Due June 10, 2016

Mr. Steven Snyderman
Office of Pesticide Programs (OPP)
Regulatory Public Docket Center (28221T),
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW.
Washington, DC 20460–0001

Subject: Malathion – Draft Biological Evaluation (Docket ID No. EPA-HQ-OPP-2009-0317)

Dear Mr. Snyderman:

On behalf of the Bay Area Clean Water Agencies (BACWA), we thank you for the opportunity to comment on the Biological Evaluation (BE) for malathion. BACWA's members include fifty-five publicly owned wastewater treatment (POTW) facilities and collection system agencies serving 6.5 million San Francisco Bay Area residents. We take our responsibilities for safeguarding receiving waters seriously and are very concerned about discharges of pesticides into wastewater systems that may compromise effluent quality, biosolids reuse, and compliance with NPDES permit requirements.

BACWA is pleased that the EPA and the Fish and Wildlife Service (FWS) are cooperating to address endangered species in pesticide registration review. As managers tasked with protecting the surface waters receiving our discharges and the species in these waters—including endangered species—we appreciate the effort being put forth in this BE. The NPDES permits issued to BACWA's member agencies include requirements that effluent limits and receiving water limits protect the beneficial uses of waters of the State including protecting rare, threatened, or endangered species. Through these Clean Water Act (CWA) permits, water quality regulators make municipalities responsible for meeting Endangered Species Act (ESA) requirements.[1]

Since our member agencies do not control indoor or other upstream pesticide uses and subsequent discharges, we seek to ensure that the pesticides ESA Consultation process will lead to mitigations that will protect endangered species and their critical habitats. Because our responsibilities extend beyond endangered species to include all other beneficial uses in our receiving water, we also seek to ensure that OPP's pesticide Registration Review process will lead to mitigations that will protect <u>all</u> beneficial uses of surface waters (not just endangered species).

[1] For example, see City of Palo Alto Regional Water Quality Control Plant and Wastewater System Permit, Order No. R2-2014-0024 (June 11, 2014), Attachment F, Page F-11, Paragraph C.7.

Our goals in providing comments are:

- to support EPA's efforts to develop a solid, functional BE process; and
- to ensure that both the BE process and EPA's Registration Review appropriately evaluate risks associated with urban pesticide use—and do so in a manner consistent with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the ESA, and the CWA.

We comment on the following areas, numbered by the suggested topic grouping in EPA's Instruction for Comments:

1. Comprehensive Federal Review Needs to Include POTWs and Indoor Uses (Topics #4a and #5)
2. The BE and Registration Review Risk Assessment Should Examine Formation of the Malaoxon Degradate during Wastewater Disinfection (Topic #4a)
3. Malathion May Interfere with POTW Treatment Processes (Topics #4a and #5)
4. A BE is Not a Replacement for a Traditional Risk Assessment (EPA Topic #6)
5. Clean Water Act Compliance Assessments Must Be an Integral Part of BEs and Registration Review Ecological Risk Assessments (EPA Topic #6)
6. The BE Procedure Is Unnecessarily Complex and Will Not Be Applicable to Most Pesticides (Topic #6)
7. The Format of the Public Review Documents Was Too Complex, Even for a Nationwide BE (Topic #6)

1. Comprehensive Federal Review Needs to Include POTWs and Indoor Uses (EPA Topics #4a and #5)

While the list of malathion uses and the exposure pathways examined in the BE are extensive, malathion's indoor use, its discharges to POTWs, and the environmental risks of these discharges were entirely omitted. All malathion uses, both indoor and outdoor, may result in exposures that can cumulatively impact human health and the environment. FIFRA, ESA, and the CWA all require that all malathion discharges be addressed together. This omission is of great concern for BACWA because any use of malathion that may be washed down indoor drains has potential to pose a threat to our members' compliance with stringent regulatory requirements under the CWA.

