United States
Environmental Protection
Agency

Prevention, Pesticides
And Toxic Substances
(7508W)

EPA 738-F-96-018
August 1997

Reregistration Eligibility Decision (RED)

Paraquat Dichloride

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case paraquat dichloride which includes the active ingredient 1,1'-dimethyl-4,4'-bipyridinium dichloride. The enclosed Reregistration Eligibility Decision (RED), which was signed on 9/30/96, contains the Agency's evaluation of the data base of these chemicals, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredients to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the date of this letter. The second set of required responses is due 8 months from the date of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that the Food Quality Protection Act of 1996 ("FQPA") became effective on August 3, 1996, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED takes into account, to the extent currently possible, the new safety standard set by FQPA for establishing and reassessing tolerances. However, it should also be noted that in continuing to make reregistration determinations during the early stages of FQPA implementation, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early case-by-case decisions, EPA does not intend to set broad precedents for the application of FQPA. Rather, these early determinations will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and any rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will pursue whatever action may be appropriate, including but not limited to reconsideration of any portion of this RED.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Venus Eagle at (703) 308-8045. Address any questions on required generic data to the Special Review and Reregistration Division representative, Ruby Whiters at (703) 308-8079.

Sincerely yours,

Lois Rossi, Division Director
Special Review and
Reregistration Division

Enclosures

SUMMARY OF INSTRUCTIONS FOR RESPONDING TO THE REREGISTRATION ELIGIBILITY DECISION (RED)

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"--You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If

you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

By U.S. Mail:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
EPA, 401 M St. S.W.
Washington, D.C. 20460-0001

By express:

Document Processing Desk **(RED-SRRD-PRB)**
Office of Pesticide Programs (7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

REREGISTRATION ELIGIBILITY DECISION

Paraquat Dichloride

LIST A

CASE 0262

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
SPECIAL REVIEW AND REREGISTRATION DIVISION

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PARAQUAT DICHLORIDE REREGISTRATION ELIGIBILITY DECISION TEAM

Office of Pesticide Programs:

Biological and Economic Analysis Assessment

George Keitt	Biological Analysis Branch
Gabe Patrick	Biological Analysis Branch
John Faulkner	Economic Analysis Branch

Environmental Fate and Effects Risk Assessment

Sharlene Matten	Science Analysis and Coordination Staff
Laura Parsons	Environmental Fate and Groundwater Branch
Harry Winnik	Ecological Effects Branch

Health Effects Risk Assessment

Mary Clock	Risk Characterization and Analysis Branch
Krystyna Locke	Toxicology Branch I
Pam Hurley	Toxicology Branch I
David Miller	Reregistration Support Chemistry Branch
Brian Steinwand	Science Analysis Branch
Tina Manville	Occupational and Residential Exposure Branch

Registration Support Risk Assessment

Vickie Walters	Fungicide-Herbicide Branch

Risk Management

Venus Eagle	Reregistration Branch
Judy Coombs	Reregistration Branch

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FAO/WHO	Food and Agriculture Organization/World Health Organization
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD_{lo}	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs

GLOSSARY OF TERMS AND ABBREVIATIONS

PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
Q^*_1	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
RUP	Restricted Use Pesticide
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
ug/L	Micrograms per liter
WP	Wettable Powder
WPS	Worker Protection Standard

ABSTRACT

The U.S. Environmental Protection Agency has completed its reregistration eligibility decision of the pesticide paraquat dichloride. This decision includes a comprehensive reassessment of the required target data supporting the use patterns of currently registered products. This decision considered the requirements of the recently enacted "Food Quality Protection Act of 1996" which amended the Federal Food Drug and Cosmetic Act and the Federal Insecticide, Fungicide and Rodenticide Act, the two Federal statutes that provide the framework for pesticide regulation in the United States. FQPA became effective immediately upon signature and all reregistration eligibility decisions (REDs) signed subsequent to August 3, 1996 are accordingly being evaluated under the new standards imposed by FQPA.

In establishing or reassessing tolerances, FQPA requires the Agency to consider available information concerning aggregate exposures to pesticide residues, including all anticipated dietary exposures and other exposures for which there is reliable information, as well as the potential for cumulative effects from a pesticide and other compounds with a common mechanism of toxicity. The Act further directs EPA to consider the potential for increased susceptibly of infants and children to the toxic effects of pesticide residue.

Paraquat dichloride is currently registered for the control of weeds and grasses in agricultural and non-agricultural areas. It is used as a preplant or preemergence herbicide on vegetables, grains, cotton, grasses, sugarcane, peanuts, potatoes, and on areas for tree plantation establishment. Paraquat is applied as a directed spray postemergence herbicide around fruit crops, vegetables, trees, vines, grains, soybeans, and sugarcane. It is used for dormant season applications on clover and other legumes, and for chemical fallow. It is also used as a desiccant or harvest aid on cotton, dry beans, soybeans, potatoes, sunflowers, sugarcane and as a post harvest desiccant on tomatoes. Finally, it is applied to pine trees to induce resin soaking. Paraquat dichloride is also used on non-crop areas such as public airports, electric transformer stations and around commercial buildings to control weeds.

The Agency has reassessed paraquat dichloride food and feed tolerances under the standards of FQPA and determined that the existing tolerances with amendments and changes as specified in this document meet the safety standards of FQPA. Based on available information, there is a reasonable certainty that no harm will result to infants and children or to the general population from aggregate exposure to paraquat dichloride residues. The Agency only evaluated dietary exposure in the aggregate assessment since there are no residential or other non-occupational uses of paraquat. Further, based on paraquat's normal use patterns and unique environmental fate characteristics, exposures to paraquat in drinking water are not expected and not a concern. Based on the available data, the Agency does not believe that the effects produced by paraquat would be cumulative with those of other structurally related compounds, and therefore has considered only paraquat exposures in the aggregate assessment.

In reaching the determination of safety for infants and children, the Agency found that the toxicity database for paraquat is complete, based on current requirements, and that the effects observed in pre- and post-natal studies did not indicate any increased sensitivity of infants and children to paraquat. Therefore, no additional uncertainty factor was used in the risk assessment.

Under FIFRA, the Agency has concluded that all uses, as prescribed in this document, will not cause unreasonable risks to humans or the environment. Accordingly, the Agency has determined that all paraquat dichloride products are eligible for reregistration.

To mitigate risks of potential dermal exposure to handlers/workers the Agency is requiring, among other changes, modifications of the personal protective equipment and reentry intervals of 12 hours for preemergence and directed-spraying uses and 24 hours for desiccation and harvesting uses. Although a few use scenarios indicated LOC exceedances on an acute basis for birds, herbivorous and insectivorous mammals, the Agency has concluded (based on paraquat's unique environmental fate characteristics) that paraquat dichloride will not typically pose a threat to birds or mammals once it dries. Also, in agreement with the registrant, the maximum label rate for paraquat dichloride of 1 lb cation/Acre is being established to reduce environmental risks to non-target terrestrial and semi-aquatic plants from drift. Additional data for product chemistry, certain cropfield trials and spray drift studies are being required to confirm the Agency's risk assessment and conclusions.

Accordingly, before reregistering the products containing paraquat dichloride, the Agency is requiring that product specific data, revised Confidential Statements of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing for each registration. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister a product. Those products which contain other active ingredients will be eligible for reregistration only when the other active ingredients are determined to be eligible for reregistration.

I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amended the FFDCA by establishing a new safety standard for the establishment of tolerances. The FQPA did not, however, amend any of the existing reregistration deadlines set forth in section 4 of FIFRA. Thus, the Agency is embarking on an intensive process, including consultation with registrants, States, and other interested stakeholders, to make decisions on the new policies and procedures that will be appropriate as a result of enactment of FQPA. This process will include a more in depth analysis of the new safety standard and how it should be applied to both food and non-food pesticide applications. However, in light of the unaffected statutory deadlines with respect to reregistration, the Agency will continue its ongoing reregistration program while it continues to determine how best to implement FQPA.

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of paraquat dichloride (commonly referred to as “paraquat” in this document) including the risk to infants and children for any potential dietary, drinking water, accidental dermal or oral exposures, and cumulative effects as stipulated under the FQPA. The document consists of six sections. Section I is the introduction. Section II describes paraquat dichloride, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for paraquat dichloride. Section V discusses the reregistration requirements for paraquat dichloride. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

II. CASE OVERVIEW

A. Chemical Overview

The following active ingredient(s) are covered by this Reregistration Eligibility Decision:

- **Common Name:** Paraquat dichloride
- **Chemical Name:** 1,1'-dimethyl-4,4'-bipyridinium dichloride
- **Chemical Family:** Bipyridylnium, dipyridylnium
- **CAS Registry Number:** 1910-42-5
- **OPP Chemical Code:** 061601
- **Empirical Formula:** $C_{12}H_{14}Cl_2N_2$
- **Trade and Other Names:** Cekuquat, Cyclone, Dextrone, Esgram, Gramoxone, Goldquat, Herboxone, Prelude, Pillarxone, Pillarquat, Surefire, Starfire, Total, Toxer
- **Basic Manufacturer:** Zeneca

B. Use Profile

The following is information on the currently registered uses with an overview of use sites and application methods. A detailed table of these use of paraquat is in Appendix A.

<u>For Paraquat dichloride</u>:

Type of Pesticide: Herbicide, Desiccant, Defoliant

Mode of Action: Contact herbicide, without residual soil activity. Destroys cell membranes and inhibits photosynthesis. Only contacted leaves are killed, so regrowth can occur from undamaged parts of perennials.

Use Groups and Sites:

TERRESTRIAL FOOD CROP
acerola (West Indies cherry); apricot; asparagus; avocado; banana; blackberry; blueberry; boysenberry; broccoli; cabbage; cabbage, Chinese; carrot (including tops); cauliflower; cherry; cocoa; coffee; collards; cucumber; eggplant; fig; filbert (hazelnut); garlic; groundcherry (strawberry tomato/tomatillo); guava; hops; kiwifruit; lettuce; loquat; macadamia nut (bushnut); manioc (cassava); melons; melons, cantaloupe; melons,musk; melons, water; mint; nectarine; olive; onion; papaya; passion fruit; peach; pear; pecan; pepino (melonpear); pepper; pepper (chili type); pineapple; pistachio; plum; potato, white/Irish; prune; pumpkin; raspberry (black, red); rhubarb; smallfruits; squash (all or unspecified); strawberry; sugarbeet; taro; walnut (English/black); yam; yautia

TERRESTRIAL FOOD+FEED CROP
almond; apple; barley; beans, asparagus; beans, dried-type; beans, mung; beans, succulent (lima); beans, succulent (snap); citrus fruits; corn (unspecified); corn, field; corn, pop; corn, sweet; cotton (unspecified); garbanzos (including chickpeas); grapes; guar; hops; legume vegetables; mint; oats; orchards (unspecified); peanuts; peanuts (unspecified); peas (unspecified); peas, field; peas, pigeon; peppermint; potato, white/Irish; safflower; safflower (unspecified); small fruits; small grains (unspecified); sorghum; sorghum (unspecified); soybeans (unspecified); soybeans, edible; spearmint; sugarbeet; sugar crops; sugarcane; sunflower; tomato; turnip; vegetables (unspecified); wheat

TERRESTRIAL FEED CROP
alfalfa; barley; beans; clover; crownvetch; legume vegetables; lespedeza; lupine; pastures; sainfoin; timothy; trefoil; tyfon; vetch; wheat

TERRESTRIAL NON-FOOD CROP
agricultural fallow/idleland; airports/landing fields; commercial/industrial lawns; commercial/institutional/industrial; premises/equipment (outdoor); fencerows/hedgerows; grasses grown for seed; industrial areas (outdoor); jojoba; nonagricultural outdoor buildings/structures; nonagricultural uncultivated areas/soils; ornamental and/or shade trees; peach (non-bearing, seed beds); recreation area lawns; tomato (post-harvest); wood protection treatment to forest products (seasoned)

FORESTRY
forest plantings (reforestation programs); pine (forest/shelterbelt); shelterbelt plantings

TERRESTRIAL NON-FOOD
ornamental and/or shade trees; ornamental herbaceous plants; ornamental woody shrubs and vines; non-crop areas such as public airports, electric transformer stations and around commericial buildings

Target Pests: Annual broadleaf and grassy weeds (top kill of perennials).

Formulation Types Registered:

MANUFACTURING PRODUCT
Soluble concentrate/liquid 43.5000%
END USE PRODUCT
Soluble concentrate/liquid 23.2000 to 43.5000%
(23.2000%, 29.1000%, 29.4200%, 30.3000%, 37.000%, 43.5000%)

Multiple active ingredient products contain:
diuron (035505)

Method and Rates of Application:

TYPES OF TREATMENT
Band treatment; Bark treatment (cut); Basal spray treatment; Bore-hole treatment; Broadcast; Directed spray; Ground spray; Soil band treatment; Soil broadcast treatment; Spot soil treatment; Spot treatment; Spray; Strip treatment.

EQUIPMENT
Aircraft; Backpack/Knapsack sprayer; Hand held spray wand; Sprayer; Ground/Tractor-drawn ground boom.

TIMING
At cracking; At planting; August; Dormant; Early spring; Established plantings; Fall; Fallow; Foliar; July; Postemergence; Postharvest; Postplant; Posttransplant; Preemergence; Preharvest; Preplant; Preplant (Spring); Ratoon; Seed bed; Seedling stage; Spring; Stubble; When needed; Winter.

C. Estimated Usage of Pesticide

This section summarizes the best estimates available for the pesticide uses of paraquat dichloride. These estimates are derived from a variety of published and proprietary sources available to the Agency. The data, reported on an aggregate and site (crop) basis, reflect annual fluctuations in use patterns as well as the variability in using data from various information sources.

Estimates of paraquat usage vary widely from different sources. Rather than providing a range of estimates, the table below gives what the Agency believes to be the most likely estimate and also a likely maximum estimate. This maximum is not a strict upper bound limit, but an estimate. There is a very small probability that the actual amount of paraquat being used would exceed this estimated likely maximum.

Most of paraquat usage is for field crops because of the high acreage of these crops. The percent crop treated and average application rates for field crops is less than that for fruits and vegetables. The average percent crop treated on fruits is significantly higher than for vegetables and field crops. The highest usages in pounds a.i. are for corn, soybeans, cotton, and apples.

PARAQUAT QUANTITATIVE USAGE ANALYSIS

VEGETABLE/MELONS	Acres Planted (000)	Acres Treated (000) Likely Estimate	Acres Treated (000) Likely Max	% of Crop Treated Likely Estimate	% of Crop Treated Likely Max	Total AI (000 lbs) Likely Estimate	Total AI (000 lbs) Likely Max	Application lbs ai/year/ treated acres
Eggplant	4	1	2	25.0%	50.0%	2	2	2.0
Peppers	101	18	33	17.8%	32.7%	18	34	1.0
Lettuce	283	8	11	2.8%	3.9%	6	8	0.8
Sweet Corn	748	6	25	0.8%	3.3%	5	21	0.8
Potatoes	1,403	40	73	2.9%	5.2%	25	39	0.6
Tomatoes	480	73	93	15.2%	19.4%	75	111	1.0
Mint	147	39	.	26.5%	.	20	.	0.5
Cole Crops	263	2	4	0.8%	1.6%	1	2	0.5
Broccoli	107	.	1	.	1.0%	.	1	1.0
Cabbage	84	.	3	.	3.0%	.	1	0.2
Cauliflower	57	.	1	.	1.0%	.	1	1.0
Collards	15	.	0	.	1.0%	.	0	2.0
Cucurbits, not melons	250	15	24	6.0%	9.6%	12	19	0.8
Cucumbers	151	12	.	7.9%	.	10	.	0.8
Pumpkins	41	1	.	2.4%	.	1	.	1.0
Squash	58	2	.	3.4%	.	1	.	0.5
Melons	349	10	16	2.9%	4.6%	8	11	0.8
Cantaloupe	110	.	6	0.0%	5.5%	.	2	0.3
Watermelons	239	.	10	0.0%	4.2%	.	8	0.8
Vegetables, Other	330	20	30	6.1%	9.1%	13	23	0.8
Asparagus	55	9	12	16.4%	21.8%	6	8	0.7
Carrots	104	1	.	1.0%	.	1	.	0.5
Garlic	22	4	.	18.2%	.	3	.	0.8
Onions	149	6	.	4.0%	.	3	.	0.5
Subtotal	4,358	232	293			185	255	
Average				5.3%	6.7%			0.8

PARAQUAT QUANTITATIVE USAGE ANALYSIS (continued)

FRUITS/CITRUS/NUTS	Acres Planted (000)	Acres Treated (000) Likely Estimate	Acres Treated (000) Likely Max	% of Crop Treated Likely Estimate	% of Crop Treated Likely Max	Total AI (000 lbs) Likely Estimate	Total AI (000 lbs) Likely Max	Application lbs ai/year/ treated acres
Citrus	1,229	108	295	8.8%	24.0%	94	192	0.9
Grapefruit	201	15	35	7.5%	17.4%	14	24	0.9
Lemons	66	1	6	1.5%	9.1%	1	5	1.0
Oranges	911	80	240	8.8%	26.3%	70	150	0.9
Citrus, Other	51	12	14	23.5%	27.5%	9	13	0.8
Pome Fruits	768	251	315	32.7%	41.0%	248	305	1.0
Apples	656	230	280	35.1%	42.7%	220	264	1.0
Pears	84	19	26	22.6%	31.0%	25	35	1.3
Pome-Like, Other *	28	2	9	7.1%	32.1%	3	6	1.5
Stone Fruits	713	197	269	27.6%	37.7%	147	206	0.7
Cherries	132	48	54	36.4%	40.9%	46	56	1.0
Peaches	248	92	120	37.1%	48.4%	61	86	0.7
Plums & Prunes	138	27	42	19.6%	30.4%	20	30	0.7
Stone-Like, Other *	195	30	53	15.4%	27.2%	20	34	0.7
Grapes	874	162	200	18.6%	22.9%	101	125	0.6
Blueberries	59	9	.	15.3%	.	5	.	0.6
Raspberries	11	2	.	18.2%	.	1	.	0.5
Strawberries	30	6	9	20.0%	30.0%	6	9	1.0
Nut Trees	1,277	180	282	14.1%	22.1%	164	227	0.9
Almonds	455	75	130	16.5%	28.6%	80	96	1.1
Pecans	496	64	97	12.9%	19.6%	50	78	0.8
Walnuts	217	26	30	12.0%	13.8%	20	29	0.8
Nut Trees, Other	109	15	25	13.8%	22.9%	14	24	0.9
Subtotal	4,961	915	1,370			766	1,064	
Average				18.5%	27.6%			0.8

* Fruit trees, other
Pome-like, other includes kiwifruit, figs, and papayas.
Stone-like, other includes apricots, nectarines, avocados, and olives.

PARAQUAT QUANTITATIVE USAGE ANALYSIS (continued)

FIELD/CERERAL CROPS	Acres Planted (000)	Acres Treated (000) Likely Estimate	Acres Treated (000) Likely Max	% of Crop Treated Likely Estimate	% of Crop Treated Likely Max	Total AI (000 lbs) Likely Estimate	Total AI (000 lbs) Likely Max	Application lbs ai/year/ treated acres
Alfalfa	24,835	130	180	0.5%	0.7%	60	100	0.5
Hay, other	32,605	20	32	0.1%	0.1%	9	14	0.5
Pasture/Rangeland	.	.	.	.	0.1%	.	.	.
Corn	78,234	1,400	2,210	1.8%	2.8%	800	1,200	0.6
Cotton	13,944	900	2,330	6.5%	16.7%	280	740	0.3
Sorghum	10,307	150	450	1.5%	4.4%	56	120	0.4
Soybeans	61,564	1,020	1,940	1.7%	3.2%	540	960	0.5
Barley	6,838	28	55	0.4%	0.8%	11	22	0.4
Oats/Rye	5,085	4	7	0.1%	0.1%	2	3	0.5
Wheat	70,014	203	335	0.3%	0.5%	81	124	0.4
Wheat, Spring	20,861	3	7	0.0%	0.0%	1	2	0.3
Wheat, Winter	49,153	200	328	0.4%	0.7%	80	122	0.4
Hops	42	35	.	83.3%	.	23	.	0.7
Beans/Peas, Dry	2,223	20	70	0.9%	3.1%	7	18	0.4
Beans/Peas, Vegetable	719	10	21	1.4%	2.9%	5	9	0.5
Peanuts	1,691	464	930	27.4%	55.0%	72	140	0.2
Sunflower	2,044	15	.	0.7%	.	11	.	0.7
Safflower	323	31	.	9.6%	.	28	.	0.9
Sugar Beets	1,465	3	9	0.2%	0.6%	2	4	0.7
Sugarcane	879	40	110	4.6%	12.5%	18	55	0.5
Subtotal	312,812	4,473	8,679			2,005	3,509	
Average				1.4%	2.8%			0.4
ALL CROPS								
Total	322,131	5,620	10,342			2,955	4,828	
Average				1.7%	3.2%			0.5

NOTES:
Numbers may not agree due to rounding.
Likely estimates and maximums are not ranges and both may not be provided when data is insufficient.
Application (last column) is the likely estimate of total lb ai divided by acres treated.

SOURCES: EPA data, USDA, National Center for Food and Agricultural Policy

D. Data Requirements

Data required in the June 1987 Registration Standard for paraquat dichloride include studies on product chemistry, ecological effects, toxicology, environmental fate, and residue chemistry. A Data Call-In issued December 1991 required further testing for ecological effects, environmental fate and residue chemistry. These data were required to support the uses listed in the Registration Standard. Appendix B includes all data requirements identified by the Agency for currently registered uses needed to support reregistration.

E. Regulatory History

Paraquat was discovered in 1882 and has been used as an oxidation-reduction indicator under the name of methyl virologen since 1932. The first commercial paraquat formulation for agricultural use was produced by Imperial Chemical Industries, Ltd. in England and was registered there in 1962.

Paraquat dichloride was registered in the United States in 1964 for use as a contact herbicide to control or suppress a broad spectrum of emerged weeds. The Agency classified paraquat dichloride as a Restricted Use pesticide due to high acute toxicity to animals and people from intentional or inadvertent exposure. This action was taken by the Agency through regulations proposed in the September 1, 1977 (42 FR 44170) and finalized in the February 9, 1978 (43 FR 5782) issues of the FEDERAL REGISTER. Under the Restricted Use classification, only certified applicators are authorized to apply paraquat dichloride end-use products.

In 1978 paraquat dichloride was accepted as a candidate for the Special Review process based on the following areas where paraquat dichloride was believed to exceed the risk criteria under 40 CFR 162.11: teratogenicity, lack of emergency treatment, chronic effects, reproductive effects, oncogenicity (data gap), mutagenicity (data gap), and acute effects. Other areas of concern included mammalian toxicity and avian reproductive effects. Upon conclusion of the Special Review evaluation in October 1982 (43 FR 30613), the Agency issued a Final Position Document which concluded that the available data did not support paraquat dichloride being placed into the Special Review status since the risk criteria identified in 1978 had not been exceeded.

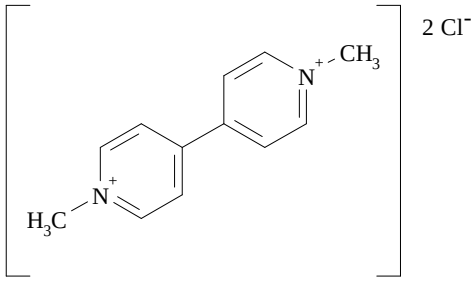
After the Special Review evaluation, the Agency believed that the acute effects level was very close to estimated applicator exposures. Therefore, a Data Call-In was issued for paraquat dichloride requiring additional dermal and inhalation data and more precise information to assess the potential of acute effects as a result of applicator exposure to this compound. A Registration Standard for paraquat dichloride was issued in June 1987 (NTIS #PB88-217005) in which the Agency

evaluated the studies submitted as a result of the previous DCI. This Reregistration Eligibility Decision reflects a reassessment of all data which were submitted in response to the Registration Standard and subsequent December 1991 DCI.

III. SCIENCE ASSESSMENT

A. Physical Chemistry Assessment

Paraquat dichloride (1,1'-dimethyl-4,4'-bipyridinium dichloride) is a nonselective contact herbicide, desiccant, defoliant, and plant growth regulator primarily used on field crops and fruit and nut crops.



Empirical Formula: $C_{12}H_{14}Cl_2N_2$
Molecular Weight: 257.2
CAS Registry No.: 1910-42-5
OPP Chemical Code: 061601

Production of the paraquat dimethyl sulfate salt [1,1'-dimethyl-4,4'-bipyridinium bis(methyl sulfate); OPP Chemical Code 061602] has been discontinued; there are no active uses or products.

IDENTIFICATION OF ACTIVE INGREDIENT

Paraquat dichloride is an off-white, odorless hygroscopic (holding moisture) powder with a melting point of approximately 340 C. Paraquat dichloride is freely soluble in water, slightly soluble in alcohols, and insoluble in nonpolar organic solvents. The Technical Grade Active Ingredient (TGAI) is corrosive to metals, hydrolyzes under alkaline conditions, and decomposes photochemically.

MANUFACTURING-USE PRODUCTS

There are two paraquat dichloride manufacturing-use products (MPs) registered to Zeneca AG Products under OPP Chemical Code 061601; they are the 43.5% formulation intermediates (FIs) (EPA Reg. Nos. 10182-115 and 10182-362).

B. Human Health Assessment

1. Toxicology Assessment

The toxicological data base for paraquat dichloride is adequate and will support reregistration eligibility.

a. Acute Toxicity

The table below defines the different Acute Toxicity Categories for the different routes of administration.

Hazard Indicators	Acute Toxicity Categories			
	Category I = very highly or highly toxic	**Category II** = moderately toxic	**Category III** = slightly toxic	**Category IV** = practically non-toxic
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including 0.05 mg/L	From 0.05 thru 0.5 mg/L	From 0.5 thru 5.0 mg/L	Greater than 5.0 mg/L
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000 mg/kg	From 2000 thru 5000 mg/kg	Greater than 5000 mg/kg
Eye Effects	Corrosive; corneal opacity not reversible within 21 days	Corneal opacity reversible within 8-21 days	Corneal opacity; irritation reversible within 7 days	Corneal opacity cleared within 24 hours
Skin Effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

The table below summarizes the acute toxicity studies on paraquat dichloride and the Toxicity Categories for the different routes of administration.

ACUTE TOXICITY DATA FOR PARAQUAT DICHLORIDE

TEST	RESULTS	CATEGORY	MRID No.
Acute oral LD_{50} (rat)	344 mg/kg ♂ 283 mg/kg ♀ #	II	43685001
Acute Dermal LD_{50} (Rat)	>2000 mg/kg#	III	43685002
Acute Inhalation LC_{50} (Rat)	1 µg/L ♂+♀ ##	I	00046105
Eye Irritation (Rabbit)	Moderate to severe irritation #	II	43685003
Dermal Irritation (Rabbit)	Minimal irritation; PIS = 0.5 #	IV	43685004
Dermal Sensitization (Guinea pig)	Negative #	--	43685005

The test material used in these studies was paraquat technical concentrate which is 45.6% paraquat dichloride (cation content: 33% w/w). The LD_{50} values are expressed in terms of paraquat dichloride (and not as paraquat cation).

The test material used in this study was crystalline paraquat dichloride. Purity was not specified, but crystalline paraquat dichloride used in other studies was 99.9% pure. The LC_{50} value is expressed as paraquat dichloride (and not as paraquat cation).

The following toxic signs were observed in the above studies:
Acute Oral LD_{50} (Rat): Decreased activity, dehydration, hypothermia, irregular breathing, chromodacryorrhea, piloerection, sides pinched in, stains around nose and mouth, upward curvature of the spine, reduced splay reflex and mottling and dark areas in the lungs. Doses tested: 100, 250, 400 or 600 mg/kg, in SPF Wistar-derived male and female rats. (MRID 43685001)

Acute Dermal LD_{50} (Rat): Slight or moderate skin irritation (edema and/or erythema), and scabbing and thickening of the skin at the application site. There was no mortality. Dose tested: 2000 mg/kg (limit dose), in SPF Wistar-derived male and female rats (intact skin, 24-hour contact period). (MRID 43685001)

Acute Inhalation LC_{50} (Rat): Pale and swollen kidneys, and lung changes (congestion, occasional petechial hemorrhages, and increased number of polymorphs and histiocytes around the bronchi and vessels) - all at the two highest concentrations tested. Concentrations tested (analytical values): 0.4, 0.75, 1.3, 1.5, 2.6, 4.8, 13.7 and 32.5 ug/L, expressed as paraquat dichloride, in Alderley Park SPF rats. 6-Hour exposure to respirable particles [2.5 u or smaller]. (MRID 00046105)

Primary Eye Irritation (Rabbit): Corneal effects (slight or mild opacity involving 1/4-1/2 of the cornea), cleared by day 17; and conjunctival effects (slight to severe redness and discharge, and slight to mild chemosis). Regression times (days after dosing): chemosis, 14; redness, 28 (end of study); and discharge, > 28 (still present in 2/3 of the surviving rabbits at the termination of the study. Dose tested: 0.1 mL of the undiluted test material, in 3 young adult female New Zealand White rabbits (unwashed eyes, Draize scoring). Moderate to severe ocular irritant = class 5 on a scale of 1-8. (MRID 43685003)

Primary Dermal Irritation (Rabbit): Very slight erythema in all 3 rabbits (score 0.7-1.0 on a scale of 0-4); very slight edema in 1 rabbit (score 1.0 on a scale 0-4); and desquamation, thickening, and scabbing in 1 rabbit. Regression times: erythema, in 2-3 days after dosing (2 rabbits) and in 27 days (1 rabbit); edema, in 7 days; and other signs, in 34 days (end of study). Primary dermal irritation score 0.5 at 72 hours. Dose tested: 0.5 mL of undiluted test material, in 3 young adult female New Zealand White rabbits (4-hour exposure, intact skin, Draize scoring). (MRID 43685004)

Dermal Sensitization (Guinea Pig): Not a skin sensitizer under the conditions of the maximization test of B. Magnusson and A.M. Kligman (Allergic Contact Dermatitis in the Guinea Pig; 1970). Positive control used: 2-mercaptobenzothiozole. (MRID 43685005)

b. Subchronic Toxicity

90-Day Feeding, Non-Rodent:

In a repeated dose oral toxicity study, male and female beagle dogs, 3/sex/group, received paraquat dichloride for 13 weeks at the following levels, expressed as paraquat cation: 0, 7, 20, 60 or 120 ppm (0, 0.18, 0.5, 1.5 or 3.0 mg/kg/day, respectively). The test material, added to the diet, was the technical grade aqueous solution containing 32.2% w/w of paraquat cation. The dogs, aged 7-8 months at the start of the study, were given 400 g of the appropriate diet mix every morning. Any remaining food was removed and weighed the following morning. At the 7 ppm (0.18 mg/kg) and the 20 ppm (0.5 mg/kg) levels, paraquat had no effect on any of the parameters examined. Toxic signs observed in the 60 ppm (1.5 mg/kg) group included increased absolute (39-41%) and relative (44-56%) lung weight, alveolitis and alveolar collapse. Unless stated otherwise, the following treatment-related symptoms were observed in both sexes at the 120 ppm (3.0 mg/kg) level: weight loss (4-8%), decreased food intake (22-67%)

for one surviving female during the last 6 weeks of the test, increased absolute (75-76%) and relative (92-104%) lung weight, marked dyspnea, harsh rales, slow and/or irregular heart beat, large lesions in the lungs (alveolitis), alveolar collapse and high mortality (2/3 males and 2/3 females during study days 16-23). Based on the above findings, the NOEL and LOEL for systemic toxicity, for both sexes, are 20 ppm (0.5 mg/kg/day) and 60 ppm (1.5 mg/kg/day), respectively. Although there was a 12% weight loss ($P<0.01$) in the female 20 ppm group during week 13, this loss was greater than that observed in the 60 ppm and 120 ppm groups, and, therefore, did not appear to be treatment-related. (MRID 00072416)

21-Day Dermal Toxicity, Rabbit:

In a repeated dose dermal toxicity study, male and female New Zealand white rabbits, 6/sex/group, were exposed (intact skin) to paraquat dichloride (cation content: 43.5%) for 21 consecutive days (6 hours/day). Paraquat dichloride was applied as an aqueous solution (1.0 mL/kg b.w.) at the following concentrations: 0, 1.5, 3.4, 7.8 or 17.9 mg/kg/day (0, 0.5, 1.15, 2.6 or 6.0 paraquat cation, respectively). Treatment-related effects were observed only at the two highest concentrations tested. In the 2.6 mg cation/kg group, scabbing at the dosing site was seen in two males and one female. The following toxic signs were observed in the 6.0 mg cation/kg group, in all rabbits, at the dosing site: scabbing; slight to well-defined erythema; minimal to moderately severe inflammation, acanthosis and hyperkeratosis (females only); slight to severe erosion/ulceration and surface exudate; and decreases in absolute weight (18%) and relative weight (organ/body weight and organ/brain weight ratios; 17-22%) of testes. No gross histological changes were found in the lungs, the target organ for paraquat. Based on dermal irritation, the NOEL and LOEL are, respectively, 1.15 mg/kg/day and 2.6 mg/kg/day, expressed as paraquat cation. (MRID 00156313)

21-Day Inhalation Toxicity, Rat:

In a repeated dose inhalation toxicity study, Sprague-Dawley rats were exposed (whole body) to respirable aerosols of paraquat dichloride (cation content: 40%; particle size: < 2 um in diameter) for 3 weeks (6 hours/day, 5 days/week). The concentrations of paraquat cation in the inhalation chambers were 0, 0.01, 0.1, 0.5 and 1.0 ug/L (nominal) or 0, 0.012, 0.112, 0.487 and 1.280 ug/L, respectively, (analytical). The numbers of rats of each sex assigned to these groups were as follows:

32 (control group), 16 (0.5 ug/L group) and 36 (remaining groups). Parameters examined included observations for toxic signs, body weights and food consumption. One-half of the rats in each group were examined grossly and microscopically after 15 exposures and the remaining rats were examined 2 weeks after the termination of the exposures (recovery period). These examinations were restricted only to the respiratory tract (nasal passages, pharynx, tongue, larynx, trachea and lungs). The 1.0 ug/L group was abandoned after the first exposure because 28 males (78%) and 29 females (80%) died from respiratory failure after that exposure.

Toxic signs were not observed in the 0.01 ug/L group and there was no mortality in this or the other test groups. All rats in the 0.1 ug/L group had nasal discharge and squamous keratinizing metaplasia, and/or hyperplasia of the epithelium of the larynx. The changes in the ephithelium were still observed in 69% of the rats sacrificed at the end of the recovery period. The following findings were reported for the 0.5 ug/L group examined after 3 weeks of treatment: (1) extensive ulceration, necrosis, inflammation and squamous keratinizing metaplasia, and marked/moderate hyperplasia of adjacent epithelia in the larynx of all rats; and (2) aggregations of foamy macrophages in the bronchioles or alveoli, hypertrophy of the epithelium and thickened alveolar walls in the lungs of most or all rats. After a 2-week recovery period, no ulceration or necrosis was observed in the larynx, but changes in the lungs were still seen. In addition, disruption of bronchiolar epithelium, adjacent to the macrophage aggregation, was noted.

Considering the above findings, the NOEL and LOEL for sub-chronic (3 weeks) inhalation toxicity, for both sexes, are 0.01 ug/L and 0.10 ug/L, respectively, expressed as paraquat cation. (MRID 00113718)

c. Chronic Toxicity

Chronic Toxicity/Oncogenicity, Rodent:

In this chronic feeding/carcinogenicity study, Fischer 344 rats, 80/sex/group, were fed diets containing paraquat dichloride (cation content: 32.69%) for 113-117 weeks (males) and 122-124 weeks (females). Based on the results of a preliminary study, the doses of paraquat selected for this study were 0 (Group 1), 0 (Group 2), 25 (Group 3), 75 (Group 4) or 150 ppm (Group 5), expressed as paraquat cation (nominal concentrations). Assuming that, for an older rat, 1 ppm

= 0.05 mg/kg/day, these doses corresponded to 0, 0, 1.25, 3.75 or 7.5 mg of paraquat cation/kg/day, respectively. Twenty rats from each group (10 of each sex) were sacrificed after one year of treatment: 5 of each sex/group, for the usual interim sacrifice and another 5 of each sex/group, to determine paraquat concentration in tissues. According to the initial protocol, this study was to be terminated after 104 weeks. However, because of the low number of deaths during that period, the study was extended until survival was reduced to 50%in any one of Groups 1-4 (Group 5 was excluded from consideration).

Starting with the test week 6, the female rats at all dose levels ingested more paraquat (15-33%) per kilogram of body weight than did the male rats at the same dose levels. With the exception of minimal lens opacities in 3/60 (5%) males and 6/60 (10%) females, nothing remarkable was observed in the 25 ppm group. Since these incidences were only 1% and 3% higher than in the control males and females, respectively, and occurred mostly after week 104, they appeared to be an acceleration of the normal aging process and not a qualitatively different effect.

