US Environmental Protection Agency
Office of Pesticide Programs

Quinclorac Final Work Plan (FWP) For Registration Review

May 2008

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Approved by: _____

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Introduction:

This is the Environmental Protection Agency's (EPA's) ***Final Work Plan*** for the registration review of quinclorac. This work plan includes the expected registration review timeline. The work plan also addresses public comments received concerning the ***Preliminary Work Plan*** in the ***Summary Document,*** which was posted in the quinclorac registration review docket, and any other comments concerning initial docket postings. The ***Summary Document*** provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

The Agency is implementing the new registration review program and plans to review each registered pesticide every 15 years to determine whether it continues to meet the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) standard for registration. Changes in science, public policy, and pesticide use practices will occur over time. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet that statutory standard. The public phase of registration review begins when the initial docket is opened for each case. Information on this program is provided at http://www.epa.gov/oppsrrd1/registration_review/.

Comments Received on Preliminary Work Plan:

EPA received comments from two stakeholders during the public comment period in the initial quinclorac docket. However, these comments, which are addressed in this document, do not change the risk assessment need or the timeline detailed in the Preliminary Work Plan.
This document finalizes the work plan for the quinclorac registration review process. The comment and the Agency's response are located in the "Comment Summary and Agency Response" section of this document.

Risk Assessment and Data Needs:

The Agency anticipates conducting a comprehensive ecological risk assessment, which will include an endangered species risk assessment. The Agency also expects to conduct an occupational risk assessment, a drinking water assessment, a residential handler assessment, and an aggregate assessment.

Ecological Risk

- The most recent comprehensive ecological risk assessment for registered uses was conducted on wheat and sorghum in 1999, and the Agency has not conducted a risk assessment that supports a complete endangered species determination.

- The planned ecological risk assessment will allow the Agency to determine whether quinclorac's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitat. If the assessment indicates that quinclorac "may affect" a listed species or its designated critical habitat, the assessment will be refined. The refined assessment will allow the Agency to determine whether use of quinclorac is "likely to adversely affect" the species or critical habitat or "not likely to adversely affect" the species or critical habitat. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Services), as appropriate.

- The Agency anticipates needing the following data in order to conduct a complete ecological risk assessment, including an endangered species assessment, for all uses:

    - (GLN 850.1010) Aquatic invertebrate acute toxicity test, freshwater daphnids[1]
    - (GLN 850.1300) Daphnid chronic toxicity test
    - (GLN 835.7100) Ground water monitoring

Human Health Risk

- The toxicological endpoint selections are adequate; however, the toxicology database for quinclorac is incomplete at this time. A 28-day inhalation toxicity study in the rat is required to assess inhalation exposure from spray uses (GLN 870.3465).

- The residue chemistry database is complete. However, newly submitted aspirated grain fraction studies on wheat and sorghum will have to be reviewed, and livestock tolerances may need to be revised based on this review.

- The dietary (food alone) assessment is adequate. However, a new drinking water assessment will be conducted; therefore, an aggregate assessment will be needed.

- The residential post application exposure assessment is adequate, therefore no residential post application assessment is needed. However, no residential handler risks were assessed; therefore, a new residential handler assessment is needed.

- No occupational risk assessments have been conducted. Occupational risk assessments will be needed for all scenarios.

[1] Since the publication of the PWP, BASF has submitted an Aquatic invertebrate acute toxicity test. If the Agency finds this study acceptable, the Agency may not require this study.

Timeline:

EPA has created the following estimated timeline for the completion of the quinclorac registration review.

Registration Review for quinclorac – Projected Registration Review Timeline	
Activities	**Estimated Month/Year**
Phase 1: Opening the docket	
Open Public Comment Period for Quinclorac Docket	2007 – Dec.
Close Public Comment Period	2008 – Mar.
Phase 2: Case Development	
Develop Final Work Plan (FWP)	2008 – Apr.- Jun.
Issue DCI	2009 – Jan - Mar.
Data Submission	2013 – Jan - Mar.
Open Public Comment Period for Preliminary Risk Assessments	2014 – Jul. – Sept.
Close Public Comment Period	2014 - Oct. – Dec.
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	2015 – Jan. – Mar.
Close Public Comment Period	2015 – Apr. – Jun.
Final Decision and Begin Post-Decision Follow-up	2015 – Jul. Sept.
Total (years)	**8**

Comment Summary and Agency Response:

The quinclorac registration review docket was opened for a 90-day comment period beginning on August 1, 2007. During that time, two comments were received – one from the FIFRA Endangered Species Task Force (FESTF) and one from the technical registrant, BASF Corporation.

