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

AUG 21 1996

FILE

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: OREB COMMENTS REGARDING ISK BIOSCIENCES'S RESPONSE TO THE HED DRAFT CHAPTER FOR THE CHLOROTHALONIL RED

FROM: Jeff Evans, Biologist
Special Review and Registration Section
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Health Effects Division (7509C)

TO: Mary R.A. Clock, Chemical Review Manager
Risk Characterization and Analysis Branch (7509C)

THRU: Francis Griffith, Acting Section Head
Special Review and Registration Section (7509C)

Edward Zager, Acting Chief
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Health Effects Division (7509C)

Please find the OREB review of ....

DP Barcode: D228520

Pesticide Chemical Code: 081901

EPA Reg. No.: N/A

EPA MRID No.: N/A

Review Time: 2 Days

PHED: No

I. INTRODUCTION:

SRRD has requested that OREB review the comments submitted by ISK Biosciences in response to the Agency's draft Reregistration Eligibility Decision (RED) for chlorothalonil. It is our understanding that SRRD has requested that OREB first, respond to the registrant's comments, then provide a revised draft chapter for the RED once additional toxicity data are reviewed by the Agency. Please note: OREB has not responded to issues related to toxicological end-points including adverse kidney effects, and measurements of dermal absorption. These matters will be addressed when the new 21 day study is reviewed.

II. DETAILED CONSIDERATIONS:

SECTION 1-Discussion of Key Issues

Issue E. "Summary points, response to occupational and residential risk characterization.

- **The draft HED RED recommends retaining a minimum 48-hour REI based on eye incidence reports**

ISK Biosciences Comment

"The recommendation that the 48-hour REI be retained appears to be based on eye irritation incidence reports from California (1982 - 1992). The data from California do not support this recommendation. During the ten year period referenced in the HED, only twelve incidences of dermal irritation or eye irritation were reported that were related to reentry. Of these only three were for incidence related to eyes. In the first incidence, eye irritation was reported during the thinning of nectarines in a field treated with chlorothalonil and triforine. Since both chlorothalonil and formulations of triforine can cause eye irritation, the actual cause of the irritation cannot be determined. In the second incidence, conjunctivitis was reported in a worker hoeing a tomato field that had been treated with chlorothalonil, sulfur and metalaxyl five days earlier. The interval between the spraying and the hoeing, together with the fact that both sulfur and metalaxyl are also eye irritants make any conclusions in this case unreliable. In the third incidence, liquid from a stem of a lily that was still wet from having been treated with chlorothalonil splashed into the eye of a worker resulting in chemical conjunctivitis.

Incidents in California probably represent a worst case because of the high number of workers. If there were a serious problem with chlorothalonil exposure/injury to workers, California would have recognized it. The incidence report suggests there is no significant concern relevant to chlorothalonil.

Technical chlorothalonil is a Category I eye irritant in rabbits. However, based on the human data cited by EPA, three reported incidents in ten years, chlorothalonil does not have high potential to put humans at risk to eye irritation. In 30 years of manufacturing and use of chlorothalonil, there has been no permanent eye damage resulting from incidents where chlorothalonil has gotten in the eye. Thus, the rabbit eye is not fully predictive of the potential for effects to the human eye where irritation but no permanent damage is seen. The 48-hour REI for chlorothalonil based on potential effects in the eye is not warranted."

OREB Response

OREB recognizes that many chemicals are applied as tank mixes and was careful to cite the incidences in the HED chapter with qualifiers such as "possible" or "probable". This is because of the uncertainties in any incidence reporting. The qualifiers that were used were cited from the CA Pesticide Illness Surveillance Program report for chlorothalonil. These qualifiers anticipate the registrant's comments that when two or more irritants are involved, it is not possible to attribute the incident to any single chemical.

OREB does not consider California "worst-case" for reentry exposures to chlorothalonil. California incident data are cited, since California is one of the few states that require any reporting of pesticide incidences at all. However, other growing regions (which do not have incident monitoring systems) may have a greater reliance on fungicides than California. In addition, the California (and EPA) recognizes that eye irritation is an under-reported incident, particularly with respect to reentry incidents.

It is OREB's understanding that California EPA is concerned about chlorothalonil's irritation potential. In the HED chapter, OREB noted that "The California Department of Pesticide Regulation has suggested that the large percentage of eye and skin reports is due to the high irritation potential of chlorothalonil.

OREB is not familiar with the specific chlorothalonil manufacturing practices, with respect to exposure (i.e., the use of closed manufacturing systems). Therefore, we cannot comment on this assertion. However, the Agency is concerned about any eye damage as a result of pesticide exposure even if it is not permanent eye damage.

OREB notes that the revised Worker Protection Standard for Agricultural Pesticides (1992) established interim restricted entry intervals based on the eye irritation potential and skin irritation potential of pesticide active ingredients. The WPS established a 48-hour REI for active ingredients classified as

toxicity category I for eye irritation or skin irritation potential. Therefore, chlorothalonil currently has a 48-hour REI due to its eye irritation potential. During the review of chlorothalonil during the reregistration process and particularly in light of the eye incidents reported by California, the Agency found no persuasive evidence that the 48-hour REI should not be continued. However, OREB recognizes the difficulty in regulating a pesticide on adverse effects such as irritation. We recommend that ISK Biosciences propose certain label language (including notification) and product stewardship measures to address the concerns noted in the incidence report. With that, OREB will consider basing the REI solely on the adverse kidney effects and cancer.

The EPA does not consider PPE for workers reentering chlorothalonil-treated fields

ISK Biosciences Comment

"The Agency's position that workers do not wear Personal Protective Equipment (PPE) when performing reentry tasks does not coincide with actual observations in the field. Discussions with ISK Biosciences field representatives and observations from the tomato harvester study with chlorothalonil in California indicate that wearing long-sleeved shirts, long pants, gloves and hats is a common practice of workers engaged in harvesting and other field activities. In fact, it is the recommendation of the EPA publication *Protect Yourself from Pesticides - Guide for Agricultural Workers* that workers wear the above mentioned attire when engaged in agriculturally related work activities. Long-sleeved shirts, long pants and hats are worn by workers to minimize the effects of long hours of exposure to sunlight in addition to protection from accidental contact with chemical residues.

Data from worker exposure studies with chlorothalonil show that clothing (long sleeved shirt, long pants and gloves), provide an effective barrier and prevent chlorothalonil deposition on skin. Any exposure estimate should take into consideration the use of this minimum PPE especially when it is already routinely worn by workers reentering chlorothalonil-treated fields. The exposure estimates should be recalculated to reflect common practices in the field, including the REI's based on the use of gloves and/or long-sleeved shirt."

