reduced the ability of the sub-species of industrial medicine to change its role from curing to preventing was the world view of the main stock of the medical profession. This main grouping would inevitably restrict the movement of any medical sub-species too far from the principle core definition of being a doctor. It would have, and still does, put limits on the rate a new sub-species could develop and how far it could evolve away from the main stock without risking loosing its species identity. The limitation extends not only to the things that industrial physicians can do but also to the way they think. The initial training of the doctors was and is firmly in tradition of clinical

curative medicine which presents a problem *and sometimes a dilemma for the industrial* physician to this day. Hatch (1984) put it succinctly during an interview for this thesis: "The preventative medicine man wants to know the cause of the disease to prevent it, the clinician wants to know the cause of it to treat it; and they are two different causes". Six or more years training in the curative mode requires considerable re-education to overcome. In the early days of preventative industrial medicine when the physician felt to be in an uncertain position there must have been a strong temptation to return to his or her roots in the curative tradition. Hatch describes the dichotomy in thinking, he observed in an industrial physician he worked within the New York Department of Labor". Early medical IH's must have felt hemmed in by both the employers preconceived ideas of their role and their own professions restricted views of the definition of what a doctor was and could do.

To re-educate the employers and legitimate their position in the eyes of their own profession the medical IH's needed to build links with supportive and respected groups, found their own organisations and forge a recognisably separate but still medical identity. They did this by getting support from the APHA in the form of the creation of the IH section in 1914 which grew sharply in size and influence. A journal, the JIH, was founded in 1919 which the earlier analysis shows was initially derivated by medical authors and subjects. By 1940 the American Medical Association (AMA) had begun to officially recognise the medical sub-species of industrial medicine. By this time however the term IH had started to take on a new meaning, a separate non-medical group had evolved and now called themselves IH's. Some industrial physicians still called themselves IH's throughout the 1940's and 1950's but they were a small and dwindling number which were eventually displaced by a new species, the non-medical IH.

1.10 Non-Medical Industrial Hygienists

The subject known as IH had been changing in content throughout the 1930's and the disciplines of the author publishing in the JIH also changed from medical to a variety of non-medical specialities. Up until the mid-1930's the number of non-medical IH's was small, however the New Deal released money into the PHS and increased their number by several hundred percent. IH activity started or increased in almost all states of union and although these units were sometimes lead by a physician often they were not and in any event non-medical IH's now held many senior and autonomous posts. As early as 1936 there were preliminary discussions amongst state IH directors on the need for co-ordinating organisation. By 1938 these discussions bore fruit and there were enough non-medical IH's with sufficient confidence and a belief in a future for a non-medical IH profession to set up the NCGIH. This organisation and the AIHA set up a year later were the first really public signs that non-medical IH was coming of age.

The profession was still very much in its infancy, as Bloomfield put it, and certain medical organisations made concerted attempts to incorporate the non-medical IH's within their ranks. Smyth (1984) relates how Shrenk a doctor in the APHA persuaded some non-medical IH's in the mid 1930's to become Fellows, thereby giving them voting rights. However the move did not improve the position of the non-medical IH's and in 1939, Symth and others broke away from the APHA, IH Section to form the AIHA. But not before the Industrial medical Association had tried to woe them into their ranks.

By 1940 Bloomfield, a non-medical IH, had been in charge of the PHS's co-ordination strategy for state IH programmes for 5 years. And the Industrial Sanitation Committee, within the APHA, was proposing that IH engineers could and should, "Operate a practical and successful local industrial hygiene program" p77, Committee on Industrial Sanitation (1940) separate from any direct medical supervision. By 1939 Bloomfield could say "We have learned that IH is not a monopoly of any one profession, but that all of them working closely together have made progress in the attainment of our common objectives", Bloomfield (1939).

The "common objectives" of the non-medical IH's by this time were in fact different from the majority of the medical IH's and industrial physicians. The latter group, constrained by their training and day to day practice were concerned with the identification and treatment of acute trauma and disease in individuals. The non-medical IH's were concerned with preventing acute and chronic disease by examining and controlling work processes. They were led to this different view by a number of factors some of which were internal to the professional or disciplinary background of the individual and others were connected with the environment in which the non-medical IH's worked, their day to day practice.

All non-medical IH's came to the field with their own disciplinary and/or professional background. Thus the sanitary engineering IH's were a sub group of public health engineering itself a sub set of civil engineering. Being engineers they would have brought a system or process based view (although I suppose some would have been machine obsessed concentrating on the minute details of hardware design?) Certainly Winslow, Craig and pupils like Hatch would and did see industrial disease as a result of "bad" engineering and the responsibility of the engineer to correct. This group, virtually single handed did the research and developed the empirical equations which allowed the relatively accurate design of local exhaust ventilation (LEV) equipment. By the late 1930's the IH engineers had developed their ideas on how to control exposure to contaminants from several processes and in had a powerful method which in a sense they could call their own. IH's with chemical backgrounds, when they learnt that the work environment could cause disease would tend to see a chemical environment and developed a series of micro-quantitative methods for sampling and quantifying this environment. In the 1920's and 1930's sensitive and selective sampling and analytical methods hardly existed and the early IH chemist had to adapt or develop their instruments and methods from scratch. Again, as with the IH engineers they were developing the tools and approaches which other non-medical IH's would use and build on in the years to come. Although small in number the early non-medical IH's given their demonstrable effectiveness must have grown to be confident of their own worth and position in relation to the medical IH's and industrial physicians and be able to defend their work amongst the organisations of their own main professional species.

The non-medical IH's approach to preventative health would be to understand the processes causing exposure and redesign or control them. The success of their efforts could be judged by airborne sampling. They were not able to appraise health of individuals, as medical examinations were the province of the physician, (although they could, in collaboration with physiologists, do simple lung function tests and take urine samples). They would however be interested in the individual and how different groups of workers interacted with the processes which caused their exposures. (Understanding of the importance of these interactions was rudimentary in the 1930's but, as will be described later, developed through the 1940's and 1950's with a qualitative leap in understanding in the 1960's). The non-medical IH's would not have suffered from the major drawback that dogged the work of physicians, ie. they would not be deflected from their preventative work into general medicine and down the path to the treatment of acute trauma and disease. The IH engineers and chemists played to their strengths unencumbered. They used engineering and organisational skills to control exposure and applied chemistry to measure their success. But their views of the kind of diseases they were preventing were wider reaching and more ambitious than the medical IH's, a point that will be amplified in the next chapter. The non-medical IH's were concerned to prevent chronic diseases caused by exposures in the workplace and they linked this goal to the setting of single figure "threshold" levels of airborne exposure. The medical IH's because of their focus on the individual patient and the diagnosis of clearly defined acute diseases, and their other medical duties, do not appear to have been as concerned with chronic disease prevention. Indeed, in McCord's case he did not appear to believe such a condition existed in the case of carbon monoxide and probably many other substances. Also physicians were not in a position to prevent chronic disease by their work methods. They could not identify individuals who would develop disease in later years. Chronic disease prevention working at the level of the individual could not work. Whereas the non-medical IH's strategy of controlling the exposure of populations might just do so. The non-medical IH's were swimming in right direction. Hayhurst, in the early 1930's emphasised the importance of chronic diseases as causes of lost time in the working population. At the time he included TB. By the late 1930's Bloomfield was hammering home the same message that the concern should be with the causes of chronic disease. But by now chronic disease caused by chemical exposure was on a par if not more important than infectious diseases. Public health having banished or at least brought under control infectious disease in the workplace was now set to tackle the chemical environment, at least in the eyes of non-medical IH's.

Apart from objective changes in the pattern of diseases in the working population two other factors probably affected the non-medical IH's perceptions. Firstly, in those states which had had active IH units in Bureaus of Labour and some compensation and welfare law, since the 1920's, the prevalence of gross over exposure to air contaminants such as silica dust and lead compounds, and the associated cases of acute poisonings, had been reduced. Hatch (1984) states that by the late 1930's, although he still saw acutely "leaded" workers with all the classic symptoms (blue line on the gums etc) it was coming under control. Exposures in

the work environment were, in his experience, being controlled to a point which did not stop occupational poisoning and disease occurring but prevented overt disease in a large proportion of the population. Also, it took time for the effects of exposure to show themselves. Partial control of exposure had reduced the incidence of acute occupational disease. This success offered the non-medical IH the possibility of controlling the incidence of chronic disease by applying IH engineering methods more rigourously. Conditions in some industries in some states had got to the point where complete control of acute and chronic effects looked like becoming a practical possibility.

The second factor was the influence of the early industrial toxicologists some of whom were non-medical IH's and the promises which the developing science of toxicology offered. There was a strong connection between at least a section of the early toxicologists and the developing profession of non-medical IH. Some of the connections have been described earlier and certainly the analysis of the JIH illustrates how important toxicology was to IH in the mid-late 1930's, when IH was definitely in the non-medical camp. The support was mutual and the JIH was a prestigious forum in which toxicologists could publish. The mutually supportive association between the industrial toxicologists and the non-medical IH's started in the 1930's and blossomed with the creation of the NCGIH and American Standards Association (ASA) standard setting committees.

By the late 1930's several exposure levels had been derived which was regarded by some, if not all, non-medical IH's as "safe" levels of exposure which, if adhered to, would result in no disease either acute or chronic. These standards and the ideas of the early toxicologists concerning thresholds of effect offered the non-medical IH's the promise of being able to control all diseases caused by chemical exposure by setting "threshold levels" of exposure. Process and engineering control coupled with maximum allowable concentrations played to the scientific and professional strengths of the non-medical IH's and, in theory at least, did awaay with the need for medical supervision and surveillance. In the next two decades the non-medical IH's were to play this card very strongly and successfully but in the late 1930's they were still in a precarious position.

The non-medical IH's in the PHS had worked with doctors for many years and the worth of the IH was recognised by the PHS physicians. When the NCGIH was set up it had a sizeable number of doctors as members and considered medical and non-medical matters at its annual meetings. The agendas of the initial meeting in 1938 was mainly concerned with co-ordinating inter-state collaboration and uniformity of approach, the kind of problem any dispersed national organisation has to tackle. However, various standing committees were created to work on longer term projects including a "Committee on Industrial Hygiene Personnel", chaired by Bloomfield NCGIH (1938). By 1939, one year later, this committee had changed its name to the "Committee on Minimum Qualifications for Industrial Hygiene Personnel", NCGIH (1939) and a further year later it reported, NCGIH (1940). In this report IH personnel were divided into three groups; the IH physician, the IH engineer and the IH chemist and their duties, necessary qualifications and training were described.

In the next ten to fifteen years the first group was to become almost extinct and in the long run the last two groups hybridised to become the IH's of the present day. However the fusion was not complete and the engineering or chemical bias of IH's still shows through and has repercussions to the present day which will be discussed later.

By 1940 the subject of practice of IH had evolved away from the medical sub-speciality it had been in 1920. It evolved, because the limitations of the medical approach to prevention were perceived within the PHS and State Boards of Health, because sanitary engineers, chemists and other scientists expanded the definition of IH by their actions and approach and because the skills of these non-medical groups, who eventually became non-medical IH's, were objectively needed to solve and control the problems which caused industrial diseases.

Patty (1948) estimated that there were fewer than 50 non-medical IH's in the early 1930's. The New Deal enabled state IH activity to expand and from the mid-1930's to 1940 the PHS was heavily involved in training state personnel. The need to co-ordinate this training and state activity led to regular meetings of senior state personnel in Washington. Very early on in this process at the second meeting in 1936 there were discussions on the need for a representative body for IH's. Even though their numbers were small, probably less than 100 in all, the leading non-medical IH's felt the time was ripe, probably buoyed up by the sudden increase in their number and the money released for training and employment. The NCGIH was set up only 3 years after the Social Security Act released its funds. For a

national, albeit small organisation, to be set up in so short a time suggests the idea had been gestating for some time but the conditions in the early 1930's, in the depths of the Depression, were judged not to be able to support such a initiative.

The first World War gave a boost to the status, influence and number of people who practiced medical-IH and industrial medicine and established the reputation of the Office of IH and Sanitation in the PHS. By 1940 non-medical IH was growing in size and stature and the second World War, which was just over the horizon, was to be the stimulus which consolidated the field as legitimate and separate from the medical profession.

1.10.1 The Public Health Service, State Boards of Health and Non-medical Industrial Hygiene

The non-medical IH was concerned with recognition, evaluation and control of workplace health hazards and not simply the recognition or "medical phase of IH", as Patty (1948) put it. The non-medical IH evolved in the USA in the 1920's and 1930's and was copied more or less faithfully by, or exported to, other countries including the UK later. The explanation of why non-medical IH did not evolve separately in other countries is noted in an understanding of the factors which encouraged its evolution in the USA. This insight gained in the following analysis will be drawn upon later in the chapter which examines IH in the UK.

Non-medical IH developed primarily in the public sector although several large insurance companies did employ a few individual non-medical IH's. The main institutions involved were the PHS Office of IH and Sanitation and the State Boards of Health and Bureaux of Labor. Why non-medical IH evolved in these institutions and non in their equivalents in other countries is connected with a multitude of factors including the different history of public health organisations, approaches to factory welfare and the relative status of different professional groups. Such developments in the UK are considered in detail in Chapter " " because of their relevance to the mechanism by which occupational exposure limits are set in this country. What follows puts the development of UK non-medical IH and standard setting in context.

A partial explanation of how non-medical personnel gained entry to the PHS's IH activity and the few state Boards has already been outlined. It is difficult to be precise about what factors allowed such people to gain entry, maintain a firm foothold and evolve into a new professional species especially as the factors I can identify would each influence the other. Whatever these factors were the over-whelming reality which any new group had to face was the presence and influence of the medical profession. For this reason the factors which I can identify and which allowed or encouraged the development of non-medical IH all, either directly or indirectly, addresses the dominance of the medical profession in defining the world view and the approaches to preventative health which could legitimately be taken. Five factors allowed non-medical IH to evolve in the public sector in the USA. They were:

1 The status of engineers.
2 The status of industrial physicians.
3 The structure and organisation of the PHS
4 The autonomy and enforcement role of the local state Boards of Health and Bureaux of Labour
5 The peculiar history of the USA.

Each of the factors will be examined in a little detail.

1 The Status of Engineers

The American engineering profession was a confident and evolving species. Sanitary engineers were a recognised separate variety but still part of this multifarious group and shared an appreciation of their worth and self confidence. By the early 1900's the sanitary engineers had already demonstrated that they could control or dramatically reduce communal public health problems by engineering means. In addition within the ranks of the engineers it appears that a significant group who argued that the profession should have a social conscious and be concerned to control the negative and harmful aspects of industrial progress. Certainly individual sanitary engineers such as Craig and Whipple held strong opinions on the moral obligations of the engineer and those beliefs reached almost evangelical heights in the latter case.

The engineers, in the early 20th Century were a strong, growing, professional species and the variety sanitary engineer had its own purposeful vision separate and distinct from the medical profession.

2 The Status of the Industrial Physician

The status of the industrial physician contrasts starkly with the relatively high status of the sanitary engineer. As McCord and other medical IH's intimate the "contract doctor" was a low status variety within the ecological range of the medical professional species for at least the first three decades of the 20th Century. As a variety of the most powerful professional species the industrial physicians would gain a lot of status and potential power. However their "contract doctor" image took many years to live down and this change in image occurred only slowly. Also the industrial physicians, those that were not simply "contract doctors", were working at the limits of their professional ecological range. The more far sighted individuals probably recognised the limitations of their species type and certainly it would appear that people like Alice Hamilton and Emery Hayhurst actively encouraged the hiring and integration of non-medical personnel into the teams led by medical IH's.

The industrial physicians were a lowly variety of the medical professional species working at the edges of their professional ecological range and were not in a position, as a group, to challenge the introduction of sanitary engineers and other science based professionals into their field. Also, from the late 1920's onwards the objective conditions of the occupational health environment began to change moving further away from the niche which best fitted the industrial physician or medical IH but encouraging the growth of the non-medical IH.

3 The Structure and Organisation of the PHS

The PHS, as described earlier is an old institution whose history and traditions go back to the first congress of the United States. It was, and still is, organised along semi-military lines even in times of peace. During the war it became a fully military type organisation integrated with the other services at federal level. Even today a significant proportion of PHS personnel are bound by military discipline and can be ordered, at short notice, to attend to PHS requests, usually public health emergencies. On Wednesdays officer ranks are obliged to wear their uniforms at work.

It is the author's contention that in civilian organisations the medical profession has now and in the past, very significant power and autonomy, whereas in military type structures it is subordinate to a military organisational structure and ranking system. This military structure has its own internal logic and goals developed before the medical profession has always had to fit in with the goals and ranking system of the military organisations within which it has worked. These organisational and promotional constraints existed within the PHS and the medical profession was less able to extend its jurisdiction over all matters concerned with health, particularly public health. Although the Office of IH and Sanitation was almost purely medically oriented before the first World War during and after the war sanitary engineers made very significant inroads into the medical domain of public health which by now had been extended to include the workplace. The sanitary engineers were able to do this not only because of their engineering professional status and confidence but also because of the military type structure of the PHS especially during the War. This allowed the sanitary engineers to grow in number and seniority of rank without interference from the PHS physicians. Because of the First World War sanitary engineers in some PHS units gained equivalent ranks and rates of pay to the medical officers a fact which was specifically singled out and celebrated by Whipple a champion of the US sanitary engineer. Once established within the PHS the sanitary engineers and other scientific personnel, particularly chemists and later toxicologists, facilitated a change in the definition of IH and allowed it to expand and evolve into non-medical IH.

4 Local State Boards of Health and Bureaus of Labor

A similar development occurred within the local state Boards and Bureaus and in fact it started earlier in the PHS. By 1914 a few states had passed some factory welfare legislation and employed inspectors to enforce the law. A very few, such as New York, Massachusetts of Ohio employed specialist personnel including doctors and sanitary engineers. These people were needed because the local state had an enforcement function and required medical and technical expertise to carry out this task. States like New York had

specific codes on ventilation and machinery guarding requirements. Whether an occupier was adhering to these codes could not be judged by an industrial physician and, as was related earlier, the Chief inspector of factories in New York, and other states, soon realised that engineers and other scientific specialities would need to be employed.

Thus the forces which led to sanitary engineers and chemists being employed in state IH organisations were not as bound up with the professional consciousness of the engineer as was the case within the PHS. Because state IH organisations were concerned with enforcement the objective need for non-medical skills to deal with the multidisciplinary problems which the workplace presented was directly felt. It became obvious to all concerned that sanitary engineers and later chemists were required. The objective need for non-medical professional skills was not as keenly felt within the PHS because the Office of IH and Sanitation was not involved in enforcement but in research. The objective need for non-medical skills was mediated and delayed by the role of the PHS and the medical dominance within the Office, until after the first World War. However whether the non-medical personnel employed by the local state IH organisations would have evolved into non-medical IH's without the existence of the small but autominous and imaginative group of sanitary engineers and chemists in the PHS Office, is a moot point. Given the status of the engineering profession in the US and the confidence of the sanitary engineers the evolution of the non-medical IH would probably have occurred but would have been more timid, limited and slower.

The expansion of the local state Bureaus and Boards in the mid-1930's has already been described. The founding of the NCGIH, dominated by PHS IH personnel but comprised mainly of members from state organisations, in 1938, marks a convergence point in the evolution of the non-medical IH. This group, whether employed by the PHS, Local Bureau or Board or other federal and local state organisation, had evolved along parallel paths for some time with the PHS IH's giving the lead. With the creation of the NCGIH the various groups were officially linked.

5 The Peculiar History of the USA

Cultural factors although difficult to pinpoint are nevertheless influential. Some specific items which I can identify include:

(i) The early US industrial physicians of merit, drew openly upon the work of their British and European colleagues. But while their British colleagues particularly, they could link their activities to a wider public health movement in the USA and some, such as Alice Hamilton, certainly appreciated the political significance of their work and campaigns. Being part of a wider public health movement in which the sanitary engineering profession had significant status probably helped individual industrial physicians to appreciate the contributions that the engineer could make to preventative health actions in the workplace, and induced them not to insist on a medial dominance of the entire field.

(ii) The Harvard postgraduate degree was open to non-medical graduates from its inception in 1918 and was run as a joint course with a number of departments and MIT. Such liberal arrangements which broke new ground were important in the evolution of non-medical IH and are seen by people such as Hatch (1984) as a positive quality which was possessed by the better US universities in the early 20th Century. Departments were not divided up by rigid subject based barriers and small multidisciplinary units were allowed and, in some universities, positively encouraged. This enabled certain US universities and institutes to evolve into or produce new subject areas rapidly and non-medical IH benefited from the liberal, innovative approach.

(iii) Non-medical IH developed concurrently with toxicology in the USA and toxicology became a mainstream federal activity from 1935 onwards, just at a time when the numbers of people practicing non-medical IH were expanding. The intimate involvement of non-medical IH's with toxicology and vice versa has been assessed and would appear to have been a unique conjunction, unique that is to the USA.

The five separate but related factors which led to the evolution of non-medical IH in the USA will be returned to when it comes to understanding the British approach to occupational health and, in particular, the British approach to setting exposure standards.

1.11 The Development of Non-medical Industrial Hygiene by 1940

As when considering the progress of the medical IH's by 1920 the success of the non-medical IH's will be assessed against the criteria previously described in Section .

Millerson's Critiera

For convenience Millerson's eight obstacles to professionalisation are reproduced below:

1 Insufficient internal and external pressure to form an organisation.

2 Underdevelopment of subject matter and/or practical technique.

3 Great variation in quality of service provided; training received by practitioners; level of study; type of employment; social origins.

4 Rivalry between occupations and organisations.

5 Small numbers of practitioners.

6 Geographical isolation.

7 Underdeveloped governmental, industrial or commercial structure.

8 Absence of enterprising individuals.

Taking each obstacle in turn the non-medical IH's faired as follows:

1 There was sufficient internal pressure to create the ACGIH (1938) and AIHA (1939) were creations of the non-medical and medical IH's working in government and industry and were strictly a product of the hygiene community. There was little obvious external pressure for their creation. The same is not the case for the IHF which was a product of the Mellon Institute and a group of industrialists who could see the need for such an organisation. Ultimately the ACGIH and AIHA, particularly the latter, were the organisations through which the non-medical IH's gained professional status. By 1940 they were in their infancy and had yet to take firm organisational shape. the goals and long term directions of the two organisations were to be decided in the next decade.

2 The subject area of IH had been transformed in the two decades between 1920 and 1940 and a large part of this change was due to the work of the non-medical IH's. Methods of air sampling had been devised and used; control methods had been devised and applied to a variety of processes; the empirical fundamentals of local exhaust ventilation had been laid and control methods applied in concert had been shown to prevent acute and to an extent chronic disease. The non-medical IH's had caused a niche of their own. By 1940 the subject of non-medical IH had come a long way and was maturing in the minds of many non-medical IH's. They had not however codified their unique approach to occupational health, this was to occur in the next decade in the non-medical IH community which the ACGIH and AIHA aimed to represent.

The non-medical IH's still faced a long uphill fight as Doyle's summary of attitudes to occupational health illustrates:

"This was a difficult period (late 1930's) in which to promote industrial hygiene ... since health agencies were concerned with basic public health programs such as sanitation and communicable disease control. It was difficult to correlate significant morbidity and mortality with specific industrial activities because of the absence of morbidity and mortality data. In the concept of most public health administrators, industrial diseases were limited primarily to silicosis and lead or mercury poisoning. Although other diseases were known to have an occupational etiology, many state health officers believed that the incidence of these diseases was so low that they had little significance when compared to mortality from other causes ... Few individuals were concerned about occupational cancer since it was thought that only coal tar derivatives had a carcinogenic potential ..." DOYLE (1977)

3 The ACGIH and AIHA did not control the registration or training of non-medical IH's in 1940. The quality and competence of individual practitioners would vary enormously. Also, a host of others with no specific allegiance to IH were practicing some aspects of IH. The need to define the functions and duties of non-medical IH's and thus their training needs was high on the agenda of the ACGIH, and almost certainly the AIHA (see NCGIH 1940). And the status and remuneration of IH engineers and IH chemists was vigorously discussed at annual NCGIH meetings. The position, in terms of accepted definitions and control was to improve in the next decade but the importance of registration and the creation of a unified and widely accepted education and training programme was not settled until the early 1960's and disaster continued into the 1970's.

4 There was still rivalry between different groups and organisations as there had been in 1920 but the territory over which the disputes were conducted had changed. There was still the longstanding Department of Labor versus PHS rivalry and this rumbles on even today. By 1940 the principle rivals of the non-medical IH's were the medical IH's and also other scientific professions such as engineering and chemistry. the late 1930's early 1940's was a period of transition when both groups of IH's would use the words IH or hygiene but would mean different things. But, by this time, the definition of IH had been expanded, by non-medical IH's and others, into areas which medical IH's could not incorporate. Likewise with the challenge posed by the scientific professions. Although each could claim expertise in part of the non-medical IH field none could claim the mix of skills required to span the range of problems which the field throw up and which the non-medical IH's addressed.

Apart from the external rivals there was internal rivalry within or between the ACGIH and AIHA as to which group was going to take the lead. Selby (1940) refers to it, and the physician versus non-medical IH friction, but gives no clue as to how the groups divided. The NCGIH was set up to further the interests of the non-medical IH's within Government and specifically excluded colleagues working in private industry. The role of the two groups was and is different and was perceived as such. The friction and urging for "the position of leadership" to which Selby refers probably occurred between the two organisations representing non-medical IH's. The difference between these two groups is touched on again later when ACGIH standards setting is discussed* .

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* Note - There is little written evidence of the differences of approach or rivalry between the NCGIH and AIHA. The two organisations have remained distinct and separate ever since their foundation and it is interesting to speculate on whey two organisations were created to foster and support a certain kind of IH at a time when there were very few non-medical IH's in existence. On the face of it, it would have made more strategic sense to create one organisation.

The NCGIH was fostered and dominated by the PHS and the local state Bureaus and Boards, it was their creation. It could be argued that the separate creation of NCGIH was a simple organisational matter and that IH's in the PHS and local state apparatus simply needed a body to coordinate their activities and give them a voice. This was certainly one of the practical reasons why NCGIH was created. However there was nothing to stop the original organisers inviting IH's in the industrial and commercial sectors to become affiliates. As it was, two years after NCGIH was set up the AIHA was created by a group of IH's working in the private sector. They felt the need for an organisation to represent their interests and they could not join the NCGIH. They were excluded and there must have been some acrimony between the different groups of IH's.

The organisational explanation by itself is not sufficient and misses the social and political factors which governed (and still governs) the activities of the IH profession. Put simply IH's working for the PHS and local government could be more "independent" than their colleagues working in private industry. They were less constrained by the immediate needs, abilities and commitment of industry, though in the long run they were constrained by all these factors, and they were not directly employed by private industry. There is some evidence that governmental IH's had an inkling of their regulatory role in the practical struggle between the employers and employees. Thus in a joke "Handbook of Industrial Hygiene" produced by trainees on one of the PHS crash IH training sessions in 1936, in answer to the question: What is industrial hygiene? The course members replied "Industrial Hygiene is a non-exact science which attempts unsuccessfully to show an exact relationship between the Utopian collaboration of capital and Labor, from which springeth

5&6 By 1940 the number of practitioners who called themselves IH (engineers or chemists) was small but growing and confident. These people were spread across a large continent and were geographically isolated as such. However, they were not spread evenly across the country but congregated in the larger cities of industrialised states. They thus had significant local presence.

7 Governmental structures were far more developed than in 1920. The state at federal and local level was now more interventionalist in character and this role was increased and extended as a result of the New Deal initiative. This initiative allowed the growth of non-medical IH at local and federal level and lead ultimately to the creation of the NCGIH. In 1937 the Office of IH and Sanitation was combined with the Office of Dermatoses Investigations to become the Division of Industrial Hygiene (DIH). The federal IH commitment was still small in size employing less than 30 professional staff, Doyle (1977) but it had attained Divisional status and within 5 years was to expand in size and influence enormously.

Industry had by 1940 increased in size, relative to agriculture and other sources of employment and had also changed qualitatively. The number and quantity of chemicals used in industrial processes and to which the consumer was exposed had increased considerably (dates to follow when I can track them down). The need for the non-medical IH who understand processes and could measure concentrations of chemicals in the workplace had also increased. The bulk of non-medical IH's were employed by the public sector but by 1940 several large insurance and private manufacturing companies also employed them. These pioneers were the group that started the AIHA.

8 Assessing the presence of "enterprising individuals" of the non-medical IH variety in 1940 is as difficult as assessing the presence of enterprising medical IH's in 1920. There were certainly some innovative, imaginative and persistent individuals who by 1940 were all practicing non-medical IH or supported the development of the area. They included, Theodore Hatch, Henry Smyth (Jnr), John Bloomfield, Frank Patty, John Dallavalle, Leslie Silverman and Yaglou. The first five individuals all started working in the 1920's and each one contributed to the development of specific areas of non-medical IH theory and practice. The first three in particular practiced for over 30 years and early on had a vision of what non-medical IH might look like. As with the assessment of the position of medical IH's by the 1920 Millerson's criteria are a useful structure with which to assess various facets of a developing profession. However the ecological analogy appropriately used and not stretched outside its bounds enables the position of the non-medical IH's to be analysed as a whole.

1.11.1 Ecology of Professions

By 1940 medical IH's still existed and non-medical IH was still a novelty. The order grouping was more widely known and probably larger in number, but the younger non-medical IH's had redefined large areas of the subject and though they did not control the subject area they had laid the foundations from which they would do so. Strictly speaking

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Brotherley Love" p1 USPHS (1936). The quotation, although it is written humorously, indicates that at least some governmental IH's understood that they were intervening in a political process and that IH was not simply a neutral scientific discipline. The quotation is of interest because it is so unusual; very little writings by IH's or industrial physicians make any political references although some such as Alice Hamilton clearly understood the different positions and power of "Capital and Labor" and the part they played in the political process (see Sicherman 1984).

There was a difference in the way that governmental IH's conducted their work but it was rarely made explicit in writing.

My conclusion is that non-medical IH's created two separate organisations to represent their interests and begin the process of developing a profession for organisational and political reasons. And the underlying political differences between the NCGIH and AIHA were and still are the reasons why the two organisations have not amalgamated.

the two groups were not competing for the same niche in the occupational health environment. The non- medical IH's had expanded the definition of the words "industrial Hygiene" and were in the process of creating a subject that best fitted their skills. The process was interactive. The non-medical IH's brought a process and measurement based approach to the subject area and the objective needs of the problems facing practitioners was for process control and a better understanding of how exposure occurred and how it could be controlled. Starting with their basic approach and borrowing from or forming alliances with other scientific groups non-medical IH's adapted themselves and the subject area to the problems which existed in the work environment. They left recognition to the medical IH's and industrial physicians but looked to toxicology and physiology to help them predict what type of harm would occur, at what level of exposure. The non-medical IH's were aiming to create a self contained subject and a self sufficient new profession.

The medical IH's wished to maintain control over the subject area even though it was evolving out of their ecological range. But, as Smyth describes the non-medical IH's in the late 1930's did not want to be incorporated in a purely medical profession and consciously made a break and set up their own organisations. The break was not clean (and however has been) and the non-medical IH's co-operated and worked with physicians who accepted the change in definition of IH and the right of non-medical IH's to exist.

By 1940 the non-medical IH's had had some success with their approach to preventing occupational ill health. Silicosis could be dramatically reduced as the work at the Vermont granite sheds showed an acute poisoning from lead, mercury and the newer hydrocarbon derived materials was also shown to be preventable. Non-medical IH's had had some success and like their sanitary engineering forebears had a belief in process control as a means of eradicating disease. Their alternative world view to the medical IH transformed the subject area and the focus moved from workers to working conditions.

1.12 Industrial Hygiene (non-medical) 1940-1950

1.12.1 IH Practice in 1940

By 1940 non-medical IH was a recognised subject and proto-profession in the PHS and local state organisations. A summary paper produced by Bloomfield (Assistant Director of the DIH) and Trasko (1942) gives an insight into the size and activities of the locally based IH's in 1940 (the term IH will be used from now on to describe non-medical IH).

In 1940 32 states and 4 cities had IH units employing 160 professional and 60 clerical workers. These units covered a working population of some 40 million and over 60% of their funds came from federal government, the direct effect of the New Deal and special war grant of funds on IH can be clearly seen. At the second meeting of the NCGIH (in 1939) Bloomfield organised a standard reporting form and used it to survey local state IH activity. The 21 units that replied had completed 1,500 studies covering ~100, 000 workers. The studies were undertaken for 3 reasons: 22% were due to requests, 75% were part of planned unit programmes and 3% were due to reports of occupational disease. The units had tried to investigate conditions "suspected of having adverse effects on the health of workers" p 167, and the table of types of exposure according to numbers exposed is reproduced as Table. Exposures to organic solvents, silica dust and lead and its compounds were top of the IH's league table in 1940. The survey also examined the type of control recommendations made, whether any action was taken and if so what type of action. Around 40% of recommendations made had been acted upon at the end of the reporting period and 98.9% of the recommendations were of "an engineering or environmental nature". The remaining 1.1% covered medical examinations or studies. Local and general ventilation together with enclosure accounts for recommendations which affected nearly half the workers potentially exposed and protective clothing was suggested for over 35% of the people exposed.

The league table of concern for the IH has changed since 1940. Asbestos has increased in importance and silica dust has decreased and there is an increasing concern over organic solvents. However, the proportional breakdown of recommendations for control looks surprisingly modern with local and general ventilation being the main methods chosen.

The survey indicates that by 1940 the practice of IH was well developed. There were few hygiene limits to work to as yet and, as the next chapter demonstrates, this was a task that the IH's set about rectifying in the next decade.

1.12.2 World War II

The Second World War (WW II) had a dramatic and stimulating effect on the size and status of IH as a subject and profession. The DIH had expanded from a position of having less than 30 staff in 1939 to having over 200 in 1943. Also an additional 60 "industrial physicians engineers and chemists" had been trained and sent to bolster state activities, Bloomfield (1944). Bloomfield estimated that there were about 500 trained professional IH workers in total in the Federal and state IH organisations. The number of IH units had expanded from 32 in 1939 to 47 in 1943. Even with a staff of 200 Bloomfield in 1942 complained bitterly of being understaffed because of lack of qualified personnel and a frozen budget which prevented recruitment, Bloomfield (1943). These figures do not take into account the independent growth of IH activities in the armed forces. Phillip Drinker advised the Navy on their training programme, DOYLE (1977) and Hatch amongst others was seconded to the army to work on problems of thermal stress in tanks. The DIH used its central position in Washington to co-ordinate the national IH effort. It gave "direct" assistance to the War and Navy Departments in the inspection of ordnance plants BLOOMFIELD (1944) and was certified to inspect 150 military establishments. It also, in conjunction with the Council on Industrial Health of the American Medical Association publicised the importance of occupational health and IH amongst part-time physicians serving the medical needs of many factories. And the message which Bloomfield and the DIH broadcast was, "that communicable diseases today account for only 3% of the mortality of the Nation (and) it is time that health agencies began to shift some of their emphasis towards adult health problems ... these are the problems of adult life, such as cancer, heart disease, and other chronic diseases ... BLOOMFIELD (1944). There was an emphasis on integrating other aspects of public health in the PHS message and IH was now a respected and autonomous part of that work.

The New Deal money which was directed into IH enabled the foundation of many small IH units in various states. This work was co-ordinated by the States Relations Branch of the Office of IH and Sanitation (the DIH from 1937 onwards), headed by J Bloomfield. WWII released additional money via a special grant program administered by the PHS States Relations Branch. The money was essential for IH to expand but was not the only or perhaps principle stimulus. The war effort, even more so than in the first world war, consolidated and expanded the influence and status of IH and industrial medicine. In 1943 the DIH produced a multi-author work entitled "Industrial Hygiene and Medical Services in War Industries". The 2,000 copies published sold out within the year and it was reprinted in 1944. The manual gives a strong flavour of the crusade on which the PHS's occupational health branch embarked especially after the attack on Pearl Harbour. In the first chapter Bloomfield reviews the "War's influence upon industrial hygiene". Although he uses the term IH in this context to describe all public health activities applied to the industrial workforce the various effects on the more narrowly focussed non-medical IH can be clearly discerned. Under the pressure of war production:

1 "New machinery, new processes, new substances - all have been introduced with incredible speed" and the general practitioner in an industrial community, "is the first to see the results of toxic exposure", Bloomfield (1943).

2 Electric arc welding was used on a mass scale particularly in ship building. Although control measures for all the hazards associated with welding were known in Bloomfield's experience they were applied "too late and too little".

3 New toxic substances were introduced as substitutes for materials in short supply and old toxic substances were reintroduced. Thus benzene was used instead of toluene which was drawn off into the production of TNT and silica sand was reintroduced into abrasive blasting because of a shortage of steel.

These rapid changes to the production process posed big problems for IH's and workers and together with the mass employment of women and the problems of fatigue caused by long hours of work threw a big responsibility onto the industrial physicians and local general practitioners. Thus Bloomfield stressed the need for teamwork: "Our air force has the answer for industrial medicine. We do not hear about a pilot, or a navigator, or bombardier any longer. We hear about a 'new' a team ... The industrial physician can meet his enemy - carry out his mission - if he learns to operate as a team drawing upon the resources available to him", Bloomfield (1943). He ends with a peroration to industrial hygiene:

"The new and renewed problems are troublesome; but in most instances, we know how to meet them. War hits hard and it hits fast - in every phase of our national life. The industrial hygienist must hit first and hit harder if we are to give our working army the health and strength necessary for victory". BLOOMFIELD (1943).

Although the prose may appear florid to a person reading them in the 1980's, they show how hard Bloomfield, and other IH's, pushed for the integrated teamwork approach to occupational health problems with IH playing an important role. The importance of IH became welded into the consciousness of many engineers and doctors during WWII. This occurred not simply because of propaganda from people such as Bloomfield but also because the IH approach to controlling health hazards demonstrably worked.

1.12.3 Postwar changes

By the end of the war the ACGIH membership had risen to ~ 300. After the war it fell to ~ 250 until 1949 when it rose to ~ 300 again and remained at this plateau until 1955 when it began to climb again, Lippmann (1983). The membership data reflect the fortunes of IH employees in federal and state government over this period. At the conclusion of WWII war assistance funds were withdrawn and many of the staff employed by the states by means of federal subsidies either left the profession or moved into private industry or universities. According to DOYLE (1977) the DIH remained intact but in order to maintain its stance of support for state programs by means of field investigations Townsend, the new director and Bloomfield decided to move the DIH to the Bureau of State Services and away from the National Institute of Health (NIH), because, within the NIH "the primary mission of the Division would have been research", Ibid. It would also have meant that the DIH would have been under dominance of a powerful and prestigious medical organisation. An unattractive proposition for a proponent of non-medical IH like Bloomfield. The DIH with a reduced budget maintained its commitment to field research and surveys of chromate producing industries and various mining populations and environments were initiated in the 1940's. The status of the DIH fell though with the end of the war and the headquarters was moved away from the political levels of power in Washington to Cincinnati which for many years had keen the location of the PHS's Water Pollution Laboratories.

In 1945 the Journal of IH and Toxicology amalgamated with the shortlived Journal of Occupational Medicine to become the Archives of IH and Occupational Medicine. Control of the journal passed from Harvard School of Public health to the American Medical Association. The IH's had lost control of their most prestigious journal. However the AIHA within a year of its foundation in 1939 had started "Industrial Hygiene Quarterly". It may not have been as prestigious as the JIH but it was wholly controlled by IH's. From 1957 it was published monthly and continues to this day.

The government education in funding, the drop or plateau in recruitment to the ACGIH and AIHA and the loss of control of the JIH are the signs of recruitment of IH post WWII. The subject and profession (or discipline as 1940's practitioners referred to it) had consolidated its position during the war. Despite opposition, the small numbers of practitioners and attempts at incorporation IH by the mid 1940's was here to stay.

Within a few years of the war several text books on occupational health and IH were produced. Frank Patty produced the first edition of his "Industrial Hygiene and Toxicology"* in 1948, maintaining the strong traditional connection between these two emerging disciplines. In the same year RT Johnstone, an industrial physician and a close associate of Alice Hamilton, published "Occupational Medicine and Industrial Hygiene". A comparison of the approaches and views of the two authors to occupational health and, particularly IH, reveals the rivalry between IH and industrial medicine and the new found confidence and self-consciousness of IH profession.

Patty traces the development of IH in the USA: "...It was not until the late twenties that industrial hygiene became more than an incipient dream in the minds of a relatively few individuals. A few farsighted pioneers in the field of public health saw the possibilities of making the control of industrial health a vocation and of enlisting the technical aid of professions other than medicine to do the job", PATTY (1948).

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* 3rd Edition of 4 volumes was published in 1985.

He viewed the conflicting views of the new style IH's with the traditional industrial physicians as a positive stimulus:

"One of the outstanding reasons that industrial hygiene has been so successful in controlling adverse environmental conditions and in preventing or controlling occupational disease is that pronounced rivalry has developed between the medical men of the sciences, as well as between the scientific professions involved, for instance, chemists and mechanical engineers. This rivalry, as has been pointed out before, has been wholesome and has resulted in advancing accomplishments in the field of industrial health that would have been improbable without it". Ibid.

And when he comes to review developments in other countries he clearly described his view of the relationship between medicine and IH. He takes as his primary source of information on International Labour Office (ILO) publication concerning the regulation and control of "poisonous materials in industry" in Europe.

