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January 15, 2010

Mr. Daniel McClure, P.E.
Water Resource Control Engineer/Project Manager TMDL Unit
Central Valley Regional Water Quality Control Board (CVWRQCB)
11020 Sun Center Dr. #200
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RE: Phase-III Water Quality Criteria (WQC) Derivation Method Developed for Malathion

Dear Mr. McClure:

On behalf of Cheminova A/S and Cheminova, Inc. (Cheminova), we are pleased to be provided with the opportunity to comment on the technical document authored by Isabel Faria, Ph.D., Amanda Palumbo, Ph.D., Tessa Fojut, Ph.D., and Ronald Tjeerdema, Ph.D., of the Environmental Toxicology Department, University of California at Davis, concerning their updated methodology for deriving freshwater water quality criteria for the protection of aquatic life that was previously developed (TenBrook et al. 2009); entitled "Malathion Criteria Derivation - Draft." Cheminova's comments on the draft criteria derivation are included in the enclosed document:

- Comments from Cheminova on the Draft Water Quality Criteria (WQC) Derivation Method Developed for Malathion. Report dated January 15, 2010.

In support of our comments, we are also providing a copy of the following study for consideration:

- Kuhajda, B.; Blanco, C.; Green, M.; et al. (1996) Impact of Malathion on Fish and Aquatic Invertebrate Communities and On Acetylcholinesterase Activity in Fishes within Stewart Creek, Fayette County, Alabama: Final Report. Unpublished study prepared by University of Alabama. 129 p. US EPA MRID 47587601.

If you have any questions, or if you need additional information, please do not hesitate to contact me at 703-373-8883 (ext 1).

Sincerely,

Paul Whatling
Paul Whatling
Director of Regulatory Science
Cheminova, Inc.
EPA Agent for Cheminova A/S

Enclosures

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TITLE

Comments from Cheminova on the Draft Water Quality Criteria (WQC) Derivation Method Developed for Malathion

SUBMITTED TO:

Central Valley Regional Water Quality Control Board

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COMPLETION DATE

January 15, 2010

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Executive Summary

This document provides Cheminova's comments on the methodology of the Central Valley Regional Water Quality Control Board (CVRWQCB) for developing acute and chronic water quality criteria (WQC) for pesticides and the specific application of that methodology for Malathion.

Our general comments on the methodology include:

- It's not clear why the Board did not rely on the water quality criteria methods developed by the United States Environmental Protection Agency (US EPA) and other agencies.
- The Board incorrectly implies that the disappearance of a single species will lead to community-wide effects in an ecosystem. In fact, such occurrences are rare and for Malathion, there exist specific data to rebut this claim.
- The conclusion that three years is required before recovery following a contaminant pulse is flawed. Even in the citations provided to justify this point, most studies show recovery on the order of days to weeks. Also, for Malathion there is a direct evidence of rapid recovery.

Cheminova identifies two new studies for consideration by the Board, including (1) a field study evaluating community effects following numerous applications of Malathion over multiple years and (2) a mesocosm study.

The field study and mesocosm study show that even at high Malathion concentrations (up to 30 ppb), there were no community-level effects in aquatic ecosystems. Given the results of the field and mesocosm studies, the most scientifically appropriate WQCs are:

- A value of 5 ppb based on the No Observed Effect Level (NOEC) from Cheminova's mesocosm study.
- A value of 0.6 ppb based on an adjustment to the Board's acute-to-chronic adjustment factor of 7.8 to the NOEC in the mesocosm study. However, Cheminova notes that chronic exposure to Malathion is highly unlikely given its rapid dissipation in water.

Introduction

The Central Valley Regional Water Quality Control Board (CVRWQCB) recently developed an updated methodology for deriving water quality criteria for pesticides for the protection of aquatic life in the Sacramento River and San Joaquin River basins. The surface waters of these basins receive pesticide inputs in runoff and drainage from agriculture, silviculture, and residential and industrial storm water (CVRWQCB 2004). The development of the methodology was carried out in three phases (TenBrook and Tjeerdema 2006; TenBrook et al. 2009; Faria et al. 2009). Phase I was a comparison and evaluation of existing criteria derivation methodologies from around the world (TenBrook & Tjeerdema 2006). Phase II used the findings of Phase I for selecting elements of methodologies, or entire methodologies, for developing the new methodology (TenBrook et al. 2009). Phase III applied the new methodology to derive criteria for five pesticides of particular concern in the Sacramento River watershed due to listings under 303(d) of the federal Clean Water Act. Malathion was one of the pesticides (Faria et al. 2009).

