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OPP Docket
Environmental Protection Agency Docket Center (EPA/DC)
(28221T)
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Attention: Mr. Alexander Hazlehurst, Chemical Review Manager
RMIB III
Pesticide Re-Evaluation Division

Subject: **Paraquat Dichloride Registration Review – Supplemental Consideration**
Syngenta Crop Protection, LLC Comments
Case Number: 0262

Dear Mr. Hazlehurst:

Syngenta Crop Protection, LLC respectfully submits the enclosed comments (Attachment 1) related to the *EPA's Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat* that was posted to the paraquat docket (ID: EPA-HQ-OPP-2011-0855) on January 31, 2024.

Syngenta appreciates the opportunity to comment and the Agency's time in reviewing our comments. Please contact me with any questions or if you need any additional information.

Sincerely,

Jordan Moseley
Regulatory Product Manager
Syngenta Crop Protection, LLC

Attachment 1

Paraquat Dichloride Case #0262
Docket ID NO. EPA-HQ-OPP-2011-0855

Syngenta Crop Protection, LLC Public Comments on EPA's Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat - January 30, 2024

Syngenta is herein providing additional comments and feedback on the registration review process, agronomic benefits of paraquat dichloride (paraquat), the consideration of restricting all ground boom application to enclosed tractors only, the aerial application restrictions implemented by the paraquat final interim decision, and the vapor pressure of paraquat.

Syngenta generally agrees with and supports EPA's conclusions regarding paraquat's benefits and human health impacts, as well as the agency's risk/benefit analysis. Paraquat is an important non-selective herbicide option for growers nationwide, and Syngenta supports the continued use of paraquat-containing products in a manner that does not cause unreasonable risk to human health or the environment.

Regarding EPA's proposed additional mitigation of requiring enclosed cabs for groundboom applications regardless of acreage, such a requirement would not be feasible for many growers and would essentially remove paraquat as a key tool for many small farms. Syngenta accordingly does not support imposing such a requirement. The mitigations EPA imposed through the 2021 registration review decision are sufficient to prevent unreasonable adverse impacts to both human health and the environment.

Additionally, Syngenta would like to voice support for comments submitted by the National Agricultural Aviation Association (NAAA) regarding the aerial application label restriction implemented by the interim decision. NAAA provided feedback that the currently imposed 350-acre limitation for all aerial uses except cotton and soybean desiccation is quite limiting for aerial applicators, especially when paraquat is used for burndown control of weeds prior to planting season.

Lastly, Syngenta is providing comment on a new vapor pressure study that was conducted in accordance with applicable EPA and OECD guidelines and recently submitted to the Agency.

Registration Review Process and Implemented Label Mitigations

The Environmental Protection Agency (EPA) completed the Interim Registration Review Decision for paraquat in July 2021. Every 15 years, EPA reviews each registered active ingredient using the best available data and risk assessment methodology to ensure that the active ingredient can be used as intended, without causing unreasonable risk to human health or the environment. The registration review process for paraquat was initiated in December 2011 with the opening of the docket and posting of the preliminary work plan. From that point, EPA's review of paraquat followed the standard registration review process, including the posting of the final work plan, a data call-in to address any data gaps, draft human health and environmental risk assessments (October 2019), the proposed interim decision (October 2020), and the final interim decision (June 2021). The posting of the preliminary work plan, draft risk assessments, and proposed interim decision were each followed by a 60-day public comment period.

The June 2021 final interim decision (FID) summarized the review process for paraquat and included required label mitigations to ensure that the continued use of the active ingredient would not

cause unreasonable risk to human health or the environment. Once the FID was posted, Syngenta and other paraquat registrants had 60 days to submit amended product labels that included the mitigations required by the FID. Labels were submitted within that timeframe, approved by the EPA on August 24, 2022, and then submitted and approved in the states. These label versions are now in commercial production and address the risks of concern identified during registration review.

In September 2021, multiple groups filed a Petition for Review of the Paraquat Interim Decision in the US Court of Appeals for the Ninth Circuit challenging the Interim Decision and raising issues related to human health, the benefits of paraquat, and risk-benefit balancing. In September 2022, the Court granted EPA's motion to hold the case in abeyance to allow the Agency the opportunity to further consider those three sets of issues. EPA declared its intention to publish one or more documents addressing those issues by January 2024, to be posted to the paraquat docket for public comment, followed by a final version of the document (or documents) by January 17, 2025.

