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Human health risk assessment of endosulfan. Part IV: Occupational reentry and public non-dietary exposure and risk

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ABSTRACT

The California Department of Pesticide Regulation (CDPR) and the United States Environmental Protection Agency (USEPA) released revised draft risk assessments for the pesticidal active ingredient, endosulfan, just 2 months apart, in November 2007 and January 2008. The exposure estimates, critical to risk assessment, were calculated by each agency using dissimilar approaches in certain aspects. The scenarios for which exposures and risks were estimated also varied somewhat between the two agencies, although there were substantial overlaps that allowed specific comparisons of exposure and risk estimates. Reasons underlying major differences in estimates of exposure for field workers working in treated crops (reentry exposure) are discussed in this paper. Differences in dislodgeable foliar residue levels calculated by CDPR and USEPA, reflecting endosulfan residues encountered by field workers entering treated orchards and fields, contributed the most to discrepancies in reentry exposure estimates between the two agencies. Additionally, because of differences in legal mandates CDPR estimated exposures for members of the public exposed to endosulfan in ambient air and when swimming, whereas USEPA did not. Exposures calculated for bystanders adjacent to a pesticide application suggest a potential health concern, but estimated swimmer exposures did not.

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1. Background

Risk assessment of pesticidal active ingredients (AIs) including endosulfan is conducted by the California Department of Pesticide Regulation (CDPR) and the United States Environmental Protection Agency (USEPA). CDPR and USEPA have authority to regulate pesticides, respectively, within the US and within the state of California. Use of pesticides in California is regulated by both CDPR and USEPA. By law, CDPR is allowed to register only pesticides that are registered by USEPA, but it can place additional restrictions on use beyond those required by USEPA. Such restrictions may be needed because of California's climate, which consists of cool, rainy winters, and hot, dry summers. California receives little or no rainfall during a typical growing season, and pesticide residues can take longer to dissipate under dry conditions than in the humid conditions occurring in many other states. Several endosulfan product labels have California-specific application directions, which in some cases require lower application rates, fewer applications per year, or additional time following applications before workers are allowed to perform tasks in treated fields.

Not only does the scope of responsibility differ between the two agencies, but legislation under which they operate differs, including the legal requirements under which the agencies conduct risk assessments on pesticides. CDPR performs risk assessments for currently registered pesticides under multiple sections of the California Food and Agriculture Code. Additionally, California has laws intended to limit ambient air concentrations of pesticides, including the Toxic Air Contaminants Act (California Health and Safety Code, Sections 39650–39761), which codifies the state program to evaluate and control toxic air contaminants (TACs). A pesticide is placed on the TAC list if its concentrations in ambient air are within an order of magnitude of the concentration that has been determined to be adequately protective of human health.

In contrast, USEPA performs risk assessments to meet requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); for example, FIFRA Section 2(bb), codified in the US Code at Title 7, Section 136(2)(bb), requires USEPA to determine that allowed pesticide uses do not cause "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits." FIFRA does not specifically require USEPA to estimate ambient air exposures to pesticides.

USEPA performs quantitative risk assessments for reregistration purposes as required by FIFRA. Uses are eligible for reregistration following one of two determinations by USEPA: (1) the use is associated with acceptable risks, or (2) uses may have unacceptable risks yet have favorable risk–benefit results that trigger USEPA to

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allow reregistration. For uses that do not meet these criteria, a registrant desiring to reregister a use may negotiate changes such as lower application rates or longer restricted entry intervals (REIs) for field workers in agricultural production. USEPA will sometimes consider these proposed changes in its exposure assessment; i.e., exposure estimates may not reflect current product labels. Exposure assessments prepared by USEPA consider a range of conditions, and post-application exposures are estimated from the day of application through as many days as needed to get acceptable risk estimates. USEPA may recommend changes in some or all REIs based on these risk estimates. Diverse requirements and approaches to exposure assessment, such as those described in this paper, can result in differing exposure estimates for the same AI.

Exposure and risk assessments for endosulfan were released for public comment by USEPA in November 2007 (USEPA, 2007a) and by CDPR in January 2008 (Beauvais, 2008; Silva, 2008). USEPA (2007a) was a revised risk assessment that incorporated data submitted in response to requirements in the Reregistration Eligibility Decision (RED) released in 2002 (USEPA, 2002). Differences between the two agencies in reviewing toxicity data and identifying hazards associated with endosulfan exposure, including "no observed effect levels" (NOELs), are addressed by Silva and Beauvais (2009). With regard to exposure and risk estimates calculated by CDPR and USEPA, Silva and Carr (2009) compare endosulfan dietary assessments, and Beauvais et al. (2009) compare exposures and risks associated with mixing, loading, and applying endosulfan. This paper discusses key differences between CDPR and USEPA in reentry exposure estimates and CDPR's estimates of endosulfan non-dietary exposure to the public.

2. Endosulfan use

Endosulfan is a chlorinated insecticide and miticide that is used on more than 50 crops in California, and on additional crops in other states. Endosulfan formulations registered in California include an emulsifiable concentrate (EC) containing 34% AI and a wettable powder (WP) containing 50% AI; other EC formulations containing 9–24% endosulfan are registered by USEPA but are not registered in California.

California requires reporting of all agricultural applications of pesticides, as well as other applications made by a licensed applicator. These data are collected in CDPR's Pesticide Use Report (PUR) database. Fig. 1 summarizes endosulfan use (reported in thousands of pounds) in California over the 15-year interval 1993–2007. During that time, use peaked in 1994 at 477,187 lb (219,903 kg) then decreased by nearly an order of magnitude, to 52,403 lb (23,820 kg) in 2007. The majority of endosulfan use in this interval was on tomatoes, lettuce, alfalfa and cotton; together, these crops accounted for 84% of pounds applied in 2007. While remaining fairly consistent on alfalfa, lettuce, and tomatoes, endosulfan use on cotton has decreased in recent years, as fewer acres of cotton have been planted in California (CDPR, 2006). During the interval 1993–2007, acres of cotton harvested ranged from a high of 1.2 million acres (490,000 ha) in 1995 to a low of 450,000 acres (180,000) in 2007 (USDA, 1996, 2008).

Nationally, USEPA (2002) estimated endosulfan use to be about 1.38 million pounds (626,000 kg) annually. The top crops treated with endosulfan in the US are cotton, tomatoes, pome fruits including apples and pears, and potatoes. USEPA (2007c) estimated that 258,900 lb (117,400 kg) is applied each year to cotton, with use in Arizona and California accounting for 54% of that amount. A total of 106,500 lb (48,300 kg) is used annually on tomatoes; 88% of that total is in Florida and California. An annual average of 104,100 lb (47,200 kg) is applied to apples and pears, 71% of that is in Oregon, Washington, and Idaho. Potatoes receive an average of 84,500 lb (38,300 kg) of endosulfan, with 89% of use occurring in the Northern Plains states of Colorado, Minnesota, North Dakota, and Wisconsin (USEPA, 2007c).

3. Exposure scenarios

In quantitative risk assessments prepared by CDPR and USEPA, numerical risk estimates are calculated for each exposure scenario from estimates of toxicity and scenario-specific exposure estimates. An exposure scenario is a situation in which exposure may occur, defined by combinations of factors such as product formulation, use site, and specific activities. USEPA (2004) notes that, "[a]n exposure scenario generally includes facts, data, assumptions, inferences, and sometimes professional judgment about how the exposure takes place."

Only agricultural uses are allowed for endosulfan; in 2000, USEPA canceled all residential uses at the request of the registrants (USEPA, 2002). These cancellations are effective in California as well, and risk assessments by CDPR and USEPA assume that all exposures associated with endosulfan use occur during or following agricultural applications.