Summary of Comments Regarding the FIFRA Endangered Species Task Force

Comment: *The FIFRA Endangered Species Task Force (FESTF) noted that EPA stated in the Registration Review summary document that quinclorac does not have a complete environmental risk assessment that is in compliance with EPA's Overview Document for Endangered and Threatened Species Effects Determinations. FESTF states that BASF, the technical registrant, is a member of FESTF and as a member, BASF can rely on previously submitted task force data. FESTF requests that EPA assure that any company*

that is relying upon FESFT data, and are not a member, files a proper offer to pay for data compensation.

Response: The Agency thanks FESTF for its comment and will consider this information as it conducts the registration review and makes its registration review decision.

Summary of comments from the technical registrant, BASF

Comment: *BASF commented that the 90-day inhalation study required in the Preliminary Work Plan is presented in the HED scoping document on pages 60 and 62 as a 28-day inhalation study and it is recommended not required. Furthermore, they noted that a NOAEL of 70 mg/kg/day is identified for residential and occupational exposure. With a NOAEL this high, the MOEs are likely to be high (i.e., >> 100) for dermal / systemic exposure. Since inhalation is generally only a very small percentage of the exposure component, an inhalation study will not add value to the risk assessment. On pages 60 and 62 of HED's section of the summary document, a 28-day study is recommended. On page 5 of the overview section, it is stated that a 90-day study is required. BASF would like clarification on this inconsistency, but still contends that conducting an inhalation study is not necessary for determining exposure assessments.*

Agency Response: The Agency thanks BASF for their comment and apologizes for the inconsistency. The Agency intends to require a 28-day subchronic inhalation study for quinclorac because there are residential and occupational exposure scenarios based on quinclorac's use patterns. These scenarios are likely to be short- and intermediate- term, not long term; therefore, a 28-day inhalation study is required to assess inhalation risk to residential and occupational handlers.

Comment: *BASF commented that the request for an drinking water assessment is inconsistent with HED's determinations on pages 58 and 61 that state that the existing assessment is adequate and no new assessment is needed.*

Agency Response: The Agency thanks BASF for their comment and apologizes for the inconsistency. A revised drinking water assessment is required because previous assessments did not provide the highest labeled application rates (two applications @0.75 lb ai/A) and current minimum intervals (14 days). In addition, current labels have ground, aerial and granular applications, which were not incorporated into previous drinking water assessments.

Comment: *BASF commented that Request for aggregate risk assessment is inconsistent with HED's determinations on pages 58 and 61 that state that the existing assessment is adequate and no new assessment is needed.*

Agency Response: The Agency apologizes for the inconsistency. Because a revised drinking water assessment is required (see comment directly above), an aggregate assessment that includes this revised drinking water assessment is required.

Comment: *BASF noted that quinclorac is not registered for use on ornamentals or corn.*

Agency Response: The Agency thanks BASF for their clarification.

Comment: *BASF noted that Data on the reanalysis of soil samples from 1988/1989 terrestrial field dissipation studies was submitted to EPA per Jim Tompkins' request on November 29, 2007.*

Agency Response: The Agency thanks BASF for their submission. The Agency will review these studies and if they are found acceptable, will use them, as appropriate, in their future assessments.

Comment: *BASF noted that MRID 41063556 acute daphnia toxicity study used 96% TGAI test substance with surfactant. The request for a new acute daphnia can be satisfied with a 2001 study not previously submitted to EPA using 98.6% TGAI. The results of this study (EC 50 > 100 mg/L) are consistent with the chronic daphnia study (MRID 44129202) with NOAEC = 110 mg/L. The submission of the 2001 study should remove the uncertainty expressed by EFED and serve as a toxicity endpoint to estimate the risks to estuarine animals. With the submission of this study, the requirements for new acute and chronic daphnia studies should also be considered fulfilled.*

Agency Response: The Agency thanks BASF for their submission. The Agency will review this study, and if it is found acceptable, will use it, as appropriate, in their ecological risk assessments.

Comment: *BASF noted that an updated dermal sensitization study is available for submission, which demonstrates that quinclorac technical is non-sensitizing.*

Agency Response: The Agency thanks BASF for their submission and looks forward to reviewing this study. If this study is found acceptable, the Agency will use it, as appropriate in future assessments.

