Department of Pesticide Regulation

Mary-Ann Warmerdam
Director

MEMORANDUM

Arnold Schwarzenegger
Governor

TO: Tracy Perry, Chemical Review Manager
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FROM: Susan Edmiston, Chief
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DATE: September 25, 2007

SUBJECT: ENDOSULFAN – RESPONSE TO US EPA'S COMMENTS ON DPR'S RISK CHARACTERIZATION DOCUMENT

Enclosed is the Department of Pesticide Regulation (DPR) Worker Health and Safety Branch's response to the United States Environmental Protection Agency's comments on DPR's risk characterization document (RCD) for the pesticide active ingredient, endosulfan.

If you have questions concerning the draft RCD, please contact Ms. Susan Edmiston at (916) 445-4222.

Enclosures

cc: William Hazel, Branch Chief, US EPA (copy w/enclosures)
Susan Edmiston, Chief (e-copy)
Joseph Frank, Senior Toxicologist (e-copy)

dpr Department of Pesticide Regulation

Mary-Ann Warmerdam
Director

MEMORANDUM

Arnold Schwarzenegger
Governor

TO: Joseph P. Frank, Senior Toxicologist
Worker Health and Safety Branch

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DATE: September 14, 2007

SUBJECT: RESPONSE TO U.S. ENVIRONMENTAL PROTECTION AGENCY REVIEW OF ENDOSULFAN RISK CHARACTERIZATION DOCUMENT, DATA PACKAGE ID NO. 221606

The California Department of Pesticide Regulation's (CDPR's) revised final draft Risk Characterization Document (RCD) for endosulfan, dated December 5, 2006, was sent for external peer review. The RCD includes DPR's Exposure Assessment Document (EAD). Staff from the Health Effects Division (HED) U.S. Environmental Protection Agency (U.S. EPA) responded with a review of the RCD, dated January 31, 2007 (Wilbur *et al.*, 2007). The review noted differences between the RCD and U.S. EPA's "upcoming 2007 risk assessment." U.S. EPA did not find fault with CDPR's approach, but only noted differences.

Section IV of Wilbur *et al.* (2007) addresses the occupational and residential exposure assessment. This section begins with five statements contrasting approaches to exposure assessment by the agencies. Tables 2 and 3 follow these statements. The tables report specific differences between the occupational handler and occupational post-application exposure assessments, respectively. Responses to the statements are given below; an explanation of CDPR's approach, and how it differs from U.S. EPA, follows each statement. Responses to Tables 2 and 3 follow.

Statements

1) The duration measured: CDPR measured short-term (1-7 days), seasonal (1 week to 1 year), and annual. HED measured short-term (1-30 days), and intermediate-term (1-6 months).

Response: CDPR policy on exposure durations is described in Andrews (2001). CDPR considers the short-term duration to include any exposure that persists for seven days or less. CDPR considers short exposure durations to be important because although an organism can generally tolerate a relatively high exposure for a short period than it can for a longer period, some adverse effects can be produced in a short duration if the exposure is sufficient. In most exposure scenarios, exposure levels are not constant, and if

exposures are estimated over intervals of several days or weeks, short intervals with elevated exposure are balanced with intervals of lower exposure, possibly resulting in an underestimate of risk.

In the absence of information that intermediate- and long-term exposures do not occur, CDPR adopts a health-protective approach toward individuals potentially exposed for longer durations. Thus, seasonal and annual exposures are included in the risk assessment. For some scenarios in the endosulfan EAD (e.g., thinning almonds), pesticide use data reported to CDPR suggest limited use on the crop involved, precluding longer exposure durations. Only short-term exposures were estimated for these scenarios.

2) CDPR uses the Pesticide Handlers Exposure Database (PHED), but adjusts the values. For short-term exposure, CDPR applies an upper confidence limit (UCL) factor on the 95th percentile. The UCL multiplier is 5 for replicates of ≥20 and is 4 for replicates <20. For seasonal and annual exposure, CDPR applies an upper confidence limit factor to the arithmetic mean. The UCL multiplier is 1 if the replicates are >15. HED uses central tendency estimates and does not adjust PHED values.

Response: With respect to handler exposures based on PHED, CDPR policy differs from U.S. EPA policy both in estimating 95th percentile upper bound exposures for short-term exposure durations, and in adjusting results from PHED to approximate UCLs on the mean and the 95th percentile (Powell, 2002).

