UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION, FARMWORKER ASSOCIATION OF FLORIDA, INC., THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH, FARMWORKER JUSTICE, ALIANZA NACIONAL DE CAMPESINAS, PESTICIDE ACTION NETWORK NORTH AMERICA, CENTER FOR BIOLOGICAL DIVERSITY, and TOXIC FREE NORTH CAROLINA, *Petitioners*, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, in his official capacity as Administrator of the United States Environmental Protection Agency, *Respondents*.	No. _____

PETITION FOR REVIEW

Pursuant to Rule 15 of the Federal Rules of Appellate Procedure and section 16(b) of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136n(b), Petitioners California Rural Legal Assistance Foundation, Farmworker Association of Florida, Inc., The Michael J. Fox Foundation for Parkinson's

Research, Farmworker Justice, Alianza Nacional de Campesinas, Pesticide Action Network North America, Center for Biological Diversity, and Toxic Free North Carolina petition this Court to review and set aside, in whole or in part, Respondent United States Environmental Protection Agency's order titled ***Paraquat Dichloride, Interim Registration Review Decision: Case Number 0262***. The challenged order was signed on July 13, 2021, and, pursuant to 40 C.F.R. § 23.6, was entered for the purpose of judicial review on July 27, 2021. A copy of the order is attached as Exhibit A to this petition.

DATED: September 24, 2021

Respectfully submitted,

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Petitioners California Rural Legal Assistance Foundation, Farmworker Association of Florida, Inc., The Michael J. Fox Foundation for Parkinson's Research, Farmworker Justice, Alianza Nacional de Campesinas, Pesticide Action Network North America, Center for Biological Diversity, and Toxic Free North Carolina state that they are non-profit organizations. None of the petitioners has a parent corporation and no publicly held corporation owns 10% or more of any petitioner organization's stock.

DATED: September 24, 2021

Respectfully submitted,

s/ Jonathan Kalmuss-Katz

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Exhibit A

Paraquat Dichloride

Interim Registration Review Decision
Case Number 0262

July 2021

Approved by: _____

Elissa Reaves, Ph.D.
Director
Pesticide Re-evaluation Division

Date: 07/13/2021

Table of Contents

I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Interim Registration Review Decision (ID) for paraquat dichloride (PC Codes 061601 and 061603, case 0262), herein referred to as paraquat. In a registration review decision under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Agency determines whether a pesticide continues to meet FIFRA's registration standard.[1] Where appropriate, the Agency may issue an interim registration review decision before completing a registration review.[2] Among other things, the interim registration review decision may determine that new risk mitigation measures are necessary, lay out interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review.[3] For more information on paraquat, see EPA's public docket (EPA-HQ-OPP-2011-0855) at www.regulations.gov.

FIFRA[4] mandates the continuous review of existing pesticides. All pesticides distributed or sold in the United States must be registered by EPA based on scientific data showing that they will not cause unreasonable adverse effects to human health or to the environment when used as directed on product labeling. In 2006, the Agency began implementing the registration review program. EPA will review each registered pesticide every 15 years. Through the registration review program, the Agency intends to verify that all registered pesticides continue to meet the registration standard as the ability to assess and reduce risk evolves and as policies and practices change. By periodically re-evaluating pesticides as science, public policy, and pesticide-use practices change, the Agency ensures that the public can continue to use products in the marketplace that do not present unreasonable adverse effects. For more information on the registration review program, see http://www.epa.gov/pesticide-reevaluation.

The Agency is issuing an ID for paraquat so that it can (1) move forward with aspects of the registration review that are complete and (2) implement interim risk mitigation (see Appendices A and B). EPA is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (the Services) to improve the consultation process for national threatened and endangered (listed) species for pesticides under the Endangered Species Act (ESA).[5] The Agency has not yet fully evaluated paraquat's risks to federally-listed species. However, EPA will complete its listed-species assessment and any necessary consultation with the Services before completing the paraquat registration review. Before completing registration review, EPA will also complete endocrine screening for paraquat under the Federal Food, Drug, and Cosmetic Act (FFDCA).[6]

Paraquat is a fast-acting, non-selective herbicide used for the control of broadleaf and grass weeds in agricultural and non-agricultural use sites. It also functions as a plant growth regulator (PGR), most commonly as a desiccant. Paraquat is a contact herbicide that inhibits

[1] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.57.
[2] 40 C.F.R. §§ 155.56, 155.58.
[3] 40 C.F.R. § 155.56.
[4] As amended by the Food Quality Protection Act (FQPA) of 1996, Pub. L. No. 104-170, 110 Stat. 1489.
[5] Endangered Species Act (ESA) § 7, 16 U.S.C. § 1536.
[6] Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), 21 U.S.C. § 346a(p).

photosynthesis, desiccating and destroying plant cell membranes within hours of application. Paraquat is only formulated as a liquid and can be used pre-plant or pre-emergence (to the crop); at planting; post-emergence, as a desiccant or harvest aid; and as a post-harvest desiccant. Paraquat is a restricted use pesticide (RUP) that can only be used by certified applicators, and there are no paraquat products registered for homeowner or residential use.

Products containing paraquat are registered for use on terrestrial food, non-food, feed, forestry, commercial, and nursery use sites and can be applied with aerial, ground, and handheld equipment. The agricultural use sites with the highest number of acres treated are soybeans, cotton, and corn. Non-agricultural use sites include rights-of-way, pastures, commercial buildings, and storage yards. EPA first registered paraquat in 1964 and published the Reregistration Eligibility Decision (RED) for paraquat in 1997. Although paraquat is an RUP, there is a history of users illegally transferring paraquat into beverage containers, leading to incidents of accidental ingestion that often resulted in death. In 2016, EPA issued an interim mitigation decision[7] to impose several restrictions intended to reduce the number and severity of human health incidents caused by the accidental ingestion of paraquat.

This document is organized in five sections:

- *Introduction* (summarizing the ID, providing updates since the proposed interim decision, and responding to public comments);
- *Use and Usage* (discussing how and why paraquat is used);
- *Scientific Assessments* (summarizing EPA's risk and benefits assessments, updating or revising previous risk assessments, and discussing risk characterization);
- *Interim Registration Review Decision* (presenting EPA's decision, regulatory rationale, and any mitigation measures to address risks of concern); and
- *Next Steps and Timeline* (discussing how and when EPA intends to complete of this registration review).

A. Updates to the Proposed Interim Decision

In October 2020, EPA published the proposed interim decision (PID) for paraquat. The Agency has made the following changes to the PID in this ID:

- Updated the risk estimates for paraquat mixers and loaders in Section III.A.1. The Agency has incorporated new data generated by the Agricultural Handler Exposure Task Force (AHETF)[8] regarding levels of exposure to occupational handlers using closed loading systems. The new data resulted in increased dermal and inhalation MOEs for mixing/loading scenarios and these updates have resulted in changes to the risk assessment conclusions as well as to the mitigation specified in this ID. For more information on these updates, see *Paraquat: HED Response to Comments on the*

[7] Paraquat Dichloride Human Health Mitigation Decision. https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0112. Dec 15, 2016.
[8] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#ahetf

Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates and Section III.A.1.

- Adjusted the mitigation regarding aerial applications of paraquat. In the paraquat PID, the Agency proposed prohibiting aerial application for all uses except for cotton desiccation. This prohibition is no longer warranted based on the new AHETF data. The updated risk estimates in the *Paraquat: HED Response to Comments on the Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates* indicate there are no longer any risks of concern to occupational handlers for typical-acreage aerial applications (up to 350 acres). As such, EPA is introducing a new mitigation measure as an alternative to the prohibition of aerial application for all uses except cotton desiccation. The new mitigation measure limits aerial applications to a maximum of 350 acres per applicator within a 24-hour period for all uses except cotton desiccation. For more information on this mitigation measure, see Section IV.A.1.
- Updated the residential buffer requirement to include all uses. Since the Agency is no longer prohibiting aerial application for all uses except cotton desiccation, the potential risks of concern to bystanders must be mitigated by other means. To fully mitigate these risks, the Agency has determined that a no-spray buffer of 50-75 feet from residential areas for all aerial applications is necessary. The size of the buffer is dependent on the application rate. For more information on the updates to this mitigation measure, see Section IV.A.2.
- Added a prohibition of the use of human flaggers to the list of mitigation measures. Since the Agency is no longer prohibiting aerial application for all uses except cotton desiccation, the potential risks of concern to human flaggers must be mitigated by other means. To fully mitigate these risks, the Agency is prohibiting the use of human flaggers. For more information on this mitigation measure, see Section IV.A.3.
- Added a statement clarifying proper rinsing instructions for closed system containers with extraction probes. The new data from AHETF also showed that removal of unrinsed extraction probes from closed systems has the potential to greatly increase exposure to pesticide handlers. Although current paraquat closed systems have unique requirements that preclude them from using removable extraction probes, the Agency is requiring a statement to ensure proper extraction probe rinsing instructions on any paraquat labels that may contain built-in extraction probes. See Section IV.A.13 for more details.
- Added pre-harvest intervals and single maximum application rates to the list of label metrics that should be added to all paraquat labels as a label clarification measure. In their comments on the PID, Syngenta Crop Protection recommended the addition of pre-harvest intervals to labels and the Agency agrees that this label metric should be added to all labels, along with single maximum application rates and the other label metrics previously identified in the PID. See Section IV.A.13 and Appendix B for more details.
- Updated the unit measurements for all application rates in the ID from pound active ingredient per acre (lb ai/A) to pound cation per acre (lb cation/A). The active ingredient paraquat dichloride is comprised of a mixture of paraquat cations and chloride anions. Paraquat cation is the toxic moiety and, therefore, it is the form that was evaluated for exposure and risk assessment purposes and the form that should be used when calculating application rates. In order to clarify this, all application rates must be measured in pound paraquat cation per acre, referenced as pound cation per acre. This update has also been

added to the label clarification measures in Section IV.A.13 and the label metrics table in Appendix B.
- Received new analytical reference standards for paraquat dichloride, with an expiration date of November 30, 2023.

This ID finalizes the Agency's interim decision and draft supporting documents *Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review* and *Paraquat: Preliminary Ecological Risk Assessment for Registration Review*, which are available in EPA's public docket (EPA-HQ-OPP-2011-0855).

B. Summary of Paraquat Registration Review

On December 21, 2011, the Agency formally initiated registration review for paraquat with the opening of the registration review docket for the case.[9] The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of paraquat:

- December 2011 – EPA posted the *Paraquat Dichloride Summary Document* (December 13, 2011), *Human Health Risk Scoping Document in Support of Registration Review* (December 6, 2011), and *EFED Registration Review: Preliminary Problem Formulation for Paraquat Dichloride* (December 12, 2011) to the public docket for a 60-day public comment period.

- June 2012 – EPA posted the *Paraquat Dichloride Final Work Plan* (FWP) (May 29, 2012) to the public docket. The Agency received four comments on the summary document. As a result of comments received on the summary document, one of the toxicity studies was removed from the list of anticipated data requirements. None of the comments resulted in changes to the schedule or risk assessment needs for paraquat registration review. In the FWP, EPA noted that various ecological and human health data requirements were needed for registration review.

- February 2013 – EPA issued a generic data call-in (GDCI) for paraquat to obtain data needed to conduct the registration review risk assessments (DCI GDCI 061601-1172). The registrants submitted all required data except anaerobic aquatic metabolism data. However, the registrants also submitted a request for a waiver of the anaerobic aquatic metabolism study (March 27, 2013). EPA has waived the requirement for anaerobic aquatic metabolism data because paraquat is persistent in sediment-water systems and no degradation products are detected. For more information, see *Waiver of Anaerobic Aquatic Metabolism Study for Paraquat Dichloride* (February 18, 2014). Accordingly, all other data requirements have been satisfied.

- March 2016 - The *Paraquat Dichloride; Proposed Interim Mitigation Decision* (March 2, 2016) was posted to the docket for a 60-day public comment period.

[9] 40 C.F.R. § 155.50

- December 2016 - The Agency issued the *Paraquat Dichloride Human Health Mitigation Decision* (December 14, 2016). This mitigation decision imposed the following restrictions with the intent of reducing the number and severity of human health incidents caused by the accidental ingestion of paraquat:
    - Specialized training for all paraquat users (available March 8, 2019);
    - Enhanced label warning statements (revised labels reflecting these changes approved March 30, 2017);
    - Closed transfer system requirements for all non-bulk paraquat products (revised labels reflecting this requirement approved December 30, 2019); and
    - Requirement that only certified applicators may use paraquat (revised labels reflecting this requirement approved December 30, 2019).

  The final label amendments for the *Paraquat Dichloride Human Health Mitigation Decision* were approved on December 30, 2019. All requirements were implemented by December 30, 2020.

- October 2019 – EPA posted *Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review* (2019 HHRA) and *Paraquat: Preliminary Ecological Risk Assessment for Registration Review* (2019 ERA) for a 60-day public comment period. The Agency received 73 comments. The comments did not change the risk assessments or registration review timeline for paraquat.

- October 2020 – EPA completed a PID for paraquat and posted the PID to the public docket for a 60-day public comment period. Several commenters requested a 90-day comment period extension; the Agency granted a 20-day extension. The Agency received 81 comments during the PID public comment period from 80 commenters. These comments and the Agency's responses are summarized in Appendix C. Along with the PID, EPA posted the following documents to the public docket:
    - *Paraquat: Response to Comments on the Draft Human Health Risk Assessment* (September 24, 2020)
    - *Paraquat: Response to Comments on the EFED Preliminary Ecological Risk Assessment for Registration Review* (September 15, 2020)
    - *Paraquat Dichloride: Addendum to the Memorandum, "Draft Human Health Risk Assessment in Support of Registration Review"* (August 10, 2020)
    - *Overview of Use, Benefits, and Impacts of Mitigation Assessment for Paraquat (PC#061601) in Agricultural Settings* (August 13, 2020)
    - *Paraquat Dichloride (Herbicide and Harvest Aid) Use, Usage, Benefits and Impacts of Potential Mitigation in Cotton* (September 17, 2020)
    - *Paraquat Use on Peanut: Usage, Benefits, and Impacts of Potential Mitigation for Registration Review* (July 31, 2020)
    - *Paraquat Dichloride (PC# 061601) Use in Soybeans: Usage, Benefits and Impacts of Potential Mitigation* (September 8, 2020)

- June 2021 – EPA completed an ID for paraquat. The ID will soon be posted to the public docket, along with the following documents:

- *Paraquat: HED Response to Comments on the Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates* (June 22, 2021)
- *Paraquat: EFED Response to Comments on the Proposed Interim Decision for Registration Review* (May 19, 2021)
- *BEAD Response to Paraquat Usage and Benefit Related Comments Received on the Preliminary Interim Decision of Paraquat (PC# 061601 and 061603) (EPA-HQ-OPP-2011-0855)* (June 29, 2021)

C. Summary of Public Comments on the PID and Agency Responses

During the 80-day public comment period for the paraquat PID (October 23, 2020 to January 11, 2020), the Agency received 81 public comments from 80 sources. Thirty-seven of the comments received were from individual citizens, including farmers, agricultural retailers, pilots for agricultural aviation companies, extension specialists, and other anonymous commenters. Ten of the comments from individual citizens were against the continued use of paraquat, stating concerns over the toxicity of paraquat and claiming a potential link to Parkinson's disease. The others expressed concerns over one or more of the mitigation measures proposed in the PID. The rest of the comments received were from a wide range of stakeholders, including environmental NGOs, government agencies, public interest advocacy groups, agricultural aviation associations, and state and national agricultural groups and associations. Comments were also submitted by Syngenta Crop Protection, LLC. and Drexel Chemical Company, two of paraquat's registrants. The comments did not change the risk assessments or mitigation for paraquat.

The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature in *Paraquat: HED Response to Comments on the Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates*, *Paraquat: EFED Response to Comments on the Proposed Interim Decision for Registration Review, BEAD Response to Paraquat Usage and Benefit Related Comments Received on the Preliminary Interim Decision of Paraquat (PC# 061601 and 061603) (EPA-HQ-OPP-2011-0855),* and Appendix C. The Agency thanks all commenters for participating and has considered all comments in developing this ID.

II. USE AND USAGE

This section provides an overview of paraquat use and usage. More detailed information is available in the following memos, available in the paraquat docket: *Overview of Use, Benefits, and Impacts of Mitigation Assessment for Paraquat (PC# 061601) in Agricultural Settings; Paraquat Dichloride (PC# 061601) Use in Soybeans: Usage, Benefits and Impacts of Potential Mitigation; Paraquat Use on Peanut*: *Usage, Benefits, and Impacts of Potential Mitigation for Registration Review;* and *Paraquat Dichloride (Herbicide and Harvest Aid) Use, Usage, Benefits and Impacts of Potential Mitigation in Cotton.*

Paraquat is a broad-spectrum, contact herbicide that targets emerged broadleaf and grass weeds by inhibiting photosynthesis, resulting in destruction of cell membranes. Paraquat is also used as a PGR, which controls plant development to provide optimal plant growth, both in quality and

quantity. Paraquat belongs to the bipyridylium chemical family and is classified by the Weed Science Society of America as a Class 22 herbicide (Photosystem I Electron Diverter site of action). Paraquat is only formulated as a liquid. Products containing paraquat are frequently used as a burn-down herbicide treatment to control existing vegetation before planting or crop emergence but can also be used at planting; post-emergence (to the crop), as a desiccant or harvest aid; and as a post-harvest desiccant. Products containing paraquat can be applied as a band, spot, broadcast, directed treatment, or with a hooded sprayer after crop emergence. Applications of paraquat are frequently recommended as tank mixes with another herbicide which may enhance or broaden the spectrum of weeds controlled in addition to extending the duration of weed control when applied with herbicides with residual activity. In addition to weed control, there are special uses of paraquat for sucker control in perennial crops (e.g., fruit and nut trees, grapes, hops) and as a pre-harvest desiccation treatment on cotton and potatoes.

Paraquat is one of the most widely used herbicides in the U.S., with an average of 8.5 million pounds applied annually to 15.8 million acres.[10] Based on agricultural usage data from 2014-2018, soybeans, cotton, and corn are the crops with the highest number of total acres treated with paraquat; grapes, pistachios, and peanuts are the crops with the highest percent of the crop treated with paraquat. Products containing paraquat are also applied to other agricultural use sites, such as artichokes; bulb vegetables; cereal grains; cucurbits; fruiting vegetables; stalk and stem vegetables; non-grass animal feeds; orchards and vineyards; fallow; pastureland, and non-agricultural use sites, such as nurseries; ornamentals; turf; landscapes; and rights-of-way. In addition, products containing paraquat are used on cotton as a desiccant or PGR to dry the leaves of the crop in preparation for a clean harvest. There are no paraquat products registered for homeowner or residential use.

Use and usage information for cotton, peanuts, and soybeans were analyzed separately, since these three use sites account for about 64% of the total area treated (TAT) with paraquat and nearly 63% of the pounds of active ingredient (lbs a.i.) applied from 2014-2018 on average. Specific details about paraquat use and usage for these commodities can be found below.

Aerial use of paraquat is most dominant, as a measure of overall acres treated, in cotton desiccation.[10] There may also be a few crops for which there are important niches, such as sunflowers. In general, however, aerial use of paraquat on large acreage crops is low.[11] From 2014-2018, paraquat was applied aerially to 2% of soybeans treated with paraquat and only 1% of cotton acres where paraquat was used as an herbicide (non-desiccant), on average. Aerial application is not approved for peanuts.

[10] Kynetec USA, Inc. 2019. The AgroTrak Study, Data Subset 2014-2018. Data collected on pesticide use for about 60 crops by annual surveys of agricultural users in the continental United States. Survey methodology provides statistically valid results, typically at the state level.

[11] Chen, C., Coy, R.M., English, L., McFarley, H., Chism, B., Hanson, C., Hodde, W., and D. Sells. 2021. BEAD Response to Paraquat Usage and Benefit Related Comments Received on the Preliminary Interim Decision of Paraquat (PC# 061601 and 061603) (EPA-HQ-OPP-2011-0855)

Cotton

Paraquat is used in cotton both as an herbicide and as a harvest aid. As an herbicide, between 2014 and 2018, an average of 1.2 million pounds of paraquat were used to treat an average of 2.3 million cotton acres, or about 20% of cotton acres, per year. As a harvest aid, 0.6 million pounds of paraquat were applied to about 1.8 million acres, or 15% of cotton acres, per year. Harvest aid use is concentrated primarily in Texas, where about 574,000 pounds are applied to about 1.7 million cotton acres per year, on average.

Peanuts

Paraquat is applied to 38% of peanut acres annually and can be effectively used at multiple timings during the growing season, and for multiple purposes (i.e., field preparation, at-plant, and post-emergence). In several peanut-producing states, paraquat is also registered for use under Section 24(c) of the FIFRA for control of late-season weed escapes.

Soybeans

Paraquat is applied to 12% of all soybean acres annually and is primarily used as a spring burndown or preplant treatment. Southern states rely more heavily on paraquat, likely because it is effective on glyphosate-resistant palmer amaranth and Italian ryegrass. Delta states, which include Arkansas, Louisiana, and Mississippi, use paraquat on 30% of soybean acres annually.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

The Agency has summarized the 2019 HHRA below. The Agency used the most current science policies and risk assessment methodologies to prepare this risk assessment in support of the registration review of paraquat. For additional details on the 2019 HHRA, see *Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review*, *Paraquat Dichloride: Addendum to the Memorandum, "Draft Human Health Risk Assessment in Support of Registration Review"*, and *Paraquat: HED Response to Comments on the Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates* in EPA's public docket (EPA-HQ-OPP-2011-0855).

1. Risk Summary and Characterization

Dietary (Food + Water) Risks

The acute and chronic dietary exposure estimates for paraquat are <100% of the population-adjusted dose and are not of concern to the Agency. The most highly exposed population subgroup is children 1-2 years old, with risk estimates at 38% of the acute population-adjusted dose (aPAD) and 25% of the chronic population-adjusted dose (cPAD), whereas the risk estimates for the general U.S. population are 20% of the aPAD and 6.6% of the cPAD. The endpoint for acute dietary effects was based on clinical signs of toxicity and mortality. The

endpoint for chronic dietary effects was based on increased severity of chronic pneumonitis and gross lung lesions in both sexes, focal pulmonary granulomas in males, and increased lung weight and incidence of alveolitis in both sexes.

An assessment of cancer risk was not performed because paraquat is classified as being a Category E chemical (evidence of non-carcinogenicity in humans).

Residential Handler and Post-Application Risks

Paraquat is a restricted use pesticide (RUP). Therefore, there are no paraquat products registered for homeowner use and no products registered for application to residential areas.

Since there are no residential exposures for paraquat, all aggregate exposures are equivalent to dietary exposure estimates and are not of concern.

Bystander Risks

There are risks of concern for adults (dermal) and children 1 to <2 years old (combined dermal and incidental oral) from indirect exposure to paraquat from the field edge up to 150 feet. These estimates vary depending on the application rate and equipment type assessed and assume screening level droplet sizes (very fine, fine, medium, and coarse droplets) and boom heights (low boom and high boom). Results indicate that the majority of spray drift risk concerns result from aerial applications.

Appropriate drift reduction technologies such as changing the spray type/nozzle configuration to coarser spray applications may result in less drift and reduced risk concerns (i.e., higher MOEs) from aerial applications. Similarly, using coarser sprays and lowering boom height for groundboom sprayers reduces risk concerns. An aerial application of very fine to fine droplets at a rate of 0.6 lbs cation/A, for example, results in an MOE of 29 at the field edge, which is of concern to the Agency (level of concern [LOC] = 100). Whereas an aerial application of coarse to very coarse droplets at the same rate results in an MOE of 59, which is still of concern to the Agency but is closer to the target MOE of 100. A groundboom application of very fine to fine droplets at a rate of 0.6 lbs cation/A with a high boom results in an MOE of 58 at the field edge. A groundboom application with the same droplet size and at the same rate, but with a low boom, results in an MOE of 130 at the field edge.

Aggregate Risks

In an aggregate assessment, EPA considers the combined pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. The Agency sums the exposures from these sources and compares the aggregate risk to quantitative estimates of hazard. EPA considers the route and duration of exposure when assessing aggregate risks. For paraquat, aggregate exposures are equivalent to dietary exposure estimates because there are no residential exposures.

Cumulative Risks

EPA has not made a common-mechanism-of-toxicity-to-humans finding for paraquat and any other substance. Paraquat does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has premised this ID and the underlying risk assessments on the belief that paraquat does not have a common mechanism of toxicity with other substances.

Occupational Handler Risks

Based on the anticipated use patterns, current labeling, types of equipment, and application techniques that can potentially be used, occupational handler exposure is expected from the registered uses of paraquat. Estimates of dermal and inhalation exposure were calculated for various levels of personal protective equipment (PPE). Paraquat product labels direct mixers, loaders, and applicators to wear baseline clothing, chemical-resistant gloves, and a NIOSH-approved PF10 respirator. Dermal and inhalation exposures have not been combined for paraquat, since the effects endpoints selected for these routes of exposure are different.

Since the completion of the draft human health risk assessment for paraquat, the occupational handler risk estimates have been updated twice. The first update was based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table – Revised March 2020"[12] and the second update was based on new data from the AHETF regarding levels of exposure to occupational handlers using closed loading systems. The updated handler risk estimates are presented in the following addendums to the paraquat draft human health risk assessment, *Paraquat Dichloride: Addendum to the Memorandum, "Draft Human Health Risk Assessment in Support of Registration Review"* and *Paraquat: HED Response to Comments on the Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates*. Both addendums are available in the public docket. The risk estimates presented in this section are based on the revised risk estimates provided in the addendums referenced above.