The most important (and perhaps only) indoor malathion product is a topical lotion (0.5% malathion), a product approved by the U.S. Food and Drug Administration (FDA) for treatment of lice on the scalp. The product instructions tell users to wash their hair after the use of this product, which causes the malathion to be discharge directly to the sewer system, where it flows to the downstream POTW. This discharge is not continuous – it occurs primarily when a head lice outbreak occurs, such as at a school or day care facility. Medicinal lice treatments, used as a result of such outbreaks, create periodic peaks of malathion concentrations being discharged to POTWs. The omission of this product appears to have been an oversight, since its omission is inconsistent with EPA precedent for pesticide risk assessments and the ESA clearly requires evaluation of all malathion uses in the BE.

BACWA appreciates that EPA has been including all pesticides regulated by both OPP and FDA in its environmental risk assessments since 2002. This step has been an important action toward ending a problematic failure at the federal level to coordinate different agencies' product approval procedures with one another to ensure that relevant environmental pathways and cumulative impacts are taken into account under each separate statutory authority.

During Phase V of the Lindane Review (2002), the EPA received comments regarding the use of lindane for lice and scabies treatments and the importance of assessing human and environmental health risks from the disposal of lindane into sewers. EPA responded by setting the following precedent:

> *"…the Agency assessed, in cooperation with FDA, the risk associated with the direct application to humans of lindane pharmaceutical products for the treatment of lice and scabies. Further, the Agency assessed both human health and environmental risk from disposal of pharmaceutical products after application/use."*[2]

Since that time, EPA has consistently included all products – including those approved by FDA – in its aquatic risk assessments.[3, 4] We request that EPA coordinate efforts on assessment of malathion with FDA, just as it is doing for triclosan:

> "EPA continues to coordinate efforts on assessment of triclosan with FDA. The two agencies are reviewing the effects of triclosan from two different perspectives. In making a regulatory decision about the pesticidal uses, EPA can only take regulatory action to mitigate risks from the uses that are pesticidal. However, **if EPA finds that there may be a risk from exposure to triclosan that arises from FDA-regulated uses, we will share that information with FDA and work with FDA, as appropriate.** FDA is aware the EPA is concerned about the potential adverse environmental impacts of triclosan."[5]

The ESA requires consideration of "interrelated" and "interdependent" actions in every BE. POTWs often discharge to water bodies (e.g., San Francisco Bay) that also receive urban and agricultural runoff. Therefore, the potential cumulative discharge of malathion to water bodies needs to be evaluated in the BE.

2. The BE and Registration Review Risk Assessment Should Examine Formation of the Malaoxon Degradate during Wastewater Disinfection (Topic #4a)

Chlorine and its compounds, which are commonly used to disinfect wastewater effluents just prior to discharge, appears to cause formation of the malathion degradate malaoxon, which is more toxic to aquatic organisms than the parent chemical. The BE recognizes this in Appendix 1-9, page 5, which says "...several studies have been conducted that indicate that OP and

[2] U.S. EPA, Agency Response to Phase V Comments on Lindane, September 27, 2002.
[3] U.S. EPA, Revised Pyrethrins RED Chapter After Additional 60-Day Comment Period, Phase 5, April 4, 2007.
[4] U.S. EPA, Reregistration Eligibility Decision (RED) for Permethrin, December 2007.
[5] U.S. EPA, Response to Public Comments on the Registration Review Preliminary Work Plan for Triclosan, April 4, 2014.

organodithiophosphate chemicals that have sulfur double bonds to the central phosphorus atom generally form oxons during chemical disinfection by chlorine compounds (Magara et al., 1994, Duirk and Collette, 2006; Wu and Laird, 2003)…."

Consequently, POTW effluent risk assessments need to include both malathion and malaoxon. Further, the BE and Registration Review risk assessment cannot rely on any POTW monitoring studies that do not include malaoxon, as such studies will not provide scientifically accurate information about malathion pass-through and subsequent transformation in effluent disinfection processes. We request that the BE and the eventual Registration Review risk assessment examine both malathion and malaoxon in POTW effluent.

3. Malathion May Interfere with POTW Treatment Processes (Topics #4a and 5)

A POTW downstream of a school lice outbreak could expect to receive an upstream pulse of lice treatments, including malathion. The BE and Registration Review risk assessments need to evaluate the potential impacts of such pulses on wastewater treatment organisms.