3.1. Reentry scenarios

Following applications, field workers can potentially be exposed to endosulfan when they enter fields or orchards that have been

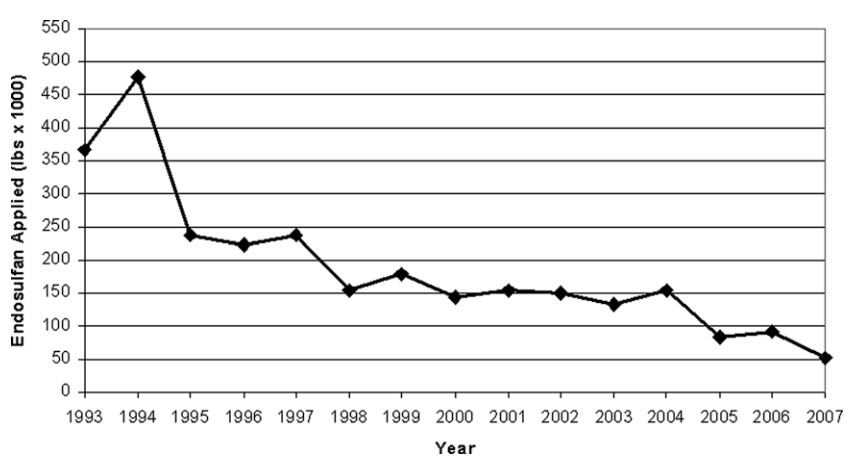

Fig. 1. Endosulfan use reported in California from 1993 to 2007 (thousands of pounds). Each point represents use reported throughout the state for a calendar year.

treated with pesticides. Such entry following treatment is termed "reentry" or "post-application" to emphasize the fact that a pesticidal application has occurred. A reentry scenario describes any situation where individuals may contact residues from previously applied pesticides. Reentry exposure scenarios are generally defined by combinations of treated crops and activities by field workers in those crops (product formulation might be specified as well, if available data suggest that reentry exposures differ between formulations).

Table 1 lists all reentry scenarios considered by CDPR and USEPA for two example crops on which endosulfan can be used, as well as the exposure potential each agency associated with a given scenario. In its assessment, USEPA provided exposure estimates for each exposure potential group for each crop. For example, USEPA (2007a) presented exposure estimates for low, medium, and high exposure-potential activities in broccoli; for grapes, USEPA calculated estimates for four exposure-potential activities groups, low, medium, high, and very high. USEPA determined a single pesticide residue transfer coefficient (TC) for each exposure potential group in each crop.

The TC is a parameter estimating rate of contact between the worker and treated plant surfaces, especially foliage. For most scenarios (including all activities in broccoli and all but one activity in grapes as listed in Table 1), CDPR and USEPA use the same TCs. The extent of worker contact with treated foliage depends on the crop height and fullness of the foliage; thus, the same activity, such as irrigation, can have different TCs in different crops. Broccoli plants are low-growing crops with full foliage when mature, and moving irrigation pipes can result in substantial contact with foliage. Although grape vines are taller, they often have more open space between rows than broccoli, resulting in a relatively low exposure potential for irrigation.

In grapes, USEPA uses a TC of 5000 cm^2/h for leaf pulling, based on an assumption that leaf pulling is similar to hand harvesting of raisin grapes (USEPA, 2000). In contrast, CDPR considers leaf removal to be a canopy management activity with similar exposure to cane turning (O'Connell et al., 1993), and uses a TC of 10,000 cm^2/h.

Both CDPR and USEPA group crops and reentry activities into a finite number of exposure scenarios. Such grouping is necessitated by the limited exposure monitoring data available, as little information is available for many scenarios. Furthermore, many scenarios are likely to have overlapping ranges of exposures. CDPR and USEPA recognize similar crop and activity groupings.

3.2. CDPR's representative reentry scenarios

To provide a more concise risk assessment, CDPR calculates exposures and risks only for the highest exposure-potential activities. This results in a smaller number of exposure calculations, limited to what CDPR identifies as representative scenarios. USEPA estimated exposure and risk for a total of 272 reentry scenarios, including 136 scenarios each following application of the WP and EC formulations (USEPA, 2007a). In contrast, CDPR assessed only 15 representative reentry scenarios, all following application of the WP as estimated exposures were higher than post-application of the EC (Beauvais, 2008). The representative scenarios are listed in Table 2.

CDPR determines representative scenarios by a two-step process that involves grouping crops then selecting representative scenarios within each crop group. 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 should not result in unacceptable risk. 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. When the risk assessment process has been completed, if CDPR determines that some representative scenarios require mitigation, then during mitigation all scenarios covered by the representative scenario would be individually assessed along with the representative scenario.

In the first step of the process through which CDPR selects representative scenarios, crops are grouped by growth form (e.g., tree)

Table 1
Reentry scenarios considered by USEPA and CDPR in two example crops.

Crop	Activity	Exposure potential	Transfer coefficient (cm^2/h)	Exposure potential	Transfer coefficient (cm^2/h)
		USEPA[a]		CDPR[b]	
Broccoli	Thinning	Low	2000	Low	2000
	Weeding (hand)	Low	2000	Low	2000
	Scouting	Medium	4000	Medium	4000
	Harvesting (hand)	High	5000	High	5000
	Irrigating	High	5000	High	5000
	Harvesting (mechanical)	High	None	Low	None
	Pruning (hand)	High	5000	–	–
	Transplanting	–	–	Low	2000
Grapes(table andraisin)	Hedging	Low	500	–	–
	Irrigating	Low	500	Low	500
	Weeding (hand)	Low	500	Low	500
	Scouting	Medium	1000	Medium	1000
	Leaf pulling	High	5000	High	10,000
	Pruning	High	5000	Medium	5000
	Thinning	High	5000	High	5000
	Training/tying	High	5000	Low	1000
	Cane turning	Very high	10,000	High	10,000
	Girdling	Very high	10,000	High	10,000
	Transplanting	–	–	Low	1000
	Harvest (hand)	–	–	Medium	5000

[a] USEPA exposure potentials and transfer coefficients from USEPA (2007a).
[b] Exposure potentials and transfer coefficients used by CDPR are based in part on USEPA (2000), with additional input from other sources (Beauvais, 2008).

Table 2
Representative reentry scenarios assessed by CDPR and the Margin of Exposure (MOE) calculated by CDPR and USEPA on days chosen by CDPR for short-term and intermediate-term exposures.

Exposure scenario	Short-term			Intermediate-term		
	Day[a]	CDPR	USEPA	Day	CDPR	USEPA
Almonds, thinning	2	**78**	**48**	NA	NA	NA
Broccoli, hand harvesting	4	**23**	**7**	14	148	**28**
Broccoli, scouting	2	**8**	**7**	10	**98**	**20**
Citrus, scouting	2	**39**	**71**	NA	NA	NA
Sweet corn, hand harvesting	2	**1**	**1**	10	**16**	**3**
Cotton, scouting	2	**11**	**24**	10	131	**71**
Cucumbers, hand harvesting	2	**13**	**11**	10	169	**32**
Grapes, cane turning	2	**2**	**2**	10	**8**	**3**
Lettuce, scouting	2	**4**	**18**	10	295	**55**
Ornamental cut flowers, hand harvesting	2	**4**	**6**	NA	NA	NA
Ornamental plants, hand harvesting	2	**78**	**71**	NA	NA	NA
Peaches, thinning	2	**13**	**9**	10	**42**	**21**
Potatoes, scouting	2	**22**	**18**	10	295	**55**
Strawberries, hand harvesting	2	**10**	**9**	NA	NA	NA
Tomatoes, hand harvesting	2	**33**	**27**	10	131	**80**

Bold indicates that MOE is below target MOE of 100.
NA, not assessed. CDPR did not estimate seasonal, annual, or lifetime exposures or risks for workers reentering treated almond or citrus orchards, ornamental flowers or plants, or strawberry fields, because infrequent endosulfan use is reported on these crops. Although USEPA calculated MOEs at 10 days post-application for these crops, those values are not reported here.
[a] Post-application day on which CDPR assessed exposure and risk.

and cultural practices. For endosulfan, CDPR grouped all pome and stone fruit crops; because of differences in numbers of applications allowed and in reentry activities, tree nut crops were grouped separately from tree fruits. Field crops such as cotton and barley were considered together. Lettuce and other leafy vegetables that grow close to the ground were assessed as a group. Tomatoes, eggplants, and peppers, which bear fruit above ground, were considered together, as were crops such as potatoes, carrots, and sugar beets, which are underground. Strawberries and pineapples were grouped together, because their plants are fairly short and the fruit is harvested by hand. The 14 CDPR crop groups used to determine representative reentry scenarios for endosulfan are summarized in Table 3.

After compiling crop groups and determining representative crops for each, CDPR listed reentry scenarios for each representative crop, in a manner similar to the list shown in Table 1 (Beauvais, 2008). From the list of reentry scenarios for each crop, representative scenarios were selected, primarily based on available information about the extent of foliar contact for each activity and the resulting potential for residue transfer. Comparison of Tables 2 and 3 show that for endosulfan CDPR selected one scenario per representative crop, with the exception of broccoli, for which two scenarios were selected.