Both acute and chronic criteria are required to be derived under the methodology. Criteria need to be expressed in a manner that is compatible with typical monitoring programs required to assess compliance. The CVRWQCB indicated that most monitoring programs will collect a daily grab sample for a site or a composite sample that represents a single day.

Cheminova has a number of concerns with regard to the new methodology and the criteria that were developed for Malathion. The following report outlines these concerns. The report is organized into three sections:

- Comments on the general methodology;
- Additional information to consider specifically for Malathion; and
- Alternative recommendations for the water quality criteria (WQC).

Comments on WQC Methodology

General Comments

1. The methodology focused on water quality in the San Joaquin and Sacramento watersheds of the California Central Valley (Page 2-2, Chapter 2). Why were watershed-specific physical/chemical, fate/behavior, and toxicity data (e.g., species used in deriving criteria) not taken into account?

2. The authors suggest that the methodology could be used nationally (i.e., any freshwater ecosystem in the United States) and the guidance reports (TenBrook and Tjeerdema 2006; TenBrook et al. 2009) are all written as though they are recommending a national protocol for water quality criteria. This point is further reflected in the fact that watershed-specific data are not used in the development of water quality criteria (see above comment). Recommendations are made throughout the guidance reports that are more reasonably applied at a national level rather than a watershed level (e.g., recommendation regarding species required to derive a species sensitivity distribution are based on species from families residing in North America rather than those residing in California). Cheminova recommends that the guidance approach be made specific to the San Joaquin and Sacramento watersheds. Development of national water quality criteria guidance should not be a focus of the California Central Valley guidance documents as this is the responsibility of US EPA's Office of Water.

Comments by Chapter

<u>Chapter 1 – Introduction and Approach</u>

Page 1-1, Section 1-1.0, 2nd Paragraph

The text indicates that the objective of the project is the development of new water quality criteria (WQC) for five pesticides. The driver for this activity is described as "Section 303(d) of the Clean Water Act (CWA)". This section of the CWA addresses the need to develop Total Maximum Daily Loads (TMDLs) for certain priority watersheds (in this case the San Joaquin and Sacramento Watershed). The CWA, however, does not indicate that new criteria are required for development of the TMDLs for the watershed. Numerous sources of water quality criteria already exist (e.g., US EPA 2006; CCME, 1999). Therefore, it is unclear why a new methodology for criteria development was undertaken. This chapter does not discuss whether deficiencies in the criterion derivation methods used by the US EPA or the California

Department of Fish and Game were of concern or caused issue with the development of criteria specific to the perceived needs of the Central Valley Regional Water Board.

There are a number of sources for water quality criteria, guidelines, and benchmarks for pesticides. For example, US EPA (2007) has published aquatic life benchmarks for pesticides based on data contained in Re-registration Eligibility Decision (REDs) documents produced by US EPA's Office of Pesticide Products (OPP). US EPA's OPP has the advantage of having access to both scientific literature (peer-reviewed journal articles, reports, etc) and databases (e.g., ECOTOX) but also data from toxicity studies conducted in support of the re-registration (e.g., GLP studies submitted by the registrant). Water quality benchmarks have been developed for the two pesticides mentioned in this section; diazinon and chlorpyrifos (see http://www.epa.gov/oppfead1/cb/csb_page/updates/2007/aquatic-life.htm).

Although TenBrook and Tjeerdema (2006) and TenBrook et al. (2009) review methods in other jurisdictions, it appears that the authors did not consult with US EPA's Office of Water (OW), US EPA's Office of Pesticide Programs (OPP), nor with other reviewed jurisdictions (e.g., Canadian Council of Ministers of the Environment - CCME) to determine what activities may be in progress. Both the OPP and OW have responsibilities for evaluating aquatic toxicity data to assess the ecological effects of chemicals in surface water. OPP uses aquatic toxicity data to develop ecological risk assessments for pesticides registration and re-registration decisions under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). OW uses aquatic toxicity data to develop recommended ambient water quality criteria (AWQC) that can be adopted into State and Tribal water quality standards under the Clean Water Act (CWA). The OPP and OW are working together to develop a common effects assessment methodology using the same datasets. A cross-program workgroup was created and is charged with developing a clear problem statement of the science, policy and program issues. This includes the development and implementation of a work plan and a scoping paper. This initiative will also engage the scientific and stakeholder community. A FIFRA and CWA Common Effects Assessment Workshop was held in Arlington, Virginia on August 26-27, 2009 to discuss these issues.