Inhalation Risks

Inhalation exposure is the risk driver for most paraquat occupational handler exposure scenarios assessed. The inhalation point of departure (POD) is based on evidence of toxicity in the upper respiratory tract observed in the route-specific subchronic inhalation study in rats.

Inhalation risks for mixer/loaders are of concern (i.e., the MOEs are < the LOC of 100) for 13 out of 26 exposure scenarios with use of a PF10 respirator, with MOEs ranging from 5.3 to 95. The same mixer/loader exposure scenarios were assessed with engineering controls in the form of closed transfer systems and 8 out of 26 scenarios result in risks of concern, with MOEs ranging from 10 to 95. Due to the new AHETF data, the Agency was also able to quantitatively determine inhalation risk estimates combining the level of protection from both PPE (gloves and a respirator) and closed transfer systems. None of the mixing/loading exposure scenarios have inhalation risks of concern when PPE and closed systems are used concurrently. One exposure scenario was assessed for loader/applicators wearing a PF10 respirator and gloves, resulting in an

[12] https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#olddata

inhalation risk estimate of concern, with an MOE of 50. For applicators, inhalation risks are of concern for 8 out of 21 scenarios, assuming engineering controls (enclosed cockpits with gloves for aerial application and enclosed cabs with gloves for groundboom application). The MOEs for applicators for those applicator exposure scenarios of concern range from 24 to 95. For flaggers, inhalation risks are of concern for 5 out of 5 scenarios, with MOEs ranging from 20 to 98. Inhalation risks for mixer/loader/applicators are of concern for 4 out of 8 scenarios assessed, with MOEs ranging from 13 to 50.

See Table D.1. in Appendix D for a full report of risk estimates for occupational handler scenarios.

Dermal Risks

The dermal POD is based on the systemic No Observed Adverse Effect Level (NOAEL) from the route specific 21-day dermal toxicity study in rabbits. Although the toxicity database indicates paraquat is not well absorbed across intact human skin, the corrosive properties of the chemical affect the integrity of the skin, particularly after repeat exposure.

For mixer/loader/applicator exposure scenarios, dermal risks are of concern for 6 of the 8 exposure scenarios assessed at the currently required level of personal protection (baseline clothing and chemical resistant gloves), with MOEs ranging from 12 to 97 (LOC = 100). Even with the addition of double layer clothing, dermal risks of concern remain for 4 of the 8 exposure scenarios, with MOEs ranging from 19 to 48. Most dermal exposure scenarios for mixer/loaders are not of concern, when assuming PPE and engineering controls in the form of closed transfer systems; only 1 out of 25 scenarios are of concern, with an MOE of 66. The one exposure scenario assessed for loader/applicators results in dermal risk estimates of concern, with an MOE of 26 assuming baseline clothing and an MOE of 48 assuming double layer clothing. Only one dermal exposure scenario is of concern for flaggers, with an MOE of 76 when assuming baseline clothing and gloves and an MOE of 86 when assuming double layer clothing and gloves. There are no dermal risks of concern for applicators, assuming engineering controls, with MOEs ranging from 130 to 4,700.

See Table D.1. in Appendix D for a full report of risk estimates for occupational handler scenarios.

Occupational Post-Application Risks

The likelihood of paraquat occupational post-application exposures is dependent on whether spray applications are “broadcasted” or directed. Directed applications of paraquat are made with the intent of minimizing the risk of injuring the crop and/or non-target vegetation which are not tolerant of direct applications. Since applications to the foliage of the crop are not expected to occur in these situations, occupational post-application exposures are not likely for directed applications and were not assessed. Broadcast applications of paraquat are applied directly to the crop for foliage desiccation to expedite harvest and reduce seed loss upon harvest and, therefore, were assessed.

Occupational post-application exposure and risk estimates of concern for cotton mechanical harvesting activities (module builder operator, picker operator, raker, and tramper) persist from 11 to 27 days following product application. Occupational post-application exposure and risk estimates for scouting activities are not of concern (i.e., an MOE ≥ 100) on the day of product application for all crops assessed except for alfalfa. For alfalfa, estimated re-entry risks are not of concern 4 days following product application.

A paraquat occupational post-application biomonitoring study was available (MRID 43618202); however, this study was reviewed and determined to have human ethics concerns. As a result, no post-application risk estimates were quantified with use of these data.

2. Human Incidents and Epidemiology

Public Health Incident Data Review

EPA reviewed paraquat incidents reported to the following databases: OPP Incident Data System (IDS), the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event Notification System for Occupational Risk-Pesticides (SENSOR), the Agency-sponsored National Pesticide Information Center (NPIC), and California's Pesticide Incident Surveillance Program (PISP).

Paraquat is highly acutely toxic when inhaled or ingested and the Agency found that the acute health effects reported are consistent across the incident databases. These health effects primarily include dermal, ocular, and neurological effects. Most incidents were classified as low to moderate severity. The effects reported were generally mild/minor to moderate and resolved rapidly. However, high severity incidents and deaths did occur due to ingestion exposure (some incidents were attributed to accidental ingestion, while others were attributed to intentional ingestion), and misuse. In 2016, EPA issued the *Paraquat Dichloride Human Health Mitigation Decision.* This mitigation decision imposed the following restrictions with the intent of reducing the number and severity of human health incidents caused by the accidental ingestion of paraquat: 1) specialized training for all paraquat users; 2) enhanced label warning statements; 3) closed transfer system requirements for all non-bulk paraquat products; 4) requirement that only certified applicators may use paraquat (may not be used by uncertified persons working under the supervision of a certified applicator). The final label amendments were approved on December 30, 2019 and all requirements were implemented by December 30, 2020. In order to measure the effectiveness of these mitigation measures in preventing incidents of accidental ingestion, the Agency will conduct a new incident analysis for paraquat in 2025 and again in 2030.

Across the databases reviewed, the majority of paraquat incidents were occupational exposure accidents which occurred during application or handling – primarily from leaks/spills/splashes, product blowback, or equipment malfunctions. Dermal symptoms were the most frequently reported symptoms among cases, including welts, hives, peeling skin, chemical burns, swelling, blisters, lesions; followed by ocular symptoms, including blurred vision, ocular pain, chemical conjunctivitis, corneal abrasion, and vision problems. Neurological, respiratory, gastrointestinal, and cardiovascular symptoms were also reported.

For the Main IDS, from January 1, 2012 to February 6, 2018, 63 paraquat incidents were reported. Of these 63 cases, there were 53 cases reported for the single chemical paraquat in the database that occurred in the U.S. Of the 63, four incidents involved deaths (two of the four deaths were intentional ingestion suicides; the other two involved accidental ingestion of paraquat). In 2013, a 70-year-old female accidentally ingested Gramoxone from an iced tea bottle that was being used to store the product. In 2014, an adult male illegally bought the product, contained in a soda bottle. He later mistook it for a beverage and drank some, which resulted in his death. Of the 53 single active ingredient (a.i.) incidents, four incidents were classified as major severity, 43 incidents were classified as moderate severity, one incident was classified as minor severity, and one incident had unknown severity.

In Aggregate IDS, queried from January 1, 2012 to February 8, 2018, there were 60 incidents involving paraquat. These incidents were classified as minor severity, meaning that the person alleged or exhibited some symptoms, but they were minimally traumatic, the symptoms resolved rapidly, and usually involved skin, eye, or respiratory irritation. A review of paraquat incidents over time in IDS was conducted. The number of paraquat incidents reported to IDS from 2008 to 2017 has remained relatively constant. There has been an average of 22 paraquat incidents (ranging from a low of 15 incidents to a high of 32 incidents) reported to IDS per year over the last 10 years.

The most current set of available SENSOR-Pesticides data spans from 1998 to 2014. During that time, there were a total of 140 cases involving paraquat reported. Most cases (68%) were low in severity and 32% of reports were moderate, high, or fatal in severity. Of the 140 cases reported, 113 were work-related exposures. Most were exposed to paraquat via dermal exposure, followed by ocular exposure, inhalation, and ingestion. Most occupational cases involved applying, mixing/loading, or repairing equipment. Many cases involved PPE issues, for example, spray/splash getting into eyes although wearing safety glasses. Many cases involved application equipment failures, including backpack leaks. Many cases were the result of workers not being adequately trained prior to applying paraquat under the supervision of a certified applicator. The symptoms most frequently reported among the paraquat cases in SENSOR were eye pain/irritation, headache, redness of skin, conjunctivitis, skin pain, skin rash, and upper respiratory pain.

In addition to OPP's routine incident data sources, the Washington State Department of Health, a SENSOR-Pesticides participant, has provided data for six incidents considered "high priority exposure events." One of these incidents occurred in 2018, involving a hazardous materials truck driver who was hauling a load of Gramoxone SL 2.0. The truck driver experienced a liquid chemical splash to his face, hands, and arms while he was unloading the truck due to a hose explosion. He experienced difficulty breathing, and his condition improved after receiving eight days of hospital care. Washington State Department of Health investigated this case and determined that 1) the truck driver did not wear all required PPE for handling paraquat and 2) the first emergency department the truck driver visited did not properly treat and decontaminate him. There were five additional paraquat incident investigations reported from Washington in 2016. These cases were not high in severity, however they involved typical occupational scenarios and many involved inexperienced applicators.

In the PISP database, there were a total of 16 cases reported involving paraquat from 2010 to 2014 and NPIC reported 9 human incidents involving paraquat from January 1, 2008 to December 31, 2017. Of the 9 incidents reported to NPIC, two were reported as symptomatic and classified as possibly related to paraquat exposure and were further reviewed. One incident involved drift and the other involved an applicator exposure due to equipment malfunction.

The Agency intends to conduct ongoing human incident monitoring for paraquat and additional analyses if that monitoring indicates risks of concerns. For additional details on human incidents related to paraquat, see the *Paraquat: Tier II Human Incidents Report* (July 25, 2018), which is available in the public docket.

Epidemiological Review

EPA performed a systematic review of the epidemiologic literature on paraquat exposure and identified 74 articles that investigated a range of health outcomes, including Parkinson's disease (PD), lung function and respiratory effects, cancer, and other health outcomes.

Parkinson's disease had the most comprehensive body of epidemiologic literature, with a total of 13 study populations, including three agricultural cohorts, nine hospital-based populations, and one PD registry in Nebraska (26 articles). Based on the findings from these studies, it was concluded that there is limited, but insufficient, epidemiologic evidence to conclude that there is a clear associative or causal relationship between occupational paraquat exposure and PD. It was also concluded that there is insufficient epidemiologic evidence to conclude that there is a clear associative or causal relationship between non-occupational paraquat exposure and PD.

Lung function and respiratory effects were examined in nine study populations (17 articles) that included general lung function, wheeze, allergic rhinitis, asthma, and chronic bronchitis. Based on the findings from these studies, it was determined that there is insufficient evidence at this time to conclude that there is a clear associative or causal relationship between occupational paraquat exposure and the lung function and respiratory effects investigated. Cancer outcomes were investigated in four study populations (8 articles) that examined occupational paraquat exposure. Based on the findings from these studies, it was determined that there is insufficient epidemiological evidence to conclude that there is a clear associative or causal relationship between paraquat exposure and the cancer outcomes investigated.

Seventeen other health outcomes (25 articles) were investigated in the literature that primarily examined occupational paraquat exposure. Most outcomes were only investigated in a single study population. The Agency concluded that there was no epidemiological evidence of an association for the following health outcomes: general mortality, suicide, and infant birth weight. For health outcomes with a single study with positive findings, it was generally concluded that there was insufficient evidence of an association for health outcomes. These outcomes included diabetes, myocardial infarction, eye disorders, injury mortality, renal/liver function, oxidative stress, abnormal skin pigmentation, actinic keratosis, depressive symptoms, thyroid disease, and aplastic anemia. The Agency also concluded that there was limited, but insufficient evidence of a clear associative or causal relationship for end-stage renal disease, based on Agricultural Health

Study (AHS) studies on male farmers and their spouses that both reported evidence of a positive association. While positive associations were reported, there were only a small number of paraquat cases in both studies, so the ability to assess the exposure-response relationship was limited.

For additional details on the epidemiological review of paraquat, see the *Paraquat Dichloride: Tier II Epidemiology Report* [13] (June 26, 2019), which is available in the public docket.

Parkinson's Disease Systematic Review

In addition to the general epidemiology systematic review, the Agency conducted a fit-for-purpose systematic review to evaluate the significance and environmental relevance of the postulated association between paraquat exposure and PD. A literature database was compiled for the PD systematic review from three primary sources of data: the OPP paraquat toxicity database for registration, the OPP paraquat general epidemiology systematic review (summarized above), and the National Toxicology Program (NTP) scoping review of open literature relevant to evaluating the association between paraquat exposure and PD. Data from the studies included in the literature database were separated into three lines of evidence – human, animal, and *in vitro* – and evaluated for quality, substance, and environmental relevance. In total, data from 26, 11, and 34 relevant, acceptable studies were considered in the evaluation of the human, animal, and *in vitro* evidence, respectively, and integrated in the weight of evidence analysis. As another line of evidence, neurotoxic effect levels reported in the literature database were compared to exposure estimates from the paraquat DRA to evaluate the likelihood of these neurobehavioral effects resulting from registered paraquat uses. Based on the weight of evidence analysis and exposure considerations, the Agency concluded that the weight of evidence was insufficient to link paraquat exposure from pesticidal use of U.S. registered products to PD in humans.

For additional details on the Parkinson's disease systematic review, see the *Paraquat Dichloride: Systematic review of the literature to evaluate the relationship between paraquat dichloride exposure and Parkinson's disease*[14] (June 26, 2019), which is available in the public docket.

3. Tolerances

Paraquat is registered for uses that result in residues in or on food. Under the FFDCA, food containing pesticide residues will be considered unsafe and adulterated, if those residues are not covered by a tolerance or exemption.[15] EPA has determined that all of the necessary tolerances are in place to cover residues resulting from paraquat's legal use. The Agency has established tolerances for paraquat under 40 C.F.R. § 180.205.

During the risk assessment process, EPA determined that some tolerance modifications are appropriate. For more information, see Section IV.B, below.

[13] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0124
[14] https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0125
[15] 21 U.S.C. §§ 342, 346(a).

4. Human Health Data Needs

The human health database for paraquat is considered complete. No additional data are required to support this registration review decision. However, there are a few data deficiencies, outlined below, which could refine human health risk estimates.

In vitro Skin Corrosion: Although not a requirement of registration, *in vitro* data on skin corrosion, such as those reported for Organisation for Economic Co-operation and Development (OECD) Guideline 431, would provide useful information on the interaction between paraquat and skin cells that could be used to refine the assumptions in the dermal toxicity characterization and dermal assessment.

Dislodgeable Foliar Residue (DFR): In the absence of chemical-specific DFR data, EPA uses default values. According to current OPP practices, a chemical-specific study is required if post-application MOEs are not minimal in comparison to the LOC. Therefore, given that the calculated MOE is not 2 times the LOC, EPA is recommending that the 40 CFR § 158 DFR data be submitted in order to facilitate any necessary exposure assessment refinements and to further EPA's general understanding of the availability of dislodgeable foliar pesticide residues.

Further, during cotton harvesting workers are expected to contact residues on cotton bolls directly for which a "dislodgeable boll residue (DBR)" study would be required to refine occupational post-application risks estimated for the crop. These chemical- and crop-specific data are unique; DFR data for other crops cannot be used as a surrogate in the absence of a DBR study. The Agency is recommending a paraquat DBR study be submitted to further EPA's general understanding of the availability of cotton dislodgeable boll residues. These data should be conducted in accordance with Guideline # 875.2100. Given the current lack of DBR data for paraquat, HED has used default DFR data for the post-application aspects of the risk assessment.

B. Ecological Risks

The Agency has summarized the 2019 ERA below. The Agency used the most current science policies and risk assessment methodologies to prepare a risk assessment in support of the registration review of paraquat.[16] For additional details on the 2019 ERA, see *Paraquat: Preliminary Ecological Risk Assessment for Registration Review* in EPA's public docket (EPA-HQ-OPP-2011-0855).

[16] The 2019 ERA only addresses potential risks to species not listed under the Endangered Species Act. EPA is working with its federal partners and other stakeholders to implement a Revised Method (EPA-HQ-OPP-2019-0185-0054) for assessing potential risk to listed species and their designated critical habitats. The Agency will complete paraquat's listed-species assessment once EPA has fully implemented the scientific methods necessary to complete listed species' risk assessments.

1. Risk Summary and Characterization

Terrestrial Risks

Mammals

For acute dose-based exposure for mammals, RQs range from <0.01 to 6.55 and exceed the LOC of 0.5 for all size classes of mammals feeding on grasses, broadleaf plants, and arthropods for all uses. These exceedances assume multiple applications of paraquat have been made prior to exposure. For a single application at the maximum application rate for most agricultural and non-agricultural uses, only exposures to mammals feeding on grasses and broadleaf plants have LOC exceedances, with RQs ranging from 0.52 to 1.13. The adverse effect upon which the acute endpoint is based is mortality.

Dietary-based chronic RQs are unavailable because there were no measurable effects in a chronic rat reproduction study at the highest treatment level tested. However, because that highest tested level was below the estimated exposure levels from use of paraquat, an additional line-of-evidence was investigated by evaluating potential chronic risk using a rat prenatal developmental study. In this study, decreased body weight gains were observed and the risk ratios (ratio of exposure to the treatment level tested) range from 0.15 to 609, potentially exceeding the LOC of 1.0 for all uses. Based on this line of evidence, EPA cannot preclude chronic risk to mammals. Additional chronic data would not likely change the risk conclusion due to acute risk concerns.

There is some uncertainty over whether chronic risk is likely due to rapid plant death. For animals feeding on living plants, rapid plant death from paraquat exposure may make plants unpalatable and therefore chronic exposure may be unlikely. This uncertainty is limited to plant-eaters and would not apply to consumers of fruits, grains, seeds, or arthropods.

There were two incidents of undetermined legality involving the mortality of dogs. They cannot be attributed to registered use but do support a line of evidence that paraquat can be toxic to mammals. For more information on ecological incidents, see Section III.B.2.

Birds, Reptiles, and Terrestrial-Phase Amphibians

For acute dietary-based exposures for birds, RQs range from 0.01 to 57, based on upper bound Kenaga exposure values. For all uses, birds feeding on short grass exceed the acute LOC of 0.5. For multiple applications modeled using a 7-day re-application interval, birds feeding on grasses, broadleaf plants, and arthropods also had LOC exceedances. The adverse effect upon which the acute endpoint is based is mortality.

For chronic exposures for birds, dietary-based RQs were based on significant reductions in reproduction and food consumption (reductions of 59% in eggs laid, 25% in viable embryos/egg set, 33% in live embryos/egg set, and 9% in mean food consumption). RQs range from 0.26 to 4.1 based on upper bound Kenaga exposure values, exceeding the chronic LOC of 1.0 in all feeding groups and for all uses, except that no exceedances were found for granivores and

fruit/pod/seed consumers with a single application, or for granivores with the longer (120-day) re-application interval.

Acute effects are likely to occur, as even a single application at the lowest application rate exceeds the LOC for most feeding groups of small-sized birds and two feeding groups of medium-sized birds. As mentioned above, however, the desiccating action of paraquat may reduce the palatability and decrease chronic exposure for plant-eaters. Also, application timing may be important in preventing reproduction effects to birds and other egg-laying animals.

Six reported bird incidents show potential for mortality, but a link to the registered use of paraquat was not made in five of the incidents. One incident was confirmed to be from a registered use. For more information on ecological incidents, see Section III.B.2.

Terrestrial Invertebrates

Toxicity endpoints are currently only available for adult honeybee acute contact and oral exposures. Chronic toxicity data for adult honeybees and toxicity data for larvae are not available. The risk estimates for honeybees can be used as surrogates for other invertebrates, such as individual bees (e.g., bumble bees) that may also forage on contaminated food items.

Based on acute contact toxicity, the highest maximum application rate did not exceed the LOC of 0.4 for pollinators (RQ = 0.08). Based on acute oral toxicity, six out of eight castes of adult bees had LOC exceedances at the highest single application rate, with RQs ranging from 0.04 to 2.2. For the highest and lowest single application rates for all other uses, two castes had LOC exceedances, workers foraging for nectar and drones. Worker nurse bees tending brood and queens also had LOC exceedances with the higher rate. Based on modeling estimates, however, lower application rates, coarser droplet sizes, low boom for ground applications, and distances of up to 46 feet are effective in removing the presumption of risk for the case with the highest RQs.

Although multiple crops for which paraquat is registered are attractive to pollinators, the use pattern does not suggest that paraquat would be applied directly to crops in the blooming (pollinator attractive) phase. Paraquat is used primarily as a burndown product before crops are planted in the spring. For paraquat applied as a burndown application before weeds are in bloom, crop attractiveness would not be a factor in bee exposure. However, there is potential for direct exposure to bees if target plants are sprayed while flowering, and if blooming plants are adjacent to the treated area, spray drift may expose foraging bees. Exposure to bees depends heavily on timing of application and proximity to blooming plants.

One bee incident involved damage to two beehives and was of possible causality but of undetermined legality. This incident suggests potential for harm to pollinators. For more information on ecological incidents, see Section III.B.2.

EPA relies on data about honeybees as a surrogate for terrestrial invertebrate species. Based on the available data, EPA believes that paraquat uses may present risks of concern to honeybees.

Terrestrial Plants

Monocots and dicots are similarly sensitive to paraquat toxicity. The seedling emergence endpoints used to calculate risk to terrestrial plants were based on 25% reductions in oat and cocklebur survival and emergence. The vegetative vigor endpoints used in the spray drift calculations were more sensitive than the seedling emergence endpoints; they were based on 25% effects in growth (dry weight and height). This is consistent with the mode of action where paraquat is expected to be absorbed into plant tissue and cause rapid damage, resulting in more localized effects than systemic uptake. Exposure in the vegetative vigor study was from direct spray to green parts of the plant, while exposure in the seedling emergency study was from treated soil.

Plants exposed to spray drift from aerial spray exceeded the LOC of 1.0 for all application rates, with RQs ranging from 1.2 to 3.6. Plants exposed to spray drift from ground spray did not exceed the LOC, with RQs ranging from 0.23 to 0.72. Distances to remove the presumption of risk range from <1 foot to 17 feet, depending in part on droplet size.

Twenty-seven plant incidents were found, with paraquat as the probable or highly probable cause in ten. One incident was from a registered use and involved damage to ornamental plants from paraquat use on peas. Four additional plant incidents attributed to registered uses of paraquat were determined to be possibly caused by paraquat. Fifteen incidents of undetermined legality were reported involving damage to various crops; of these, four were determined to have probable causality and eleven to have possible causality. These incidents support the suggestion that a potential for harm to plants is established from registered use of paraquat. For more information on ecological incidents, see Section III.B.2.

Aquatic Risks

It appears likely that paraquat only accumulates and persists in the environment when it is in a non-bioavailable state and degrades rapidly when bioavailable. Because of these unique properties of paraquat, the typical aquatic exposure assessment was modified. Acute aquatic environmental exposures were modeled as spray drift only concentrations which vary with application method (aerial vs. ground) and application rate. This assumes that the spray drift enters the waterbody, causes a brief high concentration, and then quickly dissipates via adsorption to clay in sediment.

Freshwater and Estuarine/Marine Fish and Aquatic-Phase Amphibians

Risk estimates showed no acute LOC exceedances for aquatic vertebrates from water column exposure. Paraquat dissipates via adsorption to clay in sediment in aquatic environments, therefore chronic RQs could not be calculated. However, when chronic toxicity endpoints, based on growth, were conservatively screened against the acute estimated environmental concentrations (EECs), the exposure to toxicity ratios were all less than or equal to 0.01 (LOC = 1) for all use patterns, indicating that the estimated exposure concentrations are less than those expected to produce chronic effects.

Due to its fate characteristics, paraquat is not expected to remain long in the water column. However, information from the open literature suggests that some species of fish and aquatic-phase amphibians may be as much as an order-of-magnitude more sensitive than the quantitatively usable fish endpoints used in the assessment. Nonetheless, when those endpoint estimates were screened against the estimated environmental concentrations for worst-case conditions, they did not suggest that risk conclusions would change with new data. Six incidents were reported involving aquatic organisms, with paraquat suspected of being the primary cause in four. These incidents suggest potential for harm to aquatic organisms from paraquat exposure. The pathway of damage is possibly from oxygen sinks due to aquatic plant die-offs. The available acute toxicity data do not suggest that fish will die from direct exposure. However, estimated environmental concentrations are at or above the effects concentrations for algae and so the scenario of algal die-offs resulting in aquatic animal mortality is supported. Fate characteristics suggest that spray drift is a likely pathway.

Although the available toxicity data indicate that risks to aquatic vertebrates do not exceed EPA's LOCs, the open literature indicates that the risk to fish and aquatic-phase amphibians from the use of paraquat cannot be precluded due to fish-kill incidents and the persistence of adsorbed-phase paraquat.

Freshwater and Estuarine/Marine Invertebrates

Risk estimates showed no acute LOC exceedances for aquatic invertebrates from water column exposure. However, when chronic toxicity endpoints, based on growth, reproduction, and survival, were conservatively screened against the EECs, the exposure to toxicity ratios were all less than 1 (LOC = 1) for all use patterns, indicating that the estimated exposure concentrations are less than those expected to produce chronic effects.

Calculated risk to benthic organisms is heavily influenced by the length of time available for accumulation to occur, as well as the scenario used for modeling exposure. Despite uncertainties, using conservative assumptions showed that risk to benthic organisms is low from short-term sediment exposure. However, when paraquat is allowed to accumulate in the sediment over time (30-year exposure estimate), risk to benthic organisms may be a concern. Although freshwater crustacea were more sensitive than freshwater insects or saltwater crustacea, all categories had LOC exceedances when based on the most conservative EEC estimate.