3.3. Bystander and swimmer scenarios

Both CDPR and USEPA assess exposure and risk for occupational exposure scenarios, including handlers (Beauvais et al., 2009) and reentry workers, as well as risks associated with dietary exposures to endosulfan (Silva and Carr, 2009). In addition to these scenarios, members of the public can be exposed to endosulfan residues in environmental media including air and water. Available data suggest that bystander exposures are possible to individuals who are next to fields during or following endosulfan applications, and airborne endosulfan exposure is possible even in areas that are far from application sites (ambient air exposure). Endosulfan residues have been detected in surface waters in California, suggesting that exposures are possible to individuals swimming in surface waters draining agricultural lands (swimmer exposure). CDPR considered bystander and swimmer scenarios in its risk assessment for endosulfan; USEPA did not.

4. Exposure durations

For each scenario, CDPR provided estimates for short-term (durations from less than a day up to one week), seasonal

Table 3
Crop groups used by CDPR for selecting representative scenarios.

Representative crop	Crops included in group
Almond	Filbert, macadamia nut, pecan, walnut
Broccoli	Brussels sprout, cabbage, cauliflower, chinese cabbage (bok choy), dried beans, succulent beans, peas
Citrus	Orange, etc. (non-bearing trees and nursery stock)
Corn, sweet	Tobacco
Cotton	Alfalfa, barley, oats, rye, sunflower, safflower, wheat
Cucumber	Melons, pumpkin, summer squash, winter squash
Cut flowers	Greenhouse ornamentals
Grape	Juice grapes, raisin grapes, table grapes, wine grapes
Lettuce	Celery, collards, head lettuce, kale, leaf lettuce, mustard greens, spinach, kohlrabi
Ornamental plants	Nursery stock, trees, shrubs
Peach	Apple, apricot, cherry, nectarine, pear, prune, plum
Potato	Carrot, sugar beet, sweet potato (root vegetables)
Strawberry	Pineapple
Tomato	Eggplant, peppers

(intermediate-term intervals, lasting from one week to one year), annual, and lifetime exposures. Seasonal exposure is defined by CDPR as a period of frequent exposure lasting more than a week but substantially less than a year, whether the exposure is constant or intermittent during the period. Annual exposure integrates all exposure periods during the year (Beauvais, 2008). In addition to short-term and seasonal exposures, CDPR estimated long-term exposures (i.e., annual and lifetime) exposures, because no information is available on exposure durations and over a year or multiple years it is possible that reentry workers and bystanders can potentially be repeatedly exposed. Although CDPR estimated the potential for lifetime exposures in its exposure assessment (Beauvais, 2008), as endosulfan is not a carcinogen the lifetime exposure estimates were not used in the risk assessment (Silva, 2008).

Exposure durations considered by USEPA differed somewhat from those considered by CDPR. USEPA defines short-term durations as 1–30 days, and intermediate-term durations as 1–6 months. USEPA (2007a) estimated reentry exposures for both short and intermediate-terms. Post-application (reentry) workers were assumed by USEPA to be exposed continuously to endosulfan for up to 6 months. CDPR assumed reentry exposure durations can vary between crops in proportion to the length of the high-use interval for each crop.

5. Exposure and risk estimates for reentry scenarios

5.1. Timing of reentry

Table 2 lists days at which CDPR assumed reentry when estimating short-term and seasonal exposures for each representative scenario. In estimating short-term reentry exposures for its risk assessments, CDPR assumes reentry at the expiration of the REI for all activities except harvesting. The Worker Protection Standard regulations prohibit work in fields during the REI that results in contact with treated foliage, unless workers wear label-specified protective equipment and clothing (Code of Federal Regulations, Title 40, Section 170.112). Endosulfan product labels specify a "baseline" REI of 24 h, with extended REIs required on some labels for specific crops such as sweet corn. However, California has a regulation that requires an REI of 2 days following endosulfan applications (California Code of Regulations, Title 3, Section 6772). For crops with longer REIs specified on product labels, the longer REIs must be observed.

Although harvesters are allowed to begin work at the expiration of the REI, crops cannot be harvested until the pre-harvest interval (PHI) has expired. The REI is based on worker safety, and is generally the time after which available residues on foliage are estimated to be below levels that would result in unacceptable risk. The PHI is based on pesticide residues in harvested crops, and is intended to decrease risks from dietary exposure. Generally, the PHI is longer than the REI, although in some crops treated with endosulfan it is shorter or the same duration as the REI.

For representative crops where PHI $\leqslant$ REI, harvesting was the only representative activity assessed by CDPR. For crops with PHI > REI, CDPR also included a second activity (e.g., scouting) to ensure that the scenario having the earliest reentry is assessed, and the scenario having the highest exposure was then included in the risk assessment. The earliest reentry is often associated with the highest exposure. For most crops, hand harvesting is the activity having the greatest contact with treated foliage, and can result in the highest exposure potential. However, if harvesting occurs several days after treatment (as required by a longer PHI), then less foliar residue is available for transfer, which results in a lower exposure.

For seasonal and annual exposure durations, reentry workers are expected to encounter a range of daily exposures (i.e., CDPR assumes that with increased exposure duration, repeated daily exposure at the upper-bound level is unlikely). In calculating seasonal and annual exposure estimates, CDPR assumes that workers would enter fields at some average time after the expiration of the REI or PHI, in part because of how frequently specific activities generally occur in the crops of interest (Spencer et al., 2006; UCCE, 2007). Additionally, because there are a limited number of endosulfan applications during intervals when workers are active in crops, it is considered unlikely that workers would consistently reenter soon after an application has occurred. Seasonal and annual exposures were estimated at an assumed average reentry of REI (or PHI, if longer than REI) plus 7–10 days (Beauvais, 2008).

In contrast to CDPR's approach, USEPA estimates exposure in daily increments over several days, usually from the day of application (Day 0) until acceptable risk estimates are achieved (assuming that exposures decrease with time post-application, which is generally the case). When estimating harvester exposures, USEPA does not consider the PHI, whereas CDPR assumes that harvesters do not enter before expiration of the PHI.

5.2. Risk estimates: Margin of Exposure

Risk estimates are calculated by both CDPR and USEPA as Margin of Exposure (MOE) values; the MOE divides the NOEL by the exposure estimate. Table 2 summarizes MOEs estimated by CDPR for short-term and intermediate-term (seasonal) exposures for each representative reentry scenario, along with MOEs calculated by USEPA for the same post-application day. In all but four of the 15 scenarios in Table 2, short-term MOEs calculated by CDPR were higher than those calculated by USEPA. The exceptions were citrus scouting, cotton scouting, lettuce scouting, and cut flower harvesting, in which MOEs calculated by USEPA ranged 1.5- to 4.5-fold higher than MOEs calculated by CDPR. Fig. 2 summarizes ratios of MOEs, exposure, and NOELs for these four reentry scenarios. For cut flower harvesting, USEPA's MOE on Day 2 is 1.5-fold greater than CDPR's, although CDPR estimated a lower exposure (the exposure ratio was 0.8). The critical short-term dermal NOEL selected by USEPA was 1.7-fold higher than the one used by CDPR, which was sufficient to give a higher MOE for cut flower harvesting.

Fig. 3 displays ratios of seasonal (intermediate-term) MOE and exposure for four scenarios in which MOEs calculated by USEPA were 1.8- to 5.4-fold higher than MOEs calculated by CDPR. Two of the scenarios in Fig. 3 had short-term risks summarized in Fig. 2, cotton scouting and lettuce scouting; CDPR did not estimate risks for the other two scenarios in Fig. 2 because endosulfan use is infrequently reported on sweet corn and cut flowers. Two scenarios, hand harvesting broccoli and peach thinning, were substituted

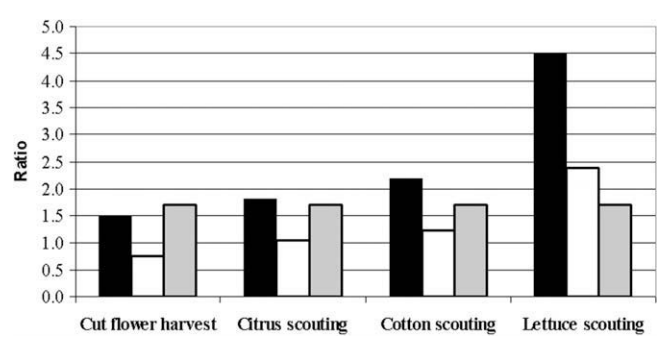

Fig. 2. Comparison of selected short-term reentry dermal risk estimates calculated by USEPA and CDPR. Black bars represent ratios of Margins of Exposure calculated by USEPA/CDPR. White bars represent ratios of dermal exposures calculated by CDPR/USEPA. Gray bars represent the ratio of the "no observed effect level" or NOEL (USEPA/CDPR).