"... The rules and regulations in these countries ... are based on the results of periodic medical examinations of workers in plants handling such substances. At certain intervals prescribed by regulation the worker must be examined by a physician. It is the task of the physician to **make an early diagnosis to recognise and evaluate the first signs of absorption of a poison** (original author's emphasis) and if necessary to remove the men from work temporarily. The ILO believes that this is a reliable method for the timely detection of endangered workers and also of the hazards in a specific plant". Ibid.

Patty is not convinced and cuts straight to the nub of the problem:

"The shortcomings of such a plan of approach obviously are in evaluating the first sign of absorption - a trick physicians in the United States have not been able to turn to their complete satisfaction. the toxic materials that give rise to recognisable, specific dependable clinical signs in advance of serious injury are disappointingly few", Ibid

As the common concern of the IH's at least was with the prevention of chronic hazards, a different method of recognition was needed apart from or in addition to routine medical examinations. However, he goes on to describe his approach which appears to consist of a medical and IH partnership:

"... Regular and more frequent medical examinations are a desirable way of discovering dangerous exposures, especially in the absence of competent industrial hygiene engineering evaluation and control. When the two methods are properly co-ordinated, however, the most dependable safeguard against harmful exposures is provided". Ibid

Judging by this quote Patty cannot see IH practice independent of the physician. The doctor is still needed to "recognise" diseases, signs and symptoms, but elsewhere, in the same chapter, he has a grander vision of IH:

"Industrial hygiene has laid aside its swaddling clothes and entered a vigorous stage of advancement. It is no longer seen by industry on the aimless effort of intellectuals collecting bottles filled with nothing ... The safeguarding of industrial health is on a business basis of evaluation and control and is recognised as such by both labor and management. The purpose of the industrial hygienist is no longer merely to "lock the door after the horse has been stolen" but to anticipate and prevent harmful situations, or to control them before serious injury results", Ibid.

Elsewhere in the same chapter he continues in the same vein:

"Industrial hygiene procedures have largely passed through the period of enquiry into the causes of ill health and now devote their energies to anticipating and avoiding harmful situations before they have time to cause injury". Ibid.

And these "harmful situations" were to be identified and avoided by the use of toxicology and maximum allowable concentrations of contaminants in air. The IH's draw support and arguments from the developing field of industrial toxicology and MAL's (later renamed TLV's) were specifically seen, by IH's such as Patty, as offering protection against chronic diseases - "avoiding situations before they have time to cause injury". The importance of

toxicology to IH can be seen in the title of Patty's seminal work. Thus, according to this view, IH could operate separate and independent from industrial medicine. This approach did not find favour with industrial physicians nor on the other end of the IH's business, the control end, with engineering. By 1946 though Patty could record that "IH has successfully withstood abortive effects at absorption by safety engineering and medicine".

This is not to say that IH's redefined the subject and occupied the expanded niche with no opposition. There were attempts referred to by Henry Smyth (1984), Patty (1946) and Bloomfield (1939) to incorporate IH or limit and subordinate its role.

Johnstone is quite specific in his view of the limited role of the IH and the central role of the industrial physician:

"Industrial hygiene is popularly conceived as a survey by industrial hygienists and engineers who periodically go through a plant with queer looking gadgets, sniffing and sampling the air in the hope of finding trouble. Some have defined industrial hygiene as the appraisal and control of industrial hazards. Actually, the ideal industrial hygiene program would concern itself with the optimum health and happiness of the worker as well as with his working environment.

An industrial hygiene program is effective only if it engages the combined efforts of the engineer, the hygienist, the chemist, and the physician. It should begin with an appraisal of the worker's physical and mental condition, by use of the pre-employment examination, and be followed by the physician's appraisal and control of the worker is as important as the engineer's appraisal and control of the working environment." JOHNSTONE (1948).

Apart from claiming that virtually the whole of public health is medical territory, he has got IH's firmly boxed into the caricature of men with "queer looking gadgets, sniffing and sampling air" which Patty specifically addressed and dismissed as an old and out-of-date view. Also in the same chapter (Chapter 28) Johnstone in effect dismisses the view that IH is an integrated and coherent discipline by arguing that it was simply a technical problem which could be put down to maintenance personnel. His text covers a range of IH techniques including dust sampling and control methods but he assiduously avoids referring to IH's as the being the profession which developed the methods and is competent to use them. He adopts a policy of either ignoring IH's independent existence or minimising its role when it has to be acknowledged. He almost certainly represents the attitude of a significant proportion of industrial physicians working in the private sector in the 1940's. His contemporaries in the PHS and local state organisations probably had greater respect for IH as they had worked alongside IH's for many years and seen the subject evolve and succeed. Certainly this seems to have been the attitude of physicians in the ACGIH.

1.13 The Position of Industrial Hygiene by 1950

Again Millerson's criteria and the ecological approach will be used to gauge the development of IH as a subject and profession.

Millerson's criteria are divided into 8 obstacles:

1 Insufficient internal or external pressure to form an organisation.
2 Underdevelopment of subject matter and/or practical technique.
3 Great variation in quality of service provided; training received by practitioners; level of study, type of employment; social origins.
4 Rivalry between occupations and organisations.
5 Small numbers of practitioners.
6 Geographical isolation.
7 Underdeveloped governmental, industrial or commercial structure.
8 Absence of enterprising individuals.

Taking the obstacles in turn:

1 The ACGIH (the NCGIH became the ACGIH in 1946) and AIHA had matured by 1950. The plethora of committees set up at the inaugural meeting of the NCGIH had been weeded out and the two most important or were about the product standards and guidance. The Standards Committee published its first list of

Maximum Acceptable Limits (MAL's) in 1947 and the Ventilation Committee was well on its way to publishing the first edition of "Industrial Ventilation" (produced in 1951). The MAL's and their derivation were the most important product of the NCGIH for the Conference and probably for the reputation of IH. The manual (now in its 20th Edition - 1986) was to become the standard reference work for control engineering in the Western world and sales in the 1950's were ACGIH's biggest source of revenue. Initially the NCGIH and AIHA worked separately and had their own annual conferences. By 1944 the two principle IH organisations had sunk their differences and had agreed to a joint annual IH event.

The internal pressure to plan co-ordinate and direct IH was maintained and the external pressure for the skills of the IH's was maintained if not increased.

2 The development IH techniques and its approach to control of health hazards at work continued in the 1940's. Silverman built on the earlier work of Dallavalle and investigated the suction characteristics of exhaust ventilation slots, Silverman (1942). Yaglen examined the response of people to different thermal environments and air conditions. And the 1940's and early 1950's were the years when the earlier research work of the IH's was drawn together into various standard texts. Patty's multiauthor work was published in 1948, Drinker and Hatch published "Industrial Dusts" in 1936, Dallavalle published his "Exhaust Ventilation" in 1952 and Brandt published "Industrial Health Engineering" in 1947. The first edition of Sax's "Dangerous Properties of Industrial Materials" (initially entitled "Handbook of Dangerous Materials") was published in 1951 although interestingly he identifies the principle readers as "the industrial physician and trained safety 'inspector' ... and the foremen and plant managers", piii Sax (1951). He makes no mention of the IH and this is perhaps symptomatic of the status of IH in some people's eyes during this period. This was not a problem when Alice Hamilton published the second edition of her book "Industrial Toxicology" in collaboration with Harriot Hardy in 1949.

3 IH was recognised and valued in some organisations and institutions, for instance certain insurance companies and the PHS but recognition was patchy. The IH's did not control entry into the subject area or profession. Courses such as the Harvard and Johns Hopkins Masters in IH co-existed with shorter duration, lower level qualification and although the "job description" and training requirements of the IH (engineer and chemist) had been addressed by the ACGIH in the early 1940's (and the AIHA) the profession was not able to institute a training and registration scheme until the early 1960's.* The scheme that was eventually drawn up was planned by the AIHA from 1956 onwards. The ad hoc Committee on Certification Standards was chaired by Henry Smyth (Junior) and one of the first proposals it made was to invite the ACGIH to join the Association in initiating a certification programme, ABIH (1983). IH as a profession had advanced by 1950 but it still did not control training and practice in the subject area.

4 As Johnstone's attitude to IH reveals there were still many industrial physicians who minimised and denigrated the value of IH as an integrated subject and profession. The techniques developed by IH's and others could not be denied but the area of industrial health, and in the case of Johnstone all of public health (see Johnstone (1948) pages 22-23), was regarded as the province of the doctor by many medical personnel. Patty too refers to the continued rivalry but felt that IH, by 1948, was secure against incorporation by either medicine or engineering. Although there was rivalry from other professions, particularly the medical and engineering occupations the antagonism was not unrelenting and uniform and it did not prevent NCGIH and AIHA having a joint annual conference with the Industrial Medical Association and other medical groups, from 1943 onwards, Lippman (1983). Also, it would be mistaken to view all IH and doctors relationships as being mutually antagonistic. For thirty years the ACGIH alternated chairpersons of the Conference between a medical member, Yaffe (1980). As to the relationship between ACGIH and AIHA, after separate development at first they sunk their differences in 1943 and helped

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* During this period other groups including the industrial physicians, sanitary engineers and radiation protection scientists all set up examination and registration schemes, ACGIH (1958)

with the Annual Conference. They continued though to represent different constituencies within the IH profession.

5&6 In 1946 the NCGIH changed its constitution to allow full membership to all IH personnel in government employment, including foreign governmental personnel. Before this date membership was limited to two individuals from each IH agency. At the same time as membership was opened up the name of the conference was changed to ACGIH, Yaffe (1980). Thus although many IH personnel left state employment after the war the membership of the ACGIH remained fairly steady at ~250 however it did not grow for another 10 years. If anything AIHA membership was less (to be confirmed). Thus although hygienists had increased in number during the 1940's they were still as an aspiring professional group thinly spread and geographically isolated.

7 They had however increased their influence and presence within government, industrial organisations concerned with industrial health. The DIH had played a key role in maintaining the "industrial army" during WWII and the IH units set up at the time in various states continued after the war albeit reduced in size. Private industry, during the 1940's steadily employed more IH's though never in large numbers and commercial companies, particularly insurance carriers did likewise. In the case of the latter companies this was really continuing a tradition started by some early on in the development of IH, in the late 1920's.

Although, by 1950, IH's were still small in number the influence of IH and its integration into routine industrial health activity was well ensconced compared with 1940. The WWII, ACGIH and AIHA, activities of the IH's and the changed perceptions of what IH was and could do by employing organisations had brought this about.

8 The early evolution of non-medical IH is dominated by the names of a few individuals who crop up again and again. They include: Bloomfield, Hatch, Hamilton, Smyth, Drinker and Dallavalle. They worked during a period in which the shape of the subject non-medical IH was forged and their were few practitioners. By 1950 a new generation of IH's had been taught and guided by the old, first generation. The boost IH received in WWII maintained a demand for the Harvard Masters course for many years after according to Drinker, Hatch (1984). It is thus more difficult to identify "pioneers" or enterprising individuals in the 1940-1950 period. As with the 1940 assessment all that can be said is that many people who became IH's in the 1940's continued to develop and broadcast the subject well into the 1950's, 60's and 70's. This generation had to consolidate the subject area and profession and charismatic individual people do not stand as readily as in the formative first generation of IH's.

1.13.1 Ecology of Professions

IH's by 1950 had convinced significant numbers of employers that IH was a non-medical subject area which was concerned with the recognition, evaluation and control of potential health hazards before they had their effects. Although small in number the IH's had codified a certain definition of IH and formed two professional organisations to further their interests. As a professional species in the industrial health environment they were small and vulnerable and did not control entry to the area or training in IH. IH was still open to predation from both the medical and engineering professions. However, by 1950 it was clearly not going to be dislodged and although individuals such as Johnstone would plainly have wished to encompass IH with industrial medicine this could not now happen.

The IH engineers and chemists had expanded the definition of IH and employers perceptions of this professional ecological niche. They were the best fitted to this new niche. For the professional species of industrial medicine and engineering to encompass IH they would have to acquire new skills. In reviewing the past and future prospects of IH Patty in 1948 faced the future by asking the question: "Will industrial hygiene engineering be absorbed by either the medical profession or by safety engineering? PATTY (1948). He answered his own question with a description of what training would be required: ..."If our educational institutions can turn out doctors of medicine who are accomplished in the sciences of chemistry and mechanical engineering, mathematics, and physics and yet who are willing to do the amount of plain drudgery associated with the engineering phases of the prevention of

occupational diseases, then IH will surely become the sole province of medicine". His description of IH in 1948 plainly puts it outside the ecological range of the medical profession. By 1950 non-medical IH had virtually displaced medical IH. The older professions claimed and still claim expertise and professional control over segments within IH niche. The IH profession responded in the 1940's, and still nowadays, that the needs of IH were best served by a person who could integrate the various skills and knowledge required and that this integrated approach is what the problems require. This argument could and can be ignored by a profession bent on working in some part of the IH niche or may simply be left unaddressed, as happened in the UK. To prevent the invasion of more powerful, older and numerically greater species it is important that a new professional species develops areas of knowledge and practical techniques which are unique and under its control. Non-medical IH developed measurement techniques, methods of air contaminant control, particularly exhaust ventilation, and a particular measurement and process based approach to occupational health problems. However the innovation which IH could claim as its own and which it refined and controlled for the next 3 decades was the hygiene standard. This more than any other development was a creation of US IH and other collaborating groups, principally toxicologists and industrial physicians: it was the product which broadcast the name of IH and increased its reputation, particularly the ACGIH, worldwide from the late 1940's onwards.

APPENDIX TWO

THE JOURNAL OF INDUSTRIAL HYGIENE (JIH) - A CONTENT AND AUTHOR ANALYSIS

The first edition of this journal was published in May 1919 by Harvard University School of Public Health. It was the first journal of Industrial Hygiene (IH) in the world and remained the principle international journal, for the English speaking world at least, until the late 1930's early 1940's. Before 1919 the only other forum for authors of works on IH was the American Journal of Public Health (AJPH), itself started a few years earlier in 1911 by the American Public Health Association. Alice Hamilton, Emery Hayhurst and a few others, did publish in the AJPH before 1919 but after the JIH was started they remained faithful to this publication and in fact were two of its founding Associate Editors . Figures Appendix 2.1 and App 2.1a shows the development of the JIH and other journals publishing in the area of IH, industrial medicine, public health and toxicology in the USA and UK, with a few examples of more recent occupational health journals from other countries.

The immediate impetus to create a journal of IH came from the newly formed School of Public Health at Harvard. The professor of this department was David Edsall who was the joint editor of the JIH together with Edward Collis, a distinguished British, Medical Inspector of Factories. From the start of the JIH was a joint US-UK effort, with an international outlook though the majority of papers accepted were always US in origin. By 1921 (Volume 3) Associate editors from three other countries, Canada, Australia and South Africa, had been appointed. Three other countries were to follow Japan in 1933 (Volume 15) and Austria ad Germany in 1934 (Volume 16). The JIH was the first specialist journal to make a break with the catch-all general category of public health. The general rise in interest in IH before the 1st World War and the boost this conflict gave the subject in the USA gave the small band of practitioners at Harvard and a few other schools of public health the confidence and resources to try and forge a separate identity for IH as a subject. The same perception of the need to specialise and be recognised as separate from general public health measures, probably accounts for the creation of the Journal of Hygiene in 1921 (2 years after the JIH) based at the Johns Hopkins University.

There were no other journals of similar status and coverage to the JIH, in the US, in the UK or internationally for some two decades. In 1930 the Archives of Industrial Pathology and Industrial Hygiene were started in Germany but the language was German and the circulation was restricted. It was not until 1939, when the American Industrial Hygiene Association (AIHA) was formed and started its own journal (in 1946) that the JIH had serious competition. It follows that most workers who regarded themselves as "hygienists" or had something to report regarding the hazards of a certain trade, working conditions or their control, reported it in the JIH. Some individual state departments produced their own local IH bulletins for instance, New York, Ohio and Massachusetts, but authors often pulled together a year or moves work into a paper for the JIH.

Although different groups might publish in journals relating to their own original case discipline, for instance, a sanitary engineer might publish in an engineering journal (eg. Hatch published his work on exhaust ventilation in the Transactions of the American Society of Mechanical Engineers), or a doctor might publish in Industrial Medicine and Surgery, the work was almost always also published in the JIH. As for the few pioneer industrial toxicologists who started work in the mid 1920's. The JIH was the obvious journal to publish in as it dealt with the work environment and the recognition of potentially hazardous materials. Other journals, all founded in the early years of the 20th Century were pharmaceutical in outlook or dealt with fundamental mechanisms of biochemistry. The industrial toxicologists were more concerned to apply biological test methods to assess the toxicity of materials. They were not concerned with a few exceptions such as Aub and Kehoe at Kettering Laboratories with fundamental mechanisms. The JIH was the obvious forum for the publication of such work and remained so for two decades. An analysis of the contents and

Figure App 2.1a. Development of pharmocological and toxicological journals in the USA and UK.

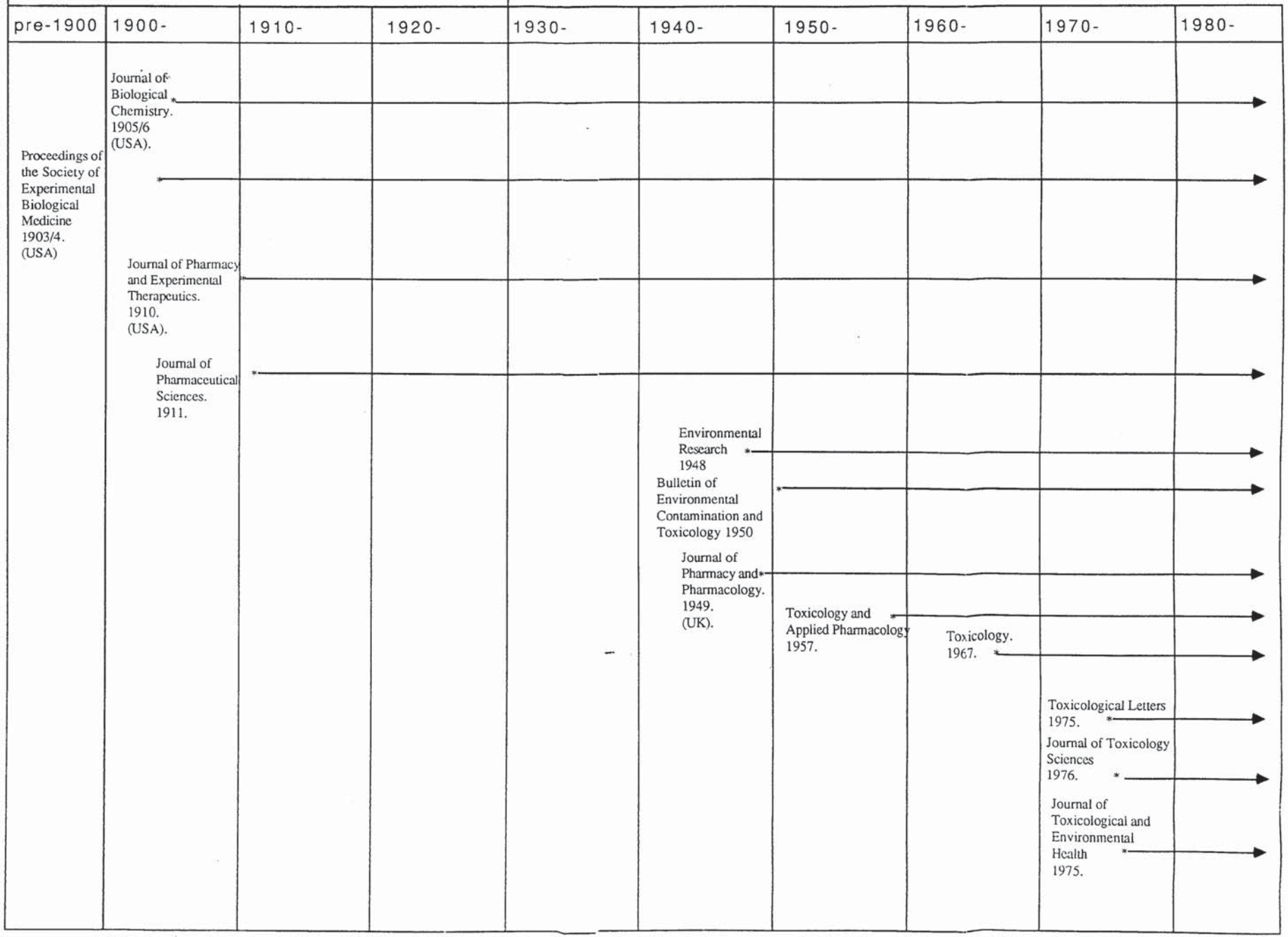
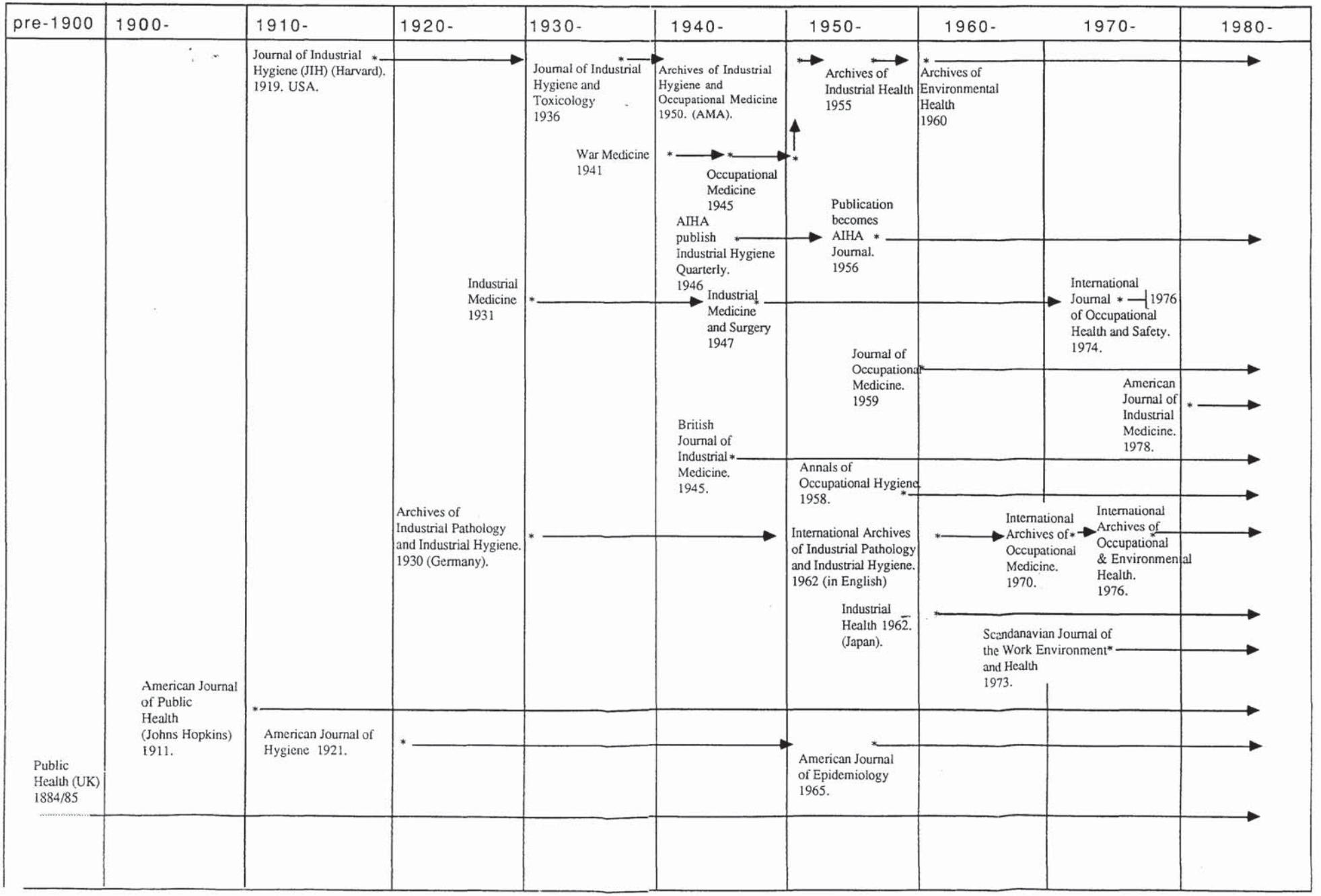
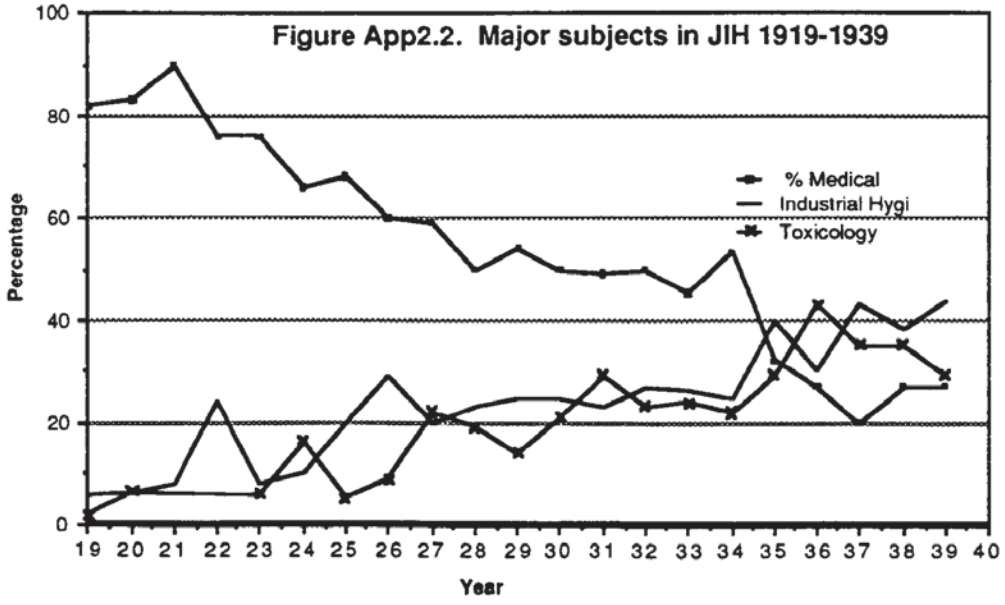


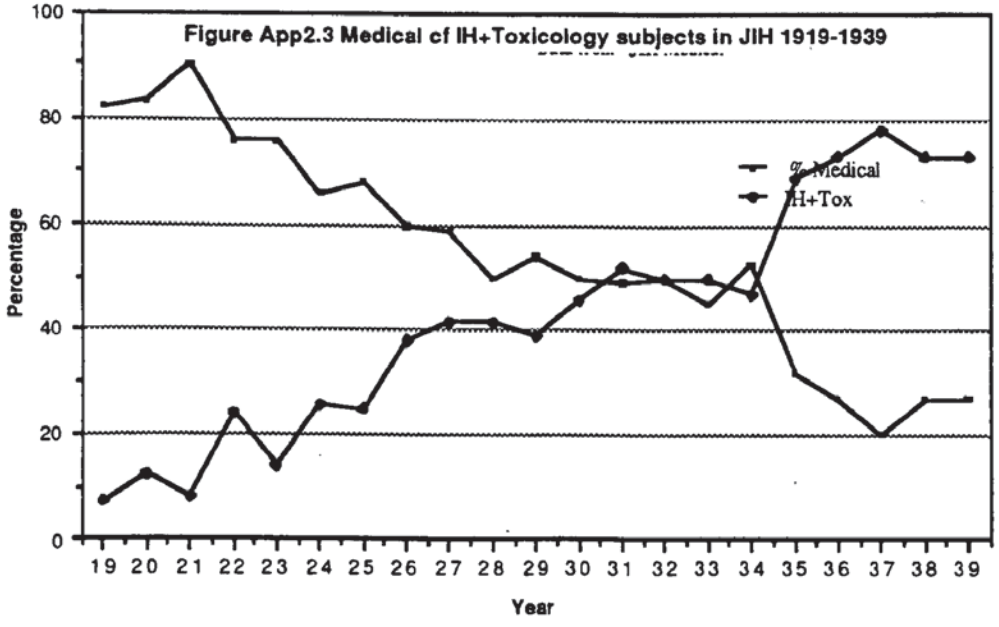
Figure App 2.1.6
Development of occupational health related journals in the USA and UK pre-1900→

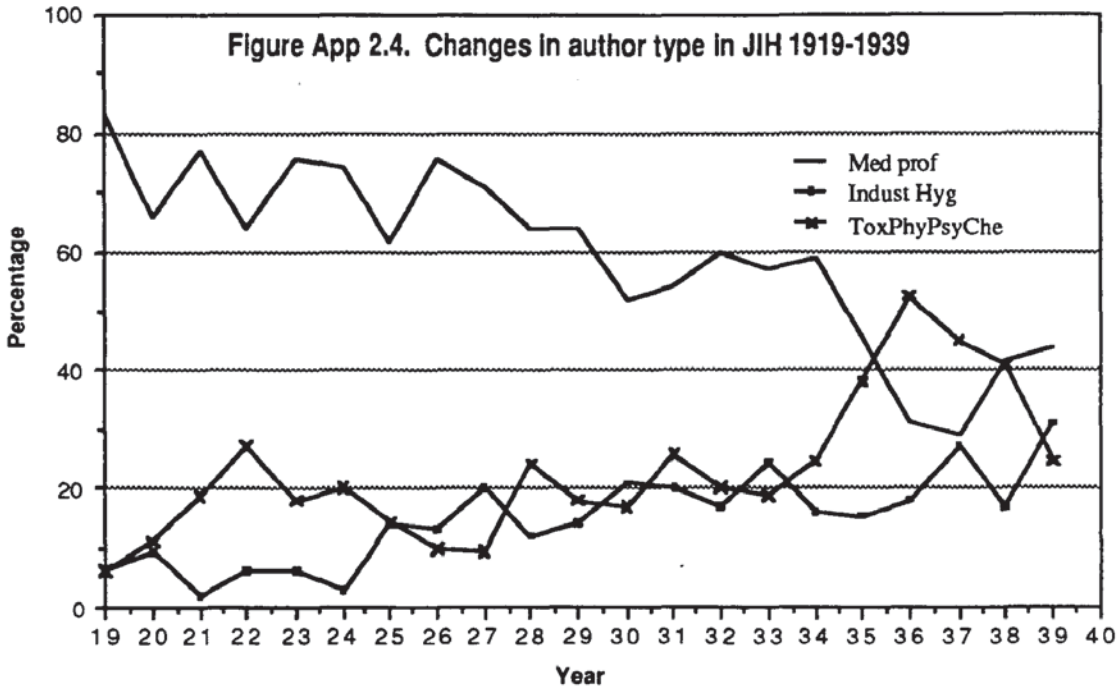


type of author writing in the JIH up to 1939 should reveal any fundamental changes in the definition of the subject and the affiliation of individuals who practiced IH or at least associated their work with IH.

The contents and first authors of papers in the JIH from 1919 to 1930 have been analysed. The basis of the analytical method was to examine the contents of each volume of the JIH and divide it into broad categories under the headings: Medical, Industrial Hygiene, Toxicology, Public Health and Safety. The first three headings were sub-divided into various specialist areas. At the same time, the first author of each paper was classified under the following headings: Medical, Industrial Hygiene, Chemist, Toxicologist/Pharmacologist, Physiologist/Biologist, Psychologist and Statistician. The method is inevitably somewhat subjective, but a standardised approach was used on each volume of the JIH, and is precise enough to identify broad changes in subject contents and another type. The results of this analysis are summarised in Table Appendix 2.1 and Figures Appendix 2.2 – 2.5.







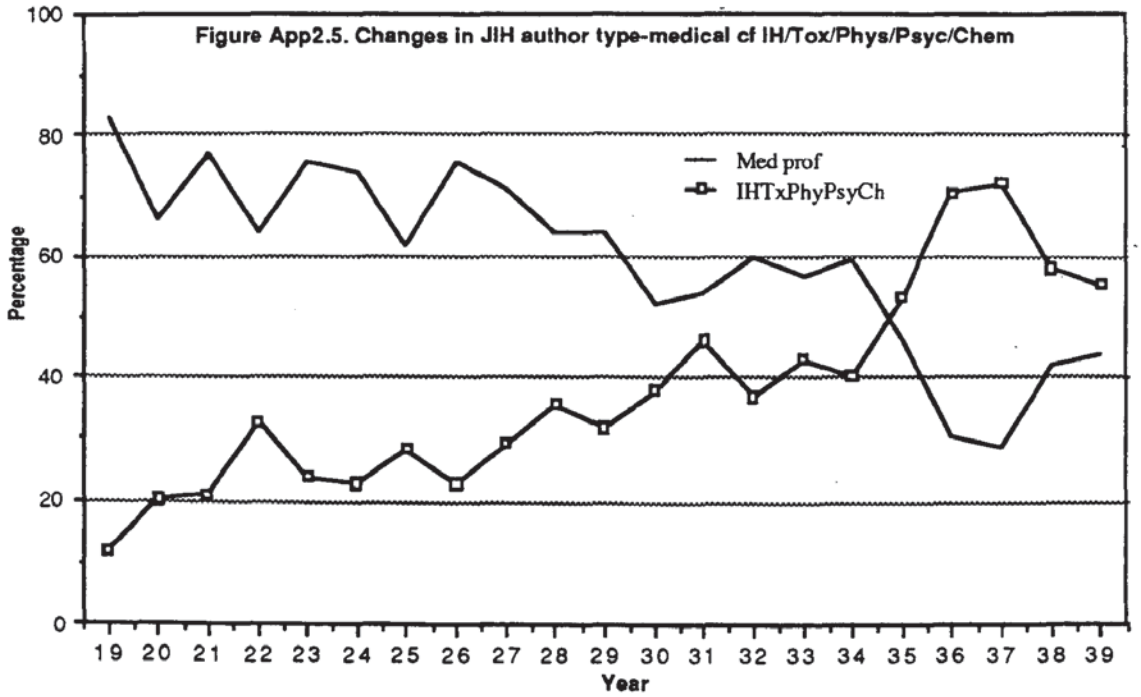


Figure Appendix 2.2 shows the changing proportion of each major subject category. Medical subjects start off occupying about 85% of the Journal's content and there is a slow and relatively constant decline from 1921 onwards until by the late 1920's their proportion has reached ~ 50%. They remain 50% until 1934 when the decline continues falling to about 35% by the late 1930's. Industrial hygiene subjects show a slow and relatively constant rise over the 20 years of the analysis, starting at ~ 5% in the early 1920's and rising to ~ 40% in the late 1930's. Toxicology follows a similar trend to IH but starts from a lower base line of 0-5% with a discernibly slowed rise in proportion in the 1920's, a plateau in the early 1930;s and a rising trend from the mirrored mid-1930's.Figure Appendix 2.3 shows how the decline in medical subjects is mirrored almost exactly by the increase in industrial hygiene and toxicological papers.

Figures Appendix 2.4 and 2.5 show the change in author type. Until the late 1920's medical categories (principally doctors) dominate and represent a variable percentage averaging ~ 75% of author types. There is then a slow decline in percentage to ~ 60% by the mid-1930's and then a more erratic but rapid decline to ~ 40% by the late 1930's. There is a reverse but not so spectacular trend in the proportion of IH's writing in the JIH. From the early to late 1920's IH's represent 5-10% of the author types. There is then a slow rise to ~ 20% by the mid-1930's and a slightly steeper rate of rise up to the late 1930's when the percentage was ~ 25%. Of the other significant author types, physiologists and others, represent a fairly stable 10% and chemists were an erratic 0-5% until the mid-1930's when they became a relatively constant 8%. Toxicologists followed a similar pattern to the chemists until the mid-1930's when there was a rapid rise in their proportion which reached a peak in 1936 at 27%. Thereafter their percentage fell back to average ~ 15% in the late 1930's.

2.1 Observations and Conclusions

There was a systematic change in author type and subject category in the JIH from 1919 to 1939. Industrial Hygiene as defined by the contents of the JIH evolved over these two decade and moved away from being simply a medical subject practiced by doctors to become a broader, multi-disciplinary subject involving a variety of non-medical groups.

As is evident from Figure Appendix 2.2, at the start of the JIH, IH was primary a medical subject. This position changed over the 1920's and medical subjects accounted for only ~ 50% of the JIH contents by 1928. The evolutionary process IH was undergoing, and the decline in medical subject content, appears to have been inhibited by the Depression which started in 1928 and this process only re-established itself with the New Deal programme and the Social Security Act of 1935.

The effect of the non-medical personnel on the definition of IH can clearly be seen: IH was a far more complex and multi-disciplinary subject by 1940 than it was in 1920. Also by 1940 the majority of people who worked in the area of IH were not medically qualified but came from a variety of scientific disciplines.

A comparison of Figures Appendix 2.2 and 2.4 indicates that the number of doctors writing in the JIH did not decline as rapidly as the medical subject categories. Although the medical author/subject pattern is similar the proportion of doctors who apparently worked in and wrote on non-medical aspects of IH was relatively constant. This may be explained in two ways. Initially doctors worked in non-medical IH, physiology and occasionally toxicology as there were no separate toxicologists or hygienists to lay claim to these areas of knowledge. As more non-medical people became involved and the definition of IH became altered the doctors would still show up disproportionately because of their senior status in the PHS, the Bureau of Mines and the state Boards of Health (the author analysis was done by noting the discipline of the first named authors only). Even so, allowing for this potential source of bias in the data, there is a steady growth in IH and biological scientist (physiologists, biologists and psychologists) authors over the 1920's and 1930's. Toxicologists (or biological/biochemists as they were probably referred to in the 1920's) represent an erratic and small proportion of the author population until well into the 1930's. In 1934 the relative percentage suddenly accelerates probably stimulated by concerns about product liability and toxicity testing and the foundation of the FDA's Division of Pharmacology in 1935. There appears to have been an intimate association between the evolving subject of IH and the developing speciality of toxicology. Early non-medical IH's such as Smyth (Junior) were intimately involved in the development of toxicology applied to industrial products and substances and other toxicologists working in the area published their research findings in the JIH. In recognition of this association and the importance of toxicology to the evolving subject of IH the JIH changed its name to the Journal of IH and Toxicology in 1936.

Appendix 2.1.1 Summary

IH in the early 1920's was still in what may be described as its medical phase. Most papers in the JIH were case histories or descriptions of detailed medical evaluations of workers health in recognised or recently identified "dangerous trades". The medical phase almost invariably dealt

with the recognition of a problem and rarely considered evaluation of the work environment or detailed control measures. The recruitment of sanitary engineers and chemists opened up the possibilities. As has been shown earlier and is evident in the JIH analysis the work of these new recruits enabled a more comprehensive and quantitative evaluation of the work environment to take place. Also, once the basic empirical research had been done, by Hatch, Dallavalle, Bloomfield and others, detailed proposals or research on specific control methods was possible. The success of the control methods could be assessed by the recently developed quantitative measurement methods. The work environment and its control became the focus of these new non-medical IH's. By the mid-1930's, recognition, evaluation and control had real meaning. But the vision of the new, non-medical IH did not stop there. The developing applied science of toxicology offered the possibility of recognising potentially hazardous new substances before, or at least soon after, they were introduced into the workplace. Thus the two Smyth's and their research associate Carpenter investigated the toxicity of various halogenated hydrocarbons and similar work was performed within the PHS Office of IH and Sanitation on a range of aliphatic and aromatic hydrocarbons. At the same time as this early industrial toxicology was starting toxicology itself was was formulating its canons based upon the results of animal experiments, the application of biostatistical methods to the animal data and building upon ideas concerning homeostasis originating from biological philosophy formulated in the 19th Century. Toxicologists offered the possibility based on their experiments and theory, of setting risk free threshold exposure levels for new substances. Such threshold levels were thought to exist from animal tests, the problem, which still exists today, was how to extrapolate from animals to humans. They concerning thresholds of toxic effect, developed by toxicologists, had a great effect on the non-medical IH's who were particularly receptive. The ideas raised the possibility and gave credence to the idea that it should be possible to set a level of exposure, based on animal and human data, below which no danger to health would exist. The development of these ideas and the use to which they were put by IH's from the late 1930's onwards are explored in Appendix 1 and the main text.