Based on the available data, the risk to aquatic invertebrates from the use of paraquat is expected to be low from water column exposure, but potentially of concern over time from sediment exposure due to paraquat's persistence when adsorbed to sediment. Long-term paraquat accumulation in the sediment may reach amounts sufficient to cause reduced survival for benthic invertebrates. Relevant amounts of accumulation may take years to occur but could potentially place benthic organisms at risk.

Aquatic Vascular and Non-Vascular Plants

Risk estimates showed LOC exceedances to non-vascular aquatic plants (algae) from all registered uses of paraquat and all application rates, with RQs ranging from 4 to 26. Vascular aquatic plants were less sensitive and had no LOC exceedances. The weight of evidence shows

that aquatic plants can be affected by paraquat exposure, but the amount of bioavailable paraquat to which they are exposed is difficult to predict. As previously discussed, paraquat's strong adsorption to particles or sediment likely reduces its bioavailability to aquatic plants. Potential effects likely depend on spray drift, and the presence of dissolved or particulate matter may also influence the amount of paraquat that reaches aquatic plant tissue.

Based on the available data, risk to aquatic plants is expected from the use of paraquat.

2. Ecological Incidents

EPA reviewed paraquat incidents reported to the Incident Data System (IDS). As of EPA's latest search on June 14, 2018, the Main IDS reported 7 incidents involving dogs and birds, 4 fish kills, 1 bee kill, and 27 plant damage incidents. In terms of certainty of the incidents being caused by paraquat, 26 incidents were determined to be of possible causality, 12 incidents are of probable causality, and one incident is of highly probable causality. Most of these incidents were either of undetermined legality or cases of misuse. One bird incident, one fish incident, and five plant incidents were from registered uses. The Aggregate IDS reported 4 vertebrate wildlife incidents, 3 non-vertebrate incidents, and 78 plant incidents.

Some of the incidents that were of undetermined legality involved mortality of dogs and several birds. These cannot be attributed to registered use but do support a line of evidence that paraquat can be toxic to terrestrial vertebrates. One bird incident involving Canada geese was from a registered use on corn and of probable causality but also involved other pesticides. In this case, however, paraquat was considered to be the pesticide present in the tank mix at an amount representing the highest acute toxicity to birds. One incident involved damage to two beehives and was of possible causality but of undetermined legality. Additionally, many of the aggregate incidents are likely bee incidents and are assumed to be from registered uses unless additional information is provided to show otherwise.

These incidents suggest potential for harm to non-target aquatic and terrestrial animals, but whether this potential extends to registered uses is not clearly substantiated. The potential for damage to non-target plants is supported by at least five incidents associated with paraquat registered use.

The Agency intends to conduct ongoing ecological incident monitoring for paraquat and additional analyses if that monitoring indicates risks of concern to nontarget organisms.

3. Ecological and Environmental Fate Data Needs

The ecological and environmental fate database for paraquat is considered complete. No additional data are required to support this registration review decision.

Given the uncertainties surrounding potential risks to terrestrial invertebrates, EPA believes that additional data may be necessary to fully evaluate risks to non-target terrestrial invertebrates, especially pollinators. Although EPA identified the need for certain data to evaluate potential effects to pollinators when initially scoping the registration review for paraquat, the problem formulation and registration review DCI for paraquat were both issued prior to the EPA's

issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees.*[17] This 2014 guidance lists additional pollinator studies that were not included in the paraquat registration review DCI. Therefore, EPA is currently determining whether additional pollinator data are needed for paraquat. If the Agency determines that additional pollinator exposure and effects data are necessary for paraquat, then EPA will issue a DCI to obtain these data. The pollinator studies that could be required are listed in Table 1, below.

Table 1: Potential Pollinator Data Requirements

Guideline #	Study
Tier 1	
850.3020	Acute contact toxicity study with adult honeybees
850.3030	Honeybee toxicity of residues on foliage
Non-Guideline (OECD 213)	Honeybee adult acute oral toxicity
Non-Guideline (OECD 237)	Honeybee larvae acute oral toxicity
Non-Guideline	Honeybee adult chronic oral toxicity
Non-Guideline	Honeybee larvae chronic oral toxicity
Tier 2†	
Non-Guideline	Field trial of residues in pollen and nectar
Non-Guideline (OECD 75)	Semi-field testing for pollinators
Tier 3†	
850.3040	Full-Field testing for pollinators

† The need for higher tier tests for pollinators will be determined based upon the results of lower tiered tests and/or other lines of evidence and the need for a refined pollinator risk assessment.

C. Benefits Assessment

The following paragraphs summarize the benefits of paraquat in crop production. For more in-depth discussions on the benefits of paraquat, see *Overview of Use, Benefits, and Impacts of Mitigation Assessment for Paraquat in Agricultural Settings; Paraquat Dichloride (PC# 061601) Use in Soybeans: Usage, Benefits and Impacts of Potential Mitigation; Paraquat Use on Peanut: Usage, Benefits, and Impacts of Potential Mitigation for Registration Review;* and *Paraquat Dichloride (Herbicide and Harvest Aid) Use, Usage, Benefits and Impacts of Potential Mitigation in Cotton,* available in the paraquat docket.

Paraquat provides a number of unique and often high benefits for crops with a high percent crop treated (PCT), such as cotton, peanuts, vineyards, fruit trees, asparagus, artichoke, watermelon, and tree nuts (hazelnuts and pistachios). Benefits are also apparent for crops with a relatively low PCT but for which large acreages are treated, such as soybeans and fruiting vegetables. Unlike many other herbicides, paraquat is effective under low temperatures and when weeds are not actively growing (e.g., early season seedbed preparation). Rainfall soon after application has little or no effect on its performance, unlike most other herbicides. Paraquat that contacts the soil is deactivated by tight adsorption to clay particles, which allows application immediately before planting crops or seedling emergence. As a broad-spectrum herbicide, paraquat is a substitute for

[17] Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

glyphosate. Weed resistance to glyphosate has meant that many growers have turned to paraquat, with a different mode of action than glyphosate, for more effective weed control.

Benefits information for cotton, peanuts, and soybeans were analyzed separately, since these three use sites account for about 64% of the total area treated (TAT) with paraquat and nearly 63% of the pounds of active ingredient (lbs a.i.) applied from 2014-2018. The benefits information for these commodities can be found below.

Cotton

Cotton is one of the crops with the highest usage of paraquat. Paraquat is important in cotton for weed control and as a harvest aid. It is one of the top herbicides used to target and control some of the most problematic weed pests in cotton such as redroot pigweed, Palmer amaranth, and marestail. Based on the available usage data, paraquat is also a top option for growers wishing to control volunteer cotton (mostly in Texas). In addition, paraquat is an important part of managing herbicide-resistant weeds. The majority of paraquat is applied before crop emergence. Herbicide alternatives (i.e., preplant, burndown) to paraquat in cotton are glyphosate, flumioxazin, and glufosinate.

Paraquat also has high benefits as a harvest aid/desiccant when used on cotton; it is one of the top harvest aids used by growers in cotton. Poor weather events can significantly impact the quality and yield of a cotton crop. Growers usually pay attention to approaching weather systems in the time just prior to harvest and will ultimately harvest sooner if a weather event is approaching. Given the rapid effects and rain-fastness that are unique to paraquat, other chemistries cannot replace this specific use as a cotton desiccant for emergency harvest scenarios common through U.S. cotton production. Potential alternative desiccants are sodium chlorate and protoporphyrinogen oxidase (PPO) inhibitor defoliant/desiccant products, which include carfentrazone, fluthiacet-methyl, pyraflufen-ethyl, and flumiclorac pentyl ester.

Although there are alternatives for each aspect of paraquat's use, there is no alternative that can perform both the herbicidal and harvest aid functions. In addition, paraquat is an important part of managing herbicide-resistant weeds. For these reasons, the use of paraquat has high benefits for cotton.

Peanuts

Paraquat is a cost-effective broad-spectrum herbicide with a unique site of action in peanuts. Peanut growers in the Southeastern and Southern Seaboard USDA production regions may find paraquat to be beneficial as it provides quick control of emerged broadleaf and grass weeds, including several yield-limiting weed pests. Additionally, paraquat does not have soil residual activity which may result in crop injury. Paraquat is less important for production of peanuts in the Prairie Gateway production region.

In the absence of paraquat, there would be no direct alternative and growers would likely replace paraquat with different control strategies that are dependent on the application timing of paraquat's current use pattern. Growers would face increased herbicide costs when replacing

paraquat for field preparation, at-plant, and post-emergence use. Growers using paraquat for its FIFRA Section 24(c) non-selective late season use may face yield loss or may be entirely unable to harvest their crop if paraquat were unavailable.

In addition to altering control strategies in the absence of paraquat, some peanut growers using strip tillage may be forced to switch to conventional tillage, which would have consequences for soil health and erosion. Paraquat also provides an important role in resistance management in peanuts.

Soybeans

The benefits of paraquat use in soybeans include effective control of glyphosate-resistant weeds, including Palmer amaranth species and Italian ryegrass that can be particularly problematic in soybean production in the south. Paraquat also costs much less compared to available alternatives. There is no one-to-one herbicide replacement for paraquat in soybean.

The greatest amount of paraquat is used in the Mississippi Delta area (which includes lands in Arkansas, Louisiana and Mississippi that lie along the alluvial floodplain of the Mississippi River) and other southern soybean production regions. To maintain an efficacy equal to paraquat, growers in the Mississippi Delta could replace paraquat with a combination of alternative herbicides at an increased cost.

Other Crops

The Agency determined that the use of paraquat provides benefits for numerous crops and crop groups including artichoke, bulb vegetables, cucurbits, alfalfa, orchards, and vineyards. In addition, the chemical characteristics of paraquat are beneficial as a resistance management tool, where few alternatives are available, and for cool and wet applications. Paraquat can be used as an herbicide to control unwanted weeds or as a plant growth regulator with a variety of niche uses such as sucker control (orchard crops), desiccant used as a crop harvest aid (grains and tomato), and as an effective cover crop burndown (cucurbits).

IV. INTERIM REGISTRATION REVIEW DECISION

A. Risk Mitigation and Regulatory Rationale

EPA has identified potential human health risks of concern to occupational handlers mixing, loading, and applying paraquat for various use scenarios. Potential post-application risks to workers and risks to bystanders from spray drift were also identified. In addition, paraquat poses potential ecological risks to mammals, birds (surrogates for reptiles and terrestrial-phase amphibians), terrestrial invertebrates, terrestrial plants, as well as some aquatic invertebrates (benthic species) and some aquatic plants (algae).

EPA has determined that the following risk mitigation measures are necessary to mitigate these potential risks:

- limit aerial applications to a maximum of 350 acres per applicator per 24-hr period for all uses except cotton desiccation. There is no acreage limit for the aerial application of paraquat to cotton for desiccation purposes;
- require a residential area drift buffer for all aerial applications (75 feet for applications of more than 0.6 lbs cation/A, 50 feet for applications of 0.6 lbs cation/A or lower);
- prohibit the use of human flaggers;
- limit the single application maximum rate for alfalfa to 1.0 lb paraquat cation/A;
- require enclosed cabs for applications to more than 80 acres in a 24-hour period;
- require PF10 respirators or enclosed cabs for applications to 80 acres or less in a 24-hour period;
- prohibit the use of mechanically pressurized handguns and backpack sprayers;
- require a 48-hour Restricted Entry Interval for all crop uses except for cotton desiccation;
- require a 7-day Restricted Entry Interval for cotton desiccation; and
- require mandatory spray drift management measures.

In evaluating potential risk mitigation for paraquat, EPA considered the risks, the benefits, and the use pattern. Although there are potential risks of concern associated with the use of paraquat, with the adoption of the mitigation measures discussed in this section, any remaining potential worker and/or ecological risks are outweighed by the benefits associated with the use of paraquat. For more information on the benefits of paraquat, see Section III.C.

EPA has also determined that the following label changes are necessary to address generic labeling requirements for all paraquat products and uses:

- an herbicide resistance management statement;
- a non-target organism advisory;
- maintaining existing PPE on all non-bulk paraquat products with closed transfer systems;
- a statement clarifying proper rinsing instructions for closed system containers with built-in extraction probes;
- standardization of paraquat label metrics and units of measurement, such as maximum annual application rates, maximum annual numbers of applications, minimum retreatment intervals, and pre-harvest intervals;
- updated glove and respirator label language; and
- an updated Restricted Use Pesticide (RUP) statement

In addition to the mitigation and label changes being proposed, the Agency would like to provide clarification on the topic of "safening" agents, such as stenches, emetics, and dyes, added to paraquat products. While most paraquat products are formulated with safening agents to deter bringing the product close to the face and swallowing, EPA does not have a registration standard for these agents. The addition of stenches, emetics, and dyes to paraquat products is at the discretion of the registrants, although all such agents added to paraquat products must be listed on the confidential statement of formula.

The expected impacts of the mitigation are presented below by mitigation measure. For more information, see the *Overview of Use, Benefits, and Impacts of Mitigation Assessment for Paraquat in Agricultural Settings; Paraquat Dichloride (PC# 061601) Use in Soybeans: Usage,*

Benefits and Impacts of Potential Mitigation; Paraquat Use on Peanut: Usage, Benefits, and Impacts of Potential Mitigation for Registration Review; and *Paraquat Dichloride (Herbicide and Harvest Aid) Use, Usage, Benefits and Impacts of Potential Mitigation in Cotton,* available in the paraquat docket.

1. **Limit Aerial Applications to a Maximum of 350 Acres per Applicator per 24-hour Period for All Uses Except Cotton Desiccation; There is No Acreage Limit for the Aerial Application of Paraquat to Cotton for Desiccation Purposes**

Based on the *Paraquat: HED Response to Comments on the Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates*, there are no risks of concern for occupational handlers making aerial applications up to 350 acres in a 24-hour period. There are, however, risks of concern to applicators for higher-acreage applications (>350 acres). In order to mitigate potential risks to aerial applicators, the Agency has determined it necessary to limit aerial applications of paraquat to a maximum of 350 acres per applicator in a 24-hour period for all uses except cotton desiccation. Potential risks to mammals, birds, and non-target plants would also be reduced by this mitigation measure, combined with the spray drift management measures outlined in Section IV.A.10.

Aerial application of paraquat is critical for timely desiccation of cotton crops prior to harvest. This use is especially important among certain production regions where field sizes are significantly larger, requiring aerial application to harvest the cotton in a timely manner. In response to this need, EPA is not requiring an acreage limit for the treatment of cotton for desiccation purposes.

Impacts of Limiting Aerial Applications to a Maximum of 350 Acres per Applicator per 24-hour Period for All Uses Except Cotton Desiccation

This mitigation measure is less restrictive than the mitigation previously proposed in the PID, which was to prohibit aerial application for all use sites except cotton desiccation. The Agency assessed the impacts of the proposed prohibition of aerial application in previous memos (Harty et al, 2020; Chen and Hanson, 2020; English and Hodde, 2020; Coy and Kells, 2020).

For the ID, the Agency considered the impacts to paraquat users from the new, less restrictive mitigation. For the high-acreage field crops, which include soybean, corn, cotton (herbicide use), potato, rice, and wheat, impacts are generally expected to be low because there is little reliance on aerial use for these crops (Chen et al., 2021). There are times when aerial applications of an herbicide/desiccant may be needed due to wet fields. Limiting aerial applications of paraquat to 350 acres per 24-hour period per applicator may be feasible. In the case where a grower requires more than 350 acres to be treated aerially in one day (i.e., a situation where growers cannot feasibly get into a wet, high-acreage field to apply paraquat via groundboom), it may be necessary to use two or more pilots per day. Because paraquat registration requires each applicator to personally hold a paraquat applicator certification, it may be difficult to find certified pilots, which could potentially delay early season burndowns and prolong harvest activities. A detailed analysis of the impact of this mitigation was not done for typical-acreage crops. However, in general, the limitation of aerial applications to 350 acres per applicator per

24-hour period is expected to have negligible impacts because this is not a typical application method for most crops that are treated with paraquat. Moreover, this mitigation is expected to effectively allow use in more small-acreage crops where growers may be less likely to require aerial applications to more than 350 acres per day. Aerial use in peanut is not approved so this mitigation has no impact to this crop.

2. Require a Residential Area Drift Buffer for All Aerial Applications

To fully mitigate residential bystander risk resulting from spray drift associated with aerial application (MOEs for children 1<2 years old = 12 to 99 (depending on application rate and droplet size); LOC = 100), a no-spray buffer from residential areas is necessary. Residential areas include schools, homes, playgrounds, parks, recreational areas, athletic fields, residential lawns, gardens, and other areas where children may be present. For applications of more than 0.6 lbs cation/A, a buffer of 75 feet is required to reach an acceptable MOE (MOE for 1.0 lbs cation/A (medium to coarse droplet size) = 110; LOC = 100). For applications of 0.6 lbs cation/A or lower, a buffer of 50 feet is required to reach an acceptable MOE (MOE for 0.6 lbs cation/A (medium to coarse droplet size) = 130; LOC = 100). Potential risks to mammals, birds, and non-target plants would also be reduced with the implementation of a buffer.

Impacts of a Residential Area Drift Buffer for Aerial Applications

The Agency originally assessed the impacts of requiring a residential drift buffer in cotton, since cotton desiccation was the only use for which aerial application could be used according to the prohibition of aerial application proposed in the PID. The Agency estimated impacts in cotton for aerial buffers using a range of key parameters such as the length of buffer, the type of buffer, field size, shape of the field, and gross revenue per acre. The Agency's cotton buffer impact estimates were based on three buffer lengths (25, 50, and 75-foot), two types of buffers (one-sided and four-sided or "perimeter" buffer), two field sizes (50th percentile - 78 acres and 90th percentile - 250 acres), and three average gross revenue estimates (low upland, high upland, and pima). The shape of the cotton field was assumed to be a rectangle. A one-sided buffer may be required to protect bystanders from exposure who are near one side of a field. A four-sided buffer would protect bystanders on all four sides and reduce the extent of potential ecological risks on all four sides. For a one-sided, in-field buffer to a "typical" cotton field (median or 50th percentile), the estimated impacts, in terms of a reduction in the land available for production, range from 2% for a 25-foot buffer to 6% for a 75-foot buffer. In monetary terms, this reduction due to the proposed buffer requirement is equal to a decline in gross revenue ranging from $10 to $162 per acre. For a four-sided, in-field buffer to a typical cotton field, the estimated impacts in terms of a reduction in the land available for production, range from 6% for a 25-foot buffer to 17% for a 75-foot buffer. In monetary terms, this reduction due to the buffer requirement, is equal to a decline in gross revenue ranging from $31 to $467 per acre. The estimated impacts for buffers are smaller for larger cotton fields (i.e., 90th percentile - 250 acres).

The financial impacts for buffer requirements may be greater in crop production systems where field sizes are smaller than typical cotton fields. EPA did not assess impacts of buffers outside of cotton, but aerial applications are registered for multiple crops including small minor crops such as artichoke, asparagus, blueberries, etc. and in these small acreage crops, mandatory buffers

could significantly reduce the land available for crop production if aerial applications are needed. The implementation of a residential area drift buffer for aerial applications may require growers to remove land from production, leave the buffer area untreated, or use an alternative that is potentially less effective and/or more expensive in those areas, thus decreasing gross revenue per acre. However, in general, buffer requirements are expected to have low impacts because aerial application of paraquat is likely minimal or sporadic outside of cotton desiccation applications.

3. Prohibit the Use of Human Flaggers

In order to fully mitigate potential risks of concern to human flaggers from aerial applications, the Agency has determined it necessary to prohibit the use of human flaggers.

Impacts of Prohibiting the Use of Human Flaggers
The practice of using human flaggers for aerial pesticide applications has decreased significantly with modern agricultural aviation.[18] Therefore, little to no impacts are expected from this mitigation.

4. Limit Single Application Maximum Rate for Alfalfa to 1.0 lb cation/A

In order to fully mitigate potential post-application risks to occupational handlers for alfalfa, the Agency has determined it is necessary to limit the single application maximum rate for alfalfa to 1.0 pound of cation paraquat per acre (lb cation/A). At the currently labeled single application maximum rate of 1.5 lb cation/A, the MOE on Day 0 after application is 68, which is of concern to the Agency (LOC = 100). At the reduced rate of 1.0 lb cation/A, the MOE on Day 0 after application is 100, which is no longer of concern.

Impacts of Limiting Single Application Maximum Rate for Alfalfa to 1.0 lb cation/A

Usage data and discussions with stakeholders suggest that all single paraquat applications to alfalfa are made at or below 1.0 lb cation/A, which also corresponds with extension recommendations for paraquat application rates in seedling alfalfa, forage alfalfa, and alfalfa grown for seed,[19,20] so there are no economic or biological impacts anticipated from this mitigation.

5. Require Enclosed Cabs for Applications to More than 80 Acres in a 24-hour Period

To mitigate potential inhalation risks to applicators, the Agency is distinguishing between lower (80 acres or less) and higher acreage (more than 80 acres) applications. Based on the *Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review*, an individual making higher acreage applications within a 24-hour period may experience greater

[18] Struttmann, Tim and Zawada, Jackie. 2019 NAAA Aerial Application Industry Survey: Operators. May 2019.
[19] Canevari, W.M., S.B. Orloff, and D.H. Putnam. 2017. UC IPM Pest Management Guidelines: Alfalfa. UC ANR Publication 3440. University of California. http://www.ipm.ucanr.edu/PDF/PMG/pmgalfalfa.pdf.
[20] Prather, T. 2019. Forage Alfalfa and Seed Alfalfa. In E. Peachey (ed). Pacific Northwest Weed Management Handbook. Oregon State University. https://pnwhandbooks.org/sites/pnwhandbooks/files/weed/chapterpdf/weed19-eforageandseed.pdf.

potential risks of concern than lower acreage applications within the same timeframe due to higher expected exposure. In order to offer the most protection to applicators, the Agency has determined it is necessary to require enclosed cabs for any individual making higher acreage applications in a 24-hour period. Enclosed cabs must have a nonporous barrier that completely surrounds the occupants and prevents contact with pesticides outside of the cab. The inhalation MOEs for higher acreage applications, using enclosed cabs, range from 52 to 170 compared to MOEs ranging from 3.1 to 10 without enclosed cabs (LOC = 100). There are only three higher acreage scenarios that have residual risks of concern with enclosed cabs, not including the scenario for alfalfa and clover, which is mitigated by the proposed label rate reduction. The MOEs for the three remaining scenarios of concern are 52, 65, and 87.

The Agency notes that the estimated inhalation MOEs for paraquat are based on upper respiratory portal of entry effects that can result from exposure to spray particles in the inhalable range. The unit exposure data used to assess inhalation exposures are based on particles in the inhalable range; however, these data were derived from nozzles generating smaller particle sizes than those that would be used to generate medium or coarser particles per the proposed paraquat mitigation. Therefore, the estimated inhalation MOEs may be conservative since a larger fraction of the particles generated during paraquat applications made according to label instructions would be expected to fall above the inhalable range, potentially resulting in lower inhalation exposures than those presented in the DRA. These conservative estimates, combined with the high benefits of paraquat discussed in Section III.C, justify the residual risks from the remaining scenarios of concern.

Impacts of Requiring Enclosed Cabs for Applications to More than 80 Acres in a 24-hour Period

The Agency assumes that growers not currently in possession of the proper enclosed cab application equipment would most likely be forced to consider alternative herbicide(s) without these restrictions to replace paraquat usage. Growers depending on paraquat for either resistance management, sucker control, and/or crop desiccation purposes may be inclined to either hire applicators who can bring in the proper equipment or collaborate with neighboring farmers to utilize their enclosed cab systems. In some cases, a grower may choose to purchase enclosed cab equipment, such as a new tractor, although this would probably only happen when existing equipment needed to be replaced.

Growers with fields that are more than 80 acres who do not have the capital to invest in a sprayer with an enclosed cab and that do not select alternative herbicides may also opt to treat fields with applications of paraquat made over multiple days while wearing a PF10 respirator.

6. Require PF10 Respirators or Enclosed Cabs for Applications to 80 Acres or Less in a 24-hour Period

As mentioned above, the Agency is distinguishing between lower (80 acres or less) and higher acreage (more than 80 acres) applications to mitigate potential inhalation risks to applicators. The Agency has determined PF10 respirators or enclosed cabs necessary to protect individuals making lower acreage applications (80 acres or less) within a 24-hour period. The MOEs for lower acreage applications with enclosed cabs range from 130 to 520 (LOC = 100) and the

MOEs for lower acreage applications with PF10 respirators range from 76 to 310 (LOC = 100). The MOEs for lower acreage applications without enclosed cabs or respirators range from 7.6 to 31 (LOC = 100). While there are residual potential risks from three of the lower acreage application scenarios with PF10 respirators (MOEs = 76, 81, and 95), the option of applying with a respirator is intended to provide flexibility to growers that do not have access to sprayers with enclosed cabs. All of the lower acreage application scenarios are fully mitigated with enclosed cabs.

As mentioned in Section IV.A.5 above, the estimated occupational inhalation MOEs may be conservative based on the medium or coarser particle size mitigation proposed which are expected to result in a higher proportion of particles falling within the inhalable range in the inhalation unit exposure data than would be expected from paraquat applications made according to label instructions. These conservative estimates, combined with the high benefits of paraquat presented in section III.C., justify the residual risks from the remaining PF10 respirator scenarios of concern, assuming growers do not have access to sprayers with enclosed cabs.