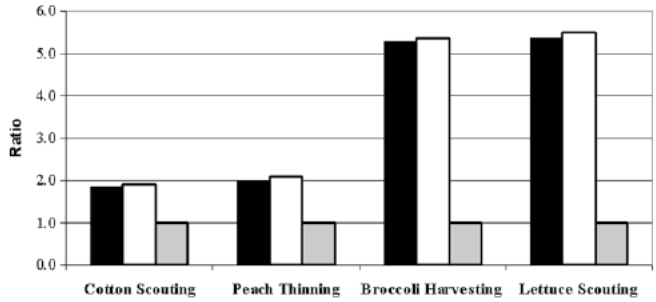

Fig. 3. Comparison of selected intermediate-term reentry dermal risk estimates calculated by USEPA and CDPR. Black bars represent ratios of Margins of Exposure calculated by CDPR/USEPA. White bars represent ratios of dermal exposures calculated by USEPA/CDPR. Gray bars represent the ratio of the "no observed effect level" or NOEL (CDPR/USEPA).

in Fig. 3; the MOE ratio for hand harvesting broccoli was higher than for intermediate-term exposure in any other scenario (5.3), and the MOE ratio for peach thinning was lower than any scenario except cotton scouting (2.0 and 1.8, respectively). The critical NOELs used by CDPR and USEPA for intermediate-term risks were nearly identical, 1.18 and 1.2 mg/kg/day, respectively, for a NOEL ratio of 0.98. Exposure accounted for nearly all the differences in intermediate-term MOEs. Exposure ratios in Fig. 3 range 1.9–5.5.

5.3. Reentry exposure calculations

Studies with several different pesticides suggest that the major route of pesticide exposure for reentry workers is the dermal route (Ware et al., 1973; Popendorf et al., 1979; Zweig et al., 1984, 1985). Contact with treated surfaces, especially foliage, causes pesticide residues to be transferred to the skin. A worker's rate of contact with treated foliage is estimated based on empirical data from studies in which both dislodgeable foliar residue (DFR) and dermal exposure have been measured. The TC for an activity is calculated by dividing DFR from a treated crop into the dermal exposure measured for workers performing reentry activities in the crop: TC (cm^2/h) = [dermal exposure ($\mu g/h$)]/[DFR ($\mu g/cm^2$)]. As the TC depends on the intensity of contact with the contaminated surface, it is activity- and surface-specific; however, TCs are only available for a limited number of activities and crops. When specific TCs were not available, TCs from similar crops and activities were used instead in exposure calculations.

Both CDPR and USEPA estimate reentry exposure as the absorbed daily dosage (ADD), calculated as shown in the equation below (Zweig et al., 1984, 1985). As discussed by Beauvais et al. (2009), CDPR assumed a dermal absorption rate (DA) of 47.3% and USEPA assumed 45%; both values were based on an unpublished study (Craine, 1988). The two agencies also assumed different default body weights (BW), 60 kg by USEPA and 70 kg by CDPR (Beauvais et al., 2009). Both USEPA and CDPR assumed default exposure duration (ED) of 8 h.

$$\mathrm{ADD}(\mu g/kg/day) = \frac{\mathrm{DA} \times \mathrm{DFR}(\mu g/cm^2) \times \mathrm{TC}(cm^2/h) \times \mathrm{ED}(h/day)}{\mathrm{BW}(kg)}$$

CDPR and USEPA used the same assumptions about personal protective equipment (PPE) in calculating reentry exposures. Reentry workers are not required to wear PPE such as respirators, gloves, or chemical-resistant aprons, unless they enter fields before the REI expires. Because a lot of reentry work occurs in hot weather and for several hours each day, PPE is often not worn by fieldworkers unless required for early reentry. In calculating reentry exposure estimates, both CDPR and USEPA assumed that workers wear long-sleeved shirts, long pants, shoes and socks, but do not wear PPE.

Exposure comparisons for scenarios in Figs. 2 and 3 are expressed as ratios. Short-term and intermediate-term exposure estimates for these scenarios are given in Table 4, reported as mg/kg/day. TCs used to calculate the exposures are also listed in Table 4; for three of the four scenarios in Fig. 2, and one of the scenarios in Fig. 3, CDPR used a higher TC than USEPA. For the remaining scenarios in Table 2, CDPR and USEPA used the same TCs.

Table 5 summarizes ratios of four factors contributing to disparities in exposure estimates: DFR, TC, percent dermal absorption, and default body weight. The ratios of these four factors, when multiplied together, equal the ratios of the exposures estimated by CDPR and USEPA. The body weight ratio is <1, indicating that CDPR's assumptions result in lower exposure estimates than USEPA's assumptions. Conversely, the dermal absorption ratios are >1 for all scenarios in Table 5, which indicates that the dermal absorption assumed by CDPR would yield a higher exposure estimate (other factors being equal) than the dermal absorption assumed by USEPA. TC ratios in Table 5 are $\geqslant 1$, as CDPR assumed the same or a greater TC than USEPA. For the remaining representative scenarios not included in Table 5, CDPR used the same TC as USEPA.

The DFR ratio is >1 for two of the four scenarios with short-term exposure ratios in Table 5, cotton scouting and lettuce scouting. The DFR ratio is <1 for the other two scenarios, cut flower harvesting and citrus scouting, because the DFR used by CDPR was less than the DFR used by USEPA. When DFR ratios are calculated for all 15 representative reentry scenarios assessed by CDPR, all are <1 except for cotton scouting and lettuce scouting.

For all four intermediate-term scenarios in Table 5, the DFR ratios are <1, as the DFR used by USEPA was greater than the DFR

Table 4
Exposures estimated by CDPR and USEPA for short-term and intermediate-term reentry exposures in selected scenarios.[a]

Scenario	CDPR		USEPA	
	Transfer coefficient (cm^2/h)	Exposure (mg/kg/day)	Transfer coefficient (cm^2/h)	Exposure (mg/kg/day)
Short-term				
Cut flower harvesting	7000	0.159	5100	0.21
Citrus scouting	1000	0.018	400	0.017
Cotton scouting	2000	0.063	1500	0.051
Lettuce scouting	1500	0.162	1500	0.068
Intermediate-term				
Cotton scouting	2000	0.009	1500	0.017
Lettuce scouting	1500	0.004	1500	0.022
Peach thinning	3000	0.028	3000	0.058
Broccoli harvesting	5000	0.008	5000	0.043

[a] Calculated with the following equation: exposure = [(0.001 $\mu g/mg$) × (dislodgeable foliar residue) × (transfer coefficient) × (dermal absorption)]/(body weight). USEPA assumed a dermal absorption of 45%, and CDPR assumed 47.3%. USEPA assumed a body weight of 60 kg, and CDPR assumed 70 kg.

Table 5
Ratios of factors contributing to differences between short-term dermal exposures estimated by CDPR and USEPA for selected scenarios.

Scenario	Exposure ratio[a]	Dislodgeable foliar residue[b]	Transfer coefficient[b]	Dermal absorption[b]	Body weight[c]
Short-term					
Cut flower harvesting	0.74	0.60	1.37	1.05	0.86
Citrus scouting	1.1	0.49	2.50	1.05	0.86
Cotton scouting	1.2	1.02	1.33	1.05	0.86
Lettuce scouting	2.4	2.65	1.00	1.05	0.86
Intermediate-term					
Cotton scouting	0.53	0.44	1.33	1.05	0.86
Peach thinning	0.48	0.53	1.00	1.05	0.86
Lettuce scouting	0.20	0.22	1.00	1.05	0.86
Broccoli harvesting	0.18	0.20	1.00	1.05	0.86

[a] Ratio of exposure estimated by CDPR to exposure estimated by USEPA.
[b] Ratio of value used by CDPR to value used by USEPA.
[c] Ratio of default body weight assumed by USEPA to CDPR (ratio inverted because exposure calculation divides by body weight).

used by CDPR. In fact, for all 10 representative scenarios for which CDPR estimated intermediate-term exposures, USEPA used higher DFR than did CDPR.

