EXHIBIT 30

FILED UNDER SEAL

CALIFORNIA CHEMICAL COMPANY
ORTHO DIVISION
RESEARCH AND DEVELOPMENT DEPARTMENT
RICHMOND, CALIFORNIA

MEETING WITH FDA AND USDA, WASHINGTON, D.C., TO DETERMINE STUDIES REQUIRED FOR SUBMISSION OF PARAQUAT TOLERANCE PETITION AND PARAQUAT NO-RESIDUE REGISTRATION — JULY 19, 1963

Those Present:

Mr. Stokes, Assistant to Mr. McFarland - Food and Drug
Dr. Fitzhugh - Food and Drug
Mr. Alpert - Food and Drug
Mr. Beusch - Food and Drug
Mr. Cummings, Chemist - Department of Agriculture
Dr. Boon - Plant Protection
Dr. Swan - ICI
Dr. Calderbank - Plant Protection
Dr. Toland - California Chemical
Mr. Kohn - California Chemical
Dr. Reed - California Chemical
Dr. Calandra - Bio Test Laboratories

The chemistry, use, method of analysis, and level of analytical data for Paraquat was discussed with this group relative to the requirements which will be required in order to establish a tolerance for Paraquat. It was explained that for the time being, Diquat was not under consideration, but would be in the future, but that Paraquat and Diquat were very similar in their chemical and biological behavior, and so the data presented and the information discussed could apply equally to both products.

Dr. Swan presented, in outline form, the various studies relative to the toxicology of Paraquat which were underway or would be inaugurated and the results prepared for presentation with a Paraquat petition at the time the petition was filed requesting a numerical tolerance. The studies outlined by Dr. Swan were as follows:

1. Acute oral toxicity in several species.

2. Subcutaneous toxicity in several species.

3. Inter-tracheal toxicity in rats.

4. Acute and 20-day subacute dermal toxicity in rabbits.

5. Preliminary observations on wildlife.

6. Preliminary metabolism and excretion studies in animals.

7. Two-year feeding studies in rats - 3 test levels.

8. Two-year feeding studies in dogs - 3 test levels.

9. Reproductive study - 3 generations in rats (not started as yet).

10. Human studies - urine analysis for Paraquat in spray operators.

11. Preliminary studies in domestic animals.

Dr. Fitzhugh stated that the following list of studies would be required in addition to the above:

1. Complete animal metabolism studies.

2. Complete plant metabolism studies.

3. If the animal and plant metabolites are the same, then the animal feeding studies, i.e., the two-year rat and dog three-level tests, will be sufficient to ascertain the toxicity of the parent compound and the metabolites in animals. If the plant metabolites are different than the animal metabolites and any of the plant metabolites are present at harvest, then 90-day studies in both rats and dogs will be required for each plant metabolite different from the animal metabolites that are present at the time the crop is harvested will be required.

4. If Paraquat-treated forage or feed containing a residue is fed to livestock, then a cow study to determine the level of Paraquat plus metabolites that may appear in milk or meat will be required. An outline of this study has been previously prepared and submitted to FDA for approval. Dr. Swan requested that an outline of this study be supplied by Dr. Calandra.

5. A meeting with Dr. Lehman to discuss the human study requirements was held later the same day. Dr. Lehman stated that at the present time FDA was requiring human studies and outlined them as follows:

   A human study should employ a minimum of 5 male and 5 female subjects. The study should last for a period of 3 to 4 weeks. The initial dosage should start at 1/10 the maximum tolerance requested. After feeding for 3 to 4 days, the dosage should be increased by increments. The first increment being that of the requested tolerance. Additional increments to be determined by the animal studies which will have been completed. Increments to be continuously increased every few days until symptoms or side effects are definitely noticed.

   The type of clinical laboratory studies will depend on the nature of the chemical studied, the results with the animal studies completed, and the studies may include the following:

Red and white blood cell count, differential white blood cell count, hemoglobin, hematocrit, clouding time, SGOT, serum alkaline phosphatase, Cephalin flocculation, BUN, B.S.P., B.S.P., cholestrol, EEG (inorganic halides), routine urine analysis and cholinesterase determinations. Biopsies of the liver, gut and bone marrow punctures may be included when indicated. Where the analysis or metabolism of the compound in animal studies indicates that it will accumulate in the fat, then fat biopsies and analysis are indicated.

The above tests will be required on all new materials, and on all old materials which have an established tolerance and which may have unresolved safety aspects or for which new tolerances are requested.

Dr. Lehman and Dr. Fitzhugh both indicated that these procedures were still open to question, and that a general policy by FDA had not yet been definitely established. Final decision relative to the extent of the requirements for human studies depend upon a decision by the Commissioner of Food and Drug due some time during the month of July or August.

6. Soil degradation and metabolism studies will be requested.

7. Where a product is to be added to water or may leach from treated soil into water, water degradation studies will be required.

8. If the plant metabolism studies demonstrate that plant metabolites will be present on or in any raw agricultural commodity, whether treated directly or indirectly by treating the soil or the water, then the residue analysis required for the tolerance will include Paraquat and the metabolites.

9. It was stated that the level of pesticide residues or metabolites made no difference, as long as there was a remeasurable and detectable residue, the same type of studies for low as for high residues would be required.

10. To satisfy the requirements relative to plant metabolites, Mr. Alpert stated that a representative number of the various groups being requested for a tolerance should be analyzed and suggested that approximately two representatives from at least three technical groups be included. Dr. Alpert also requested that before such studies were carried out that the crops selected and the method of study be outlined and submitted for approval. It was indicated that if none of the six crops show metabolites at harvest, then no further studies would be required. However, if some of the crops show metabolites and others do not, then additional studies will be required, based upon the findings.

11. Both Dr. Cummings, of USDA, and Mr. Alpert, of FDA, requested that validation data and recovery be carried out close to the lower limit accuracy of analytical methods.

At a general meeting between ICI and Ortho, it was agreed that ICI or PPL would:

1. Carry out the reproductive studies.
2. The plant metabolite studies.

It was further agreed that Ortho would:

1. Carry out the soil metabolite or degradation studies.

2. The cow studies to determine the fate of Paraquat in meat and milk.

It was further agreed that PPL would provide C-14 labeled Paraquat for the soil degradation studies. Ortho was to notify PPL as soon as possible the quantity of C-14 labeled Paraquat desired or required for the studies.

T. W. Reed

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