UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C., 20460
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

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SUBJECT: **Instructions for Commenting on the Draft Biological Evaluations for Chlorpyrifos, Diazinon, and Malathion**

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TO: Chlorpyrifos Registration Review Docket (EPA-HQ-OPP-2008-0850)
Diazinon Registration Review Docket (EPA-HQ-OPP-2008-0351)
Malathion Registration Review Docket (EPA-HQ-OPP-2009-0317)
www.regulations.gov

On March 31st, 2016, EPA is posting for public comment the draft biological evaluations (BEs) for chlorpyrifos, diazinon, and malathion in support of registration review. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to perform its intended function without unreasonable adverse effects. As part of the registration review process, the Agency has completed comprehensive draft BEs for all chlorpyrifos, diazinon, and malathion uses. These draft BEs represent the first nationwide assessments of these pesticides to federally endangered and threatened species (*i.e.*, listed species) and designated critical habitat. The BEs also include analysis of impacts to candidate and proposed species and critical habitat proposed for listing under section 7 of the Endangered Species Act (ESA). The interim scientific methods used in these draft BEs were developed collaboratively with the U.S. Fish and Wildlife Service (USFWS) and the National Marine Fisheries Service (NMFS), hereafter referred to as the Services, based on recommendations from the April 2013 National Academy of Sciences (NAS) report titled "Assessing Risks to Endangered and Threatened Species from Pesticides". As part of this effort, the U.S. Department of Agriculture has provided information on crop production and pesticide uses and assistance with the use of the National Agricultural Statistics Service Cropland Data Layer to help define the footprint of agricultural use patterns.

Through the registration review program, EPA is ensuring that each pesticide's registration is informed by the most current scientific data and methods. Furthermore, EPA is meeting its obligation under

Section 7 of the ESA by ensuring that each pesticide's registration is not likely to jeopardize the continued existence of any listed species or result in the destruction or adverse modification of designated critical habitat. More information about the endangered species program is available at: https://www.epa.gov/endangered-species/implementing-nas-report-recommendations-ecological-risk-assessment-endangered-and

The public comment period for the draft BEs will be open in April 2016. Because the file sizes of the draft BEs for chlorpyrifos, diazinon, and malathion exceed the docket system's file size limitation, the draft BEs will not be posted to the chlorpyrifos, diazinon, and malathion chemical dockets in www.regulations.gov. Instead, draft BEs for each of the three chemicals are posted on EPA's endangered species webpage. Commenters must post comments to each chemical's registration review docket at www.regulations.gov as detailed in Table 1.

Table 1. Links to the Draft BEs and Where to Post Comments

Chemical	Link to the Draft BEs	Where to Post Comments
Chlorpyrifos	https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos	EPA-HQ-OPP-2008-0850
Diazinon	https://www.epa.gov/endangered-species/biological-evaluation-chapters-diazinon	EPA-HQ-OPP-2008-0351
Malathion	https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion	EPA-HQ-OPP-2009-0317

Components of the Draft BEs

Each draft BE for each of the three chemicals is grouped into four chapters.

In Chapter 1 (the problem formulation), EPA outlines general information for each chemical (current registrations, use sites, application methods/rates, past risk mitigation, usage data, environmental fate characteristics) and its analysis plan. As part of its analysis plan, EPA outlines its approach for aquatic and terrestrial modeling to estimate exposure, the ecological effects data used to evaluate potential toxicity, and the various lines of evidence considered as part of its weight of evidence approach. Here, EPA also details the agency's approach for step 1 (making may affect [MA] or no effect [NE] determinations) and step 2 (making likely to adversely affect [LAA] or not likely to adversely affect [NLAA] determinations).

In Chapter 2 (effects characterization), EPA reviews the existing toxicological database based on information submitted by pesticide applicants as well as studies from the open literature for each chemical and describes effects to various taxa, including effects to fish/aquatic amphibians, aquatic invertebrates, aquatic plants, birds, reptiles, terrestrial amphibians, mammals, terrestrial invertebrates, and terrestrial plants. Here EPA also identifies the thresholds used to evaluate direct and indirect effects to listed species and designated critical habitat.

In Chapter 3 (environmental transport and fate characterization), EPA describes the existing environmental fate and transport data, the model inputs used to estimate aquatic and terrestrial exposure, and the results of aquatic and terrestrial modeling including a characterization of available monitoring data for each chemical.

In Chapter 4 (effects determinations), EPA makes NE, LAA, or NLAA determinations for each listed species and NE, LAA, and NLAA determinations for each designated critical habitat. There are approximately 1800 listed species and approximately 800 critical habitats for which effects determinations are concluded.

Topics for Consideration and Comment

When considering the 2013 NAS Report recommendations, EPA, FWS, and NMFS developed interim scientific methods to conduct national level pesticide risk assessments for listed species and their designated critical habitats. As the EPA and Services worked together to complete first drafts of the national-level listed species assessments of chlorpyrifos, diazinon, and malathion, they built upon these interim methods. The three assessments describe a weight of evidence approach that integrates methods for assessing exposure and effects. Although many of these methods build upon existing models and approaches used by EPA, much of these methods are new to regulatory risk assessment and are considered draft at this time. The best available science has been used to inform the risk assessment and comments from the stakeholder community on how to improve on these interim scientific methods and approaches is encouraged. Public comments pertaining to following subject areas are of particular interest:

