S.F.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

AUG 31 1989

MEMORANDUM

SUBJECT: **PP#7F1910 (Reg. No. 10182-103); Paraquat (Gramoxone) on Dry Beans. A Poultry Feeding Study and Geographical Restriction; Amendment of 4/18/89. MRID #409437-04, DEB #5595.**

FROM: Sami Malak, Ph.D., Chemist
Tolerance Petition Section III
Dietary Exposure Branch (DEB)
Health Effects Division (HED)/H7509C

TO: Robert J. Taylor, PM #25
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch II
Herbicides/Fungicides/Antimicrobials
Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch
Health Effect Division (H7509C)

Introduction and Background

This is an expedited review of subject petition, due 8/31/89 in accordance with Anne Lindsay's letter of 8/7/89 to Penelope Fenner-Crisp. Expedited reviews of dinoseb alternatives, including paraquat, are authorized by the Agency in accordance with a memo from Dr. John Moore to the Honorable Dale Bumpers of the US Senate, dated 2/12/87.

In this submission ICI responded, on 4/18/89 to DEB's memo of subject petition (F. Toghrol, 10/24/88) and submitted a poultry

feeding study and a Section B proposing use of Gramoxone Super Herbicide as a harvest aid of dry beans, except Fava beans (a cover letter and a label were received by this reviewer on 8/28/89). Use, which is not permitted in California, would allow one or two aerial or ground applications when at least 80% of the pods are yellowing and mostly ripe. The proposed rate is 1.5 to 2.5 pts/A/application for a maximum of 0.47 lb act/A/season. A non-ionic spreader is to be added at 1 qt/100 gallons of spray mix. There is a 7 day PHI. There is no restriction against grazing or feeding.

For weed control in snap and lima beans (succulent) the registered label (Gramoxone, Reg No. 10182-103) allows one preemergent ground application using 2.5 to 5 pts/A/ application for a maximum of 0.9 lb act/A/season. There is no grazing or feeding restrictions.

Paraquat (1,1'-dimethyl-4,4'-bipyridinium-ion) is regulated under 40CFR§180.205 with tolerances in or on several raw agricultural commodities (racs) at levels ranging from 0.01 to 5 ppm, including snap and lima beans (succulent) at 0.05 ppm, as well as guar beans at 0.5 ppm, beans forage at 0.1 ppm, and bean hay at 0.4 ppm. Further, tolerances are currently established for residues of paraquat in or on milk, eggs, and poultry fat, meat, and meat byproducts at 0.01 ppm; the kidney of cattle, hogs, horses, and sheep at 0.3 ppm; and the meat, fat, and meat byproducts of cattle, hogs, horses, and sheep at 0.05 ppm.

Paraquat CL is currently registered as a harvest aid on soybeans with a tolerance of 0.05 ppm. A Section-18 exemption, expired 10/15/79, was granted to the state of New York allowing use of paraquat as a harvest aid of dry beans, with a tolerance of 0.4 ppm and a grazing restriction. A temporary tolerance of paraquat as a harvest aid of dry beans with a tolerance of 0.5 ppm expired 2/18/85.

In subject petition, on 1/18/77, Chevron Chemical Company requested the establishment of a 0.3 ppm tolerance for residues of paraquat in or on dry beans grown in the states of Michigan and New York. The proposed label prohibits grazing of livestock in treated areas or feeding treated crop residues. The proposed use would allow one application by air or ground using 2.5 to 5 pts/A/application for a maximum of 0.5 lb act/A/application, when 75% of the beans are matured. DEB concluded that the residue data supported the proposed tolerance under the geographical and grazing restrictions (R. Perfetti, 5/20/77). On 3/21/80 Cheyron submitted an amended label to delete the grazing and feeding restriction and proposed a tolerance of 30 ppm for residues of paraquat in or on bean straw. DEB recommended against the tolerance because residues in liver and fat were not adequately delineated (A.