The TenBrook and Tjeerdema (2006) review was published in 2006. Subsequently, the CCME released a new Water Quality Protocol for the Development of Water Quality Guidelines for the Protection of Aquatic Life (CCME, 2007). This protocol was the product of several years of developmental work. The new protocol, which replaces the CCME (1999) protocol referenced in the TenBrook and Tjeerdema (2006) report, incorporates the use of species sensitivity distributions (SSDs) as the preferred method for developing water quality guidelines in Canada. Supporting documentation from the CCME provides detail on the application of statistical methods and software for developing SSDs (CCME, 2006; Rodney and Moore, 2007; Rodney et al., 2008). In the future, we would recommend discussing on-going guideline activities in Canada directly with the National Guidelines and Standards Office, Environment Canada.

Page 1-1, Section 1-1.1, 1st Paragraph

"The CVRWQCB requested that the proposed numeric criteria of the pesticide (in total or dissolved form) that when attained should not "produce detrimental physiological responses in aquatic life,…."

Physiological response needs to be defined. There are numerous responses that simply indicate exposure (e.g., inhibition of brain acetylcholinesterase) or minor effects that may have no consequence on populations of aquatic species (e.g., transient effects on behavior). Although the statement in the guidance document is a policy driven one, the impression given is that criteria should be developed for any physiological response.

Page 1-2, Section 1-1.1, last Paragraph

"This project focused on the Sacramento and San Joaquin River watersheds of the California Central Valley and this ecosystem is referred to in several instances. The resulting method, however, is generally appropriate for any freshwater ecosystem in the United States. Additionally, simple modifications could be made to adapt this method for saltwater criteria or other geographic areas."

How can the methodology be adapted for saltwater criteria or other geographic areas? Is this discussed in some other section of the document? If the methodology developed here can be adapted for use elsewhere, it sounds as though it could be used for National Water Quality Criteria and there is little specific to the needs of California. Thus, why would the existing national WQC methodology not be appropriate?

Page 1-3, Section 1-1.3. Table 1-1

The table in this section describes the methodologies reviewed by the Board from other jurisdictions.

As mentioned above, the CCME (1999) water quality protocol is out of date. A new protocol was developed and published in 2007 (CCME, 2007) that takes account of recent tools and approaches to guideline and criteria development that have occurred over the last decade. This includes the use of SSDs. We recommend that the proposed water quality protocol be updated before implementing this program.

Chapter 2 – Evaluation and Selection of Methods

Page 2-1, Section 2-1.0, 2nd paragraph

"This chapter describes the development of the new methodology. Criteria derivation is a process that can be broken down into a number of steps, starting with data collection and ending with numeric criteria that are protective of aquatic life with as much certainty as possible given the amount of data available."

The second sentence should be changed to indicate that both the amount of data available AND the quality of the data are critical in deriving water quality criteria for pesticides. We suggest the paragraph be re-worded as follows:

"Development of water quality criteria for the protection of aquatic life can be broken down into a number of steps, beginning with data collection and ending with numeric criteria. The goal is to derive criteria values with as little uncertainty as possible, given the quality of the available dataset."

Page 2-1, Section 2-1.1, 1st paragraph

The authors indicate that the goal of most water quality criteria methodologies is to protect ecosystems, and to do so, many aim for protection at the species level. The authors go on to say that disappearance of a single species could lead to unraveling of community structure due to complex interactions among species (these single species are typically referred to as keystone species). As a result, the authors indicate that "the new method will have the goal of protection at the species level to fully protect natural ecosystems and meet policy mandate."

Although there are a few examples where disappearance of a single species led to community-level effects, this is in fact quite rare. Much more commonly, aquatic ecosystems in the temperate zone exhibit "functional redundancy" (Baskin 1994; Moore 1998). This means that multiple species are generally present to perform each critical function. Controlled exposure-response experiments with microcosms and mesocosms have demonstrated that at some level of exposure, temporary changes occur in the abundance of a few, sensitive species. At a higher level of exposure, more severe and longer-lasting impacts occur that may have pronounced effects on community structure and function. The transition from minor to major impacts usually occurs at concentrations greater than the 10th percentile on a species sensitivity distribution (Giddings et al. 1996, 1997; Solomon et al. 1996; Versteeg et al. 1999). Except in rare instances, exposure at or below the HC5 on an SSD will not lead to community- or ecosystem-level effects.