- Identification of "best available" spatial data to represent potential pesticide use sites and species locations (Attachments 1-2 and 1-3)
- Methods used to identify potential overlaps (and extent) of species locations and potential use sites and their applications in effects determinations made in Steps 1 and 2 (Attachment 1-6)
- Estimation of exposure in various aquatic environments (bins) that have been regionally delineated and the parameterization of the bins and their relevance across the landscape (Attachment 3-1)
- Evaluation of exposures in flowing water bodies and in non-freshwater habitats (*e.g.*, tidal pools, estuaries) (Attachment 3-1)
- Evaluation of exposure to terrestrial organisms, including dietary and non-dietary routes of exposure (Attachment 1-7)
- Evaluation of mosquito adulticide applications including potential exposure and impact on the aquatic and terrestrial environments (Appendix 3-3 for chlorpyrifos and malathion)
- Use of species sensitivity distributions to evaluate effects (Attachment 1-5)
- Characterization of toxicity data from registrant submitted toxicity data and scientific literature and utility of sublethal effects data (Attachments 1-4, and 1-22)
- Use of mortality effects thresholds based on a chance of effects (*i.e.*, 1-in-a-million chance for direct effects and 10% chance of effect for indirect effects) (Attachment 1-4)
- Methodology for assessing risks to plants (Attachment 1-21)

- Weight-of-evidence approach used, including the high, medium, and low weighting assignments to the various lines of evidence to evaluate risk and make effects determinations (Attachment 1-9)
- "Qualitative" assessments for marine species and cave-dwelling terrestrial species.

These draft biological evaluations for chlorpyrifos, diazinon and malathion represent the first national-level listed species assessments. It is expected that, over time, the methods used by the EPA and Services will evolve through experience and input from stakeholders and the public. In these drafts, many of the NAS recommendations are implemented where possible in the time since the report was published. Several of the recommendations will take time to develop sufficient methods and tools to implement for all listed species. One of those recommendations includes the use of probabilistic methods for assessing risks of pesticides to individuals and populations of listed species. To that end, a refined risk assessment is conducted for a subset of listed birds using available tools (*i.e.*, TIM and MCnest; Appendix 4-7). Also of great interest is the weight of evidence approach used for all listed species as implemented in the WoE tools. Although this approach integrated a great deal of information on several types of effects (i.e., survival, growth, reproduction, sensory, behavior), it relied heavily upon thresholds for making the effects determination. Based on this WoE analysis, few species considered in step 2 resulted in NLAA determinations. For some taxa, *e.g.*, plants that are not dependent upon animal pollinators, this conclusion seems to contradict the weight of evidence. Refinements to the WoE method and the thresholds and their roles in making effects determinations will be considered.

How to Group Comments

EPA anticipates a large volume of stakeholder comments. To help facilitate EPA's review of stakeholder comments, EPA is encouraging commenters to group their comments according to the following topics:

1) Comments on the environmental models used in the draft BEs
    a. Comments addressing terrestrial models (ex. TIM/MCnest, TED tool)
        i. Model inputs
    b. Comments addressing aquatic models (ex. Pesticide in Water Calculator [PWC[1]], Downstream Dilution tool)
        i. Parameterization of the various aquatic bins
        ii. Model inputs
        iii. Spray drift parameterization, particularly for mosquito adulticide applications
2) Comments on the approach used for Step 1 (making may affect [MA] or no effect [NE] determinations)
3) Comments on the approach used for Step 2 (making likely to adversely affect [LAA] or not likely to adversely affect [NLAA] determinations) and the weight of evidence approach.
4) Areas of consideration for further refinement
    a. Comments addressing aquatic exposure
    b. Comments addressing terrestrial exposure
    c. Comments addressing effects endpoints and derivation of thresholds

[1] The Pesticide in Water Calculator is a graphical user interface shell that facilitates the running of our Pesticide Root Zone Model (PRZM v 5.02) and Variable Volume Water Model (VVWM v 1.02).

5) Comments on the use/usage of chlorpyrifos, diazinon, or malathion
6) Non-technical comments of a broader regulatory nature concerning the registration review program or the endangered species program
7) Document errors and technical corrections

Company A, for example, should submit one submission that contains several comments grouped in these categories. These categories are meant to be broad suggestions instead of firm guides. In general, commenters should keep chemical-specific comments separate from methodology-based comments that are applicable to all three chemicals.

Points of Contact for Each Chemical

For all questions related to this effort or concerning the registration reviews for chlorpyrifos, diazinon, and malathion, please direct questions to the chemical review manager identified in Table 2.

Table 2. Pesticide Contacts for Chlorpyrifos, Diazinon, and Malathion

Registration Review Case Name and Number	Pesticide Docket ID Number	Chemical Review Manager, Telephone Number, Email Address
Chlorpyrifos, case 100	EPA-HQ-OPP-2008-0850	Dana Friedman, 703-347-8827, friedman.dana@epa.gov
Diazinon, case 238	EPA-HQ-OPP-2008-0351	Khue Nguyen, 703-347-0248, nguyen.khue@epa.gov
Malathion, case 248	EPA-HQ-OPP-2009-0317	Steven Snyderman, 703-347-0249, snyderman.steven@epa.gov

Anticipated Next Steps

After reviewing comments received during the public comment period, EPA will issue revised final BEs, explain any changes, and respond to comments. For those species and designated critical habitats where registered uses of the pesticides are "likely to adversely affect" species and/or habitat, USFWS and NMFS will utilize the analyses and data from the biological evaluations in their final Biological Opinions for each of the three chemicals. Final BiOPs are scheduled to be completed in December 2017.

EPA will be holding a public webinar in April 2016 to provide a technical briefing of the analysis/interim methods used to make the effects determinations. This webinar will also provide guidance to stakeholders on how to navigate the BEs and address questions from the public. EPA will publish instructions shortly for this webinar.

EPA will be holding a stakeholder workshop in 2016 to discuss the methods used in this interim approach and possibilities for refinement. EPA will publish additional information on this stakeholder workshop in spring 2016.