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BIO-MEDICAL RESEARCH
DOCUMENT DESCRIPTION FORM

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Source (Journal, Vol., Number, Pages, Date)

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CONSIDERATIONS IN THE DECISION OF THE SWEDISH OCCUPATIONAL STANDARD FOR VCM.

Ms for report on panel "International differences in decision-making on environmental controls. Case study: Vinyl chloride." at the International Conference on the Public Health Control of Environmental Hazards, New York Academy of Sciences, June 29, 1978.

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by

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Background. - Polyvinyl chloride (PVC) was first synthesized in the laboratory in Sweden during World War II. Vinyl chloride monomer (VCM) was made conventionally by adding hydrogen chloride to acetylene over a fixed bed catalyst containing mercury salt. At the end of the war, pilot plants were operating and market research was carried out by two Swedish companies. One of these, later named Kema Nord or Kema Nobel, started commercial production shortly after the war and is still manufacturing both VCM and PVC.

VCM was considered a rather harmless gas in the fourties in Sweden, as well as elsewhere, and it may certainly be assumed that workers'exposure to VCM was badly controlled. The exposure showed probably a great variation from time to time and was generally very high during the first decade of production. Hygienic control was hampered by lack of good analytical techniques in that range of concentration which is of most interest from the hygienic point of view. However, it has been estimated that the exposure may have been several hundred ppm as a time-weighted average for an 8-hour work day. Occasionally 1000 ppm may have been exceeded for hours and it happened that concentrations were around or above the lower explosion limit.

In the mid-sixties, the exposure was controlled to a highest level of 500 ppm according to recommendations from the authorities, the figure obviously emanating from the ACGIH TLV list. These recommendations were later decreased in steps down to 200 and 50 ppm (1972) partly due to the anxiety aroused by the reports on cases of acroosteolysis. Actual exposure for most work places where VCM was handled in early 1974, when the great concern for VCM as a carcinogen arose, was around 30 ppm.

The situation for the workers cleaning autoclaves merits special attention. Although the reactors were ventilated before cleaners entered, these workers must have been heavily exposed. Compressed air gas masks were used from 1960 and on, but for some years during the sixties the use of such masks was not mandatory. After directives from the authorities they were generally used from about 1970 and on.

The VCM exposed group of workers (population at risk) in the whole PVC polymerization industry up to 1974 in Sweden may be approximated to be about 1000. Due to rationalized production the work force today is around 250 for an annual production of about 150 000 tons PVC in a total of two plants. Most of this quantity is used by the fabricator industries in Sweden. The number of workers in the fabricator plants is today about 6000, as compared to a total labour force in the country of about 4 million.

It may be appropriate at this point to remind of the organization of the Swedish National Board of Occupational Safety and Health (NBOSH). NBOSH is comparable to the US authorities NIOSH and OSHA, taken together and organized under the Ministry of Labour. The Board of NBOSH has eleven members only, two of which are civil servants, namely the president and the vice president of the Board, who are at the same time general director and vice director of NBOSH. Of the other members four come from the employees, three from the employers and two from the parliament. One employer represents the public employers (state and commune) and of the politicians one comes from the present political opposition party. Besides being ruled mainly by laymen NBOSH has good connections with the interested main parties on the labour market. It should be pointed out furthermore, that all draft rules and regulation are thoroughly discussed with the labour

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unions and employers primarily involved before brought up for final decision by the general director or by the Board. The proposed standard for VCM was also treated in this participatory manner.

Biological considerations. - The establishing of a permissible level of occupational exposure to VCM involves theoretical difficulties as concerns the extrapolation from large doses to small doses within the same population studied (whether it is a mouse model or a group of occupationally exposed men). A few extrapolation models are at hand, as reviewed by Schneiderman et al (1), but no one can, on the present state of knowledge, tell which mathematical model is the true one to use for extrapolation from high doses to low doses for human dose-responsdata. Unfortunately, very few comparisons (2) of dose-response curves based upon animal and human studies for the same chemical can presently be made.

