Comments on the National Marine Fisheries Service Draft Biological Opinion: "Environmental Protection Agency Registration of Pesticides Containing Chlorpyrifos, Diazinon and Malathion (July 31, 2008)

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I. Introduction

The National Marine Fisheries Service ("NMFS") issued a Draft Biological Opinion ("BiOp") on July 31, 2008, evaluating the potential for chlorpyrifos, diazinon, and malathion to affect endangered Pacific salmonid species in the states of Washington, Oregon, California and Idaho. NMFS concluded that use of all three pesticides, as currently allowed, "is likely to jeopardize the continued existence of these endangered or threatened species" and "is likely to result in the destruction or adverse modification of critical habitat of these endangered and threatened species." These comments specifically addresses the portions of the Draft Biological Opinion that pertain to malathion.

These comments are submitted on behalf of Cheminova, Inc., and its parent company Cheminova A/S (hereafter collectively "Cheminova"). Cheminova is the sole technical registrant for Malathion products, under the Federal Insecticide, Fungicide and Rodenticide Act, as amended ("FIFRA"), and also holds FIFRA end-use product registrations for products containing Malathion as an active ingredient.

II. Executive Summary

The Draft Biological Opinion is procedurally and substantively deficient. It is procedurally defective for at least two reasons. First, the registrants were not allowed an opportunity to provide comments before public release of the draft, in direct contravention of applicable NMFS requirements. Second, NMFS failed to solicit input from the registrants regarding data gaps in the Opinion – again in contravention of the Service's own requirements.

Substantively, the Draft Biological Opinion falls short in a number of ways. First, NMFS should have, but did not, base its risk assessment for malathion on the use patterns approved by EPA for reregistration and other required risk reduction measures identified in EPA's Reregistration Eligibility Decision Document (RED) for malathion. Second, and more broadly, the Draft Biological Opinion fails to properly consider the most recent and relevant scientific data and instead relies on less than the "best available scientific data," in violation of the applicable statutory and regulatory requirements.

III. Legal Framework

Section 7(a)(2) of the Endangered Species Act ("ESA") directs all Federal agencies to "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence" of any endangered or threatened species or result in the destruction of critical habitat. This is to be done in consultation with, and with the assistance of,

the Fish and Wildlife Service ("FWS") or the National Marine Fisheries Service ("NMFS" or the "Service"), as appropriate. 16 U.S.C. §1536(a)(2).

In carrying their responsibilities under Section 7(a)(2), each agency is required to use the "best scientific and commercial data available." *Id.*; *see also* 50 CFR § 402.14(d). Courts have interpreted this to mean that NMFS cannot ignore available biological information and the Service must consider all relevant scientific and commercial data. *Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988). Moreover, there must be "a rational connection between the facts found and the decision made" in the Biological Opinion. *Gifford Pinchot Task Force v. FWS*, 378 F.3d 1059, 1065 (9th Cir. 2004). If the Service fails to consider the best scientific and commercial data available, the final Biological Opinion will be invalidated. *See Bennett v. Spear*, 520 U.S. 154, 174 (1997).

A. Scope of EPA's Proposed Action

As indicated in the Draft Biological Opinion, the proposed agency action is the Environmental Protection Agency's ("EPA" or the "Agency's") registration of pesticide products containing the active ingredient malathion under the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §136 et seq. ("FIFRA"). BiOp at 16. More specifically, the Draft Biological Opinion states that:

> EPA, NMFS, and FWS agreed that the Federal Action for EPA's FIFRA registration actions will be defined as the "authorization for use or uses described in labeling of a pesticide product containing a particular pesticide ingredient."

Id at footnote 1.

Paradoxically, although the Federal Action is defined in terms of the approved uses of malathion, NMFS indicates in its Draft Biological Opinion that the Service has not received from EPA a comprehensive summary of approved uses. See, *e.g.*, BiOp at 19. Instead, NMFS evidently turned to a variety of sources in an attempt to glean information about potential uses of the pesticide. As a result, the Draft Biological Opinion appears to make a number of incorrect and overly broad assumptions about the approved uses of malathion, which, in turn, has resulted in distorted exposure estimates.

The only sensible way to address this problem is to regard the "federal action" that is subject to the consultation as the EPA decision on malathion use patterns that the Agency has approved for reregistration under FIFRA Section 4. That decision, along with the rationale supporting it, is set forth comprehensively in EPA's Reregistration Eligibility Decision (RED) document for malathion.[1]

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[1] The RED is available on EPA's website, at the following url: http://www.epa.gov/pesticides/reregistration status_page_m.htm The specific use patterns that EPA has approved for reregistration can be found in the malathion RED in Table 30 (pages 101 -126) and Appendix A (pages 127-137).

EPA was required by law to conduct a comprehensive pesticide ***reregistration*** program, consisting of a complete review of the human health and environmental effects of pesticides (including Malathion, Chlorprifos and Diazion) first registered before November 1, 1984, when the standards for government approval were less stringent than they are today. In reviewing a pesticide for reregistration, EPA gathers all available data on the pesticide, examines related health and environmental effects, and identifies measures to most effectively mitigate risks. EPA's regulatory conclusions and decisions regarding the registrability of a chemical, and the restrictions required for registration, are presented in the RED document. The use patterns approved for reregistration are those that EPA has found will not pose unreasonable adverse effects on human health or the environment. *See, e.g.,* RED, at p. 2.

Thus, the RED is the definitive document that identifies: (i) the use patterns that EPA will allow to be registered for a pesticide, and (ii) the risk mitigation measures that EPA will require in connection with a product's registration. Indeed, the RED may overstate the actual uses that are registered for a pesticide, because not every use that is allowed by EPA will necessary be included in the registrations for the pesticide.

As NMFS is aware, while the malathion RED definitively states EPA's regulatory position on the use patterns that will be approved for registration, the reregistration process is not completed for Malathion, because the label changes implicated by the RED have not yet been fully implemented. In this regard, it is important to recognize that there are two levels of implementation: changing the labels of the manufacturing use products (also called "technical products"), and changing the end-use product labels. Cheminova is the sole technical registrant for Malathion, and also has its own end-use registrations. In addition, it sells technical malathion to other companies that manufacture their own end-use products, under their own registrations. Because the RED is still in the process of being implemented, the label changes required under the RED are still underway. However, once reregistration is complete, the labels of all end use products and technical products containing malathion will include the label changes required by the RED, or EPA will have to take action under FIFRA to cancel those registrations and prohibit their distribution in the United States.

However, the fact that the RED has not been fully implemented in no way diminishes its significance for present purposes. It definitively reflects EPA's current regulatory position regarding the use patterns that will be allowed to continue and the risk reduction measures that will have to be implemented for Malathion. Therefore, the RED is the appropriate predicate for evaluating whether future use of Malathion poses risks to endangered salmonid species. The products that will remain in commerce pending full implementation of the RED are not, as a practical matter, something that the FIFRA regulatory system can effectively address, so it would be pointless to use those products' use patterns as the basis for the consultation. Accordingly, any risk assessment that is performed by NMFS as part of the Biological Opinion for malathion should be based on the use patterns identified in the malathion RED. This will permit the Biological Opinion to take into account the risk mitigation measures that EPA has described and required to be implemented in the RED for malathion uses that it has approved for reregistration.

IV. Procedural Deficiencies

The Draft Biological Opinion is procedurally defective on two grounds: (1) NMFS ignored the ESA as well as its own implementing regulations and guidance in failing to provide the registrants with an opportunity to comment on the Draft Opinion before releasing it to the public, and (2) the Service ignored its own procedures regarding the treatment of data gaps concerning the project's impact to listed species or critical habitats.

A. Public Release of the Draft Biological Opinion

The ESA and its implementing regulations expressly contemplate the involvement of the "permit or license applicant" (in this case, the pesticide registrant) in Section 7 consultations. For example, under 50 CFR § 402.14(d), which establishes the action agency's responsibility to provide best scientific and commercial data to the Service, the action agency must grant "any applicant ... the opportunity to submit information for consideration during the consultation." Similarly, 50 CFR § 402.14(g)(5) obligates the Service to "[d]iscuss with the Federal agency *and any applicant* the Service's review and evaluation ... the basis for any finding in the biological opinion, and the availability of reasonable and prudent alternatives (if a jeopardy opinion is to be issued) that the agency and the applicant can take to avoid violation of section 7(a)(2)."

The NMFS *Endangered Species Act Consulting Handbook* (March 2008) (the "*Handbook*") is even more explicit concerning the Service's obligation to keep the registrant involved during the consultation process. In addition to the points already mentioned, it provides that:

> During the initial 90-day formal consultation period, the Services should meet or communicate with the action agency *and the applicant*, if any, to gather any additional information necessary to conduct the consultation. The 90-day period should be used to:
>
> - assess the status of the species and/or critical habitat involved;
> - verify the scope of the proposed action, which includes identifying the area likely to be affected directly and indirectly by the proposed action, and cumulative effects;
> - identify adverse effects likely to result in jeopardy to the species and/or adverse modification of the critical habitat;
> - develop reasonable and prudent alternatives to an action likely to result in jeopardy or adverse modification;
> - identify adverse effects not likely to jeopardize listed species, but which constitute "take" pursuant to section 9 of the [ESA];
> - develop reasonable and prudent measures, and terms and conditions for the incidental take statement as appropriate; and
> - identify conservation recommendations, as appropriate.

> These actions should be undertaken *cooperatively* with the action agency and any applicant, thus allowing the Services to develop a better understanding of direct and indirect effects of a proposed action and any cumulative effects in the action area.

Handbook, at pp. 4-6 and 4-7 (*emphasis added*). Clearly, the Service's own procedures recognize the need for consultation with the registrant to ensure (1) that both potential impacts to endangered species and critical habitats are properly understood and (2) that viable reasonable and prudent alternatives are developed in the event a "jeopardy" finding is reached. *See also Handbook, at* p. 2-13 (outlining applicant's role in the consultation process by incorporating the requirements of 50 CFR § 402.14(d) and (g)).

Importantly, the *Handbook* also directs the Service to provide the applicant (here, the registrant) with an opportunity to comment on the Draft Biological Opinion before disclosing it to the public. The *Handbook* is unambiguous in this regard: "Do not release or distribute the draft biological opinion." *Handbook, at* p. 4-7. However, despite the Handbook's clear instructions, the registrants were not afforded an opportunity to comment on the Draft Biological Opinion prior to its release to the public. This is more than a simple formality. Instead, there is a real concern that the circulation of a Draft Biological Opinion that is laden with factual or legal errors may prejudice public perceptions and opinions regarding the proposed action. This is a serious and prejudicial procedural breach on the part of the Service.

B. Data Gaps

One of the primary reasons why the regulations and *Handbook* include provisions to ensure involvement by, and cooperation with, the applicant is to allow the Service to draw upon the applicant's expertise in arriving at a valid conclusion in the Biological Opinion and, if necessary, devising viable alternatives to the proposed action. By releasing the Draft Biological Opinion prematurely, the Service has failed to satisfy its regulatory obligation to use and the best scientific and commercial data available towards formulating the biological opinion. *See, e.g.,* 50 CFR § 402.14(d) and (g)(8). Consequently, it is no surprise that the Draft Biological Opinion contains sizeable data gaps, as discussed in more detail in later sections of these comments. Nor did the Service actively "seek out" such information, as the *Handbook* directs it to do. *Handbook, at* p. 1-7.

Indeed, the Service seems once again to have ignored its own guidance. The *Handbook* unequivocally anticipates the problem of data gaps and sets forth specific procedures for dealing with them:

> [w]here significant data gaps exist there are two options (1) if the action agency concurs, extend the due date of the biological opinion until sufficient information is developed for a more complete analysis; or (2) develop the biological opinion with the available information giving the benefit of the doubt to the species. *These alternatives must be discussed with the action agency and the applicant, if any*. Based on this discussion, a decision regarding the preparation of the biological opinion should be made and documented in the administrative record of the opinion. This subsequent analysis may have minor or major consequences

(worst case scenario) depending on the significance of the missing data to the effects determination. The action agency also should be advised that if and when additional data becomes available reinitiation of consultation may be required.

Handbook, at p. 1-7. Obviously in the present case, the Service did not consult with the pesticide registrants about its decision to complete the Draft Biological Opinion without considering the best available data bearing on its effects determination or the development of reasonable and prudent alternatives. Hence, although the Service may claim that its Draft Biological Opinion is deferential to the species, the Opinion is defective, in part, because the Service failed to comply with its own guidance.

V. Substantive Deficiencies in the Draft Biological Opinion

In addition to the procedural flaws just noted, the Draft Biological Opinion suffers from a number of important substantive defects as well. First, it appears that NMFS has based its risk assessment, in part, on use patterns for malathion (and associated exposures) that: (i) are not those approved for reregistration in the RED, (ii) do not occur in the action area, or (iii) are the subject of separate consultations under Section 7(a)(2) of the ESA. Second, the Service inappropriately excludes from consideration in its risk assessment mitigation measures that are required by EPA (or state agencies) for malathion registrations. Finally, and more broadly, NMFS fails to properly consider the most recent and relevant scientific data pertaining to malathion in its risk assessment. We address these deficiencies in more detail below.

A. The Draft Biological Opinion Does Not Reflect the Scope of EPA's Proposed Action in Reregistering Malathion

As discussed above, the appropriate Federal Action at issue here is EPA's approval of malathion uses for registration under FIFRA. NMFS acknowledges in the Draft Biological Opinion that, "in order to accurately capture EPA's proposed action, a comprehensive summary of all authorized uses from all labels with the specific [active ingredient] is needed." Draft BiOp at 17.

The malathion RED definitively identifies **all** use patterns for malathion that EPA has approved for continued registration in the United States. In that sense, the RED document describes the entire universe of EPA-approved use patterns for malathion. These approved uses, which should properly form the basis for the NMFS risk assessment, fall into three broad categories: agricultural uses, non-agricultural uses, and State and Municipal Public Health Mosquito Control Programs. We address these uses in more detail below.

1. Agricultural Uses

Malathion is approved for use on more than 100 agricultural use sites. The use on cotton accounts for approximately 90% of the total malathion applied to agricultural crops in the United States, and over 70% of the total acreage applied to agricultural crops. The vast majority of the use on cotton is associated with USDA's Boll Weevil Eradication Program (discussed more fully below). Another 3% is applied to alfalfa. No other crop accounts for more than 1 percent of the estimated pounds of malathion used in the U.S.

The use patterns that EPA has approved for the reregistration of malathion, along with all required label changes, can be found in the RED document in Table 30 (pages 101 -126) and Appendix A (pages 127-137). These sections from the RED are included in Appendix A to these comments (attached). In evaluating these approved uses, it is important to recognize that not all formulations are approved for use on all crops. In addition, not all use patterns are equally important in all of the states that comprise the Action Area (California, Washington, Oregon, and Idaho). Table 1, below, identifies the specific crop uses of malathion that are important in each of these states.

Table 1 Major Crop Uses of Malathion in The Action Area[2]

Crop*	California			Oregon			Washington			Idaho		
	1998	2000	2002	1998	2000	2002	1998	2000	2002	1998	2000	2002
Alfalfa	√	√	√							√	√	√
Almonds	√	√	√									
Apples						√	√		√			
Apricots		√	√									
Asparagus	√	√					√	√	√			
Avocados	√	√	√									
Barley	√	√	√					√	√			
Beans, succulent	√	√	√	√	√	√						
Beans, dry		√										
Beets (garden)		√	√									
Blackberry				√	√	√						
Broccoli	√	√	√									
Brussels sprout		√	√									
Cabbage	√	√	√									
Cantaloupe	√	√	√									
Carrots	√	√	√									
Cauliflower	√	√	√									
Celery	√	√	√									
Cherries, sweet				√	√	√	√	√	√			
Cherries, tart				√	√	√	√					
Citrus, other	√											
Collards			√									
Cotton												
Corn, sweet		√	√				√					
Cranberries							√	√	√			

[2] Source: USEPA-BEAD *Quantitative Usage Analyses for Malathion*, versions dated September 1998, July 19, 2000, and May, 6, 2002. Check marks correspond to states identified by EPA as being among the "States with Most Usage."

Crop*	California			Oregon			Washington			Idaho		
	1998	2000	2002	1998	2000	2002	1998	2000	2002	1998	2000	2002
Cucumber	√	√	√									
Dates		√	√									
Eggplant	√	√	√									
Figs		√	√									
Garlic	√	√	√									
Grapefruit	√	√	√									
Grapes	√	√	√				√	√	√			
Hay	√	√	√									
Kale			√									
Lettuce	√	√	√									
Mint				√			√					
Nectarines		√	√									
Leeks	√	√	√									
Limes	√											
Oats		√	√									
Onions	√	√	√	√	√	√		√	√	√	√	√
Oranges	√	√	√									
Pasture	√											
Peaches	√	√	√									
Pears	√						√	√	√			
Peas, dry	√		√				√	√	√	√	√	√
Peas, succulent	√		√			√			√			
Peppers, bell			√									
Peppers, hot	√	√	√									
Plums/prunes	√	√	√				√					
Potatoes					√	√				√	√	√
Pumpkin	√	√	√									
Radishes		√	√									
Raspberry				√	√		√	√	√			
Rice			√									
Rye	√	√	√									
Spinach	√	√	√									
Squash	√	√	√									
Strawberry	√	√	√			√			√			
Sugar beets	√	√	√									
Tomatoes	√	√	√									
Turnip	√											
Walnuts	√	√	√									
Watermelons	√	√	√									
Wheat												

a. Risk Reduction and Mitigation Measures

Cheminova has a firm and longstanding commitment to sound environmental stewardship. Some of our stewardship efforts have been directed toward paring back on our malathion registration by refining the registered use patterns to reflect the needs of growers, and canceling uses that have significant potential to contaminate urban waterways. These are discussed below.

b. Refining the Registered Use Patterns

In the early 1990's after Cheminova purchased the registrations for malathion, we and IR-4 developed a program to generate and submit magnitude of the residue data required by EPA to support food/feed residue tolerances. Prior to conducting these studies, growers were surveyed to identify the maximum use patterns needed (maximum single application rate, maximum number of applications per year, and the minimum retreatment intervals). The residue studies were carried out in accordance with the wishes of growers and to establish residue tolerances. The tested use patterns established the upper bound limits on the use patterns that were to be placed on all end-use labels.

In the late 1990's, EPA initiated its reevaluation of all older registered chemicals, including malathion. During that time, Cheminova worked with USDA, commodity groups, extension agents and growers to identify minimally acceptable use patterns for malathion for all of the labeled uses. From this effort, the following label changes were identified:

- 4 crop uses: growers could accept reduced maximum application rates;
- 69 crop uses: growers could accept reduced maximum number of applications allowed per year; and
- 29 crop uses: growers could accept reduced maximum application rate AND reduced maximum number of applications allowed per year.

The use patterns identified through this effort are essentially the same as those that are specified in EPA's July 2006 RED for malathion.

c. Cancellation of Certain Uses

In addition to the use pattern changes discussed above, and following issuance of the RED, Cheminova voluntarily requested cancellation of a number of approved uses for malathion, including:

- All direct animal and livestock treatments
- Animal kennels/sleeping quarters (commercial)

- Animal premises and barns used for dairy and livestock
- Cattle feedlots and holding pens
- Forest trees
- Golf course turf
- Residential lawns (broadcast)
- Grape, post-harvest use on raisin drying trays
- Safflower
- Sunflower, pre-harvest

A copy of this voluntary cancellation request, which was submitted to EPA in March of 2008, is included here as Appendix B.

It should be noted that many of the uses that we voluntarily cancelled are considered to be "urban uses". For example, malathion has historically been used as a broadcast treatment on homeowner lawns and on golf course turf. However, Cheminova decided during reregistration that it would not support these uses. Therefore, EPA is in the process of removing these uses from product labels. By voluntarily cancelling the use of malathion on homeowner lawns and golf course turf, Cheminova expects that potential risk of contamination of urban waters has been substantially reduced.

In addition to cancelling the above "urban" uses, we also agreed to restrict the malathion registrations for the following two uses that have a significant potential to contaminate waterways in the agricultural environment.

(i) Aquatic Food/Feed Uses

Malathion has historically been used on cranberries. However, Cheminova agreed during the reregistration process not to support this use.

As a result of the above action, the only aquatic food use supported by Cheminova for malathion is on rice. California is the only state in the action area that grows rice. However, the state of California has established restrictions on how malathion may be used on this crop. In particular, when malathion is used on rice in California, a 4-day holding time is mandated before releasing treated waters in order to protect aquatic life. Considering the short half-life of malathion, exposure to aquatic organisms has been substantially mitigated. Indeed, extensive water monitoring studies conducted by the California Department of Pesticide Regulation (CDPR) for rice pesticides (including malathion) have confirmed the effectiveness of this measure for reducing residues to established acceptable levels that are protective of aquatic life.

(ii) Forestry Uses

Malathion has historically been used, primarily by the U.S. Forest Service, for the control of forestry pests on a variety of deciduous and evergreen trees. However, Cheminova decided that it will not support this use for reregistration.

(iii) Home and Garden Uses for Malathion

Emulsifiable concentrate formulations of malathion are currently available to homeowners for outdoor uses on ornamental flowering plants, vegetable gardens, fruit trees, ornamental shrubs and ornamental trees. These products may also be used for homeowner mosquito control and as a perimeter treatment around residential buildings (limit 2 foot swath). Approved use rates are very low, ranging from 0.000085 lb ai/ft^2 to 0.0003 lb ai/ft^2. As mentioned above, we have requested the cancellation of malathion uses on residential lawns and golf courses.

To help NMFS understand the historical changes that have been or are being implemented on all malathion labels, we have prepared the following table to summarize these changes.

Table 2 Historical Summary of Malathion Use Patterns

Terrestrial Food Crop (Non-ULV Uses)			
Use Listed in the 1986 Registration Standard	**Application Values: Max. Application Rate (lbs ai/A) x Max. No. of Applics. Per Year x Retreatment Interval (days)**		
	Use Patterns Listed in 1986 Registration Standard	**Uses Patterns Supported by Cheminova Post-Registration Standard**	**New Use Patterns- July 2006 RED**
Alfalfa	2.5 x NS x NS	1.25 x 2/cutting x NA	1.25 x 2/cutting x NA
Almonds	8.0 x NS x NS	Not supported	Not supported
Anise	1.0 x NS x NS	Not supported	Not supported
Apple	15.0 x NS x NS	1.25 x 5 x 7	1.25 x 5 x 7
Apricot	10.0 x NS x NS	3.75 x 4 x 7	1.5 x 2 x 7
Asparagus	1.25 x NS x NS	1.25 x 9 x 7	1.25 x 2 x 7
Avocado	9.0 x NS x NS	4.70 x 2 x 30	4.70 x 2 x 30
Barley	1.25 x NS x NS	1.25 x 3 x 7	1.25 x 2 x 7
Beans (snap, green, kidney, cowpea, lima, navy, and wax)	1.75 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 7

Terrestrial Food Crop (Non-ULV Uses)			
Use Listed in the 1986 Registration Standard	**Application Values: Max. Application Rate (lbs ai/A) x Max. No. of Applics. Per Year x Retreatment Interval (days)**		
	Use Patterns Listed in 1986 Registration Standard	**Uses Patterns Supported by Cheminova Post-Registration Standard**	**New Use Patterns- July 2006 RED**
Beets (garden)	2.5 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 7
Blackberry	4.5 x NS x NS	2.0 x 4 x 7	2.0 x 3 x 7
Blueberry	2.5 x NS x 7	1.25 x 4 x 4	1.25 x 3 x 4
Boysenberry	4.5 x NS x NS	2.0 x 4 x 7	2.0 x 3 x 7
Broccoli	3.0 x NS x NS	1.25 x 5 x 7	1.25 x 2 x 7
Brussels sprout	3.0 x NS x NS	1.25 x 5 x 7	1.25 x 2 x 7
Cabbage	3.0 x NS x NS	1.25 x 10 x 7	1.25 x 6 x 7
Cantaloupe	2.25 x NS x NS	1.0 x 6 x 7	1.0 x 2 x 7
Carrot	2.0 x NS x NS	1.25 x 7 x 7	1.25 x 2 x 7
Cauliflower	3.0 x NS x NS	1.25 x 5 x 7	1.25 x 2 x 7
Celery	1.5 x NS x NS	1.88 x 6 x 5	1.88 x 6 x 5
Chayote root	Not listed	1.56 x 2 x 7	1.56 x 2 x 7
Chayote fruit	Not listed	1.88 x 3 x 7	1.75 x 2 x 7
Cherries, sweet	8.0 x NS x 10	3.75 x 6 x 7	1.75 x 4 x 3
Cherries, tart	8.0 x NS x 10	3.75 x 6 x 7	1.75 x 4 x 3
Chestnut	Not listed	5.0 x 4 x 7	2.5 x 3 x 7
Clover	2.5 x NS x NS	1.25 x 2/cutting x 14	1.25 x 2/cutting x 14
Collards	3.0 x NS x NS	1.25 x 10 x 7	1.25 x 3 x 7
Corn, field	1.5 x 5 x 5	1.25 x 3 x 7	1.0 x 2 x 7
Corn, sweet	1.5 x 5 x 5	1.25 x 5 x 5	1.0 x 2 x 5
Cotton (non BWEP)	7.25 x NS x 3	2.5 x 3 x 7	2.5 x 3 x 7
Cowpea forage and hay	Not supported	Not supported	Not supported
Cranberry	Not supported	Not supported	Not supported
Cucumber	1.88 x NS x 7	1.88 x 3 x 7	1.75 x 2 x 7
Currant	2.0 x NS x NS	2.0 x 4 x 7	2.0 x 4 x 7
Dandelion	2.0 x NS x NS	1.88 x 6 x 5	1.25 x 5 x 7
Dates	4.25 x NS x NS	4.25 x 6 x 7	4.25 x 5 x 7
Dewberry	4.5 x NS x NS	2.0 x 4 x 7	2.0 x 4 x 7
Eggplant	3.5 x NS x NS	3.43 x 5 x 5	1.56 x 4 x 5
Endive (escarole)	2.0 x NS x NS	1.88 x 6 x 5	1.25 x 2 x 7
Figs	2.5 x NS x NS	2.5 x 3 x 5	2.0 x 2 x 5
Filberts	3.0 x NS x NS		Not supported
Flax	0.583 x 1 x NA	0.5 x 1 x NA	0.5 x 3 x 7
Garlic	2.0 x NS x NS	1.56 x 5 x 7	1.56 x 3 x 7
Gooseberry	2.0 x NS x NS	2.0 x 4 x 7	2.0 x 4 x 7
Grapefruit	25 x NS x NS	6.25 x 3 x 30	CA: 7.5 x 1
Grapes	2.75 x NS x NS	1.88 x 2 x 14	1.88 x 2 x 14
Grasses, forage, fodder, and hay	2.0 x NS x NS	1.25 x 1/cutting/NA	1.25 x 1/cutting/NA
Guava	0.75 x NS x NS	1.25 x 13 x 3	1.25 x 13 x 3

Terrestrial Food Crop (Non-ULV Uses)			
Use Listed in the 1986 Registration Standard	**Application Values: Max. Application Rate (lbs ai/A) x Max. No. of Applics. Per Year x Retreatment Interval (days)**		
	Use Patterns Listed in 1986 Registration Standard	**Uses Patterns Supported by Cheminova Post-Registration Standard**	**New Use Patterns- July 2006 RED**
Horseradish	2.0 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 7
Kale	3.0 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 5
Kohlrabi	1.88 x NS x NS	1.25 x 5 x 7	1.25 x 2 x 7
Kumquat	25 x NS x NS	6.25 x 3 x 30	CA: 7.5 x 1
Leek	2.0 x NS x NS	1.56 x 5 x 7	1.56 x 2 x 7
Lentils	Not stated	Not supported	Not supported
Lemon	25 x NS x NS	6.25 x 3 x 30	CA: 7.5 x 1
Lespedeza	1.25 x NS x NS	1.25 x 2/cutting x 14	1.25 x 2/cutting x 14
Lettuce, head	2.0 x NS x NS	1.88 x 6 x 5	1.88 x 2 x 6
Lettuce, leaf	2.0 x NS x NS	1.88 x 6 x 5	1.88 x 2 x 5
Lime	25 x NS x NS	6.25 x 3 x 30	CA: 7.5 x 1
Loganberry	4.5 x NS x NS	2.0 x 4 x 7	2.0 x 2 x 7
Lupine	1.25 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 7
Macadamia nut	15.0 x NS x NS	0.94 x 7 x 7	0.94 x 2 x 7
Mango	0.75 x NS x NS	1.25 x 8 x 7	1.25 x 8 x 7
Melons (casaba, Crenshaw, honeydew, honeyball, muskmelon, and Persian)	1.88 x NS x NS	1.0 x 6 x 7	1.0 x 2 x 7
Mint	1.0 x NS x NS	0.94 x 3 x 7	0.94 x 3 x 7
Mushroom	1.5 x NS x 3	1.7 x 4 x 3	1.7 x 4 x 3
Mustard greens	3.0 x NS x NS	1.25 x 6 x 3	1.25 x 3 x 5
Nectarines	10 x NS x NS	3.75 x 4 x 7	3.0 x 3 x 7
Oats	1.25 x NS x NS	1.25 x 3 x 7	1.0 x 2 x 7
Okra	1.5 x NS x NS	1.5 x 6 x 7	1.2 x 5 x 7
Onions (bulb, green)	2.0 x NS x NS	1.56 x 6 x 7	1.56 x 2 x 7
Oranges	25 x NS x NS	6.25 x 3 x 30	CA: 7.5 x 1
Papaya	1.25 x NS x NS	1.25 x 13 x 3	1.25 x 4 x 3
Parsley	2.0 x NS x NS	1.88 x 6 x 5	1.88 x 6 x 5
Parsnip	2.0 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 7
Passion fruit	0.75 x NS x NS	1.25 x 8 x 7	1.0 x 8 x 7
Pasture grasses	1.875 x NS x NS	1.25 x 1/cutting x NA	1.25 x 1/cutting x NA
Peach	9.0 x NS x 10	3.75 x 5 x 11	3.0 x 3 x 11
Peanut	1.0 x NS x NS	Not supported	Not supported
Pears	15 x NS x NS	1.25 x 5 x 7	1.25 x 2 x 7
Peas (green)	2.5 x NS x NS	2.5 x 5 x 7	1.0 x 2 x 7
Peas (dry)	2.5 x NS x NS	2.5 x 5 x 7	1.0 x 2 x 7
Pea vine and hay	2.5 x NS x NS	2.5 x 5 x 7	Not supported
Pecan	12.5 x NS x NS	2.5 x 3 x 7	2.5 x 2 x 7
Peppers	1.5 x NS x NS	1.56 x 5 x 5	1.56 x 2 x 5