Impacts of Requiring PF10 Respirators or Enclosed Cabs for Applications to 80 Acres or Less in a 24-hour Period

Growers of crops grown on less than 80 acres may already have PF10 respirators. Growers who do not have respirators, however, would have to hire a commercial firm to make the application, purchase a respirator, or use an alternative herbicide. Respirator costs are extremely variable depending upon the protection level desired, disposability, comfort, and the kinds of vapors and particulates being filtered. Based on information available to EPA, the cost of the respirators (whether disposable or reusable) is relatively minor in comparison to the fit-test requirement under the Worker Protection Standard. The Agency expects that the average cost of a particulate filtering facepiece respirator is lower than the average cost of an elastomeric half mask respirator. The estimated cost of a respirator fit test, training and medical exam is about $180 annually.[21] The impact of the proposed respirator requirement is likely to be substantially lower for a paraquat handler who is already using a respirator because the handler or handler's employer uses other chemicals requiring a respirator in the production system or as part of the business (i.e., the handler or employer will only incur the cost of purchasing filters for the respirator on a more frequent basis). In addition to monetary costs of respirators, the use of a respirator can reduce productivity of workers, which could increase the time required to apply paraquat and increase costs.

EPA acknowledges that procuring a respirator and the associated fit testing, training, and medical evaluation places a burden on handlers or employers. However, the proper fit and use of respirators is essential to accomplish the protections respirators are intended to provide. In estimating the inhalation risks, and the risk reduction associated with different respirators, EPA's human health risk assessments assume National Institute for Occupational Safety and Health (NIOSH) protection factors (*i.e.*, respirators are used according to OSHA's standards). If the respirator does not fit properly, use of paraquat may cause unreasonable adverse effects on the

[21] Economic Analysis of the Agricultural Worker Protection Standard Revisions. Biological and Economic Analysis Division, Office of Pesticide Programs, U.S. EPA. 2015. p. 205. Available at www.regulations.gov, docket number EPA-HQ-OPP-2011-0184-2522

pesticide handler. Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection.[22]

If an applicator opted to make lower acreage applications with an enclosed cab rather than a respirator, they might incur the additional cost of purchasing a sprayer with an enclosed cab or hire a commercial firm to make the application, which could also increase application costs.

If an applicator was unable to make lower acreage applications with a PF10 respirator or an enclosed cab, they could use an alternative herbicide, which could increase treatment costs.

7. Prohibit Mechanically Pressurized Handguns and Backpack Sprayers

For mechanically pressurized handguns, the dermal MOEs range from 12 to 24 and the inhalation MOEs range from 13 to 16. For backpack sprayers, the dermal MOEs range from 21 to 190 and the inhalation MOEs range from 40 to 1,300. To fully mitigate potential risks to occupational handlers (mixers, loaders, and applicators) from mechanically pressurized handguns and backpack sprayers, the Agency has determined it necessary to prohibit these application methods.

Impacts of Prohibiting Mechanically Pressurized Handguns and Backpack Sprayers

Because of the small acreage and often difficult terrain of non-agricultural use sites, it is likely that applications to these sites would be made via handheld equipment. In areas where a backpack sprayer or mechanically pressurized handgun would be most useful, an applicator would have to choose a different active ingredient if applications of paraquat were not permissible using this equipment type. Because paraquat is usually cheaper than most other herbicide alternatives, switching to an alternative herbicide would likely result in increased operating costs for non-agricultural weed control.

According to the available usage data, spot treatments were not reported for the PGR use of paraquat and make up less than 2% of the herbicide applications of paraquat. Assuming that small area treatments potentially made with mechanically pressurized handguns or backpack sprayers are captured in spot treatment data, it does not appear that this mitigation would impact a significant number of acres treated with paraquat. While this application method may be critical for certain use sites, there are many alternatives available.

8. Require 48-hour Restricted Entry Interval for All Crop Uses Except for Cotton Desiccation

Paraquat is classified as Acute I for acute dermal, eye irritation, and primary skin irritation. As such, a 48-hour REI is required under the Worker Protection Standard.[23] Current REIs range from 12 to 24 hours and workers do not typically need to re-enter paraquat treated areas less than 2 days after application.

[22] 29 CFR § 1910.134
[23] https://www.epa.gov/sites/production/files/2016-02/documents/chap-10-feb-2016.pdf

Impacts of Requiring 48-hour Restricted Entry Interval for All Crops Except for Cotton Desiccation

The current REI for soybeans is 24 hours. The majority of paraquat is applied before crop emergence, either as a burndown or preplant application. Both of these scenarios have few requirements for growers to enter the field after an application of paraquat. For this reason, the Agency expects that a 48-hour REI should have minimal impact on how soybean growers use paraquat.

The current REI for peanuts is 12 hours. Applications of paraquat as a burndown or at-planting, as well as early-post crop emergence (majority of applications), are unlikely to be impacted from an increased REI of 48 hours due to the level of worker activities that would occur at these crop stages. Further, as the FIFRA Section 24(c) uses of paraquat must be made at least 30 days prior to harvest, it is unlikely that the increased REI would be overly burdensome to growers and worker activities prior to harvest.

Given the timing of most paraquat applications (early season burndown), the activities that are likely to be most affected by this mitigation are planting or transplanting of crops into the field. Growers may be able to accommodate these changes by re-ordering the activities they do for field preparation in the early season prior to and just at planting or transplant. However, some users could be impacted if rain occurs prior to planting, as they may have to postpone planting until the ground is dry enough to get into the field.

9. Require 7-day Restricted Entry Interval for Cotton Desiccation

To mitigate potential post-application risks to workers from mechanical harvesting of cotton, the Agency has determined that a REI of 7 days for cotton desiccation is necessary. The potential post-application risks to cotton harvesters from module builder operators and picker operators necessitate an REI of at least 7 days. For module builder operator scenarios, the MOE reaches 100 on Day 11 after application and for picker operator scenarios, the MOE reaches 100 on Day 20 after application. An REI of 11-20 days could essentially render the product unusable in some agronomic settings. In light of the substantial benefits conferred by paraquat use for cotton desiccation (see discussion in Section III.C above), the Agency is proposing a 7-day REI for cotton desiccation. A shorter REI would not be protective enough and a longer REI would essentially prohibit its use for cotton desiccation, which is a critical use in certain situations.

Impacts of Requiring 7-day Restricted Entry Interval for Cotton Desiccation

An REI increase to 7 days could have impacts for cotton growers. Timing is an important factor for the late season use of paraquat because up to three applications are allowed in one season and the second application depends on the green leaves remaining and the rate applied in the first application. The pre-harvest interval (PHI) for paraquat is 3 days, which is beneficial to growers for the late season use. An REI increase to 7 days would have impacts on the use pattern of paraquat, particularly in certain situations, such as late season use in Texas or when a poor weather event or freeze is imminent in the Mid-South. Poor weather events such as rain and freeze can significantly impact the quality and yield of a cotton crop. Growers usually pay close

attention to approaching weather systems in the time just prior to harvest and will ultimately harvest sooner if a weather event is approaching. An REI increase to 7 days could impact timely desiccation of cotton close to harvest. Impacts to quality and yield could occur for both stripper- and spindle-harvested cotton.

10. Spray Drift Management

The Agency has determined that spray drift management language on paraquat labels to reduce off-target spray drift and consistently protect against a baseline level of spray drift across all paraquat products is necessary. In conjunction with the prohibition of aerial application and residential buffers mentioned above, reducing spray drift will resolve potential risks to bystanders. It will also reduce the extent of environmental exposure and risk to non-target plants and animals. Although the Agency is not making a complete endangered species finding at this time, these label changes are expected to reduce the extent of exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of paraquat.

The Agency has determined that the following spray drift mitigation language needs to be included on all paraquat product labels for products applied by liquid spray application. The spray drift language is intended to be mandatory, enforceable statements and supersede any existing language already on product labels (either advisory or mandatory) covering the same topics. The Agency is also providing recommendations which allow paraquat registrants to standardize all advisory language on paraquat product labels. Registrants must ensure that any existing advisory language left on labels does not contradict or modify the new mandatory spray drift statements in this ID, once effective.

- Applicators must not spray during temperature inversions.
- For ground boom applications, apply with the release height no more than 4 feet above the ground or crop canopy.
- For ground and aerial applications, do not apply when wind speeds exceed 10 miles per hour at the application site.
- For ground and aerial applications, select nozzle and pressure that deliver medium or coarser droplets as indicated in nozzle manufacturers' catalogues and in accordance with American Society of Agricultural & Biological Engineers Standard 572 for ground applications and Standard 641 for aerial applications (ASABE S572 and S641).
- For aerial applications, apply with the release height no more than 10 feet above the ground or vegetative canopy, unless a greater application height is required for pilot safety.
- For aerial applications, a no-spray buffer from residential areas must be observed. For applications of more than 0.6 lbs cation/A, a buffer of 75 feet is required. For applications of 0.6 lbs cation/A or lower, a buffer of 50 feet is required.

In addition to including the spray drift restrictions on paraquat labels, all references to volumetric mean diameter (VMD) information for spray droplets are to be removed from all paraquat labels where such information currently appears. The new language above, which cites ASABE S572 and S641, eliminates the need for VMD information.

Impacts of Droplet Size Restrictions

The Agency is requiring a droplet size requirement of medium or coarser droplets for applications of paraquat. Currently, applications of paraquat do not have droplet size restrictions (ex. EPA Reg# 100-1431, 82542-3, 5481-615). Paraquat controls weeds from contacting plant foliage. Therefore, effective control of weeds with paraquat and other contact herbicides is dependent on spray coverage. In general, smaller droplets provide greater coverage of plant foliage than coarser droplets.

Growers must consider droplet size of individual pesticides when tank-mixing two or more pesticides. Smaller droplet size may be necessary when tank-mixed with insecticides. Paraquat, however, is primarily tank mixed with other herbicides. University extension publications by pesticide application specialists commonly recommend medium sized droplets for contact herbicides such as paraquat to ensure adequate coverage of weed foliage (Grisso et al., 2009[24]; Wolf and Bretthauer 2009[25]; Grisso 2019[26]). Research has found that applications of paraquat can provide efficacious weed control across a myriad of droplet sizes, including medium and coarser droplet sizes (Douglas, 1968[27]; McKinlay et al., 1974[28]; Carroll, 2017[29]; Ferguson et al, 2018[30]; Peterson and Hay, 2018[31]). Additionally, performance of paraquat was similar with fine or medium droplets and Peterson and Hay (2018) concluded medium droplets were preferable to fine droplets due to lower drift potential. Therefore, the Agency concludes that a droplet size restriction of medium or coarser droplets should have little impact on how growers use paraquat.

Impacts of Release Height Proposal

The Agency is proposing a release height of four feet or less for ground boom applications for all use sites. Spray release height is important to minimize overlap of spray from nozzles while maintaining proper coverage. If nozzles are placed too low, they will not provide adequate

[24] Grisso, R., P. Hipkins, S.D. Askew, L. Hipkins, and D. McCall. 2009. Nozzles: Selection and Sizing. Virginia Cooperative Extension 442-032. Accessed 07/2020. https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/442/442-032/BSE-262.pdf

[25] Wolf, R., and S. Bretthauer. 2009. Droplet Size Calibration: A New Approach to Effective Spraying. Kansas State University Agricultural Experiment Station and Cooperative Extension Service. MF 2869. Accessed 03/2020. https://www.bae.ksu.edu/faculty/wolf/PDF/MF2869%20Droplet%20Calibration.pdf

[26] Grisso, R. 2019. Droplet Chart / Selection Guide. Virginia Cooperative Extension 442-031. Accessed 03/2020. https://www.pubs.ext.vt.edu/content/dam/pubs_ext_vt_edu/442/442-031/BSE-263.pdf

[27] Douglas, G. 1968. The Influence of Size of Spray Droplets on the Herbicidal Activity of Diquat and Paraquat. Weed Res. 8: 205-212. Accessed 04/2020. https://doi.org/10.1111/j.1365-3180.1968.tb01423.x

[28] McKinlay, K.S., R. Ashford, and R. J. Ford, 1974. Effects of Droplet Size, Spray Volume, and Dosage on Paraquat Toxicity. Weed Science Society of America 22: 31-34. Accessed 04/2020. https://doi.org/10.1017/S0043174500036468

[29] Carroll, J.H. 2017. The Effects of Sprayer Speed and Droplet Size on Herbicide Burndown Efficacy. Theses and Dissertations. 2435. Accessed 12/2019. http://scholarworks.uark.edu/etd/2435

[30] Ferguson, J.C., R.G. Chechetto, S.W. Adkins, A.J. Hewitt, B.S. Chauhan, G.R. Kruger, and C.C. O'Donnell. 2018. Effect of Spray Droplet Size on Herbicide Efficacy on Four Winter Annual Grasses. Crop Prot. 112: 118-124. Accessed 04/2020. https://doi.org/10.1016/j.cropro.2018.05.020

[31] Peterson, D., and M. Hay. 2018. Controlling Tall, Thick Stands of Weeds in Wheat Stubble. Agronomy eUpdate. Issue 705. Kansas State University Extension. Accessed 04/2020. https://webapp.agron.ksu.edu/agr_social/m_eu_article.throck?article_id=1923

coverage and could lead to portions of the field not receiving pesticide. The Agency has determined that a maximum release height of 4 feet allows adequate coverage for the majority of nozzles.

The Agency is proposing a release height of ten feet or less for aerial applications. The Agency considers a release height of 10 feet to be standard application practice and does not anticipate any impacts.

Impacts of Wind Speed Restriction

The Agency is considering a 10-mile per hour (mph) wind speed restriction for ground and aerial applications of paraquat. Wind conditions vary across the U.S. and wind speed restrictions could prevent timely applications of paraquat. Mandatory wind speed restrictions complicate weed and crop management by reducing available time required to make applications. Limited information on general applicator practices exists for people when applying pesticides; however, Bish and Bradley (2017)[32] conducted a survey of more than 2,000 certified pesticide applicators in Missouri and they found that most applicators are aware of wind speeds when making herbicide applications, and that many typically apply at wind speeds of 10 mph or lower (more than 65% of Missouri applicators consider it too windy to spray above 10 miles per hour). However, there are situations (e.g., when rain and other weather conditions are right for application, when pest pressure is high, etc.) when applicators will spray at wind speeds greater than 10 mph (approximately 35% of survey respondents). The Agency is not aware of similar surveys of application practices in other parts of the county. The Agency welcomes comments from growers and applicators about their application practices considering wind speeds. Growers working in regions that typically encounter wind speeds of greater than 10 mph may choose to use other products that do not have this restriction.

Impacts of Buffers for Aerial Application

See discussion in Section IV.A.2: Require a Residential Area Drift Buffer for Aerial Applications.

Interaction of Individual Components of Spray Drift Mitigation

Impacts of multiple mitigations could be compounded and further reduce the time in which applicators could apply paraquat. For instance, applicators may deal with wind restrictions by spraying early in the morning/late evenings when winds are calmer; however, temperature inversions are more likely to occur several hours before sunset and can persist until 1-2 hours after sunrise. As the window of application gets smaller, growers will be forced to switch to products without these restrictions on short notice. Therefore, the alternative may be based on availability and not performance, which could be costly and reduce weed control. Additionally, growers may have situations where a tank is loaded and ready to spray, but they are not able to spray due to prolonged weather conditions that prevent application due to mandatory

[32] Bish, M. and K.W. Bradley. 2017. Survey of Missouri Pesticide Applicator Practices, Knowledge, and Perceptions. Weed Technology 31:165–177. Available at: https://weedscience.missouri.edu/Pesticide%20Applicator%20Knowledge_2017.pdf

multilayered restrictions. In rare situations, there could be scenarios where applicators cannot spray what is mixed in the tank for a long period of time and would need to dispose of a large quantity of mixed herbicides in order to switch to an alternative mixture. There may be additional concerns (e.g., tank clean-out when products settle out) when a loaded tank sits hours and possibly days.

11. Herbicide Resistance Management

The Agency has determined it necessary to add resistance-management language to paraquat labels[33] to address pesticide resistance.[34] Consistent with EPA's Pesticide Registration Notice (PRN) on herbicide resistance management,[35] EPA intends to propose herbicide resistance measures[36] for existing chemicals during registration review and for new chemicals and new uses at the time of registration. The proposed resistance-management language provides growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds.

Adding this language will provide pesticide users with easy access to important information on maintaining the effectiveness of pesticides—including paraquat—thereby preserving the benefits of paraquat and other useful pesticides.[37]

12. Non-Target Organism Advisory

The Agency has determined it necessary to add a nontarget organism advisory statement to paraquat labels. EPA prioritizes protecting pollinators, including by reducing spray drift and educating growers about potential indirect adverse effects of herbicides (including paraquat) on foliage and habitat of nontarget organisms. Based on the incomplete data available, EPA is uncertain how much risk paraquat presents to pollinators.[38] Pollinators may be exposed to paraquat from residues in pollen or nectar through spray drift. Like all herbicides, paraquat is also toxic to plants and spray drift may negatively impact forage and habitat of pollinators and other non-target organisms.

[33] For specific label language, see Appendix B.
[34] Pesticide resistance is the ability of portions of a pest population to tolerate or survive otherwise lethal doses of a pesticide through genetic or behavioral changes. EPA considers increased pesticide resistance an adverse effect that can drive increased use of pesticides. The development and spread of herbicide resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture. Currently, there are over 250 weed species worldwide with confirmed herbicide resistance, including over over 155 weed species in the United States with confirmed resistance to one or more herbicides. For more details, see PRN 2017-1 and PRN 2017-2, available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.
[35] PRN 2017-2, "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship" (Aug. 24, 2017), available at https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.
[36] Management of herbicide resistant weeds includes measures for both mitigating established herbicide resistant weeds and slowing or preventing the development of new herbicide resistant weeds.
[37] For a detailed discussion of paraquat's benefits, see Section III.C, above.
[38] For a detailed discussion of pollinator risks, see Section III.B, above. For a list of missing data that may clarify pollinator risks, see Sections III.B.3, above, and IV.D, below.

13. Additional Label Changes

In addition to the above-mentioned proposed mitigation, EPA has also determined it's necessary to add the following label changes to address generic labeling requirements and ensure consistency across all paraquat products and uses:

Maintaining Personal Protective Equipment

As of December 2020, all non-bulk paraquat product containers (<120 gallons) have been distributed in containers incorporating closed transfer systems.[39] According to the WPS, when handlers use closed systems, handler PPE requirements may be reduced or modified as specified in the WPS. However, due to the potential risks to occupational handlers, paired with paraquat's incident history, the Agency has determined it necessary to maintain existing PPE on all labels, in addition to the closed transfer system requirement. The closed transfer system requirement is meant to provide additional protection to occupational handlers when mixing and loading. It is not meant to be a substitute for PPE. This is further supported by the new data from AHETF, indicating that with the use of both PPE (gloves/respirator) and closed systems, there are no longer risks of concern to mixers and loaders for applications at rates of 1.0 lb cation/A and below.

The closed transfer system requirement does not apply to bulk paraquat products (≥120 gallons) but users are still required to wear PPE when mixing and loading to or from bulk containers.

Rinsing Instructions for Closed System Containers with Extraction Probes

Research from the Agricultural Handler Exposure Task Force (AHETF) has shown that removal of unrinsed extraction probes from closed systems has the potential to greatly increase exposure potential to pesticide handlers. Paraquat closed systems have the following requirement:

"the closed system must connect to the container in a way that the closed system is the only feasibly way to remove paraquat from the container without destroying the container; therefore, a screw cap for the pourable closure on a typical pesticide container is not sufficient."

Because of this requirement, the issue of unrinsed removable extraction probes is unlikely to affect paraquat closed systems. However, in order to be protective of closed systems that may contain built-in extraction probes, the Agency is requiring a statement to ensure proper extraction probe rinsing instructions.

Standardizing Label Metrics and Units of Measurement

There are currently 33 FIFRA Section 3 registrations and 47 FIFRA Section 24(c) registrations for paraquat, some of which are missing information regarding application metrics. EPA is requiring that all paraquat labels be updated to current standards. The components of the label that need to be updated are as follows:

[39]Paraquat Dichloride Human Health Mitigation Decision. 2016.
Available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0855-0112

- maximum number of applications per 12-month period;
- maximum annual application rates for each use;
- maximum single application rates for each use;
- minimum retreatment intervals; and
- pre-harvest intervals

The intent of this label standardization measure is not to require changes to the current label metrics, but to ensure that these parameters be clearly defined on every label in order to establish better consistency and clarity across all paraquat labels. The Agency is also requiring the standardization of units of measurement for these parameters. The active ingredient paraquat dichloride is comprised of a mixture of paraquat cations and chloride anions. Paraquat cation is the toxic moiety and, therefore, it is the form that was evaluated for exposure and risk assessment purposes and the form that should be used when calculating application rates. In order to clarify this, all application rates must be measured in pound paraquat cation per acre, referenced as pound cation per acre (lb cation/A). The application metrics and units of measurement for each registered use of paraquat can be found in Table B.2 in Appendix B.

Updated Gloves and Respirator Label Language

An update to the gloves statement currently on paraquat labels, consistent with Chapter 10 of the Label Review Manual,[40] is necessary. In particular, EPA proposes removing any references to specific categories in EPA's chemical-resistance category selection chart and specifying the appropriate types of glove. The Agency is also updating the respirator statement currently on paraquat labels. These clarifications do not fundamentally change the personal protective equipment (PPE) that workers currently must use. [41]

Updated Restricted Use Pesticide (RUP) Statement

In order to provide clarity regarding the sale of paraquat products, the Agency has determined it necessary to remove any mention of retail sale from the RUP statement on paraquat labels. The Agency is also requiring the addition of language to the RUP statement that will allow truck drivers who are not certified applicators to transport containers of paraquat that have been opened, provided certain conditions are met. The RUP statement should be updated to say:

"To be used by certified applicators only – NOT to be used by uncertified persons working under the supervision of a certified applicator, except that uncertified persons may transport containers as provided under Directions for Use."

B. Tolerance Actions

The Agency plans to exercise its FFDCA authority to update the tolerance expression to appropriately cover the metabolites and degradates of paraquat and to specify the residues to be

[40] Label Review Manual, https://www.epa.gov/pesticide-registration/label-review-manual.
[41] For specific label language, see Appendix B.

measured for each commodity for enforcement purposes. EPA expects to propose amending the tolerance expression to read as follows:

Tolerances are established for the residues of paraquat, including its metabolites and degradates, resulting from the application of the dichloride salt of paraquat in or on the commodities specified in the following table. Compliance with the following tolerance levels is to be determined by measuring only paraquat (1,1'-dimethyl-4,4'-bipyridinium) and calculated as the paraquat cation:

The Organization for Economic Cooperation and Development (OECD) rounding class practice does not recommend adding a trailing zero. The Agency is planning modifications to the paraquat tolerances to be consistent with the OECD rounding class practice and/or to revise certain commodity definitions. The Agency plans to exercise its FFDCA authority to modify the tolerances for paraquat as summarized in Appendix E.

The Codex Alimentarius Commission and Canada have each established maximum residue limits (MRLs) of paraquat for many commodities. The Agency is currently harmonized with respect to Canadian MRLs where both have established tolerances. The Agency is currently harmonized with respect to the residue level and residue definition with Codex for many commodities. Pursuant to its authority under the FFDCA, the Agency intends to increase U.S. tolerances for certain commodities to harmonize with Codex. The Agency also intends to harmonize the Brassica leafy greens subgroup 4-16B tolerance with Canada at 0.05 ppm. This harmonization is due to Canada being a major trade partner for these commodities. These recommendations can be found in Table 2 below. Numerous U.S. tolerances are based on field trials where quantifiable residues have been found so harmonization with Codex LOQ MRLs is not possible.

Table 2: Proposed U.S. Tolerance Revisions for Harmonization with Codex and Canada

Commodities	Current Tolerance	Recommended Tolerance
Endive, Vegetable, Head and Stem Brassica, Group 5-16,	0.05 ppm	0.07 ppm (Harmonization with Codex)
Brassica leafy green subgroup 3-16B	0.05 ppm	0.05 ppm (Harmonization with Canada)
Lentil, seed, pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean	0.03 ppm	0.05 ppm (Harmonization with Codex)
Olive	0.05 ppm	0.1 ppm (Harmonization with Codex)

C. Interim Registration Review Decision

The Agency is issuing this ID in accordance with 40 C.F.R. §§ 155.56 and 155.58. The Agency has made the following interim decision: (1) no additional data are required at this time; and (2) paraquat does not meet the registration standard without changes to the affected registrations and their labeling. The mitigation proposed in Sections IV.A and Appendices A and B are sufficient to address certain concerns.

The Agency conducted detailed draft HHRA and ERA. In these risk assessments, EPA observed several risks to continuing to register paraquat. Exposures to occupational handlers (Section III.A.1) and ecological taxa (Section III.B.1) are expected from the registered uses of paraquat. These risks are significantly reduced with the adoption of the mitigation measures discussed in Section IV.A.

EPA also determined that continuing to register paraquat provides high benefits. As outlined in Section III.C, paraquat provides a number of unique benefits for crops with a high PCT, as well as for crops with a relatively low PCT but for which large acreages are treated. Paraquat can be applied immediately before planting crops or seedling emergence and can be used as a substitute for glyphosate to treat glyphosate-resistant weeds. Any potential risks of concern that aren't fully mitigated by the measures discussed herein are outweighed by the benefits associated with the use of paraquat.

During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration."[42] Here, EPA determines that paraquat does not meet the FIFRA registration standard without the changes to the affected registrations and their labeling described in Section IV.A and Appendices A and B. Without these changes, the risks from exposure to paraquat are too high to meet the FIFRA risk-benefit standard.

