



Paraquat Dichloride

Proposed Interim Registration Review Decision Case Number 0262

September 2020

Approved by: _____

A handwritten signature in blue ink, appearing to read "Elissa Reaves".

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Date: 09/30/2020

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I. INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) Proposed Interim Registration Review Decision (PID) for paraquat dichloride (PC Codes 061601 and 061603, case 0262), herein referred to as paraquat, and is being issued pursuant to 40 CFR §§ 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide continues to meet, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose 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. Additional information on paraquat can be found in EPA's public docket (EPA-HQ-OPP-2011-0855) at www.regulations.gov.

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, 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 risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to make sure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at <http://www.epa.gov/pesticide-reevaluation>. In 2006, the Agency implemented the registration review program pursuant to FIFRA § 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

EPA is issuing a PID 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). The Agency is currently working with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (collectively referred to as, "the Services") to improve the consultation process for conducting national threatened and endangered (listed) species for pesticides in accordance with the Endangered Species Act (ESA) § 7. Therefore, although EPA has not yet fully evaluated risks to federally-listed species, the Agency will complete its listed species assessment and any necessary consultation with the Services for paraquat prior to completing the paraquat registration review. Likewise, the Agency will complete endocrine screening for paraquat, pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA) § 408(p), before completing registration review. See Appendices C and D, respectively, for additional information on the listed species assessment and the endocrine screening for the paraquat registration review.

Paraquat is a fast-acting, non-selective herbicide used for the control of broadleaves and grasses 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 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 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. Paraquat was first registered in the U.S. in 1964 and the Reregistration Eligibility Decision (RED) for paraquat was published in 1997.

This document is organized in five sections: *Introduction*, which includes this summary and a summary of public comments and EPA's responses; *Use and Usage*, which describes how and why paraquat is used and summarizes data on its use; *Scientific Assessments*, which summarizes EPA's risk and benefits assessments, updates or revisions to previous risk assessments, and provides broader context with a discussion of risk characterization; *Proposed Interim Registration Review Decision*, which describes the mitigation measures proposed to address risks of concern and the regulatory rationale for EPA's PID; and, lastly, *Next Steps and Timeline* for completion of this registration review.

A. Summary of Paraquat Dichloride Registration Review

Pursuant to 40 CFR § 155.50, EPA formally initiated registration review for paraquat with the opening of the registration review docket for the case. The following summary highlights the docket opening and other significant milestones that have occurred thus far during the registration review of paraquat.

- December 2011 - The *Paraquat Dichloride Summary Document, Paraquat Dichloride (Paraquat): Human Health Risk Scoping Document in Support of Registration Review*, and *EFED Registration Review: Preliminary Problem Formulation for Paraquat Dichloride* were posted to the docket for a 60-day public comment period.
- May 2012 - The *Final Work Plan (FWP)* for paraquat was issued. 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.
- February 2013 - A Generic Data Call-In (GDCI 061601-1172) for paraquat was issued for data needed to conduct the registration review risk assessments. All data were submitted and/or waived and the GDCI is satisfied.
- March 2016 - The *Paraquat Dichloride; Proposed Interim Mitigation Decision* was posted to the docket for a 60-day public comment period.

- December 2016 - The Agency 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:
 - 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 will be implemented by December 30, 2020.

- June 2019 - The Agency announced the availability of *Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review* and *Paraquat: Preliminary Ecological Risk Assessment for Registration Review* for a 60-day public comment period. Seventy-three comments were received during this period. These comments and the Agency's responses are summarized below. The comments did not change the risk assessments or registration review timeline for paraquat.
- September 2020 - The Agency has completed the PID for paraquat. The PID will be posted to the docket for a 60-day public comment period. Along with the PID, the following documents are also posted to the paraquat docket:
 - *Paraquat: Response to Comments on the Draft Human Health Risk Assessment*
 - *Paraquat: Response to Comments on the EFED Preliminary Ecological Risk Assessment for Registration Review*
 - *Paraquat Dichloride: Addendum to the Memorandum, "Draft Human Health Risk Assessment in Support of Registration Review"*
 - *Overview of Use, Benefits, and Impacts of Mitigation Assessment for Paraquat (PC#061601) in Agricultural Settings*
 - *Paraquat Dichloride (Herbicide and Harvest Aid) Use, Usage, Benefits and Impacts of Potential Mitigation in Cotton*
 - *Paraquat Use on Peanut: Usage, Benefits, and Impacts of Potential Mitigation for Registration Review*
 - *Paraquat Dichloride (PC# 061601) Use in Soybeans: Usage, Benefits and Impacts of Potential Mitigation*

B. Summary of Public Comments on the Draft Risk Assessments and Agency Responses

During the 60-day public comment period for the paraquat Draft Risk Assessments, which opened on October 16, 2019 and closed on December 16, 2019, the Agency received 73 public comments from 71 sources. Two of the comments, submitted by the Center for Biological Diversity and the Pesticide Action Network, were mass email campaigns commenting against the continued registration of paraquat. Thirty-one of the comments received were from individual citizens, many of them anonymous, of which one was in favor of continued paraquat use, 29 were against it, and one was an incomplete comment. The rest of the comments received were from a wide range of stakeholders including environmental non-government organizations, public interest advocacy groups, government agencies, state and national agricultural groups and associations, and individual members of the general public. Comments were also submitted by Syngenta Crop Protection, LLC., one of paraquat's technical registrants.

In general, comments in support of continued paraquat use and registration stated that paraquat is a valuable herbicide to farmers and the agricultural industry because it is effective, economical, and is a critical resistance management tool. In general, comments against continued registration of paraquat stated that they were concerned about the toxicity of paraquat and a potential link to Parkinson's disease. Comments of a technical nature concerning the draft paraquat risk assessments are summarized and addressed in *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*. Additional substantive comments, comments of a broader regulatory nature, and the Agency's responses to those comments are summarized below. The Agency thanks all commenters for their comments and has considered them in developing this PID.

Comments Submitted by Center for Biological Diversity (CBD) (Docket ID: EPA-HQ-OPP-2011-0855-0166)

Comment: CBD commented that it is EPA's duty to consult with the Services on the registration review of paraquat in accordance with the Endangered Species Act (ESA). The CBD comment mentioned various aspects of the risk assessment process, specifically use of the best available data, including all necessary data and studies, particularly to develop listed species risk assessments, and evaluation of effects on listed species and their designated critical habitat. CBD also expressed concern regarding the rigor of the Agency's preliminary determinations regarding the effects of paraquat on listed species and their designated critical habitat for the paraquat registration review. In addition, CBD expressed concern about effects on pollinators and other beneficial insects; effects on human health or environmental safety concerning endocrine disruption; additive, cumulative or synergistic effects of the use of the pesticide; and various aspects of the risk assessments.

EPA Response: EPA has reviewed CBD's comments and plans to address many of the concerns regarding listed species as part of the implementation plan for assessing the risks of pesticides to listed species based on the recommendations of the April 2013 National Academy of Sciences (NAS) report. See Endangered Species Assessment in Appendix C of this document for more

information. EPA will address concerns specific to paraquat particularly with regard to pollinators, ESA, and endocrine disruption, in connection with the development of its final registration review decision for this pesticide. See Endocrine Disruptor Screening Program in Appendix D of this document for more information regarding endocrine disruption. EPA is currently developing an Agency policy on how to consider claims of synergy being made by registrants in their patents. On September 9, 2019, EPA released for public comment a document describing an interim process for evaluating potential synergistic effects of pesticides, which is available at regulations.gov in docket EPA-HQ-OPP-2017-0433. After the Agency considers public comment on the proposed policy, and once that policy has been finalized, EPA will consider its implications on the Agency's final registration review decision for paraquat. Responses to comments on the specific aspects of the risk assessments can be found in the human health and ecological response to comment documents in the docket.

Comments Submitted by Agricultural Retailers Association (EPA-HQ-OPP-2011-0855-0200), American Farm Bureau Federation (EPA-HQ-OPP-2011-0855-0167), Florida Fruit and Vegetable Association (EPA-HQ-OPP-2011-0855-0178), and National Corn Growers Association (EPA-HQ-OPP-2011-0855-0189)

Comment: The commenters listed above submitted comments regarding the Paraquat Human Health Mitigation Decision¹ that was issued in 2016. While the National Corn Growers Association (NCGA) encouraged EPA to study and understand the impact of the 2016 mitigation measures before proposing additional changes to the label, the other commenters expressed concern that the requirements from the 2016 mitigation decision will make it very restrictive to purchase and apply paraquat products. The Agricultural Retailers Association (ARA) stated that the label language found on paraquat products intended to prevent the transfer of paraquat into food or beverage containers, combined with increased product awareness, provide ample protections to prevent incidents of accidental ingestion. They also expressed concern with the additional product-specific training for certified applicators, arguing that specific concerns with the handling and applications of pesticide products such as paraquat should be included in the general certified applicator training.