Terrestrial Food Crop (Non-ULV Uses)			
Use Listed in the 1986 Registration Standard	**Application Values: Max. Application Rate (lbs ai/A) x Max. No. of Applics. Per Year x Retreatment Interval (days)**		
	Use Patterns Listed in 1986 Registration Standard	**Uses Patterns Supported by Cheminova Post-Registration Standard**	**New Use Patterns- July 2006 RED**
Pineapple	5.0 x NS x NS	5.0 x 3 x 7	2.0 x 3 x 7
Plums/prunes	10 x NS x 7	Not supported	Not supported
Potatoes	3.0 x NS x NS	1.56 x 2 x 7	1.56 x 2 x 7
Pumpkin	1.88 x NS x 7	1.0 x 6 x 7	1.0 x 2 x 7
Quince	15 x NS x NS	1.25 x 5 x 7	1.25 x 5 x 7
Radish	2.0 x NS x 7	1.25 x 5 x 7	1.25 x 3 x 7
Rangeland grasses	2.0 x NS x NS	1.25 x NS x 7	1.25 x 2 x 7
Raspberry	4.5 x NS x NS	2.0 x 4 x 7	2.0 x 2 x 7
Rutabaga	2.5 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 7
Rye	1.25 x NS x NS	1.25 x 3 x 7	1.0 x 2 x 7
Safflower	1.25 x NS x NS	1.25 x 6 x 7	Not supported
Salsify	2.0 x NS x NS	1.25 x 5 x 7	1.25 x 3 x 7
Shallot	2.0 x NS x NS	1.56 x 5 x 7	1.56 x 2 x 7
Sorghum	0.938 x NS x NS	1.25 x 3 x 7	1.25 x 3 x 7
Soybeans	2.0 x NS x NS	2.0 x 4 x 7	Not supported
Spinach	2.0 x NS x NS	2.0 x 3 x 7	2.0 x 2 x 7
Squash, summer	1.88 x NS x 7	1.88 x 3 x 7	1.75 x 3 x 7
Squash, winter	1.88 x NS x 7	1.0 x 6 x 7	1.0 x 3 x 7
Strawberry	2.0 x NS x NS	2.0 x 6 x 7	2.0 x 4 x 7
Sugar beets	2.5 x NS x NS	Not supported	Not supported
Sweet potatoes	1.88 x NS x NS	1.56 x 2 x 7	1.56 x 2 x 7
Swiss chard	2.0 x NS x NS	1.88 x 6 x 5	1.25 x 3 x 5
Tangelo	25 x NS x NS	6.25 x 3 x 30	CA: 7.5 x 1
Tangerine	25 x NS x NS	6.25 x 3 x 30	CA: 7.5 x 1
Tomato (and tomatillo)	3.5 x NS x NS	3.43 x 5 x 5	1.56 x 4 x 5
Turnip	3.0 x NS x NS	1.25 x 5 x 7	Greens: 1.25 x 3 x 5 Roots: 1.25 x 3 x 7
Vetch	1.25 x NS x NS	1.25 x 2/cutting x 14	1.25 x 2/cutting x 14
Walnuts	12.5 x NS x NS	2.5 x 3 x 7	2.5 x 3 x 7
Watercress	2.0 x NS x NS	1.25 x 5 x 3	1.25 x 5 x 3
Watermelon	2.0 x NS x NS	1.0 x 6 x 7	1.5 x 4 x 7
Wheat	1.25 x NS x NS	1.25 x 3 x 7	1.0 x 2 x 7
Yams	Not listed	1.56 x 2 x 7	1.56 x 2 x 7

Terrestrial Food Crop (ULV Uses)			
Crop*	**Application Values: Max. Application Rate (lbs ai/A) x Max. No. of Applics. Per Year x Retreatment Interval (days)**		
	Labeled Use Patterns 1986 Registration Standard	**Supported Use Patterns 1986-2006**	**Proposed Use Patterns RED 2006**
Alfalfa	0.875 x NS x NS	0.61 x 2/cutting/14	0.61 x 2/cutting/14
Barley	1.25 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7
Beans, dry	0.61 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7
Beans, snap	0.61 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7
Blueberry	0.77 x NS x 7	0.77 x 5 x 10	0.77 x 3 x 10
Cherries, sweet	1.22 x NS x 10	1.22 x 6 x 7	1.22 x 4 x 7
Cherries, tart	1.22 x NS x 10	1.22 x 6 x 7	1.22 x 4 x 7
Clover	0.875 x NS x NS	0.61 x 2/cutting x 14	0.61 x 2/cutting x 14
Corn (sweet, field)	0.3 x 5 x NS	0.61 x 5 x 5	0.61 x 2 x 5
Cotton (BWEP only)	Not applicable	1.22 x 25 x 3	1.22 x 25 x 3
Cotton (non-BWEP)	1.22 x NS x NS	0.175 x 3 x 7	0.175 x 3 x 7
Flax	0.583 x 1	0.61 x 1	0.61 x 1
Grasses (Forage, fodder, and hay)	1.875 x NS x NS	0.92 x 1	0.92 x 1
Grapefruit	0.175 x 10 x NS	0.175 x 10 x 7	0.175 x 3 x 7
Kumquat	0.175 x 10 x NS	0.175 x 10 x 7	0.175 x 3 x 7
Lemon	0.175 x 10 x NS	0.175 x 10 x 7	0.175 x 3 x 7
Lime	1.25 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7
Oranges	0.175 x 10 x NS	0.175 x 10 x 7	0.175 x 2 x 7
Peas (peas, vines and hay)	0.61 x NS x NS	Not supported	Not supported
Rice (including wild rice)	2.0 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7
Rye	1.25 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7
Safflower	1.25 x NS x NS	Not supported	Not supported
Sorghum	0.938 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7
Soybeans	2.0 x NS x NS	Not supported	Not supported
Sugar beets	2.5 x NS x NS	Not supported	Not supported
Tangelo	0.175 x 10 x NS	0.175 x 10 x 7	0.175 x 3 x 7
Tangerine	0.175 x 10 x NS	0.175 x 10 x 7	0.175 x 3 x 7
Wheat	1.25 x NS x NS	0.61 x 3 x 7	0.61 x 2 x 7

Terrestrial Non-Food Crop			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Tobacco	Yes	No	No
Ornamental flowering plants	Yes	Yes	Yes
Ornamental lawns and turf	Yes	Yes	No*
Ornamental nursery stock	Yes	Yes	Yes
Ornamental woody plants	Yes	Yes	Yes
Pine seed orchards	Yes	Yes	Yes
Uncultivated non-agricultural areas	Yes	Yes	Yes**
Field and garden seeds	Yes	No	No

* Cheminova is not supporting the use of malathion ornamental lawns and turf for homeowners or on golf courses. Cheminova is supporting the use of malathion on turf farms.

**Supported only as part of USDA's Grasshopper Control Programs and for Public-health adulticide uses only (discussed in more detail below).

Aquatic Food Uses			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Cranberries	Yes (2.5 x NS x NS)	No	No
Rice (including wild rice)	Yes (2.0 x NS x NS)	Yes* (1.25 x 3 x 7)	Yes* (1.25 x 2 x 7)

* In CA, rice growers are required to hold water on their fields following application of rice pesticides that have been shown to be toxic to aquatic organisms and to ensure that established water quality targets such as Maximum Contaminant Levels (MCLs) are protected. The current holding time for malathion is 4 days. CA monitoring projects have shown this 4-day holding time to be adequate for malathion. Cheminova supports this requirement and recommends that it be carried out by all rice growers that decide to use malathion.

Aquatic Non-Food Uses			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard***	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Intermittently flooded areas			
Mosquito larvae	Yes	No	No
Mosquito eggs	Yes	No	No
Irrigation systems			
Adult mosquitoes	Yes	Yes	Yes
Mosquito larvae	Yes	No	No
Sewage systems			
For Moth fly larvae	Yes	Yes	No

* All labels must include the following general warnings and limitations: "Malathion is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. Do not apply directly to water except as specified on the label. Do not contaminate water by cleaning equipment or disposal of wastes. To be applied only by trained personnel of public health organizations, mosquito abatement districts, public mosquito control programs, and professional pest control operators." "Malathion will kill certain species of fish, particularly in shallow water."

Forestry			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Registrants Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Forest trees:			
Deciduous trees	Yes	Yes	No
Douglas fir	Yes	Yes	No
Eastern pine	Yes	Yes	No
Hemlock	Yes	Yes	No
Larch	Yes	Yes	No
Pines	Yes	Yes	No
Red pine	Yes	Yes	No
Spruce	Yes	Yes	No
True fir	Yes	Yes	No

Domestic and Non-domestic Outdoor			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Outdoor domestic dwellings	Yes	Yes	Yes*
Wide area and general outdoor treatment for flying insects	Yes	Yes**	Yes**
Around commercial and industrial buildings	Yes	No	No
Around agricultural buildings	Yes	No	No
Residential pressurized can formulations	Yes	No	No
Residential lawns (broadcast)	Yes	No	No
Residential dust formulations	Yes	No	No
Golf course turf	Yes	No	No

*Perimeter treatment limited to a 2-foot swath around domestic buildings.

**Supported for public health mosquito (adulticide) control programs only.

Greenhouse Food Crop			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Asparagus	Yes	No	No
Beans	Yes	No	No
Beets	Yes	No	No
Celery			
Cole crops (including broccoli, cabbage, kale, mustard greens, and turnips)	Yes	No	No
Corn	Yes	No	No
Cucumber	Yes	No	No
Eggplant	Yes	No	No
Endive	Yes	No	No
Lettuce	Yes	No	No
Melons	Yes	No	No
Mushrooms	Yes (1.5 x NS x 3)	Yes* (1.7 x 4 x 3)	Yes* (1.7 x 4 x 3)
Onion	Yes	No	No
Peas	Yes	No	No
Peppers	Yes	No	No
Potato	Yes	No	No
Radish	Yes	No	No
Spinach	Yes	No	No
Squash	Yes	No	No
Summer squash	Yes	No	No
Tomato	Yes	No	No
Watercress	Yes	No	No

*Cheminova is supporting the use of malathion on mushrooms grown in mushroom houses.

Greenhouse Non-Food Crop			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Epcot display crops	Yes	Yes	Yes
Ornamental plants	Yes	Yes	Yes

Indoor			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Stored commodity treatment:			
Almonds	Yes	No	No
Barley	Yes	Yes	Yes
Corn	Yes	Yes	Yes
field or garden seeds	Yes	No	No
grapes (post harvest use on raisin drying trays)	Yes	No	No
oats	Yes	Yes	Yes
peanuts	Yes	No	No
rice	Yes	Yes	Yes
rye	Yes	Yes	Yes
sorghum	Yes	Yes	Yes
sunflower	Yes	No	No
wheat	Yes	Yes	Yes
bagged citrus pulp	Yes	No	No
cattle feed concentrate blocks (non-medicated).	Yes	No	No
Direct animal and livestock treatments including pet and domestic animal uses for:			
beef cattle	Yes	No	No
cats	Yes	No	No
chickens	Yes	No	No
dairy cattle (lactating and non-lactating)	Yes	No	No
dogs	Yes	No	No
ducks	Yes	No	No
geese	Yes	No	No
goats	Yes	No	No
hogs	Yes	No	No
horses (including ponies)	Yes	No	No
pigeons	Yes	No	No
sheep	Yes	No	No
turkeys	Yes	No	No

Indoor (continued)			
Use Listed in the 1986 Registration Standard	**Use Patterns Listed in 1986 Registration Standard**	**Use Supported by Cheminova Post-Registration Standard**	**Use Supported by Cheminova – Reregistration**
Animal premise uses for:			
dairy and livestock barns, stables and pens	Yes	No	No
feed rooms	Yes	No	No
poultry houses	Yes	No	No
manure piles	Yes	No	No
garbage cans	Yes	No	No
garbage dumps	Yes	No	No
kennels	Yes	No	No
rabbits on wire	Yes	No	No
beef cattle feed lots and holding pens	Yes	No	No
cat sleeping quarters	Yes	No	No
dog sleeping quarters	Yes	No	No
Agricultural premise uses for:			
cull fruit and vegetable dumps	Yes	No	No
Household uses for:			
indoor domestic dwellings	Yes	No	No
human clothing	Yes	No	No
mattresses	Yes	No	No
Commercial and industrial uses for:			
bagged flour	Yes	No	No
cereal processing plants	Yes	No	No
dry milk processing plants	Yes	No	No
eating establishments	Yes	No	No
food processing plants	Yes	No	No
packaged cereals	Yes	No	No
pet foods	Yes	No	No
feed stuff	Yes	No	No

d. Other Mitigation Measures Intended to Protect Aquatic Habitats

In addition to the above-mentioned use pattern changes, the RED also includes the following requirements intended to help protect sensitive aquatic habitats:

- All end-use labels for agricultural uses require one of the following statements concerning buffer zones for aerial applications:

  "When making a Non-ULV application with aerial application equipment, a minimum buffer zone of 25 feet must be maintained along any water body"

"When making a ULV application with aerial application equipment, a minimum buffer zone of 50 feet must be maintained along any water body"

- The following Environmental Hazards Statements on all the manufacturing use product labels:

  "This pesticide is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

- The following Environmental Hazards Statements on all the end use product labels:

  "This pesticide is toxic to aquatic organisms, including fish and invertebrates."

  "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

  "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff after application. Use care when applying in or to an area which is adjacent to any body of water, and do not apply when weather conditions favor drift from target area. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product."

  "A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours."

- The following statements must appear on all the end use product labels for products used for Wide Area Mosquito Adulticide Applications:

  "Do not apply more than 0.23 lbs ai/acre/day. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne diseases in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort."

"When applying as a wide area mosquito adulticide, before making the first application in the season, it is advisable to consult with the state or tribal agency charged with primary responsibility for pesticide regulation to determine if other regulatory requirements exist."

"When applying as a wide area mosquito adulticide, do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body."

Pursuant to the NMFS regulations at 50 C.F.R. § 402.14(g)(8), these risk mitigation measures and the recent voluntary cancellations and use pattern modifications described above (as well as any other mitigation measures required under the RED) must be considered by NMFS as it prepares its Biological Opinion.[3]

2. Non-Agricultural Uses

Appendix A to the malathion RED lists the following non-agricultural use sites as approved uses for malathion. These approved uses also fall within the scope of the Agency Action and should be included in any exposure evaluation and risk assessment performed by NMFS as part of the Biological Opinion.

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[3] The regulations at 50 CFR § 402.14(g)(8) provide as follows:

In formulating its biological opinion, any reasonable and prudent alternatives, and any reasonable and prudent measures, the Service will use the best available scientific and commercial data available and will give *appropriate consideration to any beneficial actions taken by the Federal agency or applicant, including any actions taken prior to the initiation of consultation.* (emphasis added)

Non-Agricultural Use Sites				
Site	Form	Maximum Single Application Rate	Unit	Use Pattern Limitations
Agricultural, uncultivated areas	Non-ULV	1.0	Lb ai/A	
	ULV	0.1875		
Christmas tree plantations	Non-ULV	3.2	Lb ai/A	Maximum of 2 applications per year. 12 hr restricted reentry interval
	ULV	0.9375		
Cull piles	Non-ULV	6.857	Lb/1000 ft^2	Drench
Drainage systems	Non-ULV	0.625	Lb/2.5 gal	
Fence rows/hedge rows	Non-ULV	0.2439	Lb/1000 ft^2	
Grain/cereal/flour bins (empty)	Non-ULV	0.4762	Lb/1000 ft^2	Contact or surface treatment
	Non-ULV	5	Lb/25 gal	
Grain/cereal/flour elevators (empty)	Non-ULV	0.4762	Lb/1000 ft^2	Contact or surface treatment
	Non-ULV	5	Lb/25 gal	
Greenhouse (empty)	Non-ULV	0.0434	Lb/1000 ft^2	Apply as needed, 7 day minimum retreatment interval Soil treatment by sprayer
Household/domestic dwellings (perimeter outdoor only)	Non-ULV	0.2439	Lb/1000 ft^2	Application is limited to the structure base and a 2 ft wide swath from the structure base.
Intermittently flooded areas	Non-ULV	0.5078	Lb ai/A	
	ULV	0.232	Lb ai/A	
Non-agricultural outdoor building structures	Non-ULV	0.2057	Lb/1000 ft^2	
Non-agricultural rights-of-way/fencerows	ULV	0.9281	Lb ai/A	
Non-agricultural uncultivated areas/soil	Non-ULV	0.6	Lb ai/A	
	ULV	0.9281		
Ornamental and/or shade trees	Non-ULV	2.5	Lb/100 gal	Maximum of 2 applications per year. 10 day minimum retreatment interval. 12 hr restricted reentry interval
Ornamental herbaceous plants	Non-ULV	2.5	Lb/100 gal	12 hr restricted reentry interval
Ornamental non-flowering plants	Non-ULV	2.5	Lb/100 gal	
Ornamental woody shrubs and vines	Non-ULV	2.5	Lb/100 gal	Maximum of 2 applications per year/growing cycle. 10 day minimum re-treatment interval. 12 hr restricted reentry interval.
Pine seed orchards	Non-ULV	0.9375	Lb ai/A	Maximum of 2 applications per

Non-Agricultural Use Sites				
Site	Form	Maximum Single Application Rate	Unit	Use Pattern Limitations
	ULV	0.9375		year/growing season. 7 day minimum re-treatment interval. 12 hr restricted reentry interval
Refuse/solid waste containers (outdoors)	Non-ULV	0.2439	Lb/1000 ft^2	
Refuse/solid waste sites (outdoors)	Non-ULV	0.2439	Lb/1000 ft^2	
Swamps/marshes/stagnant water	Non-ULV	0.5075	Lb ai/A	
Wide Area – Public Health Use	ULV	0.23	Lb ai/A	Label must comply with PR-Notice 2005-1, and additional requirements outlined in the Label Table.

1: Not all formulations are supported by data, only those formulations supported by data will elegible for reregistration.

3. Public Health Mosquito Control Programs

Officials responsible for State and local mosquito control programs make decisions to use pesticides based on an evaluation of the risks to the general public from diseases transmitted by mosquitoes or on an evaluation of the nuisance level that communities can tolerate from a mosquito infestation. Based on surveillance and monitoring, mosquito control officials select specific pesticides and other control measures that best suit local conditions in order to achieve effective control of mosquitoes with the least impact on human health and the environment.

Chemical or Biological Measures to Control Mosquitoes

Controlling mosquitoes at the larval stage

Larvicides target larvae in the breeding habitat before they can mature into adult mosquitoes and disperse. Liquid larvicide products are applied directly to water using backpack sprayers and truck or aircraft-mounted sprayers. Tablet, pellet, granular, and briquet formulations of larvicides are also applied by mosquito controllers to breeding areas. Larvicides used include: bacterial insecticides, insect growth inhibitors, mineral oils and monomolecluar films, as well as the chemical pesticides methoprene and temephos. **Importantly, malathion is not approved for reregistration as a larvacide.**

Controlling Adult Mosquitoes

Adult mosquito control may be undertaken to combat an outbreak of mosquito-borne disease or a very heavy nuisance infestation of mosquitoes in a community. Pesticides registered for this use are known as adulticides and are applied either by aircraft or on the ground, employing truck-mounted sprayers. State and local agencies commonly use the organophosphate insecticides malathion and naled and the synthetic pyrethroid insecticides permethrin, resmethrin, and sumithrin for adult mosquito control.

Mosquito adulticides are mostly applied as ultra-low volume (ULV) aerial sprays. ULV sprayers dispense very fine aerosol droplets that stay aloft and kill flying mosquitoes on contact. ULV applications involve small quantities of pesticide active ingredient in relation to the size of the area treated, typically less than 3 ounces per acre, which minimizes exposure and risks to people and the environment. Thus, adulticides can be used for public health mosquito control programs without posing unreasonable risks to the general population or to the environment when applied according to the pesticide label.[4]

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[4] For more information on pesticides commonly-used in public health mosquito control programs, see the following EPA fact sheets:

Malathion for Mosquito Control: http://www.epa.gov/pesticides/health/mosquitoes/malathion4mosquitoes.htm

Larvicides for Mosquito Control: http://www.epa.gov/pesticides/health/mosquitoes/larvicides4mosquitoes.htm

Naled for Mosquito Control: http://www.epa.gov/pesticides/health/mosquitoes/naled4mosquitoes.htm

In mosquito control programs, malathion is applied by aircraft as an ultra-low volume (ULV) spray at a maximum rate of 0.23 pounds (or about 2.5 fluid ounces) of active ingredient per acre. The EC formulation may also be applied by ground via a non-thermal fogger (9.9 lb ai/gallon) or thermal truck foggers (0.51 lb ai/gallon). These applications involve small quantities of pesticide active ingredient in relation to the size of the area treated, which minimizes exposure and risks to people and the environment.

In mosquito control programs, malathion is applied as an ultra-low volume (ULV) spray at a maximum rate of 0.23 pounds (or about 2.5 fluid ounces) of active ingredient per acre. ULV applications involve small quantities of pesticide active ingredient in relation to the size of the area treated, which minimizes exposure and risks to people and the environment.

Risk Mitigation Measures

The label approved for reregistration by EPA for the public health uses of malathion specifies the following:

> FOR USE ONLY BY FEDERAL, STATE, TRIBAL, OR LOCAL GOVERNMENT OFFICIALS RESPONSIBLE FOR PUBLIC HEALTH OR VECTOR CONTROL, OR BY PERSONS CERTIFIED IN THE APPROPRIATE CATEGORY OR OTHERWISE AUTHORIZED BY THE STATE OR TRIBAL LEAD PESTICIDE REGULATORY AGENCY TO PERFORM ADULT MOSQUITO CONTROL APPLICATIONS, OR BY PERSONS UNDER THEIR DIRECT SUPERVISION.

This legally-enforceable restriction ensures that malathion is applied only by highly trained professionals who understand that they have a legal obligation to apply pesticides only in accordance with the EPA-approved labels.

EPA has also required that all malathion labels include the following restrictions to minimize potential effects on wildlife, including threatened and endangered species:

"ENVIRONMENTAL HAZARDS

> This pesticide is toxic to fish, aquatic invertebrates, and aquatic life stages of amphibians. Runoff from treated areas or deposition of spray droplets into a body of water may be hazardous to aquatic organisms.
>
> Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.
>
> This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area, except when applications are made to

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Synthetic Pyrethroids: http://www.epa.gov/pesticides/health/mosquitoes/pyrethroids4mosquitoes.htm

prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.

Do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body. Do not contaminate bodies of water when disposing of equipment rinsate or washwaters."

EPA has concluded that "when applied in accordance with the rate of application and safety precautions specified on the label, malathion can be used to kill mosquitoes without posing unreasonable risks to human health or the environment." See EPA Fact Sheet, *Melathion for Mosquito Control,* available on the internet at the following url: http//www.epa.gov/pesticides/health/mosquitoes/malathion4mosquitoes.htm.

State Agencies

In addition to the restrictions required by EPA on the pesticide label, States may impose their own lawful restrictions. Because these state and local laws and regulations can play an important role in determining what pesticides are used, when they are used, and what restrictions are imposed when pesticides are selected, Cheminova urges NMFS to consult with relevant State regulatory agencies, as well as local vector control agencies, to identify applicable restrictions for adult mosquito control operations occurring within the Action Area.

A few examples of how the individual states may be involved with mosquito control operations are provided below.

Washington State

In Washington State, Chapter 70.22 RCW establishes a statewide program for the control or elimination of mosquitos as a health hazard. The secretary of health coordinates plans for mosquito control work which may be projected by any county, city or town, municipal corporation, taxing district, state department or agency, federal government agency, or any person, group or organization, and arrange for cooperation between any such districts, departments, agencies, persons, groups or organizations.

Because of the coordinated efforts and technical expertise needed to effectively maintain surveillance and control over mosquitoes, the Department of Ecology recommended that communities actively support the formation of mosquito control districts. There are currently fourteen mosquito control districts within the State of Washington, with new ones being considered. Most of the districts are in Eastern Washington, but several have been formed in Western Washington. The activities of these districts are regulated by the Washington State

Departments of Agriculture and Ecology, and the Department of Ecology has established a set of Best Management Practices that must be used in these programs (see: http://www.ecy.wa.gov/pubs/0310023.pdf).

California

In California, mosquito control agencies are regulated under various provisions of the California Health and Safety Code and the Food and Agriculture Code. For example, Vector control technicians working at a vector control agency must be "certified" or work under the direct supervision of a "certified technician" to apply pesticides. Vector control technicians achieve certification through an examination process administered by the California Department of Public Health. In addition, Vector control agencies cannot use any pesticide not registered for use in California, and are required to keep detailed records of each pesticide application, including date, location, and amount applied. All pesticides must be applied in accordance with the labeling of the product as registered with the EPA. *See* 7 U.S.C. § 136v(b); 3 CCR 6243.

Vector control agencies also have authority to participate in review, comment, and make recommendations regarding local, state, or federal land use planning and environmental quality processes, documents, permits, licenses, and entitlements for projects and their potential effects with respect to vector production. California Health and Safety Code Section 2041.

Conclusion

In preparing its risk assessment for public health mosquito control uses, NMFS should recognize that malathion is only approved for reregistration as an adulticide. In addition, the Service should consider restrictions and risk mitigation measures imposed by EPA (through the approved label), as well as additional restrictions and risk mitigation measures that may be imposed by the states and/or the local vector control agencies in the Action Area.

4. Other-Uses of Malathion in the United States

As discussed above, the RED document sets out the entire universe of malathion uses that EPA has approved for reregistration under FIFRA. For the reasons given previously, these uses should be the basis for the Services' consultation.

In addition to the EPA-registered uses just discussed, there are a limited number of Malathion uses that are not covered by registrations issued by EPA, and therefore are not addressed in the malathion RED. These uses, which are generally limited to United States Department of Agriculture (USDA) sponsored programs, should be excluded from consideration in the Biological Opinion.

As discussed in more detail below, some of these USDA-sponsored program uses involve products that are used pursuant to "emergency exemptions" under Section 18 of FIFRA.

Under Section 18, EPA may allow a pesticide to be used for a use that is not registered under FIFRA, for a limited amount of time, if the Agency determines that an emergency condition exists.[5] Section 18 emergency exemptions may be requested by a state or federal agency when there are no available pesticide products that are registered for the specific use pattern at issue. They are granted on a case-by-case basis, for a limited period of time, to address the emergency situation only. As discussed in more detail later, most pest control programs that use (or could potentially use) malathion under a Section 18 emergency exemption are themselves subject to the consultation requirements of Section 7(a) of the ESA. Therefore, including these uses in the current Biological Opinion would be duplicative and unwarranted – particularly in light of the fact that the current consulation is remedial in nature – to cover past failures to consult. Obviously, for section 18 exemptions that were the subject of consultations, there is nothing to remedy. Finally, because Section 18 exemptions are granted for a limited time, an exemption that has already expired (and, more specifically, an unregistered malathion use that might have been permitted under the expired Section 18 exemption) can and should not be the subject of post-hoc review in this Biological Opinion.

In addition, some malathion products that are used in USDA-sponsored programs are not registered by EPA, but are allowed pursuant to "Special Local Need registrations" ("SLNs") registered by states under Section 24(c) of FIFRA. That section allows individual States to register additional uses of a federally registered pesticide product, or register a new end use product, in order to meet a "special local need."[6] When a State issues a Section 24(c) registration it notifies EPA, which then has an opportunity to disapprove the State registration. If EPA does not **disapprove** the State registration within 90 days, it becomes effective as a federal registration under FIFRA. Failure to disapprove and approval are fundamentally different actions, and failures to disapprove therefore should not fall within a consultation focused expressly on "EPA's registration of the uses (as described by product labels) of all pesticides containing [malathion]" BiOp at 16. Again, as discussed in more detail below, many of the pest control programs that use SLN registrations – including for malathion -- are themselves subject to the consultation requirements of Section 7(a) of the ESA. Therefore, including these uses in the current Biological Opinion would be duplicative and unwarranted. Moreover, because Special Local Need registrations are issued by the States, there is a real question as to whether the issuance of a SLN for a malathion use constitutes federal "Agency Action" and whether such SLNs are appropriate to consider as part of this consultation.

Finally, there are a limited number of USDA-sponsored program uses that involve EPA registered products (and that, therefore, ***are*** addressed under the RED). However, because these products are employed in federal programs that have already been subject to the review and consultation process required by ESA Section 7(a), it would be duplicative to consider them in this consultation, and outside the scope of a consultation intended to remedy past failures to consult.

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[5] EPA's regulations define an "Emergency Condition" to mean an urgent, non-routine situation that requires the use of a pesticide(s), and for which no effective registered pesticide is available and no viable alternative practices will provide adequate control. *See* 40 C.F.R. § 166.3.

[6] A "special local need" is defined as "an existing or imminent pest problem within a state for which the state . . . has determined that an appropriate federally registered pesticide product is not sufficiently available." 40 C.F.R. §162.151.

These USDA-sponsored program uses are discussed in more detail below.

USDA-APHIS Sponsored Programs

There are several programs initiated and managed by the USDA Animal and Plant Health Inspection Service (APHIS) that have used or may in the future use pesticide products containing malathion. These include:

- The Boll Weevil Eradication Program ("BWEP")
- Exotic Fruit Fly Suppression Programs
- Rangeland Grasshopper/Mormon Cricket Suppression Programs

As discussed, many of these programs are already subject to the consultation requirements of Section 7(a) of the ESA. Moreover, even if these programs were not subject to independent ESA review, they still would not be appropriate for consideration as part of the current EPA action, since (i) the programs use products that are not registered under FIFRA, and/or (ii) these programs no longer operate within the action area in CA, OR, WA, and ID. More detailed information regarding each of these USDA-APHIS programs follows.[7]

Boll Weevil Eradication Program (BWEP)

Background

The boll weevil (Anthonomus grandus), a native of Mexico and Central America, became established in Sothern Texas between 1892 and 1894. From that point of initial establishment, the weevil spread rapidly northward and eastward into the northeast limits of the U.S. Cotton Belt in North Carolina and Virginia. The weevil also spread westward into cotton-growing areas of the Southwestern U.S. and California. In 1985, an eradication program was begun in the Southwest. The original program covered 233,000 acres in southern California, western Arizona, and Northwest Mexico, and was eventually expanded to include all of the cotton growing areas California and Arizona.

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[7] For more information regarding these programs, NMFS is encouraged to contact the following:

Robert M. Baca, Ph.D.
Team Leader, Environmental Compliance
USDA - APHIS - PPQ
4700 River Road, Unit 150
Riverdale, MD 20737-1236
301-734-7592, FAX: -3308
Mobile: 301-526-8521

Relevance to the Biological Opinion

Relationship to the Action Area

Of the four states included in the action area for threatened and endangered salmonid species, cotton is grown only in California. Therefore, the BWEP uses are only relevant to California. Within the state of California, there are three regions where cotton is grown: the San Joaquin Valley, the Southern Desert Valleys, and the Sacramento Valley; however the BWEP has not been in operation in California for at least seven years.

Products used in the Program

The BWEP program utilizes a registered ULV product, with an EPA-approved supplemental label specifically intended for the BWEP uses. A copy of this supplemental label is included here as Appendix C.

Consultations Under the Program

The BWEP has not been in operation in California since at least 2001 (and it was **never** active in Oregon, Washington or Idaho). As a result, no consultation regarding federally protected species has been required on the part of APHIS. Should program operations be resumed in California, appropriate consultation with FWS and/or NMFS will be initiated under ESA Section 7(a)(2)..

Existing Mitigation Measures

All boll weevil eradication programs operate under operational procedures and mitigation measures specified in the program's Programmatic Environmental Impact Statement("PEIS"), which would have to be considered as part of any risk analysis for these programs. A summary of BWEP operational procedures and mitigation measures is included here as Appendix E. Some of the key provisions of the BWEP procedures that are specifically relevant to protected species include the following:

1. All control operations will be conducted with appropriate concern for their potential impact on endangered, threatened, and proposed species identified in this document.
2. APHIS has prepared a biological assessment for federally listed endangered, threatened and proposed species found within all U.S. cotton-producing counties from species information provided by the U.S. Department of the Interior, Fish and Wildlife Service (FWS) and State wildlife agencies.
3. Adequate protection measures are developed for federally listed endangered, threatened and proposed species through the Endangered Species Act, section 7, formal and informal consultations with FWS. Specific biological and distributional data for species is gathered in discussions between APHIS, Plant Protection and Quarantine, local FWS offices, State wildlife agencies and the Foundation before operations begin.

4. Species and habitats protected by State laws are addressed in site-specific assessments as needed.

These operational procedures and mitigation measures have been adopted for, and are an integral part of, the cooperative Boll Weevil Eradication Program. They were printed originally in the programmatic environmental impact statement, and were revised in 2005.