OREB Response

The Agency's policy regarding the use of PPE, to be routinely worn by harvesters and other workers performing early-entry hand labor tasks, arose from comments provided during the comment period, while the Agency was developing the Worker Protection Standard. Comments provided by farm worker organizations, academics, and grower organizations suggest that PPE would not be routinely worn based on the potential for heat

stress, discomfort, and loss of productivity. Excerpts from the comment period are provided as an attachment. In promulgating the revised Worker Protection Standard for Agricultural Pesticides, EPA established a policy of prohibiting routine entry during a restricted entry interval to perform hand labor tasks. The policy is described in the Response to Comments documents as:

> Furthermore, comments received in response to the NPRM [Notice of Proposed Rulemaking] questioned the feasibility of workers wearing PPE while performing hand labor tasks under normal agricultural field conditions. The Agency has studied the issue of PPE for agricultural field workers who are performing routine hand labor tasks and has concluded that routine use of PPE, such as chemical-resistant gloves, footwear, and headgear, two layers of clothing, and protective eyewear, for such field workers is, in general, not only impractical, but also may be risk-inducing due to heat stress concerns. The Agency has determined that hired agricultural workers, especially harvesters, have a disincentive to wear PPE; because they frequently are paid at a piece rate, they have little tolerance for anything that hinders their speed and efficiency. The Agency concludes that it is likely that the PPE would be removed or would be worn incorrectly if it were required routinely in most hand labor situations. Many comments also observed that routine early entry during the REI was rarely necessary.
>
> After consideration of the comments and the available data, the Agency has concluded that, under most circumstances, allowing routine entry for unlimited time to areas under an REI, even with PPE, decontamination, and training, will not reduce adequately the risk of agricultural workers' exposure to pesticides, and that the economic benefits associated with such routine early entry do not justify the risks associated with such early entry. Consequently, the Agency is convinced that routine hand labor tasks should not be allowed before the expiration of the REI, except in rare circumstances based on case-by-case consideration.

Regarding the WPS worker guides (EPA Worker Safety Poster GPO #055-000-00444-7 and EPA Worker Safety Training Handbook GPO #055-000-00443-9), the registrant appears to be confused between the Agency's recommendations regarding good general agricultural worker hygiene and safety practices, and the Agency's ability to establish label-specific requirements for certain attire, and basing risk assessments on such attire. In fact, the two cited guides **recommend** that agricultural workers **voluntarily choose** to wear long-sleeved shirts, long pants, shoes, socks, and a hat or

scarf. They do not recommend the use of gloves. As the registrant points out that the use of a hat and clothing scenario may minimize exposure to sunlight and accidental exposure to chemicals. The Agency does not base risk management decisions on the basis of attire recommended (but not required) for use by agricultural workers. The role of the restricted entry interval is to prohibit routine entry into treated areas until pesticide residues reach a level where exposure by agricultural workers is acceptable **regardless** of their attire. provide a safe level exposure expected during routine reentry activities.

Other reasons why personal protective equipment requirement for agricultural workers performing long-term, routine tasks are not considered feasible by the Agency:

- Worker tasks usually involve hard physical labor often performed for eight to ten hour days with minimal access to shade or rest breaks. Handler tasks requiring personal protective equipment, in contrast, are often short-term (for example, mixing and loading), require relatively light physical labor (for example, driving groundboom or aerial equipment), and/or are within easy access of shade and drinking water.

- The wages for many agricultural workers are based on a "piece-rate" scale, i.e., workers are paid based on the rate of harvesting (or other task) they individually are able to accomplish. Personal protective equipment, particularly chemical-resistant gloves, are frequently a disincentive to efficient productivity and are unlikely to be tolerated;

- Reentry activities, such as harvesting, are highly ergonomic (as opposed to handler activities), and therefore, additional dermal exposure to field residues is likely occur through openings of shirts, seams, cuffs etc.;

- Factors such as sweating caused by personal protective equipment (opening of pores may lead to greater absorption) may in fact lead to greater exposure.

- Many agricultural workers do not have routine access to facilities, such as hot-water showers and laundry facilities. Therefore, the necessity of reducing the likelihood of skin and eye irritation by washing thoroughly after each day of work and laundering work clothes daily is not considered by the Agency as a feasible risk-mitigation option. EPA notes that ISK states: "ISK Biosciences is convinced that skin irritation can be prevented by workers avoiding prolonged exposure to chlorothalonil on the skin. This

is accomplished by good personal hygiene--showering at the end of the work day, washing exposed areas of skin before eating, drinking or toileting and laundering work clothes before rewearing. This can be accomplished by training and education of workers." The Agency believes that training and education of workers is insufficient. Workers also must have reasonable access to facilities in which these practices may be accomplished and, at present, the Agency is not persuaded that agricultural workers have such access.

Most of the exposure for the scenarios effecting chlorothalonil's REI's are to the hands and forearms. Agency observations from our own studies and reports of studies conducted by California EPA (formerly known as CDFA) indicate that not all agricultural workers routinely wear long-sleeved shirt, long pants, and gloves. Often the scenario for worker clothing is short sleeved shirts, long pants, and no gloves. Note that cotton gloves often worn by workers for physical protection are not considered by the Agency as offering significant exposure reduction, particularly since such gloves are rarely laundered after each day of work. The Agency recognizes that crops requiring extensive hand labor are grown in other parts of the country that are hot and humid. The likelihood that all workers in all parts of the country are wearing long-sleeved shirts, long pants, and gloves is unrealistic. The most that could be said about the observations of workers at the time the tomato harvester study was conducted was that "the majority of other harvesters observed wore long sleeved shirts, ankle length trousers, gloves and hats." The study was conducted in Oceanside, California in May/June where average temperatures range from the 50's to mid 70's, and low 80's. This type of clothing may have more to do with temperature and the physical/chemical characteristics of the crop.

For the parts of the body covered by short-sleeved shirt and long pants, the Agency used a 10 percent clothing penetration rate consistent with California's findings (J. R. Spencer et al, Re: Chlorothalonil Exposure of Workers on Mechanical Tomato Harvesters, Toxicology Letters, 55 (1991)).

SECTION 2: Point-by-Point Response to HED Draft Chapter of the RED

ISSUE NO. 40:
B.2.a.ii. Non-Agricultural, Page 17.

"The non-agricultural uses of chlorothalonil include..."

ISK Biosciences Comment:
"The non-agricultural uses of chlorothalonil also include uses on fresh cut lumber to control sapstain and molds (dip vats and sprayed-on), uses in caulks, sealants, grout and in pressure treatment of wood."

OREB Response:
It is OREB's understanding that the use in caulks, sealants and grout is pending and not registered. OREB is unaware of the uses on fresh cut lumber (dip vats and sprayed-on) and pressure treatment of wood. There are no data to evaluate these uses. The Agency expects such tasks to involve relatively high rates of exposure.

ISSUE NO. 49:
B.2.C. Occupational and Residential Exposure, Page 27, Fourth paragraph.

- "Except for tomatoes, the above referenced FDR studies were conducted without concurrently monitored worker exposure."