Table Appendix 2.1 – Summary of content and author analysis of JIH 1919-1939

Volume/Date	Percentages Total by Subject						Total	Percentage Total by Author Type								Total %
	A	B	C	D	E	F	Other than A	a	b	c	d	e	f	g	h	Other than a
1/1919-20	82	6	3	3	1.5	1.5	18	83	6	-	-	6	-	45	-	17
2/1920-21	83	6.25	-	-	1.6	6.25	17	66	9.4	3.1	-	7.8	3.1	7.8	-	34
3/1921-22	90	8.0	2	-	-	-	10	77	2.0	-	2.0	17	2.0	-	-	23
4/1922-23	76	24	-	-	-	-	24	64	6	6	6	15	2	-	-	36
5/1923-24	76	8	4	-	-	6	24	76	6	2	-	16	-	-	-	24
6/1924	66	10	10	-	-	16	34	74	3	-	13	7	-	3	-	26
7/1925	68	20	5	-	2.5	5	32	62	14	1.5	-	12	-	10	-	38
8/1926	60	29	-	-	2	9	40	76	13	2	4	4	-	-	-	24
9/1927	59	20	-	2.5	-	22	41	71	20	-	2.5	7	-	-	2.5	29
10/1928	50	23	-	4	4	19	50	64	12	-	4	20	-	-	-	36
11/1929	54	25	3.5	-	3.5	14	46	64	14	11	-	7	-	3.5	-	36
12/1930	50	25	-	-	4.0	2.1	50	52	21	-	-	17	7	3.5	-	48
13/1931	49	23	-	-	-	29	51	54	20	6.0	3.0	17	-	-	-	46
14/1932	50	27	-	-	-	23	50	60	17	7.0	3	10	-	3	-	40
15/1933	45	26	2.0	2.0	-	24	55	57	24	-	-	19	-	-	-	43
16/1934	53	25	-	-	-	22	47	59	16	9.0	12.5	3	-	-	-	41
17/1935	32	40	-	-	-	29	68	46	15	8.0	10	20	-	-	-	64
18/1936	27	30	-	-	-	43	73	31	18	6.5	31	15	-	-	-	69
19/1937	20	43	-	-	2.5	35	80	29	27	9	20	16	-	-	-	71
20/1938	27	38	-	-	-	35	73	42	17	8	19	14	-	-	-	58
21/1939	27	44	-	-	-	29	73	44	31	10	12.5	2	-	-	-	56

Key:

Content

A = Medical
B = Industrial Hygiene
C = Mixed Medical/Industrial Hygiene
D = Safety
E = Public Health
F = Toxicology

Authors

a = Medical profession
b = Industrial Hygienist/Sanitary Engineer
c = Chemist
d = Toxicologist/Pharmacologist
e = Physiologist/biologist/psychologist
f = Statistcian
g = Other
h = Safety

APPENDIX THREE

FURTHER ANALYSIS OF OEL PARADIGM INTERPRETATIONS

3.0 Selection of Other Significant Individuals

In the consideration of the further development of the OEL paradigm in the USA the work of four more people will be assessed. The individuals are W Cook, HF Smyth, HE Stokinger and TF Hatch. Hatch is considered twice in this analysis because his work, as it relates to OEL's and standard setting, divide neatly into two periods: the 1920's and 30's when he worked at Harvard with P Drinker and 20 years later towards and at the end of his career at Pittsburgh University. (While many other authors made very significant contribution to the field these few are selected because of leading role in shaping the process and organisation of standard setting and the OEL paradigm. Other individuals will be referred to in the discussion of US OEL standard setting). Although there is much overlap, as with the work of the first three individuals considered, an attempt is made to consider Smyth's, Cook's Stokinger's and Hatch's work in a semi-chronological fashion.

3.1 Warren Cook

3.1.1 Reasons for Selection

Warren Cook started work in the Engineering and Inspection Division of the Travellers Insurance Company. His job was to "handle the chemical aspects of workmen's compensation and liability insurance", ACGIH (1984a). He continued to work for insurance companies for the next 25 years of his career, before accepting a lecturing post in IH at Michigan University. In 1939 he was one of the prime-movers in the setting up of the AIHA and became the third president of the Association in 1941. Cook did not write a lot on standard setting, he was active on ASA standard setting committees but did have obvious prominent position in the IH scientific community. He therefore fulfils some of the criteria listed in Section 3.2.

3.1.2 Cook's View on Standard Setting

Cook was a practicing hygienist for decades and wrote many papers on hygiene technique particularly analytical methods. He wrote very little on the theory and practice of standard setting as compared to the other US authors considered in this chapter. He is included because of one paper he published in 1945. It was entitled "Maximum Available Concentrations of Industrial Atmospheric Contaminants" and was the most complete list of potential standards which had been compiled up to that date. Various lists had been compiled by US physicians or hygienists from the mid 1930's onwards see for instance SAYERS and DALLAVALLE (1935), DRINKER (1939), BOWDITCH et al (1940) and STERNER (1943) but none were as comprehensive as Cook's. He produced a tabulation of the standards recommended by six US states, the US PHS and the ASA and added his own recommended limits in the case of 21 substances. But, the real novelty in his paper was that he systematically reviewed the literature on which the standards were probably based and thus gave the reader the chance to judge the standard. He was rather tentative in his description of the standards he listed putting them forward "... to provide a handy yard stick to be used as guidance for the routine industrial control of these health hazards", COOK (1945). He went on:

"... not that compliance with the figures listed would guarantee protection against ill health on the part of exposed workers, nor should the maintenance of the suggested concentrations be considered a substitute for medical control", Ibid

There is nothing of the later confidence of people like Stokinger or the vision of people like Frank Patty in this statement . In fact Cook makes very few claims for the standards he puts forward and recommends the reader to consult two medical industrial hygiene, TELEKY and STERNER for a

critique of the MAC. Nevertheless this paper is significant because it was the basis for the first set of ACGIH standards which were compiled and distributed to ACGIH members two years later. Cook therefore had an important early and short lived influence on OEL standard setting practice in the USA (NB: I may add more to this section once I get chance to listen to the "Cook tapes"). He was by no means, a keen exponent of the OEL paradigm which was beginning to crystalise in the minds of many in the IH and toxicological communities. Examining the work of the two authorities he cites in his 1945 paper gives the clue to his careful and limited view of MACs.

TELEKY was a medical IH and in his paper on "Toxic Limits", five years before Cook's publication, he set out his view of OELs TELEKY (1940). He had no faith in animal experiments as a means of predicting harm in humans and argued that only observation of workers would do. Limits were useful as guides to the development of control methods and should never be used without continual medical surveillance. His general view was that toxic limits had only a very limited role in prevention and, in 1940, he could not see this role being expanded. By 1948, when his important and original book on the history of IH was published, he had become perhaps even more forthright on the value of human evidence, TELEKY (1948):

"What we need are experiments or many experiences with men, and these are not easily performed or acquired except in cases where the effect is only an irritating one. In all other cases reliable statements - especially about chronic effects - can only be obtained by extensive observation of a great number of workers ... and the degree of contamination of the air to which they are exposed must be observed over a long period, **at least some months**, in order to find out whether or not there is the possibility of chronic effects", TELEKY (1948), Author's emphasis.

He goes on to say that only for a few substances can "toxic limits be set with any certainty, but with even those he has his doubts because the figures put forward by various authorities vary; "For instance, the figure for benzol given by different authors are 50, 75 and 100 ppm", Ibid* . Limits are for use as guides to control measures. The use of such chemical methods in the construction and control of ventilation is widespread in the United States. They are not so much used in any other country, except Great Britain in a few cases", Ibid. In one way Teleky is quite optimistic in that he places great store in the ability of medical observers to spot potential long term effects of toxic substances by surveying exposed workers for a period of some months".

Sterner was the other author cited by Cook. He, like Teleky was an occupational physician and felt in the paper that Cook refers to, that medical examinations were a key element in any IH control program. However he did accept that air sampling could be the prime preventative measure in some cases such as silica dust exposure, but still insisted upon physical examinations at intervals. For assessing new substances he, unlike Teleky, recommended toxicological animal testing but still the ultimate arbiter "frequent and comprehensive medical examinations" STERNER (1943). Though a decade or so later he was far more circumspect about possibility of maintaining long-term human studies:

"The cost of an adequate clinical program, carried on over many years and with continuing negative results, requires the support of an unusually intelligent and understanding management", STERNER (1956)

There is confusion at this point as a year earlier in a paper entitled "The experimental animal - man - in industrial hygiene", he argued that:

"When one reflects however, on the history of threshold limits it becomes apparent that many of our present standards have resulted from just such a succession of experimental events.

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* There is a certain irony in this observation given that different benzene limits were set, in all probability, on the basis of certain changing perception of risk and practicability. Knowledge of the chronic effects of benzene increased with time and the perception of what health effects were tolerable also changed but these perceptions were intimately linked to an appreciation of what levels were practicable at any particular point in time.

A pattern which has been repeated many times, begins with the introduction of a new industrial substance and an apparent assumption that it will be innocuous under the conditions of use. If injurious effects are observed in the exposed workmen, an effort is made to reduce the exposure. Then follows another trial period at this reduced level. If injury is again noted, a still further reduction is made, and so through a series of step-wise trials until a set of conditions reached which is acceptable", STERNER (1955).

The confusion is that if an "adequate clinical program" is difficult to sustain how can the "step-wise trials" be monitored? A question for which Sterner gives no answer.

This passage is interesting for another reason in that it too, like Teleky's 16 years earlier refers to "experiments" on human populations. The point that I wish to make is not that the metaphor is incorrect but that these two authors regard such an approach as the only way (Teleky) or simply the inevitable way (Sterner) that acceptable exposure limits can or should be set*.

Teleky and Sterner were medical IH's who partially subscribed to and were perhaps uneasy members of this new scientific profession. Their medical leanings meant that their predisposition was always to return to an insistence on medical surveillance as their lode stone. They could, it would seem, never wholly adopt the enthusiastic and optimistic view of MACs/TLVs that people like Stokinger and Smyth espoused. This may partially explain Cook's cautions and limited description of the MACs he listed in 1945.

3.2 Herbert Ellsworth Stokinger

3.2.1 Reasons for Selection

HE Stokinger trained as a chemist and a toxicologist in the 1930's. His doctorate was in immuno-chemistry and he received it in 1936. He continued doing post doctoral work in sulphonamides and after becoming chief of the industrial hygiene section of the Atomic Energy Project at Rochester University (where he worked on inhalation toxicity of uranium and beryllium) in 1943 he moved on 8 years later to join the US Public Health Service (PHS). In 1952 he became the Chief toxicologist for the PHS, which post he retained well into the 1970's.

HE Stokinger served 15 years as Chairman of the ACGIH Chemical Substances TLV Committee (1962-1976), the longest period of time any of the 7 chairmen that have been appointed so far. He was a member of the Committee for 28 years from 1951-1978. Over this period of time he has written extensively on the theory and practice of TLV standard setting. From his first paper on this subject in 1955 to 1986 he has written on the subject 31 times (29 papers and 2 letters); 21 of his papers have been published, (the other material is from the archives at NIOSH and is mainly conference papers that were presented but never published).

Of the 7 major actors considered in this chapter Stokinger has probably had the most influence on the intellectual and technical practice of standard setting and has certainly had a profound effect on the activities of the ACGIH Chemical Substances Committee. His importance warrants an in-depth study of his work.

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* Sterner in 1956 was also far more doubtful about the possibility of setting MACs (TLVs as they had become by then) than he was in 1943. In the same Symposium Stokinger replied to these doubts with typical enthusiasm for the use of toxicology and "safety factors", STOKINGER (1956c).

3.2.2 Introduction to HE Stokinger's Views on Standard Setting for TLVs

"A great debt is owed to Dr Stokinger, D R Hatch and Dr Smyth for their contributions to our scientific discipline of toxicology and for their distinguished creative insights to the basis for and the utilization of Threshold Limit Values." PFITZER (1987)

The account that follows will concentrate on certain issues. In the 30+ papers HE Stokinger has written on the subject he covers a lot of specific toxicology; most of this will be omitted unless it illustrates a general theme. The analysis will show that they are certain recurring themes in HE Stokinger's writing; some of these have hardly changed since 1955, others have been developed and elaborated. His work will be dealt with under the following subheadings:

3.2.3 Definitions of TLVs and the protection they afford
3.2.4 The theoretical basis of TLVs
3.2.5 Carcinogens
3.2.6 Description of how TLV's are set
3.2.7 Hypersusceptibility
3.2.8 Preliminary discussion of Stokinger's work

For further information on Stokinger's career see ACGIH (1984a) and STOKINGER (1969a)

As Stokinger wrote so prolifically on standard setting issues during his career in the PHS no attempt will be made to analyse each and every publication. Instead certain key papers will be dissected.

3.2.3 Definitions of TLV's and the protection they afford

HE Stokinger has described TLV's many times and the protection they offer. The first time was in 1955 when he described them as:

"Limiting values assigned to each substance in the list represent the maximal atmospheric concentration to which workers may be exposed repeatedly day after day without injury to health". (STOKINGER, 1955)

The list was for plant engineers, industrial hygienists and others and provided "an assurance of healthful conditions on the job". He goes on to describe the early days of TLVs (or Maximum Acceptable Concentrations, MACs as they were first known).

"Originally, preventing impairment of health was virtually the only consideration in the selection of the proper limiting air concentration of an injurious substance". Nowadays however, ... more subtle effects on health, such as the effects of annoying or initiating agents, are also considered", STOKINGER (1955)

Overall Maximum Upper Limits were set to prevent excessive or wanton exposure to air contaminants. The Committee took a cautious approach to all dusts having the view that "it would seem that all insoluble dusts of whatever nature should be held suspect until proved otherwise", p3

(FT1) These were

1000 ppm for gases and vapours
5mg m^{-3} for non-siliceous dusts and fumes
2-5 mppcf (millions of particles per cubic foot) for siliceous dusts

Also the ACGIH broke the 1000 ppm barrier with Freons and the Nuisance dust level was tabled to 10 mg m^{-3} in 1957.

(FT2) This phrase has a remarkably modern ring to it and could be taken straight from HSE recent publication on a Precautionary Policy for Toxic Substances (1980).

In the section of the paper subtitled "Interpretation and Use" Stokinger fleshes out his underlying philosophy on TLVs:

"Philosophically, the threshold limit represents a level to which a normally healthy worker may be exposed for 8 hours each work day without harm to his physical or mental well-being" ... the concept of the limit is that the summation of physiological effects of such exposures shall not be greater than the effect of exposure to a constant concentration at the level of the limit", STOKINGER (1955)

He continues later in the same section:

"TLV's should be used as guides in the control of health hazards and should not be used as fine lines between safe and dangerous concentrations, that is, a point above which injury is bound to occur and below which complete safety may be expected for all exposed persons. Competent judgement is required here as in the interpretation of any standard", STOKINGER (1955)

His definition of what a TLV is has changed slightly but significantly from the initial definition given at the start of the paper. TLV's do not now offer blanket protection for all workers, they offer protection for "a normally healthy worker".

This division of people who are protected by the TLV and those who are not becomes very important in Stokinger's later writings and it is interesting to see the early signs in his first paper on the subject.

The second part of the first quote is a description of Haber's Rule:

$$C \times T = (\text{Constant Toxicological Effect}) = K$$

where: C = concentration of the contaminant
T = exposure time
and K = a constant

This was assumed to hold true for many years, by the TLV Committee although as has been shown earlier both Drinker and Hatch were not particularly happy with the concept. It made no allowance for dose-rate dependent effects and these were eventually taken on board in the 1960's by the use of Short Term Exposure Limits (STEL's) and Exclusion factors.

The second quotation uncannily prefigures the wording of the preface in the TLV Booklets which were not published until 1961. In the context of Stokinger's beliefs, which will be examined in more detail in what follows, it is an ambiguous statement in that he warns others not to treat TLV's a a "fine dividing line between safe and dangerous" conditions and yet as will be shown he approaches, and later defends them, as if they are just that. A semantic point that Smyth explored in 1956.

3.2.3.1 Stokinger's later writings defining TLVs

Table 3.1 consists of quotations from papers written between 1956 and 1985 illustrate Stokinger's unswerving belief in the accuracy and efficacy of TLV's. His belief that they represent safe levels of exposure for all workers (apart from the hypersusceptibles) if anything becomes stronger over the years. "I cannot recall a single, serious hazard to health having occurred provided exposures were kept within the TLV Guidelines", STOKINGER (1986).

His experience confirms his belief, he extends the claimed protection period from the working lifetime to, "after retirement" (see 1972 quotation) and in the late 1970's argued that the TLV's for carcinogens were, in effect "practical thresholds".

Table 1 - Stokinger on TLVs

1956	TLVs - "have been used for many years as a major means of maintaining man's working environment within healthful and even comfortable limits", p2, STOKINGER (1956b)
1958	TLV's ensure that there is "no hazard to health or well being of the worker during his working lifetime", p516, STOKINGER and WOODWARD (1958)
1964	"A concentration exists for all substances from which no injurious effect will result no matter how often the exposure is repeated", p591, STOKINGER (1964)
1965	"TLV's are based on documented freedom from injury to health, or from initiation and other forms of undesirable stress following repeated daily (chronic) exposures to chemicals" p177, (Quoted in ACGIH (1984a))
1968	"To the author's knowledge of more than a decade and one-half of close association with the TLV Committee, no significant injury to health has occurred where exposures have been kept within the limits recommended by the Committee. Seeming exceptions may have assumed in those who by reason of predisposition, genetic or otherwise, were unusually susceptible" p160 (Quoted in ACGIH (1984a))
1972	"The TLV's represent time-weighted average concentrations of airborne substances associated with industrial operations and manufacture, designed to protect the health and well-being of nearly all workers ... not only for their working lifetime, but after retirement", p607, STOKINGER (1972a)
1973	"Threshold Limit Values, are numbers representing safe limits of exposure for industrial workers for a 7 to 8 hour workday, 5 days a week, for a working lifetime and even thereafter; for we do not intend that a worker retires from employment only to come down with a job-related disease", p2, STOKINGER (1973a)
1976	"There is no evidence to date that cancer will develop from exposure during a working lifetime below the limit for any of the these substances".*
1986	"In my many years of participation in the affairs of the TLV Committee ... I cannot recall a single, serious hazard to health having occurred provided exposures were kept within the TLV Guidelines". And after reviewing his career in PHS (and NIOSH) he ends: "From this position of advantage, I feel I can reiterate without quantification that the TLV's have served without exception to protect the health of the industrial worker", p416, STOKINGER (1986)

* Note: From 1972 ACGIH published a list of TLV's for certain carcinogens, others were given no number and the recommendation was that "No exposure or contact by any route ... should be permitted), ACGIH (1972)

3.2.4 The theoretical basis of TLVs

In his 1955 paper "Standards for Safeguarding the Health of the Industrial Worker" Stokinger quoted Sterner's (the medical director of Kodak) "epitomical statement":

"No substance is so toxic that it cannot be used if sufficient knowledge of its action has been made available; similarly, no substance is so non-toxic that it should be used without regard to caution" , STOKINGER (1955)

Although this statement does not describe Stokinger's understanding of the basis of TLVs it does describe his basic philosophy for dealing with toxic chemicals in the workplace. He believed and still believes that it is possible to use all chemicals in the workplace safely provided certain precautions are taken.

In his early writings the basis for this belief is implicit and not stated. It was not until 1964, 3 years after the Walsh-Healey Public Contracts Act was put into force that Stokinger first described his theoretical views on standard setting.

"Threshold limits ... are based on the premise that, although all chemical substances are toxic at some concentration, ... a concentration exists for all substances from which no injurious effect will result no matter how often the exposure is repeated ... This philosophy differs from that applied to substances possessing ionizing radiation for which on current concepts there is no threshold ... STOKINGER, 1964

It was not until 8 years later that he went into more detail in a paper whose title began "Concepts of thresholds in standard setting ..." He felt the need to go into some detail on ideas that he took to be self-evident in his practice as a toxicologist because these premises had come under attack from "nontoxicologic quarters".

According to Stokinger the term "threshold limits" was coined by LT Fairhall, his predecessor at the PHS and an early Chairman of the TLV Committee. He had not liked the earlier term "maximum allowable concentrations" as he felt this to be "inexactly descriptive" (the term was actually coined considerably earlier). After describing where the name came from Stokinger continues:

"I shall present what I believe formed the basis of the Fairhall threshold limits concept as interpreted in terms of present day usage, the evidence for the general validity of the concept, **and how thresholds are incorporated into industrial air standards**", STOKINGER (1972a), Author's emphasis.

Stokinger goes on to say:

"Stated mathematically, the threshold concept is a nonlinear relationship between dose and response at the initiation of the response, the lower end of the curve in Figure 1, as opposed to a wholly linear non-threshold response relationship that passes through the origin". (See Figure Appendix 3.1).

"The threshold concept seemed at the time (1948) entirely reasonable and sound scientifically. But it must be remembered that in the early 1940's no great depth of understanding existed in toxicology and radiation biology was in its infancy; mechanisms of carcinogenesis consisted of crude hypotheses STOKINGER (1972a)

The validity of the threshold concept was being questioned in the late 1960's. Doubts coming from two principle quarters according to Stokinger; radiation biology and carcinogenesis. In an effort to "resolve the question of their (thresholds) existence or non existence, a symposium was held in 1970". It was called "Thresholds - Do they exist?" The issue was not resolved especially in the fields of radiation biology and carcinogenesis. "Moreover, the subject basic to the threshold concept, adaptation, was not discussed". And so, a year later, Stokinger discussed it:

Figure Appendix 3.1 (from Stokinger 1972a)

Figure Appendix 3.1 (from Stokinger 1972a)

"In the thinking of the TLV Committee, adaptation represents the most cogent and convincing basis for the existence of thresholds, ... through homeostatic mechanisms which commonly find their ultimate expression in tolerance ..." Thresholds for sensory irritation of the eyes, nose and throat are well established for many irritants; sensitization even in hypersensitive individuals requires a finite dose well above zero; and inhibition of carcinogenic action is a recognised phenomena", STOKINGER (1972a)

... The entire body physiology is based on stimulating and inhibiting systems. This can only spell out one thing, the existence of thresholds ... Accordingly, with those indisputable facts, the TLV Committee has perpetuated for more than 25 years the original concept of Dr Fairhall as a basic premise of the TLVs STOKINGER (1972a)

The question then arises of how thresholds of toxic effect are to be incorporated into TLVs. Stokinger lists various factors that need to be taken into account because "in most instances the thresholds cannot be used without modification". The factors include:

(i) Differences between genetically homogeneous animals and genetically heterogeneous humans.

(ii) Animal versus human differential sensitivity

(iii) Personal dietary and other habits (eg. smoking)

(iv) Interaction with pre-existing disease

Complex though these factors are, Stokinger has confidence in the TLV Committee "... procedures ... have been devised which make allowance for these threshold shifts before incorporation into standards". He continues a little later ... "experimental thresholds are rarely, if ever, used in the final TLV without adjustment ..., a safety factor is invariably added to the determined threshold to provide a cushion of protection for those more susceptible individuals", STOKINGER (1972a)

However not all people could be "cushioned":

"However desirable it might be to incorporate a safety factor sufficiently large to protect the most sensitive individuals, the safety factor cannot be infinitely large but must be within the bounds of analytic and engineering practicability. This limitation on the magnitude of the safety factor excludes protection by means of TLV's of those workers, who because of inborn errors in metabolism, are hypersusceptible to certain industrial chemicals" STOKINGER, (1972a)

He illustrates his assertion that "hypersusceptible" individuals exit by reference to phenylalanine concentrations and the hereditary defect phenylketononia (see Figure Appendix 3.3).

Figure Appendix 3.2 (taken from Stokinger, 1972)

Figure 2 — Concept of toxicity.

Figure Appendix 3.3 (taken from Stokinger, 1972a)

Figure 3 — Distribution of plasma phenylalanine level in 33 controls and 23 heterozygous individuals.

In summary then Stokinger believes that thresholds of toxic effect exist based on evidence that the body responds to a toxic challenge and that a certain degree of challenge, for some substances, would appear to have no health effect; the body can adapt. Having demonstrated to his own satisfaction that thresholds exist he goes on the claim that the TLV Committee identifies thresholds for individual chemicals and applies a safety factor to allow for differences between the test animals and human populations. The safety factors vary in size depending upon the potential outcome of exposure, "... the more serious the potential, the larger the factor." However there are certain individuals whose response to a toxic challenge is very different from the normal population because of genetic differences and these hypersusceptible individuals cannot be encompassed within the protection of TLVs.

3.2.5 Carcinogens

Although carcinogenesis is the main area from which ideas of no-threshold of dose-response have been derived in the West, which Stokinger points out, he argues, from around the mid 1970's that a case be made for "practical thresholds" for carcinogens.

In the early 1970's Stokinger and the TLV Committee decided to develop a classification of carcinogens "as the listing of substances as occupational carcinogens was getting out of hand" Stokinger (1977). The problem was that no difference was made between animal and human carcinogens; "Each came through to the union leader and the lay worker as equally worrisome". Stokinger disagreed fundamentally with this view: "The finding of a substance to be tumorigenic, often in a half-dead mouse or rat due to intolerable doses ... is not ipso facto evidence that it will be carcinogenic in man under controlled, working conditions".

Twenty years earlier when TLVs did not have such status legally and concern over carcinogens was not so great Stokinger took a more relaxed attitude:

"There is a tendency to belittle the carcinogenic potential of many substances on the basis that carcinogenesis in animals is no proof of carcinogenesis in Man. It would seem a more reasonable view to regard all such compounds at least potentially carcinogenic in man" (1956).

On the question of whether thresholds of effect actually existed for carcinogens, Stokinger always tended towards the threshold camp. In the mid to late 1960's Druckery among others proposed theoretical models based on animal experiments which indicated that there was no threshold dose for carcinogenic substances. Stokinger, it would seem, could not bring himself to believe this and, in a letter to a Dr Wayland Hayes (Junior) at Vanderbilt University, Texas, was pleased to report other experimental work which he interpreted as evidence of a threshold for carcinogens:

"Doesn't this (the work of LM Shabad) pretty well demonstrate dose response for experimental tumours by a leading international oncologist controvert the Druckery conclusions? ... How are these two opposed demonstrations going to fit? I interpret a dose-response as having a finite threshold" STOKINGER (1971)

By 1976 he was arguing for a grading of carcinogenic potency based on animal dosages and this approach was first published in the TLV Booklet in that year. Twenty two potential human carcinogens were listed, 14 of which were given TLV numbers. This was justified because the "TLV Committee recognises practical thresholds for carcinogens" ... and "there is no evidence to date that cancer will develop from exposure during a working lifetime below the limit for any of these substances ... ACGIH (1984a)

Stokinger recognises that this approach "... flies in the face of the bioretricians deeply-rooted "one-hit" theory ..."but argues for thresholds on three counts:

(i) Epidemiological evidence

(ii) The existence of "anti-carcinogens", principally biochemicals such as glutathione containing -SH groups which combine with free radicals.

(iii) Accumulated biochemical knowledge of how carcinogens operate.

He ends his paper with the observation that:

"... We have adduced sufficient evidence for the existence of both natural and dietary sources of anti carcinogen to establish a sound basis for carcinogenesis and sound support for settling practical limits for chemical carcinogenesis in the workplace, STOKINGER (1977)

In affect the Stokinger argument for "practical thresholds" for carcinogens is a variant on the older thresholds of toxic effect idea, the theory which the TLV Committee has worked to, according to Stokinger, since its inception.

3.2.6 Descriptions of how TLVs are set

In various papers HES described how he believed TLV's were set and in one unpublished, but widely circulated paper, he described how he felt they should be set. Again, as with his various definitions of TLV it is most instructive to consider his writings on the Committees methods in chronological order. In the 1955 paper Stokinger describes how TLVs are developed, values are based on:

"... animal inhalation toxicity studies and on the basis of industrial experience ... because reliable information from industrial experience is frequently difficult to obtain" ... the Committee is often forced to rely upon the opinions of industrial hygienists, rather than on factual information, or sometimes, merely on animal data. Such opinions, however, are based on specific experience with various substances and come from occupational hygienists throughout the country" (p2), STOKINGER, (1955).

He goes on to describe the change in attitude to health and how this has affected the TLV Committee:

"Originally, preventing impairment of health was virtually the only consideration in the selection of the proper limiting air concentration of an injurious substance. Now, however, ... more subtle effects on health, such as the effects of annoying or irritating agents, are also considered" (p2).

3.2.6.1 Industrial Experience

Later, Stokinger described the effects which the Committee considered in setting TLVs, in more detail. This early description is incomplete, as it stands, but it does contain the intriguing phrase "industrial experience". This, in the context in which Stokinger uses it, appears to mean the health effects reported amongst human populations exposed to a substance. But, given that the ACGIH TLV Committee was primarily composed of industrial hygienists and their principle professional remit was to measure and control exposure, "industrial experience" would also include a knowledge of the concentrations of a particular contaminant to which people were exposed and some knowledge of the feasibility of control and possibly the levels of exposure when controls were applied.

Taking Stokinger's implied meaning prompts the question, of what "experience" of the health effects of exposure would have consisted of in 1955. Nowadays human "experience" can be assessed by means of large scale epidemiological studies of morbidity and mortality. In 1955 the beginnings of this approach were only just developing, (principally in the Public Health Service) and "experience" would consist mainly of reported health effects in the current workforce plus case reports in the medical journals. PHS field surveys and the experience of governmental (and private company) hygienists would have detected acute effects on health, and some of the more blatant chronic conditions, in the current workforce who are themselves a self selected survivor population. More subtle chronic conditions or diseases with significant latent periods would almost certainly have been missed.

Later in the paper Stokinger, in common with others (such as Patty and Hatch) look forward to the day when "Pretoxicosis tests" are available which will detect "subtle metabolic changes in the body before injury of serious proportions has developed". he develops this idea in later years into the concept of hypersusceptibility which is covered in the next section. At this point however it is useful to consider how the idea of "industrial experience" changes in Stokinger's later writings.

In 1956 as part of a round table discussion on exposure limits Stokinger faced up to the various different recommended limits for trichlorethylene. he asked himself the question; why should there be variation if the standard setting committees are all trying to protect against the same health effects? The levels recommended at the time were:

ACGIH	200ppm
ICI (England)	400ppm
Russia	9ppm
Italy	100ppm
Sweden	30ppm

Stokinger considered various reasons including impurities, sampling errors, different measures of effect and geographical variations in metabolism of genetic origin. The consensus of the "foreign investigators" was that their medical evaluations of exposed workers were more thorough, especially their "neurologic examinations". Stokinger did not agree and plumped for sampling errors and national metabolic differences. He ends:

"In defense of the US position of 200ppm threshold limit for trichoroethylene may be cited ... the lack of objective evidence in the US of injury among trichloroethylene workers chronically exposed over a period of many years", STOKINGER (1956a)

As with the phrase "industrial experience" the phase "objective evidence" is ambiguous. Various European investigators particularly the Swedes took the neurological effects of trichloroethaylene as "objective evidence" of possible harm; Stokinger did not. Also if the earlier description of the state of epidemiological surveillance in the mid-1950's in Chapter 2 is at all accurate then the potential chronic neurological effects of trichloroethylene would never have been revealed "objectively". The methods by which they would be "seen" and quantified did not exist. This is not to belittle the state of the art at the time Stokinger was writing, it is simply to point out that in retrospect his defence of the 200ppm TLV was flawed. This is a defence he continues to use in the years ahead.

In 1964 he returns to the theme of "experience" in a paper describing how the TLV Committee works.

"Because members (of the TLV Committee) have been selected from those occupational health units whose activities involve the investigation of from hundreds to thousands of plants per year, the Committee feels that there are few hazardous industrial situations of which it is not aware or on which it does not have recent first-hand experience and information", STOKINGER (1964).

Again, what the words "experience" and "investigation" mean is very important and hinges on what professional hygienists actually did in their day to day investigations and therefore what their "experience" might have been. Suffice it to say that regular investigative hygiene surveys would not usually reveal a chronic health effect due to exposure to an industrial air contaminant.

Finally, four years later in 1968 he appeals to "industrial experience" as the final test of the soundness of the TLV values:

"Some TLVs ... have been based on a decade or two of industrial experience. Clearly, such procedures can yield indisputable data on which realistic TLV's can be derived, unsurrounded by that uncertainty and doubt which requires incorporation of large safety factors, leading to wasteful over-engineering of plant processes" ACGIH (1984a).

He never defines exactly what he means by "industrial experience" although preceding the above quotation he mentions "plant industrial physicians and engineers ... making observations on the workers and their workplace environment". The limitations of this approach have already been mentioned. Also note, the quotation does imply that the TLV figures, for those substances used over two decades without any apparent problems, are exact figures, ie. almost dividing lines between safe and dangerous concentrations.

3.2.6.2 The Practicability of Control

Most of Stokinger's writing does not mention the practicability of the TLV's set and the first quotation below sums up his absolute conviction that the health of the workforce is always uppermost in the mind of the standard setting committee:

"The Committee is keenly aware of gravity of its acts ... and its final decisions must be ... unfettered by considerations other than the health and wellbeing of the industrial worker", STOKINGER (1964).

However there is some evidence that he did recognise the potential costs of an excessively and unnecessarily low limit as the next two quotations indicate:

"It should be noted also that these limits provide safety **without overprotecting the worker** or over-engineering plant processes, practices which private enterprise can afford only at the expense of the consumer public which pays the increased cost of their product" STOKINGER (1968a). (Author's emphasis).

"However desirable it might be to incorporate a safety factor sufficiently large to protect the most sensitive worker, the safety factor cannot be infinitely large but must be within the bounds of analytic **and engineering practicability**" STOKINGER (1972a) Author's emphasis.

The problems of "over-protecting the worker", "over-engineering" the plant and the "engineering practicability of any proposed limit were recognised by Stokinger though he rarely mentioned them.

The tension between the need to set a limit that protects health but at the same time is practicable is present in any committee that sets occupational exposure limits and the TLV Committee was and is no exception. Perhaps the absolute way Stokinger describes the TLV Committee's decisions as "unfettered by considerations other than the health ... of the industrial worker" could be viewed as a sign of the tension that he and his Committee experienced?

3.2.6.3 Stokinger's Ideal Method

In the early 1960's the workings of the TLV Committee came under greater scrutiny because of the incorporation of TLVs in regulations made under the Walsh-Healey Act (Federal Register, (1960)) which covered Federal supply contracts. This prompted Stokinger to lay down guidance for the Committee and for others who wanted to prepare information to be used in standard setting or simply to understand how the Committee arrived at its decisions. The guidance was never published in a journal but was available on application from about 1965 onwards. It focuses mainly on experimental animal toxicology and reflects Stokinger's main areas of expertise and interest. A summary of his protocol and reasoning is outlined, based on ACGIH (1984a).

As he believes that TLV's "are based on documented freedom from injury to health, or from irritation and other forms of undesirable stress following repeated daily exposures to chemicals", it follows that only chronic animal testing is satisfactory. Short-term tests are given short shrift because:

(i) Chronic and acute responses do not resemble each other for a large number of substances.

(ii) Some substances only really exert a chronic effect.

(iii) Some compounds only exert their affect by accumulation in the body or by their effects summating.

He recommends the use of a number of species of animal to try and make allowance for species differences and also recommends multi-level exposure tests. Two levels are a minimum and three are preferable. The first should be at a level at which frank effects develop, the second at which minimal effects are manifest and the third in the "no effect" region. This last exposure level has to be estimated from the slope of the response curve between frank and minimal effects, (which, on the face of it, makes for a very lengthy experimental procedure). He regards the "no effect" level as a relative term because if more sensitive tests are applied "effects" may be found at exposures which were previously thought to cause "no effects". Though he doesn't include the statistical argument that the sensitivity of a test is related to the size of test population.

A section of the protocol then lists the acute tests which Stokinger recommends including LC_{50}, LD_{50}, dermal and ocular toxicity and other supplemental studies into the basis of a compound toxic action. He recommends further metabolic and biochemical research to pinpoint the exact biochemical "lesion". Finally he recommends chronic studies for carcinogenesis using susceptible strains to make the test as sensitive as possible.

The pros and cons of animal research are listed and the use of safety factors is described.

He is against simply using the "no effect" level because this "fails to consider the hypersusceptibly responsive individual" ... "The magnitude of the safety factor ... is determined largely by the seriousness of the toxic potential". Where death is the "end point" the factor may be 10, more commonly it is 2-5.

The test procedures are outlined. He does point out that such tests are not useful where irritant substances are concerned and recommends tests on human volunteers.

It is not clear from the protocol or Stokinger's other writings how much his description is of what he would like to be the case and how much is actually put into practice. Nowhere does he mention the role of "industrial experience".

3.2.6.4 Actual Methods used to set TLVs - According to Stokinger

Three years after the protocol was made available Stokinger reviewed the actual effects that had been used as the basis of the 414 TLV's that had been set by that time (STOKINGER, 1968a). Excluding the "inert particulates and vapours" the breakdown of procedures used was as follows:

Industrial (human) experience	38%
Analogy	24%
Animal inhalation - chronic	20%
Human volunteer experiments	11%
Animal, oral - chronic	4.5%
Animal, inhalation - acute	2.0%
Animal, oral - acute	0.5%

Almost 50% were set on the basis of human data, about one quarter by analogy with similar compounds and 1 in 5 on the basis of chronic inhalation animal tests.

Two conclusions stand out from these data; firstly, Stokinger's idealized animal test protocol is only applied in the minority of cases, and secondly, the evidence of effects on humans either exposed involuntarily in industry (38%) or voluntarily (in irritation tests - 11%) weighs heavily in the minds of the TLV Committee. What human or "industrial experience" as Stokinger calls it, represents in practice, is a crucial question. However sensitive a test of chronic toxicity such as "experience" may be whatever else it is the knowledge is necessarily produced in retrospect, the chronic health effects have to have occurred in an exposed population before they can be revealed to the TLV Committee. Stokinger could see the problem and was in favour of animal tests and the development of

"pretoxicosis" tests but the reality, in 1968, was that around 40% of TLV's were set after exposure had occurred and health effects had been caused.

3.2.6.5 Industrial Involvement

The Walsh Healey Public Contracts Act (1960) incorporated 250 TLV's. This Act drew TLV's and activities of ACGIH to the attention of industry and the Federal government. Up until this time TLV's had been used as guidance levels by state and company hygienists, although some individual states had incorporated them in their regulations. From the early 1960's the ACGIH, principally in the shape of Stokinger (the Chairman of the TLV Committee), felt the need to explain itself and its activities. The Documentation of TLV's and the booklet of Limits were first published in 1962 and in 1964 and 1965 Stokinger published papers explaining how he felt the TLV Committee worked. In 1962 the size of the Committee was expanded from 8 to 14 members.

The 1964 paper describes the "Modus Operandi" of the TLV Committee and lists 3 criticisms which had been regularly directed at the Committee's activities:

(i) Limits based on reasons other than health
(ii) Lack of knowledge of industrial conditions
(iii) Arbitrary and capricious decisions on occasions.

Stokinger defends the Committee on each count.

By "reasons other than health" he means irritation. Apparently it had been argued that irritation is not a threat to health, it is a nuisance. He musters evidence to suggest otherwise.

As to the Committee's knowledge of industrial conditions he argues forcibly that the members collectively have wide knowledge and first hand experience based upon the many plant surveys done each year. This is not industrial involvement but it does indicate that the Committee knew of the practical problems of control in industry and probably the magnitude of the exposures that were occurring.

A year later Stokinger described how the views of industry were elicited by the Committee and how industry approach ACGIH.

As the name implies the membership of the ACGIH was open to state and federal personnel and members of the armed forces. Hygienists in private industry could join the AIHA but not the ACGIH. In later years ACGIH opened up its membership to academics. Because of this restriction on membership ACGIH has always argued that it is independent of sectional interest from whatever quarter and up until the mid-1960's industry had apparently shown little interest in the TLV Committee: "For the first time in 13 years (Stokinger joined the Committee in 1952) industrial representatives have either appeared in person or written for information to the TLV Committee" (p609, STOKINGER, 1965b). Though having said this he does record that some 25% of the TLV's were due to "industry or industry sponsored efforts", some of which, it is implied, "provided the total basis of the limit", whereas other contributions represent "only a very limited industrial effort". He continues:

"... It is counted as a contribution if (1), it was basic to the determination of the value when used in conjunction with other information, or (2) it was the sole basis for the limit even though it represented a meager effort", STOKINGER (1965b)

This would suggest that there was considerable industrial involvement in the setting of some TLV's. Apparently the input came from a very restricted number of companies, all chemical "giants" (Stokinger's word) of which 2 made the major contributions.

In the paper Stokinger lists the sort of information that he would like from industry. This included exposure measurements together with adequate medical information, "through application of

appropriate clinical an physiological studies". These two sets of information are probably what he means by "industrial experience". He goes on to make the age-old observation that:

"The greatest deficiency of such investigations is the lack of precise appraisal of the exposure of the workmen and the difficulty in finding tests indicative of early signs of response to exposure", STOKINGER (1965b)*

Four years later, in 1969, Stokinger gives his most detailed description of how industry is involved in standard setting. He describes three ways the Committee validates TLV's it has set:

1 The Chairman and members of the Committee "hold a meeting with industry's physicians and industrial hygienists and review their experience. This procedure is used where the data has not been assembled or published", STOKINGER (1969b).

2 "Where the data or reports have been published, these are reviewed by the Chairman and the committee and the action taken is mutually agreed upon by industry".

3 "Active co-operative projects with industry ... are entered into whereby industry supplies the health records or clinical data for review ...".

The approach adopted is worth quoting at length:

"To give a clearer idea of how these validation procedures work, a most productive day's meeting was held with industrial physicians and hygienists of the chromate industry. The reason for selecting the chromate industry was that no evidence of the suitability of the TLV for chronic acid or chromates had ever been brought forth for the prevention of either nasal perforation or bronchogenic carcinoma. All environmental levels had exceeded the recommended limit of 1.0mg/cu m when large excesses (29-fold) of lung cancer and nasal perforation were found in 1950, and the health experience had not been reviewed in these terms since the industry had improved its control measures to the recommended limit. In brief, the day's discussion revealed that the limit for chronic acid mist was satisfactory in preventing nasal perforation, and in addition contained a safety factor of three or four; that the limit was probably satisfactory for the prevention of lung cancer, as no new cases have appeared since the reduction in exposure occurred, but that the ten years in which the closer controls were operative are probably too short a time to be certain its validity in this respect", STOKINGER (1969b).