Conclusions

Because APHIS evaluates the potential effects of the BWEP program and engages in formal and informal consultations with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service as required under ESA Section 7(a), this program should not considered part of the EPA action and should not be included in the Biological Opinion. Moreover, because no future malathion applications are anticipated to be made as part of the BWEP in California, this program is not a threat to endangered or threatened salmonid species in this state; and since cotton is not grown in Oregon, Washington, or Idaho, malathion applications made as part of the BWEP are not applicable to listed salmonid species in these states. Finally, if USDA-APHIS were to initiate BWEP activities within the any of action areas, the required ESA consultations would be conducted, in accordance with the established program Operational Procedures and ESA regulations.

Exotic Fruit Fly Suppression Programs

Background

Fruit flies of the family Tephritidae are among the most destructive pests of fruits and vegetables around the world and pose a significant risk to agriculture in the United States. During a portion of their lifetime, Tephritidae fruit flies live and feed inside fruit, causing economic losses from spoiling and destruction of the host commodity. They are known to attack more than 400 host plants. In addition to lost production, establishment of these pest species in the United States would also result in costs associated with implementing control measures, increased pesticide usage, and loss of markets due to restrictions on shipment of host commodities.

California and Florida are at highest risk from exotic fruit fly establishment. This conclusion is based on the historical record of frequent outbreaks and the costs to eradicate them; the high approach rate of unmitigated fruit fly host material at the major ports of entry coinciding with the climatic conditions favorable to establishment of reproducing populations; public opposition to chemical control measures; and the availability of hosts. The market value of exotic fruit fly host commodities totaled about $7.2 billion in the United States in 2002, with approximately $5.1 billion of that grown in California and $1.8 billion in Florida.

Relevance to the Biological Opinion

Relationship to the Action Area

USDA has conducted its Fruit Fly Eradication Programs only in California and Florida; no similar programs have been conducted in Washington, Oregon or Idaho.

Products used in the Program

Pesticide treatments for these fruit fly programs have generally been conducted either as an emergency exemption under Section 18 of FIFRA, or using Section 24(c), special local need (SLN) products. EPA-registered products are also used in this program. Approved product labels for pesticides to be used in this program, including those for malathion, are available at the following url: http://cdfa.ca.gov/phpps/pe/InteriorExclusion/ current_product_labels.html

Consultations Under the Program

According to USDA-APHIS, each year that a fruit fly program is initiated in a specified area, it consults the California Natural Diversity Database to determine if there are any federally listed endangered or threatened species within the targeted program area. When such species are identified, APHIS prepares an environmental assessment to determine if the program action is likely to adversely affect the listed species. If a "may effect" determination is made, then consultation is requested with the FWS and/or NMFS, consistent with Section 7(a) of the ESA. This requirement is typically incorporated into the program's site-specific environmental assessment documents

Existing Mitigation Measures

APHIS responds to exotic fruit fly risks with an integrated system that incorporates surveillance activities, fruit fly control programs, and regulatory actions. This multi-tactical approach is the product of close collaboration and consultation among APHIS and its exotic fruit fly program cooperators and stakeholders. In 2001, APHIS finalized its *Fruit Fly* Cooperative *Control Program. Final Environmental Impact Statement;* this document can be accessed online at http://www.aphis.usda.gov/plant_health/ea/downloads/fffeis.pdf. As indicated on page 236 of this document, APHIS implements standard program protective measures in order to eliminate or reduce environmental impacts of its fruit fly programs. A summary of these measures, which include standard operational procedures and recommended program mitigative measures, is included here as Appendix E. In addition, the most recent *site-specific* environmental assessments for these fruit fly programs, which typically will summarize program adjustments made specifically for the targeted action areas, are available online at the following url: http://www.aphis.usda.gov/plant_health/ea/fruitfly.shtml.

According to USDA-APHIS, although malathion is identified as an option for use in these programs, it is no longer a preferred option.

Conclusions

Because APHIS evaluates the potential effects of the Fruit Fly Eradication programs and engages in formal and informal consultations with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service as required under ESA Section 7(a), these programs should not be considered part of the EPA action and should not be included in the Biological Opinion. Moreover, pesticide treatments that are conducted as emergency exemptions under FIFRA Section 18 or using Section 24(c) SLNs, rather than EPA-registered products should **not** be considered part of EPA's proposed action; nor should they be included in the NMFS risk assessment as part of the Biological Opinion for the reasons discussed previously. Finally, future malathion applications are not planned under these programs. However, if USDA-APHIS were to initiate a program utilizing malathion, the required ESA consultations would be conducted.

USDA-APHIS Rangeland Grasshopper/Mormon Cricket Suppression Program

Background

Rangeland is an important agricultural resource that is used mainly for livestock production. In rangeland ecosystems in the Western United States, grasshoppers and/or Mormon crickets (hereafter referred to collectively as grasshoppers) are a natural component of the biota. Grasshoppers have the potential for sudden and explosive population increases that can destroy rangeland forage and devastate rangeland habitats. Grasshopper outbreaks are usually preceded by several years of gradual increases in grasshopper numbers, followed by a year in which conditions favor grasshopper development. Outbreaks are difficult to predict because they depend greatly on climatic variables that cannot be predicted. The intensity of grasshopper outbreaks depends largely on the rate of population increase the previous year and temperature and moisture conditions at the time of hatching and early nymphal development.

To assist in predicting where potential grasshopper outbreaks may occur, USDA-APHIS conducts annual surveys of grasshopper populations. If an outbreak develops, contact and coordination is made with involved landowners, land managers, and federal, state and local government officials. In response from landowners/managers, APHIS would determine if an outbreak has reached an economically or environmentally critical level. If so, an appropriate treatment program would be developed, taking into account additional site-specific information.

Relevance to the Biological Opinion

Relationship to the Action Area

USDA-APHIS, in conjunction with other federal agencies, State Departments of Agriculture, Native American Tribes, and private individuals have initiated, and may initiate in the future, grasshopper suppression programs to protect rangeland from economic infestations in 17 Western States; Arizona, California, Colorado, Idaho, Kansas, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, and Wyoming.

Products Used in The Grasshopper/Mormon Cricket Suppression Program

According to APHIS, the following registered pesticide products are labeled for rangeland and may be selected for the treatment of grasshoppers in this program:

a. Sevin XLR plus
b. 2% or 5% Carbaryl bait
c. Dimilin 2L
d. ULV malathion

The program uses these products in accordance with restrictions on the registered product labels as well as any additional program-specific or site-specific restrictions and operational procedures.

Consultations Under the Program

Beginning in 1987, APHIS has consulted with FWS on a national level for the Rangeland Grasshopper Cooperative Management Program. Biological Opinions (BO's) were issued annually by FWS from 1987 through 1995 for the national program. Between 1995 and 2002 only a small number of suppression programs were conducted. These programs were performed in accordance with the 1995 Biological Opinion. They also avoided areas where the potential could exist to affect species that were either listed or proposed for listing since 1995.

In 2002, APHIS prepared an Environmental Impact Statement (EIS) to support potential grasshopper suppression programs on rangeland in the 17 Western States (available at: http://www.aphis.usda.gov/import_export/plants/manuals/domestic/downloads/eis.pdf). The EIS was prepared in accordance with the requirements of the National Environmental Policy Act (NEPA) (42 U.S.C. § 4321 et seq.). The EIS considered the potential for environmental impacts from APHIS grasshopper suppression programs in all or part of the 17 Western States.

On March 1, 2000 APHIS requested Endangered Species Act (ESA), Section 7 consultation for the Rangeland Grasshopper Cooperative Management Program, to include all 17 Western States, from FWS's Region 1 which is the designated lead region for this consultation. In February 2005 APHIS presented a Programmatic Biological Assessment (BA), along with a threat matrix, for all listed species, to FWS for comment. FWS responded in June 2005 with a request for more information on toxicity data, buffer models, and long-term effects from these programs. Although this National Consultation is proceeding, a Biological Opinion will not likely be issued in time for grasshopper suppression programs in 2008. Therefore, it was deemed necessary to consult on a state by state basis for those states where the potential exists for grasshopper suppression programs. Informal local consultations were completed for the state of Oregon in 2003-2007, resulting in annual concurrences from FWS on program activities. A new consultation and FWS concurrence was requested for 2008 in which APHIS requested a written response from FWS concurring with the "no effect" and the "not likely to adversely affect" determinations in the Biological Assessment for listed species and their critical habitat within the targeted suppression areas.

USDA reports that malathion has not been used in the Grasshopper/Mormon Cricket Suppression Program in California, Oregon, Washington, or Idaho since at least 2001. As a result, no consultations with FWS and/or NMFS have been required specifically for the use of malathion. However, treatments with other program chemicals were conducted in 2007 in Oregon and Idaho. Concurrence letters from NMFS for these programs are provided in Appendix F.

Additionally, after obtaining species lists from FWS and NMFS for federally protected species in Washington State, the USDA determined (as noted in their Environmental Assessment for 2007) that the program would have no effect on any protected species in the potential treatment area:

> Thus far, only Mormon cricket hatching bed treatments using carbaryl bran bait are anticipated. These treatments will be in dry rangeland areas where no federally listed endangered or threatened species occur at this time. Local consultation with Federal land managers, FWS, NMFS and State wildlife biologists will precede any type of treatment to discuss protective or mitigating measures for species of concern.

As a result of the 'no effect' determination on federally protected species, consultation with the Services was not required and not undertaken for the program in Washington.

Existing Mitigation Measures

Details about the grasshopper suppression programs were discussed in the 2002 EIS, which states, among other things, that APHIS intends to conduct site-specific assessments as each program is initiated. These assessments will consider protection of sensitive areas and organisms that are unique to each program area. The most recent example of this procedure can be found at the following url: http://www.oregon.gov/ODA/PLANT/IPPM/gh_ea08.shtml.

The operational procedures that were established for the grasshopper suppression programs in Oregon in 2008 can be found online at the following url: http://www.oregon.gov/ODA/PLANT/docs/pdf/ippm_gh_ea_app1_08.pdf.

Conclusions

Because APHIS evaluates the potential effects of the Grasshopper/Mormon Cricket Suppression Program and engages in formal and informal consultations with the U.S. Fish and Wildlife Service and/or the National Marine Fisheries Service as required under ESA Section 7(a), these programs should not be considered part of the EPA action and should not be included in the Biological Opinion.

B. NMFS Has Not Based its Draft Biological Opinion on the Best Available Scientific Data

In developing its assessment, NMFS failed to properly take account of the most relevant and appropriate data pertaining to malathion and relied, instead, on unwarranted assumptions and unsupported interpretations of available data and modeling. In this section we address a number of critical flaws in the science that NMFS applied in developing its risk assessment for malathion.

- Malathion uses: As already discussed, the BiOp should properly use the malathion RED as the basis for identifying the use patterns that have been approved by EPA and that constitute the "federal action." Because NMFS has not done this, the BiOp places inappropriate emphasis on monitoring data for uses that are ***irrelevant*** to Pacific salmonids.

- Review of environmental fate of malathion: The BiOp provides very little discussion of the environmental fate of malathion and its metabolites. However, such information is critical to understanding the potential for malathion to impact salmonid species.

- Monitoring data: A lot of monitoring data exist for malathion. Some of these data are relevant for salmonid species and correspond with currently allowed uses. However, some of the data are based on uses that are no longer supported or are for highly specialized, and rarely employed uses. Overall, there needs to be more spatial relevance to the evaluation of the data; the data need to be ranked in regards to how closely they reflect salmonid habitat.

- Limitation of modeling analyses: To supplement the monitoring data, NMFS has employed a variety of modeling analyses to estimate environmental concentrations of malathion. These modeling analyses greatly overestimate environmental concentrations as compared to the extensive monitoring data. The flaws and limitations of the modeling analyses are discussed.

- Toxicity to salmonid and salmonid prey species: Malathion has been registered for use as an insecticide in the United States since 1956 and there is extensive literature on its ecotoxicity. These studies are of varying quality and relevance to the current malathion formulation. However, the BiOp does not sufficiently differentiate the quality of the different studies and instead relies on the salmonid study with the lowest LC_{50} value.

- Impact of ambient mixtures: The document contains speculative statements about the effects of ambient mixtures (i.e., two or more of the subject pesticides are present simultaneously). The underlying analyses for these statements contain several flaws.

- Critique of the population model: NMFS employed a population model to estimate the percent of salmonid species that would be affected by different concentrations of malathion based on malathion toxicity to salmonids and salmonid prey. However, the toxicity inputs to the model for malathion are based on an old, irrelevant salmonid study and an outdated estimate of the variability in prey toxicity.

One of the overarching themes of these comments is that NMFS failed to consider the likelihood of any effects occurring. Throughout the document, the discussion reduces to analyzing the highest conceivable concentrations of malathion combined with the lowest conceivable effect levels. There is little or no attempt to place these results in context and to consider the likelihood of any of the effects actually occurring. Given the large amount of information that is available, NMFS should pursue a more probabilistic-based assessment.

Another overarching theme is the selection of appropriate scientific data to use for the risk assessment. In pesticide regulatory activities, the "gold standard" is a Guideline study under FIFRA or a similar type of international regulation. These studies are performed according to established protocols that were developed with extensive collaboration of qualified scientists. The documentation for the studies is extensive and the reports and findings are subjected to review and scrutiny by the Agency (or international body) before being accepted. Of paramount importance here, these studies include full testing of product purity so that future users of the data can compare the purity with the products currently on the market.

1. Environmental Fate Profile

Malathion degrades very quickly in the environment. In the EPA guideline aerobic soil metabolism study, the half-life was 0.2 days (EPA, 2005). Also, in the guideline aerobic aquatic metabolism study, the half-life was 1.1 days in the water phase and 2.6 days in the sediment phase (EPA, 2005). The rapid degradation of malathion in the environment needs to be considered when evaluating monitoring results. The monitoring data represent instantaneous grab samples from the water column. For the highest concentrations detected, it is reasonable to infer that the concentration at that point in space will be lower if it was averaged over a longer period such as 4-days, which corresponds to the length of the acute toxicity testing.

However, the BiOp raises issues about the formation of malaoxon, the primary biological metabolite of malathion and the form of malathion that is the toxic agent in the human and animal body. The BiOp states that "time course studies on malaoxon production on sand and soil show malaoxon concentration relative to initial malathion were 1.4% after 10 days on sand and 10.7% days after 21 days on soil." The BiOp also references to a high concentration (100 ppb) of malaoxon in surface water runoff. Though not noted in the BiOp, this concentration value is from a California EPA report concerning the APHIS Medfly program in California, which uses a bait formulation that is not used in agricultural pest control.

The 10.7% malaoxon conversion value noted above is from a California EPA report and it is not a field study. This study was conducted under controlled conditions in a greenhouse on a very low organic content soil (0.6%) with a low moisture content (1%). Due to difficulty obtaining the target deposition rate of malathion, the malathion was applied in a heavily diluted slurry containing 10,000:1 bait/malathion, to which 15% water had been added. In contrast, bait and malathion are typically mixed in a ratio of 4:1. The study report notes that following application, all matrices were covered with a film of bait mixture as opposed to the discrete droplets that would be associated with an application in the field. The authors indicated that the influence of this extreme bait/malathion ratio might have on malathion degradation rates is not known and requires further study. Comparison of the dissipation half-life of malathion on

tomatoes measured in this study (4 days) to those measured in dislodgeable foliar residue (DFR) studies[8] on grapes (1.6-2 days), apples (1.5 days), squash (1.2 days), blackberries (1.8 days) and nursery stock (1.7 days) further demonstrates that the controlled conditions of this study and the application of a slurry likely altered the behavior of the malathion. The applied mixture (i.e., a slurry) and the method of application (i.e., covering the test matrices with a film of slurry) raise questions about the relevance of these data to even the Medfly program, where a bait formulation was used, to public health spraying programs or agricultural uses where the bait is not used. The California study data have no relevance to agricultural uses.

Looking past the California bait study, it is clear that malaoxon is rarely formed and only at low levels in the guideline malathion fate studies. The maximum level formed in any of the guideline studies was 1.8% of the parent compound. The primary degradates of malathion in soil and in water are the dicarboxylic acid of malathion, the beta monocarboxylic acid, and the alpha monocarboxylic acid of malathion. Also, dimethyl monoacid and dimethyl diacid were found in the aerobic aquatic metabolism study. There are fish toxicity studies that evaluate the effects of the major metabolites which are discussed later.

EPA summarized the situation in the RED on page 48:

> "The Agency does not believe that the conditions necessary for the formation of malaoxon exist such that residues of malaoxon will be found in or on the food sources for terrestrial wildlife. Malaoxon can enter surface water via urban runoff when malathion converts to malaoxon and is washed off by rainfall. However, the Agency does not expect malaoxon to be a significant component of the ecological hazard of malathion to non-target organisms. While other degradates and impurities of malathion exist, they too are not expected to be present in the environment at concentrations high enough to contribute to the toxicity of malathion to nontarget organisms."

Also, like malathion, malaoxon is not persistent. It degrades particularly quickly through hydrolysis, with an 8.8 day half-life at a pH of 7 and a 0.2 day half-life at a pH of 9 (Shepler, 2004). The half-life in soil has been reported to be 4-5 days (Paschal and Neville,1976). (included as Exhibit H).

2. Monitoring Data Relevant to Salmonid Species

The BiOp provides a review of available monitoring data, but the review is incomplete and there is no effort made to assess the probability of any given concentration occurring. Furthermore, some of the highest concentrations are from wide-area aerial applications of the malathion bait over urban areas that were made as part of the California Medfly eradication program. As discussed above, aerial spraying of malathion for Medfly eradication has not occurred since 1994 and Cheminova has notified APHIS that it is not supporting this use, except

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[8] The malathion DFR and postapplication occupational exposure studies, which were submitted to EPA by the Agricultural Reentry Task Force, have been assigned the following MRID numbers: 450059-10, 454919-01, 451382-02, 454919-02, 451382-01, and 454695-01.

for smaller-scale agricultural applications. Therefore, these monitoring data are not relevant to the future use of malathion. Furthermore, most malathion in the U.S. is used in the Boll Weevil eradication program. The last application in the areas of interest occurred in 1991 in California. No further applications are planned and the USDA has stated that the boll weevil has been eradicated in California (see usage section). A discussion of some of the major data sources follows.

It is important to first mention that all water monitoring data presented in this section are from grab samples. This means that the measured concentrations represent only instantaneous values. Given that the acute toxicity data are based on 96-hour tests, the comparison of these instantaneous measurements to the toxicity results is inappropriate, in light of the short half-life of malathion (see environmental fate section).

a. Washington State Monitoring in Salmonid-Bearing Streams

The most relevant monitoring program is the Washington State Department of Agriculture study of salmonid-bearing streams (Burke et al., 2006; Anderson et al., 2007). The sampling was designed "to address the pesticide presence in Endangered Species Act (ESA)-listed, salmonid-bearing streams during typical pesticide-use periods." These data are not discussed in the BiOp. Measurements were made in two watersheds, including an urban watershed, Ceder-Sammamish (Thornton Creek), and an agricultural watershed, Lower Yakima (Marion drain, Sulphur Creek Wasteway, Spring Creek). Thornton Creek was selected due to "prior salmonid habitat enhancement efforts and the occurrence of pre-spawning mortality of coho salmon." The Lower Yakima sites were sampled due to "the predominance of agriculture within these drainages" and "their use by summer steelhead." Therefore, this sampling program provides data for pesticides in streams occupied by endangered salmonid species. The report notes that malathion is used on alfalfa, apples, asparagus, cherry, corn, mint and wheat in the Lower Yakima watershed.

The data are summarized in Table 2, below. The detection rates for malathion range from 0-30%, with median concentrations ranging from 0.014-0.034 ppb. The peak concentrations ranged from 0.020-3.1 ppb. The 3.1 ppb value was an outlier; the next highest value was 0.034 ppb.

The BiOp does not present these data, although this dataset is likely the most important dataset for this assessment.

Table 2. Malathion detections in salmonid-bearing streams in Washington state (all concentrations in ppb).

Site	2003			2004			2005			2006		
	Freq	Med	Max	Freq	Med	Max	Freq	Med	Max	Freq	Med	Max
Thornton Creek	0%	---	---	0%	---	---	0%	---	---	0%	---	---
Marion Drain	10%	0.014	0.024	20%	0.028	3.1	30%	0.021	0.021	13%	0.018	0.018
Sulphur Creek Wasteway	5%	0.020	0.020	13%	0.016	0.024	10%	0.023	0.023	0%	---	---
Spring Creek	5%	0.013	0.013	16%	0.012	0.030	3%	0.034	0.022	6%	0.015	0.034

b. Other Surface Water Monitoring Data

The BiOp presents some other surface water monitoring data from the areas of interest, including data from the United States Geological Survey (USGS) National Water Quality Assessment (NAWQA) program and the California Department of Pesticide Regulation (CDPR). However, there is more data from Oregon, Idaho and Washington state that should be considered. The relevant data are summarized in Table 2. These data are generally consistent with the Washington salmonid monitoring program. The peak detection was in the NAWQA database of 1.4 ppb.

Table 3. Surface water monitoring data in the areas of interest

Monitoring Program	Detection Rate	Mean (ppb)	Maximum (ppb)
NAWQA (CA, ID, OR, and WA) (1992-2006)	6% (n=4350)	0.049	1.4
CDPR	6% (n=1370)	0.054	0.42
Oregon[9]	n/a n>200		1 sample > 0.1 ppb
Idaho[10]	n/a	n/a	1.2
Washington State "small streams" study[11]	n/a	n/a	A few detects >0.1 ppb

[9] http://www.oregondeq.com/wq/assessment/rpt0406/search.asp.

[10] http://www.agri.state.id.us/Categories/Environment/water/waterPDF/swreports/WeiserFlat-Surface-Water-%20Pesticide-2007.pdf.

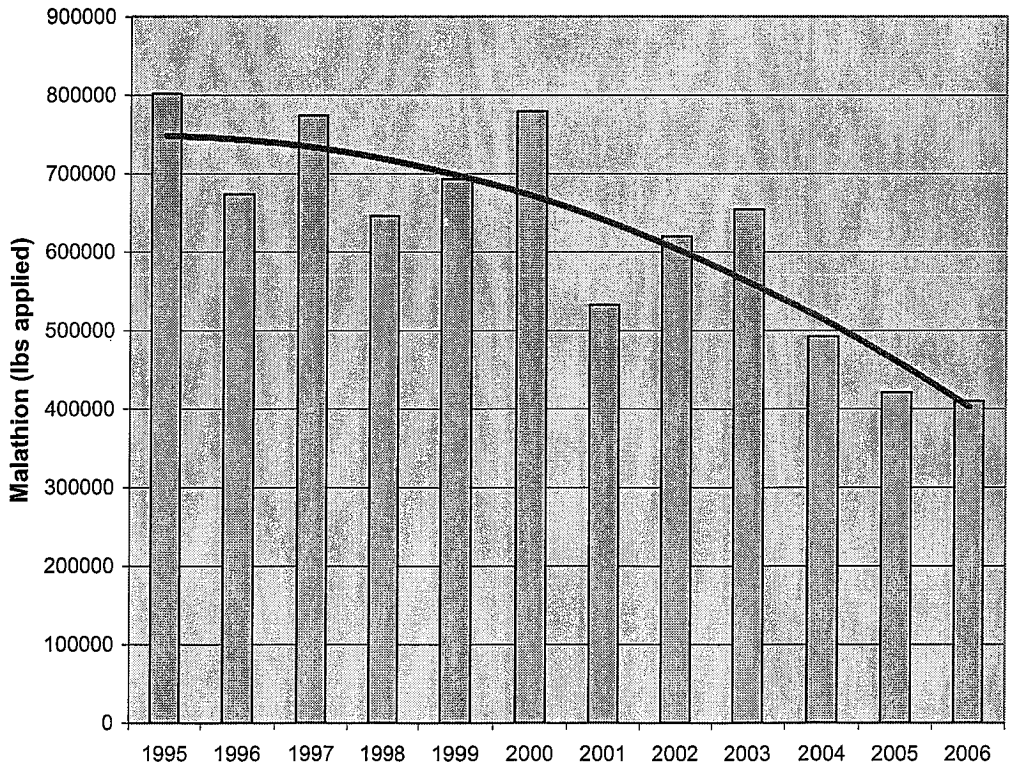
c. Irrelevant Monitoring Data

The BiOp also presents data related to urban uses from NAWQA (peak=9.6 ppb), the Boll Weevil eradication program (peak=49 ppb), Medfly program (peak=1000 ppb), a mosquito control program from the 1970s (peak=69 ppb), and a 1980s grasshopper control program (peak=85 ppb). However, most of these data are not relevant (Boll Weevil and Medfly) because future applications are not expected to occur, or less relevant (urban) because urban uses are declining (see usage section). Also, the allowable uses for mosquito control have changed significantly and there is no information in the BiOp about how malathion was applied in this 1970s program. The grasshopper control use is still supported, but under very strict use limitations that were not in place in the 1980s.

d. Usage History

It is important to consider that malathion usage is declining in the states that are a part of this action. California compiles very detailed usage data. The trend in malathion usage in California since 1995 is displayed in Figure 1. The usage in 1995 was approximately 800,000 lbs, whereas the usage in 2006 was about half at approximately 400,000 lbs. Thus, any detections found in the earlier periods must be evaluated in the context of the higher usage.

Figure 1. Trend in malathion usage in California



[11] http://wa.water.usgs.gov/pubs/fs/fs067/pest.a.html

e. Summary of Monitoring Data and Context

The peak concentrations from the most relevant programs range from 0.4-3.1 ppb. Typical detected concentrations are around 0.01-0.03 ppb. These are the most appropriate data to consider for risk assessment. Most of the measurements were taken during periods where malathion usage was larger; therefore, the current concentrations are surely lower.

3. Limitations of Modeling Methodologies

NMFS has relied on several modeling methodologies to estimate concentrations of malathion in salmonid habitats. The key question is whether these modeling methods provide reliable estimates of malathion concentrations for salmonid habitats. The BiOp provides estimates of malathion using several different modeling methodologies:

- NMFS extracted estimated environmental concentrations (EECs) from the malathion RED using the PRZM-EXAMS model for 11 crop scenarios. These estimates were developed by EPA's Environmental Fate and Effects Division (EFED).

- Additional model runs were performed by NMFS using the first-tier GENEEC model for cherries, onions, and strawberries.

- For public health, including mosquito and fly control, EPA's "interim rice model" and the AGDISP spray drift model were used.

a. PRZM-EXAMS Modeling

The PRZM-EXAMS modeling performed by EPA is generally considered to be "worst-case" and provides substantial overestimates of actual pesticide concentrations in the environment. For malathion, EPA reported peak (1-day average) concentrations ranging from 7.8 ppb (alfalfa in California) to 77.4 ppb (citrus in California). However, as discussed in the last section, across thousands of measurements, the peak concentration for relevant usages was 3 ppb. Nonetheless, NMFS takes the viewpoint that the PRZM-EXAMS concentrations are not sufficiently conservative. For example on p.213, NMFS states that "several lines of evidence discussed below suggest that EECs in the BEs may underestimate exposure of some listed organisms and designated critical habitat" and that "monitoring data suggest that some individuals are likely to be exposed to concentrations greater than predicted with the PRZM-EXAMS estimates." However, as discussed in the last section, monitoring data for relevant uses provide substantial evidence that the modeling estimates substantially overestimate environmental concentrations. It's only for the irrelevant and unsupported uses, such as Medfly spraying (direct spraying over large urban areas) or for the Boll Weevil Eradication Program (allows up to 25 applications per year), where the concentrations exceed any of the modeling estimates. The models were not designed to estimate concentrations for these uses, so these high measurements do not provide validation of the models.

There are several aspects of EPA's PRZM-EXAMS modeling that are worth reviewing to place the results into proper context.

Nature of the PRZM-EXAMS Scenario

EFED assumes that pesticide from an application to a 10 hectare field drains (from runoff and erosion) into a 1 hectare farm pond, with spray drift from 1 hectare of the field also falling into the pond. As the standard scenario used by EFED for its aquatic risk assessment, the farm pond scenario forms the basis of the EFED assessment. All of OPP's exposure estimates only apply to this farm pond. However, the farm pond scenario is very unrealistic and irrelevant for salmonid exposures, as salmonids do not reside in farm ponds. Some of the numerous reasons why the farm pond scenario is conservative and results in unrealistic estimates of pesticide exposures for the aquatic risk assessment include:

- Farm ponds only represent one type of water body that supports aquatic life, and is likely to have a less diverse biota than other more common aquatic water bodies, such as natural ponds, lakes, and streams. EFED should have developed a set of scenarios that include lakes and streams to develop more representative estimates of the concentrations of pesticides in water bodies that support aquatic life. This point is particularly relevant for salmonids, which reside in lakes and rivers.

- The farm pond is a relatively small water body (100x100 meters), and is shallow (2 meters deep) allowing for only a small amount of dilution of the pesticide runoff and spray drift.

- The field is assumed to be directly adjacent to the farm pond. In actual situations, there is generally a buffer between the field and the farm pond that would reduce the concentration of pesticide in the runoff and reduce the amount of spray drift that would fall into the farm pond. The USDA has provided a thorough summary of the impact of buffer strips on reducing runoff levels (USDA, 2000). While results are variable across the different studies that were reviewed, the percent of pesticide trapped in buffer strips ranges from 10-100% for pesticides with K_{oc} values similar to malathion (plot strips from 15-100 feet).

- All runoff from the 10 hectare field is assumed to drain into the farm pond. For most farm ponds, less runoff would be drained into the farm pond.

- The wind is assumed to be perpendicular to the part of the field where spray drift is falling into the farm pond, which will not always occur.

- The farm pond is assumed to be static, meaning there are no inflows or outflows of water that would remove or dilute pesticide concentrations. If EFED had developed scenarios for lakes and rivers, where salmonids reside, there would be inflows and outflows that would dilute pesticide concentrations. For example, there may be some inflows and outflows to a lake from other water bodies. In a river, any pesticide runoff would be transported and dispersed downstream and likely encounter other sources of dilution.

EFED's use of the farm pond scenario assures that the aquatic risk assessments will be highly conservative, and is irrelevant for salmonids.

Unrealistic Assumptions About Environmental Fate

One of the most important variables in assessing the environmental fate of a pesticide and the expected concentration of a pesticide in surface waters is the soil dissipation rate. EFED estimates the soil half-life in its malathion modeling using a laboratory aerobic soil metabolism study. In Cheminova's aerobic soil metabolism study, malathion degraded with a half-life of 0.2 days. EFED's policy is to multiply the half-life by three to account for differences between soils. However, when applying this procedure, EFED lists the half-life as <1 day, instead of 0.2 days. EFED then multiplies this value of one day by three to arrive at a half-life of three days. If EFED had correctly applied its procedures, the conservative half-life used for modeling should be 0.6 days.

EFED requires registrants to conduct two terrestrial field dissipation studies to quantify dissipation in actual field environments. However, EFED ignores the field dissipation data in its modeling analysis, and instead focuses solely on the laboratory measurements. The field dissipation data are a more reliable measure of dissipation in the environment than laboratory data. The available terrestrial field dissipation data for malathion are consistent with the aerobic soil metabolism study. In a field dissipation study in Georgia (Rice, 1990a; Jacobson, 1992a; Severn, 1993), malathion degraded too quickly to quantitatively determine a half-life, but the half-life was clearly less than one day. In a field dissipation study in California (Rice, 1990b, Jacobson, 1992b), the dissipation half-life was less than 0.2 days. These terrestrial field dissipation data are consistent with the half-life measured in the aerobic soil metabolism study. However, EFED stubbornly insists on relying on laboratory studies (with a 3X adjustment) instead of the clearly more relevant field measurement data.

