

MINUTES OF THE SECOND MEETING OF THE

COMPANY

PARAQUAT STRATEGIC ACTION COMMITTEE

SECRET

Held at Fernhurst on Friday, January 24, 1986

Present:-

Dr A K Stapleton (Chairman)	: Herbicides
Dr D H Brooks	: Development Department
Mr C A Spinks	: Development Department
Mr C S Major	: Public Affairs
Dr T B Hart	: PSRG
Mr G A Willis	: PSRG
Mr A J Robinson	: Americas Region
Mr D F Manning	: FEP Region
Mr T C Frears	: EMA Region
Mr A G Potter	: WER Region
Dr L L Smith	: CTL
Mr D J Viney	: Product Supply Department
Mr P J Bramley (Secretary)	: Herbicides

1 PARAQUAT REGULATORY POSITION

1.1 West Europe

GAW presented a summary of recent developments in Switzerland, Netherlands, West Germany, Italy and Scandinavia. These had been discussed at the Regulatory Fly-In held at Fernhurst in mid-January. Details are attached in Appendix 1.

1.2 European Parliament

CSM indicated that representations by the chemical industry against the recently drafted 'Resolution on agriculture and the environment' had succeeded in removing named agricultural chemicals (including paraquat) from the text and deleterious references to the 'Dirty Dozen'. The Environment Committee was still considering the document which will be voted on shortly.

1.3 Japan

DFM summarised developments since the last meeting in November. It now looks as if the pro-dilute, 5% 'Gramoxone' lobby in Japan was not succeeding and that dilute 'Preeglox L' would be launched in early June 1986. The registration package should be ready by end-March 1986. 'Gramoxone' sales were due to commence in Japan from late January 1986 once the restrictions/monitoring on availability had been instigated. The forthcoming visit of Professor Naito (who is involved with the SDS Biotech 'paste-like' granule) and the Guy's Hospital Paraquat Poisoning Symposium pose potential problems in the defence area. Both are being handled with the appropriate PPD resource inputs. CSM/GAW will produce the note on the Japanese situation for internal ICI circulation once the strategy looks clear.

ACTION : C S Major/G A Willis

## 2 FORMULATION DEVELOPMENT WORK GROUP

### 2.1 Solid Paraquat

The proposed two-part work programme for 1986 on solid paraquat was approved. The extra resource needed to meet this programme will be available from end-January 1986 (Appendix 2).

ACTION : WED, Yalding

This programme will cover evaluation of the new SDS 'paste-like' granule under a secrecy agreement. ICI is required to report to SDS by end-March 1986 when the agreement expires.

### 2.2 Thickened Formulation

The proposed two-part Yalding work programme for 1986 on the thickened paraquat formulation developed by Sopra was discussed (Appendix 3). It was agreed that the evaluation of such a formulation for international use (rather than just for France) was desirable as a means of increasing the 'basket of options' for future product defence and in particular of perhaps defending the 200 g/l strength formulation. However, it was felt that the proposed resource input of 1 man year (largely Experimental Officer effort) may not be appropriate.

ACTION : D H Brooks/D J Viney to review

## 3 INCREASED EMETIC CONCENTRATIONS

GAW summarised the report of the Work Group (See Appendix 4). It is hoped that France and Japan can be used to test the hypothesis that an increase in the level of emetic concentration above the current 0.5 g/l will lead to a reduction in poisoning mortality rates along the lines indicated in animal experiments recently completed at CTL. LLS indicated that the full CTL reports will be available shortly. Both markets will provide experience from diluted formulations of paraquat. The Work Group is still looking for other suitable 'test' markets so as to ensure a rapid and full data response.

ACTION : Regions to consider

## 4 GENERATION OF AGREED DATA BASES

### 4.1 Regulatory

Discussions with PSRG have led to the agreement that the following three areas of work require addressing:-

- (a) The parameters to include in the new 'Smart' system, being developed to replace the 'Delta' system.

(b) The checking of the present data base.

(c) Updating of the system.

The following parameters will be included in the new system:-

Chemical name  
Trade name  
Formulation number  
Formulation type and concentration  
Country  
Regional code  
Regulatory status  
Restrictions  
Submissions date  
Registration date  
Expiry date  
Outlet (crops)  
Tolerances  
Harvest intervals  
Current (yes and no)  
Comments (a field for further information)  
Notification date

PSRG will have changed to the new system by early February. A copy of the present print-out will be sent to all units for their updating. Within two months, this updated record should be available. PSRG will substantially update the record quarterly by using dedicated contract resource.