By using dose-response data from Maltoni's experiment Schneiderman et al (1) extrapolated mouse data to the low dose range and found that 1 ppm VCM inhaled during 4 hours at day, 5 days a week for 52 weeks would probably cause less than one Swiss mouse having a liver hemangiosarcoma out of 10 000. Now, this extrapolation did only consider hemangiosarcoma of the liver, a tumour type which in fact was in minority (3,4) among the hemangiosarcomas in the mouse and more so when all tumour types are considered. Studies (5,6) on VCM exposed workers support the idea that VCM is a multipotential carcinogen also for human populations as it is for rodents. This means that extrapolations should ideally include all tumour types and not only liver hemangiosarcomas. In Maltoni's experiment (3) the Swiss mice inhaling 50 ppm did get a life exposure dose of
50 ppm x 4 hours x 5 days x 52 weeks = 52 000 ppm x hours.
This is to be compared with the exposure for a PVC worker at a supposed TWA level of 20 ppm giving a yearly dose of
20 ppm x 8 hours x 5 days x 48 weeks = 38 400 ppm x hours.
Added to that, the worker might be exposed to other chemicals, such as tobacco smoke, alcohol or drugs, compounds which may contribute to the cancer risk.

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We don't know whether 1 ppm gives a risk above or under 1 in 10 000 among occupationally exposed men. There were no dose data at hand for VCM exposure in the VCM and PVC producing industries. No extrapolation model can thus be applied to human data. In many instances, witnesses declared that the victims of the VCM exposure occasionally have had high levels of exposure in their previous working history (7).

It might, however, be that high levels of exposure to a carcinogen for short time periods do involve a proportionally smaller risk than low levels of exposure during a longer time. Data obtained with polycyclic hydrocarbons (8) and with nitrosamines (9) seem to indicate that low levels are more effective than high levels, and this is discussed also for other carcinogenic agens (10).

An important biological information at the time of the decision of having a low Swedish occupational standard for VCM was that Maltoni (11) reported tumours in all tested species and particularly that 50 ppm, 4 hours a day, 5 days weekly for 52 weeks caused 2 % nephroblastomas, 2 % angio-sarcomas and some other tumours in Swiss mice. The Swiss mouse might be regarded as being more sensitive towards VCM than the human, but a very important additional biological information relevant to the decision of the Swedish VCM standard was that liver tumour cases were reported to have occurred also among PVC fabricator work men (12). No dose data for previous exposures were at hand for the PVC fabricators either, but certainly most or even all the fabricator industries in Sweden have had an average level of less than 20 and probably even much less than 10 ppm for many years. In that particular Swedish VCM and PVC production plant where two cases of liver hemangiosarcomas were reported (13) in 1974, the total population at risk since 1945 was 771 individuals (7) giving a hemangiosarcoma frequency of 0.26 % ($2594/10^6$).

It should be added, that today we know of two additional cases in the same worker's population, e.g. a total of 4 cases (giving a frequency of $5188/10^6$). The number of liver hemangiosarcomas in the total population (8 millions) in Sweden is 16 cases during the years 1958 through 1969 (13).

The true form of the dose response curve at low doses of a carcinogen has been much discussed both before and after the VCM event in 1974. For mutagens (14) as well as for carcinogens (15), which add to an effect already appearing in the background ("noise"), the dose response curve is probably linear from zero dose and onwards. This would mean that there does not exist a safe level for exposure to a carcinogen. By lowering the dose, the risk is only diluted, and the problem is then to define a dose giving a reasonable risk level. This level of exposure to a carcinogen we prefer to call an accepted low risk level of exposure. In the acceptance of an accepted low risk level not only toxicological information is important but so are also considerations on technological feasibility and on political issues in a more general sense. It is to be recognized that we believe that a democratic involvement is reasonable in the acceptance of the low risk level.

