A 8M

1

COMMENTS OF DOW AGROSCIENCES LLC AND MAKHTESHIM AGAN OF NORTH AMERICA, INC. ON DRAFT BIOLOGICAL OPINION ON THE EPA REGISTRATION OF PESTICIDES CONTAINING CHLORPYRIFOS, DIAZINON AND MALATHION

September 15, 2008

ATTACHMENTS A – D

TAB

A

SEPTEMBER 11, 2008

TELECONFERENCE AMONG EPA, NMFS APPLICANTS MANA, DAS, AND CHEMINOVA REGARDING DRAFT JULY 31, 2008 BIOLOGICAL OPINION RELATIVE TO PACIFIC SALMONIDS AND CHLORPYRIFOS, DIAZINON AND MALATHION

2:00 – 4:00 PM EASTERN TIME

I. Introductions and opening remarks - Arty Williams, EPA

II. Questions from NMFS regarding materials provided on August 29, 2008 (see below for list of questions provided by NMFS prior to the call) – NMFS facilitates

III. Issues on which Applicants are requesting dialogue – EPA facilitates
   a. What are NMFS plans to review the substantial additional comments Applicants expect to provide on the 15th of September?
   b. What are NMFS plans with regard to the existing October 31 BiOp finalization deadline?
   c. How can NMFS accommodate legitimate concerns regarding the confidentiality of product-specific constituent information, particularly in light of the absence in Commerce/NOAA/NMFS regulations of assurances comparable to EPA's and the criminal disclosure provisions of FIFRA section 10(f).

IV. Other Comments from NMFS or Applicants – EPA facilitates

V. Summary of any action items or follow-up – EPA summarizes

LIST OF QUESTIONS FROM NMFS ON MATERIALS PROVIDED BY APPLICANTS ON AUGUST 29, 2008:

1) Does the referenced web site (http://ppis.ceris.purdue.edu/htbin/epachem.com) contain all EPA registered labels and list all active registrants? Is the information on this site current? How often is it updated?
2) Are all companies willing to provide ingredient information for their products? What about companies not represented in this consultation as applicants? It appears there are 24, 9, and 38 active registrants of products containing chlorpyrifos, diazinon, and malathion, respectively. We would like a complete list of all ingredients for each end use product.
3) Incident data- please provide reports on all aquatic incidents that have been associated with applications of products containing chlorpyrifos, diazinon, and malathion (all incidents listed in the EPA incident database, and any other known incidents).
4) Please provide a copy of all toxicity tests on aquatic organisms with formulated products (containing the 3 active ingredients) that are currently registered in the United States. What

portion of formulated products currently registered in the United States has been tested? How many currently registered end-use products in the United States have not been tested?

5) Which pesticide formulations contain nonylphenol or other nonylphenolpoly ethoxylates? How frequently are adjuvants containing these ingredients applied? What are the range of application rates for these ingredients?
6) What non-agricultural uses currently exist for diazinon and chlorpyrifos? Are any uses permitted to residential areas by certified or non-certified applicators?
7) If all outdoor residential uses of diazinon were canceled in 2003, why was diazinon detected in 25.4% of samples collected from urban surface waters in the 2004-2006 NAWQA dataset?
8) What products that have been phased out or canceled can still be used? What are the remaining existing stocks of these products (lbs)?

TAB

B

Dow AgroSciences Comments on the 31 July 2008 Draft BiOp Specific to Chlorpyrifos

Nick Poletika, Ph.D.

Field Exposure and Effects
Regulatory Sciences and Government Affairs, Indianapolis

29 Aug 2008

Dow AgroSciences

Objective

- Provide illustrations of the points made in the general comments presentation that are specific to chlorpyrifos

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The major chlorpyrifos product labels can be obtained directly from the Dow AgroSciences website. This will allow NMFS to quickly review all significant uses and risk mitigation measures specified in the 2002 chlorpyrifos IRED document.

Best Available Data – Example of Dose-Response Data Available from Registrant

- Marino, T.A., McClymont, M.S., Yaroch, B.S. 2003. Chlorpyrifos: an acute toxicity study with the daphnid, *Daphnia magna*. Unpublished report of The Dow Chemical Company 031133.
  - 24 and 48-h EC50 value with 95% CI
  - 24 and 48-h probit slope with 95% CI
  - 48-h NOEC
- Used for EU reregistration dossiers

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This is an example of a study report generated for regulators in another region that contains dose-response data of interest to NMFS. It was not submitted to EPA because the acute toxicity data requirement for freshwater aquatic invertebrates was already met by an older study. The report could be made available to NMFS as confidential business information.

Best Available Data – Chlorpyrifos Uses Have Changed in Past Decade

- 2000 – Registrants agreed voluntary cancellation of most residential uses
- 2001 – Last year for retail sale of residential use products
- 2005 – Last year for termiticide use
- Conclusion: Federal Action excludes residential uses

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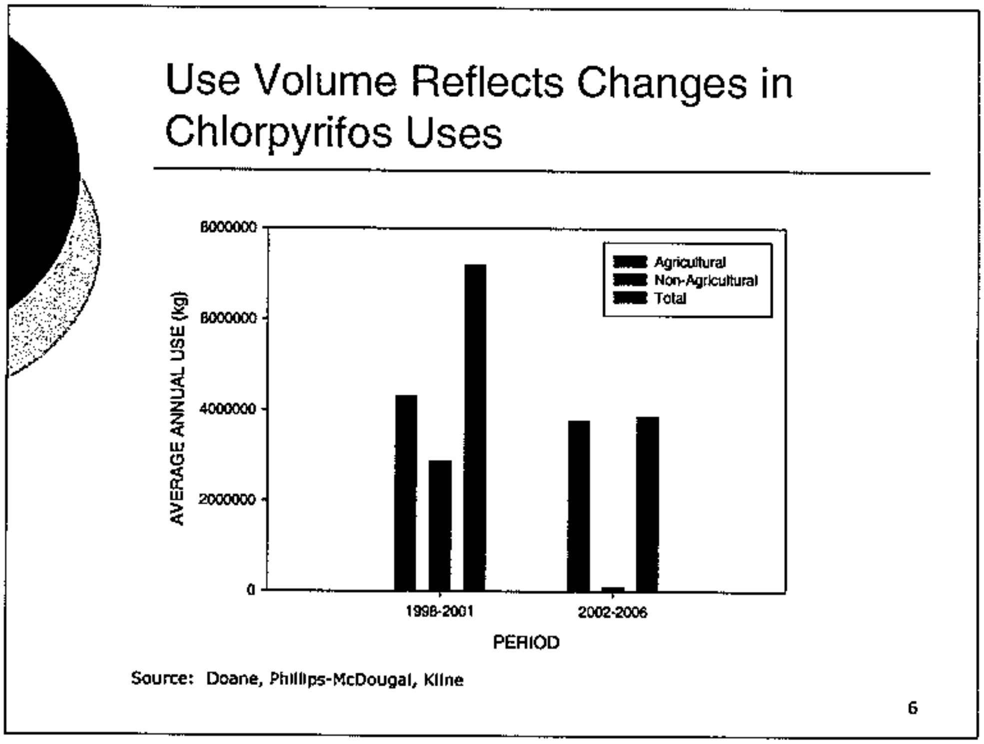
This slide outlines the major changes in the use of chlorpyrifos that have occurred since 2000. Unfortunately, the draft BiOp fails to take these changes into account. Instead, all historical uses are considered that no longer represent the Federal Action.



Changes in use patterns are clearly seen in the national sales volume reports available from standard sources. Overall, total volume has decreased significantly, with almost complete elimination of non-agricultural applications occurring by 2006. As was pointed out in the previous slide, residential uses are no longer relevant to the Federal Action.

Sources:

http://www.dmrkynetec.com/

http://www.phillipsmcdougall.com/

http://www.klinegroup.com/

Best Available Data – Chlorpyrifos Uses Have Changed in Past Decade

1998-2001	2007
Corn	Soybean
Apple	Corn
Citrus	Citrus
Alfalfa	Almond
Pecan	Alfalfa
Cotton	Apple
Almond	Walnut
Walnut	Pecan
Peanut	Sugar Beet
Sugar Beet	Broccoli

Top 10 uses by product sold

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In addition to declines in non-agricultural use, the important crops have changed significantly in the last decade due to market forces and introduction of new pests. Such changes need to be accounted for in exposure modeling and interpretation of monitoring data.

Best Available Data – Old Monitoring Data Not Representative of Current Uses

- "The insecticides diazinon, chlorpyrifos, carbaryl, and malathion were common in mixtures found in urban streams (Gilliom et al. 2006)." (Page 235)
- Recommendation: exclude historical monitoring data, especially from locations with large contributions from non-crop use sites

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Alterations in actual product use patterns significantly reduce the value of historical monitoring data when evaluating single chemicals. This is also true when considering potential concerns related to mixture toxicity. Generalized statements regarding additive or synergistic toxicity are not useful in evaluating impact of the Federal Action. Specific mixtures occur at particular sites; therefore, if monitoring data is to be used in risk assessment, current data representative of specific ESUs must be used to characterize risk.

Best Available Data (Relevancy) – Misrepresentation of Incident Data/Field Studies

- "However, a California field study in citrus revealed a peak surface water concentration of 486 ppb following a single application at 6 lbs a.i./acre (EPA 2000a)." (Page 214)
- Registrant comments to EFED RED science chapter provided context (Dow AgroSciences 1999. Report GH-C 4873 MRID 44736901)
  - "Extremely high water concentrations were attributed to misapplication of chlorpyrifos, based upon labeled procedures, where chlorpyrifos was inadvertently applied directly to the surface of the pond."
  - Part of an experimental field study

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The draft BiOp indicates the result of this California field study represents the highest relevant chlorpyrifos concentration available from monitoring data (page 238). However, NMFS failed to determine the context of this data point, which actually comes from an experimental study designed to evaluate effects on birds. It is extremely unlikely that salmonids would ever be exposed to this level of chlorpyrifos for the following reasons:

•The event represents gross mis-use of the product.

•Most, if not all, of the California counties where the 6 lb a.i./A rate is allowed drain to the Tulare Lake Basin, not the San Joaquin River.

•The study was not designed to represent water concentrations in habitat that could support salmonids.

Best Available Data – Other Ingredients

- Currently produced Lorsban-4E formulation has no nonylphenol or other non-ionic alkylphenol polyethoxylates
  - Can provide statement of formula as confidential business information
- Chlorpyrifos formulated products generally have the same biological activity as the a.i. in non-target toxicity tests
  - Acute testing routinely done for the EU
  - See also Giddings, J.M., Poletika, N.N., Havens, P.L., Hendrix, W.H., Woodburn, K.B. 2003. Chlorpyrifos analysis of risks to endangered and threatened salmon and steelhead. Unpublished DowAgroSciences report GH-C 5638, MRID 46025301.

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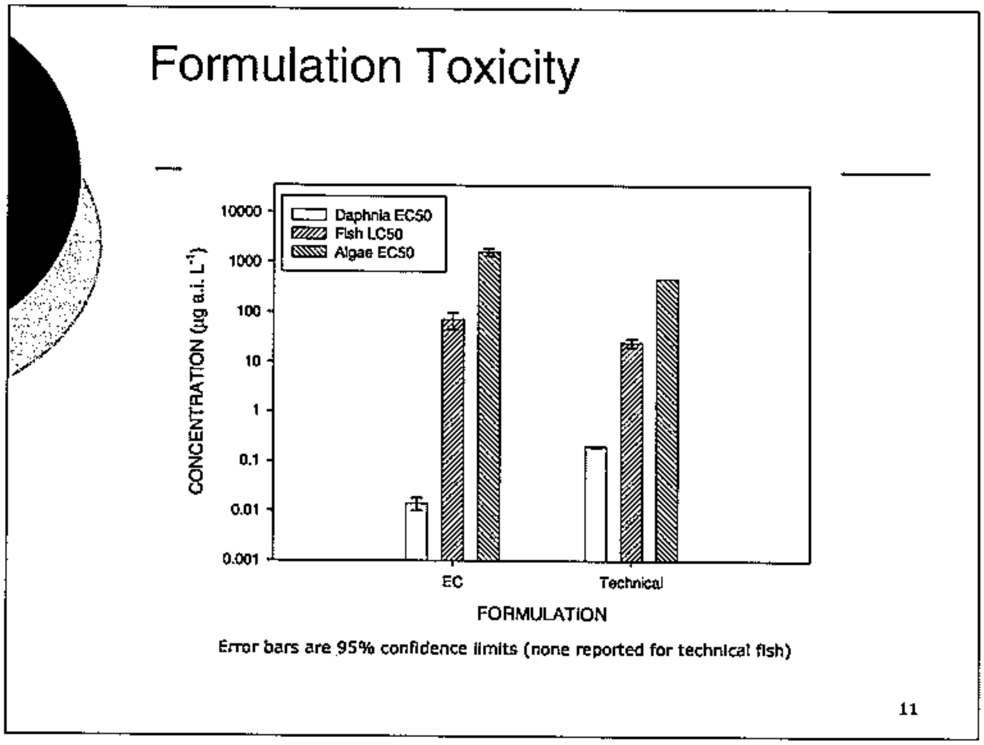
Rather than assuming that toxic surfactants are present in chlorpyrifos formulations, which results in speculative risk analysis, it would be preferable for NMFS to request actual confidential statements of formula to determine potential for hazard.

Generally, when acute aquatic toxicity tests are performed using technical material and formulated material, as is routinely done for the EU, toxicity is similar. This indicate that all of the inert ingredients added to a formulated product tend not to influence toxicity. This is not always true, but in these uncommon cases the formulation may intentionally be designed to alter biological activity for improved efficacy.

The cited report discusses these points in detail.



Here is an example where slight toxicity differences exist between an emulsifiable concentrate formulation and technical material dosed in solvent. In one species the formulated product may be slightly more toxic, in the next, the technical exhibits greater toxicity. On average, they are equivalent.

Note that daphnid EC50s are difficult to compare because immobilization is a somewhat subjective endpoint.

Best Available Data – Metabolites and Degradates

- Metabolites
  - Chlorpyrifos oxon is generally transitory in the environment (highly unstable)
  - Chlorpyrifos oxon is the metabolically activated toxic form that binds at target site
- Degradates
  - Chlorpyrifos degradates generally exhibit low toxicity

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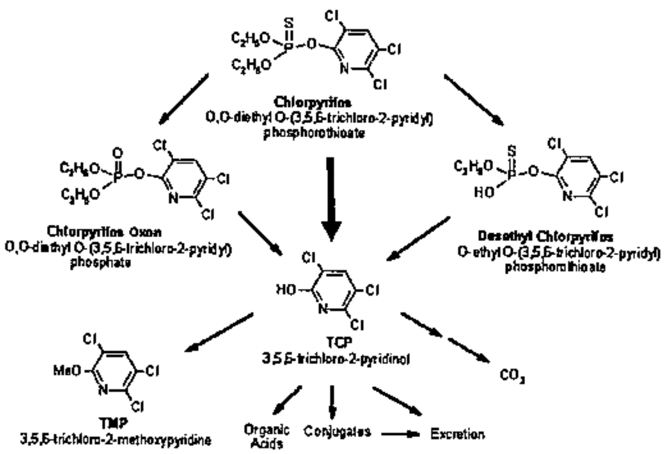
The weight of evidence from standard guideline laboratory environmental fate studies suggests that chlorpyrifos oxon is difficult to find in environmental media due to its instability (see Racke reference on next slide). It is more commonly found in animal tissues following metabolic activation of parent chlopyrifos. Therefore, there is no need to assess exposure of the oxon independent of parent chlorpyrifos.

The common chlorpyrifos degradates are generally recognized as being signifiicantly less toxic than parent.

Generalized Chlorpyrifos Transformation Pathways in the Environment



Source: Racke, K.D. 1993. Environmental fate of chlorpyrifos. Rev Environ Contam Toxicol 131:1-150

13

The key point of this generalized transformation scheme is that the major route is direct alteration of chlorpyrifos to TCP, as indicated by the larger arrow in the diagram. Formation of oxon is a minor pathway, and the oxon is rapidly converted to TCP.

Best Available Data – Exposure Model Inputs

- Table 32 PRZM-EXAMS exposure estimates do not reflect current chlorpyrifos label uses
  - Max. number of applications on cotton is 3 not 6
  - Max. rate on apples is 2 lb a.i./A
  - Aerial applications to Christmas trees (OR and WA only) require 150 foot buffer setbacks

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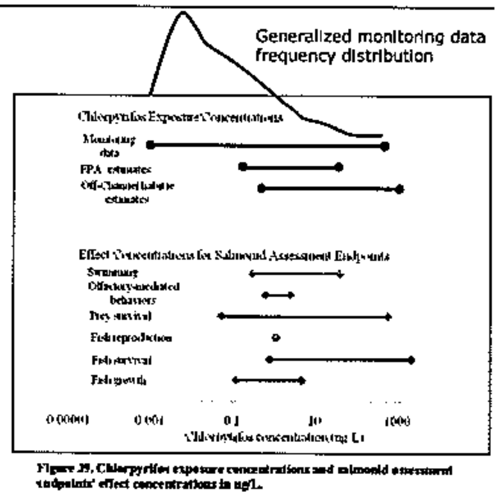
The exposure modeling cited in the draft BiOp does not represent current chlorpyrifos uses. Some examples are given.