In addition, EPA determines that there is no human dietary risk from registered uses of paraquat that is inconsistent with the FFDCA safety standard. There are no paraquat products registered for application to residential areas, therefore no residential exposures for paraquat are expected. As a result, aggregate risk is equivalent to dietary risk and is not of concern.

In this ID, the Agency is not making any human health or environmental safety findings associated with the Endocrine Disruptor Screening Program (EDSP) screening of paraquat. Similarly, the Agency is not making a complete endangered species finding, though the mitigation is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range or critical habitat co-occur with the use of paraquat. The Agency will complete a listed-species assessment and any necessary Endangered Species Act (ESA) Section 7 consultation with the Services and make an EDSP determination before issuing a final registration review decision for paraquat.

D. Data Requirements

EPA does not anticipate calling-in additional data for paraquat's registration review at this time.

[42] 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(c)(5); *see also* 7 U.S.C. §§ 136(bb) (defining "unreasonable adverse effects on the environment" as encompassing both "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide" [FIFRA's risk-benefit standard] **and** "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FFDCA safety standard]"). In a PID, EPA sets out a proposed interim decision that includes EPA's "proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." 40 C.F.R. §§ 155.56, 155.58(b)(1).

V. NEXT STEPS AND TIMELINE

Registrants must submit a cover letter, a completed Application for Registration (EPA form 8570-1) and electronic copies of the amended product labels within 60 days of publication of this ID. Two copies for each label must be submitted, a clean copy and an annotated copy with changes. In order for the application to be processed, registrants must include the following statement on the Application for Registration (EPA form 8570-1):

"I certify that this amendment satisfies the requirements of the Paraquat Interim Registration Review Decision and EPA regulations at 40 C.F.R. Section 152.44, and no other changes have been made to the labeling of this product. I understand that it is a violation of 18 U.S.C. Section 1001 to willfully make any false statement to EPA. I further understand that if this amendment is found not to satisfy the requirements of the Paraquat Interim Registration Review Decision and 40 C.F.R. Section 152.44, this product may be in violation of FIFRA and may be subject to regulatory and/or enforcement action and penalties under FIFRA."

Within the required timeframe, registrants must submit the required documents to the Re-evaluation section of EPA's Pesticide Submission Portal (PSP), which can be accessed through EPA's Central Data Exchange (CDX) at https://cdx.epa.gov/. Registrants may instead send paper copies of their amended product labels, with an application for a fast-track, Agency-initiated non-PRIA label amendment to Ana Pinto at one of the following addresses, so long as the labels and application are submitted within the required timeframe:

VIA US Mail
USEPA Office of Pesticide Programs
Pesticide Re-evaluation Division
Mail Code 7508P
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

VIA Courier
Pesticide Re-evaluation Division
c/o Front End Processing
Room S-4910, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Appendix A: Summary of Actions for Paraquat

Registration Review Case #: 0262
PC Code: 061601, 061603
Chemical Type: herbicide
Chemical Family: bipyridylium
Mechanism of Action: photosystem I electron diverter

Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Actions	Comment
• Occupational handlers (mixing, loading, applying)	• Aerial application • Ground application	• Inhalation • Dermal	Short and intermediate term	• Inhalation toxicity	• Require enclosed cabs • Require PF10 respirators • Limit aerial application (except for cotton desiccation) • Prohibit mech. pressurized handgun/backpack	
• Occupational post-application (scouting and harvesting)	• Residues on treated sites	• Dermal	Short and intermediate term	• Skin damage/corrosion	• Increase REI • Decrease single application maximum rate for alfalfa	Risks for alfalfa (scouting) and cotton (harvesting)
• Residential bystanders	• Aerial application •	• Dermal • Incidental oral	Short and intermediate term	• Lung effects • Skin damage/corrosion	• Require a buffer for aerial application • Require spray drift management measures	Spray drift risk concern is from aerial applications
• Mammals	• Dietary	• Ingestion	Acute and chronic	• Mortality • Growth	• Limit aerial application (except for cotton desiccation) • Require spray drift management measures	

• Birds	• Dietary	• Ingestion	Acute and chronic	• Reproduction • Food consumption	• Limit aerial application (except for cotton desiccation) • Require spray drift management measures	
• Pollinators	• Dietary	• Spray contact and ingestion	Acute	• Acute toxicity		
• Terrestrial plants	• Spray drift	• Foliar absorption		• Emergence • Growth	• Limit aerial application (except for cotton desiccation) • Require spray drift management measures	
• Benthic invertebrates	• Runoff • Spray drift	• Sediment	Chronic	• Growth • Survival • Reproduction	• Limit aerial application (except for cotton desiccation) • Require spray drift management measures	Bioavailability may be limited
• Aquatic plants (algae)	• Runoff • Spray drift	• Surface water • Sediment		• Cell density • Frond number	• Limit aerial application (except for cotton desiccation) • Require spray drift management measures	

Appendix B: Labeling Changes and Clarifications for Paraquat Products

Table B.1.: Label Language for Paraquat Products

Description	Proposed Label Language for Paraquat Products	Placement on Label
	End Use Products	
Mechanism of Action Group Number 22	**Note to registrant:** • Include the name of the **ACTIVE INGREDIENT** in the first column • Include the word "**GROUP"** in the second column • Include the **SITE OF ACTION CODE** in the third column (for herbicides this is the Mechanism of Action, for fungicides this is the FRAC Code, and for insecticides this is the Primary Site of Action) • Include the type of pesticide (*i.e.*, **HERBICIDE** or **FUNGICIDE** or **INSECTICIDE)** in the fourth column. **PARAQUAT DICHLORIDE** | **GROUP** | **22** | **HERBICIDE**	Front Panel, upper right quadrant. All text should be black, bold face and all caps on a white background, except the mode of action code, which should be white, bold face and all caps on a black background; all text and columns should be surrounded by a black rectangle.
Limit Aerial Application to a Maximum of 350 Acres per Applicator per 24-hour Period for All Uses Except Cotton Desiccation	"Individual applicators must not apply this product aerially to more than 350 acres in a 24-hour period, except for cotton desiccation applications. There is no acreage limit for the treatment of cotton for desiccation purposes."	Application Directions, under "Methods of Application" and Restrictions and Precautions, under "Use Restrictions"
Prohibit Use of Human Flaggers	"Human flaggers must not be used when making aerial applications."	Restrictions and Precautions, under "Use Restrictions"
Limit Single Application	"Do not exceed 1.0 lb cation/A for a single application of paraquat-containing products for all combined uses."	Crop Use Directions, under "Alfalfa"

Description	Proposed Label Language for Paraquat Products	Placement on Label
Maximum Rate for Alfalfa		
Require Enclosed Cabs	"When applying to more than 80 acres in a 24-hour period, applications must be made using an enclosed cab. Enclosed cabs must have a nonporous barrier that totally surrounds occupant and prevents contact with pesticides outside of the cab."	Engineering Controls
Require PF10 Respirator	"When applying to 80 acres or less in a 24-hour period, if not using an enclosed cab, applicators must wear a minimum of a NIOSH-approved particulate respirator with any N*, R or P filter, NIOSH approval number prefix TC-84A; OR a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Prohibit Mechanically Pressurized Handguns and Backpack Sprayers	"Do not apply this product by mechanically pressurized handgun or backpack sprayer. Application by manually pressurized handwand is permitted."	Application Directions, under "Methods of Application" and Restrictions and Precautions, under "Use Restrictions"
Require 48-Hour REI	"**For all applications except cotton desiccation:** Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours."	Agricultural Use Requirements
Require 7-Day REI for Cotton Desiccation	"**For cotton desiccation applications:** Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 7 days."	Agricultural Use Requirements
Require Rinsing Instructions for Extraction Probes	For products in closed system containers that have a built-in extraction probe, add the following statement to label: "The built-in chemical extraction probe must be rinsed within the pesticide container prior to removal."	Directions for Use and Storage and Disposal
Standardize Label Metrics	The following parameters must be clearly defined on all labels: 1. maximum annual number of applications 2. maximum annual application rates 3. maximum single application rates 4. minimum retreatment intervals 5. pre-harvest intervals All application rates must be presented as pounds cation paraquat per acre (lbs cation/A).	Crop Use Directions

Description	Proposed Label Language for Paraquat Products	Placement on Label
	Refer to Table B.2. for units of measurement and specific application metrics by crop.	
Update Engineering Controls Statement	Replace existing Engineering Controls Statement with the following language: "Handlers performing mixing and loading activities using paraquat closed systems may not reduce or modify handler PPE requirements as described in 40 CFR 170.607 of the Worker Protection Standard for agricultural pesticides."	Under the Engineering Controls Statement
Update Gloves Statement	Update the gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, remove reference to specific categories in EPA's chemical-resistance category selection chart and list the appropriate chemical-resistant glove types to use.	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Update Respirator Language	[**Note to registrant**: If your end-use product only requires protection from particulates only (low volatility), use the following language:] "Wear a minimum of a NIOSH-approved particulate filtering facepiece respirator with any N*, R or P filter; OR a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; OR a NIOSH-approved powered air purifying respirator with HE filters." *Drop the "N" option if there is oil in the product's formulation and/or the product is labeled for mixing with oil-containing products.	In the Personal Protective Equipment (PPE) within the Precautionary Statements
Restricted Use Pesticide Statement	Remove all mention of retail sale from RUP statement. Statement should read: "To be used by certified applicators only – NOT to be used by uncertified persons working under the supervision of a certified applicator, except that uncertified persons may transport containers as provided under Directions for Use."	RUP box
Conditions for Transportation of Paraquat by Uncertified Persons	"Persons who are not certified applicators may transport containers of paraquat that have been opened, subject to the following conditions: • Closures have been applied by a certified applicator to all openings on the paraquat container, including tank cars, so the closures are secured against loosening and prevent any non-negligible release of paraquat from the openings. • Each opening on portable containers containing non-negligible amounts of paraquat must have a tamper-evident device applied by a certified applicator, a one-way valve, or both for portable refillable containers used to sell or distribute pesticides. • Containers of paraquat not permanently attached to a motor vehicle must be secured against shifting, including relative motion between packages, within the vehicle. • Truck drivers who are not certified applicators must not transfer paraquat or any formulation containing paraquat into or out of the container or tank car.	Directions for Use

Description	Proposed Label Language for Paraquat Products	Placement on Label
	• Truck drivers who are not certified applicators must have no contact with or access to paraquat or any formulation containing paraquat. • Any full or emptied portable containers of paraquat must be delivered to a certified applicator, to a secured and locked storage facility controlled by the certified applicator, or to a licensed waste disposal facility. • A certified applicator must ensure that truck drivers understand the risks associated with paraquat, the consequences of misuse, and the conditions outlined herein."	
Non-target Organism Advisory	"NON-TARGET ORGANISM ADVISORY: This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift."	Environmental Hazards
HERBICIDE RESISTANCE MANAGEMENT: Weed Resistance Management	Include resistance management label language for herbicides from PRN 2017-1 and PRN 2017-2 (https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year)	Directions for Use, prior to directions for specific crops under the heading "WEED RESISTANCE-MANAGEMENT"
Additional Required Labelling Action **Applies to all products delivered via liquid spray applications**	Remove information about volumetric mean diameter from all labels where such information currently appears.	Directions for Use
Spray Drift Management Application Restrictions for all products delivered via liquid spray application and allow aerial application	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Aerial Applications**: • Do not release spray at a height greater than 10 ft above the ground or vegetative canopy, unless a greater application height is necessary for pilot safety. • Do not apply within 50-75 feet of a residential area. (For applications of more than 0.6 lbs cation/A, a buffer of 75 feet is required. For applications of 0.6 lbs cation/A or lower, a buffer of 50 feet is required.) Residential areas include schools, homes, playgrounds, parks, athletic fields, residential lawns, gardens, and other areas where children may be present. • Applicators are required to use a medium or coarser droplet size (ASABE S572). Do not apply when wind speeds exceed 10 mph at the application site. Applicators must use ½ swath displacement upwind at the downwind edge of the field.	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Aerial Applications" Placement for these statements should be in general directions for use, before end use-

Description	Proposed Label Language for Paraquat Products	Placement on Label
	• The boom length must not exceed 65% of the wingspan for airplanes or 75% of the rotor blade diameter for helicopters. • Do not apply during temperature inversions.	specific directions for use.
Spray Drift Management Application Restrictions for products that are applied as liquids and allow ground boom applications	**"MANDATORY SPRAY DRIFT MANAGEMENT** **Ground Boom Applications:** • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. • Select nozzle and pressure that deliver medium or coarser droplet size (ASABE S572). • Do not apply when wind speeds exceed 10 mph at the application site. • Do not apply during temperature inversions."	Directions for Use, in a box titled "Mandatory Spray Drift Management" under the heading "Ground Boom Applications"
Advisory Spray Drift Management Language for all products delivered via liquid spray application	**"SPRAY DRIFT ADVISORIES** THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS. **IMPORTANCE OF DROPLET SIZE** An effective way to reduce spray drift is to apply large droplets. Use the largest droplets that provide target pest control. While applying larger droplets will reduce spray drift, the potential for drift will be greater if applications are made improperly or under unfavorable environmental conditions. **Controlling Droplet Size – Aircraft** ***(note to registrants:*** *remove if aerial application is prohibited on product labels)* • Adjust Nozzles - Follow nozzle manufacturers' recommendations for setting up nozzles. Generally, to reduce fine droplets, nozzles should be oriented parallel with the airflow in flight. **Controlling Droplet Size – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* • Volume - Increasing the spray volume so that larger droplets are produced will reduce spray drift. Use the highest practical spray volume for the application. If a greater spray volume is needed, consider using a nozzle with a higher flow rate. • Pressure - Use the lowest spray pressure recommended for the nozzle to produce the target spray volume and droplet size. • Spray Nozzle - Use a spray nozzle that is designed for the intended application. Consider using nozzles designed to reduce drift. **BOOM HEIGHT – Ground Boom** ***(note to registrants:*** *remove if ground boom is prohibited on product labels)* For ground equipment, the boom should remain level with the crop and have minimal bounce. **SHIELDED SPRAYERS**	Directions for Use, just below the Spray Drift box, under the heading "Spray Drift Advisories"

Description	Proposed Label Language for Paraquat Products	Placement on Label
	Shielding the boom or individual nozzles can reduce spray drift. Consider using shielded sprayers. Verify that the shields are not interfering with the uniform deposition of the spray on the target area. **TEMPERATURE AND HUMIDITY** When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation. **TEMPERATURE INVERSIONS** Drift potential is high during a temperature inversion. Temperature inversions are characterized by increasing temperature with altitude and are common on nights with limited cloud cover and light to no wind. The presence of an inversion can be indicated by ground fog or 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. Avoid applications during temperature inversions. **WIND** Drift potential generally increases with wind speed. AVOID APPLICATIONS DURING GUSTY WIND CONDITIONS. Applicators need to be familiar with local wind patterns and terrain that could affect spray drift."	

Table B.2.: Paraquat Application Metrics by Crop

Crop/Site	Timing of Application[43]	Maximum Single Application Rate	Maximum Number of Applications per 12-month Period	Maximum Annual Application Rate	Minimum Retreatment Interval	Pre-Harvest Interval
Acerola (West Indies cherry)	All uses	1.0 lbs cation/A	5 apps	5.0 lbs cation/A/year	7 days	28 days
Alfalfa	Preplant/preemergence	1.0 lb cation/A	2 apps	1.0 lb cation/A/year	7 days	NCH
	New seedlings grown for hay (CA only)	0.5 lb cation/A	1 app	0.5 lb cation/A/year	N/A	70 days
	Between-cuttings treatment	0.26 lbs cation/A	3 apps	0.75 lb cation/A/year	1 app per cutting interval	30 days
	Dormant season	0.75 lbs cation/A	1 app	0.75 lb cation/A/year	N/A	Region A – 42 days Region B – 60 days
	Desiccation to facilitate harvest of alfalfa seed	1.0 lbs cation/A	2 apps	1.0 lb cation/A/year	N/A	4

[43] Pre/postemergence refers to the crop, not the pest.

Crop/Site	Timing of Application[43]	Maximum Single Application Rate	Maximum Number of Applications per 12-month Period	Maximum Annual Application Rate	Minimum Retreatment Interval	Pre-Harvest Interval
Almond	All uses	1.0 lbs cation/A	5 apps	5.0 lbs cation/A/year	7days	
Apple	All uses	1.0 lbs cation/A	5 apps	5.0 lbs cation/A/year	7 days	NCH
Apricot	All uses	1.0 lbs cation/A	3 apps	3.0 lbs cation/A/year	7 days	28 days
Artichoke	All uses	1.0 lbs cation/A	3 apps	2.0 lbs cation/A/year	7 days	1 day
Asparagus	All uses	1.0 lbs cation/A	1 app	1.0 lb cation/A/year	N/A	6 days
Avocado	All uses	1.0 lbs cation/A	5 apps	5.0 lbs cation/A/year	7 days	NCH
Banana	All uses	1.0 lbs cation/A	5 apps	5.0 lbs cation/A/year	7 days	NCH
Barley	All uses	1.0 lbs cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Beans, dried-type	Preplant/preemergence	0.5 lbs cation/A	3 apps		7days	NCH
	Harvest aid		2 apps	0.5 lb cation/A/year	7 days	7 days
Brassica (head and stem) vegetables	All uses	1.0 lbs cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Berries	All uses	1.0 lb cation/A	2 apps	1.0 lb cation/A/year	7 days	NCH
Carrot (including tops)	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Cherry	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	28 days
Citrus	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	1 day
Cacao	All uses	1.0 lb cation/A	5 apps	2.0 lbs cation/A/year	7 days	1 day
Coffee	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	14 days
Coniferous/evergreen/softwood (non-food)	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NA
Corn (field, pop, seed, sweet)	Preplant/preemergence	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
	Postemergence	0.5 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	14 days
	Harvest aid	0.5 lb cation/A	1 app	1.5 lbs cation/A/year	N/A	7 days
	All combined uses		7 apps	5.0 lbs cation/A/year	7 days	
Cotton	Preplant/preemergence	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
	Postemergence	0.5 lb cation/A	3 apps	1.5 lbs cation/A/year	14 days	NCH
	Harvest aid/postharvest	0.5 lb cation/A	4 apps	0.50 lb cation/A/year	7 days	Western Cotton - 7 days All others - 3 days
	All combined uses		10 apps	3.0 lbs cation/A/year	7 days	
Cucurbit vegetables	All uses	1.0 lb cation/A	3 apps	2.5 lbs cation/A/year	14 days	NCH

Crop/Site	Timing of Application[43]	Maximum Single Application Rate	Maximum Number of Applications per 12-month Period	Maximum Annual Application Rate	Minimum Retreatment Interval	Pre-Harvest Interval
Deciduous/broadleaf/hardwood (non-food)	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NA
Fallow land	All uses	1.0 lb cation/A	2 apps	2.0 lbs cation/A/year	7 days	NA
Fig	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	13 days
Flowering plants	All uses	1.0 lb cation/A	2 apps	2 lbs cation/A/year	7 days	NCH
Fruiting vegetables	Preplant/preemergence	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	14 days	NCH
	Postemergence		3 apps	1.4 lbs cation/A/year		NCH
	All combined uses			4.5 lbs cation/A/year		
Garlic	All uses	1.0 lb cation/A	1 app	1.0 lb cation/A/year	N/A	California – 200 days All others – 60 days
Ginger	All uses	1.0 lb cation/A	6 apps	6.0 lbs cation/A/year	30 days	Immature roots – 14 days Mature roots – 75 days
Grapes	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	NCH
Grasses grown for seed	All uses	1.0 lb cation/A	3 apps	2.0 lbs cation/A/year	14 days	28 days
Guar	Harvest aid	0.5 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	4 days
Guava	All uses	0.938 lb cation/A	4 apps	3.76 lbs cation/A/year	7 days	NCH
Hops	All uses	0.5 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	14 days
Kiwifruit	All uses	1.0 lb cation/A	3 apps	2.0 lbs cation/A/year	7 days	14 days
Leafy vegetables (except brassica)	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Legume vegetables (succulent)	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Manioc (cassava)	All uses	1.0 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	90 days
Mint	All uses	0.75 lb cation/A	2 apps	0.75 lb cation/A/year	7 days	NCH
Nectarine	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	28 days
Non-grass animal feed (forage, feed, straw, hay)	All uses	0.75 lb cation/A	1 app	0.75 lb cation/A/year	N/A	60 days
Okra	Preemergence	1.0 lb cation/A	1 app			NCH
	Postemergence	0.5 lb cation/A	2 apps			21 days
	All combined uses		3 apps	2.0 lbs cation/A/year	14 days	
Olive	All uses	1.0 lb cation/A	4 apps	4.0 lbs cation/A/year	7 days	13 days
Onion, dry bulb	Preemergence	1.0 lb cation/A	1 app		7 days	60 days
	Postemergence	0.5 lb cation/A	1 app			60 days

Crop/Site	Timing of Application[43]	Maximum Single Application Rate	Maximum Number of Applications per 12-month Period	Maximum Annual Application Rate	Minimum Retreatment Interval	Pre-Harvest Interval
	All combined uses		2 apps	1.5 lbs cation/A/year		
Onion, seeded	Preplant/preemergence	1.0 lb cation/A	1 app	1.0 lb cation/A/year		California – 200 days All others – 60 days
	All combined uses		1 app	1.5 lbs cation/A/year	N/A	
Papaya	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	NCH
Passion fruit (granadilla)	All uses	0.938 lb cation/A	4 apps *None during harvest season, unless all fruit has been picked up off the ground.	3.76 lbs cation/A/year	28 days	14 days
Pastureland/rangeland	Conservation reserve, conservation compliance programs	0.5 lb cation/A	3 apps	2.0 lbs cation/A/year	7 days	NA
	Pasture reseeding		3 apps	1.5 lbs cation/A/year	7 days	40 days
	Control of endophyte-fungus in forage legume/grass pastures		2 apps	1.0 lb cation/A/year	10 days	NA
	Juniper species leaf moisture reduction or desiccation		3 apps	1.5 lbs cation/A/year	7 days	NA
	Native pastures		2 apps	0.45 lb cation/A/year	7 days	40 days
Peach	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	14 days
Peanuts	Preplant	0.938 lb cation/A	2 apps		7 days	
	Postemergence at ground crack	0.25 lb cation/A	2 apps	0.25 lb cation/A/year	7 days	NCH
	Postemergence ropewick application		1 app	0.25 lb cation/A/year	N/A	30 days
	All combined uses		5 apps	2.8 lbs cation/A/year	7 days	
Pear	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	NCH
Peas, dried-type	Preplant/preemergence	0.5 lb cation/A	3 apps		7 days	NCH
	Harvest aid		2 apps	0.5 lb cation/A/year		7 days
Peas, pigeon	All uses	0.5 lb cation/A	1 app	0.5 lb cation/A/year	N/A	60 days
Persimmon	All uses	0.938 lb cation/A	4 apps	3.76 lbs cation/A/year	28 days	14 days
Pineapple	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	20 days
Pistachio	After shells split	1.0 lb cation/A	2 apps		7 days	
	All combined uses		5 apps	5.0 lbs cation/A/year		7 days
Plum	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	28 days
Potato, white/Irish (or unspecified)	All uses	1.0 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	NCH

Crop/Site	Timing of Application[43]	Maximum Single Application Rate	Maximum Number of Applications per 12-month Period	Maximum Annual Application Rate	Minimum Retreatment Interval	Pre-Harvest Interval
Premises/areas (around commercial buildings, public airports, storage yards, etc.)	All uses	1.0 lb cation/A	10 apps	10.0 lbs cation/A/year	7 days	NA
Prune	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	28 days
Rhubarb	All uses	1.0 lb cation/A	2 apps	2.0 lbs cation/A/year	7 days	NCH
Rice	All uses	1.0 lb cation/A	3 apps	1.0 lb cation/A/year	7 days	NCH
Root and tuber vegetables	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Safflower	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Sage, clary	All uses	0.75 lb cation/A		1.125 lbs cation/A/year	10 days	
Sorghum	Preplant/preemergence	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	Forage – 20 days Grain – 48 days
	Postemergence	0.5 lb cation/A	2 apps	1.0 lb cation/A/year		
	All combined uses		5 apps	4.0 lbs cation/A/year		
Soybeans	Preplant/preemergence	1.0 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	NCH
	Postemergence (Directed Spray)	0.5 lb cation/A	2 apps	1.0 lb cation/A/year	14 days	46 days
	Postemergence (Spot Spray)		2 apps	1.0 lb cation/A/year	14 days	46 days
	Harvest Aid (soybeans only grown for research and field trials)	0.25 lb cation/A	1 app	0.25 lb cation/A/year	NA	3 days
	Harvest aid	0.25 lb cation/A	1 app	0.25 lb cation/A/year	NA	Grain only – 15 days
	All combined uses		9 apps	2.9 lbs cation/A/year		
Strawberry	All uses	0.5 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	21 days
Subtropical/tropical fruit	All uses	0.94 lb cation/A	4 apps	3.76 lbs cation/A/year	28 days	14 days
Sugar beet	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Sugarcane	Postemergence (Louisiana)	0.75 lb cation/A	2 apps	1.5 lbs cation/A/year	7 days	30 days
	Postemergence (Florida and Hawaii)	0.5 lb cation/A	2 apps	1.0 lb cation/A/year		NCH
	Harvest aid (Florida and Texas)	0.25 lb cation/A	1 app	0.25 lb cation/A/year		3 days
Sunflower	Preplant/preemergence	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	7 days
	Preharvest	0.5 lb cation/A	2 apps	1.0 lb cation/A/year		
Taniers	Preemergence	1.0 lb cation/A	1 app	1.5 lbs cation/A/year	30 days	180 days
	Postemergence	0.5 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	90 days
Taro	All uses	0.75 lb cation/A	2 apps	1.5 lbs cation/A/year	7 days	180 days
Tobacco	All uses	0.938 lb cation/A	2 apps			NCH
Tomato	Preplant/preemergence	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	30 days

Crop/Site	Timing of Application[43]	Maximum Single Application Rate	Maximum Number of Applications per 12-month Period	Maximum Annual Application Rate	Minimum Retreatment Interval	Pre-Harvest Interval
	Postemergence	0.5 lb cation/A	3 apps	1.5 lbs cation/A/year		30 days
	Post-harvest	0.9 lb cation/A	2 apps	1.9 lbs cation/A/year		NA
	All combined uses		8 apps	3.0 lbs cation/A/year		
Tree nuts	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	NCH
Trees (non-food)	All uses	1.0 lb cation/A	5 apps	5.0 lbs cation/A/year	7 days	NA
Tuberous and corm vegetables	All uses	0.26 lb cation/A	3 apps	1.5 lbs cation/A/year	7 days	NCH
Turnip (greens)	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Tyfon	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Wheat	All uses	1.0 lb cation/A	3 apps	3.0 lbs cation/A/year	7 days	NCH
Yam	All uses	0.5 lb cation/A	2 apps	1.0 lb cation/A/year	7 days	90 days

The information in this table is based on EPA Reg. no. 100-1652
NCH = Normal Crop Harvest
NA = Not Applicable

Appendix C: Response to Comments on PID

During the 80-day public comment period for the paraquat PID (December 7, 2020 to January 11, 2020), the Agency received 81 public comments from 80 sources. Thirty-seven of the comments received were from individual citizens, including farmers, agricultural retailers, pilots for agricultural aviation companies, extension specialists, and other anonymous commenters. The rest of the comments received were from a wide range of stakeholders, including environmental NGOs, government agencies, public interest advocacy groups, agricultural aviation associations, and state and national agricultural groups and associations. Comments were also submitted by Syngenta Crop Protection, LLC. and Drexel Chemical Company, two of paraquat's registrants.

