



Department of Pesticide Regulation



Brian R. Leahy
Director

MEMORANDUM

Edmund G. Brown Jr.
Governor

TO: Dr. Marylou Verder-Carlos
Assistant Director
Pesticide Programs Division

FROM: Lisa Ross, Ph.D. *[Original signed by L. Ross]*
Environmental Program Manager II
Worker Health and Safety Branch
(916) 324-4116

DATE: October 17, 2014

SUBJECT: COMPLETION OF ENDOSULFAN MITIGATION

The attached memorandum from the Worker Health and Safety Branch describes our findings in regards to the need for mitigation of endosulfan exposures. The Endosulfan Risk Characterization Document (Silva 2008) identified exposure scenarios for handlers and fieldworkers where levels of concern were exceeded. In addition, bystander exposure from airblast applications also exceeded levels of concern which led to the declaration of endosulfan as a Toxic Air Contaminant (Warmerdam 2008).

Since this declaration, U.S. EPA and endosulfan registrants signed a Memorandum of Agreement in 2010, mandating a multi-year phase-out culminating in the cancellation of all endosulfan products and uses of existing stocks by July 31, 2016. Endosulfan use has steadily declined from about 240,000 pounds in 1997 to 11,000 pounds reported in 2012, with use estimated in 2013 of less than 2,000 pounds. In addition, no endosulfan exposure incidents have been reported in California from 2007 – 2011 (2011 is the most recent data available online).

Given the continued decline and low use of endosulfan products, commensurate with the voluntary cancellation and phase out, WHS Branch finds that there is no need to develop additional mitigation measures during the final 22 months of the U.S. EPA phase-out. Your approval of this conclusion is requested.

cc: Linda O'Connell, Environmental Program Manager I
Michael Zeiss, Senior Environmental Scientist (Specialist)

Attachment

APPROVAL

[Original signed by M. Verder-Carlos]
Marylou Verder-Carlos, Assistant Director

October 17, 2017
Date





Department of Pesticide Regulation



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MEMORANDUM

Edmund G. Brown Jr.
Governor

TO: Lisa Ross, Ph.D.
Environmental Program Manager II
Chief, Worker Health and Safety Branch

Via: Linda O'Connell
Environmental Program Manager I
Worker Health and Safety Branch

[Original signed by L. O'Connell]

FROM: Michael Zeiss
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[Original signed by M. Zeiss]

DATE: October 16, 2014

SUBJECT: ENDOSULFAN MITIGATION

Summary

This memorandum presents the facts that support a determination that no additional mitigation measures are needed for the agricultural insecticide endosulfan. The memorandum is based on a 2013 draft prepared by Joshua Ogawa. Within currently registered uses of endosulfan, twelve exposure scenarios have unacceptably high risks for handlers or fieldworkers (Silva 2008, U.S. EPA 2010c). In addition, bystander exposure from airblast application exceeded levels of concern, resulting in declaration of endosulfan as a Toxic Air Contaminant (Warmerdam 2008). Nonetheless, I recommend that DPR consider endosulfan mitigation complete, for five reasons:

- 1) Endosulfan use within California is low and declining. Reported use in 2012 was less than 11,000 pounds statewide, a decrease of more than 80% since 2008 (DPR 2014a).
- 2) The U.S. Environmental Protection Agency (U.S. EPA) is implementing a voluntary cancellation by registrants of all remaining registrations of endosulfan products. All endosulfan registrations and all uses of existing stocks are scheduled to end by August 2016 (U.S. EPA 2010b).
- 3) As part of the voluntary cancellation, endosulfan airblast applications are only allowed on apple, and endosulfan aerial applications are prohibited (U.S. EPA 2010b).
- 4) Within California, endosulfan users appear to be adhering to the use restrictions required by the voluntary cancellation, as indicated by DPR data on reported use (DPR 2014a) and residue detections (DPR 2014c).
- 5) From 2007 to 2011 (the most recent statistics available), no endosulfan exposure incidents have been reported within California (DPR 2014b).

For all these reasons, I conclude that no additional mitigation measures are needed for endosulfan.



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Endosulfan classification and utilization

Endosulfan is an insecticide classified in the chemical group of cyclodiene organochlorines. It has high acute oral and inhalation toxicity, and moderate dermal toxicity (U.S. EPA 2002). Endosulfan was first registered as a pesticide in the U.S. in 1954 (U.S. EPA 2002). It is applied to above-ground portions of plants, and has been used to control more than 100 species of insects and mites (Silva 2008). Historically, endosulfan was used in California on more than 50 crops, but currently is registered in California for only 12 use sites (11 crops plus cattle ear tags).

Recent regulatory history

2002 Reregistration Eligibility Decision

The U.S. EPA Reregistration Eligibility Decision (RED) for endosulfan (U.S. EPA 2002) determined that risk levels were of concern for twelve occupational exposure scenarios, as well as for acute dietary exposure to children ages 1–6 years. The RED quantified risk via the standard metric of Margin of Exposure (MOE), calculated as follows:

$$MOE = \frac{NOEL}{absorbed\ daily\ dose}$$

Where NOEL stands for No Observable Effect Level. Because MOE is calculated as a ratio, a low risk is indicated by a *high* MOE. Regarding endosulfan, the RED stated, “Generally, MOEs greater than 100 are not of concern” (U.S. EPA 2002, p. 3). DPR likewise considers that, for endosulfan, risk is acceptable when the MOE is 100 or higher (Silva 2008).

To mitigate risk for the scenarios of concern, the RED made reregistration of endosulfan conditional upon registrants adopting changes to product labels and formulations, and canceling use on several commodities including succulent beans, succulent peas, spinach, grapes, and

pecans (U.S. EPA 2002). In addition, the RED stipulated a data call-in and supplementary reevaluation to assess the proposed use and formulation changes.