ISK Biosciences Comment:
"That sentence is not correct. In addition to the tomato harvester study, both the golfers (MRID No. 42433811) and the golf course workers (MRID 42433810) were monitored with valid dosimetric techniques. The statement raises concern as to whether the golf course study was actually reviewed by EPA."

OREB Response:
OREB reviewed the ISK-referenced studies and used them to estimate the golfer and mower exposures (presented on page 64 of the HED document). The point of the comment was that the only worker reentry study in which concurrent FDR samples and worker exposure monitoring samples were collected was the tomato harvester study. This statement is still correct.

Foliar Dislodgeable Residue (FDR) samples of chlorothalonil and HCB were not reported in the ISK-referenced studies. OREB reminds ISK that not having concurrent worker exposure monitoring was a concern raised upon reviewing the protocols for ISK Biosciences's cucumber, broccoli, and cherry FDR studies. At that time, ISK indicated they were willing rely on the generic transfer factor used by the Agency. Coupled with the use of a transfer factor that was a high estimate of exposure and

particularly since the studies were already being conducted, OREB approved the protocol. Subsequent to those agreements, ISK proposed using the transfer factor from the tomato harvester study, since it was similar to the Agency's generic transfer factor.

ISSUE NO. 51:
B.2.c. Occupational and Residential Exposure, Page 25, Last paragraph.

- "Mixer/loader/applicator (M/L/A) exposure data were..."

ISK Biosciences Comment:
"Mixer, loader and applicator studies for ground and aerial application to celery and tomatoes have been conducted and submitted to the Agency. These studies were as follows:

MRID No.	Document Number	Name of Document
00144248	091-5TX-80-0202-002	Toxicological Report on the "Applicator Exposure Studies with Chlorothalonil (BRAVO 500) Fungicide (Appendix A reports study on Celery and Tomato using both ground and aerial application methods)
00147972	091-5TX-80-0202-003	Estimation of Potential Chlorothalonil Doses to Agricultural Applicators from the Study, "Applicator Exposure Studies With Chlorothalonil (BRAVO 500) Fungicide"

Reference to these studies should be included in the final RED."

OREB Response:
OREB used the Pesticide Handlers Exposure Database (PHED) to estimate handler exposure for ground boom and aerial applications. OREB was unaware of the above referenced studies since they were not part of the data package nor submitted with the other referenced studies in the HED document. However, they were noted in California publications. OREB will consider these studies as part of the revised chapter if the data will significantly change any exposure estimates.

ISSUE NO. 52:
B.2.C. Occupational and Residential Exposure, Page 27, Third paragraph.

- "A Tomato Harvester Exposure Study with Chlorothalonil [MRID 470025-045];"

ISK Biosciences Comment:

"The MRID number for the tomato harvester exposure study (Document No. 655-3HE-84-0043-001) should be 00147976. The number "470025-45" is not consistent with the Agency's MRID numbering system."

OREB Response:
The registrant is correct.

ISSUE NO. 53:
B.2.C. Occupational and Residential Exposure, Page 27, Fourth paragraph.

- "Except for tomatoes, the above referenced FDR studies were conducted without concurrently monitored worker exposure."

ISK Biosciences Comment:
"That sentence is not correct. In addition to the tomato harvester study, both the golfers (MRID No. 42433811) and the golf course workers (MRID 42433810) were monitored with valid dosimetric techniques. The statement raises concern as to whether the golf course study was actually reviewed by EPA."

OREB Response:
See OREB Response to Issue 49.

ISSUE NO. 67:
B.1.c. Risk from Handler Exposures, Page 37.

- "The use of a designated flagger is assumed to be the highest exposure..."

ISK Biosciences Comment:
"This statement is not supported by the exposure estimates presented in Table 10. The intermediate risks range from 83 to 300 and the carcinogenic risk is well below 10^{-4}. The risks associated with other handlers, that is, mixer/loaders of wettable powders, are much higher. For example, the Margins of Exposure (MOE) for mixer/loaders of wettable powders for aerial and ground application range between 3 and 24. Therefore, the above sentence should be omitted."

OREB Response:
This sentence was meant to convey that the exposure to a designated flagger is assumed to be the highest **flagger** exposure, among the possible flagger exposure scenarios.

ISSUE NO. 68:
B.1.c. Tables, Pages 38 - 46.

- Table 7, Summary Exposure/Risk Values for Mixer/Loaders Using Chlorothalonil

- Table 8. Summary Exposure/Risk Values for Applicators Using Chlorothalonil
- Table 9. Summary Exposure/Risk Values for Mixer/Loader/Applicator Using Chlorothalonil

ISK Biosciences Comment:

"It is not very clear what is meant by "not likely" under Intermediate Term MOE. It appears to mean that the specific exposure scenario is unlikely to result in intermediate level exposure. A footnote explaining this would be helpful. It should be noted that ISK Biosciences believes the MOE's on pages 38-64 of the draft RED should be based on the new 21-day dermal toxicity study in rats when the results are available. Interim calculations based on the available 21-day dermal study in rabbits are given in Appendix 3."

OREB Response:

The registrant is correct in assuming that "not likely" means that specific exposure scenario is unlikely to result in intermediate-term exposure. We appreciate the suggestion regarding the footnote and will provide one in the revised chapter.

ISSUE NO. 69:

B.3.c. Occupational and Residential Risk Characterization, Handler Exposure Risk Summary, Occupational Uses, Page 51, Third paragraph.

- "Based on the intermediate-term endpoint, additional PPE are recommended for mixer/loaders supporting aerial applications when using the dry and liquid flowable formulations. The PPE consist of a...and a respirator,..."

ISK Biosciences Comment:

"The requirement for a respirator for mixing and loading the liquid flowable formulations or dry dispersible granules manufactured by ISK Biosciences Corporation is not appropriate. ISK Biosciences has conducted studies to determine the extent to which respirable particles can form in pouring and mixing the viscous liquid flowable formulations of chlorothalonil and has determined that no respirable droplets are formed during those operations.

ISK Biosciences has also conducted studies on the dispersible granular formulation and has determined that the hardness and integrity of the granules is such that little or no dust of respirable particle size is formed during shipping, warehousing and handling. Thus, this requirement for respirators for these formulations is not necessary to provide an adequate margin of safety. These exposure assessments should be re-evaluated in the final RED. ISK Biosciences agrees that additional respiratory protection may be necessary for mixing and

loading the wettable powder for aerial application, unless packaged in water-soluble bags."

OREB Response:

OREB used surrogate data available in the Pesticide Handlers Exposure Database (PHED) to evaluate exposure to ISK Biosciences's liquid and dry flowable formulations. Therefore, the inhalation values may be influenced by the physical properties of the formulations that make up the subsets for these scenarios. OREB has no way of knowing the exposure potential for these specific ISK Bioscience formulations of chlorothalonil. The options available are 1) conduct an inhalation study using the above formulations for mixer/loaders, 2) submit the data to the Agency's toxicologists supporting the claims discussed above, or 3) wait for the results of the toxicity study which may result in a higher NOEL for regulating intermediate-term occupational exposure and higher corresponding MOE's .

