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VINYL CHLORIDE TOXICITY

MEETINGS HELD AT MCA HEADQUARTERS, WASHINGTON DC AND
NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH. ROCKVILLE, MARYLAND
ON 16TH AND 17TH JULY 1973

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INTRODUCTION

At the meeting of the European Group in Brussels on 15th June 1973, it was agreed that MCA would be given permission to reveal to NIOSH data arising from the Bologna study. This agreement was communicated to the MCA Group which attended the Brussels meeting. MCA were told that Drs Garlanda of Montedison and Duffield of ICI would attend the NIOSH meeting. MCA were requested to allow time for the European Group to approach their respective Governments before the NIOSH presentation and for this reason the NIOSH meeting was arranged for July 17th.

During the week of 9th July, Montedison requested an urgent meeting of the doctors representing the European Group and this took place in Bologna on 12th July. At that meeting, Montedison stated that they were strongly against giving NIOSH any results of European work, as some of the Group had not yet approached their own Governments and as NIOSH might take precipitate action on the basis of data given to them. Montedison also stated that Dr Garlanda would not be attending the NIOSH presentation.

The Solvay and Rhone-Progil doctors felt that, as these statements were a change in attitude, they would have to consult their Managements, in order to clarify Duffield's remit at the NIOSH meeting. As a result, Bernardi of Rhone Progil and Gosselin of Solvay were contacted by ICI. They felt that Duffield should exercise "as much discretion as possible" when presenting European information.

MEETING AT MCA HEADQUARTERS - 16TH JULY 1973

Present :	G E Best A Clark B Barrackman	MCA
	V K Rowe	Dow Chemical
	R N Wheeler	Union Carbide
	W E Hinehart	Ethyl Corporation
	D P Duffield	ICI

Before the meeting, Duffield took the opportunity of speaking to G E Best and outlined the developments which had occurred since the Brussels meeting. Duffield said that at the NIOSH meeting, he planned to give an outline of the protocol of the Bologna work and the fact that tumours had occurred in the test animals. After that, any questions posed by NIOSH would be answered frankly. Best stated that MCA would be happy to accept that form of presentation.

This position was reiterated at the full meeting, which was held in order to go through the presentation.

The only item of any note at this meeting was that it had been planned to give NIOSH a version of the results of Viola's work which was given to MCA orally by, it is thought, Lefevre. These results included approximate numbers of cerumenous gland tumours arising at levels lower than 30,000 ppm. No published data of this sort has ever appeared and

Duffield said that the information could well be inaccurate. This was agreed and it was, therefore, deleted from the presentation.

MEETING AT NIOSH HEADQUARTERS, ROCKVILLE, MARYLAND - 17TH JULY 1973

Present :	Dr Marcus Key - Director Dr Donald Lassiter - Toxicologist Mr Richard James Dr Keith Jacobsen - Toxicologist/Biochemist Dr Frank Mitchell - Priorities Analyst	NIOSH
	G E Best V K Rowe R N Wheeler W E Rinehart	MCA representatives
	D P Duffield	European Group representative

Rowe acted as spokesman for the MCA Group. He opened by saying that the meeting was requested by MCA in order to inform NIOSH of the carcinogenic potential of VCM in rats and to outline the MCA programme for further investigating this effect and the evaluation of any hazard to man.

He indicated the size of the industry in the USA and abroad and then went on to speak about the published Viola work and the work on AOL. The changes in the TLV for VCM, due to the finding of minor liver effects by Dow some years ago were also mentioned at this stage and then Duffield was asked to speak.

Duffield opened by saying that,

a) not all European members had yet had an opportunity to approach their Governments.

b) the European investigation was not yet complete.

c) the European work would be published in late 1974.

The Viola work was then outlined and the criticisms of it, on the basis of :-

1 Experimental conditions

2 Doubtful strain of rat used

3 The high acute mortality

4 The very high exposure levels, and

5 The histological interpretation of the tumours.

In spite of this, the European Group had felt it necessary to investigate the matter further in three areas:-

i) Risk to Man. At this point the Hillhouse epidemiology was outlined, as were the methods used in the study. It was emphasized that the exposure levels in the past were higher than those appertaining at present, as measures to reduce exposure had been and will continue to be used.

ii) Animal Work. The European Group had considered that an independent investigator should be used and that the work was being done in Italy.

A range of exposure levels was being used together with a control group and a vinyl acetate group. The strain of rat was the Sprague-Dawley, known to have a low natural tumour incidence. The work had been started in 1971. Follow up work, involving a repeat of the 30,000 ppm and short term exposures was at present being undertaken.

iii) Oral carcinogenicity tests were being planned at present, although technical difficulties were possible in this work.

As it was known that MCA were also concerned with this problem, the European results were passed to them in order to assist in determining the form of future investigations.

Finally, it was emphasized that on the basis of the limited epidemiological data available at present, there was no indication of employees having suffered any ill effect as a result of working in contact with VCM.

Rowe then explained the protocols for the work to be done by Industrial Biotest and Tabershaw Cooper and left these protocols with NIOSH, together with the press releases by MCA, announcing that the work has been contracted.

After the presentation NIOSH asked a number of questions:-

1 Duffield was asked again when the work in Italy had been started, the answer being 1971.

2 He was asked the lowest level at which tumours had occurred and the answer given was that the lowest effect level was 250 ppm.

3 Again in response to a question, Duffield stated that tumours had occurred in multiple sites, but these sites were not specified.

4 MCA was asked if any metabolic studies were planned. They said that this was being considered. Rowe revealed that Dow are doing independent work which indicated that VCM reacted with cysteine and glutathione, although the significance of this with regard to the carcinogenic activity of VCM was not apparent.

5 Rowe was asked if, with regard to the epidemiological data, it was possible to estimate, although approximately, the exposure levels on VCM and PVC plants, retrospectively. Rowe said that this was possible.

6 MCA were asked whether they would be agreeable to H Stokinger (a member of the ACGIH Committee and also NIOSH) seeing the protocols for the future MCA investigation. This was agreed to.

7 The question of sales of aerosols using VCM as propellant was raised by NIOSH. MCA replied that only one or two US companies still sold VCM for this purpose and that it was expected that by the end of this year, all sales for this purpose would be discontinued.

8 NIOSH asked whether interim reports on the MCA investigation could be given to them. This was agreed.

Dr Key said that he was very pleased that NIOSH had been approached by industry and wished that this was done more often. He stated that it would ease the Government's task in setting standards for industrial hygiene in industry.

APPRECIATION OF MEETING

The response of NIOSH appeared to be good and there was no indication that they would take precipitate action. It is clear that NIOSH is unhappy with the "blunderbuss" type of legislation being introduced to apply severe restrictions to the use of materials which, although rodent carcinogens, have never been shown to be human carcinogens.

There was no indication, although of course it is impossible to be sure, that NIOSH will take any action to impose tighter legislative control on exposure to VCM, until there is more indication from further MCA work as to whether or not a hazard to man exists.

It was surprising to both MCA and Duffield that there was not a protracted discussion of European work. It was not until after the meeting that Rinehart of Ethyl told the other MCA representatives and Duffield that Jacobsen, one of the members of NIOSH present at the meeting, had worked at Ethyl until recently and was aware of the results of the European work. It was known before the meeting that Jacobsen would be attending and the reason for Rinehart not telling the other industry representatives of this fact is extraordinary. This may account for the lack of discussion.

NOTE :

MCA once again asked that a meeting between Maltoni and the Industrial Biotest experimenters should be arranged. Duffield undertook to pass this request to the European Group.

D P DUFFIELD

DPD/MT