ACTION : C A Spinks/M S Thomas by next meeting

#### 4.2 Commercial

Investigation of available Group data on past sales of paraquat indicated that it should be possible to generate sales histories back to 1980 by major formulation by market. This work should be completed in 2-3 months. The key requirement is an agreed Regionally-owned, consistent data base.

ACTION : P J Bramley/M S Thomas

#### 5 SOILS WORK GROUP

On the basis of recent analytical work it is clear that the strong adsorption capacity of some extremely sandy soils and highly organic soils is capable of being exceeded if very high rates of paraquat are applied annually.

This fact, combined with the regulatory action which has been taken over paraquat in West Germany and Holland makes it important that ICI's views on this subject should be clear and explicit.

The key technical facts remain as follows:-

- \* On contact with soil, paraquat is rapidly and strongly adsorbed to clay minerals. This process deactivates it and renders it biologically inactive.
- \* Most soils can strongly adsorb and deactivate paraquat residues resulting from hundreds or thousands of normal applications.
- \* Sands and organic soils have the lowest capacities to deactivate paraquat, but even these soils can deactivate residues resulting from very many applications.
- \* Long-term field investigations show that paraquat residues in soil are slowly decomposed.
- \* The rate of decomposition means that the deactivation capacity of almost all soils can never be exceeded as a result of the prolonged use of paraquat.
- \* There is no risk that adsorbed paraquat residues will be leached out of the soil, nor displaced by fertilisers or other agricultural chemicals.
- \* There is no known case where the normal use of paraquat has led to the deactivation capacity of any soil being exceeded, nor where paraquat once adsorbed has been subsequently reactivated.
- \* Adsorbed paraquat residues are not taken up by crops and have no effect on plants or crop yield. They do not affect earthworms, micro-arthropods or micro-organisms in the soil, nor do they alter the availability of nutrients.
- \* Adsorbed residues therefore have no agronomic or environmental consequences.

Diquat is also rapidly and strongly adsorbed to clay minerals, however its use pattern and rates preclude the possibility of a soil's strong adsorption capacity being exceeded even on extremely sandy and highly organic soils.

In order to ensure that no problems ever arise as a result of the strong adsorption capacities of extremely sandy or highly organic soils being exceeded, a precautionary statement should be added to paraquat product labels during the normal process of label revision. The Technical Review Committee of 12 July 1985 gave strong support to the recommendation that the Soils Work Group should draft label recommendations covering the further use of paraquat and paraquat mixtures. It was agreed that such recommendations should be produced for wider internal discussion and that the timing of the process would be governed by the regulatory climate in Western European countries.



At subsequent meetings it has been decided that a proposal will be made to the Regions for a 'blanket' statement to be placed on all paraquat and paraquat/diquat mixture labels. Regions will be asked to justify any specific exemptions. The label recommendation for paraquat-only products will be something like:-

'To avoid the possibility of crop damage do not apply more than an average of 3 l of product/ha/year on very sandy or organic soils'.

A draft of such a recommendation will be available in February 1986 and responses from the Regions are planned to be available before end April. Therefore by May 1986 an internally agreed amendment should be available which can then be placed on labels in a timescale appropriate to the regulatory strategies and label reprinting plans for all countries.

The Committee expressed concern at the possible commercial/regulatory implications of such a label recommendation particularly in the current regulatory environment for paraquat.

ACTION : C A Spinks to bring forward specific recommendations to the Committee before finalising

## 6 OVERALL STRATEGY FOR THE INTRODUCTION OF PARQUAT/DIQUAT MIXTURES

The recent crisis in Japan has thrown into focus the current strategy for introducing paraquat-diquat mixtures as one method of defending the paraquat business in a particular market. In particular it revealed gaps in PPD's data base on acute toxicity of the new liquid formulations and on poisoning case histories. The crisis also highlighted the fact that diquat is now being drawn into the regulatory limelight.

It was agreed that Herbicides Department and Development Department should co-ordinate a review of the overall strategy of introducing these liquid formulations covering:-

- \* Biological implications and field data base
- \* Toxicity implications and data base (including current CTL studies)
- \* Poisoning treatment
- \* Economic implications (active ingredient, formulation, packaging)
- \* Diquat toxicological and environmental data base (including soil)

It was proposed to bring this study forward to the next Paraquat Strategic Action Committee meeting.