The only treatment-related statistically significant effects observed in the 75 ppm group, were increased incidence of (1) opacities/cataracts in the males (4%) and the females (19%, $P< 0.01$); (2) ptosis/swollen eyelids in the females (7%); and (3) non-neoplastic lung lesions in the male nonsurvivors (alveolar macrophages; 14%, $P<0.05$). In the case of the ocular lesions, there were about as many opacities as there were cataracts.

In the 150 ppm group, the incidence of eye opacities/cataracts was 37% (controls, 4%) in the males and 58% (controls, 4%) in the females. Only one opacity and all cataracts were observed in each male and female high-dose groups. Compared with the controls, other findings observed in the 150 ppm group were (1) slight decreases in the food consumption for the males (3-7%) and the females (3-8%) during most of the study; (2) decreased body weight gain during weeks 11-68 for the males (10-34%) and during weeks 27-78 for the females (11-34%); (3) decreased food utilization for the males (12-21%) and females (11-13%) during weeks 13-52; (4) increased relative weight of the lungs (lung/body weight ratio) in the males (16%, $P<0.05$) and the females (14%, $P<0.05$) sacrificed at the termination of the study; (5) increased incidence of hydrocephalus in the females sacrificed at the termination of the study (36%, $P<0.01$); (6) increased incidence of alveolar macrophages in the male nonsurvivors (25%, $P<0.01$) and in rats

sacrificed at the termination of the study (males, 30% and females, 17%); and (7) increased incidence of alveolar epithelization (12%) and slight peribronchial lymphoid hyperplasia (26%, $P<0.05$) in the males at the termination of the study.

The above findings show that paraquat enhanced the development of ocular lesions in all of the treated groups. The predominant lesions detected ophthalmoscopically were lenticular opacities and cataracts. These lesions were either not observed or were observed infrequently before the week 103. At test week 103, dose-related statistically significant ($P<0.001$) increases in the incidence of ocular lesions were observed only in the mid-dose and high-dose male and female groups. Based on these findings, the NOEL (approximate) and the LOEL for systemic toxicity, for both sexes, are 25 ppm (1.25 mg/kg/day) and 75 ppm (3.75 mg/kg/ day), respectively. (MRID 00138637)

In another chronic feeding/carcinogenicity study, Wistar strain rats, 62/sex/group, were fed diets containing technical grade paraquat dichloride (purity: 98%) for 104 weeks. Based on the results of a preliminary study, the doses of paraquat selected for this study were 0, 6, 30, 100 or 300 ppm, expressed as paraquat dichloride (nominal concentrations). These values were equivalent to 0, 0.25, 1.26, 4.15 or 12.25 mg/kg/day, respectively (males) and 0, 0.30, 1.50, 5.12 or 15.29 mg/kg/day, respectively (females), expressed as paraquat dichloride (analytical concentrations). The interim sacrifices, using 6 rats/sex/ group, took place after 26 and 52 weeks of treatment.

Findings different from those in the controls were observed only in the 300 ppm group and included (1) increased mortality in males (66%; controls, 40%) and females (52%; controls, 42%); (2) decreased erythrocytes, hemoglobin, and serum protein in males and females; (3) decreased hematocrit, glucose and corpuscular cholinesterase activity in males (7.9% at week 52); (4) decreased leucocytes, albumin/globulin ratio and alkaline phosphatase (34%), GOT (glutamic-oxaloacetic transaminase, 18%) and GPT (glutamic-pyruvic transaminase, 23%) activities in females; (5) increased polymorphonucleocytes in males; (6) increased potassium and glucose in females; (7) decreased absolute and/or relative weights of heart in males (10%) and females (14%); and liver (14%) and brain (8%) in females; and (8) decreased absolute weights of kidneys in males (13%) and females (17%), and ovaries (32-39%).

Ocular changes were not detected before the initiation of treatment. After the treatment was started, cataracts were observed during each examination (weeks 26, 52 and 104) in 1 to 4 rats per group, including controls. At test weeks 52 and 104, corneitis (keratitis) and conjunctivitis were also observed in all groups, including controls. In this study, the incidence of ocular changes was low and dose-unrelated. Considering the test weeks 26-104, the incidence of ocular changes in the male and female treated rats was as follows: cataracts, 1.6-17.6% (controls 1.6-13.8%); corneitis, 0-5.9% (controls, 0-6.7%); and conjunctivitis, 0-5.4% (controls, 0-6.7%). Ocular changes, therefore, do not appear to be caused by paraquat in this study.

Based on the above findings, the systemic NOEL is 100 ppm of paraquat dichloride (4.15 and 5.12 mg/kg/day, for males and females, respectively); or 3.0 mg/kg/day (males) and 3.7 mg/kg/day (females), expressed as paraquat cation. The systemic LOEL is 300 ppm of paraquat dichloride (12.25 and 15.29 mg/kg/day, for males and females, respectively); or 9.0 mg/kg/day (males) and 11.2 mg/kg/day (females), expressed as paraquat cation.(MRID 40218001)

Chronic Toxicity, Non-Rodent:

Groups of 6 male and 6 female Alderley Park beagle dogs were fed diets containing technical grade paraquat dichloride (cation content: 32.3%) for 52 weeks. The amount of food offered daily each dog was 400 g. The dose levels used were 0, 15, 30 or 50 ppm, expressed as paraquat cation. Based on the actual group mean body weights and food consumption, these doses corresponded to 0, 0.45, 0.93 or 1.51 mg of paraquat cation/kg/day, respectively, in the case of male dogs. For female dogs, these doses corresponded to 0, 0.48, 1.00 or 1.58 mg or paraquat cation/kg/day, respectively. The doses used in this study were based on the results obtained in the 90-day feeding study (MRID 00072416) which has been discussed in the subchronic toxicity section of this document.

The major effect of paraquat was a dose-related increase in the severity and extent of chronic pneumonitis in the mid-dose and high-dose male and female dogs. This effect was noted also in the low-dose male group, but was minimal when compared with the male controls. Chronic pneumonitis was less severe in the low-dose female group than in the female controls. Because 44 dogs (out of 48 studied), including 6 male and 5 female controls, had some degree of chronic pneumonitis, paraquat had no effect on the incidence of this lesion. Other findings

observed only in the high-dose dogs were (1) significant ($P<0.01$) increases in the group mean lung weights (absolute or adjusted for body weight, 36% in males and 61% in females) and in spleen weights (absolute or adjusted for body weights, 50-55% in males and 38-43% in females), when the paraquat-treated dogs were compared with the controls; (2) hyperpnea in 67% males and females; and (3) increased vesicular sound in 50% males and 67% females. Only one lenticular cataract (minimal, in a mid-dose female) was observed in this study. Based on the above findings, the systemic NOEL is 15 ppm (males: 0.45 mg/kg/day and females: 0.48 mg/kg/day, expressed as paraquat cation). The systemic LOEL is 30 ppm (males:0.93 mg/kg/day and females: 1.00 mg/kg/day, expressed as paraquat cation). (MRID 00132474)

d. Carcinogenicity

The Agency has received and reviewed four carcinogenicity studies as are detailed below.

Chronic Feeding/Carcinogenicity Study with Fischer 344 Rats

In this chronic feeding/carcinogenicity study, Fischer 344 rats, 80/sex/group, were fed diets containing paraquat dichloride (cation content: 32.69%) for 113-117 weeks (males) and 122-124 weeks (females). Based on the results of a preliminary study, the doses of paraquat selected for this study were 0 (Group 1), 0 (Group 2), 25 (Group 3), 75 (Group 4) or 150 ppm (Group 5), expressed as paraquat cation (nominal concentrations). Assuming that, for an older rat, 1 ppm = 0.05 mg/kg/day, these doses corresponded to 0, 0, 1.25, 3.75 or 7.5 mg of paraquat cation/kg/day, respectively. Twenty rats from each group (10 of each sex) were sacrificed after one year of treatment: 5 of each sex/group for the usual interim sacrifice, and another 5 of each sex/group, to determine paraquat concentration in tissues. According to the initial protocol, this study was to be terminated after 104 weeks. However, because of the low number of deaths during that period, the study was extended until survival was reduced to 50% in any one of Groups 1-4 (Group 5 was excluded from consideration). Gross necropsy was performed on all rats on the study. With the exception of the rats which were used for the determination of paraquat concentration in tissues, all rats on the study were also examined microscopically.

During the initial review of this study, there were concerns that paraquat might be carcinogenic in the rat. There was a dose-related

increase in the incidence of pulmonary neoplasms (adenomas and carcinomas), but especially adenomas, in the male and female rats. The incidence of pulmonary neoplasms was 2.9, 5.7, 8.6 and 10.1% in the control, low-dose, mid-dose and high-dose male groups, respectively. The corresponding values for the female groups were 0, 2.9, 4.3 and 14.3%, respectively. A statistically significant ($P<0.001$) increase was observed only in the pulmonary adenomas and only in the high-dose female rats. Most of the neoplasms were observed at the termination of the study. However, there were difficulties in characterizing pulmonary lesions as non-neoplastic or neoplastic, or as adenomas or carcinomas and lung tissue was, therefore, examined by four independent pathologists. Following submission of these data to the Agency, the lung tissue was then reexamined by two additional pathologists, one designated by the registrant and another by the Agency. The findings of these pathologists were very similar and were within the historical incidence of adenomas and carcinomas. According to one pathologist, the incidence of pulmonary adenomas and carcinomas in the control, low-dose, mid-dose and high-dose male rats was 2.9, 5.7, 2.8 and 5.8%, respectively. The corresponding incidences for the female groups were 0, 1.4, 2.8 and 0%, respectively. According to another pathologist, the incidence of pulmonary adenomas and carcinomas in these groups was 2.9, 5.7, 4.3 and 5.8%, respectively (males) and 0, 1.4, 2.8 and 2.8%, respectively (females). Based on these findings, paraquat did not appear to be carcinogenic in the lungs of rats.

There was a higher incidence of squamous cell carcinomas in the head region (middle ear, hard palate, head tissue and skin), an uncommon tumor, but the incidence was generally low and dose-unrelated. The incidence of these carcinomas (combined) was 2.1, 4.3, 0 and 8.6% in the control, low-dose, mid-dose and high-dose male groups respectively. The corresponding incidences for the female groups were 0, 0, 4.3 and 2.9%, respectively. All of these carcinomas occurred during the second year of study. The incidence of benign pheochromocytomas in the adrenal medulla and perifollicular adenomas and carcinomas in the thyroid was also increased in the high-dose male rats. However, the relationship of these neoplasms to treatment was unclear and additional data were, therefore, requested to evaluate adequately the carcinogenic potential of paraquat in tissues other than the lungs. An independent pathologist, selected by the Agency, reviewed slides from the head region and concluded (as did the registrant) that there was no justification for combining squamous cell carcinomas (which occurred in four different sites of the head) for assessment purposes. According to the pathologists (EPA's and the

registrant's), the skin and oral and nasal cavities have different morphology and physiology, and separate biological functions, and cannot be considered as a single organ in terms of assessment of carcinogenic effects. When each of these sites was considered independently, in the accepted manner for assessing tumor incidence, in no instance was there a statistically significant difference between the treated and control rats. Paraquat was, therefore, not carcinogenic in the head region of the rat.

The incidence of pheochromocytoma in the adrenal gland of the control, low-dose, mid-dose and high-dose male rats was 8.6, 12.6, 11.4 and 17.4%, respectively. The incidence of pheochromocytoma in the historical control male rats ranged from 6.7% to 38.8% and this tumor occurred in each of the eight studies from which historical data were obtained. Considering the historical incidence, the incidence of pheochromocytoma in this study (11.4- 17.4%) did not appear to be paraquat-related because it fell within the range reported for the historical control male rats.

The incidence of parafollicular adenomas and carcinomas in the thyroid gland of the concurrent control, low-dose, mid-dose and high-dose male rats was 11.9, 16.9, 13.6 and 18.8%, respectively. The incidence of these neoplasms in the historical control male rats ranged from 13.3% to 35.4%. Considering the historical incidence, the incidence of parafollicular adenoma and carcinoma in the high-dose male rats (18.8%), in this study, did not appear to be treatment-related. (MRIDs: 00138637, 00153223, 40202401, 40202402 and 41317401)

Chronic Feeding/Carcinogenicity Study with Wistar Strain Rats

In another chronic feeding/carcinogenicity study, Wistar strain rats, 62/sex/group, were fed diets containing technical grade paraquat dichloride (purity: 98%) for 104 weeks. Based on the results of a preliminary study, the doses of paraquat selected for this study were 0, 6, 30, 100 or 300 ppm, expressed as paraquat dichloride (nominal concentrations). These values were equivalent to 0, 0.25, 1.26, 4.15 or 12.25 mg/kg/day, respectively (males) and 0, 0.30, 1.50, 5.12 or 15.29 mg/kg/day, respectively (females), expressed as paraquat dichloride (analytical concentrations). The interim sacrifices, using 6 rats/sex/group, took place after 26 and 52 weeks of treatment.

Paraquat was not carcinogenic in this study. Gross, non-neoplastic and neoplastic lesions were observed in various organs of

males and females, but did not appear to be treatment-related (either a dose-relationship was lacking or the incidence was similar in the controls and the paraquat-treated groups). The most frequent lesions were observed in the following organs: (1) lungs (congestion, nodes, peribronchiolitis, pneumonia and thickening of alveolar walls); (2) liver (bile duct proliferation and fibrosis); (3) kidneys (rough surface and nephritis); (4) pituitary (hypertrophy, hematoma and benign tumors); (5) thyroid (benign tumors); (6) adrenals (cysts); (7) spleen (swelling); (8) mesenteric lymph node (swelling and inflammation); (9) testes and ovaries (atrophy); (10) uterus (cysts and polyps); and (11) mammary glands (cysts, adenomas, fibromas, fibroadenomas and adenocarcinomas). (MRID 40218001)

Chronic Feeding/Carcinogenicity Study with SPF Swiss-Derived Mice

Groups of SPF Swiss-derived mice (Alderley Park strain), 60/sex/dose, were administered paraquat dichloride (cation content: 32.7%) for 23 months (when mortality was approaching 80% in all groups). The dose levels used in this study were 0 (two control groups), 12.5, 37.5 or 100/125 ppm, expressed as paraquat cation, and were based on the results of two preliminary (28-day) studies (MRID 00087921 and 00087922). Assuming that, for a mouse, 1 ppm = 0.15 mg/kg/day, these doses corresponded to 0, 1.87, 5.6 or 15.0/18.7 mg of paraquat cation, kg/day, respectively. Because no toxic signs appeared after 35 weeks of dosing, the 100 ppm level was increased to 125 ppm at week 36.

Nothing remarkable was observed in the low-dose male and female group. Toxic signs observed in the mid-dose group included (1) decreased food consumption (15-22%) in the females during weeks 56-84, when compared with the controls; (2) decreased body weight gain (5-7%) in the females during weeks 68-88; and (3) renal tubular degeneration in the males (nonsurvivors, 40% and at the terminal sacrifice, 38%). Toxic signs observed in the high-dose group included (1) decreased food consumption in the males (7-15%) during weeks 4-24 and in the females (8-34%) during weeks 5-88, when compared with the controls; (2) decreased body weight gain in the females (12-45%) during weeks 44-96; and (3) renal tubular degeneration in the males (nonsurvivors, 65% and at the terminal sacrifice, 67%) and the females (nonsurvivors, 50% and at the terminal sacrifice, 63%). A high incidence of lenticular changes (degeneration, swelling and lens fibers broken up into eosinophilic globules) were observed in the control and paraquat-treated male and female mice, in both the nonsurvivors (81-

93%) and at the termination of the study (92-100%). This finding was surprising, but special staining and fixation techniques were not used to distinguish true pathological changes from artifacts in the eye tissue. The incidence of cataracts was low (males, 0-8% and females, 0-21%) and dose-unrelated.

Paraquat was not carcinogenic in this study. Paraquat, at all levels tested, had no effect on the incidence of benign and malignant neoplasms in both male and female mice. The most prevalent benign neoplasms were lung adenomas and Harderian gland adenomas in the males and the females, pituitary adenomas in the females, and liver nodules (Type A) in the males. The most prevalent malignant neoplasms were lymphosarcomas in the males and females, and liver nodules (Type B) in the males.

Based on the above findings, the systemic NOEL for both sexes is 12.5 ppm (1.87 mg/kg/day) and the systemic LOEL is 37.5 ppm (5.6 mg/kg/day), each expressed as paraquat cation. (MRID 00087924)

Chronic Feeding/Carcinogenicity Study with Groups of JCL:ICR Mice

Groups of JCL:ICR mice (Japan Clea Laboratories Co., Tokyo), 80/sex/dose, were administered paraquat dichloride (purity: 98%) for 104 weeks. Based on the results of a preliminary study (not submitted), the doses of paraquat dichloride selected for this study were 0, 2, 10, 30 or 100 ppm (nominal concentrations). These values were equivalent to 0, 0.26, 1.31, 3.92 or 13.09 mg/kg/day, respectively (males) and 0, 0.26, 1.32, 3.82 or 13.03 mg/kg/day, respectively (females), expressed as paraquat dichloride (analytical concentrations). The interim sacrifice, using 10 mice/sex/group, took place after 26 and 52 weeks of treatment.

Treatment-related findings were observed only in the 100 ppm group and included (1) increased mortality in the females; (2) decreased total protein, erythrocytes, leukocytes, hemoglobin and hematocrit in the males and females; (3) decreased polymorphonucleocytes in the males and GPT and alkaline phosphatase activities in the females; (4) decreased absolute and/or relative weights of adrenals, thyroid, liver and urinary bladder in the males; (5) decreased absolute weight of brain in the females; and (6) increased absolute and/or relative weights of kidneys, lungs and heart in the males.

Paraquat was not carcinogenic in this study. Gross, non-neoplastic and neoplastic lesions were observed in various organs of the

male and female mice, but were not treatment-related. The most frequent lesions were observed in the following organs: (1) lungs (congestion, nodes, pneumonia, thickening of alveolar walls and adenocarcinoma, all in both sexes); (2) liver (dilatation in the females and tumors in the males); (3) kidneys (discoloration and coarse surface in both sexes; dilatation of renal pelvis and cell infiltration in the males; and nephropathy in the females); (4) spleen (swelling in both sexes); (5) thymus (atrophy in both sexes and hypertrophy in the females); (6) mesenteric lymph node (swelling and cell infiltration in both sexes); and (7) eyes (corneal cell proliferation in both sexes and corneal calcification in the females). Leukemia, amyloid degeneration and leukemia cell infiltration were also observed frequently in the males and females.

Based on the above findings, the systemic NOEL is 30 ppm of paraquat dichloride (3.92 and 3.82 mg/kg/day, for males and females, respectively); or 2.9 mg/kg/day (males) and 2.8 mg/kg/day (females), expressed as paraquat cation. The systemic LOEL is 100 ppm of paraquat dichloride (13.1 mg/kg/day, for both sexes); or 9.4 mg/kg/day, expressed as paraquat cation. (MRID 40202403)

The carcinogenic potential of paraquat was evaluated by the Toxicology Branch Peer Review Committee (now Carcinogenicity Peer Review Committee) in 1986, 1988 and 1989, and by the FIFRA Scientific Advisory Panel (SAP) in 1989.

The first Committee classified (July 9, 1986) paraquat as a Category C carcinogen (limited evidence of carcinogenicity in animals), without the Q^* (developing of a quantitative estimation of the carcinogenic potential). This decision was based on an increased incidence of squamous cell carcinoma, an uncommon tumor, in the head region (ear, skin, and oral and nasal cavities) of the high-dose male Fischer 344 rats, when the treated animals were compared with the concurrent or the historical controls (Study No. 82/ILY 217/328; MRID 00138637). The registrant contended that those tumor sites should not be combined and an independent laboratory, which re-evaluated the data, agreed with the registrant. When each of these sites was considered separately, there was no statistically significant difference in the incidence of squamous cell carcinomas between the treated and control rats.

Considering the above findings and the subsequent (negative) carcinogenicity studies with rats and mice (MRIDs 40218001 and

40202403, respectively), the second Committee placed paraquat in Category E (no evidence of carcinogenicity in animal studies) on June 15, 1988.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) SAP met on February 15, 1989 and, considering a squamous cell carcinoma in the nasal cavity of two high-dose rats as an equivocal evidence of carcinogenicity, placed paraquat in Category D. However, the SAP also commented that further testing was not required and that endpoints other than carcinogenicity were more relevant for the regulation of paraquat.

The third Toxicology Branch Peer Review Committee met on March 15, 1989 and decided to retain the Category E carcinogenicity classification for paraquat.

e. Developmental Toxicity

The Agency has received and reviewed four developmental toxicity studies as are detailed below.

Developmental Toxicity Studies with Alderley Park, Wistar-Derived Rats

In a developmental toxicity study, paraquat dichloride (38.2% purity as paraquat ion content) was administered to 24 female Alderley Park, Wistar-derived (Alpk:APfSD) rats/dose by gavage in deionized water at dose levels of 0, 1, 3, or 8 mg paraquat ion/kg/day from days 7 through 16 of gestation. The developmental NOEL is 8 mg paraquat ion/kg/day (HDT). (MRID 43964701)

No maternal or developmental effects were observed in the study.

The maternal NOEL is 8 mg paraquat ion/kg/day (HDT).

In another study, paraquat dichloride (purity: 100%) was administered by gavage in 0.5% aqueous Tween 80 to groups of 29-30 Alderley Park SPF rats at dose levels of 0, 1, 5 or 10 mg/kg/day, expressed as paraquat cation, from gestation day 6 through 15. The test solutions were administered in a volume of 1 ml/100 g of body weight. Control females received the same volume of 0.5% Tween 80 alone. Females were observed for changes in appearance or behavior and body

weights were determined at intervals during gestation. The rats were sacrificed on gestation day 21 and reproductive observations were made and uteri examined for live fetuses and intra-uterine deaths. Fetuses were weighed, sexed, and examined for external, visceral and skeletal alterations. Doses used in this study were based on the results of a range-finding study in which doses (paraquat cation) of 5, 10, 20 or 40 mg/kg/day were tested and which was briefly summarized in this submission. (In the range-finding study, all rats died in the 40 mg/kg group and one rat died in the 20 mg/kg group. The nonsurvivors had dark red lungs or dark red patches on the lungs).

Maternal toxicity was reported at the two highest doses and included (1) clinical signs such as piloerection, thin and hunched appearance, and decreased body weight gain (24% and 29% less than controls for the mid-dose and high-dose groups, respectively); (2) deaths of 6 high dose animals versus none in the control group; (3) respiratory distress in 3 high-dose females; and (4) histopathological findings in the lungs (edema in the alveoli and polymorph infiltration) and in the kidneys (degenerative changes in the proximal tubules) of the nonsurvivors.

Treatment-related developmental effects (delayed ossification in the forelimb and hindlimb digits) were observed only in the mid-dose and high-dose groups. It was reported that 41.9% of the control group fetuses had good forelimb digit ossification compared with 28.8% and 23.0% of the mid-dose and high-dose fetuses, respectively. Similar results were noted for the hindlimb digit ossification.

Based on the above findings, the NOEL and LOEL for maternal toxicity are 1 mg/kg/day and 5 mg/kg/day, respectively, expressed as paraquat cation. The NOEL and LOEL for developmental toxicity are also 1 mg/kg/day and 5 mg/kg/day, respectively. (MRID 00113714)

The overall maternal NOEL for the rat is 3 mg/kg/day based on the results from the two previously summarized studies (MRID's 43964701 and 00113714).

Developmental Toxicity Study with Crl:CD1 (ICR) BR Mice

In another developmental toxicity study, paraquat dichloride (38.2% purity as paraquat ion content) was administered to 26 female Crl:CD1 (ICR) BR mice/dose by gavage in water at dose levels of 0,

7.5, 15 or 25 mg paraquat ion/kg/day from days 6 through 15 of gestation.

At 25 mg/kg/day, paraquat is maternally toxic, inducing clinical signs (piloerection, labored respiration, hunched posture, hypothermia, hypoactivity and/or pale extremities and eyes); death; decreases in body weight and body weight gain ($p < 0.01$); dark red lung lobes; increases in lung with trachea and kidney weights and a possible decrease in pregnancy rate. No maternal effects were observed at either 7.5 or 15 mg paraquat ion/kg/day.

At 25 mg/kg/day, significant decreases in mean fetal weights were observed. In addition, skeletal effects were observed which included increases in the number of litters with retarded ossification of the occipital ($p < 0.05$), the number of fetuses and litters with ≤ 6 caudal centra ($p < 0.01$ and < 0.05 for fetuses and litters, respectively), the number of litters with uni- or bilateral extra 14th ribs ($p < 0.05$) and the number of fetuses and litters with non-ossified astragalus in the hindlimb ($p < 0.01$ and < 0.05 for fetuses and litters, respectively). No other developmental effects were observed at this dose level. No developmental effects were observed at either 7.5 or 15 mg paraquat ion/kg/day.

The maternal LOEL is 25 mg paraquat ion/kg/day, based on clinical signs, death, decreases in body weight and body weight gain, dark red lung lobes, increases in lung with trachea and kidney weights and a possible decrease in pregnancy rate. The maternal NOEL is 15 mg/kg/day.

The developmental LOEL is 25 mg paraquat ion/kg/day, based on decreases in mean fetal weights and retarded ossification of the occipital, increases in the number with ≤ 6 caudal centra, increases in the number with uni- or bilateral extra 14th ribs and increases in the number with non-ossified astragalus in the hindlimb. The developmental NOEL is 15 mg/kg/day. (MRID 43949902)

Developmental Toxicity Study with SPF Alderley Park Mice

In another study, paraquat dichloride (purity: 100%) was administered by gavage in 0.5% aqueous Tween to groups of SPF Alderley Park mice at dose levels of 0, 1, 5 or 10 mg/kg/day, expressed as paraquat cation, from gestation day 6 through 15. The test solutions were administered in a volume of 0.1 ml/10 g of body weight. Control

animals received Tween 80 alone. The study was started with 120 mated mice, 30/dose. Because several mice in each group either were not pregnant, died or littered (and were excluded from the study), insufficient litters were available for examination. An additional 42 females were, therefore, mated 4-5 weeks after the first matings and were allocated to the four test groups as follows: 6 each to the control and the low-dose groups, 20 to the mid-dose group and 10 to the high-dose group. The mice were sacrificed on gestation day 18. Maternal parameters examined included body weight, clinical observations, reproductive observations (resorptions, viable fetuses and number of implantations), necropsy, and histopathology on the following tissues: lungs, kidneys, heart, spleen, liver, ovaries, uterus and placenta. Fetuses were weighed, sexed, and examined for external, visceral and skeletal alterations. Doses used in this study were based on the results of a range-finding study in which doses (paraquat cation) of 5, 10, 20 or 40 mg/kg/day were tested and which is briefly summarized in this submission. (In the range-finding study, all mice died in the 40 mg/kg group and one mouse died in the 10 mg/kg group. The nonsurvivors had dark red lungs or dark red patches on the lungs).

The only possible treatment-related maternal toxicity observed was a reduction in body weight gain in the mid-dose group (14%, $P<0.05$) and the high-dose group (11%). However, in the range-finding study with nonpregnant females, there was one death at 10 mg/kg/day. In addition, there was a statistically significant increase in the number of litters and fetuses with partially ossified 4th sternebrae in the high-dose group. There was also a statistically significant increase in trend. This is indicative of maternal toxicity. Gross necropsy and histopathology of maternal tissues revealed no treatment-related abnormalities. The only treatment-related developmental effect was the increase in the number of litters and fetuses with partially ossified 4th sternebrae in the high-dose group. Based on these findings, the NOEL and LOEL for maternal toxicity are 5 mg/kg/day and 10 mg/kg/day, respectively, expressed as paraquat cation. The NOEL and LOEL for developmental toxicity are also 5 mg/kg/day and 10 mg/kg/day, respectively. (MRID 00096338)

f. Reproductive Toxicity

Wistar-derived Alderley Park strain of rats, 15 males and 30 females/group, were fed technical grade paraquat dichloride (cation content: 32.7%) for 11-12 weeks before they were mated to produce F_1, F_2 and F_3 A litters, and subsequently F_1, F_2 and F_3 A litters. The following levels of paraquat cation were fed in the diet: 0, 25, 75 or 150

ppm. Assuming that, for an older rat, 1 ppm = 0.05 mg/kg/day, these doses correspond to 0, 1.25, 3.75 or 7.5 mg of paraquat cation/kg/day, respectively. These doses are identical to those used in the chronic feeding/carcinogenicity study with rats (MRID 00138637).

Paraquat, at all levels tested, had no effect on body weight gain, food consumption and utilization, fertility and length of gestation of the F_0, F_1 and F_2 parents. However, there was a high incidence of mortality (27-43%) in the high-dose F_0, F_1 and F_2 females, due mostly to severe lung damage caused by paraquat. The incidence of lung injury (red or purple discoloration, congestion, edema, fibrosis, hyaline membrane formation, inflammatory cell infiltration and/or hyperplasia) ranged from 27% to 35%. There was also an increased incidence of alveolar histiocytosis in the lungs of the mid-dose and high-dose male and female parents. In the case of the F_0, F_1 and F_2 females, the incidence was 28-40% (control groups), 28-54% (low-dose groups), 62-80% (mid-dose groups) and 80-100% (high-dose groups). The corresponding incidences for the males were 11-30%, 0-13%, 10-71% and 50-86%, respectively.

The most frequent histological findings at the termination of the study were hydronephrosis, nephrocalcinosis, lung congestion and/or alveolar hemorrhage, perivascular inflammatory cell infiltration in the lungs, focal accumulation of lymphocytes in the liver, and hypoplasia, atrophy and/or necrosis of the testes. However, the incidence of these findings was not dose-related.

Based on the above findings, the NOEL and LOEL for systemic toxicity are 25 ppm (1.25 mg/kg/day) and 75 ppm (3.75 mg/kg/day), respectively, expressed as paraquat cation. The NOEL for reproductive toxicity is $\geq$ 150 ppm (7.5 mg/kg/day; HDT), expressed as paraquat cation. (MRID 00126783)

g. Mutagenicity

Paraquat was weakly positive in the mouse lymphoma cell assay, but only with metabolic activation (in the presence of Aroclor 1254-stimulated rat hepatic microsomes, S-9, plus appropriate cofactors). It induced forward mutation in the L5178Y mouse lymphoma cell line as monitored by cell growth in the presence of trifluorothymidine (TFT). Mouse lymphoma L5178Y cells were exposed for 2 hours to paraquat dichloride (technical grade; active ingredient content: 45.7%) at concentrations ranging from 31.25 to 1000 ug/mL, both in the presence

and absence of the S-9 mix. Five separate experiments were performed. Positive controls used were ethyl methane sulfonate (EMS) and benzo(a)pyrene [B(aP]. Concentration-related cytotoxicity to paraquat was observed in all experiments. Concentrations of 500-1000/mL were either severely cytotoxic or lethal. This study satisfies Guideline requirements for genetic effects, Gene Mutations. (MRID 00152690)

Paraquat dichloride (purity: 99%) was not mutagenic in the Ames test using *Salmonella typhimurium* histidine-requiring strains TA1535, TA1538, TA98 and TA100, with and without metabolic activation. The concentrations of paraquat dichloride tested were 0.16, 0.8, 4, 20, 100, 500, 2500 and 5000 ug/plate. Concentrations above 100 ug/plate were cytotoxic. Positive controls used were N-2-acetylaminofluorene (AAF), 2-nitrofluorene (2NF), 2-(1-chloro-2-isopropylaminoethyl) naphthalene (CPE) and meclorethamine (nitrogen mustard). This study satisfies Guideline requirements for genetic effects, Gene Mutations. (MRID 00100441)

Paraquat was weakly positive in the mammalian cells (human lymphocytes) in culture cytogenetic assay, with and without metabolic activation (S-9 mix). The lymphocytes were obtained from two healthy donors, male and female. The concentrations of paraquat dichloride (analytical grade; active ingredient content: 99.6%) tested ranged from 0.75 to 3500 ug/mL. Positive controls used were mitomycin-C (MC) and cyclophosphamide (CP). Severe cytotoxicity was observed in cultures exposed to the highest concentration of paraquat tested (3500 ug/mL). Concentration-related decreases in mitotic indices were recorded at 125-2500 ug/mL. Increases in chromosome damage were found in non-activated cultures exposed to the 1250 ug/mL and higher levels of paraquat. In the presence of S-9, statistically significant ($P<0.01$) increases in chromosome damage were observed at 1750 ug/mL in the case of one donor and at 2500 ug/mL in the case of another donor. This study satisfies Guideline requirements for genetic effects, Structural Chromosome Aberrations. (MRID 00152692)

Analytical grade paraquat dichloride (active ingredient con-tent: 99.4%) was positive in the sister chromatid exchange (SCE) assay, with and without metabolic activation. Duplicate mono- layer cultures of DON cells (derived from Chinese hamster lung fibroblasts) were exposed for 3 hours to paraquat dichloride ranging in concentration from 1.2 to 2470 ug/mL, with and without the metabolic activation system (S-9). Cell cultures were then incubated with brom deoxyuridine for 20 hours, incubated with cholchicine for 2 hours and

then processed for microscope slide scoring for SCE according to standard procedures. Mitomycin C (MC) and cyclophosphamide (CP) were used as positive controls. This study satisfies Guideline requirements for genetic effects, Structural Chromosome Aberrations. (MRID 00152695)

Technical grade paraquat dichloride (cation content: 33%) was negative for chromosomal aberrations in the bone marrow test system. Positive results were obtained with cyclophosphamide, a known clastogen. In this study, Alderley Park Wistar-derived male and female rats received by gavage single doses of paraquat dichloride and then were sacrificed for bone marrow sampling at 12, 24 or 48 hours after treatment. The doses used, expressed as paraquat cation, were 0, 15, 75 or 150 mg/kg. Based on the results from a preliminary study, the 150 mg/kg dose approximated a maximum tolerated dose (MTD). This study satisfies Guideline requirements for genetic effects, Structural Chromosome Aberrations. (MRID 40202405)

No evidence of dominant lethal mutagenicity or suppression of fertility was seen in the study with CD-1 mice. In this study, male mice were administered paraquat dichloride (cation content: 28.3%) by gavage for 5 consecutive days and then were mated with different untreated female mice for 8 weeks. The doses of paraquat used were 0, 0.04, 0.4 and 4.0 mg/kg, expressed as paraquat cation. These doses were based on the results of a preliminary study in which the 4.0 mg/kg dose was the maximum tolerated dose (MTD). Mutagenic effects were observed with positive controls, ethyl methane sulphonate (EMS) and cyclophosphamide (CP). This study satisfies Guideline requirements for genetic effects, Structural Chromosome Aberrations. (MRID 00100442)

Analytical grade paraquat dichloride (active ingredient content: 99.6%) did not induce unscheduled DNA synthesis in rat hepatocytes exposed *in vitro*. Hepatocytes from an untreated male rat (Alderley Park SPF albino) were allowed to attach to cover slips for 2 hours and then were exposed for 19 hours to tritiated thymidine together with paraquat dichloride at concentrations ranging from 10^{-2} to 10^{-9} M. Diethylnitrosamine (DEN) was used as a positive control. This assay was repeated once using hepatocytes from another rat. This study satisfies Guideline requirements for genetic effects classified as Other Genotoxic Effects. (MRID 00152693)

Technical grade paraquat dichloride (cation content: 33%) was negative for unscheduled DNA synthesis in rat hepatocytes exposed *in vivo*. Suspensions of hepatocytes were prepared from male Alderley Park SPF albino rats dosed by gavage with paraquat dichloride, water (controls) or 6BT (6-dimethylaminophenylazo-benzthiazole; positive control). The single doses of paraquat dichloride used were 0, 45, 75 or 120 mg/kg and the rats were sacrificed at 4 and 12 hours after dosing. Two separate experiments were performed for each time point. The selection of doses was governed by the need to evaluate paraquat at adequate concentrations and that these doses should not induce toxicity in the hepatocytes. No increase in unscheduled DNA synthesis was observed at any dose of paraquat dichloride at either time point when compared with concurrent negative controls, but positive results were obtained with 6BT. Although hepatocytes from rats in the 120 mg/kg group showed marked signs of toxicity, sufficient cells of normal morphology were available to be examined for unscheduled DNA synthesis. This study satisfies Guideline requirements for genetic effects classified as Other Genotoxic Effects. (MRID 40202404)

h. Metabolism

Paraquat was not metabolized by rats. After oral administration (gastric intubation) of single doses of paraquat dichloride or dimethylsulfate to Wistar strain male and female rats, most of the administered radioactivity (69-96%) was excreted in feces as unchanged paraquat. After subcutaneous injection of these compounds, unchanged paraquat appeared mostly in urine (73-96% of the administered radioactivity). Paraquat used in this study (radiochemical purity: 99-100%) was labeled with 14-C in the methyl groups. The doses used for gastric intubation ranged from 0.5 to 50 mg/kg and for subcutaneous injection, from 12.5 to 24 mg/kg. Most of the radioactivity was detected in feces within 2-3 days after dosing and in urine, within 1 day after dosing.