ISSUE NO. 70:

B.1.c. Handler Exposure Risk Summary, Occupational Uses, Page 51, Paragraph 6.

- "For flaggers supporting aerial applications, the risks from intermediate-term exposures are borderline. HED has information about poisoning incidents involving flaggers."

ISK Biosciences Response:

"If there are "poisoning incidents" specific to chlorothalonil, then they should be described and references given. This statement contradicts the statement at the bottom of page 52 of the draft RED which correctly states that there are no cases of human systemic poisoning reported for chlorothalonil."

OREB Response:

There are two incidents for a flagger (eye -not determined) and several drift exposure (37) in the California Pesticide Illness Surveillance Program from 1982 to 1992. These incidents resulted from treatments that were tank mixes including chlorothalonil. The incidences were reported as "not determined" apparently, since the sprays were tank mixes. However, the MOE for intermediate-term exposure still requires the use of flagging in enclosed cabs. The systemic effect for intermediate-term exposure is unlikely to be reported in an incident system.

ISSUE NO. 71:

B.3.c. Occupational Uses, Page 52, Paragraph 1.

- "HED believes that the intermediate term exposure (continuous use for one week to several months) to fungicide-containing paints is relatively uncommon. However, MOE's for intermediate-term exposure to workers handling chlorothalonil-containing paints were calculated."

ISK Bioscience Comment:

"In making these calculations of MOE's, the Agency failed to consider the relatively low market share for chlorothalonil in paints. As reported in "Assessment of Painter Exposure and Risk Resulting from the Airless Sprayer Application of Chlorothalonil Containing Paints" (MRID No. 43824501) chlorothalonil is used in about 5%, 6%, and 0.2% of the exterior alkyd points, exterior latex paints and interior latex paints, respectively. The volumes used by the Agency constitute the total average gallons of paint applied by a commercial painter per year and did not take into account the amount of chlorothalonil containing paint that would be applied annually. This should be reconsidered in the final RED."

OREB Response:

It has been OREB's position that painter exposure is not intermediate-term exposure based on the percent of paint used.

ISSUE NO. 73:

B.3.c. Incidence Information for Chlorothalonil, Page 53 Paragraph 1.

- "Between 1982 and 1992, 133 incident case reports were received by the California Pesticide Illness Surveillance Program."

ISK Biosciences Comment:

"ISK Biosciences has requested that this report be evaluated by our Medical Consultant, Dr. Morris Chelsky, M.D., MPH, Dr.PH. Dr. Chelsky is familiar with the symptoms of chlorothalonil exposure and has concluded that many of the symptoms described in this report were not caused by chlorothalonil. He has recommended precautionary measures to avoid exposure in most of the reports which may have been due to chlorothalonil. The discussion in the draft RED implies that these were exposure incidents that involved only chlorothalonil, whereas most of them involved a mixture of pesticides, several of which may have resulted in the symptoms described. This should be pointed out in the final RED.

Based on over 20 years of experience at the manufacturing site, ISK Biosciences is convinced that skin irritation can be prevented by workers avoiding prolonged exposure to chlorothalonil on the skin. This is accomplished by good personal hygiene--showering at the end of the work day, washing exposed areas of skin before eating, drinking or toileting and laundering work clothes before rewearing. This can be accomplished by training and education of workers."

OREB Response:

OREB is aware of the problems associated with pesticide incidence reporting. The lack of incidence data may not be significant justification for saying there are no problems

associated with a chemical. While verification of incidences is justification for saying there are problems associated with a chemical. For handlers (mixer/loader/applicators) and flaggers, skin and eye irritation can be mitigated by the PPE required in this RED. For workers, mitigation is more difficult. However, the good hygiene practices outlined above by registrant's consultant, are already **recommended by EPA** since many uses of chlorothalonil are in-scope of the Worker Protection Standard (WPS). Many of those hygiene practices are listed as user-safety recommendations in the label language section of the RED. However, as discussed earlier, the Agency is not persuaded that agricultural workers have sufficient access to facilities that would allow them to practice the hygiene measures cited by ISK Biosciences and recommended by the Agency.

For reentry (field workers), OREB was careful to mention the other chemicals that were in the various tank mixes specific to each incidence for the very reasons listed by the registrant. Practices, such as avoiding prolonged exposure to the skin, are difficult to regulate with respect to field workers. This is why there is an REI. The difficulty in establishing an REI for eye irritation is the lack of a model. The Agency has not established an REI (outside of interim REI's set by the WPS) for skin irritation. Often skin and eye irritation can be mitigated by extending the REI for other systemic effects. These include cholinesterase suppression for organophosphates, or the reported adverse kidney effect associated with chlorothalonil. However, OREB has previously stated that eye incidents are often under-reported, particularly with regard to agricultural workers.

ISSUE NO. 74:
B.1.c. Incidence Information for Chlorothalonil, Page 53.

- "There were also 13 incidents that were either identified as possible or probable cause for reentry workers exposed to field residues for chlorothalonil. Again, the symptoms included skin and eye irritation. The California Department of Pesticide Registrations has suggested that a large percentage of eye and skin reports is due to the high irritant potential of chlorothalonil. These findings appear at odds with the classification of the TGAI of chlorothalonil as Toxicity Category IV for primary skin irritation. However, these incidences suggest that the eye irritation potential of chlorothalonil is not only an acute exposure (one day) danger. HED has recommended REI's for chlorothalonil-treated crops with these incidences in mind."

ISK Biosciences Comment:
"This description is misleading. Twelve of the thirteen incidence reports are described in the section on **Risk From Post-Application Exposures**. All except two of the cited incidents were to multiple chemicals, some of which are known skin and eye

irritants. Thus it is not possible to determine which product resulted in the irritation. In the two incidents where chlorothalonil was the only chemical mentioned, the adverse effects, if any were not reported in the summary.

As indicated above, chlorothalonil has demonstrated only low potential for skin irritation in animal studies, with irritation potential increasing only with prolonged exposure (greater than a 12-hour work shift). The incidence reports support the observations in animals studies of low potential for skin irritation. Of the nine incidence reports where skin irritation was noted, only three might be attributable to chlorothalonil. Three of the nine incidents were with chlorothalonil and chemicals that are not known skin irritants. One incidence was in combination with metalaxyl, a slight skin irritant. Three incidents potentially involved a combination of chemicals where one of the other chemicals (sulfur, esfenvalerate, and permethrin) is a known skin irritant. For two of the incidents no adverse effects were listed. Therefore, only three of the incidents might be due to exposure to chlorothalonil. This is not a high incidence rate.