Best Available Data – Misleading Integration and Evaluation of Exposure and Effect Information

- Ranges eliminate distribution information
- Generalized worst-case screening model predictions unrealistic
- Effects endpoints given equal weight



15

Drawn on Figure 39 from the draft BiOp is a generalized chlorpyrifos monitoring data frequency distribution. Because only ranges are considered, the frequency of occurrence of a particular concentration is neglected, thus limiting the value of the data integration performed by the BiOp authors. The best information was discarded. Also, there is no relationship between chlorpyrifos exposure profiles and specific ESUs. Finally, all effects endpoints are assumed to represent assessment endpoints relevant to population persistence, but this case was not made in the draft BiOp.

Probabilistic Risk Characterization Uses Best Available Data Applied to Specific Sites (1)

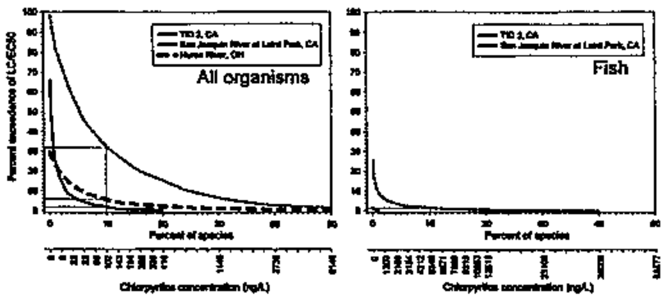


Fig. 28. Chlorpyrifos exceedence profiles for species distributions of all organisms at selected sites.

Source: J. P. Giesy, K. R. Solomon, J. R. Coats, K. Dixon, J. Giddings, E. E. Kenaga, "Ecological Risk Assessment of Chlorpyrifos in North American Aquatic Environments," *Rev. Environ. Contam. Toxicol.* **160**, 1-129 (1999). MRID for report GH-C 4660: 44696701

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This slide shows an example of an aquatic ecological risk assessment published for chlorpyrifos that appropriately uses all available information from monitoring data to provide both a probabilistic and site-specific characterization of risk. Such an integration of exposure and effects information is much more valuable to risk managers, as it communicates a description of the greatest risks (taxa, location).

Important to Relate Monitoring Data to Specific ESUs

Table 54. Monitoring data reported from may effect ESUs.

ESU	HABITAT	NO. STATIONS	MAX. AVG. CONC (ug/L)	MAX. MAX CONC. (ug/L)	NO. SAMPLES	FIRST DATE	LAST DATE	MIN. MRL (ug/L)	MAX. MRL (ug/L)
A1 Southern California Steelhead	ESU	2	[illegible]	1.6	16	[illegible]	[illegible]	[illegible]	0.010
A2 South-Central California Coast Steelhead	ESU	[illegible]	0.004	0.12	65	[illegible]	[illegible]	0.050	0.050
A4 California Central Valley Steelhead	ESU	103	0.1	1.6	4407	3/1/96	5/22/02	0.004	0.050
A6 Upper Columbia River Steelhead	ESU	40	0.015	0.066	329	11/19/91	5/30/02	[illegible]	0.050
	SR	30	0.015	0.066	140	11/19/91	11/25/98	[illegible]	0.050
	C	10	0.01	0.040	189	[illegible]	5/30/02	0.000	0.060
A9 Snake River Basin Steelhead	ESU	36	0.01	0.046	367	[illegible]	5/30/02	[illegible]	0.050
	SR	16	0.004	0.011	172	3/27/91	[illegible]	0.004	0.004
	C	10	0.02	0.046	189	[illegible]	5/30/02	[illegible]	0.050
A10 Middle Columbia River Steelhead	ESU	[illegible]	0.015	0.040	454	4/11/96	5/30/02	0.004	0.140
	SR	[illegible]	0.012	0.05	276	4/11/90	5/14/02	0.004	0.140
	C	[illegible]	0.01	0.046	183	[illegible]	5/30/02	[illegible]	0.050
B1 Sacramento River Winter-Run Chinook	ESU	24	0.01	0.019	1092	3/1/96	5/22/02	0.004	0.050
	SR	23	0.01	0.019	1091	3/1/96	5/22/02	0.004	0.050
	C	1	0.010	0.010	1	2/10/92	2/10/92	[illegible]	0.050
B2 Snake River Fall-Run Chinook	ESU	10	0.004	0.005	36	4/11/96	11/7/00	0.004	0.140
	SR	[illegible]	0.004	0.005	31	4/11/96	11/7/00	0.004	0.140
	C	2	0.004	0.004	6	5/3/94	[illegible]	0.015	0.050
B4 Central Valley Spring-Run Chinook	ESU	24	0.01	0.019	1097	3/1/96	5/22/02	0.004	0.050
	SR	21	0.010	0.019	1072	3/1/96	5/22/02	0.004	0.050
	C	3	0	0	25	[illegible]	[illegible]	0.010	0.050
B8 California Coastal Chinook	ESU	2	0.000	0.000	31	5/16/94	1/9/95	0.050	0.050
B10 Central Valley Fall/Late Fall-Run Chinook	ESU	[illegible]	0.3	1.6	4446	3/1/90	5/22/02	[illegible]	0.050
C1 Central California Coast Coho	ESU	2	0.000	0.000	31	5/16/94	1/9/95	0.050	0.050

Source: Giddings et al. 2003. Table from available report presented as an example. Updating of monitoring data recommended.

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Dow AgroSciences used a similar approach when we assessed the risk to salmonids in the report submitted to EPA as part of the lawsuit effects determination public comment process. Monitoring data were related to specific ESUs, and where sufficient data were available, probability of exceeding an effects endpoint could be estimated.

Best Available Data – Olfactory-Mediated Behaviors and Actual Environmental Concentrations

- Summary of chlorpyrifos effects
  - "Juvenile coho salmon lost 25, 50, and 50 % of olfactory function following 7 d exposures to 0.625, 1.25, and 2.50 ug/L, respectively (Sandahl, et al. 2004)." (Page 260)
  - Decreased odor-evoked field potentials not related to a population assessment endpoint
  - There is no evidence in the draft BiOp that there has been a 7-d exposure of 0.625 ug/L in any ESU
- NMFS does not make a strong case for population impact of transitory olfactory effects in ESUs
- See also MANA comments regarding diazinon studies

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Study selection for assessment endpoints requires consideration of several important elements. For example,

•Does a single peer-reviewed study have utility for risk assessment?

•Is the reported effect endpoint relevant to survival of individuals or populations?

•Is there sufficient quality and consistency in comparison to other studies supporting endpoint development?

The slide bullets indicate why the study is not appropriate for risk assessment.

Probabilistic Risk Characterization Uses Best Available Data Applied to Specific Sites (2)

- Conclusion of Giesy et al. 1999: "Overall, the data on concentrations in freshwater does not suggest ecologically significant risk, except in a few locations, primarily in California."
  - Subsequent large research and monitoring programs in CA
  - Regulatory actions by state regional water quality control boards and DPR
  - Increase in Dow AgroSciences stewardship activity
- Elimination of uses and reduction in application volume not considered in Giesy et al. 1999

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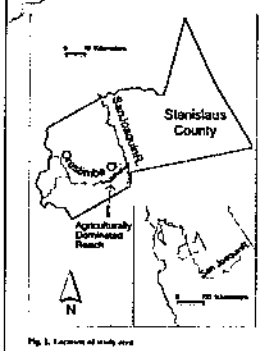
Giesy et al. 1999 concluded that aquatic animal communities are not at risk in most locations. Where there was some potential for risk, the identified systems in California have subsequently been studied intensively, resulting in increased regulatory, education, and stewardship activity.

Note that Giesy et al. 1999 was published before residential use ended. Therefore, current exposure, on average, should be lower.

California Research and Monitoring Uses Best Available Data (1)

- Orestimba Creek
  - Targeted monitoring and site-specific ecological risk assessment
    - Poletika, N.N., Woodburn, K.B., Henry, K.S. 2002. An ecological risk assessment for chlorpyrifos in an agriculturally dominated tributary of the San Joaquin River. Risk Anal 22:291-308. MRID for report GH-C 4854: 44711601
      - Conclusion: Fish population persistence and invertebrate community productivity were not adversely affected
      - Uncertainties: actual community status and potential, time-varying concentrations, contribution of other stressors



20

An intensive targeted monitoring study and site-specific risk assessment concluded that, based on the current fish community and sensitivity of surrogate species typical of lotic habitat, chlorpyrifos is not impacting this agriculturally dominated stream. Some uncertainties remained.

California Research and Monitoring Uses Best Available Data (2)

- Orestimba Creek
  - Multiple year biological monitoring and physical habitat assessment
    - Hall, Jr., L.W., Killen, W.D., Alden III, R.W. 2007. Relationship of farm level pesticide use and physical habitat on benthic community status in a California agricultural stream. HERA 13:843-869.
      - Conclusion: in general, both pesticide applications and physical habitat have a similar but modest statistical association with benthic communities. However, the relationship of both stressors appear to be insignificant compared to the magnitude of spatiotemporal patterns reported

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Therefore, the previous assessment was followed up with several years of biological and physical habitat monitoring to better understand the relative impacts of multiple stressors identified in the stream. Pesticide use, including use of chlorpyrifos, did not appear to be a significant stressor in this system.

The sequence of detailed quantitative assessments summarized in slides 16-21 represent a more robust approach than that taken by NMFS in the draft BiOp, which is neither probabilistic nor spatially explicit.

Regulatory Actions

- Central Valley Regional Water Quality Control Board
  - 303(d) listings and TMDLS
    - Implementation plans underway in some watersheds such as Sacramento/Feather River
  - Irrigated Lands Program
    - Coalition monitoring and education
- Department of Pesticide Regulation
  - Chlorpyrifos re-evaluation of state registrations
    - Dow AgroSciences exceedence investigations and grower education

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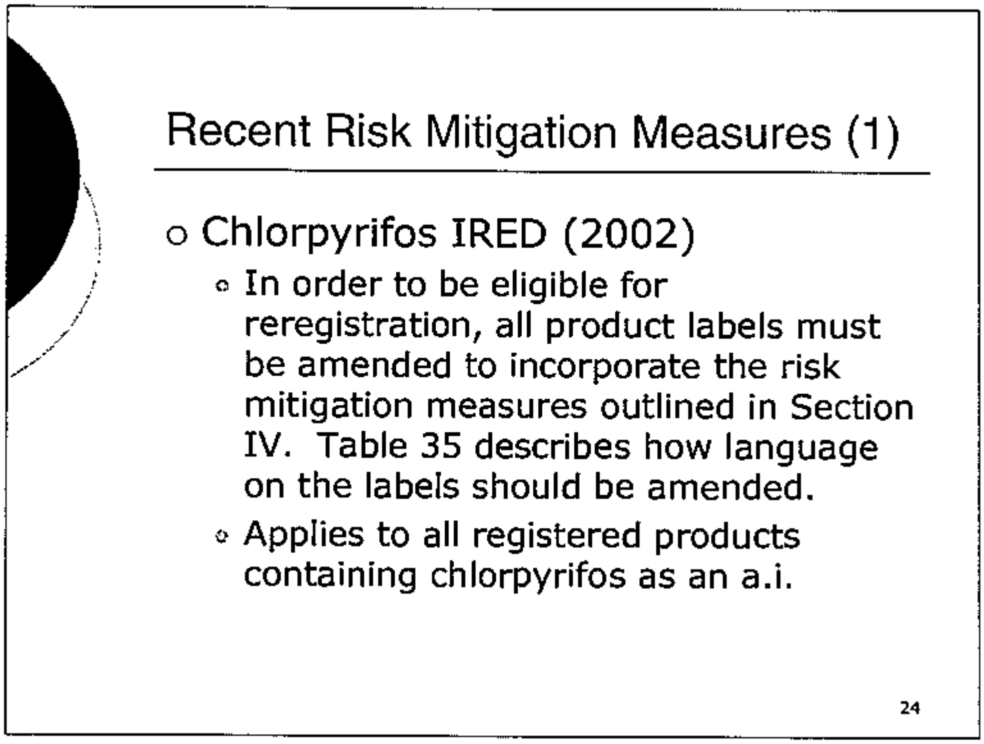
The draft BiOp failed to consider the impact of various regulatory actions in California related to salmonid ESUs. They are very likely to result in reduced exposure.

Stewardship

- Dow AgroSciences serves on the board of directors of the Coalition for Urban/Rural Environmental Stewardship (CURES) and provides support
  - CURES stewardship materials available at http://www.curesworks.org/home.asp
- Dow AgroSciences field scientists participate in grower educational meetings to raise awareness of water quality concerns and recommend practices to reduce exposure

23

Stewardship activities also were not considered in the draft BiOp. These should, over time, reduce off-site transport and exposure of salmonids to chlorpyrifos as more growers with water release or application problems are identified and educated.



The draft BiOp states that it is very difficult to account for all product uses and to know whether risk mitigation measures are in place. This is not true. The bullets in this slide indicate that a single EPA document provides this information. It is applicable to all products containing chlorpyrifos as an active ingredient.

Recent Risk Mitigation Measures (2)

- Implementation of mitigation language on chlorpyrifos labels
  - Spray drift management
    - Buffer zones
    - Best management practices
  - Specific use restrictions by crop
    - Total amount of a.i. applied per season
    - Number of applications
    - Re-treatment intervals
    - Maximum single application rate

25

The risk mitigation language on chlorpyrifos labels falls into two categories, spray drift management and specific use restrictions by crop. For spray drift the two major practices are mandatory no-spray buffer zones and detailed instructions on setting up application equipment and spraying practices. Use restrictions limit the amount of chemical that can be applied, the numbers of applications that can be made, and the intervals between treatments.

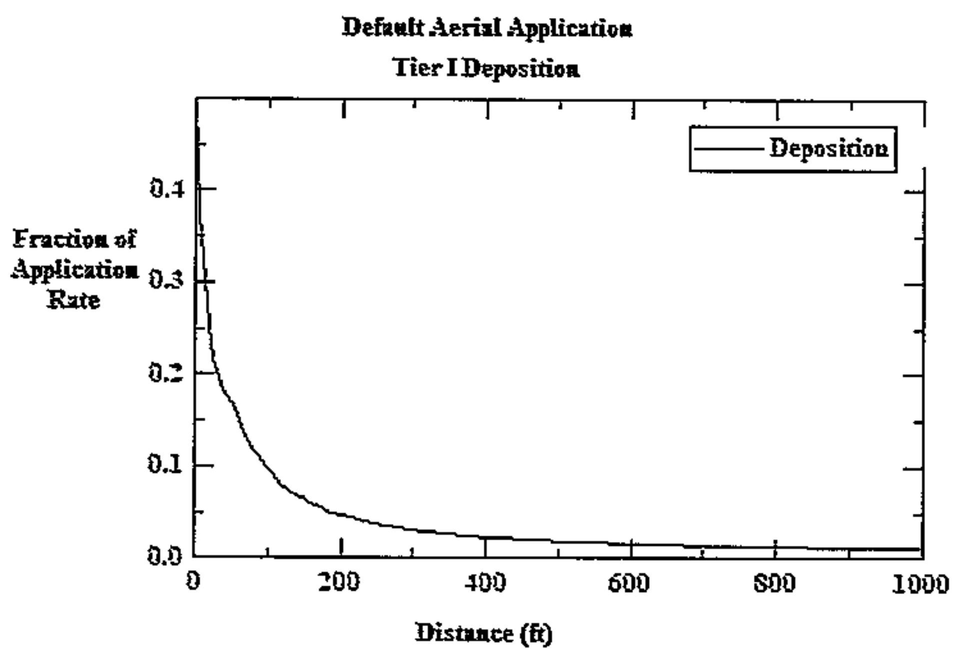
Recent Risk Mitigation Measures (3)

- Spray drift buffer zones

Application Method	Required Setback (Buffer zone)(feet)
ground boom	25
chemigation	25
orchard airblast	50
aerial (fixed wing or helicopter)	150

26

From Lorsban 4E label. These are the buffer zones tied to specific application methods. The distances were selected to provide significant reduction in spray droplet deposition at distances that can be implemented by growers. Note that increasing buffer size provides minimal additional benefit.



AgDRIFT® 2.0.05

Recent Risk Mitigation Measures (4)

- Best management practices
  - Aerial application
  - Aerial drift reduction advisory
    - Information on droplet size
    - Controlling droplet size
    - Boom length
    - Application height
    - Swath adjustment
    - Wind
    - Temperature and humidity
    - Temperature inversions
    - Sensitive areas

Source: Marlin E. Rice, Iowa State U.

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From Lorsban 4E label. Aerial application refers to practices such as boom width, nozzle direction, droplet size, height above canopy, swath displacement, and interaction with no-spray zone.

The aerial drift reduction advisory section gives advice on how to implement the practices mentioned above. There also is a discussion on how to deal effectively with wind speed, temperature and humidity, temperature inversions, and sensitive areas such as water bodies.