Microorganisms do the basic work of removing fecal matter and dissolved organics in sewage. If a pesticide enters a treatment plant in sufficient quantities to upset the biological diversity or inhibit chemical oxygen demand (COD) oxidation, it could cause a "process interference," or a plant "upset" where wastewater is no longer able to be treated properly before discharge. A 2014 study by Wright-Patterson Air Force Base that examined sorption and biodegradation of malathion in wastewater activated sludge (AS), finding that malathion had an impact to the biological diversity within AS and induced a "stress response that inhibits COD oxidation." [6, 7]

Both process interference and plant upset reduce the quality of a POTW's effluent, which has potential impacts on CWA compliance and surface waters receiving the effluent. In the case of a plant upset, microorganisms may either be impaired or killed, such that treatment does not occur for hours, days, or even weeks, resulting in impacts to water quality, fish and wildlife, as well as NPDES permit violations. NPDES permit violations are costly to wastewater agencies, expose wastewater agencies to third party lawsuits under the CWA, and can cause immeasurable damage to the aquatic environment.

4. A BE is Not a Replacement for a Registration Review Ecological Risk Assessment (EPA Topic #6)

The EPA titled the set of documents out for public comment as the "Draft Biological Evaluations: Chlorpyrifos, Diazinon, and Malathion Registration Review," suggesting some confusion as to whether this is considered a BE or a registration review ecological risk assessment. In addition, the May 5th webinar reviewing these BEs included only the following future milestones:

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[6] Janeczko, et al., Fate of malathion and a phosphonic acid in activated sludge with varying solids retention times, Water Research, Vol 57, pg 127-139, 2014.

[7] While the study found that most removal of malathion was by biodegradation rather than sorption, "Depending on the compound and degree of influence heterotrophic and nitrifying bacteria have on biological degradation, OPs and their degradation products may pass through an activated sludge wastewater treatment plant largely unchanged."

- December 2016: Final BE
- April 2017: Draft Biological Opinion (BO)
- December 2017: Final BO

Our representatives participated in the webinar and in subsequent email communications. Through these outlets we have sought to identify when the malathion Registration Review ecological risk assessment will be released for public review. The responses we have received suggest that EPA intends the BE to fulfill the function of the Registration Review risk assessment.

An ESA consultation neither supplants nor displaces other aspects of Registration Review for this or any other pesticide. EPA's periodic Registration Reviews are meant to ensure that pesticide usage meets current standards for human health and environmental safety – neither of which can be completely evaluated within the scope of an ESA BE.

We understand—and hope—that we may have misinterpreted EPA's responses to our questions. But, in the event that this BE is being considered as an alternative to a Registration Review ecological risk assessment, we would like to clarify why such a precedent setting adjustment in the reregistration process is outside of EPA's Procedural Regulations for Registration Review and could lead to negative consequences.

a) By itself, the BE and the current public participation process do not comply with EPA's Procedures for Registration Review

In 2006, U.S. EPA published the Procedural Regulations for Registration Review.[8] Within that document are the following statements (emphasis added):

> "…the scope of a pesticide's registration review includes **all aspects** of a pesticide's registration specified in section 3(c)(5) of FIFRA with respect to product composition, labeling and other required material, and risks and benefits."
>
> "EPA **intends to incorporate new requirements**, such as endocrine disruptor screening and testing or **endangered species** assessments into the registration review program as these aspects of risk assessment mature into routine evaluations for pesticides.

While this suggests that EPA anticipated that this process would evolve, this does not suggest that incorporating new requirements, such as endangered species assessments, would supersede other aspects that could impact a registration review decision.

Further, according to the procedures defined in 2006, typically a risk assessment is the last opportunity for public comment prior to the Registration Review decision. If EPA is indeed seeking to insert the BE in the place of a risk assessment, then it is possible that this could be the last chance for public comment prior to the decision, suggesting that EPA's assessment of human or environmental risks (which forms the essential groundwork for development of

[8] Federal Register / Vol. 71, No. 153 / Wednesday, August 9, 2006.

mitigations) could be outside of a public discourse, which goes against both the written word and the spirit and intent of the Procedural Regulations for Registration Review.

