United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
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EPA

Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED)

Diquat Dibromide

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

April 25, 2002

CERTIFIED MAIL

This is the Environmental Protection Agency's (hereafter referred to as EPA or the Agency) "Report of FQPA Tolerance Reassessment Eligibility Decision (TRED) for **diquat dibromide**. A Notice of Availability, soliciting public comment for a thirty day period will be published in the *Federal Register* (FR) shortly.

The Federal Food, Drug and Cosmetic Act (FFDCA), as amended, requires EPA to reassess all the tolerances for registered chemicals in effect on or before the date of the enactment of the Food Quality Protection Act (FQPA) in August of 1996 against the new safety standard adopted in the FQPA. In reassessing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made. A reregistration eligibility decision (RED) for diquat dibromide was completed in July 1995, prior to FQPA enactment. Therefore, it needed to be updated to reassess the tolerances under the FQPA standard.

The Agency has evaluated the dietary risk associated with diquat dibromide and has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to diquat dibromide when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, no mitigation measures are needed, and the forty-six tolerances established for residues of diquat dibromide in/on raw agricultural commodities are now considered reassessed as safe under section 408(q) of the FFDCA.

FQPA requires that EPA consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health

effect, as would a higher level of exposure to any of the other substances individually. EPA did not perform a cumulative risk assessment as part of this reregistration review of diquat dibromide, because the Agency has not determined that there are any other chemical substances that have a mechanism of toxicity common with that of diquat dibromide. If EPA identifies other substances that share a common mechanism of toxicity with diquat dibromide, then a cumulative risk assessment will be conducted that includes diquat dibromide once the final framework EPA will use for conducting cumulative risk assessments is available. Further, EPA is in the process of developing criteria for characterizing and testing endocrine disrupting chemicals and plans to implement an Endocrine Disruptor Screening Program. Diquat dibromide will be reevaluated at that time and additional studies may be required.

The Agency's human health findings for the pesticide diquat dibromide were discussed in a closure conference call and are summarized in the enclosed chemical overview of the risk assessments. The risk assessments and other documents pertaining to the diquat dibromide tolerance reassessment decision are listed at the end of this document and are available on the Internet at http://www.epa.gov/pesticides/reregistration/diquat_dibromide.htm and the public docket for viewing.

The Codex Commission has established several maximum residue limits (MRLs) for residues of diquat dibromide in/on various raw agricultural and processed commodities. The Codex MRLs are expressed in terms of diquat dibromide *per se*. The Codex MRLs and the U.S. tolerances will be incompatible when the U.S. tolerance expression for plant commodities is revised to include both residues of diquat dibromide.

Tolerances are established for residues of diquat dibromide in/on raw agricultural commodities as defined in 40 CFR 180.226. The tolerance reassessment for diquat dibromide recommends raising tolerances for fat, meat byproducts, and meat for the following: cattle, goats, hogs, horses, poultry, and sheep. The tolerance reassessment also recommends raising tolerances for avocados, cottonseed, eggs, citrus fruits, small fruits, hops, fruiting vegetables, leafy vegetables, seed/pod vegetables, fish, forage grasses, forage legumes and shellfish.

New tolerance recommendations have been established for alfalfa seed, clover seed, sorghum grain, soybean hulls and soybean seed. The Agency recommends the revocation of tolerances for sugarcane and potable water because there are no diquat dibromide registered products for direct application to sugarcane and the Agency no longer establishes a tolerance for potable water. The EPA's Office of Water has designated a maximum contaminant level goal (MCLG) for potable water. Table I summarizes EPA's tolerance reassessment decision.