CDPR uses the 95th percentile upper bound to estimate short-term exposure because doing so allows CDPR to protect individuals exposed to pesticides as a result of legally-permitted uses. Protecting only those exposed at the "average" level, by relying solely on central tendency estimates, would allow many individuals (i.e., anyone with an above-average exposure) to be exposed to potentially acutely toxic concentrations. For intermediate- and long-term exposure durations, CDPR assumes that a handler encounters a range of daily exposures (i.e., CDPR assumes that with increased exposure duration, repeated daily exposure at the upper-bound level is unlikely). To estimate the average, CDPR uses the arithmetic mean of daily exposure.

Additionally, when exposure estimates are based on PHED, UCLs are used to increase confidence in these estimates. Although there is uncertainty inherent in any estimate based on data, CDPR finds that additional uncertainty is introduced by using PHED data, as the relevance to a target scenario usually cannot be fully assessed due to incomplete information about the application equipment and other aspects of the scenario.

However, PHED reports only average exposures. Estimating upper bounds (including 95th percentiles) and UCLs requires also knowing the standard deviation. Thus, instead of

calculating the needed UCLs, they are approximated. Two assumptions are required for this approximation: first, that exposures are lognormally distributed, and second, that exposures have a coefficient of variation (CV) of 100 percent. The UCL multipliers were derived from these assumptions.

3) CDPR assessed the worse-case (highest transfer coefficient) for major crop groupings and HED assessed all crops and all transfer coefficients applicable to each crop.

Response: Both CDPR and U.S. EPA group crops and reentry activities into relatively few exposure scenarios. Such grouping is necessitated by the limited exposure monitoring data available. In addition, little information is available for many scenarios, and several scenarios are likely to result in overlapping ranges of exposures.

CDPR and U.S. EPA recognize very similar crop and activity groupings. U.S. EPA provides exposure estimates for each of these groups. In contrast, in its risk assessments CDPR determines representative scenarios by first grouping crops then selecting representative scenarios within each group that would be anticipated to have the highest potential for exposure. Scenarios grouped under a representative scenario are not all expected to have identical exposures; however, the representative scenario is anticipated to involve exposures similar to or greater than all scenarios covered by it. In other words, representative scenarios might overestimate exposure for other scenarios, but should not underestimate exposure.

The principle behind CDPR's approach is that each representative scenario is protective of other scenarios it represents; if the representative scenario does not result in unacceptable risk, then all scenarios grouped with it also do not result in unacceptable risk. CDPR uses this approach to simplify its document for the reader. Scenarios covered by each representative scenario are spelled out in the exposure assessment, allowing scenario-specific exposure and risk estimates to be readily determined if needed.

4) CDPR assessed public exposure to ambient air and to bystanders estimating the concentration of endosulfan in the air and uptake of endosulfan from the air. HED typically does not assess this exposure scenario unless specifically triggered by physical properties, use pattern, and/or incident data.

Response: CDPR policy requires comprehensive risk assessment, which includes exposures of members of the public to airborne pesticide residues. Ambient air and application site air monitoring conducted in California detected endosulfan, suggesting that the public may be exposed to airborne endosulfan.

5) CDPR assessed swimmer exposure using the Swimodel. HED does not assess this exposure scenario unless a pesticide is directly applied to a body of water or swimming pool.

Response: CDPR policy requires comprehensive risk assessment, which includes exposures of members of the public to pesticide residues in water. Endosulfan residues have been detected in surface waters in California, suggesting that exposures can occur to individuals swimming in surface waters. Although CDPR is aware that Swimodel is not generally used by HED to estimate swimmer exposures to pesticides that have not been intentionally added to surface waters, the model should be equally valid for pesticides that have not been intentionally added to a body of water. CDPR considers Swimodel to give the best available estimates of swimmer exposures.

Table 2

Table 2 lists specific differences between the occupational handler exposure assessments conducted by U.S. EPA and CDPR. The table consists of three columns, the first of which is titled, "Occupational Handler Exposure Data." The second and third columns summarize how CDPR and U.S. EPA estimated specific exposures. In the list below, each item is labeled with text from the first column, followed by a brief explanation of the difference between agencies.

- **Dermal Absorption:** Both U.S. EPA and CDPR based dermal absorption estimates on the same study (Craine, 1988). This study monitored female rats up to 168 hours following a dose that was administered for 10 hours. Because of the large amount of bound skin residues that continued to be absorbed throughout the study, both U.S. EPA and CDPR based dermal absorption estimates on measures taken 168 hours post-dose. However, CDPR included bound skin residues in the absorbed dose estimate, whereas U.S. EPA did not. Furthermore, at 168 hours absorption of the mid-level dose was slightly higher than the low-dose absorption (45%, excluding bound skin residues) that U.S. EPA used. The dermal absorption estimate used by CDPR (46.7%) is the mean penetration of the two lowest doses (46.5% and 48.0%, including bound skin residues).