With the exception of citrus scouting, where the TC used by CDPR was 2.5-fold higher and the DFR used by USEPA was twice the DFR used by CDPR (inverting the DFR ratio reported in Table 5), DFR ratios (or their inverses, for ratios <1) were greater than TC, dermal absorption, or body weight ratios, suggesting that for endosulfan the differences in DFR used by the two agencies contributed the most to the divergent reentry exposure estimates. The next section examines how CDPR and USEPA calculate and use DFR.

5.4. Dislodgeable foliar residue

Both CDPR and USEPA define DFR as the pesticide residue removed from both sides of treated leaf surfaces with an aqueous surfactant, and the two agencies assume that DFR is the portion of an applied pesticide available for transfer to humans from leaves and other plant surfaces. Measurements of DFR can be used, along with an appropriate TC, to estimate the amount of pesticide adhering to clothing and skin surfaces following entry into a previously treated field. The DFR is reported as residue per leaf area ($\mu g/cm^2$).

Studies measuring DFR were evaluated by CDPR and USEPA for acceptability based on criteria described in Iwata et al. (1977) and USEPA (1996). For example, there should be no rain events during the study; replicate samples should be collected on more than one day extending at least through the REI; residues should be dislodged from leaf surfaces with a detergent solution (rather than an organic solvent); and ideally, the application rate should be at or near the maximum stated on the product label for the crop (although application rates might not affect the dissipation rate, the relationship has not been studied for endosulfan). CDPR also considered whether DFR studies were performed under climate conditions typical for the crop's growing season in California.

Numerous DFR dissipation studies have been conducted for endosulfan, in which DFR was quantified in foliage sampled over a series of days, typically starting with the day of application (Day 0) and continuing intermittently for a few days to a few weeks. In the main study used by both CDPR and USEPA, Whitmyre et al. (2004) evaluated DFR dissipation following applications of the EC and WP endosulfan formulations on melons, peaches and grapes in Fresno, California. The study was conducted in July through September 1995. Crops were furrow-irrigated. Applications occurred twice at 1-week intervals on melons and grapes at application rates of 1.0 and 1.5 lbs AI/acre (1.1 and 1.7 kg AI/ha), respectively, and once on peaches at 3.0 lbs AI/acre (3.4 kg AI/ha). Four replicate samples per day were collected at 0, 1, 3, 5, and 7 days after the first application on melons and grapes and at 0, 1, 3, 5, 7, 14, 17, 21, 24, and 28 days after the second application on melons and grapes and after the first application on peaches. Residues were removed from 40 5-cm^2 leaf discs with an aqueous surfactant solution. Gas chromatography was used for quantification of α- and β-endosulfan and endosulfan sulfate; combined residues were reported as total endosulfan. The limit of quantification (LOQ) was 0.01 $\mu g/cm^2$. Following all applications, on days when all four replicates were above the LOQ, the coefficient of variation was below 50%.

Regressions of dissipation data can be used to predict DFR at a given time, including on days when samples were not collected. In many cases, log-transformed DFR data fit a first-order dissipation curve: $DFR_t = DFR_0 \times e^{-kt}$, in which e is the natural logarithm base; k is the slope of the log-linear, first-order dissipation curve, with units of $days^{-1}$; and t represents the time interval in days (Popendorf and Leffingwell, 1982). Initial regression analysis of the data by Whitmyre et al. (2004) indicated that the decay curves did not follow a simple log DFR vs. time relationship. Use of a two-phase linear model for characterization of the residue decay proved to fit the data better, at least during the first several days (Whitmyre et al., 2004). However, biphasic curve fitting with a limited number of observations has a large uncertainty with respect to the inflection point. For this reason, the CDPR practice is to try a log-quadratic model to improve fit over the log-linear regression, and to select the log-quadratic model if it gives a substantial improvement in fit over the log-linear regression (defined as an increase in R^2 of $\geqslant 0.05$). Fig. 4 shows an example of log-linear and log-quadratic curves fitted to DFR quantified on melons following a wettable powder application by USEPA and CDPR, respectively. Whitmyre et al. (2004) sampled melons through Day 28, and Fig. 4 shows that within this interval the log-quadratic equation

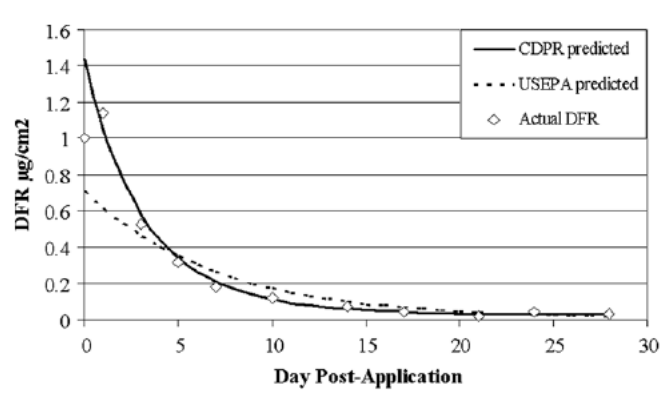

Fig. 4. Prediction curves prepared by CDPR (solid line) and USEPA (dashed line) for endosulfan dissipation on melons following a wettable powder application. Individual points represent measured DFR values.

provides a better fit. USEPA used log-linear regressions to predict DFR, but used measured DFR values if they exceeded those predicted by the regression (USEPA, 2007a).

In addition to their different approaches in estimating predicted DFR, CDPR and USEPA also differ in the data included in regressions to determine dissipation. As several DFR studies suggest that Day 0 data can vary substantially (Serat, 1973; Spencer et al., 1988), CDPR practice is to omit Day 0 data from regressions. In contrast, USEPA includes Day 0 DFR. Fig. 5 displays log-linear regressions for predicting DFR following endosulfan WP applications to peaches, using data from Whitmyre et al. (2004). In Fig. 5, regressions were prepared according to the practice of CDPR and USEPA. Examination of Fig. 5 shows that the DFR predicted by USEPA exceeds that predicted by CDPR from Day 0 through Day 17.

One more source of difference between the DFR values used by the two agencies is that CDPR applies a correction for the bias in back-transformed predicted log values, while USEPA does not. A regression equation fit to logarithms of the original data predicts the mean log at each time point. Simple back-transformation of the predicted log by taking the antilog is biased, underestimating the true mean. Instead of the simple antilog, therefore, CDPR uses the unbiased back-transformation method of Bradu and Mundlak (1970), implemented in SAS by Powell (1991).

Table 6 summarizes the results of log-linear and log-quadratic regressions, biased and unbiased back-transformations, and the inclusion or exclusion of Day 0 data on DFR predicted for Day 2 and Day 10 on melon and peach foliage. Exclusion of Day 0 resulted in lower predicted DFR on Day 2, with the exception of melon DFR predicted by log-quadratic regression. On Day 2, the unbiased back-transformation consistently yielded higher predicted DFR than the biased back-transformation. Log-quadratic regressions resulted in higher predicted DFR on both melon and peach foliage on Day 2. The reverse was true on Day 10: log-linear regressions resulted in higher predicted DFR than log-quadratic regressions. Excluding or including Day 0 from the regression, or using a biased or unbiased back-transformation had limited impact on Day 10 predicted DFR.

Whitmyre et al. (2004) measured DFR following applications of either the EC or WP formulation of endosulfan. CDPR conducted two other studies in which DFR was measured following endosulfan EC or WP applications. Maddy et al. (1985) examined foliar dissipation on tomato, celery, and bok choy. Rech and Edmiston (1988) measured DFR on greenhouse flower foliage. On all crops in all three studies, the WP formulation resulted in higher DFR. For this reason, CDPR based all reentry exposure estimates on DFR values from WP applications. USEPA reported exposures for reentry following both formulation types. All comparisons presented in this paper use DFR data from WP applications.