2008 Risk Characterization Document

DPR's Risk Characterization Document (RCD) for endosulfan identified short-term, seasonal, and chronic occupational exposure scenarios and 15 short term reentry interval activities (REIs) as having MOEs of concern (Beauvais 2008, Silva 2008). Short term dermal exposures were the highest concern. Some scenarios of concern subsequently have been eliminated by registration cancellations and changes to product labeling. However, 12 scenarios of concern are still compatible with currently-registered crop uses and application methods (Table 1).

Table 1. Unacceptable Margins of Exposure (MOE<100) for handler and reentry worker exposure scenarios¹ that were still registered uses after the 2010 Memorandum of Agreement (U.S. EPA 2010b).

Scenario ⁶	STADD ²		SADD ³		AADD ⁴	
	Dermal	Inhalation	Dermal	Inhalation	Dermal	Inhalation
<i>Airblast (40 A)</i>						
Applicator	4		25		71	
M/L WP-WSP	37	97				
M/L EC	28					
<i>Groundboom (80 A)</i>						
Applicator	16					
M/L EC	18					
M/L WP-WSP	23	65				49
<i>Groundboom, High-acre (200 A)</i>						
Applicator	8	97	n/a ⁵	n/a ⁵	n/a ⁵	n/a ⁵
M/L EC	9	97	n/a ⁵	n/a ⁵	n/a ⁵	n/a ⁵
M/L WP-WSP	11	32	n/a ⁵	n/a ⁵	n/a ⁵	n/a ⁵
<i>Reentry Workers (2 day REI)</i>						
Potato, Scouting	11					
Strawberry, Hand Harvest	8					
Tomato, Hand Harvest	17					

¹ Summarized from tables 39–42 in Silva 2008.

² STADD: Short-Term Absorbed Daily Dose.

³ SADD: Seasonal Average Daily Dose.

⁴ AADD: Annual Average Daily Dose.

⁵ Silva 2008 (Table 40) did not estimate seasonal or annual exposures for high-acre groundboom applications.

⁶ EC: emulsifiable concentrate formulation. M/L: mixer/loader personnel. WP: wettable powder formulation. WSP: water soluble packaging.

2009 Toxic Air Contaminant designation

California Food and Agricultural Code section 14022 requires DPR to determine whether pesticides “emitted into the ambient air of California” are Toxic Air Contaminants (TAC) requiring additional mitigation measures to reduce exposure via inhalation. In order for DPR to designate a pesticide as a TAC, the pesticide must have measured concentrations in the ambient air greater than one-tenth of the air concentration that has been determined to be health protective (California Code of Regulations, title 3, section 6864). For endosulfan, another way to express this is that ambient air concentrations must have been equivalent to MOEs of less than 1,000 (Warmerdam 2008).

A 1997 monitoring study of an endosulfan airblast application (ARB 1998) identified acute, seasonal, and annual bystander inhalation exposure MOEs as below 1,000 (Silva 2008). This led to designation of endosulfan as a TAC within California Code of Regulations, title 3, section 6860 (Warmerdam 2008). That regulatory amendment went into effect in April 2009 (Randy Segawa, personal communication).

2010 Memorandum of Agreement, and subsequent implementation

U.S. EPA's 2007 and 2010 reassessments of endosulfan use identified several worker health and environmental risks not adequately mitigated by the 2002 RED actions (U.S. EPA 2007, 2010c). To mitigate those risks, in 2010 U.S. EPA and registrants signed a Memorandum of Agreement (MOA) mandating a multi-year phase-out (Table 2) that culminates in cancellation of all endosulfan products and all uses of existing stocks by July 31, 2016 (U.S. EPA 2010b). During the phase-out period, additional mitigation measures are required, including:

- cancellation of aerial application methods on most crops,
- additional restrictions on ground application methods,
- reductions in application rates, and
- lengthening of Restricted Entry Intervals and Pre-Harvest Intervals.

In November 2010, U.S. EPA published the phase-out schedule within a Final Product Cancellation Order (U.S. EPA 2010a). In September 2011, U.S. EPA published the scheduled revocation dates for endosulfan residue tolerances on harvested commodities (U.S. EPA 2011), with revocations of tolerances timed to match cancellations of uses.

Table 2. Cancellation schedule for endosulfan uses registered¹ at the time of the Memorandum of Agreement (U.S. EPA 2010b).

Crops	Cancellation Date²
Broccoli; Brussels sprouts; Cabbage; Carrots; Cauliflower; Celery; Citrus (non-bearing); Collard greens; Cotton; Cucumbers; Dry beans; Dry peas; Eggplant; Kale; Kohlrabi; Lettuce; Mustard greens; Nuts (almonds, filbert, macadamia, walnut); Poplars; Stone fruits (apricot, cherry, nectarine, peach, plum, prune); Strawberry (annual); Summer melons (cantaloupe, honeydew, watermelon); Summer squash; Sweet potato; Tobacco; Turnip; Ornamental trees and plants	July 31, 2012
Pear	July 31, 2013
Apple; Blueberry; Peppers; Potato; Pumpkin; Sweet corn; Tomato; Winter squash	July 31, 2015
Livestock ear tags; Pineapple; Strawberry (perennial/biennial only, annual use was canceled July 31, 2012); Vegetable crops grown for seed ³ (alfalfa, broccoli, Brussels sprouts, cabbage, cauliflower, Chinese cabbage, collard greens, kale, kohlrabi, mustard greens, radish, rutabaga, turnip)	July 31, 2016

¹ Not all of these uses were registered within California.