Following oral administration of paraquat, up to 30% of the dose appeared in feces in a degraded form. This was due to the microbial degradation of paraquat in the gut. That microbial degradation of paraquat occurred in feces was shown in an *in vitro* experiment in which fecal homogenates were incubated with added paraquat for 24 hours. In that experiment, 40-50% of paraquat was destroyed. However, a similar experiment with sterilized fecal homogenates produced only minor loss (trace amounts) of added paraquat. (MRID 00055107)

Paraquat was poorly absorbed after oral administration to rats, dogs and mice. Once absorbed, paraquat was rapidly distributed to most tissues but especially to lungs and kidneys. Tissues other than lungs did not retain paraquat. (MRID 00138637, 00132474 and 40202403)

i. Neurotoxicity

Considering the chemical nature of paraquat and the fact that it has not been shown to inhibit cholinesterase activities, does not produce cholinergic-like toxic signs and does not affect morphology of the central and peripheral nervous systems, the following studies are not required: acute delayed neurotoxicity study in the hen (81-7); acute (81-8 SS) and subchronic (82-5b or 82-7) neurotoxicity screening battery studies in the rat; and developmental neurotoxicity study in the rat (83-6). There is currently no evidence to suggest the need for these studies.

j. Dermal Absorption

In a dermal absorption study with healthy adult male volunteers, 0.3% of the applied ^{14}C-paraquat dichloride was absorbed through the intact skin (forearms, and back of the hands and lower legs) during the 24-hour exposure period. (MRID 00153439).

k. Poisoning Incidents

From 1985 through 1994, there were 17 paraquat-related deaths reported to Poison Control Center's national database from oral ingestion. Most of the fatal oral ingestions (13 out of 17) have been related to suicidal incidents. Of the four remaining cases, two were unknown as to intent and two were accidental ingestions. These two accidental ingestions occurred when paraquat end-use products were formulated into a brown liquid which could have been mistaken for a cola-type of soft drink (prior to 1988). However, since 1988 the manufacturer has added an emetic (a substance that induces vomiting), a stenching agent and changed the color (to blue), to try and prevent the accidental and intentional ingestions from occuring. U.S. Poison Control Center data, show a decline of almost 50 percent when comparing the proportion of all pesticide exposures due to paraquat ingestion for the four years pre- and post 1988.

Dermal exposure to paraquat usually results in minor skin or eye irritation. Rarely, with heavier exposures resulting from misuse, more serious effects may occur such as blistered or ulcerated skin, loss of fingernails, skin burns, ulcers of the mouth, nosebleeds, and protracted or even permanent blindness. These more serious effects typically result when protective clothing is not worn, skin has abrasions or open cuts, and/or when extensive exposure is allowed to persist without washing. The label currently warns against these hazards. Heavy, prolonged dermal exposure, as from a leaking knapsack type of sprayer, can result in severe poisoning and, rarely, even death. Six such deaths have been reported outside of the United States when workers failed to follow label requirements for proper hygiene.

l. Toxicological Endpoints of Concern Identified for Use in Risk Assessment

Reference Dose (RfD)

On July 20, 1995, the Agency's Reference Dose (RfD)/Peer Review Committee verified the reference dose (RfD) for paraquat which was last revised on February 1, 1991. The Committee recommended that the already established RfD, 0.0045 mg/kg/day (expressed as paraquat cation), be retained. This value was based on the systemic NOEL of 15 ppm (0.45 mg/kg/day) from the 1-year dog feeding study (MRID 00132474) and the uncertainty factor (UF) of 100. Chronic pneumonitis was observed at the next dose of paraquat tested, 30 ppm (0.93 mg/kg/day), expressed as paraquat cation. The WHO RfD (ADI), which was last reviewed in 1986, is 0.0040 mg/kg/day, expressed as paraquat cation.

The following endpoints were determined by the Agency's Toxicology Endpoint Selection Committee (TESC) on July 25, 1995:

Acute Dietary (1 day)

An acute dietary (1 day) risk assessment is not required. No data are available that suggest a need for an acute dietary endpoint.

An examination of the data did not provide any toxicological endpoints that could have resulted from a single acute dietary exposure when paraquat is used as labeled. In addition, there are many tolerances for paraquat on raw agricultural commodities (RAC) and virtually all of

them are at the detection limit. Therefore, the TESC felt that there would not be any acute dietary problems or concerns with paraquat.

Short Term Occupational Exposure (1-7 days)

The Toxicology Endpoint Selection/Peer Review Committee indicated inhalation endpoints should be used for risk assessment only in cases in which the spray particles are of a respirable size. This endpoint was based on the NOEL and LOEL for subchronic (3 weeks) inhalation toxicity, for both sexes, of 0.01 ug/L and 0.10 ug/L, respectively, expressed as paraquat cation. This endpoint will not be used for risk assessment unless the particle size is small enough to be respirable (such as aerosol spray). (MRID 00113718)

For all other use scenarios (such as agricultural applications), a "dermal endpoint" is used: NOEL of 3 mg/kg/day, expressed as paraquat cation, based on maternal and developmental toxicity effects: unscheduled deaths, thin and hunched appearance, decreased body weight gain, and histological changes in the lungs and kidneys of the nonsurvivors. Exposure by the dermal route, obtained by extrapolating data (NOEL) from a combination of two rat developmental toxicity studies and correcting for dermal absorption (0.3%), is appropriate for short term occupational and residential exposure. (MRIDs 00113714, 43964701 and 00153439).

Intermediate Term Occupational (1 week to several months)

The endpoint used is the same as for the Short Term Occupational or Residential Exposure (above).

Chronic Occupational Exposure (Longer Than Several Months)

The endpoint and dose for use in risk assessment: 0.45 mg/kg/day, expressed as paraquat cation (NOEL for systemic toxicity, based on the severity and extent of chronic pneumonitis in both sexes), in the one-year dog feeding study. (Guideline No.: 83-1b, MRID: 00132474)

This risk assessment is not required as there are no chronic occupational nor residential exposure scenarios for the use of paraquat.

Cancer Classification and Basis:

The Agency has classified paraquat as a Group E carcinogen (evidence of non-carcinogenicity for humans), based on a lack of evidence of carcinogenicity in acceptable studies with two animal species, rat (Guidelines 83-1a/83-2a; MRIDs 00138637, 00153223, 40202401, 40202402, 41317401, 40218001) and mouse (Guidelines 83-2b; MRIDs 00087924, 40202403), by the Toxicology Branch Peer Review Committee (now Carcinogenicity Peer Review Committee) on June 15, 1988, and (again) on March 15, 1989.

2. Exposure Assessment

a. Registered Uses

Paraquat dichloride is currently registered for the control of broadleaf weeds and grass in agricultural and non-agricultural areas. It is used as a preplant or preemergence herbicide on vegetables, grains, cotton, grasses, sugar cane, peanuts, potatoes, and on areas for tree plantation establishment. Paraquat is applied as a directed spray postemergence herbicide around fruit crops, vegetables, trees, vines, grains, soybeans, and sugar cane. It is used for dormant season applications on clover and other legumes, and for chemical fallow. It is also used as a desiccant or harvest aid on cotton, dry beans, soybeans, potatoes, sunflowers, and sugar cane. It is use as a post harvest desiccant on staked tomatoes, and on pine trees to induce resin soaking.

Paraquat dichloride is applied by aerial, groundboom, backpack sprayer, and low pressure handwand.

A soluble concentrate/liquid (SC/L) is the sole paraquat formulation type registered for all uses. This formulation may be applied to crops pre-plant, at planting, pre-emergence (broadcast or band), post-emergence (broadcast, band, split, directed, or spot), post-harvest (as a pre-harvest desiccant or harvest aid), and for suckering and stripping of hops.

i. Agricultural

Paraquat dichloride end-use products (EPs) with food/feed uses registered to Zeneca Ag Products are listed below.

EPA Reg. No.	Acceptance Date	Formulation Class	Product Name
10182-103 [a]	4/4/95	1.5 lb/gal SC/L	Gramoxone® Super Herbicide

EPA Reg. No.	Acceptance Date	Formulation Class	Product Name
10182-111 [b]	4/4/95	2 lb/gal SC/L [c]	Cyclone® Herbicide
10182-120	4/4/95	29.42% SC/L [c]	Surefire® Herbicide
10182-280 [d,e]	4/4/95	2.5 lb/gal SC/L	Gramoxone® Extra Herbicide
10182-372	4/4/95	3 lb/gal SC/L [c]	Cyclone® Concentrate Herbicide

[a] Including SLN Nos. LA870004, LA870005, OH880002, PA870002, SC820011, and TN940007.

[b] Including SLN Nos. AR820020, NC820010, NM940003, OK940004, SC820024, TX810032, and TX940011.

[c] The 2 and 3 lb/gal SC/L (EPA Reg. Nos. 10182-111 and 10182-372) and the 29.42% SC/L (EPA Reg. No 10182-120) formulations are coded by REFs as emulsifiable concentrate (EC) formulations. However, these products were previously identified as SC/L formulations in the Registration Standard Update.

[d] Including SLN Nos. AL940005, AR950002, CA910021, CA910022, CA910023, CA910024, CA910031, CA910036, CA920006, CT900001, DE940002, FL900009, FL910004, FL910006, GA940006, HI910001, HI910010, HI920008, ID920010, ID920011, ID930006, LA940007, MI910009, MN900004, MT940005, NH900001, NH920001, NJ900005, NV910002, NV910003, OH910001, OR910023, OR910024, OR930009, OR930019, PA900001, SD940005, TN940008, VA930006, VA940012, WA910044, WA910048, WA930014, WA940037, WA950007, and WI900004.

[e] The 2.5 lb/gal SC/L formulation (SLN No. MN940006) was unavailable for review; the registration jacket did not contain a label.

ii. Non-agricultural

The non-agricultural uses of paraquat are for nonselective weed control on conservation reserves and non-crop areas such as public airports, storage yards and electric transformer stations.

One formulation of paraquat dichloride, ICI Spot Weed and Grass Control (EPA Reg. No. 10182-114), was intended for homeowner use and was packaged as a ready-to-use pressurized spray (aerosol) containing 0.276 percent active ingredient. It was labelled to control weeds and grasses around walks, driveways, trees, shrubs, and flower beds. However, this product has never been sold in the U.S. even though it was registered and has been voluntarily cancelled at the request of the registrant because of unacceptable risk to the applicator identified through this reregistration process.

b. Dietary Exposure

The Residue Chemistry data base for paraquat is substantially complete. The registrant is required to submit data for a few outstanding data requirements. Sufficient data are available to reassess the adequacy of the majority of the established tolerances for paraquat as listed in the relevant sections of 40 CFR. The Agency is requiring that the tolerance for residues in or on several of the crops be changed, as detailed in section IV of this document, Tolerance Reassessment Summary Table.

GLN 171-4 (a): Plant Metabolism

For purposes of reregistration and risk assessment, the qualitative nature of the residue in plants is adequately understood based on studies depicting the metabolism of paraquat in carrots and lettuce following pre-emergence treatment and in potatoes and soybeans following desiccant treatment. The residue of concern in plants is the parent, paraquat; the current tolerance expression for plant commodities, as defined in 40 CFR §180.205(a) and (b), 185.4700, and 186.4700, is adequate.

In plant metabolism studies reflecting *pre-emergence* treatment, the total radioactive residues (TRR) were 0.0048 ppm in carrot root and 0.0034 ppm in lettuce leaf samples following a single pre-emergence application at ~13x the maximum rate of 1 lb cation/A. These data suggest that radioactive residues of paraquat are not readily taken up from the soil in significant quantities by these crop commodities following this mode of treatment. No further residue characterization and identification was conducted on these samples because of the low magnitude of radioactivity obtained.

In plant metabolism studies reflecting *desiccant* treatment, the total radioactive residues were 0.075 and 0.087 ppm in potatoes, 0.652 and 0.841 ppm in soybeans, and 506.3 and 768.5 ppm in soybean foliage following a single foliar desiccant application at ~6x the maximum seasonal rate of 1.25 lb cation/A for potatoes and 29x the maximum single application rate of 0.25 lb cation/A for soybeans). Paraquat cation was the major ^{14}C-residue identified, and accounted for ~91% of the total radioactivity in potatoes, ~84% of the total radioactivity in soybeans, and virtually all of the total radioactivity in soybean foliage. Other minor metabolites found in soybean foliage were QINA (quaternary iso-nicotinic acid), a photodegradant and monoquat (1-methyl-4,4'-bipyridinium ion), each at 0.3% of TRR.

GLN 171-4 (b): Animal Metabolism

For purposes of reregistration and risk assessment, the qualitative nature of the residue in animals is adequately understood based on the combined results of studies conducted with ruminants (goats and cows), swine, and poultry. The residue of concern in eggs, milk, and poultry and livestock tissues is the parent, paraquat; the current tolerance expression for animal commodities, as defined in 40 CFR §180.205(a), is adequate.

In a *ruminant metabolism study*, a lactating goat was dosed with ring-labeled [^{14}C]paraquat dichloride at 103 ppm in the diet for seven days. The total radioactive residue, expressed as ppm paraquat, was 0.02-0.03 ppm in fat (peritoneal and subcutaneous), 0.08-0.12 ppm in muscles (fore- and hind-quarter), 0.56 ppm in liver, and 0.74 ppm in kidney. The maximum total radioactivity in milk increased daily to a maximum of 0.0092 ppm paraquat ion equivalents four hours before slaughter; 75.7% of the TRR of this sample was found to be paraquat. In edible tissues, paraquat accounted for the majority of the identified residues including ~49-120% of TRR in fat, ~90-100% of TRR in muscle, ~48% of TRR in liver, and ~95% of TRR in kidney. Other metabolites that were identified in tissues were the monopyridone of paraquat (1,2-dihydro-1,1'-dimethyl-4,4'-bipyridinium ion) which accounted for 3.2% of TRR in liver and monoquat which accounted for 3.4% of TRR in liver and 6.5% of TRR in peritoneal fat.

A *pig metabolism study* reflecting use of ring-labeled [^{14}C]paraquat and a feeding level of 2.44 ppm is also available. Total radioactive residues were 0.20 ppm paraquat equivalents in liver, 0.38 ppm in kidney, 0.05 ppm in muscle, and 0.01 ppm in fat. Paraquat was found to comprise ~70% of TRR in liver, 101% of TRR in kidney, 95% of TRR in muscle, and 106% of TRR in fat. Liver tissue, the only tissue analyzed for residues other then paraquat, was found to contain monoquat at ~4% of TRR.

In a *poultry metabolism study*, laying hens were dosed with ring-labeled [^{14}C]paraquat at 30 ppm in the diet for ten consecutive days. Radioactive residues were found in all examined tissues (including liver, abdominal and subcutaneous fat, and leg and breast muscle). Paraquat was the major residue (~80-98% of TRR) identified in all poultry tissues; monoquat was a minor metabolite (~4% of TRR each) in liver and kidney. Virtually all of the radioactivity in the yolk was identified as paraquat; no analysis of albumen was reported.

GLN 171-4 (c) and (d): Residue Analytical Methods-Plants and Animals

The requirements for residue analytical methods are partially fulfilled for purposes of reregistration, pending submission of supporting raw data for the radiovalidation study of the method for plant commodities. Acceptable methods are available for enforcement and data collection purposes both in plant and animal commodities.

Methods for determination of residues in/on plant commodities: The Pesticide Analytical Manual (PAM Vol. II) lists a spectrophotometric method, designated as Method I (LOD = 0.01-0.06 ppm), as available for the enforcement of tolerances in plant commodities. Several modifications of Method I have been developed for analysis of specific crops, and these modified methods were used for data collection. Samples from field trial and processing studies, submitted to fulfill reregistration requirements, were analyzed for residues of paraquat using Methods 1B, 2B, 3A, and 3B, and Methods RM-8, RM-8-9, RM-8-10, and RM-8-11. Method I along with its modifications all include extraction in acid solution, adsorption of residues on a cation-exchange resin, elution with saturated ammonium chloride, reduction with sodium dithionite to give a blue-colored solution of free radical, and detection by spectrometry. The registrant provided adequate method validation data to verify the suitability of Methods 1B, 2B, 3A, and 3B for data collection.

In conjunction with recently submitted plant metabolism studies, the registrant has provided radiovalidation data for Method 1B using radiolabeled samples. The Agency tentatively concluded that Method 1B adequately recovers paraquat cation residues from samples of potatoes and soybeans treated with [^{14}C]paraquat. The registrant has recently submitted representative spectra and other supporting raw data from the radiovalidation study; upon the Agency's review of this additional information, the requirements for residue analytical methods for plant commodities will be considered fulfilled for reregistration purposes.

Methods for determination of residues in animal commodities: The Pesticide Analytical Manual (PAM Vol. II) lists a spectrophotometric method, designated as Method Ia (LOD = 0.005 ppm), as available for the enforcement of tolerances in animal commodities. The registrant has submitted descriptions and adequate independent laboratory validation data for a high-performance liquid-chromatography method (HPLC; designated as Method 4B) to determine paraquat residues in animal tissues and eggs. The method has been validated by the Agency's Beltsville laboratory, and the registrant is required to make minor changes in the method write-up.

Multiresidue Methods: The FDA PESTDATA database (dated 1/94) does not have an entry for paraquat. The existing FDA multiresidue methods are not likely to recover paraquat residues owing to its ionic nature.

GLN 171-4 (e): Storage Stability

Provided that the final results of storage stability studies for cabbage, carrots, and milk are acceptable, the requirements for storage stability data will be considered fulfilled for reregistration purposes; these requested studies have recently been submitted to the Agency (MRID#'s 43954003 and 43954004) and will be reviewed in the near future. Although the storage stability of paraquat has not been investigated in any oilseed or nut and the storage stability data on processed commodities are rather limited, no additional storage stability data are required for reregistration purposes provided the recently submitted stability study data are adequate; in practically all examined cases, paraquat residues were found to be stable at the maximum storage intervals tested. The available data for corn grain may be translated to oilseeds.

GLN 171-4 (k): Magnitude of the Residue in Plants

Pending required label amendments and/or revised tolerances, the reregistration requirements for magnitude of the residue in/on plants are fulfilled for the following commodities: acerola; almond hulls; apples; apricots; asparagus; avocados; bananas; barley grain, forage, and straw; beans, dry and succulent; beans, forage, hay, and straw; broccoli; cabbage; cacao beans; carrots; cassava; cauliflower; cherries; Chinese cabbage; citrus fruits group; coffee beans; collards; corn, field, grain; corn, field, forage and fodder; corn, pop, grain; corn, pop, fodder; corn, sweet (K + CWHR); corn, sweet, forage and fodder; cottonseed; cucurbit vegetables group; figs; fruiting vegetables (except cucurbits) group; grass, rangeland, forage; grass, pasture, forage; grass, pasture, hay; guar; guava; hops, dried; kiwifruit; lentils; lentils, forage; lettuce; mint tops; nectarines; non-grass animal feeds group, forage; non-grass animal feeds group, hay; olives; onions, dry bulb and green; papayas; passion fruit; peanuts; peanuts, hay and hulls; pears; peas, pigeon; peas, succulent; peas, hay and vines; pineapples; peaches; pistachios; plums; potatoes; rhubarb; rice, grain and straw; safflower, seed; small fruits and berries group; sorghum, grain; sorghum, forage and fodder; soybeans; soybeans, forage, and hay; strawberries; sugar beets, roots and tops; sugarcane; sunflower seeds; taniers; taro corms; tree nuts group; turnips, roots and tops; tyfon; wheat grain, forage, and straw; and yams. Adequate field trial data depicting residues of paraquat following treatments according to the maximum registered use patterns have been submitted for the commodities listed above or have been translated where appropriate.

Table I (OPPTS 860.1000) recognizes barley hay, cotton gin byproducts (formerly called gin trash), and wheat hay as raw agricultural commodities (RACs). Residue data are now required for these RACs, and appropriate tolerances should be proposed once acceptable data have been submitted and evaluated. The required data for wheat hay may be translated to barley hay.

Table I of OPPTS 860.1000 no longer recognizes cotton forage, popcorn forage, pineapple forage, sorghum hay, safflower forage, sorghum silage, and sugarcane forage as RACs. Therefore, no residue data are required for these commodities and tolerances need not be established. In addition, Table I no longer recognizes fresh hops, hop vines, lentil hay, and peanut vines as RACS; therefore, the established tolerances for these commodities will be revoked.

The registrant has expressed an intention to petition the Agency for the revocation of the established tolerances for oat grain and rye grain since the registrant claims there are no longer any registered uses of paraquat on these commodities. Therefore, the tolerances for oat grain and rye grain will be revoked.

No residue data or tolerance currently exists for taro foliage. The registrant must submit field residue data and a tolerance proposal for residues of paraquat in/on taro foliage.

Additional data are required for soybean aspirated grain dust. The Agency has recently revised its policy on aspirated grain dust and determined that it should be considered a RAC [see memo on "Aspirated Grain Fractions (Grain Dust): A Tolerance Perspective", E. Saito and E. Zager, 6/7/94]. The Agency also determined that a tolerance for aspirated grain fractions for a pesticide should be established based on the use of the pesticide on corn, wheat, sorghum, and soybeans; paraquat is presently registered for use on these crops. A soybean grain dust study has been submitted and was deemed unacceptable because the data from the study could not be used reliably to calculate the potential for concentration of paraquat residues in the subject commodity. The Agency believes that based on paraquat registered uses on soybeans, which include post-emergence directed spray and use as a harvest aid, a potential exists for paraquat residues to concentrate in/on soybean grain dust, and the registrant has committed to conduct a new soybean aspirated grain dust study.

No grain dust data are required for wheat and sorghum because finite residues are not expected on the grain dust of these crops since paraquat is registered for use only during the vegetative (and not the reproductive) stages. With respect to corn, however, the Agency has recently approved a SLN registration (TN940007) for use on corn as a harvest aid (PHI of 7 days). To support this use, the Agency will require additional field trials with corn as well as an aspirated grain fraction study.

GLN 171-4 (l): Magnitude of the Residue in Processed Food/Feed

The reregistration requirements for magnitude of the residue in processed food/feed commodities are fulfilled for: apples; barley; cacao beans; citrus; coffee; corn, field; cottonseed; figs; hops; mint; olives; peanuts; pineapples; plums; potatoes; rice; safflower; sorghum; soybeans; sugar beets; sugarcane; sunflower; tomatoes; and wheat. Data depicting the magnitude of the residue in the processed commodities of grapes remain outstanding. The registrant must submit data depicting the potential for concentration of paraquat residues in the processed commodities of grapes bearing detectable weathered residues. Residue data showed that residues concentrate in corn flour, soybean hulls, pineapple processing residue, and sugarcane molasses. Tolerances have been proposed accordingly for these commodities (see section IV, Tolerance Summary Table). No processing data are required for processed commodities of oats or rye since the registrant does not wish to support the RAC tolerances for oat grain and there are presently no registered uses of paraquat on rye grain.

GLN 171-4 (j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

There are no registered direct animal treatments for paraquat on cattle, goats, hogs, horses, sheep, or poultry. Based on acceptable animal metabolism studies and magnitude of the residue in animal studies, uses of paraquat are classified as Category (1) of 40 CFR §180.6(a); finite residues will be incurred in foods from feed use of the RAC including its byproducts. The residue of concern in eggs, milk, and poultry and livestock tissues has been determined to be the parent, paraquat; the current tolerance expression for animal commodities, as defined in 40 CFR §180.205(a), is adequate.

Magnitude of the residue in milk, fat, meat, and meat byproducts of ruminants: The maximum expected dietary intake of paraquat

residues by beef and dairy cattle was previously calculated to be approximately 11 ppm. Based on tolerance reassessments of many livestock feed items [including the forage and hay of non-grass animal feeds (e.g., alfalfa) as well as grass forage], the new dietary burdens for beef cattle and dairy cattle are recalculated to be 216 ppm and 252 ppm, respectively.

The Agency has reevaluated the existing magnitude of the residue data for milk and ruminant tissues and has determined that these data are considered sufficient for reliable risk and tolerance assessments: while the 170 ppm feeding rate represents only 0.7x the maximum theoretical dietary burden, the Agency believes that a new feeding study is not required since there do not appear to be significant changes in tissue levels between 25 ppm and 170 ppm dosing levels. In addition, the cows in the feeding study were dosed at 170 ppm (0.7x) for 86-95 days. Since 170 ppm represents a concentration very close to the concentration expected following immediate consumption of a treated crop (i.e., a 0-day PHI), it is unlikely that a cow would consume this dietary level for any extended period of time.

Based on the existing magnitude of the residue data for meat and ruminant tissue, the Agency will recommend the following tolerances for meat, fat, kidney and liver:

Muscle:	0.05 ppm
Fat:	0.05 ppm
Kidney:	0.5 ppm
Liver:	0.05 ppm

The Agency does not believe that detectable residues will result in milk (normally considered a 180.6(a)(3) situation), but will recommend retention of the present 0.01 ppm tolerance in the interest of harmonization with the CODEX MRL of 0.01 ppm.

Magnitude of the residue in eggs, fat, meat, and meat byproducts of poultry: The maximum expected dietary intake of paraquat residues by laying hens was previously calculated to be 1.4 ppm. Based on tolerance reassessments of many poultry feed items, the new dietary burden for poultry is calculated to be 1.1 ppm.

The Agency has reevaluated the existing magnitude of the residue data in eggs and poultry tissues in conjunction with the reassessments of tolerances for all poultry feed commodities. The

available poultry feeding data indicate that non-egg poultry commodities are a 180.6(a)(3) situation and no tolerances need be established. In the interest of harmonization with CODEX, the Agency will recommend maintaining the current 0.01 ppm tolerance on eggs.

GLNs 165-1 and 165-2: Confined/Field Rotational Crops

An acceptable confined rotational crop study has been submitted. The study indicated that residues of paraquat do not accumulate in rotated crops planted up to 120 days following treatment; therefore, no plantback restrictions or field rotational crop studies are required.

c. Occupational and Residential

Handler Exposures & Assumptions

The Agency has determined that there is potential exposure to mixers, loaders, applicators, and other handlers during usual use-patterns associated with paraquat dichloride. The Agency has identified exposures to handlers during the agricultural and non-agricultural uses of paraquat dichloride, including mixing and loading, and during application by ground and aerial equipment, particularly backpack applicators. Mixer/loader/applicator (M/L/A) exposure data for paraquat dichloride were required in the December 1991 Data Call-In (DCI) and in response to the Worker Protection Standard. These data are discussed below.

Based on the use patterns, several major occupational exposure scenarios were identified for paraquat dichloride: (1) mixing/loading liquid formulations for ground boom application; (2) mixing/loading liquid formulations for aerial application; (3) applying as a spray with a tractor-drawn ground boom; (4) applying as a spray with aerial equipment; (5) mixing/loading liquid formulations for backpack spraying; (6) applying as a spray with a backpack sprayer; (7) flagging for aerial spray applications; (8) mixing, loading, and applying the liquid formulation for spot treatment with a low pressure sprayer; (9) mixing, loading, and applying the liquid formulation for spot treatment with a backpack sprayer; and (10) mixing, loading, and applying the liquid formulation for resin soaking uses with a low pressure sprayer.

The following chemical-specific mixer/loader/applicator study was submitted by the registrant:

- *MRID Number: 436442-02. 1995. D. Meier. Paraquat: Worker Exposure During Mixing, Loading, and Application of GRAMOXONE® EXTRA to Pecans Using Vehicle-Mounted Ground Boom Equipment.*

This worker biomonitoring study was performed to support label revisions related to personal protective equipment required for mixers, loaders, and applicators. Paraquat formulated as GRAMOXONE® EXTRA herbicide in water was applied at a maximum application rate of 0.94 lb cation/Acre by ground boom spray to pecan orchards in southwestern Georgia and southeastern Alabama in September, 1994. Urinary excretion of paraquat was measured as the indicator of exposure to workers mixing, loading, and applying the herbicide. A total of 17 combined mixer/loader/applicator replicates were monitored. The Agency has reviewed this study and considers it acceptable since it adequately meets Subdivision U Guidelines of the Pesticide Assessment Guidelines.

Application of paraquat was conducted on fifteen separate pecan farms using ground boom spray equipment mounted on open-cab tractors. Three pints Gramoxone® EXTRA herbicide were mixed with surfactant and water to 13 to 42 gallons/acre spray mixture. Workers either poured the formulated product directly into the spray tank or measured it into a calibrated container before transferring it to the spray tank.

Although the study sponsor requested that the workers comply with label requirements for personal protective equipment (PPE), they did not interfere with the individual subject's typical practices. As a result, a wide variety of PPE was employed. Of a total of 17 individuals, only eight wore gloves while mixing. The remaining nine wore only normal work clothing. Three wore face/eye protection, and wore an apron in addition to protective gloves. Two workers wore Tyvek suits during application. The time spent mixing and loading ranged from 14 to 104 minutes, and the total time of exposure from 230 to 660 minutes. Activities relevant to exposure were reported. The total amount of paraquat handled varied from orchard to orchard, with a range of 9.5 to 69 pounds of active ingredient.

The Limit of Quantification (LOQ) was stated to be 10 ng/ml for a 1 ml urine sample. The level of detection was given as 5 ng/ml. The study results showed that six of the 17 urine samples collected contained detectable paraquat. All were in the Day 1 (application

exposure day) samples. Absorbed paraquat was estimated using a referenced excretion rate of 59% from a paraquat pharmacokinetics study in monkeys. The pharmacokinetics of paraquat have been verified by the Agency.

Of the six workers with detectable paraquat exposure, none wore protective equipment while handling the formulation. There was no discernable trend between the amount of pesticide handled and the exposure incurred.

The available biomonitoring data for uses of paraquat are summarized in Table A. These data originate from the groundboom study (MRID 436442-02).

Total daily dose is calculated using the following formula:

Total Daily Dose (mg/kg/day) =
Unit Dose (mg/kg/lb ai) X Appl Rate (lb cation/acre) X Acres Treated/Day

Margin of Exposure is calculated using the following equation:

MOE = NOEL ÷ Total Daily Dose

Table A. Short- and Intermediate-Term Risk From Paraquat, Derived From Biological Monitoring Data.

Exposure Scenario	Unit Dose (mg/kg/lb ai)	Equipment Used	Clothing Scenario Monitored	No. of Obs.	Total Daily Dose (mg/kg/day)[a]	Total MOE[b]
Mixer/Loader/Applicator Internal Dose						
Ground boom (MRID 436442-02) **[note: 1 lb cation/A and 80 Acres are assumed to calc. daily dose; actual body weights of subjects used to calc. unit dose.]**	4.0×10^{-6}	Open cab tractor	9 reps no PPE worn; 4 reps gloves worn only when mixing; 2 reps gloves, face shield, and apron; 1 rep respirator, face shield, goggles, apron, gloves, and Tyvek for applying; 1 rep face shield, goggles, apron, gloves, and Tyvek for applying	17	3.2×10^{-4}	9,400
Aerial **[Note: 1 lb cation/A and 350, 800, and 1200 acres are assumed to calc. daily dose; the groundboom unit dose is being used as a surrogate for the aerial applicators.]**	4.0×10^{-6}	Ground boom tractor surrogate	9 reps no PPE worn; 4 reps gloves worn only when mixing; 2 reps gloves, face shield, and apron; 1 rep respirator, face shield, goggles, apron, gloves, and Tyvek for applying; 1 rep face shield, goggles, apron, gloves, and Tyvek for applying	17	350Acres: 1.4×10^{-3}	350A: 2,100
					800Acres: 3.2×10^{-3}	800A: 940
					1200Acres: 4.8×10^{-3}	1200A: 630

[a] Total Daily Dose (mg/kg/day) = Unit Dose (mg/kg/lb cation) X appl rate (lb cation/A) X acres per day.

[b] MOE = NOEL / Total Daily Dose (mg/kg/day). Where: NOEL = 3 mg/kg/day.

PHED V1.1 data are used to estimate short- and intermediate-term exposure, dose, and risk from paraquat for backpack sprayer mixer/loaders and applicators, for flaggers for aerial spray applications, for mixers/loaders/applicators for spot treatments using a backpack sprayer or low pressure wand, and for mixers/loaders/applicators for resin soaking uses using a low pressure wand. These exposure scenarios are presented in Tables B and C. Inhalation exposure and doses were not calculated since spray particles used in applying paraquat are well beyond the respirable range and paraquat has a very low vapor pressure. The potential daily dermal dose is calculated using the following formula:

Potential Daily Dermal Dose (mg/kg/day) =

Dermal Unit Exposure (mg/lb ai) X max. Appl. Rate (lb cation/amount) X max. area treated (amount/day) X Dermal Absorption ÷ Body Weight (kg)

These calculations of daily dose of paraquat received by handlers are used to assess the risk to those handlers. The dermal Short-Term and Intermediate-Term MOE was calculated using the following formula:

Dermal MOE = NOEL (mg/kg/day) ÷ Potential Daily Dermal Dose (mg/kg/day)

Table B. Short-Term and Intermediate-Term Exposure and Risk to Paraquat Dichloride Derived From PHED V1.1 Data.

Exposure Scenario (#)	Baseline Dermal Unit Exposure[a] (mg/lb cation)	Maximum Label Application Rate[b]	Daily Maximum Area Treated[c]	Potential Daily Dermal Dose[d] (mg/kg/day)	Dermal MOE[e]	Risk Mitigation[f]	
						[Dermal Unit Exposure] [(mg/lb cation)] Potential Daily Dermal Dose[d] (mg/kg/day)	Dermal MOE[e]
Mixer/Loader							
Mixing/loading liquids for backpack sprayer application (5)	2.9	1 lb cation/A	20 acres[g]	0.0029	1000	NA	NA
Applicator							
Backpack Sprayer (6)	483	1 lb cation/A *0.625 lb cat/A	4 acres[g]	0.097	31 *100	[234] 0.0468	64
Flagger							
Flagging (liquids) (7)	0.01	1 lb cation/A	350 to 1,200	0.00018 to 0.0006	17,000 to 5,000	NA	NA
Mixer/Loader/Applicator							
Low Pressure Hand-held Sprayer (Spot Treatment) (8)	104	0.0195 lb cation/gal	40 gals	0.0041	730	NA	NA
Backpack Sprayer (Spot Treatment) (9)	486	0.0195 lb cation/gal	40 gals	0.019	160	NA	NA
Low Pressure Sprayer (Resin Soaking) (10)	104	0.4 lb cation/gal	40 gals	0.083	36	[4.1] 0.0033	910

a Long pants, long-sleeved shirt, no gloves. Mixer/loader assessments are from using open mixing systems.
b Label Reg No. 10182-103, 10182-111, 10182-120.
c Values represent the maximum area or the maximum volume of spray solution which can be used in a single day to complete treatments for each exposure scenario of concern.
d Potential daily dermal dose (mg/kg/day) = Dermal Unit Exposure (mg/lb cation) X 0.003 (0.3 percent dermal absorption) X Maximum Application Rate (lb cation/acre or lb cation/gal) X Maximum Treated (acres/day or gal/day) ÷ 60 kg BW.
e Dermal MOE = NOEL/Potential daily dermal dose (mg/kg/day) (short- and intermediate-term NOEL = 3 mg/kg/day)
f Addition of gloves to long pants & long-sleeved shirt.
g If 40 gal/day can be applied by a backpack sprayer, then 4 acres will be treated at a finish spray volume of 10 gal/A
* See Tina Manville's memo/response - An application rate of 0.625 lb cation/Acre is acceptable and will provide MOE's of 100 for backpack application.

Table C. Exposure Scenario Descriptions of Baseline and Risk Mitigation Measures for Uses of Paraquat Dichloride from PHED Data.

Exposure Scenario (#)	Data Source	Additional PPE	Standard Assumptions[a] (8-hr work day)	Comments[b]
Mixer/Loader Exposure				
Mixing/loading liquids for backpack sprayer application (5)	PHED V1.1 (including PHED study # 9003)	NA	200 gallons (for 20 acres) mixer/loader supporting five backpack sprayers	**Baseline[c]:** Dermal acceptable grades & 25 to 122 replicates; High confidence data. PHED data used for baseline; no PF necessary.
Applicator Exposure				
Backpack Sprayer (6)	PHED V1.1 (including PHED study # 9003)	gloves	4 acres at a finish spray volume of 10 gal/acre (therefore 40 gals/day)	**Baseline and Additional PPE:** Dermal acceptable grades & 60 to 69 replicates; High confidence data. Baseline exposures were calculated from total deposition using a 50% PF for the addition of a single layer of clothing (feet data were deleted). Additional PPE exposure was calculated by adding a 90% PF for the addition of gloves to the baseline exposure.
Flagger				
Flagging (liquids) (7)	PHED V1.1	NA	350 to 1,200 acres	**Baseline:** Dermal grades acceptable & 16 to 18 replicates; High confidence data. PHED data used for baseline; no PF necessary.
Mixer/loader/applicator Exposure				
Low Pressure Hand-held Sprayer- Spot Treatment (8)	PHED V1.1	NA	40 gals total using two to three gallon hand held wand sprayers	**Baseline:** Dermal all grades & 25 to 96 replicates; Low confidence data. PHED data used for baseline; no PF necessary.
Backpack Sprayer - Spot Treatment (9)	PHED V1.1 (liquid m/l unit exposure + backpack appl. unit exposure [2.9 + 483 mg/lb cation])	NA	40 gals	**Baseline:** Dermal acceptable grades & 60 to 69 replicates; High confidence data. Baseline exposures were calculated from total deposition using a 50% PF for the addition of a single layer of clothing (feet data were deleted).