Smith, 9/7/80). In accordance with the Paraquat RS (11/15/85), the nature of residues of paraquat in animals is now considered adequately understood. Therefore, the proposed 30 ppm tolerance for residues of paraquat in or on bean straw will be considered in this memo.

A Registration Standard (RS) for Paraquat was published in November 15, 1985. Poultry and cattle feeding studies, as well as an enforcement method for animal tissue were listed as outstanding data gaps.

According to the Paraquat Registration Standard, the maximum expected dietary intake of paraquat by beef cattle is 11 ppm, if the diet consists of 45% alfalfa forage, 30% sorghum grain, 20% wet citrus pulp, and 5% spent mit hay. The contribution of alfalfa forage and wet citrus pulp were corrected for dry material; thus alfalfa forage was multiplied by a factor of 4.8 and wet citrus pulp by 7.1 prior to determining their residue contribution.

If the livestock diet consists of 45% alfalfa forage, 30% sorghum, 20% dry beans and 5% bean straw, the maximum expected dietary intake of paraquat by beef cattle was calculated at 12.3 ppm as follows:

Feed Item	Tolerance ppm	Concentration Factor	% In Diet	Residues ppm
Alfalfa	5.0	4.8	45	10.8
Sorghum grain	0.05	---	30	0.015
Dry Beans	0.3	---	20	0.06
Bean straw	30.0	---	5	1.5
		Totals	100	12.375

This level is slightly higher than 11.2 ppm, but will not change the already established tolerances in commodities of animal origin.

Review and Comments

In this review, we list each of the deficiencies listed in DEB's memo of 10/24/88, followed by the petitioners response and DEB's comments.

Deficiency 1

No residue data have been submitted for California, a major bean growing area. Residue field trials for dry beans from California are necessary.

Petitioner's Response

The petitioner acknowledged that California produces about 12% of the dry beans in the US. Further, a consultant report was included in this submission, entitled "Evaluation of Dry Bean Desiccant Usage in California." The report was compiled by G. C. Crowell of ICI, dated 4/17/89. It contains a 3-page summary and supporting correspondences and data on California dry bean cultural practices from the Cooperative Extension personnel of the University of California, as well as from grower/co-op organizations from the major dry bean areas in California.
In the report, it was emphasized that the use of desiccants/harvest aids is not within the scope of normal California cultural practices since the combination of water management programs and climate provides the most effective and preferred method of desiccation.

DEB's Comments

We accept the petitioner's argument that paraquat is not likely to be used as a desiccant on dry beans in California. The available residue data in subject petition are adequate to allow use of paraquat as harvest aid of dry beans. R. Perfetti's memo of 5/20/77 stated "Residue data submitted in this petition reflected treatment of 10 varieties of beans grown in 6 states with paraquat (CL formulation only). The only major dry-bean producing state not represented was California. However, since this use is limited to New York and Michigan we will not require data on dry beans grown in California at this time (Note: Since California has a dry climate there is little likelihood that this harvest aid would be needed in that area at all). The petitioner should be informed, however, that expansion of this use to dry beans grown in California will engender the need for additional residue data and possibly reevaluation of any existing tolerance."

Deficiency 1 has been resolved provided the label prohibits use in California.

Deficiency 2

Dry beans can be used up to 15 % in poultry feed. A poultry feeding study at levels high enough and long enough is needed to support existing poultry tolerances.

Petitioner's Response

ICI re-submitted a poultry feeding study, previously submitted on 12/20/88, included in MRID #409437-04, entitled "Paraquat: Residue Transfer Study with Laying Hens Fed a Diet Containing

the Herbicide." The 110-page report is authored by M. Earl and A. D. Boseley of ICI; Lab. Project No. RJ0703B, dated 12/15/88.