² Specifically, these are the final dates on which the Memorandum of Agreement (MOA) allows the use of existing stocks of any end-use product that is labeled for the crops listed in this table. The MOA sets correspondingly earlier deadlines to halt formulation and sale of such end-use products.

³ Within "Vegetable crops grown for seed", only cabbage is included in current California registered endosulfan products.

Current regulatory status within California

Endosulfan is a federal and California restricted use material. Currently, there are four California-registered endosulfan products: two emulsifiable concentrates (EC), one wettable powder in water-soluble packaging (WP-WSP), and one cattle eartag product.

Labeling for the EC and WP-WSP products specifies mandatory drift-control restrictions for applications within California. Except for apples, on which airblast applications are allowed, the EC and WP-WSP formulations may only be applied in California via low-pressure groundboom (boom pressure not to exceed 30 pounds per square inch).

At the time of this memorandum, endosulfan is only registered for 12 use sites within California (Table 2): apple, blueberry, cabbage grown for seed, cattle (via eartags), peppers, pineapple, potato, pumpkin, strawberry (perennial/biennial only), sweet corn, tomato, and winter squash. All registrations of endosulfan products and all uses of existing stocks are scheduled to be cancelled by July 31, 2016 (U.S. EPA 2010b).

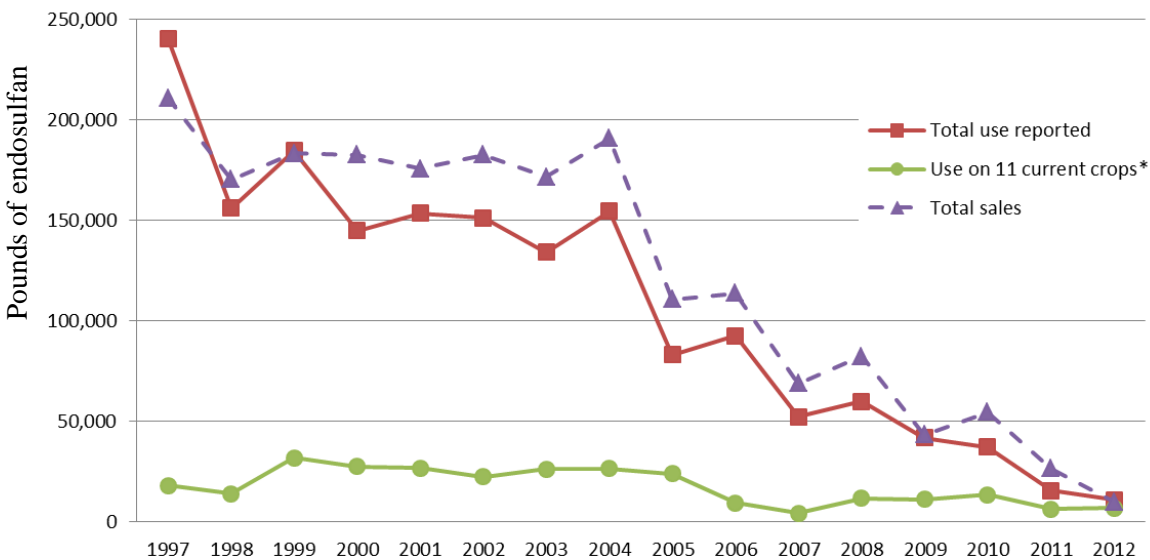
Use and Sales in California

There are no available use figures for endosulfan cattle ear tags because pesticide use on livestock is exempt from pesticide use reporting (California Code of Regulations, title 3, section 6624).

From 1997–2012 reported endosulfan use on California crops has declined steadily, from 240,310 lbs reported in 1997 to 10,965 lbs reported in 2012 (Figure 1). Endosulfan sales within California (DPR 2014c) show a comparable decline (Figure 1).

Figure 1. Reported endosulfan use and sales within California, 1997 – 2012.

Source of data: DPR 2014a, DPR 2014c.