Exposure Scenario (#)	Data Source	Additional PPE	Standard Assumptions[a] (8-hr work day)	Comments[b]
Low Pressure Sprayer (Resin Soaking) (10)	PHED V1.1	gloves	40 gals total using two to three gallon hand held wand sprayers	**Baseline and Additional PPE:** Dermal all grades & 15 to 96 replicates; Low confidence data. PHED data used for baseline and additional PPE; no PF necessary.

[a] Standard Assumptions based on an 8-hour work day as estimated by OREB. BEAD data were not available.

[b] "Acceptable grades," as defined by OREB SOP for meeting Subdivision U Guidelines, are grades A and B. All grades that do not meet OREB's SOP are listed individually.

[c] Baseline is defined as long pants, long-sleeved shirt and no gloves

Post-Application Exposures & Assumptions

The Agency has determined that there is potential exposure to persons entering treated sites following: (1) preemergent/early-season treatments, particularly in crop areas; (2) directed spray treatments, particularly in orchard or vegetable-crop sites with heavy weed density; and, (3) desiccant/harvest-aid treatments particularly when performing harvesting-related tasks, such as removal or compacting (i.e. trampling) of desiccated foliage and stems on crops such as cotton, dry beans, potatoes, sunflowers, and sugar cane.

Post-application exposure data were required in the December 1991 DCI and in response to the Worker Protection Standard.

The following post-application study was submitted by the registrant:

- *MRID Number - 436182-02. Tak Iwata and Malcolm Findlay, 1994. Worker Exposure During Re-Entry into Paraquat-Treated Cotton Fields: Biological Monitoring in Georgia in 1994.*

This worker biomonitoring study measured urinary excretion of paraquat as a indicator of exposure to workers reentering the treated fields for the purpose of scouting. Cotton fields were treated with STARFIRE, a product normally used by growers as a harvest aid, at a rate of 0.55 lb cation/A. Scouting activities started at 4 hours (12 replicates) and 24-hours (13 replicates) post-application. Scouting activities consisted of walking into the field, handling and cracking a few bolls, and bending foliage and stems for a total field exposure of 2.5 hours. Complete 24 hour urine samples were collected from each subject on the reentry exposure day and on the next 5 days.

The study results showed that only one urine sample contained detectable paraquat. This was from a Day 1 (reentry exposure day) urine sample from a subject in the 4 hour reentry test group. Based on a reported urinary level of 6 mg/ml and a sample volume of 400 ml, a total amount of paraquat excreted was estimated as 0.0024 mg. An exposure of 0.00004 mg/kg/day was calculated for this subject using a 204 pound body weight and a referenced excretion rate of 59% from a paraquat pharmacokinetics study in monkeys (see MRID No. 436182-01). All other (non-detect) data points were treated as containing no (0) paraquat.

The authors also present an exposure assessment in a separate submission (MRID No. 436182-01) which contains an estimate of a Margins of Exposure (MOE). Using a NOEL value of 0.6 mg/kg for a 90 day feeding study in dogs (from the 1987 Registration Standard, which identifies this level as 0.5 mg/kg/day), a MOE of 15,000 was derived. Based on this value and the stated "worst case" conditions of the study, the authors suggest that workers could safely reenter paraquat-treated fields (cotton as well as other crops) 4 hours after application (when sprays have dried).

The Agency has confirmed the pharmacokinetic data used in this study. A single dose of paraquat dichloride administered subcutaneously to rats was excreted mostly in urine (73-96%) as unchanged paraquat within 24 hours after dosing. Therefore adequate time was allowed in this experiment for urine collection.

The Agency considers this study acceptable since the EPA-approved protocol was followed. After the protocol was approved, the Agency exempted certified or licensed crop advisors and their employees from the Worker Protection Standard requirements, except for obtaining pesticide safety training, based partially on the assumption that such activities result in low exposures (FR, Vol. 60, No. 85, 5/3/95). In addition, the 2.5 hour duration of exposure may suggest that this study was not in fact a worst-case scenario relative to other crops and cultural practices. Therefore, the Agency is requiring reentry intervals longer than 4 hours which had been previously suggested (see Risk from Post-Application Exposures for specific Agency requirements).

3. Risk Assessment

a. Dietary

Residues

Tolerances for paraquat residues in/on raw agricultural and animal commodities are published in 40 CFR §180.205(a) and (b), in processed food in 185.4700, and in feed at 186.4700. The available data support the established tolerances on all but sorghum forage, ruminant kidney, oats, rye, soybeans and hops. Thus, for the purposes of this analysis, the tolerances for sorghum forage was reassessed from 0.05ppm to the higher value of 0.1 ppm, while kidney was reassessed

from 0.3 ppm to 0.5 ppm, soybeans from 0.05 ppm to 0.25 ppm, and hops from 0.2 ppm to 0.5 ppm.

Chronic Dietary Exposure

A DRES (Dietary Risk Evaluation System) chronic exposure analysis was performed using tolerance level residues and percent crop treated to estimate the Anticipated Residue Concentration (ARC) for the general population and 22 population subgroups. Even with rye, oats, and poultry commodities included, the Reference Dose (RfD) was not exceeded for any of the 22 population subgroups analyzed.

As there are presently no registered uses of paraquat on rye, it is recommended that tolerances for this commodity be revoked. It is also recommended to revoke the tolerance on oats, as the registrant has indicated that they do not wish to support this use. Additionally, it is recommended that tolerances for poultry (except for eggs) be revoked. Further, a tolerance for popcorn (0.05 ppm) was included in this analysis and should be proposed (See Section IV, Tolerance Reassessment Summary and Table).

Chronic Dietary Exposure Using Tolerances

Existing tolerances result in a Theoretical Maximum Residue Contribution (TMRC) which represents 10% of the RfD for the U.S. general population. The highest subgroup, non-nursing infants (<1 year old) occupies 31% of the RfD.

Dietary Risk to Paraquat

Subgroup	Exposure (mg/kg/day)	%RfD
U.S. Population	0.000442	10
Non-Nursing Infants (<1 year old)	0.001398	31
Children (1-6 years old)	0.001070	24

b. Occupational and Residential

Risk From Handler Exposures

Based on biological monitoring data, the margins of exposure (MOEs) are acceptable (greater than 100) for: (1) mixing/loading to support ground applications; (2) mixing/loading to support aerial

applications; (3) applying using ground boom equipment; and (4) applying using aerial equipment (ground boom data were used as a surrogate for aerial). Surrogate exposure data from PHED indicate that: (1) mixing/loading liquid formulations to support several applicators using backpack sprayers; (2) flagging; (3) mixing/loading/applying for spot treatments using low-pressure sprayers or backpack sprayers are acceptable; and (4) with the addition of gloves mixing/loading/applying for resin soaking uses using low-pressure sprayers (MOEs greater than 100).

Based on exposure data from PHED, the MOE for backpack applicators (non-spot treatment) is unacceptable (MOE less than 100) when applicators are wearing long pants and long sleeved-shirt, and chemical-resistant gloves. The Agency is concerned about the practicality of adding another layer of PPE (woven material), due primarily to heat stress considerations and the "wicking" affect of multiple layers. As a risk mitigation measure, all paraquat labels could be modified to specify that backpack applications for spot treaments be made at application rates no higher than 0.0195 lb cation/gal (or 0.23% cation wt/wt spray solutions).

Risk From Post-Application Exposures

Based on the postapplication biological monitoring study The Agency has determined that a 12-hour restricted-entry interval is adequate for the uses of paraquat for preemergent or early-season weed control. In these use-situations, the paraquat is directed at the soil and weeds (if present) that are generally less than six inches tall and the workers' degree and duration of contact with treated surfaces is likely to be similar to or less than that for the scouts in the biological monitoring study.

Based on the postapplication biological monitoring study, The Agency also has determined that a 12-hour restricted-entry interval is adequate for the uses of paraquat for weed control in orchard and vegetable crops where the spray is directed solely at the weeds (not broadcast over the entire crop area). In these directed-spray use-situations where the paraquat is directed at the weeds, entering workers' degree and duration of contact with treated surfaces are likely to be similar to or less than that for the scouts in the biological monitoring study.

For desiccation and harvest aid applications of paraquat, The Agency is establishing a 24-hour restricted-entry interval (REI). The Agency believes that such uses may result in exposures to workers of greater degree and duration than that for the scouts in the biological monitoring study, particularly when the workers are performing harvesting-related tasks, such as removal or compacting (i.e. trampling) of desiccated foliage and stems on crops such as cotton, dry beans, potatoes, sunflowers, and sugar cane. It is well documented that paraquat is rendered biologically inactive upon contact with the soil. However less is known about its residues on leaves. After 21 days, 66% of paraquat is lost from plant surfaces. The Agency does not have any foliar dissipation curves for paraquat to better quantify post-applicator exposure. Personal protective equipment is required for workers who enter the treated area before the REI has expired.

The 12 and 24-hour post-application entry restrictions for paraquat dichloride do not apply to uses outside the scope of the Worker Protection Standard (WPS) for Agricultural Chemicals. The predicted frequency, duration, and degree of exposure by such uses do not warrant the same risk mitigation measures required for users covered by the WPS who are engaged in agriculture for commercial or research purposes. However, the Agency is concerned about exposures immediately following applications while the sprays are still wet.

Additional Occupational/Residential Exposure Studies Handler Studies

None are necessary.

Post-Application Studies

If the registrant believes that a restricted-entry interval of less than 24 hours is appropriate for the desiccation/harvest-aid uses of paraquat, an additional study is required. Requirements for post-application exposure studies are addressed by Subdivision K of the Pesticide Assessment Guidelines. The required data include: Guideline 132-1(a): Foliar Residue Dissipation.

4. Food Quality Protection Act Considerations

The Food Quality Protection Act of 1996 (FQPA) amended the FFDCA by setting a new safety standard for the establishment of tolerances. In determining whether a tolerance meets the new safety standard, section

408(b)(2)(C) directs EPA to consider information concerning the susceptibility of infants and children to pesticide residues in food, and available information concerning aggregate exposure to infants and children of such residues, as well as the potential for cumulative effects from pesticide residues and other substances that have a common mechanism of toxicity.

The FQPA amendments to section 408(b)(2)(C) also direct the Agency, in the case of threshold effects, to add an additional 10-fold margin of safety for the protection of infants and children unless the Agency concludes, based upon reliable data, that a different safety margin will be safe for infants and children.

Section 408(b)(2)(D) establishes factors that the Agency must consider in determining whether the safety standard is met in deciding to issue or reassess tolerances. These factors include the consideration of available information on the aggregate exposures to the pesticide from dietary sources including drinking water as well as non-occupational exposures such as those derived from pesticides used in and around the home. The Agency must also consider available information concerning the potential cumulative effects of the pesticide for which a tolerance is being sought as well as other substances that have a common mechanism of toxicity for the general population and major subgroups of the population.

Because paraquat has food uses, specific consideration of the risks to infants and children, as well as aggregate exposures and potential cumulative effects is warranted.

a. Potential Risks to Infants and Children

In determining whether a safety factor different than the additional 10-fold factor is or is not appropriate for assessing risks to infants and children, EPA considers all reliable data and makes a decision using a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature of the effects observed in pre and post-natal studies, and other information such as epidemiological data.

For the purpose of assessing the pre- and post-natal toxicity of paraquat, EPA has evaluated four developmental (of which two were used to evaluate developmental and maternal toxicity) and one reproduction study. Based on current data requirements, these three studies constitute a complete data base for evaluating pre and post natal effects for food use chemicals when considered along with other

required toxicity studies. However, as EPA fully implements the requirements of FQPA, additional data related to the special sensitivity of young organisms may be required.

Developmental and Reproductive Effects

The effects observed in the paraquat developmental and reproduction studies can be summarized as follows:

Four developmental/maternal toxicity studies were evaluated for paraquat. The following two were used to assess the developmental/maternal toxicity of paraquat. In the first of the two studies, no developmental effects were found, and the developmental NOEL was set at 8 mg/kg/day (HDT), and the maternal NOEL at 8 mg/kg/day (HDT).

In the second of the two studies, maternal toxicity was reported at the two highest doses and included clinical signs, decreased body weight gain, deaths of 6 high dose animals versus none in the control group, respiratory distress in 3 high-dose females, histopathological findings in the lungs and kidneys of the nonsurvivors. Developmental effects (delayed ossification in the forelimb and hindlimb digits) were observed only in the mid-dose and high-dose groups. Based on these findings, the NOEL and LOEL for maternal toxicity are 1 mg/kg/day and 5 mg/kg/day, respectively, expressed as paraquat cation. The NOEL and LOEL for developmental toxicity are also 1 mg/kg/day and 5 mg/kg/day, respectively.

The overall maternal and developmental NOEL for the rat is 3 mg/kg/day (paraquat cation) based on a weight-of-evidence of the results from two developmental studies in the rat.

In a reproductive study in rats, the NOEL and LOEL for systemic toxicity are 1.25 mg/kg/day and 3.75 mg/kg/day, respectively. The NOEL for reproductive toxicity is $\geq$ 7.5 mg/kg/day (HDT), based on severe lung damage caused by paraquat (red or purple discoloration, congestion, edema, fibrosis, hyaline membrane formation, inflammatory cell infiltration and/or hyperplasia) and incidence of alveolar histiocytosis. Paraquat, at all levels tested, had no effect on body weight gain, food consumption and utilization, fertility and length of gestation.

The developmental data for paraquat indicate developmental effects occurred at doses that were the same as or higher than doses

which cause maternal toxicity. The Agency would generally be concerned when developmental/reproductive effects are seen at doses lower than those which cause maternal effects. The developmental studies in conjunction with the reproduction study do not indicate any additional sensitivity of young organisms to paraquat. Based on current toxicological data requirements, the data base, relative to pre- and post-natal toxicity, is complete.

Uncertainty Factor

Based on reliable data as outlined above, the Agency concludes that an additional uncertainty factor is not warranted for the paraquat chronic risk assessment, nor is the use of an additional uncertainty factor indicated for estimating risk from acute exposures detailed below.

b. Aggregate Exposure/Risk

In examining aggregate exposure, FQPA directs EPA to take into account available information concerning exposures from the pesticide residue in food and all other exposures for which there is reliable information. These other sources of exposure include drinking water, and non-occupational exposures, e.g., to pesticides used in and around the home. For estimating acute and chronic risks the Agency considers aggregate exposures form the diet and from drinking water. Exposures from uses in and around the home that may be of short term, intermediate or other duration may also be aggregated as appropriate for specific chemicals.

Paraquat has no residential or other non-occupational uses that might result in exposure to children. In addition, paraquat is not expected to be a contaminant of groundwater. Paraquat dichloride binds strongly to soil clay particles and it did not leach from the surface in terrestrial field dissipation studies. There were, however, detections of paraquat in drinking water wells from two states cited in the Pesticides in Ground Water Database(1991). These detections are not considered to be representative of normal paraquat use. Therefore, paraquat is not expected to be a groundwater contaminant or concern based on normal use patterns.

Due to its persistent nature, paraquat could potentially be found in surface water systems associated with soil particles carried by erosion, however, paraquat is immobile in most soils, and at very high application rates (50-1000X), there was no desorption of paraquat from

soils. Therefore, based on paraquat's normal use patterns and unique environmental fate characteristics, exposures to paraquat in drinking water are not expected to be obtained from surface water sources .

Thus, the only exposures considered in acute and chronic risk assessments are dietary.

Acute Risk

No data are available that suggest an acute dietary endpoint of concern, therefore an acute dietary risk assessment was not required for paraquat.

Chronic Risk

Dietary Exposure

A chronic dietary exposure analysis was performed using tolerance-level residues and percent crop treated information for some crops resulting in an ARC (Anticipated Residue Concentration) of 10% of the RfD for the US population, 24 and 31% of the RfD for children (ages 1-6) and non-nursing infants (<1 yr), respectively.

Tolerances have been established in/on over 80 crops. The available data support the established tolerances listed in 40 CFR section 180.205 (a) and (b) in processed food in 185.4700, and in feed at 186.4700 on all but sugar beet tops, ruminant kidney, oats, rye, soybeans and hops which need to be amended.

Conclusion Regarding Chronic Aggregate Exposure to Paraquat

The Agency concludes that the aggregate risks to the general U.S. population, and to the population subgroup of infants and children, resulting from paraquat uses are not of concern.

c. Cumulative Effects

In assessing the potential risk from cumulative effects of paraquat and other chemical substances, the Agency has considered structural similarities that exist between paraquat and other bipyridylium compounds such as diquat dibromide. Examination of the toxicology databases of paraquat and diquat dibromide, indicates that the two compounds have clearly different target organs. At doses at which

paraquat is a highly specific pulmonary toxicant in rats and dogs, diquat produces cataracts and no significant pulmonary toxicity in the same species. Although both chemicals presumably can induce tissue damage via the generation of oxygen free radicals, the two compounds differ in their tissue distribution pattern. Unlike paraquat, diquat shows no special affinity for the lung and appears to be taken up by the transport mechanism that selectively concentrates paraquat in the lung. Paraquat is accumulated in the lungs and is thus a lung toxicant, whereas diquat is not accumulated in the lungs and is not a lung toxicant.

Although paraquat also produced a dose-related incidence of cataracts in Fisher 344 rats after 103 weeks, a dose-related incidence of cataracts was not seen in chronic studies with Wistar rats, beagle dogs or JCL-ICR mice. Thus, paraquat appears to be a weaker cataractogenic agent when compared to diquat.

Based on the available data, the Agency does not believe that the toxic effects produced by paraquat would be cumulative with those of diquat dibromide.

C. Environmental Assessment

The environmental fate and ecological toxicity data bases are complete. Paraquat dichloride poses a risk to nonendangered and endangered non-target terrestrial and aquatic plants. Acute risk to terrestrial organisms only exists immediately after application. Although a chronic risk to birds is not expected as a result of residues on dietary food items, the Agency is concerned that direct application of paraquat dichloride to eggs may affect avian reproduction.

1. Ecological Toxicity Data

Sufficient ecological toxicity data exist to assess the risk of paraquat dichloride to non-target wildlife.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of paraquat dichloride to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species (preferably mallard or bobwhite quail); two subacute dietary

studies (LC_{50}) on one species of waterfowl (preferably the mallard duck) and one species of upland game bird (preferably bobwhite quail). The following two tables summarize the avian acute oral toxicity findings and the avian subacute dietary toxicity findings.

Avian Acute Oral Toxicity Findings

Species	% A.I.	LD_{50} mg/kg[1] (cation equivalent)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	93.3	176 (128.1)	00029001 (Fink, et al/1979)	Moderately toxic	Yes
Mallard	21	199 (144.8)	00160000 (Hudson, et al/1984)	Moderately toxic	Partial

[1]**LD_{50} values given are in terms of technical paraquat dichloride not in terms of the cation**

Avian Subacute Dietary Toxicity Findings

Species	% A.I.	LC_{50}ppm (cation equivalent)	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	29.1	981 (714)	00022923 Hill et al/1975	Moderately toxic	Yes
Ring-neck	29.1	1468 (1068.5)	00022923 Hill et al/1975	Slightly toxic	Yes
Mallard	29.1	4048 (2946.3)	00022923 Hill et al/1975	Slightly toxic	Yes

[1]**The 29.1% test material is an end use product (paraquat dichloride CL) which contains 21.0% cation. The EP is prepared by diluting the TGAI (paraquat dichloride concentrate, 43% cation) with water.**
[2]**LC_{50} values given are in terms of technical paraquat dichloride not in terms of the cation**

These results indicate that paraquat dichloride is moderately toxic to avian species on an acute oral and subacute dietary basis. The guideline requirements are fulfilled. (MRIDs 00029001, 00022923, 00016000)

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Present product labeling for use of paraquat dichloride on a variety of crops allows several applications of the end-use product per growing season. The following table summarizes the avian reproduction findings.

Avian Reproduction Findings[1]

Species	% A.I.[2]	NOEC ppm	LOEC ppm	Endpoints affected	MRID No. Author /Year	Fulfills Guide-line Requir e-ment
Northern Bobwhite	31.5	100	215	mortality	00110453 Fink et al./1981	yes
Northern Bobwhite	31.5	100	>100 (highest level tested)	no effects	00110454 Fink et al./1982	partial
Mallard Duck	31.5	30	100	% viable eggs, eggs set, normality of hatchlings and number of 14-day old survival	00110455 Fink et al./1982	yes

[1]NOEC and LOEC values given in terms of the cation not the technical paraquat dichloride
[2]%a.i. reflects % cation by weight

Additional data showed that significant mortality and reduced growth resulted when mallard eggs were treated at 0.5 and 5.0 lb cation/A. (MRID 00162746)

The avian reproductive studies indicate that paraquat dichloride can affect reproduction or hatchability in birds when adult birds are exposed to more than 30 ppm of paraquat or when eggs are treated at 0.5 and 5.0 lb ai./A. The guideline requirements are fulfilled. (MRIDs 00110453, 00110454, 00110455, and 00162746)

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD_{50} is used to determine toxicity to mammals. This LD_{50} is reported below.

Mammalian Acute Oral Toxicity Findings

Species	LD_{50} mg/kg[1] (cation equivalent)	MRID #	Toxicity Category
Rat (small mammal surrogate)	344 (male) (250) 283 (female) (206)	43685001	moderately toxic

[1]**LD_{50} values given are in terms of technical paraquat dichloride not in terms of the cation.**

The available mammalian data indicate that paraquat dichloride is moderately toxic to small mammals on an acute oral basis. (MRID 43685001)

The table below shows the chronic toxicity of paraquat dichloride to mammals.

Chronic Toxicity to Mammals

Test Organism	Type of Study	Duration of Study	Chronic Effects	NOEL[1] (ppm)	MRID #
Fisher 344 Rats	Feeding/Carcinogenicity	113-124 wks	Eye Opacity/Cataracts	25	00138637
Wistar Rats	Feeding/Carcinogenicity	104 wks	Opacity/Cataracts	100	40218001
Wistar-Derived Alderley Park Strain	Reproductive Toxicity	11-12 wks	Lung Damage and Mortality	25	00126783

[1]**NOEL data given in terms of cation**

The available mammalian chronic data indicate paraquat is lethal to some small mammals at levels below 25 ppm after 12 weeks of exposure.

Additional data showed that exposure of rabbits to freshly sprayed foliage can produce toxic symptoms and death. The LD_{50} is 110 mg/kg for rabbit and 35 mg/kg for Belgian hare. Also, the residues of paraquat measured in vegetation coupled with evidence of pulmonary and lingual lesions demonstrate the sensitivity of the hare to paraquat. (MRID 00162747, MRID 00162741)

(4) Insects

A honey bee acute contact LD_{50} study is required if the proposed use will result in honey bee exposure. The available insect acute contact toxicity findings are summarized in the following table.

Nontarget Insect Acute Contact Toxicity Findings

Species	% AI	LD_{50} μg a.i./bee[1]	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Honey Bee	99% Tech. and 1.67 lb/gal SC (Gramoxone)	Contact LD_{50} >144 ug ai/bee (tech) = 72 ug ai/bee (Gramoxone) Oral LD_{50} 51 ug ai/bee (tech) 31 ug ai/bee (Gramoxone)	43942603 Bull and Wilkinson/1977	practically nontoxic	yes
Honey Bee	Technical	2.74% mortality at 6.04μg/bee	00028772 Atkins et al./1973	relatively non-toxic	yes
Honey Bee	Technical	contact LD_{50} > 48 μg/bee	05001991 Stevenson/ 1978	relatively non-toxic	yes
Honey Bee	4 lb ai./A spray	55% mortality after 2 days and 90% after 3 days. (LD_{50} Not obtained)	00111488 Moffett et al./1972	N/A	supplemental

[1]Toxicity data are given in terms of technical paraquat dichloride not the cation.

There is sufficient information to characterize technical paraquat dichloride and a formulated product as relatively non-toxic to bees. The guideline requirement is fulfilled. (MRID#s

00028772, 05001991, 00111488, 43942603). An additional study showed that bees exposed to direct application of paraquat dichloride CL at 4 lbs cation/A caused 55% mortality within 2 days exposure and 99% mortality after 3 days exposure (MRID 00111488). This study was performed with an end-use product of Paraquat dichloride and a surfactant. It is possible that the surfactant caused paraquat to be more easily absorbed by the honey bees resulting in the observed mortality.

b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish). The 96-hour freshwater fish acute toxicity findings for the technical grade of the active ingredient are summarized in the following table.

Freshwater Fish Acute Toxicity Findings

Species	% A.I.	LC_{50} ppm a.i.[1]	MRID No. Author/year	Toxicity Category	Fulfills Guideline Requirement
Rainbow trout	24% liquid 2 lb. cation/gal concentrate	15	40098001 Mayer, F.L. and M.R. Ellersieck/1986	slightly toxic	yes
Bluegill sunfish	24% liquid 2 lb. cation/gal concentrate	13	40098001 Mayer, F.L. and M.R. Ellersieck/1986	slightly toxic	yes
Rainbow Trout	29.1 (cation)	38.68	00162736 Palmateer/1980	slightly toxic	yes
Bluegill sunfish	29.1 (cation)	156	00162737 Palmateer/1979	practically non-toxic	yes
Rainbow Trout	29.1	29	00162738 McCann, J./1977	slightly toxic	yes

[1] **LC_{50} values given are in terms of the cation not the technical paraquat dichloride.**

The results of the 96-hour acute toxicity studies indicate that paraquat dichloride is slightly toxic to fish. The guideline requirements are fulfilled. (MRID 40098001, 00162736, 00162737, 00162738)

Data from fish early life-stage tests or life-cycle tests are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected; or physicochemical properties indicate cumulative effects; or the pesticide is persistent in water (e.g. half-life greater than 4 days).

Chronic fish studies are not required at this time because paraquat dichloride is not registered for aquatic uses, is tightly bound to soil, is not likely to be transported to aquatic environments in significant quantities from runoff or drift and is only slightly toxic to fish species.

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges. The freshwater invertebrate toxicity findings are summarized in the following table.

Freshwater Invertebrate Toxicity Findings					
Species	**% A.I.**	**EC_{50}[1]** (ppm ai)	**MRID NO. Author/Year**	**Toxicity Category**	**Fulfills Guideline Requirement**
Daphnia pulex	24% liquid 2 lb. cation/gal concentrate	4.0	40098001 Mayer, F.L. and M.R. Ellersieck/1986	Moderately toxic	Yes
Daphnia magna	92.3	1.2	00114473 Wheeler/1978	Moderately toxic	Yes
Daphnia magna	29.1	8.0	GS0262-028 Thompkins/1979	Moderately toxic	Yes

[1]LC_{50} values given are in terms of the cation not the technical paraquat dichloride.

There is sufficient information to characterize paraquat dichloride as moderately toxic to aquatic invertebrates. The guideline requirement is fulfilled. (MRID 40098001, 00114473, GS0262-028)

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. Paraquat dichloride is not registered for aquatic use and is not expected to reach the marine/estuarine environment in significant concentration. Therefore, marine/estuarine studies are not required at this time.

c. Toxicity to Plants

(1) Terrestrial

Currently, terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides which have terrestrial non-residential outdoor use patterns and appear to move off site of application through volatilization (vapor pressure $\geq 1.0 \times 10^{-5}$mmHg at 25°C) or drift (aerial or irrigation); and/or which may have endangered or threatened plant species associated with the site of application. Paraquat has a low vapor pressure and extremely high adsorption coefficients such that it

would not be expected to volatilize once applied to the soil. However, some of the use patterns for paraquat dichloride may allow off site movement as a result of drift from either ground or aerial application, terrestrial plant testing is required.

Tier 2 Toxicity data on the TEP material for the most sensitive species are summarized in the following table.

Nontarget Terrestrial Plant Toxicity Findings

Species	**% A.I.**[1]	**Seedling emergence** EC_{25}[2] (lbs cation/A)	**Vegetative vigor** EC_{25}[2] (lbs cation/A)
Dicot- (Cocklebur)	29.4	0.85	0.013
Monocot- (Wheat)	29.4	>0.86	0.061

[1]**Expressed as %Technical product not cation.**
[2]**Expressed as lbs cation/A cation**

The terrestrial plant testing guideline requirements are fulfilled. (MRID # 426396-01, 426010-01)

(2) Aquatic

Currently, aquatic plant testing is required for any herbicide which has outdoor non-residential terrestrial uses that may result in offsite movement by runoff (solubility >10 ppm in water), by drift (aerial or irrigation), or is applied directly to aquatic use sites (except residential). Since the use patterns for paraquat dichloride may allow off site movement as a result of drift from either ground or aerial application, aquatic plant testing is required.

The following species should be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

Tier 2 Toxicity data on the technical/TEP material are summarized in the following table.

Nontarget Aquatic Plant Toxicity Findings				
Species	**% A.I.[1]**	**NOEC/LOEC/EC_{50} [2]** (ppb)	**MRID NO. Author/Year**	**Fulfills Guideline Requirement**
Navicula pelliculosa (Freshwater diatom)	32.7	0.22 / 0.45 / 0.55ppb	426010-06 Smyth et al/1992	Yes
Lemna gibba	32.7	16 / 32 / 98ppb	426010-03 Smyth et al/1992	Yes
Selenastrum capricornutum	32.7	0.08 / 0.20 / 0.32ppm	426010-02 Smyth et al/1992	Yes
Skeletonema costatum	32.7	0.22 / 0.47 / 2.84ppm	426010-04 Smyth et al/1992	Yes
Anabaena flos-aquae	32.7	3.2 / 6.3 / 15 ppb	426010-05 Smyth et al/1992	Yes

[1]Expressed as % Technical product not cation.
[2]Expressed as ppb Technical

The guideline requirements are fulfilled. (MRID #s 426010-02, -03, -04, -05, -06)

2. Environmental Fate

The environmental fate data base for paraquat dichloride is sufficiently complete to make a thorough fate assessment for paraquat for the following registered uses: terrestrial food crops (field, vegetable, and orchard), terrestrial non-food crops (ornamentals and turf), terrestrial noncrop, forestry (directed sprays in shelter belts and pine resin soaking), and domestic outdoor sites.

a. Environmental Fate Assessment

The primary route of environmental dissipation of paraquat dichloride is adsorption to biological materials and soil clay particles. Paraquat dichloride has been shown to adsorb to clay crystalline lattices with no apparent correlation between organic matter content and paraquat adsorption. Paraquat dichloride does not hydrolyze, does not photodegrade in aqueous solutions, and is resistant to microbial degradation under aerobic and anaerobic conditions. Essentially no microbial degradation of paraquat was seen after 180 days of aerobic incubation or after 60 days of anaerobic incubation following a 30-day aerobic incubation.

Paraquat dichloride was shown to be very immobile in soil with batch equilibrium studies conducted on four soils in the laboratory. High rates of paraquat were added because at realistic field application rates, paraquat was below detection in the batch equilibrium adsorption solution. Adsorption Kd's ranged from 68-50,000 ml/g, and there was no detectable desorption.

In laboratory studies with radiolabeled paraquat, no radioactivity volatilized from the soil surface to adsorb to glass or to collect in volatile traps. With low vapor pressure and extremely high adsorption coefficients, paraquat would not be expected to volatilize once applied to the soil. However, spray drift could potentially be a problem because paraquat is extremely biologically active and toxic to plants and animals before it becomes adsorbed to clay particles in the soil and therefore biologically unavailable.

In short- and long-term field dissipation studies, paraquat residues were extractable only by refluxing with 6 M sulfuric acid and were shown to be persistent and to accumulate slightly with repeated applications. Paraquat dichloride is inactivated (dissipated) by rapid adsorption to clay particles. Due to the apparent adsorption strength of paraquat for soil clays, these bound residues do not appear to be environmentally available. Adsorbed radiolabeled paraquat did undergo isotopic exchange when soil samples were shaken with a highly concentrated, non-labeled paraquat solution (7440 ppm paraquat in water). Therefore, the potential for desorption does exist; however, since there was no apparent exchange with calcium chloride in the batch equilibrium study, this exchange will probably not affect the environmental behavior of paraquat.

Paraquat dichloride is very persistent and could potentially be found in surface water systems associated with soil particles carried by erosion. Paraquat dichloride is not expected to be a contaminant of groundwater. A minor photodegradate, 4-carboxy-1-methylpyridinium (QINA) which comprised 6% of applied radioactivity after 85 weeks of natural sunlight irradiation, was determined to be mobile. According to the field data reviewed in this submission, paraquat degraded very slowly. Therefore, the minor photodegradate, QINA, would apparently not be an important environmental concern.

b. Environmental Fate, Chemistry, and Transport

(1) Degradation

(a) Hydrolysis (161-1)

The hydrolysis data requirement is fulfilled. Paraquat dichloride at 91 ppm did not hydrolyze at pH 5, 7, and 9 when incubated at 25 or 40º C. (Upton, Hendley, and Skidmore, 1985. No MRID).

(b) Photodegradation in Water (161-2)

The photolysis in buffered solution data requirement is fulfilled. Paraquat dichloride at 28 ppm in sterile pH 7 aqueous buffer solution did not photodegrade when continuously irradiated with a xenon arc lamp for 32 days at 25º C. Paraquat dichloride accounted for 90.2-98.0% of the applied radioactivity throughout the study in the irradiated and dark control samples; no degradates were reported from TLC or HPLC analyses. Volatiles were trapped during this experiment and 0.15% of the applied radioactivity was recovered as CO_2. (MRID 40562301)

(c) Photodegradation on Soil (161-3)

The photodegradation on soil surfaces data requirement is fulfilled. Paraquat dichloride did not photodegrade when mixed with a sterile soil and exposed to natural sunlight for 85 weeks. (Pack, 1982, no MRID).

(d) Aerobic soil metabolism (162-1)

The aerobic soil metabolism data requirement is fulfilled. Paraquat dichloride at 4.32 ppm did not degrade in sandy loam soil incubated under aerobic conditions at 20 $\pm$ 2º C for 180 days. Paraquat dichloride comprised 93% of the applied radioactivity at 180 days posttreatment. Most of the radioactivity was extracted with technical grade paraquat by isotopic exchange. There was no volatile radioactivity. No degradates were

reported from TLC or HPLC analyses. (MRID 41319301)

(e) Anaerobic soil metabolism (162-2)

The anaerobic soil metabolism data requirement is fulfilled. Paraquat dichloride at 4.32 ppm did not degrade in sandy loam soil incubated under anaerobic conditions for 60 days following a 30-day aerobic incubation. Paraquat dichloride comprised 88.8% of the applied radioactivity at 90 days posttreatment [60 days of anaerobic incubation]. Most of the radioactivity was extracted with technical grade paraquat by isotopic exchange. A trace amount of radioactivity (0.29% of applied) was recovered in the water phase at 61 days posttreatment [30 days postflooding]. There was no volatile radioactivity. No degradates were reported from TLC or HPLC analyses. (MRID 41319302)

(f) Anaerobic aquatic metabolism (162-3)

No studies were submitted; however, none are required since an acceptable anaerobic soil metabolism study was submitted.

(g) Aerobic aquatic metabolism (162-4)

Although no studies were required, one study was submitted and reviewed in 1985. This study included an aerobic aquatic metabolism section with paraquat dichloride applied to the surface of soil:water systems in plastic swimming pools. Paraquat dichloride was removed from the water column with a "resident half-life" of <2 weeks. The soil layer was not sampled. This study was considered scientifically valid, but does not fulfill guideline requirements. (MRID 00055093)

(2) Mobility

(a) Leaching, adsorption/desorption (163-1)

The unaged mobility data requirement is fulfilled. Paraquat dichloride was immobile in silty clay loam,

loam, loamy sand, and sand soils. It was not possible to determine Freundlich K_{ads} values because no paraquat was detected in the adsorption solution at the lower application rates. At high application rates (50-1000 times the field application rate), K_{ads} values ranged from at 68-50,000 ml/g . There was no desorption of paraquat from these soils. (MRID 40762701)

The aged mobility data were not required.

(3) Accumulation

The fish bioaccumulation data requirement was waived. The $\log K_{ow}$ for paraquat dichloride is -4.5 at 20^{o} C indicating that bioaccumulation is unlikely.

(4) Field Dissipation

The terrestrial field dissipation data requirement is fulfilled with one short-term dissipation and four long-term dissipation studies.

(a) Terrestrial field dissipation (164-1)

Paraquat dichloride degraded very slowly in Delaware on a loamy sand soil which was planted to soybeans. Residues decreased from an average of 1.1 mg/kg soil immediately posttreatment to 0.76 mg/kg at 86 days posttreatment and remained at 0.42-0.50 mg/kg from 296 to 657 days posttreatment. Paraquat dichloride did not leach below the 0- to 3.5-inch soil depth and was only recovered at the detection limit of 0.05 mg/kg in the 4.5- to 10-inch soil segment from one subplot at 296 days posttreatment.

(b) Dissipation -- Long term field (164-5)

Four long term field dissipation studies were reported with data from: Champaign, Illinois (MRID 42802101); Visalia, California (MRID 42738701); Leland, Mississippi (MRID 42738702); and Pikeville, North Carolina (MRID 42802102). Paraquat dichloride

was applied in three or four single annual applications to plots of bare ground, corn, peach trees, soybeans, and cotton.