To illustrate the impact of the conservative assumption made by EFED for the soil dissipation, we performed PRZM/EXAMS modeling for malathion using a 0.2 day half-life (the value from the aerobic soil metabolism study) and a 0.6 day half-life (three times the aerobic soil metabolism value). Using the 0.2 day half-life, the peak EECs were reduced by as much as 90 percent with typical application rates, and 90 percent with maximum application rates. Using the 0.6 day half-life, the peak EECs were reduced by as much as 53 percent with typical application rates, and 56 percent with maximum application rates. These results are still highly conservative estimates of actual environmental concentrations because the estimates were developed using EFED's farm pond scenario, and indeed still exceed the measured concentrations. However, the revised analysis presented in this section shows that altering just one of EFED's many conservative assumptions dramatically changes the results of the analysis.

"90th Percentile" Estimates

EFED describes its modeling results as a "90th percentile," and NMFS cautions users that 90th percentile values may not be sufficiently conservative (p.214 of BiOp). This designation is very misleading. It implies that 10 percent of the surface water bodies might

actually have higher concentrations than estimated by EFED, when, in fact, EFED's modeling estimates of the "90th percentile" are substantially higher than any actual measured concentration. EFED's modeling estimates are not "90th percentile" values, but are actually concentration values that would, at best, be seen in nature only extremely rarely. The major reasons why EFED's estimates are not "90th percentiles" are as follows:

- To derive probabilistic exposure estimates (e.g., a 90th percentile), it is necessary to model all key variables as distributions that reflect the range of plausible values for each variable. However, the only probabilistic variable in EFED's modeling is the meteorology (most importantly rainfall). High-end or implausible assumptions are made for most other key variables, such as the soil dissipation (see previous subsection). The compounding effect of these multiple, conservative assumptions is an implausible exposure estimate.

- Before estimating a "90th percentile," EFED first determines the highest daily pesticide concentration (or longer-term concentrations for non-acute exposures) for each year in a 30-40 year period. EFED then calculates the 90th percentile from these 30 to 40 values. Therefore, for a 40 year period, EFED's "90th percentile" is actually a concentration that would only be exceeded on three days in 40 years (or a 1 in 10 year event). On a daily basis, this estimate would actually be a 99.97th percentile. In other words, the concentration estimated by EFED would be less for 99.97 percent of days, assuming all of the other components of the modeling were correct (which they are not).

- For environmental fate parameters that account for the dissipation of the pesticide, EFED makes a high-end, worst-case assumption in almost every case. In particular, EFED significantly overestimated the soil dissipation half-life for malathion (see previous subsection).

- Because EFED only uses the farm pond scenario for its ecological modeling instead of a scenario for a water body with more extensive aquatic life, the "90th percentile" only applies to farm ponds directly adjacent to a 10-hectare field that slopes into the farm pond. Concentrations for other water bodies, particularly ones that salmonids reside in, are likely to be far lower.

Concentrations in flowing water bodies are likely to be substantially different. Immediately upon entering the water body, the chemical will begin to disperse from the turbulence of the river flow. Furthermore, malathion dissipates quickly in aquatic systems, as discussed earlier. Thus, not surprisingly, the concentrations found in the relevant surface water monitoring studies show substantially smaller concentrations than those predicted by PRZM-EXAMS.

Context Provided by EPA

EPA largely agrees that its modeling analyses are highly conservative. The purpose of EPA's methods is to estimate worst-case concentrations for purposes of evaluating the

registration of new chemicals and the reregistration of existing chemicals. As Dr. Norman Birchfield of EPA's Environmental Fate and Effects Division wrote in his declaration in the lawsuit that resulted in this consultation:

> The screening models, when used according to standard operating procedures with adequate data, generally predict EECs that are higher than most, if not all, analogous concentrations in the environment resulting from labeled uses. (Birchfield, 2003).

This discussion shows that the modeling estimates should be approached with skepticism. The estimates provide no rational scientific basis to override the extensive monitoring results that are available.

b. GENEEC

NMFS also applied the EFED GENEEC model to estimate concentrations resulting from use on cherries, onions, and strawberries. The peak concentrations ranged from 40.1-88.6 ppb and the 60-day average concentrations ranged from 6.2-13.7 ppb. While these concentrations are not much different than those estimated by PRZM-EXAMS, GENEEC is considered a lower-tiered, less refined model than PRZM-EXAMS and its estimates are likely to be even more inflated.

c. Direct Overspray into Aquatic Habitats

NMFS reports that "Direct overspray of standing water is permitted for control of mosquito larvae using malathion." Table 35 of the BiOp provides modeling estimates for direct overspray with different depths of water. However, the use of malathion as a mosquito larvacide is not an approved use in the malathion RED, so it is not relevant to a forward-looking risk assessment.

Malathion use as a mosquito adulticide is supported for reregistration, but the RED specifies the following label language:

> "Do not apply more than 0.23 lbs ai/acre/day. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne diseases in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.
>
> When applying as a wide area mosquito adulticide, before making the first application in the season, it is advisable to consult with the state or tribal agency charged with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.

> When applying as a wide area mosquito adulticide, do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body."

Therefore, applications over water can only occur under weather conditions that are favorable to dispersion of the malathion to minimize deposition into the water body. Also, applicants are advised to consult with regulatory authorities.

The modeling estimates provided by NMFS assume worst-case deposition into the water body and are not appropriate given the revised label language in the RED. Most state programs do not allow malathion to be directly applied over water except during public health emergencies.

d. Rice Usage

NMFS also references some results from EPA's interim rice model. However, malathion is used very infrequently on rice. Only about 3000 lbs of malathion were used on rice in California in 2006 of a total of more than 5.5 million lbs of pesticide use on rice[12]. The other states considered in the BiOp are not large rice-growing areas.

Also, the modeling results fail to account for the use restrictions in place in California. Malathion use on rice in California is permitted, but CDPR requires a 4-day holding time before releasing treated waters in order to protect aquatic life (CDPR, 2002). Considering the short half-life of malathion, exposure is substantially mitigated with this holding period.

e. Pesticide Drift into Aquatic Habitats

NFMS also calculated estimates for incidental drift from applications near aquatic habitats. NMFS used the AgDrift model to estimate concentrations in surface waters of different depths and for different application rates. The malathion RED states:

> "To further reduce potential exposure to both non-target fish and aquatic invertebrates, the technical registrant has agreed to add instructions to product labels to reduce potential off-target drift to aquatic areas, including requirements for a 25 foot buffer zone along aquatic areas for all non-ULV aerial applications, and a 50 foot buffer zone along aquatic areas for all ULV aerial agricultural applications."

The BiOp should include these use restrictions in its evaluation of this potential exposure pathway.

Also, the BiOp states that the AgDrift estimates "represent mean projected drift." However, this statement is misleading. The estimates assume that the wind is exactly

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[12] http://www.cdpr.ca.gov/docs/pur/purmain.htm

perpendicular to the water body, thus resulting in worst-case deposition. Also, the probability of the event that NFMS modeled must be considered. The water body needs to be directly adjacent to the field (or at the specified buffer distance), the application must occur when salmon are present in the off-channel habitat, and when the wind is blowing in the right direction.

f. EPA's More Realistic Estimates for the OP Cumulative Assessment

EPA developed more realistic modeling estimates for the OP Cumulative assessment. The estimates developed in this assessment were for drinking water but apply to surface water concentrations as the result of the similar methodologies that were employed.

The principal differences between the modeling estimates in the individual chemical assessments and the cumulative assessment were:

- Typical usage rates were assumed, instead of the maximum label use patterns.

- Instead of the farm pond scenario, EFED used its index reservoir scenario, which includes some dilution by inflows and outflows. The index reservoir scenario is actually more realistic for exposures to salmonids that reside in moving water bodies than the farm pond scenario because it includes some inflows and outflows.

- Cumulative adjust factors (CAFs) were applied to adjust for the amount of usage of particular compounds in each region of the assessment. The use of CAFs moves away from the consideration of only the concentrations of pesticide in a water body directly adjacent to a field immediately after the application. While the use of CAFs limit the utility of estimating the absolute worst-case concentrations that occur immediately after runoff and/or spray drift from application adjacent to a water body, the use of the CAFs allows for a more representative profile of the concentrations of pesticide expected across a watershed. Thus, these estimates would be ideal for a probabilistic assessment.

The estimates derived in the cumulative assessment much more closely reflect the measurement data. EFED estimated a "maximum" malathion surface water concentration of 0.015 ppb for the Northwest Fruitful Rim (i.e., the Pacific Northwest) and a maximum concentration of 0.0083 ppb for the North Central Valley Fruitful Rim (i.e., includes parts of California and Nevada, including Sacramento). These values are dramatically lower than the estimates in malathion assessment that are cited in the BiOp. EFED notes, for the North Central Valley Fruitful Rim, "when compared to detections from streams in agricultural watersheds only, the estimated concentrations of chlorpyrifos and malathion were similar to reported NAWQA detections ..." Given the better agreement with the monitoring data, NMFS should include the OP Cumulative assessment modeling estimates in the assessment.

4. Toxicity to Salmonid and Salmonid Prey Species

a. Salmonid Toxicity

NMFS states that the "acute toxicity studies reported indicate that freshwater fishes exposed to malathion or formulations containing malathion die following 96 h exposures in the low µg/L range" (p.252). NMFS reports a range of LC_{50}s for salmonids of 4.1-174 ppb. This range is cited in the diazinon RED chapter, but presumably the correct source is the EFED RED chapter for malathion. Also, the lower end of the range is cited as 1.5 ppb in Table 50, but there is no mention of an LC_{50}=1.5 ppb for fish survival. We assume that this is an error.

The value at the low end of the range (LC_{50}=4.1 ppb) is for rainbow trout (*oncorhynchus mykiss*) and is referenced to a review document by Mayer and Ellersieck (1986) in EPA's online Pesticide Ecotoxicity Database (ECOTOX). However, Mayer and Ellersieck only provide a listing of toxicity values for numerous chemicals; the citations for most of the values, including this one for malathion, are not available. A thorough literature search was conducted, but the original citation of the study with the LC_{50}=4.1 ppb could not be located. The ECOTOX database includes the following admonition: "It is recommended that users consult the original scientific paper to ensure an understanding of the context of the data retrieved from the ECOTOX database." Given that the original study cannot even be located, it is not appropriate to rely on this study for risk assessment purposes. In fact, it is impossible to argue that this constitutes the use of best available science as is required in the consultation.

There is another rainbow trout study from 1968 that gives a similar LC_{50}. A review of this study shows why one must be wary of relying on older open literature studies. Smith and Grigoropoulus (1968) reported an LC_{50} of 2.8 ppb for a 96-hour rainbow trout exposure. Apparently, the formulation used in that test contained only 57% malathion. No information was provided about the other components of the formulation (the other 43%). Furthermore, no information is given about the purity of the malathion used to make the formulation, or the identity of the impurities in that formulation. Given the unknown impurity content of the formulation, this study is not adequate for use in risk assessment.

The European Union (EU) dossier discusses the issue of malathion impurities in regard to ecological risk assessment (EU, 2008):

> Malathion toxicity to vertebrates is highly influenced by the impurity pattern of the material. Therefore detailed information on the composition of the test batch is important when evaluating the results of toxicity testing on malathion in relation to birds ... Malathion is a non-systemic organophosphorous insecticide of low mammalian toxicity primarily exerting its toxic effect via inhibition of acetyl cholinesterase activity. Highly purified malathion has very low toxicity. However, all technical grades of malathion, as well as all malathion formulations will inevitably contain various impurities leading to higher toxicity of the material. The majority of the impurities occur during the manufacturing process. Also, storage conditions may affect the composition of the material.

Over the years, a wide range of impurities have been reported in malathion produced from different sources. Most of the impurities are more toxic than malathion. Some may potentiate malathion toxicity by inhibiting detoxifying enzymes. Others exert their toxic effect via mechanisms apart from acetyl cholinesterase enzyme inhibition. In addition, some of the impurities are known to interfere with each other via synergistic or antagonistic effects. Therefore the toxicity of any grade of malathion is highly dependent upon, and cannot be predicted without, knowledge of the impurity pattern of the material.

As a consequence, information on total purity and also detailed information on the individual impurities present in the test batch are important when evaluating the result of toxicity testing on malathion. Importantly, the composition of the test material is usually not available when evaluating findings reported in the open literature. Such studies are usually conducted using technical material or formulated products with either sparse or no information on source, purity and composition. For these reasons, wherever possible the ecological risk assessment is based on results from the latest studies carried out using a batch of technical malathion from a verified source. (emphasis ours).

One key impurity is isomalathion. The legally allowed level of isomalathion in technical malathion (as reflected in the product's Confidential Statement of Formula filed with EPA) has been reduced by a factor of more than four, compared to pre-1993 isomalathion limits. Going back further in time (1960s-1980s), there is no available information on the isomalathion content of the malathion that was used. However, given that modern chemical processing technologies are required to produce the relatively pure product sold today, it is likely that pre-1980 products had even higher levels than the pre-1993 products.

Of far greater relevance to evaluating the effects of the current formulation are the 2001 guideline rainbow trout studies by (Gries and Purghart, 2001a, Gries and Purghart, 2001b) for both the technical and formulated product[13]. In the study with technical malathion, groups of seven rainbow trout (*Oncorhynchus mykiss*) were exposed to concentrations of technical malathion in a freshwater flow through test system for 96 hours at 16 ± 1°C. The nominal malathion concentrations were 100, 200, 400, 800, and 1600 ppb; a freshwater control was also included in the study. Measured concentrations of malathion technical were determined at 0 and 96 hours by chemical analysis. Records of mortality and symptoms of toxicity were made at 0, 24, 48, 72 and 96 hours, and at other times during the study.

No treatment-related sub lethal effects were observed (i.e., rapid or reduced respiration, complete loss of equilibrium, lying on the bottom of the test vessel, dark coloration) in the control or at the measured test concentration of 91 ppb, thus establishing a NOEC of 91 ppb. Based on mean measured concentrations, the LC_{50} values for rainbow trout after 24, 48, 72 and 96-hour exposure to malathion technical were 410, 370, 270 and 180 ppb, respectively. The results for the formulated product are discussed later.

The previous malathion registrant, American Cyanamid, conducted a flow through life-stage toxicity test for rainbow trout (Cohle, 1989). The exposures began in incubation cups to

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[13] The study with the formulated product was conducted with the formulation used in the EU.

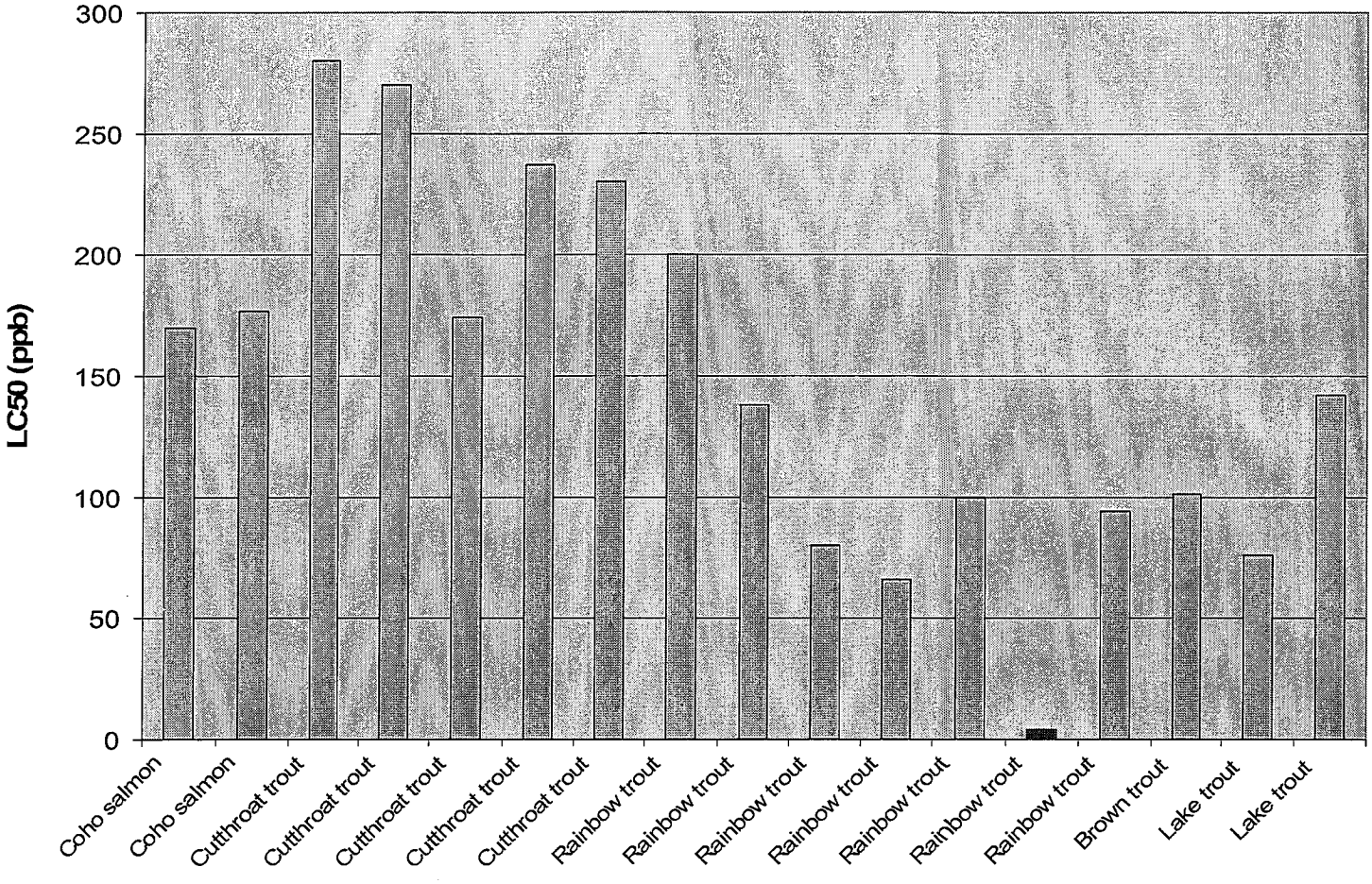
rainbow trout eggs. After hatching was completed, fry were released to growth chambers on day 46. Observations were made through day 97. The No Observed Effect Concentration (NOEC) was 21 ppb. Notably, this NOEC for a 97-day life-stage toxicity study is substantially greater than the older 2-4 ppb LC_{50} values over 4 days. NMFS notes on p.252 of the BiOp that "we cannot comment on lifestage sensitivity as no age information was provided." This study rectifies this uncertainty.

The Guideline rainbow trout studies conducted by Gries and Purghart (2001a) and Cohle (1989) are clearly superior to the older studies cited in the BiOp. The new studies better reflect the purity of the current product. Furthermore, these are flow-through studies, meaning that the concentrations were maintained at a nominally constant value through the study period. The older studies used static systems where the malathion levels likely declined significantly over the study period. The newer Guideline studies use modern methods developed through scientific consultation and provide all of the information that are needed for a thorough scientific evaluation.

Figure 2, below, provides a summary of LC_{50} values for salmonid species from the Mayer and Ellersieck (1984) review. The outlier value of 4.1 ppb is displayed in red. We cannot verify the citations of the original studies, and thus the formulation and/or impurity content of many of the studies, but it is notable that most of the LC_{50}s fall closer to the range from the guideline rainbow trout study of 180 ppb (over 96-hours). Quite clearly, the use of the 4.1 ppb value does not represent best available scientific data as required in the consultation.

Another issue raised in the BiOp is the effect of metabolites. The EU dossier describes a number of studies for bluegill sunfish (Gries and Purghart, 2001c; Gries, 2001a; Gries, 2001b; Gries 2001c). The tests included technical malathion and the major degradates, including malathion dicarboxylic acid and monocarboxylic acid. For technical malathion, the 96-hour LC_{50} was 54 ppb. The LC_{50}s were >100 ppm (or 100,000 ppb) and 79 ppm (or 79,000 ppb) for malathion dicarboxylic acid and monocarboxylic acid, respectively. This shows that the major degradates for malathion are substantially less toxic (at least three orders of magnitude less toxic) than malathion itself.

Figure 2. Salmonid acute LC_{50} values in the open literature

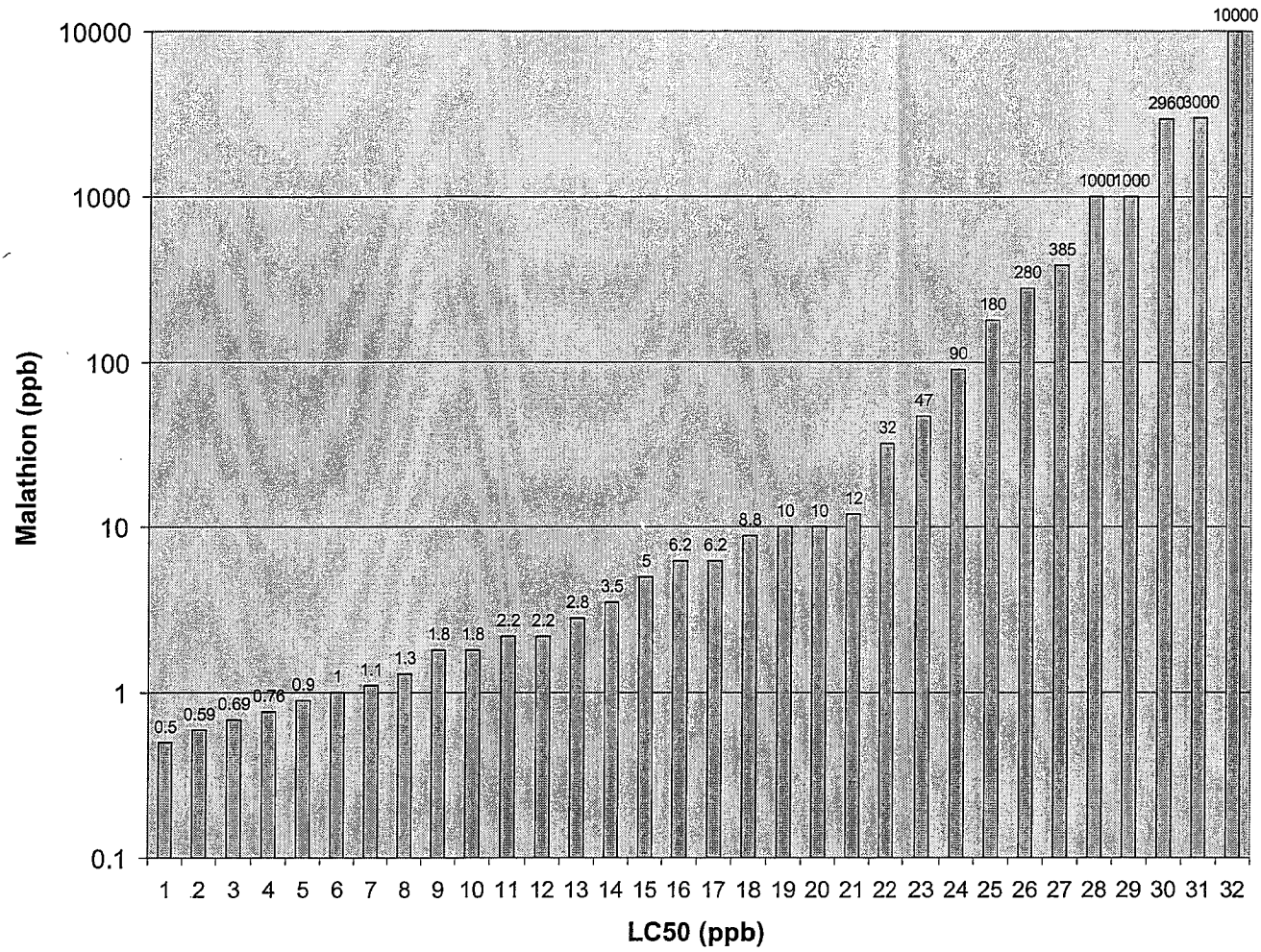


b. Invertebrate Toxicity

While some invertebrate species that salmonids may prey upon are sensitive to malathion, there is a large variability in toxicity among invertebrates. Figure 3, below, displays a range of LC_{50} values for different invertebrate species that were compiled in the malathion RED and the 1986 Fish and Wildlife Service review (FWS, 1986). The range is from 0.5-10000 ppb. This range must be considered when evaluating prey availability. As before, the original studies for many of these values are not available or were done at a time when the purity of malathion was likely very different.

There is a 2002 guideline study from the EU (Gries and Purghart, 2001d) for acute toxicity to *daphnia magna* for the technical. The 48-hour EC_{50} for technical malathion was 2.1 ppb, which is comparable to the older literature data.

Figure 2. Variability in malathion LC50 values for invertebrates



c. Mesocosm Studies

There are two mesocosm studies for malathion that were not considered in the BiOp but provide highly useful information for assessing population-level impacts of malathion.

The first study was conducted by the University of Alabama as part of the Boll Weevil eradication program (Kuhajda et al., 1996). Sampling was conducted in Stewart Creek following applications on two cotton fields (7.6 and 11.6 acres) within 25 feet of the stream bank. There were nine applications in 1993 and 15 applications in 1994. The concentrations ranged from non-detect to 31.1 ppb (immediately after the application). The study authors concluded:

> Within the fish community, numbers of individuals did not show any depression in the experimental locations during spray periods relative to the Control; in fact

numbers were greatest for the Downstream location for all time periods except for spray Year 1, where the control location averaged just one more specimen.

This study represents a worst-case situation where numerous applications of malathion were made very close to a stream, relatively high, transient concentrations were detected, but there were no significant population-level effects.

Another mesocosm study was conducted in 2002 in Europe. Malathion was applied in concrete basins filled with naturalized aqueous ecosystems. The initial concentrations ranged from 0-30 ppb. Two enclosures were used per concentration and untreated enclosures were used for controls. There were no effects whatsoever at concentrations below 5 ppb. At 10-30 ppb, there were no impacts on macrophytes, macroinvertebrates, emergent insects, chlorophyll *a*, phytoplankton, and periphyton. There were some transient effects to zooplankton in the *daphnia* family that were observed at 3 days (at 30 ppb) or 14 days (10 ppb) after treatment, but full recovery occurred within 28 days. At any concentration, "no species were eliminated from any enclosures during the study."

These two studies demonstrate that malathion does not adversely effect either fish or invertebrate populations at concentrations up to 30 ppb. While there were some transient effects at higher concentrations, these effects did not cause any population-level effects or long-term ecosystem degradation. As discussed in the next section, the population model used by NMFS should agree with the results of these mesocosm studies. However, due to flaws in some of the model inputs, the population model predicts greater impacts.

d. Other Chemicals in the Formulation

Gries and Purghart (2001b) conducted an acute rainbow trout study with the formulated product in the same laboratory with the same protocol as the study with the technical product (Gries and Purghart, 2001a). The product contains 40.6% technical malathion. The nominal test concentrations were 200, 400, 800, 1600, and 3200 ppb. Based on mean measured concentrations, the LC_{50} values for rainbow trout after 24, 48, 72 and 96-hour exposure to the malathion formulation were 890, 810, 810 and 740 ppb, respectively. The LC_{50} over 96-hours was 180 ppb for the technical study. This demonstrates that the EU formulation is much less toxic than technical malathion.

Also, there is 2002 *daphnia magna* study to compare to the study with the technical formulation (Mattock, 2002). It was conducted in the same laboratory with the same protocol. The EC_{50} of the formulated product was 5.1 ppb on the basis of the full formulation and 2.1 ppb on the basis of the technical portion. Given that the EU formulation has 40.6% malathion, this shows that the technical material was wholly the cause of the toxicity; the formulated product did not add to the toxicity.

There are differences between Cheminova's EU and U.S. formulations. However, these data are offered to show, qualitatively, that the results for malathion follow the same pattern as for chlorpyrifos (see chlorpyrifos comments). The technical material dominates the toxicity of the formulated product. While the same data are not available for the U.S. formulation, given

the available data, there is certainly no basis to conclude that it adds significantly to the toxicity of the technical material.

NMFS expressed concern about the potential additive toxicity from nonionic detergent ingredients that may be used in some formulations, including nonylphenol and nonylphenol ethoxylates. Cheminova has confirmed that none of its technical, ULV, or formulated products contain these chemicals.

More broadly, the combination of approved inerts used in registered pesticide products is formulation and end-product specific and there are many different end-use products containing malathion and these are manufactured by different companies. The list of inerts used in each end use product is considered proprietary confidential business information. Obviously, Cheminova cannot speak for those other companies.

5. Potential Effects of Ambient Mixtures

NMFS conducts some hypothetical analyses to assess the impact on toxicity for mixtures of different organophosphates (p.273-275), alleging additive and/or synergistic effects of the mixture. These analyses are largely based on a submitted paper (Laetz et al.) that has not been peer reviewed (and therefore, arguably, not the best available data source) and is unavailable for our review at this time. The entire analysis is very difficult to follow, particularly without the benefit of the Laetz et al. paper. However, there are a number of clear flaws.

First, NMFS needed to make an assumption for the slope of the dose-response curve in its analysis. It states that it used "EPA's standard pesticide slope as used for acute mortality (3.63 or probit slope of 4.5) [EPA 2004]. The slope used for AchE inhibition was based on pooling data from five cholinesterase-inhibiting insecticides, including carbofuran, carbaryl, diazinon, and malathion." The effect of assuming this slope is stated by NMFS: "Due to the very steep slopes of the two dose-response curves, and especially the mortality slope, small changes in concentration elicit large changes in observed toxicity." However, the probit slope of 4.5 is actually based on organochlorine data and EPA has revised the analysis for organophosphates. EPA (2004) states:

> It should be noted that the discussion (originally part of the 1975 regulations for FIFRA) is based upon slopes of primarily organochlorine pesticides, stated to be 4.5 probits per log cycle at that time. As organochlorine pesticides were phased out, OPP undertook an analysis of more current pesticides based on data reported by Johnson and Finley (1980), and determined that the "typical" slope for aquatic toxicity tests for the "more current" pesticides was 9.95. Because the slopes are based upon logarithmically transformed data, the probability of mortality for a pesticide with a 9.95 slope is again exponentially less than for the originally analyzed slope of 4.5.

Therefore, the analysis needs to be updated with the more accurate slope, which will show much lower risk.

On Table 51 of the report, NMFS provides predicted cholinesterase inhibition levels and percent mortalities for various mixture concentrations. However, the concentrations that are assumed are beyond worst-case. NMFS assumes the maximum values for each of the three pesticides from the PRZM-EXAMS and GENEEC modeling, and the maximum values from the NAWQA, CDPR, and Lower Salinas valley measurements. In one case, the mean values from the Lower Salinas valley are used. The probability of these values occurring together is virtually impossible. For example, for the NAWQA measurements, there were approximately 4350 measurements. Assuming independence of applications, the probability of each of the maximum values for the three pesticides occurring together is more than 1 in 80 billion.

A scientifically sound analysis would be to evaluate the co-occurrence of pesticides in the different databases and select a reasonable upper-bound of pesticide co-occurrence from the actual data. Reviewing the NAWQA data in the four states, there were 39 occurrences with all three pesticides being detected with a peak total concentration (all three pesticides combined) of 1.2 ppb and an average total concentration of 0.15 ppb. By contrast, the total concentration in the NMFS analysis using the NAWQA data was 8.1 ppb. NMFS refers to the frequency of detections of multiple pesticides, but this is not adequate. Actual quantities need to be evaluated to determine reasonable, high-end mixture levels. Just assuming that the maximum concentration for each pesticide occurs simultaneously is very misleading.

More broadly, organophosphates generally degrade quickly in the environment and are only rarely applied together. This limits the potential for high concentrations of multiple organophosphates to occur together.

There are also some unexpected results in Table 51. When using the PRZM-EXAMS and GENEEC monitoring data, NMFS predicts substantial mortality without much cholinesterase inhibition. This result needs to be checked.