Comment: *BASF noted that based on the existing environmental fate lab data submitted to the Agency, it has been determined that under certain conditions quinclorac can exhibit mobility in soil toward ground water. Detailed terrestrial field dissipation studies conducted by BASF also indicate that the molecule can exhibit this same mobility. Based on the existing data for the molecule, it is clear that mobility in the field is a possibility, therefore conducting an additional environmental fate (PGW), study that will indicate the same results does not provide any additional value. Given that prospective ground water studies are not predictive of possible residues in drinking water supplies, the studies have dubious value for a human health assessment. The registrant has conducted a dietary assessment for the molecule and determined that if drinking water sources contained 1,000 ug/L, the MOE for infants (the most susceptible population subgroup) is still acceptable at a calculated MOE value of ~505 (food and water). Using the SciGrow model, the Agency has calculated a maximum expected ground water concentration of ~*

29 ug/L. The 1,000 ug/L value used by the registrant in their dietary assessment is 30 times higher than the highest expected ground water exposure value calculated by the Agency. Even at this exaggerated level, the molecule still has acceptable MOEs based on its low toxicological profile.

Agency Response: The estimated drinking water concentration (EDWC) from groundwater (29 µg/L) was used in the dietary assessment because these are greater than the surface water values. Since there is relatively little temporal variation in groundwater concentrations compared to surface water, the concentration (29 ug/L) was used for both acute and chronic exposure assessments. Prospective ground water studies are predictive of possible residues in drinking water supplies due to the mixing of groundwater and drinking water supplies especially with persistent mobile pesticides such as quinclorac.

Based on the high mobility and stability under hydrolysis as well as aerobic and anaerobic soil metabolism, there is a potential for accumulation of quinclorac in groundwater due to consecutive yearly multiple applications which may result in higher concentrations. Therefore, the Agency is requesting a small-scale prospective groundwater contamination study for quinclorac (and possibly its metabolites) to better quantify risks to human health via residues in drinking water supplies.

Comment: *BASF noted that based on the maximum seasonal use rate for quinclorac (1.5 lb ai/ac), an estimate of exposure in ground water was made using SciGrow. From the SciGrow estimate of exposure, the resulting concentration in water (ug/L) was calculated up to the mass of quinclorac in an acre-foot of water (325,851 gallons). Once the mass was figured, it was estimated that 0.009 lb ai/ac of quinclorac would be applied to a field in an acre with a foot of water. The University of Florida has estimated that a vegetable crop would require a maximum of 8.52 inches of water during the most demanding thirty-day growing period. From the non-target plant study, we selected a sensitive species (NOEC of 0.005 lb ai) based on a single application for comparison. If we take the estimated mass in the foot of water (0.009 lb ai/ac) and adjust it for the peak 30 day water requirement (8.52"/12" = 0.71), the load per acre in 30 days is 0.006 lb/ac ai (0.009 lb ai/ac x 0.71 ~ 0.006 lb ai/ac). Since the time required to deliver this amount of ai is 30 days, the dose is far below the single application rate NOEC of 0.005 lb/ac ai. Therefore, based on these calculations, it is not possible that any non-target plant injury could occur via contaminated ground water even using worst-case assumptions.*

Agency Response: The Agency agrees that for a single application of quinclorac to turf based on the maximum use rate of 1.5 lb ai/A (two applications @0.75 lb ai/A) and minimum intervals (14 days), would not likely result in non-target plant injury via groundwater exposure. However, based on the high mobility and stability under hydrolysis as well as aerobic and anaerobic soil metabolism, there is a potential for accumulation of quinclorac in groundwater due to consecutive yearly multiple applications which may result in higher concentrations. Therefore, the potential for groundwater impacts to non-target crops via contaminated groundwater are possible.

Because of these potential ground water impacts, the Agency is requesting a small-scale prospective groundwater contamination study for quinclorac (and possibly its metabolites) under the expected conditions of use of all currently registered crops.

Appendix A: Quinclorac Data Call-in Rationales

Guideline Number: 875.3465 **Study Title: 28-day inhalation - rat**
Rationale for Requiring the Data
These studies are triggered when there is the likelihood of significant repeated inhalation exposure to the pesticide as a gas, vapor or aerosol. Because quinclorac is applied as a liquid spray, inhalation exposure to quinclorac as an aerosol can occur. Inhalation exposure to quinclorac is predicted to occur because there are residential and occupational exposure scenarios based on quinclorac's use patterns (aerial application for rice, sorghum, wheat, residential lawns, and turf grass). These scenarios are likely to be short- and intermediate- term. Therefore, a 28-day inhalation study is required to assess inhalation risk to residential and occupational handlers. This study is required in 40 CFR 158 for all use patterns if there is the likelihood of repeated inhalation exposure. The Agency has recently expanded the data requirements to include persons exposed to pesticide residues in residential settings and occupational settings. The Agency needs application inhalation data in order to perform the residential risk assessments needed to fulfill the requirements of the Food Quality Protection Act.
Practical Utility of the Data
How will the data be used? The study will be used to determine the toxicity of quinclorac via the inhalation route of exposure. This toxicity data will be used to assess risks for occupational and residential scenarios. **How could the data impact the Agency's future decision-making?** These data are needed to fully characterize and quantify the exposure and risks to the U.S. general population including infants and children exposed to this pesticide and its metabolites. Due to the lack of data, the Agency has used assumptions in developing the preliminary registration review human health risk assessment. These data will allow the Agency to refine its risk assessment. In addition, more precise information could lower residential and aggregate exposure estimates, which could allow for the registration of new uses if submitted to the Agency.