- **Body Weight:** In calculating exposure estimates, CDPR assumes a body weight of 70 kg (Thongsinthusak *et al.*, 1993). Similarly, in its publicly available Reregistration Eligibility Decision (RED) and risk assessment (U.S. EPA, 2002a; 2002b) assumed a body weight of 70 kg. However, Wilbur *et al.* (2007) state that in the pending 2007 risk assessment U.S. EPA will make the following body weight assumptions: "60 kg for dermal; 70 kg for inhalation." U.S. EPA (1997) guidance recommends that exposure assessors "use 60 kg for females when the selected

endpoint is from a reproductive or developmental study." Wilbur *et al.* (2007) note that "The major reason for the Agency's 2007 revision to the 2002 risk assessment is the completion and subsequent review by HED of a developmental neurotoxicity (DNT) study." Unlike U.S. EPA, CDPR does not alter body weight assumptions in exposure estimates due to critical endpoints selected in risk assessment.

- **Duration Assessed:** U.S. EPA (2002b) states assumptions that handlers are exposed "short-term only (one day to one month)," and reentry workers are exposed short-term and intermediate-term (one month to one year). No explanation was given by U.S. EPA (2002b) for only considering short-term scenarios for handlers, although an explanation was provided for considering intermediate-term exposures: "Postapplication workers are assumed to be exposed continuously to endosulfan, since endosulfan is used on over 50 crops and an occupational worker could move from treated field to treated field." In the absence of evidence that a handler might be exposed for intermediate- or long-term durations, U.S. EPA only estimated short-term exposures. In contrast, CDPR includes estimates for long-term exposures for handler and reentry scenarios (as well as intermediate-term exposures for handlers), because no information is available on exposure durations and it is possible that both commercial applicators and reentry workers might be repeatedly exposed.

- **Unit Exposure Value Source:** Both CDPR and U.S. EPA based the majority of handler exposures on PHED, as well as on the Agricultural Handlers Exposure Task Force (AHETF) study for open-cab airblast application. U.S. EPA (2002a) substituted studies submitted by Outdoor Residential Exposure Task Force for PHED to estimate handgun and low pressure handwand scenarios, and an AHETF study of closed system mixing/loading to support aerial application. CDPR has not completed its review of these studies, and has continued to rely on PHED for these scenarios.

- **PHED Unit Exposure Value Adjustments:** U.S. EPA policy is to use only central tendency estimates from PHED (U.S. EPA, 1999). In contrast, CDPR uses upper-bound estimates when estimating short-term exposure, and an estimated UCL to approximate the arithmetic mean when estimating intermediate- and long-term exposures from PHED. See the response to Statement 2, above, for a more detailed explanation.

- **Airblast (Carbaryl) Unit Exposure Value Adjustments:** U.S. EPA based exposure estimates for airblast applicators on geometric mean unit exposure values from an open-cab airblast exposure monitoring study (Smith, 2005). CDPR used data from the same study, but rather than basing estimates on the geometric mean, CDPR used the 95th percentile upper-bound for short-term exposure and the arithmetic

mean for long-term exposure. No additional adjustment was required, and the data were not adjusted in the same way as PHED data (i.e., no UCL was calculated).

- **Mixing/Loading Liquids:** As U.S. EPA's risk assessment included recommendations for measures to mitigate unacceptable risks, a variety of exposure estimates were provided for each scenario, assuming different levels of clothing and personal protective equipment (PPE). In contrast, risk assessment and risk mitigation proceed in sequence at CDPR, and potential mitigation measures are not considered in the risk assessment. Instead, when CDPR estimates exposure for each scenario, only the clothing, PPE, and engineering controls required by product labels and regulations are assumed. Any scenarios for which risks are considered unacceptable are subject to mitigation after the exposure and risk assessments are completed.

- **Mixing/Loading Wettable Powder:** See the previous response; CDPR estimates assume only the clothing and PPE required by product labels and regulations.

- **Aerial Application:** See above response to comment on mixing/loading liquids. CDPR estimates assume only the clothing, PPE, and engineering controls required by product labels and regulations.

- **Groundboom Application:** See above response to comment on mixing/loading liquids. CDPR estimates assume only the clothing, PPE, and engineering controls required by product labels and regulations.