6. Critique of NMFS Population Model

NMFS developed two population models to examine the productivity of salmon populations exposed to various concentrations of malathion. The acute toxicity model examined the direct impacts of malathion exposure on the population growth rate based on juvenile salmon mortality, and the second model examined the impact of reduced juvenile growth from malathion exposure, as a function of feeding success and prey availability, on population growth rate (Appendix I, Tables 13-16).

The acute toxicity model excluded sub-lethal and indirect effects, focusing on the population-level outcomes from an annual 4-day exposure of juveniles to malathion (Tables 52-55). The output of the model was a change in first year survival rate that was implemented into each of the generalized life history models for coho salmon, sockeye salmon, and ocean-type and stream-type Chinook salmon to produce the change in population growth rate (λ).

The population model that examined changes in juvenile growth resulting from exposure to malathion attempted to link the consequences of biochemistry, behavior, prey availability, and somatic growth of individual salmon to changes in population growth rate (λ). This model examined 4, 21, and 60-day exposures to malathion at eight different concentrations in each of

the generalized life history models for coho salmon, sockeye salmon, and ocean-type and stream-type Chinook salmon.

a. Population model is not peer-reviewed or validated

The model appears to have been developed specifically for this consultation. The model has not been subjected to scientific peer review and there is no discussion about any validation that has been conducted for the model. The use of such unproven methods for a critical risk assessment such as this consultation is questionable.

b. Inappropriate slope used to calculate fish lethality slope and prey abundance EC_{50}

As also discussed in the last section, the NMFS used an out-dated probit slope to approximate the dose response curve for malathion. The fish lethality slope and prey abundance EC_{50} were calculated using a slope corresponding to a probit slope of 4.5, which is the default slope recommended in the Standard Evaluation Procedure for Risk Assessment (Urban and Cook, 1986). EPA states in the Biological Evaluation (BE) for malathion that a 4.5 probit slope was developed using primarily organochlorine pesticide data (EPA, 2004). The Office of Pesticide Programs (OPP) developed a probit slope for "more current" pesticides of 9.95 using data from Johnson and Finley (1980). "[T]he probability of mortality for a pesticide with a 9.95 slope is again exponentially less than the originally analyzed slope of 4.5" (EPA, 2004, pg. 10).

Low prey abundance is the driving factor for the population model based on juvenile growth. The prey abundance input was developed from a probit slope for typical aquatic toxicity tests based on out-dated organochlorine pesticides. This input parameter should have been calculated using the OPP slope for "more current" pesticides of 9.95. This slope will likely change the prey abundance EC_{50} for malathion, reducing the population impacts from potentially limited prey abundance following malathion exposure.

c. Unclear derivation of toxicity values

NMFS states that the magnitude of the population growth rate change in the population model based on changes in juvenile growth resultant from chlorpyrifos, diazinon, and malathion exposure is driven by the relative acetylcholinesterase (AChE) activity and prey abundance parameters determined by the toxicity values for each chemical. "The low Prey Abundance EC_{50} values drive the effects for diazinon and malathion models which have much higher AChE IC_{50} values" (p.288).

The prey abundance EC_{50} values are derived from the median EC_{50} for chlorpyrifos from data in the EPA BE, multiplied by 1.2 for malathion and 0.6 for diazinon (Table 3, footnote 4; Appendix 1). There is no explanation in the NMFS BiOp text to explain the derivation of the 1.2 or 0.6 factors used to calculate EC_{50}s for malathion and diazinon, respectively. The derivation of the prey abundance slope is also not explicitly detailed. NMFS needs to, at a minimum, clarify and justify the derivation of these values.

The NMFS also does not explain the derivation of the AChE Activity slope. NMFS needs to explicitly describe the data used to estimate the IC_{50} values and activity slope for AChE Activity so that the appropriateness of these selections can be evaluated.

d. Outlier fish lethality LC_{50} value for malathion used in acute toxicity population model

The BiOp used a fish lethality LC_{50} for malathion of 4.1 ppb. NMFS comments, "For example the LC_{50} of 4.1 μg/L for malathion is low compared to other reported LC_{50}s. We selected the lowest reported LC_{50} value to ensure that risk is not underestimated, however, if this is an outlier then it will over-predict mortality" (p. 283). The NMFS goes on to note that " . . .the choice of LC_{50} is a major driver" for the acute toxicity population model results and an "LC_{50} above or below the ones used here will result in a different does response" (p. 283).

As discussed in the toxicity above, the 4.1 ppb LC_{50} value is of unknown provenance; the original study cannot be located. A recent guideline study for the same species (rainbow trout) found an LC_{50} of 180 ppb over 96-hours. Clearly, the 4.1 ppb value is not the best available information.

e. Concentration averaging periods

The population model uses different averaging periods for different purposes, including 4, 21 and 60-day averages. NMFS does not appear to have given any consideration of appropriate values for different averaging periods. Clearly, the instantaneous grab samples are not representative of 4-day periods, let alone 21 or 60-day periods. More clarity is needed about what is being assumed.

f. Failure to accurately compare results with monitoring data

The NMFS concludes that there is "strong evidence that given expected concentrations in salmonid habitats that populations will be adversely affected if juvenile life stages are exposed" (p. 289). The acute and juvenile growth-based population models do not demonstrate a modeled population-level affect from malathion until the concentration reaches 3 ppb. As discussed earlier, malathion concentrations rarely exceed 1 ppb, let alone 3 ppb for 4-60 days (EPA, 2004, p. 68-102).

Therefore, even with the assumptions that overestimate risk, the population model shows there are not significant effects at concentration levels found in the environment for uses that are part of the federal action.

7. Summary and Conclusions

Based on all of the foregoing, our comments on the NMFS BiOp assessment of potential effects of malathion on salmonid species can be summarized as follows:

- NMFS has not adequately evaluated the quality of the underlying toxicity studies that it relied upon in the assessment. In particular, it has not considered that the purity of malathion has improved since it was first

introduced more than 40 years ago, and that there have also been changes in the formulation. Even more problematic, the most sensitive endpoint for salmonid species used by NMFS is an LC_{50} of 4.1 ppb for 96-hours for rainbow trout from a study result summarized in a table from a 1986 review document. The citation for the study is not even available so that it can be reviewed; a thorough literature search failed to find it. By contrast, the registrant has conducted an acute guideline study for rainbow trout in 2001. The LC_{50} for 96-hours was 180 ppb, or about 40-fold less toxic.

- NMFS has cited the lack of life-stage sensitivity testing as a data gap. However, an acceptable guideline early life-stage test for rainbow trout is available in EPA's malathion database. The NOEC in this study was 21 ppb, which is even substantially higher than the LC_{50} in the study relied upon by NMFS.

- In addition to salmonid toxicity, NMFS has evaluated potential effects on salmonid prey, including aquatic invertebrates. While aquatic invertebrates are more sensitive to malathion than salmonids, NMFS has not considered two mesocosm studies that evaluated population effects of both fish and aquatic invertebrates in real-world ecosystems. There were only modest, transient effects to aquatic invertebrates in these studies at high concentrations. There was no long-term damage to any species in these studies.

- NMFS provided a review of monitoring data, but overemphasized the results from programs such as Medfly eradication and the Boll Weevil eradication program, where applications are not likely to ever occur again in the study area. NMFS did not consider data from the Washington state-monitoring program specifically designed to evaluate salmonid habitat. This program found a peak concentration of 3.1 ppb, with median concentrations in the 0.01-0.03 ppb range. Other relevant monitoring data are similar, such as the USGS NAWQA survey. By contrast, there is a value as high as 1000 ppb from a 1981 Medfly spraying program that appears prominently in the assessment. The registrant is not supporting this use for wide area spraying over urban areas.

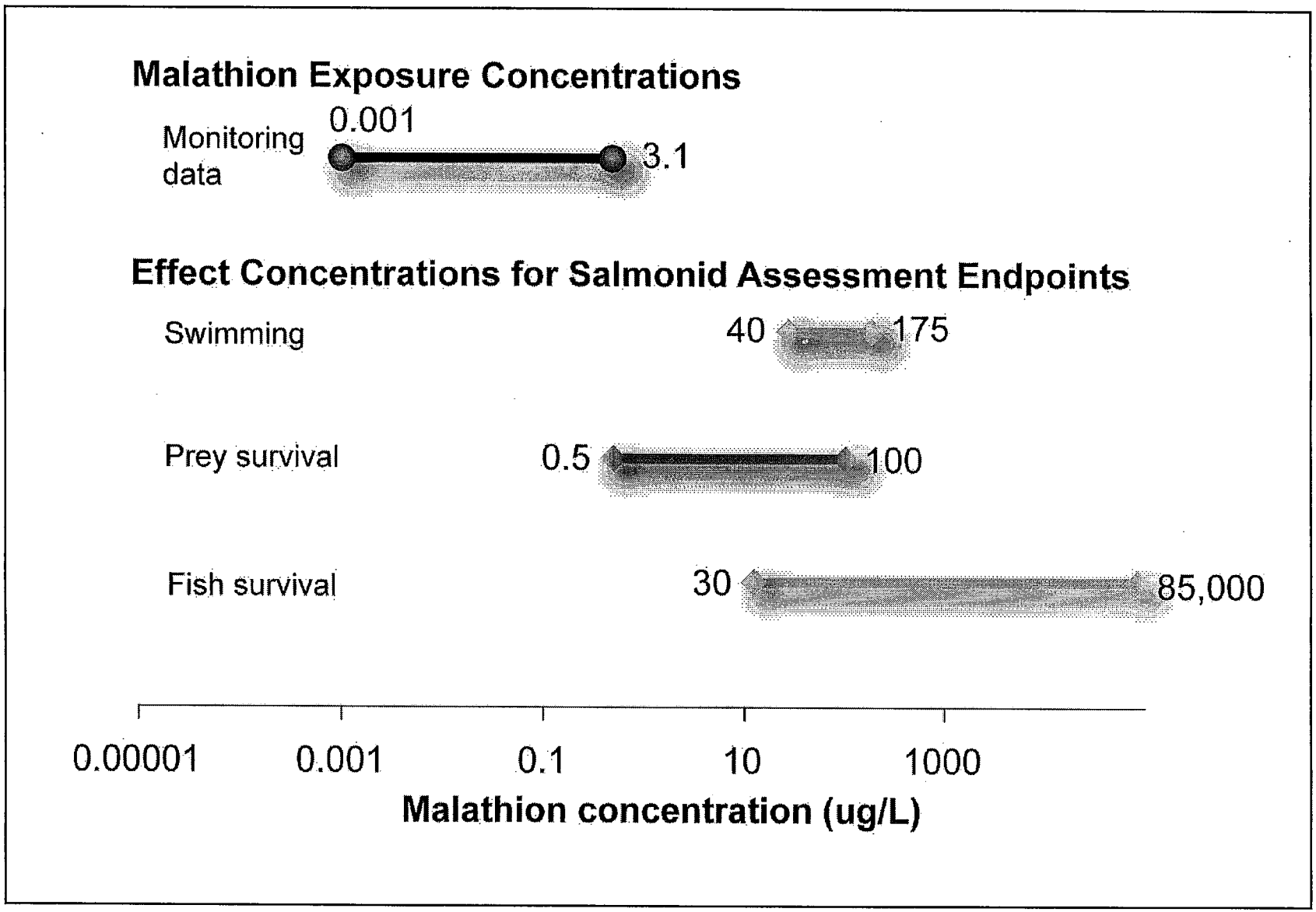
- NMFS relied on modeling analyses that are not relevant to salmonid habitat and further did not properly acknowledge the many conservative assumptions that are built in to the models, which result in the models significantly overpredicting EECs.

- NMFS also provides an analysis of the effects of ambient mixtures of organophosphates and an assessment of population-level effects. However, these analyses rely on the toxicity data discussed above and an outdated dose-response slope. Also, the ambient mixture analysis gives no consideration to the probability of high concentrations of pesticides occurring together. Nonetheless, the population model shows that there are little or no effects

below 3 ppb, which is at the absolute maximum of the relevant monitoring data.

Finally, on page 273 of the BiOp, NMFS provides a graphic that shows the overlap of monitoring results and modeling concentration predictions with the toxic effect levels for malathion. Figure 4 provides an update to this figure using relevant monitoring data and deleting the inappropriate rainbow trout LC_{50}. The revised results show that there is no overlap between the monitoring data and salmonid toxicity levels. There is some overlap with the monitoring results and the toxicity of prey, but malathion does not affect the majority of prey. Furthermore, the mesocosm studies provide significant evidence that any effects on prey are transient and have no lasting ecological impacts.

Figure 3. Revised comparison of monitoring results and toxicity levels



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Appendix A

Table 30 Labeling Changes Summary

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 30: Summary of Labeling Changes for Malathion		
Description	**Amended Labeling Language**	**Placement on Label**
Manufacturing Use Products		
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"Only for formulation into an insecticide or ***miticide*** for the following use(s): [fill blank only with those uses that are being supported by MP registrants]." "This product can not be formulated into end-use products formulated as a dust with directions for use in residential settings." "This product can not be formulated into end-use products that are formulated as a pressurized (i.e., aerosol) can." This product can **NOT** be formulated into end-use products that contain directions for use on: • all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating) • animal kennels/sleeping quarters (commercial) • animal premise and barns used for dairy and livestock • stables and pens • poultry houses • animal kennels/sleeping quarters • cattle feedlots and holding pens • feed rooms • cattle feed concentrate blocks (non-medicated) • dogs and cats • pet food and pet stuffs • cereal processing plants • packaged cereals • commercial and industrial uses for bagged flour • commercial shipping containers –feed/food- empty • commercial storages/ warehouses premises	Directions for Use

	• commercial transportation facilities –feed/food –empty • commercial transportation facilities –nonfeed/nonfood • commercial/institutional/industrial premises/equipment (indoor) • commercial/institutional/industrial premises/equipment (outdoor) • dairies/cheese processing plant equipment (food contact) • edible and inedible commercial establishments • edible and inedible eating establishments • edible and inedible food processing plants • field or garden seeds • forest trees • rabbits on wire • golf course turf • greenhouse – empty, or in-use • human clothing (woolens and other fabrics) • manure piles • mattresses • quince • residential lawns (broadcast) • sewage systems • lentils • tobacco	
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards	"This pesticide is toxic to aquatic organisms, including fish and invertebrates. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."	Precautionary Statements immediately following the User Safety Recommendations
End Use Products Intended for Occupational Use (WPS and Non-WPS)		
Personal Protective Equipment		

PPE Requirements Established by the RED[1] for **liquid concentrate and wettable powder end-use products** *Note: all wettable powder products must be in water soluble packets to be eligible for reregistration.* Note: if the end-use product does not contain directions for use as a dip, the statement referring to dip applications may be eliminated. Note: if the end-use product does not contain directions for use permitting application with aerial or motorized ground equipment, the exception to the glove statement may be removed.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are *(registrant inserts correct chemical-resistant material)*. If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H]* on an EPA chemical-resistance category selection chart." "For all formulations and all use patterns – mixers, and loaders, applicators, flaggers, and other handlers must wear: • Long sleeved shirt and long pants, shoes plus socks, (referred to as *"baseline PPE"*) For all formulations and all use patterns – mixers and loaders must wear: • Baseline PPE and, • Chemical resistant gloves. For all formulations being applied using either aerial or motorized ground equipment – flaggers and applicators must wear: • Baseline PPE; and, • Chemical resistant gloves such as *(registrant insert correct chemical-resistant materials)*. For all ULV formulations, applications must be Closed Systems – mixers and loaders must wear: • Baseline PPE, and, • Chemical resistant gloves; and, • Chemical resistant apron For all dip applications – mixers, loaders, and applicators must wear: • Baseline PPE; and, • Chemical resistant gloves; and, • Chemical resistant apron. For all airblast applications – applicators must wear: • Baseline PPE; and, • Chemical resistant gloves; and, • Chemical resistant headgear." "All ULV formulations must be packaged in closed mixing and loading systems." "All wettable powders (WP) formulations must be packaged in water soluble packaging." "See engineering controls for additional requirements."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals

PPE Requirements Established by the RED[1] for **dust end-use products.** Note: if the end-use product does not have directions permitting use in power duster equipment, the statements related to persons participating in power duster applications may be removed.	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are *(registrant inserts correct chemical-resistant material)*. If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H]* on an EPA chemical-resistance category selection chart." "For all dust formulations – mixers, loaders, and applicators must wear: • Coveralls over baseline PPE; and, • Chemical resistant gloves such as *(registrant insert correct chemical-resistant materials)*; and, • A NIOSH-approved dust/mist filtering respirator with MSHA/NIOSH approval number prefix TC-21C or a NIOSH-approved respirator with any N, R, P or HE filter" and, • Chemical-resistant headgear (if overheat exposure is expected)" "All other loaders, applicators, and other handlers must wear: • Baseline PPE; and, • Chemical resistant gloves, such as *(registrant insert correct chemical-resistant materials)* when loading."	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
PPE Requirements Established by the RED[1] for **ready-to-use liquid products**	"Personal Protective Equipment (PPE)" "Some materials that are chemical-resistant to this product are *(registrant inserts correct chemical-resistant material)*. If you want more options, follow the instructions for category *[registrant inserts A,B,C,D,E,F,G,or H]* on an EPA chemical-resistance category selection chart." For all ready-to-use liquid products; applicators, and other handlers must wear: • Baseline PPE	Immediately following/below Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry." "Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
Engineering Controls		
Engineering Controls for **liquid concentrate end-use products** which may	"Engineering Controls" "Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural	Precautionary Statements: Hazards to Humans and Domestic Animals

be aerially applied.	Pesticides [40 CFR170.240(d)(6)]. Pilots must wear the PPE required on this labeling for applicators."	(Immediately following PPE and User Safety Requirements.)
Engineering Controls for **wettable powders packaged in water-soluble packets.** *All wettable powders must be in water soluble packets to be eligible for reregistration.*	"Engineering Controls" "Water soluble packets when used correctly qualify as a closed mixing/loading system under the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(4). Mixers and loaders using water soluble packets must: ➢ wear the personal protective equipment required on this labeling for mixers and loaders, and ➢ be provided, have immediately available, and wear in an emergency, such as a broken package, spill, or equipment breakdown: ➢ chemical resistant footwear and ➢ NIOSH-approved respirator equipped with —a dust/mist filter with MSHA/NIOSH approval number prefix TC-21C or —any N, R, P, or HE filter." "Pilots must use an enclosed cockpit in a manner that is consistent with the WPS for Agricultural Pesticides [40 CFR170.240(d)(6)]. Pilots must wear the PPE required on this labeling for applicators."	Precautionary Statements: Hazards to Humans and Domestic Animals (Immediately following PPE and User Safety Requirements.)
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazard Statement	"This pesticide is toxic to aquatic organisms, including fish and invertebrates." "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate." "This product may contaminate water through drift of spray in wind. This product has a high potential for runoff after application. Use care when applying in or to an area which is adjacent to any body of water, and do not apply when weather conditions favor drift from target area. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product. "	Environmental Hazards

	"A level, well maintained vegetative buffer strip between areas to which this product is applied and surface water features such as ponds, streams, and springs will reduce the potential for contamination of water from rainfall-runoff. Runoff of this product will be reduced by avoiding applications when rainfall is forecasted to occur within 48 hours." *Environmental Hazards for Wide Area Mosquito Adulticide Applications* "When applying as a wide area mosquito adulticide, before making the first application in a season, it is advisable to consult with the state or tribal agency charged with primary responsibility for pesticide regulation to determine if other regulatory requirements exist." "This product is toxic to bees. Do not apply this product while bees are actively visiting a treatment area." "When applying as a wide area mosquito adulticide, do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body."	
Restricted-Entry Interval (for labels with WPS uses)	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI). " "Required REIs are listed with each crop."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment established by the RED (for labels with WPS uses)	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is: ➢ coveralls, ➢ shoes plus socks, and ➢ chemical-resistant gloves made of any waterproof material."	Place in the Directions for Use In Agricultural Use Requirements box, immediately following the REI
Entry Restriction for Non-WPS uses	***Entry Restriction for non-WPS uses applied as a spray:*** "Do not enter or allow others to enter until sprays have dried." ***Entry Restriction for non-WPS uses applied dry:***	If no WPS uses on the label, place the statements in the Directions for Use Under General Precautions and Restrictions.

	"Do not enter or allow others to enter until dusts have settled."	If WPS uses are also on the labeling, place these statements in a NonAgricultural Use Requirements box as specified in PR Notice 93-7 and 93-11.
General Application Restrictions (for labels with WPS uses)	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application."	Place in the Directions for Use directly above the Agricultural Use Box.
Other Application Restrictions (Risk Mitigation)	**All Products/Formulations Containing Malathion** Delete all directions for use for the following use-patterns: • all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating) • animal kennels/sleeping quarters (commercial) • animal premise and barns used for dairy and livestock • stables and pens • poultry houses • animal kennels/sleeping quarters • cattle feedlots and holding pens • feed rooms • cattle feed concentrate blocks (non-medicated) • dogs and cats • pet food and pet stuffs • cereal processing plants • packaged cereals • commercial and industrial uses for bagged flour • commercial shipping containers –feed/food- empty • commercial storages/ warehouses premises • commercial transportation facilities –feed/food –empty • commercial transportation facilities –nonfeed/nonfood • commercial/institutional/industrial premises/equipment (indoor) • commercial/institutional/industrial premises/equipment (outdoor) • dairies/cheese processing plant equipment (food contact) • edible and inedible commercial establishments • edible and inedible eating establishments • edible and inedible food processing plants	Directions for Use

	• field or garden seeds • forest trees • rabbits on wire • golf course turf • greenhouse – empty, or in-use • human clothing (woolens and other fabrics) • manure piles • mattresses • quince • residential lawns (broadcast) • sewage systems • lentils • tobacco • All uses at residential sites – for dust formulations only	
Buffer Zones	**"Buffer Zones for Aerial Application** When making a Non-ULV application with aerial application equipment, a minimum buffer zone of 25 feet must be maintained along any water body. When making a ULV application with aerial application equipment, a minimum buffer zone of 50 feet must be maintained along any water body."	In the Directions for Use section in a section titles: "Buffer Zones for Aerial Application"
Storage and Disposal	"*Product Name Here* should be stored in the original unopened container in a secure, dry place." "Do not contaminate with other pesticides or fertilizers. The product should never be heated above 55^0 C (131^0 F), and should not be stored for long periods of time at a temperature in excess of 25^0 C (77^0 F)."	In the Storage and Disposal section of the labeling
Products with use instruction for use as a Wide Area Mosquito Adulticide	Note: All product labels must be amended to reflect requirements and recommendations specified in Pesticide Registration Notice 2005-1. The following statements must also be added. "Do not apply more than 0.23 lb ai/A/day. More frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne diseases in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort."	Directions for Use under General Precautions and Restrictions

	"Apply when wind speed is greater than or equal to 1 mph." "Do not apply by fixed wing aircraft at height less than 100 feet, or by helicopter at a height less than 75 feet unless specifically approved by the state or tribe based on public health needs." "Aerial Application: Spray equipment must be adjusted so that the median diameter product is less than 60 microns (Dv 0.5 < 60 um) and that 90% of the spray is contained in droplets smaller than 80 (Dv 0.9< 80 um). The effect of flight speed and, for non-rotary nozzles, nozzle angle on the droplet size spectrum must be considered. Directions from the equipment manufacturer or vendor, pesticide registrant or a test facility using a wind tunnel and laser-based measurement instrument must be used to adjust equipment to produce acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated." "Ground-based application: Spray equipment must be adjusted so that the volume median diameter is less than 30 microns (Dv 0.5 < 30 um), and that 90% of the spray is contained in droplets smaller than 50 microns (Dv 0.9 < 50 um). Directions from the equipment manufacturer or vendor, pesticide registrant or test facility using a laser-based measurement instrument must be used to adjust equipment to product acceptable droplet size spectra. Application equipment must be tested at least annually to confirm that pressure at the nozzle and nozzle flow rate(s) are properly calibrated."	
Spray Drift	Observe the following requirements when spraying in the vicinity of aquatic areas such as lakes; reservoirs; rivers; permanent streams; marshes or natural ponds; estuaries and commercial fish ponds. "Use the largest droplet size consistent with acceptable efficacy. Formation of very small droplets may be minimized by appropriate nozzle selection, by orienting nozzles away from the air stream as much as possible, and by avoiding excessive spray boom pressure." "For groundboom and aerial applications, use only medium or coarser spray nozzles according to ASAE (S572) definition for standard nozzles, or a volume mean diameter (VMD) of 300 microns or greater for spinning atomizer nozzles. Aerial applicators must consider flight speed and nozzle orientation in determining droplet size." "Make aerial or ground applications when the wind velocity favors on target product deposition (approximately 3 to 10 mph). Do not apply when wind velocity exceeds 15 mph. Avoid applications when wind gusts approach 15 mph. For all non-aerial applications, wind speed must be measured adjacent to the application site on the upwind side, immediately prior to application." "Do not make aerial or ground applications into areas of temperature inversions. Inversions are	

	characterized by stable air and increasing temperatures with increasing distance above the ground. Mist or fog may indicate the presence of an inversion in humid areas. Where permissible by local regulations, the applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface." "Low humidity and high temperatures increase the evaporation rate of spray droplets and therefore the likelihood of increased spray drift to aquatic areas. Avoid spraying during conditions of low humidity and/or high temperatures." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind." "For aerial applications, the spray boom should be mounted on the aircraft as to minimize drift caused by wingtip or rotor vortices. The minimum practical boom length should be used and must not exceed 75% of wing span or 90% rotor diameter." "Spray should be released at the lowest height consistent with pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided. For groundboom applications, apply with nozzle height no more than 4 feet above the ground or crop canopy." "For airblast applications, turn off outward pointing nozzles at row ends and when spraying the outer two rows. To minimize spray loss over the top in orchard applications, spray must be directed into the canopy."	
Specific Application Restrictions for Use on Cotton to Control Boll Weevil	**ULV Malathion Label Regarding Applications Made for Boll Weevil Eradication** "Treatment supervisors and applicators must be aware of all sensitive areas near cotton fields, including: schools, hospitals, nursing homes, churches, occupied dwellings, parks, recreation areas, bodies of water, and potential habitat for threatened and endangered species." "For aerial applications, spray equipment must be adjusted so that the volume median diameter is 100 microns (Dv 0.5 = 100um) or greater. The effects of flight speed, nozzle angle and type, and pump pressure on the droplet size spectrum must be considered." "For aerial applications, the spray boom should be mounted on the aircraft as to minimize drift caused by wingtip or rotor vortices. The minimum practical boom length should be used and outermost nozzles must not be placed beyond 75% of the wingspan or rotor diameter." "Spray should be released at the lowest height consistent with pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided."	Directions for Use associated with the specific crop or use-site.

	"Global positioning systems (GPS) should be used to guide pilots and to monitor each application." "Ground equipment should utilize a controlled air flow to facilitate particle size and spray deposition, and should be used at a vehicle speed of 4 to 10 mph. Spray equipment must be adjusted so that the volume median diameter is 100 microns (Dv 0.5 = 100um) or greater." "Ground equipment should be used to treat field edges when possible, covering areas that can not be treated effectively with aircraft because of obstructions which may affect applicator safety, or where there is boll weevil over-wintering habitat adjacent to the treatment area, or if there are adjacent sensitive areas." "Do not apply when wind velocity exceeds 10 mph. Treatments should be applied when winds are calm, or moving away from adjacent sensitive areas." "When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind." "Do not make aerial or ground applications into temperature inversions. Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface." "Applications will not be made when people are in or near infested cotton fields or, to the degree possible, when people are present in or near adjacent sensitive areas." "Application will not be made when rainfall is imminent. "Before beginning treatment, program personnel shall notify all registered apiarists in or near the treatment area of the date and approximate time of treatment."	

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Specific Application Restrictions (Note: The maximum allowable rate per crop per application or per year must be listed as pounds or gallons of formulated product per acre, not solely as pounds active ingredient per acre.)	Alfalfa: the Restricted-Entry Interval (REI) is 12 hours. Apricot: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Asparagus: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Avocado: The Restricted-Entry Interval (REI) is 48 hours. The maximum application rate is 4.7 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 30 days. Barley: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Beans (dry, lima, and snap): The Restricted-Entry Interval (REI) is 12 hours. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Beets (including tops): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Blackberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Blueberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.77 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 10 days. Boysenberry: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 2.0	Directions for Use associated with the specific crop or use-site

	pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7days. Broccoli: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Broccoli raab: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Brussels sprouts: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Cabbage: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Cabbage, Chinese: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Cantaloupe: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Carrots, roots: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Cauliflower: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 1; and the minimum retreatment interval is 7 days. Celery: The Restricted-Entry Interval (REI) is 24 hours. The maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7days. Chayote fruit and roots: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the	

	maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Cherry (sweet): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.75 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 3 days. For ULV applications: the maximum application rate is 1.22 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Cherry (tart): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.75 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 3 days. For ULV applications: the maximum application rate is 1.22 pounds active ingredient per acre; the maximum number of applications per year is 6; and the minimum retreatment interval is 7 days. Chestnut: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.5 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Chinese Broccoli: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 1; and the minimum retreatment interval is 7 days. Chinese Greens (Chinese Cabbage): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Citrus (grapefruit, lemon, lime, orange, tangerine, and tangelo): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is in California, EITHER 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1; OR 1.5 pounds active ingredient per acre; and the maximum number of applications per year is 3, and the minimum retreatment interval is 30 days. In all other states, EITHER 4.5 pounds active ingredient per acre; with a maximum number of applications per year is 1; OR 1.5 pounds active ingredient per acre; and the maximum number of applications per year is 3, and the minimum retreatment interval is 30 days. Collards: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days.	

	Corn (field): The Restricted-Entry Interval (REI) is 72 hours for detasseling, and 12 hours for all other activities. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Corn (sweet, pop): The Restricted-Entry Interval (REI) is 72 hours for detasseling, and 12 hours for all other activities. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 5 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 5 days. Cucumber: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.75 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Currant: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 1 pounds active ingredient per acre; the maximum number of applications per year is 1. Dandelion: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Dates: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.25 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 7 days. Dewberry: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7 days. Eggplant: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 5 days. Eggplant (Oriental): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 5 days.	

	Endive: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Fig: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 5 days. Flax: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 0.5 pounds active ingredient per acre; the maximum number of applications per year is 32; and the minimum retreatment interval is 7 days. Garlic: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Gooseberry: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7days. Grapefruit (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Grapefruit (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Grapes: The Restricted-Entry Interval (REI) is 72 hours for girdling and tying, and 24 hours for all other activities. The maximum application rate is 1.88 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 14 days. Horseradish: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days.	

	Kale: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 5 days. Kohlrabi: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Kumquat: The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Leeks: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Lemon (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Lemons (Florida only): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Lespedeza: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Lettuce, head: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.88 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 6 days. Lettuce, leaf: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.88 pounds active ingredient per acre; the maximum number of applications per year	

	is 2; and the minimum retreatment interval is 5 days. Limes (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Limes (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 30 days. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Loganberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Lupine, seed: The Restricted-Entry Interval (REI) is 12 hours. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 1. Macadamia Nut: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 0.94 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Mushrooms: The Restricted-Entry Interval (REI) is 12 hours. The maximum application rate is 1.7 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 3 days. Mustard greens: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 5 days. Nectarines: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 3.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Oats: For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For	

	ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Okra: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.2 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 7 days. Onions (bulb and green): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Oranges (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Oranges (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Papaya: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 3 days. Parsley: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Parsnip: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Passion fruit: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 8; and the minimum retreatment interval is 7 days. Peach: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum	

	application rate is 3.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 11 days. Pears: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Peas (succulent): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Pecans: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Peppers: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 5 days. Pineapple: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Pumpkin: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Radish: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Raspberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Rice: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days.	