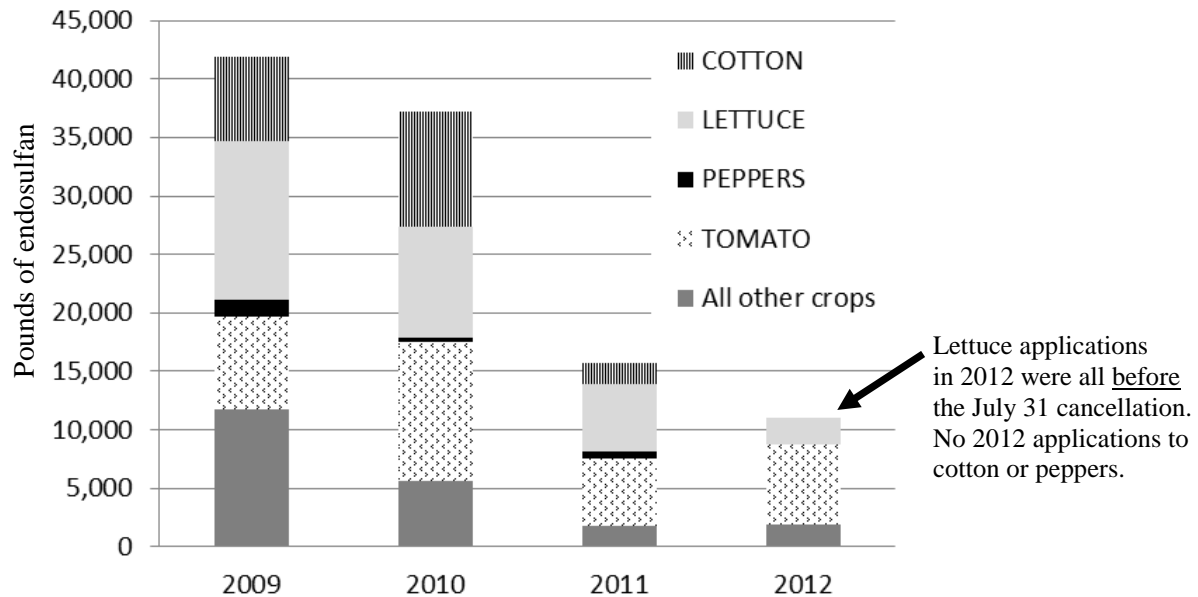


* Use on 11 current crops: sum of reported use on the 11 crop use sites registered within California at the time of this memorandum: apple, blueberry, cabbage grown for seed, peppers, pineapple, potato, pumpkin, strawberry (perennial/biennial only), sweet corn, tomato, and winter squash. No use data are available for cattle eartags.

When categorized by crop (Figure 2), reported use indicates that endosulfan users are adhering to the use restrictions required by the MOA-mandated cancellations. In July 2012, U.S. EPA cancelled uses on cotton, lettuce, and peppers (U.S. EPA 2010b). Similarly, reported endosulfan use on cotton and peppers ceased in 2011, with a few applications reported on lettuce before the July 31, 2012 deadline (Figure 2).

Figure 2. Endosulfan reported use within California, by crop, 2009-2012.

Source of data: DPR Pesticide Use Reports



In California, tomato is the largest remaining registered crop use for endosulfan. In 2012, reported use on tomato was 6,778 lbs of endosulfan. Endosulfan is allowed to be applied to tomato through July 31, 2015 (U.S. EPA 2010b).

The voluntary cancellation allows application to various vegetable crops grown for seed through July 31, 2016. Of these vegetable-seed crops, only cabbage is a California-registered use. No endosulfan use was reported on cabbage in either 2011 or 2012 (DPR 2013a).

Residue data

Each week, DPR collects samples of harvested fruits and vegetables throughout the channels of trade, and analyzes the produce samples for pesticide residues (DPR 2014d). When collecting samples, DPR staff record information about the origin of the produce from the produce packaging.

The analytical method used for DPR's residue-monitoring program detects both endosulfan and endosulfan sulfate. Endosulfan sulfate is a chemical breakdown product of endosulfan. In the following discussion, the phrase "endosulfan residue" should be understood as "residue of endosulfan or endosulfan sulfate, or both".

In recent years, endosulfan residue has been detected only rarely on produce known, or likely, to have been grown in California (Table 3). Like data on reported endosulfan use, the endosulfan residue data indicate that most endosulfan users are adhering to the use restrictions required by the MOA. In particular, from 2009-2011 endosulfan residues were detected most often on summer melons and summer squash. U.S. EPA cancelled uses on those crops on July 31, 2012 (U.S. EPA 2010b). After those cancellations, endosulfan residue was detected on only a single summer melon sample in 2012, and was not detected on summer squash (Table 3).

Some detected endosulfan residues may be the result of environmental contamination, rather than the result of an endosulfan insecticide product having been applied to the crop. Endosulfan sulfate is relatively persistent in the environment, and conceivably could contaminate nearby crops via windborne particles of contaminated soil (Michael Papathakis, personal communication). All endosulfan residues on California-grown commodities were below 1 part per million, and were within legal tolerances established by U.S. EPA.

Table 3. Residues of endosulfan and endosulfan sulfate on California-grown produce (including "1US" samples on which state of origin was not specified).

Source of data: Queries of DPR's residue-program database, run on Sept. 12, 2014 by Amna Hawatky.

Crop	Category of sample	2009	2010	2011	2012	2013
Apple	With endosulfan	2	0	0	0	0
	Total samples	12	38	88	170	34
	% w/ endosulfan	16.7%	0.0%	0.0%	0.0%	0.0%
Gai lon (Chinese broccoli, part of Crop Group 5)	With endosulfan	0	0	1	0	0
	Total samples	0	6	26	4	4
	% w/ endosulfan	N/A	0.0%	3.8%	0.0%	0.0%

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Table 3. Residues of endosulfan and endosulfan sulfate on California-grown produce
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Crop	Category of sample	2009	2010	2011	2012	2013
Kale	With endosulfan	0	0	0	0	1
	Total samples	3	62	59	82	201
	% w/ endosulfan	0.0%	0.0%	0.0%	0.0%	0.5%
Lettuce (including leaf, head, romaine)	With endosulfan	1	3	3	1	0
	Total samples	195	95	92	135	121
	% w/ endosulfan	0.5%	3.2%	3.3%	0.7%	0.0%
Peppers (including bell and chili)	With endosulfan	0	1	2	0	0
	Total samples	36	75	66	68	42
	% w/ endosulfan	0.0%	1.3%	3.0%	0.0%	0.0%
Potato	With endosulfan	0	1	2	0	0
	Total samples	78	51	129	149	78
	% w/ endosulfan	0.0%	2.0%	1.6%	0.0%	0.0%
Snow peas	With endosulfan	0	1	0	0	0
	Total samples	30	18	12	32	36
	% w/ endosulfan	0.0%	5.6%	0.0%	0.0%	0.0%
"Summer melons" (cantaloupe, honeydew, watermelon)	With endosulfan	9	3	0	1	0
	Total samples	54	17	8	8	13
	% w/ endosulfan	16.7%	17.6%	0.0%	12.5%	0.0%
Summer squash (including zucchini and bitter melon)	With endosulfan	6	4	0	0	0
	Total samples	43	29	12	23	28
	% w/ endosulfan	14.0%	13.8%	0.0%	0.0%	0.0%
Tomato (including fresh, processing, and tomatillo)	With endosulfan	0	0	1	0	0
	Total samples	14	24	24	66	39
	% w/ endosulfan	0.0%	0.0%	4.2%	0.0%	0.0%
Winter squash (including pumpkins)	With endosulfan	0	0	0	0	0
	Total samples	9	8	2	6	3
	% w/ endosulfan	0.0%	0.0%	0.0%	0.0%	0.0%
Yard-long beans (Vigna sp., part of Crop Group 6A)	With endosulfan	0	0	2	0	0
	Total samples	0	1	3	8	2
	% w/ endosulfan	N/A	0.0%	66.7%	0.0%	0.0%
All other California commodities sampled	With endosulfan	0	0	0	0	0
	Total samples	1259	1219	1098	1608	1695
	% w/ endosulfan	0.0%	0.0%	0.0%	0.0%	0.0%
YEARLY TOTALS, all California commodities sampled	With endosulfan	18	13	11	2	1
	Total samples	1733	1643	1619	2359	2296
	% w/ endosulfan	1.0%	0.8%	0.7%	0.1%	0.0%