The American Farm Bureau Federation (AFBF) stated that the bolstered training requirements and additional label language cautioning against misuse are adequate in ensuring that paraquat is handled safely, and that additional mitigation measures are not required. AFBF encouraged EPA to ensure that farmers can continue applying paraquat using a variety of spray methods, including backpack sprayers. The Florida Fruit and Vegetable Association (FFVA) argued that the closed system requirement may not be compatible with Florida vegetable/citrus/sugar crop application systems and will place a burden on smaller farms. FFVA also disagreed with the elimination of jar-testing.

EPA Response: Paraquat is extremely toxic and as little as 1.5 teaspoons can be fatal if ingested. There is a history of users illegally transferring paraquat into beverage containers, leading to incidents of accidental ingestion. Between 2000 and 2019, 19 deaths occurred as a result of accidental ingestion of paraquat. EPA's human health mitigation decision, issued in 2016,

¹ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0855-0112>

determined that several restrictions intended to reduce the number and severity of human health incidents caused by the accidental ingestion of paraquat are necessary in order for pesticide products containing paraquat dichloride to meet the FIFRA standard for registration (i.e. reasonable certainty of no harm to human health or the environment). By December 2020, all of the label and packaging changes required through the 2016 decision will be implemented. As with all registration review cases, EPA intends to conduct a periodic re-evaluation of incident data in the future, at which point EPA will determine if any adjustments to the implemented mitigation measures are warranted. The Agency reserves the right to make changes to pesticide registrations at any point based on risk or new information.

The mitigation being proposed in this PID is intended to address the occupational handler and ecological risks shown in the Agency's draft human health and ecological risk assessments. While some of the 2016 human health mitigation will also help to reduce risks to occupational handlers, its main intent is to address accidental ingestion risks. The additional mitigation proposed in this document is necessary to mitigate the risks identified in the assessments.

Comments Submitted by the Weed Science Society of America (WSSA) (EPA-HQ-OPP-2011-0855-0201)

Comment: WSSA commented that all paraquat product labels should have statements that clearly and prominently prohibit pouring paraquat into food or beverage containers. They also recommended adding statements intended to minimize potential exposure to residential areas.

EPA Response: EPA notes that the statements recommended by the WSSA to prohibit pouring paraquat into food and beverage containers are already included on labels in an effort to eliminate the illegal transfer of paraquat, consistent with the 2016 *Paraquat Dichloride Human Health Mitigation Decision*. In addition to the label statements, closed transfer systems are required on all non-bulk (less than 120 gallon) paraquat containers, as an additional measure to prevent the pouring of paraquat into food and beverage containers. The December 2020 implementation deadline for closed transfer systems on all paraquat products as part of the 2016 *Paraquat Dichloride Human Health Mitigation Decision*² will ensure that paraquat cannot be transferred from the product container into other unauthorized containers.

As for the statements regarding exposure to residential areas, paraquat labels contain statements intended to prevent off-target movement of paraquat (in English and Spanish). Additional mitigation, including the prohibition of aerial application for most uses, residential drift buffers, and spray drift management language, is being proposed in this PID to further minimize off-target drift to the greatest extent possible.

² <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0855-0112>

II. USE AND USAGE

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 bipyridylum chemical family and is classified by the Weed Science Society of America as a Class 22 herbicide (Photosystem I Electron Diverter site of action). Products containing paraquat are frequently used as a burn-down herbicide treatment to control existing vegetation before planting or crop emergence. Products containing paraquat are also 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. 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 help farmers harvest their crop more effectively and quickly by making the leaves dry up. Over 15% of cotton, about 1.8 million acres per year, are treated for this use. As an herbicide, 1.2 million pounds of paraquat are used to treat about 2.3 million cotton acres. 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 percent of the total area treated (TAT) with paraquat and nearly 63 percent of the pounds of active ingredient (lbs a.i.) applied from 2014-2018. Specific details about paraquat use and usage for these commodities can be found below.

Cotton

Paraquat is used in cotton both as an herbicide and as a harvest aid. Nationally, over 2.3 million acres of cotton have over 1.2 million pounds paraquat applied as an herbicide. Paraquat is applied to about 20% of the cotton crop as an herbicide. As a harvest aid, paraquat is applied to about 15% of the cotton crop. Harvest aid use is concentrated primarily in Texas, where about 574,000 pounds are applied to about 1.7 million acres on average. Total harvest aid use is about 628,000 pounds applied to about 1.8 million acres, annually.

Peanuts

Paraquat is applied to 38% of peanut acres annually and can be effectively used at multiple timings to the crop, 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 Federal Insecticide, Fungicide, and Rodenticide Act (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. Delta states, which include Arkansas, Louisiana and Mississippi, treat 30% of soybean acres annually.

For more information on paraquat use and usage, 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.

III. SCIENTIFIC ASSESSMENTS

A. Human Health Risks

A summary of the Agency's human health risk assessment is presented 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. For additional details on the human health assessment for paraquat, see the *Paraquat Dichloride: Draft Human Health Risk Assessment in Support of Registration Review*, the *Paraquat Dichloride: Addendum to the Memorandum, "Draft Human Health Risk Assessment in Support of Registration Review"*, and the *Paraquat: Response to Comments on the Draft Human Health Risk Assessment*, which are available in the public docket.

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, Post-Application, and Aggregate 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 and boom heights. 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 a.i./A, for example, results in an MOE of 29 at the field edge, which is of concern to the Agency (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 a.i./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.

Cumulative Risks

EPA has not made a common mechanism of toxicity to humans finding as to paraquat and any other substance and it does not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that paraquat has a common mechanism of toxicity with other substances for this assessment.

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 protection 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 were updated based on the “Occupational Pesticide Handler Unit Exposure Surrogate Reference Table – Revised March 2020³”. The updated handler risk estimates are presented in an addendum to the paraquat draft human health risk assessment, *Paraquat Dichloride: Addendum to the Memorandum, “Draft Human Health Risk Assessment in Support of Registration Review,”* which is available in the public docket. The risk estimates presented in this section are based on the revised risk estimates provided in the addendum referenced above.

Inhalation Risks

Inhalation exposure is the risk driver for almost all 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.

All the inhalation exposure scenarios that were assessed assumed the currently-registered level of respiratory personal protection from a PF10 respirator or with engineering controls. 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 16,000. The same mixer/loader exposure scenarios were assessed with engineering controls in the form of closed transfer systems and 21 out of 26 scenarios result in risks of concern, with MOEs ranging from 1.4 to 4,200. Respirators offer more protection for inhalation routes of exposure, whereas closed transfer systems offer more protection for dermal routes of exposure. Due to current data and methodologies, the Agency cannot quantitatively determine risk estimates combining both forms of protection (respirators and closed transfer systems) but notes that the combination of both forms of protection offers more protection than either method would separately. One exposure scenario was assessed for loader/applicators wearing a PF10 respirator, resulting in an 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 for aerial application and enclosed cabs for groundboom application). The MOEs for applicators range from 24 to 570. 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 1,300.

³<https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#olddata>

See Table E.1 in Appendix E 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 1900 (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 2200. Most dermal exposure scenarios for mixer/loaders are not of concern, when assuming engineering controls in the form of closed transfer systems; only 4 out of 26 scenarios are of concern, with MOEs of 31, 47, 58, and 93. 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, assuming baseline clothing (scenario of concern results in an MOE of 76). There are no dermal risks of concern for applicators, assuming engineering controls, with MOEs ranging from 130 to 4,700.

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

Handler Biomonitoring Data

A supplemental occupational handler biomonitoring study is available for paraquat (MRID 43644202) and the data were used to estimate an internal dose reflective of exposures associated with mixing/loading and applying paraquat via groundboom spray equipment. The biomonitoring data result in estimated risks of concern for paraquat; however, there are several uncertainties related to its interpretation. Occupational handler risk estimates, outlined above, were quantified using the absorbed doses measured from the biomonitoring study. The resulting MOEs for mixing, loading and applying paraquat via groundboom range from 13 to 97 (LOC = 100) depending on the combination of application rate and area treated daily.

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 \geq 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

The Agency performed a review of human incidents using the following sources: 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) databases.

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.

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 that was in a Pepsi 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 will continue to monitor the incident information. Additional analyses will be conducted if ongoing human incident monitoring indicates a concern. For additional details on human incidents related to paraquat, see the *Paraquat: Tier II Human Incidents Report*, 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*⁴, 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*⁵, which is available in the public docket.

3. Tolerances

Tolerances for paraquat residues, including its metabolites and degradates, are currently established in 40 CFR § 180.205. The current tolerance expression for paraquat is:

Tolerances are established for residues of the desiccant, defoliant, and herbicide paraquat (1,1'-dimethyl-4,4'-bipyridinium-ion) derived from application of either the bis (methyl sulfate) or the dichloride salt (both calculated as the cation) in or on the following food commodities:

In accordance with the 2009 guidance on tolerance expressions (S. Knizner, 05/27/2009), the Agency anticipates revising the tolerance expression to read:

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:

⁴ <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0124>

⁵ <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0125>

The Organization for Economic Cooperation and Development (OECD) rounding class practice does not recommend adding a trailing zero. The Agency is proposing modifications to the paraquat tolerances to be consistent with the OECD rounding class practice and/or to revise certain commodity definitions (see Appendix F). The Agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

The Codex Alimentarius Commission and Canada have 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. The Agency recommends increasing U.S. tolerances for certain commodities to harmonize with Codex. These recommendations can be found in Table 1 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 1: Proposed U.S. Tolerance Revisions for Harmonization with Codex

Commodities	Current Tolerance	Recommended Tolerance
Endive, Vegetable, Head and Stem Brassica, Group 5-16, Brassica leafy green subgroup 4-16B	0.05 ppm	0.07
Lentil, seed, pea and bean, dried shelled, except soybean, subgroup 6C, except guar bean	0.03 ppm	0.05 ppm
Olive	0.05 ppm	0.1 ppm

4. Human Health Data Needs

Analytical standards for paraquat dichloride need to be submitted.