The Agency has summarized and responded to all substantive comments and comments of a broader regulatory nature below and in the following documents, available in the docket:

- *BEAD Response to Paraquat Usage and Benefit Related Comments Received on the Preliminary Interim Decision of Paraquat (PC# 061601 and 061603) (EPA-HQ-OPP-2011-0855)* (June 29, 2021)
- *Paraquat: HED Response to Comments on the Proposed Interim Decision for Registration Review and Updated Occupational Handler Exposure and Risk Estimates* (June 22, 2021)
- *Paraquat: EFED Response to Comments on the Proposed Interim Decision for Registration Review* (May 19, 2021)

The Agency thanks all commenters for participating and has considered all comments in developing this ID.

Comments Against the Continued Registration of Paraquat

Comments Submitted by Alaska Community Action on Toxics et. Al (Docket ID: EPA-HQ-OPP-2011-0855-0272), Center for Biological Diversity (CBD) (Docket IDs: EPA-HQ-OPP-2011-0855-0273 and EPA-HQ-OPP-2011-0855-0274), and several private citizens

Comment:

1. The groups listed above commented against the continued use of paraquat. They state concerns over the toxicity of paraquat, claim a potential link between paraquat exposure and Parkinson's disease, and note that paraquat has been banned in many other parts of the world, including Thailand, China, Brazil, and the European Union.

2. CBD claims that EPA's proposed continuation of paraquat registrations violates FIFRA because the Agency has not considered all of the economic and social costs associated with registration. One example CBD provides is the economic implications of Thailand's recent decision to prohibit the export of food commodities that contain any residues of paraquat from the U.S. to Thailand beginning in June 2021. They claim that resource utilization that paraquat

demands from poison control centers is an example of costs that have not been accounted for in paraquat's cost-benefit analysis, according to CBD. CBD claims that EPA must account for all costs associated with paraquat's continued registration in determining whether no unreasonable adverse effects will occur.

CBD also notes that EPA may not issue an interim registration decision for paraquat without first consulting the Services in accordance with the Endangered Species Act (ESA).

EPA Response:

1. A number of countries have taken domestic regulatory measures to ban the production, use, import, and export of paraquat, based on their regulatory approach. The approach required by U.S. law, however, involves assessing both the risks and benefits of pesticide use and considering the most robust scientific data available. In evaluating mitigation measures for paraquat, EPA considered the risks, the benefits, and the use pattern. Although there are potential risks of concern associated with the use of paraquat, with the adoption of the mitigation measures discussed in this ID, any remaining potential worker and/or ecological risks are outweighed by the benefits associated with the use of paraquat. The Agency has conducted a systematic review to evaluate the significance and environmental relevance of the postulated association between paraquat exposure and Parkinson's disease. The Agency concluded that the weight of evidence was insufficient to link paraquat exposure from pesticidal use of U.S. registered products to Parkinson's disease in humans.[44]

2. During registration review, EPA considers whether a pesticide registration "continues to satisfy the FIFRA standard for registration," which defines "unreasonable adverse effects on the environment" as encompassing the FFDCA safety standard as well as the FIFRA risk-benefit standard of "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." EPA conducted this risk-benefit analysis and concluded that, with the labeling changes described in Section IV.A and Appendices A and B, paraquat meets the FIFRA registration standard. EPA is addressing many of CBD's concerns regarding listed species as part of its ongoing collaborative work with the Services and USDA to improve the consultation process for listed species for pesticides in accordance with the Endangered Species Act (ESA) § 7.

<u>Comments on Paraquat's Agricultural Importance and Benefits</u>

Comments Submitted by H&M Flying Service LLC (Docket ID: EPA-HQ-OPP-2011-0855-0228), Centrol Ag Consulting (Docket ID: EPA-HQ-OPP-2011-0855-0290), Virginia Tech Extension Weed Science Specialist (Docket ID: EPA-HQ-OPP-2011-0855-0237), National Alliance of Independent Crop Consultants (Docket ID: EPA-HQ-OPP-2011-0855-0264), Illinois Farm Bureau (Docket ID: EPA-HQ-OPP-2011-0855-0281), National Corn Growers Association (Docket ID: EPA-HQ-OPP-2011-0855-0289), National Sunflower Association

[44] Paraquat Dichloride: Systematic review of the literature to evaluate the relationship between paraquat dichloride exposure and Parkinson's disease. https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0125

(Docket ID: EPA-HQ-OPP-2011-0855-0292), and Mississippi Farm Bureau Federation (Docket ID: EPA-HQ-OPP-2011-0855-0297)

Comment: Several commenters provided information regarding the importance of paraquat to various different agricultural commodities. They provided usage, resistance management, and benefits information in order to emphasize what a critical tool paraquat is to the agricultural community.

EPA Response: The Agency thanks the commenters for this information. More detailed responses regarding usage and benefits can be found in *BEAD Response to Paraquat Usage and Benefit Related Comments Received on the Preliminary Interim Decision of Paraquat: (PC# 061601) (EPA-HQ-OPP-2011-0855),* available in the docket.

Comments Against Proposed Mitigation

Comments Submitted by Aurora Cooperative (Docket ID: EPA-HQ-OPP-2011-0855-0300), Missouri Soybean Association (Docket ID: EPA-HQ-OPP-2011-0855-0219), South Dakota Agri-Business Association (Docket ID: EPA-HQ-OPP-2011-0855-0301), and Missouri Corn Growers Association (Docket ID: EPA-HQ-OPP-2011-0855-0224)

Comment: The commenters listed above assert that the mitigation proposed in the paraquat PID is too restrictive and will result in a highly effective weed control product being taken out of availability. They claim that the majority of paraquat incidents are the result of rare but deliberate misuse and mishandling of the product in direct violation of label instructions and that further restricting paraquat is neither necessary nor justified.

EPA Response: The Agency acknowledges the concerns commenters have expressed regarding the proposed mitigation for paraquat. While EPA does take incidents into consideration when making a registration review decision, the potential risks of concern identified in the human health and ecological risk assessments are the basis for the Agency's risk management decisions. EPA has weighed the high risks associated with paraquat exposure along with the high benefits paraquat provides to growers and has determined that the mitigation measures outlined in this ID are protective enough to mitigate the potential risks from paraquat use but not so prohibitive as to effectively discontinue use of paraquat.

Comments on Proposed Aerial Prohibition

Comments Submitted by National Agricultural Aviation Association (NAAA) (Docket ID: EPA-HQ-OPP-2011-0855-0293), Mississippi Farm Bureau Federation (Docket ID: EPA-HQ-OPP-2011-0855-0297), TLB Air LLC (Docket ID: EPA-HQ-OPP-2011-0855-0296), Weed Science Society of America (Docket ID: EPA-HQ-OPP-2011-0855-0295), Drexel Chemical Company (Docket ID: EPA-HQ-OPP-2011-0855-0294), National Sunflower Association (Docket ID: EPA-HQ-OPP-2011-0855-0292), Louisiana Agriculture Aviation Association (Docket ID: EPA-HQ-OPP-2011-0855-0288), North Dakota Agricultural Aviation Association (Docket ID: EPA-HQ-OPP-2011-0855-0287), Right Way Ag. LLC

(Docket ID: EPA-HQ-OPP-2011-0855-0286), Rubbert Aerial Incorporated (Docket ID: EPA-HQ-OPP-2011-0855-0284), United States Department of Agriculture (USDA) (Docket ID: EPA-HQ-OPP-2011-0855-0282), BearCreek Flying Service LLC (Docket ID: EPA-HQ-OPP-2011-0855-0280), National Cotton Council (Docket ID: EPA-HQ-OPP-2011-0855-0279), Agricultural Retailers Association(Docket ID: EPA-HQ-OPP-2011-0855-0278), North Dakota Department of Agriculture (Docket ID: EPA-HQ-OPP-2011-0855-0277), Syngenta Crop Protection (Docket ID: EPA-HQ-OPP-2011-0855-0276), Western Integrated Pest Management Center (Docket ID: EPA-HQ-OPP-2011-0855-0271), Association of Washington Aerial Applicators et al. (Docket ID: EPA-HQ-OPP-2011-0855-0267), Louisiana Farm Bureau Federation, Inc. (Docket ID: EPA-HQ-OPP-2011-0855-0266), Washington State Department of Agriculture (Docket ID: EPA-HQ-OPP-2011-0855-0265), North Caroline State University (Docket ID: EPA-HQ-OPP-2011-0855-0259), Agricultural Council of Arkansas (Docket ID: EPA-HQ-OPP-2011-0855-0256), University of Arkansas (Docket ID: EPA-HQ-OPP-2011-0855-0255), South Dakota Agri-Business Association (Docket ID: EPA-HQ-OPP-2011-0855-0301), Aurora Cooperative (Docket ID: EPA-HQ-OPP-2011-0855-0300), National Association of Wheat Growers (Docket ID: EPA-HQ-OPP-2011-0855-0275), H&M Flying Service LLC (Docket ID: EPA-HQ-OPP-2011-0855-0228), Sturdivant Bros. Flying Service, Inc. (Docket ID: EPA-HQ-OPP-2011-0855-0221), and several private citizens

Comments:

1. The commenters listed above object to the Agency's proposal to prohibit aerial applications for all paraquat uses except for cotton desiccation. The commenters claim that paraquat is applied aerially to several crops, including cotton, corn, soybeans, alfalfa, dry beans, sorghum, wheat, potatoes, rice, and sunflowers, and that it's an effective and affordable tool in many states/regions, including Louisiana, California, North Dakota, Montana, Arkansas, Washington, and Mississippi. It's particularly integral as a preplant burndown for controlling glyphosate-resistant weeds and provides growers with the ability to schedule their harvest in a timely manner when adverse weather events occur. Many commenters believe that EPA has misjudged the importance of aerial applications of paraquat and argue that it is just as critical for other uses as it is for cotton desiccation.

2. USDA points out that aerial applications of paraquat increase in years with uncommonly wet weather conditions and that these applications may be needed further as climate change is likely to lead to more unpredictable and severe weather events. USDA suggests that a state-level analysis of the relationship between weather conditions at planting and harvest could potentially identify states for which aerial paraquat applications could be retained. USDA also recommends rate reductions as an alternative mitigation measure to address the risks from aerial applications of paraquat.

3. NAAA proposes requiring closed loading systems as well as full personal protective equipment (PPE) when mixing and loading paraquat for aerial applications, as an alternative way to mitigate the risks of concern from aerial application scenarios. NAAA notes that this is the approach EPA proposed for mixing and loading paraquat for ground applications. EPA's assumption that closed systems and PPE combined would more fully mitigate risks to

mixers/loaders for ground applications should also hold true for mixing/loading scenarios for aerial applications. In addition, NAAA proposes banning the use of human flaggers for aerial applications. Many of the commenters listed above agree with NAAA's recommendations.

4. The National Cotton Council (NCC) provides detailed information on how paraquat is applied throughout all parts of the cotton production system, emphasizing that aerial application is important at many points during the crop season. They are concerned that best management practices (BMPs) and weed resistance management (WRM) programs would be negatively impacted by EPA's proposal to prohibit aerial application of paraquat. They reiterated that the availability of aerial applications is essential to assisting farmers in making timely pesticide applications prior to adverse weather events. Aerial application also allows for terminating field vegetation with minimal disturbance to the soil. Lack of access to aerial application would force producers to till the land, which would lead to erosion of the soil.

5. In their comment, the Washington State Department of Agriculture (WSDA) suggests allowing aerial application for Special Local Need 24(c)[45] registrations as an alternative to prohibiting it entirely.

6. In their comment, the Western Integrated Pest Management Center states that extension advisors with weed control responsibilities in California believe that the proposed paraquat mitigation would be inconvenient for growers, but not insurmountable. They claim, however, that the changes would significantly impact weed control efforts in alfalfa production in California and that alfalfa producers would not be able to control their winter weeds without aerial applications of paraquat.

EPA Responses:

1. EPA thanks the commenters for the additional usage information submitted to the Agency regarding aerial application. The Agency's new mitigation measure allowing aerial applications to a maximum of 350 acres per applicator per 24-hour period for all uses except cotton desiccation should provide growers with more flexibility than the previously proposed prohibition of aerial application. EPA acknowledges that paraquat is applied aerially to several other crops outside of cotton. Growers will likely need to switch to alternative herbicides if aerially applying to areas greater than 350 acres in advance of adverse weather events, which may result in increased production costs. Whereas there are alternative options to aerial application of paraquat for most uses, there is no direct alternative for cotton desiccation. Therefore, the Agency has decided not to limit the acreage for the treatment of cotton for desiccation purposes.

2. EPA thanks USDA for the information regarding aerial application rates. Although lower application rates do present lower risks for aerial applicators, there are still risks of concern for rates above 0.3 lbs cation/A. A maximum application rate of 0.3 lbs cation/A would not be efficacious for growers and due to the limited aerial use of paraquat, the risks from higher

[45] Refer to Chapter 17 of Pesticide Registration Manual for more information on Special Local Needs 24(c) registrations.

application rates outweigh the benefits from this application method. Therefore, the Agency does not consider rate reductions for aerial applications an effective alternative mitigation measure.

3. EPA agrees with NAAA that requiring closed loading systems in addition to PPE for mixers and loaders would mitigate the risks of concern for mixing and loading scenarios for aerial applications. The new AHETF data mentioned in Section III.A.1 verifies that none of the mixing/loading scenarios are any longer of concern, when assuming the use of closed systems and PPE (gloves/PF10 respirators). This measure would not, however, mitigate the risks to aerial applicators. The Agency is limiting aerial applications to 350 acres in order to fully mitigate these risks.

4. The Agency's new mitigation measure allowing aerial applications to a maximum of 350 acres per applicator per 24-hour period for all uses except cotton desiccation should have less of an impact on BMPs and WRM programs than the previously proposed prohibition of aerial applications.

5. The Agency's new mitigation measure allowing aerial applications to a maximum of 350 acres per 24-hour period for all uses except cotton desiccation applies to standard FIFRA Section 3 registrations as well as FIFRA Section 24(c) registrations.

6. The Agency recognizes the challenges alfalfa growers may face when no longer able to apply paraquat aerially. Growers may need to switch to alternative herbicides, which could have financial impacts.

Comments on Proposed Spray Drift Buffer

Comments Submitted by National Agricultural Aviation Association (NAAA) (Docket ID: EPA-HQ-OPP-2011-0855-0293), American Farm Bureau Federation (Docket ID: EPA-HQ-OPP-2011-0855-0283), United States Department of Agriculture (USDA) (Docket ID: EPA-HQ-OPP-2011-0855-0282), BearCreek Flying Service LLC (Docket ID: EPA-HQ-OPP-2011-0855-0280), and Syngenta Crop Protection (Docket ID: EPA-HQ-OPP-2011-0855-0276)

Comments:

1. NAAA, with the support of the other commenters listed above, agrees with EPA's proposed buffer zones for aerial applications used for cotton desiccation. They believe, however, that buffer zones should be wind directional, since drift only moves downwind. USDA reinforces this suggestion, stating that wind directionally specific spray drift buffers are more practical for aerial applicators to implement and more likely to effectively reduce risks to bystanders. They state that aerial applicators have the tools necessary to provide immediate and onsite wind direction measurement, so if wind direction does change during application, they can respond immediately.

2. In their comment, Syngenta states that the requirement for a residential area drift buffer for aerial applications is redundant because paraquat is already prohibited from use in residential settings.

EPA Responses:

1. The intent behind the buffer requirement for aerial applications is to mitigate risks to bystanders from spray drift. The Agency is requiring residential area drift buffers in order to ensure that drift from aerial applications of paraquat do not reach areas where bystanders may be present (i.e., schools, homes, playgrounds, parks, recreational areas, athletic fields, residential lawns, and gardens). The location of these sites is permanent, whereas the direction of the wind can change. Therefore, buffers based on distance from residential areas is more protective than wind-directional buffers. The Agency appreciates the NAAA's suggestions and continues to work with industry to update and improve modeling methods and mitigation considerations to better reflect typical application practices.

2. The prohibition of paraquat use in residential settings protects residents from direct contact with paraquat, but they can still be exposed to spray drift from aerial applications of paraquat on residential areas adjacent to agricultural areas being treated. A buffer is needed to ensure that spray drift from these applications does not reach bystanders.

Comments on Proposed Limit of Single Application Maximum Rate for Alfalfa to 1.0 lb ai/A

Comments Submitted by Wyoming Crop Improvement Association (Docket ID: EPA-HQ-OPP-2011-0855-0254) and Wyoming Ag-Business Association (Docket ID: EPA-HQ-OPP-2011-0855-0270)

Comment: The Wyoming Crop Improvement Association and the Wyoming Ag-Business Association state that a reduction in the application rate or the option for additional applications will have a significant negative impact on alfalfa seed production in Wyoming. Commenters claim that when current label directions are followed, and with specific regard to application timing for this crop, the use of paraquat is inherently safe, with minimal potential impact to the environment, pollinators, and humans. The commenters note that the poisoning examples given in support of the proposed changes were all in California and they suggest that the issue may lie with that specific state, rather than all paraquat users. They say that the examples given were the result of misuse and that they do not support significant label changes.

EPA Response: The Agency would like to clarify that the proposal to limit the maximum single application rate for alfalfa is a result of the post-application risks of concern for alfalfa scouting presented in the 2019 HHRA. This mitigation measure was not a response to the ingestion incidents the commenters referenced. The mitigation intended to address those incidents is

outlined in the *Paraquat Dichloride Human Health Mitigation Decision.*[46] The mitigation outlined in the PID is intended to address the potential risks of concern to occupational handlers and ecological taxa identified in the human health and ecological risk assessments conducted for registration review. Please see Section III for more information on these scientific assessments.

Comments on Proposed Prohibition of Mechanically Pressurized Handguns and Backpack Sprayers

Comments Submitted by Aurora Cooperative (Docket ID: EPA-HQ-OPP-2011-0855-0300), South Dakota Agri-Business Association (Docket ID: EPA-HQ-OPP-2011-0855-0301), Syngenta Crop Protection (Docket ID: EPA-HQ-OPP-2011-0855-0276), Agricultural Retailers Association (Docket ID: EPA-HQ-OPP-2011-0855-0278), United States Department of Agriculture (USDA) (Docket ID: EPA-HQ-OPP-2011-0855-0282), American Farm Bureau Federation (Docket ID: EPA-HQ-OPP-2011-0855-0283), Drexel Chemical Company (Docket ID: EPA-HQ-OPP-2011-0855-0294), and Weed Science Society of America (WSSA) (Docket ID: EPA-HQ-OPP-2011-0855-0295)

Comments:

1. The commenters listed above object to the Agency's proposal to prohibit mechanically-pressurized handguns and backpack sprayers, claiming that it will have negative impacts on smaller producers and in non-agricultural settings where the use of common ground application equipment is not possible. Commenters are concerned that if these areas cannot be treated with paraquat, they will quickly become infested with weeds that are resistant to other herbicides. USDA and Weed Science Society of America (WSSA) state that these application methods are also important for small plot research activities.

2. USDA encourages EPA to consider area- or temporally-based label restrictions for mechanically-pressurized handguns and backpack sprayers, as an alternative to prohibiting them.

3. Several commenters state that individuals applying paraquat with these handheld application equipment mitigate exposure by wearing personal protective equipment and use a more diluted spray concentration than what's used for aerial or groundboom applications.

4. In their comment, Syngenta notes that they are developing a closed system backpack/knapsack spraying system that would meet the Agency's closed system requirement for all containers smaller than 120 gallons. They will seek EPA's regulatory approval of this system once it is commercially available in order to retain the agronomic benefits of paraquat in situations where backpack sprayer application is the only practical method of application.

[46] Paraquat Dichloride Human Health Mitigation Decision. 14 December 2016. https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0112

EPA Responses:

1. EPA appreciates the usage information commenters provided regarding the use of these handheld application methods. The Agency recognizes that this mitigation measure may require users to switch to alternative active ingredients when making applications to areas where other application methods are not practical. There are many alternatives available, including glyphosate, 2,4-D, picloram, diuron, clopyralid, dicamba, imazethapyr, triclopyr, dichlobenil, fluazifop-P-butyl, and indaziflam. As for using backpack sprayers in a research capacity, this prohibition does not apply to experimental use of paraquat under an Emergency Use Permit[47] or 40 CFR 172.3(b).[48]

2. EPA cannot consider area- or temporally-based label restrictions for mechanically-pressurized handguns and backpack sprayers at this time because no closed systems have been developed for these types of application equipment. Since all paraquat containers smaller than 120 gallons are required to have closed systems, the Agency cannot require label requirements for handheld application containers that do not have closed systems.

3. PPE and application rates/concentrations for handheld application equipment were factored into the Agency's calculations and the resulting estimates of concern encompass those components. They do not prevent risks of concern and are not sufficient in protecting workers from paraquat exposure.

4. EPA thanks Syngenta for the information regarding their plans to develop a closed system for backpack sprayers. The Agency will review the pesticide registration application to ensure that it meets the paraquat closed system requirements[49] and will assess potential risks to human health and the environment from the product at that time.

Comments on Proposed 7-day REI for Cotton Desiccation

Comments Submitted by Arizona Farm Bureau Federation (Docket ID: Docket ID: EPA-HQ-OPP-2011-0855-0268), Western Integrated Pest Management Center (Docket ID: EPA-HQ-OPP-2011-0855-0271), and American Farm Bureau Federation (Docket ID: EPA-HQ-OPP-2011-0855-0283)

Comment: The commenters listed above strongly urge EPA to reconsider the 7-day restricted entry interval (REI) for cotton desiccation proposed in the PID. Western IPM Center states that paraquat is not likely to transfer to the skin once it's been deposited somewhere in the soil or on vegetation and questions whether an increased REI would significantly increase product safety. The other commenters note that paraquat's fast-acting quality allows farmers to quickly begin harvest 4-5 days following application. Commenters fear that if farmers are required to wait 7

[47] https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-12-applying-experimental-use-permit#intro
[48] https://www.ecfr.gov/cgi-bin/text-idx?node=pt40.26.172&rgn=div5#se40.26.172_13
[49] Paraquat Dichloride Human Health Mitigation Decision. 2016.
Available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0855-0112

days before harvest, adverse weather conditions could further delay cotton harvesting. These delays often result in quality and yield depletion.

EPA Response: The Agency acknowledges the challenges a 7-day REI may present to cotton growers, particularly when a poor weather event is imminent. The Agency recognizes that given the rapid effects and rain-fastness that are unique to paraquat, other chemistries cannot replace this specific use as a cotton desiccant for emergency harvest scenarios. The potential post-application risks of concern for mechanical harvesting of cotton are too high, however, to decrease the proposed REI to less than 7 days. Although paraquat does adsorb tightly to soil, there is potential for residues to transfer to the skin, based on the assumptions used in the 2019 HHRA.

Comments on Proposed Spray Drift Management

Comments Submitted by National Agricultural Aviation Association (NAAA) (Docket ID: EPA-HQ-OPP-2011-0855-0293), American Farm Bureau Federation (Docket ID: EPA-HQ-OPP-2011-0855-0283), United States Department of Agriculture (USDA) (Docket ID: EPA-HQ-OPP-2011-0855-0282), BearCreek Flying Service LLC (Docket ID: EPA-HQ-OPP-2011-0855-0280), National Cotton Council (Docket ID: EPA-HQ-OPP-2011-0855-0279), and Syngenta Crop Protection (Docket ID: EPA-HQ-OPP-2011-0855-0276)

Comments:

1. The NAAA provided comments regarding the spray drift analysis conducted in the draft risk assessment, particularly concerning the spray drift model, AgDRIFT, and the inputs used in the model. NAAA believes that the Tier-1 component of the AgDRIFT model is inadequate because some of the assumptions it uses are unrealistic and recommends a refined assessment with a higher tiered model be used instead.