Technological considerations. - In the spring of 1974 it seemed inevitable, according to the judgment accepted by NBOSH to conclude that VCM is a potent animal and human carcinogen. The first step made by NBOSH was to demand the PVC-producer and also the PVC-fabricators to control that exposure was not higher than 20 ppm as an 8 hours'TWA. This seemed possible to achieve by more stringent operation of the technical equipment and processes already in use. Although almost no measurements had been made in the fabricator industry which transfer the PVC resin into moulded articles, floorings, coatings, films etc. it seemed certain that the general exposure among the fabricators was almost everywhere well below 20 ppm. Higher VCM concentrations over some hoppers for PVC-powder and in similar places could easily be reduced drastically. So the technological problem was mainly confined to the process industry. In the PVC-polymerization industry 20 ppm was in the spring of 1974 believed to be the best achievable level in the immediate future. Therefore a tentative value on 20 ppm was set.

In the autumn of 1974 more information was available. Taking into account the possibility that even very low exposures might carry some risk and taking into account the technical and economic possibilities of eliminating exposure, NBOSH finally stated late in the autumn of 1974 that the maximum permissible concentration (MPC) should be 1 ppm (8-hours TWA). However, the industry was given the whole year of 1975 for adjustment to the standard. Current exposures were around 10 ppm TWA or more at that time. The decision followed very much the same lines that had been drawn up in the U.S. and the OSHA Standard for VCM was of course studied thoroughly. A possibility which was considered for a while was a stepwise decrease to the permissible level, but it seemed more suitable to give the industry a more definite figure at once and by that give them due time to plan and adjust their technology accordingly. The labour union representative at the PVC plant concerned urged for a zero value but was content with 1 ppm. Also the central trade union was in favour of a stringent but not draconic move. 1 ppm seemed stringent and still possible to measure with satisfactory accuracy.

The technological considerations were based, amongst other things, on two facts. First it was known that the formaldehyde industry had long been operating in the few-ppm range and the ethylene oxide industry at not very much higher levels (16). What these industries could do, the VCM industry would also be able to achieve. Secondly, it was obvious that VCM, earlier believed to be safe, had been hitherto handled carelessly.

The company Kema Nobel engaged in intenese work during 1975 in order to comply with the promulgated standard and it succeeded. The measures taken were many and some examples are given below:

1. Thorough investigation of processes and process equipment was carried out in order to avoid all major emissions of VCM. This included better gadgets in flanges, pump shafts etc, closing reject water systems and air outlets from pressureless tanks and vessels and a lot of similar measures.

2. Special ventilation was installed to catch every small emission at the source. Well designed hoods were necessary in many places (17).

3. All PVC-products were, as far as possible, stripped of unpolymerized VCM before handled openly.

4. Special care was taken that all PVC-crust from reactor cleaning is handled in closed systems.

5. New processes were installed in order to avoid crust formation. High-pressure cleaning of reactors was introduced.

6. Automation and remote control was installed.

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7. Special pressure ventilation rooms were installed for autoclave operators.

8. General ventilation of a thoroughly designed type with jet-stream distribution of air flow was installed (16).

9. Special care was taken that spent air was not recycled to work premises.

10. All work areas are continuously controlled with instruments.

11. Personal protective equipment, mainly respirators, but also protective clothing is thoroughly controlled. Respirators should be used as soon as VCM levels exceed a certain peak value.

12. Some processes and equipments are not used any more.

13. All worker exposure is carefully monitored.

It is to be noted that all these hygienic measures were possible by applying known technology only. True technological innovations were unnecessary.