Table I: Diquat Dibromide Tolerance Reassessment Summary.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Tolerances Listed Under 40 CFR §180.226(a)			
Cattle, fat	0.02	0.05	The established tolerance for ruminant, swine and egg commodities may be raised to achieve compatibility with the Codex MRL. *[Cattle, meat byproducts]* *[Goat, meat byproducts]* *[Hog, meat byproducts]* *[Horse, meat byproducts]*
Cattle, mbyp	0.02	0.05	
Cattle, meat	0.02	0.05	
Eggs	0.02	0.05	
Goats, fat	0.02	0.05	
Goats, mbyp	0.02	0.05	
Goats, meat	0.02	0.05	
Hogs, fat	0.02	0.05	
Hogs, mbyp	0.02	0.05	
Hogs, meat	0.02	0.05	
Horses, fat	0.02	0.05	
Horses, mbyp	0.02	0.05	
Horses, meat	0.02	0.05	
Milk	0.02	0.02	
Potatoes	0.1	0.1	*[Potato]*
Poultry, fat	0.02	0.05	The established tolerance for poultry fat, meat and meat byproducts may be raised to achieve compatibility with Codex. *[Poultry, meat byproducts]*
Poultry, mbyp	0.02	0.05	
Poultry, meat	0.02	0.05	
Sheep, fat	0.02	0.05	The established tolerance for ruminant commodities may be raised to achieve compatibility with Codex. *[Sheep, meat byproducts]*
Sheep, mbyp	0.02	0.05	
Sheep, meat	0.02	0.05	
Sugarcane	0.05	Revoke	No registered direct application uses of diquat dibromide on sugarcane exist.
Additional Tolerances That Need To Be Proposed Under 40 CFR §180.226(a)			
Alfalfa seed	None	3.0	*[Alfalfa, seed]*
Clover seed	None	2.0	*[Clover, seed]*
Sorghum, grain	None	2.0	*[Sorghum, grain, grain]*
Sorghum, grain, aspirated grain fractions	None	TBD	*[Aspirated grain fractions]*
Soybean, seed	None	0.2	*[Soybean, seed]*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Soybean, aspirated grain fractions	None	TBD	*[Aspirated grain fractions]*
Tolerances Listed Under 40 CFR §180.226(a)(2)(I) (Irrigation Uses)			
Avocados	0.02	0.2	Higher tolerances are needed based on available data. *[Avocado]* *[Cotton, undelinted seed]*
Cottonseed	0.02	0.2	
Cucurbits	0.02	0.02	*[Vegetable, cucurbit, group]*
Fish	0.1	2.0	Higher tolerances are needed based on available data.
Fruits, citrus	0.02	0.05	*[Fruit, citrus, group]*
Fruits, pome	0.02	0.02	*[Fruit, pome, group]*
Fruits, small	0.02	0.05	*[Fruit, small and berry group]*
Fruits, stone	0.02	0.02	*[Fruit, stone, group]*
Grain, crops	0.02	0.02	*[Grain, cereal, group]* and *[Grain, cereal, forage, fodder, and straw, group]*
Grasses, forage	0.1	0.2	*[Grass, forage, fodder and hay, group]*
Hops	0.02	0.2	Higher tolerances are needed based on available data. *[Hop, dried cones]*
Legumes, forage	0.1	0.2	*[Vegetable, foliage of legume, group]*
Nuts	0.02	0.02	*[Nut, tree, group]*
Shellfish	0.1	20	Higher tolerances are required based on available data.
Sugarcane	0.02	0.2	Higher tolerances are required based on available data.
Vegetables, fruiting	0.02	0.05	Higher tolerances are required based on available data. *[Vegetable, fruiting, group]*
Vegetables, leafy	0.02	0.05	Higher tolerances are required based on available data. *[Vegetable, leafy, except Brassica, group]* and *[Vegetable, brassica, leafy, group]*
Vegetables, root crop	0.02	0.02	*[Vegetable, root and tuber, group]*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	Comment/*Correct Commodity Definition*
Vegetables, seed and pod	0.02	0.05	*[Vegetable, seed and pod, group]*
Potable water	0.01	Revoke	A maximum contaminant level of 0.02 mg/L for residues of diquat in potable water has been established.
Processed potatoes (including potato chips)	0.5	0.5	Based on the 5.3x concentration factor observed in dried potato.[Expressed in terms of potatoes, granules/flakes at 0.50 ppm and potato chips at 0.50 ppm.] *[Potato, chips]* *[Potato, granules/flakes]*
Processed potato waste	1.0	1.0	*[Potato, processed potato waste]*
Tolerances Listed Under 40 CFR §180.226(a)(3)			
Banana	0.05	0.05	Tolerance with no US Registration / *Banana*
Coffee	0.05	0.05	Tolerance with no US Registration / *Coffee*
Additional Tolerances That Need To Be Proposed			
Soybean, hulls	None	0.6	A tolerance is needed based on a concentration factor of ~3x in soybean hulls. *[Soybean, hulls]*

Table II lists generic and/or product specific data requirements for this chemical. Note that you will be sent a Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 3(c)(2)(B) data call-in (DCI) letter in a separate mailing.