NAAA, with the support of the other commenters listed above, also recommends changing the spray drift management parameters for aerial applications proposed in the PID, including a coarse droplet size and a wind speed limit of 15 mph. NAAA claims that reducing the boom length restriction to 50% of the wingspan for fixed wing aircraft and 60% of the rotor diameter for helicopters and increasing the swath displacement to ¾ would mitigate the risk of drift when applying paraquat in winds from 11 to 15 mph, stating that this concept has been accepted by EPA in recent PIDs for other active ingredients.

NAAA also points out that setting a wind speed limit of 10 mph could force more applications to be made when wind speeds are too low. A windspeed of less than 4 mph can be an indicator of a low-level temperature inversion.

2. Syngenta commented in agreement with the parameters proposed for mandatory spray drift management. They pointed out that the following reference to aerial application requirements in the directions for groundboom applications would not be applicable: *"The boom length must be 75% or less of the wingspan for fixed-wing aircraft and 90% or less of the rotor diameter for helicopters."*

3. The North Dakota Department of Agriculture commented that there have not been any reported instances of misuse or damage related to the aerial application of paraquat in North Dakota since 2012. They are concerned that EPA's drift modeling may overestimate spray drift exposures when compared to real world use.

4. USDA is concerned that the label requirement for a maximum windspeed of 10 mph during aerial and groundboom applications of paraquat is not sufficiently clear to be consistently enforced. USDA argues that this measure should include more detailed instructions outlining exactly when and where an applicator should measure the windspeed at the application site.

EPA Responses:

1. The Agency acknowledges and thanks the commenters for their comments. AgDRIFT is the currently approved model for evaluating potential spray drift from a pesticide application. The Agency appreciates the additional suggestions provided by NAAA for revising the AgDRIFT modeling inputs and continues to work with industry to update and improve modeling methods to better reflect typical application practices. At the December 2020 Center of Excellence in Regulatory Science in Agriculture (CERSA) workshop, EPA, NAAA, and other stakeholders discussed these potential refinements for AgDRIFT modeling. EPA is currently reviewing these suggestions and will consider them for future risk assessment. However, modeling for a national-level assessment is first conducted using maximum application rates, limitations, and instructions listed on the paraquat labels.

The Agency is moving forward with the spray drift parameters that were proposed in the PID in order to reduce off-target spray drift, establish a baseline level of protection against spray drift, and reduce potential risks to bystanders. A medium or coarser droplet size provides users with more flexibility when tank-mixing paraquat with other active ingredients, and a maximum windspeed of 10 mph during application reduces the extent of drift. Increasing the windspeed limit would require extending the buffers for aerial applications, which would have negative impacts for growers. EPA has allowed 15 mph windspeed limits for other cases that have minimal risks from spray drift. For paraquat, a 10 mph windspeed is more protective, in order to mitigate the potential ecological and bystander risks from spray drift.

To avoid applications during temperature inversions, EPA would recommend that aerial applicators apply at windspeeds greater than 4 mph. In some parts of the country, applicators can access publicly operated weather systems to determine when and where low-level temperature inversions exist or are forming.

2. EPA thanks Syngenta for their comment and has removed the language referring to aerial applications from the label directions for groundboom applications.

3. As previously mentioned, AgDRIFT is the currently approved model for evaluating potential spray drift from a pesticide application. The Agency must take these modeling estimates into consideration, along with incident data, when making a regulatory decision for a pesticide. The

modeling shows that there are potential risks of concern to bystanders from paraquat spray drift, so the Agency is requiring spray drift management measures to adequately address that risk.

4. EPA thanks USDA for their comment suggesting additional details be added to the windspeed requirement. The Agency will take this suggestion into consideration for future decisions.

Remaining Comments

Comment Submitted by Center for Biological Diversity (Docket IDs: EPA-HQ-OPP-2011-0855-0273 and EPA-HQ-OPP-2011-0855-0274)

Comment: CBD attached the comments they previously submitted to the Agency regarding the human health and ecological risk assessments for paraquat.

EPA Response: The Agency provided responses to the comments previously submitted by CBD. Please see *Paraquat: Response to Comments on the Draft Human Health Risk Assessment* and *Paraquat: Response to Comments on the EFED Preliminary Ecological Risk Assessment for Registration Review* in the docket for more information.

Comment Submitted by National Association of Wheat Growers (Docket ID: EPA-HQ-OPP-2011-0855-0275)

Comment: The National Association of Wheat Growers commented that requirements for closed systems will lead to additional equipment costs for producers. They believe that the state pesticide certification requirements and the safety and use information on previous product labels provide sufficient protection for those properly applying paraquat, and urge the Agency to reconsider the decisions for new requirements on closed systems.

EPA Response: The Agency would like to clarify that the closed system requirement was not part of the proposed mitigation in the PID. The closed system requirement is part of the *Paraquat Dichloride Human Health Mitigation Decision*. It is one of several restrictions imposed on paraquat products with the intent of reducing the number and severity of human health incidents caused by the accidental ingestion of paraquat. All of the requirements from that decision were implemented on paraquat labels as of December 30, 2020. The mitigation being finalized in this ID is intended to address the occupational handler and ecological risks shown in the Agency's draft human health and ecological risk assessments.

Comment Submitted by Syngenta Crop Protection (Docket ID: EPA-HQ-OPP-2011-0855-0276)

Comment: Syngenta commented in support of EPA's proposal to standardize label metrics across all paraquat labels. They note, however, that the Agency should add the pre-harvest interval (PHI) as one of the label metrics and they provided the Agency with a table identifying the PHI for each labelled use.

EPA Response: EPA thanks Syngenta for bringing this to the Agency's attention and for providing a table of the missing information. The PHI was inadvertently left off of the list of required label metrics in the PID, as was the single maximum application rate. The Agency has updated the ID to include this information. See Table B.2. in Appendix B for the updated list of label metrics.

Comment Submitted by Washington State Department of Agriculture (WSDA) (Docket ID: EPA-HQ-OPP-2011-0855-0265)

Comment: WSDA has a couple of questions and suggestions for the Agency's consideration regarding the proposed mitigation in the paraquat PID:

1. Are multiple applications per year allowed on alfalfa as long as each individual application does not exceed 1.0 lb ai/A, or is the 1.0 lb ai/A limit for all applications combined?
2. Would the proposed 1.0 lb ai/A limitation apply only to the FIFRA Section 3 label or would FIFRA Section 24(c) labels also be limited to 1.0 lb ai/A?
3. The PID says that EPA is proposing to "require enclosed cabs for applications to more than 80 acres in a 24-hour period", and "require PF10 respirators or enclosed cabs for applications to 80 acres or less in a 24-hour period". Can EPA provide additional clarification on how these two requirements are different and when each would apply?
4. The PID only references PF10 respiratory protection. This should be expanded to include other respiratory protection options that are equivalent or more protective.
5. WSDA believes that the PID should include language that prohibits applications when the winds are in the direction of sensitive sites, such as residential areas. WSDA also believes that the PID should include sensitive crops under sensitive sites.
6. The active ingredient in the PID is paraquat dichloride (the salt formulation). However, the term "paraquat" is used throughout the document and could mean either the salt or the cation in solution. Depending on how the lbs ai/acre is calculated (using lbs/gal of the salt or the cation), the application rate changes. Please clarify. Please also clarify if the 1.0 lb ai/A limit for alfalfa is for the salt or the cation.

EPA Response: EPA has provided the following responses to WSDA's questions and considerations:

1. The 1.0 lb ai/A rate for alfalfa is the maximum rate allowed for a single application. The maximum annual application rates can be found in Table B.2. in Appendix B. The Agency notes that the units of measurement for application rates must be presented as pounds cation paraquat per acre (lbs cation/A).
2. The maximum single application rate of 1.0 lb cation/A for alfalfa applies to all labels, including both FIFRA Section 3 and 24(c) labels.
3. As described in the mitigation, the different requirements depend on the size of the area that is being treated. If the area being treated is greater than 80 acres, applicators must use enclosed cabs to apply paraquat. If the area being treated is 80 acres or less, applicators have the option of using PF10 respirators to apply paraquat, if enclosed cabs are not

available. The purpose of this mitigation is to provide growers more flexibility in cases where enclosed cabs may not be a feasible application option.

4. The PF10 respirator requirement refers to respirators with a protection factor of 10. This is the minimum protection requirement. Respirators with higher protection factors are certainly acceptable as well.
5. For aerial applications, EPA is requiring a buffer in order to protect residential areas from spray drift from aerial applications of paraquat. This measure will also protect other fields/crops from paraquat spray drift.
6. The shorthand "paraquat" that is used throughout the PID refers to the active ingredient paraquat dichloride. The application rates used in the draft risk assessments, however, are based on pound paraquat cation per acre (lb cation/A). A rate of 1.0 lb cation/A is equivalent to 1.417 lb paraquat dichloride/A. Therefore, the 1.0 lb ai/A limit for alfalfa applies to the cation. The Agency has updated the rates in this ID to reflect that.

Appendix D: Occupational Handler Exposure and Risk Estimates

Table D.1.: Summary of Paraquat Occupational Handler Exposure and Risk Estimates

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	Crop or Target	Dermal Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control[2]	Inhalation Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate[3]	Area Treated or Amount Handled Daily[4]	Dermal LOC = 100		Inhalation LOC = 100	
								Dose[5] (mg/kg/day)	MOE[6]	Dose[7] (mg/kg/day)	MOE[8]
Mixer/Loader											
Liquid, Backpack, Broadcast	All Use Sites	37.6	SL/G	0.0219	PF10 R	0.015 lb ai/gallon	40 gallons	0.00028	21,000	0.00000016	16,000
		29.1	DL/G					0.00022	27,000		
		30.4	EC/No G	0.011	EC/No-R			0.00023	26,000	0.000000083	32,000
				0.0011	EC/PF10 R					0.0000000083	320,000
		4.02	EC/G	0.011	EC/No-R			0.000030	200,000	0.000000083	32,000
				0.0011	EC/PF10 R					0.0000000083	320,000
	Pastureland	37.6	SL/G	0.0219	PF10 R	0.019 lb ai/gallon		0.00036	17,000	0.00000021	13,000
		29.1	DL/G					0.00028	22,000		
		30.4	EC/No G	0.011	EC/No-R			0.00029	21,000	0.00000011	25,000
				0.0011	EC/PF10 R					0.000000011	250,000
		4.02	EC/G	0.011	EC/No-R			0.000038	160,000	0.00000011	25,000
				0.0011	EC/PF10 R					0.000000011	250,000
Liquid, Mechanically pressurized Handgun, Broadcast	All Use Sites	37.6	SL/G	0.0219	PF10 R	0.015 lb ai/gallon	1000 gallons	0.0071	850	0.0000041	630
		29.1	DL/G					0.0055	1,100		
		30.4	EC/No G	0.011	EC/No-R			0.0057	1,100	0.0000021	1,300
				0.0011	EC/PF10 R					0.00000021	13,000
		4.02	EC/G	0.011	EC/No-R			0.00075	8,000	0.0000021	1,300
				0.0011	EC/PF10 R					0.00000021	13,000
	Pastureland	37.6	SL/G	0.0219	PF10 R	0.019 lb ai/gallon		0.0089	670	0.0000052	500
		29.1	DL/G					0.0069	870		

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat

Exposure Scenario	Crop or Target	Dermal Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control[2]	Inhalation Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate[3]	Area Treated or Amount Handled Daily[4]	Dermal LOC = 100		Inhalation LOC = 100	
								Dose[5] (mg/kg/day)	MOE[6]	Dose[7] (mg/kg/day)	MOE[8]
		30.4	EC/No G	0.011	EC/No-R			0.0072	830	0.00000261	1,000
				0.0011	EC/PF10 R					0.000000261	10,000
		4.02	EC/G	0.011	EC/No-R			0.00096	6300	0.00000261	1,000
				0.0011	EC/PF10 R					0.000000261	10,000
Liquid, Aerial	Nursery (ornamentals, vegetables, trees, container stock)	37.6	SL/G	0.0219	PF10 R	1.0 lb ai/A	60 A	0.028	210	0.000016	160
		29.1	DL/G					0.022	270		
		30.4	EC/No G	0.011	EC/No-R			0.023	260	0.0000083	320
				0.0011	EC/PF10 R					0.00000083	3,200
		4.02	EC/G	0.011	EC/No-R			0.0030	2,000	0.0000083	320
				0.0011	EC/PF10 R					0.00000083	3,200
	Field crop, typical: Asparagus; Brassica (head and stem) Vegetables; Carrots (Including Tops); Corn, Sweet; Cucurbit; Vegetables; Eggplant; Fruiting Vegetables; Leafy Vegetables; Lettuce; Melons; Peas (Unspecified); Pepper; Sugar Beet; Tomato; Turnip Greens Orchard/Vineyard; Almond	37.6	SL/G	0.0219	PF10 R	1.0 lb ai/A	350 A	0.17	**36**	0.000096	**27**
		29.1	DL/G					0.13	**47**		
		30.4	EC/No G	0.011	EC/No-R			0.13	**45**	0.000048	**54**
				0.0011	EC/PF10 R					0.0000048	540
		4.02	EC/G	0.011	EC/No-R			0.018	340	0.000048	**54**
				0.0011	EC/PF10 R					0.0000048	540
	Field crop, typical: Legume Vegetables; Sage, Clary	37.6	SL/G	0.0219	PF10 R	0.80 lb ai/A	350 A	0.13	**46**	0.000077	**34**
		29.1	DL/G					0.10	**59**		
		30.4	EC/No G	0.011	EC/No-R			0.11	**57**	0.000039	**68**
				0.0011	EC/PF10 R					0.0000039	680
		4.02	EC/G	0.011	EC/No-R			0.014	430	0.000039	**68**
				0.0011	EC/PF10 R					0.0000039	680
	Field crop, typical: Lentils; Peas, Dried Type; Tuberous and Corm Vegetables; Orchard/Vineyard; Grapes	37.6	SL/G	0.0219	PF10 R	0.50 lb ai/A	350 A	0.082	**73**	0.000048	**54**
		29.1	DL/G					0.064	**94**		
		30.4	EC/No G	0.011	EC/No-R			0.067	**90**	0.000024	110

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	**Crop or Target**	**Dermal Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control[2]**	**Inhalation Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control**	**Maximum Application Rate[3]**	**Area Treated or Amount Handled Daily[4]**	**Dermal LOC = 100**		**Inhalation LOC = 100**	
								Dose[5] (mg/kg/day)	**MOE[6]**	**Dose[7] (mg/kg/day)**	**MOE[8]**
				0.0011	EC/PF10 R					0.0000024	1,100
		4.02	EC/G	0.011	EC/No-R			0.0088	680	0.000024	110
				0.0011	EC/PF10 R					0.0000024	1,100
	Field crop, typical: Root and Tuber Vegetables	37.6	SL/G	0.0219	PF10 R	0.30 lb ai/A	350 A	0.049	120	0.000029	**90**
		29.1	DL/G					0.038	160		
		30.4	EC/No G	0.011	EC/No-R			0.040	150	0.000015	180
				0.0011	EC/PF10 R					0.0000015	1,800
		4.02	EC/G	0.011	EC/No-R			0.0053	1,100	0.000015	180
				0.0011	EC/PF10 R					0.0000015	1,800
	Field crop, high acreage: Alfalfa; Clover	37.6	SL/G	0.0219	PF10 R	1.5 lb ai/A	1200 A	0.85	**7.1**	0.00049	**5.3**
		29.1	DL/G					0.66	**9.2**		
		30.4	EC/No G	0.011	EC/No-R			0.68	**8.8**	0.00025	**10**
				0.0011	EC/PF10 R					0.000025	100
		4.02	EC/G	0.011	EC/No-R			0.091	**66**	0.00025	**10**
				0.0011	EC/PF10 R					0.000025	100
	Field crop, high-acreage; Barley; Beans, Dried-Type; Corn, Field; Corn, Pop; Cotton; Deciduous/Broadleaf/ Hardwood; Fallowland; Forestry; Grasses Grown for Seed; Mint; Nonagricultural Areas; Pastureland/Rangeland; Peas (Unspecified); Potato, White/Irish (or Unspecified);	37.6	SL/G	0.0219	PF10 R	1.0 lb ai/A	1200 A	0.56	**11**	0.00033	**7.9**
		29.1	DL/G					0.44	**14**		
		30.4	EC/No G	0.011	EC/No-R			0.46	**13**	0.00017	**16**
				0.0011	EC/PF10 R					0.000017	160

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat

Exposure Scenario	Crop or Target	Dermal Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control[2]	Inhalation Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate[3]	Area Treated or Amount Handled Daily[4]	Dermal LOC = 100		Inhalation LOC = 100	
								Dose[5] (mg/kg/day)	MOE[6]	Dose[7] (mg/kg/day)	MOE[8]
	Rice; Root and Tuber Vegetables; Safflower; Sorghum; Soybeans; Sugarcane; Sunflower; Tuberous and Corm Vegetables; Wheat	4.02	EC/G	0.011	EC/No-R			0.060	100	0.00017	**16**
				0.0011	EC/PF10 R					0.000017	160
	Field crop, high acreage: Legume Vegetables	37.6	SL/G	0.0219	PF10 R	0.80 lb ai/A	1200 A	0.45	**13**	0.00026	**9.9**
		29.1	DL/G					0.35	**17**		
		30.4	EC/No G	0.011	EC/No-R			0.37	**16**	0.00013	**20**
				0.0011	EC/PF10 R					0.000013	200
		4.02	EC/G	0.011	EC/No-R			0.048	120	0.00013	**20**
				0.0011	EC/PF10 R					0.000013	200
	Field crop, high acreage: Peas, Dried-Type	37.6	SL/G	0.0219	PF10 R	0.50 lb ai/A	1200 A	0.28	**21**	0.00016	**16**
		29.1	DL/G					0.22	**27**		
		30.4	EC/No G	0.011	EC/No-R			0.23	**26**	0.000083	**32**
				0.0011	EC/PF10 R					0.0000083	320
		4.02	EC/G	0.011	EC/No-R			0.030	200	0.000083	**32**
				0.0011	EC/PF10 R					0.0000083	320
Liquid, Groundboom	Nursery (ornamentals, vegetables, trees, container stock)	37.6	SL/G	0.0219	PF10 R	1.0 lb ai/A	60 A	0.028	210	0.000016	160
		29.1	DL/G					0.022	270		
		30.4	EC/No G	0.011	EC/No-R			0.023	260	0.0000083	320
				0.0011	EC/PF10 R					0.00000083	3,200
		4.02	EC/G	0.011	EC/No-R			0.0030	2,000	0.0000083	320
				0.0011	EC/PF10 R					0.00000083	3,200
	Orchard/Vineyard: Arecola (West Indies Cherry); Apple; Apricot: Avocado; Banana;	37.6	SL/G	0.0219	PF10 R	1.0 lb ai/A	40 A	0.019	320	0.000011	240
		29.1	DL/G					0.015	410		

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat

Exposure Scenario	Crop or Target	Dermal Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control[2]	Inhalation Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate[3]	Area Treated or Amount Handled Daily[4]	Dermal LOC = 100		Inhalation LOC = 100	
								Dose[5] (mg/kg/day)	MOE[6]	Dose[7] (mg/kg/day)	MOE[8]
	Bushberries; Caneberries; Citrus; Cocoa; Coffee; Fig; Grapes; Guava; Kiwi; Nectarine; Olive; Papaya; Passion Fruit (Granadilla); Peach; Pear; Persimmon; Pistachio; Plum; Prune; Subtropical/Tropical Fruit; Tree Nuts	30.4	EC/No G	0.011	EC/No-R			0.015	390	0.0000055	470
				0.0011	EC/PF10 R					0.00000055	4,700
		4.02	EC/G	0.011	EC/No-R			0.0020	3,000	0.0000055	470
				0.0011	EC/PF10 R					0.00000055	4,700
	Orchard/Vineyard: Macadamia Nut (Bushnut)	37.6	SL/G	0.0219	PF10 R	0.50 lb ai/A	40 A	0.0094	640	0.0000055	470
		29.1	DL/G					0.0073	820		
		30.4	EC/No G	0.011	EC/No-R			0.0076	790	0.0000028	950
				0.0011	EC/PF10 R					0.00000028	9,500
		4.02	EC/G	0.011	EC/No-R			0.0010	5,900	0.0000028	950
				0.0011	EC/PF10 R					0.00000028	9,500
	Field crop, typical: Artichoke; Asparagus; Brassica (head and stem) Vegetables; Carrots (Including Tops); Corn, Sweet; Cucurbit Vegetables; Eggplant; Flowering Plants; Fruiting Vegetables; Garlic; Ginger; Leafy Vegetables; Lettuce; Manioc (Cassava); Melons; Okra; Onions; Peas (Unspecified); Pepper; Pineapple; Root and Tuber Vegetables; Rhubarb; Sugar Beet; Tomato; Turnip Greens; Yam	37.6	SL/G	0.0219	PF10 R	1.0 lb ai/A	80 A	0.038	160	0.000022	120
		29.1	DL/G					0.029	210		
		30.4	EC/No G	0.011	EC/No-R			0.030	200	0.000011	240
				0.0219	EC/PF10 R					0.0000011	2,400
		4.02	EC/G	0.011	EC/No-R			0.0040	1,500	0.000011	240
				0.0011	EC/PF10 R					0.0000011	2,400
	Field crop, typical: Tobacco	37.6	SL/G	0.0219	PF10 R	0.94 lb ai/A	80 A	0.035	170	0.000021	130
		29.1	DL/G					0.027	220		
		30.4	EC/No G	0.011	EC/No-R			0.029	210	0.000010	250

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	**Crop or Target**	**Dermal Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control[2]**	**Inhalation Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control**	**Maximum Application Rate[3]**	**Area Treated or Amount Handled Daily[4]**	**Dermal LOC = 100**		**Inhalation LOC = 100**	
								Dose[5] (mg/kg/day)	**MOE[6]**	**Dose[7] (mg/kg/day)**	**MOE[8]**
				0.0011	EC/PF10 R					0.0000010	2,500
		4.02	EC/G	0.011	EC/No-R			0.0038	1,600	0.000010	250
				0.0011	EC/PF10 R					0.0000010	2,500
	Field crop, typical: Legume Vegetables; Sage, Clary; Taro; Vegetables (Unspecified)	37.6	SL/G	0.0219	PF10 R	0.80 lb ai/A	80 A	0.030	200	0.000018	150
		29.1	DL/G					0.023	260		
		30.4	EC/No G	0.011	EC/No-R			0.024	250	0.0000088	300
				0.0011	EC/PF10 R					0.00000088	3,000
		4.02	EC/G	0.011	EC/No-R			0.0032	1,900	0.0000088	300
				0.0011	EC/PF10 R					0.00000088	3,000
	Field crop, typical: Guar; Lentils; Peas, Dried Type; Peas, Pigeon; Strawberry; Tuberous and Corm Vegetables;	37.6	SL/G	0.0219	PF10 R	0.50 lb ai/A	80 A	0.019	320	0.000011	240
		29.1	DL/G					0.015	410		
		30.4	EC/No G	0.011	EC/No-R			0.015	390	0.0000055	470
				0.0011	EC/PF10 R					0.00000055	4,700
		4.02	EC/G	0.011	EC/No-R			0.0020	3,000	0.0000055	470
				0.0011	EC/PF10 R					0.00000055	4,700
	Field crop, high acreage: Alfalfa; Clover	37.6	SL/G	0.0219	PF10 R	1.5 lb ai/A	200 A	0.14	**43**	0.000082	**32**
		29.1	DL/G					0.11	**55**		
		30.4	EC/No G	0.011	EC/No-R			0.11	**53**	0.000041	**63**
				0.0011	EC/PF10 R					0.0000041	630
		4.02	EC/G	0.011	EC/No-R			0.015	400	0.000041	**63**
				0.0011	EC/PF10 R					0.0000041	630
	Field crop, high acreage: Barley; Coniferous/Evergreen/Softwood (non-food); Corn, Field; Corn, Pop; Cotton; Fallowland; Peanuts; Peas	37.6	SL/G	0.0219	PF10 R	1.0 lb ai/A	200 A	0.094	**64**	0.000055	**47**
		29.1	DL/G					0.073	**82**		
		30.4	EC/No G	0.011	EC/No-R			0.076	**79**	0.000028	**95**
				0.0011	EC/PF10 R					0.0000028	950

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat

Exposure Scenario	Crop or Target	Dermal Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control[2]	Inhalation Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate[3]	Area Treated or Amount Handled Daily[4]	Dermal LOC = 100		Inhalation LOC = 100	
								Dose[5] (mg/kg/day)	MOE[6]	Dose[7] (mg/kg/day)	MOE[8]
	(Unspecified); Rice; Safflower; Sorghum; Soybean; Sugarcane; Sunflower; Tyfon; Wheat	4.02	EC/G	0.011	EC/No-R			0.010	590	0.000028	**95**
				0.0011	EC/PF10 R					0.0000028	950
	Field crop, high acreage: Legume Vegetables; Mint	37.6	SL/G	0.0219	PF10 R	0.80 lb ai/A	200 A	0.075	**80**	0.000044	**59**
		29.1	DL/G					0.058	100		
		30.4	EC/No. G	0.011	EC/No-R			0.061	**99**	0.000022	120
				0.0011	EC/PF10 R					0.0000022	1,200
		4.02	EC/G	0.011	EC/No-R			0.0080	750	0.000022	120
				0.0011	EC/PF10 R					0.0000022	1,200
	Field crop, high acreage: Grasses Grown for Seed; Potato, White/Irish (or Unspecified)	37.6	SL/G	0.0219	PF10 R	0.60 lb ai/A	200 A	0.056	110	0.000033	**79**
		29.1	DL/G					0.044	140		
		30.4	EC/No. G	0.011	EC/No-R			0.046	130	0.000017	160
				0.0011	EC/PF10 R					0.0000017	1,600
		4.02	EC/G	0.011	EC/No-R			0.0060	1,000	0.000017	160
				0.0011	EC/PF10 R					0.0000017	1,600
	Field crop, high acreage: Beans, Dried-Type; Hops; Pastureland; Peas, Dried-Type; Peas, Pigeon; Tuberous and Corm Vegetables	37.6	SL/G	0.0219	PF10 R	0.50 lb ai/A	200 A	0.047	130	0.000027	**95**
		29.1	DL/G					0.036	160		
		30.4	EC/No. G	0.011	EC/No-R			0.038	160	0.000014	190
				0.0011	EC/PF10 R					0.0000014	1,900
		4.02	EC/G	0.011	EC/No-R			0.0050	1,200	0.000014	190
				0.0011	EC/PF10 R					0.0000014	1,900
	Field crop, high acreage: Root and Tuber Vegetables	37.6	SL/G	0.0219	PF10 R	0.30 lb ai/A	200 A	0.028	210	0.000016	160
		29.1	DL/G					0.022	270		
		30.4	EC/No. G	0.011	EC/No-R			0.023	260	0.0000083	320
				0.0011	EC/PF10 R					0.00000083	3,200