Recent Risk Mitigation Measures (5)

- Best management practices
  - Ground boom application
    - Droplet size
    - Nozzle height
    - Wind speed
  - Orchard airblast application
    - Canopy height
    - Wind speed
    - Turning corners with outside nozzles off
    - Adjustment of airblast equipment
    - Nozzle orientation
    - Passing gaps in crop canopy with sprayer off
    - Spraying outside rows outside in with outside nozzles off
    - Spraying smaller crops with top nozzles off

Source: CURES

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From Lorsban 4E label. Ground boom practices include nozzle selection and pressures, maximum spray release height, and maximum wind speed (tied to effectiveness of no-spray zone).

Orchard airblast applications have additional considerations due to the acceleration of the spray droplets needed to penetrate the crop canopy and the three-dimensional nature of the crop (trees and vines, geometry of planting grid).

Recent Risk Mitigation Measures (6)

- Examples of specific use restrictions by crop
  - Alfalfa
    - Reduced allowed applications from 8 to 4
    - 10-d interval, max. 1 lb a.i./A per application
  - Citrus
    - Reduced maximum rate from 6 to 4 lb a.i./A
    - Highest rate limited to 5 CA counties
    - Limit of 2 applications, 30-d interval
    - Aerial application eliminated
  - Corn
    - Reduced seasonal limit from 7.5 to 3 lb a.i./A
    - Limited to 3 applications, 10-d interval

29

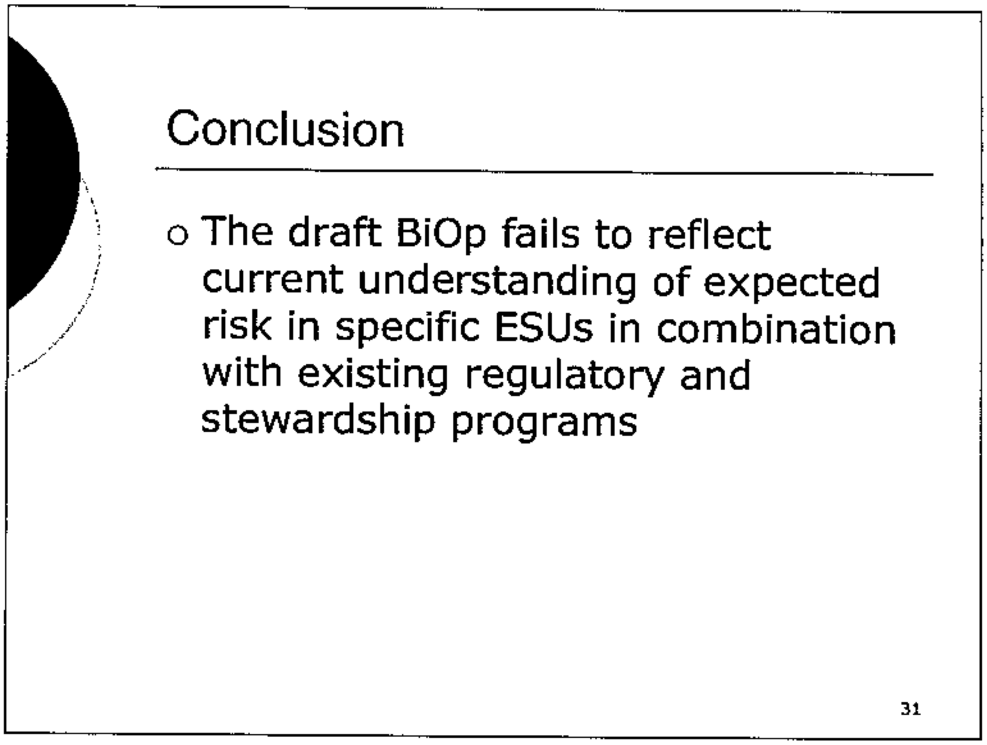
From Lorsban 4E label. The slide gives examples of the specific use restrictions by crop that incorporate the elements listed in an earlier slide: limiting the amount of chemical that can be applied, the numbers of applications that can be made, and the intervals between treatments.

Recent Risk Mitigation Measures (7)

- Examples of specific use restrictions by crop
  - Tree nuts
    - Seasonal limit reduced from 8 to 4 lb a.i./A
  - Tree fruits
    - Total of 2 lb a.i./dormant-delayed dormant season, 1 dormant application, 10-d interval between dormant and foliar
    - Only post-bloom apple use allowed is a directed trunk spray;
    - Reduction from 2 to 1 applications per season for any use on apples

30

Additional examples from the Lorsban 4E label.



We conclude that problems with data selection, methodology, lack of awareness of current uses and risk mitigations, and no consideration of state level regulation or local stewardship activity render the chlorpyrifos risk conclusions in the draft BiOp inadequate to address the Federal Action.

Additional Slide (1)

- Suggested sources to update monitoring data
  - Washington
    - WSDA Surface Water Monitoring Program for Pesticides in Salmonid-Bearing Streams

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Additional Slide (2)

- Suggested sources to update monitoring data
  - California
    - Sacramento/Feather River system
      - DPR surface water database
      - USGS
      - Sacramento Valley Water Quality Coalition
      - Sacramento River Watershed Program
      - University of Californa, Davis (Mike Johnson)

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Additional Slide (3)

- Suggested sources to update monitoring data
  - California
    - San Joaquin River system
      - DPR surface water database
      - Central Valley Regional Water Quality Control Board
      - USGS
      - Westside San Joaquin River Water Quality Coalition
      - East San Joaquin Water Quality Coalition
      - San Joaquin County Delta Water Quality Coalition

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Additional Slide (4)

- Chlorpyrifos microcosm/mesocosm studies are an extremely valuable line of evidence receiving little attention in the draft BiOp. Suggested publications to bring into the NMFS assessment:
  - Van Wijngaarden, R.P.A, Brock, T.C.M., van den Brink, P.J. 2005. Threshold levels for effects of insecticides in freshwater ecosystems: a review. Ecotoxicology 14:355-380.
    - Twelve chlorpyrifos studies reviewed and evaluated for effects thresholds (EU perspective)
    - Places into context the van den Brink et al. (1996) papers used in the draft BiOp population modeling
  - See also section in Giesy et al (1999) that reviews microcosm/mesocosm studies and relates the endpoints to other lines of evidence (US perspective)

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TAB

C

Diazinon Use Information

Scott Rawlins, Director of Governmental Relations & Trade
Makhteshim Agan of North America

Overview

- Since 2000, Diazinon use nationwide has dropped by more than 90%.
- ESA buffers have been in place since 2001 around Pacific Salmon supporting waters.

Background

- Pre – 2000: Diazinon use nationwide totaled roughly 13 million pounds annually.

1. 70% of all use was for household lawn and garden pest control.
2. 5% of all use was for crack & crevice and for flea collars.
3. 25% of all use was for agricultural applications.

Source: 7/2006 Diazinon RED

Background

- December 2000: EPA and the registrants signed a Memorandum of Agreement (MOA) to phase out and cancel all residential uses according to the following schedule.

1. All *indoor* residential uses were cancelled in March of 2001. Retail sales of these products ended on December 31, 2002.
2. All *outdoor* residential uses were cancelled with distribution to retailers ending in September of 2003. Retail sales of these products ended on December 31, 2004.
3. After 12/31/04, a buy-back program prevented further sales of existing stocks.

Source: 12/5/00 EPA News Release

Background

- The MOA also began the process to cancel 20 different uses on food crops.
- In July of 2002, EPA issued an Interim Reregistration Eligibility Decision which proposed significant changes to the remaining labeled crops, including use deletions and additional restrictions.
- EPA completed the Diazinon RED in July of 2006.

Changes in Diazinon Use

- In the draft BiOp, EPA estimates that 4 million pounds is applied annually for agricultural applications.
- The IRED changes have brought total use today to less than 750,000 pounds annually.

IRED Food Crop Label Mitigation

- **Cancellation of all granular registrations.** The only exception are two current Section 24(c) registrations held by Washington and Oregon for control of the cranberry girdler. Three other Section 24(c) registrations held by Massachusetts, New Jersey, and Wisconsin will be phased out in 2008. Granular use on lettuce will only be allowed in California until 2008.

- **Deletion of aerial application for all uses, except lettuce in California.**

- **Deletion of foliar application on all vegetable crops.** The only exception will be for treatment of leafhopper on honeydew melons in California and ginseng.

Source: Diazinon RED

IRED Label Mitigation

- **Application rate reduction.** The maximum rate for omamentals (except cut flowers) will be reduced from 2 lb ai/acre to t lb ai/acre. The maximum granular rate for lettuce (during the five year phase out) will be reduced from 4 lb ai /acre to 1 lb ai/acre.

- **Cancellation of all seed treatment uses.** Five uses will be cancelled: beans (snap), beans (lima), corn (field), com (sweet), and green peas.

- **Reduction in the number of applications of diazinon per growing season.** On most uses only one application per growing season will be allowed. Crops with dormant season and in season uses (e.g., stone fruits) will have one application per season for a total of two applications per year.

Source: Diazinon RED

IRED Label Mitigation

- **Application limitations and labeling on orchard crops.** For all orchard crops (nuts, stone fruits, pome fruits, etc) with dormant season uses, label language only allows applications every other year unless pest pressures are such that consecutive, annual treatments are necessary. The only exception is apples.

- **Cancelled uses.** Section 3 uses: Chinese broccoli, Chinese cabbage, Chinese mustard, Chinese radish, corn, grapes, hops, mushrooms, sugar beets, walnuts, and watercress.

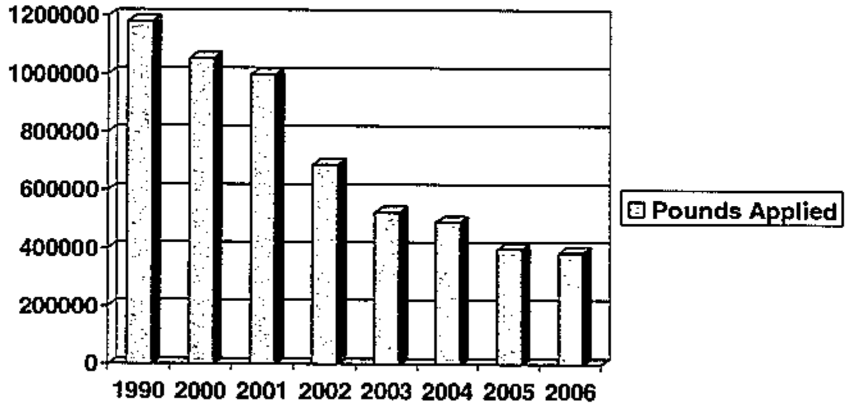
Source: Diazinon RED

Diazinon Use in California

- Represents 70% of total use.
- California has had mandatory pesticide recordkeeping and reporting since 1990.

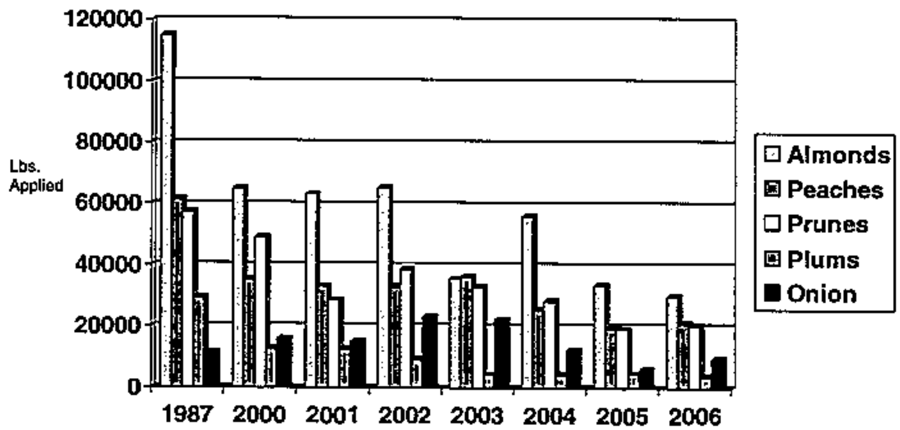
Source: Diazinon IRED & California Pesticide Use Reports at
http://www.cdpr.ca.gov/docs/pur/purmain.htm

Diazinon Use in California



Source: California Pesticide Use Reports

Changes on Key CA Crops



Source: CA Pesticide Use Reports

Pounds Applied

Coalition for Urban/Rural Environmental Stewardship (CURES)

- Developed Diazinon-specific best management practices for dormant season applications in California.
- BMPS included:

1. Development and maintenance of a 10-foot buffer strip for orchards that are adjacent to and within 100 feet of a sensitive aquatic site.
2. Restrictions on applications made 100 feet upslope of a sensitive aquatic site.
3. Use of ground application equipment only
4. Sprays must be directed away from sensitive aquatic sites.
5. No applications when soil moisture is at field capacity

Source: www.cures.org

ESA Restrictions

- Washington Toxics Coalition settlement imposed 20-yard buffers for ground applications and 100 yards for aerial applications around all Pacific Salmon-supporting waters in WA, OR and CA.

Source: EPA website at http://www.epa.gov/oppfead1/endanger/

County Bulletin Restrictions in CA

- Four restrictions in place in all but two counties in California:

1. Do not use in currently occupied habitat (see Species Descriptions table for possible exceptions).
2. Provide a 20 foot minimum strip of vegetation (on which pesticides should not be applied) along rivers, creeks, streams, wetlands, vernal pools and stock ponds or on the downhill side of fields where run-off could occur. Prepare land around fields to contain run-off by proper leveling, etc. Contain as much water "on-site" as possible. The planting of legumes, or other cover crops for several rows adjacent to off-target water sites is recommended. Mix pesticides in areas not prone to runoff such as concrete mixing/loading pads, disked soil in flat terrain or graveled mix pads, or use a suitable method to contain spills and/or rinsate. Properly empty and triple-rinse pesticide containers at time of use.

Source: EPA "Bulletins Live" website at http://www.epa.gov/opplead t/endanger/

County Bulletin Restrictions in CA

3. Conduct irrigations efficiently to prevent excessive loss of irrigation waters through run-off. Schedule irrigations and pesticide applications to maximize the interval of time between the pesticide application and the first subsequent irrigation. Allow at least 24 hours between application of pesticides listed in this bulletin and any irrigation that results in surface run-off into natural waters. Time applications to allow sprays to dry prior to rain or sprinkler irrigations. Do not make aerial applications while irrigation water is on the field unless surface run-off is contained for 72 hours following the application.
4. For sprayable or dust formulations: when the air is calm or moving away from habitat, commence applications on the side nearest the habitat and proceed away from the habitat. When air currents are moving toward habitat, do not make applications within 200 yards by air or 40 yards by ground upwind from occupied habitat. The county agricultural commissioner may reduce or waive buffer zones following a site inspection, if there is an adequate hedgerow, windbreak, riparian corridor or other physical barrier that substantially reduces the probability of drift.

Source: EPA "Bulletins Live" website at http://www.epa.gov/oppfead1/endanger/

Summary

- Since 2000, Diazinon use has plummeted from 13 million pounds annually to less than 750,000 pounds today.
- IRED/RED label mitigation has already addressed ESA issues through the cancellation of crops, changes in label rates and number of applications, deletion of aerial uses and other measures.
- Court imposed buffers as well as county bulletin restrictions are already in place.

TAB

D

Makhteshim-Agan of North America, Inc.

DIAZINON REGISTRANT COMMENTS to National Marine Fisheries Service Endangered Species Act Section 7 Consultation, Draft Biological Opinion dated July 31, 2008

September 10, 2008

MANA comments to the draft Biological Opinion prepared by the National Marine Fisheries Service (NMFS) are provided herein. Areas addressed include impact of diazinon usage changes, problems with field-scale computer modeling, utility as well as limitations of water monitoring data, aquatic toxicity endpoints and suggestions to improve the risk characterization.

Regulatory-Driven Changes in Diazinon Usage

Since 2000, diazinon use nationwide has dropped by more than **90%**. Prior to the year 2000, diazinon use total approximately 13 million pounds annually. For that overall usage, 70% was for household lawn and garden pest control. Another 5% of all uses were for crack and crevice treatments and for flea collars. The remaining 25% of all use was for agricultural applications (Slide 4).

In December 2000, EPA and the diazinon registrants signed a Memorandum of Agreement (MOA) to phase out and cancel all residential uses. Specifically, all indoor residential uses were cancelled in March 2001 with retail sales of existing stocks ending on December 21, 2002. All outdoor residential uses were cancelled with distribution to retailers ending in September 2003 and retail sales of existing stock ending on December 31, 2004. After that date, a buy-back program prevented further sales of existing stocks (Slide 5).

The MOA also began the process of cancelling 20 different uses on food crops. In addition to those crop cancellations, EPA in July 2002 issued an Interim Reregistration Eligibility Decision (IRED) which proposed significant changes to the remaining labeled crops, including use deletions and additional restrictions. The diazinon RED was completed by EPA in 2006 (Slide 6).

These changes have brought total diazinon use today to less than 750,000 pounds or about 6% of what was used in the year 2000.