The authors further appear to be confusing levels of ecological organization in discussing the protection goal. A population is a group of individuals of one species that live within a defined spatial boundary (e.g., California). A community is considered an assemblage of two or more populations of different species occupying the same geographical area. A species is a biological classification (taxonomic group) generally defined as unique organisms with common characteristics and capable of interbreeding. The protection goal stated by the author is to "have the goal of protection at the species level to fully protect natural ecosystems…." This may be equated to protecting *populations* of aquatic organisms in California. Toxicity testing is generally conducted on an *individual* basis due to the obvious difficulties in testing whole populations. Responses of these higher levels of ecological organization (i.e., populations, communities) cannot be easily predicted from toxicity tests alone (Barnthouse, 1993). The next section presents some targeted field study and laboratory mesocosm studies for Malathion that attempt to evaluate potential community-level effects. However, the ecological risk assessment paradigm generally applies the results of effects to individuals from exposure to chemical stressors as a predictor of potential effect to populations (Barnthouse, 1993). This is most applicable to threatened and endangered species (T&E species) where the loss of an individual from a population may ultimately result in an adverse effect to the entire remaining population. On the other hand, Efroymson and Suter (1999) and others (*e.g.*, Pack, 1993) have suggested that a >20% reduction in survival, growth, or reproduction of individuals is indicative of significant effects to aquatic life and wildlife populations. These effects are not necessarily adverse effects. For example, a stressor causing a 20% decline in reproductive fecundity of brook trout was shown to lead to a general lowering of risks of population decline compared to unexposed conditions because the negative consequences of overcrowding were diminished (Ferson et al., 1996). Similar effects on other fish species, however, have led to population collapses (Myers et al., 1995).

Given that criteria are therefore only indicators of *potential* adverse effects, identifying adverse effects at the individual level is an exceptionally conservative approach to identifying the potential for adverse effects at higher levels of ecological organization. This is appropriate for science-based criteria used for screening purposes, but policy and regulation-based water quality objectives or standards require a different approach to establishing an appropriate level of protection. Thus, criteria generated using the methods described in this report should not be directly adopted as regulatory standards or objectives used to derive, for example, TMDLs.

Therefore language used in the report to describe the protection goal is unclear. We suggest that this section be re-written. The protection goal should be much more clearly defined and use appropriate biological classification and organization terminology.

Page 2-2, Section 2-2.0

"For thorough evaluation of pesticide effects it is necessary to collect physical-chemical and ecotoxicity data. Although not used directly in derivation of aquatic life criteria, dietary exposure effects data for wildlife and humans should also be collected for assessment of potential hazards due to pesticide bioaccumulation."

Can it be assumed from this paragraph that physical/chemical data also include fate and behavior data and information on transformation products? The language used to describe the desirable data appears exclusive, limiting it to toxicity and physical/chemical properties.

Page 2-3, Section 2-2.1.1, Acute

First bullet states "Acute toxicity: Concurrent and delayed adverse effect(s) that results from an acute exposure and occurs within any short observation period which begins when the exposure begins, may extend beyond the exposure period, and usually does not constitute a substantial portion of the life span of the organism."

Bullet 1 – It would make more sense and be more inclusive to state "acute data for aquatic invertebrates and aquatic life-stages of terrestrial invertebrates" rather than "crustacean or insect tests". It may be desirable, for example, to include data for oligochaetes (aquatic worms) in criteria development, which are neither crustaceans nor insects.

Page 2-9, Section 2-2.1.5

"For pesticides with log K_{OW} between 5 and 7, laboratory toxicity test data should be carefully reviewed to ensure that feeding regimes eliminated, or minimized any effects from interaction of the pesticide with food particles (e.g., reduction of test solution concentration due to partitioning into the food particles, or introduction of a dietary exposure route if animals ingest food that has had a chance to sorb pesticide)."

Given the consideration of the log K_{ow} between 5 and 7, the only monitoring data that appears appropriate for use against the developed criteria are filtered surface water samples. Is specific guidance provided with respect to monitoring data to be used for comparison?

Page 2-21, Section 2.2-7

Bullet #4 – A short discussion on what constitutes a reasonable statistical analysis should be provided.