No other data are required to support this registration review decision at this time; however, there are a few data deficiencies, as 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

A summary of the Agency's ecological risk assessment is presented 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. For additional details on the ecological assessment for paraquat, see the *Paraquat: Preliminary Ecological Risk Assessment for Registration Review* and the *Paraquat: Response to Comments on the EFED Preliminary Ecological Risk Assessment for Registration Review*, which are available in the public docket.

EPA is currently working with its federal partners and other stakeholders to implement a Revised Method⁶ for assessing potential risk to listed species and their designated critical habitats. Once the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats have been fully implemented, the Agency will complete its endangered species assessment for paraquat. See Appendix C for more details. As such, potential risks for non-listed species only are described below.

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

⁶ <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0185-0084>

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 (honeybees)

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.

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 EPA's issuance of the June 2014 *Guidance for Assessing Pesticide Risks to Bees*⁷. 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 2 below.

⁷ Available at https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf

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.

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 probably 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.

Vascular and Non-Vascular Aquatic 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

The Incident Data System (IDS) provides information on the available ecological pesticide incidents reported since registration and up to June 14, 2018, the date of the most recent search. 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 will continue to monitor ecological incident information as it is reported to the Agency. Detailed analyses of these incidents are conducted if reported information indicates concerns for risk to non-target organisms.

3. Ecological and Environmental Fate Data Needs

No additional data are required to support this proposed interim registration review decision at this time.

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. For more information on the pollinator studies that could be required, see Section III.B.1 – Terrestrial Invertebrates.

C. Benefits Assessment

Paraquat provides a number of unique and often high benefits for crops with a high percent crop treated (PCT), such as cotton, peanuts soybeans, and several others such as 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 it to be applied immediately before planting crops or seedling emergence. As a broad-spectrum herbicide, paraquat is a substitute for glyphosate. Weed resistance to glyphosate has meant that many growers have turned to paraquat, with a different mode of action than that of 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 percent of the total area treated (TAT) with paraquat and nearly 63 percent 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 marehail. 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 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 that can be particularly problematic in soybean production in the south, and the low cost of paraquat compared to other herbicides. There is no one-to-one herbicide replacement for paraquat in soybean. Without paraquat, soybean growers would require a minimum of two herbicides to replace it.

The *Paraquat Dichloride (PC# 061601) Use in Soybeans: Usage, Benefits and Impacts of Potential Mitigation* focuses on the Delta and other southern soybean production regions, where the greatest amount of paraquat is used. To maintain an efficacy equal to paraquat, growers in the 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).

For more information 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.

IV. PROPOSED INTERIM REGISTRATION REVIEW DECISION

A. Proposed 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).

To mitigate these potential risks, EPA is proposing to:

- prohibit aerial application for all uses except cotton desiccation;
- require a residential area drift buffer for cotton desiccation by aerial application

- limit the single application maximum rate for alfalfa to 1.0 lb active ingredient per acre (ai/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. The registrants have agreed to the proposed mitigation in principle. For more information on the benefits of paraquat, see Section III.C.

EPA is also proposing label changes to address generic labeling requirements for all paraquat products and uses. These proposed label changes include:

- an herbicide resistance management statement;
- a non-target organism advisory;
- maintaining existing PPE on all non-bulk paraquat products with closed transfer systems;
- standardization of paraquat label metrics, such as maximum annual application rates, maximum annual numbers of applications, and minimum retreatment intervals;
- updated glove 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 stenchers, 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 stenchers, 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 proposed mitigation are presented below by mitigation measure. The Agency encourages submission of comments about these and other possible impacts of the proposed mitigation measures. 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. Prohibit Aerial Application for All Uses Except Cotton Desiccation

To mitigate potential risks to occupational handlers and residential bystanders and to reduce significant ecological risks, the Agency is proposing to prohibit aerial application of paraquat for all uses except cotton desiccation. For occupational handler scenarios, prohibiting aerial application would fully mitigate potential risks from this application method to mixers/loaders, applicators, and flaggers. In conjunction with the spray drift management measures and residential buffers discussed in Section IV.A.2. below also being proposed by the Agency, the prohibition of aerial application would fully mitigate potential risks to bystanders from spray drift. Potential risks to mammals, birds, and non-target plants would also be significantly reduced by the prohibition of aerial application combined with spray drift management measures.

According to feedback from cotton producers and extension specialists, aerial application of paraquat is critical for timely desiccation of cotton crops prior to harvest. This use is especially important among western 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 proposing to retain the use of aerial application for cotton desiccation.

Based on the difference in aerial and state-level use patterns, the impacts of prohibiting aerial application for desiccation on cotton are expected to be concentrated in certain regions. There are many cotton growing states that have reported some recent use of paraquat aerially; however, the following four states comprise most (i.e., 95%) of the cotton acres treated aerially with paraquat: Arizona, California, Louisiana, and Texas. The cancellation of aerial applications could be highly impactful for states like Arizona and California, and certain regions of Texas and Louisiana, but not very impactful for other cotton growing states that do not have significant aerial use of paraquat.

In order to substantiate this proposal to retain aerial application for cotton desiccation and to more fully understand the scope of aerial application of paraquat, the Agency is seeking additional information on when this application method is used, for what purpose (e.g., for herbicidal or desiccation purposes) and on what crops. The Agency encourages commenters to provide comments, data submissions, or references to additional information related to the proposal to retain aerial application of paraquat for cotton desiccation and to cancel it for all other uses (including cotton herbicidal use).

Impacts of Prohibiting Aerial Applications for All Uses Except Cotton Desiccation

Prohibiting aerial applications is likely to have little impact for most crops, as aerial application only accounts for 3% of all paraquat-treated acres.

Some growers may choose to use alternatives if they cannot apply paraquat aerially. The estimated impacts for growers who need to use alternatives in the absence of paraquat are declines in per acre net revenue of up to 7% (or \$9/acre) for herbicide applications and declines of up to 3% (or \$4/acre) for harvest aid applications. Most alternatives can be applied aerially in cotton. However, this alternative impact analysis does not explicitly take application method into account. Over 85% of all aerial applications of paraquat in cotton are as a harvest aid, so acres

and states using paraquat as a harvest aid would be most impacted by this change. Paraquat is very fast acting, which allows additional flexibility to desiccate and harvest the cotton crop before rainfall, which can reduce the quality of the cotton fibers and lower the market value (e.g., lower price received per pound of lint). If growers need to harvest their cotton quickly with aerial applications of paraquat, then impacts may be even greater than the estimated 3% per acre.

2. Require a Residential Area Drift Buffer for Cotton Desiccation by Aerial Application

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), the Agency is requiring a no-spray buffer from residential areas. 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 a.i./A, a buffer of 75 feet is required to reach an acceptable MOE (MOE for 1.0 lbs a.i./A (medium to coarse droplet size) = 110; LOC = 100). For applications of 0.6 lbs a.i./A or lower, a buffer of 50 feet is required to reach an acceptable MOE (MOE for 0.6 lbs a.i./A (medium to coarse droplet size) = 130; LOC = 100). Potential risks to mammals, birds, and non-target plants would also be reduced by requiring a buffer.

Impacts of Requiring a Residential Area Drift Buffer for Cotton Desiccation by Aerial Application

The requirement of a residential area drift buffer for aerial applications may require growers to remove land from production or use an alternative that is potentially less effective and/or more expensive in those areas, thus decreasing gross revenue per acre. The impacts for using an alternative in the absence of paraquat in cotton were presented in the previous section. In this section, estimates are provided for two types of buffers on a rectangular cotton field: a one-sided buffer and a four-sided (i.e., perimeter) buffer. A one-sided buffer may be required to protect bystanders or other people against 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 ecological risks on all four sides.

For a one-sided, in-field buffer, estimated impacts, in terms of a reduction in the land available for production, range from 2% for a 50-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 \$12 to \$162 per acre.

For a four-sided, in-field buffer, estimated impacts in terms of a reduction in the land available for production, range from 6% for a 50-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 \$35 to \$467 per acre.

The impacts per acre are quite high for some scenarios (e.g., fields/acres with lower gross revenue). These cotton growers may opt to use ground applications if possible. However, in the event of inclement weather, it may not be possible to use ground equipment. Therefore, as was

previously stated, if growers needed to harvest their cotton quickly with paraquat, then impacts may be even greater than the 3% decline that was previously estimated.