	Rutabagas: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Rye: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.00 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 1 Salsify (including tops): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Shallots: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Sorghum: The Restricted-Entry Interval (REI) is 12 hours. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Spinach: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Squash, summer: The Restricted-Entry Interval (REI) is 24 hours. . For Non-ULV applications: the maximum application rate is 1.750 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Squash, winter: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Strawberry: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7 days. Swiss Chard: The Restricted-Entry Interval (REI) is 24 hours. The maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum	

	retreatment interval is 7 days. Tangerine (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tangerine (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tangelos (California only): The Restricted-Entry Interval (REI) is 72 hours. For Non-ULV applications: the maximum application rate is 7.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tangelos (U.S., except California): The Restricted-Entry Interval (REI) is 48 hours. For Non-ULV applications: the maximum application rate is 4.5 pounds active ingredient per acre; the maximum number of applications per year is 1. For ULV applications: the maximum application rate is 0.175 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Tomatoes: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 5 days. Tomatilloes: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 5 days. Trefoil, birdsfoot: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 5; and the minimum retreatment interval is 14 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 14 days.	

	Turnip (greens): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 5 days. Turnip (roots): The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Vegetables, leafy, Brassica (Cole) are listed above, and include: broccoli, Chinese broccoli, broccoli raab; Brussels sprouts; cabbage; Chinese cabbage; cauliflower; collards; kale; and mustard greens. Vegetables, leafy (except Brassica) are listed above and include: celery; dandelion; endive; lettuce (head, and leaf). Parsley: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Spinach: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 2.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Swiss chard: The Restricted-Entry Interval (REI) is 24 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Walnut: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 2.5 pounds active ingredient per acre; the maximum number of applications per year is 3; and the minimum retreatment interval is 7 days. Watermelon: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.5 pounds active ingredient per acre; the maximum number of applications per year is 4; and the minimum retreatment interval is 7 days. Wheat (spring and summer): The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.0 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days.	

	Wild Rice: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.25 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. For ULV applications: the maximum application rate is 0.61 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days. Yams: The Restricted-Entry Interval (REI) is 12 hours. For Non-ULV applications: the maximum application rate is 1.56 pounds active ingredient per acre; the maximum number of applications per year is 2; and the minimum retreatment interval is 7 days.	
End Use Products Intended Primarily for Use by Homeowners		
Environmental Hazards	"ENVIRONMENTAL HAZARDS" "This product is toxic to fish. Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate." "Do not apply when weather conditions favor drift from treated areas. Drift and runoff from treated areas may be hazardous to organisms in neighboring areas."	Precautionary Statements
Application Restrictions	**All products:** "Do not apply this product in a way that will contact any person or pet, either directly or through drift. Keep people and pets out of the area during application."	Directions for Use under General Precautions and Restrictions Statements must be in the color red and in all caps.
Entry Restrictions	**Products Applied as a Liquid:** "Do not allow people or pets to enter the treated area until sprays have dried." When applied as a fogger, do not enter treated area until vapors, mists, and aerosols have dispersed, and the treated area has been thoroughly ventilated	Directions for Use under General Precautions and Restrictions
Other Application Restrictions (Risk Mitigation)	**All Products/Formulations Containing Malathion** Delete all directions for use for the following use-patterns: • all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating)	Directions for Use

	• animal kennels/sleeping quarters (commercial) • animal premise and barns used for dairy and livestock • stables and pens • poultry houses • animal kennels/sleeping quarters • cattle feedlots and holding pens • feed rooms • cattle feed concentrate blocks (non-medicated) • dogs and cats • pet food and pest stuffs • cereal processing plants • packaged cereals • commercial and industrial uses for bagged flour • commercial shipping containers –feed/food- empty • commercial storages/ warehouses premises • commercial transportation facilities–feed/food –empty • commercial transportation facilities–nonfeed/nonfood • commercial/institutional/industrial premises/equipment (indoor) • commercial/institutional/industrial premises/equipment (outdoor) • dairies/cheese processing plant equipment (food contact) • edible and inedible commercial establishments • edible and inedible eating establishments • edible and inedible food processing plants • field or garden seeds • forest trees • rabbits on wire • golf course turf • greenhouse – empty, or in-use • human clothing (woolens and other fabrics) • manure piles • mattresses • quince • residential lawns (broadcast) • sewage systems • lentils • tobacco	

[1] PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.
[2] The registrant must drop the N type filter from the respirator statement if the pesticide product contains or is used with oil.
Instructions in the Labeling section appearing in quotations represent the exact language that should appear on the label.
Instructions in the Labeling section not in quotes represents actions that the registrant should take to amend their labels or product registrations.

Appendix A
List of Malathion Use Sites and Application Rates

Crop	Application Type, Application Method (Formulation[1])		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
Alfalfa	Foliar Ground/aerial		1.25	2 per cutting	14	0	12 hr
Apricot	Foliar Ground		1.5	2	7	6	12 hrs
Asparagus	Foliar Ground/aerial		1.25	2	7	1	12 hrs
Avocado	Foliar ground		4.7	2	30	7	2 days
Barley	Foliar Ground/aerial	Non-ULV	1.25	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	7	
Beans, dry, snap, Lima	Foliar Aerial	ULV only	0.61	2	7	1	12 hrs
Beets, garden	Foliar Ground		1.25	3	7	7	12 hrs
Blueberry (high bush and low bush)	Foliar Ground	Non ULV	1.25	3	7	1	12 hrs
		ULV/RTU	0.77	3	10	1	12 hrs
Broccoli, Chinese Broccoli, Broccoli rabb	Foliar Ground/aerial		1.25	1	7	2	2 days
Brussels sprouts	Foliar Ground/aerial		1.25	1	7	2	2 days
Cabbage	Foliar		1.25	6	7	7	2 days

Crop	Application Type, Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Cantaloupe	Foliar Ground/aerial		1.0	2	7	1	12 hrs
Caneberries (blackberry, boysenberry, dewberry, loganberry, raspberry)	Foliar ground		2.0	3	7	1	12 hrs
Carrots	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Cucumber	Foliar Ground/aerial		1.75	2	7	1	24 hrs
Cauliflower	Foliar Ground/aerial		1.25	1	7	2	2 days
Celery	Foliar Ground/aerial		1.5	2	7	7	24 hrs
Cherries, sweet	Foliar Ground/ Aerial	Non-ULV	1.75	4	3	3	12 hrs
		ULV/RTU	1.22	4	7	1	
Cherries, tart	Foliar Ground/ Aerial	Non-ULV	1.75	4	3		12 hrs
		ULV/RTU	1.22	6	7	1	
Citrus Fruits (grapefruit, lemon, lime, organge, tangerine, tangelo)	Foliar Ground/ aerial	Non-ULV	**All states other than CA:** 4.5 or 1.5	1 3	NA 30	7	3 days
			~~CA only:~~				

Crop	Application Type, Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
			7.5 or 1.5	1 3	NA 30		
		ULV/RTU	0.175	3	7	7	12 hrs
Clover	Foliar Ground/ aerial	Non-ULV	1.25	2 per cutting	14	0	12 hrs
		ULV/RTU	0.61	2 per cutting	14	0	
Collards	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Corn, field	Foliar Ground/ aerial	Non-ULV	1.0	2	7	7	3 days for detasseling 12 hrs for all other activites
		ULV/RTU	0.61	2	7	7	
Corn, sweet, and pop	Foliar Ground/ aerial	Non-ULV	1.0	2	5	5	3 days for detasseling 12 hrs for all other activities
		ULV/RTU	0.61	2	5	5	
Chayote fruit	Foliar Ground/aerial		1.75	2	7	1	24 hrs
Chayote root	Foliar Ground		1.56	2	7	0	24 hrs
Chestnut	Foliar Ground		2.5	3	7	2	24 hrs
Chinese greens (Chinese cabbage)	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Clover	Foliar		1.25	2 per cutting	14	0	12 hrs

Crop	Application Type, Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Cotton (non boll weevil treatment use)	Foliar	Non-ULV	2.5	3	7	7	2 days
	Ground/aerial	ULV/RTU	1.22	3	7	7	
Currant	Foliar Ground/aerial		1.25	3	7	1	12 hrs
Dandelion	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Dates	Dust		4.25	5	7	21	2 days
Eggplant	Foliar Ground/aerial		1.56	4	5	3	12 hrs
Eggplant, oriental	Foliar Ground/aerial		1.56	5	5	3	12 hrs
Endive (escarole)	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Fig	Foliar Ground		2.0	2	5	5	24 hrs
Flax	Foliar Ground		0.5	3	7	52	12 hrs
Garlic	Foliar Ground/aerial		1.56	3	7	3	24 hrs
Grains, stored (barley, corn, oats, rye, wheat)	Surface treatment		Loading: 0.624 lb ai/1000 bushels Storage: 0.312 lb ai/100 bushels	3 per storage period	60	NA	12 hrs
Grapes, raisin, table, wine	Foliar Ground Root dip		1.88	2	14	3	3 days for girdling and tying; 24 hrs for all other

Crop	Application Type, Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
							activities
Grass, forage, hay	Foliar Ground/aerial		1.25	1	NA	0	12 hrs
Grasses, Bermuda,	Foliar Ground/ aerial	Non-ULV	1.25	1 per cutting	NA	0	12 hrs
		ULV/RTU	0.92				
Guava	Foliar Ground		1.25	13	3	2	12 hrs
Hops	Foliar Ground/aerial		0.63	3	7	10	12 hrs
Horseradish	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Kale	Foliar Ground/aerial		1.25	3	5	7	24 hrs
Kohlrabi	Foliar Ground/aerial		1.25	2	7	7	24 hrs
Kumquats	Foliar Ground	Non-ULV	4.5	1	30	7	2 days
		ULV/RTU	0.175	2	7	1	12 hrs
Leeks	Foliar Ground/aerial		1.56	2	7	3	24 hrs
Lespedeza	Foliar Ground/ aerial	Non-ULV	1.25	2 per cutting	14	0	12 hrs
		ULV/RTU	0.61				
Lettuce, head	Foliar Ground/aerial		1.88	2	6	14	24 hrs
Lettuce, leaf	Foliar Ground/aerial		1.88	2	5	14	24 hrs
Lupine	Foliar Ground/	ULV only	0.61	1	NA	1	12 hrs

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Crop	Application Type, Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Aerial						
Turnips	Foliar Ground/aerial		1.25	3	5 day for turnip greens 7 day for turnip root	7	24 hrs
Macadamia nut	Foliar Ground		0.94	2	7	1	12 hrs
Mango	Foliar Ground		1.25	8	7	1	12 hrs
Melons (other than watermelon)	Foliar Ground/aerial		1.0	2	7	1	12 hrs
Mint	Foliar Ground/aerial		0.94	3	7	7	12 hrs
Mushrooms	Foliar		1.7	4	3	1	12 hrs
Mustard greens	Foliar Ground/aerial		1.25	3	5	7	24 hrs
Nectarines	Foliar Ground		3.0	3	7	7	24 hrs
Oats	Foliar Ground/ aerial	Non-ULV	1.0	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	7	12 hrs
Okra	Foliar Ground/aerial		1.2	5	7	1	12 hrs
Onions, bulb, and green	Foliar Ground/aerial		1.56	2	7	3	12 hrs
Papaya	Foliar Ground		1.25	4	3	1	12 hrs
Parsley	Foliar		1.5	2	7	2	24 hrs

Crop	Application Type, Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Parsnip	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Passion fruit	Foliar Ground		1.0	8	7	3	12 hrs
Pasture and rangeland	Foliar Ground/ aerial	ULV only	0.9375	2	7	1	12
Peaches	Foliar Ground		3.0	3	11	7	24 hrs
Pears	Foliar Ground		1.25	2	7	1	12 hrs
Peas, dried	Foliar Ground		1.0	2	7	3	12 hrs
Peas, green	Foliar Ground/aerial		1.0	2	7	3	12 hrs
Pecans	Foliar Ground		2.5	2	7	7	24 hrs
Peppers	Foliar Ground/aerial		1.56	2	5	3	12 hrs
Pineapple	Foliar Ground		2.0	3	7	7	24 hrs
Potatoes	Foliar Ground/aerial		1.56	2	7	0	12 hrs
Pumpkins	Foliar Ground/aerial		1.0	2	7	1	12 hrs
Radish	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Rutabagas	Foliar		1.25	3	7	7	24 hrs

Crop	Application Type, Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
	Ground/aerial						
Rice	Foliar Ground/ aerial	Non-ULV	1.25	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	14	
Rye	Foliar Ground/ Aerial	Non-ULV	1.0	3	7	7	12 hrs
		ULV/RTU	0.61	1	NA	7	
Salsify	Foliar Ground/aerial		1.25	3	7	7	24 hrs
Shallot	Foliar Ground/aerial		1.56	2	7	3	24 hrs
Sorghum	Foliar Ground/ aerial	ULV only	0.61	2	7	7	12 hrs
Spinach	Foliar Ground/aerial		2.0	2	7	7	24 hrs
Squash, summer	Foliar Ground/aerial		1.75	3	7	1	24 hrs
Squash, winter	Foliar Ground/aerial		1.0	3	7	1	12 hrs
Strawberry	Foliar Ground/aerial		2.0	4	7	3	12 hrs
Sweet potatoes	Foliar Ground/aerial		1.56	2	7	0	12 hrs
Swiss chard	Foliar Ground/aerial		1.5	2	7	14	24 hrs
Tomatoes, Tomatilloes	Foliar Ground/aerial		1.56	4	5	1	12 hrs
Vetch	Foliar Ground/ aerial	Non-ULV	1.56	5	14	3	12 hrs
		ULV/RTU	0.61	2 per cutting	14	0	

Crop	Application Type; Application Method (Formulation)		Maximum Single Application Rate (lb ai/A)	Maximum Number of Applications Per Year	Minimum Application Interval (days)	Minimum Pre-Harvest Interval (days)	Restricted Entry Interval (days)
Walnuts	Foliar Ground		2.5	3	7	7	24 hrs
Watercress	Foliar Ground/aerial		1.25	5	3	3	24 hrs
Watermelons	Foliar Ground		1.5	4	7	1	12 hrs
Wheat, spring and winter	Foliar Ground/ aerial	Non-ULV	1.0	2	7	7	12 hrs
		ULV/RTU	0.61	2	7	7	12 hrs
Wild Rice	Foliar Ground/ aerial	Non-ULV	1.25	2	7	7	24 hrs
		ULV/RTU	0.61	2	7	14	12 hrs
Yams	Foliar Ground/aerial		1.56	2	7	0	24 hrs

APPENDIX B

CHEMINOVA

Cheminova, Inc.
Washington Office
1600 Wilson Boulevard
Suite 700
Arlington, VA 22209

Phone: (703) 373-8883
Fax: (703) 373-8887

March 26, 2008

Eric Miederhoff
Special Review and Reregistration Division
Office of Pesticide Programs, 7508C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Fyfanon Technical (EPA Reg. No. 4787-5) and
Malathion Technical (EPA Reg. No. 4787-43)

Dear Mr. Miederhoff:

This letter is a follow-up to our letters of December 16, 2005, and December 19, 2006, in which we identified several uses for which we were requesting voluntary cancellation. Our intention is that this letter provide the definitive list of malathion uses we are not supporting.

Thus, on behalf of Cheminova A/S (Company #4787), I am requesting voluntary cancellation of the following uses from our malathion technical registrations:

- all direct animal and livestock treatments including (goats, hog, horse, poultry, fowl, sheep and cattle: dairy, non-dairy, lactating and non-lactating)
- animal kennels/sleeping quarters (commercial)
- animal premise and barns used for dairy and livestock
- cats
- cattle feed concentrate blocks (non-medicated)
- cattle feedlots and holding pens
- cereal processing plants
- commercial and industrial uses for bagged flour
- commercial storages/warehouses premises (excluding stored grain facilities such as silos)
- commercial transportation facilities - feed/food - empty
- commercial transportation facilities - nonfeed/nonfood
- commercial/institutional/industrial premises/equipment (indoor)
- dairies/cheese processing plant equipment (food contact)
- direct animal treatments including all livestock (horse, hog, sheep, goat, poultry, fowl and dairy, non-dairy, lactating and non-lactating cattle) and pets
- dogs
- edible and inedible commercial establishments
- edible and inedible eating establishments

- edible and inedible food processing plants
- feed rooms
- field or garden seeds
- forest trees (including Douglas fir, eastern pine, hemlock, larch, pines, red pine, spruce, and true fir)
- golf course turf
- greenhouse - empty
- greenhouse - in use
- human clothing (woolens and other fabrics)
- indoor hard surfaces
- indoor premises
- manure piles
- mattresses
- packaged cereals
- pet foods and feed stuff
- poultry houses
- rabbits on wire
- residential dust formulations
- residential lawns (broadcast)
- residential pressurized can formulations
- sewage systems
- stables and pens
- citrus, post-harvest use on dried citrus pulp
- cranberry
- flax
- grape, post-harvest use on raisin drying trays
- lentil
- pea vine
- safflower
- sunflower, pre-harvest
- tobacco

Please note that the residential lawn broadcast use was the subject of a previous voluntary cancellation request dated March 18, 2002.

Cheminova is willing to waive the 180-day comment period for the Federal Register 6(f) notice that our request triggers, if that would assist the Agency in facilitating our request.

If you have any questions or concerns regarding this request, please do not hesitate to call me at 703-373-8883, ext 2.

Sincerely,

Diane Allemang

Diane Allemang
Vice President, Global Regulatory Affairs
Cheminova, Inc.
EPA Agent for Cheminova A/S

cc: Inge Margrethe Jensen, Cheminova A/S
Kari Mavian, Cheminova, Inc.
David Menotti, Pillsbury Winthrop
Paul Whatling, Cheminova, Inc.

Appendix C

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Kari Mavian
Senior Regulatory Affairs Manager
Cheminova Inc.
1700 Route 23, Suite 300
Wayne, NJ 07470

MAR 14 2007

Dear Ms. Mavian:

SUBJECT: Supplemental Label for Boll Weevil Eradication Program
Fyfanon ULV
EPA Registration No. 67760-34
Your Submission Dated January 5, 2003

The supplemental labeling referred to above and submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. At your next label printing, or within one year, whichever comes first, you must incorporate this supplemental labeling into the main product labeling.

A stamped copy of the label is enclosed for your records. Submit one copy of your final printed label before you release the product for shipment.

Sincerely yours,

Marilyn A. Mautz
Biologist
Insecticide-Rodenticide Branch
Registration Division (7504P)

SUPPLEMENTAL LABEL

ACCEPTED
MAR 14 2007
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide Registered under EPA Reg. No. 67760-34

Fyfanon® ULV
EPA Reg. No. 67760-34

KEEP OUT OF REACH OF CHILDREN

CAUTION

DIRECTIONS FOR USE
It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Read the entire label. Use strictly in accordance with precautionary statements and directions, and with applicable state and federal regulations.

IN CASE OF A MEDICAL EMERGENCY INVOLVING THIS PRODUCT, CALL TOLL FREE, DAY OR NIGHT, 1-866-303-6950

Use Directions

Crop	Pests controlled	Fl. oz/acre	Comments	Pre-harvest interval
Cotton	Boll Weevils	8 – 16 16	Early to midseason Late season	0
For use on cotton: Fyfanon ULV can be used alone as a Fyfanon ULV concentrate spray or diluted in once-refined cottonseed or vegetable oil sufficient to make at least one quart of finished spray per acre.				

USE PRECAUTIONS FOR APPLICATION TO COTTON TO CONTROL BOLL WEEVIL

Treatment supervisors and applicators must be aware of all sensitive areas near cotton fields, including: schools, hospitals, nursing homes, churches, occupied dwellings, parks, recreation areas, bodies of water, and potential habitat for threatened and endangered species."

"For aerial applications, spray equipment must be adjusted so that the volume median diameter is 100 microns (Dv 0.5 = 100um) or greater (Very Fine or coarser spray according to ASAE S572. The effects of flight speed, nozzle angle and type, and pump pressure on the droplet size spectrum must be considered."

"For aerial applications, the spray boom should be mounted on the aircraft as to minimize drift caused by wingtip or rotor vortices. The minimum practical boom length should be used and outermost nozzles must not be placed beyond 75% of the wingspan or rotor diameter."

"Spray should be released at the lowest height consistent with pest control and flight safety. Applications more than 10 feet above the crop canopy should be avoided."

"Global positioning systems (GPS) should be used to guide pilots and to monitor each application."

"Ground equipment should utilize a controlled air flow to facilitate particle size and spray deposition, and should be used at a vehicle speed of 4 to 10 mph. Spray equipment must be adjusted so that the volume median diameter is 100 microns (Dv 0.5 = 100um) or greater."

"Ground equipment should be used to treat field edges when possible, covering areas that can not be treated effectively with aircraft because of obstructions which may affect applicator safety, or where there is boll weevil over-wintering habitat adjacent to the treatment area, or if there are adjacent sensitive areas."

"Do not apply when wind velocity exceeds 10 mph. Treatments should be applied when winds are calm, or moving away from adjacent sensitive areas."

"When applications are made with a cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind."

"Do not make aerial or ground applications into temperature inversions. Inversions are characterized by stable air and increasing temperatures with height above the ground. Mist or fog may indicate the presence of an inversion in humid areas. The applicator may detect the presence of an inversion by producing smoke and observing a smoke layer near the ground surface."

"Applications will not be made when people are in or near infested cotton fields or, to the degree possible, when people are present in or near adjacent sensitive areas."

"Application will not be made when rainfall is imminent.

"Before beginning treatment, program personnel shall notify all registered apiarists in or near the treatment area of the date and approximate time of treatment."

THIS LABEL MUST BE IN THE POSSESSION OF THE USER AT THE TIME OF APPLICATION. PLEASE REFER TO CONTAINER LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS. IN ADDITION TO THE RESTRICTIONS LISTED HERE, THE USER MUST FOLLOW ALL APPLICATION DIRECTIONS, RESTRICTIONS, AND PRECAUTIONS OTHERWISE LISTED ON THE EPA REGISTERED LABEL.

®Fyfanon is a registered trademark of Cheminova

1/5/07

Appendix D

BWEP Operational Procedures and Mitigation Measures

BWEP Operational Procedures

All Methods of Control

1. All applicable Federal, State, and local environmental laws and regulations will be followed during boll weevil control operations.
2. Sensitive areas (water bodies; parks; and occupied dwellings, such as homes, schools, churches, hospitals, and recreation areas) that may be adjacent to cotton fields will be identified. The program will be adjusted accordingly to ensure that these areas are not negatively affected.
3. Environmental monitoring of the program will be in accordance with the current environmental monitoring plan.
4. All cotton fields will be trapped. During the initial diapause year of the program, all fields will be treated from "ten percent cracked boll" until there is no hostable material remaining. In subsequent years, only hostable fields from which boll weevils have been caught will be treated.
5. All program personnel involved in chemical applications will be instructed on the safe use of malathion, the safe use of equipment, and on operational procedures. Field supervisors will train Field Technicians, mist blower operators and high-clearance sprayer operators on operational procedures, and monitor their conduct during working hours.

Aerial Applications

1. All materials will be applied in strict accordance with EPA- and State-approved label instructions.
2. Aircraft, spray equipment, and pilots that do not meet all contract requirements will not be allowed to operate.
3. All USDA, APHIS, Plant Protection and Quarantine employees who plan, supervise, recommend or perform pesticide treatments must be certified under the APHIS pesticide certification plan. They are also required to meet any additional requirements of the State where they perform duties involving pesticide use. All Foundation personnel involved in pesticide application must maintain State pesticide applicator certification as required by state law.
4. Only certified aerial applicators who have been familiarized with local conditions will be used by the program.

5. To minimize drift and volatilization, applications will not be made when any of the following conditions exist in the treatment area: wind velocity exceeds 10 miles per hour (or less if required by State law); prevailing wind is blowing toward a nearby residence or other sensitive site; rain is falling or is imminent; fog is present, or air is turbulent enough to seriously affect the normal spray pattern; or temperature inversions exist that could lead to offsite movement of applied material.

BWEP Mitigation Measures

All required State and local authorities will be notified upon initiation of the program. The notification will advise State and local authorities of the need for any assistance in identifying sensitive areas in proposed treatment areas.

Protection of Bees

Before beginning treatment with malathion, program personnel shall notify all registered apiarists in or near the treatment area of the date and approximate time of chemical treatment.

Protection of Wildlife

5. All control operations will be conducted with appropriate concern for their potential impact on endangered, threatened, and proposed species identified in this document.
6. APHIS has prepared a biological assessment for federally listed endangered, threatened and proposed species found within all U.S. cotton-producing counties from species information provided by the U.S. Department of the Interior, Fish and Wildlife Service (FWS) and State wildlife agencies.
7. Adequate protection measures are developed for federally listed endangered, threatened and proposed species through the Endangered Species Act, section 7, formal and informal consultations with FWS. Specific biological and distributional data for species is gathered in discussions between APHIS, Plant Protection and Quarantine, local FWS offices, State wildlife agencies and the Foundation before operations begin.
8. Species and habitats protected by State laws are addressed in site-specific assessments as needed.

Appendix E

Fruit Fly Cooperative Control Program
Summary of Operational Procedures and Mitigation Measures

Standard Operational Procedures

A. General

1. All applicable environmental laws and regulations will be followed.
2. All program personnel will be instructed on procedures and proper use of equipment and materials. Field supervisors will emphasize these procedures and monitor the conduct of program personnel.
3. All materials will be used, handled, stored, and disposed of according to applicable laws so as to minimize potential impacts to human health and the environment.
4. All applications will be made and timed in such a manner as to minimize potential impact to the public and nontarget organisms, including endangered and threatened species.
5. Environmental monitoring of fruit fly programs will be according to individual site-specific monitoring plans that take into account the characteristics of the specific program areas. Monitoring components may vary from program to program.

B. Chemical Applications

1. All pesticides will be applied by certified applicators according to label instructions and applicable quarantine or emergency exemptions.
2. All pesticides will be stored according to U.S. Environmental Protection Agency guidelines and local regulations. Pesticide storage areas will be inspected periodically.
3. All mixing, loading, and unloading will be in an area where an accidental spill will not contaminate a stream or other body of water.
4. To the degree possible, pesticides will be delivered and stored in sealed bulk tanks, and then pumped directly into the tank of the aircraft or ground equipment.
5. Any pesticide spills will be cleaned up immediately and disposed of in a manner consistent with the label instructions and applicable environmental regulations.
6. All program personnel will be instructed on emergency procedures in the event of accidental pesticide exposure. Equipment necessary for emergency washing procedures will be available.

7. All APHIS employees who plan, supervise, recommend, or perform pesticide treatments are also required to know and meet any additional State and local qualifications or requirements of the area where they perform duties involving pesticide use.
8. All pesticide applicators will meet State licensing requirements for the program area State; reciprocal Federal/State licensing agreements may be honored for this program.
9. Pilots, loaders, and other personnel handling pesticides will be advised to wear proper safety equipment and protective clothing.
10. Manufacturers' Safety Data Sheets for program pesticides will be made available for program personnel.
11. Program officials will notify hospitals and public health facilities of pesticide treatment schedules and the types of pesticides used.

C. Aerial Operations

1. Prior to beginning operations, aerial applicators will be briefed by program staff regarding operational procedures, application procedures, treatment areas, local conditions, and safety considerations.
2. All lead aircraft will use loran RNAV-R-40 guidance systems or an equivalent system to assure the accurate placement of insecticide. All aircraft used in aerial insecticide application will use the Pathlink System or an equivalent system which provides a permanent record of the flight and applications.

D. Risk Reduction

1. Program personnel will use dye cards (cards sensitive to malathion bait spray), as needed, to determine swath width during calibration and monitoring. Dye cards are used in monitoring to validate swath width and droplet size, and for evaluation of the potential for drift.
2. Aircraft, dispersal equipment, and pilots that do not meet all contract requirements will not be allowed to operate.

E. Ground Operations

1. Ground applications of chemical pesticides will be made to fruit fly host environments only.

Mitigative Measures

A. Protection of Human Health Workers

1. Applicators, mixers, and loaders of chemical pesticides will be advised to have periodic cholinesterase testing.
2. Unprotected agricultural workers will be advised of the respective reentry periods following treatment in agricultural crop areas.

B. The Public

1. Program personnel shall notify area residents by at least 24 hours (but in practice, often as much as 1 week) in advance of the date and time of planned pesticide treatment.

    a. Notifications will be in English, Spanish, or other languages as necessary, based on the ethnic structure of the community.

    b. The notification shall include basic information about the program and, if applicable, procedures to prepare residents for the presence of aircraft.

2. Any residents within the treatment area who are listed on State public health registries as hypersensitive to chemical exposure will be informed of the planned times and locations of all applications of malathion bait spray. They will also be advised that they may contact their physicians regarding ways to minimize their exposure t to program chemicals.

3. Residents will be advised to remain indoors, take pets indoors (or provide cover for them), and cover garden fish ponds during spraying operations.

4. Residents will be advised to cover cars to protect them from possible damage caused by the bait spray.

5. A telephone hot line will be established before an eradication program and maintained during the program to keep the public informed of the most current and complete information available.

C. Protection of Nontarget Species

1. Honey Bee Protection

a. APHIS or a State cooperator will notify registered beekeepers of program treatments before chemical applications are conducted.

b. Information describing protection measures which can be taken by beekeepers to protect their colonies will be made available through beekeeper associations and State Agricultural Extension Agents.

c. The telephone hot line will describe protective procedures for beekeepers in addition to its primary function of informing the general public and answering questions concerning the fruit fly eradication program.

D. Risk Reduction

1. Beneficial species

a. Program managers will consult with State plant protection officials regarding programs involving the use or release of beneficial species and biocontrol agents and will adhere to any recommendations provided by the State officials.

2. Endangered and Threatened Species

a. APHIS or its designated non-Federal representative will consult with the U.S. Department of Interior's Fish and Wildlife Service,

under the provisions of the Endangered Species Act, Section 7, for the protection of endangered and threatened species.

b. APHIS will implement measures mutually agreed upon with the Fish and Wildlife Service for the protection of endangered and threatened species.

3. Wildlife, Livestock, and Pets

a. All control operations will be conducted with appropriate concern for potential impact on nontarget organisms, including wildlife, livestock, and pets.

b. Homeowners and agriculturalists will be advised by written notification and telephone hot line of the ways in which they can protect livestock and pets.

E. Protection of the Physical Environment

- Program activities will take into account site-specific aspects of the program area and will be tailored accordingly to maximize program efficiency and minimize potential adverse effects.
- Treatment areas will be inspected before any treatment to determine the presence, location, and nature of sensitive areas. Where aerial applications could result in an unacceptable potential risk to a sensitive area, the program manager(s) will determine the need for approved alternative controls, as described in this analysis.
- Aerial chemical applications will not be made where water contamination poses a major concern. Buffers with no aerial treatment (i.e., ground applications only) will be maintained around "major" water bodies (those named on 1:24,000 USGS Quadrangles) unless monitoring results and/or consultations with the State and EPA conclude otherwise.
- Applications may be made by helicopters to enhance accurate delivery of pesticides, as well as increase safety for applicator pilots.
- To minimize drift, volatilization, and runoff, pesticide applications will not be made when any of the following conditions exist in the treatment area: wind velocity exceeding 10 mph (or less if required by State law), rainfall or imminent rainfall, foggy weather, air turbulence that could seriously affect the normal spray pattern, or temperature inversions that could lead to off-site movement of spray.
- Sensitive areas (including reservoirs, lakes, parks, zoos, arboretums, schools, churches, hospitals, recreation areas, refuges, and organic farms) near treatment areas will be identified. The program will take appropriate action to ensure that these areas are not adversely affected.
- To the maximum extent possible, program managers will coordinate with other programs to reduce potential for cumulative impacts.