- **Airblast Application:** See above response to comment on mixing/loading liquids. CDPR estimates assume only the clothing, PPE, and engineering controls required by product labels and regulations.

- **Flaggers:** See above response to comment on mixing/loading liquids. CDPR estimates assume only the clothing, PPE, and engineering controls required by product labels and regulations.

- **Mixer/Loader/Applicators (backpack, low-pressure handwand, high-pressure handwand and handgun applications):** See above response to comment on mixing/loading liquids. CDPR estimates assume only the clothing and PPE required by product labels and regulations.

- **Mixer/Loader/Applicators (dip applications):** U.S. EPA and CDPR both estimated exposure for mixing/loading liquids with a closed system, and for open-pour mixing/loading of wettable powders. CDPR did not estimate exposure during

open-pour mixing/loading liquids because that is prohibited in California for Toxicity Category I liquids.

- **Worse-Case Scenario Selection: Aerial:** CDPR estimated handler exposures associated with aerial applications to tree nuts, using the maximum rate allowed on product labels in California (2.5 lbs AI/acre). U.S. EPA also estimated exposure for this scenario, but used the maximum rate allowed in any state (3.0 lbs AI/acre). However, U.S. EPA also estimated exposure for a high-acre application to cotton, assuming an application rate of 1.5 lbs AI/acre and 1,200 acres treated/day. CDPR will consider whether to include this scenario in the revised EAD; a study recently submitted by Agricultural Handlers Exposure Task Force, which is being reviewed by CDPR, might result in substantially lower exposures for this scenario.

- **Worse-Case Scenario Selection: Groundboom:** CDPR estimated handler exposures assuming application of 2.0 lbs AI/acre to 80 acres/day. U.S. EPA estimated exposures with these assumptions, but also estimated exposure for a high-acre application to cotton and sorghum, assuming an application rate of 1.5 lbs AI/acre and 1,200 acres treated/day, according to Wilbur *et al.* (2007). The high-acre scenario for groundboom should probably assume 200 acres/day (U.S. EPA, 2001). CDPR will consider whether to include this scenario in the revised EAD.

- **Worse-Case Scenario Selection: Airblast:** CDPR estimated handler exposures associated with airblast applications to tree nuts, assuming the maximum rate allowed on product labels in California (2.5 lbs AI/acre). U.S. EPA estimated exposure for this scenario assuming the maximum rate allowed in any state (3.0 lbs AI/acre).

- **Worse-Case Scenario Selection: Backpack and Low-Pressure Handwand:** CDPR estimated handler exposures associated with these applications using the maximum rate allowed on product labels in California of 0.01 lb AI/gallon. U.S. EPA also estimated exposure for this scenario, but used the maximum rate allowed in Southeastern states of 0.025 lb AI/gallon.

- **Worse-Case Scenario Selection: Handgun and High-Pressure Handwand:** See the previous response; the maximum application rate allowed in California is less than the maximum allowed in Southeastern states.

- **Worse-Case Scenario Selection: Dip:** Wilbur *et al.* (2007) state that U.S. EPA assumed that handlers would prepare and use a maximum of 100 gallons dipping solution per day, and that CDPR did not specify a maximum number of gallons/day. However, CDPR estimates assumed that handlers would prepare and use 40

gallons/day. CDPR is not aware of any information regarding amounts of solution prepared or used during nursery stock dipping, and U.S. EPA (2002a) states that there are no data for this scenario. CDPR selected 40 gallons/day because product labels give directions to prepare a 40-gallon batch.

Table 3

Table 3 lists specific differences between the occupational reentry exposure assessments conducted by U.S. EPA and DPR. The table consists of three columns, the first of which is titled, "Occupational Postapplication Exposure Data." The second and third columns contain entries taken from the CDPR and U.S. EPA exposure assessments. In the list below, each item is labeled with text from the first column, followed by a brief explanation of the difference between agencies.

- **Dermal Absorption:** Duplicate from Table 2. CDPR included bound skin residues in the dermal absorption estimate, and U.S. EPA did not. See response to Table 2 comment above.

- **Body Weight:** Duplicate from Table 2. In calculating exposure estimates, CDPR assumes a default body weight of 70 kg; U.S. EPA assumes a default body weight of 70 kg unless the critical endpoint is based on a reproductive or developmental study, in which case a 60-kg body weight is assumed. See response to Table 2 comment above.

- **Duration Assessed:** Duplicate from Table 2. U.S. EPA estimated reentry exposure for short- and intermediate-term exposures, and CDPR also estimated exposure for long-term exposure durations. See response to Table 2 comment above.