Based on the data presented in the section on **Risk From Post-Application Exposures**, human incidence reports indicate that problems associated with eye irritation during reentry into chlorothalonil-treated areas are minimal and not "an acute exposure (one day) danger." In the ten-year reporting period, only three incidence reports involving eyes were cited. This is not a high incidence rate.

1. Eye irritation was reported during the thinning of nectarines in a field treated with chlorothalonil and triforine. Formulations of triforine are severe eye irritants; thus the actual cause of the irritation cannot be determined.

2. Conjunctivitis was reported in a worker hoeing a tomato field treated with chlorothalonil, sulfur and metalaxyl. Both sulfur and metalaxyl are eye irritants; therefore, it cannot be concluded that the conjunctivitis is due to chlorothalonil, at the exclusion of the other chemicals.

3. Liquid from a stem of a lily that had been treated with chlorothalonil splashed into the eye of a worker. This activity was being conducted on lilies still wet from DACONIL spray; the spray was not allowed to dry before the worker reentered the area. No information was provided whether there were any adverse effects.

A report included in Appendix 6 has been prepared by Morris Chelsky, M.D., MPH, Dr.PH. Dr. Chelsky assessed each of the

reported incidents in California and provided his opinion in this report of the most likely cause of exposure and recommended measures to prevent such exposure. Dr. Chelsky provided health surveillance services to the company on chlorothalonil from 1980 to 1993 and currently serves as a consultant of ISK Biosciences."

OREB Response:

ISK and OREB are using the same incidence report. We know the limitations of incidence reporting as discussed under other issue numbers in this memorandum. Again, OREB was careful to list other chemicals in the tank mix knowing that others may also contribute to the incident.

The Agency was careful with respect to reentry incidents to list the California designation of "possible" or "probable." These designations are an indication of how confident California is that the incident was caused by a pesticide or particular group of pesticides. California has often noted that relating a skin or eye irritation incident involving a reentry worker to a particular pesticide is very difficult. However, the fact that chlorothalonil is present in a number of incidents does not allow the Agency to dismiss it as the cause or contributor in some or all of those incidents. Both California and the Agency are concerned about the number of incidents of skin and eye irritation in which chlorothalonil is one of the possible causes. Furthermore, as ISK Bioscience knows, chlorothalonil is not used as heavily in California (one of the few states that require pesticide incident reporting). The low incidence rate in California does not that mean skin and eye irritation incidences have not occurred in other regions where disease pressure requires greater use, such as the southeastern United States.

As for systemic effects, we did not intend to imply that chlorothalonil causes dizziness (particularly when it is used in a mixture with an organophosphate). We believe the registrant appears to have misinterpreted our intent in listing this incident in the chapter. On the other hand, the type systemic effect (adverse kidney effects) that chlorothalonil may cause would not be expected to be a symptom that would be reported by physicians as related to pesticide poisoning and would not, therefore, be expected to show up in incident reports.

We appreciate Dr. Chelsky's comments and will take them under advisement when we revise our draft.

ISSUE NO. 75:
Risk from Post-Application Exposure, Pages 54-63.

- Tables 12-20 Daily exposure (mg/kg/day)

ISK Biosciences Comment:

The label on the column "Daily exposure (mg/kg/day)" does not accurately identify what is presented in the tables. This column is actually the estimated absorbed dose. It is suggested that the column be labeled "Estimated daily absorbed dose (mg/kg/day)."

OREB Response:
We will consider this in our revised chapter, if one is required.

ISSUE NO. 76:
Risk from Post-Application Exposure, Page 55.

- "INCIDENCE: 1989, one possible case involving a worker hoeing weeds-conjunctivitis. The field was treated with chlorothalonil, sulfur and metalaxyl."

- "In 1990, one possible case where a worker got rash while harvesting tomatoes treated 12 days prior with an adjuvant, chlorothalonil, esfenvalerate, methomyl, and sulfur."

- In 1990, one worker developed a rash on the forearm while moving tomato vines in a field treated with an adjuvant, chlorothalonil, esfenvalerate, methomyl, and sulfur."

ISK Biosciences Comment:
"All three incidences reported on Page 55 of the draft RED included exposure to multiple chemicals and in all three cases at least one other chemical was associated with the effect reported. Sulfur is a skin irritant and an eye irritant that has been identified with conjunctivitis. Esfenvalerate is associated with skin rashes. Metalaxyl is an eye irritant.

It is suggested that the Agency qualify the incidence reports with the following:
Three incidences related to tomato cultivation have been reported. In all three cases, the area had been treated with multiple chemicals. In all cases, at least one of the other chemicals has been associated with the reported effect. Sulfur is a skin and an eye irritant that has been identified with conjunctivitis. Metalaxyl is an eye irritant. Esfenvalerate is associated with skin rashes. Thus, the skin and eye effects observed may not have been due to chlorothalonil."

OREB Response:
We will consider this in our revised chapter, if one is required. However, please note our previous response to this concern and our response to issue number 85.

ISSUE NO. 77:
Risk from Post-Application Exposure, Table 13, Page 55.

- "ASSUMPTIONS:Eight hour work days (120 work days per year), FDR data from a tomato study..."

ISK Bioscience Comment:

"For the MOEs for hand harvesting and for the staking of tomatoes, FDR data from a tomato harvester study done in California with Chlorothalonil were used. In this study there was little dissipation of the foliar dislodgeable residues over the seven-day period that the workers were monitored and foliar residues measured. It needs to be noted that the FDR data from California not only represent the worst case exposure, but are not representative of parts of the country, (the southeast), where chlorothalonil is most extensively used. In the dry flood irrigated desert environment of California it is expected that residues would not dissipate as rapidly as those in the humid wet conditions of the Southeast which favor rapid dissipation of chlorothalonil from treated crop surfaces. The environmental conditions, especially rain, that favor disease also favor wash off from the foliage and fruit, and rapid dissipation of chlorothalonil."

OREB Response:

According to the registrant, chlorothalonil dissipates via leaf expansion, or via moisture/rainfall. The study was conducted along the coast of southern California in the vicinity of Oceanside. This is an area where pole tomatoes are grown for fresh market. Although, site specific weather data were not provided in the report of the tomato harvester study, the estimated temperatures in that area at that time of year average in the low 50's to the mid-70's to low 80's F. This area can also be very foggy, hence, the need for a fungicide. The registrant's position that the study was conducted in a desert environment seems to be overstated. However, the registrant may consider conducting a supplementary FDR study on tomatoes in the southeastern United States.

In the tomato study, four biweekly sprays were made to the study site prior to harvest. In the humid southeast, applications may have to be made more frequently with shorter intervals. According to the USDA's Agricultural Chemical Usage Summary for Vegetables (1994), a total of 7.7 and 7.3 applications per season are made to tomatoes grown in Florida and Georgia respectively while 3.9 applications are made in California. Also, if the conditions are dry when the study is conducted in the Southeast, the results may be the same as the study conducted in California.