Acid-reflux extractable paraquat did not appreciably degrade at any of the four sites from which data were provided. Half-lives were not calculated in any study although the study authors cited references of field studies with paraquat half-lives of >10 years. In these four studies, paraquat generally did not leach below the 3.5-inch depth.

Paraquat dichloride was stable for 1376 days (45 months) in soil samples treated at 1.0 mg/kg and stored frozen at -14º C. (MRID 42738703)

(c) Aquatic field dissipation (164-1)

No studies are required because there are no aquatic uses for paraquat.

(5) Spray Drift

Spray drift data are required by 40 CFR Sec. 158.142 when aerial application and/or mist blower or other ground application are proposed and it is expected that the effect levels for nontarget organisms (humans, domestic animals, fish, wildlife, and nontarget plants) expected to be present, are exceeded.

Droplet size spectrum (201-1) and drift field evaluation (202-1) data are required. The registrant (Zeneca) may elect to satisfy these data requirements through the Spray Drift Task Force, provided that these data are not required in advance of the Task Force's final report. If the registrant wishes to satisfy these data requirements in this manner, the procedures outlined in PR Notice 90-3 should be followed.

c. Water Resources

Although there were detections of paraquat in drinking water wells from two states cited in the Pesticides in Groundwater Database, these detections are not considered to be representative of normal

paraquat use. Paraquat dichloride binds strongly to soil clay particles (Kd 68-50,000 mL/g) and did not leach from the surface in the terrestrial field dissipation studies. Therefore, paraquat is not considered to be a groundwater concern from normal use patterns.

3. Exposure and Risk Characterization

Paraquat dichloride is applied primarily as a broadcast treatment by aerial and ground equipment but is also applied as a bark treatment, bore-hole treatment, tree injection treatment, basal spray and spot treatment by a variety of other methods. The non-broadcast treatment methods above, because of limited application sites and application rates ranging from 3.3×10^{-4} to 1 lb cation/A, are not expected to pose significant risk to non-target wildlife and will not be considered further in this risk assessment. Instead, the Ecological Exposure and Risk Characterization that follows will be concerned only with the aerial and ground broadcast application uses of paraquat dichloride and their effect on non-target and endangered species.

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC_{50}. The acute effect levels typically are:

-EC_{25} (terrestrial plants),
-EC_{50} (aquatic plants and invertebrates),
-LC_{50} (fish and birds), and
-LD_{50} (birds and mammals)

The chronic test results are the:
-NOEL (or the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), which is the geometric

mean of the NOEL and the LOEL (or LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds

IF THE	LOC	PRESUMPTION
acute RQ≥	0.5	High acute risk
acute RQ≥	0.2	Risk that may be mitigated through restricted use
acute RQ≥	0.1	Endangered species may be affected acutely
chronic RQ≥	1	Chronic risk, endangered species may be affected chronically,

Fish, Aquatic invertebrates

IF THE	LOC	PRESUMPTION
acute RQ≥	0.5	High acute risk
acute RQ≥	0.1	Risk that may be mitigated through restricted use
acute RQ≥	0.05	Endangered species may be affected acutely
chronic RQ≥	1	Chronic risk, endangered species may be affected chronically

Plants

IF THE	LOC	PRESUMPTION
RQ≥	1	High risk
RQ≥	1	Endangered plants may be affected

Currently, no separate criteria for restricted use or chronic effects for plants exist.

(1) Exposure and Risk to Nontarget Terrestrial Animals

(a) Birds

Acute

Residues found on dietary food items following paraquat dichloride application may be compared to LC_{50} values to predict acute risk. The maximum estimated environmental concentrations (EECs) of residues of paraquat dichloride which may be expected to occur on selected avian or mammalian dietary food items following a single application are provided in the table below along with the respective risk quotients (RQs) and pertinent LOCs.

Avian RQs based on a Bobwhite quail LC_{50} of 714 ppm (cation)

Food items	Maximum Application Rates[1] (lbs cation/A)	EEC (ppm) (cation)	RQ (EEC/ LC_{50})
Short Grass	0.07	16.80	0.02
	1.0	240.00	0.34**
	1.6	384.00	0.54***
Long Grass	0.07	7.70	0.01
	1.0	110.00	0.15
	1.6	176.00	0.25**
Broadleaf Plants/ Small Insects	0.07	9.45	0.01
	1.0	135.00	0.19*
	1.6	216.00	0.30**
Fruits/ Large Insects/ Seeds	0.07	1.05	0.00
	1.0	15.00	0.02
	1.6	24.00	0.03

[1]0.07lb/A = lowest maximum application rate for broadcast uses
1.0 lb/A = typical maximum application rate for food and non-food/non-feed uses
1.6 lb/A = absolute maximum application rate for various food uses
*** Exceed Endangered species (ESP) LOC (ESP LOC≥0.1)**
**** Exceeds ESP LOC ≥0.1 and Restricted Use (RU) LOCs (RU LOC≥0.1 and ≤0.2)**
***** Exceeds ESP, RU and High Acute Risk (HR) LOCs (HR LOC≥0.5)**

Results indicate that the high acute risk, restricted use and endangered species LOCs are exceeded for birds at application rates at or above 1.49, 0.60 and 0.3 lbs cation/A respectively. Therefore the use of paraquat dichloride at higher rates is expected to pose acute risk to non-target avian species. However, because of the environmental fate of the chemical, the risk posed by paraquat only exists shortly after application. Once the applied paraquat has dried (usually within 4 hours), its risk is greatly reduced. It should be noted that the potential exists for the paraquat to again pose risk as a result of rewetting by rain, dew or humidity but at a much lower level.

Chronic

Residues found on dietary food items following paraquat dichloride application may be compared to NOEC values to predict chronic hazard. The maximum estimated environmental concentration (EEC) of residues of paraquat dichloride which may be expected to occur on selected avian dietary food items following a single application is provided in the table below along with the respective risk quotients (RQs) and pertinent LOCs.

Chronic Risk Quotients (RQs) based on a Mallard duck NOEL of 30 ppm (cation)
(RQs[1] and EECs expressed as cation)

Food items	Maximum Application Rates[2] (lbs cation./A)	EEC (ppm)	RQ (EEC/ NOEL)
Short Grass	0.07	16.80	0.56
	1.0	240.00	8.00*
	1.6	384.00	12.80*
Long Grass	0.07	7.70	0.26
	1.0	110.00	3.67*
	1.6	176.00	5.87*
Broadleaf Plants/ Small Insects	0.07	9.45	0.32
	1.0	135.00	4.50*
	1.6	216.00	7.20*

Chronic Risk Quotients (RQs) based on a Mallard duck NOEL of 30 ppm (cation) (RQs[1] and EECs expressed as cation)			
Food items	**Maximum Application Rates[2] (lbs cation./A)**	**EEC (ppm)**	**RQ (EEC/ NOEL)**
Fruits/Large Insects/ Seeds	0.07	1.05	0.04
	1.0	15.00	0.50
	1.6	24.00	0.80

[1] 0.07lb/A = lowest maximum application rate for broadcast uses
1.0 lb/A = typical maximum application rate for food and non-food/non-feed uses
1.6 lb/A = absolute maximum application rate for various food uses
*** Exceeds Chronic Risk LOC**

The above table shows that at rates of 1.0, and 1.6 lbs cation/A the chronic LOCs for avian species are exceeded. Normally this would indicate a chronic risk to birds. However, the environmental fate data indicate that once paraquat is applied and dries, it is not expected to pose a risk. If it is washed off plant surfaces, it is very strongly adsorbed to clay particles in the soil and therefore not biologically available. Therefore, the registered uses of paraquat dichloride are not expected to pose a chronic risk to avian species.

Although a chronic risk is not expected as the result of residues on dietary food items, the Agency is concerned that the use of paraquat dichloride may affect avian reproduction. There is evidence to show that following direct application at rates of 0.5 and 5.0 lbs cation/A to mallard duck eggs, paraquat can cause a reduction of hatchability, significant mortality and reduced growth (MRIDs 00110453, 00110454, 00110455, 00162746).

(b) Mammals

Acute

Small mammal exposure is addressed using acute oral LD_{50} values converted to estimate a LC_{50} value for dietary exposure. The estimated LC_{50} is derived using the following formula:

$$LC_{50} = \frac{LD_{50}}{\text{\% of body weight consumed}}$$

Mammals can be separated into five general groups according to food habits: herbivores, insectivores, granivores, omnivores and carnivores. For the purposes of this risk assessment only three groups will be considered; herbivores, insectivores and granivores.

Risk quotients were calculated using the calculated LC_{50}'s and the EEC's for the 0.07, 1.0, and 1.6 lbs cation/A application rates. These are summarized along with the LOC exceedances in the following tables.

Mammalian Herbivore/Insectivore RQs (based on a female rat LD_{50} of 206 mg/kg) and EECs expressed as cation									
Appl. Rate lbs cation/A	Body Weight (g)	% Body wt. Consumed	Est. mg/kg/d in diet	EEC Short Grass	EEC Broadleaf Plants/ Small Insects	EEC Fruits and Large Insects	RQ Short Grass	RQ Broadleaf Plants/ Small Insects	RQ Fruits and Large Insects
0.07	15	95	216.84	16.80	9.45	1.05	0.08	0.04	0.00
	35	66	312.12				0.05	0.03	0.00
	1000	15	1,373.33				0.01	0.01	0.00
1.0	15	95	216.84	240.00	135.00	15	1.11 ***	20.62 ***	0.07
	35	66	312.12				0.77 ***	0.43**	0.05
	1000	15	1,373.33				0.17*	0.10*	0.01
1.6	15	95	216.84	384.00	216.00	24	1.77 ***	1.00 ***	0.11*
	35	66	312.12				1.23 ***	0.69 ***	0.08
	1000	15	1,373.33				0.28**	0.16*	0.02

* Exceeds ESP LOC
** Exceeds RU and ESP LOCs
*** Exceeds HR, RU and ESP LOCs

Mammalian Granivore RQs (based on a female rat LD_{50} of 206 mg/kg) and EECs expressed as cation					
Appl. Rate lbs cation /A	Body Weight (g)	% Body wt. Consumed	Est. mg/kg/d in diet	EEC seeds	RQ
0.07	15	21	980.95	1.05	0.00
	35	15	1,373.33		0.00
	1000	3	6,866.67		0.00
1.0	15	21	980.95	15	0.02
	35	15	1,373.33		0.01
	1000	3	6,866.67		0.00
1.6	15	21	980.95	24.00	0.02
	35	15	1,373.33		0.02
	1000	3	6,866.67		0.00

The two tables above show that for the lowest application rate, 0.07 lbs cation/A, no LOCs are exceeded for any exposure scenarios. As such, at application rates of 0.07 lbs cation/A or below, the registered uses of Paraquat dichloride are not expected to pose acute risk to non- endangered mammalian species. Also, the registered uses of Paraquat dichloride are not expected to pose acute risk to any granivorous mammals at application rates up to and including 1.6 lbs a.i./L.

The application rate of 1.0 lbs cation/A may produce residues on grass that result in risk quotients that exceed HR, RU and ESP LOCs for small and medium herbivorous and small insectivorous mammals. Restricted use LOCs are exceeded for medium insectivorous mammals. Endangered species LOCs are exceeded for large herbivorous and insectivorous mammals. The highest application rate of 1.6 lbs cation/A (food and feed uses) produces residues in grass that result in risk

quotients that exceed HR, RU and ESP LOCs for small and medium herbivorous and insectivorous mammals, restricted use LOCs for large herbivorous mammals and endangered species LOCs for large insectivorous mammals. However, because of the environmental fate of the chemical, the risk posed by paraquat only exists shortly after application. Once the applied paraquat has dried, its risk is greatly reduced. It should be noted that the potential exists for paraquat to again pose risk as a result of rewetting by rain, dew or humidity, but this risk is at a much lower level.

Chronic

Residues found on dietary food items following paraquat dichloride application may be compared to NOEC values to predict chronic risk. The maximum estimated environmental concentrations (EECs) of residues of paraquat dichloride which may be expected to occur on selected mammalian dietary food items following a single application is provided in the table below along with the respective risk quotients (RQs) and pertinent LOCs. The EECs and the RQs are summarized in the following table.

Chronic risk quotients based on a 12 week study with Wistar-Derived Alderley Park Strain Rats resulting in a NOEL of 25 ppm (cation) and EECs (expressed as cation)			
Food items	**Maximum Application Rates[1] (lbs cation/A)**	**EEC (ppm)**	**RQ (EEC/NOEL)**
Short Grass	0.07	16.80	0.67
	1.0	240.00	9.6*****
	1.6	384.00	15.36*****
Long Grass	0.07	7.70	0.31
	1.0	110.00	4.4*****
	1.6	176.00	7.04*****
Broadleaf Plants	0.07	9.45	0.38
	1.0	135.00	5.4*****
	1.6	216.00	8.64*****
Fruits	0.07	1.05	0.04
	1.0	15.00	0.60
	1.6	24.00	0.96*****

[1]0.07lb/A = lowest maximum application rate for broadcast uses
1.0 lb/A = typical maximum application rate for food and non-food/non-feed uses
1.6 lb/A = absolute maximum application rate for various food uses
*** Exceeds Chronic LOC**

The above table shows that at rates of 1.0, and 1.6 lbs cation/A the chronic LOCs for mammals are exceeded. Normally this would indicate a chronic risk to mammals. However, environmental fate data indicate that paraquat once applied and dried is not expected to pose risk and if washed off plant surfaces is very strongly adsorbed to clay particles in the soil and therefore not biologically available. Therefore, the registered uses of paraquat dichloride are not expected to pose a chronic risk to mammalian species.

(c) Insects

Laboratory data indicates that, based on the application of dry crystalline and liquid formulations of technical and Technical End-Product (TEP) Paraquat dichloride, the contact LD_{50} to honey bees ranged from 6.04->144 ug/bee. This classifies Paraquat dichloride as relatively non-toxic to bees. Another study (MRID# #00111488) shows that when Paraquat dichloride CL (formulated product) was sprayed on honey bees at the rate of 4 lbs cation/A, 55% mortality was observed after 2 days and 90% mortality after 3 days. The study, in which Paraquat in combination with a surfactant was sprayed at rates 2.5 to 4 times maximum label rates, seems to indicate that potential for risk to honey bees may exist as

a result of direct contact with paraquat sprayed at labeled rates. However, the extent of the risk, if any, is expected to be very minimal because paraquat technical is classified as relatively nontoxic to honey bees and because, for most of the major uses, paraquat will be applied at times when honey bees will not be active in the field

(2) Exposure and Risk to Nontarget Aquatic Animals

Risk to nontarget aquatic animals is assessed by comparing actual or estimated environmental concentrations (EECs) to toxicity data and calculating Risk Quotients (RQs). These RQs are then compared to the LOCs to assess the potential for risk to non-target aquatic animals. Aquatic EECs are generally considered the result of direct application to water or the additive effect of runoff or drift. The EECs used in risk assessments are usually obtained either by utilizing the GENEEC Model as an initial screening tool or more advanced models to obtain more refined values. Both types of models utilize fate data including hydrolysis and photolysis half lives, Koc, Kads, solubility, etc. Because paraquat dichloride dissipates by binding very strongly to clay minerals in soils, using models that depend on degradation parameters would yield inappropriate EEC predictions. Due to paraquat dichloride's strong adsorption to soil, no aquatic residues are expected as a result of runoff. The only residues expected are those resulting from drift of paraquat dichloride during application. The following formula was used to calculate EECs due to drift.

EEC = Application Rate X %drift[1] X 61ppb[2]

The following table lists the EECs and resultant RQs expected following application of paraquat dichloride at registered label rates.

[1]Values used are; 1% drift for ground application and 5% drift for aerial application

[2]The concentration of a pesticide expected in a 1 Acre pond, 6 ft. deep, following application of 1 lb/A.

Application Rate (lb/A)	Acute Risk Quotients (RQs for the Most Sensitive Aquatic Organism, *Daphnia magna* EC_{50} = 1.2 ppm)					
	Drift Ground Application (lb cation/A)[1]	Drift Aerial Application (lb cation/A)[1]	Exposure Scenario			
			Residues from Ground Application (ppb)[2]	Residues from Aerial Application (ppb)[2]	RQs (Ground Application)	RQs (Aerial Application)
0.07	0.001	0.004	0.043	0.214	0.000	0.000
1	0.010	0.050	0.610	3.050	0.001	0.003
1.6	0.016	0.080	0.976	4.880	0.001	0.00

[1]Values used are; 1% drift for ground application and 5% drift for aerial application
[2]The concentration of a pesticide expected in a 1 Acre pond, 6 ft. deep, following application of 1 lb/A.

Comparing the RQs to the LOCs (High acute risk LOC ≥ 0.5; Restricted Use LOC ≥ 0.1; Endangered species LOC ≥ 0.05), no LOCs are exceeded. Therefore, the registered uses of paraquat dichloride are not expected to pose an acute risk to any aquatic organisms.

(3) Exposure and Risk to Nontarget Plants

(a) Terrestrial and Semi-aquatic

Non-target terrestrial plants inhabit areas which are dry. Non-target semi-aquatic plants are plants that usually inhabit low-lying wet areas that may be dry in certain times of the year. These plants are not obligatory aquatic plants in that they do not live in a continuously aquatic environment. The terrestrial and semi-aquatic plants may be exposed to pesticides from runoff, drift or volatilization.

Spray drift exposure from ground and aerial application (including airblast, forced-air, and chemigation applications) is assumed to be 1 and 5% respectively, of the application rate.

As was stated previously, paraquat dichloride binds strongly to soil and it is therefore not expected to affect non-target terrestrial and semi-aquatic plants as a result of runoff. Therefore, the risk of the use of paraquat dichloride to non-target terrestrial and semi-aquatic plants is expected to come only as a result of drift during application. The EECs were calculated using the following formulas:

EEC Formulae

Calculating EECs for terrestrial plants inhabiting areas adjacent to treatment sites:

Unincorporated ground application:

Drift = maximum application rate x 0.01

Aerial, airblast, forced-air, and chemigation applications:

Drift = maximum application rate (lbs cation/acre) x 0.05

Calculating EECs for semi-aquatic plants inhabiting wet, low-lying areas:

Unincorporated ground application:

Drift = maximum application rate x 0.01

Aerial, airblast, and forced-air applications:

Drift = maximum application rate (lbs cation/acre) x 0.05

To assess risk, the EECs are then compared to the EC_{25} of the most sensitive plant species, the Cocklebur (EC_{25} = 0.013 lb cation/A. The RQs are then compared to the LOC for plants (LOC=1). The following table lists EECs and RQs for the registered label rates of paraquat dichloride.

Acute High Risk Quotient (RQs) for Terrestrial and Semi-Aquatic Plants (based on a Cocklebur vegetative vigor EC_{50} of 0.013 lbs cation/A)				
Application Rate (lb/A) (cation)	Unincorporated Ground Application EECs (lb cation/A)	Aerial Application EECs (lb cation/A)	Terrestrial & Semi-Aquatic Rqs (Ground Application)	Terrestrial & Semi-Aquatic Rqs (Aerial Application)
0.0700	0.00	0.00	0.00	0.00
1.0000	0.01	0.05	0.77	3.85*****
1.6000	0.02	0.08	1.54*****	**6.15***

*** Exceeds LOC**

The use of paraquat dichloride is not expected to pose risk to non-target terrestrial and semi-aquatic plants at the lowest application rate of 0.07 lb cation/A. Aerial application of paraquat dichloride at the 1.0 lb cation./A rate is expected to pose risk to non-target terrestrial and semi-aquatic plants due to drift. Ground application at the same rate is not expected to pose risk. At the maximum rate of 1.6 lb cation/A both aerial and ground application of paraquat dichloride are expected to pose risk to non-target plants.

Acute Endangered Species Risk Quotient (RQs) for Terrestrial and Semi-Aquatic Plants (based on a Cocklebur vegetative vigor NOEL of 0.004 lbs cation/A)				
Application Rate (lb/A) (cation)	Unincorporated Ground Application EECs (lb cation/A)	Aerial Application EECs (lb cation/A)	Terrestrial & Semi-Aquatic Rqs (Ground Application)	Terrestrial & Semi-Aquatic Rqs (Aerial Application)
0.0700	0.00	0.00	0.00	0.00
1.0000	0.01	0.05	2.50*****	12.50*****
1.6000	0.02	0.08	5.00*****	20.00*****

**** Exceeds LOC***

The use of paraquat dichloride is not expected to pose risk to endangered terrestrial and semi-aquatic plants at the lowest application rate of 0.07 lb cation/A. Aerial and ground application of paraquat dichloride at the 1.0 lb cation./A rate and above are expected to pose risk to endangered terrestrial and semi-aquatic plants due to drift.

(b) Aquatic Plants

Exposure to nontarget aquatic plants may occur through runoff or spray drift from adjacent treated sites or, directly from such uses as aquatic weed or mosquito larvae control. An aquatic plant risk assessment is usually done for aquatic vascular plants from the surrogate duckweed *Lemna gibba*. Non-vascular aquatic plant risk assessments are performed using either algae or

diatom, whichever is the most sensitive species. These non-vascular plants are useful to determine impact to food sources of aquatic organisms. Only short term risk to aquatic plants is estimated. The risk ratio is determined by dividing the pesticide's initial concentration in water by the pesticide's EC_{50} for each surrogate species.

As was stated previously, paraquat dichloride binds strongly to soil and it is therefore not expected to affect non-target aquatic plants as a result of runoff. The risk of the use of paraquat dichloride to non-target aquatic plants is expected to come only as a result of drift during application. In the case of submerged aquatic plants, such as aquatic algae, diatoms, and submerged macrophytes, paraquat dichloride exposure results from aquatic residues resulting from spray drift. In the case of floating aquatic plants, such as duckweed, waterlilies, etc., exposure results not only from aquatic residues but also from direct contact with pesticide drift. The following table lists the EECs expected resulting from ground and aerial application of paraquat dichloride at registered label rates. The EECs were calculated using the same formulas as used for the aquatic organism risk assessment and only reflect aquatic residues resulting from spray drift.

Acute RQ's and EEC's for duckweed and the diatom, *Navicula pelliculosa*, are shown in the Tables below.

Estimated Environmental Concentrations (EECs) and Acute Risk Quotients (RQ) for Aquatic Plants based upon a duckweed EC50 of 0.0713 ppm and a non vascular plant the diatom *Navicula pelliculosa* EC50 of 0.40 ppb.						
Rate of Application (lb cation/A)	Surrogate Plant	EC_{50} (ppb)	Aquatic Residue in 6' of Water from Drift from Ground Application (ppb)	Aquatic Residue in 6' of Water from Drift from Aerial Application (ppb)	RQ (Ground Application) (EEC/ EC50)	RQ (Aerial Application) (EEC/ EC50)
0.07	duckweed *Lemna gibba*	71.3	0.04	0.21	0.0006	0.0029
	diatom *Navicula pelliculosa*	0.4			0.1000	0.5250
1	duckweed *Lemna gibba*	71.3	0.61	3.05	0.0086	0.0428
	diatom *Navicula pelliculosa*	0.4			1.5250	7.6250
1.6	duckweed *Lemna gibba*	71.3	0.98	4.88	0.0137	0.0684
	diatom *Navicula pelliculosa*	0.4			2.45	12.2000

The above results indicate that for aquatic plants high acute risk LOCs are not exceeded for rates equal to or below 1.6 lb cation/A for non-target vascular plants as a result of ground or aerial applications of paraquat dichloride. Aquatic plants high acute risk LOCs are not exceeded for rates equal to or below 0.07 lb cation/A for non-target non-vascular plants as a result of ground or aerial applications of paraquat dichloride, but are exceeded at the 1.0 and 1.6 lb cation/A rates. Currently, no separate criteria for restricted use or chronic effects for plants exist.

In order to assess the risk of paraquat dichloride to endangered plants, the same formulas were used to calculate the EECs. However, the RQs were calculated using NOEC values in the place of EC_{50} values and are summarized in the following table.

Estimated Environmental Concentrations (EECs) and Endangered Species Risk Quotients (RQ) for Aquatic Plants based upon the *Lemna gibba* NOEC of 16 ppb.						
Rate of Application (lb cation/A)	Surrogate Plant	NOEC (ppb)	Aquatic Residue in 6' of Water from Drift from Ground Application (ppb)	Aquatic Residue in 6' of Water from Drift from Aerial Application (ppb)	RQ (Ground Application) (EEC/ EC50)	RQ (Aerial Application) (EEC/ EC50)
0.07	*Lemna gibba*	11.6	0.04	0.21	0.00	0.02
1	*Lemna gibba*	11.6	0.61	3.05	0.05	0.26
1.6	*Lemna gibba*	11.6	0.98	4.88	0.08	0.42

Based on the calculated RQs, the LOCs are not exceeded for endangered aquatic plants. Therefore, the registered uses of paraquat dichloride are not expected to pose risk to non-target endangered aquatic plants.

(4) Endangered Species

Levels of Concern have been exceeded for endangered species of birds at application rates greater than or equal to 0.30 lb cation/A. Levels of Concern have also been exceeded for endangered mammalian species for all labeled application rates $\geq$ 0.55 lb cation/A. These risks exist only until the paraquat dichloride residue dries or becomes bound.

LOCs for endangered aquatic organisms have not been exceeded at even the highest rate of 1.6 lbs cation/A. Levels of Concern have been exceeded for endangered terrestrial and semi-aquatic plants at the 1.0 lb cation/A application rate. The endangered species LOCs for aquatic plants are exceeded at the 1.0 and 1.6 lb cation/A rates for ground application and at all rates for aerial application.

When the Endangered Species Protection Program becomes final, limitations in the use of paraquat dichloride may be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. The Agency anticipates that a consultation with the Fish and Wildlife Service may be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would most likely consist of the generic label

statement referring pesticide users to use limitations contained in county Bulletins.

IV. RISK MANAGEMENT AND REREGISTRATION DECISION

A. Determination of Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredients are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of products containing paraquat dichloride as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing paraquat dichloride under the conditions specified in the RED. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of paraquat dichloride, and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered uses of paraquat dichloride and to determine that paraquat dichloride can be used without resulting in unreasonable adverse effects to humans and the environment if used according to the label as amended by this RED. The Agency therefore finds that all products containing paraquat dichloride as the active ingredient are eligible for reregistration under the conditions specified in this RED. The reregistration of particular products is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of paraquat dichloride are eligible for reregistration under the conditions specified in this RED, it should be understood that the Agency may take additional appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing paraquat dichloride, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

B. Determination of Eligibility Decision

1. Eligibility Decision

The Agency has determined that paraquat dichloride products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Under the Food Quality Protection Act of 1996, the Agency has determined that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to paraquat dichloride. There are no residential uses of paraquat dichloride, therefore, there are no risks of dermal or inhalation exposure to infants, children or the general population. Additionally, paraquat is not expected to be a contaminant of drinking water. The Agency has also concluded that there are no other chemicals with a common mode of toxicity as that of paraquat. Therefore, the Agency concludes that products containing paraquat dichloride for all uses are eligible for reregistration as specified in this RED.

2. Eligible and Ineligible Uses

The Agency has determined that all uses of paraquat dichloride are eligible for reregistration under the conditions specified in this RED.

C. Regulatory Position

The following is a summary of the regulatory positions and rationales for paraquat dichloride. Where labeling revisions are imposed, specific language is set forth in Section V of this document.

1. Food Quality Protection Act Findings

a. Determination of Safety for U.S. Population

EPA has determined that the established tolerances with amendments and changes as specified in this document for paraquat meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered the available information on the aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water, as well as the possibility of cumulative effects from paraquat and other bipyridylium compounds that may have a similar mode/mechanism of toxicity.

Since there are no residential or non-occupational uses of paraquat, no dermal or inhalation exposure is expected in and around the home. Additionally, paraquat residues are not expected to be found in either groundwater or drinking water.

No acute toxicity endpoints of concern have been identified for paraquat.

The chronic dietary risk assessment showed the percent of the RfD utilized by dietary exposure to residues of paraquat is 10% for the general U.S. population. Therefore, the Agency concludes that aggregate risks for the general population resulting from paraquat uses are not of concern.

In evaluating the potential for cumulative effects, EPA compared structural similarities and toxic effects seen in paraquat studies with other bipyridylium compounds such as diquat dibromide. The Agency determined that diquat and paraquat have different effects. Paraquat is a lung toxicant and diquat is not. Paraquat appears to be a weaker cataractogenic agent then diquat. Therefore, based on available data the Agency does not believe that the toxic effects produced by paraquat would be cumulative with the toxic effects produced by diquat.

b. Determination of Safety for Infants and Children

EPA has determined that the established tolerances for paraquat, with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of paraquat residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from paraquat residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature and severity of the effects observed, and other information.

Based on the current data requirements, paraquat has a complete database for developmental and reproductive toxicity. In the developmental studies effects were seen (delayed ossification in the forelimb and hindlimb digits) in the fetuses only at the same or higher dose levels than effects in the mother. In the reproduction study, no effects on reproductive performance were seen. Also because the NOELs from the developmental and reproduction studies were equal to

or greater than the NOEL used for establishing the reference dose, EPA concludes that it is unlikely that there is additional risk concern for immature or developing organisms. Finally, the Agency has no epidemiological information suggesting special sensitivity of infants and children to paraquat. Therefore, the Agency finds that the uncertainty factor (100X) routinely used in RfD calculations is adequately protective of infants and children, and an additional uncertainty factor is not warranted for paraquat.

EPA estimates that paraquat residues in the diet of non-nursing infants (less than 1 year) account for 31% of the RfD and 24% of the RfD for children aged 1-6 years. Further, residues in drinking water are not expected. Therefore, the Agency has determined that there is reasonable certainty that dietary exposure to paraquat will not cause harm to infants and children.

In deciding to continue to make reregistration determinations during the early stages of FQPA implementations, EPA recognizes that it will be necessary to make decisions relating to FQPA before the implementation process is complete. In making these early, case-by - case decisions, EPA does not intend to set broad precedents for the application of FQPA to its regulatory determinations. Rather, these early decisions will be made on a case-by-case basis and will not bind EPA as it proceeds with further policy development and rulemaking that may be required.

If EPA determines, as a result of this later implementation process, that any of the determinations described in this RED are no longer appropriate, the Agency will consider itself free to pursue whatever action may be appropriate, including but not limited to, reconsideration of any portion of this RED.

2. Tolerance Reassessment

The tolerances listed in 40 CFR §180.205(a) are expressed in terms of residues of paraquat derived from application of either the bis(methyl sulfate) or the dichloride salt (both calculated as a cation). A summary of paraquat tolerance reassessments is presented below in table form.

Sufficient data are available to ascertain the adequacy of the established tolerances for the following commodities, **as defined** in 40 CFR §180.205(a): acerola; almond hulls; apples; apricots; asparagus; avocados; bananas; barley grain; bean straw; beans, dry; beans, forage; beans, hay; beans, lima

(succulent); beans, snap (succulent); beets, sugar; beets, sugar (tops); broccoli; cabbage; cacao beans; carrots; cauliflower; cherries; Chinese cabbage; citrus fruit; coffee beans; collards; corn, fresh (inc sweet corn) (K + CWHR); corn grain; cottonseed; cucurbits; eggs; figs; guar beans; guava; kiwifruit; lettuce; mint, hay; nectarines; nuts; olives; onions, dry bulb; onions, green; papayas; passion fruit; peaches; peanuts; peanut, hay; peanut, hulls; peanut, vines; pears; peas (succulent); peas, forage; peas, hay; pineapples; pistachio nuts; plums (fresh prunes); potatoes; poultry, fat; poultry, meat; poultry, mbyp; rhubarb; rye grain; safflower seed; small fruit; sorghum grain; soybean forage; soybeans; strawberries; sugarcane; sunflower seeds; turnips (roots); turnips (tops); vegetables, fruiting; and wheat grain. Some of these commodities need revisions with respect to commodity definitions to conform with the accepted commodity names (see the Tolerance Reassessment Summary Table located below for recommendations in revisions to commodity definitions) and some are no longer regulated as significant feed items. The phrase "negligible residue" [designated as "(N)"] will be administratively deleted from all entries of 40 CFR §180.205(a).

Tolerances for rice grain and rice straw of 0.05 and 0.06 ppm, respectively, have recently been established (60 FR 7457, 2/8/95) in conjunction with PP#5F03188. Tolerances for lentils and lentil forage and hay of 0.3, 0.1, and 0.4 ppm, respectively, have recently been established (60 FR 27421, 5/24/95) in conjunction with PP#4E4359; lentil forage and hay are no longer considered to be significant feed items and these tolerances will be revoked.

Label revisions are required for paraquat dichloride uses on pastures and rangelands in order to reflect the use patterns for which adequate residue data are available. The individual tolerances for "grass, pasture" and “grass, range" will be administratively revised to grass, forage at 90 ppm; and grass, hay at 40 ppm. A tolerance for pasture grass hay need not be proposed since this item is not a recognized RAC (Table I of OPPTS 860.1000).

Label revisions are required for paraquat dichloride uses on alfalfa, clover, and other legumes (including velvetbean, lespedeza, lupine, sainfoin, trefoil, vetch, crown vetch, and milk vetch) in order to reflect the use patterns for which adequate residue data are available. The individual tolerances for "alfalfa", "birdsfoot trefoil", and "clover" will be redefined as non-grass animal feeds group, forage at 75ppm and non-grass animal feeds group, hay at 210ppm. A tolerance for alfalfa meal need not be proposed since this item is not a recognized RAC (Table I of OPPTS 860.1000).

The ruminant feeding study is adequate to support the reassessment of the following tolerances for milk and ruminant tissues: meat: 0.05 ppm; fat: 0.05 ppm, and liver (mybp): 0.05 ppm. However, the tolerance for ruminant kidney will be raised from 0.3 to 0.5 ppm based on current data. Furthermore, the commodity definitions will be revised to comply with Table I (of OPPTS 860.1000). While no tolerance would normally be considered necessary for milk, in the interest of harmonization with CODEX, the Agency recommends that the current 0.01 ppm tolerance be maintained. Also, all poultry and poultry commodity tolerances except those for eggs will be revoked [180.6(a)(3)]; in the interest of harmonization with CODEX, the current 0.01 ppm tolerance for eggs should remain.

The available field trial data indicate that the current tolerances for "corn forage" and "corn fodder", each established at 0.05 ppm, will be administratively increased. Furthermore, the commodity definitions will be revised to reflect the respective corn types (i.e., field, sweet, and pop) in compliance with Table I (of OPPTS 860.1000) commodity definitions. The following tolerances will be administratively amended to distinguish the fodder of various corn types: corn, field, stover at 6 ppm; corn, pop, stover at 6 ppm; and corn, sweet, stover at 6 ppm. Additionally, the following tolerances will be administratively amended to distinguish the forage of various corn types: corn, field, forage at 3 ppm; and corn, sweet, forage at 3 ppm. Due to the recent Registration Division approval of use of paraquat dichloride as a harvest aid (TN940007), the Agency required that additional field trials simulating this use and a separate grain dust study be performed.

The established tolerance for soybeans will be administratively increased from 0.05 ppm to 0.25 ppm. Additional data are required for soybean grain dust to determine a specific numerical concentration factor; a tolerance for aspirated grain fractions, as a RAC, may have to be proposed pending the outcome of the required soybean grain dust study. The registrant has expressed an intention to propose a lower tolerance for soybean forage at 0.03 ppm and to propose a tolerance for soybean hay at 0.05 ppm. Sufficient data are available to support these proposed tolerance levels and will be changed or established accordingly.

The available data indicate that the established tolerance for sorghum forage is too low. The tolerance will be increased to 0.1 ppm for sorghum forage. Label revisions are required to establish a 20-day PHI.

No tolerances currently exist for the following cereal grain commodities: barley straw; popcorn grain; and wheat forage and straw. Sufficient field residue data are available to determine appropriate tolerance

levels for barley straw, wheat forage and straw, and popcorn grain. These tolerances will be established at 1 ppm, 0.5 ppm, 1 ppm and 0.05ppm respectively.

No field residue data or a tolerance proposal for taro foliage have been submitted. When the use of paraquat dichloride on taro was registered, Section B of the petition included a restriction against the use of treated taro leaves for food or feed purposes; however, this restriction is no longer permitted. The registrant must submit field residue data and a tolerance proposal for residues of paraquat dichloride in/on taro foliage.

The Agency now recognizes barley hay, cotton gin byproducts (commonly called gin trash), and wheat hay as raw agricultural commodities (Table I of OPPTS 860.1000). Residue data are now required for these commodities, and appropriate tolerances should be proposed once acceptable data have been submitted and evaluated. The required data for wheat hay will be translated to barley hay.

Crop group tolerances of 0.05 ppm will be established for the members of the Brassica (cole) leafy vegetables group and pome fruits group. Established tolerances for broccoli; cabbage; cauliflower; Chinese cabbage; collards will be combined under the Brassica group at the tolerance of 0.05 ppm. Established tolerances for apples and pears will be combined under the pome fruit group at a tolerance of 0.05 ppm. Established tolerances for apricots;, cherries; nectarines; peaches; and plums will be combined under the stone fruits group at a tolerance of 0.05 ppm. Label revisions to establish a maximum seasonal rate and a PHI are required for members of the stone fruits group.