- **Short-Term Assumptions:** CDPR estimates a reasonable worst-case exposure for each representative scenario and exposure duration. In contrast, U.S. EPA estimates exposure in daily increments until the Margin of Exposure (MOE) exceeds their level of concern. When estimating harvester exposures, U.S. EPA does not consider the pre-harvest interval (PHI), whereas CDPR assumes that harvesters do not enter before expiration of the PHI. CDPR acknowledges this as a potential source of error in the exposure assessment, but believes that failure to consider the PHI could result in extreme overestimates of exposure, especially in cases where the PHI greatly exceeds the restricted entry interval (REI).

- **Personal Protective Equipment:** No difference between CDPR and U.S. EPA.

- **Exposure Route Assessed:** No difference between CDPR and U.S. EPA.

- **DFR Data Used:** Wilbur *et al.* (2007) state that CDPR failed to indicate which DFR data were used to represent which crops. That information is summarized in Table 10 in the EAD.

- **Crop Scenarios Assessed: Scenario: Almond, Thinning:** CDPR used an estimated TC of 500 cm^2/hr for thinning (erroneously stated in the EAD as 1,500 cm^2/hr), whereas U.S. EPA used an estimated TC of 2,500 cm^2/hr for hand harvesting and hand pruning. Both TCs are defaults from U.S. EPA policy (U.S. EPA, 2000). CDPR did not estimate exposure for hand harvesting of almonds because harvesting in California is done mechanically (Connell *et al.*, 2006; Duncan *et al.*, 2006). Although "hand harvesting" is sometimes done with a rubber mallet, this consists of pounding on the tree trunk with the mallet. As with mechanical harvesting, nuts are collected on a tarp and no foliar contact is involved. CDPR did not estimate exposure for hand pruning because in California that activity occurs following harvest and during the dormant season (Connell *et al.*, 2006; Duncan *et al.*, 2006), and endosulfan product labels specify early-season applications prior to petal fall.

- **Scenario: Broccoli, Hand Harvesting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Broccoli, Scouting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Citrus, Thinning:** U.S. EPA calculated only the exposure following application to nursery stock, as neither thinning nor harvesting are anticipated activities in non-bearing citrus. CDPR erroneously estimated exposure to workers thinning and harvesting citrus, although product labels specifically prohibit application to trees that will bear fruit within a year. Exposure estimates for this scenario will be corrected when the EAD is revised.

- **Scenario: Sweet Corn, Hand Harvesting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Cotton, Scouting:** U.S. EPA used an estimated TC of 2,000 cm^2/hr, from a study in which exposure of scouts in dry peas was monitored (U.S. EPA, 2000). CDPR used an estimated TC of 2,000 cm^2/hr, from exposure monitoring studies of cotton scouts (Dong, 1990).

- **Scenario: Cucumber, Hand Harvesting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Grape, Cane Turning:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Lettuce, Scouting:** CDPR used an estimated TC of 1,500 cm^2/hr for scouting, whereas U.S. EPA used an estimated TC of 2,500 cm^2/hr for hand harvesting as well as 1,500 cm^2/hr for scouting. Both TCs are defaults from U.S. EPA policy (U.S. EPA, 2000). Because lettuce has a preharvest interval (PHI) of 14 days, and a restricted entry interval (REI) of 2 days, CDPR used scouting to covering all activities in lettuce. Although the TC for harvesting is greater than the TC for scouting, the DFR at the expiration of the REI is much higher than the DFR at the expiration of the PHI, resulting in higher exposure estimates for scouting than for harvesting.

- **Scenario: Ornamental Plants, Hand Harvesting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Ornamental Cut Flowers, Hand Harvesting:** CDPR used an estimated TC of 7,000 cm^2/hr, from U.S. EPA policy based on an exposure monitoring study conducted in Europe (Brouwer *et al.*, 1992; U.S. EPA, 2000). U.S. EPA used an estimated TC of 5,100 cm^2/hr, from a study submitted by Agricultural Handlers Exposure Task Force. CDPR has not completed review of that study, and continues to use the TC from U.S. EPA (2000).

- **Scenario: Peach, Thinning:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Potato, Scouting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Strawberry, Hand Harvesting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Tomato, Hand Harvesting:** No difference in CDPR and U.S. EPA assumptions.

- **Scenario: Public Exposure to Ambient Air and to Bystanders:** CDPR estimated exposures for this scenario. U.S. EPA did not.

- **Scenario: Swimmer Exposure:** CDPR estimated exposures for this scenario. U.S. EPA did not.

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