3. Limit Single Application Maximum Rate for Alfalfa to 1.0 lb ai/A

In order to fully mitigate potential post-application risks to occupational handlers for alfalfa, the Agency is proposing to limit the single application maximum rate for alfalfa to 1.0 pound of active ingredient per acre (lb ai/A). At the currently labeled single application maximum rate of 1.5 lb ai/A, the MOE on Day 0 after application is 68, which is of concern to the Agency (LOC = 100). At the proposed reduced rate of 1.0 lb ai/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 ai/A

Usage data and discussions with stakeholders suggest that all single paraquat applications to alfalfa are made at or below 1.0 lb ai/A, so there are no economic impacts anticipated from this mitigation.

4. 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 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 is proposing 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.

5. 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 is proposing to require PF10 respirators or enclosed cabs for 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.4 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.⁸ 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 requiring 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 pesticide handler. Respirator fit tests are currently required by the Occupational Safety and Health Administration (OSHA) for other occupational settings to ensure proper protection.⁹

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.

6. 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

⁸ 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

⁹ 29 CFR § 1910.134

occupational handlers (mixers, loaders, and applicators) from mechanically pressurized handguns and backpack sprayers, the Agency is proposing 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.

7. 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 Standard¹⁰. 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.

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

Given the timing of most paraquat application (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.

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

¹⁰ <https://www.epa.gov/sites/production/files/2016-02/documents/chap-10-feb-2016.pdf>

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.

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

To mitigate potential post-application risks to workers from mechanical harvesting of cotton, the Agency is proposing to require a longer REI of 7 days for cotton desiccation. 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 have grower impacts that would 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.

In order to substantiate this proposal and to more fully understand post-application activities associated with the mechanical harvesting of cotton, the Agency is seeking additional information on how quickly workers need to re-enter the field after application of paraquat as a desiccant on cotton. The Agency encourages commenters to provide comments, data submissions, or references to additional information related to the proposed 7-day REI for cotton desiccation.

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

An REI increase to 7 days would 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 would impact timely desiccation of cotton close to harvest. Impacts to quality and yield would likely occur for both stripper- and spindle-harvested cotton.

9. Spray Drift Management

The Agency is proposing label changes to reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all paraquat products. In conjunction with the prohibition of aerial application and residential buffers being proposed 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 is proposing the following spray drift mitigation language to be included on all paraquat product labels for products applied by liquid spray application. The proposed 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 proposed in this PID, 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 a.i./A, a buffer of 75 feet is required. For applications of 0.6 lbs a.i./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 proposed to be removed from all paraquat labels where such information currently appears. The proposed new language above, which cites ASABE S572 and S641, eliminates the need for VMD information.

Impacts of Droplet Size Restrictions

The Agency is considering 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., 2009¹¹; Wolf and Bretthauer 2009¹²; Grisso 2019¹³). 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, 1968¹⁴; McKinlay et al., 1974¹⁵; Carroll, 2017¹⁶; Ferguson et al., 2018¹⁷; Peterson and Hay, 2018¹⁸). 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 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.

¹¹ 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

¹² 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>

¹³ 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

¹⁴ 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>

¹⁵ 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>

¹⁶ 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>

¹⁷ 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>

¹⁸ 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

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)¹⁹ 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 percent 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% percent 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 Cotton Desiccation by Aerial Application.

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 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.

¹⁹ Bish, M. and K.W. Bradley. 2017. Survey of Missouri Pesticide Applicator Practices, Knowledge, and Perceptions. *Weed Technology* 31:165–177. Available at: https://weeds.cscience.missouri.edu/Pesticide%20Applicator%20Knowledge_2017.pdf

10. Herbicide Resistance Management

On August 24, 2017, EPA finalized a Pesticide Registration Notice (PRN) on herbicide resistance management.²⁰ Consistent with the Notice, EPA is proposing the implementation of herbicide resistance measures for existing chemicals during registration review, and for new chemicals and new uses at the time of registration. In registration review, herbicide resistance elements will be included in every herbicide PID.

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. While herbicide resistant weeds have been known since the 1950s, the number of species and their geographical extent has been increasing rapidly. Currently, there are over 250 weed species worldwide with confirmed herbicide resistance. In the United States, there are over 155 weed species with confirmed resistance to one or more herbicides.

Management of herbicide resistant weeds, both in mitigating established herbicide resistant weeds and in slowing or preventing the development of new herbicide resistant weeds, is a complex problem without a simple solution. Coordinated efforts of growers, agricultural extension, academic researcher, scientific societies, pesticide registrants, and state and federal agencies are required to address this problem.

EPA is proposing to require measures for the pesticide registrants to provide growers and users with detailed information and recommendations to slow the development and spread of herbicide resistant weeds. This is part of a more holistic, proactive approach recommended by crop consultants, commodity organizations, professional/scientific societies, researchers, and the registrants themselves.

11. Non-Target Organism Advisory

The Agency is also proposing the addition of a non-target organism advisory. The protection of pollinating organisms is a priority for the Agency. Given that paraquat is toxic to plants, spray drift from its use may negatively impact forage and habitat of pollinators and other non-target organisms. It is the Agency's goal to reduce spray drift whenever possible and to educate growers on the potential for indirect effects on the forage and habitat of pollinators and other non-target organisms. Therefore, EPA is proposing non-target organism advisory language to be placed on paraquat labels to address this potential concern.

12. Additional Label Changes

In addition to the above-mentioned proposed mitigation, EPA is also proposing the following label changes to address generic labeling requirements and ensure consistency across all paraquat products and uses:

²⁰ PRN 2017-2, "Guidance for Herbicide Resistance Management Labeling, Education, Training, and Stewardship". Available at <https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year>

Maintaining Personal Protective Equipment

As of December 2020, all non-bulk paraquat product containers (<120 gallons) will be distributed in containers incorporating closed transfer systems.²¹ 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 is proposing 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.

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.

Standardizing Label Metrics

There are currently 33 Section 3 registrations and 47 Section 24(c) registrations for paraquat, some of which are missing information regarding application metrics. EPA is proposing to update all paraquat labels to current standards. The components of the label the Agency proposes to update are as follows:

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

The Agency proposes that these parameters be clearly defined on every label in order to establish better consistency and clarity across all paraquat labels. The Agency also proposes the standardization of units of measurement for these parameters. Maximum single and annual application rates should be presented as pounds of active ingredient per acre (lbs ai/A). The application metrics for each registered use of paraquat can be found in Table B.2 in Appendix B.

The Agency encourages commenters to provide additional information for registered uses that are missing application metrics.

Updated Glove Label Language

The Agency is requiring an update to gloves statements to be consistent with Chapter 10 of the Label Review Manual. In particular, the Agency is requiring the removal of reference to specific categories in EPA's chemical-resistance category selection chart and requiring that labels specify the appropriate glove types to use. All statements that refer to the chemical resistance category selection chart are required to be removed from paraquat labels, as they might cause confusion for users. These statements are required to be replaced with specific chemical-resistant glove

²¹Paraquat Dichloride Human Health Mitigation Decision. 2016.
Available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2011-0855-0112>

types, as appropriate. This minor clarification does not fundamentally change the personal protective equipment that workers are currently required to use.

Updated Restricted Use Pesticide (RUP) Statement

In order to provide clarity regarding the sale of paraquat products, the Agency is proposing to remove any mention of retail sale from the RUP statement on paraquat labels. The Agency is also proposing to add 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 is proposing to make modifications to the paraquat tolerances to be consistent with the OECD rounding class practice and/or to revise certain commodity definitions (see Appendix E). The Agency intends to undertake these tolerance actions pursuant to its Federal Food, Drug Cosmetic Act (FFDCA) authority.

The Agency is also proposing that some U.S. tolerances be increased to harmonize with Codex. Refer to Section III.A.3 and Appendix F for details.

C. Proposed Interim Registration Review Decision

In accordance with 40 CFR §§ 155.56 and 155.58, the Agency is issuing this PID. Except for the Endocrine Disruptor Screening Program (EDSP) and the Endangered Species Act (ESA) components of this case, the Agency has made the following proposed interim decision: (1) no additional data are required at this time; and (2) changes to the affected registrations and their labeling are needed at this time, as described in Section IV.A and Appendices A and B.

In this PID, the Agency is making no human health or environmental safety findings associated with the EDSP screening of paraquat, nor is it making a complete endangered species finding. Although the Agency is not making a complete endangered species finding at this time, the proposed mitigation described in this document is expected to reduce the extent of environmental exposure and may reduce risk to listed species whose range and/or critical habitat co-occur with the use of paraquat. The Agency's final registration review decision for paraquat will be dependent upon the result of the Agency's ESA assessment and any needed § 7 consultation with the Services and an EDSP FFDCA § 408(p) determination.

D. Data Requirements

The Agency does not anticipate calling-in additional data for registration review of paraquat at this time. EPA will consider requiring submission of pollinator data as a separate action.

The analytical reference standard for paraquat must be submitted to EPA's National Pesticide Standards Repository (see <https://www.epa.gov/pesticide-analytical-methods/national-pesticide-standard-repository>).