It is evident from the papers of Stokinger, particularly the last one quoted in some length, that although no industry based members are allowed to serve on the TLV Committee nevertheless the Committee gets a lot of information from industrial sources and takes into account the views of industrial physicians and hygienists. This is a perfectly legitimate procedure and if the Committee has no first had knowledge of the use of a certain substance there was only one source it could turn to for information.* Also, since ~1963 Tentative TLV's have been published, which almost certainly led to representations being made by industry. Indeed that was the purpose of listing Tentative TLV's.

Although the TLV Committee would be principally interested in exposure and toxicological/medical data from industry it is almost certain that industry representatives would impress on the Committee the cost of control down to certain levels and their view on what was a practicable exposure limit, which in Stokinger's words did not "overprotect" the worker and lead to "over-engineering" of the plant.

Stokinger's account of standard setting becomes contradictory at this point. On the one hand he argues that only health effects are the concern of the Committee yet on the other hand it is very probable that he and the Committee knew of, and took into account, the current exposure levels and

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* Nowadays this is not so as NIOSH has right of entry to all industrial premises. A right upheld every time it has been challenged in the courts, MILLAR (1987).

the cost of control. The extensive analysis of the TLV Chemical Substances Committee Minutes in Chapter ? examines these factors in more depth.

Although the day-to-day workings of the ACGIH Committee are not subject of this chapter the description that Stokinger offers of the standard setting process in his writings covered in this section, on careful analysis, shows up a contradiction between the ideal or OEL paradigm and the practice of the Committee. The "modus operandi" of the Committee has always been more complex than Stokinger's paper of the same title would imply.

3.2.7 Hypersusceptibility

Stokinger in his first paper on TLVs described them as levels which would protect "normally healthy" workers. Seven years later he floats for the first time in his writings the idea of genetically determined sensitivity to toxic chemicals. He argues that abnormal levels of glucose-6-phosphate dehydrogenase (G-6-PD) in red blood cells will make an individual more sensitive to chemicals that interfere with blood forming metabolism (eg. benzene). It so happens that the incidence of G-6-PD deficiencies appears to be higher in Negroes compared with Caucasians particularly Negro men.

Three years later he justifies the use of safety factors to allow for "hypersusceptibility responsive individual", STOKINGER (1965a). However in three years following this pronouncement he changes his view and comes to believe that "hypersusceptible workers" can only be protected by "preplacement job examination to screen out those individuals who by virtue of some genetic fault in metabolism hyper-react to certain industry chemicals" (p161, ACGIH) these individuals are "not presently covered by the TLV's, STOKINGER (1968b). Also at this time he produces his first lengthy list of theoretical possibilities; errors in metabolism which might make the individual more sensitive to a toxic chemical.

The genetic argument comes to dominate his view in a paper written a year later though the argument is not about hypersusceptibility but is applied more generally to environmental carcinogenesis. Hereditary resistance and susceptibility is seen as "Another controlling factor, if not the main determinant", STOKINGER (1969a), and this view is confined with the belief in homeostasis:

"The homeostatic mechanisms leading to adaptation provide the balance to counteract the effects of pollutants ... It is only when this balance is upset through predisposing disease or genetic fault (susceptibility) that environmental pollutants exert their effects on man", STOKINGER, (1969a).

He is referring to environmental pollution, not the workplace but the quote indicates an apparently significant consolidation in his views on sensitivity; people react to airborne contaminants because they have a pre-existing disease or they are in some way genetically weakened.

Ten years after the first paper which mentions hypersusceptibility he published a major review in the Journal of Occupational Medicine. He termed it a "consensus report" and claimed it represented "national and international opinion". In it he updates the list of potential tests. He reviewed around 150 enquiries after his first paper but acknowledges that almost no one had instituted mass screening tests. He ascribes this to spinelessness in the face of the labour unions but acknowledges that a number of correspondents gave as their reason for not using the tests "... insufficient epidemiological evidence to support the use of any of the tests as a criterion of employability"*, p572, STOKINGER (1973c).* Stokinger's general view of why people are affected at exposures levels around the TLV appears to have become more and more a matter of genetics and the individual, or at least the metabolism of groups of genetically similar individuals.

In 1976 while reviewing the benzene TLV he argues that the then current level of 10ppm while protecting man may not protect women or black men because:

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* In the same year a resumé of his views was published in a major report from the National Academy of Sciences, NAS (1973).

"Each may prove more susceptible to benzene exposure than those that have been studied (principally white men), and hence the present TLV may not contain sufficient safety factor for these two groups", STOKINGER (1976b).

The idea of the hypersusceptibility of small groups of people seems to have swollen in his mind to cover, in the case of benzene, all women and all negro men. The statement appears to be based on a general belief of Stokinger's in that he has never suggested, in any of the lists of genetic factors which could make people susceptible, a connection between an enzyme deficiency, leukaemia and benzene.

In 1982 Stokinger reviewed the development of his ideas concerning the sensitive worker and occupational health standards, STOKINGER (1982). As he described it:

"... linking inborn errors of metabolism to hypersusceptibility to diseases from common exposures in industry (was) seized upon by the TLV Committee as offering a solution to the vexing problem of how to protect the sensitive worker without altering the industrial air standards (TLVs)", STOKINGER (1982).

It was quite clear to him that:

"... most if not all, of the hypersusceptible responses in workers were genetic in origin", (ibid);

and in the rest of the paper he describes:

"How the TLV Committee found a way around this annoying deficiency in the TLV's without lowering the limits to absurd values ... ", ibid

He goes on to describe three tests developed in his laboratories at NIOSH including one to detect the sickle cell trait.

This sub-section, although it is concerned with the development of Stokinger's views on hypersusceptibility reflects an interesting light onto the previous analysis of his views on TLV's in general particularly his theoretical views. His general belief that people who suffer ill health at or below the TLV are all hypersusceptible is the mechanism by which he reconciled his adherence to the OEL paradigm with the need to set practicable limits.

3.2.8 Preliminary discussion of Stokinger's work

The foregoing description and analysis show that Stokinger modifies his views over time and in many ways became more dogmatic. For instance, he would now appear to be sure that TLV's are safe levels of exposure for the normal worker and only hypersusceptible people respond at or below the TLV* . While he is strongly convinced that "practical thresholds" can be set for carcinogens and that the TLV's for human carcinogens represent such levels. He was not so sure that there was a big difference between animal and human carcinogens in his earlier writings. This view took sometime to solidify and was not publicly expressed until 1977, by which time Stokinger's mind was made up.

The analysis shows that Stokinger was a strong adherent to the OEL paradigm in his theoretical and philosophical descriptions. But, the analysis also shows up the tension between the idealized description of the standard setting process and the practical realities which Stokinger and his committee faced. His day to day practice as a senior toxicologist reinforced his personal commitment to the ideas and practices which are summarised in the working definition of the paradigm. In this

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* His early attitude to TLV's was less dogmatic and he hedged his description with the warning not to treat the limits "as fine lines between safe and dangerous concentrations, that is, a point above which injury is bound to occur and below which complete safety may be expected for all persons" (STOKINGER, 1955). He was not so sure of TLV's in his early writings.

sense Stokinger is a purist. He is also an enthusiast for the paradigm and sometimes his confidence in the concepts have taken him into contradictory waters. Thus, in his first paper in 1955, he urged people not to use TLV's as an index of toxicity, as safe levels of exposure, and he warned that they should not be used to set ambient air or drinking water standards, they were meant for use in the workplace. Three years later he broke his own rule and derived water quality standards from TLV's by means of a simple algorithm based on water intake rates, likely degrees of absorption etc. In his summary he describes the standards for airborne substances as "safe limits of toxic substances in the air of industrial environments - the so-called threshold limits" (STOKINGER, 1958).*

In first warning against the universal application of TLV's and then using them to set water quality standards Stokinger can be seen as implying two different definitions of the process by which TLV's were set. This contradiction shows up so starkly in Stokinger's writings because on the one hand he was so completely committed to the OEL paradigm and on the other hand he was a practical toxicologist committed to a setting practical standards which did not "overprotect" the worker. Although Stokinger's toxicological understanding and techniques was far more sophisticated than early workers such as Drinker or the early work of Hatch or Smyth when it came to the practicalities of setting an OEL their techniques look remarkably similar.

Stokinger was the longest serving individual on the TLV Committee and the longest serving Chairman, 28 and 15 years respectively. He served as chair from 1962 to 1976 the period in which the TLV's were incorporated first in the Walsh-Healey Act and then later, in 1970, in the OSHA Act, (this was also the most productive period for the TLV Committee in terms of numbers of standards set). He also presided over an increase in the size of the Committee and various innovations including; the list of tentative standards, short term exposure limits (STEL's) and the appendices of carcinogens. As head of toxicology for the US PHS and chair of the ACGIH TLV Committee he was in a key position to impose his views and his will on the standard setting process and the theories and explanations used to describe that process and the products of the Committee.

Stokinger has always been a forceful and energetic exponent of his ideas. He has an unequivocal way of stating his case which comes across in his papers. Thus, the Committee is not simply uninfluenced by questions of practicality, it is "unfettered" (1964): On the question of carcinogenesis and the existence of thresholds there is no doubt, the evidence he musters is "indisputable" (1977). TLV's are not simply feasible guidance levels or reasonably practicable levels at which exposure levels there is some residual risk, they are levels, "at which no significant injury to health has occurred" (1986). His unequivocal, unswerving belief in the reality of a theory is perhaps most obvious when it comes to "hypersusceptibles". The existence of such people grew in his mind from being simply a theoretical possibility which should be explored to sure-fire certainty which should be made the basis of a pre-employment medical screening process.

Sometimes his advocacy becomes just that, thus when describing how chemicals were introduced onto the market by industry in an ILO/WHO meeting in 1968 he paints a rosy picture of pre-prediction testing with results made available to the ACGIH. This, as the work of Smyth and the need for the TOSCA regulations indicates, was a wildly optimistic view of what was actually happening in the USA.

By virtue of his position in the PHS and the ACGIH Stokinger has had a large influence on OEL standard setting in the USA and, as a consequence of the world wide use of ACGIH TLV's, his influence has been extended way beyond the borders of the USA to many other Western countries including the UK. His energetic espousal and forceful interpretation of the OEL paradigm still have

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* I do not mention this contradiction meaning to overly criticise Stokinger. I mention it because for me it is indicative of the way TLV's became transformed into "safe levels" in his mind and the minds of many others. He, as the architect of many of the standards knew the poor quality of the data and the probable errors of estimated "safety factors" which were wrestled with by the TLV Committee yet he could not avoid the temptation to use TLV's as almost absolute indexes of toxicity. If he, a leading member of the Committee, fell foul of such a temptation what chance was there for lesser mortals.

lasting influence. All his views are not shared by other influential individuals but there is no denying that he has many modern adherents. Thus the idea of hypersusceptibility drawing heavily upon Stokinger's work is promulgated regularly in the scientific literature, see for instance; LEWIS (1986), de SILVA (1985) and CALABRESE (1984 & 1986). In 1982, the ACGIH denoted a whole volume of the Annals to a conference on the sensitive individual which leaned heavily on Stokinger's earlier work (ACGIH, 1982). * His influence unquestionably (or should I say indisputably) lives on.

3.3 Theodore F Hatch

"His contemplation of the dividing line between functional change at the homeostatic level and adaptive pre-morbid alteration was elaborated at a conceptual level in the early 1960's. At that time, because of the **Paulovian challenge** to our concept of the dividing line between health and disease, he focussed attention on this barely perceived issues in standard setting." DINMAN (1984). (Author's emphasis).

Hatch has already been mentioned in relation to the development of the new profession of non-medical industrial hygiene. He trained as an engineer and planned to become a civil engineer but became inspired to pursue a career in sanitary engineering by his graduate profession, EL Sprague. In 1926 he joined the staff at the Harvard School of Public Health where he taught on the masters course and conducted research with Phillip Drinker and others. One of his early doctoral students has JM Dallavalle whose work on exhaust ventilation hoods laid the empirical foundations of the subject. This work, to a large extent, is still relied upon by hygienists and engineers nowadays, (see for instance ACGIH (1984c), FIRST (1983)).

In 1936 Hatch left Harvard and joined the Division of Industrial Hygiene in the New York Department of Labour. Four years later he moved to the University of Pennsylvania but after only 2 years here, just after the outbreak of World War II, he was sent to an Armored Medical Research Laboratory at Fort Knox to work on ergonomic problems for the armed forces particularly problems of thermal stress in tanks. After the war he became the Professor of Industrial Health Engineering at the new Pittsburgh, Graduate School of Public Health. The School gained an international reputation and Hatch officially retired in 1966. However, he still remained active well into his 70's and in fact, as far as this thesis is concerned, wrote some of his most thought provoking papers on occupational exposure limits during this period.

WALTON (1987) recently reviewed Hatch's life and contribution to occupational hygiene. An analysis of the 116 papers Hatch published (plus four important papers omitted from Walton's bibliography), gives some feel for his major interests and how they evolved with time. Table Appendix 3.2 gives a breakdown by subject matter over 10 year periods.

Up to the early 1940's Hatch's major interests were dust measurement and analysis and exhaust ventilation design. However he and Drinker did have some comments to make about how hygienists and engineers should approach maximum permissible dust standards in their book "Industrial Dusts" DRINKER and HATCH (1936).

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* I do not mean to imply that Stokinger is the sole cause of this trend. There is obviously a deeply held belief amongst a certain sub-section of the toxicology/hygiene community that genetically determined hypersensitivity exists and explains why certain individuals react to toxic substances. The question of whether hypersusceptibility exists, as a general or restricted phenomena, or if it does how it can be used in practice, is discussed in more detail at the end of this section when the work of Cook, Smyth, Stokinger and Hatch is considered in toto.

Table Appendix 3.2

Publications by TF Hatch (1901-1985) (based mainly on Walton (1987))

	1920-1930[1]	1931-1940	1941-1950	1951-1960	1961-1970	1971-1980[2]
Dust measurement and analysis	3	9	3	2		
Exhaust ventilation	1	20	6	2	1	
Particle deposition in the lungs			3	4	6	
Effect of heat on human beings			4	4	4	
Ergonomics			3	5	2	
Industrial hygiene			2	6	1	
Occupational exposure limits				1[3]	5	4
Other	2		2	6	7	4
Totals	***6***	***29***	***21***	***30***	***26***	***8***

Grand total = 120

(1) Hatch's first paper was published in 1927
(2) Hatch's last paper was published in 1974
(3) Published in 1955

From the early 1940's Hatch's interests began to expand and included particle deposition in the lungs, ergonomics and heat stress, stimulated by his war work at Fort Knox, and the general promotion of industrial hygiene. Not until 1955 (29 years after he got his first appointment at Harvard) did he explicitly address the question of occupational exposure limits. He published key papers on the subject in 1964, 1965, 1970 and 1972. Out of the 116 papers listed by WALTON (1987) plus the four additions only 10 were on standard setting for chemical substances. The last; "The role of permissible limits for hazard or airborne substances in the working environment in the prevention of occupational diseases", had the most impact and it, or its derivatives, is probably one of the most widely cited references on the subject, (see for instance, SCHILLING (1981)).

Thus, although Hatch did not write prolifically on standard setting, unlike Herbert Stokinger, an examination of the few papers he did produce is important to get a complete picture of the subtle differences and similarities in the range of interpretations of the standard setters paradigm by key figures in the scientific community. Although Hatch did not concentrate on standard setting* in his career and wrote nothing like the volume of papers that Stokinger and Smyth did, he was certainly a key figure in the interpretation and defence of the OEL paradigm. His work with Drinker has already been examined (3.5.2.2B). It remains to examine the three papers he wrote in the 1960's and 70's. The potential influence of his career path and interests on his view of the paradigm will be left until later.

3.3.1 Hatch's views on standard setting

The first paper considered was published in 1962 and was the first time Hatch specifically addressed the basis of standard setting.

*Although apparently he was involved for a short time in the ASA's Z37 standard setting committee for chemical substances.

3.3.1.1 Hatch in 1962

His paper was the first in a series based on a joint meeting of the ACGIH and AIHA in April 1961. It is, in effect the keynote paper of the conference and in it Hatch surveys the field of occupational health and identifies future objectives for the professions.

Early on in the paper he makes the point that the:

"Early objective was to prevent frank diseases ... which could terminate in serious disability or death", HATCH (1962)

He continues

The very success in meeting this objective has inevitably changed the nature of the remaining problem", Ibid

And identifies the fact that times have changed and that;

"... the modern objective is to secure and maintain the health and wellbeing ... of the people in industry. **This involves far more than the prevention of frank disease and obvious disability**" (Author's emphasis), Ibid

These new objectives present a challenge which;

"... depends upon the specificity with which the new problems can be defined", Ibid

Figure App 3.4 Chart developed by Hatch Figure 1 in Hatch (1962)

Figure App 3.5 (taken from HATCH (1962))

After describing a model of the man environment relationship (see Figure Appendix 3.4) he concludes:

"The ultimate proof of adequate understanding of etiology is in the demonstrated success of control measures developed and applied", Ibid

As control measures bite so measurement methods both of the environment and of the health effects become more important. Hatch refers to these as "details" and draws upon the example of silica and silicosis. His view is worth quoting in full:

"As the goal is approached, however, these "details" may take over and dominate the relationship. In silicosis, for example, the influence of particle size on hazard or variation in composition of the dust with size may be of little importance in the face of overwhelming dust concentrations but in plants having reasonably good control, such differences from one exposure to another may make the difference between a real hazard and no problem. Methods of dust analysis and criteria of diagnosis which served usefully in the days of gross hazard fail increasingly to meet needs as control advances and, in the end, may become risky in the sense of providing a sense of false security", Ibid

He clearly understands how the problems that he as an industrial hygienist has faced have changed in his lifetime. He speaks from personal experience. When he first started at Harvard he saw cases of virulent silicosis and acute, frank lead poisoning (could quote Hatch tape and Alice Hamilton book here). By the late 1940's Hatch claims from his own experience that acute lead poisoning was then fairly rare. In his own lifetime he had seen the problem change from controlling acute health effects clearly visible in individuals and seen in a large percentage of individuals exposed, to one of chronic health effects visible in populations with some more clearly demonstrable health effects visible in a minority of the population exposed.

His final observation in the last quote is particularly interesting. It prompts the question: Does increasing sophistication in the methods of detecting health effects amongst the exposed population

reveal previously undetected health effects which then leads eventually, to more stringent exposure limits which in turn results in improved control or is it the other way round? The ability to control dictates the standard and therefore the degree and prevalence of the health effects. Certainly Hatch's view in the early 1960's seems to have been that the latter sequence of events was closer to reality, that is the implication.

It implies further that the hygiene standard has and will change as the ability to reliably control to lower levels of exposure becomes possible. This sequence of events is possible and also defensible in the minds of the hygienists or doctors at the time, because methods of detecting health effects and views of what constitute health effects, have also changed and become more sensitive and refined over time.

Relatively crude measures systematically applied were found to control frank disease to a level where relatively crude methods of detecting health effects indicated that the problem was fairly well or completely controlled. As more effective controls were applied and more sensitive tests of effect were applied to populations whose exposure had been reduced health effects were still found, even though at previous high levels of exposure minimal or acceptable health effect had been reported. Is this what has happened? It's certainly one way of describing the cycle through which a number of substances, and the perception which we have of their health effects, seem to have gone.

Hatch does appear to be saying that better and better control has been achieved without pressure from health effects recorded at current exposure levels. And he fears that "criteria of diagnosis ... fail increasingly to meet needs as control advances ...," ie. exposure levels have been brought down yet it is suspected that health is still being adversely affected but the old, crude measures of effect are not detecting anything.

Later in the paper he takes the reverse view, ie. the tests for health effects dictate the degree of control applied and he goes on to argue that this process should not be continued and infinitum because not all effects of exposure to a stress are adverse. His argument is that homeostatic and compensatory mechanisms in the body can cope with a certain degree of stress. He summarises his model in Figure Appendix 3.5. This figure and description prefigures his later more subtle and influential model.

When discussing the beneficial effects of work on health he actually suggests that "certain kinds and degrees of stress are said to be desirable for health maintenance". But clearly has some doubt himself in that he immediately asks the question: "Is this just a wishful generality ...?" In his later two papers his views become more hard and fast.

He also recognises that the diseases which hygienists and doctors will have to deal with in the future are, and will, change from specific occupational diseases to increased incidences of non-specific diseases found in the general population. In the former work is the first and primary cause in the latter it is an aggravating or addictive cause; nowadays WHO refer to this as Work Related Ill Health (WHO, 1984).

He shares Stokinger's view of hypersusceptibility to an extent though it is not so doctrinaire and does not dominate his writings.

"On the human side of the man-environment relationship, too, the need for refinement in understanding of etiology increases as the magnitude of hazard goes down. Differences in individual susceptibility are always recognized as factors which may influence dose-response relationships but the influence is largely submerged when the hazard is high. Again, as progress is made in control, a point may be reached finally where the risk of ill-health depends more on the status of the host than it does on the conditions of exposure", Ibid

On the question of how IH's and doctors should tackle the new "non-specific diseases" he makes two points, which have a remarkably modern ring to them:

"First, as we select increasingly sensitive measures of response on the impairment scale to demonstrate disturbance in consequence of environmental stress, we must keep constantly in mind that these become increasingly non-specific and, hence, provide less dependable evidence of a real man-environment problem than is the case when clear-cut disturbances, peculiar to specific occupational diseases, are employed ...

Obviously, such non-specific disturbances have occupational meaning only after it is demonstrated that in the exposed population there is a higher incidence of the disturbance than in the general population. Thus, the existence of a problem is demonstrated statistically and epidemiologically and not by virtue of unique findings, either in man or in the environment.

Second, the particular terminal disease state may not, itself, bear a direct relation to the environmental stress and, hence apparent aetiological relationships between the final disease and conditions of exposure can be misleading ... Thus, right-heart failure in the coal miner is not caused directly by his dust exposure but, rather, is the ultimate response from continued cardiac compensation for the lung impairment caused by the dust. ... Continued exposure to air pollution may have contributed to the progressive impairment, along with other stresses and previous illnesses, **but such chronic effect does not necessarily follow from the evidence of serious disturbance during the acute episodes.** The point of distinction is an important one and needs critical study", Ibid.

These long quotations are included because they show that Hatch was not locked into his own past and that he appreciated that the problems to be solved had moved on but were still real and should be considered. He understood that the methods used to detect health effects in workers subjected to modern exposure levels would not often find specific signs of unique effects, rather the signs would be non-specific. Also he makes the very pertinent observation that the focus has to move from detectable effects demonstrable in the individual to effects, often non-specific, which are only detectable in populations as statistical trends. He also makes the point that the chronic effects of exposure to a material, because the material acts as one of a number of factors or as a "secondary insult" as he calls them, may bear little or no relationship to the acute effects of that material. This is a subtle different version of the point made by Stokinger and Smyth, that the acute and chronic effects of a material are often very different.

3.3.1.1 Summary of 1962 paper

The paper is written in a relaxed and confident style, it is wide ranging and speculative. Hatch knows that gross occupational disease can be controlled, he has seen it done and contributed materially to the process via his original work on exhaust ventilation and dust measurement. He also realises that the problems to be tackled have become more subtle and "work" may be one of the factors in the etiology of a disease and that the effect of exposures may only be detectable in populations by statistical techniques.

He also makes the point that measurement and diagnosis have failed behind in their ability to detect effects at current exposure levels.

The problem was to know where to stop. His solution is a model based on homeostasis and compensation but, interestingly, there is no discussion of how this can be used to identify an exposure range, or level, which could be regarded as tolerable. Hatch, in this paper, is not concerned with exposure limits and does not mention them once. He does appear though to believe that the more subtle, harmful effects of exposure are being missed and should be taken seriously.

3.3.2 Hatch in 1970

Eight years later the environment in which Hatch and others operated appears to have changed. His next paper, published in 1970, is far less relaxed and more defensive. It was read before a joint symposium of the American Academies of industrial hygiene and occupational medicine and has a similar title to papers written by Stokinger and others at around this time: "Thresholds: Do they exist?".

Hatch states the precept to which many if not all hygienists and doctors worked:

"One of the most important principles upon which occupational health programs are based is that exposure to a toxic agent may be permitted up to some limit of tolerance above zero, within which man can cope successfully with the insult with no significant threat to his health. It is only on the demonstrated reality of this concept that the establishment and continued operation of a great segment of modern industry can be justified, insofar as health maintenance is a determinant. The hazardous industries would have to shut down otherwise, since a zero level of contact with the toxic agent is probably not attainable in practical industrial situations. **Any challenge to this operating principle must, therefore, be met with the utmost vigour by those responsible for industrial health maintenance**; and, in this effort, they must be given full support by all others concerned with the survival and progress of industry", HATCH (1972)

This is a very defensive statement and the section on "zero levels" prompts the question - who is asking for such levels and why? The last sentence reads as though it is written by a 'defender of the faith'.

He appeals to the record of past achievements, "... which support the claim for the reality of tolerable levels of exposure to many toxic agents ..." And that workers have had regular contact with toxic substances, ... "without demonstrable ill effects, as revealed by acceptable medical criteria ...".

He describes "the doubts being raised in many quarters ... concerning the acceptability of currently employed tolerable values and the soundness of the criteria on which they are based".

He continues his version of the arguments used against current "tolerance values".

"Failure to demonstrate ill effects below the presently accepted limits, it is argued, resulted from the use of insufficiently sensitive measures of response to the poisons or from failure to continue the assessment over a long enough period of time. The demonstration of any biological response, of whatever nature and magnitude, the argument continues, must be taken as evidence of excessive exposure. Since there is no foreseeable limit to the sensitivity of indices of response that may be devised in the future, it is clear that this argument must lead ultimately to zero as the only safe level of exposure to toxic agents. Indeed, there is already a growing number from the scientific community with a large following among the general public, who do argue that any substance known to be poisonous must necessarily constitute a threat to health at any level of contact above zero", Ibid

The symposium he addressed "was organised in recognition of this serious challenge".

His method of establishing tolerance values is based on 2 tests:

"1 A kind and maximum degree of response has to be selected which serves with sufficient uniqueness and sensitivity to distinguish between states of health and ill health (existing or potential). 2 The magnitude of this response must be shown to remain below the critical level over a range of doses of the toxic agent from zero up to the established tolerance limit", Ibid.

And he goes on to describe the early days and the development of more stringent criteria:

"In the early days of concern over the gross health hazards of industry, tolerance limits were easily established in accordance with these two requirements simply because the criteria for distinguishing between states of health were so rudimentary ... Later the objective was set to prevent diagnosable illness, usually of acute form, and a safe dose was fixed below which such frank medical cases of occupational disease were not found. With further advances in diagnostic techniques, states of impending ill health became detectable before the onset of obvious illness, and these more sensitive criteria served to distinguish between acceptable and hazardous levels of exposure. With further progress in toxicology, various indices were developed from the areas of pathology, physiology, and biochemistry to detect the beginning of unwanted responses to toxic agents well in advance of clinical

disturbance. These were not in themselves manifestations of ill health but they were selected on the basis of demonstrated significance as early predictors of impending ill health", Ibid.

He develops this theme, ie.that "Pressures have continued to build up to find even more sensitive indices of early response", and ends:

"To meet these demands, distinctions in respect to tolerance limits are now made for many substances at the psychological level, using such indices as increased reaction time and others that are not only uncertain predictors of ill health but are themselves quite non-specific manifestations of response to many common environmental stimuli to which man regularly adjusts without harm and indeed, to which he perhaps must respond as a necessary experience for maintaining health tone", Ibid.

What is Hatch responding to and how have his views changed since 1962?

Firstly, Hatch is not alone. At around this time, the mid-late 1960's and early 1970's other key spokesmen like Stokinger and Smyth felt impelled to defend the basis on which standards had been set and the actual TLV values themselves. They were all responding to a challenge which came from a number of different directions but all of which tended to undermine the legitimacy of the TLV. It is at times of crisis when the paradigm is under attack that key members of the scientific community come to its defence. The more philosophical, general and fundamental tenets, which are not usually discussed in the day-to-day work of normal science, are marshalled. The assumptions which the hygienists, toxicologists and others make implicitly and learnt as part of the process of entering the profession are laid bare in the attempt to defend the paradigm.

Hatch agrees with some of the criticisms that have been levelled at tolerance levels but feels that the critics have gone too far:

"Undoubtedly the criticisms respecting established tolerance values are valid for some stress agents because of the insensitivity of the response indices employed, or of the shortness of the observation period, or, especially, because of failure to look into possible contributions to ill health outside the limitations of specific occupational disease. On the other hand, the critics are also subject to criticism for employing some extreme extrapolations from limited evidence to support their arguments and for their contributions to the confusion that now exists between states of ill health and other forms of disturbance in consequence of exposure to stressful environmental agents", Ibid.

He calls on the symposium to "establish criteria for the determination of tolerable limits well beyond the limited objective of short-term prevention of specific disease" and warns the participants:

"Those responsible for health maintenance in industry have a particularly heavy responsibility, for the use of poisonous substances in industry is on sufferance, so to speak, from society, and proof of safety resides with the user", Ibid.

In the late 1960's industry and those "responsible for industrial health maintenance" were on the defensive and Hatch's views on standard setting had become more doctrinaire in the eight years between 1962 and 1970:

(i) He comes out far more strongly in favour of tolerance doses and sees the homeostatic view of the world as under attack and "that only the demonstrated reality of this concept", allow the, "continued operation of a great segment of modern industry". He calls the delegates to support this principle which he holds so fervently and urges them to defend it with the "utmost vigour".

(ii) He now claims that past achievements support the claim for the reality of thresholds, which is not a claim he felt the need to make before. He has also become completely uncritical of current diagnostic abilities; "... workers have had regular contact with toxic substances ... without demonstrable ill effects, as revealed by acceptable medical criteria". Eight years earlier he was calling for more sensitive measurement and diagnostic methods.

(iii) He tends to caricature his opponents, or perhaps he simply lumps all critics into one category with some of the more extreme environmentalists. Thus he argues that, "as there is no foreseeable limit to indices of response" then the logical conclusion is zero exposure. This is a disingenuous argument if, for instance, one takes the Russian approach as an example. In this case their criteria result in lower "tolerable values" but nowhere near zero.

By posing the argument this way Hatch presents the audience with only two alternatives, either "zero dose" or as we are now doing, there is no middleway as there was in 1962.

(iv) In his tracing of the development of criteria used to assess harm he states:

"With further advances in diagnostic techniques, states of impending ill health became detectable before the onset of obvious illness, and these more sensitive criteria served to distinguish between acceptable and hazardous levels of exposure. With further progress in toxicology, various indices were developed from the areas of pathology, physiology, and biochemistry to detect the beginning of unwanted responses to toxic agents well in advance of clinical disturbance", Ibid.

There are still relatively few diseases which can be predicted by toxicological indices still less so by "diagnostic techniques". Hatch overstates the case in two ways: Firstly his description of what can be done to predict future harm is very optimistic. But secondly, and more importantly in some ways, he goes on to suggest that these "sensitive criteria" are now used regularly to "distinguish between acceptable and hazardous levels of exposure".

(v) Finally, he is now far more sure, though not totally convinced, that some effects are:

"... non specific manifestations of response to ... common environmental stimuli to which man regularly adjusts and, indeed, to which he perhaps must respond as a necessary experience for maintaining health tone".

Whereas before he was sure that some stress was a desirable thing and indeed asked the rhetorical question: "Is this just a wishful generality ...?", HATCH (1962)

The tone of this paper feels similar to the writings of Stokinger at around this time, it is defensive and justifactory though Hatch accepts a more complex view of how exposure to toxic agents can affect health than Stokinger ever did. He developed his model of how people react to toxic stress still further in his last paper in the subject in 1972.

3.3.3 Hatch's views in 1972

In 1972 Hatch published the penultimate paper on his underlying view of standard setting. It is his most detailed and considered paper and its tone is in sharp contrast to the previous paper; almost as it he had collected his wits, pondered the contradictions which he saw as so threatening two years earlier, and recovered his composure.

He starts in a similar vein to this previous paper but is less defensive and makes no mention of the need to defend the principle:

"A basic principle of occupational disease prevention rests upon the reality of threshold levels of exposure for the hazardous agents of industry, below which man can cope successfully with the stress without significant threat to this health", HATCH (1972).

He goes on to describe a simple dose-response curve which reaches "a level of no response at a point greater than zero on the dose axis". He points out that there are in fact several types of response to stress and the;

"... occurrence of zero response at an exposure level above zero does not identify an absolute no-response benchmark but simply reflects the limit of sensitivity of the particular kind of response

being measured. A threshold dose so determined has not certain meaning, therefore, as an index of safety", Ibid.

He goes back to his earlier 1962 definition and argues that "response" and "threat to health" are not necessarily synonymous;

"... subtle physiological and biochemical changes are not, in themselves, manifestations of ill health. Below certain levels of response, they may not even serve as early predictors of impending injury and at still lower levels, some can be measures of healthy response", Ibid.

He thus argues that there is a division between responses which are manifestations of ill health (or impending ill health) and those which are not. The problem is to identify the point of division. This is relatively easy for "clearcut disease" and even "preclinical signs of impending illness" but:

"In view of the many variables and unknowns in the dose response relationship, however, this is not good enough. It is necessary to establish the cut-off point sufficiently below the obvious levels of deleterious response to insure an adequate margin of safety. The question is: how far below and in terms of what kind of response?, Ibid.

He describes the conceptually different approaches of the USA and USSR and concludes that the two societies start at different ends of the dose-response curve.

"In the US, dose response studies have been continued down from the higher levels of demonstrable ill effects through the use of increasingly sensitive measures of preclinical, physiological, biochemical and other indices of functional disturbances. These new measures have been constantly subjected to critical tests of usefulness, however, in terms of their significance a predictors of ill health and the threshold limit values set to insure that the kind and degree of response which is produced is kept below the limit of such significance", Ibid.

And he summarises his view of the differences between the US and USSR's approach:

"In the first case, no threat to health is anticipated so long as the exposure does not induce a disturbance of a kind and degree that overloads the normal protective mechanisms of the body. In the second, a potential for ill health is said to exist as soon as the organism undergoes the first detectable change of whatever kind from its normal state", Ibid.

He amplifies his point by discussing the difference between impairment and disability with reference to his widely quoted model (Figure App 3.6-)

He talks in terms of the organisms "defence mechanism" and argues that "the organism is protected from breakdown and failure so long as these adaptive and compensatory capacities are not "overloaded". He then relates an impairment versus disability curve to a 3 point composite dose-response curve covering psycho-physiological, subclinical toxicological and medical responses. And goes on to argue that response in the first region is simply "homeostatic adjustment", and,

"... therefore include the normal adaptive processes which reflect the behaviour of the healthy organism rather than an injured one", Ibid.

He identifies 3 points on the curve:

A' Which represents "critical limits based on the prevention of minimum diagnosable illness".

B' Which represents a level set to keep response "... below the region of those detectable physiological disturbances that are the precursors of illness".

C' Which represent levels set "... to prevent the earliest demonstrable change from normal behaviour".

Point B' represents levels set; "In accordance with criteria commonly employed in the USA" whereas point C' represents the approach of the USSR.

He continues to compare the US and USSR:

"According to the US position, the defence mechanisms in the compensatory zone, as well as the normal adaptive processes in the homeostatic region, can be safely drawn upon, within certain limits of permissible load, to offset the levels of stress imposed by minimum exposure to hazardous agents at the work place, just as they are regularly called upon to counter the wear and tear of ordinary living. The contrasting view in the USSR is that the protective mechanisms in both zones should be saved for use only under emergency conditions to take care of unexpected insults and that their effectiveness should not be weakened by the continuing demands of avoidable stress, knowingly permitted at the work place. In the extreme, this view holds that only a zero concentration of the toxic agent will remove all health risk; short of this, it permits no significant departure from the normal behaviour of the organism in consequence of exposure to the offending substance", Ibid.

And recognises that the US approach requires:

"... a constant search for improvements in meaningful indices of disturbance to sharpen the point on the response axis that marks the upper limit of no health risk and continuing medical surveillance of exposed workers to make sure that the compensatory processes are not over-loaded and to validate the limits of exposure in current use. Such validation over many years is reported in support of this approach. There is some danger, of course, that delayed ill effects may show up in directions not anticipated in the initial toxicological evaluation of the agent or in the subsequent medical and epidemiological assessment", Ibid.

Figure App 3.6 (taken from HATCH 1972)

Having said this he admits that the USSR approach provides a "greater safety factor but also asks the rhetorical question: "... is it necessary to go so far to ensure adequate health protection?". His answer is in effect "No" in that he believes that the USSR's approach appear to deny:

"... the basic purpose of the homeostatic processes and to be in conflict with a common definition of a state of health which requires constant use of the adaptive processes to maintain health tone", Ibid.

Given the large differences in standards between the USA and USSR Hatch does not see that a simple compromise is possible and calls for a review of the "basic concepts" (of which his paper is a carefully marshalled statement of what he regards as the US position). But he goes on to argue against restrictions on industry;

"... beyond those actually needed to insure adequate health protection since over-design of controls can put serious if not impossible restraints on many operations and can add greatly to production costs. These practical considerations are not the direct concern of occupational health professionals but there is a responsibility, certainly, to support the regulations for occupational disease prevention with hard facts rather than theoretical criteria", Ibid.

And continues that; "True validation of tolerance limit values must come, of course, from the actual health experiences of exposed workers ..."

3.3.3.1 Summary of Hatch in 1972

This is the most influential paper that Hatch wrote on standard setting. Apart from publishing it in the JOM he presented much the same views at an ILO/WHO international conference. The international impact on the scientific communities concerned with occupational health of this work has been important and sustained.

He does not claim that TLV's are thresholds as do Stokinger and Smyth, and his view of the relationship between exposure and health effect is more subtle. As the "threshold" of effect depends upon the sensitivity of the method used to detect effects and the definition of what is regarded as an effect there can, by definition, be no absolute "threshold". In its place Hatch erects the idea of tolerance and in fact at the end of the paper refers to "tolerance limit values", his version of TLV.

He tends, in this paper, to describe in idealistic terms. Thus US TLV's are based on ... "the constant search for improvements in meaningful indices of disturbance to sharpen the point on the response axis that makes the upper limit of no health risk", and, ..."new measures have been constantly subjected to critical tests of usefulness ... to insure the kind and degree of response which is produced is kept below the limit of significance".

It all sounds very well organised, responsible and thorough. Yet the last part of the quote is based on Stokinger's report to the 1968 WHO/ILO Symposium on exposure limits and it is evident from this data that many limits are based on very crude indices of effect, such as irritation. It is also interesting that he refers to, "a point on the response axis". He may not like the idea of thresholds but arrives at a similar place by a different route, a point I will pick up on later.

His description of the US approach to TLV's is mirrored by his idealised description of the USSR. It does not follow, even from his description of the Soviet attitude to homeostasis and compensation, that permissible limits to toxic exposure need to approach zero. The Soviet tests of effect for substances which can affect the CNS and the PNS are more sensitive indices than are used in the West. That is the main reason why the limits for such materials are so much lower. Although some are 1/100 of the US equivalent, none are close to zero. All that the Soviet approach demands is that "avoidable stress" as measured by certain prescribed tests is avoided. In fact the description of the Soviet approach is incomplete in that materials which do not affect the CNS/PNS have similar or higher exposure limits than the West.

His attitude to homeostasis and "health tone" has become firmer. In 1962 the idea was described as possibly wishful thinking; in 1970 it was still prefaced by the word "perhaps". By 1972 it had become part of a "... common definition of a state of health which requires constant use of the adaptive processes to maintain health tone".

This last phrase has an almost naturist ring about it; a certain amount of tolerable stress is good for you. Similar in many ways to Smyth's "sufficient challenge".

Although Hatch's view is more subtle than Stokingers in particular, and he, in this paper, not the one produced 2 years earlier, is less dogmatic in style, he comes to similar conclusions. He does so because he draws upon the same bedrock concepts. If he starts with a view of toxic stress meeting mechanisms of homoeostasis, compensation and adaptation he inevitably arrives at a balance point where the stress is just dealt with by the body. For Hatch this is the tolerance level, for Stokinger it is the threshold.

Hatch is also concerned at the cost implications of the USSR's approach; "... is it necessary to go so far to ensure adequate health protection?" he asks rhetorically. He voices his concern about standards that go, "beyond those needed for health protection" causing, "over-design of controls", "serious if not impossible restraints" and adding greatly to "production costs". While these, "practical considerations are not the direct concern of occupational health professionals" , there is a responsibility to support regulations with "hard facts rather than theoretical criteria".

The need to propose feasible standards, which do not require excessive resources is there lurking beneath the surface and now and again surfaces in Hatch's writings as it does in Stokinger's. And the phrase "hard facts" in this context pinpoints an important tension. What does "hard facts" mean? It means evidence of a health effect is strong, it means illness. It pushes the criteria defining "harm" (or "below the level of significance" as Hatch describes it) away from the "subclinical toxicology" region into the "medical region". That is away from the "compensation region", the region in which Hatch claims TLV's are situated. Again Hatch, in a sense, is very clear about where he would like TLV's to be set in his model and makes extravagant claims for them. But his clarity also shows the problem clearly. It is very difficult to produce hard convincing facts of harm from the subclinical toxicological region and much easier to do so when operating in the "medical region". Accepting his terminology if not his entire model, this is a perennial problem which is still faced by standard setters nowadays.