Bullet #6 – Insert the word "acceptable" before NOEC and LOEC. Although the data quality discussion comes before this, readers should be reminded that the studies must be acceptable (RR rating in this system) to develop the MATC.

Page 2-16, 3rd Paragraph

"To establish a rating scale, the chlorpyrifos data set collected for this report was evaluated using the scoring systems detailed in Tables 3.6-3.8 of Chapter 3. The chlorpyrifos set was broken down as follows: scores in the 75th or higher percentile of all scores were rated reliable; scores between the median and the 75th percentile were rated less reliable; and scores below the median were rated unreliable. Similarly, relevance scores in the 90th or higher percentile were rated relevant; scores between the median and the 90th percentile were rated less relevant; scores below the median were rated not relevant. The 75th percentile of scores is suggested for the reliability rating because, in the case of the chlorpyrifos data set, higher percentiles were too restrictive, resulting in rejection of too much data that others have accepted for criteria derivation. On the other hand, the selection of the 75th percentile resulted in rejection of a few tests accepted by others, indicating that this rating system is a bit more rigorous than those used previously. The relevance scoring system was designed to include six major requirements for a study to be used in criteria derivation. Lack of one of these requirements would lower the score below 90 so only studies scoring above 90 should be used for criteria derivation."

High quality data and information should always be used when generating criteria. This necessarily requires a thorough review of all studies, and in the process, considerable professional judgment is applied. However, providing artificial numerical cutoffs for reliability and relevance appears arbitrary and in this case, is likely to result in loss of data that may reasonably be used in the criteria derivation process. Although to generate a science-based criteria, high quality studies are desirable, studies that are 'secondary' or in this case given a score slightly below 90 for relevance may still be of use with appropriate justification. The 90 value was also selected based on the review of studies from one pesticide (chlorpyrifos). It may be too high for other pesticides where datasets are somewhat smaller.

In the case of Malathion, all technical grades of Malathion, as well as all Malathion formulations, will inevitably contain various impurities which can influence the toxicity of the material. The majority of the impurities occur during the manufacturing process. Over the years, a wide range of impurities have been reported in Malathion produced from different sources. Many 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. Moreover, improvements in the manufacturing process over time have resulted in significant reductions in impurity levels. For these reasons, wherever possible the ecological risk assessment should be based on results from the latest studies carried out using a batch of technical Malathion from a verified source. This should be a criteria used for evaluating the acceptability of any data on Malathion.

Page 2-19, Section 2-2.6, Bullets

"The rationale for exclusion of items c, g, and h in the US EPA list is as follows:

c. Two fish species (one warm-water and one cold-water) are sufficient to represent the phylum Chordata;

g. Rotifers, annelids and mollusks are typically insensitive to pesticides (e.g., Giesy et al. 1999);

h. This category is very general and simply fills out the eight minimum data required by the US EPA SSD method (US EPA 1985; 2003d)."

Three items were excluded from the US EPA list – items c, g, and h. Item c. corresponds to the number of fish species and the justification for only one warm water species and one cold water species is "they are sufficient to represent the phylum *Chordata*". Why do the authors believe this is the case?

Second, the removal of rotifers, annelids, and mollusks from consideration simply because the authors would like to shrink the minimum dataset requirements does not seem to mesh with the goal of a representative "unbiased" species sensitivity distribution (Forbes and Calow, 2002).

The SSD is supposed to represent the entire ecological community. It is possible that rotifers, annelids and/or mollusks could be sensitive species for some substances. A stronger approach would be to include one or more 'blank' data requirements that could be filled by any families not represented by the minimum data requirements, or where the data indicate that a particular family is more sensitive than the others.

Page 2-21, Section 2.2-7, Bullets

Bullet 1 – Consideration should also be given to consistent study parameters (e.g., pH, hardness, etc) and other toxicity modifying factors when calculating the geometric means between studies. This is generally described in bullet 9, but needs to be stated more clearly.

Bullet 2 – What does statistical analysis mean? Which statistic analyses are acceptable?

Bullet 12 – Polymodal distributions can occur in these datasets as well.

Page 2-22, Section 2.2-7, 2nd last paragraph

Reduction of data points by considering regional parameters (e.g., water hardness, pH, etc), when setting site-specific or watershed specific criteria is a reasonable approach. For state-wide criteria or national criteria, this would be less of an acceptable approach, as stated by the authors. Because the authors indicate that the criteria being developed are for well-studied Sacramento and San Joaquin River watersheds, using only toxicity data generated with parameters more representative of the watersheds would be justifiable and reasonable.