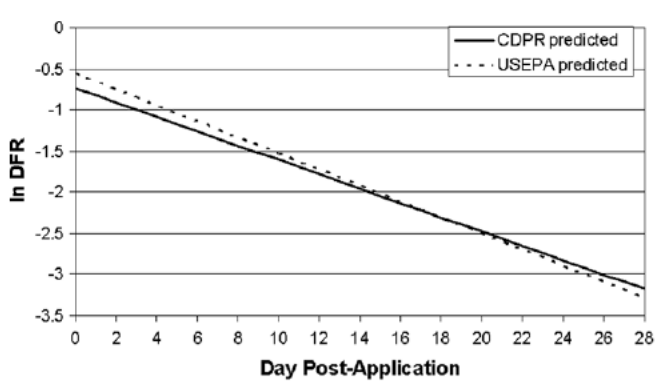

Fig. 5. Predicted log-linear regressions for endosulfan dissipation prepared by CDPR (solid line) and USEPA (dashed line) following application of the wettable powder to peaches.

Table 6
Dislodgeable foliar residue (DFR) following wettable powder endosulfan applications to melons and peaches, predicted by different regression models.

Crop	Model	Adjusted R^2	Predicted DFR (μg/cm^2)	
			Day 2	Day 10
Melons[a]	Log-linear			
	Day 0 included	0.87		
	Biased		0.53	0.17
	Unbiased		0.59	0.20
	Day 0 excluded	0.84		
	Biased		0.48	0.17
	Unbiased		0.53	0.19
	Log-quadratic			
	Day 0 included	0.97		
	Biased		0.69	0.11
	Unbiased		0.71	0.11
	Day 0 excluded	0.97		
	Biased		0.76	0.11
	Unbiased		0.78	0.11
Peaches[b]	Log-linear			
	Day 0 included	0.92		
	Biased		0.39	0.18
	Unbiased		0.41	0.19
	Day 0 excluded	0.95		
	Biased		0.33	0.17
	Unbiased		0.34	0.17
	Log-quadratic			
	Day 0 included	0.95		
	Biased		0.44	0.15
	Unbiased		0.45	0.15
	Day 0 excluded	0.96		
	Biased		0.37	0.15
	Unbiased		0.38	0.15

[a] Study application rate and maximum allowed rate both are 1 lb AI/acre.
[b] Study application rate was 3.0 lbs AI/acre and maximum allowed rate is 2.5 lb AI/acre. DFR in this table have been adjusted by 2.5/3.0 = 0.83.

Table 7 summarizes predicted DFR used to estimate short-term exposures for the scenarios shown in Figs. 2 and 3. USEPA estimated higher Day 2 DFR than CDPR on cut flowers and citrus; however, on cotton and lettuce CDPR estimated higher DFR. Cotton DFR estimates differed because USEPA assumed a foliar application rate of 0.75 lbs AI/acre, which is the maximum allowed once bolls are open, and CDPR assumed the maximum rate of 1.5 lbs AI/acre, which is only allowed prior to boll opening. CDPR selected the higher rate because some varieties of cotton under certain conditions can grow quite tall prior to boll opening, resulting in substantial exposure to scouts moving through the field (Ware et al., 1973; Boquet et al., 2004; Spencer et al., 2006). In estimating short-term reentry exposures in lettuce, CDPR relied on DFR data from spot sampling (Hernandez et al., 2002), which exceeded estimates from the potential surrogate crops sampled by Whitmyre et al. (2004). In all crops but lettuce, spot sampling conducted by CDPR resulted in lower DFR values than predicted from Whitmyre et al. (2004).

For intermediate-term exposures, USEPA estimated higher DFR than CDPR on all crops. Unlike Day 2 DFR, the higher application rate on cotton assumed by CDPR did not result in a Day 10 DFR that exceeded USEPA's estimate. CDPR estimated Day 10 DFR on lettuce using surrogate data from Whitmyre et al. (2004) because Hernandez et al. (2002) conducted spot sampling in lettuce only at 2 days post-application and no crop-specific DFR were available for lettuce at 10 days post-application.

5.5. Aggregate exposure and risk estimates

Reentry workers can be exposed to pesticides in the diet as well as through their work, which could potentially increase their risk, and CDPR's risk assessments consider aggregated risks. Table 8 summarizes aggregate exposure and risk estimates, which

Table 7
Dislodgeable foliar residue values used by USEPA and CDPR for selected short-term and intermediate-term reentry exposures following applications of endosulfan wettable powder products.

Scenario	Post-application day	USEPA			CDPR		
		Crop[a]	Rate[b]	DFR[c]	Crop[a]	Rate[b]	DFR[c]
Short-term							
Cut flower harvesting[d]	2	Peach	2.5	0.700	Grape	1.0	0.42
Citrus scouting	2	Peach	2.5	0.700	Peach	2.5	0.34
Cotton scouting	2	Melon	0.75	0.567	Melon	1.5	0.58
Lettuce scouting	2	Melon	1.0	0.756	Lettuce	1.0	2.00
Intermediate-term							
Cotton scouting	10	Melon	0.75	0.186	Melon	1.5	0.082
Peach thinning	10	Peach	2.5	0.321	Peach	2.5	0.17
Lettuce scouting	10	Melon	1.0	0.248	Melon	1.0	0.055
Broccoli harvesting	14	Melon	1.0	0.142	Melon	1.0	0.029

[a] Crop on which foliar residues were measured following endosulfan application.
[b] Application rate used in study, in pounds active ingredient per acre.
[c] Dislodgeable foliar residue (DFR) in $\mu g/cm^2$.
[d] Maximum application rate on cut flowers and other ornamental plants is 1.0 lb/100 gallons (5.8 g/L).

combine dietary exposures described by Silva and Carr (2009) with dermal exposures. USEPA (2007a) did not estimate aggregate exposures for endosulfan; instead, USEPA considered dietary exposures separately (USEPA, 2007b). The short-term dietary exposure, based on the 99.9th percentile of adults ages 20–49 years, was estimated by USEPA (2007b) at 0.003546 mg/kg/day; this value was added to the workers' dermal exposures to provide aggregate exposure estimates in Table 8. In comparison, CDPR estimated dietary exposure, based on the 95th percentile of user-day exposure for nursing females 13 years old and above, at 0.00206 mg/kg/day (Silva and Carr, 2009).

The higher dietary exposure estimated by USEPA corresponded to greater estimated dietary contributions to total exposure. In aggregate exposure estimates for the scenarios summarized in Table 8, the dietary contribution estimated by CDPR ranged from 1% to 10% for short-term exposures, while the contribution to short-term exposures calculated from USEPA estimates ranged 2–17%. For intermediate-term (seasonal) exposures, the dietary contribution estimated by CDPR ranged 1–4%, and the contribution calculated from USEPA estimates ranged 6–17%.

As with MOEs shown in Table 2, most of the MOEs in Table 8 fall short of the target MOE of 100. In Table 2, all of the representative reentry scenarios assessed by CDPR were associated with unacceptable risks for short-term exposures, although some of the intermediate-term exposures exceeded the target MOE. All of USEPA's MOEs for these reentry scenarios were associated with unacceptable risks; it is not surprising that the aggregate MOEs calculated using USEPA exposure estimates for these scenarios are also <100. In Table 8, CDPR estimated seasonal MOEs for both worker and aggregate exposures in three scenarios, cotton scouting, lettuce scouting, and broccoli harvesting, to be above the target MOE of 100.

As short-term MOEs were below target levels for all representative reentry scenarios, mitigation measures such as decreased application rates or extended REI could be required by both CDPR and USEPA, even for scenarios with intermediate-term MOEs above the target MOE.

6. Non-dietary exposures and risks to the public from endosulfan in the environment

These scenarios were assessed by CDPR but not by USEPA, as part of the comprehensive human health risk assessment prepared by CDPR.

6.1. Bystander scenarios

The Toxic Air Contaminant Act of 1983 established a procedure for identification and control of toxic air contaminants (TACs) in California. The statute defines TACs as air pollutants that may cause or contribute to an increase in mortality or in serious illness, or that may pose a present or potential hazard to human health. Endosulfan was reviewed by CDPR as a potential TAC, and CDPR's risk assessment included estimates of airborne exposures to members of the public.