In all these papers describing the philosophy of standard setting Hatch talks in generalities particularly in this, his last paper on the topic. He very rarely cites a specific example to illustrate a general statement and on these rare occasions when he does the example is usually silicosis or lead poisoning. He uses a number of engineering terms in this last and most comprehensive paper, terms such as; "permissible load", "stress", "wear and tear" and in describing the "organisms defence mechanisms" his explanation has a distinctly engineering ring about it: "... the organism is protected from breakdown and failure so long as these adaptive and compensatory capacities are not overloaded".

There is a paradigmatic feel about this paper. In its own terms on first reading it appears logical, coherent and is certainly carefully argued. It has a strong common sense appeal. Hatch articulated the paradigm that many hygienists and doctors felt able to subscribe to. It coped with the past efforts of the professions and explained the contemporary dilemmas that had to be faced and all within a framework that did not break faith with cherished bedrock beliefs about homeostasis and compensation. Hatch was lauded by his own profession, the hygienists, and by the occupational physicians; he was one of four people to have been made honorary members of the US Faculty of Occupational Medicine. The other three are Warren Cooke (a hygienist), Henry Doyle (a hygienist) and Richard Schilling (a UK occupational physician).

Hatch wrote four other papers which were wholly or partly concerned with OELs, two in the 1960's and two in the early 1970's, HATCH (1965, 1968, 1973 and 1974).

His 1965 paper was not much concerned with OEL's but was more focussed on how the conditions of work effected people's health and how much working conditions contributed to morality overall. He read the paper before a medical audience at a meeting of the Academy of Occupational Medicine. Describing himself as a "non-medical specialist" he sees the present and future health problems in the USA as concerned with "chronic degenerative diseases"; a point he made in 1962. And he compares the change in death rates of men and women divided into three social classes. Men and women in the lower social class have a similar pattern of mortality. Hatch quotes a similar pattern revealed in the social class standardised data from the Registrar General's report for England and Wales (1949-1953). He concludes:

"... the differences in the overall male mortality rates appear not to result from differences in the risks of work and of the work environment, but, rather, the socioeconomic classification reflects a selective process which separates the population into different levels of vitality according to the background and heritage from which both husband and wives come from", HATCH (1965).

Hatch convinces himself in this analysis that environmental hazards and the exposed population can be divided into two categories. The first division is the same as in 1962: specific occupational diseases versus non-specific degenerative or malignant diseases. The second division is new: environmental stresses either overwhelm all people or exacerbate existing conditions or hasten their development but only in some people;

"... in individuals who, for reasons of poor vital endowment, have a higher potential for the disease than other, stronger, individuals", Ibid.

Later he refers to such people as "psychological and physiological cripples" and calls for particular attention to be paid to such groups by occupational physicians*.

His thesis in 1965 is that exposure levels are now generally too low to cause old style occupational disease; that the problem has moved on to chronic degenerative disease which work exposures do effect but only in those individuals in the lower social classes who have "poor vital endowment". This is the first time he has spoken in these terms. The overall feel of the paper is relaxed and confident, as in 1962, though a specific source of doubt is mentioned by name, Rachel Carson's book, "Silent Spring". The overall message is that occupational disease can be more or less completely beaten by well worn techniques and that now the problem is not the environment but the "vital endowment" of the individual. Hatch was speaking to a medical audience and he obviously pitched his paper in a medical direction concentrating on the population exposed rather than the environment. However this paper reveals a hitherto hidden facet of Hatch's belief system. The belief that the "vitality" of the individual was more important than work environment is clear and was sustained by the apparent fact that men and women in the lower social classes had a similar mortality experience. Hatch was following a generally held interpretation of the data which unfortunately would now appear to be incorrect and far too sweeping.

A similar argument was made in the UK Decennial Supplement to which he referred in the paper. Comparing the mortality from bronchitis between men and women they found:

"Mortality ... in men and women was almost six times as high among the unskilled manual workers ... as among farmers and professional people. It is evident, though, from similar tendencies displayed by married women (classified by their husbands occupation) that these **age differences**

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* One can see the influence of Hatch's early education in medical statistics. The simple model he quotes is based on a book by Henderson entitled "Mortality Laws and Statistics" published in 1915. The simple division of difference into fixed vitality determined by genetic factors which is treated as rigidly separate from environmental heritage stems directly from this book. There is none of the sublty found in more modern treatments of the "genome" and the "environment" which do not treat either as independent, static categories. Hatch, in following Spencer, was locked into a static view of inheritance and the environment which created the tautologous, nature/nurture dichotomy that plagued biology and psychology for much of the 20th Century.

in mortality owe little to direct occupational effects, and must be attributed to more general socio-economic or environmental factors", Registrar General (1958), quoted in Registrar General (1978).

The commentary in the 1970-72 Decennial Supplement offers an alternative explanation. An analysis of the occupations of the wives of miners and quarry men showed that many worked in the potteries and textile mills and that:

"... the high bronchitis SMR's for the wives of men in Order II Mining and quarrying reflects the effects of the wives' exposures to occupational hazards", Registrar General (1978).

The conclusions of the 1958 supplement weighed heavily with the Medical Research Council's (MRC) committee which considered whether coal dust caused bronchitis in coal miners and other occupations. The MRC Committee published its conclusion that the high bronchitis levels in miners were a function of social class and not occupation in 1966, one year after Hatch's paper, MRC (1966). And he, as has been shown, drew similar conclusions though he went further with his emphasis on "poor vital endowment".

Three years later Hatch specifically addressed the question of setting OEL's in a paper which prefigures his most influential model of 1973. Although it was not published until 1968 the paper was in fact read before an audience at the New York University Medical Centre in 1965. Hatch was introduced as a Visiting Lecturer in Toxicology. The tone of the paper is more defensive than 1962 but not as urgent as his call to the defence of IH was to become in 1971. The threat as he sees it comes from environmentalists and other outside the health profession and from toxicologist and others within the health professions who responded too far to indices of response which ..." have little value as a predictor of ill health under conditions of real exposure". The model he develops is sophisticated and paradigmatic and is clearly a derivative of the earlier two dimensional model described in 1962. Apart from his warning not to attach too much meaning to ever more sensitive indices he gives his views on the utility of what Smyth and Stokinger would have described as "industrial experience". He praises the use of "field studies" but goes on to make the following critical points:

"Without doubt, some of these studies revealed useful aetiological relationships despite weaknesses in the quality and quantity of measurements of both exposure and response and in the epidemiological aspects of these investigations. This was because the dose-response relationship was operating at such a gross level as to overcome these inadequacies", HATCH (1968).

He is saying in effect that "field studies" have only worked because, in the past, exposures were high and the responses were plain to see. The implications are similar to his 1962 paper; better epidemiological methods must be applied and more sensitive measures of early response are needed. Also, although it is not said, the implication is there the past "experience" as judged by field surveys of current employees should be viewed more critically. A point I will return to later in the thesis. However at this point in the paper Hatch returns to and combines two mid 1960's themes, the environmentalists and the "physiological cripples", The prophesies that the former raises issues:

"... simply not answerable by animal studies which ignore what may be the dominating dimension in the host-agent-environmental triad: the vitality of the host", Ibid.

In 1973, a year after the publication of his most influential paper on OEL's Hatch reiterates and expands on some of the themes of a year earlier, again in a relaxed and confident tone. He says:

"Neither the criteria for establishing the limits of permissible exposure not the indicators to be employed for routine surveillance of exposed workers to validate standards or to detect failure of protection can come from within the range of the usual medical signs of disturbance", HATCH (1973).

But again this statement of best practice sits uncomfortably with the insistence on "hard facts" of a year earlier. The question of where "hard facts" end and shade into more "theoretical criteria" has always bedevilled the debate and is not solved in Hatch's model.

While a year earlier he cites no specific examples of how his model could be applied in practice this time he returns to an old faithful, the problem he started his career with; silicosis. However the probability plot deals with are two dimensions of the three dimensional module. The point I wish to emphasise is not the specific conclusions Hatch draws from this figure but that for him silicosis and its control was his exemplary model and, I would argue, it was one of the important exemplars used in the teaching of IH's all through the 1940's, 50's and 60's.

Apart from arguing that only the "long term health records of exposed workers" will settle the USSR/USA differences of approach Hatch faces the environmentalists head on. He poses their question thus:

"Why should I be exposed to greater hazards at work than at home"?, Ibid.

And he sounds a warning that if: "... the basic differences in the dose response relationship" between working people and the community are not researched the answer to the environmentalist question is likely to be: "There should be no difference", Ibid* .

If further discussion of toxic "stresses" on the health of the community the phrase, "physiological cripples" crops up again. This time Hatch argues that such people are not simply at one end of the dose-response curve but that they "do not even belong in one characteristic group much less constitute (only) an extra-susceptible fraction of the total population", Ibid.

Hatch's use of the term is unclear. In 1965 he appeared to believe such "cripples" were part of the workforce and were the ones who succumbed, because they had less "vital endowment", to the non-specific stresses of the work environment. And he believed there was a class difference in the distribution of this "endowment". Whereas here "cripple" is used in a different more specific context.

In his final paper Hatch addresses the American Medical Association and calls for continued interdisciplinary research and reviews the achievements of non-medical specialists (IH's plus others) working with physicians. While most of the paper is of no interest here it is quite evident that Hatch feels relaxed and confident about the threat from the environmentalists which is "fashionable today". It, due in no small measure to his work in the defence of the OEL paradigm, has been contained.

3.3.4 Preliminary Overview of Theodore Hatch

Hatch's career in occupational health spans almost 50 years. His early work was mainly concerned with exhaust ventilation and dust control, later he worked on sampling methods and methods of analysing samples. hen the ACGIH was formed in 1938 he was the first chair of the Standards Committee which was initially concerned with methods of sampling and analysis and their standardisation. It was only later that the remit of the Committee was expanded to include exposure levels, by this time Hatch had relinquished the chair. He himself, during his early career was mainly concerned directly with standard setting although he developed a number of sampling methods and used standards as benchmarks to evaluate control methods he designed.

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* Stokinger raised the same problem four years earlier: "How to explain, for example, that when a community has a limit for lead in air of 5 µg/cu M (Pennsylvania) that it is alright for their "boys" to breathe 40 times this amount for their working lifetime in industrial plants", p280, STOKINGER (1964b). He is more pessimistic than Hatch that the problem will ever be resolved; "It is doubtful that the rational bases for the differences can be made sufficiently convincing to be generally accepted ..". p280, Ibid. The gap between the "occupational hygienists" and the environmentalists or those from "nontoxicological quarters", as Stokinger refers to them, is too big.

This together with his background as an engineer meant he was not constrained in his later writings on standard setting by the knowledge f the specific practicalities of setting a limit for an individual substance. He was perhaps then more unhindered than people such as Stokinger and Smyth who tend to use example after example to demonstrate (in Stokinger's case "conclusively" or "indisputably") the correctness of their suppositions. Hatch was freer to survey the whole panorama and write in broad generalities. In doing so he struck a chord in the minds of many in the hygiene and occupational medical profession. Although his model is clearer and more subtle than either Stokingers or Smyth's stripped to the essentials it is very similar. And perhaps in the case of Hatch and Smyth is based on similar life experiences. Hatch and Smyth had seen cases of virulent silicosis and acute lead poisoning. They could remember times when such health effects had been commonplace and they had seen the exposure which caused the effects brought broadly under control. In the case of Hatch his work on control was instrumental in developing the control methods. Once the overt acute diseases had been more or less controlled it must have been tempting to regard any residual effects as less important. Hatch resisted this temptation in a lot of his writings though when on the defensive, as in the 1970 paper, he argued strongly that current exposures represent "tolerable levels" "... without demonstrable ill effects". He appears to believe at this time that exposure levels had been set to deal with any residual sub-clinical effects and furthermore it was the occupational exposure limits which pushed the control methods. This order of events is far less clear in his 1962 paper where he suggests that controls lead the methods of identifying health effects. This tension is evident again at the end of the last paper. He argues eloquently for a tolerance level to be set somewhere in the "sub-clinical toxicological" region but also calls for limits set on the basis of "hard facts".

It could be a caricature but I find it persuasive that Hatch, Smyth and Stokinger, especially the first two, all came from the era of "hard facts", and this experience taught them that overt disease can be controlled and that under these controlled conditions people can survive and not become obviously ill. Such exposure levels appeared to be tolerable and could be maintained by applying the existing control methods. There was no need for more refined controls or for the banning of certain substances; industry could continue to use or create toxic substances as long as the appropriate controls were applied. It was only when these controls were not applied that frank disease reared its ugly head:

"Where occupational disease cases have continued to develop, one finds, in most cases, a failure to employ safeguards of known effectiveness rather than a lack of scientific and technical know-how to deal with the hazard", (Hatch 1970).

3.4 Henry Field Smyth (Junior)

"I look upon environmental toxicology as a form of epidemiology. It is epidemiology in reverse, prospective epidemiology". SMYTH (1960)

3.4.1 Reasons for Selection

Henry Smyth (Jr) and his father were two of the first industrial toxicologists in the USA. Smyth (Jr)'s career spanned four decades from the mid 1920's and the late 1960's. He was one of the earliest non-medical IH's and was an important influence on the AIHA, industrial toxicology, standard setting practice and the OEL paradigm. Apart from generating and publishing a huge amount of toxicity data - (Range Finding data as it became known), he published a number of papers examining the basis of TLV's and the role of the toxicologist in setting such standards. He was also on occasions a member of ASA's Z37 standard setting committee. He therefore fulfils all the selection criteria . For further information on the career of HF Smyth (Jr) see AMDUR (1985).

3.4.2 Smyth's views on standard setting

Smyth was both a toxicologist and an IH and he wrote extensively on both toxicological principles and OEL setting particularly TLV's. The analysis which follows examines firstly his views on toxicology and secondly his views on standard setting.

3.4.2.1 Smyth on Toxicology

Smyth and his father did contract toxicology research from the late 1920s. They developed their own protocols and techniques and developed their practice in the era before the Food and Drug Administration (FDA) was founded and became dominant. Also, initially they worked through a period when quantitative techniques such as profit analysis had not been applied to biological data. Though Smyth (Jr) soon took up this approach and applied it to the Range Finding data which was published regularly throughout the 1940's, 50's and into the 1960's, (SMYTH et al, 1944, 1948, 1951, 1954b and 1962b).

Although trained as a chemical engineer Smyth (Jr) was a hybrid professional for almost all of his career. He was both a non-medical IH and a professional industrial toxicologist. As one of the first in IH and industrial toxicology and because of the quality of his work Smyth had an important influence on both professions. His views on toxicology are worth examining as they influenced at least one and probably more generations of toxicologist and coloured his approach to TLV's and OEL standard setting in general. The development of his ideas over time will be examined.

Most of Smyth's toxicological testing was sponsored by industry and the short term "Range Finding" tests were developed in the 1940's to cater for the needs of companies, that wanted some basic test results on new or planned products. Smyth and his associated did occasional long term chronic studies, the results of first series being published in 1936, and this first study provides an interesting insight into Smyth's approach to toxicology and a snapshot of what the better industrial physicians and toxicologists were capable of doing in the mid-1930's.

The two Smyth's and Carpenter, who was to become their longterm associate, worked as a team. Smyth senior organised the medical examinations, Smyth junior did the air measurements and worked with Carpenter as well on the animal exposure and pathology work. The work was jointly funded by a consortium of five companies, including Diamond Alkali and Dow Chemical's; it was published in 1936 in a paper entitled "The chronic toxicity of carbon tetrachloride; animal exposures and field studies", SMYTH et al (1936).

The aim of the work was clearly stated:

"... to obtain experimental and clinical evidence on which to **establish a safe concentration** of carbon tetrachloride vapour in work rooms where men are continuously exposed", SMYTH et al (1936). (Author's emphasis).

The experimental animal work is dealt with first. Groups of 24 rats, 24 and 16 guinea pigs and 4 monkeys were exposed to a range of carbon tetrachloride concentrations from 50-400ppm, together with controls. The animals were exposed for 8 hours a day, 5 days a week for 10.5 months. The rats were allowed to litter and some of the guinea pig groups had calcium supplemented diets. The results of test groups were compared with control groups. After describing the pathology they found the authors emphasised the importance of longterm studies:

"The results obtained emphasize the value of long continued exposures in studying industrially important materials. **Many of the lesions noted would have been completely missed in a briefer study**", Ibid (Author's emphasis)

The guinea pigs were much more badly effected than the rats, for instance it took 13 weeks for cirrhosis of the liver to develop at 100ppm exposures compared with 34 weeks for rats. All types of animals demonstrated nerve damage (optic and sciatic nerves) the order severity being guinea pigs, monkeys and rats. For monkeys it took 40 weeks at 200ppm exposures and for rats 27 weeks at 50ppm or 11 weeks at 110ppm exposures. Central nervous system damage was not examined but the authors cite other work that suggested it would occur if peripheral damage was evident. Recovery from the lesions, in animals which were rested for up to 176 days was "slow". The authors were not sure of the relevance of nervous damage to man as:

"... none had been reported, and the lesions found here were not severe enough or general enough to produce complete loss of function", Ibid.

The authors felt differently about the results from the different test animals. Early on in the Results section they had the following observation to make on the guinea pig results:

"The pigs were much more susceptible to the carbon tetrachloride vapours than were the white rats or monkeys, and when this data is compared with concentrations of solvent found in industry, it will be seen that they must be much more susceptible than the humans. Consequently very little weight has been placed on the guinea pig results", Ibid.

There is certain circularity to this argument and it is strange to virtually dismiss the data from on a species of test animal before even presenting the test results. These results will be returned to later in the discussion of this paper.

After reviewing the results the authors conclude:

"... it is felt that omnivorous animals such as monkeys and rats ... may maintain health, fertility and weight probably indefinitely with daily exposures of 8 hours to 100ppm carbon tetrachloride vapours, and for months to 200ppm", Ibid.

The report goes on to describe the atmospheric measurements made at 25 dry cleaning establishments which, together, contained the full range of machines. The authors do point out however that the equipment was probably not typical as "... most of the machines (had) been installed within the past 5 years". The survey thus represented the spread of conditions in the better end of the industry. "Breathing zone" measurements were made and linking these results to a time and motion study of the work cycle and a knowledge of the daily pattern of work, "... the maximum exposure found for an 8-hour day was 117ppm, the next 111ppm, and all the rest ranged from 5 to 90ppm", Ibid.

Finally the physical examinations are described. The plan had been to examine 200 men, in the event only about half the occupiers would co-operate and 96 men were examined. From the animal work and the literature they selected a list of what might be significant blood and urine findings. The four tests of particular value were considered to be icteric index, blood calcium, visual fields and van der Bergh reaction.

The authors found that "... no worker was found to be seriously affected or definitely injured by carbon tetrachloride exposure". But they go on to point out why:

"In field studies of this character this is to be expected ... Those less resistant workers who are likely to suffer serious injury are soon weeded out if exposures are high, and if exposures are low only moderate damage results. Seriously affected workers do not as a rule continue working in mildly toxic concentrations of harmful materials; they would be encountered in the hospital clinic, if at all", Ibid.

The authors understand that what they had examined was a survivor population working in some of the best conditions in the dry cleaning industry. Even so there would appear to have been a pretty rapid turnover in staff: of the men examined some 25% had worked for 2 years or less and 75% had worked for 5 years or less.

There was some evidence of damage to workmen but no, "definite correlation between degree or duration of exposure and evidence of injury", p294* . Although abnormal findings were thought to

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* Although there is no obvious correlation between the number of abnormal symptoms recorded and the ppm x years of exposure there would appear to be a relationship between duration of exposure and abnormal symptoms. If the exposure durations are divided into three categories; >1-2 years, 3-5 years and ≥6 years the number of abnormal results per individual is 0.83, 1.5 and 1.2 respectively. While this is a relatively weak relationship, together with the other evidence of "damage" it is

be real and, "not (due to) random variations" they could not be ascribed to carbon tetrachloride exposure as no control group had been examined. Nevertheless:

"On the basis of the finding of abnormal data, a number of workmen were moved to other work in the same plants. They were not regarded as definitely injured, but as probably above average susceptibility and therefore poor risks for continued exposure", p295, Ibid.

The section on physical examinations ends on a description of the medical examination of carbon tetrachloride workers which it was recommended should take place every 6 months. And even in those workers with abnormal findings they offer the hope that people exposed and rested are likely to develop an increased tolerance because of; "... the development of regenerated, more resistant parenchymatous cells in the liver", p246, Ibid. They base this belief on the animal work and on the physical examinations and state their view quite boldly:

"... in most cases men working with carbon tetrachloride under reasonable conditions of ventilation and care increase their resistance rather than increase their susceptibility", Ibid.

The comments and observations on this paper will be divided into two parts. Firstly the specific results and interpretations will be reviewed and secondly some general observations on the approach to toxicology will be made.

One of the things that strikes the reader of this paper is that the authors are very much in favour of the 100ppm limit. The text is regularly punctuated by statements either approving of other workers recommendations of 100ppm or clearly stating that 100ppm is safe; five statements to this effect are made including the recommendation in the conclusion. This would explain the rather strange mismatch between the pathology and animal evidence presented and the conclusion that 100ppm (8 hour TWA) was satisfactory. The animal evidence demonstrated significant harm could occur at exposures below 100ppm with prolonged exposure to rats, which the authors regarded as one of the more resistant species.

Indeed, in a paper a year later, Carpenter, one of the authors, cites the carbon tetrachloride work in a review of the toxicology of tetrachlorethylene and says:

"... typical cirrhosis of the liver occurred when guinea pigs, rats and monkeys were exposed to concentrations of carbon tetrachloride ranging from 25ppm to 400ppm", CARPENTER (1937).

He continues a little later:

"Definite damage to the sciatic nerves was seen ...", and that; "this sort of injury was found in a number of exposed animals but always in concentrations of 200 or 400ppm or **after many exposures to lower concentrations**", Ibid (Author's emphasis).

Earlier he proposes that:

"The exposure of small animals to vapours ... over long periods of time and under concentrations approximating those found in industry comparatively furnishes a tentative basis for establishing safe limits", Ibid.

It would appear then that Carpenter at least, out of the three authors believed that carbon tetrachloride could cause serious health effects in animals at concentrations below 100ppm, albeit after prolonged exposure. But then both the studies, on carbon tetrachloride and tetrachlorethylene were concerned with "chronic toxicity" and the effects after prolonged exposure were the concern of the authors.

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suggestive of an overall increase in effect with duration of exposure. (Based on a reanalysis of the data in Table 3, p291/292, SMYTH et al (1936)).

The human evidence shows clinical and biochemical effects especially in the men at the higher end of the exposure range (of the 48 men examined for which 8 hour TWA assessments were available only 7 had exposures > 100ppm, 2 = 111ppm and 5 = 117ppm). And these effects were detected in a group that was acknowledged to be a self selected survivor population. Taken at face value the evidence would suggest that a limit solely based on potential health effects should be lower than 100ppm. What appears to have constrained the authors is the review two years earlier by Davis which ended by recommending 100ppm and the issue of the practicability of the standard. The exposure data indicate that 100ppm was easily attainable for most dry cleaning operations but there were a few which might find some difficulty complying. However while Smyth performed his assessments he gave advice on ways control could be improved "... so that present conditions are now slightly better than those found", p240, Ibid. The 100ppm limit was a practicable limit, ie. it was technically feasible in those establishments using modern equipment and with commitment to achieve effective control.

In many ways the three authors approach the problem of setting a standard to protect against chronic effects in a similar way to Drinker and Hatch. They wanted a standard which protected people's health and, at the same time, was practicable to meet. This results in a certain interpretation of the data which, with hindsight, appears to have underplayed the health effects of carbon tetrachloride at 100ppm (8 hour TWA). And the author's know from their past IH consultancy experience that 100ppm would be a great improvement on current conditions in much of the dry cleaning industry. It's interesting, in retrospect, to consider how the carbon tetrachloride standard changed. Some of the changes are listed below:

1934	Davis =	100ppm
1936	Smyth, Smyth & Carpenter =	100ppm
1942	Most states =	100ppm
	Michigan =	75ppm
1946	Cook's list =	100ppm
	Massachusetts	50ppm
1946	ACGIH =	50ppm
1953	ACGIH =	25ppm
1962	ACGIH =	10ppm
1978	ACGIH =	5ppm (A2)

A2 = "Industrial substance suspect of carcinogenic potential for man", ACGIH (1986)

In 1936 the authors dismissed the evidence of the guinea pig tests arguing that these animals were far more sensitive than humans, citing as evidence the fact that their field studies revealed no evidence of effect at comparable levels of exposure. In 1963 when the TLV documentation was first published one of the important pieces of evidence cited in the reasons for reducing the TLV from 25 to 10ppm were the guinea pig tests results. The view of the appropriateness of guinea pigs as a test species has changed*.

What does this paper reveal about Smyth's views on toxicology?

Relatively large groups of animals were used, both test and controls. More than one species was tested at several concentrations and the exposure period was relatively long. The investigators realised that it was important to observe the animals for a long time after exposures had ceased. The experimental methods were advanced but the data analysis was not. Little use was made of statistics or statistical tests. This was not surprising in that such tests were not introduced until the late 1930's and the organisation that pioneered the numerical approach, the FDA, was not set up until 1935.

*This paper perhaps also shows the subtle pressures that can weigh on scientific researchers whose work is financed solely by one industry. While the authors were almost certainly not influenced directly they would undoubtedly have been aware of the practical implications of any standard they proposed. And their sponsors would certainly have discussed the practicabilities of control with their consultants.

The paper shows that the Smyth's were competent, conscientious toxicologists. It also shows that Smyth (Jr) had not gained the full confidence in the capabilities of toxicology which he was to display in the 1950's. Where toxicological evidence was at variance with human field study results, as it was in this case, the human evidence won out. In later years, especially the 1950's (when Smyth was perhaps more confident and the science of toxicology was more firmly established) he was to take the opposite view.

Their attitude to sensitivity and resistance is important for two reasons. Firstly it is raised as a possible explanation of why some animals succumb and others do not when exposed to the same concentrations. The experiment is described as "limited" and the hypothesis is put tentatively forward that; "The regenerated cells in both the liver and kidneys are more resistant", p287 in those animals previously exposed to carbon tetrachloride. This possibility becomes translated into a sure-fire certainty when the medical management of workers is discussed. A period away from exposure to carbon tetrachloride will enable "the development of regenerated, more resistant parenchymators cells", p246, Ibid. A possibility has become a fact. The second point worth recording is that Smyth (Jr) does not mention "resistant cells" again until one of his last papers on standard setting in the late 1960's. It is evident that the existence or creation of multiplication of such cells was one of his fundamental tenets* .

Having considered Smyth's earliest paper in toxicology it remains to examine, briefly, how he amplified or changed his views. He wrote seven papers between 1936 and 1979 in which he discusses the setting of OEL's and his views on toxicology. An attempt is made in what follows to consider the development and consolidation or reiteration of his views chronologically.

Smyth starts his 1954 paper with the standard definition of the toxicologists main actions:

"Any substance can be tolerated in some particular daily intake", SMYTH (1954).

He goes on to throw doubt on Habers Rule and the usefulness of simply relying on a TWA standard for every substance. And he questions the assumptions that all people are equally sensitive: ".. and their sensitivity does not vary from time to time with changes in their general health", p204, Ibid.

He is not sure of the solution to this problem as ignoring it would result in "serious injury" while protecting all, "would require uncalled for expenditure". His ultimate solution looks forward to the day when: "... knowledge of toxicology is sufficient" to identify individuals "long before irrevocable injury is done", p204, Ibid.

He goes on to list six questions to which the IH and physician would ideally like answers from the toxicologist:

"1 What uniform concentration is tolerable eight hours a day for a working life time?
2 What correction in the average must be made for brief peak concentrations?
3 What single brief exposure to a high concentration is tolerable each day when there is no exposure the rest of the day"?

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* It is now known that a number of enzymes responsible for detoxification in the liver can be induced, ie. the number of sites available for catalysis can be increased rapidly. Also the amount of enzyme per liver cell can be increased by stimulation of protein synthesis although this process takes far longer (weeks). The two processes enable a toxic material to be processed more rapidly than before induction had occurred. While the rate at which induction occurs may vary from individual to individual, it is not normally possible to identify why this is so. It may be constitutional and inherent but may also be due to the past history of the persons exposure to particular toxic materials and can be influenced by general factors such as nutrition and infections. Smyth's use of the term resistant, which he applies to both cells and people, has a more absolute quality about it. Resistance is seen as a fixed quality located in individuals and not as a variable quality determined by past exposure history, genetics and other factors such as the effects of diseases.

4 What biological test upon the workman can measure his actual intake of the chemical at his job"?
5 What are the earliest symptoms and objective signs of excessive exposure, and how severe can they become before removal from exposure fails to prevent permanent injury"?
6 What is the best treatment for the effects of excessive single exposure or excessive repeated exposure"?, Ibid.

These questions are an amplification of his criticisms of the ACGIH for simply listing TLV's as a table of 8 hour TWAs. They are also remarkably perceptive and hygienists and physicians would dearly like the answers for many substances nowadays.

He ends by arguing that; "Despite an infinite amount of animal work ... the tolerable human intake will remain only tentatively defined until human observations have been made", p205, Ibid.

At this time then, although he was far more confident of the toxicologists ability he still sees field studies or epidemiology as the final arbiter.

Five years later he again returned to the toxicological needs of the standard setter and again reports his belief:

"... that the ideal basis ... (for setting an OEL) ... is the prolonged critical examination of several considerable groups of workmen exposed to different constantly monitored concentrations", SMYTH (1959).

He then proceeds to analyse 148 TLV's which were in the 1953 and 1958 lists and concludes that long term animal inhalation or human studies produced OEL's which "stood-up well" and changed less than others based on other criteria. He makes a similar statement on animals tests as in 1936 but this time he refers to the TLV:

"If a threshold limit is required to guard workmen against slowly developing chronic toxic effects, quite prolonged and extensive animal experiment is called for", Ibid.

A year later he expressed even greater confidence in the capabilities of toxicology:

"I look upon quantitative toxicological studies as a scaled-down model of the contemplated future environmental exposure to the substance under study", SMYTH (1960).

The need for human studies is downplayed and Smyth is at his most optimistic in believing that toxicologists were able to predict a safe level of human exposure. He makes a most revealing comment on his attitude to toxicological tests when he says:

"Some of us have an almost religious faith in their mystic symbolism for the exposure of human subjects to the substance", Ibid.

The powers of the toxicologist would appear to be unbounded. The paper ends with a series of questions which toxicologists need to answer including:

"Can the hypothesis of 'sufficient challenge' be established, or is it an illusion?", Ibid.

This is the first time he has used this phrase but it echoes back, as I will show, to the early thoughts on"resistant" liver cells first positted in 1936. This paper was addressed to toxicologists and was entitled "Recognition of toxicology as a scientific discipline". It is perhaps no surprise that Smyth should sing the praises and paint a rosy future for his prime scientific profession. Three years later he gave a paper to a mixed group of IH's; physicians and toxicologists and addressed the "toxicological aspect" of IH. He was careful to emphasise the place of human evidence:

"Our information is derived from experimental toxicological studies upon animals, and from epidemiological studies of exposure and response, made upon humans. I do not see how the two can be separated. To me they are both arts of toxicology", SMYTH (1962a).

And like Hatch and Stokinger at around the same time he explored the fundamental axioms which:

"... underlay all of experimental toxicology". He listed four:

"First, any substance contacting or entering the body will be injurious at some degree of exposure, and will be tolerated without effect at some lower exposure", Ibid.

This axiom is a constant in Smyth's writings:

"Second, the nature of the injuries which may develop in man can be determined by the study of the reactions of experimental animals. This axiom derives from our conviction of the essential, uniformity of the mechanisms of living things", Ibid.

This is the clearest statement yet the basis of Smyth's optimism at the essential correctness of using animal tests to predict effects on humans:

"Third, it is not possible to define an exposure of animals which has no effect upon their health ... We can only determine that there is no effect which the sensitivity of our method will detect ... It is not always easy to distinguish clearly between a transient reaction and an early sign of progressive injury", Ibid.

This is a cautious statement defining some of the limitation toxicologists in practice have to be aware of. The fundamental problem which toxicologists have had to wrestle with since the "Biological/physiological chemists" first started experimenting on animals is dealt with in his next, and last axiom:

"Fourth, from the results with experimental animals, we can define the degree of exposure which will be without effect upon humans. This axiom plays down the fact that both individual animals and individual humans differ in their susceptibilities and that we do not know the full range of susceptibility among either animals or humans. We study a small number of animals, and we may contemplate exposing an essentially infinite number of humans. Our safeguard is the use of higher exposures of animals than we expect humans will contact, and some degree of observation of human use to detect effects before they become irreversible", Ibid.

The last phrase again places a great burden on human evidence: it is still, for Smyth, the final arbiter. While in the paper in 1960 there is almost no doubt in the "soundness of judgements", in this paper Smyth acknowledges some of the fallibilities of the method. But he is fundamentally an optimist when considering the social value of chemicals.

"We derive tremendous benefit to the kind of life we wish to lead from the use of chemicals. Very little injury results", Ibid.

He again returns to the question of sensitivity and the differences between the animal population under test and the human population on to which the results will be extrapolated. His views are worth quoting at length because they show how large was the breadth and number of variables which Smyth believed could affect human response to toxic chemicals.

"We use only a few animal species, and through ignorance we may not include one which is susceptible to the type of injury humans may develop. We use animals initially in good health and of uniform stock, while the human population includes a wide range of degrees of health, and all genetic variations. The nutrition of our animals is constant and near ideal. Our animals receive little physiological stress, and when we are studying the effects of inhalation they may be quiescent, whereas the human may be exposed to heat or vibration and working actively", Ibid.

While "genetic variations" are included on the list and are singled out for special mention later in the paper, Smyth's view of human variability are wider and more comprehensive than Stokingers. As in 1954 he poses the question of whether IH aims to protect 95% of the workforce or everyone "no matter how susceptible". He answers:

"I myself think that industrial hygiene aims to control exposure to the extent that almost no workman can suffer discomfort or adverse effect, and that effects in the most susceptible develop so slowly that they will be detected by the alert occupational physician before irreversible disability is inevitable", Ibid.

His answer in 1954 was similar though then he hoped the toxicologist would develop methods of identifying sensitive people before they were injured. In this paper this difficult, if not impossible, task falls to the, "alert occupational physician".

The penultimate paper was presented the year before Smyth retired and deals with many of the fundamental assumptions which he held throughout his career. Smyth states:

"A familiar maxim of my childhood was, 'You've got to eat a peck of dirt before you die'", SMYTH (1967).

He argues that this maxim, "... is well established in respect to infections which produce immunities", Ibid.

And can be applied to "physical factors of the environment". This leads him to argue that people and societies in general require "sufficient challenge" and he quotes Huntingdon as evidence for the latter contention:

"We are stimulated and our health is improved by a moderately high degree of variability from day to day, whereas our health is injured by great changes and still more by monotonous uniformity ... No nation has risen to the highest grade of civilization except in regions where the climatic stimulation is great ... Changes of temperature from day to day are of great importance", Ibid.

In fact he got the phrase "sufficient challenge" from Toynbee the historian who in his writings on civilisations argued that they required, "Sufficient (but not overwhelming) challenge".

Pharmacologists "have long been convinced of the reality of sufficient challenge" and, "This is the basis of all chemotherapy"* , Ibid, Smyth argued.

So he could not understand why the toxicologists apparently did not believe. In fact he believed that toxicologists had painted themselves into a corner:

"Yet toxicologists have manoeuvred themselves into the position where they regard every evidence of adaptive response as a manifestation of injury":, Ibid.

He justified this view by quoting evidence from laboratory studies that stimulation of growth in tests animals at low doses. And he explains this phenomena as due to homeostasis quoting first on A Carrell who wrote in 1935:

"An organ atrophies when not in use. It is a primary datum of observation that physiological and mental functions are improved by work ... We become adapted to the lack of use of our organic and mental systems by degenerating... The exercise of the adaptive functions appears to be indispensable to the optimum development of man", Ibid.

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* This certainly would not be regarded as the case nowadays when the principle mode of action of for instance, many antibiotics is based on selective toxicity. An attempt is made to discover molecules which interfer with some aspect of the biochemistry of procaryotic bacteria which does not exist or is different in eucoryotic human cells.

And Smyth continues in his own words:

"I think that most of the small non-specific responses which we measure in chronic toxicity studies at low dosages are re-adjustments or adaptations to sufficient challenge", Ibid.

But homeostasis is not the only, or perhaps for Smyth, the main blank in his beliefs:

"Closely allied to my concept of sufficient challenge is the homeopathic dose which one school of medicine relies (decreasingly) upon in therapy, possibly more on mystical than demonstrated grounds. (My own father was an allopath). Here a trace of a chemical is relied upon to cure an injury such as would be caused by a lot of the chemical, a hair of the dog which bit you", Ibid.

Homeopathic principles which predate the development of the profession of modern scientific toxicology were important for Smyth (Jr) although his father did not subscribe to such principles.

This may partially explain how Smyth could recoincide the animal test results on carbon tetrachloride with the 100ppm standard, which he and his father and Carpenter proposed in 1936. Some of the effects at least, he could see as a homeostatic/homeopathic response to "sufficient challenge".

In 1960 Smyth wondered to himself whether the "hypothesis of sufficient challenge" was an "illusion". This paper indicates that for him it was not, it was a reality. And the belief goes back to his very earliest work. The "resistant cells" that were hypothesizes to exist in previously exposed rats were evidence for Smyth for the existence of a general response to toxic insult, which view he elaborates in this paper.

He appealed to the toxicologist to come into what he regarded as the pharmacologists camp and decided the fact that;

Their, "mental reservations (about detecting responses at lower and lower doses) does not lead them to speak with conviction about the safety their studies aim to confirm", Ibid.

The toxicologists did not heed his advice and 12 years later Smyth appears to have become much more irritated and intolerant of the use of animal tests and epidemiology. He has changed his views on the need for high dose tests and is unhappy about the arbitrary use, as he sees it, of the FDA's 100 fold safety factor. Also he does not like what he sees as premature warnings being given of effects based on epidemiology and in particular he is most exercised over the unwarranted use of models*.

This last paper is untypical. It was written over a decade after Smyth retired and is far less relaxed and confident than his other work. He appears to be going back on a number of beliefs which he held firmly during his professional career. His irritation with animal high dose extrapolation etc appears to stem from what he sees as a clash between the use of these techniques and his most firmly held belief that it is possible to derive standards that "... protect(ed) health, while still allowing practical industrial production", SMYTH (1979).

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* The year before Smyth published this paper OSHA (Occupational Safety and Health Administration) published a review paper on the percentage of cancers attributable to occupation (BRIDBORD et al (1978)). The estimates were very high (~ 20-30%) and caused a storm of activity in Congress and in the scientific community. As global estimates they are now seen as incorrect and the work of Doll and Peto indicates the figure to be ~4% and it could be as low as 2% or as high as 8%, DOLL and PETO (1981). It may well be that Smyth was responding to this OSHA intervention although he does not mention the work by name.

To summarise:

Smyth showed increased confidence in the capabilities of toxicology and toxicologists from the early 1980's onwards as compared with his earlier work in the 1930's. By the 1930's the ACGIH had been established, TLV's were regularly published and industrial toxicology was better established. His confidence reached its zenith in 1960 when he compared industrial toxicology to prospective epidemiology* . He based this belief on what he described, 3 years later, as "the essential uniformity of the mechanisms of living things".

He never cut free of the need for human observation or epidemiology and with more or less emphasis argued that toxicological predictions should always be checked by medical surveillance.

He never waivered in his belief that it was possible to set OEL's which were compatible with "practical industrial production".

A final general observation of Smyth's views on toxicology has been left until this point. From his first paper on the chronic toxicity of carbon tetrachloride through his various papers in the 1950's and 1960's it is clear that he understood the importance of prolonged exposure and observation in animal tests. And yet as a practical toxicologist most of his work in the three decades from 1936-1966 was on the short term testing of over 300 chemicals which resulted in the "Range Finding" series of papers. Each of these papers is prefaced with a similar statement:

"... the range-finding test is relied upon only to allow predictions of the competitive hazards of handling new chemicals. Acute toxicity studies, no matter how precisely executed, yield no more than an indication of the degree of care necessary to protect exposed workmen or lead to an opinion that certain technically feasible applications of a chemical may or may not eventually be proved safe", SMYTH et al (1962b).

This is an extremely carefully worded statement and it is not entirely clear what it means.

It appears to say that acute toxicity studied have limited utility yet at the same time the exact limitations are left ambiguous. The suggestion is left that the tests produce information on the "... comparative hazards of new chemicals ..." but this key phrase is never amplified. The statement does not say acute toxicity data is no use for assessing longterm chronic toxicity probably because Smyth could not bring himself to say this and he hid his ambivalence about range-finding in the opaque warning statement. The answer to the question of where this ambivalence came from becomes clear if one considers Smyth's writings and the constraints he described when interviewed recently, SMYTH (1984). The range-finding tests were so limited in scope because client industries would not, and Smyth argues, could not, pay for more detailed long term studies. Yet Smyth, it is clear from his written discussion on toxicology, knew that chronic toxicity studies were what were required. And he had described what he hoped would happen after the range-finding tests: "As it becomes certain that a chemical will be a regular item of commence more advanced work is performed", SMYTH (1953). The tension between what Smyth knew was needed and what industry would pay for was the ultimate cause of the ambivalent statements. And it was evident in the recent interview that Smyth was still sensitive on this subject (quotation to come).