In any case, the exposure data from the California site are considered by the Agency as reasonable for that location. Chlorothalonil is registered for use in the dry conditions of California as well as in other climatic conditions. Barring the receipt of far more extensive data from a number of different

sites representing a broad range of climatic conditions that would enable the Agency to require climate- or region-specific entry restrictions, the California data are considered reasonable worse-case and appropriate for establishing national entry restrictions.

ISSUE NO. 78:
Risk from Post-Application Exposure, Page 59.

- "INCIDENTS: In 1987, one possible case involving an irrigation worker getting dizzy and feeling itchy around the neck. The worker...entered the field 2 hours after the field was sprayed with *Bacillus thuringiensis*, chlorothalonil, mevinphos, and permethrin..."

ISK Biosciences Comment:
"This incident involves multiple chemical exposure and the effects associated with this incident may be associated with other chemicals, Permethrin is a known skin irritant in humans. Dizziness is more likely associated with the organophosphate, mevinphos, than chlorothalonil."

OREB Response:
Please refer to our response to ISSUE 74.

ISSUE NO. 79:
Risk from Post-Application Exposure, Page 60.

- "INCIDENCE: in 1989, one probable case involving a nursery worker handling treated conifer seedlings...some of the seedlings brushed against the worker's face. The seedlings have been treated with chlorothalonil, which was detected...on the seedlings."

ISK Biosciences Comment:
"Were there any adverse effects related to the contact? If there is no information available about potential adverse effects, then that should be stated."

OREB Response:
OREB will add contact dermatitis (face and front of neck) to that paragraph. OREB notes that, in this incident, no other active ingredients are implicated as being involved and that California has judged it "likely" or "probable" that the irritation effects were caused by chlorothalonil.

ISSUE NO. 80:
Risk from Post-Application - Greenhouse Workers, Page 61.

- "TASKS: Cutting and bundling greenhouse grown flowers.

ASSUMPTIONS: In the Brower study, an application rate of 0.6 lb ai/80 - 100 gallons of water...was applied to carnation sprays and carnations grown for cut flowers...

To estimate exposure to workers during cutting and bundling flowers HED used FDR data from the cucumber study because sampling was longer (35 vs. 7 days) and the applications were similar."

ISK Biosciences Comment:

"A more complete reference for the "Brower [sic] study" should be included in the document. It is assumed that the reference is to the 1992 publication in the American Industrial Hygiene Association Journal 63(9):582-587 by R Brouwer et al., *Pesticides in the Cultivation of Carnations in Greenhouses: Part II - Relationship Between Foliar Residues and Exposure*. (Note: The name of the primary author of the publication is spelled Brouwer.

What the first sentence in the second paragraph refers to is not clear. FDR data for 35 days are from the FDR study on cucumbers, but what the reference to 7 days, and the significance of the reference is, is not clear. What does "the applications were similar" mean? Applications to carnations in greenhouses and application to field-grown cucumbers would not be similar."

OREB Response:

What is missing in that paragraph is a reference to the tomato harvester study which OREB believes has a similar per acre rate as reported in the Brouwer study (see page 61). We will revise accordingly. Because the tomato data showed limited dissipation, an REI could never be reached under current tox considerations. Therefore, OREB chose the cucumber dissipation data, which matched, as best as possible, the estimated FDR data from the Brouwer study. However, with drip irrigation, it is possible that dissipation under greenhouse conditions could be very slow and could, in fact, more closely match the tomato study where limited dissipation was observed.

ISSUE NO. 81:

Risk from Post-Application - Greenhouse Workers, Page 61.

- "INCIDENCE: In 1982, a probable incident occurred when a worker was cutting lilies still wet with spray. Liquid from a stem splashed into the workers [sic] eye. The lilies were treated with chlorothalonil."

ISK Biosciences Comment:

"The report indicates the lilies were being cut while still wet after being sprayed with DACONIL. Reentry should have been delayed until the spray had dried. What were the consequences of

getting the liquid in the eye? If known, they should be stated. If not then that should be stated."

OREB Response:

OREB will add chemical conjunctivitis which, we believe is already incorporated in the SRRD draft. It should be noted that the definition of sprays have dried and dusts have settled seems to be subject to personal interpretation. That is why the Agency has established minimum 12-hour interim REI's in the WPS to replace the concept of "sprays have dried" on agricultural use sites. In addition, it should be noted that no other active ingredients are implicated as being involved and that California has judged it "likely" or "probable" that the irritation effects were caused by chlorothalonil.

ISSUE NO. 82:
Risk from Post-Application - Greenhouse Workers, Page 63.

- Table 20

ISK Biosciences Comment:

"What is the source of the field residue data used in this table? The footnote states that the Agency does not have data for this study. How can data that the Agency does not have access to and, therefore cannot critically review, be used? Note that the data from the Brouwer study are from a publication that gives no detail about the data that were used to determine the transfer coefficient for the greenhouse scenario."

OREB Response:

The source of the data used in the table was the published Brouwer study. The data from the Brouwer study are available in many forms and levels of detail in various publications. Perhaps the most complete version is titled "Pesticides in the Cultivation of Carnations in Greenhouses: Part II-Relationship between Foliar Residues and Exposures." This paper is available in the September 1992 Journal of American Industrial Hygiene Association, page 582. How these limited data are used is described in the RED proceeding Tables 19 and 20. The publication available in the Journal differs from the one Dr. Ralph Burton of ISK Biosciences submitted. The version Dr. Burton submitted, after our discussion at the Reentry Workshop in April 1994, was one he received from Joop van Hemmen of TNO Toxicology, the Netherlands another investigator in those studies. The footnote will be amended to state that the full raw data are not available.

The registrant is correct in pointing out that the Agency has no data regarding worker reentry exposure in greenhouses. In the RED process, the Agency uses every effort to conduct an exposure assessment. This was recognized as a datagap and reentry data for this scenario are required in the RED.

ISSUE NO. 83:
Post-Application Risk Summary, Occupational Uses, Page 64.

- "HED recommends increasing the WPS-imposed REI for many crops and reentry tasks. The use of PPE is currently not an option based on the Agency's long standing belief that PPE will not be worn by workers."

ISK Biosciences Comment:
"The Agency's position that workers do not wear Personal Protective Equipment (PPE) when performing reentry tasks does not coincide with actual observations in the field. Discussions with ISK Biosciences field representatives and observations from the tomato harvester study with chlorothalonil in California indicate that wearing long-sleeved shirts, long pants, gloves and hats is a common practice of workers engaged in harvesting and other activities. In fact, it is the recommendation of the EPA publication *Protect Yourself from Pesticides-Guide for Agricultural Workers* that workers wear the above-mentioned attire when engaged in agriculturally related work activities. This practice is done to protect workers from the effects of sunlight as well as reduce the incidental contact with foliar residues of chemicals. In estimating reentry worker exposure and risk, common attire, including PPE, should be taken under consideration."