V. NEXT STEPS AND TIMELINE

A. Proposed Interim Registration Review Decision

A Federal Register Notice will announce the availability of this PID for paraquat and will allow a 60-day comment period. If there are no significant comments or additional information submitted to the docket during the comment period that leads the Agency to change its proposed interim decision, EPA may issue an interim registration review decision for paraquat. However, a final decision for paraquat may be issued without the Agency having previously issued an interim decision. A final decision on the paraquat registration review case will occur after: (1) an EDSP FFDCA § 408(p) determination, and (2) an endangered species determination under the ESA and any needed § 7 consultation with the Services.

B. Implementation of Mitigation Measures

Once the Interim Registration Review Decision is issued, the paraquat registrants must submit amended labels that include the label changes described in Appendices A and B. The revised labels and requests for amendment of registrations must be submitted to the Agency for review within 60 days following issuance of the Interim Registration Review Decision in the docket.

Appendix A: Summary of Proposed Actions for Paraquat

Registration Review Case#: 0262 PC Code: 061601, 061603 Chemical Type: Herbicide Chemical Family: Bipyridylum Site of Action: Photosystem I Electron Diverter						
Affected Population(s)	Source of Exposure	Route of Exposure	Duration of Exposure	Potential Risk(s) of Concern	Proposed Actions	Comment
Occupational Handlers (mixing, loading, applying)	Aerial and ground application	Inhalation and dermal	Short and intermediate term	-Inhalation toxicity	-Require enclosed cabs -Require PF10 respirators -Prohibit 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 and ground application	Dermal and incidental oral	Short and intermediate term	-Lung effects -Skin damage/corrosion	-Prohibit aerial application (except for cotton desiccation) -Require a buffer for cotton desiccation by aerial application -Require spray drift management measures	Spray drift risk concern is from aerial applications
Mammals	Dietary	Ingestion	Acute and chronic	-Mortality -Growth	-Prohibit aerial application (except for cotton desiccation)	

					-Require spray drift management measures	
Birds	Dietary	Ingestion	Acute and chronic	-Reproduction -Food consumption	-Prohibit 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	-Prohibit aerial application (except for cotton desiccation) -Require spray drift management measures	
Benthic Invertebrates	Runoff and spray drift	Sediment	Chronic	-Growth -Survival -Reproduction	-Prohibit aerial application (except for cotton desiccation) -Require spray drift management measures	Bioavailability may be limited
Aquatic Plants (Algae)	Runoff and spray drift	Surface water and sediment		-Cell density -Frond number	-Prohibit aerial application (except for cotton desiccation) -Require spray drift management measures	

Appendix B: Proposed Labeling Changes and Clarifications for Paraquat Products

Table B.1.: Proposed Label Language for Paraquat Products

Description	Proposed Label Language for Paraquat Products				Placement on Label
	End Use Products				
Site of Action Group Number 22	<p>Note to registrant:</p> <ul style="list-style-type: none"> • 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>i.e.</i>, HERBICIDE or FUNGICIDE or INSECTICIDE) in the fourth column. 				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.
	PARAQUAT DICHLORIDE	GROUP	22	HERBICIDE	
Prohibit Aerial Application for All Uses Except Cotton Desiccation	“Do not apply this product aerially, except for cotton desiccation.”				Application Directions, under “Methods of Application” and Restrictions and Precautions, under “Use Restrictions”
Limit Single Application Maximum Rate for Alfalfa	“Do not exceed 1.0 lb ai/A for a single application of paraquat-containing products for all combined uses.”				Crop Use Directions, under “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

Description	Proposed Label Language for Paraquat Products	Placement on Label
Require PF10 Respirator	<p>“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; <u>OR</u> a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C.”</p> <p>*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.</p>	In the Personal Protective Equipment (PPE) within the Precautionary Statements and Agricultural Use Requirements, if applicable
Prohibit Mechanically Pressurized Handguns and Backpack Sprayers	<p>“Do not apply this product by mechanically pressurized handgun or backpack sprayer. Application by manually pressurized handwand is permitted.”</p>	Application Directions, under “Methods of Application” and Restrictions and Precautions, under “Use Restrictions”
Require 48-Hour REI	<p>“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.”</p>	Agricultural Use Requirements
Require 7-Day REI for Cotton Desiccation	<p>“For cotton desiccation applications: Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 7 days.”</p>	Agricultural Use Requirements
Standardize Label Metrics	<p>The following parameters should be clearly defined on all labels:</p> <ol style="list-style-type: none"> 1. maximum annual number of applications 2. maximum annual application rates 3. minimum retreatment intervals <p>Refer to Table B.2. for specific application metrics by crop.</p>	Crop Use Directions
Update Engineering Controls Statement	<p>Replace existing Engineering Controls Statement with the following language:</p> <p>“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.”</p>	Under the Engineering Controls Statement
Updated Gloves Statement	<p>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.</p>	In the Personal Protective Equipment (PPE) within the Precautionary Statements and

Description	Proposed Label Language for Paraquat Products	Placement on Label
		Agricultural Use Requirements, if applicable
Updated Respirator Language	<p>[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; <u>OR</u> a NIOSH-approved elastomeric particulate respirator with any N*, R or P filter; <u>OR</u> a NIOSH-approved powered air purifying respirator with HE filters.”</p> <p>*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.</p>	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: <ul style="list-style-type: none"> • 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. • 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.” 	Directions for Use

Description	Proposed Label Language for Paraquat Products	Placement on Label
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-notice-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	<p>“MANDATORY SPRAY DRIFT MANAGEMENT <u>Aerial Applications (for cotton desiccation):</u></p> <ul style="list-style-type: none"> • 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 a.i./A, a buffer of 75 feet is required. For applications of 0.6 lbs a.i./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. • 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. 	<p>Directions for Use, in a box titled “Mandatory Spray Drift Management” under the heading “Aerial Applications”</p> <p>Placement for these statements should be in general directions for use, before end use-specific directions for use.</p>
Spray Drift Management Application Restrictions for	<p>“MANDATORY SPRAY DRIFT MANAGEMENT <u>Ground Boom Applications:</u></p> <ul style="list-style-type: none"> • User must only apply with the release height recommended by the manufacturer, but no more than 4 feet above the ground or crop canopy. 	Directions for Use, in a box titled “Mandatory Spray Drift Management” under the

Description	Proposed Label Language for Paraquat Products	Placement on Label
<p>products that are applied as liquids and allow ground boom applications</p>	<ul style="list-style-type: none"> • 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. 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 • Do not apply during temperature inversions.” 	<p>heading “Ground Boom Applications”</p>
<p>Advisory Spray Drift Management Language for all products delivered via liquid spray application</p>	<p>“SPRAY DRIFT ADVISORIES THE APPLICATOR IS RESPONSIBLE FOR AVOIDING OFF-SITE SPRAY DRIFT. BE AWARE OF NEARBY NON-TARGET SITES AND ENVIRONMENTAL CONDITIONS.</p> <p>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.</p> <p>Controlling Droplet Size – Aircraft <i>(note to registrants: remove if aerial application is prohibited on product labels)</i></p> <ul style="list-style-type: none"> • 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. <p>Controlling Droplet Size – Ground Boom <i>(note to registrants: remove if ground boom is prohibited on product labels)</i></p> <ul style="list-style-type: none"> • 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. <p>BOOM HEIGHT – Ground Boom <i>(note to registrants: remove if ground boom is prohibited on product labels)</i> For ground equipment, the boom should remain level with the crop and have minimal bounce.</p> <p>SHIELDED SPRAYERS 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.</p>	<p>Directions for Use, just below the Spray Drift box, under the heading “Spray Drift Advisories”</p>

Description	Proposed Label Language for Paraquat Products	Placement on Label
	<p>TEMPERATURE AND HUMIDITY When making applications in hot and dry conditions, use larger droplets to reduce effects of evaporation.</p> <p>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.</p> <p>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.”</p>	

Table B.2.: Paraquat Application Metrics by Crop

Crop/Site	Use	Maximum Number of Applications per 12-month Period	Maximum Annual Application Rate	Minimum Retreatment Interval
Acerola (West Indies cherry)	All uses	5 apps	5.0 lb ai/A/year	7 days
Alfalfa	Preplant/preemergence	2 apps	1.0 lb ai/A/year	7 days
	New seedlings grown for hay (CA only)	1 app	0.5 lb ai/A/year	N/A
	Between-cuttings treatment	3 apps	0.75 lb ai/A/year	1 app per cutting interval
	Dormant season	1 app	0.75 lb ai/A/year	N/A
Almond	All uses	5 apps	5.0 lb ai/A/year	7days
Apple	All uses	5 apps	5.0 lb ai/A/year	7 days
Apricot	All uses	3 apps	3.0 lb ai/A/year	7 days
Artichoke	All uses	3 apps	2.0 lb ai/A/year	7 days
Asparagus	All uses	1 app	1.0 lb ai/A/year	N/A
Avocado	All uses	5 apps	5.0 lb ai/A/year	7 days
Banana	All uses	5 apps	5.0 lb ai/A/year	7 days
Barley	All uses	3 apps	3.0 lb ai/A/year	7 days
Beans, dried-type	Preplant/preemergence	3 apps		7days