3.9.2.2 Smyth on TLVs

Smyth was a founder member and leading light in the AIHA for over two decades. He was not a Governmental IH and was not eligible to join the ACGIH. His perceptive criticisms and commentaries on the work of ACGIH TLV Committee in the late 1940's and through the 1950's had a large impact on the thinking and activity of the Committee. He shared the platform on a number of

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* Interestingly Figure Appendix 2.1 which plots the history of various IH/medical/toxicological journals shows that it was not until the late 1950's that a journal of toxicology was founded (1959). Journals of toxicology independent of pharmacology were not created until the mid-1970's.

occasions and was cited many times by Stokinger. And that the Committee took his critical analyses to heart is evident in their actions.

Table Appendix 3.4 is a resumé of Smyth's views on OEL standards/TLV's. His views have varied. Initially there would appear to be no doubt that a safe level of exposure to carbon tetrachloride could be identified by means of animal experiments, and human observation, and that this level was practical "for any reasonable industrial operation". Later, especially in his influential 1956 paper (see later in this sub-section) he has doubts that claims to be able to identify OELs which cause injury to health can "truthfully" be made for "most of them", if the data are studied carefully. His doubts are overcome in later papers and he places great emphasis on the collective "experience" of the IH profession and soundness of the "judgements" which have to be made. His paper in 1960 is the most optimistic when he describes the TLV values as being under "constant scrutiny". His descriptions prompt a number of questions: What did the experience of the IH or industrial physician consist of? How sound, given the constraints of their experience, could the "judgement" of such people be? What was the reality of the "constant scrutiny" to which TLV's were said to be subject? The question of what "experience" consisted of for IH's is addressed in the analysis of Stokinger's work. Consideration of answers to the other questions will be deferred until the discussion of the OEL paradigm in the USA.

Table Appendix 3.3 - Smyth on Standards/TLVs (Author's emphasis)

Date	
1936	"The present work was undertaken to obtain experimental and clinical evidence on which to establish a safe concentration for CCl_4 vapours ..."
	"On the basis of animal experiments it is concluded that **100ppm CCl_4 vapour is a safe concentration for continuous exposure** ... day after day".
	"**It is practical to use the solvent** for any reasonable industrial operation **without exceeding a concentration of 100ppm**".
1953	"**The values** (TLV's) are well considered and they usually **represent the consensus of several years widespread experience** with each material ... A pressing need is for the publication of workroom analyses and clinical examination of the workmen in order to validate more fully or to correct the commonly used hygienic standards for inhalation".
1956	"**Threshold limits are**, and must continue to be **the products of judgement** ... some few truly represent their definition and are approximations of maximum concentrations which can be inhaled continuously and repeatedly without injury to health ..."
	"... In the introduction to its 1956 list ... the Committee on Threshold Limits says, 'Values are given ... for the maximum average atmospheric concentration of contaminants to which workers may be exposed for an eight-hour working day without injury to health'. **Careful study of the data which supports the currently accepted values suggests that no such description can be truthfully attached to most of them. Industrial hygienists recognise this. They are accustomed to emphasise that the values should be regarded as benchmarks, guides to good practice**". (Author's emphasis).
1959	"**The best information** we have on the greatest concentrations of respirable substances which are acceptable in the working environment **is the accumulated experience of the profession of industrial hygiene**, expressed in the annually revised list of threshold limits".
1960	"In the limited field of inhalation of substances in the occupations, we have an organised program to observe them in use and to correct the estimates of safety in accord with the observations ... This program constitutes a continuous check upon the soundness of judgements about safe occupational inhalation. We have great confidence in the validity of

threshold limits for their intended purpose. The essential constancy of the values over the year, under continued scrutiny, establishes the validity of the process of environmental toxicology by which they were derived" ... **The list of threshold limits constitutes a list of daily intakes of several hundred substances which are known to be tolerable without effect upon men**".

1962 "**It is the collection of experience** through industrial hygienists and industrial physicians, with annual reconsiderations of values, **which has made the threshold limits lists dependable**". And later, after describing the Russian approach; "Experience under standards based upon our concept, during almost twenty years, gives us confidence that we are protecting health".

1963 "It is only recently that experimental toxicology has been applied to essentially every new chemical to be handled industrially. Many chemicals were earlier put into use without experimental study. With these, **a gradual accumulation of observations ... has resulted in defining safe conditions of exposure**".

The rest of this sub-section will look at Smyth's criticisms and suggestions for improvements of TLV's, not only because of the effect they had on the ACGIH but also because they reveal something of Smyth's underlying attitude to OEL's in general.

Three years after the ACGIH proposed its first list of exposure standards in 1946 Smyth chaired a Committee at the 9th Congress on Industrial Health which considered "Hygiene Standards of Exposure", SMYTH et al (1950). The committee was comprised of sixteen members including Cook, Drinker and Stokinger and it presented the critical views of IH's and industrial toxicologists who, at the time, were not directly involved in setting OEL's although both Fredrick and Drinker had been on the ACGIH Committee on Threshold Limits.

They started by describing the current practice of the IH:

"In the industrial hygiene survey a frequent operation is the estimation of the degrees to which workmen are exposed to air-borne substances. The measurements of the exposures are made by physical or chemical analysis of samples of the atmosphere in working places. The existing exposure is usually evaluated by comparing the concentration found by analysis with a numerical value listed in one or another table of concentrations "accepted" for that particular substance", SMYTH et al (1950).

They went on to describe the four different concepts which could be identified as the basis of the MAC's:

"(a) Plus or minus: The maximal time-weighted average concentreation which produces only minor injury, and that in a very small proportion of exposed workmen.

(b) Safe: The maximal time-weighted average concentration which sound evidence leads one to believe will cause no demonstrable illness or other symptoms of toxic effect in any workman during a lifetime of industrial exposure.

(c) Bench mark: A concentration based on the belief that any unnecessary exposure is undesirable - a concentration lower than that of "a" or "b", one as low as is consistent with practical engineering control.

(d) Comfort: A concentration lower than that of "a" or "b", and representing the maximum which in a short time is not objectionable to 9 out of 10 of a group of persons not accustomed to inhalation of the substance", Ibid.

These were referred to by Smyth seven years later and are discussed more later. The Committee objected to the use of words "maximum" and "allowable" arguing that these were misleading. They

preferred "hygienic standards". Again, this point was amplified by Smyth in 1956 and is examined more fully later.

Interestingly, Yant, in a long paper on IH codes and regulations in general published a year earlier, made a very similar point:

"The commonly used terminology, "maximum allowable concentration", "maximum permissable concentration", "toxic limit", ... are unfortunate ... These phrases connote a rather precise quantitation ... they convey to many persons an understanding that such standards are (also) rather precise critical values just below which a person is safe and above which he will be injured ... Such a concept of a hygienic standard is unsound", YANT (1948).

Apart from the name the Committee felt that misinterpretation or misuse would be reduced if the table of MAC's also revealed "... which concept led to (the) selection of each concentration listed". Together with additional information including the proviso that: "The table is intended to be used by those versed in industrial hygiene", p605, Ibid. And they urged the Committee to publish the "full text of its report and not just the table. They were also critical of the fact that the MACs were published in the US PHS's Division of IH (DIH) Newsletter as this gave MACs as a quasi-legal status.

In the event the ACGIH Committee eventually acceeded to a few of those demands. They published the MAC list in the Archive of IH and Occupational Medicine in 1950. This was a new journal formed from the merged of the Journal of IH and Toxicology and the short lived Journal of Occupational Medicine. This may simply have been an opportune move in that the DIH Newsletter ceased publication 2/3 years later, or it may have been the Committee's attempt to reach a wider audience. In 1953 the first preface to the ACGIH TLV list was openly published. Apart from these changes none of the other suggestions were actioned until the early 1960's. The ACGIH simply published the TLV list, plus preface, all the way through the 1950's and into the 1960's (see Section 5.??) for a resume of the evolution of ACGIH Chemical Substances Committee policy).

Apart from criticisms of ACGIH policy the Committee had two important points amongst others, to make about the use and state of toxicology. To increase the "accuracy" of "accepted hygiene standards" they wanted all clinical observations published as:

"The majority of hygienic standards are based on injury or objectionable effects; **the standard is approached from the high concentration side.** It is desirable that the low side of each standard be more definitely defined by the collection of reports of exposure **which were without detectable effect**", Ibid (Author's emphasis).

In two sentences the Committee touch on two factors which became central in the debate on the basis of standards in the 1960's. The US, and Western approach in general has been to "approach(ed) from the high concentration side". And the use of the phrase "... exposures which were without detectable effect" raises two questions; how sensitive were the epidemiological methods that were employed and how does one define "detectable effect". The Committee also reminded its audience that:

"... If there exists sufficient knowledge of the behaviour of a chemical in the body, the estimation of one of its metabolites may yield a better approximation of the degree of a workman's total daily exposure than can a time-weighted average based on air analysis", Ibid.

And again the issue of biological monitoring was not officially actioned by the ACGIH until almost four decades later when the first Biological Exposure Indices (BEI's) were published. The Committee knew that biological measurements could be useful but IH's generally and ACGIH in particular were to be firmly wedded to air sampling and air standards for many years to come.

On a different issue the Committee sounded a warning:

"... facilities for the toxicological study of new chemicals are inadequate to devote sufficient attention to all the new commercial products developed each year", Ibid.

In the federal context the fulfillment of this demand had to wait upon the creation of NIOSH and later the National Toxicology Program (NTP).

In 1953 Smyth described what he believes to be the IH's emotional attitude to OEL's:

"The IH feels insecure ... until he has an authoritative statement of a value known variously as the hygienic standard of inhalation, the threshold limit and the maximum allowable concentration. When he has obtained such a statement his insecurity tends to approach zero", SMYTH (1953).

He then goes no to describe the various reasons why the IH needs to be circumspect including the time dependency of the toxic effects of some substances and the possible existence of susceptible individuals. He then lists a very perceptive six questions to wihch the IH or IP would ideally like answers to for every chemical they come across.

Three years later he published a lengthy paper, given originally as his Cummings Memorial Lecture* which analysed the current TLV list, examining the basis of each value, much as Cook had done in 1946, but taking this approach further by looking at what was known of the effects of each substance at x2 and x10 the TLV.

He reiterates the criticisms of the original Committee on Chemical Agents which he chaired in 1949: the bases for the standards (TLV's) should be published, the name should be changed and the health effect of concern should be indicated. He amplifies these points:

On the need to publish the documentation he says:

"No oracular or *excathedra* statement on health deserves serious attention. Only when the facts upon which a decision are based are furnished for general scrutiny and evaluation can the decision be considered even tentatively sound, and only after there has been adequate opportunity for criticism and modification can it be considered established", SMYTH (1956).

On the question of what's in a name he spends some time discussing semantics:

"No matter how thoroughly a concept is originally presented, it always becomes known and referred to by a brief name, a catch-word. Most persons who learn of the concept hear the catch-word name, and do not go back to the original presentation. The meaning they attach to the name comes from their previous experience with the particular words", Ibid.

*Donald Cummings was the third president of the AIHA. He was killed in a plane crash in 1942 and the Memorial Lecture was organised in his memory. It was given every year by an eminent hygienist or related professional selected by the AIHA Board.

He objects to the words "allowable" or "permissible" because, "These two words have connotations of legal regulation". And continues, "Such connotations cannot properly attach to the judgement of a voluntary professional association (the ACGIH)", p3, Ibid. Then he comes to three key words regularly used by standard setters at the time:

"The values now known as threshold limits are usually identified by phrases containing the words *allowable* or *permissible*. These two words have connotations of legal regulations. Such connotations cannot properly attach to the judgement of a voluntary professional association. The identifying phrases may also contain the words *maximum, threshold* and *limit*. These words all imply that below the concentration specified, human response is negligible above the concentration it is dangerous", Ibid.

He concludes:

"In the introduction to its 1956 list (ACGIH, 1956) the Committee on Threshold Limits says, "Values are given ... for the maximum average atmospheric concentrations of contaminants to which workers may be exposed for an eight-hour working day without injury to health". Careful study of the data which support the currently accepted values suggests that no such description can be truthfully attached to most of them. Industrial hygienists recognize this. They are accustomed to emphasize that **the values should be regarded as bench marks, guides to good practice.** Indeed, the Threshold Limits Committee itself confusingly warns "Threshold limits ... should not be regarded as fine lines between safey and dangerous concentrations", Ibid. (Author's emphasis).

Smyth puts his finger on a longstanding contradiction (ie. having implied in the name that the TLV is in some way a dividing line between safe and dangerous concentrations by the use of words such as threshold and limit the TLV Committee then says that the TLV's must not be treated this way). This contradiction is more than semantic and will regularly bubble to the surface in this and the following chapters and the message and function of OEL's will be examined in some detail in the penultimate chapter.

The AIHA started to publish its hygienic guide series in the early 1950's and continues to do so. To Smyth it is a standard not simply based on toxicology but also on "good practice". And in the four concepts of level which were put forward in 1949 there is the implication in the third, the "Benchmark" level, that standards of good practice should prevent any injury.

As part of the justification for the need for more information on standards he argues that IH; "could then show that their recommendations are quite defensible, that **they are not arbitrary decisions having no regard for the realities of competitive industrial existence**", Ibid. (Author's emphasis).

What does this quotation mean or at least imply? It seems that IH's have been criticised for being out of touch with the "realities" of the work environment. Which would appear to mean that exposures in the workplaces they visit are in some cases higher than the TLV's they cite. It also implies, taking his earlier "benchmark" concept that IH's, by using TLV's, were not asking for the impossible, for pie-in-the- sky, they were asking, or should be asking according to Smyth, for exposures "consistent with practical engineering control". At this point in the paper it appears as though Smyth has convinced himself that this approach will result in safe exposure levels and will satisfy "the realities of competitive industrial existence". The next paper is concerned with the problems of how to apply a single figure OEL in practice which allows the IH some leeway in the severity of enforcement.

His solution to the problems of simply relying on a table of figures is to expand the tables to include 2 levels of standard; "... One of inoffensive level, another a concentration which cannot be safely exceeded under any pressure of practicability" and another 2 layer standard:

"One concentration should be low enough so that no injurious effect can be expected in any workman, but it may have a detectable odor, it may cause a detectable eye, nose or throut irritation. The second concentration should produce somewhat more severe, but still reversible and non-progressive effects", Ibid.

The idea was that the distance between the two standards gave a measure of how strictly the first standard should be enforced. Smyth next considers judgement:

"Judgements should be made to determine which hygienic standards for daily inhalation must be carefully observed, and which may be exceeded when it is impractical to observe them. These judgements will be most consistent if we first decide for each substance what objectionable action we are guarding against by the standard", Ibid.

He lists 9 categories of human response: (1) chronic toxicity; (2) acute toxicity; (3) narcosis; (4) irritation; (5) asphyxiation; (6) fume fever; (7) eye pigmentation; (8) cancer and (9) allergy.

In the case of chronic toxicity no leeway was supposed to be allowed:

"The lower standard for these substances should be a concentration believed not to produce any effect in any workkman, and no considerations of practicality are sufficient to justify inhalation in excess of the standard", Ibid.

And the same, if not stricter logic applied to carcinogens:

"It appears probable that the minimum cancerigenic exposure will never be defined. At this time it is prudent to set the standard for a cancerigenic substance substantially at zero, as has already been done for nickel carbonyl and no considerations can justify alalowing the inhalation of any concentration which is avoidable", Ibid.

On the question of how to approach substances where main effect is irritation he says:

"Even with strong irritants like ammonia and acrolein, physical circumstances, or a sense of duty, may keep a man at his post to be seriously injured by a concentration which, all would predict, cannot be inhaled voluntarily", Ibid.

Which would appear at first sight to contradict his earlier stated belief in the same paper that some irritation was not harmful and could not be regarded as a health effect.

He ends by claiming that "upwards of 20,000 people" consulted the TLV tables each year and harking back to one of his earlier points reiterates that:

"Despite specific disclaimers, printed with each year's table, these readers tend to regard each threshold limit as defining the line between safety and injury", Ibid.

He sees his tabulation of evidence and judgement:

"... as a beginning in the extensive job of improving communication by developing a rational and informative series of hygienic standards for daily inhaltion", Ibid.

ACGIH became more circumspect in the claims it made for its TLV's but it never changed the name and Smyth's discussion of semantics is still pertinent. Likewise his suggestions for 2 tier or level standards were never taken up. However, on the question of documentation, he was, in a sense, knocking at an open door. Within the TLV Committee internal documentation had circulated since the early 1950's. Smyth refers to it in his bibliography. His paper plus the internal documentation was the basis on which the TLV Committee prepared the first volume of TLV documentation which was published in 1962. His earlier request for the publication of the basis of TLV's in 1949 had fallen on stony ground. Perhaps his efforts in 1956 catalysed ACGIH into action. They certainly started the process of compilation and writing soon after his paper was published.

In 1959 Smyth looked at the basis of TLV's which had been on the list for at least 5 years.

He found 148 substances which had been on the list in 1953 or earlier and which were still on in 1958. For 87 substances (59%) the TLV values were the same. He examined the evidence on which the TLV had first been based and found that where it was repeat animal inhalation or huan experience and surveys the limits changed least. For the 45 limits which came into the former category he made the following observation:

"It is clear that most of these threshold limits are not relied upon to guard against chronic toxic effects although they were set on the basis of experiments designed to evaluate chronic toxicity", SMYTH (1959).

Which would imply that although animal evidence demonstrated an effect in many cases the evidence was overuled or downplayed in favour of another effect such as irritation in exposed human

populations. The 45 animal inhalation results also showed another effect. The earlier they were set the more likely they were to change:

"Three factors seem to have contributed to the situation, the increased degree of health and comfort protection we now expect from a threshold limit, increasingly stringent standards for animal experimentation, and the length of time required to detect minor objections to a threshold limit by industrial experience", Ibid.

No overall pattern was discerned and no type or combination of types of experiment seemed better than any other. What Smyth could say was that those TLV's with the greatest "safety factor" (the level which had no effect on animals ÷ TLV) changed least. He concluded:

"The pragmatic test of experience shows that experimental study of the effects of repeated inhalation by animals has been as sound a basis for setting threshold limits as any other basis which has been applied to widely used respirable substances", Ibid.

By this exercise Smyth was confirming to his own satisfaction that toxicological testing was as good a basis as any for setting OEL's.

A year later he was at his most optimistic before an audience of toxicologists as the quote in Table Appendix 3.4 demonstrates. In fact he was so convinced that TLV's represented proven safe levels that suggested that:

"More use should be made of these data in judging the safety of environmental exposures", SMYTH (1960).

And he goes on to quote approvingly of Stokinger's use of TLV's to set water quality standards.

It would appear then that at this point Smyth was wholly convinced of the OEL paradigm (Working Definition) and, as Kuhn has described, suggested that the use of the paradigm be extended as part of normal scientific activity to other areas.

Another two years later he takes both the ACGIH and ASA standard setting committees to task and discusses the impact that knowledge of the alternative paradigm used by scientists in the USSR had on IH in the USA.

Smyth is less than complementary about the ASA Z37 Committee:

"This large Committee, operating under the awkward rule of consensus, with some members unable to vote until official action of their societies has instructed them, has made less than moderate progress. Since 1957 four standards have been issued, Carbon Tetrachloride, Benzene, Toluene and Xylene. The numerical values of these MAC's are identical with the 1960 Threshold Limits Values of the ACGIH, namely 25, 25, 200 and 200 parts per million by volume (ppm) respectively", SMYTH (1962a).

Earlier he described ASA MACs as "... authoritative opinions, which are not widely referred to", p37, Ibid. His point about the numerical correspondence between ASA and ACGIH standards is of particular interest, and he raised it because in 1957 the ASA changed its definition of what a MAC represented. Before 1954 MACs were 8 hour Time Weighted Averages like TLV's. After 1957 ASA claimed that future MACs would be peak concentrations. This sudden change in definition caused some consternation amongst IHs and it is not clear that the Z37 Committee appreciated the implications of its decision. In the early 1960's the Committee reverted to the earlier definition of MAC but added other concepts including peak and emergency values.

Smyth takes the Z37's 1957 peak definition at face value:

"Thus the numerical identity of the standards of MAC and TL for four vapors, actually mean that the Z-37 Committee concludes that the exposures of workmen should be considerably less than those which the ACGIH Committee concludes are unlikely to cause adverse effect", Ibid.

He does not discuss this point any further but goes on to discuss what type of standard should be used to protect against what type of injury. He concludes that the ASA's peak MAC is good for acute effects and the ACGIH's for chronic effect but that neither organisation tailors its OEL's to the kind of injury of which a substance was capable. Returning to the numerical equivalence of 4 ASA and ACGIH standards prompts some very pertinent observations. In retrospect it seems unlikely that the ASA really intended its MAC's to be regarded as peak exposure values for this would imply a TWA exposure value at least an order of magnitude lower (depending upon the sampling time of the peak value measurement method). Assuming they actually intended the four MAC's referred to, to be 8 hour TWA's this would indicate that a tripartite committee which relied upon consensus to reach agreement had chosen the same standard as a professional scientific expert committee. The tripartite committee overtly took into account questions of practicability and cost as well as the potential health effects of a substance. Any party could veto a proposal and all decisions had to be unanimous. This contrasts with the ACGIH Committee which, according to its own descriptions of its workings and the writings of its longest serving chairman, only considered the health effects of a material in its deliberations and arrived at decisions by a scientific concensus. There are two conclusions that can be drawn from Smyth's observations:

Either the ACGIH TLV Committee was behaving like the ASA Z37 Committee and in fact took questions of practicability and cost into account in arriving at its TLV's; or it was possible to set a standard which was primarily based on health effects and when questions of cost and practicability were addressed these in reality made little or no difference to the end result, ie. a practicable, or more likely in the case of the ASA a reasonably practicable limit, turned out to be a limit which would protect "nearly all" workers.

Given the previous discussion of Winslow, Drinker and Hatch the second possibility seems unlikely. This insight into the workings of the ACGIH TLV Committee is raised here because Smyth pointed out the contradiction.

Smyth in this paper also describes the impact of the USSR's approach to standard setting on the IH community. It was one of the factors which led Smyth, Stokinger, Hatch and others to re-examine the basis of TLV's and to mount a concerted defence of the OEL paradigm.

According to Smyth the work of the Russian standard setters only became generally known in 1957 following the seventh International Congress on Occupational Health in Helsinki. He describes the impact of this contact:

"... serious uncertaintly was evoked several years ago when it was rumored that values enforced in Russia are in some instances one-tenth or less of the ACGIH values. It was obvious that such a difference could be due only to a difference in concept of waht the values should accomplish, because it is thoroughly demonstrated in American industry that guidance by the ACGIH values results in safe working conditions", Ibid.

In this statement he apparently has no doubt about the soundness of the American method. The "rumours" he alludes to at first sight might seem odd as the USSR had been setting OEL's for decades. However the scientific communities of East and West concerned with occupational health had been relatively isolated especially in the years of the Cold War immediately after World War Two. The period when IH began to consolidate as a profession and OEL's were developed and used widely. Smyth lists various translations of Russian work on "Limits of Allowable Concentrations of Atmospheric Pollutants" which were published by the USSR from 1952 onwards. The PHS began to translate them after the Helsinki conference and the bulk were published in 1959 and 1960. It was only once this was done that US scientists could begin to explain to themselves why the Russian standards were different. There was in effect a clash of paradigms and this will be explored in more

detail at the end of this chapter. The concern here is with Smyth's response and what this reveals of his views on OEL's.

Based on the translations Smyth describes the Russian experimental approach and ends:

"By relying upon the results of these six tests, the Russians indicate their belief that people should not be subjected to inhalation of a substance at a concentration which results in any detectable physiological response ... **I have seen no evidence that experience in industry plays any part in setting their standards**", Ibid. (Author's emphasis).

He quotes the example of benzene for which the Russian MAC was 6ppm whereas:

"This is to be compared with the ACGIH figure of 25ppm, based on long industrial experience", Ibid.

Two other examples were dichloroethane (US = 100ppm cf USSR = 2.5ppm) and formaldehyde (US = 5ppm cf USSR = 0.08ppm). Smyth places great store on "industrial experience" or simply "experience" and this phrase or word crops up again and again in his discussion of the Russian approach and defence of the ACGIH method. Great weight is given to "experience", for more than in earlier papers and nowhere does Smyth explicitly describe what he means by the word. The meaning is left to define itself implicitly.

Smyth travelled to Russia in 1963 as part of a delegation to investigate the occupational health system. Apart from the report of the visit this paper is the only other time Smyth deals with the differences in philosophy between the USA and USSR. In his case their approach appears to have been so alien and extreme that for him it was not science as he knew it and therefore did not have to be addressed seriously. Stokinger as head of toxicology in the PHS and Chair of the ACGIH TLV Committee all through the 1960's was far more concerned to defend the ACGIH way. And Hatch, of all the scientists considered in this chapter, was the person who faced the implications of the Russian OEL paradigm and produced a synthesis which appeared to incorporate the Russian school of thought while preserving the ACGIH/US paradigm intact.

A year later Smyth published another paper which outlined and defended the four axioms that he believed governed the application of toxicology to standard setting and IH.

3.4.3 Concluding Comments on Smyth

Smyth did not comment on any set of standards in particular and did not mention OEL's again until 12 years after his retirement in 1979, when he made this statement:

"Measurement, interpretation and correction of exposure is the only new tool for the protection of occupational health introduced since the 1700s of which Ramazzini wrote. After about 30 years of reliance upon TLV's, we are in the process of shifting to OSHA standards. To the extent that OSHA standards may better protected health, **while still allowing practical industrial production** the change cannot be lamented", p323, ACGIH, (1984b).

Having described his early experiences of bad conditions in industry he continues:

"I attribute a major part of the improvement to the promulgation and application of TLV's", Ibid.

Whatever the various views Smyth had of OEL's and TLV's in particular, and he certainly changed his views over his career, he defended them as a hygienist. They were an innovation and their application dramatically improved conditions in the workplace, "while still allowing practical industrial production".

In a revealing passage he goes onto examine the benzene standards which at the time had just been lowered to 10ppm by OSHA. He starts and ends with Winslow's study:

"He said that 100ppm was the lowest exposure that engineering known-how of this day could maintain. He said that injury developing in those exposed to 100ppm (and careful study of his tables shows that he found one-third of them responding adversely) would not be irreversible by the time that periodic medical examination could detect it. Since Winslow's day we have found no new information which defines a lower acceptable level of exposure, but our concept of what is acceptable has changed", Ibid.

In this quotation Smyth is misinterpreting Winslow's work as the analysis of NSC report shows. It was evident that ~ 1/5 of workers would be affected at 100ppm, some would be identified and removed quickly enough to recover, others would die. The revealing point is not that Smyth misinterpreted Winslow's work but that he shows where his faith and optimism came from. He himself had been exposed to benzene at concentrations way over 100ppm while doing IH work in 1926 which caused no untowards effects apart from a "trivial response" in his white cell count. Smyth continues:

"At about the same time, a friend worked in a linoleum printing operation, cleaning printing blocks over an open vat of benzene, with no ventilation whatever. Every night he was essentially drunk from inhalation of vapors, and probably also from skin penetration. His exposure must have been a multiple of the 100ppm standard being set by Winslow at about the same time. My friend did not realize until years later that he should have been severely injured, or doomed. He is alive and well today", Ibid.

Smyth had not practiced IH for some years when he wrote this passage and he was probably feeling provoked by current events. It could be argued that his views are not representative of his time as an IH/industrial toxicologist; perhaps so but I believe it is unlikely. It is more likely that his views on benzene are a magnified version of his personal gut feelings for toxicology and human health. In a nut shell; he had seen massive exposures yet no apparent harm, he believed in homeostasis and in reality that human metabolism required and responded well to "sufficient challenge" and he also knew from his own experience as a practicing IH that adherence to TLV's usually represented a great improvement in working conditions.

My contention is that this powerful reality informed his views on toxicology and IH all his professional life. This was always part of the, usually tacit knowledge that shaped his views when he thought, wrote or spoke about TLV's or OELs in general.

There are other patterns evident in his writings. He, like Stokinger, varies in his belief in the possible use of toxicology and his belief in TLV's. Smyth the toxicologist is generally more optimistic on both counts than Smyth the hygienist who is more circumspect and pragmatic. Also, like Stokinger, Smyth in the 1950's is more careful in his claims for TLV's than the 1960's.

Looking back over Smyth's career and writings which span the evolution of IH and the OEL paradigm it is difficult to give a simple answer to the question; what are TLV's in Smyth's view? At different times TLV's have been "Benchmarks of good practice"; (1956) "a list of daily intakes ... which are known to be tolerable without effect upon men" (1960); "accumulation of observations ... has resulted in defining safe conditions of exposure" (1963) and ... the only new tool for the protection of occupational health introduced since the 1700's ... (which) still allow practical industrial production ..." (1979). In his influential critiques of TLV's in the late 1940's and throughout the 1950's it is quite evident that Smyth could see the problems inherent in setting a single number standard and understood the limitations of the data, such as was available. However he never reconciled the problem of whether it was in fact possible to set a limit which not only protected health but was "practicable". His solution was to imply, in effect, that there was no problem. As his adherence to and defence of TLV's grew during the 1980's he, like Stokinger, laid more and more emphasis upon his lexicon of three repeated words "experience", "judgement" and "observation". Not being actively involved in OEL standards setting Smyth does not delve into what those words mean in practice. His repeated reliance upon experience and observation as the

backstop against which TLV's are judged to be safe puts a heavy burden upon occupational epidemiology. And it must be said that while Smyth certainly combined the skills of a hygienist and a toxicologist he was not an epidemiologist. The question of what experience and observation might be in practice is addressed in the section on Stokinger.

APPENDIX FOUR

ANALYSIS OF TLV COMMITTEE MINUTES 1962-1984

4.1 Analytical Method

The Minutes give enough information to identify the main person on the Committee or Sub-Committee responsible, for instance, for writing documentation or proposing a TLV for discussion. They also record which people and what companies should be contacted concerning particular substances. Where the committee deals with contentious or difficult issues the main points of the discussion are recorded. An example of the TLV Committee Minutes is given at the end of this Appendix.

The analytical method was simple:

Firstly I was concerned to see where the Committee got its information from and what that information consisted of. Table Appendix 4.1 therefore consists of 140 instances where data, suggestions or recommendations were received from outside, usually industrial, sources or where a comment was recorded which related to a particular TLV number. Not all the instances were therefore judged to represent influence by outside organisations. (see for instance, item 6 in Table Appendix 4.1). A summary table of abstracted totals under different categories is presented in Table Appendix 4.3.

Secondly, I was concerned to identify discussion or decisions on ACGIH TLV Committee workings, policy or process. The results of this selection process are to be found in Table Appendix 4.2.

Examination of the results of this analysis are to be found in Chapter 8.

Table Appendix 4.1
ACGIH TLV Minutes references to suggestions, sources or recommendations received from outside organisations or generated internally

Date		
26/27.11.62	1	New South Wales, (Australia), investigators want phosphine limit raised.
	2	Corning Glass Co to be contacted concerning Fiberglass definition.
	3	Beaman (Proctor and Gamble) suggested a TLV for dimethylamine. Thought to be too high by Committee.
2/3.3.64	4	Kettering Fiberglass report indicates average exposure ~ 1.25 mg/m^3 **below** the TLV being considered of 5mg/m^3.
	5	Phosgene proposed TLV sent to Zapp at Dupont; "can Zapp provide Dupont plant data?"
	6	Silver TLV - "Feeling that 0.01mg/m^3 is pretty low to maintain, but accepted".
15/16.11.65	7	Acetonitrile: "Leave at 40ppm hold for consideration until receipt of new data from RD Montgomery, Sohio Chemical Co".
	8	Beryllium (NIC) - "Possible revision upward". Stokinger commented on recent data and comments from Berylco and British Beryllium (Company)".
	9	"Hexachlorethane - leave at 1ppm. To be considered for possible revision upon availability of industrial data. Baier to write to James Morgan, Dupont, for information".
	10	Maleic anhydride - "Stokinger to write to Reichold Chemicals for data on Maleic and Phthallic anhydrides".
	11	"Diphenyl phosphirous - contact Stauffer Chem Co for data".
	12	"Baier: Hexamethylene diisocyanate - 0.02ppm. Contact Zapp (Dupont) about level".
	13	"Iso-propyl chloride. Dow Chem for data".
18/19.4.66	14	"Check with Shell on the tentative 100ppm value".
15/16.11.66	15	"Gross suggested that decision for change be withheld until Spencer (Dow) data is completed. Be (beryllium) value is in all probability too low but how high should it be set"?
	16	Carbon monoxide - "Frederick commented that steel industry less concerned with lowered value (50ppm) than when it was first announced. Values in steel plants found to be around 50-60ppm".

17 "Revised report from Zenz (Allis Chalmers) on V_2O_5 exposed workers to be evaluated before a change considered".

18 Boron tribromide - "Write to American Potash and Chemical Corp for toxicological data".

19 Diethylenetriamine - "Write Schaefer (Shell Corp - Resin and Plastics Div)".

20 Diphenylamine - "Mastromatteo to contact Canadian manufacturers (Div US Rubber). Macfarland check with J Wolfsie, Med Div, US Rubber."

21 Silanes - "Contact VK Rowe for data (Dow Chem)".

22 Xylene hexafluoride - "Write VK Rowe (Dow Chem)".

30/31.3.67

23 "Stokinger and Zavon commented on their March 22, 1967 meeting with representatives of the chromate industry for the purpose of learning whether the present TLV for chromic acid was protecting the workers. It was concluded that the present limit, although it protected against perforation of the nasal septum, had a very low (2-3 fold) factor of safety (0.4 mg/m^3 can produce (perforations)), and that the limit (0.1 mg/m^3) probably was sufficiently low to prevent the development of bronchogenic carcinoma although only one of the 4 manufacturers has had approximately sufficient experience to make such a determination". (The current chromic acid and chromate TLV at the time was 0.1 mg/m^3).

The importance of the chromate industry's co-operation has already been discussed in Chapter 9.0. It would appear, from this minute, that industry data and interpretation were very influential in determining the TLV for chromates.

24 EGDN/NG: Statement developed from meeting of representatives of industry and TLV Committee accepted: "An atmospheric concentration of 0.2ppm, or personal protection may be necessary to avoid headache".

25 Isopropylether - "Stokinger write Union Carbide for industrial exposure data".

26 Vanadium - "Zavon suggested a meeting of representatives of the TLV Committee and industry to discuss V compounds".

13/14.11.67

27 Kehoe has written to Stokinger suggesting a downward revision of the tetraethyl and tetramethyl lead TLV's. "Zavon to contact TEL manufacturers and blenders in an attempt to obtain their recent experiences with the compound". The TLV's were revised upwards from 0.075 mg/m^3 to 0.1 mg/m^3 and 0.15 mg/m^3 respectively. Because of a change from static to personal sampling.

28 "O-chlorostyrene - deferred - justification written but deferred pending confirmation of industry data release from Rowe (Dow Chem)".

6/7.11.68	29	Methyl chloride - "Stokinger contacts ... Dow for current data to substantiate 100ppm value. What are the minimal signs (and dose) of methyl chloride intoxication in Dow employees?"
	30	PTFE decomposition products - "Stokinger to rewrite A4, suggest a level, and forward to J Zapp (Dupont for review and additions").
	31	2/4-vinyl pyridine (a potential new addition). "Stokinger contact Dow Chemical".
1/2.4.69	32	Decision deferred "1,1,2-trichloro, 1,2,2-tri-fluoro-ethane - Stokinger cited Dupont documentation and March 1969 discussion with Reinhardt and Stopps (Dupont)".
	33	"Formaldehyde - deferred. Defer pending data from R Clyne (American Cyanamid) on the extent of formaldehyde exposures in industry".
5/6.11.69	34	"Asphalt fumes (Mastromatteo) No change Surveys (7) of Canadian industry support the current TLV". No mention of whether the surveys were epidemiological, concerned with health effects, or hygiene, concerned with current exposures.
	35	Butyl alcohol. Proposed reduction from 100-50ppm. "Stokinger contact D Fossett (Kodak) for industrial data".
	36	"TDI. No Change. 0.02ppm Mastromatteo reported that recent plant survey data is at or near the TLV. Does value provide adequate safety?" The Committee know what exposures were occurring in industry but what does the concern about adequate safety indicate?
	37	"Stokinger: To solicit comment from Hayes on impact of reducing limits as regards agricultural chemicals now listed or prepared". (This refers to the reduce of the Nuisance Dust limit).
1/2.4.70	38	"Diethylene triamine - Reduce 10ppm to 5ppm Reduction questioned. Industrial experience do not support".
	39	"2,4,5-T (Rowe) No change. Dow industrial experiences are negative".
	40	"Vinyl chloride (Rowe): Reduce to 200ppm. Dow data supports reduction. (March '70 review of medical and industrial hygiene records from industrial exposures)".
19/20.11.70	41	Chloroform "Reduce 50ppm to 25ppm. Obtain data from Dow Chemical (Torkelson) on rat toxicity".
	42	Dibromethane No change. C25ppm Torkelson review Dow data (industrial) and forward data to Elkins".
	43	"Fluorine. No change, 0.1ppm. Stokinger contact Dernell (Union Carbide) for data".

44 Lead "Stokinger reports on a joint AIHA - ACGIH meeting. "Present TLV, 0.2 mg/m^3 acceptable to industries represented. Caplan and Padden in favour of reducing limit".

45 "Hexachlorocyclopentadiene (Zavron) Discuss with McGilvray (Shell Chemical) Develop document (0.1ppm)."

8/9.4.71

46 "Methylene bischloranline. Deferred. Dupont data to be published."

47 "Paraffin wax fume. (Elkins) - Revise documentation. Contact R Scala (ESSO) for references".

18/19.11.71

48 "Dichlorobenzidine (Smith): Upjohn questions listing of DCB in Appendix A ... Consider applying EC (experimental carcinogens) notation to such substances as DCB".

49 "Caprolactam (Smith): Industry questions TL reduction to 5 mg/m^3. Data from R Brief (ESSO) justified".

And again later - "Request additional data from Brief. J. Morgan to check Dupont experiences".

50 "Subtilism (Stokinger): Defer action for reduction to 0.00006 mg/m^3 until representative industries are consulted on tentative Committee action to reduce value".

51 "Vinyl chloride (Torkelson). No change 200ppm Stokinger discussed correspondence from Dramer (Dow) and Knapp (Allied Chemical). Request Knapp to provide data justifying retention of the adopted c500ppm value."

52 Stoddard solvent - "include data from Natl Inst of Dry Cleaning and API".

53 "Baygon (R) Zavon to contact Spea (Natl Pest Control Assoc) for opinion on proposed limit" ...

13/14.4.72

54 "Report of sub-committee on hydrocarbons". Various changes are considered based on American Petroleum Industry (API) data via R. Scala. The data are judged as, "indicative of a possible need for re-evaluation of these TLV's."

55 The Ammonia TLV is considered.
Ferguson from Allied Chemicals has written. It is not clear what it is in Ferguson's letter but it certainly points out that with regular exposure workers become "inured" and complaints from people, such as office workers, occurred because they do not become "inured".

"Stokinger to request Allied Chem to provide data on the rapidity and degree of worker inurement to NH_3 ... Is cost of engineering control warrented for the few employees who complain? Should TLV Committee consider two limits for those substances which produce inurement - continuously exposed workers (day after day) vs intermittent, occasional exposures?"

56 Butyl lactate "Stokinger contact Phillip Co for data substantiating their recommended 1ppm value". In 1975 the Tentative TLV was listed as 1ppm.

57 "Caprolactam (Smith). Recommended that two limits be listed (based on data from Ferguson - Allied Chem)".

58 Carbon dioxide "Stokinger presented data (by CJ Lambertsen) from Liquid Carlonic Corp". The Committee was undecided.

59 Dimethyl sulphate Morgan Listed as an experimental carcinogen. Quotes a Dupont study of production workers showing no effect.

60 "Dioxane Torkelson Reduce100ppm to 50ppm. Dow Chem experimental data showed carcinogenic potential at high concentrations".

61 Isophorone - "Morgan to forward data from Dupont. GD Ware (Westem Electric) may have additional information contact".

62 Subtilism (Stokinger)
Statement from R Fuliviler (Proctor and Gamble) concerning proposed change in TLV. "Defer action. Blejer to report on California enzyme/detergent industries exposure data. Fuliviler to provide Committee with P&G industrial experience data to substantiate position".

63 Adipic acid - "Morgan provide data on Dupont plant practices and incidence of dust exposure".

64 "Isoparaffins (Melvin) contact J. Hammond (Humble Oil) for data".

16/17.11.72

65 Acetone - "New data from human experience ... Consider reduction of TLV? (Contact B. Astill, Eastman - Kodak)."

66 Coal Tarpitch "No change A1a 0.2 mg/m^3. Reference made to letter from MacClay (Koppers Co). Send note of appreciation for data".

67 "Dimethyl sulphate - Morgan No change A2. Deferred ... current enviromental (plant) data will be provided to the TLV Committee" (from Dupont).

68 Butyl lactate - "Reference made to letter from D Turner, BP Co. Analyses may have been in error on British and Dutch plant surveys. Defer until differences resolved".

69 "Ethyl lactate - R. Henderson (Olin Corp) will do human volunteer, 4-hour inhalation study".

70 Mono isopropanolamine - "contact C Dernehl (Union Carbide) for data".

71 Petroleum distillates "Request C Carpenter/R Scala, API Toxicology Committee members to speak to TLV Committee at next meeting. Purpose is to clarify definitions of petroleum distillates. Should Stoddard solvent value be reduced from 200 to 100ppm?"