Guideline Number: 850.1010
850.1300
Study Titles: Aquatic invertebrate acute toxicity test, freshwater daphnids
Aquatic invertebrate lifecycle, freshwater daphnids

Rationale for Requiring the Data

The Agency requires acute and chronic toxicity freshwater invertebrate data using the technical grade active ingredient (TGAI) to support all outdoor end-use product uses in 40 CFR part 158. The current study results were uncertain and a new study is requested because the 21-day NOAEC unexpectedly exceeds the 48-hour EC_{50} for the same species (Daphnid). This observation is likely the result of differences in test water conditions, or as the result of surfactant use in the acute toxicity test. As quinclorac is an acid subject to dissociation in water, differences in water hardness may influence the toxicity of the compound. An alternative explanation for the disparate toxicity results may be the presence of surfactant in the acute test, whereas no surfactant is evident for the chronic test. Because of this inconsistency in the acute and sub-chronic study results, the Agency cannot use the available 21-day chronic study or the 48-hour acute study as toxicity endpoints for freshwater invertebrates.

Additionally, these freshwater studies will be used to estimate chronic estuarine marine invertebrate toxicity.

Practical Utility of the Data

How will the data be used?

Both of these aquatic toxicity studies will allow the Agency to refine the screening level risk assessment for the registration review of quinclorac. The results of these studies will be used to estimate chronic risks to estuarine and marine invertebrates based on acute to chronic ratios (ACRs). The aquatic invertebrate toxicity studies would allow EPA to analyze acute and chronic effects on freshwater, estuarine, and marine invertebrates, primarily through the calculation of an accurate EC_{50} and NOAEC value, which will be used in future assessments. The effects data would be used to determine the likelihood that acute and chronic risks can potentially affect aquatic communities, either by direct effects on invertebrates or by indirect effects on fish by reducing their food sources.

How could the data impact the Agency's future decision-making?

By refining the assessment, the Agency would be able to determine what mitigation, if any, should be implemented for quinclorac as part of the registration review process. A future endangered species risk assessment will be performed as part of the registration review of quinclorac in compliance with the Endangered Species Act. Without these data, the Agency would have to assume that quinclorac "may affect" endangered invertebrates directly (and endangered species from other taxa indirectly), and use of quinclorac might need to be restricted in areas where endangered species could be exposed. The lack of these data will limit the flexibility the Agency and registrants have in coming into compliance with the Endangered Species Act and could result in use restrictions for quinclorac, which are unnecessarily severe.

Guideline Number: 835.7100
Study Title: Ground water monitoring

Rationale for Requiring the Data

Based on the high mobility and stability under hydrolysis as well as aerobic and anaerobic soil metabolism, there is a potential for accumulation of quinclorac in groundwater due to consecutive yearly multiple applications which may result in higher concentrations. Therefore, the Agency is requesting a small-scale prospective groundwater contamination study for quinclorac (and possibly its metabolites) under the expected conditions of all currently registered crops to better quantify risks to human health via residues in drinking water supplies and potential impacts to non-target crops via contaminated groundwater.

Practical Utility of the Data

How will the data be used?

For the preliminary quinclorac risk assessment, modeling was used to estimate drinking water risks and non-target plant exposure. Because of the assumptions used in the modeling, modeling is considered to be conservative, and would tend to over estimate quinclorac residues in ground water resources.

How could the data impact the Agency's future decision-making?

After submission and review of the water monitoring data with quinclorac, the Agency will be able to compare modeled estimates against actual measured concentrations of total quinclorac residues. If the monitoring data is less than the Agency's modeled concentrations, then the risk for dietary exposure and non-target plant risk will also decrease. If this monitoring data is not conducted, the Agency must rely on modeling to estimate drinking water and non-target plant risks, the Agency's conservative assumptions may cause the Agency to impose mitigation that is unnecessarily restrictive.

A future endangered species risk assessment will be performed as part of the registration review of quinclorac in compliance with the Endangered Species Act. Without these data, the Agency would have to assume that quinclorac "may affect" endangered plants directly (and endangered species from other taxa indirectly), and use of quinclorac might need to be restricted in areas where endangered species could be exposed. The lack of these data will limit the flexibility the Agency and registrants have in coming into compliance with the Endangered Species Act and could result in use restrictions for quinclorac, which are unnecessarily severe.