On January 31, 2024, EPA's *Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat* was published to the docket. In this document, the Agency further expanded on the registration review process and how they arrived at the conclusions presented in the Final Interim Decision. Syngenta recognizes the value of the registration review process as it ensures the continued use of active ingredients does not cause unreasonable risk to human health or the environment. Syngenta has complied and assisted with the registration review process for paraquat, including by submitting additional data to address the data call-in and submitting amended labels with mitigation language required by the Agency.

Benefits of Paraquat

One of the challenges raised by petitioners in the Ninth Circuit centered around the balancing of paraquat's risks and benefits. Regarding the benefits, EPA has rightly recognized that paraquat has certain important advantages over alternative herbicides, which can make it a preferred choice for weed control in a wide range of crops as well as in specific agricultural scenarios. While that remains true, in the supplemental document, EPA notes that BEAD determined that the use of paraquat has high benefits for numerous crops and crop groups including artichoke, cotton, peanuts, soybeans, bulb vegetables, cucurbits, alfalfa, orchard and vineyards, but lower benefits for other uses including grains, tomato, and pastureland. Syngenta contends that the preplant burndown use of paraquat to clear fields of weeds prior to planting is a high benefit regardless of the crop planted.

Some of the key benefits of paraquat include:

1. **Fast-Acting**: Paraquat acts quickly to desiccate and kill weeds, often showing visible results within hours or a few days. This rapid action can be crucial for farmers needing to remove existing weeds in a field before planting or to manage weed growth during the growing season.
2. **Effectiveness Against Resistant Weeds**: Paraquat has a unique mode of action, which makes it effective against weeds that have developed resistance to other herbicides, such as glyphosate-resistant species.
3. **No Soil Activity**: Paraquat is quickly immobilized upon contact with soil, which means it doesn't have residual activity that could affect subsequent crops. This characteristic makes it suitable for use in crop rotation systems.
4. **Use in Conservation Tillage**: Because paraquat can control weeds without disturbing the soil, it is compatible with conservation tillage and no-till farming practices, which help prevent soil erosion and maintain soil health. The Agency has proposed a point system in the *Draft Herbicide Strategy Framework to Reduce Exposure of Federally Listed and Endangered Species and Threatened Species and Designated Critical Habitats from the Use of Conventional Agricultural Herbicides* (EPA-HQ-OPP-2023-0365-0009). In the draft document, no till and reduced till farming practices have been designated as a medium efficacy measure to reducing pesticide offsite transport due to runoff and erosion. The importance of paraquat in conservation tillage can have additional benefits in reducing exposure to endangered and threatened species. Moreover, conservation tillage and no-till farming practices have a major role to play in carbon sequestration, further corroborating the value paraquat provides to these agricultural practices.
5. **Desiccation**: Paraquat is used as a desiccant to dry out crops like cotton and soybeans before harvest, facilitating easier and more efficient harvesting.
6. **Rainfastness**: Paraquat is rainfast shortly after application, which is particularly beneficial in regions with unpredictable weather patterns.
7. **Yield Increase**: The aforementioned benefits of paraquat can also increase crop yields by providing effective and rapid weed control, facilitating conservation tillage practices (improving soil health), aiding in a more uniform and timely harvest, and helping manage herbicide resistance, ensuring that effective weed control can be maintained over time.

These properties, especially when considered altogether, characterize the uniqueness of paraquat as an active ingredient, which correctly factored into the EPA's balancing of risks and benefits as required by FIFRA, 7 U.S.C. § 136(a)(c)(5) & (bb).

The Feasibility of Requiring Enclosed Tractor Cabs As An Additional Mitigation

In the January *Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat*, EPA indicated that "The Agency may consider requiring enclosed cabs for groundboom application regardless of acres treated. EPA is seeking comment on the feasibility of this mitigation in addition to information regarding the usage, typical application rates, and benefits information for use sites other than cotton, soybean, and peanuts as it considers whether the benefits continue to outweigh the risks associated with groundboom application of paraquat to specific crops."

A requirement to use an enclosed cab for groundboom application regardless of acres treated would not be feasible for many growers and would essentially remove paraquat as a key tool for many small farm operations for several reasons:

Economic Constraints

1. **Cost of Retrofitting or Replacement:** Many farmers operate with older equipment that may not have been designed for enclosed cabs. Retrofitting these tractors with enclosed cabs can be prohibitively expensive. Moreover, replacing older tractors with new models featuring enclosed cabs requires significant capital investment that many small or medium-sized farms may not be able to afford.
2. **Diverse Farm Sizes and Budgets**: Farms vary greatly in size and economic stability. Smaller operations may not have access to tractors with enclosed cabs and would, therefore, be forced to choose other chemistries that don't offer the attributes of paraquat and are less fit-for-purpose.