72 Vinylcyclohexane. "Stokinger contact C Dernhel (Union Carbide Group) for additional data relative to carcinogenic potential, other toxicity data and industrial experiences".

3/5.5.73

73 Acetone - Morgan "Recommended that environmental data be collected to substantiate any reduction of value".

74 Butyl lactate - No change, 1ppm. "Contact SG Luxon at Boston Conf".

75 Copper fumes raised 0.1 mg/m^3 to $0.2mg/m^3$. "Modify doc to include data, from Luxon (England) letter of 1 Aug, 1972"

76 Dimethylsulphate (Morgan) No change, A2. "Dupont will have acceptable analytical method by 1 June. Environmental sampling will follow to estimate the degree of worker exposure as a possible human carcinogen".

77 Lead, inorganic. 0.15 mg/m^3 is proposed, a lowering of the limit. Chairman of the sub-committee agrees to meet lead industry representative with NIOSH personnel to "review statistical evaluation of data submitted by lead industries".

78 "Arc-welding fumes (Elkins) Stokinger send copy of Elkin's doc to F. Speight, Amer Welding Society, and HB Cary, Hobart Brothers Tech Center for comments".

79 Benzyl dimethyl amine - "contact C. Carpenter (Union Carbide) for data".

80 Ethyl lactate "Develop Doc. Henderson (Olin) to provide industrial data".

81 Isothaloinitrile - "Prepare documentation. Data available from Sherwin Williams Co?"

82 "Petroleum distillates (Stokinger). Hydrocarbons sub-committee to develop TLV's from API data".

83 "Thioglycolic acid (Stokinger). Data available from Gillette and Alberto-Culver"?

84 "m-Xylene diamine (Zavon) - Data available from Sherwin Williams Co and Dupont"?

1/2.11.73

85 "Dimethyl sulphate (Morgan) No change. A2. Dupont epidemiological study completed. Report will be forwarded to Stokinger".

86 Isophorone - "Data from G Ware (Gen Elect) letter of 26 June 73 supports reduction".

87 Phosgene - "Defer revision. Contact Z Bell (PDG) for data on current phosgene study (industrial exposures) and for analytical method sensitive to 0.02ppm".

	88	Chloroethamine. "Deferred. Contact Eli Lilly for information on product use, exposure data, etc".
	89	Cyanamide "Contact B Shaffer (Am Cyan) for additional data".
	90	Dibutyltin diacetate. "Contact AW Sheldon (Tin Research Inst) for data".
	91	Potassium permanganate. "Contact Imp Chem for data".
	92	Resorcinol. "Contact Koppers Co for data".
	93	4,4-Thiobis. "Prepare doc data from Monsanto".
	94	1,2,4-trichlorobenzene "Dow studies in progress".
	95	Tobacco dust. "Contact Am Tob Inst for data".
	96	"m-Xylene,-$\alpha\alpha^1$-diamine 5ppm prepare doc (Dupont data)".
16/17.4.74	97	Dimethyl sulphate (Morgan). Morgan relates progress of Dow epidemiology: "... Studies indicate expected incidence of non-DMS malignancies. No cases of larynx or bronchial malignancies reported".
	98	"Tobacco dust (Stokinger) - tabled. No information according to Amer Tob Co".
20/21.11.74	99	"Isophorone (Stokinger). No change. C5ppm. Validity of "intended value" questioned by D Turner (BP Co). Review data from G Ware (Western Electric)".
	100	Manganese fume. "Contact Witaker (Bethelehem Steel) for data. Lieberman obtain Brementon shipyard data and forward to Stokinger".
6/7.5.75	101	Atrazine (Steinberg). "Get data from Ciba-Geigy. Prepare doc".
	102	Benlate - "awaiting Du Pont data (J. Zapp)".
	103	"Bromacil (Morgan - Steinberg). Deferred doc prepared. Get additional data (human from DuPont. Modify statement in skin irritancy".
	104	Captafol. "Steinberg contact Dr Richmond (Chevron Chem) for data. Stopps contact Ciba-Geigy for data".
25/26.11.75	105	"Atrazine - no new data available from Ciba Geigy. Data from K Long lab will be presented at next TLV meeting".
	106	"Antimony trioxide production (Stokinger) No change. Documentation based on British industrial experience and input from Harshaw Chemial Co".
	107	"Cobalt (Fredrick, Stokinger) 0.1 mg/m^3 to 0.05 mg/m^3. Final decision on value awaits response from industries concerned. Animal data alone cannot justify reduction to

0.01 mg/m^3". In 1981 cobalt was put on NIC at 0.05 mg/m^3. This is because the TLV in 1987/88.

108 Phosgene (Morgan). No change. Dupont conducting rat inhalation study at 0.2, 0.1 and 1.0ppm, 4 hour exposures, 5 days per week for 2 weeks. Final report due in about 3 months. Study is for confirmation of British data (Cameron)".

109 Stokinger met Salt Industry Institute representatives to see whether a Sodium chloride TLV could be set. The industry was to supply the data if it existed. No TLV has ever been set for sodium chloride.

110 "Chrome pigments (Morgan). No change. 0.1 mg/m^3. Final report on chromate industry studies not completed".

111 Paraquat - "Schneider send Chevron data to Stokinger".

112 "Phosgene (Morgan) c.0.5ppm to 0.1ppm. Morgan reviewed doc prepared by Steinberg. Cameron study criticised. Morgan revise doc and include Dupont animal inhalation studies and industry environmental/medical data".

6/7.12.76

113 Hydrogen cyanide. "Stokinger will contact Woolsey, Medical Director, Equitable Life Ins Co, for most recent information".

15/16.2.77

114 H and HH sub-committee: The API summary on hydrocarbons was tabled.

115 Diesel fuel - "Torkelson will ask API for human experience data ... Melvin will contact Shell, Phillips and Exxon".

116 "Methyl chloride - Nothing positive indicating need to lower limit. However, the margin of safety at 100ppm is small. Dow Chemical has begun suggesting 50ppm as a guide for industrial exposure. Torkelson will rewrite documentation for committee consideration at September meeting".

(NB: Methyl chloride TLV was listed as 50ppm in NIC (1979) down from 100ppm. It remains at 50ppm in 1988).

The Dow internal company limit became the ACGIH TLV.

7/8.11.77

117 Chlorine - "NIOSH recommends 0.5ppm ... decision be postponed until Ralph Smith has completed Chlorine Institute Study". The Committee argued that the NIOSH criteria document "did not support a reduction from the 1ppm standard".

118 "Manufacturers of flurocarbons solicited for updated reviews on the following compounds:

trichloromonofluoromethane
dichlorodifluoromethane
dichloromonofluoromethane
monochloromonofluoromethane

recommend a TLV of 15ppm, animal carcinogens".

119 Tetrasodium pyrophosphate. "Agree with Dow, recommend TLV of 5 mg/m^3".

12/13.4.78

120 Trimellitic anhydride. NIOSH had produced a report. A supplier of the material suggested a TLV of 0.05 mg/m^3. Three years later the Committee recommended a TLV of 0.005 mg/m^3, x10 lower.

121 Silver - raised to 0.1 mg/m^3 because workers in the Taunton silver mines exposed in excess of this value show no signs of argynosis.

23/24.4.79

122 Silver - "Letter from Kodak on soluble silver to be added to documentation".

123 "Navy found that NG (Nitroglycerin) may cause headaches at levels slightly above 0.2ppm. Elkins recommended 0.02ppm, STEL 0.04ppm. This change from 0.02 ppm was accepted".

The "safety margin", if the US Navy's work is accurate, would appear to be slim, especially as 0.05ppm was "finally adopted, (see Table 16.2 item No. 152).

124 "Isopropoxyethanol: An addition. A TLV of 25ppm prepared by Shell (GB). Accepted".

125 Grain Dust TLV "... based on work performed by the Univ of Wisconsin under a NIOSH contract".

126 Amoco requests that Trimellitic anhydride TLV be put back on NIC at 0.05ppm. Request was ignored, TLV set at 0.005ppm.

127 "Rhodium information awaited from supplier". (Johnson & Matthey).

19/20.4.82

128 Gross proposes a grain dust TLV of 4 mg/m^3. "General Mills and Grain Association believe it is too low, but don't give any reason. They want to talk to sub-committee in June ..." A TLV of 10 mg/m^3 was eventually set in 1987.

129 "Cobalt - ready to move last year (1981), but communication from cemented carbide industry has study in progress. Hold until data is developed". Cobalt TLV was reduced from 0.1 to 0.05 mg/m^3 in 1987.

130 "Phosphorous oxychloride: Dow experience indicates it might produce delayed eye irritation".

131 Ethylene oxide: "Johnson and Johnson in a preliminary report linked chromosomal effects in employees. Survey included several plants. TLV of 1ppm based on this study".

132 "Hexafluoroacetone: Should have skin notation based on new information from Dupont".

30/31.8.82

133 Formaldehyde. "It was reported that Dupont uses a TWA of 1ppm and a STEL of 2ppm". The TLV at the time was a ceiling of 2ppm. This was reduced to 1ppm in 1985.

"Epi studies by Dupont have not found any problems (about 2,000 people studied)".

134 2-Nitro-propane - "Purcell of Angus Chemical and Don McPhee of Occusafe ... laid out a number of questions and McPhee demanded answers". (No change was made, apart from eliminating the STEL value in 1988).

26/27.3.84

135 Angus Chemicals argued that the rat was not an appropriate experimental model for 2-Nitropropane because of high liver glutathione levels. The Committee rejected their reasoning saying here was; "No proof of the theory".

136 1,3-butadiene. "Present TLV is 1,000ppm. Rats and mice show oncogenic response at 625. Industry levels are in the range 3-5ppm ... Wagner ... wants to set a 10ppm TLV with an A2 designation".

A 10ppm TLV, A2 designation joined the main list in 1988.

137 "Acetyl acetone: Walt Melvin recommends 100ppm, but very little information is available on this substance. Ted Torkelson suggests he call Kodak and talk to George Divincenzo".

138 Amitol - "Kimmerle provided a document with a TLV number, but deleted the A2 designation". He argued that "thyroid hyperplasias and thyroid tumours in rats has no significance for human conditions".

139 Persulphates: (Sulphur fluoxide) Correspondence with the industry shows; "... that industrial operations have been running at 5 mg/m^3 without problems". (No irritation).

Committee decide to raise the TLV from 2 to 5 mg/m^3.

140 Carbon dioxide. The Navy argued that 50,000 ppm was OK. The current TLV was 15,000. A TLV of 30,000ppm was agreed.

The Committee appears to have split the difference.

APPENDIX TABLE 4.2 ACGIH STANDARD SETTING POLICY AND PROCESS

Date		
26/27.11.62	1	MacFarland, a member of the Committee works for Hazelton Laboratories. Query concerning his eligibility. Board of Conference to decide. Results - appear to have decided in his favour - he remains on the Committee.
2.3.63	2	Discussion of whether "problems of interest to the Committee be published as possible research problems". Never done publicly but perhaps unofficial professional contacts were made.
	3	Under the heading "More systematic approach to TLV list" a discussion on how substances should be chosen ensued. Two choices: "... tonnage production of chemicals or via a survey of the AIHA/ACGIH membership.
	4	Long discussion of whether the "primary effect" of a substance should be listed, as Smyth suggested in 1956. Committee rejected the idea.
2/3.3.64	5	Still discussing, "how often and how many new substances should be added to the list". Appear to have decided upon periodic review of US Tariff list of organic compounds plus experience of State units.
	6	AIHA approach rejected (see Chapter 7).
18/19.4.66	7	The AIHA-ACGIH Committee attempt to draft a joint statement on the use of TLV's. Committee adopts the following: "This conference does not consider TLV's appropriate for adoption in legislative codes and regulations unless the intent of the concepts contained in the preface be maintained and provisions be made to keep the list current".
	8	Committee responds to comments and criticisms of the "IMA Committee on Industrial Hygiene". "We will not add MD's to the Committee ... it was pointed out that four of our present members are medically qualified ... we are well aware of the impact of our actions on industry since at least seven of our members are in intimate contact with industry". The criticisms implied by the response sound very similar to those made early on in the Committee life, ie. not enough doctors and out of touch with industrial reality (see Chapter).
	9	In November 1965 MacFarland proposed 8 subcommittees but the Committee eventually accepted a proposal by Smith for 6 sub-committees: (i) Inorganic compounds, chair - Stokinger (ii) Economic poisons, chair - Hayes (iii) Insoluble respirable dusts, chair - Gross (iv) Oxygenated organic substances, chair - Smith (v) Hydrocarbons and halogenated compounds, chair - Elkins (vi) Miscellaneous organic compounds, chair - Mac Farland

15/16.11.66 10 The ASA Z37 Committee was considering a 10ppm limit for chloroform. Irish, chair of the ASA Committee wrote to the ACGIH suggesting it lowered its current TLV of 50ppm. Committee decided to wait. (In 1971 the Committee proposed halving the TLV to 25ppm). It was added to the list at this value in 1974. Two years later the committee added it to the NIC lis at 10ppm (A2) which became the adopted value in 1978.

11 Baier comments on the reception of Pennsylvian short term limits - "compliance with and acceptance of the regulations have been well received by industry".

12 "Uranium 6+ (soluble) Stokinger to write to C Morgan (Oak Ridge) and request data supporting NCRP level of 0.25 mg/m^3. This data to be received by Committee for possible revision of existing TLV to coincide with NCRP level.

13 Formaldehyde - "Considerable discussion as to supporting data for reduction of existing value. Equivocal data on human responses at lower concentrations, 3ppm. Committee decision to leave value at existing 5ppm level". (NB: 1970 NIC = 2ppm, 1981 NIC = A2 (Suspect of carcinogenic potential), 1983 NIC = A2 and TLV of 1ppm).

14 Short Term Limits - Mastromatteo suggested a new Committee and Zavon an extra committee member. Committee decided "... that for the time being no committee be formed to consider STL's nor should the TLV Committee assume this task. "C" values adequate at present".

15 Draft preface to the Notice of Intended Changes (NIC):

"This NIC is published so that industry-connected individuals principally, but others also, may have an opportunity to help shape the deliberations of the Committee prior to its recommendations of tentative changes in the 1966 Threshold Limits list".

The preface was never published in this form and a far more neutral one was eventually published. Although it would appear that the NIC with the quotation above was circulated to industry "and the IHF/AIHA".

30/31.3.67 16 Air Pollution Limits vs TLV's: ... These values are so low and of such uncertain validity that they may ultimately undermine the TLV's for industry. Labor backers may make active objection to exposure of their workers at levels often many times greater than that permitted for the same substance for their families".

The question of low air pollution limits touched a sensitive spot in the mid-late 1960's.

17 Segregation of Limits. Committee opposed to listing TLV's on a "basis of comfort and/or good industrial hygiene practice".

Presumably the separation proposed was based on those TLV's set on the basis of known health effects and those based simply on comfort criteria or what could be achieved by "good IH practice". This proposal harks back to a similar point made by Fiarhall and his

discussion with Morse in 1947, twenty years earlier (see Chapter 7.0, sub-section 7.4.3).

18 Carcinogens. Should a separate listing be made in TLV's of carcinogenic or potential carcinogenic materials ? ... Zavon expressed concern for exaggerating, in this manner, publicity of the carcinogenicity of a compound. Do not have a separate list".

13/14.11.67 19 Systematic Additions to List. Discussed again (see 3 and 5) Smith and discussion suggests use of abstracting services, Chem Week Buyers Guide plus Merck Index, foreign publications and meetings or correspondence with industry.

20 Status of Air Pollution Criteria and TLV's. A draft letter to the Surgeon General, has been prepared "expressing Committee's concern for possible repercussions arising from the establishment of additional, differing sets of criteria and standards of air pollutants. It is suggested that TLV Committee establish liaison with PHS Committee considering air pollution standards".

21 In a minute on the use of TLV's Hosey cites 3 ways TLV's are used. In Regulations, referred to in Regulations as evidence in courts. He preferred incorporation in State codes as these could be most easily amended.

22 Stokinger comments under an item entitled ILO/WHO meeting on International TLV's - ... "The TLV's are now being reviewed more critically than in the past by foreign groups".

He probably means the German DFG, the British BOHS and the Swedish Commission.

6/7.11.68 23 Hosey puts forward a scheme for selecting substances which require standards. Five criteria are considered: 1 Population Index for a given study. 2 Incidence and Prevalence Index, 3 Trend index - usage. 4 Quality Index. 5 Disability Index.

24 Dr Stokinger reported that the ACGIH Board of Directors has directed the TLV Committee to expand its membership to include liaison or consultant representatives from both labour and industry.

The Committee selected D Padden (UAW) and VK Rowe (Dow) who was well known to the Committee and had regularly supplied information and views in the past.

26 Ammonia "On the basis of probable reduction for ammonia, Formaldehyde should be considered for reduction".

Probably because both standards were based on an assessment of the degree of irritation caused to humans, although this is not made explicit.

27 A foot note (page 2) "Note: In requesting data from industry, attempt to get more specifics on nature of study, survey, or industrial exposures".

It would appear from this statement that some or perhaps much of the "industrial data" were sketchy. It also indicates what information the Committee wanted from industry.

1/2.4.70 28 Nuisance dust level is reduced from 15 mg/m^3 to 10 mg/m^3. All substances where TLV's are effectively based on the Nuisance Dust value and which are in the main list are moved into the NIC category.

29 Padden (UAW) unable to attend. Asked to suggest a nominee to cover. Torkelson (Dow) recommended as an alternative to Rowe.

30 "Representation on TLV Committee from Mexico/Latin America. Proposal put to Conference Executive Committee". No action taken as far as I am aware.

19.20.11.70 31 Z37 Committee has criticised TLV Committee for failure to review limits and update documentation. And, "In revising documentations, Elkins found a number of limits which cannot be justified by listed references".

32 Committee recommends biannual issuance of TLV's with an addenda inserted in each year's booklet. Never actioned.

33 "Stokinger commented on criticism by Runyan (Gulf Oil) that too few substances are on TLV list". A reply reiterated the absence or lack of acceptable data to justify establishing limits for many suggested substances. Industrial contribution of substances for consideration is essentially non-existent".

It would appear that for some substances already on the TLV list, industry contacts the Committee but for substances not on the list few approaches are made and little information is volunteered. The Committee has to chase information via its personal contacts in industry. A point reinforced by Zavon's plea: see next note.

34 "Systematic Approach to Developing TLV's for New Substances". Zavon: Industry should be more aware of their lack of contribution of substances or data for consideration towards development of TLV's. With increasing regulatory legislation, it would behove industries interests to participate in this activity. What stimuli can be applied?"

8/9.4.71 35 It was an agenda item but it was never discussed or actioned (apparently). "Advisability of Development of TLV's for Mixed Exposures with Synergistic Effects".

36 "Role of TLV Committee under Occupational Safety and Health Act". Stokinger reviewed Act and the implications, present and future, for TLV Committee activities ... impact of Committee recommendations will be greatly magnified".

Some on the Committee suggested the need for an ACGIH Secretariat. Others suggested the Committee should be designated an OSHA advisory group.

(NB: Most of the ~ 400 OSHA Federal standards were based on the 1968 TLV list).

37 A trawl of hydrocarbon, halogenated and oxygenated organic substances reveals: "Documentation revisions indicated nonconformity of values with data". A review is instigated.

18/19.11.71 38 NIOSH have indicated that TLV's may not be recognised by the DOL (Dept of Labour) as "consensus standards". They may be review by a NIOSH "Concensus" Review Board. Wagner, the recording secretary adds the following question: "Is the need to reorganise the TLV Committee to have broader representation? (NCRP as a model committee?)

39 The DOL ... "expressed their difficulty in using the time-weighted-average TLV's for their inspections (an 8 hour monitoring period)". The DOL wanted a "short-term limit" list for enforcement purposes. The Committee unanimously opposed this idea. Hygienists working for companies and enforcement agencies still champ against the bit of the 8 hour sample. However, if the 8 hour TWA OEL is to have meaning there are few short cut ways of assessing exposure.

40 Caplan proposes an addition to the TLV preface - it was seconded by Stokinger and accepted: The amount and nature of the information available for establishing a TLV varies from substance to substances. Consequently, the validity and precision of the estimated TLV is also subject to variation and the documentation should be consulted in order to assess the extent of the data available for a given substance".

41 NIOSH has set up an in-house committee on "Biologic TLV's" (almost certainly chaired by Stokinger).

42 Committee had a joint meeting with "IMA Environmental Hygiene Committee". They agreed an IMA Committee remit which included "to promote industrial physicians to do epidemiological or medical studies within their industry". OSHA could provide funds for such studies.

13/14.4.72 43 High vapour pressure substances may be of greater toxic significance as vapours than as particulates. This issue has rumbled on until the present day.

44 Stokinger had written to Henschler, chair of the German (FDR) equivalent of the ACGIH, the DFG, concerning the apparent banning of various known human carcinogens. This obviously concerned the Committee which had set TLV's for some of these substances. The DFG believed, differently from the ACGIH that "no scientific documentation can be put forward for the threshold values of materials whose carcinogenic action in the human has been sufficiently established". HENSCHLER (1972). A little later Henschler continues: ... "we do not put a "complete ban" on the listed materials, especially not on these "heavy" industrial chemicals for which no satisfactory substitutes are available. We do by no means prohibit the use of these substances and nowhere in the list you will find the term "verboten".

45 Mastromatteo proposed 3 classes of carcinogen and a subcommittee was set up to consider revising Appendix A. It consisted of Zavon, Mastromateo and Torkelson.

	46	Dr M Key. NIOSH Director spoke to the Committee. Apart from praise for its productivity he felt that the "Committee should remain independent of NIOSH or other reviewing groups". Discussion on how to get the Committee accepted on a consensus committee by the DOL took place. Zavon proposed a "semi-autonimous" committee as proposed by the IMA with representatives of industry, labour and the public. It was agreed that Zavon's (IMA's) idea be considered by the ACGIH Executive and the IMA.
16/17.11.72	47	SG Luxon (British Factory Inspectorate) requested increase of copper TLV from 0.1 to 0.4 mg/m^3. Request additional data from Luxon to support increase.
	48	Benzyl alcohol "contact M Okawa (NIOSH San Francisco Office), to consider industry survey for data".
	49	Torkelson (industrial liaison member) appears to have been primarily responsible for changes or amendments to clopidol, cruformate, dicyclopentadiene, zoalene, chlorpyrifos, dimetholate, dicloram, 1,2,4-trichlorobenzene, plictram and vinylidene chloride (ie. mainly agrochemicals of one sort or another).
3/4.5.73	50	Stokinger was a member of ASA's Z37 Committee. He reported that they had considered preparing criteria documents for NIOSH but he did not believe either ASA or ASTM E34 committee were set up.
	51	Formaldehyde - "Publication by H. Rosenkrantz, Columbia University, infers a mutagenic potential for formaldehyde based on in vitro studies. Do Not include as ref in doc. (Emphasis in the original). Fifteen years later formaldehyde was found to cause nasal cancer in test rats and is now regarded as an experimental carcinogen. Why did the Committee not want to list the Rosenkrantz reference? Were the implications too daunting?
	52	Torkelson appears to be primarily responsible, in addition to those substances listed in (49) for: O-chlorostyrene.
	53	Morgan (hygienist for Dupont) the other industrial liaison member was primarily responsible for Divron and tris(2,3,-Dibromopropyl) phosphate.
1/2.11.73	54	Executive Committee decides it will review all "decisions of TLV Committees on matters of policy that are of 'national interest', eg. Appendix A carcinogens. Any revisions considered after annual ACGIH meeting and vote of membership must also be reviewed by Exec Comm". The EC were getting sensitive about the implications of some of the decisions the TLV Committee might make.
	55	A representative from OSHA to be considered for Comm.
	56	Concern expressed at Ind Vent manual statement that in recirculating exhaust ventilation systems 10% of the TLV concentration may be recycled back into the workroom. Decided to develop a list of those substances that could be recirculated.

57 Prime responsibility for Dursban TLV now tranferred to Mastromateo. He works with Torkelson who prepares documentation.

58 Killian (Dow Chem) to speak to next Committee on "chromosomal aberrations related to industrial chemicals".

59 Deferred decision on petroleum pitch until the results of a NIOSH survey are available.

60 Torkelson primarily responsible for: Dipropylene glycolmethyl ester.

Morgan primarily responsible for: Lammate, cyclopentane, m-xylene, -$\alpha\alpha^1$-diamine and dimethylsulphate. They now have joint responsibility for Tris-2,3-dibromopropyl phosphate.

61 The subcommittee on Short Term Limits put forward a 3-tier classification:

TWA - 7 or 8 hour
EL - Excursion Level TWA 15 mins
C - Ceiling level "limited in time, only by the ability of the analytical system to respond and measure".

Proposal was not accepted. Its tiered approach reminds me of the pre-paradigm standard descriptions of Henderson and Haggard or Kobert.

16/17.4.74 62 "OSHA standards reorganised, 400 adopted TLV's accepted by OSHA".

63 Dr J Knatel, WHO Ind Hyg (also representing Rep West Germany) recommends that co-operative effort be established with a cartel of European countries for development of reciprocating documentations".

This tentative discussion of the need to co-ordinate its efforts with other standard setters pre-figures regular liaison with the West German DFG MAK Committee.

64 "AIHA has requested liaison representation between IAHA and TLV Committee. Exec Comm will consider at Annual meeting".

65 "Carcinogens - General Discussion: Zavron critical of lack of consistency of TLV Comm on Carcinogenic Substances (known or potential). Establish a philosophy and practice for establishing substances as carcinogens and limits for establishing a value. A value is needed for each designated carcinogen. Zavron review TLV's for categorisation".

Torkelson submitted a minority report on this subject.

66 "Improper use of TLV's by DOT Office"

Not explained but DOT material on Hazardous Materials used TLV's in a misleading way.

67 Arsenic and compounds - proposed reduction "Torkelson cited Dow manuscript reporting multiple lung cancers from inhalation exposures to lead arsenate". Probably in animal tests.

68 Methylene chloride - "Review literature and NIOSH Criteria Document for evaluation of present TLV".

69 "Vinyl chloride (Torkelson) revise 200ppm to A/Sc."New arrival exposure data has shown angiosarcomas in mice following 7 months exposure, 5 days per week, 7 hours per day, at 50ppm concentration".

70 Torkelson assigned calcium hydroxide.

71 From 1974 onwards Mitchell R Zavon was listed as a Industrial Liaison Member of the Committee in the TLV booklet.

20/21.11.74 72 Stokinger brings "the Committee's attention to the paucity of new substances for consideration".

73 "A new approach to developing TLV's will be utilized. Values will be related and tailored more directly to industrial processes with a value pegged to a specific process rather than generalizations such as Arsenic and compounds ..."

74 Discussion of the need to add a "Medical surveillance" (MS) notation, ..."to certain substances which require medical surveillance of workers exposed to concentrations at or near the TLV".

75 Cadmium fumes and dusts - "Prepare doc subsequent to receipt of data from Jeff Lee (NIOSH) on industrial surveys". Hydrazine - "Revise doc in light of recent Wright Patt. Air Force Base toxicity data".

76 Morgan has primary responsibility for lead, zinc and other chromate pigments. Biomacil, cyanamide and perfluoroalkanes. Torkelson has primary responsibility for 1, 2 dibromoethane, 1,2 dibromomethane, dioxane, 1,2-dibromo-3-chloro propane.

77 From 1975 Torkelson, Morgan and Zavon were listed as "consultants" in the TLV booklet, their industrial affiliations were not made clear.

78 Stokinger repeats his belief in linking processes and some substances. "Complex mixtures of chemicals and multiple processing production operatins pose problems for such a concept".

79 Committee considers brief and Scala's paper on "Novel Work Schedules".

80 Padden (Trade Union liaison member) retires. The choice of replacements is between Mr Beliczky and Mr Samuels.

81 Medical Surveillance (MS) proposal discussed. Various points of view recorded including Zavon: "For what substances should the exposed worker not receive medical surveillance? Will MS contribute to control, identification, or reduction of ill health due to exposure to a specific substance?" The implication of the first question

contradicts the implication of the second. The sub-committee were unsure of how to proceed and decided to go to the main committee.

82 Zavon now primarily responsible for Dicrotophics and m-phthalodinitrile.

83 Isophorone diisocyanate - "Stokinger check Republic West Ger TLV's Doc".

25/26.11.75

84 "Zavon commented that government regulations, promulgated and proposed, for medical surveillance and tests are "out of hand". He suggested: "Develop statement for preface regarding Med Surv with emphasis and reference to those substances which have limited data/validation for the adopted value".

85 "Stokinger to develop paper considering the question of exposure limits for novel work schedules". He never did.

86 Wands presented a carcinogenic classification system including a 3 tier division of potency based on animal tests. "Future observations and data will hopefully provide a means for better delineation of a numerical zone for a given level of potency". The proposal was put to the conference and accepted.

87 As an example of Stokinger's process/substance approach Nickel is listed under 3 headings: Nickel carbonyl, nickel one roastings, nickel, soluble compounds.

88 Morgan adds hexamethyl phosphcramide and m-toluene diamine to his list.

28/29.4.76

89 Stokinger request EC to develop statement regarding rationale/justification for differences between TLV's and NIOSH/OSHA standards for some substances".

90 Wands proposes the unworkable definition of a STEL - "maximal allowable concentration not to be exceeded at any time during the 15 minute excursion period".

91 Committee decides to do nothing about novel work schedules but does decide to take NIOSH to task for using a reference period of 10 hours.

92 Cobalt - Fredrick and Stokinger propose two TLV's of 0.01 and 0.05 mg/m^3 for grinders and manufacturers, "based on different modes of exposure".

This must be a reference to the different particle size distributions of cobalt aerosols in the two processes. Decision was never actioned. TLV remained at 0.1 mg/m^3 until 1988 when it fell to 0.05 mg/m^3.

93 The Armed Forces have made "repeated requests" for TLV's for phenyl mercaptan, 1,2-propylene glycol dinitrate and nitrogen trifluoride. Wands suggests a meeting to discuss "... available data and if necessary consider type of data/research to develop values". This is one of the few times that a clear research initiative is suggested by the Committee.

94 "Epichlorhydin (Wands) No change. 5ppm. Review Dow epidemiological report (Torkelson)".

95 "Dichloromonofluoromethane (Morgan). No change. Proposed 1,000ppm. Dupont animal studies near completion. Data indicates reduction in value in order". (A tentative value of 10ppm was listed under NIC in 1978 and was adopted in 1980).

96 Meeting of TLV Sub-committee on Hydrocarbons and chlorinated hydrocarbons. 9.9.76
Chaired by Torkelson (Dow Chem Co). Torkelson sent a covering letter with the agenda for this meeting. He says: "I have asked the American Petroleum Institute (API) to have representatives present who can discuss the results and conclusions of the extensive research they have sponsored at Carnegie-Mellon University ... Mr Disbennett will be sending you a set of reprints. It is important that we be familiar with these since they will be the basis for any changes we make in TLV's for those hydrocarbons". (Author's emphasis).

The importance and influence of company sponsored research could hardly be clearer.

97 Sub-committee on Chemical Carcinogens, 22.11.76.
"A discussion was held about Dr Finklea's concerns for special standards for women in the workplace. The subcommittee recommends that the TLV Committee take this problem especially the issue of occupational teratogens, under advisement".

6/7.12.76

98 Union liaison person. Belcsky listed as a member of the Committee but does not attend.

99 Committee agrees to publish disclaimer stating that TLV's are not official but are "primarily for the use of the ACGIH membership".

100 The AIHA set up a "Committee on Workplace Environmental Exposure" and had asked for a TLV Committee liaison member. Ralph Wands was obviously riled by the AIHA's action stating that "... it was redundant, constituted a dilution of a limited pool of competent professionals and was instituted without polling the AIHA membership".

After various tactful but firm rejections from the ACGIH the AIHA had decided to go it alone in competition with the Conference. On the face of it, it was a project that was doomed to failure.

101 The Hydrocarbon and Halogenated Hydrocarbon Sub-Committee chairman (Torkelson) requested an epidemiologist on his subcommittee and permission to bring in outside consultants as he saw fit. Permission was granted.

102 A teratogenic substances subcommittee was started.

103 A translation of the 1974 Swedish TLV's was distributed.

104 Torkelson primarily responsible for acrylonitrile.

Morgan primarily responsible for dimethyl sulphoxide, formamide, MOCA, and perfluoro alkanes.

105 Wegman believed the TDI TLV should be reduced from 0.02 to 0.005ppm or lower "based on his experience".

106 Mastromatteo disagreed with the NIOSH criteria document on nickel ... "there was no rationale for changing the TLV for nickel" ... He mentions that an epidemiological survey was in progress.

1977

107 In the 1977 TLV Booklet Mastromatteo, Morgan, Steinberg, Torkelson and Zavon are all listed as "consultants". Whether Steinberg and Mastromatteo were employed by industry is not clear, but they were both former longstanding members of the Committee.

15/16.2.77 Minutes of H & HH Subcommittee

108 The NIOSH/ACGIH Crisis
"The Sub-committee unanimously supported the need for TLV's and for the existence of the TLV Committee within the ACGIH".

Dr Finklea, director for NIOSH had forbidden NIOSH personnel to use NIOSH resources in their work with ACGIH TLV Committee. He was unhappy as to the independence of ACGIH and was particularly concerned at the divided loyalties some of the NIOSH staff may have had in producing NIOSH REL's while developing TLV's for the same substances with higher values.

The subcommittee discussed alternative sources of funds and data.

18/19.4.77

110 "Stokinger has revised about half of the documentations; the rest will be done by Elkins".

111 "Zavon suggested a new structuring of the TLV Committee. ACGIH should serve as sponsor of Committee, but include representation by AIHA, AMA, Academy of Occupational Medicine etc". He was asked to make a formal proposal. Whether or not he did, it was never actioned; the ACGIH maintained its exclusive control of TLV's.

Torkelson, "... suggests as an alternative to the expansion suggested by Dr Zavon that the Committee's TLV's be established for ACGIH members. Others can use them if they want to. This may solve some of the political problems that now exist". He is referring to the differences between TLV values and some proposed NIOSH REL's (Recommended Exposure Levels).

112 "A suggestion was made that the committee should tap the NIOSH Hazard Investigation Group". This was an inventory of substances, people and processes being compiled by NIOSH.

113 Antimony trioxide production - "Newcastle study showed that since 1961 when exposures of workers in the Trioxide production plant was reduced to 0.5 mg/m^3 no more pulmonary cancer deaths were observed. Hence the 0.5 mg/m^3 standard ..."

The TLV was set at an exposure level already achieved and the "safety factor" referred to by a number of Committee members in their writings is unqualified. A TLV of 5.0 mg/m^3 for antimony trioxide handling and use was suggested. This was eventually

shelved and both production and use were assigned values of 0.5 mg/m^3. Finally, the production value was deleted and antimony trioxide production was simply listed as an A2 carcinogen with no TLV value in 1980.

114 "TLV for nickel sulphide roasting set at 1 mg/m^3 A1(a) to protect against nickel cancer. Exposures at Sudbury, INCO, at this level for 15 years produced no cancers".

15 years is not a long time in comparison to some known carcinogenic latent periods and similar points concerning "safety factors" apply as for antimony trioxzde.

7/8.10.77 115 The Chairman (Elkins) comments on "The inevitable trend to lower TLV's. Why?" He gives three reasons: (a) substances more widely used, more information on them is available. (b) animal data do not indicate conditions found in practice, (c) increased standard of living, workers will not tolerate the stresses they used to".

116 "Future of Committee on TLV's" is discussed and various resolutions are agreed including:

"ACGIH favours continuation of committee-room for more than one opinion, not in competition with NIOSH".

"TLV meetings should be open. Public welcome to attend but not participate, but meetings should not be advertised".

"TLV Committee should be strengthened".

"TLV Committee should be enlarged, more subcommittees needed to reduce load on chairmen".

"Exchange ideas with unions relative to TLV Committee activities. A better relationship sought".

"Co-operation with and idea exchange with AIHA Workplace Environmental Exposure Level Committee desirable".

This was a period of insecurity for the Committee (see text, Chapter) It was responding to criticisms and perhaps some self doubt now that NIOSH and OSHA were the official Federal OEL setting organisation.

117 "Recommended that someone from EPA or pesticide regulatory board be added to Committee". By being more open, expanding and inviting members of other agencies on board the TLV Committee was attempting to be more representative".

118 Under the heading "Reconciliation of TLV's and NIOSH recommendations" the discrepancies between TLV's and NIOSH prepared REL's were discussed. They reveal a difference in approach. Benzene: "NIOSH recommends 1ppm because it believes carcinogens have no threshold levels. Benzene standard of 10ppm is retained until data from OSHA hearings have been reviewed". (The benzene TLV is still 10ppm (1988)).

NIOSH has proposed a single standard for arsenic and regarded it as carcinogenic. ACGIH had set two TLV's and only regarded arsenic production as posing a carcinogenic risk.

"Arsenic is carcinogenic under certain conditions in humans. Does not cause cancer in animals. The concept of zero thresholds for carcinogens is not accepted by the TLV Committee". (NIOSH recommended 0.002 mg/m^3 whereas ACGIH recommended 0.2 mg/m^3 for production with A2 carcinogen category and 0.2 mg/m^3 for soluble salts).

119 "Validation of TLV's - should we introduce a note on the confidence of specific TLV's? Discussion, but no resolution followed".

This is a regularly recurring theme - and it is never resolved.

120 The Minutes continue to deal with issues raised by the differences in NIOSH's approach and conclusions.

"Committee polled on if they believe thresholds exist for carcinogens. The majority voted yes, but were in agreement that there may not be a practical threshold in some instances. In those instances the effect level and zero concentration may be too close to distinguish".

The policy of ACGIH, as laid out in Appendix A did not change. The "instances" where the "practical threshold" is close to zero are not listed.

121 The Committee run through the substances reviewed by NIOSH making some changes to the TLV's as follows:

Substance	ACGIH old	ACGIH new	NIOSH (REL)
Epichlorhydrin	5ppm	2ppm	Carcinogen-minimise exposure 1ppm
Nitrogen dioxide	5ppm	5ppm	
Sulphur dioxide	5ppm	5ppm(c)	0.5
Quartz	0.1mg/m^3	0.1 mg/m^3	0.05 mg/m^3
Carbon tetra-chloride	10ppm	5ppm	2ppm (Ca)
Nickel (soluble)	0.1	0.1	0.015 (Ca)
Nickel (insoluble)	1.0	1.0	0.015 (Ca)
Acrylonitrile	20ppm	(20ppm)*	1ppm (Ca)

*Reduced to 2ppm (A2) eventually.

122 Mastromatteo is primarily responsible for nickel and clearly influences the Committee not to change the nickel TLV's. He argues that there was any evidence of carcinogenic effects in refinery workers plus "a few isolated case reports in literature on cancer of nose". And although the Swedes were lowering their limit values he

made, the "Recommendation that TLV's be left at present levels until the epidemiological results were available".

The nickel TLV's have never been changed.

123 Dow asked the Committee to consider setting TLV's for n-acetyl-p-aminophenol and acrylic acid.

12/13.4.78

124 ILO had produced a compilation of national standards. Mastromateo noted, "that USSR has MAC's for about 450 substances that ACGIH doesn't cover; perhaps TLV Committee should consider these substances".

125 "Misuse of ACGIH TLV's". Apparently Michigan State was using 0.01 x TLV values as emission standards. A company had phoned ACGIH suggesting the Conference should sue. The practice was apparently widespread. "Consensus of committee was that it is counter to ACGIH policy, that TLV's should not be used for air pollution situation. ACGIH, however, may not be able to enforce that policy".

126 By this date (1978) 17 OSHA PEL's were lower than the corresponding TLV. "Elkins asked if ACGIH should consciously recommend a higher level than OSHA". Issue not resolved apart from agreement to add a statement in the preface that "... government regulations may differ from TLV's".

127 STEL Advisory Group reports. For substances that have no chronic effects STEL = 5 x TLV. For marked, moderate and mild irritants STEL's should be 1 x TLV, 2 x TLV and 3 x TLV respectively. STEL's for substances with known acute effects: 2 x TLV and no STEL's should be set for substances with C values.

128 Some reorganisation of subcommittees into advisory group: "Advisory groups were set up so that NIOSH members and industrial liaison members could assume leadership in group. NIOSH members were not supposed to serve as chairmen of committees which recommend standards".

This appears to be a bureaucratic ruse to enable NIOSH members to continue chairing sub-committees. Technically all the sub-committees became Advisory but in reality their role and influence would remain unchanged. Dr Finklea's edict was observed on paper if not in the spirit.

129 Getting documentation written appears difficult. Long offers the services of a student to revise the pesticide documentation. "Elkins felt that in some cases it is possible to set a TLV based on professional judgement without formal detailed documentation. Much discussion on this topic".

130 Mastromatteo felt that TLV's for drugs and hormones should be set. "Torkelson felt that pharmaceutical companies should be asked to police themselves". Difference was not resolved.

Given that the Committee's business was setting TLV's, Torkelson's view appears strange. Why not apply this logic to the petroleum or other industries?

131 Halothane discussed. NIOSH recommended 1ppm, Teisinger 46 ppm and V.Thoras 150ppm. The Committee resolved to set no TLV.The range of potential TLV values is of interest.

132 Asbestos: "Hand vote of committee forward 0.2 f/cc for crocidolite. Amosite considered to be less toxic. Elkins suggested 0.5 f/cc. Hand vote of committee was in favour of recommendation". 0.2 f/cc was the UK OEL for crocidolite.