Two studies by the California Air Resources Board (ARB) monitored airborne concentrations of endosulfan in urban and rural residential areas away from applications (Sava, 1985; ARB, 1998). Less than 0.05 $\mu g/m^3$ endosulfan was measured in most samples in both studies. The highest measured concentration in either study was 0.318 $\mu g/m^3$ (ARB, 1998). An additional study monitored air concentrations downwind of crop lands in California; in that study all samples contained less than 0.005 $\mu g/m^3$ endosulfan (LeNoir et al., 1999). Ambient air monitoring conducted in the Eastern United States has generally reported endosulfan concentrations below 0.001 $\mu g/m^3$ (Hoh and Hites, 2004; Gioia et al., 2005; Sun et al., 2006).

Studies with pesticides have found that the highest pesticide concentrations in air occur adjacent to an application (Siebers et al., 2003; Garron et al., 2009), and CDPR considers risk estimates based on exposures of bystanders adjacent to pesticide applications to be health-protective for exposures away from applications. ARB monitored endosulfan concentrations in air near an airblast application of endosulfan in a WP formulation to a 6-acre (2.4-ha) apple orchard in San Joaquin County in 1997 (ARB, 1998). ARB measured airborne endosulfan at four samplers positioned around the field edges.

CDPR estimated short-term bystander exposure to endosulfan in air using the 24-h time-weighted average (TWA) of 1.63 $\mu g/m^3$ at the sampler approximately 6.4 m from the eastern edge of the field; ARB measured the highest concentrations at this sampler. The application rate used in the study (1.5 lb AI/acre, or 1.7 kg AI/ha) was below the maximum rate allowed on apples (2.5 lbs AI/acre or 2.8 kg AI/ha), suggesting that bystanders near fields where the maximum allowed rate is used would be exposed to higher concentrations than were measured by ARB (1998). CDPR assumes that airborne concentrations are directly proportional to application rate, and for short-term exposures CDPR adjusts measured concentrations upward to estimate the 24-h concentration associated with the maximum application rate. For endosulfan,

Table 8
Occupational and aggregate exposure and risk estimates by CDPR and USEPA for selected reentry scenarios.

Scenario	USEPA				CDPR			
	Worker exposure	Aggregate (% diet)[a]	Worker MOE[b]	Aggregate MOE[c]	Worker exposure	Aggregate (% diet)	Worker MOE	Aggregate MOE
Short-term								
Cut flower harvest	0.21	0.21 (2%)	**6**	**6**	0.159	0.161 (1%)	4	4
Citrus scouting	0.017	0.021 (17%)	**71**	**60**	0.018	0.020 (10%)	39	35
Cotton scouting	0.051	0.055 (7%)	**24**	**22**	0.063	0.065 (3%)	11	11
Lettuce scouting	0.068	0.072 (5%)	**18**	**17**	0.162	0.164 (1%)	4	4
Intermediate-term								
Cotton scouting	0.017	0.021 (17%)	**71**	**50**	0.009	0.009 (2%)	131	129
Lettuce scouting	0.022	0.026 (14%)	**55**	**41**	0.005	0.004 (4%)	295	283
Peach thinning	0.058	0.062 (6%)	**21**	**18**	0.028	0.028 (1%)	42	42
Broccoli harvest	0.043	0.046 (8%)	**28**	**24**	0.008	0.008 (2%)	148	144

[a] Aggregate = [(total worker exposure: dermal + inhalation)] + dietary exposure. % Diet = (dietary exposure ÷ aggregate exposure) × 100. CDPR calculated short-term dietary exposure = 0.00206 mg/kg/day based on the 95th percentile of user-day exposure for females (13+ years), nursing; CDPR calculated seasonal and annual dietary exposure = 0.00017 mg/kg/day [%CT; mean annual consumption for females (13+ years)]. USEPA calculated short-term dietary exposure = 0.003546 mg/kg/day based on the 99.9th percentile of adults ages 20–49 years.

[b] Bold indicates that MOE is below target MOE of 100. MOE = oral NOEL ÷ exposure dosage. CDPR used the following NOELs: *For worker and dietary MOE:* acute (short-term) oral NOEL = 0.7 mg/kg, based on salivation, convulsions/thrashing, noisy/rapid breathing, hyperactivity salivation and nasal discharge in a rabbit developmental study. Subchronic (seasonal) oral NOEL was 1.18 mg/kg/day, based on increased relative liver and kidney weights, decreased food consumption and decreased body weights in a rat reproduction study. Chronic (annual) oral NOEL = 0.57 mg/kg/day, based on premature deaths and neurotoxicity in a 1-year dog study. USEPA used the following NOELs: *For worker MOE:* acute (short-term) and subchronic (seasonal/intermediate-term) estimated NOEL = 1.2 mg/kg/day, based on decreased pup weight in rat developmental neurotoxicity study. *For dietary MOE:* acute (short-term) oral NOEL = 1.5 mg/kg/day, based on neurobehavioral toxicity in a rat neurotoxicity study. Chronic oral NOAEL = 0.6 mg/kg/day, based on effects in kidney and aneurysms in a 2-year rat chronic dietary feeding study. MOE values were rounded to whole integers.

[c] Aggregate MOE calculation for CDPR: dietary MOE contribution to aggregate estimations: acute = 340, 95th percentile for females (13+ years), nursing; chronic (used also for subchronic) = 3448 (females [13+ years]), nursing. Aggregate MOE calculation:

$$\text{Aggregate Total MOE } (\text{MOE}_T) = \frac{1}{\frac{1}{\text{MOE dermal}} + \frac{1}{\text{MOE diet}}}$$

Aggregate MOE calculation for USEPA (calculated for this paper, not included in USEPA risk assessment): dietary MOE contribution to aggregate estimations: acute = 422, 99.9th percentile of adults ages 20–49 years. Aggregate MOE calculation:

$$\text{Aggregate Total MOE } (\text{MOE}_T) = \frac{1}{\frac{3}{\text{MOE dermal}} + \frac{1}{\text{MOE diet}}}$$

CDPR multiplied the 24-h TWA by 1.67 (2.5/1.5), resulting in a 24-h concentration estimate of 2.72 μg/m^3.

Unlike short-term exposures, seasonal and annual exposure estimates do not include an adjustment to the maximum allowed application rate, as repeated applications at the maximum rate are considered unlikely. Estimates were based on an assumed high-use period of 1 month, as repeated applications adjacent to any one individual are considered unlikely for longer intervals.

Bystander exposure and risk estimates are summarized in Table 9. CDPR estimated exposure for adults to allow comparisons with exposures from other scenarios, and for infants as likely worst-case estimates for airborne exposures because infants have the greatest inhalation rate per body weight. Under California regulation, a pesticide meets the criteria for listing as a TAC if it is found in concentrations that are greater than the level that is "10-fold below the air concentration which has been determined by the director to be adequately protective of human health" (California Code of Regulations, Title 3, Section 6890). For endosulfan, the criteria are met if the MOE is not at least 10-fold greater than the occupational target MOE of 100, and CDPR incorporates an additional 10-fold uncertainty factor (UF), along with the 10-fold intraspecies and 10-fold interspecies UFs for a NOEL based on an animal study, which results in a target MOE for bystander exposure of 1000. All bystander scenarios exceed the threshold for listing endosulfan as a TAC. Effective April 2009, CDPR formally listed endosulfan as a TAC (Title 3, California Code of Regulations, Section 6860(a)).

6.2. Swimmer scenarios

Endosulfan has been monitored over several years in both surface and ground water in California. The monitoring data relevant to human exposure to endosulfan include surface waters where swimming or wading may occur (e.g., rivers or farm ponds), as well as surface and ground water sources of drinking water in California. To detect endosulfan in ground water, between 1986 and 2003 a total of 2758 well water samples collected in 48 California counties (out of 58 counties total) were tested for the presence of endosulfan and endosulfan sulfate (Schuette et al., 2003). Endosulfan was detected in 10 samples, at concentrations ranging from 0.01 to 34.7 μg/L. However, all 10 detections were classified as "unverified," because follow-up sampling failed to detect endosulfan or endosulfan sulfate. The lack of confirmed detections, along with reported non-detection of endosulfan residues in monitoring of drinking water systems (USDA, 2003, 2004, 2005), indicate that drinking water systems in California drawing from ground water are not likely to be a source of human exposure to endosulfan.