In addition to cancellations, the IRED brought significant food crop label mitigation. For example, all granular registrations were cancelled. The only exceptions are two current Section 24(c) registrations held by Washington and Oregon for control of the cranberry girdler. Granular use on lettuce will only be allowed in California until 2008. All aerial applications for all uses were deleted except for lettuce in California. Furthermore, foliar application on all vegetable crops was deleted except for the treatment of leafhopper on honeydew melons in California and on ginseng. There were also reductions in the number of applications of diazinon per season. That is, on most uses, only one application per growing season will be allowed. Crops with dormant season and in-season uses (e.g., stone fruits) will have one application per season for a total of two applications per year. Application rates in most cases were reduced. The maximum rate for ornamentals (except cut flowers) was reduced from 2 lbs active ingredient (ai)/acre to 1 lb ai/acre. The maximum granular rate for lettuce was reduced from 4 lb ai/acre to 1 lb ai/acre. All seed-treatment uses were also cancelled, including snap and lima beans, field and sweet corn and green peas.

Other label mitigations coming out of the IRED included application and labeling limitations on orchard crops. For most orchard crops with dormant season uses (i.e., nuts, stone and pome fruits, etc.), label language will only allow applications every other year unless pest pressures are such that consecutive, annual treatments are necessary. Finally, Section 3 uses for Chinese broccoli, Chinese cabbage, Chinese mustard, Chinese radish, corn, grapes, hops, mushrooms, sugar beets and walnuts were all cancelled (Slides 8-10).

Taken together, these actions very substantially reduce diazinon usage which, as stated above, now represents about 6% of what was used in the year 2000.

California represents 70% of the total use of diazinon nationally. Based on California pesticide reporting data since 1990, pounds applied have gone from slightly less than 1.2 million pounds in 1990 to less than 400,000 pounds in 2006. Crops such as almonds, peaches, prunes, plums and onions, all treated with diazinon over that approximate time period, have all shown substantial reductions in use (Slide 11-13).

Industry stewardship and other best-management practice approaches have further minimized the possible transport of diazinon to aquatic bodies from spray drift, runoff and erosion. For instance, the Coalition for Urban/Rural Environmental Stewardship (CURES) developed diazinon-specific best management practices (BMPs) for dormant season applications in California. These BMPs include development and maintenance of a 10-foot buffer strip for orchards that are adjacent to and within 100 feet of a sensitive aquatic site, restrictions on applications made 100 feet upslope of a sensitive aquatic site, use of ground application equipment only, spraying away from sensitive aquatic sites and not applying when soil moisture is at field capacity. These practices are now required by state water quality regulators (CVRWQCB) and CDPR dormant spray regulations (Slide 14).

In addition to industry stewardship, California county bulletins have also been used to minimize spray drift and runoff of diazinon into aquatic bodies in all but two counties in California. These bulletins restrict usage in currently occupied habitat (with some exceptions for specific species). In addition, the county bulletins provide a 20-foot minimum vegetative strip on which pesticides should not be applied along rivers, creeks, streams, wetlands, vernal pools and stock ponds or on the downhill side of fields where run-off could occur. Other recommendations are to prepare land around treated fields to contain runoff by proper leveling. The planting of legumes and other cover crops for several rows adjacent to off-target water sites is recommended. Care in mixing pesticides to contain spills and in areas not prone to runoff is emphasized as is properly emptying and triple-rinsing pesticide containers at the time of use. Other restrictions included in the county bulletins include guidelines for conducting irrigations to minimize runoff. For sprayable or dust formulations, when the air is calm or moving away from the habitat, the county bulletins indicate applying on the side nearest the habitat and proceeding away from the habitat. When air currents are moving toward the habit, the county bulletins caution not to make applications within 200 yards by air or 40 yards by ground upwind from occupied habitat. These buffers may be reduced or waived following a site inspection by the county agricultural commissioner if there is an adequate hedgerow, windbreak, riparian corridor or other physical barrier that substantially reduces the probability of drift (Slides 15-16).

Problems with Computer Modeling

All modeling provided in the Biological opinion was based on obsolete labels. Input parameters used do not take into consideration the significant label changes negotiated during the RED process. Furthermore, only one of the seven modeling crop scenarios was applicable to Pacific salmonids (i.e., California almonds). The remainder of crop scenarios used in modeling are east coast or midwest scenarios that are irrelevant to Pacific salmon. That is, meteorological inputs appropriate to east coast and midwest scenarios feature heavier rainfall than west coast scenarios leading to less runoff. This was aptly pointed out at the time of EPA's effects determination for diazinon by Turner 2002[1] who wrote that, in general, the modeling scenarios were "quite unrealistic for use with Pacific salmon and steelhead. The primary difficulty is that all except the almonds were modeled for areas that will have far more runoff than will occur in the Pacific states, even including the mesic parts of western Oregon and Washington because the precipitation there, while substantial, does not typically occur in large runoff events." (Slide 41)

In addition to not using crop scenarios that were appropriate for the region containing the critical habitats, the very substantial reduction in the total amount of diazinon used in the Pacific states for the reasons described above would further reduce computer-predicted deposition of diazinon in nearby water bodies. Furthermore, although difficult to incorporate into existing computer models (specifically the runoff component), the addition of buffers resulting from various best management practices including California's endangered species county bulletins (see above) and from the Washington Toxics lawsuit further serve to reduce diazinon deposition into water bodies from drift and runoff.

Second, in addition to using inappropriate input parameters, neither of the models used are considered accurate for salmonid habitats. Both PRZM-EXAMS and GENEEC are based on a 10 ha-treated field that surrounds and directly abuts a 1 ha pond that is 2-meters deep. Although the models can incorporate the use a spray-drift model (AgDRIFT®) to reduce spray drift deposition into the farm pond, buffers cannot be used to predict the amount of runoff that could be reduced. As noted, the models are static, accounting for neither inflow of outflow of water and the pesticide reaching the pond is assumed to be instantaneously and homogeneously distributed throughout the pond. The models also assume maximum slopes for runoff. These assumptions built into the models make them very unrealistic for streams and rivers relevant to the habitat of salmonids. Although EPA makes the case for these models representing a worst-case scenario, they probably, in fact, represent a "worst-worst case" scenario which may be too unrealistic for regulatory actions (Slides 38,39).

Based on limitations of the edge-of-the-field models, the registrant has explored the utility of using another computer model that would better represent and predict diazinon exposure concentrations in large, complex watersheds. This model would be also be useful in quantifying the benefits of best management practices such as application setbacks, limiting applications within 72 hours of significant rainfall and including a vegetated filter strip. Thus, the Soil and Water Assessment Tool (SWAT)[2] was used to develop a transport model to determine the concentrations of diazinon in surface water throughout the Feather

River watershed in northern California. A model such as SWAT integrates the effect of land use, soil characteristics, hydrology and management practices to predict the regions of a watershed most vulnerable to chemicals such as pesticides. The Feather River watershed was selected because within it there is significant diazinon dormant-season orchard use. It also had a history of elevated diazinon concentrations and it had readily available datasets necessary for model development and model calibration. Importantly, the Feather River watershed has a number of different hydrologic environments ranging from small agricultural drainage canals to the mainstem Feather River with high flows and volumes.

The aim of model development was to simulate conditions representing actual application patterns occurring within the watershed. This required accurately determining locations of orchard areas where diazinon was applied, the timing of diazinon applications and specific diazinon application rates. This information was obtained from the California Pesticide Use Records (PUR) database. The model was calibrated against environmental fate parameters based on three diazinon soil dissipation studies conducted in California. Parameters included leaching data, soil half lives and Koc values. The model was also calibrated for stream flows using gauging stations located throughout the watershed. Water monitoring results were obtained from eight locations representing a range of areas, including smaller agricultural drainages to a large water body location such as the Feather River at Nicolaus, to best calibrate the model throughout the entire watershed. Data were specifically obtained from the California Department of Pesticide Regulations, Surface Water Database, the Sacramento River Watershed Program and the USGS NAWQA water quality program (234 samples collected and analyzed between 1994 and 2001).

After development and calibration, the model simulated diazinon concentrations throughout the watershed from 1993 to 2001 that closely matched actual water monitoring data. In general, the magnitude and frequency of diazinon levels above an acute invertebrate criterion standard (set by the California Department of Fish and Game at 80 ng/L) decreased over the nine-year period.

The potential for reducing diazinon levels throughout the watershed by employing three best management practices was assessed using the SWAT model. The effects of using a 150-foot application setback from surface waters, limiting applications within 72 hours of a significant rain event and employing a ten-foot vegetated filter strip were evaluated individually as well as in combination. The model showed that the most effective means of reducing diazinon levels below the regulatory threshold was by use of the ten-foot vegetative strip, followed by limiting applications within 72 hours of rainfall followed by employing a 150-foot setback from surface waters.

Although more work would have to be done, before it could be relied upon for final decision-making, the watershed-scale SWAT model appears to have more relevance for predicting diazinon concentrations in salmonid habitats than field-scale models like GENEEC and PRZM-EXAMS. With model calibration, it integrates modeling and water monitoring which serves to increase confidence in its predictions and allows assessment in all parts of the watershed.

Until such time that a watershed-scale model such as SWAT could be developed for salmonid habitats throughout the Pacific States, greater weight be given to the extensive monitoring data collected by the United States Geological Survey (USGS) and the states of California and Washington. However, monitoring sites would have to be limited to bona-fide salmonid habitats and data have to be recent enough to reflect the significant reductions in diazinon use that have occurred in the last few years. A discussion of monitoring data follows.

Monitoring

Monitoring data compiled in the draft Biological Opinion does not represent current and future exposure conditions. NMFS relies on outdated data (1990s and early 2000s) that clearly is not reflective of current usage. There is no discussion in the Biological Opinion of the reductions in both frequency of detections and concentrations of diazinon in exposure water resulting from reductions in usage, label changes and BMPs. Equally important, the monitoring data are expressed simplistically in the form of overall ranges with emphasis on highest detections found. A frequency distribution analysis dividing the data up into percentiles (such as 80th, 90th, 95th) to gauge probabilities of exposures that exceed toxicity benchmarks was not performed. All detections were considered relevant, particularly the highest ones, when, in fact, these high concentrations came from drainage ditches which should not be considered relevant to salmonid habitats (Slide 19).

Considering NAWQA Cycle II data[3] between 2001 and 2006, the number of diazinon detections was reduced from a high in 2002 of 684 to a low of 42 in 2006. This is an overall percentage detection reduction from 40.76% and 7.64%. These data are also mirrored by Washington State monitoring data[4, 5] where detection frequency within an urban watershed between 2003 and 2006 dropped from 39% in 2003 to only 6% in 2006. Furthermore, only one detection (0.21 ppb) in 114 samplings over the four-year period exceeded a chronic invertebrate water quality criterion (0.17 ppb) and, based on reviewing the Washington State report, that actual detection may have belong to the herbicide diuron, not diazinon. Diazinon detections were also very low in Washington State agricultural watersheds sampled, with the highest concentration being 0.07 ppb based on 243 samples collected and analyzed (Slides 20-22, 27).

From NAWQA data collected from 2002 – 2005 in California surface waters from agricultural land covers (summarized by EPA[6]), the average diazinon concentration was calculated to be 0.048 μg/L, the 90th percentile concentration was 0.099 μg/L and the maximum concentration was 1.06 μg/L. These values are quite a bit less than those summarized in Table 40, Page 225 of the draft Biological Opinion (Slide 24).

From analyses of diazinon monitoring data from Hall et al., 2003[7, 8] and Hall 2008[9], it is clear that older diazinon monitoring data report higher concentrations than more current data and should not be used to assess ecological risk to salmonids (Slide 23). For example, trends analysis of current San Joaquin, California watershed data from 2001 to 2007 show a large percentage of non-detectable diazinon residues. Monitoring data collected from the Sacramento River watershed from 1991 to 2001 show declining concentrations of diazinon (Slide 24). An updated trend analysis for the Sacramento River watershed (2001 to 2007) shows further significant declines in both diazinon concentrations and target exceedences (Slide 24). For instance, diazinon annual mean concentrations in all Sacramento and Feather River mainstem sites were reduced from ~ 0.0.021 μg/L in 2001 to ~ 0.007 μg/L in 2007 (Slide 25). Diazinon annual mean concentrations in all Sacramento and Feather River tributary sites were reduced from ~ 0.111 μg/L in 2001 to ~ 0.025 μg/L in 2007 (Slide 26). These results indicate that older diazinon monitoring data report higher concentrations than current monitoring data and should not be used in assessing ecological risk to salmonids.

There were a few seemingly high diazinon detections that were cited in the Biological Opinion that require comment. For instance, the maximum diazinon water concentration reported from the California monitoring results (Table 38, Page 224 of the Biological Opinion) was 36.8 ppb from a river sample. However, the source of this detection was incorrect. Upon further investigation, the actual detection occurred at Newman Wasteway, which is not a salmonid habitat (Slides 28-29). A maximum diazinon concentration of 29 ppb was reported from Orestimba Creek, California during 1996/1997 (see Table 40). However, Orestimba Creek is an ephemeral creek that receives its recharge in the winter from storm runoff and in the spring and summer from irrigation water coming off pesticide-treated fields and is not considered a salmonid habitat (Slide 30). The highest diazinon detection (67 ppb) came from the Salinas Valley. However, this sample came from an agricultural ditch that is also not considered a salmonid habitat. Furthermore, this sample was apparently collected in the 1990s and not representative of current usage patterns. Finally, the analytical method employed (ELISA) is questionable (Slide 31).

As mentioned previously, rather than emphasize the overall range of diazinon detections obtained from water monitoring, it would be more useful to analyze a frequency distribution of the detections to arrive at probabilities for exposures that might cause effects. The tables below describe diazinon detections from NAWQA Cycle II data from 2001 – 2004 and from 2004 – 2006[3].

Distribution of Diazinon Detections between 2001 – 2004 (expressed as % of samples for land use categories)					
Land Use	**% of All Samples**	**% > 0.01 µg/L**	**%>0.10 µg/L**	**%>1.0 µg/L**	**Overall Range of Detections (µg/L)**
Agricultural	14.14	4.94	0.38	0	0.0007 – 0.53
Urban	71.85	49.11	6.67	0	0.0013 – 0.78
Other	26.76	13.96	1.99	0	0.0017 – 0.36
Mixed	34.38	14.37	0.32	0	0.001 – 0.33
Distribution of Diazinon Detections between 2004 – 2006 (expressed as % of samples for land use category)					
Agricultural	2.5	2.0	0.60	0	0.0048 – 0.5
Urban	25.4	2.6	0	0	0.0038 – 0.11
Other	10.5	1.8	0.15	0	0.004 – 0.5
Mixed	7.6	1.5	0.3	0	0.0036 – 0.029

These monitoring data show that both the frequency of detections and the distribution of the magnitude of the detections have markedly declined in recent years.

Discussion of Effects Data

Comments on Survival Testing ($LC_{50}s$)

The lowest reported LC_{50} for diazinon is 90 µg/L for rainbow trout. Interestingly, another test result using a similar percent active ingredient with the same fish species resulted in a LC_{50} of 400 µg/L[1] (Slide 43). Nevertheless, based on the lowest LC_{50} of 90 µg/L, the "trigger" for exceeding EPA's endangered species Level of Concern (LOC) would be 4.5 µg/L. Using monitoring data and eliminating some of the highest detections because they were not relevant to salmonid habitats, the vast majority would fall below the LOC. Furthermore, mean diazinon concentrations were calculated to be 0.084 and 0.159 ppb for the NAWQA and California surface water monitoring data, respectively, which are also well below the LOC. Moreover, these monitoring data represent older diazinon usage patterns.

Comments on the Issue of Diminished Food Sources

Diazinon is highly toxic to certain kinds of aquatic invertebrates, particularly Cladocerans – including *Daphnia magna* and *Ceriodaphnia dubia*, two common bioassay species. However, as summarized in Table 50 in the draft Biological Opinion, the range of $LC_{50}s$ is substantial, namely, five orders of magnitude. This indicates that while some aquatic invertebrates could be severely impacted by exposure to diazinon, others would be relatively unaffected. This in turn means that salmonids in search of food would have alternative sources. In fact, this point was addressed in Giddings *et* al., 2000[10] (Slide 47-48).

As part of a probabilistic risk assessment in the Sacramento-San Joaquin River basins, the authors addressed the possible effects of diazinon on reducing invertebrate populations, which in turn could have adverse impacts on species of fish that feed on the invertebrates. Two of the nine fish species considered in the risk assessment were chinook salmon and steelhead trout. The authors concluded that "the risk of diazinon reducing food sources for chinook salmon and steelhead trout, however, is low because diazinon-tolerant invertebrates, such as aquatic and terrestrial insects, crustaceans, mysids and amphipods, are the major food organisms of these fish". The probabilistic risk assessment determined diazinon exposures based on water monitoring programs from 1991 – 1994 and evaluated diazinon effects using laboratory toxicity data for 63 species supplemented by results from field mesocosm and microcosm studies. Effects implications can now only be lessened because of the substantial diazinon reductions that have taken place since the monitoring data was generated in the early 1990s.

On page 263 of the draft Biological Opinion, it is mentioned that "reduced prey availability due to OP toxicity and subsequent reduced salmonid growth remains plausible, yet untested". The foregoing analyses show this speculation is incorrect. Furthermore, as noted by NMFS on page 278, trying to attribute reduced growth in salmonids to specific insecticide exposures that reduced prey is difficult because of other variables in the habitat such as water quality, riparian zone condition, etc.

Importance of Impaired Swimming from Diazinon

As shown in Figure 40 and in Table 50 of the draft Biological Opinion, the concentration of diazinon required to produce effects on swimming barely overlapped with exposure concentrations based on modeling and monitoring. Thus, the effect of diazinon on swimming behavior of salmonids should be considered minimal, if at all relevant (Slide 45).