Table II: Data Requirements.

Guideline Number	Guideline Name	Products Required	Comment
860.1200	Directions for Use	All	
860.1500	Magnitude of residue in plant studies for sorghum and soybean aspirated grain fractions.		The soybean processing data indicate that residues of diquat dibromide concentrated 2.6x in soybean hulls processed from soybean bearing detectable residues. No concentration was observed in other soybean processed fractions. The sorghum processing data indicate that residues of diquat dibromide concentrated 4x in sorghum dry milling bran fraction processed from sorghum bearing detectable residues. Residue data are not needed for flour at this time, since sorghum flour is used exclusively in the U.S. as a component for drywall, and not as either a human or animal feed item. The Agency reserves the right to require data if needed at a later date.
830.1700	Batch Analysis	100-1062	Due to presence of ethylene dibromide (EDB).
830.7050	UV/Visible Absorption	100-1062	Data will be used to satisfy requirement for 100-1062 and 100-1063.

If you have questions on this document, please contact the Chemical Review Manager, Tyler Lane, at (703) 305-2737.

Sincerely,

Lois A. Rossi

Lois A. Rossi, Director
Special Review and
Reregistration Division

2 Enclosures:
Diquat Dibromide Overview (4/2/02).
Diquat Dibromide Summary (4/2/02).

Relevant Documents:

1) Use Closure Memo. Tyler Lane (10/31/01).
2) HED Risk Assessment for Tolerance Reassessment Eligibility Document (TRED). B. Daiss (4/25/02, D281890).
3) Tier I Drinking Water and Aquatic Ecological Exposure Assessments for Diquat Dibromide. J Breithaupt (3/5/02, D281199).

Diquat Dibromide Summary

Uses

- Diquat dibromide is a non-selective contact algicide, defoliant, desiccant, and herbicide. As an herbicide/algicide it is used to control broadleaf and grassy weeds in non-crop (including residential) and aquatic areas. As a desiccant/defoliant, it is used on seed crops and potatoes. Its largest use is as a desiccant on potato crops, while other food applications include use as a desiccant on crops grown for seed that are used for feed.

- Diquat dibromide may be applied pre-plant, at plant, post-plant, and post-harvest at a maximum application rate of 4.0 lbs diquat cation/A (up to 12 lbs diquat cation/surface acre for certain Special Local Need (SLN) labels when application to water 12 ft. in depth).

- On average, less than 500,000 lbs of active ingredient (a.i.) are applied annually.

Health Effects

- Diquat dibromide exhibits low acute toxicity via the oral and inhalation routes of exposure, but exhibits moderate to severe acute toxicity via the dermal route of exposure. Diquat dibromide is not an acute skin irritant, nor a dermal sensitizer, but it is considered a moderate to severe eye irritant.

- Diquat dibromide acute dietary risk assessments are based on clinical signs of systemic toxicity and decreased body weight gain. Chronic dietary risk assessments are based on cataracts and decreased adrenal and epididymide weights. Epididymides are tubules at the back of the testis which aid in sperm storage and maturation.

Risks

Dietary Food Risks are not of concern

- The acute and chronic Population Adjusted Doses are well below the Agency's level of concern for all population sub-groups.

Drinking Water Risks are low

- The acute and chronic estimated environmental concentrations (EECs) of diquat dibromide in ground and surface water are low and not of concern to the Agency.

- Diquat dibromide is essentially immobile in the environment, indicating that it will most likely associate with the soil and sediment instead of water.

Residential Risks are low

- Residential handler risks are not of concern.

- Post-application recreational risks to golfers and swimmers in treated lakes are not of concern.

Aggregate Risks are moderate

- The acute and chronic aggregate risks (food and drinking water) are considered highly conservative and not of concern to the Agency.

- The short term aggregate risks (food, drinking water and residential/recreational) for adults and children are not of concern to the Agency.

Worker Risk Decisions are to be issued separately

- Occupational risks are not evaluated as part of the tolerance reassessment decision. The technical registrant, Syngenta, has requested residential broadcast spray uses be added to diquat dibromide labels and a reevaluation of worker Personal Protective Equipment (PPE) requirements specified in the 1995 Reregistration Evaluation Decision (RED). The Agency will address any PPE adjustments separately, as an amendment to the 1995 RED.