Endosulfan residues have been detected in surface waters in California, suggesting that exposures can occur to individuals swimming in surface waters. Guo and Spurlock (2000) summarized historical monitoring data, reported by nine different agencies between 1990 and July 2000, for pesticides in surface water in California. Monitoring for α-endosulfan, β-endosulfan, and endosulfan sulfate was conducted between August 1990 and July 1996; no monitoring has been reported since 1996 (CDPR, 2004). The LOQ in surface water sampling studies ranged from 0.00005 to 0.10 μg/L.

CDPR estimated exposures of adults and children via non-dietary ingestion (i.e., water incidentally swallowed while swimming), inhalation, and dermal routes, based on equations listed in USEPA (2003). Table 10 summarizes exposure and risk estimates for swimmers by the major exposure routes. Inhalation exposures were several orders of magnitude lower than dermal and non-dietary ingestion exposures, and were omitted from Table 10. Exposure estimates were based on estimated total endosulfan concentrations; the 95th percentile concentration of 0.15 μg/L was used in estimating short-term swimmer exposure and the

Table 9
Exposure and risk estimated by CDPR for bystanders at endosulfan application sites.

Bystander scenario	Short-term[a]		Seasonal[b]		Annual[c]	
	Inhalation	Aggregate (% diet)[d]	Inhalation	Aggregate (% diet)	Inhalation	Aggregate (% diet)
Exposure (mg/kg/day)						
Infants[e]	0.0016	0.0048 (67%)	0.00056	0.00084 (33%)	0.000047	0.00033 (86%)
Adults[f]	0.00076	0.0028 (73%)	0.00027	0.00044 (39%)	0.000022	0.00019 (89%)
MOE[g]						
Infants	**121**	**78**	**346**	**296**	**413**	**343**
Adults	**255**	**146**	**719**	**595**	**882**	**702**

[a] Short-term exposures were calculated with the following equation: exposure = [(short-term concentration) × (inhalation rate). For infants, CDPR assumed an inhalation rate of 0.59 m^3/kg/day (Layton, 1993; USEPA, 1997). For adults, CDPR assumed an inhalation rate of 0.28 m^3/kg/day (Wiley et al., 1991; USEPA, 1997; OEHHA, 2000). CDPR assumed 100% absorption for both infants and adults. Values were rounded to 2 significant figures. Short-term exposure estimates were multiplied by 1.67, because the application rate used in the study (1.5 lbs AI/acre) was below the maximum rate allowed on apples (2.5 lbs AI/acre).
[b] Seasonal exposure was calculated using the same equation as short-term exposure, but with a seasonal rather than short-term concentration.
[c] Annual exposure was calculated with the following equation: exposure = (seasonal exposure) × (high use months per year)/(12 months per year).
[d] Aggregate exposure = (occupational exposure: dermal + inhalation) + dietary exposure. % Diet = (dietary exposure ÷ aggregate exposure) × 100.
[e] Infant short-term dietary exposure = 0.00318 mg/kg/day based on the 95th percentile of user-day exposure for non-nursing infants less than one year old; seasonal and annual dietary exposure = 0.00028 mg/kg/day (%CT; mean annual consumption for non-nursing infants less than one year old).
[f] Adult short-term dietary exposure = 0.00206 mg/kg/day based on the 95th percentile of user-day exposure for females (13+ years), nursing; seasonal and annual dietary exposure = 0.00017 mg/kg/day (%CT; mean annual consumption for females [13+ years]).
[g] Margin of Exposure = NOEL ÷ exposure. Bold indicates that MOE is below target MOE of 1000. Dietary MOE contribution to aggregate MOE estimations were: Acute MOE = 340, 95th percentile for females (13+ years), nursing; chronic MOE (used also for subchronic) = 3448 (females [13+ years]), nursing). Aggregate MOE = 1 ÷ (1 ÷ (MOE inhalation) + 1 ÷ [MOE diet]).

median total endosulfan concentration of 0.01 μg/L was used to estimate long-term exposures.

Table 10 includes aggregate exposures and risks. For both child and adult swimmers at all durations, endosulfan absorbed from dietary sources exceeded both dermal and non-dietary ingestion exposures from swimming. All swimmer MOEs exceeded the target MOE of 100, suggesting that risks are not of concern based on available surface water monitoring data.

USEPA does not assess swimmer exposure unless a pesticide is directly applied to a body of water or swimming pool. Although CDPR is aware that SWIMODEL is not generally used by USEPA 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.

7. Conclusions

Although CDPR and USEPA use the same equation for calculating reentry exposure estimates, differing inputs into the equation result in differing exposure estimates. In spite of these differences, short-term reentry risk estimates calculated by both CDPR and USEPA fell short of target MOEs for all assessed reentry scenarios, indicating potential health concerns for reentry following endosulfan applications.

The dominant factor leading to differing exposure estimates in all but one assessed scenario was the DFR. For most crops treated with endosulfan, USEPA calculated a higher DFR than did CDPR. For peaches, where CDPR relied on a log-linear regression, lower DFR was predicted than by USEPA's log-linear regression because CDPR omitted Day 0 DFR data in regressions to predict DFR. Serat (1973) noted that rapidly decreasing DFR on Day 0, which is found in many studies, could result in underestimates of DFR on subsequent days if Day 0 data are included in the regression. However, for endosulfan regressions including Day 0 data have higher predicted DFR for all days of interest in the risk assessment. USEPA also used measured DFR in cases where it exceeded predicted DFR; CDPR relied on predicted DFR to estimate all reentry exposures.

In this paper, reentry exposures calculated by CDPR and USEPA were compared on the basis of which estimate was higher for any given scenario. However, both CDPR and USEPA consider their

Table 10
Endosulfan exposure and risk estimated by CDPR for swimmers in surface water.

Scenario	Short-term			Seasonal			Annual		
	Dermal	Non-dietary[a]	Aggregate (% diet)[b]	Dermal	Non-dietary	Aggregate (% diet)	Dermal	Non-dietary	Aggregate (% diet)
Exposure (mg/kg/day)									
Adult	2.2×10^{-6}	2.7×10^{-4}	2.0×10^{-3} (88%)	3.8×10^{-8}	4.6×10^{-6}	2.0×10^{-4} (97%)	1.0×10^{-8}	1.3×10^{-6}	2.0×10^{-4} (99%)
Child	3.0×10^{-6}	1.6×10^{-3}	5.0×10^{-3} (68%)	9.2×10^{-8}	4.8×10^{-5}	4.5×10^{-4} (89%)	2.6×10^{-8}	1.3×10^{-5}	2.0×10^{-4} (93%)
MOE[c]									
Adult	321,102	2612	308	3,1216,931	254,310	6755	55,339,806	448,819	3328
Child	234,114	449	144	12,868,048	24,635	2634	22,709,163	43,511	3113

[a] Non-dietary ingestion includes incidental swallowing of water while swimming.
[b] Aggregate = dermal + non-dietary ingested + dietary exposure. Adult dietary exposure = 0.00206 mg/kg/day based on the 95th percentile of user-day exposure for females (13+ years), nursing; seasonal and annual dietary exposure = 0.00017 mg/kg/day (%CT; mean annual consumption for females [13+ years]). Acute dietary exposure = 3.30 μg/kg/day based on the 95th percentile of user-day exposure for Children (1–6 years) and chronic dietary exposure in children = 0.41 μg/kg/day (%CT; mean annual consumption for infants, non-nursing, <1 year). Values were rounded to 2 significant figures. % Diet = (dietary exposure ÷ aggregate exposure) × 100.
[c] Margin of exposure = NOEL ÷ exposure dosage: acute (short-term) NOEL = 0.7 mg/kg/day, based on salivation, convulsions/thrashing, noisy/rapid breathing, hyperactivity, salivation and nasal discharge in a developmental study in rabbits. Subchronic (seasonal) NOEL = 1.18 mg/kg/day, based on increased relative liver and kidney weights, decreased food consumption, and decreased body weights in a reproduction study in rats. Chronic (annual) NOEL = 0.57 mg/kg/day, based on premature deaths, neurotoxicity in a 1-year dog study.

exposure estimates to be health-protective. In the future, CDPR and USEPA might require additional mitigation measures for endosulfan in response to the risks identified by the two agencies.

Because of additional legal mandates in California, CDPR included exposures from airborne endosulfan and swimmer exposures in its risk assessment. CDPR determined that risks to bystanders adjacent to endosulfan applications raise potential health concerns, and CDPR has listed endosulfan as a TAC.

8. Conflicts of interest

The authors declare that there are no conflicts of interest.

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