According to Table I (OPPTS 860.1000), the following items are no longer recognized RACs, therefore, the established tolerances on these items will be administratively revoked: fresh hops; hop vines; lentil hay; lentil forage; bean straw; and peanut vines. In consideration of the designation of dried hops as a RAC and not a processed food commodity, the entry in 40 CFR §185.4700 for dried hops will be transferred to 40 CFR §180.205(a). In addition, the available data indicate that the established tolerance for dried hops is too low; the Agency will administratively increase the established tolerance for dried hops, as a RAC, from 0.2 ppm to 0.5 ppm and redefined it as hops, cone, dried. Additionally, the current tolerance for bean hay is being redefined as cowpea, hay at 0.4 ppm and bean forage is being redefined as cowpea, forage at 0.1 ppm.

The established tolerance for "small fruit" will be amended to read "berries". The present tolerances of 0.05, 0.05, and 0.25 ppm for grapes, cranberries, and strawberries, respectively, will be considered under the "Miscellaneous" grouping and listed individually.

The established tolerance for sugar beet tops will be lowered from 0.5 ppm to 0.05 ppm.

The established tolerances for oat grain and rye grain will be revoked since there are presently no registered uses of paraquat on rye and the registrant has indicated that they do not wish to support use of paraquat on oats.

A tolerance for corn, field, flour at 0.1 ppm will be established based on a concentration factor of 1.5x in flour and the reassessed tolerance of 0.05 ppm for the RAC.

The registrant should propose a tolerance for the processed commodities of grapes.

A tolerance of 0.25 ppm will be established for paraquat residues in pineapple processed residue based on a concentration factor of 4.5x in bran and the reassessed tolerance of 0.05 ppm for the RAC.

Additionally, a tolerance for residues of paraquat in soybean hulls at 2 ppm will be established based on a concentration factor of 6.1x and the reassessed tolerance of 0.25 ppm for the RAC.

Further, a tolerance of 3 ppm for residues of paraquat in sugarcane molasses will be established based on a concentration factor of 5.5x in blackstrap molasses and the reassessed tolerance of 0.5 ppm for the RAC.

Tolerances Listed Under 40 CFR §180.205(b):

The tolerances listed in 40 CFR §180.205(b) have been established with regional registration and are expressed in terms of residues of paraquat derived from application of either the bis (methyl sulfate) or the dichloride salt (both calculated as a cation). A summary of paraquat tolerance reassessments is presented in table form below.

Sufficient data are available to ascertain the adequacy of the established tolerances for the following commodities, as defined in 40 CFR §180.205(b): cassava; pigeon peas; taniers; taro (corms); tyfon; and yams. Some of these commodities need revisions with respect to commodity definitions to conform

with the accepted commodity names; see the tolerance reassessment summary table presented below for recommendations in revisions to commodity definitions.

Tolerances Listed Under 40 CFR §185.4700:

Sufficient data are available to ascertain the adequacy of the established tolerance in 40 CFR §185.4700 for dried hops. The data indicate that the established tolerance is too low. Since dried hops are now considered a RAC and not a processed food item, the entry in 40 CFR §185.4700 for dried hops will be transferred to 40 CFR §180.205(a) [see discussion above under "Tolerances Listed Under 40 CFR §180.205(a)"].

Tolerances Listed Under 40 CFR §186.4700:

Sufficient data are available to ascertain the adequacy of the established tolerances in 40 CFR §186.4700 for spent mint hay. However, Table I (OPPTS 860.1000) no longer specifies that data on spent mint hay are needed for material balance, and a tolerance should not be set for this commodity. Therefore, the existing tolerance for spent mint hay at 3 ppm should be revoked. Additionally, Table II no longer specifies a tolerance is required for sunflower seed hulls. Therefore, the existing tolerance for sunflower seed hulls at 6 ppm should will be revoked.

Pending Tolerance Petitions:

The following petitions for the establishment of tolerances for residues of paraquat in/on various commodities and applications for amended use patterns are pending:

PP#5F01625/5H05088: The petition requests the registration of an additional harvest-aid use for field corn and requests the following tolerances: popcorn at 0.05 ppm; corn grain at 0.05 ppm; corn, fresh (inc. sweet) at 0.05 ppm; corn forage at 3.0 ppm; corn fodder at 10.0 ppm; and corn flour at 0.1 ppm. This petition is currently in reject status because of several issues including the need to submit a revised Section F and a full set of label directions for popcorn.

PP#5F1639: The petition requests label use amendments for alfalfa, clover, other legumes, and pasture and rangeland reseeding; the petition also proposes revised tolerances for non-grass animal feeds group forage and hay, alfalfa meal, and grass forage, fodder, and hay. This petition is currently in

reject status because of several issues including the need for adequate field trial data in support of petitioner-proposed changes in labeling.

PP#1E4019: The petition requests for the establishment of a tolerance for artichokes. This petition is currently in reject status because additional field trial data are required to support the proposed 1-day PHI.

Tolerance Reassessment Summary for Paraquat Dichloride

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Tolerances Listed Under 40 CFR 180.205(a):			
Acerola	0.05	0.05	
Alfalfa	5	Will be replaced with crop group tolerances for forage at 75 ppm and hay at 210 ppm	Crop group tolerance proposals must be made in conjunction with required label revisions. [*Non-grass animal feeds group, forage*] and [*Non-grass animal feeds group, hay*]
Birdsfoot trefoil	5		
Clover	5		
Almond hulls	0.5	0.5	[*Almond, hulls*]
Apples	0.05(N)	--	A crop group tolerance of 0.05 ppm for [*Pome fruits group*] will be established.
Pears	0.05(N)	--	
Apricots	0.05(N)	--	Following the required label revisions, a crop group tolerance of 0.05 ppm for the [*Stone fruits group*] will be established.
Cherries	0.05(N)	--	
Nectarines	0.05(N)	--	
Peaches	0.05(N)	--	
Plums (fresh prunes)	0.05(N)	--	
Asparagus	0.5	0.5	
Avocados	0.05(N)	0.05	
Bananas	0.05(N)	0.05	
Barley grain	0.05(N)	0.05	[*Barley, grain*]
Bean straw	30.0	Revoke	[*Beans, straw*]
Beans, dry	0.3	0.3	
Beans, forage	0.1	0.1	[*Cowpea, forage*]
Beans, hay	0.4	0.4	[*Cowpea, hay*]
Beans, lima (succulent)	0.05	0.05	[*Beans, lima, succulent*]
Beans, snap (succulent)	0.05	0.05	[*Beans, snap, succulent*]
Beets, sugar	0.5	0.5	[*Sugar beets, roots*]
Beets, sugar (tops)	0.5	0.05	[*Sugar beets, tops*] Residues were ND (<0.025 ppm) on all treated sugar beet top samples from field trials conducted at a 1X rate.
Broccoli	0.05	--	A crop group tolerance of 0.05 ppm for *Brassica (cole) leafy vegetables group* will be established.
Cabbage	0.05	--	
Cauliflower	0.05	--	
Chinese cabbage	0.05	--	
Collards	0.05	--	
Cacao beans	0.05	0.05	
Carrots	0.05	0.05	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Cattle, fat	0.05	0.05	
Cattle, kidney	0.3	0.5	CODEX Harmonization
Cattle, meat	0.05	0.05	
Cattle, mbyp (except kidney)	0.05	0.05	
Citrus fruit	0.05(N)	0.05	[*Citrus fruit group*]
Coffee beans	0.05(N)	0.05	[*Coffee, bean, green*]
Corn, fresh (inc sweet corn) (K+CWHR)	0.05(N)	0.05	[*Corn, sweet (K + CWHR)*]
Corn fodder	0.05(N)	6	The following tolerances will be established to distinguish the fodder of various corn types: [*Corn, field, stover* at 6 ppm], [*Corn, pop, stover* at 6 ppm], and [*Corn, sweet, stover* at 6 ppm].
Corn forage	0.05(N)	3	The following tolerances will be established to distinguish the forage of various corn types: [*Corn, field, forage* at 3 ppm], and [*Corn, sweet, forage* at 3 ppm].
Corn grain	0.05(N)	0.05	Since paraquat use as a harvest aid in TN (TN940007) has recently be approved, the Agency will require that additional field trials be conducted by the registrant to support this use. [*Corn, field, grain*]
Cottonseed	0.5	0.5	[*Cotton, seed*]
Cucurbits	0.05	0.05	[*Cucurbit vegetables group*]
Eggs	0.01(N)	0.01	[*Egg*]
Figs	0.05(N)	0.05	[*Fig*]
Goats, fat	0.05	0.05	[*Goat, fat*]
Goats, kidney	0.3	0.5	CODEX Harmonization ; [*Goat, kidney*]
Goats, meat	0.05	0.05	[*Goat, meat*]
Goats, mbyp (except kidney)	0.05	0.05	[*Goat,mbyp (except kidney)]*
Grass, pasture	5	Will be replaced with crop group tolerances for grass forage at 90 ppm and grass hay at 40 ppm	Crop group tolerance proposals must be made in conjunction with required label revisions.
Grass, range	5		[*Grass, forage*], and [*Grass, hay*]
Guar beans	0.5	0.5	
Guava	0.05(N)	0.05	[*Guava*]
Hogs, fat	0.05	0.05	[*Hog, fat]*
Hogs, kidney	0.3	0.5	CODEX Harmonization ; [*Hog, kidney]*
Hogs, meat	0.05	0.05	[*Hog, meat]*
Hogs, mbyp (except kidney)	0.05	0.05	[*Hog,mbyp (except kidney)]*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Hops, fresh	0.1	Revoke	These items are not recognized RACs of hops (Table I, OPPTS 860.1000).
Hop vines	0.5	Revoke	
Horses, fat	0.05	0.05	[*Horse, fat]*
Horses, kidney	0.3	0.5	CODEX Harmonization; [*Horse, kidney]*
Horses, meat	0.05	0.05	[*Horse, meat]*
Horses, mbyp (except kidney)	0.05	0.05	[*Horse, mbyp (except kidney)]*
Kiwifruit	0.05	0.05	[*Kiwifruit*]
Lentils	0.3	0.3	Recently established (60 FR 27421, 5/24/95) in conjunction with PP#4E4359.
Lentil, forage	0.1	Revoke	Recently established (60 FR 27421, 5/24/95) in conjunction with PP#4E4359; however, this item is no longer recognized as a RAC of lentils [Table I (OPPTS 860.1000)].
Lentil, hay	0.4	Revoke	Recently established (60 FR 27421, 5/24/95) in conjunction with PP#4E4359; however, this item is not a recognized RAC of lentils [Table I (OPPTS 860.1000)].
Lettuce	0.05(N)	0.05	
Milk	0.01(N)	0.01	
Mint, hay	0.5	Revoke	[*Peppermint, tops] [Spearmint, tops]*
Nuts	0.05(N)	0.05	[*Tree nuts group*]
Oat grain	0.05(N)	Revoke	Registrant has indicated that they do not wish to support use of paraquat on oats.
Olives	0.05(N)	0.05	[*Olive]*
Onions, dry bulb	0.05	0.05	[*Onion, dry bulb (only)*]
Onions, green	0.05	0.05	[*Onion, green*]
Papayas	0.05(N)	0.05	[*Papaya]*
Passion fruit	0.2	0.2	
Peanuts	0.05	0.05	[*Peanut, nutmeat*]
Peanut, hay	0.5	0.5	[*Peanut, hay*]
Peanut, hulls	0.2	0.2	[*Peanut, hulls*]
Peanut, vines	0.5	Revoke	This item is not a recognized RAC of peanuts (Table I OPPTS 860.1000).
Peas (succulent)	0.05	0.05	[*Pea, succulent*]
Peas, forage	0.2	0.2	[*Pea, field, vines*]
Peas, hay	0.8	0.8	[*Pea, field, hay*]
Pineapples	0.05(N)	0.05	[*Pineapple*]
Pistachio nuts	0.05	0.05	[*Pistachio*]
Potatoes	0.5	0.5	[*Potato*]
Poultry, fat	0.01(N)	Revoke	40 CFR 180.6(a)(3)

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Poultry, meat	0.01(N)	Revoke	
Poultry, mbyp	0.01(N)	Revoke	
Rhubarb	0.05(N)	0.05	
Rice grain	0.05	0.05	Recently established (60 FR 7457, 2/8/95) in conjunction with PP#5F03188. [*Rice, grain*]
Rice straw	0.06	0.06	Recently established (60 FR 7457, 2/8/95) in conjunction with PP#5F03188. [*Rice, straw*]
Rye grain	0.05(N)	Revoke	There are no registered uses of paraquat on rye.
Safflower seed	0.05(N)	0.05	[*Safflower, seed*]
Sheep, fat	0.05	0.05	
Sheep, kidney	0.3	0.5	CODEX Harmonization
Sheep, meat	0.05	0.05	
Sheep, mbyp (except kidney)	0.05	0.05	
Small fruit	0.05(N)	0.05	[*Berries group*]
Sorghum forage	0.05(N)	0.1	The reassessed tolerance is contingent on a required proposal to establish a PHI of 20 days. [*Sorghum, grain, forage*]
Sorghum grain	0.05(N)	0.05	The reassessed tolerance is contingent on a required proposal to establish a PHI of 48 days. [*Sorghum, grain, grain*]
Soybeans	0.05(N)	0.25	Available data indicate current tolerance is too low.
Soybean forage	0.05(N)	0.03	This tolerance is based on preemergence use. Restrictions exist against the grazing or harvesting for hay following postemergence or harvest aid use. [*Soybeans, forage*]
Strawberries	0.25	0.25	[*Strawberry*]
Sugarcane	0.5(N)	0.5	
Sunflower seeds	2	2	[*Sunflower, seed*]
Turnips (roots)	0.05	0.05	[*Turnip, roots*]
Turnips (tops)	0.05	0.05	[*Turnip, tops*]
Vegetables, fruiting	0.05	0.05	[V*egetables, fruiting (exc. cucurbits) group*]
Wheat grain	0.05(N)	0.05	[*Wheat, grain*]
Tolerances That Will Be Established or Need To Be Proposed Under 40 CFR§180.205(a)			
Aspirated Grain Fraction	--	TBD[a]	The tolerance will be based on the results from the higher of the soybean and corn aspirated grain fraction study, which have been required by the Agency.
Barley, hay	--	TBD [a]	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/ *[Correct Commodity Definition]*
Barley, straw	--	1	
Corn, field, flour	--	0.1	
Corn, pop, grain	--	0.05	
Cotton, gin byproducts	--	TBD [a]	
Cranberry	--	0.05	Cranberry, grape and strawberry have been moved from the old "Small Fruits and Berries" crop grouping to the "Miscellaneous" crop grouping.
Grape	--	0.05	
Grape, juice	--	TBD [a]	
Pineapple, process residue	--	0.25	
Raisins	--	TBD [a]	
Soybeans, hay	--	0.05	
Soybeans, hull	--	2	
Sugarcane, molasses	--	3	
Taro foliage	--	TBD [a]	A restriction against the use of treated foliage for *food* purposes is no longer permitted. Taro foliage is no longer considered to be an animal *feed* item.
Wheat, forage	--	0.5	
Wheat, hay	--	TBD [a]	
Wheat, straw	--	1	
Tolerances Listed Under 40 CFR 180.205(b):			
Cassava	0.05	0.05	[*Cassava (manioc)*]
Pigeon peas	0.05	0.05	
Taniers	0.05	0.05	[*Tanier]*
Taro (corms)	0.1	0.1	[*Taro, corm*]
Tyfon	0.05	0.05	
Yams	0.05	0.05	[*Yam*]
Tolerances Listed Under 40 CFR 185.4700:			
Dried hops	0.2	0.5	In consideration of the designation of dried hops as a RAC and not a processed feed commodity, the entry in 40 CFR §185.4700 for dried hops will be transferred to 40 CFR §180.205(a). [*Hops, cones, dried*]
Tolerances Listed Under 40 CFR 186.4700:			
Mint, hay, spent	3.0	Revoke	No longer listed as a Table I (8/96) feed item.
Sunflower; seed hulls	6.0	Revoke	No longer listed in Table I.

[a] TBD = To be determined. Assessment or reassessment of tolerance(s) cannot be made at this time because additional data are required.

a. CODEX Harmonization

The Codex Alimentarius Commission has established several maximum residue limits (MRLs) for paraquat residues in various commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part 2, FAO CX/PR, 4/91*). The Codex and U.S. tolerance are in harmony with respect to MRL/tolerance expression; both regulate the parent paraquat only. A comparison of the Codex MRLs and the corresponding **reassessed** U.S. tolerances is presented in the Table below.

The following conclusions can be made regarding efforts to harmonize the U.S. tolerances with the Codex MRLs with respect to MRL/tolerance level:

- Compatibility between U.S. tolerances and Codex MRLs exists for eggs, passion fruit, sunflower seed, and vegetables [including beans (succulent), Brassica (cole) leafy vegetables group, carrots, cassava, corn (sweet), cucurbits, fruiting vegetables, lettuce, onions (dry bulb and green), peas (succulent), pigeon peas, turnips (roots and tops), and yams], milk and ruminant tissue, and poultry eggs.

- Incompatibilities of U.S. tolerances and Codex MRLs on the following raw plant commodities remain because of differences in agricultural practices: cottonseed, dry hops, maize, olives, potatoes, rice, sorghum, and dry soya bean.

- No questions of compatibility exist with respect to commodities where: (i) no Codex MRLs have been established but U.S. tolerances exist; or (ii) Codex MRLs have been established but U.S. tolerances do not exist.

Codex MRLs and applicable U.S. tolerances. Recommendations for compatibility are based on conclusions following reassessment of U.S. tolerances (see the tolerance reassement summary table above).

Codex		U.S. Tolerance	
Commodity (As Defined)	MRL (mg/kg)[a]	(ppm)	Recommendation And Comments
Cattle, kidney	0.5	0.5	Compatability exists.
Cotton seed	0.2	0.5	

Codex		U.S. Tolerance	
Cotton seed oil, edible	0.05 (*)	--	
Edible offal of cattle, pig, and sheep (except as otherwise listed)	0.05 (*)	0.05	Compatability exists
Egg	0.01 (*)	0.01	Compatibility exists.
Hop, dry	0.2	0.5	
Maize	0.1	0.05	
Meat of cattle, pig, and sheep	0.05 (*)	0.05	Compatability exists
Milk	0.01 (*)	0.01	
Olive	1	0.05	
Passion fruit	0.2	0.2	Compatibility exists.
Pig, kidney	0.5	0.5	Compatability exists
Potato	0.2	0.5	
Rice	10	0.05	
Rice, polished	0.5	--	
Sheep, kidney	0.5	0.5	Compatability exists
Sorghum	0.5	0.05	
Soya bean (dry)	0.1 [b]	0.25	
Sunflower seed	2	2	Compatibility exists.
Sunflower seed oil, crude	0.05 (*)	--	
Sunflower seed oil, edible	0.05 (*)	--	
Vegetables	0.05 (*)	0.05	Compatibility exists for many vegetables including beans (succulent), Brassica (cole) leafy vegetables group, carrots, cassava, cucurbits, fruiting vegetables, lettuce, onions (dry bulb and green), peas (succulent), rhubarbs, turnips (roots and tops), and yams.

a All paraquat dichloride MRLs are final (CXL) except on soya bean (dry). Asterisk (*) signifies that the MRL was established at or about the limit of detection.
b A proposal to establish an MRL of 0.2 mg/kg for soya bean (dry) reached Step 6. However, during the 23rd Session of the CCPR (4/91), the Committee decided to withdraw the proposal and the CXL for soyabean (dry) at 0.1 mg/kg was retained.

3. Tolerance Revocations and Import Tolerances

As part of the Agency's reregistration eligibility decision for paraquat dichloride several food/feed uses will be cancelled/voluntarily cancelled. Once a pesticide use is no longer registered in the United States, the related pesticide residue tolerance and/or food/feed additive regulation generally is no longer needed. It is the Agency's's policy to propose revocation of a tolerance, and/or food/feed additive regulation, following the deletion of a related food use from a registration, or following the cancellation of a related food-use registration.

The Agency recognizes, however, that interested parties may want to retain a tolerance and/or food/feed additive regulation in the absence of a U.S. registration, to allow legal importation of food into the U.S. To assure that all food marketed in the U.S. is safe, under FFDCA, the Agency requires the same technical chemistry and toxicology data for such import tolerances (tolerances without related U.S. registrations) as are required to support U.S. food use registrations and any resulting tolerances. See 40 CFR Part 158 for the Agency's data requirements to support domestic use of a pesticide and establishment and maintenance of a tolerance and/or food/feed regulation.

In addition, the Agency requires residue chemistry data (crop field trials) that are representative of growing conditions in exporting countries in the same manner that the Agency requires representative residue chemistry data from different U.S. regions to support domestic use of the pesticide and the tolerance and/or regulation. Additional guidance on the Agency's import tolerance policy will be published in an upcoming *Federal Register* Notice.

Parties interested in supporting an existing paraquat tolerance as an import tolerance should ensure that all of the data noted above are available to the Agency during its further assessments of existing tolerances and regulations, so that the Agency may determine whether maintenance of the tolerance and/or regulation would be protective of the public health.

4. Summary of Risk Management Decisions

a. Human Health

(1) Dietary

Acute Dietary

The Agency has determined that a risk assessment for acute dietary (1 day) risk is not necessary, since no data presented/available suggest a need for an acute dietary endpoint.

Chronic Dietary (including cancer)

The Agency has evaluated the chronic dietary risk associated with the use of paraquat based on established and proposed tolerance levels and assuming 100% of each crop is treated. The RfD was established at 0.0045 mg/kg/day (expressed as paraquat cation) based upon a chronic toxicity (1 year) study in dogs with a NOEL of 15ppm (.45 mg/kg/day) and an uncertainty factor (UF) of 100. The chronic dietary risk is considered to be minimal. The chronic exposure analysis results in a TMRC where the RfD was not exceeded for any of the 22 populations subgroups analyzed. The chronic dietary exposure using the existing tolerances result in a Theoretical Maximum Residue Contribution (TMRC) which is 10% of the RfD for the U.S. general population. The subpopulation with the highest exposure is non-nursing infants (<1 year old). This subpopulation's TMRC utilizes 31% of the RfD. The Agency considers exposures which utilize 100% or less of the RfD to be adequately protective.

(2) Worker (Mixer/Loader/Applicator)

Acute (Short-Term) and Intermediate Term

The Toxicological Endpoint Selection Committee (TES) indicated inhalation endpoints should be used for risk assessment only in cases in which the spray particles are of a respirable size. This endpoint was based on the NOEL and LOEL for subchronic (3 weeks) inhalation toxicity, for both sexes, of 0.01 ug/L and 0.10 ug/L, respectively, expressed as paraquat cation. The Agency decided that particles used in agricultural practices (400 to 800 um) are well beyond the resipirable range and therefore there is no need for this endpoint.

The Agency has determined that there is a potential dermal exposure to pesticide handlers. Therefore, for all other use scenarios (such as agricultural applications), a "dermal endpoint" is used: NOEL of 3 mg/kg/day, expressed as paraquat cation, based on maternal toxicity effects: unscheduled deaths, thin and hunched appearance, decreased body weight gain, and histological changes in the lungs and kidneys of the nonsurvivors. Exposure by the dermal route, obtained by extrapolating data (NOEL) from a combination of two rat developmental toxicity studies and correcting for dermal absorption (0.3%), is appropriate for short term occupational and residential exposure. (MRIDs 00113714, 43964701 and 00153439). The rat developmental toxicity study was selected over the rabbit 21-day dermal study because the Toxicology Endpoint Selection Committee (TES) generally looks for systemic toxicity endpoints. The only biologically significant endpoint observed in the 21-day dermal study was dermal irritation which is not considered to be a systemic effect. Therefore, the NOEL for developmental effects from the rat developmental toxicity study was selected as the endpoint of choice.

The MOEs for short and intermediate-term occupational exposure dermal effects to paraquat are greater than 100 for all the exposure scenarios considered except for backpack sprayer for applicators and low pressure sprayer (resin soaking) for mixer/loader/applicators. For applicators using the backpack sprayer the MOE for dermal exposure is 31 and for the mixer/loader/applicator using the low pressure sprayer (resin soaking) the MOE for dermal exposure is 36. These MOES assume the use of long pants and long-sleeve shirts (no gloves). However, with the addition of gloves, the MOE for backpack spayer is raised to 64 and the MOE for the mixer/loader/applicator using the low pressure sprayer (resin soaking) is raised to 910. Since the backpack spayer scenario MOE is still below 100, even with the addition of gloves, the Agency and the registrant have agreed to the following requirements to mitigate (bring the unsatisfactory MOE up to100) the remaining risk :

- Modifying all paraquat labels to specify that the maximum backpack applications (non-spot) be 0.625 cation/A with a minimum volume of 20 gallons per Acre.

- This mitigation for backpack non-spot application reduces the finish spray dilution concentration of paraquat in the spray tank to approximately 0.4% w/w of cation.

Post-Application

Based on the postapplication biological monitoring study the Agency has determined that a 12 hour restricted-entry interval is adequate for the uses of paraquat for preemergent or early-season weed control and weed control for orchard and vegetable crops where the spray is directed solely at the weeds (not broadcast over the entire crop area). A 24-hour restricted-entry interval is required for desiccation and harvest aid applications of paraquat since the Agency concludes such uses result in exposures to workers of a greater degree. These 12/24 hour post-application REI's measures should be sufficient to mitigate the potential exposure to workers.

b. Environmental

(1) Avian

Acute

The Agency has evaluated data to determine the acute effects of paraquat dichloride to birds. At the use rate of 1.49 lbs cation/A the risk quotients were determined to be more than 0.5, the LOC for presuming adverse effects to avian species. At the proposed mitigation rate of 1.0 cation/A, restricted use and endangered species LOCs will still be exceeded. However, because of the environmental fate characteristics of paraquat, the risk to birds only exists shortly after application. Once the applied paraquat has dried its risk is greatly reduced. Therefore the Agency concludes the registered uses of paraquat dichloride are not expected to pose significant acute risk to avian species.

Chronic

The Agency has evaluated data on the chronic effects of paraquat to birds. The chronic risk quotients for birds range from 0.80 - 12.80 for the 1.6 lb cation/A rate and 0.5 - 8.00 for the 1.0 lb cation/A rate. Normally these high LOCs would indicate a chonic risk to birds. However, as noted above, the environmental fate

data indicate that paraquat once applied and dried is not expected to pose a risk. Therefore, the registered uses of paraquat dichloride are not expected to pose a significant chronic risk to avian species.

Although a chronic risk is not expected, the Agency was concerned that direct use of paraquat dichloride may affect avian reproduction. However, after reviewing additional information regarding the uses of paraquat (Row Crop, Tree/Vine/Fruit, Vegetable, Alfalfa, and Harvest-Aid uses) the Agency has concluded that the greater risk to eggs within a treated field is from subsequent agricultural practices such as mowing, bailing, fungicide and insecticide spraying, irrigation, etc.. Regarding effects to off-field nesting areas, assuming 5% drift, the resulting "in egg" concentrations of paraquat are not expected to be sufficient to cause significant mortality or reductions in hatchability and growth.

(2) Mammals

Acute

Even though some of the risk quotients for paraquat dichloride exceed high acute risk for the 1.6 lb cation/A and 1.0 cation/A application rate, the Agency concludes that the use of paraquat will not harm mammals, including endangered species through acute toxicity since it becomes biologically unavailable once it dries.

Chronic

The Agency has evaluated data to determine the chronic effects of paraquat dichloride to mammals. At the use rate of 1.6 lb cation/A and 1.0 lb cation/A some of the risk quotients were determined to be more than 1, the LOC for presuming chronic risk to mammals. However, environmental fate data indicate that paraquat once applied and dried is not expected to pose risk. Likewise, the risk mitigation measures (reduced application rates) proposed above for birds should also reduce the exposure of paraquat to mammals.

(3) Insects

Paraquat is practically non-toxic to honeybees and for the most part paraquat will be used at times when honey bees will not be active in the field. Therefore, the use of paraquat is not likely to affect honey bees.

(4) Freshwater Fish

No acute or chronic LOCs have been exceeded for freshwater fish. Therefore, the use of paraquat dichloride is not likely to adversely affect freshwater fish.

(5) Aquatic invertebrates

No acute or chronic LOCs have been exceeded for freshwater invertebrates. Therefore, the use of paraquat dichloride is not likely to adversely affect freshwater invertebrates.

(6) Estuarine and Marine Organisms

No acute LOCs have been exceeded for estuarine and marine organisms. Therefore, the use of paraquat dichloride is unlikely to adversely impact estuarine/marine endangered or non-endangered species. Data were not available to assess the chronic risk to estuarine and marine organisms. Due to paraquat dichloride's strong adsorption to soil which makes it biologically unavailable, chronic testing on estuarine and marine organisms is not required.

(7) Nontarget Plants (Terrestrial, Semi-Aquatic, and Aquatic)

The Agency has evaluated data which indicate that LOCs are exceeded for terrestrial, and semi-aquatic plants. As was stated previously, paraquat dichloride binds strongly to soil and it is therefore not expected to affect non-target terrestrial and semi-aquatic plants as a result of runoff. Rather the risk of paraquat to non-target terrestrial and semi-aquatic plants is expected to come only as a result of drift during application. Depending on the application method and application rates, the risk quotients for non-endangered terrestrial and semi-aquatic plants range from 0.0 -6.15 and the endangered species risk quotients range from 0.0 - 20.0. Therefore, drift from paraquat may adversely affect nontarget terrestrial and semi-aquatic plants, including endangered species.

At paraquat's lowest application rate of 0.07 lb cation/A, no risk to endangered terrestrial and semi-aquatic plants is expected. In order to mitigate the upper end risk quotients, the registrant has agreed to lower the maximum use rate to 1 lb cation/A. However, aerial application of paraquat at the 1.0 lb cation/A rate is still expected to pose some risk to non-target terrestrial and semi-aquatic plants due to drift, but ground application at the same rate is not expected to pose risk.

To provide additional protection to non-target terrestrial and semi-aquatic plants the following mitigation measures are being required:

- Aerial applications must include the most current spray drift language (see description under Actions Required by Registrants)

- All paraquat products must place a statement in the "Environmental Hazard"section of the label that warns the user about possible adverse effects to non-target and semi-aquatic plants due to drift. (See section V for the specific labeling statement).

(8) Endangered Species

The Agency has concerns about the exposure of threatened and endangered plant and animal species to paraquat as discussed above in the science assessment chapter. Endangered species LOCs have been exceeded for chronic effects on birds, small mammals and for acute effects on semi-aquatic and terrestrial plants. The risk for birds and small mammals only exist until the paraquat dichloride residues dries (or becomes bound).

Currently, the Agency is developing a program ("The Endangered Species Protection Program") to identify all pesticides whose use may cause adverse impacts on endangered and threatened species and to implement mitigation measures that will eliminate the adverse impacts. The program would require use restrictions to protect endangered and threatened species at the county level. Consultations with the Fish and Wildlife Service may be necessary to assess risks to newly listed species or from proposed new uses. In the future, the Agency plans to publish a description of the Endangered Species Program in the Federal Register and have available voluntary county-specific bulletins. Because the Agency is taking this approach for protecting endangered and threatened species, it is not imposing label modifications at this time through the RED. Rather, any requirements for product use modifications will occur in the future under the Endangered Species Protection Program.

(9) Water Resources

Although there were detections of paraquat in drinking water wells from two states cited in the Pesticides in Groundwater Database, these detections are not considered to be representative of normal paraquat use. Paraquat dichloride binds so strongly to soil clay particles that it did not leach from the surface in the terrestrial field dissipation studies. Therefore, the Agency concludes there is no concern for paraquat contaminating groundwater from normal use patterns.

(10) Restricted Use Classification

All paraquat products are currently classified as pesticides (February 9, 1978, 43 FR 5782). Originally, this restriction was based on acute toxicity and the potential for intentional or inadvertent exposure. More recent acute data indicate lower toxicity for all routes of exposure except inhalation (a new inhalation study was not submitted). However, the spray droplets of paraquat from all currently registered products are not of respirable size and inhalation is not an exposure route of concern. Notwithstanding the lack of acute toxicity concerns, the Agency is maintaining the Restricted Use classification for all paraquat products based on the severity of effects from paraquat oral ingestion and inappropriate dermal exposure, limited effectiveness of therapeutic treatment after exposure and in order to continue to deter misuse of this product.

5. Occupational/Residential Labeling Rationale

The Worker Protection Standard (WPS)

Scope of the WPS

The 1992 Worker Protection Standard for Agricultural Pesticides (WPS) established certain worker-protection requirements (personal protective equipment, restricted-entry intervals, etc.) to be specified on the label of all products that contain uses within the scope of the WPS. Uses within the scope of the WPS include all commercial (non-homeowner) and research uses on farms, forests, nurseries, and greenhouses to produce agricultural plants (including food, feed, and fiber plants, trees, turf grass, flowers, shrubs, ornamentals, and seedlings). Uses within scope include not only uses on plants, but also uses on the soil or planting medium the plants are (or will be) grown in.

At this time some of the registered uses of paraquat are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) and some uses are outside the scope of the WPS. Some examples of uses that are outside the scope of the WPS include use:

- on pastures or rangelands,
- on plants that are in ornamental gardens, parks, golf courses, and public or private lawns and grounds and that are intended only for decorative or environmental benefit.
- in a manner not directly related to the production of agricultural plants, including, for example, control of vegetation along rights-of-way and in other non-crop areas.

Compliance With the WPS

Any product whose labeling can be reasonably interpreted to permit use in the production of an agricultural plant on any farm, forest, nursery, or greenhouse must comply with the labeling requirements of PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7," which reflect the requirements of the Agency's labeling regulations for worker protection statements (40 CFR part 156, subpart K). These labeling revisions are necessary to implement the Worker Protection Standard for Agricultural Pesticides (40 CFR part 170) and must be completed in accordance with, and within the deadlines specified in, PR Notices 93-7 and 93-11. Unless otherwise specifically directed in this RED, all statements required by PR Notices 93-7 and 93-11 are to be on the product label exactly as instructed in those notices.

- After April 21, 1994, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by the primary registrant or any supplementally registered distributor.

- After October 23, 1995, except as otherwise provided in PR Notices 93-7 and 93-11, the labeling of all products within the scope of those notices must meet the requirements of the notices when the products are distributed or sold by any person.

Personal Protective Equipment/Engineering Controls for Handlers

For each end-use product, PPE requirements for pesticide handlers are set during reregistration in one of two ways:

1. If the Agency determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, the PPE for pesticide handlers will be based on the acute toxicity of the end-use product. For occupational-use products, PPE must be established using the process described in PR Notice 93-7 or more recent EPA guidelines.

2. If the Agency determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects, etc.):

- In the RED for that active ingredient, the Agency may establish minimum or "baseline" handler PPE requirements that pertain to all or most end-use products containing that active ingredient.

- These minimum PPE requirements must be compared with the PPE that would be designated on the basis of the acute toxicity of the end-use product.

- The more stringent choice for each type of PPE (i.e., bodywear, hand protection, footwear, eyewear, etc.) must be placed on the label of the end-use product.

Personal protective equipment requirements usually are set by specifying one or more pre-established PPE units -- sets of items that are almost always required together. For example, if chemical-resistant gloves are required, then long-sleeve shirts, long pants, socks, and shoes are assumed and are also included in the required minimum attire. If the requirement is for two layers of body protection (coveralls over a long- or short-sleeve shirt and long or short pants), the minimum must also include (for all handlers) chemical-resistant footwear and chemical-resistant headgear for overhead exposures and (for mixers, loaders, and persons cleaning equipment) chemical-resistant aprons.

Occupational-Use Products

The Agency has determined that regulatory action regarding the establishment of active-ingredient-based minimum PPE requirements for occupational handlers must be taken for paraquat. Even though the MOE's were greater than 100 for occupational mixers, loaders, and applicators (except backpack applicators and resin-soaking uses) without personal protective equipment requirements beyond long-sleeve shirt, long pants, shoes, and socks, the Agency notes the relatively significant epidemiological evidence of poisonings from intentional/accidental oral ingestion and numerous non-systemic skin and eye effects in California (see California Pesticide Illness Surveillance System Data in OREB memo form J. Blondell, entitled: “Review of Paraquat Acute Illness Data”, 12/5/95). These considerations have led to the determination that active ingredient-based minimum PPE should be required for all occupational paraquat handlers.

Since potential handler exposure is similar for WPS and nonWPS uses, there is only one set of active-ingredient-based minimum (baseline) PPE requirements for all occupational uses of paraquat (specified in Section V). These requirements must be followed in the labeling of all paraquat end-use products intended primarily for occupational use.

Homeowner-Use Products

There are no registered homeowner-use products.

Post-Application/Entry Restrictions

Occupational-Use Products (WPS Uses)

Restricted-Entry Interval:

Under the Worker Protection Standard (WPS), interim restricted-entry intervals (REI's) for all uses within the scope of the WPS are based on the acute toxicity of the active ingredient. The toxicity categories of the active ingredient for acute dermal toxicity, eye irritation potential, and skin irritation potential are used to determine the interim WPS REI. If one or more of the three acute toxicity effects are in toxicity category I, the interim WPS REI is established at 48 hours. If none of the acute toxicity effects are in category I, but one or more of the three is classified as category II, the interim WPS REI is established at 24 hours. If none of the three acute toxicity effects are in category I or II, the interim WPS REI is established at 12 hours. A 48-hour REI is increased to 72 hours when an organophosphate pesticide is applied outdoors in arid areas. In addition, the WPS specifically retains two types of REI's established by the Agency prior to the promulgation of the WPS: (1) product-specific REI's established on the basis of adequate data, and (2) interim REI's that are longer than those that would be established under the WPS.