	Harvest aid	2 apps	0.5 lb ai/A/year	7 days
Brassica (head and stem) vegetables	All uses	3 apps	3.0 lb ai/A/year	7 days
Berries	All uses	2 apps	1.0 lb ai/A/year	7 days
Carrot (including tops)	All uses	3 apps	3.0 lb ai/A/year	7 days
Cherry	All uses	3 apps	3.0 lb ai/A/year	7 days
Citrus	All uses	5 apps	5.0 lb ai/A/year	7 days
Cacao	All uses	5 apps	2.0 lb ai/A/year	7 days
Coffee	All uses	5 apps	5.0 lb ai/A/year	7 days
Coniferous/evergreen/softwood (non-food)	All uses	3 apps	3.0 lb ai/A/year	7 days
Corn (field, pop, seed, sweet)	Preplant/preemergence	3 apps	3.0 lb ai/A/year	7 days
	Postemergence	3 apps	1.5 lb ai/A/year	7 days
	Harvest aid	1 app	1.5 lb ai/A/year	N/A
	All combined uses		5.0 lb ai/A/year	7 days
Cotton	Preplant/preemergence	3 apps	3.0 lb ai/A/year	7 days
	Postemergence	3 apps	1.5 lb ai/A/year	14 days
	Harvest aid/postharvest	4 apps	0.50 lb ai/A/year	7 days
	All combined uses		3.0 lb ai/A/year	7 days
Cucurbit vegetables	All uses	3 apps	2.5 lb ai/A/year	14 days
Deciduous/broadleaf/hardwood (non-food)	All uses	3 apps	3.0 lb ai/A/year	7 days
Fallow land	All uses	2 apps	2.0 lb ai/A/year	7 days
Fig	All uses	5 apps	5.0 lb ai/A/year	7 days
Flowering plants	All uses	2 apps	2 lb ai/A/year	7 days
Fruiting vegetables	Preplant/preemergence	3 apps	3.0 lb ai/A/year	14 days
	Postemergence	3 apps	1.4 lb ai/A/year	
	All combined uses		4.5 lb ai/A/year	
Garlic	All uses	1 app	1.0 lb ai/A/year	N/A
Ginger	All uses	6 apps	6.0 lb ai/A/year	30 days
Grapes	All uses	5 apps	5.0 lb ai/A/year	7 days
Grasses grown for seed	All uses	3 apps	2.0 lb ai/A/year	14 days
Guar	Harvest aid	3 apps	1.5 lb ai/A/year	7 days
Guava	All uses	4 apps	3.76 lb ai/A/year	7 days
Hops	All uses	3 apps	1.5 lb ai/A/year	7 days
Kiwifruit	All uses	3 apps	2.0 lb ai/A/year	7 days
Leafy vegetables (except brassica)	All uses	3 apps	3.0 lb ai/A/year	7 days

Legume vegetables (succulent)	All uses	3 apps	3.0 lb ai/A/year	7 days
Manioc (cassava)	All uses	3 apps	1.5 lb ai/A/year	7 days
Mint	All uses	2 apps	0.75 lb ai/A/year	7 days
Nectarine	All uses	3 apps	3.0 lb ai/A/year	7 days
Non-grass animal feed (forage, feed, straw, hay)	All uses	1 app	0.75 lb ai/A/year	N/A
Okra	Preemergence	1 app		
	Postemergence	2 apps		
	All combined uses		2.0 lb ai/A/year	14 days
Olive	All uses	4 apps	4.0 lb ai/A/year	7 days
Onion, dry bulb	Preemergence	1 app		7 days
	Postemergence	1 app		
	All combined uses	2 apps	1.5 lb ai/A/year	
Onion, seeded	Preplant/preemergence		1.0 lb ai/A/year	
	All combined uses	1 app	1.5 lb ai/A/year	N/A
Papaya	All uses	5 apps	5.0 lb ai/A/year	7 days
Passion fruit (granadilla)	All uses	4 apps *None during harvest season, unless all fruit has been picked up off the ground.	3.76 lb ai/A/year	28 days
Pastureland/rangeland	Conservation reserve, conservation compliance programs	3 apps	2.0 lb ai/A/year	7 days
	Pasture reseeding	3 apps	1.5 lb ai/A/year	7 days
	Control of endophyte-fungus in forage legume/grass pastures	2 apps	1.0 lb ai/A/year	10 days
	Juniper species leaf moisture reduction or desiccation	3 apps	1.5 lb ai/A/year	7 days
	Native pastures	2 apps	0.45 lb ai/A/year	7 days
Peach	All uses	3 apps	3.0 lb ai/A/year	7 days
Peanuts	Preplant	2 apps		7 days
	Postemergence	2 apps	0.25 lb ai/A/year	7 days
	Postemergence ropewick application	1 app	0.25 lb ai/A/year	N/A
	All combined uses		2.8 lb ai/A/year	7 days
Pear	All uses	5 apps	5.0 lb ai/A/year	7 days

Peas, dried-type	Preplant/preemergence	3 apps		7 days
	Harvest aid	2 apps	0.5 lb ai/A/year	
Peas, pigeon	All uses	1 app	0.5 lb ai/A/year	N/A
Persimmon	All uses	4 apps	3.76 lb ai/A/year	28 days
Pineapple	All uses	3 apps	3.0 lb ai/A/year	7 days
Pistachio	After shells split	2 apps		7 days
	All combined uses	5 apps	5.0 lb ai/A/year	
Plum	All uses	3 apps	3.0 lb ai/A/year	7 days
Potato, white/Irish (or unspecified)	All uses	3 apps	1.5 lb ai/A/year	7 days
Premises/areas (around commercial buildings, public airports, storage yards, etc.)	All uses	10 apps	10.0 lb ai/A/year	7 days
Prune	All uses	3 apps	3.0 lb ai/A/year	7 days
Rhubarb	All uses	2 apps	2.0 lb ai/A/year	7 days
Rice	All uses	3 apps	1.0 lb ai/A/year	7 days
Root and tuber vegetables	All uses	3 apps	3.0 lb ai/A/year	7 days
Safflower	All uses	3 apps	3.0 lb ai/A/year	7 days
Sage, clary	All uses		1.125 lb ai/A/year	10 days
Sorghum	Preplant/preemergence	3 apps	3.0 lb ai/A/year	7 days
	Postemergence	2 apps	1.0 lb ai/A/year	
	All combined uses		4.0 lb ai/A/year	
Soybeans	Preplant/preemergence	3 apps	1.5 lb ai/A/year	7 days
	Postemergence	2 apps	1.0 lb ai/A/year	14 days
	Harvest aid	1 app	0.25 lb ai/A/year	14 days
	All combined uses		2.9 lb ai/A/year	
Strawberry	All uses	3 apps	1.5 lb ai/A/year	7 days
Subtropical/tropical fruit	All uses	4 apps	3.76 lb ai/A/year	28 days
Sugar beet	All uses	3 apps	3.0 lb ai/A/year	7 days
Sugarcane	Louisiana	2 apps	1.5 lb ai/A/year	7 days
	Florida and Hawaii	2 apps (postemergence)	1.0 lb ai/A/year	
		1 app (harvest aid)		
Texas	2 apps	0.25 lb ai/A/year		
Sunflower	Preplant/preemergence	3 apps	3.0 lb ai/A/year	7 days
	Preharvest	2 apps	1.0 lb ai/A/year	
	All combined uses			
Tanier	Florida	1 app (preemergence)	1.5 lb ai/A/year	30 days
		1 app (postemergence)		
	Puerto Rico		1.5 lb ai/A/year	90 days

Taro	All uses	2 apps	1.5 lb ai/A/year	7 days
Tobacco	All uses	2 apps		
Tomato	Preplant/preemergence	3 apps	3.0 lb ai/A/year	7 days
	Postemergence	3 apps	1.5 lb ai/A/year	
	Post-harvest	2 apps	1,875 lb ai/A/year	
	All combined uses		3.0 lb ai/A/year	
Tree nuts	All uses	5 apps	5.0 lb ai/A/year	7 days
Trees (non-food)	All uses	5 apps	5.0 lb ai/A/year	7 days
Tuberous and corm vegetables	All uses	3 apps	1.5 lb ai/A/year	7 days
Turnip (greens)	All uses	3 apps	3.0 lb ai/A/year	7 days
Tyfon	All uses	3 apps	3.0 lb ai/A/year	7 days
Wheat	All uses	3 apps	3.0 lb ai/A/year	7 days
Yam	All uses	2 apps	1.0 lb ai/A/year	7 days

Appendix C: Endangered Species Assessment

In 2013, EPA, along with the Fish and Wildlife Service (FWS), the National Marine Fisheries Service (NMFS), and the United States Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations that discussed specific scientific and technical issues related to the development of pesticide risk assessments conducted on federally threatened and endangered species.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, after receiving input from the Services and USDA on proposed revisions to the pilot interim method and after consideration of public comments received, EPA released an updated Revised Method for conducting national level BEs in March 2020.²²

Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA InterAgency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role in this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting this PID for paraquat does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this PID, EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of paraquat. This will allow EPA to focus its future evaluations on the types of species where the potential for effects exists once the scientific methods being developed by the agencies have been fully vetted. Once that occurs, these methods will be applied to subsequent analyses for paraquat as part of completing this registration review.