Ecological Risks

- Ecological risk management decisions were made as part of the 1995 diquat dibromide RED. No new data have been received to warrant a reevaluation.

OVERVIEW OF DIQUAT DIBROMIDE RISK ASSESSMENT

April 18, 2002

Introduction

This document summarizes EPA's human health findings and conclusions for the pesticide diquat dibromide, as presented fully in the documents: *Diquat Dibromide-HED Risk Assessment for Tolerance Reassessment Eligibility Document (TRED), April 25, 2002*; and: *Tier I Drinking Water and Aquatic Ecological Exposure Assessments for Diquat Dibromide, March 5, 2002.* The purpose of this summary is to assist the reader by identifying the key features and findings of this risk reassessment in order to better understand the conclusions reached in the tolerance reassessment. This summary was developed in response to comments and requests from the public, which indicated that the risk assessments (and other like documents) were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to the use of different assessment formats.

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996, requires EPA to review all the tolerances for registered chemicals in effect on or before the date of the enactment of FQPA. In reviewing these tolerances, the Agency must consider, among other things, aggregate risks from non-occupational sources of pesticide exposure, whether there is increased susceptibility to infants and children, and the cumulative effects of pesticides with a common mechanism of toxicity. The tolerances are considered reassessed once the safety finding has been made or a revocation occurs. A reregistration eligibility decision (RED) for diquat dibromide was completed in July 1995, prior to FQPA enactment; therefore it needed to be updated to consider the provisions of the Act.

FFDCA, as amended, requires that the Agency, when considering whether to establish, modify, or revoke a tolerance, consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." At this time, the Agency has not identified any pesticides which share a common mechanism of toxicity with diquat dibromide. Additionally, the Agency is currently in the process of developing criteria for characterizing and testing endocrine disrupting chemicals, in accordance with FQPA. EPA plans to implement an Endocrine Disruptor Screening Program at a later date; diquat dibromide will be reevaluated at that time and additional testing may be required.

The risk assessment, and additional supporting documents for diquat dibromide are available on the Internet at http://www.epa.gov/pesticides/reregistration/diquat_dibromide.htm and are available in the Pesticide public docket for viewing. Because the dietary risks posed by

the use of diquat dibromide are low and not of concern to the Agency, the report on FQPA tolerance reassessment progress and interim risk management decision for diquat dibromide will be announced in the Federal Register and no further actions are warranted at this time. The Agency conducted a closure conference call to describe the risk and tolerance reassessment findings that will be presented in the TRED.

Further, occupational risks are not reevaluated as part of the tolerance reassessment decision. The technical registrant, Syngenta, has submitted biomonitoring information to refine data regarding diquat dibromide and requested the Agency reduce worker Personal Protective Equipment (PPE) requirements and reinstate the residential broadcast spray use cancelled in the 1995 diquat dibromide RED. The Agency has reviewed these requests and will address any necessary changes in PPE or broadcast spray uses in a separate document as an amendment to the 1995 RED.

Use Profile

- **Manufacturer/Technical Registrant:** Syngenta Crop Protection, Inc.
- **Type of Pesticide:** Non-selective contact algicide, defoliant, desiccant, and herbicide.
- **Target Pests:** Algae; aquatic and terrestrial weeds; pre-harvest and post-harvest desiccant/defoliant.
- **Crop Use Sites:**

  Food Applications: Potatoes; crops grown for seed (alfalfa, clover, sorghum and soybean); directed spray around trees, vines, small fruits and vegetables.

  Non-food Applications: Pre-harvest desiccant (carrot, radish, and turnip grown for seed); post-harvest desiccant (cantaloupe, cucumber, pepper, squash, tomato and watermelon).
- **Other Use Sites:** Aquatic areas (for aquatic weed control), greenhouses, ornamental seed crops, turf/lawn maintenance, golf course turf, non-agricultural fields, rights of way.
- **Formulations:** Ready-to-use solution and soluble concentrate/liquid.
- **Methods of Application:** Aircraft, broadcast sprayers (golf courses), directed sprayers, foammaking generators, groundbooms, high and low pressure handwands, spot treatments, sprinkler cans, subwater injections, trailing hoses and trigger spray bottles.
- **Timing:** Pre-harvest and post-harvest.