Page 2-23, Section 2-2.7, Last paragraph

Bimodal distributions are mentioned, but the user may encounter polymodal (or multimodal) distributions in toxicity datasets on occasion. Change bimodal to polymodal or multimodal.

Page 2-60, Section 2-3.4

The conclusions of this section on the allowable frequency of exceedance are highly questionable. The authors indicate that Yount and Niemi (1990) and then the same author in a second paper from the same year (Niemi, 1990) came to the same conclusion that three years after a contaminant pulse, organisms at various organizational levels should be recovered. Arriving at the frequency of exceedance of three years based on the literature reviewed is very questionable. The vast majority of the papers cited in the report indicate recoveries at different levels of organization within days to weeks. Occasionally, months were required for pesticides applied directly to the aquatic system (e.g., rotenone to kill undesirable fish). Very occasionally, longer periods were required, usually for banned organochlorine pesticides that are highly persistent (i.e., DDT). The report authors even provide their opinion that the Sacramento and San Joaquin River basins would undergo rapid recovery following brief, mild, limited scope excursions above criterion levels (Page 2-62). In cases where other factors make rapid recovery less likely, the authors suggest that site-specific frequency components of criteria may need to be derived (Page 2-62).

Thus, it is unclear why the authors recommend an allowable frequency of exceedance of three years? Furthermore, for Malathion, there is a mesocosm study that directly shows rapid ecological recovery (days) following a pulsed Malathion exposure (see later discussion of study).

Page 2-60, Section 2-3.3.1, Last Paragraph

The averaging period selected for acute and chronic exposures (1 hr and 4 d) is not readily comparable to available monitoring data in the Central Valley. Data from NAWQA, for example, report values twice monthly in most years for pesticides (USGS, 2009). Therefore, maximum monthly concentrations will likely be used to compare to both acute and chronic values regardless of averaging period. The averaging periods and monitoring data should be reconciled in some manner or appropriate direction provided in the methodology to address this issue.

Page 2-72, Section 2-4.2.1.1

Criteria are science-based and are not based in regulation; therefore, use of the word "compliance" is inappropriate. Exceedance of water quality criteria suggests the need for more refined activities to determine whether there are issues specific to that spatial location. This may take many forms and ultimately may lead to the establishment of an objective or some other regulation-based approach where compliance is required.

Mixtures of pesticides may be comprised of a wide range of substances with different modes and sites of action. How can they therefore be evaluated by determining the most toxic component and developing a TEF-like relationship as for PAHs?

Chapter 3 – Methodology

Page 3-2, last paragraph

Cheminova recommends removing the phrase "As this methodology is for derivation of criteria in the United States". The methodology proposed here is for the San Joaquin and Sacramento watersheds of California, not for the entire country. National criteria are developed by US EPA's Office of Water.

Page 3-3, Section 3-2.1.1.1, Acute

Recommend stating "data for aquatic invertebrates and aquatic life stages of terrestrial invertebrates" rather than crustacean or insect tests.

Page 3-4, Section 3-2.1.1.2, Toxicity Values

NOECs and LOECs are not consistent measures of effect. Moore and Caux (1997) found that NOECs in 24 toxicity studies on aquatic biota corresponded to effect levels ranging from near zero to 37%. The corresponding range for LOECs was even larger, from just below 10% to 76%. Thus, it would be more scientifically defensible to use a consistent effect metric (e.g., EC20) to derive a chronic SSD rather than MATCs which are calculated as the geometric mean of a NOEC and its corresponding LOEC. Most NOECs are typically in the range of 10-20% effect while LOECs typically range from 10 to 50% effect (Moore and Caux 1997). This information combined with recent reviews (e.g., Moore et al. 2010) suggesting that most aquatic populations are not impacted by effects of 20% suggests that EC20s would be a preferable effects metric for derivation of the chronic SSD. Cheminova recommends that EC20s be considered the preferred effect metric for deriving a chronic SSD but that MATCs may be used in cases where EC20s cannot be calculated (e.g., raw data are unavailable for regression analysis).

Page 3-6, Section 3-2.2.1, last paragraph

"The recommended values in the LOGKOW database (Sangster Research Laboratories 2004) may be used without further review because they have been thoroughly reviewed before inclusion in the database."

Stating that database values from ANY database can be used without review is somewhat reckless. Cheminova recommends removing this statement. Only data from high quality sources should be considered, but the data should always be evaluated.