²² <https://www.epa.gov/endangered-species/revised-method-national-level-listed-species-biological-evaluations-conventional>

Appendix D: Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, sub-chronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for paraquat, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA § 408(p), paraquat is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA § 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all of the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013,²³ and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Paraquat is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit EPA website.²⁴

In this PID, EPA is making no human health or environmental safety findings associated with the EDSP screening of paraquat. Before completing this registration review, the Agency will make an EDSP FFDCA § 408(p) determination.

²³ See <http://www.regulations.gov/#!documentDetail:D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

²⁴ <https://www.epa.gov/endocrine-disruption>

Appendix E: Occupational Handler Exposure and Risk Estimates

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

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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	APF10 R	0.015 lb ai/gallon	40 gallons	0.000283	21000	0.000000164	16000
		29.1	DL/G					0.000219	27000		
		8.6	EC	0.083	EC			0.0000645	93000	0.000000623	4200
	Pastureland	37.6	SL/G	0.0219	APF10 R	0.019 lb ai/gallon		0.000358	17000	0.000000208	13000
		29.1	DL/G					0.000276	22000		
		8.6	EC	0.083	EC			0.0000818	73000	0.000000789	3300
Liquid, Mechanically-pressurized Handgun, Broadcast	All Use Sites	37.6	SL/G	0.0219	APF10 R	0.015 lb ai/gallon	1000 gallons	0.00705	850	0.00000411	630
		29.1	DL/G					0.00546	1100		
		8.6	EC	0.083	EC			0.00161	3700	0.0000156	170
	Pastureland	37.6	SL/G	0.0219	APF10 R	0.019 lb ai/gallon		0.00893	670	0.0000052	500
		29.1	DL/G					0.00691	870		
		8.6	EC	0.083	EC			0.00204	2900	0.0000198	130
Liquid, Aerial	Nursery (ornamentals, vegetables, trees, container stock)	37.6	SL/G	0.0219	APF10 R	1.0 lb ai/A	60 A	0.0283	210	0.0000164	160
		29.1	DL/G					0.0219	270		

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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
		8.6	EC	0.083	EC			0.00645	930	0.0000623	42
	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	APF10 R	1.0 lb ai/A	350 A	0.165	36	0.0000959	27
29.1		DL/G	0.128					47			
8.6		EC	0.083	EC	0.0376			160	0.000364	7.1	
	Field crop, typical: Legume Vegetables; Sage, Clary	37.6	SL/G	0.0219	APF10 R	0.80 lb ai/A	350 A	0.131	46	0.0000766	34
29.1		DL/G	0.102					59			
8.6		EC	0.083	EC	0.0301			200	0.00029	9	
	Field crop, typical: Lentils; Peas, Dried Type; Tuberos and Corn Vegetables; Orchard/Vineyard; Grapes	37.6	SL/G	0.0219	APF10 R	0.50 lb ai/A	350 A	0.0823	73	0.0000479	54
29.1		DL/G	0.0636					94			
8.6		EC	0.083	EC	0.0189			320	0.000181	14	
	Field crop, typical: Root and Tuber Vegetables	37.6	SL/G	0.0219	APF10 R	0.30 lb ai/A	350 A	0.0494	120	0.0000288	90
29.1		DL/G	0.0383					160			
8.6		EC	0.083	EC	0.0113			530	0.000109	24	
	Field crop, high acreage: Alfalfa; Clover	37.6	SL/G	0.0219	APF10 R	1.5 lb ai/A	1200 A	0.846	7.1	0.000493	5.3
29.1		DL/G	0.655					9.2			
8.6		EC	0.083	EC	0.194			31	0.00186	1.4	
	Field crop, high-acreage; Barley; Beans, Dried-Type; Corn, Field; Corn, Pop; Cotton; Deciduous/Broadleaf/Hardwood;	37.6	SL/G	0.0219	APF10 R	1.0 lb ai/A	1200 A	0.564	11	0.000329	7.9

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat												
Source of Exposure	Scenario	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	
Liquid, Groundboom	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; Sugarcane; Sunflower; Tuberos and Corn Vegetables; Wheat	29.1	DL/G					0.436	14			
		8.6	EC	0.083	EC			0.129	47	0.00125	2.1	
	Field crop, high acreage: Legume Vegetables	37.6	SL/G	0.0219	APF10 R	0.80 lb ai/A	1200 A	0.451	13	0.000263	9.9	
		29.1	DL/G					0.349	17			
		8.6	EC					0.103	58			0.000996
	Field crop, high acreage: Peas, Dried-Type	37.6	SL/G	0.0219	APF10 R	0.50 lb ai/A	1200 A	0.283	21	0.000164	16	
		29.1	DL/G					0.219	27			
		8.6	EC					0.0645	93			0.000623
	Nursery (ornamentals, vegetables, trees, container stock)	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	37.6	SL/G	0.0219	APF10 R	1.0 lb ai/A	60 A	0.0283	210	0.0000164	160
			29.1	DL/G					0.0219	270		
			8.6	EC					0.00645	930		
		Liquid, Groundboom	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	37.6	SL/G	0.0219	APF10 R	1.0 lb ai/A	40 A	0.0188	320	0.000011
29.1				DL/G	0.0145					410		
8.6				EC	0.0043					1400	0.0000415	

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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
	Orchard/Vineyard: Macadamia Nut (Bushnut)	37.6	SL/G	0.0219	APF10 R	0.50 lb ai/A	40 A	0.0094	640	0.0000548	470
		29.1	DL/G					0.00728	820		
		8.6	EC	0.083	EC			0.00215	2800	0.0000208	130
	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	APF10 R	1.0 lb ai/A	80 A	0.0376	160	0.0000219	120
		29.1	DL/G					0.0291	210		
		8.6	EC	0.083	EC			0.0086	700	0.000083	31
	Field crop, typical: Tobacco	37.6	SL/G	0.0219	APF10 R	0.94 lb ai/A	80 A	0.0354	170	0.0000206	130
		29.1	DL/G					0.0274	220		
		8.6	EC	0.083	EC			0.00809	740	0.000078	33
Field crop, typical: Legume Vegetables; Sage, Clary; Taro; Vegetables (Unspecified)	37.6	SL/G	0.0219	APF10 R	0.80 lb ai/A	80 A	0.0301	200	0.0000175	150	
	29.1	DL/G					0.0233	260			
	8.6	EC	0.083	EC			0.00688	870	0.0000664	39	
Field crop, typical: Guar; Lentils; Peas, Dried Type; Peas, Pigeon; Strawberry; Tuberos and Corm Vegetables;	37.6	SL/G	0.0219	APF10 R	0.50 lb ai/A	80 A	0.0188	320	0.000011	240	
	29.1	DL/G					0.0145	410			
	8.6	EC	0.083	EC			0.0043	1400	0.0000415	63	

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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
Field crop, high acreage: Alfalfa; Clover		37.6	SL/G	0.0219	APF10 R	1.5 lb ai/A	200 A	0.141	43	0.0000821	32
		29.1	DL/G					0.109	55		
		8.6	EC	0.083	EC			0.0323	190	0.000311	8.4
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		37.6	SL/G	0.0219	APF10 R	1.0 lb ai/A	200 A	0.094	64	0.0000548	47
		29.1	DL/G					0.0728	82		
		8.6	EC	0.083	EC			0.0215	280	0.000208	13
Field crop, high acreage: Legume Vegetables; Mint		37.6	SL/G	0.0219	APF10 R	0.80 lb ai/A	200 A	0.0753	80	0.0000438	59
		29.1	DL/G					0.0583	100		
		8.6	EC	0.083	EC			0.0173	350	0.000166	16
Field crop, high acreage: Grasses Grown for Seed; Potato, White/Irish (or Unspecified)		37.6	SL/G	0.0219	APF10 R	0.60 lb ai/A	200 A	0.0564	110	0.0000329	79
		29.1	DL/G					0.0436	140		
		8.6	EC	0.083	EC			0.0129	470	0.000125	21
Field crop, high acreage: Beans, Dried-Type; Hops; Pastureland; Peas, Dried-Type; Peas, Pigeon; Tuberos and Corm Vegetables		37.6	SL/G	0.0219	APF10 R	0.50 lb ai/A	200 A	0.047	130	0.0000274	95
		29.1	DL/G					0.0364	160		
		8.6	EC	0.083	EC			0.0108	560	0.000104	25
Field crop, high acreage: Root and Tuber Vegetables		37.6	SL/G	0.0219	APF10 R	0.30 lb ai/A	200 A	0.047	130	0.0000164	160
		29.1	DL/G					0.0219	270		