Illness Data

From 2007 to 2011 (the most recent statistics available), no endosulfan exposure incidents have been reported within California. The most recent report was one "possible" exposure incident in 2006 (DPR 2014b). In that 2006 incident, a nursery employee developed symptoms consistent with endosulfan exposure after mixing, loading, and applying pesticides containing two active ingredients (endosulfan and myclobutanil) without using either the Personal Protective Equipment (PPE) or the engineering controls required by the product label.

Assessment of Need for Additional Mitigation Measures

Occupational Exposure

Due to the ongoing phase-out of endosulfan registrations, only nine handler and three reentry worker exposure scenarios identified in the RCD are still of concern (Table 1). Endosulfan use in California is low and declining (Figure 1), thus only a small number of workers engage in these scenarios. Nonetheless, DPR must mitigate any pesticide use that has unacceptable risk.

The most effective mitigation measure is to cancel the endosulfan registrations that include exposure scenarios of concern. That cancellation already is being implemented via U.S. EPA's Memorandum of Agreement (MOA), which will cancel all remaining uses of endosulfan, including use of existing stocks, by July 31, 2016 (U.S. EPA 2010a, 2010b).

Cancellations would be less effective if endosulfan users failed to comply. Fortunately, all available data indicate that most endosulfan users are adhering to the use restrictions required by the MOA-mandated cancellations. These supporting data include:

- reported endosulfan use by crop (Figure 2);
- monitoring of endosulfan residues on harvested produce (Table 2); and
- absence of reports of illnesses from endosulfan during the most recent 5-year period.

In addition, for each of the occupational-exposure scenarios of concern, the 2010 MOA established mitigation measures that will help protect workers until registration and use of existing stocks ultimately are cancelled. These interim mitigation measures are analyzed in detail in the Appendix.

Because current use is low, interim measures are in place, and all uses will be cancelled within two years, I recommend that DPR consider endosulfan mitigation of occupational exposure complete.

Bystander Exposure

A 1997 air monitoring study of an endosulfan airblast application to apple (ARB 1998) indicated an unacceptable risk for bystander inhalation exposure. As a result, DPR designated endosulfan as a Toxic Air Contaminant (Warmerdam 2008).

Endosulfan use in California is low and declining (Figure 1), thus only a small number of bystanders are exposed to endosulfan airblast applications. In particular, the only remaining California registration that includes airblast applications is on apple, and the most recent reported application to apple was in 2010 (a total of less than 9 pounds applied). For all other crops, endosulfan product labeling specifies mandatory drift-control restrictions for applications within California. Crops other than apple may only be treated via low-pressure groundboom (boom pressure not to exceed 30 pounds per square inch). Currently registered products do not allow aerial applications of endosulfan to any crop within California.

Although only a small number of bystanders currently may be exposed, California Food and Agricultural Code section 14023 requires DPR to, “determine . . . the need for and appropriate degree of control measures for each pesticide listed as a toxic air contaminant.” The most effective control measure is to cancel the endosulfan registrations that include exposure scenarios of concern. Registrations and use of existing stocks on apple, the only crop on which airblast application is allowed, will be cancelled within one year, on July 31, 2015 (U.S. EPA 2010b).

Because current use of airblast application is low, and will be cancelled within one year, I recommend that DPR consider endosulfan mitigation of bystander exposure complete.

REFERENCES

- Air Resources Board. 1998. Report for the Air Monitoring of Endosulfan in Fresno County (Ambient) and in San Joaquin County (Application). Project No. C96-034. Sacramento, CA Engineering and Laboratory Branch, Air Resources Board, California Environmental Protection Agency.
- Beauvais, S. 2008. Estimation of Exposure of Persons in California to Pesticide Products that Contain Endosulfan. HS-1647. January 2008. Worker Health and Safety Branch, California Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA.
- Beauvais, S., S. Powell, and W. Zhao. 2007. Surrogate Handler Exposure Estimates for use in Assessments by the California Department of Pesticide Regulation. HS-1826. September 2007. Worker Health and Safety Branch, California Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA.
- Department of Pesticide Regulation. 2014a. California Pesticide Information Portal (CALPIP), Pesticide Use Report Database. Available at <http://calpip.cdpr.ca.gov/main.cfm> (accessed September 22, 2014)
- Department of Pesticide Regulation. 2014b. California Pesticide Illness Query (CalPIQ) [Online]. Available at http://apps.cdpr.ca.gov/calpiq/calpiq_input.cfm (accessed September 19, 2014)
- Department of Pesticide Regulation. 2014c. Reports of Pesticide Sold in California. Available at: <http://www.cdpr.ca.gov/docs/mill/nopdsold.htm> (accessed September 17, 2014)
- Department of Pesticide Regulation. 2014d. Pesticide Residues in Fresh Produce. Available at: <http://www.cdpr.ca.gov/docs/enforce/residue/rsmonmnu.htm> (accessed September 12, 2014).
- Powell, S. 2007. Recommended Method for Approximating Confidence Limits for Upper Bound and Mean Exposure Estimates from the Pesticide Handlers Exposure Database (PHED) to Replace the Method of HSM-02037. Memo No. HSM-07004. Sacramento, CA: Worker Health and Safety Branch, California Department of Pesticide Regulation, California Environmental Protection Agency.