The petitioner, however, believes that the review of these data could be deferred and the proposed tolerances and registration be granted on the following basis: "(1) Tolerances have been already established on eggs, poultry fat, poultry meat and poultry meat by-products; (2) According to subdivision -O of the Registration Guidelines, bean seed and pod represent only 10 to 15% of the poultry diet; and (3) Paraquat is already approved for use on crops such as barley, oats, corn, sorghum, soybeans, peanuts and wheat which can represent individually from 20 to 70% of the poultry diet. The use of desiccant/ harvest aid represents no incremental exposure/risk to poultry as shown below:

CROP - FEED	% OF DIET	RESIDUES (PPM)	FEED (PPM)
Sorghum-grain	60	2.0	1.2
Dry beans - seed	15	0.3 (proposed)	0.045
Other components	25	0.05	0.0125
	Totals	100	1.2575

The above calculations are based on the proposed tolerance of 0.3 ppm and a contribution of bean seed to the poultry diet of 15% show that this use would contribute only 0.045 ppm of paraquat to the overall poultry diet (1.2575). This additional increment is insignificant and would not result in current tolerances for eggs, meat and meat by-products being exceeded."

We note that the petitioner cited a tolerance of 2 ppm for sorghum grain, whereas the correct tolerance is 0.05 ppm.

<u>For our records, the following is our review of the poultry feeding study:</u>

The study was conducted in the United Kingdom during 1988. In this study, two sets each containing two groups of ten laying hens were fed for 35 consecutive days on a diet containing 6 and 13 ppm paraquat dichloride salt. Further, three groups each of ten laying hens were fed for 35 consecutive days on a diet containing 30 ppm paraquat dichloride salt. Control groups each of ten birds were fed on untreated diet over the same period of time. Eggs were collected daily and tissue samples were taken immediately after sacrifice.

Tissue samples were analyzed within 5 months of storage and egg samples were analyzed within 6 months of storage at -18°C. Paraquat is known to be stable in commodities of plant origin

for a period of up to 5 months in a freezer (Paraquat RS, 11/15/85). Storage stability of paraquat in commodities of animal origin was cited by the Paraquat RS as a data gap. However, in this submission, the petitioner stated that sample analysis of frozen eggs and poultry tissue indicated stability of paraquat in eggs for up to 6 months and poultry tissue for up to 5 months.

The method used in the analysis is referenced in this submission under the title "ICI Agrochemicals Residue Analytical Method 4B: The Determination of Residues of Paraquat in Animal Tissues and Eggs, authored by M. Earl and A. D. Boseley." There is no enforcement method for poultry. The Paraquat RS discussed a method for commodities of plant and animal origin, acceptable for residue data, but is only minimally adequate for enforcement/monitoring purposes because it is too long and cumbersome. It needs long digestion times, use of ion-exchange columns, and the determination step is colorimetric.

In the Earl and Boseley method, the samples are extracted with 10% trichloroacetic acid, centrifuged and the combined supernatant is filtered then percolated through a column of cation exchange resin which retains the paraquat and some of the coextractives. The column is then washed with water and 2.5% ammonium chloride and water. The paraquat is then eluted with saturated ammonium chloride solution. Quantitation is accomplished by the use of HPLC equipped with an UV detector. Minimum detection limit for the method is reported at 0.005 ppm.

Sample chromatograms are included. The method was validated by fortifying eggs and various poultry tissue with paraquat. Recoveries ranged from 72 to 87%.

Test results are summarized below:

Poultry Eggs & Tissue	Residues of Paraquat in ppm at Feeding Levels 6 ppm	13 ppm	30 ppm
Eggs	0.01	0.02	0.04
Muscle	ND[1/]	ND	0.05
Fat	ND	ND	ND
Kidney	ND	ND	0.14
Liver	ND	ND	0.10

ND = Non-detectable (<0.005 ppm).