- **Use Rates:** 0.93 - 4.0 lbs diquat cation/A (up to 12 lbs diquat cation/surface acre for certain Special Local Need (SLN) labels when application to water 12 ft. in depth).

- **Annual Pounds Applied:** <500,000 lbs a.i./year, mainly for aquatic uses and as pre-harvest desiccant/defoliant on potatoes.

Human Health Risk Assessment

Acute Dietary (Food) Risk

Acute dietary risk from food is calculated considering what is eaten in one day. Dietary exposure that is less than 100% of the acute Population Adjusted Dose (aPAD) does not exceed the Agency's level of concern. The aPAD is the Reference Dose (RfD) adjusted for the FQPA Safety Factor. The acute RfD is the dose at which an individual could be exposed on any given day with no expected adverse health effects.

The acute dietary risk assessment for diquat dibromide was conducted using a conservative deterministic (Tier I) analysis at the 95th percentile (assuming tolerance level residues, based on existing and/or tolerances reassessed as part of the 1995 RED, and 100 % crop treated (%CT)). The acute dietary exposure analysis is based on the Dietary Exposure Evaluation Model (DEEM™). The DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989-92 Continuing Surveys for Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

- The acute dietary risk estimate is <1% of the aPAD for all population subgroups.

- The acute dietary (food) endpoint was derived from an acute neurotoxicity study in rats. The No Observed Adverse Effect Level (NOAEL) is 75 mg/kg/day and the Lowest Observed Adverse Effect Level (LOAEL) is 150 mg/kg/day, based on clinical signs and decreased body-weight gain.

- An uncertainty factor (UF) of 100 was applied to account for interspecies extrapolation (10x) and intraspecies variability (10x).

- The FQPA safety factor was removed (reduced to 1x) because: 1) the toxicology data base is complete; 2) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; 3) a developmental neurotoxicity study is not required; and 4) the dietary (food and drinking water) and residential exposure assessments will not underestimate the potential exposures for infants and children.

- The aPAD and the acute RfD are identical at 0.75 mg/kg/day because the FQPA Safety Factor was removed (reduced to 1x) for acute exposures.

Chronic Dietary (Food) Risk

Chronic dietary risk from food is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime[1]. Dietary exposure that is less than 100% of the chronic Population Adjusted Dose (cPAD) does not exceed the Agency's level of concern. The cPAD is the Reference Dose (RfD) adjusted for the FQPA Safety Factor. The chronic RfD is the dose at which an individual could be exposed over the course of a lifetime with no expected adverse health effects.

The chronic dietary analysis for diquat dibromide was conducted using a conservative deterministic (Tier I) analysis (assuming tolerance level residues, based on existing and/or reassessed tolerances, and 100% crop treated (%CT)). The chronic dietary exposure analysis is based on the Dietary Exposure Evaluation Model (DEEM™). A three-day average of consumption for each subpopulation is combined with tolerance level residues in commodities to determine average exposures in mg/kg/day.

- Chronic dietary (food) risk is not of concern for any population subgroup. For the most highly exposed subpopulation, children (1-6 years), exposure is 62% of the cPAD; while exposure for the general U.S. population is 38% of the cPAD.

- The chronic dietary endpoint was derived from a chronic toxicity study in dogs. The NOAEL is 0.5 mg/kg/day and the LOAEL is 2.5 mg/kg/day, based on unilateral cataracts in females, and decreased adrenal and epididymide weights in males.

- An uncertainty factor of 100 was applied to account for interspecies extrapolation (10x) and intraspecies variability (10x).

- The FQPA Safety Factor was removed (reduced to 1x) for chronic exposures for reasons mentioned in the acute dietary risk section; therefore the cPAD and the chronic RfD are identical at 0.005 mg/kg/day.

Cancer Risk

Based on available data, diquat dibromide is not carcinogenic, and has been classified as a Group E "not likely" carcinogen; therefore, a cancer dietary risk assessment was not conducted.

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[1]For an infant, the chronic risk is calculated over 1 year; for a child (ages 1-6) over 6 years; for females of child bearing age (ages 13-50) over 37 years.