Only with a complete risk assessment can properly targeted and useful mitigation measures be proposed for urban uses of malathion. We will continue to query staff regarding when the traditional risk assessment elements will be available for public comment so we have an opportunity to evaluate the analysis and consider appropriate mitigation measures.

b) The BE Does Not Address Many Sensitive Aquatic Species That Must Be Addressed in Pesticide Registration Review

While understandable that the scope of this large undertaking was "limited by the ESA," entire categories of species were ignored because they are not on the Endangered Species List (ESL). This BE and the subsequent communications regarding next steps suggest that EPA might be seeking to avoid evaluation of risks to aquatic habitats as a whole, i.e., habitat other than endangered species habitat. There are sensitive species (particularly aquatic invertebrates) that are identified and considered in a traditional risk assessment in order to develop appropriate mitigation measures. These species need not be endangered, are present in aquatic ecosystems at many, if not most, locations and times when ESL species are not present), and need not be a food supply to an endangered species.

Any mitigation drawn from the current BE process would only cover endangered species and their habitats. To fulfill its Registration Review obligations, OPP must complete a full ecological risk assessment to form the basis for risk mitigation decision addressing all species and all habitats.

5. Clean Water Act Compliance Assessments Must Be an Integral Part of BEs and Registration Review Ecological Risk Assessments

CWA compliance is an integral part of endangered species and aquatic habitat protections. It is inextricably linked to the ESA in its structure and implementation. Its mandates must be coordinated with FIFRA implementation to avoid untenable regulatory gaps for CWA permittees.

In addition to ESA integration, there is a second reason that CWA compliance should be at the core of Registration Review – regulatory consistency between OPP and OW. Because local agencies in California (as in most other states) lack the statutory authority to regulate pesticide use in urban areas, it is essential that EPA employ the pesticide registration and Registration Review processes to assess and prevent urban water pollution as defined by the CWA. Since FDA controls lice treatments and OPP controls pesticides labels, even our state pesticide regulatory agency cannot readily address pesticide water pollution stemming from consumer pesticide products.

Every day, BACWA members treat millions of gallons of wastewater that is then discharged to fresh or salt water bodies, including local creeks and rivers, bays, and the Pacific Ocean. In some cases, receiving waters may be effluent-dominated in that there is little to no dilution either because the receiving water is small or there is a lack of mixing at certain times due to thermal or

saline stratification. These waterways provide crucial habitat to a wide array of aquatic species and waterfowl, including ESL and non-ESL species. It is therefore essential that both the BE and pesticide registration and Registration Review processes adequately consider potential impacts to wastewater quality, so that such impacts to the beneficial uses of the receiving water are *prevented*.

If the Registration Review process fails to prevent toxic releases of pesticides to the aquatic environment, an undue burden to address the problem is placed on local governments. Acute or chronic toxicity is one of the most common adverse impacts of pesticides in effluents and surface waters. Under the Clean Water Act, wastewater facilities are often required to conduct and pay for accelerated tests weekly for a minimum of six weeks if toxicity is observed. Should toxicity be observed in two or more of these weekly accelerated tests, the discharger is required to implement a toxicity identification evaluation (TIE), to identify what is causing toxicity, the cost of which can vary widely from $10,000 to well over $100,000 depending on complexity and persistence of the toxicant.

Once identified, the cost to treat or remove the toxicity causing compound(s) can vary dramatically. Often, there are few ways for a discharger to mitigate the problem other than extremely costly treatment plant upgrades. The California State Water Board is currently considering a regulatory proposal that would move toxicity from a narrative standard to a numeric standard. Exceedances would not only trigger the expensive test described above, but would also be subject to both fines and citizen lawsuits.

In addition, when surface water bodies become impaired by pesticides, wastewater facilities may be subject to additional requirements established as part of Total Maximum Daily Loads (TMDLs) set for the water bodies by U.S. EPA and state water quality regulatory agencies.