During the reregistration process, the Agency considers all relevant product-specific information to decide whether there is reason to shorten or lengthen the previously established REI.

During the reregistration process, the Agency determined that the restricted-entry interval (REI) for all occupational-use products that contain paraquat and are within the scope of the Worker Protection Standard for Agricultural Pesticides (WPS) should be 12 hours for preemergence and directed-spraying uses and 24 hours for desiccation and harvesting uses.

Early-Entry PPE:

The WPS establishes very specific restrictions on entry by workers to areas that remain under a restricted-entry interval, if the entry involves contact with treated surfaces. Among those restrictions are a prohibition of routine entry to perform hand labor tasks and a requirement that personal protective equipment be worn. Under the WPS, these personal protective equipment requirements for persons who must enter areas that remain under a restricted-entry interval are based on the acute toxicity category of the active ingredient.

During the reregistration process, the Agency considers all relevant product-specific information to decide whether there is reason to set personal protective equipment requirements that differ from those set through the WPS.

The RED requirements for early-entry personal protective equipment are set in one of two ways:

1. If the Agency determines that no regulatory action must be taken as the result of the acute effects or other adverse effects of an active ingredient, it establishes the early-entry PPE requirements on the basis of the acute dermal toxicity category, skin irritation potential category, and eye irritation potential category of the active ingredient.

2. If theAgency determines that regulatory action on an active ingredient must be taken as the result of very high acute toxicity or to certain other adverse effects, such as allergic effects or delayed effects (cancer, developmental toxicity, reproductive effects), it may establish early-entry PPE requirements that are more stringent than would be established otherwise.

The Agency is establishing PPE for dermal protection on the basis of the acute toxicity of the active ingredient. Paraquat is classified as toxicity category III for acute dermal toxicity. Since paraquat is classified as category II for eye irritation potential, protective eyewear is required.

WPS Notification Statement:

Under the WPS, the labels of some pesticide products must require employers to notify workers about pesticide-treated areas orally as well as by posting of the treated areas. The reregistration process also may decide that a product requires this type of "double notification."

Based on the acute toxicity of the active ingredient, the Agency is not requiring double notification.

Occupational-Use Products (NonWPS Uses)

Since the Agency has concerns about post-application exposures to persons after nonWPS occupational uses of paraquat, it is establishing entry restrictions for all nonWPS occupational uses of paraquat end-use products. For specific requirements, refer to Section V of this document.

Homeowner-Use Products

There are no registered homeowner-use products.

Other Labeling Requirements

The registrant has agreed to lower application rates and label changes for tree injection. These changes are summarized in Section V. The Agency is also requiring other use and safety information to be placed on the labeling of all end-use products containing paraquat. For the specific labeling statements, refer to Section V of this document.

V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

A. Manufacturing-Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of paraquat dichloride for the above eligible uses has been reviewed and determined to be substantially complete. However, EPA is requiring data to establish tolerances for paraquat dichloride on taro foliage, corn and soybean aspirated grain fractions, wheat and hay, cotton and gin byproducts and processed grapes. The Agency is also requiring data to confirm that the existing tolerance for field corn is adequate to cover the specialized use of paraquat as a harvest aid. See the chart below for data requirements:

Guideline #	Study Title
62-3	Analytical Methods (For the MP, EPA Reg. No. 10182-362)
171-3	Directions for Use
171-4(k)	Magnitude of the Residue in Plants - Taro foliage
171-4(k)	Mag. of the Res. in Plants - Soybean aspirated grain fractions
171-4(k)	Mag. of the Res. in Plants - Corn, field, grain and aspirated grain fractions
171-4(k)	Mag. of the Res. in Plants - Wheat and hay*
171-4(k)	Mag. of the Res. in Plants - Cotton, and gin byproducts
171-4(l)	Mag. of the Res in Processed Food/Feed - Grapes
201-1	Droplet size spectrum
202-1	Drift field evaluation

* The registrant should refer to the 4/23/96 CBRS memorandum and cite the available data for wheat straw.

2. Labeling Requirements for Manufacturing-Use Products

To remain in complaince with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

> "Only for formulation into an _____[fill blank with Insecticide, Herbicide or the applicable term which describes the type of pesticide use(s)] for the following use(s) _____ [fill blank only with those uses that are being supported by MP registrant."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

> "Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

(a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

(b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

2. Labeling Requirements for End-Use Products

a. Application Rates and Label Deletions

In cooperation with the Agency the registrant has agreed to the following application rates and label deletions:

○ The maximum paraquat dichloride application rate for all products will be lowered from 1.6 lb cation/A to 1.0 lb cation/A.

- For broadcast applications of paraquat with backpack sprayers, **non-spot**, the application rate should not exceed 0.625 lb cation/A and the application volume should be no less than 20 gallons per acre.

- The maximum application rate for **spot spraying** on all paraquat labels will be no more than 0.0195 lbs cation/gallon.

○ Delete the plastic acid bottle and the tree injection directions for use from the resin soaking sections of all paraquat dichloride labels.

b. Hazard Statement

The following hazard statement must be placed in the "Environmental Hazard" section of all paraquat labels to warn the user about possible adverse effects to non-target terrestrial and semi-aquatic plants due to drift:

> "Paraquat dichloride is toxic to nontarget crops and plants if off-target movement occurs. Extreme care must be taken to ensure that off-target drift is minimized to the greatest extent possible."

c. PPE/Engineering Control Requirements for Pesticide Handlers

For **sole-active-ingredient** end-use products that contain paraquat, the product labeling must be revised to adopt the handler personal protective equipment/engineering control requirements set forth in this section. Any conflicting PPE requirements on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain paraquat, the handler personal protective equipment/engineering control requirements set forth in this section must be compared to the requirements on the current labeling and the more protective must be retained. For guidance on which requirements are considered more protective, see PR Notice 93-7.

d. Products Intended Primarily for Occupational Use (WPS and nonWPS)

Minimum (Baseline) PPE/Engineering Control Requirements

Although the MOE's were greater than 100 for all but two scenarios (backpack applicators and resin-soaking uses) without personal protective equipment requirements beyond long-sleeve shirt, long pants, shoes and socks, the Agency notes the relatively significant epidemiological evidence of poisonings from intentional/accidental swallowing and numerous non-systemic skin and eye effects in California (see OREB J. Blondell memo, 12/5/95). These considerations have led to the Agency establishing the following minimum (baseline) PPE for all occupational uses of paraquat end-use products:

"Mixers and loaders must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks,
--chemical-resistant apron,
--face shield"

Although there is no direct evidence that occupational handlers have ever ingested a lethal amount of paraquat from a splash or spill, the requirement for a face shield for all mixers and loaders reflects the Agency's particular concern about accidental swallowing in case of a spill or splash back.

"Applicators and other handlers (other than mixers and loaders) must wear:
--long-sleeved shirt and long pants,
--chemical-resistant gloves*,
--shoes plus socks"

* For the glove statement, use the statement established for paraquat through the instructions in Supplement Three of PR Notice 93-7.

Determining PPE Requirements for End-use Product Labels

The PPE that would be established on the basis of the acute toxicity category of the end-use product must be compared to the active-ingredient-based minimum (baseline) personal protective equipment specified above. The more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

Products Intended Primarily for Occupational Use

There are no registered homeowner-use products

Entry Restrictions

For **sole-active-ingredient** end-use products that contain paraquat the product labeling must be revised to adopt the entry restrictions set forth in this section. Any conflicting entry restrictions on the current labeling must be removed.

For **multiple-active-ingredient** end-use products that contain paraquat the entry restrictions set forth in this section must be compared to the entry restrictions on the current labeling and the more protective must be retained. A specific time period in hours or days is considered more protective than "sprays have dried" or "dusts have settled."

e. Products Intended Primarily for Occupational Use - Entry Restrictions and Labeling

WPS Uses

Restricted-entry interval:

"For preplant or preemergence (broadcast or banded) applications, post-emergence directed-spray applications, dormant-season applications, and "between cutting" alfalfa applications: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours."

"For harvest-aid and desiccation applications: Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 24 hours."

Early-entry personal protective equipment (PPE):

The PPE required for early entry is:

-- coveralls,
-- chemical-resistant gloves*,
-- shoes plus socks,

-- protective eyewear.

* For the glove statement, use the statement established for paraquat through the instructions in Supplement Three of PR Notice 93-7.

WPS Notification Statement:

Not reqiured on label.

Placement in labeling:

The REI statements must be inserted into the Agricultural Use Requirements box as required by Supplement Three of PR Notice 93-7. The PPE required for early entry must be inserted into the standardized early-entry PPE statement required by Supplement Three of PR Notice 93-7. The double notification statement must be placed into the Agricultural Use Requirements box as required by Supplement Three of PR Notice 93-7.

NonWPS uses

Entry restrictions:

The Agency is establishing the following entry restrictions for nonWPS occupational uses of paraquat end-use products:

"Do not enter or allow others to enter the treated area until sprays have dried."

Placement in labeling:

If WPS uses are also on label -- Follow the instructions in PR Notice 93-7 for establishing a Non-Agricultural Use Requirements box, and place the appropriate nonWPS entry restrictions in that box.

If no WPS uses are on the label -- Place the appropriate nonWPS entry restrictions in the Directions for Use, under the heading "Entry Restrictions."

Products Intended Primarily for Homeowner Use

Entry restrictions:

There are no registered homeowner-use products.

f. Other Labeling Requirements

Products Intended Primarily for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing paraquat that are intended primarily for occupational use.

Application Restrictions

"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."

Engineering Controls

"When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR 170.240(d)(4-6), the handler PPE requirements may be reduced or modified as specified in the WPS."

User Safety Requirements

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable, use detergent and hot water. Keep and wash PPE separately from other laundry."

"DO NOT USE AROUND HOMES, SCHOOLS, RECREATIONAL PARKS, GOLF COURSES, OR PLAYGROUNDS"

User Safety Recommendations

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."
- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

- "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."

C. Spray Drift Labeling

The following language must be placed on each paraquat product label that can be applied aerially:

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions.

The following drift management requirements must be followed to avoid off-target drift movement from aerial applications to agricultural field crops. These requirements do not apply to forestry applications, public health uses or to applications using dry formulations.

1. The distance of the outer most nozzles on the boom must not exceed 3/4 the length of the wingspan or rotor.

2. Nozzles must always point backward parallel with the air stream and never be pointed downwards more than 45 degrees.

Where states have more stringent regulations, they shall be observed.

The applicator should be familiar with and take into account the information covered in the Aerial Drift Reduction Advisory Information.

The following aerial drift reduction advisory information must be contained in the product labeling:

[This section is advisory in nature and does not supersede the mandatory label requirements.]

INFORMATION ON DROPLET SIZE

The most effective way to reduce drift potential is to apply large droplets. The best drift management strategy is to apply the largest droplets that provide sufficient coverage and control. Applying larger droplets reduces drift potential, but will not prevent drift if applications are made improperly, or under unfavorable

environmental conditions (see Wind, Temperature and Humidity, and Temperature Inversions).

CONTROLLING DROPLET SIZE

- Volume - Use high flow rate nozzles to apply the highest practical spray volume. Nozzles with higher rated flows produce larger droplets.

- Pressure - Do not exceed the nozzle manufacturer's recommended pressures. For many nozzle types lower pressure produces larger droplets. When higher flow rates are needed, use higher flow rate nozzles instead of increasing pressure.

- Number of nozzles - Use the minimum number of nozzles that provide uniform coverage.

- Nozzle Orientation - Orienting nozzles so that the spray is released parallel to the airstream produces larger droplets than other orientations and is the recommended practice. Significant deflection from horizontal will reduce droplet size and increase drift potential.

- Nozzle Type - Use a nozzle type that is designed for the intended application. With most nozzle types, narrower spray angles produce larger droplets. Consider using low-drift nozzles. Solid stream nozzles oriented straight back produce the largest droplets and the lowest drift.

BOOM LENGTH

For some use patterns, reducing the effective boom length to less than 3/4 of the wingspan or rotor length may further reduce drift without reducing swath width.

APPLICATION HEIGHT

Applications should not be made at a height greater than 10 feet above the top of the largest plants unless a greater height is required for aircraft safety. Making applications at the lowest height that is safe reduces exposure of droplets to evaporation and wind.

SWATH ADJUSTMENT

When applications are made with a crosswind, the swath will be displaced downwind. Therefore, on the up and downwind edges of the field, the applicator must compensate for this displacement by adjusting the path of the aircraft upwind.

Swath adjustment distance should increase, with increasing drift potential (higher wind, smaller drops, etc.)

WIND

Drift potential is lowest between wind speeds of 2-10 mph. However, many factors, including droplet size and equipment type determine drift potential at any given speed. Application should be avoided below 2 mph due to variable wind direction and high inversion potential. NOTE: Local terrain can influence wind patterns. Every applicator should be familiar with local wind patterns and how they affect spray drift.

TEMPERATURE AND HUMIDITY

When making applications in low relative humidity, set up equipment to produce larger droplets to compensate for evaporation. Droplet evaporation is most severe when conditions are both hot and dry.

TEMPERATURE INVERSIONS

Applications should not occur during a temperature inversion because drift potential is high. Temperature inversions restrict vertical air mixing, which causes small suspended droplets to remain in a concentrated cloud. This cloud can move in unpredictable directions due to the light variable winds common during inversions. Temperature inversions are characterized by increasing temperatures with altitude and are common on nights with limited cloud cover and light to no wind. They begin to form as the sun sets and often continue into the morning. Their presence can be indicated by ground fog; however, if fog is not present, inversions can also be identified by the movement of smoke from a ground source or an aircraft smoke generator. Smoke that layers and moves laterally in a concentrated cloud (under low wind conditions) indicates an inversion, while smoke that moves upward and rapidly dissipates indicates good vertical air mixing.

SENSITIVE AREAS

The pesticide should only be applied when the potential for drift to adjacent sensitive areas (e.g. residential areas, bodies of water, known habitat for threatened or endangered species, non-target crops) is minimal (e.g. when wind is blowing away from the sensitive areas).

D. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell paraquat dichloride products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.

VI. APPENDICES

APPENDIX A. Table of Use Patterns Subject to Reregistration

Appendix A is 213 pages long and is not being included. Copies of Appendix A are available upon request per the instructions in Appendix E

GUIDE TO APPENDIX B

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Paraquat Dichloride covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Paraquat Dichloride in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. Bibliographic citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

APPENDIX B

Data Supporting Guideline Requirements for the Reregistration of Paraquat Dichloride

REQUIREMENT		USE PATTERN	CITATION(S)
PRODUCT CHEMISTRY			
61-1	**Chemical Identity**	All	N/A
61-2A	**Start. Mat. & Mnfg. Process**	All	40479001, 42297601
61-2B	**Formation of Impurities**	All	40479001, 42297601
62-1	**Preliminary Analysis**	All	43429001, 40624701, 42297601
62-2	**Certification of limits**	All	N/A
62-3	**Analytical Method**	All	Data Gap
63-2	**Color**	All	40479001, 42297601
63-3	**Physical State**	All	40479001, 42297601
63-4	**Odor**	All	40479001
63-5	**Melting Point**	All	40479001
63-6	**Boiling Point**		N/A
63-7	**Density**	All	40479001, 42588201
63-8	**Solubility**	All	40479001
63-9	**Vapor Pressure**	All	40479001
63-10	**Dissociation Constant**	All	40479001
63-11	**Octanol/Water Partition**	All	40479001
63-12	**pH**	All	40479001, 42297601
63-13	**Stability**	All	43099701, 40479001, 42297601

REQUIREMENT		USE PATTERN	CITATION(S)
63-14	**Oxidizing/Reducing Action**		N/A
63-15	**Flammability**		N/A
63-16	**Explodability**		N/A
63-17	**Storage stability**		N/A
63-18	**Viscosity**		N/A
63-19	**Miscibility**		N/A
63-20	**Corrosion characteristics**		N/A
63-21	**Dielectric breakdown volt**		N/A
64-1	**Submittal of Samples**		N/A
ECOLOGICAL EFFECTS			
71-1A	**Acute Avian Oral - Quail/Duck**	A,B,C,J	00029001,00102038,00160000, 05008363
71-1B	**Acute Avian Oral - Quail/Duck TEP**		Not required
71-2A	**Avian Dietary - Quail**	A,B,C,J	00022923
71-2B	**Avian Dietary - Duck**	A,B,C,J	00022923
71-3	**Wild Mammal Toxicity**		Not required
71-4A	**Avian Reproduction - Quail**	A,B,C,J	00110453, 00110454
71-4B	**Avian Reproduction - Duck**	A,B,C,J	00110455
71-5A	**Simulated Field Study**		Not required
71-5B	**Actual Field Study**		Not required
72-1A	**Fish Toxicity Bluegill**	A,B,C,J	40098001, 00162737

REQUIREMENT		USE PATTERN	CITATION(S)
72-1B	**Fish Toxicity Bluegill - TEP**		Not required
72-1C	**Fish Toxicity Rainbow Trout**	A,B,C,J	40098001, 00162736, 00162738
72-1D	**Fish Toxicity Rainbow Trout- TEP**		Not required
72-2A	**Invertebrate Toxicity**	A,B,C,J	40098001, 00114473, GS0262-028
72-2B	**Invertebrate Toxicity - TEP**		Not required
72-3A	**Estuarine/Marine Toxicity - Fish**		Not required
72-3B	**Estuarine/Marine Toxicity - Mollusk**		Not required
72-3C	**Estuarine/Marine Toxicity - Shrimp**		Not required
72-3D	**Estuarine/Marine Toxicity Fish- TEP**		Not required
72-3E	**Estuarine/Marine Toxicity Mollusk - TEP**		Not required
72-3F	**Estuarine/Marine Toxicity Shrimp - TEP**		Not required
72-4A	**Early Life Stage Fish**		Not required
72-4B	**Life Cycle Invertebrate**		Not required
72-5	**Life Cycle Fish**		Not required
72-6	**Aquatic Organism Accumulation**		Not required
72-7A	**Simulated Field - Aquatic Organisms**		Not required
72-7B	**Actual Field - Aquatic Organisms**		Not required

REQUIREMENT		USE PATTERN	CITATION(S)
122-1A	**Seed Germination/Seedling Emergence**		Not required
122-1B	**Vegetative Vigor**		Not required
122-2	**Aquatic Plant Growth**		
123-1A	**Seed Germination/Seedling Emergence**	B,J	42639601
123-1B	**Vegetative Vigor**	B,J	42601001
123-2	**Aquatic Plant Growth**	B,J	42601002, 42601003, 42601004, 42601005, 42601006
124-1	**Terrestrial Field**		Not required
124-2	**Aquatic Field**		Not required
141-1	**Honey Bee Acute Contact**	A,B,C,J	05001991, 00028772, 00111488
141-2	**Honey Bee Residue on Foliage**		Not required
141-5	**Field Test for Pollinators**		Not required
TOXICOLOGY			
81-1	**Acute Oral Toxicity - Rat**	A,B,C,J	00054573, 00162748, 00081825 00162870,43685001
81-2	**Acute Dermal Toxicity - Rabbit/Rat**	A,B,C,J	00054574, 00162748,43685002
81-3	**Acute Inhalation Toxicity - Rat**	A,B,C,J	00046105, 00153733
81-4	**Primary Eye Irritation - Rabbit**	A,B,C,J	00054575, 43685003
81-5	**Primary Dermal Irritation - Rabbit**	A,B,C,J	00054576
81-6	**Dermal Sensitization - Guinea Pig**	A,B,C,J	00155289, 00162744, 43685005

REQUIREMENT		USE PATTERN	CITATION(S)
81-7	**Acute Delayed Neurotoxicity - Hen**		Not required
82-1A	**90-Day Feeding - Rodent**		Not required
82-1B	**90-Day Feeding - Non-rodent (Dog)**	A,B,C,J	00072416
82-2	**21-Day Dermal - Rabbit/Rat**	A,B,C,J	00156313
82-3	**90-Day Dermal - Rodent**		Not required
82-4	**90-Day Inhalation - Rat**	A,B,C,J	00030788, 00113718
82-5A	**90-Day Neurotoxicity - Hen**		Not required
82-5B	**90-Day Neurotoxicity - Mammal**		Not required
83-1A	**Chronic Feeding Toxicity - Rodent**	A,B,C,J	00138637, 40218001
83-1B	**Chronic Feeding Toxicity - Non-Rodent**	A,B,C,J	00132474
83-2A	**Oncogenicity - Rat**	A,B,C,J	00138637, 00153223, 40183501, 40202401, 40202402, 41317401, 40218001
83-2B	**Oncogenicity - Mouse**	A,B,C,J	00087924, 40202403
83-3A	**Developmental Toxicity - Rat**	A,B,C,J	00113714
83-3B	**Developmental Toxicity - Rabbit**	A,B,C,J	00096338
83-4	**2-Generation Reproduction - Rat**	A,B,C,J	00126783
84-2A	**Gene Mutation (Ames Test)**	A,B,C,J	00152690, 00152691
84-2B	**Structural Chromosomal Aberration**	A,B,C,J	00073487, 00152692, 40202404
84-4	**Other Genotoxic Effects**	A,B,C,J	0015293, 00100442, 00152695, 40202405
85-1	**General Metabolism**	A,B,C,J	00028597, 00036297, 00028598 00055107, 00028599, 00126096

REQUIREMENT		USE PATTERN	CITATION(S)
85-2	**Dermal Penetration**	A,B,C,J	00126096, 00126097, 00126098 00126099, 00153439
86-1	**Domestic Animal Safety**		Not required
OCCUPATIONAL/RESIDENTIAL EXPOSURE			
132-1A	**Foliar Residue Dissipation**		Not requried
132-1B	**Soil Residue Dissipation**		Waived
133-3	**Dermal Passive Dosimetry Exposure**		Waived
133-4	**Inhalation Passive Dosimetry Exposure**		Waived
231	**Estimation of Dermal Exposure at Outdoor Sites**		Not required
232	**Estimation of Inhalation Exposure at Outdoor Sites**		Not required
233	**Estimation of Dermal Exposure at Indoor Sites**		Not required
234	**Estimation of Inhalation Exposure at Indoor Sites**		Not required
ENVIRONMENTAL FATE			
160-5	**Chemical Identity**		Not required
161-1	**Hydrolysis**	A,B,C,J	Upton[3]

Guideline fulfilled; No MRID #'s for this study - review dated 2/14/85

REQUIREMENT		USE PATTERN	CITATION(S)
161-2	**Photodegradation - Water**	A,B,C,J	40562301
161-3	**Photodegradation - Soil**	A,B,J	Pack[4]
161-4	**Photodegradation - Air**		Not required
162-1	**Aerobic Soil Metabolism**	A,B,C,J	41319301
162-2	**Anaerobic Soil Metabolism**	A,B,C,J	41319302
162-3	**Anaerobic Aquatic Metabolism**		Not required
162-4	**Aerobic Aquatic Metabolism**		Not required
163-1	**Leaching/Adsorption/Desorption**	A,B,C,J	40762701
163-2	**Volatility - Lab**		Not required
163-3	**Volatility - Field**		Not required
164-1	**Terrestrial Field Dissipation**	A,B,C	41352101, 41352102
164-2	**Aquatic Field Dissipation**		Not required
164-3	**Forest Field Dissipation**		Not required
164-5	**Long Term Soil Dissipation**	A,B	42802101, 42802102, 42738701 42738702
165-1	**Confined Rotational Crop**	A,B	41645601
165-2	**Field Rotational Crop**		Not required
165-3	**Accumulation - Irrigated Crop**		Not required
165-4	**Bioaccumulation in Fish**		Not required

Guideline fulfilled; No MRID #’s for this study - review dated 2/14/85

REQUIREMENT		USE PATTERN	CITATION(S)
165-5	**Bioaccumulation - Aquatic NonTarget**		Waived
166-1	**Ground Water - Small Prospective**		Not required
166-2	**Ground Water - Small Retrospective**		Not required
166-3	**Ground Water - Irrigated Retrospective**		Not required
201-1	**Droplet Size Spectrum**	ALL	DATA GAP
202-1	**Drift Field Evaluation**	ALL	DATA GAP
RESIDUE CHEMISTRY			
171-3	**Directions for Use**	ALL	DATA GAP
171-4A	**Nature of Residue - Plants**	A,B	00065602, 00065604, 00091365, 00091366, 00091378, 00114411 42324301, 43492602, 43492603
171-4B	**Nature of Residue - Livestock**	A,B	00028596, 00028597, 00028598, 00028599, 00089748, 00114414 00114422, 00117783, 42324302

REQUIREMENT		USE PATTERN	CITATION(S)
171-4C	**Residue Analytical Method - Plants**	A,B	00025269, 00030476, 00032141 00032240, 00037058, 00090400 00112663, 00114411, 00114421, 00114446, 00114453, 00114465 00114466, 00138258, 40048401, 40098502, 41151508, 41151514 41151519, 41151522, 41151528, 42217402, 42217403, 42217404 42217405, 43492603
171-4D	**Residue Analytical Method - Animal**	A,B	00036306, 00037058, 00112663, 00114421, 00114422, 40943701 42217401, 43226902, 43226903, 43492601
171-4E	**Storage Stability**	A,B	00037057, 00113702, 40943702, 40943703, 41151511, 41151535 41151536, 41151537, 41151538, 41151539, 41151540, 41151541 42217401, 42217440 through 42217450
171-4F	**Magnitude of Residues - Potable H2O**		Not required
171-4G	**Magnitude of Residues in Fish**		Not required
171-4H	**Magnitude of Residues - Irrigated Crop**		Not required
171-4I	**Magnitude of Residues - Food Handling**		Not required
171-4J	**Magnitude of Residues - Meat/Milk/Poultry/Egg**	A,B	

REQUIREMENT		USE PATTERN	CITATION(S)
	- Milk and the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep		00036305, 00090978, 00114414, 00114422, 00117783
	- Eggs and the fat, meat, and meat byproducts of poultry		00038503, 40943704
171-4k	**Magnitude of Residue in Plants:**	A,B	
	<u>Root and Tuber Vegetables Group</u>		
	- Carrots		00030476
	- Cassava		00160250
	- Potatoes		00033612, 00091376, 00105060
	- Sugar beet roots		00113709, 41151514, 42217418
	- Taniers		00160250
	- Taro corms		41017901
	- Turnips, roots		00030476
	- Yams		00160250
	<u>Leaves of Root and Tuber Vegetables Group</u>		
	- Sugar beet tops		00113709, 41151514, 42217418
	- Taro foliage		DATA GAP
	<u>Bulb Vegetables Group</u>		
	- Onions, dry bulb and green		00113680, 00136330

REQUIREMENT	USE PATTERN	CITATION(S)
Leafy Green Vegetables (except Brassica veg.) Group		
- Lettuce		0114474, 00139741
- Rhubarb		00031863
Brassica Leafy Vegetables Group		
- Broccoli		00103245
- Cabbage		00103245
- Cauliflower		00030476
- Chinese cabbage		00030476
- Collards		00030476
Legume Vegetables Group		
- Beans (succulent, lima, snap and dry)		00030476, 00033223
- Guar		00114420
- Peas (succulent)		00030476
- Pigeon peas		00147206
- Soybean seed and aspirated grain fractions		00015768, 00025268, 00015769 00015771, 00032427, 00015772, 00015774, 00098579, 00015775, 00030676, 00015770, 00031742 00033530, 00015773, 00034112 00109728, 00114446, 41151524, 41151530, 42217426, 42217438, 43226904, DATA GAP for aspirated grain fractions

REQUIREMENT	USE PATTERN	CITATION(S)
Foliage of Legume Vegetable Group		
- Bean forage, hay, and straw		00030476, 00033223, 41151504, 42217409
- Pea vines and hay		00030476, 41151505, 42217410
- Soybeans forage and hay		00015768, 00025268, 00015769, 00030676, 00015770, 00032427, 00015771, 00033530, 00015772, 00034112, 00015773, 00098579, 00015774, 00109728, 00015775, 41151524, 41151527, 41151530, 42217426, 42217429, 42217438
Fruiting Vegetables (except cucurbits) Group		00030476, 00033223, 00059596, 41151507, 42217412
Cucurbit Vegetable Group		00027298, 00030476, 00033223, 41151503, 42217401
Citrus Fruits Group		00023329, 00027298, 00033695, 00035665, 00070779, 00070780, 00113821
Pome Fruits Group		
- Apples		00033695, 00035664, 00070779, 00113821
- Pears		00033695, 00035664, 00113821
Stone Fruits Group		
- Apricots		00035663, 00113821
- Cherries		00023329, 00033695, 00027965, 00113821
- Nectarines		00035663, 00113821

REQUIREMENT	USE PATTERN	CITATION(S)
- Peaches		00023329, 00035663, 00023883, 00033035, 00113709, 00033694, 00070780, 00027695, 00070784 00113821, 00033695
- Plums		00023329, 00035663, 00033035, 00113709, 00033695, 00114436, 42217431
Small Fruits and berries Group		00023329, 00113709, 00023883, 00033695, 00138258, 00070780 00113821, 00027968, 00114411,
Tree Nuts Group		00023329, 00035666, 00023883 00070780, 00027971, 00113821 00030929, 00033695
Cereal Grains Group		
- Barley grain		00114411
- Corn, field, grain and aspirated grain fractions		00015751, 00023512, 00015752, 00015955, 00030647, 00016441, 00031744, 00016442, 00033223, 00016444, 00093182, 00016445, 00023131, 41151523, 42217437, DATA GAP for aspirated grain fraction
- Corn, sweet		00030683, 00033223, 41151506
- Oat grain		00114411
- Rice grain		42670801
- Sorghum grain and aspirated grain fractions		00023131, 00026963, 00027178, 00033223, 00070872, 00113709, 41151531, 42217430
- Wheat grain and aspirated grain fractions		00027311, 00113693, 00114411 00140828, 41151525, 42217439

REQUIREMENT	USE PATTERN	CITATION(S)
Forage, Fodder, Hay, and Straw of Cereal Grains Group		
- Barley forage, hay, and straw		00114411
- Corn, field, forage and fodder		00015751, 00015752, 00015955, 00016441, 00016442, 00016444, 00016445, 00023131, 00023512, 00027972, 00027973, 00030647, 00031519, 00031744, 00033208, 00033223, 00093182, 41151523, 42217437
- Corn, sweet, forage, and fodder		00030683, 00033223, 41151506, 42217411
- Oat forage, hay, and straw		00114411
- Rice straw		42670801
- Sorghum forage and fodder		00026963, 00027178, 00070872, 41151531, 42217430
- Wheat forage, hay, and straw		00027311, 00114411, 41151525, 42217401, 42217439, 42961401 DATA GAP
Grass Forage, Fodder,and Hay Group		00033223, 00058773, 00114424, 00114466, 00117783, 00160817, 41151515, 41151516, 41151526, 42217419, 42217420, 42217425 DATA GAP
- Alfalfa		00032140, 00114464, 00058774 00114465, 00105061, 00114467 00114405, 00126671, 00114421 00128624, 00114424, 00165364, 41151501, 42217406
- Birdsfoot Trefoil		00114424, 41151542, 42217434
- Clover		00114424, 00117783, 41151509, 42217414
Miscellaneous Commodities		

REQUIREMENT	USE PATTERN	CITATION(S)
- Acerola	`	00128221
- Asparagus		00033532, 00113675
- Avacodos		GS0262-006
- Bananas		00113709, 00139733
- Coffee		00139734
- Cotton, seed, and gin byproducts		00031739, 00033612, 00091372, 42217401,DATA GAP for cotton gin byproducts
- Figs		00139735, 41151502, 42217407, 42961401
- Guava		00114419
- Hops, cones, dried		00113686, 41151521, 42217435
- Kiwifruit		00088195
- Mint hay		00137859
- Olives		00139737
- Papaya		00033695
- Passion Fruit		00037056
- Peanut nutmeats, hay, and hulls		40098501, 40098503
- Pineapple		00114411, 41151534, 42217432, 42217433
- Pistachios		00027550, 00035666, 00113699
- Safflower seed and forage		00114411
- Strawberries		00138258
- Sugarcane		00114411, 00114469

REQUIREMENT		USE PATTERN	CITATION(S)
	- Sunflower seeds and forage		00106570, 00114422, 41151512, 42217416
171-4(l)	**Magnitude of Residues in Processed Food/Feed**	A,B	
	- Citrus fruits		00033695
	- Coffee		41151529, 42217401, 42217428
	- Corn, field		00114426, 41151528, 42217401, 42217427
	- Cottonseed		00091372
	- Figs		41151502, 42217407, 42961401
	- Grapes		DATA GAP
	- Hops		41151521, 42217435
	- Mint		00137859, 42217401
	- Olives		41151522, 42217401
	- Pineapples		41151533, 42217432
	- Plums		41151532, 42217401, 42217431
	- Potatoes		41151508, 42217401, 42217413
	- Sorghum		00114421, 41151520, 42217424
	- Soybeans		00034112
	- Sugar beets		41151519, 42217401, 42217423
	- Sugarcane		00114411, 00114469, 41151518, 42217422
	- Sunflower		00114422
	- Tomatoes		41151510, 42217415

REQUIREMENT		USE PATTERN	CITATION(S)
	- Wheat		41151517, 42217401, 42217421
171-5	**Reduction of Residues**		N/A
171-6	**Proposed Tolerance**		N/A
171-7	**Support for Tolerance**		N/A
171-13	**Analtyical Reference Standard**		N/A

GUIDE TO APPENDIX C

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

   b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

   c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

GENERIC AND PRODUCT SPECIFIC DATA CALL-IN NOTICE

CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment A of this Notice, the Data Call-In Chemical Status Sheet, to submit certain data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 7; or

2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3 (for both generic and product specific data), the Requirements Status and Registrant's Response Form, (see section III-B); or

3. Why you believe EPA should not require your submission of data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2. All products are listed on both the generic and product specific Data Call-In Response Forms. Also included is a list of all registrants who were sent this Notice (Attachment 5).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this

information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 3-31-99).

This Notice is divided into six sections and seven Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

Section I - Why You are Receiving this Notice
Section II - Data Required by this Notice
Section III - Compliance with Requirements of this Notice
Section IV - Consequences of Failure to Comply with this Notice
Section V - Registrants' Obligation to Report Possible Unreasonable Adverse Effects
Section VI - Inquiries and Responses to this Notice

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions (Form A)
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions (Form B)
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Cost Share and Data Compensation Forms

SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient(s) and reevaluated the data needed to support continued registration of the subject active ingredient(s). This reevaluation identified additional data necessary to assess the health and safety of the continued use of products containing this active ingredient(s). You have been sent this Notice because you have product(s) containing the subject active ingredients.

SECTION II. DATA REQUIRED BY THIS NOTICE

II-A. DATA REQUIRED

The data required by this Notice are specified in the Requirements Status and Registrant's Response Forms: Attachment 3 (for both generic and product specific data requirements). Depending on the results of the studies required in this Notice, additional studies/testing may be required.

II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in the Requirements Status and Registrant's Response Forms (Attachment 3) within the timeframes provided.

II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (Telephone number: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160].

II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

You must use the correct forms and instructions when completing your response to this Notice. The type of Data Call-In you must comply with (Generic or Product Specific) is specified in item number 3 on the four Data Call-In forms (Attachments 2 and 3).

III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for generic and product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

III-B. OPTIONS FOR RESPONDING TO THE AGENCY

1. Generic Data Requirements

The options for responding to this Notice for generic data requirements are: (a) voluntary cancellation, (b) delete use(s), (c) claim generic data exemption, (d) agree to satisfy the generic data requirements imposed by this Notice or (e) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option, the Delete Use(s) option or the Generic Data Exemption option is presented below. A discussion of the various options available for satisfying the generic data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

Two forms apply to generic data requirements, one or both of which must be used in responding to the Agency, depending upon your response. These two forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, (contained in Attachments 2 and 3, respectively).

The Data Call-In Response Forms must be submitted as part of every response to this Notice. The Requirements Status and Registrant's Response Forms also must be submitted if you do not qualify for a Generic Data Exemption or are not requesting voluntary cancellation of your registration(s). Please note that the company's authorized representative is required to sign the first page of both Data Call-In Response Forms and the Requirements Status and Registrant's Response Forms (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation -

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit completed Generic and Product Specific Data Call-In Response Forms (Attachment 2), indicating your election of this option. Voluntary cancellation is item number 5 on both Data Call-In Response Form(s). If you choose this option, these are the only forms that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice, which are contained in Section IV-C.

b. Use Deletion -

You may avoid the requirements of this Notice by eliminating the uses of your product to which the requirements apply. If you wish to amend your registration to delete uses, you must submit the Requirements Status and Registrant's Response Form (Attachment 3), a completed application for amendment, a copy of your proposed amended labeling, and all other information required for processing the application. Use deletion is option number 7 under item 9 in the instructions for the Requirements Status and Registrant's Response Forms. You must also complete a Data Call-In Response Form by signing the certification, item number 8. Application forms for amending registrations may be obtained from the Registration Support Branch, Registration Division, Office of Pesticide Programs, EPA, by calling (703) 308-8358.