Appendix F

UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
NATIONAL MARINE FISHERIES SERVICE
Northwest Region
7600 Sand Point Way N.E., Bldg. 1
Seattle, WA 98115

Refer to NMFS No:
2006/01045

May 9, 2006

Mr. Mitchell Nelson
USDA APHIS
6135 NE 80th Ave, Ste A-5
Portland, Oregon 97218-4033

Re: Reinitiation of Endangered Species Act Section 7 Informal Consultation and Magnuson-Stevens Fishery Conservation and Management Act Essential Fish Habitat Consultation for the Animal and Plant Health Inspection Service's Rangeland Grasshopper and Mormon Cricket Suppression Program for Eighteen Counties in Central and Eastern Oregon

Dear Mr. Nelson:

On March 13, 2006, the National Marine Fisheries Service (NMFS) received your request for written concurrence that the effects of implementing the Animal and Plant Health Inspection Service's (APHIS) Rangeland Grasshopper and Mormon Cricket Suppression Program, as proposed, pursuant to section 417 of the Plant Protection Act, is "not likely to adversely affect" (NLAA) species listed as threatened or endangered under the Endangered Species Act (ESA) or their designated critical habitat. The request included the information necessary to complete an essential fish habitat (EFH) assessment under the Magnuson-Steven Fishery Conservation and Management Act (MSA). This consultation is a reinitiation of a previous informal consultation, which concluded with a letter of concurrence dated June 15, 2004 (refer to NMFS No.: 2004/00559). Consultation is being reinitiated due to the September 2, 2005, designation of critical habitat (70 FR 52630) for several species addressed in the June 15, 2004 letter of concurrence. The critical habitat designation became effective on January 2, 2006.

This response to your letter was prepared by NMFS pursuant to section 7(a)(2) of the ESA, implementing regulations at 50 CFR 402 and agency guidance for preparation of letters of concurrence,[1] and concludes that the action, as proposed, is NLAA Lower Columbia River (LCR) steelhead (*Oncorhynchus mykiss*), Middle Columbia River (MCR) steelhead, Snake River Basin (SRB) steelhead, Upper Columbia River (UCR) steelhead, LCR Chinook salmon (*O. tshawytscha*), Snake River (SR) fall-run Chinook salmon, SR spring/summer run Chinook salmon, UCR spring-run Chinook salmon, LCR coho salmon (*O. kisutch*), Columbia River chum salmon (*O. keta*), and SR sockeye salmon (*O. nerka*) or their designated critical habitats.

[1] Memorandum from D. Robert Lohn, Regional Administrator, to ESA Consultation Biologists (guidance on informal consultation and preparation of letters of concurrence) (January 30, 2006).

This letter also transmits the results of our analysis of the effects of the proposed action on EFH pursuant to section 305(b) of the MSA, implementing regulations at 50 CFR 600.920, and agency guidance for use of the ESA consultation process to complete EFH consultation,[2] and concludes that the action, as proposed, is not likely to adversely affect EFH designated for Chinook salmon and coho salmon. Therefore, no conservation measures are provided at this time and no further response is necessary.

DESCRIPTION OF THE PROPOSED ACTION

The proposed action is intended to suppress outbreaks of grasshoppers and Mormon crickets on Federal, state, and privately-owned rangelands in eighteen counties of central and eastern Oregon, including Baker, Crook, Deschutes, Gilliam, Grant, Harney, Hood River, Jefferson, Lake, Klamath, Malheur, Morrow, Sherman, Umatilla, Union, Wallowa, Wasco, and Wheeler Counties. Malathion, carbaryl, and diflubenzuron insecticides will be used. The program is intended to reduce the economic impact of grasshopper and Mormon cricket infestations on rangeland.

The present consultation differs from the proposed action in the consultation completed June 15, 2004, in three aspects. The proposed ground application buffers beside perennial streams within HUC4 subbasins with listed species is now 300 feet instead of 500 feet; no-application buffers for intermittent streams have been added, and ground application of diflubenzuron has been included.

In response to a lawsuit against the Environmental Protection Agency (EPA), the United States District Court for the Western District of Washington ordered an injunction establishing buffers for pesticide application beside "salmon-supporting waters" in Washington, Oregon, and California.[3] On January 22, 2004, the court ordered buffers of 100 yards for aerial application and 20 yards for ground application of certain pesticides. Carbaryl, malathion, and diflubenzuron are included in the list, however APHIS has proposed buffers that are a minimum of four times that of the court order (¼ mile for aerial application and 300 feet for closest ground application).

The eighteen central and eastern Oregon counties covered by this consultation are surveyed annually to help predict where outbreaks of grasshoppers or Mormon crickets may occur. Treatments will only occur when these areas have infestations of grasshoppers or Mormon crickets at a level that is economically prudent to suppress with treatment. Annual suppression activities may begin as early as May 1, and continue through grasshopper season which ends by July 31 of the same year. This consultation covers suppression activities described by APHIS beginning on May 1, 2006, and will expire September 30, 2009.

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[2] Memorandum from William T. Hogarth, Acting Administrator for Fisheries, to Regional Administrators (national finding for use of Endangered Species Act section 7 consultation process to complete essential fish habitat consultations) (February 28, 2001).

[3] Washington Toxics Coalition, et al. v. EPA. Information and final ruling available at http://www.epa.gov/oppfead1/endanger/wtc/

APHIS proposes to suppress economically-damaging infestations of grasshoppers and Mormon crickets using conventional rates of application of malathion, carbaryl, and diflubenzuron or reduced agent area treatments (RAAT) with these insecticides. The RAAT strategy alternates treated and untreated swaths rather than treating the entire infested area. Four methods of insecticide dispersal are proposed by APHIS: (1) An ultra-low volume (ULV) liquid spray applied aerially; (2) applying diflubenzuron using a vehicle-mounted sprayer; (3) applying carbaryl bait aerially; and (4) applying carbaryl bait using ATVs with a vehicle-mounted spreader. All applicable Federal, state, tribal, and local environmental laws and regulations will be followed during suppression activities.

For conventional rates of application, APHIS proposes to use malathion at 0.62 pounds/acre (lbs/ac) of active ingredient for ULV spray, carbaryl at 0.5 lbs/ac of active ingredient for ULV spray, carbaryl at 0.5 lbs/ac of active ingredient for bait applications, and diflubenzuron at 0.016 lbs/acre of active ingredient for ULV spray.

The RAAT method would use malathion application at 0.31 lbs/ac of active ingredient for ULV spray, carbaryl at 0.25 lbs/ac of active ingredient for ULV spray, carbaryl at 0.20 lbs/ac of active ingredient for bait application, and diflubenzuron at 0.012 lbs/ac of active ingredient for ULV spray. In addition to the reduced concentrations, the RAAT method also affects a smaller area. The area of insecticide application will vary from 20% to 67% of the total treatment area. All malathion and carbaryl ULV sprays will be applied aerially, diflubenzuron ULV sprays and carbaryl bait may be applied aerially or by ATVs.

The following conservation measures will be implemented as part of the proposed action:

1. APHIS will contact NMFS' Eastern Oregon Habitat Branch (EOHB) prior to application to determine proximity of ESA-listed fish to area to be treated.
2. Perennial streams within HUC4 subbasins with listed species will have a ¼-mile no-application buffer for ULV aerial applications.
3. Intermittent streams within five miles of habitat occupied by listed species will have a 300-foot no-application buffer for ULV aerial applications[4].
4. Perennial streams within HUC4 subbasins with listed species will have a 500-foot no-application buffer for carbaryl bait aerial applications.
5. Intermittent streams within five miles of habitat occupied by listed species will have a 100-foot no-application buffer for carbaryl bait aerial applications.
6. Perennial streams within HUC4 subbasins with listed species will have a 300-foot no-application buffer for ground ULV and carbaryl bait applications.
7. Intermittent streams within five miles of habitat occupied by listed species will have a 100-foot no-application buffer for ground ULV and carbaryl bait applications.
8. All insecticides will be used in accordance with the label.

[4] Conservation measures for intermittent streams in this document refer only to those streams identified at the 1:100,000 scale in the StreamNet Pacific NW Interactive Mapper (http://map.streamnet.org/snetmapper/viewer.htm) that do not contain water at the time of pesticide application. These streams will be identified cooperatively by APHIS and NMFS when NMFS is notified of proposed application.

9. Mixing, loading, and unloading will take place in areas where an accidental spill would not contaminate a water body.
10. Global Positioning System (GPS) coordinates or shape files if available, will provide pilot guidance on the parameters of the spray block. Ground flagging or markers should accompany GPS coordinates, when necessary, to delineate the project area and to omit areas from treatment.
11. Appropriate field personnel will utilize two-way communication equipment. Communication will be available for continuous contact between pilots and the contracting officer.
12. To minimize drift and volatilization, aerial applications will not be conducted when wind velocity exceeds 10 miles per hour, a temperature inversion is in place, rain is imminent, fog is present, or foliage is wet.
13. Weather conditions at the treatment area will be monitored by trained personnel before and during application. Operations will be suspended at any time that weather conditions could jeopardize the safe or effective placement of the spray on target areas.

ENDANGERED SPECIES ACT

In the request for concurrence, APHIS determined that the action, as proposed, is NLAA LCR steelhead, MCR steelhead, SRB steelhead, UCR steelhead, LCR Chinook salmon, SR fall-run Chinook salmon, SR spring/summer run Chinook salmon, UCR spring-run Chinook salmon, LCR coho salmon, Columbia River chum salmon, and SR sockeye salmon or their designated critical habitats (Table 1).

For purposes of the ESA, "effects of the action" means the direct and indirect effects of an action on the listed species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action (see, 50 CFR 402.02). The applicable standard to find that a proposed action is NLAA listed species or critical habitat is that all of the effects of the action are expected to be discountable, insignificant, or completely beneficial (Lohn, 2006). Discountable effects cannot be reasonably expected to occur. Insignificant effects are so mild that the effect cannot be meaningfully measured, detected, or evaluated as take. Beneficial effects are contemporaneous positive effects without any adverse effect to the listed species or critical habitat, even if the long-term effects are beneficial.

Table 1. Federal Register notices for final rules that list threatened and endangered species, designate critical habitats, or apply protective regulations to listed species considered in this consultation. (Listing status: 'T' means listed as threatened under the ESA; 'E' means listed as endangered).

Species	Listing Status	Critical Habitat	Protective Regulations
Chinook salmon (*Oncorhynchus tshawytscha*)			
Lower Columbia River	T 6/28/05; 70 FR 37160	9/02/05; 70 FR 52630	6/28/05; 70 FR 37160
Upper Columbia River spring-run	E 6/28/05; 70 FR 37160	9/02/05; 70 FR 52630	ESA section 9 applies
Snake River spring/summer run	T 6/28/05; 70 FR 37160	10/25/99; 64 FR 57399	6/28/05; 70 FR 37160
Snake River fall-run	T 6/28/05; 70 FR 37160	12/28/93; 58 FR 68543	6/28/05; 70 FR 37160
Chum salmon (*O. keta*)			
Columbia River	T 6/28/05; 70 FR 37160	9/02/05; 70 FR 52630	6/28/05; 70 FR 37160
Coho salmon (*O. kisutch*)			
Lower Columbia River	T 6/28/05; 70 FR 37160	Not applicable	6/28/05; 70 FR 37160
Sockeye salmon (*O. nerka*)			
Snake River	E 6/28/05; 70 FR 37160	12/28/93; 58 FR 68543	ESA section 9 applies
Steelhead (*O. mykiss*)			
Lower Columbia River	T 1/05/06; 71 FR 834	9/02/05; 70 FR 52630	6/28/05; 70 FR 37160
Middle Columbia River	T 1/05/06; 71 FR 834	9/02/05; 70 FR 52630	6/28/05; 70 FR 37160
Upper Columbia River	T 1/05/06; 71 FR 834	9/02/05; 70 FR 52630	6/28/05; 70 FR 37160
Snake River Basin	T 1/05/06; 71 FR 834	9/02/05; 70 FR 52630	6/28/05; 70 FR 37160

The effects of the action, as proposed, are reasonably likely to include exposure of listed juveniles, prey, and critical habitat to low concentrations of malathion, carbaryl, and diflubenzuron. All of the effects associated with the proposed action will be limited to a day or two. The biological assessment includes GLEAMS modeling results for expected chemical concentrations in water for each chemical. A worst-case scenario was modeled separately for each chemical and included maximum aerial application rates with no buffer along a stream that is 0.76 meters (m) deep, 1.52 m wide, with a velocity of 3.60 m/second. The model predicted a concentration of diflubenzuron which would result in sublethal effects to *Daphnia* and no apparent effects to salmonids or other prey items, a concentration of carbaryl which would result in sublethal effects to invertebrates and may result in sublethal effects to salmonids, and a concentration of malathion which would result in lethal and sublethal effects to salmonids. However, the no-application buffers along perennial and intermittent streams in HUC4 subbasins with listed fish and other conservation measures will function to prevent harmful concentrations of diflubenzuron, carbaryl, and malathion from entering stream water.

The NMFS concludes that all effects of the action, as proposed, are insignificant and therefore are NLAA LCR steelhead, MCR steelhead, SRB steelhead, UCR steelhead, LCR Chinook salmon, SR fall-run Chinook salmon, SR spring/summer run Chinook salmon, UCR spring-run Chinook salmon, LCR coho salmon, Columbia River chum salmon, SR sockeye salmon and designated critical habitat. There is a chance that small amounts of insecticide will enter streams through drift during application or through overland flow during an extraordinary summer rain event. The concentrations of insecticides expected to enter streams are so small that the greatest effects would be slight changes in invertebrate prey behavior. Listed juveniles would not be directly affected, but changes in the ability of invertebrates to avoid predators could slightly

increase or decrease juvenile salmonid prey availability. A change in prey behavior and the corresponding change in availability to listed juvenile salmonids would be so small and slight that it could not be meaningfully measured.

Reinitiation of consultation is required and shall be requested by the APHIS, or by the NMFS, where discretionary Federal involvement or control over the action has been retained or is authorized by law and: (1) new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (2) the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in this concurrence letter; or (3) a new species is listed or critical habitat designated that may be affected by the identified action [50 CFR 402.16]. This concludes the ESA portion of this consultation.

MAGNUSON-STEVENS FISHERY CONSERVATION AND MANAGEMENT ACT

In supplemental information provided following the request for ESA concurrence, the APHIS determined that the action, as proposed, is not likely to adversely affect EFH designated for Chinook and coho salmon.[5]

For purposes of MSA, "adverse effect" means any impact which reduces quality and/or quantity of EFH. Adverse effects may include direct (*e.g.*, contamination or physical disruption), indirect (*e.g.*, loss of prey, reduction in species' fecundity), site-specific or habitat-wide impacts, including individual, cumulative, or synergistic consequences of actions [50 CFR 600.910(a)]. Avoidance and minimization measures are analyzed by NMFS as part the action, as proposed. However, NMFS will not consider proposed compensatory mitigation as part of the effects analysis, although completing sufficient compensatory mitigation for the effects of action may make the net effect of that action neutral or positive for EFH.

The effects of the action, as proposed, on EFH are the same as those described above in the ESA portion of this document and NMFS concurs with the findings in the EFH assessment.

Because the properties of EFH that are necessary for the spawning, breeding, feeding or growth to maturity of managed species in the action area are the same or similar to the biological requirements of ESA-listed species as analyzed above, and because the conservation measures that the APHIS included as part of the proposed action are adequate to avoid, minimize, or otherwise off set those adverse effects to designated EFH, NMFS has no conservation recommendations to make at this time and no reporting is necessary. This concludes the EFH portion of this consultation.

The APHIS is required to complete a supplemental EFH consultation with NMFS if it substantially revises its plans for this action in a manner that may adversely affect EFH or if new

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[5] Pacific Fishery Management Council, 1999, Amendment 14 to the Pacific Coast Salmon Plan. Appendix A: Description and Identification of Essential Fish Habitat, Adverse Impacts and Recommended Conservation Measures for Salmon. Pacific Fishery Management Council, Portland, Oregon (March 1999). http://www.pcouncil.org/salmon/salfmp/a14.html.

information becomes available that affects the basis for NMFS' EFH conservation recommendations [50 CFR 600.920(k)].

Please direct questions regarding this letter to Scott Hoefer, Fishery Biologist in the Eastern Oregon Habitat Branch of the Oregon State Habitat Office at 509.962.8911, ext. 225.

Sincerely,

for D. Robert Lohn
Regional Administrator

cc: Kevin Martin, USFS
Steve Ellis, USFS
Roger Williams, USFS
Jeff Walter, USFS
Leslie Weldon, USFS
Karen Shimamoto, USFS
Gary Larsen, USFS
David Henderson, BLM
Barron Bail, BLM
Nancy Gilbert, USFWS
Gary Miller, USFWS
Tim Bailey, ODFW
Jeff Zakel, ODFW
Tim Unterwegner, ODFW
Rod French, ODFW

UNITED STATES DEPARTMENT OF COMMERCE
National Oceanic and Atmospheric Administration
NATIONAL MARINE FISHERIES SERVICE
Northwest Region
7600 Sand Point Way N.E., Bldg. 1
Seattle, WA 98115

March 1, 2007

Rob McChesney
Plant Protection and Quarantine Officer
Animal and Plant Health Inspection Service
9134 West Blackeagle Drive
Boise, Idaho 83709

RE: 2007 Idaho Rangeland Grasshopper and Mormon Cricket Suppression Program

Dear Mr. McChesney:

This responds to the January 29, 2007, letter regarding Endangered Species Act (ESA) and Magnuson-Stevens Fishery Conservation and Management Act issues pertinent to the subject action. The Animal and Plant Health Inspection Service (APHIS) has determined this project would have no effect on ESA listed Snake River salmon and steelhead, designated critical habitat, or Essential Fish Habitat (EFH) under the jurisdiction of National Marine Fisheries Service (NMFS) so consultation is not necessary.

We appreciate your sharing the basis of the no effect determination so we have an understanding of the basis of your determination if questions arise. If new information becomes available, or if circumstances occur that may affect ESA-listed species, designated critical habitat, or EFH, please contact us. We look forward to working with you to provide technical assistance to this year's treatment program. If you have questions regarding this project, please contact Mr. Rick Edwards (208/378-5645) at the Idaho State Habitat Office.

Sincerely,

D. Robert Lohn
Regional Administrator

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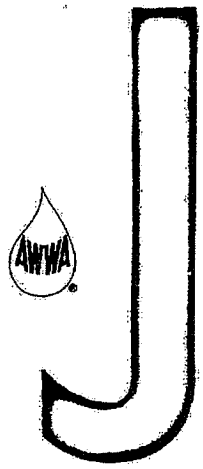
Appendix G



Journal

AMERICAN WATER WORKS ASSOCIATION

VOLUME 60 • 1968

AMERICAN WATER WORKS ASSOCIATION
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Toxic Effects of Odorous Trace Organics

John W. Smith and Sotirios G. Grigoropoulos

A contribution submitted to the Journal *on May 18, 1968, by John W. Smith, Sr. Research Asst., and Sotirios G. Grigoropoulos, Prof. of Civ. Eng., both of the Environmental Health Research Center, Univ. of Missouri-Rolla, Rolla, Mo.*

ORGANIC micropollutants in water may originate from several sources, including industrial and domestic wastes, accidental spillage, agricultural runoff, and bioresistant metabolic byproducts of the natural biota. The USPHS, in recognizing the importance of trace organics in drinking water, has set the maximum permissible limit of chloroform soluble organics at 200 μg/l. Many of the trace organics possess an odor potential and could cause problems of an esthetic nature. Of greater importance, however, is the health hazard represented by these organic micropollutants. This threat is emphasized by the recovery of carcinogenic substances from drinking water in Japan[1] and Germany,[2] and the large-scale fish kills on the lower Mississippi River due to the buildup of a pesticide in the fish.[3] Sproul and Ryckman[4] and Sletten[5] found that trace organics recovered from Missouri River water, both raw and treated, were toxic to rainbow trout at high concentrations (milligrams per liter range) over a short exposure time (4 days); the long-term effect of these materials at lower concentrations was not evaluated. Because trace organics are not completely removed from surface waters by ordinary water treatment practices and subsurface waters are not usually treated in any manner, the presence of these organic micropollutants could represent a serious health threat to the water consumer.

Scope and Objectives

The principle objectives of this investigation are the recovery of organic micropollutants from subsurface and surface Missouri waters; the characterization and identification of these substances; the evaluation of their toxic effects, both acute and long-term; and the development of methods for their destruction or removal.

In a previous article,[6] the authors reported on the recovery and partial characterization of organic micropollutants from several subsurface waters, and the evaluation of the carbon adsorption method with regard to the number of filters required for the effective recovery of organic materials. This article reports on continuing studies to characterize further the trace organics and evaluate their acute and long-term toxic effects.

Recovery of Organics

Organic micropollutants were recovered[6] from subsurface and surface waters using the carbon adsorption method. A spring and two deep wells were sampled using a modified carbon

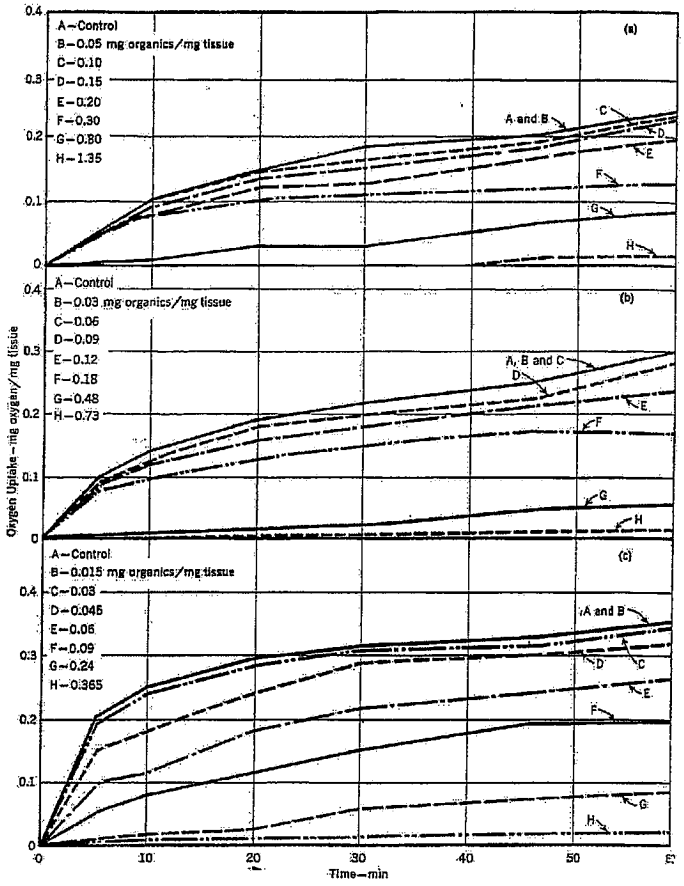


Fig. 1. Effects of Surface Water Organics on Respiratory Trout Tissue Enzyme Activity

(a) 20 mg gill homogenate tissue; (b) 33 mg heart homogenate tissue; (c) 67 mg liver homogenate tissue.

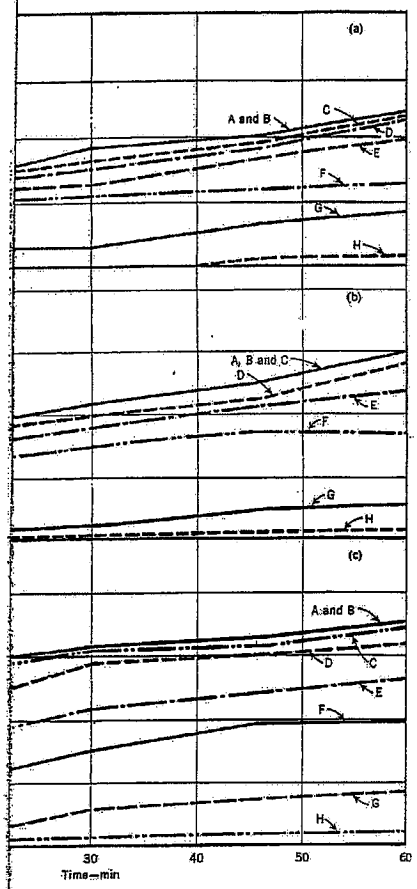
adsorption technique (three 1.5-cu ft activated carbon filters in series). Two filter runs were made at the spring and one at each well. The spring is one of the largest in Missouri and is thought to be contaminated by surface water. Well 1 had not been in use at the time of sampling because it had shown evidence of contamination; Well 2 is presently being used to supply water to a municipality. Although detectable amounts of trace organics were present in the well waters, the quantity of material recovered was not enough to perform extensive characterization studies. Significant quantities of organics, however, were recovered from the spring water, enabling the evaluation of the odor characteristics and toxic effects of these materials. The surface water extract was a yearly composite of chloroform soluble organics in treated Missouri River water. The water was filtered through a standard carbon adsorption unit[7] at a rate proportional to the water production of the treatment plant for 2 weeks; the carbon was removed, dried, and eluted with chloroform.[8] Twenty-four bimonthly samples collected in 1966 were combined to form the yearly composite.

Organoleptic Studies

The odor potential of some of the organics was determined using a panel of six members as outlined in *Standard Methods*.[7] Aqueous solutions of the organics for both the organoleptic and toxicity studies were prepared using a mixer* and an evaporator.† An accurately weighed amount of organics was placed in the mixing flask with a

*Model 26-400, a product of the VirTis Co., Inc., Gardiner, N.Y.

†Model VE-1000-B, a product of Rinco Instrument Co., Inc., Greenville, Ill.



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*Model 26-400, a product of the VirTis Co., Inc., Gardiner, N.Y.

†Model VE-1000-B, a product of Rinco Instrument Co., Inc., Greenville, Ill.

TABLE 1

Characteristic Odor and Odor Potential of Trace Organics in Subsurface Waters.

Extract	Characteristic Odor	Threshold Odor Concentration—μg/l	
		20°C	60°C
Spring Run 1 Unit 1 CCE	Musty	2,310	203
CAE	Musty-flowery	3,400	151
Unit 2 CCE	Musty	110	52
CAE	Earthy-chemical	166	35
Unit 3 CCE	Musty-chemical	364	110
Spring Run 2 Unit 1 CCE	Musty-medicinal	226	127
CAE	Musty-medicinal	553	140
CCE	Musty-flowery	110	58
CAE	Musty-flowery	267	140
Well 1 Unit 1 CCE	Chemical	15,500	880
CAE	Medicinal-chemical	28,300	3,440

The odor potential and characteristic odor of the carbon chloroform extract (CCE) and carbon alcohol extract (CAE) materials recovered from the spring and Well 1 waters were evaluated and the results are presented in Table 1. As can be seen from the data in this table, the spring extracts exhibited a low threshold odor concentration (or high odor potential), while the threshold odor concentration of the Well 1 extracts was quite high. The

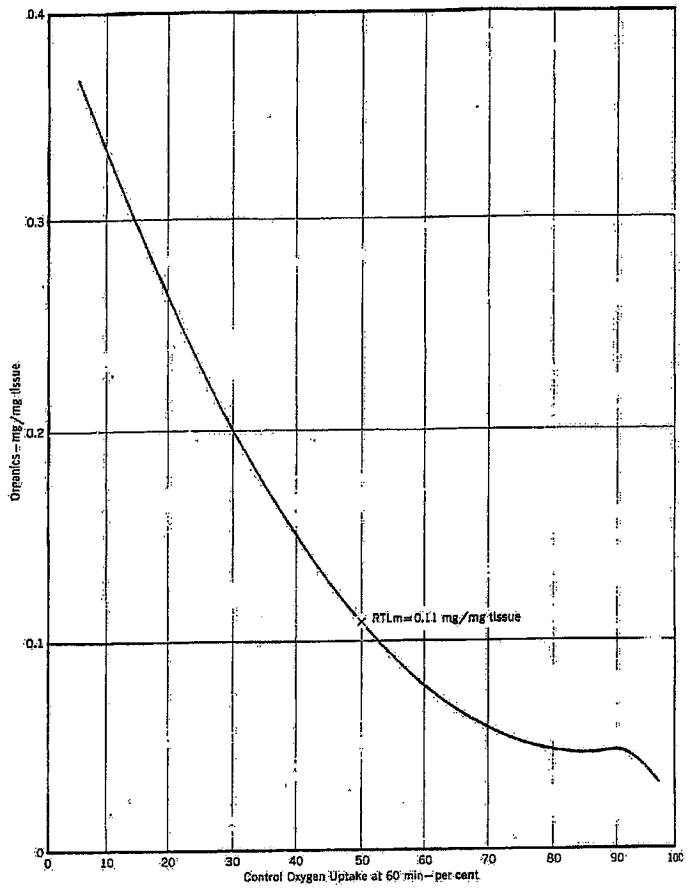

Fig. 2. Median Respiratory Tolerance Limit (RTLm)

Surface water organics with trout liver homogenate are used.

Spring Run 1 Unit 2 CCE and the Well 1 Unit 1 CAE were the most and least odorous, respectively.

Toxicity Studies

Toxic effects of the organic micropollutants and two pesticides were evaluated using fish and fish tissue. Acute and long-term studies and enzyme studies were performed. Rainbow trout, blue green sunfish, mosquito fish, and minnows (red and golden shiners) were utilized in the acute toxicity studies, and trout and minnows were employed to evaluate the long-term effects. Tissue studies were made using homogenized trout liver, heart, and gill tissues. The trout, sunfish, and mosquito fish were obtained from the Missouri Conservation Commission and the minnows supplied by a local hatchery. The trout studies were performed at 12°C (54°F) in a walk-in cold room, while the minnow, sunfish, and mosquito fish studies were run at 22°C (72°F) in the laboratory. The test fish were held in glass aquaria for an acclimation period of at least 10 days before being utilized. Periodic formalin baths (1 ml 25 per cent formalin/gal water for 1 hr) were given as well as daily dosages of an antibiotic* during the acclimation period to suppress biologic growths in the fish. The toxicity studies were performed using previously aerated and settled tap water obtained from several deep wells (Table 2).

Acute Studies

The acute toxicity studies were performed as outlined in *Standard Methods*[7] with supplemental aeration being utilized. The results of these studies are presented in Table 3. Individual

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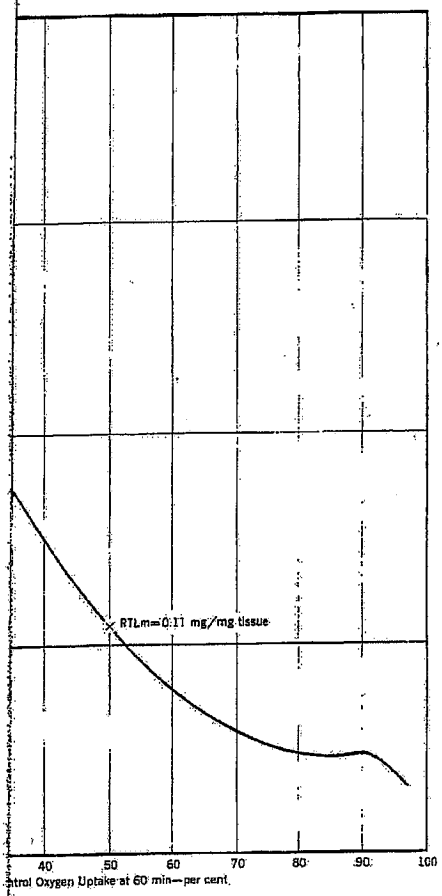

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Toxic effects of the organic micropollutants and two pesticides were evaluated using fish and fish tissue. Acute and long-term studies and enzyme studies were performed. Rainbow trout, blue green sunfish, mosquito fish, and minnows (red and golden shiners) were utilized in the acute toxicity studies, and trout and minnows were employed to evaluate the long-term effects. Tissue studies were made using homogenized trout liver, heart, and gill tissues. The trout, sunfish, and mosquito fish were obtained from the Missouri Conservation Commission and the minnows supplied by a local hatchery. The trout studies were performed at 12°C (54°F) in a walk-in cold room, while the minnow, sunfish, and mosquito fish studies were run at 22°C (72°F) in the laboratory. The test fish were held in glass aquaria for an acclimation period of at least 10 days before being utilized. Periodic formalin baths (1 ml 25 per cent formalin/gal water for 1 hr) were given as well as daily dosages of an antibiotic* during the acclimation period to suppress biologic growths in the fish. The toxicity studies were performed using previously aerated and settled tap water obtained from several deep wells (Table 2).