REFERENCES (continued)

- Silva, M.H. 2008. Endosulfan Risk Characterization Document I. January 2008. Medical Toxicology Branch, Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento CA. Available at <http://www.cdpr.ca.gov/docs/risk/rcd/endosulfan.pdf>
- U.S. Environmental Protection Agency. 2002. Reregistration Eligibility Decision for Endosulfan. Case 0014. November 2002. Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency, EPA 738-R-02-013. www.epa.gov/oppsrrd1/REDs/endosulfan_red.pdf
- U.S. Environmental Protection Agency. 2007. Revision of Occupational and Residential Exposure/Risk Assessment for the Endosulfan Reregistration Eligibility Decision Document (RED) (Revised). DB Barcode D339509, Dated May 3. Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency, Washington, D.C.
- U.S. Environmental Protection Agency. 2010a. Endosulfan: Final Product Cancellation Order. Federal Register Vol. 75, No. 217: 69065-69069, November 10, 2010. www.regulations.gov Docket EPA-HQ-OPP-2002-0262-0188.
- U.S. Environmental Protection Agency. 2010b. Memorandum of Agreement Between the Environmental Protection Agency and Makhteshim Chemical Works, Ltd., Makhteshim Agan of North America, Inc., Drexel Chemical Company, and KMG-Bernuth, Inc., Regarding the Registration of Pesticide Products Containing Endosulfan. July 23, 2010. www.regulations.gov Docket EPA-HQ-OPP-2002-0262-0181.
- U.S. Environmental Protection Agency. 2010c. Endosulfan: The Health Effects Division's REVISED Human Health Risk Assessment. DB Barcode D372569, Dated June 30. Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, Washington, D. C.
- U. S. Environmental Protection Agency. 2011. Atrazine, Chloroneb, Chlorpyrifos, Clotencet, Endosulfan, *et al.*; Tolerance Actions. Final Rule. Federal Register Vol 76, No 178 / Wednesday, September 14, 2011 / Rules and Regulations, pages 56648–56657.

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October 16, 2014
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REFERENCES (continued)

Warmerdam, M. 2008. Director's Proposed Decision Concerning Endosulfan as a Toxic Air Contaminant. Memo dated August 27. Sacramento, CA: Department of Pesticide Regulation, California Environmental Protection Agency. Available at:
<http://www.cdpr.ca.gov/docs/emon/pubs/tac/finaleval/endosulfan.htm>

Whitmyre, G.K, J.H. Ross, C. Lunchick, B. Volger, and S. Singer. 2004. Biphasic Dissipation Kinetics for Dislodgeable Foliar Residues in Estimating Postapplication Occupational Exposures to Endosulfan. Arch. Environ. Contam. Toxicol. 46:17–23.

Appendix: Interim Mitigation for Occupational Exposure Scenarios of Concern

This Appendix summarizes the nine handler and three reentry-worker exposure scenarios identified by DPR's Risk Characterization Document (RCD) (Beauvais 2008, Silva 2008) that are still compatible with currently-registered crop uses and application methods. For each scenario, the summary includes current endosulfan usage patterns and an analysis of the interim mitigation measures that will help protect workers and bystanders until registration and use of existing stocks ultimately is cancelled.

Handler exposure scenarios were recalculated by Joshua Ogawa of DPR's Worker Health and Safety Branch, using:

- applicable Pesticide Handlers Exposure Database (PHED) dermal subsets and RCD NOELs (Beauvais *et al.* 2007, Beauvais 2008);
- short-term and long-term Upper Confidence Limit (UCL) multipliers from Powell 2007 (these multipliers supersede multipliers used in Beauvais 2008);
- current maximum label rates (2lbs ai/A for apples, 1 lb ai/A all other crops); and
- 1995–2010 endosulfan Pesticide Use Reports (PURs).

Similarly, Joshua Ogawa recalculated reentry worker exposure scenarios using dislodgeable foliar residue (DFR) estimates from the RCD endosulfan dissipation regression models (Beauvais 2008) and current label application rates and REIs.

Airblast: Applicators (All formulations)

2008 RCD

Dermal short term absorbed, seasonal, and annual average daily dose MOEs for airblast applicators were < 100 (Short-Term Absorbed Daily Dose (STADD) MOE=4, Seasonal Average Daily Dose (SADD) MOE=25, Annual Average Daily Dose (AADD) MOE=71). Exposure estimates were derived directly from a worker exposure study (Smith 2005, cited in Beauvais 2008). Airblast applicators used an open cab and wore long-sleeved shirt and long pants, shoes plus socks, Chemical Resistant (C-R) gloves, and either a C-R wide-brimmed hat or a C-R hooded jacket. Short-term and long-term dermal exposure rate estimates were 276 µg/lb and 70.2µg/lb ai handled, respectively. Exposure estimates were based on 40 A/day applications (U.S. EPA 2001, cited in Beauvais 2008) at 2.5 lbs ai/A (2008 max application rate), and two use-months per year, as established by the RED (U.S. EPA 2002).