Present worker exposure is currently around 0.5 ppm or lower. Kema Nobel says the firm has spent 20 million Swedish Crowns (around 4 million US dollars) on technical changes. This has added a cost of 1-2 million Swedish Crowns per year compared to the production cost at an air quality standard of 5-10 ppm. Kema Nord also claims that a longer adjustment period would have meant essential savings in the economical investment. However, the judgment of the situation is difficult even in retrospective. It seems probable that the immaterial gain of the producer in restored confidence on behalf of the workers and the general public is worth much more than a portion of 4 million dollars. This sum should in its turn be seen in proportion to the profit per year of the company's PVC-division and seems then not to be a frightening fraction of money.

The results of all these endeavours can be seen in Table 1, which shows exposure at different time periods for different cathegories of workers. Personal monitors have been used and samples have been analysed chromatographically.

Also in the fabricator industry the situation is now satisfactory. This is partly owing to the fact that the standard PVC resin produced and selled by Kema Nobel now contains less than 10 mgs of VCM per kg of resin. Some qualities even come as low as below 3 mgs/kg. On the other hand, some PVC resin products are still on the market with as much as 1000-1500 mgs/kg of VCM. Thanks to special measures taken at the plants using this particular resin, the exposure to VCM today is well under 1 ppm among the fabricator industries too.

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PVC-Workers' exposure to VCM in ppm.*

Occupation	Quarter 2 1974	Quarter 3 1974	Quarter 4 1974	Quarter 1 1975	Quarter 2 1975	Quarter 3-4 1975	Year 1976	Year 1977	Quarter 1978
Shift foreman	8	4,7	1,4	1,1	1,8	0,9	0,1	0,1	0,2
Operator, general	14	11,5	5,3	1,9	1,4	1,0	0,3	0,3	0,2
Operator, polymerisation	11	10,8	3,4	1,4	0,9	0,7	0,2	0,3	0,2
Operator, treatment	8	6,2	2,3	0,8	1,4	0,4	0,2	0,2	0,1
Store worker	-	2,4	0,4	0,1	2,1	0,5	0,3	0,2	0,1
Repair man	44	25,3	2,2	1,0	0,6	0,3	0,2	0,1	0,2
Service man	18	9,5	4,0	1,1	0,7	0,7	0,3	0,2	0,3
Chemicals preparations	25	12,4	1,7	0,8	0,3	0,7	0,3	0,1	0,1
Cleaner	7	8,6	3,0	1,4	0,8	1,0	0,2	0,2	0,2
VCM-charger	10	13,0	13,3	2,3	0,4	0,5	0,3	0,3	0,3
Packer	-	4,0	2,4	1,8	0,9	0,8	0,3	0,3	0,2
House cleaner	-	3,5	2,1	1,2	0,8	0,3	0,2	0,1	0,1
Engineers	5	6,4	1,8	0,9	0,7	0,3	0,2	0,1	0,1
Number of measurement:	20	71	32	40	46	40-46	52-60	57-59	60
Average values:	16,5	10,3	3,4	1,3	1,1	0,9	0,3	0,2	0,2 ppm

*Figures are 8 hours' TWA based on personal dose measurements.

Biographical notes

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Experimental biologist, papers in experimental tumour research, the toxicology of organic solvents and vinyl chloride, occupational cancer epidemiology and on quantitative aspects on chemically induced cancer.

Westlin, Arne, Eng., Head of the Department of Supervision and inforcement, National Board of Occupational Safety and Health, Stockholm. Graduated Royal Technical University, Stockholm, 1942. Occupied with industrial research and chemical engineering 1942-1956. Publications on pulp chemistry, solvents, plastics, fuel chemistry, etc. From 1957 in occupational safety and health. Several publications in the field of occupational hygiene.

National Board of Occupational Safety and Health (NBOSH), Stockholm, is a governmental body under the Ministry of Labour, although with a high degree of autonomy. It is the central and highest body for regulating the work environment and is supervising and coordinating the regional and partly autonomous Factory Inspectorates. NBOSH consists of three subdepartments, the department of Supervision and Enforcement, the department of occupational health (a research dept) and an administrative department. The Board of NBOSH consists mainly of laymen, employers and employees representatives and politicians.