OREB Response:
The Agency is not alone in this belief. Please refer to II. DETAILED CONSIDERATIONS, SECTION 1-Discussion of Key Issues, Issue E, Summary points, response to occupational and residential risk characterization, for OREB's response.

ISSUE NO. 85:
Restricted Entry Intervals, Footnote, Page 66.

- "*HED recommends retaining a minimum 48-hour REI based on eye incidence reports."

ISK Biosciences Comment:
"What reports is this referring to? If it is the California data, only three incidence reports involving eyes were noted over a ten year period. This is not a high incidence.

1. Eye irritation was reported during the thinning of nectarines in a field treated with chlorothalonil and triforine. Formulations of triforine are severe eye irritants.

2. "Conjunctivitis was reported in a worker hoeing a tomato field treated with chlorothalonil, sulfur and metalaxyl. Both sulfur and metalaxyl are eye irritants; therefore, it

cannot be concluded that the conjunctivitis is due to chlorothalonil at the exclusion of the other chemicals.

3. Liquid from the stem of a lily that had been treated with chlorothalonil splashed into the eye of a worker. No information was provided whether there were any adverse effects. The report indicates that lilies were cut before the spray had dried.

Based on the California data, human incidence reports are extremely few, inconclusive as to causal agent, and provide very weak evidence which would implicate chlorothalonil as the cause of eye irritation associated with work tasks during reentry into chlorothalonil-treated areas. Experience at the manufacturing plant has confirmed that while chlorothalonil can cause eye irritation, there has never been a serious eye injury and no permanent eye damage from ocular exposure to chlorothalonil. It is apparent from more than 25 years of commercial use of chlorothalonil on many crops, including hand-harvested vegetable crops such as tomatoes and cucurbit crops, that there have been extremely few cases implicating chlorothalonil as the cause of eye exposure/injury to workers reentering treated fields to perform hand labor. Thus there is no convincing justification to warrant a 48-hour REI."

OREB Response:

The report OREB is referring to is the Case Reports Received by the California Pesticide Illness Surveillance Program, for Chlorothalonil, Alone or in Combination, 1982-1992. This is the same report OREB provided via fax, at ISK Biosciences's request.

Note that the Agency's data indicate that while some triforine end use products are eye irritants, the active ingredient is classified as toxicity category IV for eye irritation potential. Therefore, in a reentry situation, presuming sprays had dried (and therefore the eye-irritating inert in triforine end-use products has dissipated), the Agency would not expect triforine to be the cause of the eye irritation incident. Also note that sulfur is classified as toxicity category II for eye irritation and metalaxyl is classified as category III for eye irritation potential, while chlorothalonil is classified as toxicity category I for eye irritation potential. Finally, note that in the lily incident, the adverse effect was chemical conjunctivitis, no other active ingredient is implicated as being involved and that California has judged it "likely" or "probable" that the irritation effects were caused by chlorothalonil.

Please refer to II. DETAILED CONSIDERATIONS, SECTION 1- Discussion of Key Issues, Issue E, Summary points, response to occupational and residential risk characterization, for OREB's

response. Also refer to the specific *Issue Numbers* where applicable.

ISSUE NO. 86:
Homeowner Uses, page 66.

- "Additionally, HED has concerns about potential eye-irritation effects..."

ISK Biosciences Comment:
"See previous comment."

OREB Response:
See previous reply. In addition, like in the lily worker incident, "the sprays have dried, dusts have settled" statement, often printed on homeowner labels, would not prevent immediate reentry.

ISSUE NO. 92:
B.4.c. Occupational/Residential Labeling Rationale, Occupational-Use Products, Page 74, Paragraph 6.

- "For spray applications in green houses and other enclosed areas, HED is requiring applicators to wear a respirator, since chlorothalonil is classified as toxicity category I for acute inhalation toxicity..."

ISK Biosciences Comment:
"The statement relative to chlorothalonil being in Category I for acute inhalation toxicity is incorrect. HED had previously indicated the correct category (Category II) on page 6 of the draft RED. This statement on page 74 should be corrected in the final RED.

In addition, the use of respirators for applicators in greenhouses **has been on the DACONIL 2787 labels for 15 years**, dating from the time we made the label expansion to include greenhouse uses in 1981. ISK Biosciences Corporation voluntarily added such directions to the label as a pro-active measure to minimize applicator exposure in enclosed areas. The current draft RED chapter is worded in a manner which implies that this is something new, which EPA is imposing upon the registrant. The final RED should recognize the initiative taken by ISK Biosciences."

OREB Response:
OREB defers to the Agency's toxicologists to make the determination regarding the acute inhalation toxicity of chlorothalonil. OREB welcomes voluntary protection measures such as the one reportedly proposed by the registrant in 1981. However during reregistration, the Agency does not consider which PPE may be required on current labeling or the history of how/why such

PPE is currently being required. Instead during reregistration, the Agency considers what personal protective equipment, if any, is necessary for the various use patterns for which an active ingredient is registered. With respect to respirators, the Agency is particularly opposed to imposing unnecessary requirements due to the heat and respiratory stress that respirators tends to cause. Therefore, if the Agency found a respirator to be unnecessary in a given scenario, it would request that such a requirement be removed from the labeling. Also, it should be noted that ISK Biosciences are supporting the reregistration of their product with an exposure study in which respirators are worn by the test subjects. In general, when the Agency bases a risk assessment on an exposure study in which PPE is worn, that PPE becomes mandatory and is listed as such in the RED.

ISSUE NO. 93:
Restricted Entry Interval: Page 77, Paragraph 2.

- "However, HED has evidence of poisoning incidents due to chlorothalonil and is particularly concerned about eye irritation incidents; therefore, HED is retaining the 48-hour REI as the minimum REI for all crops/uses within the scope of the WPS."

ISK Biosciences Comment:
"Reference should be made to Response Nos. 73, 74, 76, 77, 79, 80, 81, 82, and 83 and to Dr. M. Chelsky's review (Appendix 7) of California's reported incidents. As pointed out in Response No. 76, only three incidence reports involving eyes were noted over a ten-year period. Those incidents provide very weak evidence that would implicate chlorothalonil as the cause of eye irritation associated with work tasks during reentry into chlorothalonil-treated areas. Experience at the manufacturing plant has confirmed that while chlorothalonil can cause eye irritation, there has never been a serious eye injury and no permanent eye damage from ocular exposure to chlorothalonil. It is apparent from more than 25 years of commercial use of chlorothalonil on many crops, including hand-harvested vegetable crops such as tomatoes and cucurbit crops, that there have been extremely few cases implicating chlorothalonil as the cause of eye exposure/injury to workers reentering treated fields to perform hand labor. Thus, there is no convincing justification to warrant a 48-hour reentry interval."