If you choose to delete the use(s) subject to this Notice or uses subject to specific data requirements, further sale, distribution, or use of your product after one year from the due date of your 90 day response, is allowed only if the product bears an amended label.

c. Generic Data Exemption -

Under section 3(c)(2)(D) of FIFRA, an applicant for registration of a product is exempt from the requirement to submit or cite generic data concerning an active ingredient if the active ingredient in the product is derived exclusively from purchased, registered pesticide products containing the active ingredient. EPA has concluded, as an exercise of its discretion, that it normally will not suspend the registration of a product which would qualify and continue to qualify for the generic data exemption in section 3(c)(2)(D) of FIFRA. To qualify, all of the following requirements must be met:

(i). The active ingredient in your registered product must be present solely because of incorporation of another registered product which contains the subject active ingredient and is purchased from a source not connected with you;

(ii). Every registrant who is the ultimate source of the active ingredient in your product subject to this DCI must be in compliance with the requirements of this Notice and must remain in compliance; and

(iii). You must have provided to EPA an accurate and current "Confidential Statement of Formula" for each of your products to which this Notice applies.

To apply for the Generic Data Exemption you must submit a completed Data Call-In Response Form, Attachment 2 and all supporting documentation. The Generic Data Exemption is item number 6a on the Data Call-In Response Form. If you claim a generic data

exemption you are not required to complete the Requirements Status and Registrant's Response Form. Generic Data Exemption cannot be selected as an option for responding to product specific data requirements.

If you are granted a Generic Data Exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Data Call-In Notice, the Agency will consider that both they and you are not compliance and will normally initiate proceedings to suspend the registrations of both your and their product(s), unless you commit to submit and do submit the required data within the specified time. In such cases the Agency generally will not grant a time extension for submitting the data.

d. Satisfying the Generic Data Requirements of this Notice

There are various options available to satisfy the generic data requirements of this Notice. These options are discussed in Section III-C.1. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the Requirements Status and Registrant's Response Form and item 6b on the Data Call-In Response Form. If you choose item 6b (agree to satisfy the generic data requirements), you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "GENERIC" in item number 3.

e. Request for Generic Data Waivers.

Waivers for generic data are discussed in Section III-D.1. of this Notice and are covered by options 8 and 9 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

2. Product Specific Data Requirements

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this Notice or (c) request a data waiver(s).

A discussion of how to respond if you choose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific data requirements of this Notice is contained in Section III-C.2. A discussion of options relating to requests for data waivers is contained in Section III-D.2.

Two forms apply to the product specific data requirements one or both of which must be used in responding to the Agency, depending upon your response. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form,

for product specific data (contained in Attachments 2 and 3, respectively). The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form also must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected. Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Reqistrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

a. Voluntary Cancellation

You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on both the Generic and Product Specific Data Call-In Response Forms. If you choose this option, you must complete both Data Call-In response forms. These are the only forms that you are required to complete.

If you choose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

b. Satisfying the Product Specific Data Requirements of this Notice.

There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C.2. of this Notice and comprise options 1 through 6 of item 9 in the instructions for the product specific Requirements Status and Reqistrant's Response Form and item numbers 7a and 7b (agree to satisfy the product specific data requirements for an MUP or EUP as applicable) on the product specific Data Call-In Response Form. Note that the options available for addressing product specific data requirements differ slightly from those options for fulfilling generic data requirements. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements. It is important to ensure that you are using the correct forms and instructions when completing your response to the Reregistration Eligibility Decision document.

c. Request for Product Specific Data Waivers.

Waivers for product specific data are discussed in Section III-D.2. of this Notice and are covered by option 7 of item 9 in the instructions for the Requirements Status and Registrant's Response Form. If you choose this option, you must submit the Data Call-In Response Form and the Requirements Status and Registrant's Response Form as well as any other

information/data pertaining to the option chosen to address the data requirement. Your response must be on the forms marked "PRODUCT SPECIFIC" in item number 3.

III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

1. Generic Data

If you acknowledge on the Generic Data Call-In Response Form that you agree to satisfy the generic data requirements (i.e. you select item number 6b), then you must select one of the six options on the Generic Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide you to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified timeframe (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data

If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG) and be in conformance with the requirements of PR Notice 86-5. In addition, certain studies require Agency approval of test protocols in advance of study initiation. Those studies for which a protocol must be submitted have been identified in the Requirements Status and Registrant's Response Form and/or footnotes to the form. If you wish to use a protocol which differs from the options discussed in Section II-C of this Notice, you must submit a detailed description of the proposed protocol and your reason for wishing to use it. The Agency may choose to reject a protocol not specified in Section II-C. If the Agency rejects your protocol you will be notified in writing, however, you should be aware that rejection of a proposed protocol will not be a basis for extending the deadline for submission of data.

A progress report must be submitted for each study within 90 days from the date you are required to commit to generate or undertake some other means to address that study requirement, such as making an offer to cost share or agreeing to share in the cost of developing that study. This 90-day progress report must include the date the study was or will be initiated and, for studies to be started within 12 months of commitment, the name and address of the laboratory(ies) or individuals who are or will be conducting the study.

In addition, if the time frame for submission of a final report is more than 1 year, interim reports must be submitted at 12 month intervals from the date you are required to commit to generate or otherwise address the requirement for the study. In addition to the other information specified in the preceding paragraph, at a minimum, a brief description of current activity on and the status of the study must be included as well as a full description of any problems encountered since the last progress report.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports or protocols. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2. Agreement to Share in Cost to Develop Data

If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms.

Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3. Offer to Share in the Cost of Data Development

If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept the offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost-sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed to or, failing agreement, to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant normally will be subject to initiation of suspension proceedings, unless you commit to submit, and do submit, the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4. Submitting an Existing Study

If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly Met:

a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3 'Raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3, means "any material derived from a test system for examination or analysis."

b. Health and safety studies completed after May 1984 also must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants also must certify at the time of submitting the existing study that such GLP information is available for post May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.

c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data usually are not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If EPA has previously reviewed a protocol for a study you are submitting, you must identify any action taken by the Agency on the protocol and must indicate, as part of your certification, the manner in which all Agency comments, concerns, or issues were addressed in the final protocol and study.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5. Upgrading a Study

If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option also should be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally, your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria, as well as a certification regarding protocol compliance with Agency requirements.

Option 6. Citing Existing Studies

If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable, or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core-minimum." For ecological effects studies, the classification generally would be a rating of "core." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option, you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

2. Product Specific Data

If you acknowledge on the product specific Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select option 7a or 7b), then you must select one of the six options on the Requirements Status and Reqistrant's Response Form related to data production for each data requirement. Your option selection should be entered under item number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

(1) I will generate and submit data within the specified time-frame (Developing Data)
(2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
(3) I have made offers to cost-share (Offers to Cost Share)
(4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
(5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
(6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been
submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1. Developing Data -- The requirements for developing product specific data are the same as those described for generic data (see Section III.C.1, Option 1) except that normally no protocols or progress reports are required.

Option 2. Agree to Share in Cost to Develop Data -- If you enter into an agreement to cost share, the same requirements apply to product specific data as to generic data (see Section III.C.1, Option 2). However, registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your

product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option.

Option 3. Offer to Share in the Cost of Data Development --The same requirements for generic data (Section III.C.I., Option 3) apply to this option. This option only applies to acute toxicity and certain efficacy data as described in option 2 above.

Option 4. Submitting an Existing Study -- The same requirements described for generic data (see Section III.C.1., Option 4) apply to this option for product specific data.

Option 5. Upgrading a Study -- The same requirements described for generic data (see Section III.C.1., Option 5) apply to this option for product specific data.

Option 6. Citing Existing Studies -- The same requirements described for generic data (see Section III.C.1., Option 6) apply to this option for product specific data.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, and in the generic data requirements section (III.C.1.), as appropriate.

III-D REQUESTS FOR DATA WAIVERS

1. Generic Data

There are two types of data waiver responses to this Notice. The first is a request for a low volume/minor use waiver and the second is a waiver request based on your belief that the data requirement(s) are not appropriate for your product.

a. Low Volume/Minor Use Waiver

Option 8 under item 9 on the Requirements Status and Registrant's Response Form. Section 3(c)(2)(A) of FIFRA requires EPA to consider the appropriateness of requiring data for low volume, minor use pesticides. In implementing this provision, EPA considers low volume pesticides to be only those active ingredients whose total production volume for all pesticide registrants is small. In determining whether to grant a low volume, minor use waiver, the Agency will consider the extent, pattern and volume of use, the economic incentive to conduct the testing, the importance of the pesticide, and the exposure and risk from use of the pesticide. If an active ingredient is used for both high volume and low volume uses, a low volume exemption will not be approved. If all uses of an active ingredient are low volume and the combined volumes for all uses are also low, then an exemption may be granted, depending on review of other information outlined below. An

exemption will not be granted if any registrant of the active ingredient elects to conduct the testing. Any registrant receiving a low volume minor use waiver must remain within the sales figures in their forecast supporting the waiver request in order to remain qualified for such waiver. If granted a waiver, a registrant will be required, as a condition of the waiver, to submit annual sales reports. The Agency will respond to requests for waivers in writing.

To apply for a low volume, minor use waiver, you must submit the following information, as applicable to your product(s), as part of your 90-day response to this Notice:

(i). Total company sales (pounds and dollars) of all registered product(s) containing the active ingredient. If applicable to the active ingredient, include foreign sales for those products that are not registered in this country but are applied to sugar (cane or beet), coffee, bananas, cocoa, and other such crops. Present the above information by year for each of the past five years.

(ii) Provide an estimate of the sales (pounds and dollars) of the active ingredient for each major use site. Present the above information by year for each of the past five years.

(iii) Total direct production cost of product(s) containing the active ingredient by year for the past five years. Include information on raw material cost, direct labor cost, advertising, sales and marketing, and any other significant costs listed separately.

(iv) Total indirect production cost (e.g. plant overhead, amortized plant and equipment) charged to product(s) containing the active ingredient by year for the past five years. Exclude all non-recurring costs that were directly related to the active ingredient, such as costs of initial registration and any data development.

(v) A list of each data requirement for which you seek a waiver. Indicate the type of waiver sought and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vi) A list of each data requirement for which you are not seeking any waiver and the estimated cost to you (listed separately for each data requirement and associated test) of conducting the testing needed to fulfill each of these data requirements.

(vii) For each of the next ten years, a year-by-year forecast of company sales (pounds and dollars) of the active ingredient, direct production costs of product(s) containing the active ingredient (following the parameters in item 2 above), indirect production costs of product(s) containing the active ingredient (following the parameters in item 3 above), and costs of data development pertaining to the active ingredient.

(viii) A description of the importance and unique benefits of the active ingredient to users. Discuss the use patterns and the effectiveness of the active ingredient relative to

registered alternative chemicals and non-chemical control strategies. Focus on benefits unique to the active ingredient, providing information that is as quantitative as possible. If you do not have quantitative data upon which to base your estimates, then present the reasoning used to derive your estimates. To assist the Agency in determining the degree of importance of the active ingredient in terms of its benefits, you should provide information on any of the following factors, as applicable to your product(s): (a) documentation of the usefulness of the active ingredient in Integrated Pest Management, (b) description of the beneficial impacts on the environment of use of the active ingredient, as opposed to its registered alternatives, (c) information on the breakdown of the active ingredient after use and on its persistence in the environment, and (d) description of its usefulness against a pest(s) of public health significance.

Failure to submit sufficient information for the Agency to make a determination regarding a request for a low volume/minor use waiver will result in denial of the request for a waiver.

b. Request for Waiver of Data

Option 9, under Item 9, on the Requirements Status and Registrant's Response Form. This option may be used if you believe that a particular data requirement should not apply because the requirement is inappropriate. You must submit a rationale explaining why you believe the data requirements should not apply. You also must submit the current label(s) of your product(s) and, if a current copy of your Confidential Statement of Formula is not already on file you must submit a current copy.

You will be informed of the Agency's decision in writing. If the Agency determines that the data requirements of this Notice are not appropriate to your product(s), you will not be required to supply the data pursuant to section 3(c)(2)(B). If EPA determines that the data are required for your product(s), you must choose a method of meeting the requirements of this Notice within the time frame provided by this Notice. Within 30 days of your receipt of the Agency's written decision, you must submit a revised Requirements Status and Registrant's Response Form indicating the option chosen.

2. Product Specific Data

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the product specific Requirements Status and Registrant's Response Form. Product specific data

requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

SECTION IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.

2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.

3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.

4. Failure to submit on the required schedule acceptable data as required by this Notice.

5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.

7. Withdrawal of an offer to share in the cost of developing required data.

8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:

i. Inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form.

ii. Fulfill the commitment to develop and submit the data as required by this Notice; or

iii. Otherwise take appropriate steps to meet the requirements stated in this Notice,

unless you commit to submit and do submit the required data in the specified time frame.

9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1) EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.

2) EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.

3) EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding generally would not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You also must explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden, the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on a case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due, unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3-year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice must include completed Data Call-In Response Forms (Attachment 2)and completed Requirements Status and Registrant's Response Forms (Attachment 3), for both (generic and product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Generic and Product Specific Data Call-In Response Forms need be submitted.

The Office of Compliance (OC) of the Office of Enforcement and Compliance Assurance (OECA), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Director
Special Review and
Reregistration Division

Attachments

The Attachments to this Notice are:

1 - Data Call-In Chemical Status Sheet
2 - Generic Data Call-In and Product Specific Data Call-In Response Forms with Instructions
3 - Generic Data Call-In and Product Specific Data Call-In Requirements Status and Registrant's Response Forms with Instructions
4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
5 - List of Registrants Receiving This Notice
6 - Confidential Statement of Formula, Cost Share and Data Compensation Forms

PARAQUAT DICHLORIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Paraquat Dichloride.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of 0262. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), (6) a list of registrants receiving this DCI (Attachment 6) and (7) the Cost Share and Data Compensation Forms in replying to this 0262 Product Specific Data Call-In (Attachment 7). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Paraquat Dichloride are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Paraquat Dichloride are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Paraquat Dichloride products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Venus Eagle at (703) 308-8045.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Venus Eagle
Chemical Review Manager Team 81
Product Reregistration Branch
Special Review and Reregistration Branch 7508W
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460

RE: **PARAQUAT DICHLORIDE**

PARAQUAT DICHLORIDE DATA CALL-IN CHEMICAL STATUS SHEET

INTRODUCTION

You have been sent this Generic Data Call-In Notice because you have product(s) containing Paraquat Dichloride.

This Generic Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Paraquat Dichloride. This attachment is to be used in conjunction with (1) the Generic Data Call-In Notice, (2) the Generic Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 2), (4) a list of registrants receiving this DCI (Attachment 4), (5) the EPA Acceptance Criteria (Attachment 5), and (6) the Cost Share and Data Compensation Forms in replying to this Paraquat Dichloride Generic Data Call In (Attachment F). Instructions and guidance accompany each form.

DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the generic database for Paraquat Dichloride are contained in the Requirements Status and Registrant's Response, Attachment C. The Agency has concluded that additional product chemistry data on Paraquat Dichloride are needed. These data are needed to fully complete the reregistration of all eligible Paraquat Dichloride products.

INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the generic data requirements and procedures established by this Notice, please contact Ruby Whiters at (703) 308-8079.

All responses to this Notice for the generic data requirements should be submitted to:

Ruby Whiters, Chemical Review Manager
Reregistration Branch
Special Review and Registration Division (H7508W)
Office of Pesticide Programs
U.S. Environmental Protection Agency
Washington, D.C. 20460
RE: PARAQUAT DICHLORIDE

Instructions For Completing The "Data Call-In Response Forms" For The Generic And Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Data Call-In Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-Ins as part of EPA's Reregistration Program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Data Call-In Response Forms." Only registrants responsible for generic data have been sent the generic data response form. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both generic and product specific data, instructions for completing these forms are different. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms with a number of items. DO NOT use these forms for any other active ingredient.

Items 1 through 4 have been preprinted on the form. Items 5 through 7 must be completed by the registrant as appropriate. Items 8 through 11 must be completed by the registrant before submitting a response to the Agency.

The public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, Mail Code 2136, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Management and Budget, Paperwork Reduction Project 2070-0107, Washington, D.C. 20503.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS**: This item identifies your company name, number and address.

Item 2. **ON BOTH FORMS:** This item identifies the case number, case name, EPA chemical number and chemical name.

Item 3. **ON BOTH FORMS:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

Item 4. **ON BOTH FORMS:** This item identifies the EPA product registrations relevant to the data call-in. Please note that you are also responsible for informing the Agency of your response regarding any product that you believe may be covered by this Data Call-In but that is not listed by the Agency in Item 4. You must bring any such apparent omission to the Agency's attention within the period required for submission of this response form.

Item 5. **ON BOTH FORMS:** Check this item for each product registration you wish to cancel voluntarily. If a registration number is listed for a product for which you previously requested voluntary cancellation, indicate in Item 5 the date of that request. Since this Data Call-In requires both generic and product specific data, you must complete item 5 on both Data Call-In response forms. You do not need to complete any item on the Requirements Status and Registrant's Response Forms.

Item 6a. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and you are eligible for a Generic Data Exemption for the chemical listed in Item 2 and used in the subject product. By electing this exemption, you agree to the terms and conditions of a Generic Data Exemption as explained in the Data Call-In Notice.

If you are eligible for or claim a Generic Data Exemption, enter the EPA registration Number of each registered source of that active ingredient that you use in your product.

Typically, if you purchase an EPA-registered product from one or more other producers (who, with respect to the incorporated product, are in compliance with this and any other outstanding Data Call-In Notice), and incorporate that product into all your products, you may complete this item for all products listed on this form. If, however, you produce the active ingredient yourself, or use any unregistered product (regardless of the fact that some of your sources are registered), you may not claim a Generic Data Exemption and you may not select this item.

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 6b. **ON THE GENERIC DATA FORM:** Check this Item if the Data Call-In is for generic data as indicated in Item 3 and if you are agreeing to satisfy the generic data requirements of this Data Call-In. Attach the Requirements Status and Registrant's Response Form that indicates how you will satisfy those requirements.

NOTE: **Item 6a and 6b are not applicable for Product Specific Data.**

Item 7a. **ON THE PRODUCT SPECIFIC DATA FORM:** For each manufacturing use product (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

Item 7b. For each end use product (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "yes."

FOR BOTH MUP and EUP products

You should also respond "yes" to this item (7a for MUP's and 7b for EUP's) if your product is identical to another product and you qualify for a data exemption. You must provide the EPA registration numbers of your source(s); do not complete the Requirements Status and Registrant's Response form. Examples of such products include repackaged products and Special Local Needs (Section 24c) products which are identical to federally registered products.

If you are requesting a data waiver, answer "yes" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with option 7 (Waiver Request) for each study for which you are requesting a waiver.

NOTE: **Item 7a and 7b are not applicable for Generic Data.**

INSTRUCTIONS FOR COMPLETING THE DATA CALL-IN RESPONSE FORMS
Generic and Product Specific Data Call-In

Item 8. **ON BOTH FORMS:** This certification statement must be signed by an authorized representative of your company and the person signing must include his/her title. Additional pages used in your response must be initialled and dated in the space provided for the certification.

Item 9. **ON BOTH FORMS:** Enter the date of signature.

Item 10. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 11. **ON BOTH FORMS:** Enter the phone number of your company contact.

Note: You may provide additional information that does not fit on this form in a signed letter that accompanies your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

Instructions For Completing The "Requirements Status and Registrant's Response Forms" For The Generic and Product Specific Data Call-In

INTRODUCTION

These instructions apply to the Generic and Product Specific "Requirements Status and Registrant's Response Forms" and are to be used by registrants to respond to generic and product specific Data Call-In's as part of EPA's reregistration program under the Federal Insecticide, Fungicide, and Rodenticide Act. If you are an end-use product registrant only and have been sent this DCI letter as part of a RED document you have been sent just the product specific "Requirements Status and Registrant's Response Forms." Only registrants responsible for generic data have been sent the generic data response forms. **The type of Data Call-In (generic or product specific) is indicated in item number 3 ("Date and Type of DCI") on each form.**

Although the form is the same for both product specific and generic data, instructions for completing the forms differ slightly. Specifically, options for satisfying product specific data requirements do not include (1) deletion of uses or (2) request for a low volume/minor use waiver. Please read these instructions carefully before filling out the forms.

EPA has developed these forms individually for each registrant, and has preprinted these forms to include certain information unique to this chemical. DO NOT use these forms for any other active ingredient.

Items 1 through 8 have been preprinted on the form. Item 9 must be completed by the registrant as appropriate. Items 10 through 13 must be completed by the registrant before submitting a response to the Agency.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 1. **ON BOTH FORMS:** This item identifies your company name, number and address.

Item 2. **ON THE GENERIC DATA FORM:** This item identifies the case number, case name, EPA chemical number and chemical name.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the case number, case name, and the EPA Registration Number of the product for which the Agency is requesting product specific data.

Item 3. **ON THE GENERIC DATA FORM:** This item identifies the type of Data Call-In. The date of issuance is date stamped.

ON THE PRODUCT SPECIFIC DATA FORM: This item identifies the type of Data Call-In. The date of issuance is also date stamped. Note the unique identifier number (ID#) assigned by the Agency. This ID number must be used in the transmittal document for any data submissions in response to this Data Call-In Notice.

Item 4. **ON BOTH FORMS:** This item identifies the guideline reference number of studies required. These guidelines, in addition to the requirements specified in the Data Call-In Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart c.

Item 5. **ON BOTH FORMS:** This item identifies the study title associated with the guideline reference number and whether protocols and 1, 2, or 3-year progress reports are required to be submitted in connection with the study. As noted in Section III of the Data Call-In Notice, 90-day progress reports are required for all studies.

If an asterisk appears in Item 5, EPA has attached information relevant to this guideline reference number to the Requirements Status and Registrant's Response Form.

INSTRUCTIONS FOR COMPLETING THE "REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORMS"

Generic and Product Specific Data Call-In

Item 6. **ON BOTH FORMS:** This item identifies the code associated with the use pattern of the pesticide. In the case of efficacy data (product specific requirement), the required study only pertains to products which have the use sites and/or pests indicated. A brief description of each code follows:

A Terrestrial food
B Terrestrial feed
C Terrestrial non-food
D Aquatic food
E Aquatic non-food outdoor
F Aquatic non-food industrial
G Aquatic non-food residential
H Greenhouse food
I Greenhouse non-food crop
J Forestry
K Residential
L Indoor food
M Indoor non-food
N Indoor medical
O Indoor residential

Item 7. **ON BOTH FORMS:** This item identifies the code assigned to the substance that must be used for testing. A brief description of each code follows:

EUP	End-Use Product
MP	Manufacturing-Use Product
MP/TGAI	Manufacturing-Use Product and Technical Grade Active Ingredient
PAI	Pure Active Ingredient
PAI/M	Pure Active Ingredient and Metabolites
PAI/PAIRA	Pure Active Indredient or Pute Active Ingredient Radiolabelled
PAIRA	Pure Active Ingredient Radiolabelled
PAIRA/M	Pure Active Ingredient Radiolabelled and Metabolites
PAIRA/PM	Pure Active Ingredient Radiolabelled and Plant Metabolites
TEP	Typical End-Use Product
TEP ___%	Typical End-Use Product, Percent Active Ingredient Specified
TEP/MET	Typical End-Use Product and Metabolites
TEP/PAI/M	Typical End-Use Product or Pure Active Ingredient and Metabolites
TGAI	Technical Grade Active Ingredient
TGAI/PAI	Technical Grade Active Ingredient or Pure Active Ingredient

TGAI/PAIRA Technical Grade Active Ingredient or Pure Active Ingredient Radiolabelled
TGAI/TEP Technical Grade Active Ingredient or Typical End-Use Product
MET Metabolites
IMP Impurities
DEGR Degradates
* See: guideline comment

Item 8. This item completed by the Agency identifies the time frame allowed for submission of the study or protocol identified in item 5.

ON THE GENERIC DATA FORM: The time frame runs from the date of your receipt of the Data Call-In notice.

ON THE PRODUCT SPECIFIC DATA FORM: The due date for submission of product specific studies begins from the date stamped on the letter transmitting the Reregistration Eligibility Decision document, and not from the date of receipt. However, your response to the Data Call-In itself is due 90 days from the date of receipt.

Item 9. **ON BOTH FORMS:** Enter the appropriate Response Code or Codes to show how you intend to comply with each data requirement. Brief descriptions of each code follow. The Data Call-In Notice contains a fuller description of each of these options.

Option 1. **ON BOTH FORMS:** (Developing Data) I will conduct a new study and submit it within the time frames specified in item 8 above. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice and that I will provide the protocols and progress reports required in item 5 above.

Option 2. **ON BOTH FORMS:** (Agreement to Cost Share) I have entered into an agreement with one or more registrants to develop data jointly. By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to sharing in the cost of developing data as outlined in the Data Call-In Notice.

However, for Product Specific Data, I understand that this option is available for acute toxicity or certain efficacy data **ONLY** if the Agency indicates in an attachment to this notice that my product is similar enough to another product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension.

Option 3. **ON BOTH FORMS:** (Offer to Cost Share) I have made an offer to enter into an agreement with one or more registrants to develop data jointly. I am also submitting a completed "Certification of offer to Cost Share in the Development of Data" form. I am submitting evidence that I have made an offer to another registrant (who has an obligation to submit data) to share in the cost of that data. I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice apply as well.

However, for Product Specific Data, I understand that this option is available only for acute toxicity or certain efficacy data and only if the Agency indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option.

Option 4. **ON BOTH FORMS:** (Submitting Existing Data) I will submit an existing study by the specified due date that has never before been submitted to EPA. By indicating that I have chosen this option, I certify that this study meets all the requirements pertaining to the conditions for submittal of existing data outlined in the Data Call-In Notice and I have attached the needed supporting information along with this response.

Option 5. **ON BOTH FORMS:** (Upgrading a Study) I will submit by the specified due date, or will cite data to upgrade a study that EPA has classified as partially acceptable and potentially upgradeable. By indicating that I have chosen this option, I certify that I have met all the requirements pertaining to the conditions for submitting or citing existing data to upgrade a study described in the Data Call-In Notice. I am indicating on attached correspondence the Master Record Identification Number (MRID) that EPA has assigned to the data that I am citing as well as the MRID of the study I am attempting to upgrade.

Option 6. **ON BOTH FORMS:** (Citing a Study) I am citing an existing study that has been previously classified by EPA as acceptable, core, core minimum, or a study that has not yet been reviewed by the Agency. If reviewed, I am providing the Agency's classification of the study.

However, for Product Specific Data, I am citing another registrant's study. I understand that this option is available **ONLY** for acute toxicity or certain efficacy data and **ONLY** if the cited study was conducted on my product, an identical product or a product which the Agency has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the MRID or Accession number (s). If I

cite another registrant's data, I will submit a completed "Certification With Respect To Data Compensation Requirements" form.

FOR THE GENERIC DATA FORM ONLY: The following three options (Numbers 7, 8, and 9) are responses that apply only to the "Requirements Status and Registrant's Response Form" for generic data.

Option 7. (Deleting Uses) I am attaching an application for amendment to my registration deleting the uses for which the data are required.

Option 8. (Low Volume/Minor Use Waiver Request) I have read the statements concerning low volume-minor use data waivers in the Data Call-In Notice and I request a low-volume minor use waiver of the data requirement. I am attaching a detailed justification to support this waiver request including, among other things, all information required to support the request. I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

Option 9. (Request for Waiver of Data) I have read the statements concerning data waivers other than lowvolume minor-use data waivers in the Data Call-In Notice and I request a waiver of the data requirement. I am attaching a rationale explaining why I believe the data requirements do not apply. I am also submitting a copy of my current labels. (You must also submit a copy of your Confidential Statement of Formula if not already on file with EPA). I understand that, unless modified by the Agency in writing, the data requirement as stated in the Notice governs.

FOR PRODUCT SPECIFIC DATA: The following option (number 7) is a response that applies to the "Requirements Status and Registrant's Response Form" for product specific data.

Option 7. (Waiver Request) I request a waiver for this study because it is inappropriate for my product. I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my only opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will not be required to supply the data pursuant to Section 3(c) (2) (B) of FIFRA. If the Agency denies my waiver request, I must choose a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within 30 days-of my receipt of the Agency's written decision, submit a revised "Requirements Status" form specifying the option chosen. I also understand that the deadline for submission of data as specified by the original Data Call-In notice will not change.

Item 10. **ON BOTH FORMS:** This item must be signed by an authorized representative of your company. The person signing must include his/her title, and must initial and date all other pages of this form.

Item 11. **ON BOTH FORMS:** Enter the date of signature.

Item 12. **ON BOTH FORMS:** Enter the name of the person EPA should contact with questions regarding your response.

Item 13. **ON BOTH FORMS:** Enter the phone number of your company contact.

NOTE: You may provide additional information that does not fit on this form in a signed letter that accompanies this your response. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily cancelled this

EPA'S BATCHING OF PARAQUAT DICHLORIDE PRODUCTS FOR MEETING ACUTE TOXICITY DATA REQUIREMENTS FOR REREGISTRATION

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing paraquat dichloride as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Notwith-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant

depends on another's data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

Eight products were found which contain paraquat dichloride as an active ingredient. In addition, a number of Special Local Need (SLN) registrations based on these products were found. The products have been placed into three batches and a "no batch" category in accordance with the active and inert ingredients, type of formulation and current labeling. Table 1 identifies the batched products. Table 2 lists the products which have been placed in the "no batch" category.

Table 1

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
1	10182-115	43.5	Liquid
	10182-362	43.5	Liquid
	10182-372	43.5	Liquid
	NM95000300	43.5	Liquid
	OK95000400	43.5	Liquid
	TX95001000	43.5	Liquid
	48273-6	43.5	Liquid
2	10182-111	30.3	Liquid
	NC82001000	29.1	Liquid
	NM94000300	30.3	Liquid
	OK94000400	30.3	Liquid
	SC82001100	29.1	Liquid
	TX81003202	29.1	Liquid
	TX93001400	29.1	Liquid
	TX94001100	30.3	Liquid
	TX96000500	30.3	Liquid
	10182-280	37.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	AL94000500	37.05	Liquid
	AR95000200	37.0	Liquid
	CA91002100	37.05	Liquid
	CA91002200	37.05	Liquid
	CA91002300	37.05	Liquid
	CA91002400	37.05	Liquid
	CA91003100	37.05	Liquid
	CA91003600	37.05	Liquid
	CA92000600	37.05	Liquid
	CT90000100	37.05	Liquid
	CT91000400	37.05	Liquid
	DE94000200	37.0	Liquid
	DE96000200	37.0	Liquid
	FL90000900	37.05	Liquid
	FL91000300	37.05	Liquid
	FL91000600	37.05	Liquid
	FL96000900	37.0	Liquid
	GA94000600	37.05	Liquid
	GA95000800	37.0	Liquid
	HI91000100	37.05	Liquid
	HI91001000	37.05	Liquid
	HI92000800	37.05	Liquid
	ID92001000	37.05	Liquid
	ID92001100	37.05	Liquid
	ID93000600	37.0	Liquid
	ID95000800	37.0	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	KY95000100	37.0	Liquid
	LA94000700	37.0	Liquid
	LA95000300	37.0	Liquid
	MD95000100	37.0	Liquid
	ME95000700	37.0	Liquid
	MI91000900	37.05	Liquid
	MN90000400	37.05	Liquid
	MN94000600	37.05	Liquit
	MO95000300	37.0	Liquid
	MS95000500	37.0	Liquid
	MT94000500	37.05	Liquid
	NC95000300	37.0	Liquid
	NC95000600	37.0	Liquid
	NH90000100	37.05	Liquid
	NH92000100	37.05	Liquid
	NJ90000500	37.05	Liquid
	NC91000200	37.05	Liquid
	NV91000300	37.05	Liquid
	NV93000500	37.05	Liquid
	NV93000501	37.05	Liquid
	OH90000600	37.0	Liquid
	OH91000100	37.05	Liquid
	OR91002300	37.05	Liquid
	OR93000900	37.05	Liquid
	OR93001900	37.05	Liquid
	PA90000100	37.05	Liquid

Batch	EPA Reg. No.	% Active Ingredient	Formulation Type
	PA96000400	37.0	Liquid
	SC95000700	37.0	Liquid
	SD94000500	37.0	Liquid
	TN94000300	37.05	Liquid
	TN94000800	37.0	Liquid
	TN95000200	37.0	Liquid
	TX90000900	37.0	Liquid
	VA93000600	37.05	Liquid
	VA94001200	37.0	Liquid
	VA96000500	37.0	Liquid
	WA91004400	37.05	Liquid
	WA91004500	37.0	Liquid
	WA91004800	37.05	Liquid
	WA91004900	37.05	Liquid
	WA93001400	37.05	Liquid
	WA94003700	37.05	Liquid
	WA95000700	37.0	Liquid
	WI90000400	37.05	Liquid
	WY95000200	37.0	Liquid
3	10182-103	23.2	Liquid
	AR95000900	23.2	Liquid
	LA95001500	23.2	Liquid
	MS95001400	23.2	Liquid
	OH88000200	23.2	Liquid
	PA87000200	20.4	Liquid
	TN94000700	23.2	Liquid

The following table lists a product that was considered not to be similar and was not placed in any batch. The registrant of this product is responsible for meeting the acute toxicity data requirements separately.

Table 2 (No Batch)

EPA Reg. No.	% Active Ingredient	Formulation Type
10182-120	29.42 paraquat dichloride 10.66 diuron	Liquid

Products in Batch 1 may be supported by the data cited in the RED on the 45.6% technical concentrate. Data on crystalline paraquat dichloride may be bridged to support Batch I.

Products in Batch 2 and Batch 3 may also bridge data from Batch 1 or from the RED for support.

LIST OF REGISTRANTS RECEIVING THIS DCI
(Please remove this page and insert registrants mailing list)

Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

a. All the blocks on the form must be filled in and answered completely.

b. If any block is not applicable, mark it N/A.

c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.

d. All applicable information which is on the product specific data submission must also be reported on the CSF.

e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.

f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.

g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.

h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.

i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.

j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).

k. All the items under column 13.b. must total 100 percent.

1. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.

m. The upper and lower certified limits for ail active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.

n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

Confidential Business Information: Does Not Contain National Security Information (E.O. 12065) Form Approved. OMB No. 2070-0060. Approval Expires 2/28/94

EPA

United States Environmental Protection Agency
Office of Pesticide Programs (TS-767)
Washington, DC 20460

Confidential Statement of Formula

A. ☐ Basic Formulation ☐ Alternate Formulation

B. Page of

See Instructions on Back

1. Name and Address of Applicant/Registrant *(Include ZIP Code)*

2. Name and Address of Producer *(Include ZIP Code)*

3. Product Name

4. Registration No./File Symbol

5. EPA Product Mgr/Team No.

6. Country Where Formulated

7. Pounds/Gal or Bulk Density

8. pH

9. Flash Point/Flame Extension

EPA USE ONLY	10. Components in Formulation *(List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)*	11. Supplier Name & Address	12. EPA Reg. No.	13. Each Component in Formulation a. Amount	13. b. % by Weight	14. Certified Limits % by Weight a. Upper Limit	14. b. Lower Limit	15. Purpose in Formulation

16. Typed Name of Approving Official

17. Total Weight 100%

18. Signature of Approving Official

19. Title

20. Phone No. *(Include Area Code)*

21. Date

EPA Form 8570-4 (Rev. 12-90) **Previous editions are obsolete.** If you can photocopy this, please submit an additional copy. White - EPA File Copy (original) Yellow - Applicant copy

United States Environmental Protection Agency
Washington, D.C. 20460

Certification of Offer to Cost Share in the Development of Data

Form Approved
OMB No. 2070-0106, 2070-0057
Approval Expires 3-31-99

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below:

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firms on the following date(s):

Name of Firm(s)	Date of Offer

Certification:

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date

Name and Title (Please Type or Print)

EPA Form 8570-32 (5/91) Replaces EPA form 8580 which is obselete

United States Environmental Protection Agency
Washington, DC 20460

Form Approved
OMB No. 2070-0107, 2070-0057
Approval Expires 3-31-99

CERTIFICATION WITH RESPECT TO DATA COMPENSATION REQUIREMENTS

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

Please fill in blanks below.

Company Name	Company Number

Product Name	EPA Reg. No.

I Certify that:

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.

2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)

[ ] The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"

3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature	Date

Name and Title (Please Type or Print)

GENERAL OFFER TO PAY: I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature	Date

Name and Title (Please Type or Print)

EPA Form 8570-31 (4-96)

The following is a list of available documents for Paraquat Dichloride that my further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic
File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Venus Eagle at (703)-308-8045.

1. Appendix A.

2. PR Notice 86-5.

3. PR Notice 91-2 (pertains to the Label Ingredient Statement).

4. A full copy of this RED document.

5. A copy of the fact sheet for Paraquat Dichloride.

The following documents are part of the Administrative Record for Paraquat Dichloride and may included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.

2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.

2. EPA Acceptance Criteria