Comments Related to Impaired Sense of Olfaction from Diazinon

Relevance from one of the two studies cited (Moore and Warring, 1996[11]) was discounted by EPA[1,6] because the test system could not be quantitatively related to exposures in the natural environment. The other study, Scholz *et al.*, 2000[12] showed potential effects of diazinon on chinook salmon behavior at nominal concentrations of 1 and 10 μg/L and suggested that effects of diazinon at environmentally relevant concentrations could disrupt olfactory-mediated behaviors in chinook salmon and would have negative consequences for the survival and reproductive success of these animals in the wild. However, even the authors agreed that their study was preliminary as to homing behavior, because the number of overall returning salmon was low (40% for controls) and there were no significant differences between control fish and fish treated at all diazinon-exposure concentrations in the approximate time it took for the salmon to return to the hatchery. Thus, these data are far too preliminary to conclude that diazinon at environmentally relevant concentrations have any effect on the homing ability of fully grown adult salmon.

Additionally, behaviors related to chinook skin extract "alarm" scents cannot be considered conclusive because the baseline activity of the fish prior to the olfaction stimulus was not statistically compared to the post-stimulus activity for all treatments. These results also seem to contradict Tucker and Leitzke's (1979) generalized "6X hypothesis," which says that sublethal effects typically do not occur at concentrations less than one-fourth to one-sixth the lethal concentration. This hypothesis is based on an extensive review of ecotoxicological data on pesticides (see Turner 2002[1] for further discussion).

Finally, EPA, in their diazinon ecological risk assessment related to the California red-legged frog[5] wrote on pages 89 – 90, "This study [Scholz et al., 2000] has been more thoroughly reviewed (Appendix A) and there is considerable uncertainty regarding the extent to which diminished olfactory response as it related to predator avoidance and homing behavior will affect the survival and reproduction of fish. In this study, chinook salmon survival was not impaired. In addition, EPA did not use these data in development of the aquatic life water quality criteria for diazinon because population level effects of specific chemicals on the olfactory system of aquatic organisms can only be hypothesized at this time and not substantiated (no articles were obtained that evaluated this issue satisfactorily)". NMFS does not appear to have properly considered these factors.

At the 2007 annual Society of Environmental Toxicology and Chemistry (SETAC) meeting last November, Palm and Powell presented two papers[13, 14] that studied alarm substance recognition and predator avoidance by chinook salmon following exposure to diazinon. These were controlled laboratory studies with appropriate controls that tested whether diazinon could affect olfaction, leading to changes in avoidance behaviors and a reduced ability to detect alarm scents increasing susceptibility to predation. These studies were not able to reproduce the results of Scholz et al. 2002[12].

The first study[13] focused on olfactory function and behavior of chinook salmon in two-choice ("Y") maze systems (Slides 53-59). Juvenile chinook salmon were exposed to various concentrations of diazinon (0, 1, 10 or 100 μg/L) for two hours, after which chinook skin extract or L-serine (serving as alarm substances) was added to the test system. The proportion of diazinon-treated chinook salmon choosing the "arm" of the Y maze containing the skin extract alarm scent (roughly 32 – 40%) was significantly less than those salmon choosing the arm of the test system containing no skin extract alarm scent (60 – 68%) at every diazinon treatment level. The proportion of chinook salmon choosing the arm of the maze not containing alarm scent in the solvent control group (roughly 68%) was similar to all diazinon treatment groups. In other words, none of the diazinon-treated groups differed statistically in their alarm-scent behavior from the non-diazinon treated solvent control group.

This data indicates that environmentally relevant levels of diazinon do <u>not</u> significantly impair olfaction in chinook salmon.

The objective of the second study[14] was to expose chinook salmon to diazinon at 1, 10 and 100 µg/L and determine if exposure affected their ability to avoid predation from rainbow trout, their natural predator (Slides 60-62). Results showed that the proportion of diazinon-exposed chinook salmon who survived predation by following a skin extract alarm scent warning was no different between any treatment group and also no different than the control group ($p>0.05$ in every case). Thus, results suggest that diazinon exposure at these concentrations do not affect olfaction as it influences predator avoidance.

Both of these presentations have been prepared as final manuscripts and are currently in review for publication in the peer-reviewed journal, Environmental Toxicology and Chemistry.

Comments for Risk Characterization

The NMFS approach relies on both screening model estimates of expected environmental concentrations and monitoring data from the USGS NAWQA program and the state of California's databases. As discussed above, the modeling used inputs that were incorrect because of label changes and inappropriate crop scenarios, including (but not limited to) meteorological characteristics. Furthermore, exposure modeling, based on GENEEC or PRZM/EXAMS, is more relevant to "farm-pond" models than to salmonids in streams and rivers, i.e., flowing water bodies. Water monitoring, on the other hand, emphasized simple ranges with emphasis on maximum concentrations rather than mean and median concentrations or on frequency distributions. Furthermore, investigations revealed that the highest detections of diazinon highlighted in the draft Biological Opinion were not even relevant to salmonid habitats. In addition, NMFS relied on older monitoring results that are no longer relevant because of very substantial diazinon usage reductions, application methods and best management practices. In fact, more recent monitoring in both California and in Washington State show diazinon water residues are clearly being detected less frequently and at lower concentrations for reasons already mentioned.

Risk involves both exposure and effects testing. Specific comments on effects testing are provided above. However, several additional comments merit note. First, the fish survival data focuses exclusively on the LC_{50} for rainbow trout (90 μg/L). The fact, however, is that fish survival testing results for diazinon are variable. That is, diazinon toxicity has been evaluated in numerous freshwater fish species including rainbow and brook trout, bluegill sunfish, fathead minnow, tilapia, zebrafish, goldfish and carp. Acute LC_{50} values for freshwater fish exposed to diazinon range from 90 to 7,800 μg/L[5]. In fact, variability was seen even within a single species such, as rainbow trout (*Oncorhynchus mykiss*), where testing with active ingredient of either 89 or 91% resulted in LC_{50} values of 90 or 400 μg/L[6]. Additional tests with the same fish species and with active ingredient at a lower percentage or tests with formulated product had LC_{50}s that ranged from 635 to 1800 (Slides 43-44).

Putting aside this observed variability, and even if 90 μg/L is considered the survival endpoint, the vast majority of relevant monitoring data (i.e., monitoring data from bona-fide salmonid habitats) are less than 5% of the fish LC_{50} (which in turn is less than EPA's Endangered Species Level of Concern). Furthermore, this data set predominantly includes older monitoring data that does not reflect the regulatory-driven use pattern changes seen for diazinon in recent years (Slide 51).

In addition to single-species effects testing, aquatic field studies are also a valuable contribution to assessing risk. Mesocosm studies with diazinon provide aggregate responses of multiple species in aquatic communities. Because sensitivity of fish and other organisms is variable to diazinon, an overall response of the aquatic community may differ from single-species laboratory testing. Moreover, mesocosm studies allow for population and community recovery from diazinon's effects. Mesocosm studies also take into account partitioning, degradation and dissipation of the pesticide that are purposely avoided in single-species laboratory testing. Thus, results of an outdoor mesocosm study conducted with diazinon with nominal concentrations of 5.7, 11.4, 22.9, 45.8 and 91.5 μg/L showed expected effects on many aquatic invertebrates at exposure concentrations > 11.4 μg/L. However, most taxa recovered after treatment. Furthermore, fish (and plants) were generally unaffected by diazinon treatments (Slide 44). EPA commented on page 92 of their diazinon ecological risk assessment related to the California red-legged frog[5] that "under the study conditions tested, mesocosms treated with multiple applications of diazinon did not reveal any statistically significant direct or indirect effects on fish even though there were significant fluctuations in aquatic macroinvertebrates due to diazinon."

In conclusion, rather than using either a simple risk-quotient approach (as does EPA in their initial screen) or a more qualitative approach of overlapping exposure concentrations with toxicity endpoints (as does NMFS), it would have been more meaningful to compare distributions of recently monitored diazinon water concentrations found in bona-fide salmonid habitats with differing sensitivities of salmonid species as well as sensitivities of their potential prey to diazinon in order to generate a probabilistic interpretation of risk to salmonid populations. Sufficient data exists to allow such analysis (Slides 49-50).

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1. Larry Turner, Ph. D., "Diazinon: Analysis of Risks to Endangered and Threatened Salmon and Steelhead", Environmental Field Branch, Office of Pesticide Programs, November 29, 2002.

2. "Development and Analysis of a Diazinon Transport Model Using SWAT for the Feather River Watershed", Stone Environmental, Inc., SEI Project 02-1366F, June 20, 2003.

3. http://water.usgs.gov/nawqa

4. Chris Burke, Paul Anderson, Dan Dugger and Jim Cowles, "Surface Water Monitoring Program for Pesticides in Salmonid-Bearing Streams, 2003 – 2005", A Cooperative Study by the Washington State Departments of Ecology and Agriculture, September 2006.

5. Paul Anderson, Dan Dugger and Chris Burke, "Surface Water Monitoring Program for Pesticides in Salmonid-Bearing Streams, 2006 Monitoring Data Summary", March 2007.

6. Kristina Garber, Shomas Steeger and Elizabeth Behl, "Risks of Diazinon Use to the Federally Listed California Red Legged Frog (*Rana aurora draytonii),* Pesticide Effects Determination", Environmental Fate and Effects Division, Office of Pesticide Programs, Washington, D. C., 20460.

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10. Jeff Giddings, Lenwood Hall, Jr. and Keith Solomon, "Ecological Risks of Diazinon from Agricultural Use in the Sacramento-San Joaquin River Basins, California", Risk Analysis, 20(5), 2000, pp. 545 – 572.

11. A. Moore and C. P. Waring, "Sublethal Effects of the Pesticide Diazinon on Olfactory Function in Mature Male Atlantic Salmon Parr", J. Fish Biol. 48: 758 – 775.

12. Nathaniel L. Scholz, Nathan K. Truelove, Barbara L. French, barry A. Berejikian, Thomas P. Quinn, Edmundo Casillas and Tracy K. Collier, "Diazinon Distrupts Antipredator and Homing Behaviors in Chinook Salmon *(Oncorhynchus tshawytscha)*", Can. J. fish. Aquat, Sci, 57: 1911 – 1918, 2000.

13. David Powell and Roger Palm, Jr., "Effects of Environmentally Relevant Levels of Diazinon on the Olfactory Function and Behavior of Chinook Salmon in Two-Choice Maze Systems", presented at the 2007 SETAC annual meeting, November 2007.

14. Roger Palm, Jr. and David Powell, "Predator Avoidance by Juvenile Chinook Salmon (*Oncorhynchus tshawytscha*) Following Exposure to Sublethal Levels of Diazinon", presented at the 2007 SETAC annual meeting, November 2007.

Diazinon Registrant Comments

- Label changes and use information
- Monitoring data
- Risk characterization
- Modeling Inputs
- Aquatic toxicity endpoints
- Olfactory impairment

MANA

Makhteshim Agan of North America, Inc.

August 29, 2008

Presenters

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Diazinon Use Information

Since 2000, Diazinon use nationwide has dropped by more than 90%.

Background

- Pre – 2000: Diazinon use nationwide totaled roughly 13 million pounds annually.
- 70% of all use was for household lawn and garden pest control.
- 5% of all use was for crack & crevice and for flea collars.
- 25% of all use was for agricultural applications.

Background: Elimination of Residential Uses

- December 2000: EPA and the registrants signed a Memorandum of Agreement (MOA) to phase out and cancel all residential uses according to the following schedule.
  - All *indoor* residential uses were cancelled in March of 2001. Retail sales of existing stocks of these products ended on December 31, 2002.
  - All *outdoor* residential uses were cancelled with distribution to retailers ending in September of 2003. Retail sales of existing stocks of these products ended on December 31, 2004.
- After 12/31/04, a buy-back program prevented further sales of existing stocks.

Background: Limitation of Food Crop Uses

- The MOA also began the process to cancel 20 different uses on food crops.
- In July of 2002, EPA issued an Interim Reregistration Eligibility Decision which proposed significant changes to the remaining labeled crops, including use deletions and additional restrictions.
- EPA completed the Diazinon RED in July of 2006.

Resulting Changes in Diazinon Use

- In 2000, EPA estimated that 25% of the 13 million pounds of diazinon applied annually – 3.25 million pounds –was for agricultural applications.
- The IRED changes have brought total use today to less than 750,000 pounds annually.

IRED Food Crop Label Mitigation

- **Cancellation of all granular registrations**. The only exception are two current Section 24(c) registrations held by Washington and Oregon for control of the cranberry girdler. Granular use on lettuce will only be allowed in California until 2008.

- **Deletion of aerial application for all uses**. (Except for lettuce in California)

- **Deletion of foliar application on all vegetable crops**. The only exception will be for treatment of leafhopper on honeydew melons and in California and gensing.

IRED Label Mitigation

- **Reduction in the number of applications of diazinon per growing season.** On most uses only one application per growing season will be allowed. Crops with dormant season and in season uses (e.g., stone fruits) will have one application per season for a total of two applications per year.

- **Application rate reduction.** The maximum rate for ornamentals (except cut flowers) will be reduced from 2 lb ai/acre to 1 lb ai/acre. The maximum granular rate for lettuce will be reduced from 4 lb ai /acre to 1 lb ai/acre.

- **Cancellation of all seed treatment uses**. Five uses will be cancelled: beans (snap), beans (lima), corn (field), corn (sweet), and green peas.

IRED Label Mitigation

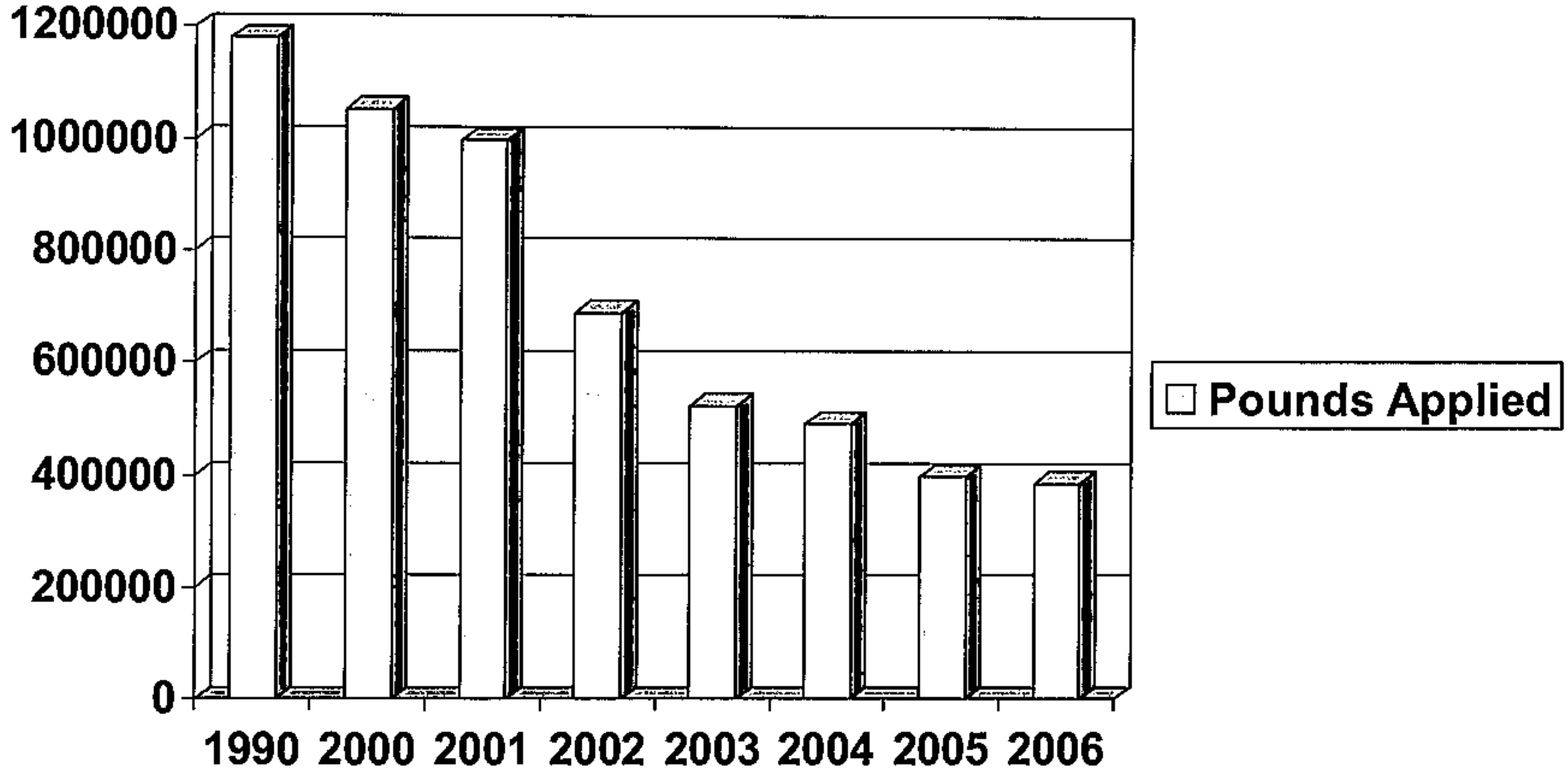
- **Application limitations and labeling on orchard crops.** For all orchard crops (nuts, stone fruits, pome fruits, etc) with dormant season uses, for most crops label language only allows applications every other year unless pest pressures are such that consecutive, annual treatments are necessary.