OREB Response:
It should be noted that cucurbits and tomatoes have a 0-day preharvest interval. State agencies are petitioning EPA to reduce the current interim 48-hour interval imposed by the Worker Protection Standard. Currently, the conclusion in the Draft, Chlorothalonil RED (indicating a requirement for a 4 day REI for hand labor) has thus far prevented any exemption requests from

being granted by the Assistant Administrator. The exemption requests are coming from states having little or no incident reporting systems. Furthermore, these states are predominantly in the east and midwest where there is greater disease pressure resulting in repeated applications, while harvest is in progress. We believe, the California incident data may not represent a worst case. OREB is aware of the limitations of incidence reporting. OREB is unaware of the working conditions at the registrant's manufacturing facility. However, the fact that eye irritation is being observed at the manufacturing facility would appear to be collaborating evidence of the irritating effects of chlorothalonil. The Agency routinely takes regulatory action to prevent eye irritation effects regardless of whether the effects are likely to be judged "serious" or "permanent." We refer the registrant to our opening response presented in: II. DETAILED CONSIDERATIONS, SECTION 1-Discussion of Key Issues, Issue E, Summary points, response to occupational and residential risk characterization. Also refer to the specific *Issue Numbers* where applicable.

ISSUE NO. 95:
B.4.c. Early-Entry PPE:, Page 78, Paragraph 4.

- "For non-hand labor tasks, HED is...active ingredient. Chlorothalonil is classified as toxicity Category III for acute dermal toxicity..."

ISK Biosciences Comment:
"The incorrect category (III) is stated for acute Dermal Toxicity. Chlorothalonil is in Category IV for dermal toxicity. See Page 6 of the Draft RED which states the correct category for all acute effects."

OREB Response:
At the time OREB's RED chapter for chlorothalonil was prepared, the acute dermal toxicity of chlorothalonil for the TGAI was classified as Category III, and the acute dermal inhalation toxicity for inhalation was classified as Category I. OREB defers to the Agency's toxicologists to make the determination regarding the acute dermal toxicity (and acute inhalation toxicity) of chlorothalonil.

III. CONCLUSIONS:

OREB will defer any changes to the exposure assessment, with respect to the intermediate-term endpoint, until after the Agency's toxicologists have evaluated the new 21-day dermal study, and have reevaluated the appropriate previously submitted studies.

OREB does not consider cotton gloves and long-sleeved shirts PPE for early entry, nor does it account for any protection that may be afforded by such attire. The Agency has been on record since the initiation of the Worker Protection Standard that it too, does not consider routine early entry to perform hand labor tasks feasible even if PPE is worn. Farmworker groups, grower organizations, and academics also substantiate this belief. This is a policy affecting other chemicals as well as chlorothalonil.

OREB recognizes the limitations of many incidence data, such as:

- many chemicals are applied as tank mixes so it is difficult to pinpoint the chemical responsible for the incident;
- eye incidents are known to be under-reported;
- most states have no pesticide incident reporting systems;
- reporting systems do not take into account existing REI's or preharvest intervals, which can mitigate the effects.

OREB also recognizes that there is no model to assess the exposure potential to the eye even though it is clear that chlorothalonil residues dissipate over time. OREB recognizes the difficulty in regulating a pesticide on adverse effects such as irritation. We recommend that ISK Biosciences propose certain label language (including notification) and product stewardship measures to address the concerns noted in the incidence report. With that, OREB will consider basing the REI solely on the adverse kidney effects and cancer.

cc (w/attachment):
J. Evans
A. Ertman (SRRD [7508W])
Correspondence File,
Chemical File (081901).

RDI:ActSecHd:FDGriffith:8/20/96:ActBrSrSci:SHummel:8/21/96.

Attachment

b. Entry to perform routine hand labor tasks. EPA proposed to allow worker entry into treated areas after sprays have dried or dusts have settled, but before the REI has expired, to perform any activity, if the workers are provided appropriate personal protective equipment, training, and decontamination facilities. The Agency anticipated that agricultural producers seldom would require workers to enter treated areas before the REI has expired because of the increased risk to the workers, the cost of providing personal protective equipment, and the problems of heat-related illnesses. It is expected that most agricultural management practices can be carried out after the REI expires; thus, few workers would need these protective measures.

Numerous commenters, including farmworker representatives and advocacy organizations, occupational health service organizations, legal service organizations, universities, and State agencies, oppose any early entry. Evergreen Legal Services (Ref. C98) stated: "It is an exercise in fantasy to imagine that whole crews of workers sent in to weed or harvest will be fitted with PPE, receive training, decontamination facilities, etc." The University of Arizona Rural Health Office (Ref. C103) stated: "Given hot weather and cost of equipment, the most viable way to protect farmworkers is by keeping them out of the fields until it is safe."

> The California Department of Food and Agriculture (Ref. C248) stated in its comments that: The EPA proposal for an additional layer of clothing, rubber boots, goggles, respirator, and carrying individual eyewash bottles is not practical [for field workers]. These measures are not likely to be adhered to in many situations without constant monitoring.

The Farmworker Justice Fund, Inc. (Ref. C157) commented:

> The reentry interval should be treated as a quarantine period so that the concept of routine early reentry workers should be eliminated. . . [T]he agency's proposal undercuts the protective purpose of the reentry interval. . . . Nor has the agency offered any health or safety justification for eliminating this long established modicum of protection. The agency comment that it expects that few workers will be required to reenter before expiration of the reentry interval is ludicrous. Many poisoning incidents occur precisely because workers are required to enter before the reentry interval. . .

The Migrant Legal Action Program (Ref. C126) states:

> The whole purpose of a quarantine period is to keep nonhandlers OUT of the pesticide-treated area until the time period has expired. Dr. Richard Fenske of Rutgers University, in a paper prepared in January 1986 . . . states that, "The use of protective clothing among fieldworkers appears impractical for a number of reasons, including possible heat stress, discomfort, and loss of work efficiency."

A few other commenters specifically supported the proposal that early entry be permitted with the use of personal protective equipment. The North Carolina Farm Bureau Federation (Ref c180) commented:

> . . . we feel that an absolute prohibition to routine hand labor is excessive, and that routine hand labor should be allowed if the worker is wearing such personal protective equipment as may be required by EPA.

Most growers and grower organizations did not comment on the issue of allowing workers to enter areas before the expiration of the REI. The National Council of Agricultural Employers (Ref C71) seemed to imply that routine early-entry activities were not probable when they commented: ". . . for some crops 48 hours represents the maximum REI feasible under current crop production techniques." Florida Citrus Mutual (Ref C88) and other growers stated that REI's may be costly to workers because they may be inactive during intervals when other work cannot be scheduled. They also said:

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R117847

Chemical: Chlorothalonil

PC Code:
081901
HED File Code: 12100 Other Exposure Documents
Memo Date: 8/21/1996
File ID:
Accession #: 412-06-0009

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