DEB's Comments

From the data presented, it is our assessment that the established tolerance of 0.01 for poultry eggs and tissue will not be exceeded if a 0.3 ppm tolerance for dry beans is considered. The maximum dietary burden for poultry was calculated at 0.09 ppm as follow:

Feed Item	Tolerance ppm	% In Diet	Residues ppm
Sorghum grain	0.05	60	0.03
Dry Beans	0.3(proposed)	15	0.045
Wheat grain	0.05	25	0.0125
	Totals	100	0.0875

It appears that the poultry feeding study and the storage stability of paraquat in eggs and poultry tissue are adequate. By the use of Earl and Boseley method referenced in this submission, it was shown that paraquat is stable in a freezer (-18°C) when treated eggs and poultry tissue are stored for periods of up to 6 and 5 months, respectively.

Deficiency 2 has been resolved.

Deficiency #3

Submit a methodology for enforcement of the current residues of concern in animal tissues. If TOX determines that additional residues of concern are needed to be regulated, then additional methodology may be needed for enforcement. All proposed enforcement methodology will require validation by the EPA laboratory.

Petitioner's Response

No information were presented for this deficiency. The petitioner has indicated that data were submitted to the Agency on 12/20/88, MRID #409437-01 to address this concern. According to the petitioner, since no incremental exposure/risk to poultry expected from the proposed use as a desiccant on dry beans, review and validation of these data are not necessary at this time.

DEB's Comments

We concur with the petitioner that EPA validation of these analytical methods is not necessary for establishment of the proposed tolerances on dry beans and bean straw.

Deficiency 3 has been resolved.

We do note, however, that validation of these methods will still be required as part of the re-registration process for paraquat. In the interest of obtaining better methods for monitoring paraquat residues, the available data concerning a methodology for commodities of animal origin previously submitted to the Agency on 12/20/88 under MRID #409437-01 should be made available to DEB as soon as possible for our evaluation. In addition, the complete method by Earl and Boseley used in the poultry feeding study needs to be submitted.

Comments/Conclusions

1. We accept the petitioner's argument that paraquat is not likely to be used as a desiccant on dry beans in California. The 0.3 ppm tolerance for residues of paraquat in or on dry beans and 30 ppm in or on bean straw are adequate provided the label clearly prohibits use in California.

2. It appears that the poultry feeding study and the storage stability of paraquat in eggs and poultry tissue are adequate. By the use of Earl and Boseley method referenced in this submission, it was shown that paraquat is stable in a freezer (-18°C) when treated eggs and poultry tissue are stored for periods of up to 6 and 5 months, respectively. The feeding study shows that the existing poultry tolerances are adequate to cover the proposed use on dry beans.

3. EPA validation of the analytical methods for paraquat in animal commodities will not be required for establishment of the dry bean and bean straw tolerances. However, such validation will be needed as part of the re-registration process.

4. Dry beans and bean straw are also used in livestock diets (other than poultry). Existing tolerances for residues of paraquat in or on commodities of livestock origin will not be exceeded as a result of the proposed use on dry beans.

Recommendations

DEB recommends for establishment of a 0.3 ppm tolerance for residues of paraquat in or on dry beans and 30 ppm in or on bean straw provided that the label clearly prohibits use in California.

NOTE TO PM: In the interest of obtaining better methods for monitoring paraquat residues, the available data concerning a methodology for commodities of animal

origin previously submitted to the Agency on 12/20/88 under MRID #409437-01 should be made available to DEB as soon as possible for our evaluation. In addition, the petitioner should be requested to submit the complete method by Earl and Boseley used in the poultry feeding study. We will request validation of these methods by Agency laboratories as soon as sufficient information on them has been made available.

c: S. Malak, R. D. Schmitt, PP#7F1910 for paraquat, Paraquat RS file, Paraquat SF, E. Eldredge (ISB/PMSD), RF, and Circulation.

RDI: J. Garbus: 8/31/89: R. A. Loranger: 8/31/89.
H7509C;DEB/HED:CM#2:RM814A:S.Malak:X557-4379:s.m.:8/29/89.