- **Cancelled uses.** Section 3 uses: Chinese broccoli, Chinese cabbage, Chinese mustard, Chinese radish, corn, grapes, hops, mushrooms, sugar beets and walnuts.

Substantial Data Documents Diazinon Use in California

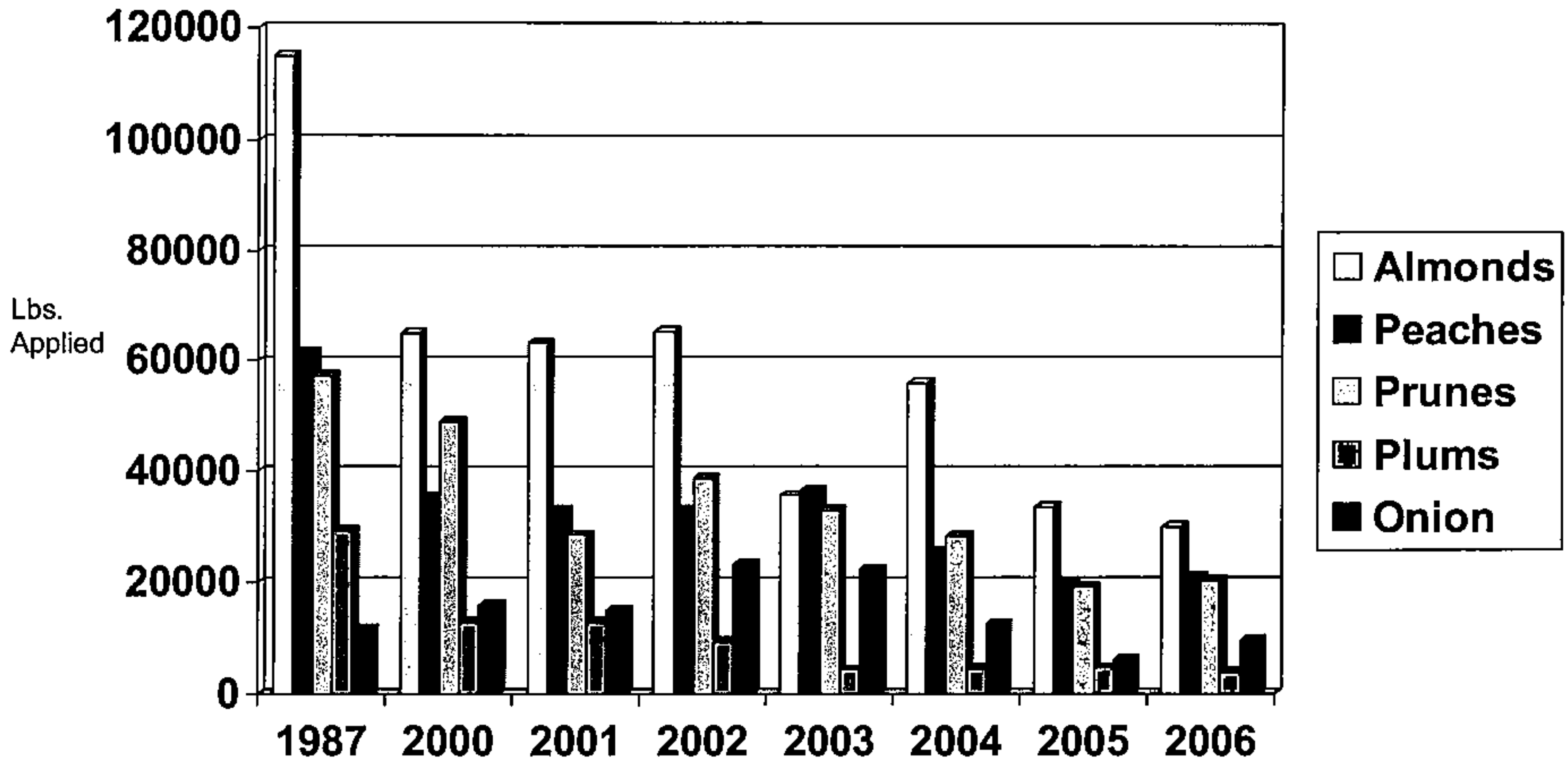
- Represents 70% of total use.
- California has had mandatory pesticide recordkeeping and reporting since 1990.
- Data is available at http://calpip.cdpr.ca.gov/cfdocs/calpip/prod/main.cfm

Diazinon Use in California



Source: California Pesticide Use Reports

Changes on Key CA Crops



Source: CA Pesticide Use Reports

Coalition for Urban/Rural Environmental Stewardship (CURES)

- Industry-supported stewardship program
- Developed Diazinon-specific best management practices for dormant season applications in California.
- BMPs included:
  - Development and maintenance of a 10-foot buffer strip for orchards that are adjacent to and within 100 feet of a sensitive aquatic site.
  - Restrictions on applications made 100 feet upslope of a sensitive aquatic site.
  - Use of ground application equipment only
  - Sprays must be directed away from sensitive aquatic sites.
  - No applications when soil moisture is at field capacity
- These practices now required by state water quality regulators (CVRWQCB) and CDPR dormant spray regulations

County Bulletin Restrictions in CA

The following restrictions in place in all but two counties in California:

1. Do not use in currently occupied habitat (some exceptions for specific species).
2. Provide a 20 foot minimum strip of vegetation (on which pesticides should not be applied) along rivers, creeks, streams, wetlands, vernal pools and stock ponds or on the downhill side of fields where run-off could occur. Prepare land around fields to contain run-off by proper leveling, etc. Contain as much water "on-site" as possible. The planting of legumes, or other cover crops for several rows adjacent to off-target water sites is recommended. Mix pesticides in areas not prone to runoff such as concrete mixing/loading pads, disked soil in flat terrain or graveled mix pads, or use a suitable method to contain spills and/or rinsate. Properly empty and triple-rinse pesticide containers at time of use.

County Bulletin Restrictions in CA

3. Conduct irrigations efficiently to prevent excessive loss of irrigation waters through run-off. Schedule irrigations and pesticide applications to maximize the interval of time between the pesticide application and the first subsequent irrigation. Allow at least 24 hours between application of pesticides listed in this bulletin and any irrigation that results in surface run-off into natural waters. Time applications to allow sprays to dry prior to rain or sprinkler irrigations. Do not make aerial applications while irrigation water is on the field unless surface run-off is contained for 72 hours following the application.
4. For sprayable or dust formulations: when the air is calm or moving away from habitat, commence applications on the side nearest the habitat and proceed away from the habitat. When air currents are moving toward habitat, do not make applications within 200 yards by air or 40 yards by ground upwind from occupied habitat. The county agricultural commissioner may reduce or waive buffer zones following a site inspection, if there is an adequate hedgerow, windbreak, riparian corridor or other physical barrier that substantially reduces the probability of drift.

Summary

- Since 2000, Diazinon use has plummeted from 13 million pounds annually to less than 750,000 pounds today.
- IRED/RED label mitigation has already addressed ESA issues through the cancellation of crops, changes in label rates and number of applications, deletion of aerial uses and other measures.
- Buffers are already in place.

The Monitoring Data in the Draft BiOp Does Not Represent Current and Future Conditions

Overview

- NMFS discussion of monitoring data relies on outdated data (1990s, early 2000s); not reflective of current uses
- No discussion of substantial reductions in diazinon detects as RED changes were implemented
- No quantitative use of of monitoring data
  - No frequency distributions (e.g., 80^{th}, 90^{th}, 95^{th} percentiles)
  - No discussion of percentage of detects above benchmark concentrations (e.g., 0.01 ug/L, 0.1 ug/L, 1.0 ug/L)
  - No clear indication of whether max values relied on are from representative salmon waters *(Some max values appear to be either concentrations in runoff rather than streams or drainage ditches - not salmon habitat)*
  - No temporal component of occurences
- Instead, a qualitative discussion of ranges and max values

Updated Water Monitoring Data

- Updated through 2006
- Number and percent diazinon detects
  - 2001: 133; 43.61%
  - 2002: 684; 40.76%
  - 2003: 607; 34.63%
  - 2004: 294; 23.05%
  - 2005: 86; 13.83%
  - 2006: 42; 7.64%

***NAWQA Cycle 2 Data**

Updated Water Monitoring Data NAWQA Cycle II Data (http://water.usgs.gov/nawqa)

- Distribution of diazinon detects **2001-2004** (as percent of samples for land use category)
  - **Agricultural**
    - All: **14.14%;** >0.01 ug/L: 4.94%; >0.10 ug/L: 0.38%; >1.0 ug/L: 0.00%;
    - Range 0.0007 – 0.53
  - Urban
    - All: **71.85%;** >0.01 ug/L: 49.11%; >0.10 ug/L: 6.67%; >1.0 ug/L: 0.00%
    - Range 0.0013 – 0.78
  - Other
    - All: **26.76%;** >0.01 ug/L: 13.96%; >0.10 ug/L: 0.1.99%; >1.0 ug/L: 0.00%
    - Range 0.0017 – 0.36
  - Mixed
    - All: **34.38%;** >0.01 ug/L: 14.37%; >0.10 ug/L: 0.32%; >1.0 ug/L: 0.00%
    - Range 0.0010 – 0.33

Updated Water Monitoring Data NAWQA Cycle II Data (http://water.usgs.gov/nawqa)

- Distribution of detects **2004-2006** (as percent of samples for land use category)
  - **Agricultural**
    - All: **2.5%;** >0.01 ug/L: 2.0%; >0.10 ug/L: 0.60%; >1.0 ug/L: 0.00%;
    - Range 0.0048 – 0.50
  - Urban
    - All: **25.4%;** >0.01 ug/L: 2.6%; >0.10 ug/L: 0.00%; >1.0 ug/L: 0.00%
    - Range 0.0038 – 0.11
  - Other
    - All: **10.5%;** >0.01 ug/L: 1.8%; >0.10 ug/L: 0.15%; >1.0 ug/L: 0.00%
    - Range 0.004 – 0.50
  - Mixed
    - All: **7.6%;** >0.01 ug/L: 1.5%; >0.10 ug/L: 0.30%; >1.0 ug/L: 0.00%
    - Range 0.0036 – 0.029

*NAWQA Cycle 2 Data

- (

Better Monitoring Data is Readily Available (Per Draft BiOp, page 226, line 1 and 2)

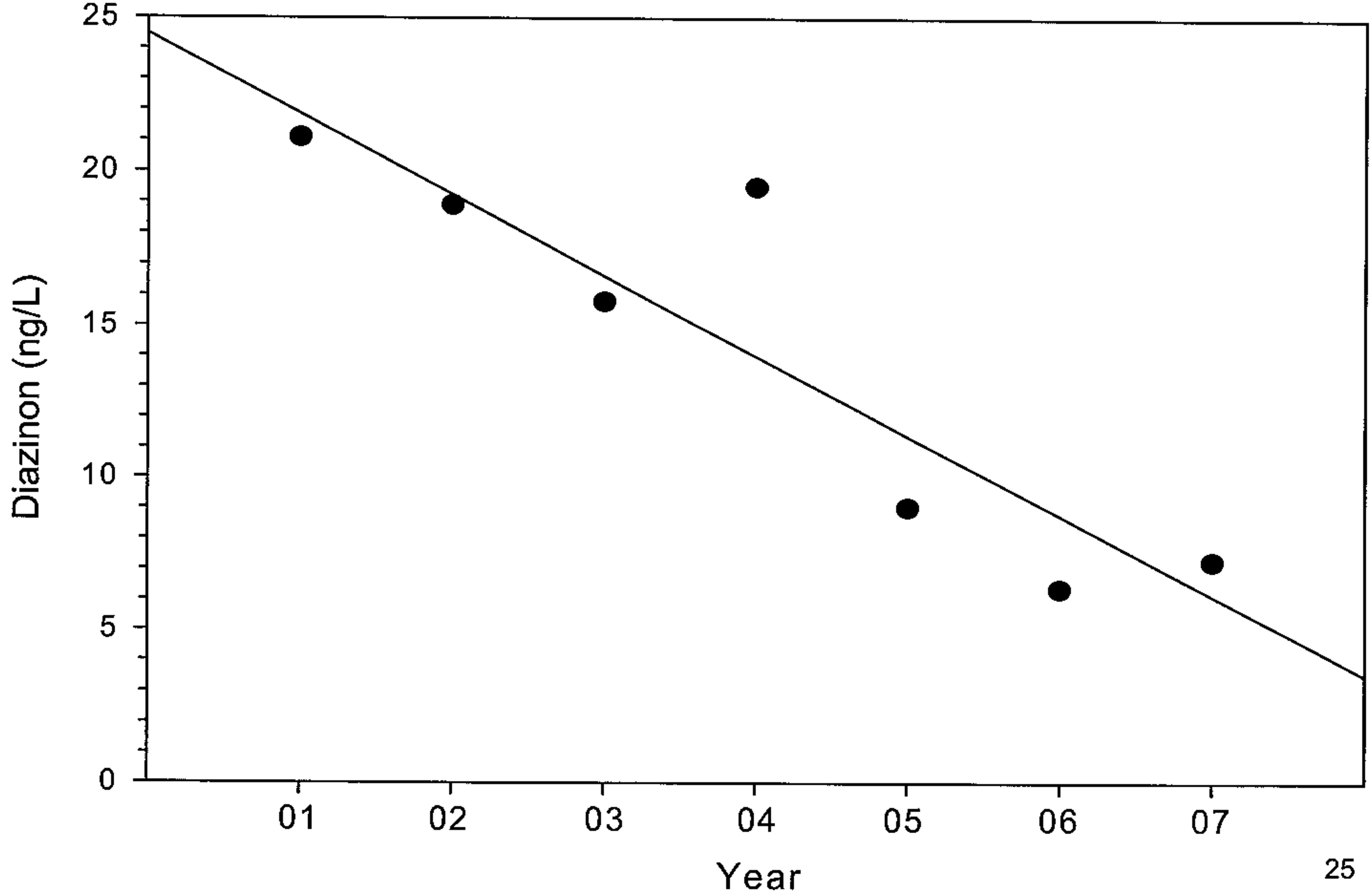
- The report correctly states that diazinon monitoring data may not be representative of current and future uses and conditions

- Older diazinon monitoring data report higher concentrations than more current data and should not be used to assess ecological risk to salmonids (see Hall 2003a, Hall 2003b, Hall and Anderson, 2008)

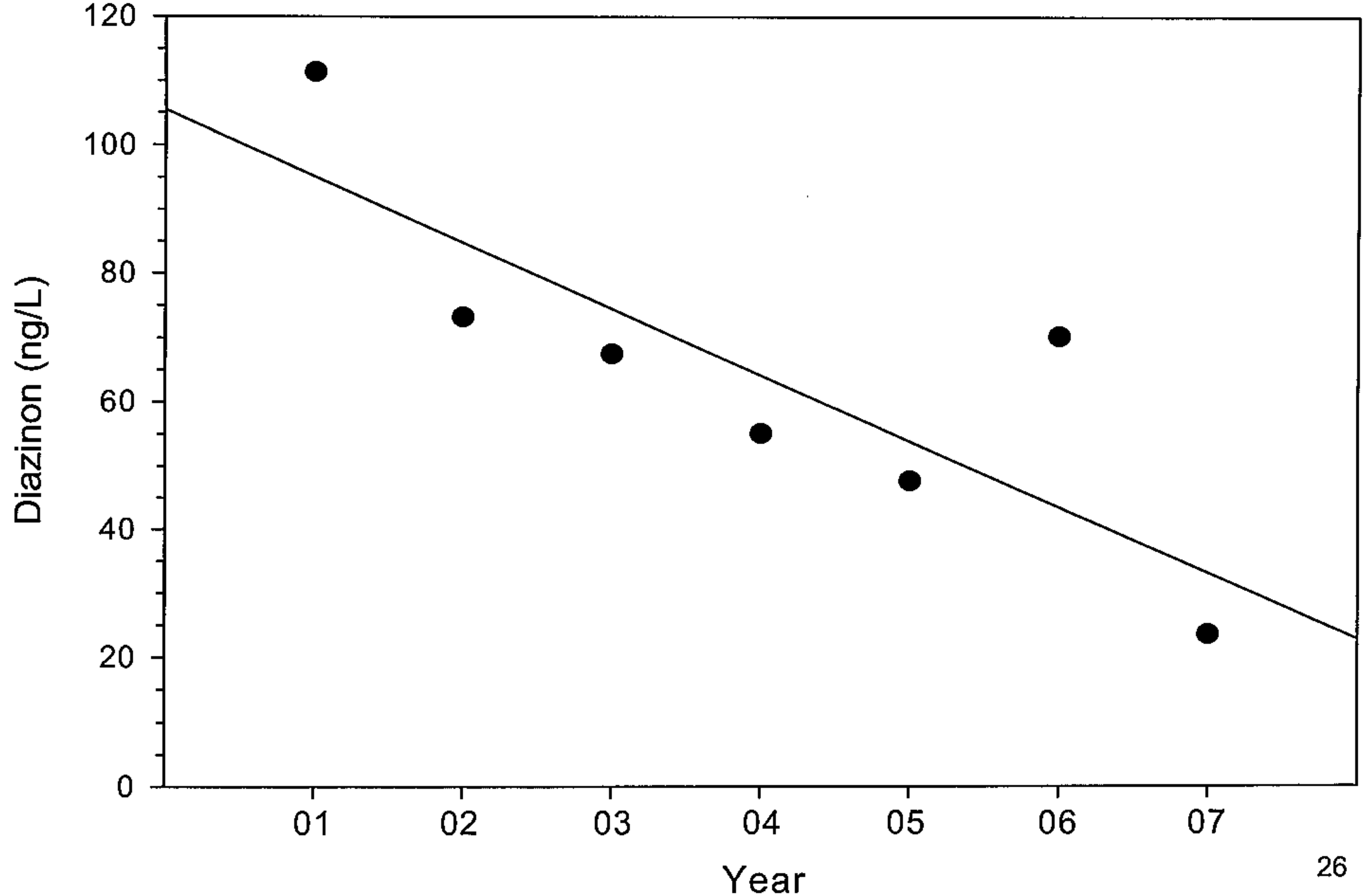
More on Currently-Available Monitoring Data (Draft BiOp, page 225, Table 40)