Page 3-8, Section 3-2.3, Fill Chronic Toxicity Data Gaps ...

It is not clear why the effects metrics estimated from the ALS, LRA or MPA models to "represent a NOEC" are so low (1% for ALS, 0.01% for the other models). As stated in the Page 3-4 comment, NOECs are most commonly associated with 10-20% effect in aquatic toxicity studies.

Cheminova recommends that 20% effect levels would be appropriate when using models to fill chronic toxicity data gaps (see Page 3-4 comment).

Page 3-19, Section 3-5.0

Determining the toxicity of mixtures of pesticides, their degradation products and other associated substances is a very difficult task that is currently undergoing significant research. Part of the difficulty with addressing chemical mixtures through legislation and/or regulations is the complexity associated with understanding their potential impacts. As mentioned in TenBrook and Tjeerdema (2006) there are several methods that may be used to estimate the toxicity of mixtures. However, no methodology has yet been developed that accurately predicts the toxicity of a variety of mixtures of pesticides to aquatic biota. Thus, Cheminova recommends that the issue of toxicity of pesticide mixtures be set aside until scientific methods improve.

Page 3-20, Section 3-5.1

At some point in the report, it should be made clear what monitoring data are required for comparison to water quality criteria. It appears most likely that filtered surface water samples are the most appropriate, however, this can change depending on other factors (as noted by the Board in this section). However, other considerations such as frequency of collection, required number of samples, etc are not discussed. There is little point in specifying allowable exceedance frequencies for acute criteria, for example, if samples are only collected monthly.

Targeted Field and Mesocosm Studies

The Board's methodology description (TenBrook et al., 2009) states that:

> "The Phase I report (TenBrook & Tjeerdema 2006, TenBrook *et al.* 2009) discusses how the goal of most water quality criteria methodologies is to protect ecosystems, and to do so, many aim for protection at the species level. Also discussed in the Phase I report is how the disappearance of a single species could lead to the unraveling of community structure due to complex interactions among species, suggesting that ecosystems might not be fully protected if water quality criteria are derived by a method that does not have the goal of protecting all species."

This statement provides part of the motivation for the Board's recommendation of the low-end of the SSD curve or the most sensitive species for setting the criteria. However, targeted field and laboratory mesocosm studies with Malathion provide a scientific basis to test the theory that the community structure of an ecosystem will unravel with the disappearance of a single species.

The first study was conducted by the University of Alabama as part of the Boll Weevil eradication program (Kuhajda et al., 1996). The Boll Weevil program included a large number of applications of Malathion over multiple years with significantly higher application rates than are allowed in other agricultural settings. Sampling was conducted in Stewart Creek (south of Winfield in Fayette County, Alabama) following applications on two cotton fields (7.6 and 11.6 acres) within 25 feet of the stream bank. There was a lack of riparian vegetation, making runoff likely. There were nine applications in 1993 and 15 applications in 1994. In 1993, the researchers sampled in Stewart Creek at (1) the spray location, (2) a site downstream of the spray location (half-mile from spray site), and (3) an upstream site. The downstream and control locations were sampled in 1994.

The peak concentrations ranged from non-detect to 31.1 ppb (immediately after the application). The average concentrations ranged from 0.88 to 3.7 ppb.

The authors made a survey of fish and invertebrate taxa at the sampling locations and 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."

Further, the authors state that "the aquatic invertebrate community in Stewart Creek does not show any adverse affects due to the application of Malathion to the adjacent cotton fields.

This study represents a worst-case situation where numerous applications of Malathion were made very close to a stream and relatively high, transient concentrations were detected. Yet, there were no significant community-level effects at concentrations well above the proposed water quality criteria.

Also, a mesocosm study was conducted in 2002 in Europe (Ebke, 2002; US EPA MRID 46525901). Malathion was applied in a single pulse in concrete basins filled with naturalized aqueous ecosystems. The initial concentrations ranged from 0-30 ppb and Malathion degraded rapidly with a DT_{50} of less than 1 day in higher dose groups. Two enclosures were used per concentration and untreated enclosures were used for controls. Observations were made for 90 days. There were no effects whatsoever on any biota 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." Thus, this study showed only modest, transient effects up to 30 ppb with full recovery within 28 days.