Practical and Technical Issues

3. **Equipment Compatibility**: Certain broadcast application scenarios may require heightened sensory awareness that an enclosed cab can inhibit, such as listening for changes in engine noise or other machinery operations.
4. **Maintenance and Repairs**: Enclosed cabs can add complexity and cost to maintenance and repair processes. Farmers who are accustomed to performing their own equipment maintenance may find enclosed cabs to be a barrier to easy access to engine components and other machinery parts.
5. **Climatic Considerations**: In hot climates, operating an enclosed cab without air conditioning can be extremely uncomfortable and potentially dangerous due to heat stress. Conversely, in cooler climates, heating becomes a necessity, adding to fuel and maintenance costs.

While enclosed tractor cabs can offer safety and comfort advantages, especially in terms of operator exposure, dust, and noise, mandating their use when applying paraquat is not feasible for many smaller and mid-size farms due to the above economic and practical challenges.

Aerial Application Mitigations

The 2022 *Amendment to Paraquat Dichloride Interim Registration Review Decision* included a label mitigation requirement that individual applicators must not apply paraquat-containing products aerially to more than 350 acres in a 24-hour period except for cotton and soybean desiccation purposes. Syngenta has received feedback from the National Agricultural Aviation Association (NAAA) that the 350-acre limitation is restrictive and prevents growers from making timely applications to ensure optimal control. This contrasts with the Agency's statement in the Interim Decision that "the limitation of aerial applications to 350 acres per applicator per 24-hour period is expected to have negligible impacts because this is not a typical application method for most crops that are treated with paraquat."

Paraquat is often applied in the early spring in the south as a burndown application before planting. Due to the common occurrence of wet soils during this time of year, growers rely on aerial applications to ensure timely and effective treatment. Given the potential rapid spring growth of weeds such as palmer amaranth, aerial applicators need the flexibility to make timely applications of paraquat to ensure control before weeds reach a size where control is no longer possible. Syngenta supports comments submitted by NAAA regarding the aerial application of paraquat.

Vapor Pressure

Syngenta voluntarily (on its own initiative) conducted a new vapor pressure study on paraquat (Analytical Master Standard 99.9% purity), which complies with GLP and applicable US EPA and OECD guidelines. This was to generate a robust data point for an inherent property of the compound, recognizing that the previous study conducted (Wollerton, 1987) relied on a Limit of Detection and subsequent estimations. Paraquat dichloride is a high melting point organic salt with a low vapor pressure. The registration in the U.S. is for a formulated end use product where paraquat will be dissolved, fully dissociated and effectively non-volatile. The results of this vapor pressure study do not change the fact that paraquat dichloride (in the form registered in the U.S.) is essentially non-volatile.

The test material utilized in this study is the active ingredient contained in Paraquat Concentrate ES (EPA Reg. No. 100-1067). It should be noted that Paraquat Concentrate ES is the registered manufacturing-use product used to formulate Syngenta's paraquat containing end-use product in the United States and that Syngenta does not have an active registration for the pure analytical technical material used as the test substance in this study.

The vapor pressure of paraquat dichloride was determined by extrapolation to be 4.0 x 10-4 Pa at 20°C and 5.3 x 10-4 Pa at 25°C. The study was conducted to meet the standards set by the OECD guidance. The method employed was designed to be compatible with: OECD Guidelines for Testing of Chemicals, Section 1, No. 104: "Vapour Pressure" adopted 23 March 2006; Method A4 Vapour Pressure of Commission Regulation (EC) No 440/2008, dated May 30, 2008; and Method 830.7950 Vapor Pressure of US EPA Office of Chemical Safety and Pollution Prevention (OCSPP) formerly the Office of Prevention, Pesticides and Toxic Substances (OPPTS), Series 830: Product Properties Test Guidelines.

The results of an ambient air monitoring study from the California Air Resources Board (CARB) confirmed that paraquat is not expected to volatilize from previously treated fields.[1]

Conclusion

Syngenta appreciates the EPA's thorough review of paraquat via the registration review process under FIFRA. EPA's conclusions regarding paraquat's benefits and risks, which were reached through the science-based risk assessment process and set forth in the final interim decision as well as EPA's supplemental document, are fundamentally sound. With the label mitigations already in place, Syngenta contends that all criteria have been met to support the continued registration of paraquat dichloride and the safety of its registered use patterns.

[1] https://www.cdpr.ca.gov/docs/emon/airinit/community_monitoring.htm State of California. Summary of Assembly Bill 1807/3219. Pesticide Air Monitoring Results Conducted by the California Air Resources Board 1986-1995.