133 Benzene - "Elkins wrote documentation on benzene. Committee voted: 10 for 10 ppm and 7 members voted for a TLV of 5 ppm. It appears that 10 ppm is the choice of the majority of those who voted.

Interestingly, the TLV value does not come out of the documentation which was written before the committee voted.

134 Chloroform - "Majority of the committee voted to retain present standard of 10ppm".

135 Mastromatteo reports on the INCO epidemiology: "Workers exposed to nickel metal dust, 0.2-2 mg/m^3. No nasal concerns reported ... 30 years follow up, 1000 cohort".

136 Calcium hydroxide set at 5 mg/m^3 and calcium oxide at 2.0 mg/m^3 because it is "more irritating". The value 5 mg/m^3 crops up a lot and would appear to be followed because it is half the "Nuisance Dust" value of 10mg/m^3. The exact value 5 is thus the product of the arbitrary decision to set the Nuisance Dust limit at 10.

23/24.4.79 137 Sub-committees met in the Autumn - the main committee meeting rate has dropped off. Perhaps because of Elkin's being reitred or because of the withdrawal of NIOSH's assistance or because of both.

138 Dr G Kimmerle from the FDR MAK Commission attends the Committee for the first time. (He works at the Toxicology Institute of Bayer, the largest chemical company in Germany).

From this date he regularly attended committee meetings and is now (1988) listed as "German MAK Commission Liaison" consultant.

139 The voting by hands procedure is formally proposed. "If rejected, then polled votes by active members are required". (Note sure how to interpret this. What did the Committee do before when people could not agree?)

140 Committee agrees on hard and soft wood dust TLV's of 1 and 5 mg/m^3 respectively by a vote of 8:1.

(The number of votes is a little confusing in that 20 people were present at the meeting of whom 12 were eligible to vote).

141 NB: The 1979 TLV booklet lists the following as consultants: Gross, Masstromateo, Morgan, Steinberg, Torkelson, Wands and Zavon. Assuming all these people are in this category because they are either employed by or consultants to industry, the preportion of industrial consultants appears to be increasing. And the seven people listed are all longstanding and active members of the Committee.

142 Carcinogens: "Elkins suggested that TLV's should be listed in general terms. For hexamethylphosphoramide as an example TLV should be in lower micrograms per m^3. **The range is given to avoid giving a single number**". (Author's emphasis).

Elkin's suggestion, if actioned, would have meant a break with the past imperative of the Committee. It was never carried out.

143 Wagner recommends nitrogen dioxide TLV of 3 ppm. Accepted. He prepares the documentation.

144 Trent Lewis suggests a sub-committee on Reproductive Hazards. "Special treatment for women on TLV's should not (be) made". Sub-committee never started.

145 Methylchloride. "Lowered from 100ppm to 50ppm, STEL 100ppm, to provide a wider margin of safety. neurological effects produced by 150ppm".

This implies a "safety margin" of x3 or less.

146 Trichloroethylene. TLV reduced from 100 to 50ppm ... "to provide a wider margin of safety from headaches, dizziness and narcotic effects".

147 n-hexane - evidence of polyneuropathy and similarity in metabolism to MEK convinces Committee to reduce TLV from 100 to 25ppm.

TLV eventually listed in 1982 at 50ppm. Why?

148 "Propylene oxide: Old data indicated it to be 1/2 as toxic as ethylene oxide. The TLV should be twice as great".

The TLV was reduced from 100 to 20ppm in line with the above. (Ethylene oxide TLV = 10ppm).

The toxicological analysis on which this decision was based is stark and simple.

1980 149 Dr Blejer transfers from the main committee listing in the TLV booklet to "Consultant" status.

No 1980 minutes available.

11/12.1.81 150 Dr G Rausch (Monsanto) joins the Committee.

151 Carter (chair of the TLV Committee) met the AIHA WEEL Committee which was set up in 1976 to set OEL's. Carter agreed to maintain liaison and saw no problems occurring.

152 Carter also met with legal counsel of Explosive Industry Association, Mr Hempell, on the TLV for nitroglycerin".

(NB: the pressure seems to have had an effect. Elkins proposed 0.02 was revised upwards to 0.05ppm and joined the main list in 1985 - see Table 16.1 of Factors Influencing Standard Setting Decisions, item No 123).

153 The Federal Office of Management and Budget (OMB) had drafted guidelines (A119) on "Federal employees participating in voluntary standard setting organisations". The OMB guidelines would have meant that the Committee would have to become a consensus committee if it wished to retain Federal employees. The minutes record that "The pressure appears to be off. Reagan Administration freeze, March 25, 1981, has prevented the guidelines being enacted".

154 Much discussion of asbestos TLV and the relevance of area and personal sampling differences. Unresolved.

155 Steinberg reviewed the Carcinogenesis Guidelines. He was in favour of deleting the "potency guidelines". This was eventually done in 1987.

155a "Schneider reported he was having problems in getting basic information because of the proprietary nature of the data on economic poisons in the hands of various manufacturers".

156 Torkelson, in his sub-committee report mentions for the first time in the Minutes the need to "consider the genetic/epigenetic modes of carcinogenesis".

157 "Copper fumes: Copper is not a pressing item, but a review of documentation is recommended".

This raises the intriguing question of how the Committee decides on and selects "pressing items"?

1982 158 TLV Booklet lists Wagner and Lewis as consultants. Almost certainly not because of any industrial affiliation but because they were both NIOSH employees. Making them, nominally at least, consultants was a means of keeping them on the Committee.

In 1983 they were back on the main membership list. The OMB and Finklea's threat had receded.

19/20.4.82 159 "The TLV Committee has established good liaison with MAK Commission through George Kimmerle".

160 "Cal-OSHA hopes to adopt TLV's".

161 Policy decision - "Personal communications will not appear in documentations unless filed with secretary".

162 "Lists of Trade Names prepared on pesticides by Kimmerle and industrial chemicals by Torkelson". The people in the best position to compile such lists.

163 The ASTM F34, consensus committee, still struggles on, dealing with silica.

164 Committee unhappy that conference may be out of line with MAK Commission and IARC on the human carcinogenicity of arsenic. Ask the sub-committee to think again.

165 The gasoline TLV was set at 300ppm. However, "some refiners are reducing their exposure levels to 100ppm. No indication is given for this action".

166 Glycol ethers: "Torkelson reported that there is reason to believe that (EGME) and ECEE are considerably more toxic than thought in the past ... Most manufacturers are recommending lower exposures ... Documentation to be prepared by Torkelson ... The Committee voted in favour of adopting on an emergency basis 5 ppm for the glycol ethers and their acetates".

This is the first time the word "emergency" has occurred in the minutes.

167 Kinmerle to prepare documentation in Fenamiphos, Metribuzian and Sulprofos. He, "(will) write a letter to the TLV Committee on the material he cites in the documentation. The letter would be cited as personal reference".

This appears to he a mechanism by which Kimmerle can quote internal Bayer data and appraisals of 3 of their products. This access to internal information contrasts with Schneider's complaint (No 155a) that he was having difficulty getting proprietary information.

The Committee accepted the three documentations without query.

168 "Halothane Trent can't go along with 50 ppm ... and 75ppm for Enfluorane". He wanted the TLV's to be considerably lower. Action was postponed. Still no TLV's for either of these substances in 1988. The HOC sub-committee appears to have reached an impasse on these substances.

169 STEL's Committee reports. It is agreed that "STEL's are basically 15 minute TWA's allowed four times a day with at least an hour between each exposure".

The arrival of the 15 minute TWA at last makes the STEL measurable and meaningful!

30/31.8.82 170 Six sub-committees reorganised into three:

1 Inorganic dust
2 Halo/mix carbon
3 HOC

Done for two reasons: (1) wider view of information and documentation, (2) better co-ordination with outside contacts, and "handling of interpretation of TLV's".

171 Committee and sub-committee annual programme phased; "Action plans" launched.

172 ASME (American Society of Mechanical Engineers) had lost a case in the Supreme Court over the interpretation of one of its standards.

The ACGIH Board instituted a more rigid and rigorous system for dealing with requests for TLV interpretation. Including the decree that; "No individual shall interpret TLV's".

173 Biological Exposure Indices (BEI's) are in the offing. Zavon (an MD) commented on, ..."the competition between physicians and IH's for control of the programs of biological monitoring".

174 J Lynch (Exxon) questioned the committees use of the word "instantaneous" in the definition of "ceiling values". A working group was set up.

(NB: As all measuring systems have a "response time", even if short, the idea of "instantaneous measurement" with no definition of response time had always been problematic).

26/27.3.84 175 Committee agreed to "sponsor an international input on TLV's".

Note that the wording in phrase suggests that the committee sees itself and its approach as pivotal. The symposium is to improve TLV's.

176 The Carbide Institute has different TLVs for women of child bearing age, eg. 10ppm for 2-methoxy-ethanol and 2ppm for women. "Wagner was not in favour of this concept".

177 Kimmerle reported on the MAK Commissions four category classification of substances for reproductive effects. Hammond (the HOC sub-committee chair) suggested similar scheme:

"1 Substances like glycol ethers that are known to have those hazardous characteristics below the level of effects (toxic?) in adults and animals. An asterisk can be put on these compounds.

2 Substances that have no effect on fetus development in experimental animals at concentrations below the TLV.

3 Substances that have not been adequately tested for this effect.

4 Substances that have been known to cause harm in man and female reproductive systems at (TLV) concentrations otherwise considered safe concentrations for adults".

"It was estimated that 90% of substances would fall under the third class".

178 Decided that primary irritants should have ceiling but no TWA TLV's. Preface wording changed and includes the sentence:

"There is no implication that brief small excursions above the ceiling are life-threatening or have the potential for creating permanent harm".

This signals a change in attitude to irritation.

Table Appendix 4.3

Summary of influence analysis based on Table Appendix 4.1

Note 1:
There are 108 instances where the Committee either actively sought or was supplied with data from outside usually industrial sources, and usually the main producers or users of a material. This data was used in setting TLV's and on ocassions were the main, sometimes the only, source of information, (see Note 2).

Note 2:
In 38 of the 108 instances the data supplied by industry would appear to be the main source of information on which the TLV was based.

Note 3:
There are three instances where it is clear that the Committee knew the exposure levels of a substance in industry. Moreover, in many other instances there is a strong possibility that this information was available, (see Notes 2, 4 and 5). Also, in many cases the Minutes refer to "industrial experienced". Although the terms is ambiguous it almost certainly included exposure "experiences".

Note 4:
In seven cases it is clear that the industries which supplied the data on which the TLV were set were already complying with the TLV level.

Note 5:
In nine instances it is clear that the industry or industries determined what TLV level was set ie. their recommendations were accepted without reservation by the Committee.

Note 6:
In four instances the Committee ignored company objections and set a lower TLV than the objectors wanted.

Note 7:
Table 16.1 is based on the analysis of 31 sets of Minutes. But there are gaps in the material, especially in the 1980's. An estimated 10 sets of Minutes were not obtained by the author. The figures listed in Notes 1 to 6 should be increased by one quarter to give a more realistic picture of Committee activity.

Assuming this correction factor is valid the figures for the various categories covered in Notes 1 to 6 are now as follows:

Industrial data sought or supplied	134
TLV based mainly on industrial data	47
Exposures in industry known implicitly	4
Industry already complying with the TLV	9
Industry determined the TLV	11
Committee ignored company protests	5

APPENDIX FIVE

USE OF ACGIH TLV'S WORLDWIDE

Continent	AUSTRALIA
Country	Australia
Date(s) of first use	1948 (State of Victoria)
Status of TLV	Advisory recommendations [Jones (1987)]
Date(s) of general countrywide acceptance	1956
Status of TLV	Recommendation [Jones (1987)]

Development and current position, (including organisations that recommend/set and enforce OEL's)

Before TLV's (or MAC's as they were described at first) were published Australian practitioners used the limits recommended by the US PHS (1943). TLV's took over as guidance levels except in the case of New South Wales where various TLV's were incorporated as statuatory limits in Welding Regulations under the Factory Shops and Industries Act of 1958, Jones (1987).

National Health and Medical Research Council's (NHMRC) Occupational Health Committee arrange annual meetings of scientific officers (hygienists) employed by State and Federal Governments from 1956. ACGIH TLV's "were the major influence ... and were generally recommended to be followed by Government authorities" Jones (1987). The Occupational Hygiene sub-committee of the NHMRC was established in 1965 and in ~1974 the TLV list was published by the NHMRC in its entirity.

There has always been some variation from the TLV list. The coal dust standard has been UK influenced, as were the asbestos standards, "... but lower standards were adopted here on the basis of industries ability to comply", Jones (1987). Silica limits were derived locally in Australia. The National Health and Safety Commission (NHSC) was set up, under new Federal legislation in 1984. Since 1985 a tripartite committee of the NHSC is responsible for OEL's but the 1984 TLV list is used in the interim. The limits published by this committee will be recommended OEL's.

Continent	EUROPE
Country	Belgium
Date(s) of first use	?
Status of TLV	Recommended

Date(s) of general countrywide acceptance	?
Status of TLV	Recommended

Development and current position, (including organisations that recommend/set and enforce OEL's)

According to Vigliani Belgium reproduces the ACGIH TLV list. How long the Mistry of Labour has done so is not known.

Continent	AMERICAS
Country	Canada
Date(s) of first use	1946
Status of TLV	Guidance levels
Date(s) of general countrywide acceptance	1971/2
Status of TLV	Guidelines

Development and current position, (including organisations that recommend/set and enforce OEL's)

The information Services of the Occupational Health Division of the Department of Health in Ottawa have published an "Occupational Health Bulletin" since 1945. Each year it has reproduced the list of MAC/TLV's set by the ACGIH. Hygienists in Ottawa have probably used TLV's since the first list was published in 1946. But TLV's were not recommended nationally until ~1972 when the 1971, and subsequent lists, were incorporated into the Canada Labour Code, PURDHAM (1987). Nowadays both Alberta and Ontario publish their own lists but, according to Purdham, in the case of Alberta, "perusal quickly shows them to be almost identical to those of the ACGIH", p9, PURDHAM (1987). Cherrie found that "... only 12 values (in the 1985 list) were different (from the ACGIH list)", p14, CHERRIE (1986).

Continent	EUROPE
Country	Denmark
Date(s) of first use	Early 1960's
Status of TLV	Guidance

Date(s) of general countrywide acceptance	1968
Status of TLV	Guidance

Development and current position, (including organisations that recommend/set and enforce OEL's)

Since 1968 the TLV list has officially been used by the Danish Directorate of Labour Inspection; it was used unofficially for some time before then, HARAJCHI (1986). In 1976 the Directorate published a list of 420 Danish TLV's which relied mainly on the ACGIH list but also drew upon Swedish and German lists. Where TLV values were changed the values chosen were usually lower than ACGIH TLV's but higher than Swedish Limit Values, VIGLIANI (1977). The Danish list is published with revisions every 2 years, RIALLA (1986).

Continent	EUROPE
Country	Holland
Date(s) of first use	mid-1950's (?)
Status of TLV	Guidance

Date(s) of general countrywide acceptance	Mid-1950's
Status of TLV	Guidance

Development and current position, (including organisations that recommend/set and enforce OEL's)

The Dutch Labour Inspectorate and hygienists have used TLV's as guidance levels since the 1950's. In 1976 a National MAC - Commission was founded (3 employers, 3 employees and 2 Expert Commission representatives) and a 2-tier method of setting OEL's instituted (ZIELHUIS and NOTTEN (1979)). The Working Group of Experts (WDG) assess the scientific evidence and puts forward a health based OEL to the Commission on OEL's (the tripartite body). This, second tier committee then assesses the socio-economic factors and recommends a MAC to the Labour Inspectorate (LI). The MAC's are published by the LI. Originally, if the Commission's recommended MAC differed greatly from the WDG's recommendation then the OEL would be designated a TAG (Temporary Accepted Guideline). But the idea was not thought to be feasible and was discarded, ZIELHUIS (1988). The LI published its first MAC list in 1978, "largely adopted from the ACGIH list", BALEMANS (1986). Gradually MAC's were influenced by the FDR DFG list and Swedish Limit Values and the WDG and Commission made more and more recommendations. By 1987 the WDG had advised on 30 OEL's and the Commission had recommended 150 MAC's. In the 1986 MAC list, there are ~730 MAC's based on OEL's set by the ACGIH, DFG (FDR) and Sweden and the 150 recommended MAC's from the Commission BALEMAN (1987) and NOORDAM (1987). Of the 30 proposals put forward by the WDG, 22 appear in the 1986 list. AI (1986).

Recently the National MAC Commission has been disbanded and under a new Dutch law a "Commission for exposure limits for health-damaging chemical agents" has been set up. This Commission is still tripartite and the 2 tier approach is still maintained, ZIELHUIS (1988).

Continent	EUROPE
Country	Finland
Date(s) of first use	Late 1950's
Status of TLV	Unofficial guidance

Date(s) of general countrywide acceptance	1962
Status of TLV	Guidance (of good practice).

Development and current position, (including organisations that recommend/set and enforce OEL's)

The Ministry of Social and Health Affairs published a TLV list based mainly on ACGIH values in 1962. It published a revised list in 1972, based on ACGIH, Swedish and FDR lists. Another, revised list was published in 1981 by the National Board of Labour Protection. The Finnish TLV list is not legally binding but represents guidance as to good practice, RIALLA (1986).

Continent	EUROPE
Country	France
Date(s) of first use	1960's (?)
Status of TLV	Guidance

Date(s) of general countrywide acceptance	(?)
Status of TLV	(?)

Development and current position, (including organisations that recommend/set and enforce OEL's)

France has never published a list of OEL's although according to a document published in 1985 "... designers and operators were keen to escape from the uncertainty in which they were placed regarding the targets to be achieved (generally they referred to foreign values, chiefly American)", p11/12 HSE (1985). Also the TLV's have been published regularly by the INRS (a French National Research Institute) though for how long is not known, VIGLIANI (1977). Some recommended values which usually correspond to TLV's are recommended by the state institution responsible for compensating industrial diseases. The limit values refer to substances like asbestos which are directly linked to diagnosable diseases. More recently, stimulated by EEC Directive 80-1107 "Code du Travail" "allows exposure limits to be fixed by decree". The Supreme Council for the Prevention of Occupational Hazards was asked in 1980 to prepare a list "for hazardous substances in frequent use" HSE, (1985). Four bulletins from the Council listing 109 substances and exposure limits have been circulated to the Ministry of Labour.

Continent	EUROPE
Country	Italy
Date(s) of first use	1969
Status of TLV	Recommendation

Date(s) of general countrywide acceptance	1975 (?)
Status of TLV	Recommendation (?)

Development and current position, (including organisations that recommend/set and enforce OEL's)

In compensation cases, TLV's have been cited in court for many years. In 1969 the National Chemical Industry Union negotiated a contract with their employers to include the TLV list in the agreement and up-date it annually (the Italian Industrial Hygienists Association (IIHA) publishes the TLV list annually). SILVESTRI (1986)

In 1975 the IIHA and the Italian Society of Occupational Medicine submitted a list of OEL's for chemical substances to the Ministry of Labour. Although it was accepted it had not become law by 1977. It was based on ACGIH TLV's, and values from Germany (FDR), Sweden, Japan and the State of Pennsylvania, PARMEGGIANI (1977). Out of a total of 165 TLV's, 47 changes were made.

Continent

Country JAPAN

Date(s) of first use 1952

Status of TLV Recommendation

Date(s) of general countrywide acceptance 1952

Status of TLV Recommendation

Development and current position, (including organisations that recommend/set and enforce OEL's)

A committee within the Japanese Society for Industrial Health started to set PEL's (Permissible Exposure Levels) in 1952. The first list numbered 17 substances and by 1984 had grown to 160 ... "the majority of PEL values were adopted from the ACGIH TLV's, and about 10% of the substances on the list were based on additional sources ..." TOYAMA (1985).

More recently the Japanese have developed a different standard based on area or static sampling. These are known as control limit indices (CLI) and are used to rank air quality in the workplace as, acceptable, borderline and not acceptable. Some 56 CLI's have been set and most have similar values to Japanese PEL's and ACGIH TLV's. There enforcement requires a lot of sampling and they are only really practicable at present for large industries. There is also the problem of relating CLI measurements to the personal exposure of individual workers which necessitates considerable research, see for instance KUSUMOTO and IWAO (1979) and KADOWAKI et al (1983) work on the relationship between personal and static sampling in the lead industry in Japan.

Continent	EUROPE
Country	Norway
Date(s) of first use	1950
Status of TLV	Guidance

Date(s) of general countrywide acceptance	1950
Status of TLV	Guidance

Development and current position, (including organisations that recommend/set and enforce OEL's)

From 1950-74 the Institute of Occupational Health published the ACGIH TLV list. In 1975 a tripartite working group was formed and in 1978 they published their own TLV list, "which is based on medical, technical and economic grounds", RIALLA (1986). The list was revised in 1981 and 1984.

Continent	EUROPE
Country	Spain
Date(s) of first use	1962
Status of TLV	Statutory

Date(s) of general countrywide acceptance	1962
Status of TLV	Statutory

Development and current position, (including organisations that recommend/set and enforce OEL's)

The 1958 TLV list was incorporated into Spanish national legislation in 1961 and became law in 1962. The list was included as an Appendix to "Decreto de Presidencia de Gobierno sobre Industries Molestos, Insalubres, Nociuas y Peligrosas de 30.11.61". In an erroneous translation TLV's were defined in the 1961 regulations as: "A concentration that should not be exceeded during any part of the working exposure", ie. as ceiling values, GUARDINO (1986). However, "the up-to-date values of ACGIH TLV's are widely used by Safety Engineers, Chemists, Trade Unionists and INSHT (National Institute of Occupational Health and Safety)". And, "Even though they aren't legal values, Factory Inspectors usually use them", GUARDINO (1986).

Continent	EUROPE
Country	Sweden
Date(s) of first use	1950's
Status of TLV	Unofficial guidance

Date(s) of general countrywide acceptance 1969

Status of TLV	Non-mandatory guidance

Development and current position, (including organisations that recommend/set and enforce OEL's)

The untranslated ACGIH TLV list was used by hygienists, engineers and chemists, unofficially in the 1950's and 1960's. In ~1967 a working group composed of 7 representatives from the National Institute of Occupational Medicine and 8 members from the Board of Social Affairs, the National Board of Occupational Safety and Health and the Swedish Confederation of Trade Unions and Employers was set up which put recommendations to the National board, HOLMBERG and WINELL (1977). The first official "Limit Value" list was published by the Board in 1969 based mainly on ACGIH TLV values. Lists with additions and some revisions have been published in 1974, 1978, 1981 and 1984, RIALLA (1986). The latest list, amended in 1987, contains about 350 limit values, NBOSH (1987) and NBOSH (1984). The composition and organisation of the committee is described by HOLM (1981).

Continent	EUROPE
Country	Switzerland
Date(s) of first use	1946
Status of TLV	Guidance

Date(s) of general countrywide acceptance	1946
Status of TLV	Guidance

Development and current position, (including organisations that recommend/set and enforce OEL's)

The Swiss Institute for Insurance against Accident (SUVA) has published a MAC list since 1945. The basis of the SUVA list was the ACGIH TLV list and more recently the ACGIH/FDR lists whichever were the lowest values. In 1975 a tripartite commission of the Swiss Occupational Hygiene Association was set up to advise SUVA. VIGLIANI (1977) estimated that Swiss MAC values were based 80% on ACGIH TLV's, 15% on FDR MAC's and 5% on Swiss experience.

Continent	EUROPE
Country	United Kingdom
Date(s) of first use	Early-mid 1950's
Status of TLV	Guidance

Date(s) of general countrywide acceptance	1960
Status of TLV	Guidance

Development and current position, (including organisations that recommend/set and enforce OEL's)

In the 1950's various pieces of legislation and inspectorates covered different groups within the British workforce. The Factor Inspectorate were the largest and covered the majority of industry. In the early 1950's individuals were sent to study industrial hygiene at Harvard in the USA and came back to set up what became known as the Chemical Inspectorate, HARVEY (1987). Other people were seconded to the group. TLV's were used as unofficial guidance levels by this group and others in industry and private consultancies SHERWOOD (1986). Large companies, such as ICI had their own internal OEL's which were similar to the TLV list. In 1959 the British embassy in Washington wrote to the ACGIH requesting permission to publish the TLV list, ACGIH (1959). Permission was granted in 1960 the Ministry of Labour published "Toxic Substances in Factor Atmospheres" in its Safety, Health and Welfare series, MOL (1960). The list of "Maximum Permissible Concentrations" were defined as ceiling values, and not TWA's and were offered as guides to "best practice". Later editions of the booklet reproduced the TLV booklet in its entirety including the preface DoP (1968). In 1970 the list was published in a new series of Technical Data Notes and was updated each year. After the creation of the Health and Safety Executive (HSE) in 1974 a new series of Guidance Notes was started and the ACGIH list was reproduced in EH15 each year up to 1980. From 1968 onwards the ACGIH list was supplemented by a preface which listed UK standards. The British Occupational Hygiene Society (BOHS) put forward hygiene standards for asbestos in 1968 and these were incorporated in the 1969 Asbestos Regulations. These were the first standards, published by the Department of Employment, which differed from the ACGIH TLV's. In the late 1970's additional control limits were listed in the UK preface. The 1980 EH15 was the last one published and in 1984 EH40 "Occupational Exposure Limits 1984" superceded the TLV list. EH40 is a product of the Advisory Committee on Toxic Substances (ACTS) which is a tripartite committee of the Health and Safety Commission and was set up in 1976, (see Chapter 20.0 for more details). The ACTS with its various sub-committees set two types of standard, Control Limits and Recommended Limits. The former are judged to be reasonably practicable ... " and should not normally be exceeded". p2, HSE (1984) and the latter, "are considered to represent good practice and realistic criteria for the control of exposure", p2. Recommended Limits are used, "... as part of the criteria for assessing compliance with the HSW Act ...", p2 and did not have the same force in law as the Control Limit. Apart from the hygiene limits for asbestos and vinyl chloride the limits listed in EH15 were guidance and not statutory levels. Control limits are not simply guidance levels like Recommended Limits but are intended to be statutory. They are enforced by HSE inspectorates

who usually draw upon the services of the Specialist Chemical Inspectors for assessments and expert opinion. More recently Control and Recommended Limits have been transmuted into Maximum Exposure Limits (MELs) and Occupational Exposure Standards (OESs) (see main text for details and explanation of this transformation).

Continent	EUROPE
Country	West Germany
Date(s) of first use	1958
Status of TLV	Recommendation

Date(s) of general countrywide acceptance	1958
Status of TLV	Recommendation

Development and current position, (including organisations that recommend/set and enforce OEL's)

Until recently the FDR was the only country in Europe to set its own OEL's. In 1955 the German Research Association (Deutsche Forschungsgerreinschaft) set up a special Committee for examining hazardous substances. In 1958 the Committee published its first list of MAK's (Maximum Concentration at Work) consisting of 262 eight hour TWA values of which 240 were 1958 TLV values and 22 were German derived.

The following are extracts from the introduction to the first MAK list:

"Many substances which are industrially produced ... can be hazardous if they are inhaled ... if the effects of such substances cannot be completely prevented then at least conditions can be defined under which the presence of such substances in man's environment may be regarded as harmless according to the latest scientific developments.

... for a number of substances the Commission has set limits ... considering the vast number of substances which are used in industry and which are particularly hazardous the Commission finds it necessary for the time being to use the publications of other commissions. Therefore the following list contains MAK data set by the Commission and information published by the American Conference of Governmental Industrial Hygienists as indicated. .....

Introduction to the following list of MAK data....

On the basis of experience of handling these substances together with reference to long term animal experiments it may be said that the concentrations given in the list are generally not hazardous even for daily 8 hour exposure. The data listed should not be regarded as generally valid constants ... MAK data on their own are not suitable for a comparison of potentially hazardous substances. Nor should they be regarded as standards if alleged hazards have to be judged. Apart from these circumstances it is medical diagnosis which is important in the final judgement." DFG (1958).

The DFG regularly published* an extended list and slowly became independent of the ACGIH. Thus although the DFG introduced "skin" notation and ceiling values it introduced its own "allergy" notation in 1968 and in the 1970's introduced TRK value (Technical Guide Concentration) for known or suspected carcinogens, which were based on practicability. From

1969 an annual list was produced which, it was claimed, was based only on "German experience". Given that the DFG had more or less followed the ACGIH since 1958 it seems inconceivable that the TLV values did not exert some influence on the DFG's deliberations. DFG (1958 & 1969) and VIGLIANI (1977).

* 1958, 1961, 1964, 1966, 1969

APPENDIX SIX

ANALYSIS OF THE MINUTES OF THE ACTS (1980-1986)

A simple textual analysis of the Minutes was conducted by placing each intervention in one of seven categories and noting the affiliation of the speaker. The categories are as follows:

(i) Question (Q)

(ii) Answer (A)

(iii) Statement (S)

(iv) Response (R)

(v) Observation (O)

(vi) Proposal (P)

(vii) Proposal for a limit (Pl)

While the categories are relatively crude they produce an interesting and revealing picture of the workings of the ACTS over a seven year period and certain patterns are evident in Tables x-y and Figures a-d.

KEY

TUC	-	Trades Union Congress
CBI	-	Confederation of British Industry
HSE	-	Health and Safety Executive
IND	-	Independents
LA	-	Local Authority
Other	-	Other attendees at the Committee meetings

Tables Y1-Y20: ACTS Meetings Analaysis

Table Y1 – 28 February 1980 meeting number 10

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	3	75	0	0	5	25	5	23	0	0	2	33	0	0
CBI	1	25	0	0	2	10	9	41	1	83	1	17	0	0
HSE	0	0	5	100	9	45	4	18	10	83	3	50	0	0
IND	0	0	5	100	9	45	4	18	10	83	0	0	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	1	5	1	4.5	0	0	0	0	0	0

Table Y2 – 2 July 1980 meeting number 11

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	8	53	0	0	8	21	2	29	1	6.7	5	63	0	0
CBI	5	33	0	0	7	18	1	14	0	0	2	25	0	0
HSE	0	0	11	92	14	36	1	14	12	80	1	13	0	0
IND	1	6.7	0	0	8	21	3	43	1	6.7	0	0	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	1	6.7	1	8.3	2	5.1	0	0	1	6.7	0	0	0	0
													0	

Table Y3 – 11 November 1980 meeting number 12

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	2	100	3	25	13	38	4	31	1	33	3	100	0	0
CBI	0	0	1	8.3	2	5.9	1	7.7	0	0	0	0	0	0
HSE	0	0	8	67	18	53	5	38	2	67	0	0	0	0
IND	0	0	0	0	1	2.9	1	7.7	0	0	0	0	0	0
LA	0	0	0	0	0	0	1	7.7	0	0	0	0	0	0
Other	0	0	0	0	0	0	1	7.7	0	0	0	0	0	0

Table Y4 – 4 February 1981 meeting number 13

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	3	50	1	25	13	27	1	50	6	21	1	33	1	100
CBI	0	0	0	0	6	12	0	0	4	14	0	0	0	0
HSE	1	17	3	75	23	47	0	0	11	38	2	67	0	0
IND	1	17	0	0	5	10	1	50	5	17	0	0	0	0
LA	0	0	0	0	1	2	0	0	1	3.4	0	0	0	0
Other	1	17	0	0	1	2	0	0	2	6.9	0	0	0	0

Table Y5 – 10 May 1981 meeting number 14

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	7	78	1	13	5	16	0	0	1	10	0	0	0	0
CBI	1	11	0	0	4	13	0	0	1	10	0	0	0	0
HSE	1	11	7	88	15	48	0	0	7	70	6	100	0	0
IND	0	0	0	0	4	13	0	0	1	10	0	0	0	0
LA	0	0	0	0	1	3.2	0	0	0	0	0	0	0	0
Other	0	0	0	0	2	6.5	0	0	0	0	0	0	0	0

Table Y6 – 22 January 1982 meeting number 15

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	11	69	1	7.7	22	30	1	13	3	11	4	31	0	0
CBI	0	0	0	0	5	6.8	1	13	3	11	1	7.7	0	0
HSE	2	13	9	69	35	48	3	38	20	74	7	54	1	50
IND	2	13	2	15	8	11	3	38	0	0	0	0	1	50
LA	1	6.3	0	0	1	1.4	0	0	0	0	0	0	0	0
Other	0	0	1	7.7	2	2.7	0	0	1	3.7	1	7.7	0	0

Table Y7 – 10 May 1982 meeting number 16

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	7	70	0	0	12	21	0	0	0	0	5	50	2	67
CBI	0	0	0	0	6	10	0	0	1	8.3	0	0	0	0
HSE	2	20	6	86	32	55	1	100	10	83	4	40	1	33
IND	0	0	1	14	7	12	0	0	1	8.3	1	10	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	1	10	0	0	1	1.7	0	0	0	0	0	0	0	0

Table Y8 – 30 November 1982 meeting number 17

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	7	78	0	0	10	34	0	0	5	31	0	0	2	50
CBI	1	11	0	0	1	3.4	0	0	2	13	1	33	0	0
HSE	0	0	9	100	15	52	1	100	6	38	2	67	2	50
IND	1	11	0	0	3	10	0	0	3	19	0	0	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y9 – 30 March 1983 meeting number 18

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	1	100	0	0	2	8.7	0	0	0	0	0	0	0	0
CBI	0	0	0	0	0	0	1	25	0	0	1	20	0	0
HSE	0	0	1	100	16	70	0	0	2	100	4	80	2	50
IND	0	0	0	0	5	22	3	75	0	0	0	0	2	50
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y10 – 29 June 1983 meeting number 19

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	3	43	1	14	2	6.1	2	29	3	230	0	0	0	0
CBI	2	29	0	0	0	0	0	0	2	15	0	0	0	0
HSE	1	14	4	57	22	67	3	43	3	23	0	0	0	0
IND	1	14	0	0	8	24	2	29	5	38	0	0	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	2	29	1	3	0	0	0	0	0	0	0	0

Table Y11 – 29 September 1983 meeting number 20

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	2	50	0	0	7	35	2	100	2	15	1	20	0	0
CBI	1	25	0	0	0	0	0	0	1	7.7	0	0	0	0
HSE	1	25	2	67	11	55	0	0	6	46	4	80	0	0
IND	0	0	0	0	1	5	0	0	4	31	0	0	0	0
LA	0	0	0	0	1	5	0	0	0	0	0	0	0	0
Other	0	0	1	33	0	0	0	0	0	0	0	0	0	0

Table Y12 – 10 January 1984 meeting number 21

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	2	67	0	0	11	20	0	0	1	13	0	0	0	0
CBI	1	33	0	0	8	15	0	0	2	25	0	0	0	0
HSE	0	0	2	100	26	48	0	0	2	25	5	83	1	100
IND	0	0	0	0	9	17	0	0	3	38	1	17	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y13 – 8 May 1984 meeting number 22

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	1	25	0	0	12	18	0	0	9	24	0	0	0	0
CBI	2	50	0	0	13	20	0	0	12	32	1	13	1	50
HSE	1	25	3	100	32	49	0	0	8	22	5	63	1	50
IND	0	0	0	0	8	12	1	100	8	22	2	25	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y14 – 2 November 1984 meeting number 23

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	1	20	0	0	11	16	0	0	4	18	1	14	2	50
CBI	2	40	0	0	5	75	0	0	3	14	2	29	0	0
HSE	0	0	3	100	36	54	0	0	8	36	3	43	2	50
IND	1	20	0	0	14	21	0	0	7	32	1	14	0	0
LA	1	20	0	0	1	15	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y15 – 7 February 1985 meeting number 24

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	1	11	0	0	12	18	0	0	4	17	1	20	1	11
CBI	1	11	1	20	13	20	0	0	10	43	1	20	1	11
HSE	4	44	3	60	31	47	1	50	8	35	2	40	7	78
IND	3	33	1	20	10	15	1	50	1	43	1	20	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y16 – 2 May 1985 meeting number 25

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	3	23	0	0	13	18	0	0	5	14	0	0	0	0
CBI	2	15	0	0	6	82	0	0	7	19	2	40	1	17
HSE	4	31	8	100	40	55	3	60	17	46	3	60	5	83
IND	4	31	0	0	14	19	2	40	8	22	0	0	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y17 – 22 August 1985 meeting number 26

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of Pl's	% of Pl's
TUC	1	14	0	0	4	78	0	0	0	0	0	0	0	0
CBI	0	0	2	40	10	20	0	0	3	15	1	17	3	50
HSE	4	57	3	60	24	47	0	0	7	35	3	50	3	50
IND	1	14	0	0	13	25	1	100	9	45	2	33	0	0
LA	1	14	0	0	0	0	0	0	1	5	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y18 – 7 November 1985 meeting number 27

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of PI's	% of PI's
TUC	3	43	0	0	7	12	2	50	5	16	1	63	0	0
CBI	1	14	0	0	6	10	0	0	5	16	1	63	1	11
HSE	0	0	3	100	33	56	0	0	11	35	6	38	8	89
IND	3	43	0	0	13	22	2	50	10	32	8	50	0	0
LA	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y19 – 5 February 1986 meeting number 28

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of PI's	% of PI's
TUC	0	0	0	0	8	13	1	20	4	18	0	0	0	0
CBI	1	25	0	0	12	20	1	20	7	32	1	14	1	25
HSE	2	50	1	100	34	57	1	20	7	32	3	43	3	75
IND	0	0	0	0	6	10	2	40	3	14	3	43	0	0
LA	1	25	0	0	0	0	0	0	1	45	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y20 – 2 May 1986 meeting number 29

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of PI's	% of PI's
TUC	1	8.3	1	9.1	7	10	0	0	3	14	0	0	0	0
CBI	5	42	1	9.1	10	14	1	100	5	24	6	40	0	0
HSE	3	25	9	82	42	60	0	0	7	33	5	33	1	100
IND	3	25	0	0	10	14	0	0	0	0	0	0	0	0
LA	0	0	0	0	1	1.4	0		0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table Y21 – Summary of ACTS Meetings (1980–1986)

Organisation	Nº of Q's	% of Q's	Nº of A's	% of A's	Nº of S's	% of S's	Nº of R's	% of R's	Nº of O's	% of O's	Nº of P's	% of P's	Nº of PI's	% of PI's
TUC	67	46	8	6.6	184	19	20	23	57	15	24	18	8	14
CBI	26	18	5	4.1	116	12	15	17	69	18	21	15	8	14
HSE	26	18	100	82	508	52	23	27	164	44	68	50	39	67
IND	21	14	4	3.3	150	15	25	29	76	20	23	17	3	5.2
LA	4	2.7	0	0	6	0.6	1	12	3	0.8	0	0	0	0
Other	3	2	5	4.1	10	1	2	2.3	4	1.1	1	0.7	0	0
TOTAL	147		122		974		86		373		137		58	

APPENDIX SEVEN

INTERVIEWS

PEOPLE INTERVIEWED DURING RESEARCH TRIP TO THE USA

Date of visit: 30 July - 17 September 1984

Place		Person
Cincinnati	1	William Wagner* (Chief of Criteria Document Section and Secretary of ACGIH TLV Committee for 1962-1982)
	2	Bill Kelley* (ACGIH Executive Secretary)
	3	Herbert Stokinger (ex-Head of NIOSH Toxicology and longest serving Chairman of ACGIH TLV Committee)
	4	Dick Lemen* (Director, Division of Standards Development and Technology Transfer, NIOSH
	5	Larry Mazzuckell* (Science Adviser in DSDTT)
	6	David Dunnom* (Criteria Document Section)
	7	Kent Hatfield* (Criteria Document Section)
Baltimore	8	Morton Corn* (Professor of School of Public Health - ex-Head of OSHA)
	9	Jacqueline Corn* (Historian of Occupational Health)
Washington	10	Peter Infante (OSHA - Director, Office of Carcinogen Identification and Classification)
Wilmington	11	Emile Christophano* (Corporate Hygienist at Hercules Corp.)
Pittsburgh	12	Henry Smyth* (Industrial Hygienist and Toxicologist)
	13	Industrial Health Foundation (founded in 1936 – various people)
Chapel Hill	14	Warren Cook* (Hygienist, Emeritus Professor, author of list from which first TLVs were drawn)
Cincinnati	15	Dick Niemeier (NIOSH, Experimental Toxicology Branch)
	16	Larry Lowry* (NIOSH Biochemist)
	17	Ed Leininger (NIOSH Training Branch)
Columbus	18	Vernon Carter (Present Chairman ACGIH-SSC)
Boston	19	Harvey Elkins* (ex-Chairman of ACGIH-SSC)
Concord	20	Theodore Hatch* (Hygienist (retired) early lecturer on Harvard course - 1920 one of the grandfathers of IH)
Boston	21	Nich Ashford (author of "Crisis in the Workplace")

* Substantial interview

APPENDIX 7.2

PEOPLE INTERVIEWED IN THE UK

1. Mr S Silk (former head of occupational hygiene in HSE) 2nd August 1983.
2. Dr R Schilling (Professor of Occupational Medicine, TUC Centenary Institute, London School of Hygiene and Tropical Medicine). 2nd and 23rd May 1986.
3. Mr S Luxon (former Head of HMFI Occupational Hygiene and Deputy Chief Factory Inspector) 13th May 1986.
4. Mr B Harvey (former Chief Inspector of Factories) 25th April 1986.
5. Mr J Hamilton (TUC Social Insurance and Welfare Department) 18 November 1986.