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	**Crop or Target**	**Dermal Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control[2]**	**Inhalation Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control**	**Maximum Application Rate[3]**	**Area Treated or Amount Handled Daily[4]**	**Dermal LOC = 100**		**Inhalation LOC = 100**	
								Dose[5] (mg/kg/day)	**MOE[6]**	**Dose[7] (mg/kg/day)**	**MOE[8]**
		4.02	EC/G	0.011	EC/No-R			0.0030	2,000	0.0000083	320
				0.0011	EC/PF10 R					0.00000083	3,200
Applicator											
Spray (all starting formulations), Aerial	Field crop, typical: Asparagus; Brassica (head and stem) Vegetables; Carrots (Including Tops); Corn, Sweet; Cucurbit; Vegetables; Eggplant; Fruiting Vegetables; Leafy Vegetables; Lettuce; Melons; Peas (Unspecified); Pepper; Sugar Beet; Tomato; Turnip Greens; Orchard/Vineyard; Almond	2.08	EC/G	0.0049	EC/No-R	1.0 lb ai/A	350 A	0.0091	660	0.000022	120
	Field crop, typical: Legume Vegetables; Sage, Clary	2.08	EC/G	0.0049	EC/No-R	0.80 lb ai/A	350 A	0.0073	820	0.000017	150
	Field crop, typical: Lentils; Peas, Dried Type; Tuberous and Corm Vegetables; Orchard/Vineyard; Grapes	2.08	EC/G	0.0049	EC/No-R	0.50 lb ai/A	350 A	0.0046	1,300	0.000011	240
	Field crop, typical: Root and Tuber Vegetables	2.08	EC/G	0.0049	EC/No-R	0.30 lb ai/A	350 A	0.0027	2,200	0.0000064	400
	Field crop, high acreage: Alfalfa; Clover	2.08	EC/G	0.0049	EC/No-R	1.5 lb ai/A	1200 A	0.047	130	0.00011	**24**
	Field crop, high-acreage; Barley; Beans, Dried-Type; Corn, Field; Corn, Pop; Cotton; Deciduous/Broadleaf/ Hardwood; Fallowland; Forestry; Grasses Grown for Seed; Mint; Nonagricultural Areas; Pastureland/Rangeland; Peas (Unspecified); Potato, White/Irish (or Unspecified); Rice; Root and Tuber Vegetables; Safflower; Sorghum; Soybeans;	2.08	EC/G	0.0049	EC/No-R	1.0 lb ai/A	1200 A	0.031	190	0.000074	**35**

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	**Crop or Target**	**Dermal Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control[2]**	**Inhalation Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control**	**Maximum Application Rate[3]**	**Area Treated or Amount Handled Daily[4]**	**Dermal LOC = 100**		**Inhalation LOC = 100**	
								Dose[5] (mg/kg/day)	**MOE[6]**	**Dose[7] (mg/kg/day)**	**MOE[8]**
	Sugarcane; Sunflower; Tuberous and Corm Vegetables; Wheat										
	Field crop, high acreage: Legume Vegetables	2.08	EC/G	0.0049	EC/No-R	0.80 lb ai/A	1200 A	0.025	240	0.000059	**44**
	Field crop, high acreage:; Peas, Dried-Type	2.08	EC/G	0.0049	EC/No-R	0.50 lb ai/A	1200 A	0.016	380	0.000037	**71**
Spray (all starting formulations), Groundboom	Nursery (ornamentals, vegetables, trees, container stock)	16.1	SL/G	0.034	PF10 R	1.0 lb ai/A	60 A	0.012	500	0.000026	100
		5.1	EC/G	0.02	EC/No-R			0.0038	1,600	0.000015	170
	Orchard/Vineyard: Arecola (West Indies Cherry); Apple; Apricot: Avocado; Banana; Bushberries; Caneberries; Citrus; Cocoa; Coffee; Fig; Grapes; Guava; Kiwi; Nectarine; Olive; Papaya; Passion Fruit (Granadilla); Peach; Pear; Persimmon; Pistachio; Plum; Prune; Subtropical/Tropical Fruit; Tree Nuts	16.1	SL/G	0.034	PF10 R	1.0 lb ai/A	40 A	0.0081	750	0.000017	150
		5.1	EC/G	0.02	EC/No-R			0.0026	2,400	0.00001	260
	Orchard/Vineyard: Macadamia Nut (Bushnut)	16.1	SL/G	0.034	PF10 R	0.50 lb ai/A	40 A	0.0040	1500	0.0000085	310
		5.1	EC/G	0.02	EC/No-R			0.0013	4,700	0.000005	520
	Field crop, typical: Artichoke; Asparagus; Brassica (head and stem) Vegetables; Carrots (Including Tops); Corn, Sweet; Cucurbit Vegetables; Eggplant; Flowering Plants; Fruiting Vegetables; Garlic; Ginger; Leafy Vegetables; Lettuce; Manioc (Cassava); Melons; Okra; Onions; Peas (Unspecified); Pepper; Pineapple; Root and Tuber	16.1	SL/G	0.034	PF10 R	1.0 lb ai/A	80 A	0.016	370	0.000034	**76**
		5.1	EC/G	0.02	EC/No-R			0.0051	1,200	0.00002	130

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat

Exposure Scenario	Crop or Target	Dermal Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control[2]	Inhalation Unit Exposure[1] (µg/lb ai)	Level of PPE or Engineering control	Maximum Application Rate[3]	Area Treated or Amount Handled Daily[4]	Dermal LOC = 100		Inhalation LOC = 100	
								Dose[5] (mg/kg/day)	MOE[6]	Dose[7] (mg/kg/day)	MOE[8]
	Vegetables; Rhubarb; Sugar Beet; Tomato; Turnip Greens; Yam										
	Field crop, typical: Tobacco	16.1	SL/G	0.034	PF10 R	0.94 lb ai/A	80 A	0.015	400	0.000032	**81**
		5.1	EC/G	0.02	EC/No-R			0.0048	1,300	0.000019	140
	Field crop, typical: Legume Vegetables; Sage, Clary; Taro; Vegetables (Unspecified)	16.1	SL/G	0.034	PF10 R	0.80 lb ai/A	80 A	0.013	470	0.000027	**95**
		5.1	EC/G	0.02	EC/No-R			0.0041	1,500	0.000016	160
	Field crop, typical: Guar; Lentils; Peas, Dried Type; Peas, Pigeon; Strawberry; Tuberous and Corm Vegetables;	16.1	SL/G	0.034	PF10 R	0.50 lb ai/A	80 A	0.0081	750	0.000017	150
		5.1	EC/G	0.02	EC/No-R			0.0026	2,400	0.00001	260
	Field crop, high acreage: Alfalfa; Clover	16.1	SL/G	0.034	PF10 R	1.5 lb ai/A	200 A	0.060	**99**	0.00013	**20**
		5.1	EC/G	0.02	EC/No-R			0.019	310	0.000075	**35**
	Field crop, high acreage: Barley; Coniferous/Evergreen/Softwood (non-food); Corn, Field; Corn, Pop; Cotton; Fallowland; Peanuts; Peas (Unspecified); Rice; Safflower; Sorghum; Soybean; Sugarcane; Sunflower; Tyfon; Wheat	16.1	SL/G	0.034	PF10 R	1.0 lb ai/A	200 A	0.040	150	0.000085	**31**
		5.1	EC/G	0.02	EC/No-R			0.013	470	0.00005	**52**
	Field crop, high acreage: Legume Vegetables; Mint	16.1	SL/G	0.034	PF10 R	0.80 lb ai/A	200 A	0.032	190	0.000068	**38**
		5.1	EC/G	0.02	EC/No-R			0.010	590	0.00004	**65**
	Field crop, high acreage: Grasses Grown for Seed;	16.1	SL/G	0.034	PF10 R	0.6 lb ai/A	200 A	0.024	250	0.000051	**51**

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	**Crop or Target**	**Dermal Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control[2]**	**Inhalation Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control**	**Maximum Application Rate[3]**	**Area Treated or Amount Handled Daily[4]**	**Dermal LOC = 100**		**Inhalation LOC = 100**	
								Dose[5] (mg/kg/day)	**MOE[6]**	**Dose[7] (mg/kg/day)**	**MOE[8]**
	Potato, White/Irish (or Unspecified)	5.1	EC/G	0.02	EC/No-R			0.0077	780	0.00003	**87**
	Field crop, high acreage: Beans, Dried-Type; Hops; Pastureland; Peas, Dried-Type; Peas, Pigeon; Tuberous and Corm Vegetables	16.1	SL/G	0.034	PF10 R	0.5 lb ai/A	200 A	0.020	300	0.000043	**61**
		5.1	EC/G	0.02	EC/No-R			0.0064	940	0.000025	100
	Field crop, high acreage: Root and Tuber Vegetables	16.1	SL/G	0.034	PF10 R	0.3 lb ai/A	200 A	0.012	500	0.000026	100
		5.1	EC/G	0.02	EC/No-R			0.0038	1,600	0.000015	170
Flagger											
Spray (all starting formulations), Aerial	Field crop, high acreage: Alfalfa; Clover	12	SL/G	0.0202	PF10 R	1.5 lb ai/A	350 A	0.079	**76**	0.00013	**20**
		10.6	DL/G					0.070	**86**		
	Field crop, typical: Asparagus; Brassica (head and stem) Vegetables; Carrots (Including Tops); Corn, Sweet; Cucurbit; Vegetables; Eggplant; Fruiting Vegetables; Leafy Vegetables; Lettuce; Melons; Peas (Unspecified); Pepper; Sugar Beet; Tomato; Turnip Greens; Orchard/Vineyard; Almond; Field crop, high-acreage; Barley; Beans, Dried-Type; Corn, Field; Corn, Pop; Cotton; Deciduous/Broadleaf/ Hardwood; Fallowland; Forestry; Grasses Grown for Seed; Mint; Nonagricultural Areas; Pastureland/Rangeland; Peas (Unspecified); Potato, White/Irish (or Unspecified); Rice; Root and Tuber	12	SL/G	0.0202	PF10 R	1.0 lb ai/A	350 A	0.053	110	0.000088	**29**
		10.6	DL/G					0.046	130		

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	**Crop or Target**	**Dermal Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control[2]**	**Inhalation Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control**	**Maximum Application Rate[3]**	**Area Treated or Amount Handled Daily[4]**	**Dermal LOC = 100**		**Inhalation LOC = 100**	
								Dose[5] (mg/kg/day)	**MOE[6]**	**Dose[7] (mg/kg/day)**	**MOE[8]**
	Vegetables; Safflower; Sorghum; Soybeans; Sugarcane; Sunflower; Tuberous and Corm Vegetables; Wheat										
	Field crop, typical: Legume Vegetables; Sage, Clary	12	SL/G	0.0202	PF10 R	0.80 lb ai/A	350 A	0.042	140	0.000071	**37**
		10.6	DL/G					0.037	160		
	Field crop, typical: Lentils; Peas, Dried Type; Tuberous and Corm Vegetables; Orchard/Vineyard; Grapes; Field crop, high acreage: Peas, Dried-Type	12	SL/G	0.0202	PF10 R	0.50 lb ai/A	350 A	0.026	230	0.000044	**59**
		10.6	DL/G					0.023	260		
	Field crop, typical: Root and Tuber Vegetables	12	SL/G	0.0202	PF10 R	0.30 lb ai/A	350 A	0.016	380	0.000027	**98**
		10.6	DL/G					0.014	430		
Mixer/Loader/Applicator											
Liquid, Backpack, Ground/soil-directed	All Use Sites	8260	SL/G	0.258	PF10 R	0.015 lb ai/gallon	40 gallons	0.062	**97**	0.0000019	1,300
		4120	DL/G					0.031	190		
	Pastureland	8260	SL/G			0.019 lb ai/gallon		0.079	**76**	0.0000025	1,100
		4120	DL/G					0.039	150		
Liquid, Backpack, Broadcast	All Use Sites	30500	SL/G	6.91	PF10 R	0.015 lb ai/gallon		0.229	**26**	0.000052	**50**
		16900	DL/G					0.13	**48**		
	Pastureland	30500	SL/G			0.019 lb ai/gallon		0.29	**21**	0.000067	**40**

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Exposure Scenario	**Crop or Target**	**Dermal Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control[2]**	**Inhalation Unit Exposure[1] (µg/lb ai)**	**Level of PPE or Engineering control**	**Maximum Application Rate[3]**	**Area Treated or Amount Handled Daily[4]**	**Dermal LOC = 100**		**Inhalation LOC = 100**	
								Dose[5] (mg/kg/day)	**MOE[6]**	**Dose[7] (mg/kg/day)**	**MOE[8]**
		16900	DL/G					0.16	**38**		
Liquid, Manually-pressurized Handwand, Broadcast	All Use Sites	430	SL/G	2.36	PF10 R	0.015 lb ai/gallon		0.0032	1,900	0.000018	150
		365	DL/G					0.0027	2,200		
	Pastureland	430	SL/G			0.019 lb ai/gallon		0.0041	1,500	0.000022	120
		365	DL/G					0.0035	1,700		
Liquid, Mechanically-pressurized Handgun, Broadcast (foliar); Drench/Soil-/Ground-directed	All Use Sites	2050	SL/G	0.868	PF10 R	0.015 lb ai/gallon	1000 gallons	0.39	**16**	0.00016	**16**
		1360	DL/G					0.26	**24**		
	Pastureland	2050	SL/G			0.019 lb ai/gallon		0.49	**12**	0.00021	**13**
		1360	DL/G					0.32	**19**		
Loader/Applicator											
Liquid, Backpack, Broadcast	Rights-of-Way	30500	SL/G	6.91	PF10 R	0.015 lb ai/gallon	40 gallons	0.23	**26**	0.000052	**50**
		16900	DL/G					0.13	**48**		

1.MOEs in **bold** represent scenarios of concern.
2. Based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table – Revised May 2021" (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data); Level of mitigation: Baseline, PPE, Eng. Controls.
3. SL/G = single layer clothing/gloves; DL/G = double layer clothing/gloves; APF 10 R = assigned protection factor 10 respirator; EC = engineering control.
4. Based on registered labels as summarized in the Line by Line, and Maximum Use Scenario Pesticide Label Usage Summary (PLUS) Reports as generated by OPP's Biological and Economic Analysis Division (BEAD).
6. Dermal Dose = Dermal Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) ÷ BW (80 kg).
7. Dermal MOE = Dermal NOAEL (6 mg/kg/day) ÷ Dermal Dose (mg/kg/day).
8. Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/acre or gal) × Area Treated or Amount Handled Daily (A or gal/day) ÷ BW (80 kg).
9. Inhalation MOE = Inhalation NOAEL (0.0026 mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

Appendix E: Proposed Tolerance Actions

Table E.1: Summary of Proposed Tolerance Actions for Paraquat

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
(a) General. (1) Tolerances are established for residues of paraquat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only paraquat dichloride and calculated as the paraquat cation in or on the following food commodities:			
Commodity/**Correct Commodity Definition**	Established Tolerance (ppm)	Revised Tolerance (ppm)	Comments
Acerola	0.05	0.05	
Almond, hulls	0.5	0.5	
Animal feed, nongrass, group 18, forage	75.0	75	Corrected value to be consistent with OECD Rounding Class Practice.
Animal feed, nongrass, group 18, hay	210.0	200	Corrected value to be consistent with OECD Rounding Class Practice.
Artichoke, globe	0.05	0.05	
Asparagus	0.5	Remove	Remove; covered by 22A
Atemoya	0.05	0.05	
Avocado	0.05	0.05	
Banana	0.05	0.05	
Barley, grain	0.05	0.05	
Barley, hay	3.5	3.5	
Barley, straw	1.0	1.0	
Beet, sugar, roots	0.5	0.5	
Beet, sugar, tops	0.05	0.05	
Berry and small fruit, group 13-07		0.05	Commodity definition revision
Berry group 13	0.05	remove	
Biriba	0.05	0.05	
Cabbage, chinese, napa	0.05	0.07	Harmonization with Codex
Cacao, dried bean			Commodity definition correction
Cacao bean, bean	0.05	0.05	
Canistel	0.05	0.05	
Carrot, roots	0.05	0.05	
Cattle, fat	0.05	0.05	

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Cattle, kidney	0.5	0.5	
Cattle, meat	0.05	0.05	
Cattle, meat byproducts, except kidney	0.05	0.05	
Cherimoya	0.05	0.05	
Coffee, green bean			Commodity definition correction
Coffee, bean, green	0.05	0.05	
Corn, field, forage	3.0	3	Corrected value to be consistent with OECD Rounding Class Practice
Corn, field, grain	0.1	0.1	
Corn, field, stover	10.0	10	Corrected value to be consistent with OECD Rounding Class Practice
Corn, pop, grain	0.1	0.1	
Corn, pop, stover	10.0	10	Corrected value to be consistent with OECD Rounding Class Practice
Corn, sweet, kernel plus cob with husks removed	0.05	0.05	
Cotton, gin byproducts	110.0	150	Corrected value to be consistent with OECD Rounding Class Practice
Cotton, undelinted seed	3.5	3.5	
Cowpea, forage	0.1	0.1	
Cowpea, hay	0.4	0.4	
Cranberry	0.05	0.05	
Custard apple	0.05	0.05	
Egg	0.01	0.01	

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(a) General. (1) Tolerances are established for residues of paraquat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only paraquat dichloride and calculated as the paraquat cation in or on the following food commodities:			
Endive	0.05	0.07	Harmonization with Codex
Feijoa	0.05	0.05	
Fig	0.05	0.05	
Fruit, citrus, group 10-10		0.05	Commodity definition revision
Fruit, citrus, group 10	0.05	Remove	
Fruit, pome, group 11-10		0.05	Commodity definition revision
Fruit, pome, group 11	0.05	Remove	
Fruit, stone, group 12-12		0.05	Commodity definition revision
Fruit, stone, group 12	0.05	Remove	
Goat, fat	0.05	0.05	
Goat, kidney	0.5	0.5	
Goat, meat	0.05	0.05	
Goat, meat byproducts, except kidney	0.05	0.05	
Grain, aspirated fractions	65.0	65	Corrected value to be consistent with OECD Rounding Class Practice
Grape	0.05	0.05	
Grass, forage	90.0	90	Corrected value to be consistent with OECD Rounding Class Practice
Grass, hay	40.0	40	Corrected value to be consistent with OECD Rounding Class Practice
Guar, seed	0.5	0.5	
Guava	0.05	0.05	
Hog, fat	0.05	0.05	
Hog, kidney	0.5	0.5	
Hog, meat	0.05	0.05	
Hog, meat byproducts, except kidney	0.05	0.05	
Hop, dried cones	0.5	0.5	
Horse, fat	0.05	0.05	

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
(a) General. (1) Tolerances are established for residues of paraquat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only paraquat dichloride and calculated as the paraquat cation in or on the following food commodities:			
Horse, kidney	0.5	0.5	
Horse, meat	0.05	0.05	
Horse, meat byproducts, except kidney	0.05	0.05	
Ilama	0.05	0.05	
Jaboticaba	0.05	0.05	
Kiwifruit	0.05	0.05	
Lentil, seed	0.3	0.5	Harmonization with Codex
Lettuce	0.05	0.05	
Longan	0.05	0.05	
Lychee	0.05	0.05	
Mango	0.05	0.05	
Milk	0.01	0.01	
Nut, tree, group 14-12		0.05	Commodity definition revision
Nut, tree, group 14	0.05	Remove	
Okra	0.05	0.05	
Olive	0.05	0.1	Harmonization with Codex
Onion, bulb, subgroup 3-07A		0.1	Commodity definition revision
Onion, bulb	0.1	Remove	
Onion, green, subgroup 3-07B		0.05	Commodity definition revision
Onion, green	0.05	Remove	
Papaya	0.05	0.05	
Passionfruit	0.2	0.2	
Pawpaw	0.05	0.05	
Pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean	0.3	0.5	Harmonization with Codex
Pea and bean, succulent shelled, subgroup 6B	0.05	0.05	

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
(a) General. (1) Tolerances are established for residues of paraquat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only paraquat dichloride and calculated as the paraquat cation in or on the following food commodities:			
Pea, field, hay	0.8	0.8	
Pea, field, vines	0.2	0.2	
Peanut	0.05	0.05	
Peanut, hay	0.5	0.5	
Peppermint, fresh leaves		0.5	Commodity definition correction
Peppermint, tops	0.5	Remove	
Persimmon	0.05	0.05	
Pineapple	0.05	0.05	
Pineapple, process residue	0.25	0.3	Corrected values to be consistent with OECD Rounding Class Practice
Pistachio	0.05	Remove	Covered by Nut, tree, group 14-12
Pomegranate	0.05	0.05	
Pulasan	0.05	0.05	
Rambutan	0.05	0.05	
Rhubarb	0.05	0.05	
Rice, grain	0.05	0.05	
Safflower, seed	0.05	0.05	
Sapodilla	0.05	0.05	
Sapote, black	0.05	0.05	
Sapote, mamey	0.05	0.05	
Sapote, white	0.05	0.05	
Sheep, fat	0.05	0.05	
Sheep, kidney	0.5	0.5	
Sheep, meat	0.05	0.05	
Sheep, meat byproducts, except kidney	0.05	0.05	
Sorghum, forage, forage	0.1	0.1	

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
(a) General. (1) Tolerances are established for residues of paraquat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only paraquat dichloride and calculated as the paraquat cation in or on the following food commodities:			
Sorghum, grain, forage	0.1	0.1	
Sorghum, grain, grain	0.05	0.05	
Soursop	0.05	0.05	
Soybean, forage	0.4	0.4	
Soybean, hay	10.0	10	Corrected value to be consistent with OECD Rounding Class
Soybean, hulls	4.5	4.5	
Soybean, seed	0.7	0.7	
Spanish lime	0.05	0.05	
Spearmint, fresh leaves		0.5	Commodity definition correction.
Spearmint, tops	0.5	Remove	
Star apple	0.05	0.05	
Starfruit	0.05	0.05	
Strawberry	0.25	0.3	Corrected values to be consistent with OECD Rounding Class Practice.
Sugar apple	0.05	0.05	
Sugarcane, cane	0.5	0.5	
Sugarcane, molasses	3.0	3	Corrected values to be consistent with OECD Rounding Class Practice.
Sunflower, seed	2.0	2	Corrected values to be consistent with OECD Rounding Class Practice.
Turnip, greens	0.05	Remove	Remove; covered by 4-16B
Turnip, roots	0.05	0.05	
Vegetable, Head and Stem *Brassica,* Group 5-16		0.05	Crop group conversion/revision*
Vegetable, brassica, leafy, group 5	0.05	Remove	

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
(a) General. (1) Tolerances are established for residues of paraquat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only paraquat dichloride and calculated as the paraquat cation in or on the following food commodities:			
Brassica leafy greens subgroup 4-16B	--	0.07	**Change in crop group 5.** *Brassica leafy greens subgroup 4-16B** *Harmonizing with Canada*
Stalk and Stem Vegetable Subgroup 22A	--	0.05	**Change in crop group 5**. *Stalk and Stem Vegetable Subgroup 22A**
Vegetable, cucurbit, group 9	0.05	0.05	
Vegetable, fruiting, group 8-10			Crop group conversion/revision.
Vegetable, fruiting, group 8	0.05	0.05	
Vegetable, legume, edible podded, subgroup 6A	0.05	0.05	
Vegetable, tuberous and corm, subgroup 1C	0.50	0.5	Corrected values to be consistent with OECD Rounding Class Practice.
Wax jambu	0.05	0.05	
Wheat, forage	0.5	0.5	
Wheat, grain	1.1	1.1	
Wheat, hay	3.5	3.5	
Wheat, straw	50.0	50	Corrected value to be consistent with OECD Rounding Class
c) *Tolerances with regional registrations.* Tolerances with regional registration as defined in §180.1(l), are established for residues of paraquat, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only paraquat dichloride and calculated as the paraquat cation in or on the following food commodities:			
Pea, pigeon, seed	0.05	0.05	
Taro, corm	0.1	0.1	
Tyfon	0.05	0.05	

* These recommended conversions of existing tolerances in/on crop subgroup **5A** to crop group **5-16** (*Brassica*, head and stem vegetable) and subgroup 5B to subgroup 4-16B (*Brassica* leafy greens) are consistent with the document entitled "Attachment - Crop Group Conversion Plan for Existing Tolerances as a Result of Creation of New Crop Groups under Phase IV (4-16, 5-16, and 22)," dated 11/3/2015.