Drinking Water Dietary Risk

Drinking water exposure to pesticides can occur through surface and/or ground water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or monitoring data, if available, to estimate those risks. Modeling is carried out in tiers of further refinement, but is designed to provide high-end estimates of exposure. The Agency conducted a Tier I drinking water assessment for terrestrial uses of diquat dibromide using both monitoring and modeling data to find estimated environmental concentrations (EECs) in surface and ground water. As diquat dibromide is applied directly to water for aquatic weed control, the Agency also conducted a Tier I drinking water assessment for aquatic uses of diquat dibromide.

Based on environmental fate data, diquat dibromide strongly adsorbs to soil, sediment, aquatic vegetation, and organic matter, and is persistent but essentially immobile in the environment. Diquat dibromide does not hydrolyze or photodegrade and is resistant to microbial degradation under aerobic and anaerobic conditions.

- The FQPA Index Reservoir Screening Tool (FIRST) model was used to estimate environmental concentrations in drinking water from surface water contaminated by terrestrial use of diquat. The terrestrial surface water EECs generated by FIRST ranged from 6.3-13.2 ppb for peak exposure and 0.2-0.4 ppb for annual average exposure.

- The Office of Water (OW) monitored for diquat dibromide at intake pumps at drinking water utilities that use surface water and ground water. In eight states, 0.06 percent of combined surface water and ground water systems reported exceedences of the 20 ppb Maximum Contaminate Level (MCL). Based on the municipal monitoring data, the Agency used the EECs of 20 ppb for both peak and average terrestrial uses for groundwater. The Agency used the same EECs for both surface and groundwater contaminated by aquatic uses of diquat dibromide because the chemical is used near wells located next to lakes and ponds resulting in interaction between surface water and ground water.

- Acute Drinking Water. For aquatic uses, the highest EEC for diquat dibromide in either surface or ground water is 20 ppb, based on the highest detected concentration in monitoring data found in the OW studies and the established MCL. For terrestrial uses, the highest EEC is 13.2 ppb in surface water, based on FIRST modeling from diquat dibromide use on trees, vines, small fruits and vegetables. The recommended acute EEC for groundwater is 20 ppb based on OW monitoring data and the MCL. These acute EECs represent exposure levels that are below the Agency's risk level of concern.

- Chronic Drinking Water. For aquatic uses, the highest EEC for diquat dibromide in either surface or ground water is 20 ppb based on monitoring data and the MCL from the

EPA's Office of Water. For terrestrial uses, the highest EEC is 0.4 ppb in surface water based on modeling data from diquat dibromide use on trees, vines, small fruits and vegetables. The recommended chronic EEC for groundwater is 20 ppb based on monitoring data and the MCL established by the EPA's Office of Water. These chronic EECs represent exposure levels that are below the Agency's risk level of concern.

Residential/Nonoccupational Risk

Diquat dibromide is currently registered for general weed control on turf (spot treatment only), in backyard ponds, on garden sites, and landscapes. As previously noted, at the request of the technical registrant, the Agency also reevaluated residential broadcast spray uses, based on the submission of biomonitoring data from the technical registrant. The results will be addressed separately, as an amendment to the 1995 RED. This assessment evaluated both residential handlers who can mix, load and apply diquat dibromide, and post-application exposures to adults and children who may come in contact with treated turf or water bodies. Residential risk is measured by a Margin of Exposure (MOE) which determines how close the residential exposure comes to a No Observed Adverse Effect Level (NOAEL) taken from animal studies.

- The Agency assumed that residents and recreational users can be exposed to diquat dibromide for short-term (1-30 days) durations.

- The short-term dermal and oral endpoints were derived from a rabbit oral developmental study. A NOAEL of 1 mg/kg/day and LOAEL of 3 mg/kg/day were established based on body weight loss and decreased food consumption. For the dermal endpoint, a 4.1% dermal absorption factor was used to account for differences in absorption between the oral and dermal routes based on a dermal absorption study. Therefore, the effective dermal NOAEL is 24 mg/kg/day for this assessment.

- A human dermal absorption study cited by the registrant in comments submitted to EPA estimated dermal absorption to be about 0.3% (Feldman RJ and Maibach HI, "Percutaneous penetration of some pesticides and herbicides in man" Tox. Appl. Pharm. 28 126-132, 1974). In this risk assessment, dermal absorption is assumed to be 4.1%, based on a rat dermal absorption study. The new dermal absorption data provides evidence of further conservatism in the residential assessment. Use of the 0.3% dermal absorption factor in a refinement of the existing risk assessment for dermal exposure scenarios would further increase the estimated MOEs.