Acute Studies

The acute toxicity studies were performed as outlined in *Standard Methods*[1] with supplemental aeration being utilized. The results of these studies are presented in Table 3. Individual subsurface water CCE and CAE were not toxic even at concentrations approaching the upper limit of their solubility (400 mg/l for one CAE). In some instances, however, when the CCE and CAE were combined in the same proportion as they were recovered from the water, the combined extract was toxic to the test fish. The extent of the toxicity of the subsurface water organics depended on both the species of fish and the organic micropollutant being tested. The fish that died from exposure to the subsurface water extracts exhibited a loss of balance, rapid operculum movement, and violent swimming before death. Both healthy, unexposed fish, and fish that were killed by the organics were dissected and examined visually to determine the affected organs. The only organs that appeared to be affected were the gills, which showed a lack of red color and an accumulation of light-colored material on the gill lamina, and the gas blatter which was empty and devoid of gas.

TABLE 2

Toxicity Studied on Settled Tap Water after Aeration

Characteristics	Average	Range
pH, units	7.6	7.4–8.2
Total hardness, mg/l as $CaCO_3$	140	95–170
Calcium hardness, mg/l as $CaCO_3$	70	46–89
Alkalinity, mg/l as $CaCO_3$	130	100–160
Dissolved oxygen, mg/l	6.9	6.7–7.1
Ammonia-nitrogen, mg/l	5.0	4.0–6.2
Temperature, °C		
Trout studies	12.2	12.0–13.0
Sunfish, mosquito fish, and minnow studies	21.0	20.0–21.5
Total chlorine, mg/l	<0.1	<0.1

The surface water CCE was also toxic to the test fish, but at a significantly lower concentration. The affected fish before death showed characteristics very similar to the test fish exposed to toxic levels of subsurface materials; however, visual observation

*Terramycin, a product of M-F-A, Columbia, Mo.

TABLE 3

Acute Toxicity of Trace Organics

Test Material	Ratio CCE/CAE	Test Fish (Length—cm/ Weight—g)	TLm Value—mg/l			
			24 hr	48 hr	96 hr	120 hr
Spring* Run 1 Unit 1	1/1.56	Trout (9.4/9.7)	138	130	96	92
		Red Shiners (5.0/2.0)		no effect up to 240		
Unit 2	1/3.65	Red Shiners (2.9/1.3)		no effect up to 200		
Spring* Run 2 Unit 1	1/1.48	Trout (10.3/16.3)	130	125	95	82
		Red Shiners (2.8/1.2)		no effect up to 305		
		Red Shiners (5.6/2.2)		no effect up to 305		
		Sunfish (7.5/9.1)	166	141	115	103
Unit 2	1/3.35	Trout (10.5/16.0)	88	75	61	56
		Trout (5.0/2.6)	201	186	155	130
		Red Shiners (5.7/2.3)	195	170	148	120
		Golden Shiners (6.4/4.0)	180	171	160	152
		Sunfish (7.0/8.7)	137	121	114	100
		Mosquito Fish (2.0/0.2)		no effect up to 270		
Unit 3	1/2.46	Trout (10.1/16.2)		no effect up to 180		
		Trout (5.2/2.0)		no effect up to 180		
Missouri River CCE	N/A	Trout (5.3/2.8)	36	32	28	24
		Golden Shiners (6.6/4.3)	59	52	39	33
		Sunfish (7.7/11.7)	56	49	45	39
Sevin†	N/A	Trout (10.0/15.0)	2.3	1.5	1.0	0.7
		Red Shiners (4.6/1.4)	13	12	9.2	7.4
Malathion‡	N/1	Trout (10.0/15.0)	0.0050	0.0046	0.0028	0.0023
		Red Shiners (4.8/1.9)	0.040	0.036	0.025	0.023

* Combined extract.
† Based on 50 per cent active ingredients.
‡ Based on 57 per cent active ingredient.

of the affected organs indicated that the mode of action was probably different for the two types of extracts. The gills and gas blatter of the test fish killed by the surface water organics appeared normal, but extreme hemorrhaging around the heart and liver was noted.

The acute toxicity of two pesticides, sevin * and malathion,† was also determined in an attempt to evaluate the toxicity procedures with known compounds. The results of these studies are shown in Table 3. Dissection and visual examination of the fish killed by these two materials revealed that the heart, liver, gills, and intestines appeared to be normal.

Tissue Studies

The behavior of the fish before death indicated that the trace organics were affecting the respiratory process; this could be the result of an external physical blockage of oxygen transfer or an internal disruption of respiratory enzyme activity. Enzyme studies using homogenized trout liver, heart, and gill tissue were therefore performed to measure and evaluate indirectly respiratory enzyme activity in the presence of trace organics. The studies were performed with a respirometer‡ at 20°C using a modification of the procedure outlined by Umbreit, *et al.*[8]

Medium to large (12–16 in.) trout were sacrificed and their organs were removed and homogenized in a blender§ at 5°C; the tissue homogen-

* 50 per cent active ingredient, a product of Union Carbide Corporation, New York, N.Y.

† 57 per cent active ingredient, a product of M-F-A, Columbia, Mo.

‡ Model RWBP3, a product of Gilson Medical Electronics, Middleton, Wis.

§ Model 1042, a product of Waring Products Co., Winsted, Conn.

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Toxicity of Trace Organics

Test Fish (ength—cm/ Weight—g)	TLm Value—mg/l			
	24 hr	48 hr	96 hr	120 hr
ut (9.7)	138	130	96	92
Shiners (2.0)		no effect up to 240		
Shiners (1.3)		no effect up to 200		
ut (3/16.3)	130	125	95	82
Shiners (1.2)		no effect up to 305		
Shiners (2.2)		no effect up to 305		
fish (9.1)	166	141	115	103
ut (5/16.0)	88	75	61	56
ut (2.6)	201	186	155	130
Shiners (2.3)	195	170	148	120
den Shiners (4.0)	180	171	160	152
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ut (2.0)		no effect up to 180		
ut (2.8)	36	32	28	24
den Shiners (4.3)	59	52	39	33
fish (11.7)	56	49	45	39
ut (0/15.0)	2.3	1.5	1.0	0.7
Shiners (1.4)	13	12	9.2	7.4
ut (0/15.0)	0.0050	0.0046	0.0028	0.0023
Shiners (1.9)	0.040	0.036	0.025	0.023

of the affected organs indicated that the mode of action was probably different for the two types of extracts. The gills and gas blatter of the test fish killed by the surface water organics appeared normal, but extreme hemorrhaging around the heart and liver was noted.

The acute toxicity of two pesticides, sevin* and malathion,† was also determined in an attempt to evaluate the toxicity procedures with known compounds. The results of these studies are shown in Table 3. Dissection and visual examination of the fish killed by these two materials revealed that the heart, liver, gills, and intestines appeared to be normal.

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Medium to large (12–16 in.) trout were sacrificed and their organs were removed and homogenized in a blender § at 5°C; the tissue homogenates were then suspended in sterilized Robinson's EDTA isotonic solution[8] and stored at 5°C until use. Because of the limited solubility of the organics in water, a dispersant capable of dissolving large quantities of organics was required. In addition to its solvent properties, the dispersant had to be nonbiodegradable, nontoxic, and possesses a low vapor pressure. Several different compounds and combinations of compounds were evaluated including the cellosolve-surfactant combination employed by Sletten.[5] A surfactant‡ essentially met these requirements when used individually. Test solutions of the organics were prepared by first liquifying the surfactant at 40°C in a shaker water bath, and then using enough liquid surfactant to dissolve a known amount of sample and diluting to the desired concentration with warm water. Several simple compounds, including sucrose, glucose, citric acid, and succinic acid, were evaluated as substrates for the enzyme systems. Succinic acid gave the best oxygen utilization and was employed in the tissue studies.

Enzyme Activity

To measure enzyme activity, 1 ml of tissue homogenate and 1 ml of surfactant solution of trace organics were placed in a 15 ml flask equipped with a side arm; 1 ml of 0.3 M solution of succinic acid was placed in the side arm; and $\frac{1}{10}$ ml of potassium hydroxide (20 per cent) was placed in the center well of the flask to absorb the carbon dioxide. The mixture was equilibrated at 20°C for 5 min, the side arm emptied into the flask, and readings taken for 2 hr. Inhibition of enzyme activity was determined by

*50 per cent active ingredient, a product of Union Carbide Corporation, New York, N.Y.

†57 per cent active ingredient, a product of M-F-A, Columbia, Mo.

‡Model RWBP3, a product of Gilson Medical Electronics, Middleton, Wis.

§Model 1042, a product of Waring Products Co., Winsted, Conn.

‡M-14019, a product of Tretolite Co., St. Louis, Mo.

comparing the oxygen uptake of the test mixture with that of a control flask containing surfactant instead of a surfactant-organics mixture. Individual subsurface water CCE and CAE were evaluated, as well as combined extracts. The subsurface water extracts exerted no inhibition to any homogenate at any of the concentrations studied, which ranged from 0.01–3.6 mg organics per milligram of tissue. On the other hand, the surface water CCE definitely inhibited the activity of all three tissue homogenates. Oxygen uptake curves for the three homogenates are presented in Fig. 1. The median respiratory tolerance limit (RTLm), defined by Sletten[6] as the concentration of toxicant that would reduce the activity of the test solution to 50 per cent of the control, was calculated for each type of tissue preparation, as shown in Fig. 2. The values obtained are given in Table 4.

TABLE 4

Median Respiratory Tolerance Limit

Tissue Homogenate	Milligrams Organics per Milligrams Tissue
Liver	0.11
Heart	0.22
Gill	0.38

Sletten[6] has reported a 60 min RTLm of 0.108 mg organics per 1 mg tissue for trout liver homogenate in the presence of chloroform-soluble organics recovered from tap water.

The effect of sevin and malathion on trout tissue homogenate respiratory activity was also evaluated. These pesticides did not exhibit an effect on the activity of the enzyme systems at the concentrations evaluated (0.01–7.2 mg pesticide per 1 mg tissue, based on the active ingredient in the commercial preparation). Hiltibrand and Johnson[10] have studied the effects of rotenone and amytal on several trout liver mitochondrial enzyme systems and found that the toxicants did inhibit certain respiratory systems.

Long-Term Toxicity

The acute toxicity studies illustrated that some of the trace organics were toxic to fish at high concentrations over a relatively short period. Some of the higher concentrations investigated may never be reached under normal conditions; however, the long-term effects of these materials at low concentrations over an extended period could be significant. Studies were performed with some of the trace organics to evaluate their long-term effects. Because of the limited quantity of test materials available, continuous flow studies which have been used by other investigators[11,12] were ruled out and an alternate procedure developed. It consisted of exposing the fish to the test solution under static conditions for 5 days, removing the fish, and placing them in a recovery solution for 5 days during which time they were fed daily. The recovery solution consisted of either fresh water or water containing one-tenth of the test concentration of organics. At the end of the recovery period, the fish were placed in fresh test solutions for another 5 days and the procedure continued until at least 50 per cent of the test animals had been killed. The 5-day exposure time was considered to be the maximum period the fish could be maintained without feeding. The 5-day recovery time was selected on the basis of preliminary work undertaken to evaluate the minimum time required by the fish to return to normal feeding conditions; periods shorter than 5 days did not allow complete recovery, while longer periods were unnecessary. The results of the long-term studies are presented in Table 5; corresponding 96-hr TLm values are also presented to facilitate comparison. As can be seen from these data, when the exposure time was lengthened the trace organics were toxic to fish at concentrations well below those of the acute toxicity levels. A comparison of the time required for 50 per cent kill at a given concentration level in studies using recovery water consisted of fresh water and studies using a 10 per cent concentration of the test solution further indicated that the organic micropollutants did have an accumulative effect, and that there was a buildup of the toxicant in the fish.

TABLE 5

Long-Term Toxicity of Trace

Test Material	Test Fish (length—cm, weight—g)	Total Accumulated Test Time / Test Material Con				
		10		7.5		
		0*	1.0*	0	0.75	0.
Spring Run 2 Unit 2 / Missouri River CCE	Trout (6.2/11) / Trout (5.3/2.2)	30 / 10	20 / 5	37 / 13	23 / 11	46 / 19
		24		13.5		
		0	2.4	0	1.35	0
Spring Run 2 Unit 2	Red Shiners (4.7/1.5)	30	20	39	30	>65
		0.0010		0.00075		0.0
		0	0.00010	0	0.000075	0
Malathion	Trout (6.0/3.8)	7	5	15	8	>17

* Test material concentration in recovery water, mg/l.
† Fish died because of loss of temperature control.
‡ Values for trout having 10.5/16 and 5./2.6, length/weight, resp
§ Fish showed signs of disease; test discontinued.

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Long-term studies were also performed with malathion, and the results are also shown in Table 5. Pesticides were again used in the long-term toxicity studies to provide data with known materials for the reevaluation of the procedure if necessary.

TABLE 5

Long-Term Toxicity of Trace Organics

Test Material	Test Fish (length—cm; weight—g)	Total Accumulated Test Time for 50 Per cent Kill—days									96 hr TLm Value—mg/l
		Test Material Concentration; mg/l									
		10		7.5		4.2		1.0		Control	
		0*	1.0*	0	0.75	0	0.42	0	0.10		
Spring Run 2 Unit 2	Trout (8.2/11)	30	20	37	23	48	29	>54	>54	>54†	61–155‡
Missouri River CCF	Trout (5.3/2.2)	10	5	13	11	19	13	>19	>19	>19§	28
		24		13.5		5.6				Control	
		0	2.4	0	1.35	0	0.56				
Spring Run 2 Unit 2	Red Shiners (4.7/1.5)	30	20	30	30	>65	45			>65§	148
		0.0010		0.00075		0.00056		0.00024		Control	
		0	0.00010	0	0.000075	0	0.000056	0	0.000024		
Malathion	Trout (6.0/3.8)	7	5	15	8	>17	10	>17	>17	>19	0.0028

* Test material concentration in recovery water, mg/l.
† Fish died because of loss of temperature control.
‡ Values for trout having 10.5/16 and 5./2.6, length/weight, respectively.
§ Fish showed signs of disease; test discontinued.

Summary and Conclusions

The carbon adsorption method of recovering trace organics from water provided an adequate procedure for concentrating the organic micropollutants from large volumes of water and furnishing a sufficient quantity of extract for characterization studies. All the subsurface water organics were odorous; however, the odor potential

and characteristic odor of those in spring water were greatly different from those in deep well water. Because of the higher concentration of organics in the spring water, large quantities of extracts were obtained and permitted extensive toxicity studies. The acute and long-term toxic effects of the surface and subsurface organics were quite different, as were their effects upon respiratory enzyme systems. The batch-type long-term bioassay, necessary because of the limited quantity of organics available, provided a workable procedure for the evaluation of the cumulative long-term effects of the trace organics. Tissue studies and visual observation of dissected exposed fish provided an insight on the mode of action of the toxicants. Studies are in progress at the Sanitary Engineering Laboratories of the University of Missouri-Rolla to ascertain further the mode of action of these organics and establish a procedure for determining long-term toxic levels on the basis of short-term studies.

On the basis of the findings of this study, the following conclusions may be drawn.

1. The Missouri subsurface water trace organics were odorous; the spring water extracts had a much lower threshold odor concentration than the deep well extracts and different characteristic odor.

2. The surface and subsurface trace organics were toxic to fish under both acute and long-term conditions.

3. *In vitro* toxicity studies using tissue homogenates proved useful in establishing whether a material was toxic and helpful in determining the probable mode of action.

4. The subsurface water organics appeared to clog the gills and physically block the transport of oxygen into the fish, while the mode of action for the surface water organics was probably an internal disruption of respiratory enzyme activity.

5. A static long-term bioassay procedure which can be used when the quantity of test material is limited was developed and evaluated with both the trace organics and a commercially available pesticide.

Acknowledgment

The authors wish to express appreciation to the St. Louis County Water Co. for providing samples of Missouri River trace organics; the James Foundation, St. James, Mo., the City of Rolla, and the University of Missouri-Rolla, for providing sampling locations; and the Division of Fisheries, Missouri Dept. of Conservation, and Huzzah Fishery, Salem, Mo., for providing test fish.

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Appendix H

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Chemical and Microbial Degradation of Malaoxon in an Illinois Soil[1]

Daniel C. Paschal and M. E. Neville[2]

ABSTRACT

Chemical and microbial degradation of malaoxon was studied in an Illinois silty loam. This soil sample is typical of the glacial till soil used for agriculture in the Midwest. This sample had no history of pesticide application and demonstrates high microbial activity as evidenced by rapid degradation of malathion. To differentiate between microbial degradation and chemical decomposition, both heat-sterilized and nonsterile soil samples were prepared. Because pH has been shown to affect the rate of chemical hydrolysis, samples were adjusted to three different values of pH: 6.2, 7.2, and 8.3. Malaoxon (10 ppm) was added to both sterile and nonsterile samples, and chemical and microbial analyses were performed over a 5-day period. Chemical analyses were performed as hexane extractions followed by electron capture gas chromatography. Microbial numbers were estimated by conventional dilution and spread-plate techniques.

Half-lives for malaoxon were determined for the samples. A pronounced effect was noted with pH; malaoxon has a half-live of approximately 3 days in the basic samples and a half-life of approximately 7 days in acidic samples. Only a minor effect on half-lives was noticed from microbial activity. This may be due in part to a demonstrated biocidal effect of malaoxon on soil microorganisms. The disappearance of malaoxon in soil was interpreted to be chemical hydrolysis. The persistence of malaoxon in acidic soils may be of significance in agricultural usage where acidic soils is desirable.

Additional Index Words: malathion, organophosphorous insecticides, oxidative desulfuration, biotransformation.

Malathion, *S*-(1,2 dicarbethoxyethyl)-*O*,*O*-dimethyldithiophosphate, is an extensively used organophosphorous insecticide. Because of its rapidity of disappearance, malathion is often used in place of the more persistent chlorinated hydrocarbon insecticides. When applied to soil or plants at the rate recommended by the manufacturer, malathion has been shown to degrade rapidly (VanMiddelem, 1965; American Cyanamid, 1974; Walker and Stojanovik, 1974). The short half-life of the malathion molecule does not necessarily indicate short-lived toxicity. In fact, the toxicity of malathion has been attributed to malaoxon, its oxo-analog formed by oxidative desulfation of the thiophosphoryl group (Eto, 1974). Microsomal mixed function oxidase (mfo) systems are responsible for this process in animals, whereas peroxidases are throught to play this role in plants; also the oxo-analogs may be formed photochemically on and in plants (Eto, 1974). Soil microflora, among them *Aspergillus niger* and *Penicillium notatum*, have been shown to enzymatically transform malathion into malaoxon and other metabolites (Mostafa et al., 1972). If the malaoxon produced is sufficiently persistent, then its higher toxicity presents a potential hazard to extensive or long term use of malathion.

This study was designed to investigate the persistence of malaoxon in an Illinois loam. Both nonsterile and heat-sterilized soil samples at three pH values were used to investigate microbial and chemical effects on decomposition of malaoxon. Previous studies (Walker and Stojanovik, 1973) have shown that malathion is decomposed by microbial metabolism and chemical hydrolysis. It was hypothesized that the structurally similar malaoxon decomposes by the same two mechanisms.

MATERIALS AND METHODS

Materials

The soil sample was taken from topsoil which had no history of pesticide exposure and which had demonstrated high microbial activity. The sample is representative of the Catlin-Muscatine-Sabile soil association of McLean County, Illinois. This association consists of moderately sloping to nearly level soils of silty loess over loam glacial till (Hudelson, 1969). This loam is typically high in organic content and blackish-brown to black in color. The soil sample was sieved to uniform size, air dried, and stored in closed containers until used.

Duplicate soil samples were sterilized by autoclaving in two different times, 24 hours apart, for 20 minutes at 1.3×10^4 kg/m^2 (124C). Aseptic technique was used during all manipulations. All sterilized samples were confirmed to be "bacteriologically sterile" at the end of the sampling periods by plating 0.1- and 1.0-ml aliquots of a 1:1 soil/water suspension on Trypticase Soy Agar (BBL, Cockeyville, MD) supplemented with 0.2% yeast extract. No colonies were formed from any sample.

Malathion (99.5% pure) and malaoxon (98.0 + % pure) were obtained from American Cyanamid Co. (Princeton, N. J.). Stock solutions of both compounds were prepared in analytical grade *n*-hexane. Malaoxon was added at the rate of 10 ppm to sterile and nonsterile samples of air-dried soils, previously adjusted to appropriate pH and maintained for 3–4 days. Samples were approximately 25 g and were incubated in covered glass containers at 25C during decomposition studies. All samples were mixed thoroughly to insure homogeneity and maximize exposure of pesticide to the soil. Duplicate samples were analyzed before pesticide was added, immediately after pesticide addition, and 1,2,3,4, and 5 days thereafter for malaoxon content and microbial numbers. Malathion was added at the rate of 12 ppm to sterile and nonsterile samples of pH 7.2 to compare degradation rates of this parent compound with malaoxon. This concentration of malathion facilitated comparison of the results presented here to those of the previous work by Walker and Stojanovik (1973). Duplicate samples were analyzed as for malaoxon except samples were analyzed after 4, 8, 12, 24, and 48 hours. Control samples were prepared which received only *n*-hexane; no noticeable effect on microbial populations was observed.

Methods

The pH was measured with a glass electrode in a 1:1 distilled water/soil suspension as described by Black (1965). The pH was adjusted from its "natural" value of 7.2 to pH 6.2 by the addition of aluminum sulfate or to pH 8.2 by adding calcium hydroxide (lime). The pH of each soil sample was verified to be within 0.1 pH unit of the original value after 2 days for malathion and 5 days for malaoxon.

GAS CHROMATOGRAPHIC ANALYSIS

Malaoxon and malathion content of soils was measured by electron capture gas chromatography. Pesticides were extracted by shaking 10 ml of 3:1 pesticide grade hexane/acetone with 1.0 g of soil. Samples were shaken for 20 min on a wrist-action mechanical

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Table 1—Selected physical and chemical properties of the soil used in this study

Moisture	1%
pH	7.2
Nitrogen	
Total	1,190 ppm
Ammonium	13.2 ppm
Nitrite	0.0 ppm
Nitrate	49.1 ppm
Carbon	
Total	3.3%
Carbonate	0.023%
Organic matter	5.7%
Carbon/nitrogen ratio	27.5/1

shaker, allowed to settle for 5 min, and 5 ml of supernatant was evaporated to dryness and then redissolved in pesticide grade *n*-hexane up to 0.5 ml. Control experiments show that this extraction procedure recovers at least 93% of malathion and malaoxon. After the addition of 10 μl of dieldrin (10 ppm) as an internal standard, 5 μl of the resultant extract was injected into the chromatograph for analysis. A 1.8 m × 0.3 cm (6 foot × 1/8 inch) glass column packed with 3% OV-101 was used with a Varian model 1440 gas chromatograph. Column, inlet, and detector temperatures were 160C, 200C, and 240C, respectively. The flow rate of high purity N was 30 ml/min, and the scandium-tritium detector was set with an electrometer attenuation of 8×10^{-9} amps/mV. Retention times for malathion and malaoxon under these conditions were 4.9 and 5.1 min, respectively. No interference was noted in control experiments from any hexane-extractable compounds from the soil samples. Pesticide content was determined by calculating the ratio of malathion or malaoxon peak areas to those of dieldrin by comparison with calibration curves obtained from standards containing an equal amount of dieldrin.

MICROBIAL POPULATIONS

The estimation of microorganisms in soils was by conventional dilution and spread-plate techniques. Duplicate aliquots of 0.1 ml were spread over the surface of trypticase soy-yeast extract agar, actinomycetes agar (Difco, Detroit, Mich.) supplemented with 0.4% potato starch, and Littman agar (Difco) supplemented with 25 μg/ml penicillin for counting total bacteria, actinomycetes, and fungi, respectively. Because actinomycetes agar is not selective for actinomycetes, only crusty, leathery colonies with a powdery appearance (Buchanan and Gibbons, 1974) that give a characteristic "earthy odor" were counted as actinomycetes. All plates were incubated at 30C for 5 days before counting.

In an effort to follow microbial populations as a function of time after addition of pesticides, plates were made after 1, 2, 3, 4, and 5 days exposure to malaoxon, and 4, 8, 12, 24, and 48 hour exposure to malathion. For the control or "0 time" samples, all plates were finished within 20 minutes after addition of pesticide.

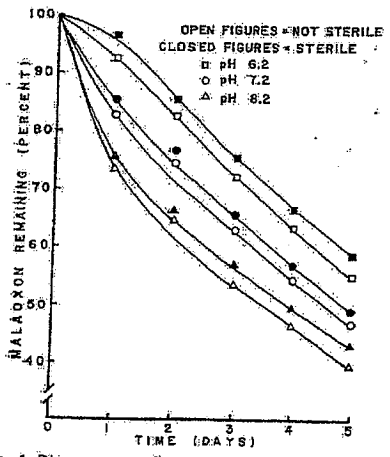

Fig. 1—Disappearance of malaoxon in sterile and nonsterile soil samples at pH 6.2, 7.2, and 8.2 as a function of time.

Table 2—Half-life values for malaoxon and malathion in sterile and nonsterile soil samples at pH 6.2, 7.2, and 8.2

pH	Pesticide	Condition	Half-life (days)
6.2	Malaoxon	Sterile	7.5
		Nonsterile	6.5
7.2	Malaoxon	Sterile	5.1
		Nonsterile	4.6
8.2	Malaoxon	Sterile	3.9
		Nonsterile	3.5
7.2	Malathion	Sterile	8.3
		Nonsterile	0.4

SOIL ANALYSIS

Moisture content, nitrogen (total, ammonium, nitrite, and nitrate), and carbon (total and carbonate) were determined before sterilization with slightly modified routine analytical procedures described by Black (1965).

RESULTS AND DISCUSSION

Results of the soil analysis are given in Table 1. As can be seen from the data, this sample is typical of many silty loams used for agricultural purposes (Hudelson, 1969).

Malaoxon disappearance from sterile and nonsterile soil samples at the three pH values examined in this study are shown in Fig. 1. These data indicate very little difference in the rate of decomposition between sterile and nonsterile samples. The experimental points were curve-fitted using an exponential least squares fit of the function $y = ae^{bx}$ employing a commercially available program (Wang Laboratories, 1972). Correlation coefficients obtained were all > 0.98. The half-lives presented in Table 2, obtained by both substitution into the curve-fitted equations and by graphical analysis, agreed within 0.1%. Very little microbial degradation of malaoxon was observed under the conditions of this experiment. Table 3 presents the microbial populations immediately before and after the malaoxon was mixed with the soil sample. The data indicate that malaoxon is a potent antimicrobial agent, as evidenced by approximately 50% decrease of bacteria and 95% decrease of fungi. The effects of malaoxon on soil populations at pH 7.2 as a function of time can be seen in Fig. 2. These curves are representative of pH 6.2 and 8.2 as well. After an initial loss of bacteria and fungi, the

Table 3—Effects of malaoxon on the estimated numbers of microorganisms per gram of soil samples at pH 6.2, 7.2, and 8.2

pH	Pesticide	Bacteria	Actinomycetes	Fungi
7.2	Control	1.0×10^7	3.0×10^6	5.0×10^4
	Malaoxon	6.0×10^6	6.0×10^5	2.4×10^3
6.2	Control	9.0×10^6	8.0×10^6	7.0×10^4
	Malaoxon	5.0×10^6	7.2×10^5	2.6×10^3
8.2	Control	1.0×10^7	4.0×10^6	6.0×10^4
	Malaoxon	5.0×10^6	5.0×10^5	2.7×10^3

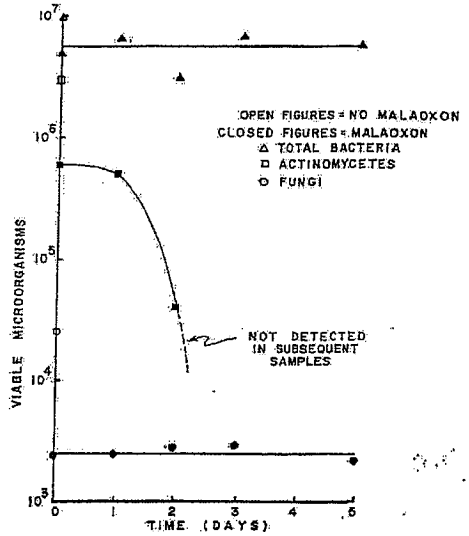

Fig. 2—Effects of malaoxon on number of viable microorganisms per gram of soil sample (pH 7.2) as a function of time.

microbial populations remain constant. However, it is apparent that at least one part of the bacterial population, namely the actinomycetes, is more susceptible to the malaoxon. It is interesting to note that while the actinomycetes decrease below the detectable level, the total bacteria remain nearly constant.

A large effect of pH is seen on the decomposition of malaoxon, indicating that chemical hydrolysis is an operative mechanism for degradation. As has been previously noted in studies in aqueous media, the rate of decomposition of most organophosphorous pesticides increases with pH (Faust and Gomaa, 1972). Malaoxon follows this general pattern of behavior. At the "natural" pH of 7.2 for samples used in this study, the half-life of malaoxon is about 5 days in both sterile and nonsterile samples.

In order to verify the activity of the microbial population in the present sample as to pesticide degradation, the decomposition of malathion was also studied under sterile and nonsterile conditions at pH 7.2. The results of this study are presented in Fig. 3 and Table 4. As can be seen, malathion under the same experimental conditions is rapidly degraded in nonsterile samples. The half-lives for

Table 4—Effects of malathion on the estimated numbers of microorganisms per gram of soil samples at pH 6.2, 7.2, and 8.2

pH	Pesticide	Bacteria	Actinomycetes	Fungi
7.2	Control	1.3×10^7	1.4×10^6	5.0×10^4
	Malathion	1.3×10^7	1.6×10^6	4.5×10^4
6.2	Control	1.3×10^7	1.2×10^6	5.0×10^4
	Malathion	1.3×10^7	1.2×10^6	4.5×10^4
8.2	Control	1.2×10^7	1.4×10^6	5.0×10^4
	Malathion	1.1×10^7	1.3×10^6	3.7×10^4

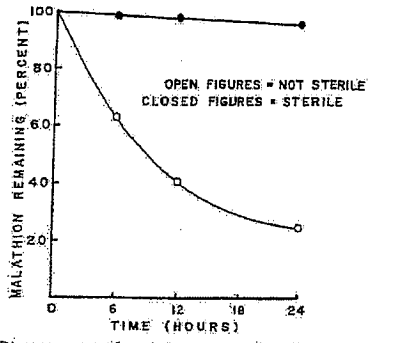

Fig. 3—Disappearance of malathion in sterile and nonsterile soil samples at pH 7.2 as a function of time.

the sterile and nonsterile samples are similar to those of Walker and Stojanovik (1973).

In conclusion, chemical hydrolysis appears to be the principal operative mechanism in the decomposition of malaoxon in soil. It is possible that microorganisms not present in the sample used in this study could significantly degrade malaoxon, or that some of the surviving organisms could eventually adapt to metabolize this molecule. In this study, however, the microbial effects were minimum. A practical application of this study which should be noted involves the significantly long half-life of malaoxon under slightly acidic conditions. In many agricultural environments a slightly acidic soil is desirable. This condition when combined with heavy use of malathion could result in persistence of toxic malaoxon residues.

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