- Trends analysis of current San Joaquin watershed data (01-07) is in progress; initial review of data shows a large % of non-detects
- Hall et al. 2003b have reported declining concentrations of diazinon in the Sacramento River watershed from 1991 to 2001
- Updated trends analysis for the Sacramento River watershed (2001 to 2007) has also shown further significant declines in both diazinon concentrations and target exceedances (Hall and Anderson, 2008)

Diazinon Mean Concentrations by Year for all Sacramento and Feather River Mainstem Sites (r^2 = .813; P=.006)



Diazinon Mean Concentrations by Year for all Sacramento and Feather River Tributary Sites (r^2 = .665; P=.025)



Washington State SW Monitoring (2003 – 2005)
Burke et al., 2006

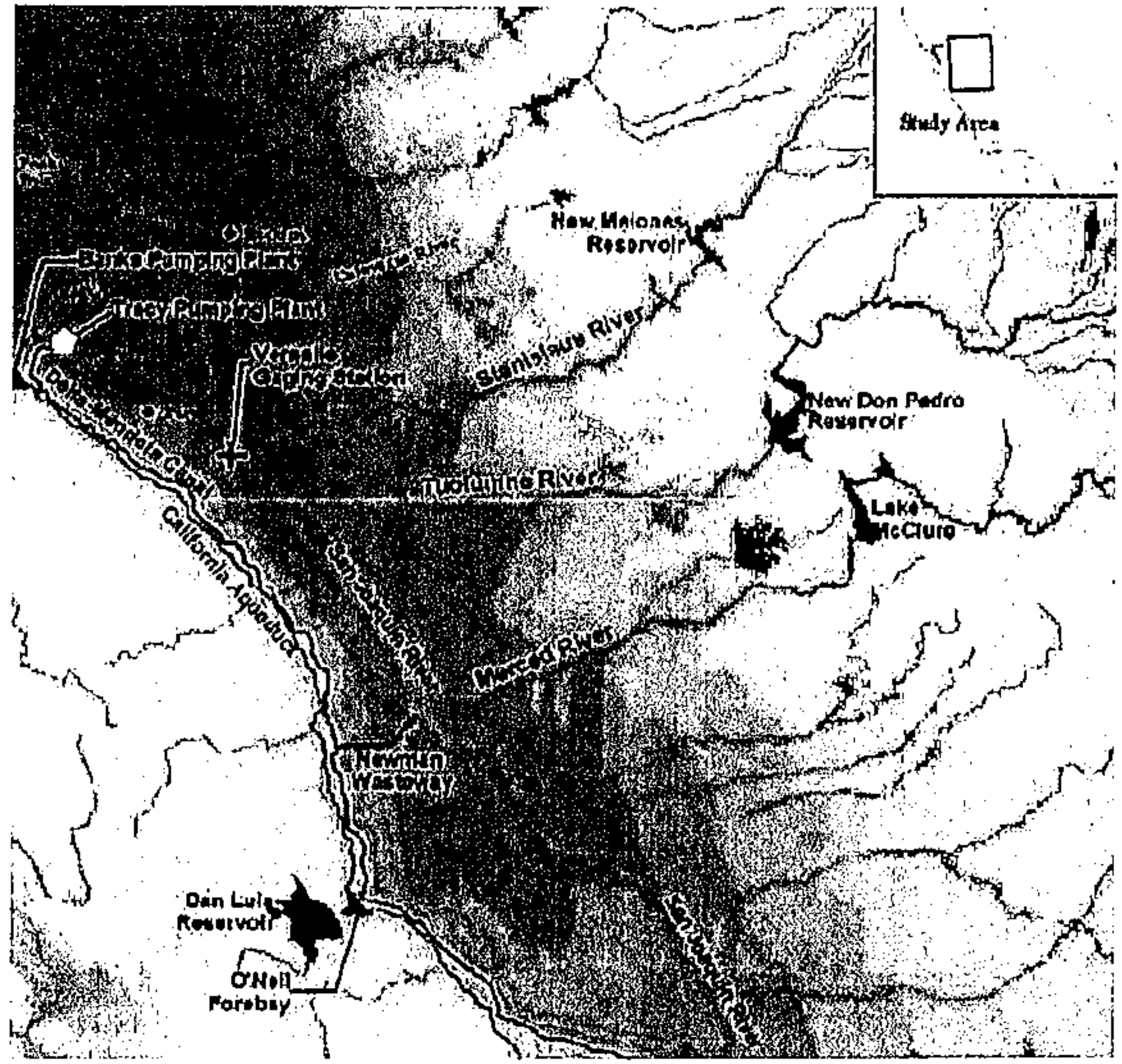
- Monitoring in salmonid-bearing streams during pesticide use season
- 1 urban and 3 agricultural watersheds within critical habitats
- Only 1 diazinon detection (0.21 ppb*) out of 78 samplings in urban watershed exceeded chronic invertebrate water quality criterion; RQs for rainbow trout never exceeded
- In urban watershed, detection frequency declined from 39% (2003) to 3% (2005) due to cancelling homeowner uses in 2004
- In agricultural watersheds, max concentration 0.023 ppb out of 125 samplings; no water quality exceedances
- *Apparent 0.21 ppb detection attributable to diuron, not diazinon in reporting table. Diazinon max concentration 0.095 ppb.

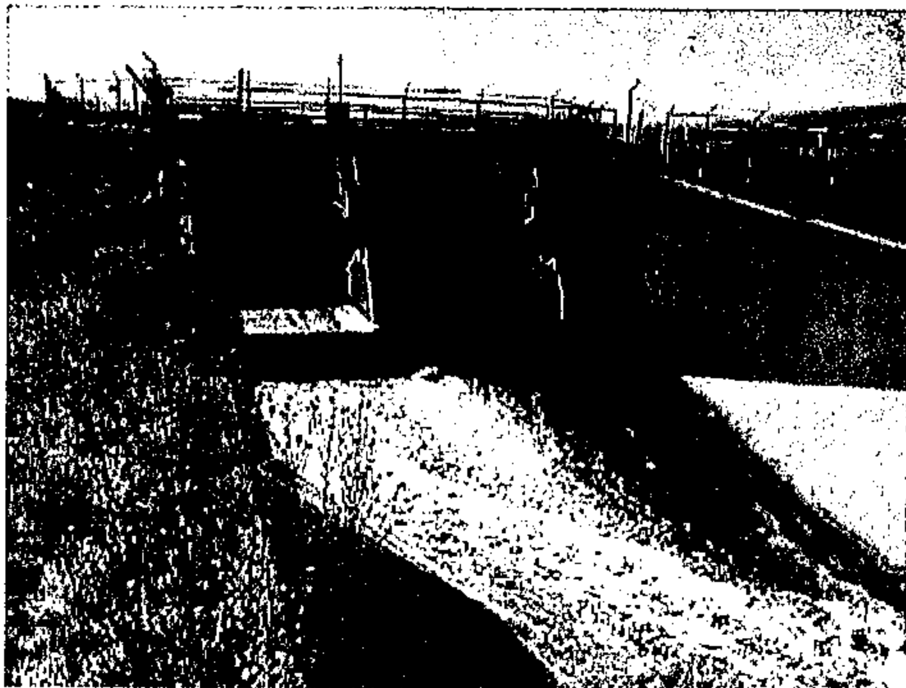
Monitoring Values not relevant to Salmonid Risk Assessment: Newman Wasteway

Maximum diazinon value of 36.8 ug/L for Rivers is incorrect.

This value was reported for Newman Wasteway (drain/tributary) of the San Joaquin River Watershed

Newman wasteway is not a habitat for salmonids





Newman Wasteway

1.5 Miles are concrete lined

7.5 miles are natural

Subject of 2004 Bureau of Reclamation

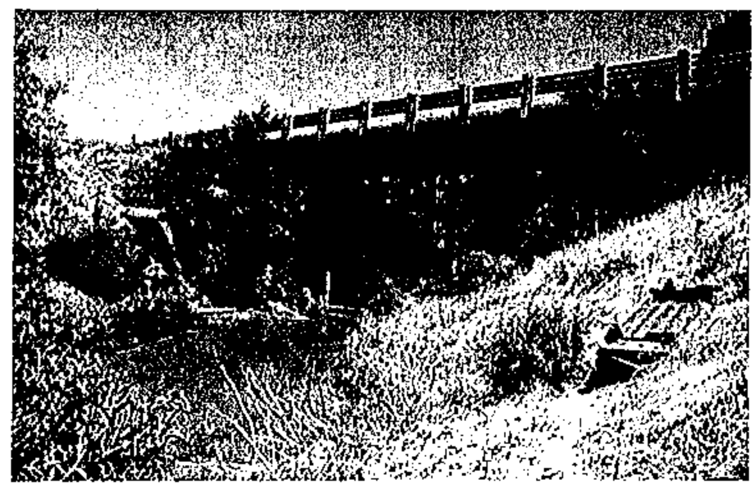
Recirculation Pilot Study

to purge accumulating sediment

Orestimba Creek

Maximum value of 29.371 ug/L was reported from Orestimba Creek during 1996/1997

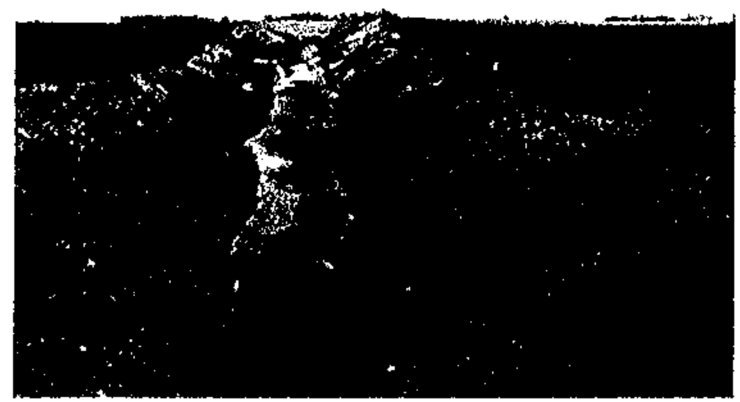
- Older diazinon monitoring data are not valid based on current use patterns



Salinas Valley

The use of maximum diazinon concentrations of 67 ug/L for the Salinas Valley is inappropriate.

- The Salinas Valley value was reported from an ag ditch that is:
  - not a habitat for salmonids,
  - Based on a value from early '90s that does not represent current use patterns,
  - the analytical method for analysis (ELISA) is questionable.



Rationale for Employing Modeling Is Flawed (Draft Bi-Op, page 225, Point #1)

- The statement that diazinon monitoring data were not designed to capture peak values is partly incorrect
  - CA monitoring data from 1991 to 2007 included measurements from some stream sites located beside ag fields where diazinon was applied during the wet season
  - Therefore, for at least some sites maximum values were reported

Rationale for Employing Modeling Is Flawed (Draft Bi-Op, page 226, Para. 3, lines 5-7)

- The statement that sampling for these studies was not conducted in coordination with specific applications of diazinon is incorrect.

- As stated above, diazinon concentrations at some stream sites were measured after application and the first major storm event

Concern With Sediment Concentration Requires Reconsideration (Draft Bi-Op, page 228, Table 44

- Sediment diazinon concentrations (3,916,689 ng/kg dw) are suspect and need to be carefully checked.
- Well documented physical and chemical properties of diazinon reported in various documents (including page 203 of draft BiOP) state that this insecticide is not expected to strongly adsorb to sediment.

References

- Hall, L.W. Jr. 2003a. Historical analysis of diazinon from the San Joaquin River watershed with implications for exceeding water quality targets. CA Fish and Game 89:1-19.
- Hall, L. W. Jr. 2003b. Analysis of diazinon monitoring data from the Sacramento and Feather River watersheds:1991-2001. Environ. Mont. Assess. 86: 233-253.
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Concerns Regarding Risk Characterization

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Overview of Risk Characterization

- NMFS approach relies on screening model estimates of environmental concentrations
- Monitoring data from USGS NAWQA and State of California are reported, but emphasis placed on maximum concentrations rather than mean and median concentrations. In fact, highest detects found in regions not relevant to salmonid habitats
- Further assessment involves endpoints such as invertebrate food sources, prey survival, growth, reproduction, swimming and olfactory-mediated behaviors.
  - Impact on populations has not been established.

Exposure Issues

Exposures based on modeling and monitoring.

- **Modeling Issues**
  - For diazinon, 7 crops modeled but only one (almonds) used western-states scenario. Unrealistic for Pacific salmonids and steelhead because, except for almonds, crop scenarios have more runoff than will occur in Pacific states. In addition, aerial applications have been eliminated for all crops and application rates, and repeat applications have been reduced. These steps will lead to substantially reduced deposition of diazinon in adjacent water bodies.
  - Exposure models based on a farm pond. Very unrealistic for streams and rivers relevant to habitat of salmonids. *(Turner 2002)*

PRZM-EXAMS and GENEEC Modeling

- Conceptual model:
  - 10 ha treated field surrounds and directly abuts a 1ha surface area, 2-m deep stagnant pond (USDA farm pond)
  - EPA-EFED Default: No buffer between pond, field; models cannot account for run off reductions due to buffers
  - Pond assumed to be directly downwind of treated field (maximize drift)
  - No inflow or outflow of water
  - Pesticide assumed to be instantaneously and homogeneously distributed throughout pond
  - Maximize runoff slopes (runoff loading)

Conceptual model does not simulate off-site transport to salmon habitat

The Appropriate Application of PRZM-EXAMS and GENEEC Screening Models

- What the output tells you: If EECs are below effect concentrations, high confidence of a low potential for adverse effects;
- But: If EECs exceed effect concentrations, this does not mean a high potential for adverse effects under actual use conditions – it means that the assessment needs to be refined

Flaws in NMFS Modeling Inputs

- All modeling based on obsolete labels (pre-EPA RED)
- Does not account for significant reductions in use, use phase-outs negotiated during RED process
- Only 1 of 7 modeling scenarios applicable to Pacific salmon (CA almonds); remainder of scenarios are east coast or midwest scenarios that are irrelevant to Pacific salmon
  - East coast, midwest scenarios feature heavier rainfall than west coast scenarios
  - Aquatic loading for east coast, midwest scenarios driven by run off loading
  - Drift loading significant for west coast scenarios

Weakness of Effects Data for Fish -- Generally

- Survival data: No species sensitivity distributions, even for salmonid species despite multiple tests
- Selected endpoints include several sublethal endpoints based on literature data
  - Literature data of questionable quality
  - Have not been able to reproduce some effects reported in the literature (e.g., olfactory results)
- LC50 testing conducted with fish ranging from approximately 0.5 g to 5.0 g (EPA FIFRA guideline)
  - Sensitive life stage
  - Tested life stage not related to size, life stages of salmon

Weakness of Effects Data for Fish – Diazinon Specific

- Growth data:
  - Rely only on 1977 Allison and Hermanutz trout partial life cycle (274 day continuous exposure) study
    - Most sensitive endpoint: Hatching of F1 fish from exposed F0 parents; Growth of F1 from exposed F0 parents
  - Ignored more relevant, recent chronic studies
    - Minnow full lifecycle (NOEC: 3 ug/L)
    - Minnow ELS
      - NOEC: 90 ug/L
      - Most sensitive endpoint: larval growth
      - NOEC for egg hatching and larval survival: 1.6 mg/L (Highest Conc. Tested.)
    - Minnow partial lifecycle (reported NOEC 3.5 ug/L; EFED NOEC 0.92 ug/L)

Weakness of Effects Data for Fish – Diazinon Specific

- Mesocosm data ignored
  - Highly sensitive species tested (bluegill sunfish)
  - No effects on spawning, survival, growth at concentrations up to 34 ug/L (HCT)
  - More representative of potential effects under field conditions than laboratory continuous exposure tests
- No discussions of recovery from transient sublethal effects (e.g., swimming, olfaction)
- Considerable speculative discussions concerning effects of pesticide mixtures (chlorpyrifos, diazinon, malathion) on fish

Diazinon and Sublethal Effects on Salmonids

- Swimming
  - Concentration of diazinon needed to produce effects on swimming barely overlapped with exposure concentrations based on modeling and monitoring. Thus, the effect of diazinon on swimming behavior of salmonids should be considered minimal, if at all relevant. Effects seen only at 500 ppb.
- Olfaction
  - Moore and Waring, 1996 has been dismissed by EPA because test system could not be quantitatively related to exposures in the natural environment.