- The short-term inhalation endpoint was derived from 21 day rat inhalation study. A NOAEL of 0.024 mg/kg/day and LOAEL of 0.117 mg/kg/day were established based on increased lung weight and mottling and reddening of lungs.

- Due to differing endpoints for dermal and inhalation, exposures from different routes are not combined and separate MOEs were calculated. However, dermal and oral exposure pathways share common toxicological endpoints, and therefore these exposures and risks were combined for children contacting treated turf.

- An uncertainty factor of 100 was applied (10x for inter-species extrapolation and 10x for intra-species variation) to calculate risks for exposure from dermal, inhalation and oral routes.

- The FQPA safety factor was removed (reduced to 1x) for the reasons mentioned in the acute dietary risk section. All MOEs were greater than 100 and do not exceed the Agency's level of concern.

- The Agency assessed spot treatment applications using a trigger pump sprayer to residential lawns, gardens, driveways, fence lines and around buildings. Residential handler risks are not of concern for spot treatments using 0.125 to 5 gallons of formulated product. Dermal MOEs ranged from 330 to 24,400, while inhalation MOEs ranged from 360 to >12,000,000, based on application method and rate. These risks are not of concern to the Agency.

- Post-application dermal risks to adult golfers, and adult and child swimmers are not of concern. Golfer MOEs range from 3,200 to 7,100, while swimmer MOEs range from 180-630 for children and 770-10,000 for adults, based on application method and rate. In order to assess potential exposures to swimmers who re-enter treated ponds and lakes, the Agency used the Swimmer Exposure Assessment Model (SWIMODEL). The SWIMODEL was developed for estimating the human exposure doses to the pesticides and toxic pollutants in swimming pools. The Agency considers this assessment conservative due to the variance between the closed water system found in swimming pools and the flowing water system found in most lakes and ponds.

Aggregate Risk

Aggregate risk examines the combined risk from exposure through food, drinking water, and nonoccupational residential uses. This assessment evaluates aggregate risks for acute, short-term, and chronic exposures. Generally, all risks from these exposures must be less than 100% of the aPAD and cPAD or greater than the target MOE of 100. For diquat dibromide, because water monitoring data are available, the Agency incorporated water exposures in the aggregate risk estimates. For this assessment, aggregate risks are presented as MOEs. MOEs greater than 100 do not exceed the Agency's risk level of concern.

- The acute aggregate risk is the estimated risk associated with combined acute dietary (food) and drinking water exposures. Children (1-6 years) are the most highly exposed

subpopulation and yield the lowest acute aggregate MOE of 2388, which does not exceed the Agency's risk level of concern.

- The short-term aggregate risk is the estimated risk associated with the combined chronic dietary (food), drinking water, and dermal exposure from swimming. The short-term aggregate risk was calculated using the recommended chronic EEC for groundwater of 20 ppb and the most highly exposed subpopulation, children swimmers.

- The short-term aggregate MOE for high-end toddler exposure (dietary + drinking water + dermal) is 150 and is therefore not of concern to the Agency. The Agency considers this assessment conservative because it assumes tolerance level residues, highly conservative drinking water concentrations and a dermal absorption factor of 4.1%.

- The chronic aggregate risk is the estimated risk associated with the combined chronic dietary (food) and drinking water exposures. No chronic residential scenario has been identified. The calculated chronic aggregate MOEs for all population subgroups are above the target MOE of 100 except for children (1-6 years). The MOE for this subgroup is 98. Due to the conservative nature of the assessment (i.e., use of tolerance level residues and 100% crop treated), this MOE is not of concern to the Agency.

Occupational Risk

The technical registrant, Syngenta, has requested a reevaluation of worker Personal Protective Equipment (PPE) requirements specified in the 1995 Reregistration Evaluation Decision (RED) for diquat dibromide, based on the submission of biomonitoring data. The Agency is reassessing occupational exposure and associated PPE requirements separate from this tolerance reassessment decision as an amendment to the 1995 RED.

Ecological Risk

Ecological risk management decisions were made as part of the 1995 diquat dibromide. No new data have been received to warrant a reevaluation.

Summary of Pending Data

No data are pending at this time.