A number of pesticide-related TMDLs have been adopted or are in preparation in California. The cost to wastewater facilities and other dischargers to comply with TMDLs can be up to millions of dollars per water body per pollutant. This process will continue as long as pesticides are approved for uses that result in water quality impacts; it is therefore imperative that EPA conducts a Registration Review to impact water quality and for EPA to take action to ensure that any impacts are prevented or fully mitigated.

6. The BE Procedure Is Unnecessarily Complex and Will Not Be Applicable to Most Pesticides (Topic #6)

As noted in the BEs, diazinon, chlorpyrifos, and malathion are the first three pilot chemicals for which this analysis is being conducted. We further understand that what has been provided to date is only the result of the first two steps of an eventual three-step process to craft a BO regarding potential risk to endangered or threatened species and/or designated critical habitats. While this was clearly a massive undertaking, we are unclear how this procedure will be the basis for future BEs.

This profoundly detailed analysis is unlikely to set the stage for future ESA pesticide consultation processes because it requires extensive ecotoxicity data. For most other pesticides only a small set of aquatic toxicity data are available. Often only 1 to 3 aquatic species have

been tested, as this is all that is required by EPA for pesticide registration. Therefore, EPA's thoughtfully developed process will likely have very limited applicability.

We suggest that EPA examine two alternative approaches for BEs:

(1) Develop and use water quality criteria using the EPA Office of Water (OW) methodology, which is specifically designed to be protective of the beneficial uses of the nation's waters – including endangered species habitats. OW is currently working on an update to its criteria development procedures and OPP has been invited to participate. OW is specifically examining the data requirements for its process, providing an opportunity for creation of a single Agency-wide effects assessment process, which could be designed to rely only on ecotoxicity data routinely available to OPP.
(2) Complete and use the OPP-OW Common Effects Assessment methodology. This methodology provides a means for development of an effects threshold value based solely on aquatic toxicity data typically available for pesticides as a requirement of their registration. It has already been through EPA Science Advisory Panel review and needs only a relatively small additional investment of scientific work to bring it to completion. Unless this approach is soon to be supplanted by an improved, jointly-accepted water quality criteria methodology, we urge EPA to break through the current delays and finish this nearly complete project immediately.

7. The Format of the Public Review Documents Was Too Complex, Even for a Nationwide BE (Topic #6)

We recognize that this was the first time that EPA scientists have carried out a pesticide BE covering the entire nation. While we commend EPA on the comprehensiveness of its approach, we are distressed by the lack of summary information. This makes the BE effectively inaccessible for organizations without scientists with hundreds of hours to devote to a review of a single pesticide BE. As public agencies with broad responsibilities for water quality protection, we simply do not have the resources to review and comment on such an analysis for even one pesticide. Yet malathion is only one among the dozens of pesticides known to or that have potential to pollute the nation's urban surface waters.

A typical registration review docket contains a handful of documents, including an Ecological Risk Assessment as a single file. In contrast, the BE docket for malathion consists of at least 115 separate files (including 36 attachments and 75 appendices, each requiring a separate download and multiple clicks to open due to varying and usually "read-only" formats). Such a format is onerous for local and state governments desiring to examine EPA's work for scientific accuracy and to determine if the risk assessment includes any of the scientific, procedural, and informational gaps that have led to current pesticides water pollution. The fact that 20 slides of EPA's 82-slide May 5 introductory webinar were titled "Navigating the Documents" is an indication that a comprehensive review of the BE is far beyond the capabilities of most reviewers.

BACWA stands ready to engage our member agencies and others in the wastewater community to ensure that the eventual registration review for malathion fully addresses indoor uses in the

sewershed as well as potential wastewater process interference.

Thank you for your consideration of our comments. If you have any questions, please contact BACWA's Project Managers, Melody LaBella, at (925) 229-7370 or mlabella@centralsan.org or Karin North at (650) 329-2104 or Karin.north@cityofpaloalto.org.

Respectfully Submitted,

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