Diazinon and Adverse Effects on Salmonids

- Olfaction - continued
  - Scholz *et al*., 2000 showed potential effects of diazinon on Chinook salmon behavior on a nominal diazinon concentration of 1 ppb.
  - The authors indicated that the results were preliminary with regard to homing behavior
  - Results not reproducible:
    - Palm & Powell, Presentation to Society of Environmental Toxicology & Chemistry. November 2007"
  - Since the presumption that diazinon causes salmonids to have impaired olfaction at very low concentrations is based essentially on a single study, the "effect" is not sufficiently demonstrated to support reliable risk assessment.

Diazinon and Indirect Adverse Effects on Salmonids

- Aquatic Invertebrate Food Sources
  - Diazinon is highly toxic to aquatic invertebrates.
  - Wide range of sensitivities among various invertebrate species
    - LC_{50}s is five orders of magnitude (Table 50).
  - This suggests that while some aquatic invertebrates could be severely impacted by exposure to diazinon, others would be relatively unaffected and would serve as alternative food sources.

Diazinon and Indirect Adverse Effects on Salmonids

- Aquatic Invertebrate Food Sources (cont.)

- Invertebrate populations undergo natural changes in numbers, composition throughout a season
- Fish are opportunistic feeders, will change prey and forage on a wide variety of invertebrate species
- The draft BiOp assumes a domino effect, but offers no data to support hypothesis
- No matching of monitoring data for salmon streams to invertebrate effect concentrations

Corroborated by Giddings et al., 2000 " Ecological Risks of Diazinon from Agricultural Use in the Sacramento-San Joaquin River Basins, California" Risk Analysis, 20(5),2000,pp. 545-572

Summary

- It would have been more meaningful to compare distributions of recently monitored diazinon water concentrations found in bona-fide salmonid habitats with differing sensitivities of salmonid species as well as sensitivities of their potential prey to diazinon in order to generate a probabilistic interpretation of risk to salmonid populations.

Summary

- Because of the significant limitations with exposure modeling, and the wealth of monitoring data from salmonid-relevant habitat, it is obvious that monitoring data for diazinon should be the main component of the risk characterization.

Appropriate Monitoring Values for Risk Assessment

- Eliminate high concentration that are not from salmon habitat
  - 36.8 ppb: Newman Wasteway
  - 67 ppb: Salinas Valley agricultural drain
  - 29.4 ppb: Orestimba Creek- ephemeral stream created from ag field irrigation return water
- Use current monitoring data
  - Highest *relevant* detect from NAWQA II
  - Water Monitoring is **0.5 ppb**,
  - Use mean concentrations; **0.084 ppb** (NAWQA) and **0.159 ppb** (Cal.)
  - Apply appropriate end-points i.e. Survival Rainbow Trout LC_{50} = **90 ppb**
  - Apply EPA Endangered Species LOC = **4.5 ppb**
- Relevant detections are well below Level of Concern

Assessment of Olfactory Effects in Salmon

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ALARM SUBSTANCE RECOGNITION AND PREDATOR AVOIDANCE BY CHINOOK SALMON (*ONCORHYNCHUS TSCHAWYTSCHA*) FOLLOWING EXPOSURE TO AN ORGANOPHOSPHATE PESTICIDE

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- Two controlled laboratory studies were presented at the annual meeting of the Society of Environmental Toxicology & Chemistry in November of 2007 *(currently in review for publication in Environmental Toxicology and Chemistry)*
- Attempt to reproduce results of Scholz et al. 2002 relating to olfactory mediated behaviors of Chinook Salmon exposed to Diazinon

Research Rationale

- Study reports show diazinon to affect physiology and behavior associated with olfaction.

- A loss of olfaction can be detected by changes in avoidance behaviors.

- A reduced ability to detect alarm scents could increase their susceptibility to predation.

Study 1: Effects of Diazinon on the Olfactory Function and Behavior of Chinook Salmon in Two-Choice Maze Systems

Study 2: Predator Avoidance by Juvenile Chinook Salmon Following Exposure to Diazinon and Alarm Scents

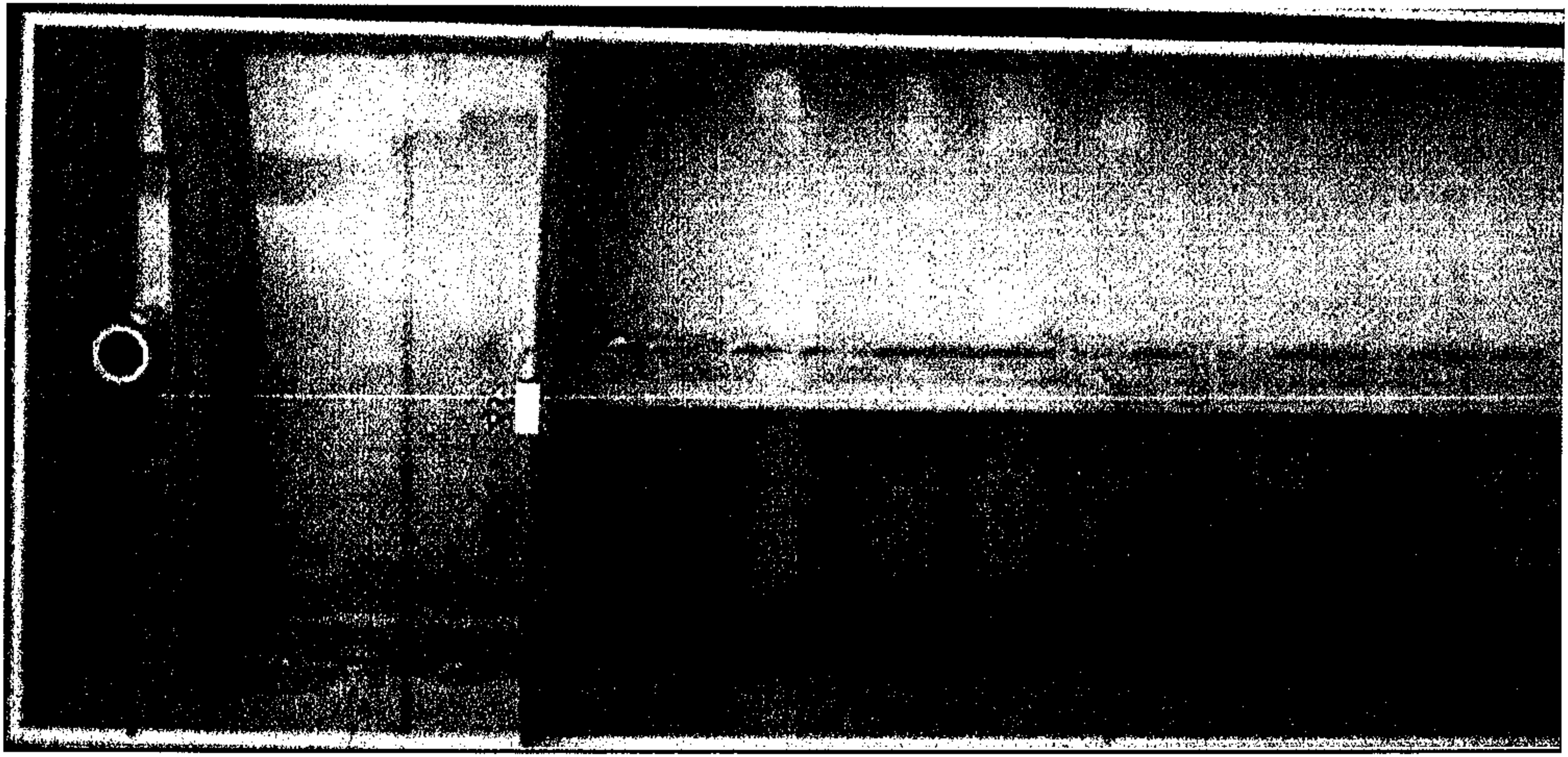
David B. Powell, Ph.D.

Roger C. Palm, Ph.D.

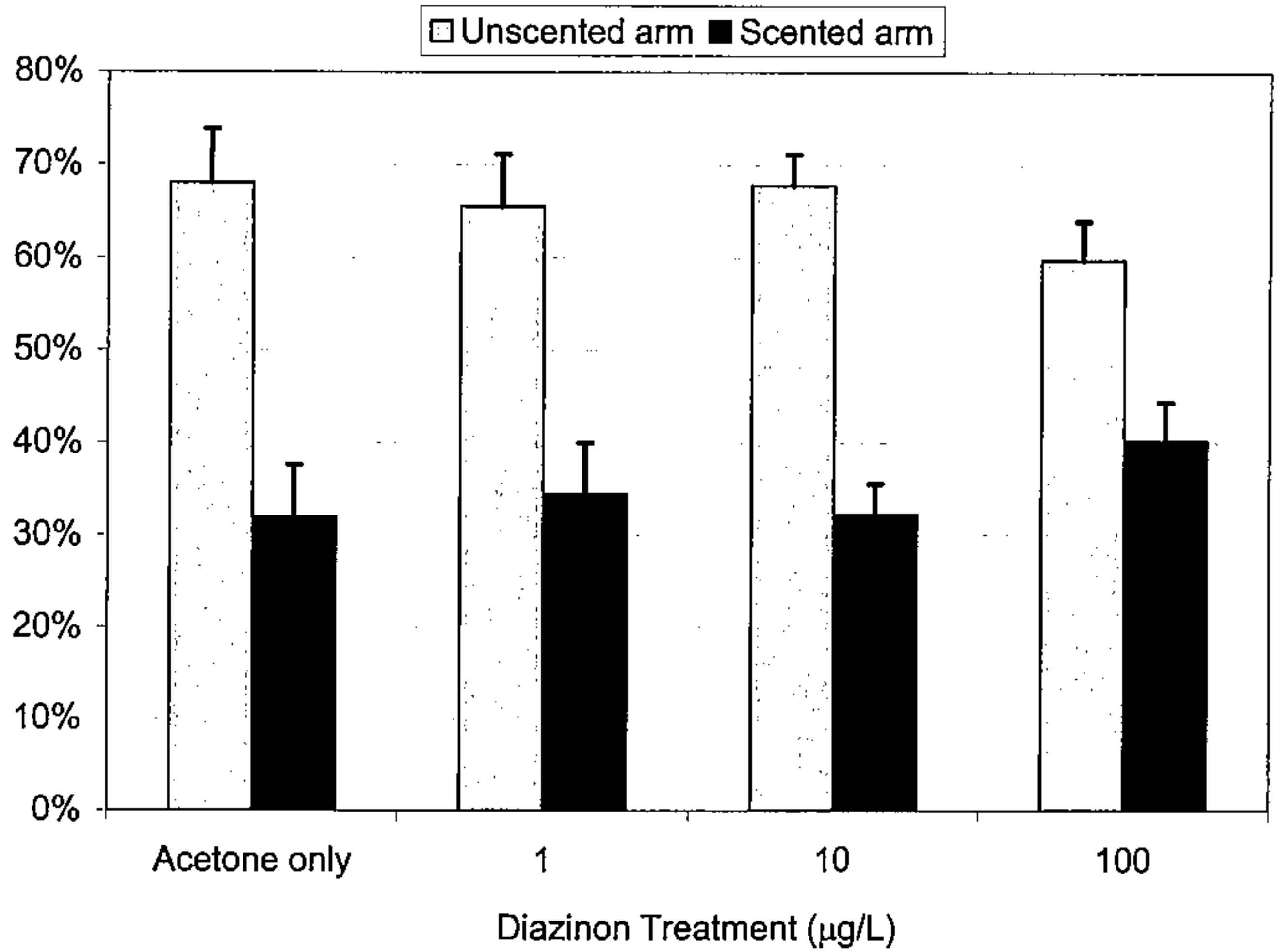
Study 1: Design

- Chinook salmon juveniles
- 2 hour Diazinon exposure (0, 1, 10 or 100 μg/L)
- 10 salmon per Y-maze test
- 20 runs per treatment dose
- Chinook skin extract (alarm substance)

Study 1: Food grade dye demonstrates path of "alarm" scents



Proportion of Diazinon-treated Chinook Salmon Choosing Water Containing Skin Extract Alarm Scent



Study 1: Conclusions

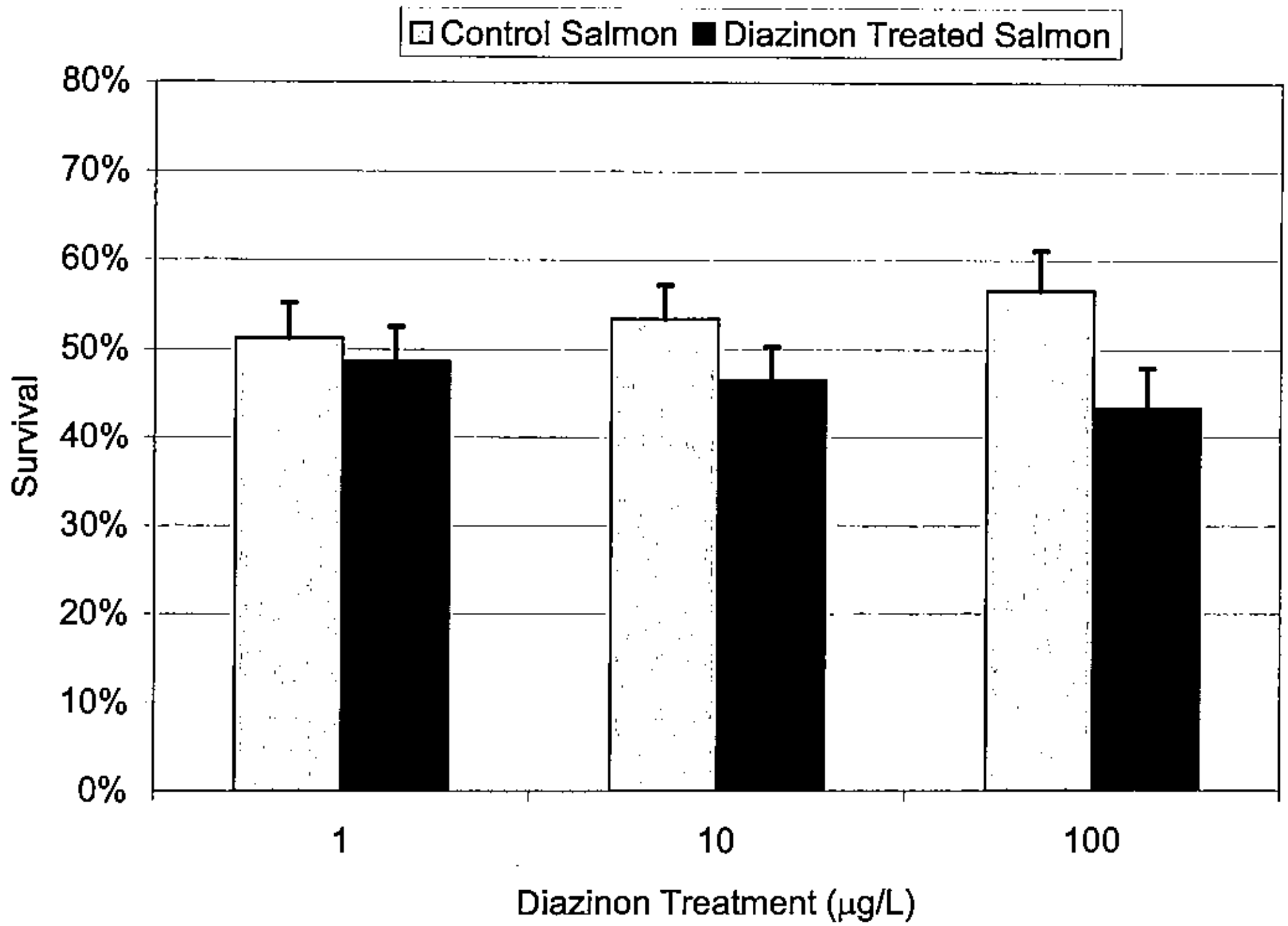
- None of the diazinon-exposed treatment groups differed from the respective control groups (ANOVA, $p>0.05$).

- These results suggest that environmentally relevant levels of diazinon do not significantly impair olfaction in chinook salmon.

Study 2: Design

- Chinook salmon prey and rainbow trout predators
- Olfactory cues: chinook skin extract and predator fish scent
- Randomized design, 50% untreated prey
- Predation target = 50% consumption
- 12 tests per Diazinon dose, 20 salmon/test

Control and Diazinon-treated Chinook Salmon Surviving Predation Following a Skin Extract Alarm Scent Warning



Study 2: Conclusions

- No significant difference in survival was detected between any treatment group and its control (ANOVA, $p>0.05$)
- None of the 3 diazinon-exposed groups differed from either of the other 2 ($p>0.05$)
- Results also suggest diazinon exposure at these levels does not impair any physiological or behavioral mechanism that may be important for predator avoidance