WQCs for Malathion

Acute Water Quality Criteria Value

To derive an acute or chronic criterion using an SSD method, the methodology states that a minimum of five effects metrics from five different families are required (TenBrook et al. 2009). These include: 1) a salmonid, 2) a warm water fish, 3) a planktonic crustacean, of which one must be in the family *Daphniidae* in the genus *Ceriodaphnia*, *Daphnia* or *Simocephalus*, 4) a benthic crustacean, and 5) an insect (aquatic exposure). Faria et al. (2009) stated that acceptable acute toxicity data were available for only four of the five required taxa. A member of the benthic crustacean family was unavailable. Thus, they concluded that the SSD approach could not be applied. Instead, a more conservative approach was used to derive the acute criterion. The approach involved dividing the lowest mean acute value (1.5 ppb for *Chironomus tentans*) by an assessment factor of 5.1 to extrapolate to a HC5 and then dividing the result by a safety factor of 2 to obtain the final acute criterion value of 0.15 ppb. The safety factor of 2 is applied because 50% effect to the 5^{th} percentile species is not considered acceptable (TenBrook et al. 2009). The derivation of the safety factor of 2 was based on 219 acute toxicity tests with various chemicals. The test results indicated that the mean concentration that did not cause mortality greater than control was 0.44 times the LC_{50} (34 FR 97, p 21508-21218). The inverse of 0.44 (2.27) was rounded to 2 for deriving acute water quality criteria.

While Cheminova is generally supportive of SSD methods, it disagrees with the approach taken by the Board for derivation of a WQC for Malathion. The WQC derived using this method is driven primarily by one 96 hour EC_{50} value of 1.5 ppb for *Chironomus tentans* (Belden and Lydy, 2000), which is not a species mean acute value (SMAV). Additional studies that were performed in Dr. Lydy's lab (Pape-Lindstrom and Lydy 1997) resulted in a 96 hour EC_{50} of 19.1 ppb. These data were excluded in the Board's data reduction process (i.e., "1. More sensitive endpoint available"), although we found little difference in the endpoint used in the two studies (unable to perform normal swimming motion –vs- failure of the midges to execute three figure-eight motions). It appears that this data was discounted erroneously or the data reduction process is seriously flawed. When this data is included, the SMAV for *Chironomus tentans* would then be 10.7 ppb.

Nevertheless, there are unique field and laboratory data for Malathion that directly measure the potential for community-level effects, whereas the Board's approach provides only an indirect and highly conservative method of assessing community-level effects.

The Alabama field study and mesocosm data clearly indicate that there are not community-level effects at concentrations of up to 30 ppb and the goal of the water quality criteria are to prevent such community-level effects. Also, there were no effects to any biota at 5 ppb in the mesocosm study. Therefore, Cheminova recommends basing the acute WQC on the NOEC in the mesocosm study of 5 ppb.

Chronic Water Quality Criteria Value

Faria et al. (2009) determined that the five taxa requirement was also not met for the chronic SSD method. Specifically, no chronic studies were available for benthic crustaceans or insects exposed to Malathion. Instead, the chronic criterion was calculated by applying an acute-to-chronic ratio to the acute water quality criterion value. Three acute-to-chronic ratios (ACRs) for fish could be calculated from the available data: bonytail (*Gila elegans*) (ACR=10.8); Colorado squawfish *(Phytocheilus lucius*) (ACR = 3.7); and flagfish (*Jordanella floridae*) (ACR=36.0). No ACR values were available for invertebrate species (Faria et al. 2009). A default ACR of 12.4 was thus included in the ACR data set to account for the missing invertebrate data (TenBrook et al. 2009). The species mean ACR (SMACR) was determined by taking the geometric mean of the three data-based ACRs and the default ACR (SMACR = 11.8). Dividing the previously obtained acute HC5 (1.5 ppb / 5.1 = 0.29 ppb) by the SMACR resulted in a chronic criterion of 0.03 ppb.

Cheminova disagrees with the SMACR developed by the Board. The flagfish study is old and used a product with unknown impurities (Hermanutz, 1978). Therefore, it does not provide a reliable basis to estimate an ACR. Without the flagfish study, the SMACR is 7.8.

Cheminova recommends using the Board's procedures, but with the proposed acute criteria value of 5 ppb from the mesocosm study. Applying the SMACR results in a chronic criteria value of 0.6 ppb (5 ppb / 7.8).

More broadly, Cheminova believes that setting a chronic WQC for Malathion is unnecessary given its rapid degradation in the environment (see mesocosm study). Therefore, exposure over a chronic duration is unlikely.

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