Interim mitigation established by the Memorandum of Agreement (MOA)

The 2010 MOA between registrants and U.S. EPA (U.S. EPA 2010b) established the following mitigation measures to cover the interim until final cancellation. Current labels require airblast applicators to use an enclosed cab and wear long-sleeved shirt and long pants, shoes and socks,

and goggles or face shield. However, applicators are exempted from using enclosed cabs in apple orchards provided they wear maximum PPE clothing (baseline clothing plus organic vapor respirator, coveralls over long-sleeved shirt and long pants, C-R gloves, C-R shoes plus socks, goggles or face shield, and C-R headgear).

As of July 31, 2013, airblast applications are allowed only for apples. During the most recent 6-year period (2007–2012), within California there was a single 4 acre endosulfan application to apples, in 2010.

Mitigation outlook

The existing open-cab allowance for applications to apple orchards suggests that current and future airblast applications in apple orchards will be done with open cabs. Given the RCD daily application acreage assumption (40 A/day) and incorporating the lower daily application rate (2lbs/A), the additional post-MOA PPE requirements (C-R shoes plus goggles or face shield and all of the RCD factored in PPE) do not lower dermal exposure rates enough to mitigate risk. Considering only PPE protection factors, without restricting the amount of material applied, short-term exposure rates would have to be lowered in excess of twenty-fold before the absorbed daily dose is small enough to no longer be of concern for short term exposure. Requiring an enclosed cab, label required PPE for enclosed cab airblast applications (long sleeved shirt, long pants, goggles, and C-R gloves), and restricting the size of a single application to less than 4 acres, will reduce short-term, seasonal and annual dermal exposure rates to acceptable levels (STADD MOE=105, SADD MOE=590, AADD MOE=1710; derived from PHED closed cab airblast application subset, Beauvais *et al.* 2007).

Considering the infrequent past use on apples during 2007-2012, and the scheduled July 31, 2015 cancellation date for use of existing stocks on apple, endosulfan likely will be applied only rarely with airblast equipment.

Airblast: Mixer/Loader (WP-WSP formulation)

2008 RCD

Both dermal and inhalation STADD MOEs for airblast mixer/loader (M/L) using the WP-WSP formulation were less than 100 (dermal MOE=37, inhalation MOE=97). Exposure estimates were derived from the PHED M/L WP-WSP scenario and adjusted for handlers wearing long pants and long sleeved shirt, gloves, coveralls, and a C-R apron. Short-term dermal and inhalation exposure rate estimates were 28.4 µg/lb and 1.38 µg/lb ai handled, respectively. Exposure estimates were based on 40 A/day applications (U.S. EPA 2001, cited in Beauvais 2008) at 2.5 lbs ai/A (max application rate in 2008), and two use-months per year.

Interim mitigation established by 2010 MOA

The 2010 MOA between registrants and U.S. EPA (U.S EPA 2010b) established the following mitigation measures to cover the interim until final cancellation. Maximum application rates reduced to 2.5 lbs/A, with a maximum annual rate of 2.0 lbs/A. The current label requires M/L to wear long-sleeved shirt, long pants, shoes and socks, CR-gloves, CR-apron, and face shield or goggles.

After July 31 2013, airblast applications are allowed only on apples. Over the most recent 6-year reporting period (2007–2012), there was a single 4 acre application to apples in 2010.

Mitigation outlook

Correcting for multiplier difference and factoring in the lower application rate reduced short term dermal and inhalation exposure rates. The inhalation exposure rate is no longer of concern (MOE=194), but the dermal exposure rate is still problematic (MOE=60). Adopting the same acreage limitation that mitigates airblast applicator dermal exposure, will lower the M/L exposure rate enough to mitigate concern (MOE=599).

Airblast: Mixer/Loader (EC formulation)

2008 RCD

Based on PHED M/L estimates for liquid formulations in closed systems and adjusted for handlers wearing long pants, long sleeves, gloves, coveralls, and a C-R apron, only the dermal STADD had an MOE less than 100. Exposure assumptions were the same as the airblast M/L WP-WSP exposure scenario.

Interim mitigation established by 2010 MOA

The 2010 MOA between registrants and U.S. EPA (U.S EPA 2010b) established the following mitigation measures to cover the interim until final cancellation. The WP-WSP application restrictions and requirements also apply for the EC formulations

Mitigation outlook

Correcting the UCL multiplier difference and factoring in the lower application rate reduces the short term dermal exposure rate. However, this is not enough to mitigate exposure concerns (MOE=43). Adopting the same acreage limitation that mitigates airblast applicator dermal exposure, will lower the M/L exposure rate enough level to mitigate the concern (MOE=405).

Groundboom: Applicators (All formulations)

2008 RCD

Only the dermal STADD had an MOE less than 100. Short dermal exposure rate was 40.6 $\mu\text{g}/\text{lb ai}$ and assumed handlers wore long sleeved shirt, long pants, coveralls, and gloves. STADD exposure estimate was based on treating 80A/day at an application rate of 2.0 lbs ai/A.

Interim mitigation established by 2010 MOA

The 2010 MOA between registrants and U.S. EPA (U.S EPA 2010b) established the following mitigation measures to cover the interim until final cancellation. Currently labeled products can only be applied at a rate of 1.0 lb ai/A to field and vegetable crops. Applicators are required to wear goggles or a face shield in addition to the PPE considered in the 2008 RCD.