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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
		8.6	EC	0.083	EC			0.00645	930	0.0000623	42
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	0.0049	EC	1.0 lb ai/A	350 A	0.0091	660	0.0000215	120
	Field crop, typical: Legume Vegetables; Sage, Clary	2.08	EC	0.0049	EC	0.80 lb ai/A	350 A	0.00728	820	0.0000171	150
	Field crop, typical: Lentils; Peas, Dried Type; Tuberos and Corm Vegetables; Orchard/Vineyard; Grapes	2.08	EC	0.0049	EC	0.50 lb ai/A	350 A	0.00455	1300	0.0000107	240
	Field crop, typical: Root and Tuber Vegetables	2.08	EC	0.0049	EC	0.30 lb ai/A	250 A	0.00195	3100	0.0000046	570
	Field crop, high acreage: Alfalfa; Clover	2.08	EC	0.0049	EC	1.5 lb ai/A	1200 A	0.0468	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; Sugarcane; Sunflower; Tuberos and Corm Vegetables; Wheat	2.08	EC	0.0049	EC	1.0 lb ai/A	1200 A	0.0313	190	0.0000735	35

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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
	Field crop, high acreage: Legume Vegetables	2.08	EC	0.0049	EC	0.80 lb ai/A	1200 A	0.025	240	0.0000588	44
	Field crop, high acreage: Peas, Dried-Type	2.08	EC	0.0049	EC	0.50 lb ai/A	1200 A	0.0156	380	0.0000368	71
Spray (all starting formulations), Groundboom	Nursery (ornamentals, vegetables, trees, container stock)	5.1	EC	0.020	EC	1.0 lb ai/A	60 A	0.00383	1600	0.0000323	170
		16.1	APF10 R	0.034	APF10R			0.0121	500	0.0000255	100
	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	5.1	EC	0.020	EC	1.0 lb ai/A	40 A	0.00255	2400	0.0000215	260
		16.1	SL/G	0.034	APF10 R			0.00805	750	0.000017	150
	Orchard/Vineyard: Macadamia Nut (Bushnut)	5.1	EC	0.020	EC	0.50 lb ai/A	40 A	0.00128	4700	0.0000108	520
		16.1	SL/G	0.034	APF10 R			0.00403	1500	0.0000085	310
	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	5.1	EC	0.020	EC	1.0 lb ai/A	80 A	0.0051	1200	0.000043	130
		16.1	SL/G	0.034	APF10 R			0.0161	370	0.000034	76
	Field crop, typical: Tobacco	5.1	EC	0.020	EC	0.94 lb ai/A	80 A	0.0048	1300	0.0000404	140
		16.1	SL/G	0.034	APF10 R			0.0151	400	0.000032	81
	Field crop, typical: Legume Vegetables; Sage, Clary; Taro; Vegetables (Unspecified)	5.1	EC	0.020	EC	0.80 lb ai/A	80 A	0.00408	1500	0.0000344	160
		16.1	SL/G	0.034	APF10R			0.0129	470	0.0000273	95

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat												
Source of Exposure	Scenario	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	
Field crop, typical: Guar; Lentils; Peas, Dried Type; Peas, Pigeon; Strawberry; Tuberos and Corm Vegetables;	Field crop, typical: Guar; Lentils; Peas, Dried Type; Peas, Pigeon; Strawberry; Tuberos and Corm Vegetables;	5.1	EC	0.020	EC	0.50 lb ai/A	80 A	0.00255	2400	0.0000215	260	
		16.1	SL/G	0.034	APF10 R			0.00805	750	0.000017	150	
	Field crop, high acreage: Alfalfa; Clover	5.1	EC	0.020	EC	1.5 lb ai/A	200 A	0.0191	310	0.000161	35	
			SL/G	0.034	APF10 R			0.0604	99	0.000128	20	
	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	5.1	EC	0.020	EC	1.0 lb ai/A	200 A	0.0128	470	0.000108	52	
			SL/G	0.034	APF10 R			0.0403	150	0.000085	31	
	Field crop, high acreage: Legume Vegetables; Mint	5.1	EC	0.020	EC	0.80 lb ai/A	200 A	0.0102	590	0.000086	65	
			SL/G	0.034	APF10 R			0.0323	190	0.0000680	38	
	Field crop, high acreage: Grasses Grown for Seed; Potato, White/Irish (or Unspecified)	5.1	EC	0.020	EC	0.6 lb ai/A	200 A	0.00765	780	0.0000645	87	
			SL/G	0.034	APF10 R			0.0241	250	0.0000510	51	
	Field crop, high acreage: Beans, Dried-Type; Hops; Pastureland; Peas, Dried-Type; Peas, Pigeon; Tuberos and Corm Vegetables	5.1	EC	0.020	EC	0.5 lb ai/A	200 A	0.00638	940	0.0000538	100	
			SL/G	0.034	APF10 R			0.0201	300	0.0000425	61	
	Field crop, high acreage: Root and Tuber Vegetables	5.1	EC	0.020	EC	0.3 lb ai/A	200 A	0.00383	1600	0.0000323	170	
			SL/G	0.034	APF10 R			0.0121	500	0.0000255	100	
	Flagger											
	Spray (all starting formulations), Aerial	Field crop, high acreage: Alfalfa; Clover	12	SL/G	0.020	APF10 R	1.5 lb ai/A	350 A	0.079	76	0.00013	20
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		1.0 lb ai/A					350 A	0.0525	110	0.000088	29	

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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
	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; Sugarcane; Sunflower; Tuberos and Corm Vegetables; Wheat										
	Field crop, typical: Legume Vegetables; Sage, Clary					0.80 lb ai/A	350 A	0.042	140	0.000071	37
	Field crop, typical: Lentils; Peas, Dried Type; Tuberos and Corm Vegetables; Orchard/Vineyard; Grapes					0.50 lb ai/A	350 A	0.0263	230	0.000044	59
	Field crop, high acreage: Peas, Dried-Type										
	Field crop, typical: Root and Tuber Vegetables					0.30 lb ai/A	350 A	0.0158	380	0.000027	98
Mixer/Loader/Applicator											
Liquid, Backpack, Ground/soil-directed	All Use Sites	8260	SL/G	0.258	APF10 R	0.015 lb ai/gallon	40 gallons	0.062	97	0.00000194	1300
		4120	DL/G					0.0309	190		
	Pastureland	8260	SL/G					0.0785	76	0.00000245	1100
		4120	DL/G					0.0391	150		
	All Use Sites	30500	SL/G	6.91	APF10 R	0.015 lb ai/gallon		0.229	26	0.0000519	50

Occupational Handler Non-Cancer Exposure and Risk Estimates for Paraquat											
Source of Exposure	Scenario	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
Liquid, Backpack, Broadcast	Pastureland	16900	DL/G	430	APF10 R	0.019 lb ai/gallon	1000 gallons	0.126	48	0.0000656	40
		30500	SL/G					0.29	21		
		16900	DL/G					0.16	38		
Liquid, Manually-pressurized Handwand, Broadcast	All Use Sites	430	SL/G	430	APF10 R	0.015 lb ai/gallon	1000 gallons	0.0032	1900	0.000018	150
		365	DL/G					0.0027	2200		
	Pastureland	430	SL/G					0.0041	1500	0.000022	120
		365	DL/G					0.0035	1700		
Liquid, Mechanically-pressurized Handgun, Broadcast (foliar); Drench/Soil-/Ground-directed	All Use Sites	2050	SL/G	0.868	APF10 R	0.015 lb ai/gallon	1000 gallons	0.385	16	0.000163	16
		1360	DL/G					0.255	24		
	Pastureland	2050	SL/G					0.488	12	0.000206	13
		1360	DL/G					0.323	19		
Loader/Applicator											
Liquid, Backpack, Broadcast	Rights-of-Way	30500	SL/G	6.91	APF10 R	0.015 lb ai/gallon	40 gallons	0.229	26	0.0000519	50
		16900	DL/G					0.126	48		

1. MOEs in **bold** represent scenarios of concern.

2. Based on the “Occupational Pesticide Handler Unit Exposure Surrogate Reference Table – Revised March 2020” (<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 F: Proposed Tolerance Actions

Table 1: Summary of Proposed Tolerance Actions for Paraquat

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
<i>(a) General.</i> (1) Tolerances are established for residues of paraquat, <u>including</u> 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	
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	

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
<i>(a) General.</i> (1) Tolerances are established for residues of paraquat, <u>including</u> 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:			
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	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	

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
<i>(a) General.</i> (1) Tolerances are established for residues of paraquat, <u>including</u> 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	0.05	
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.			
<i>(a) General.</i> (1) Tolerances are established for residues of paraquat, <u>including</u> 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	
llama	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.			
<i>(a) General.</i> (1) Tolerances are established for residues of paraquat, <u>including</u> 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.			
<i>(a) General.</i> (1) Tolerances are established for residues of paraquat, <u>including</u> 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		
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 <i>Brassica</i>, Group 5-16		0.07	Crop group conversion/revision*
Vegetable, brassica, leafy, group 5	0.05	Remove	

Summary of Paraquat Established and Recommended Tolerances for Registration Review.			
<i>(a) General.</i> (1) Tolerances are established for residues of paraquat, <u>including</u> 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. <i>Brassica leafy greens subgroup 4-16B*</i>
Stalk and Stem Vegetable Subgroup 22A	--	0.05	Change in crop group 5. <i>Stalk and Stem Vegetable Subgroup 22A*</i>
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	Corrected value to be consistent with OECD Rounding Class
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
<i>c) Tolerances with regional registrations.</i> Tolerances with regional registration as defined in §180.1(l), are established for residues of paraquat, <u>including</u> 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.