Considering only currently labeled uses, over the most recent six year PUR period (2007–2012), endosulfan was primarily applied to processing/canning tomatoes (Table A1). Between 2007–2011, an average 122 acres were treated per tomato application (range: 7–466 acres). In 2012, 6,484 lbs of endosulfan were applied by ground to tomatoes in California, primarily in Fresno County (5,018 lbs).

Mitigation outlook

Factoring in the lower application rate and UCL multiplier correction does not lower the short-exposure dermal rate enough to mitigate exposure risk concerns. Additional PPE requirements would have to yield at least a three-fold reduction to the short-term dermal exposure rate. Requiring enclosed cabs, long pants, long sleeve shirts, and CR-gloves for groundboom applications will not achieve enough of a reduction to short-term dermal exposure (MOE=69). Limiting applications to less than 30 A in addition to the label's PPE requirements will lower dermal exposure rate to an acceptable level (MOE=106). Requiring applicators to use an enclosed cab, will allow the acreage to rise to 50 A per application (MOE=110). Based on 2007–2012 PURs, only 11% of the tomato applications (41/390) were less than 30 acres and 18% (70/390) were less than 50 acres. Endosulfan use on tomatoes is prohibited after July 31, 2015.

Table A1. Pounds of endosulfan applied to currently labeled crops (2007–2012).

Crop	2007	2008	2009	2010	2011	2012
Apple	0	0	0	9	0	0
Cabbage ¹	107	28	14	10	0	0
Corn (Human Consumption)	1,489	986	0	0	0	0
Pear	18	0	0	0	0	0
Peppers (Fruiting)	1,191	1,942	1,452	354	572	0
Potato (White, Irish, Red, Russet)	252	495	1,804	1,222	77	103
Pumpkin	0	0	0	0	0	0
Squash (Winter)	0	0	0	0	0	0
Strawberry ²	908	9	14	1,354	70	20
Tomatoes	10	248	151	131	712	294
Tomatoes (For Processing/Canning)	1,422	8,026	7,789	11,825	5,071	6,484
<i>Total</i>	<i>5,397</i>	<i>11,734</i>	<i>11,225</i>	<i>14,906</i>	<i>6,502</i>	<i>6,901</i>

¹2012 onward: cabbage grown for seed

²2012 onward: biennial and perennial strawberries

Groundboom: Mixer/Loader (WP–WSP formulation)

2008 RCD

The STADD dermal and inhalation, and the AADD inhalation MOEs were less than 100. Application assumptions were 80 A/day, 2 lbs ai/A for the STADD and 1.5 lbs ai/A for the AADD with five use-months/year. Exposure rates were calculated using the PHED subset for M/Ls of WP-WSP and PPE consisted of long pants, long sleeved shirt, coveralls, a C-R apron, and gloves.

Interim mitigation established by 2010 MOA

The 2010 MOA between registrants and U.S. EPA (U.S EPA 2010b) established the following mitigation measures to cover the interim until final cancellation. The maximum application rate for currently labeled crops is 1.0 lbs ai/A. The WP-WSP formulation cannot be applied to tomatoes and sweet corn. The current label requires M/L to wear long-sleeved shirt, long pants, shoes and socks, CR-gloves, CR-apron, and face shield or goggles.

Only pumpkins, winter squash, peppers, potatoes, and strawberries can be treated with the WP-WSP formulation using groundboom equipment. Based on the year PUR period 2007–2011, endosulfan was only applied to peppers, potatoes, and strawberries. On average, 26 applications were annually applied to peppers across the state (average application size = 10A).

Approximately 20% of those applications used WP-WSP formulations. On average eleven endosulfan applications were applied to strawberries annually (average application size = 33A). All strawberry applications were with WP-WSP product formulations. From 2007–2012, the WP-WSP formulation was not used on potatoes. The majority of endosulfan applications to peppers, potatoes, and strawberries are limited to three months a year.

Mitigation outlook

Factoring in the lower application rate, UCL multiplier correction, and fewer use-months short and long-term inhalation exposure rates are lowered enough to mitigate the STADD and AADD inhalation exposure risk concerns. However, these adjustments do not lower the dermal STADD enough. Restricting application size to less than 30 A (the same limit proposed for groundboom applicators) reduces short-term dermal exposure rates enough to mitigate exposure concerns (MOE=160). Based on 2007–2011 PURs, 52% of strawberry applications were less than 30 A (29/56). Endosulfan use on biennial and perennial strawberries is prohibited after July 31, 2016.

Groundboom: M/L (EC formulation)

2008 RCD

Only the STADD dermal MOE was < 100. Application assumptions were 80 A/day and 2 lbs ai/A. Exposure rates were calculated using PHED subset for M/L for liquid formulations with handlers wearing long sleeved shirt, long pants, coveralls, C-R gloves, C-R apron, and using a closed system.

Interim mitigation established by 2010 MOA

The 2010 MOA between registrants and U.S. EPA (U.S EPA 2010b) established the following mitigation measures to cover the interim until final cancellation. Maximum application rate for currently labeled crops is 1.0 lbs ai/A. The current EC labels requires, in addition to the RCD considered PPE, M/L to wear a face shield or goggles. Endosulfan EC formulations can be applied to all current crop uses, with strawberries representing the highest annual crop use (see *Groundboom: Applicator* section for additional information).

Mitigation outlook

Factoring in the lower application rate and multiplier-correction does not lower the short-exposure dermal rate enough to mitigate the exposure risk concerns. Adopting the 30 A application limit required to mitigate applicator exposure will also mitigate the M/L exposure (MOE=108).

Groundboom High-Acre: M/L and Applicators

The 2008 RCD evaluated handler endosulfan exposure during high-acreage applications (200 A). Margins of exposure for both short-term dermal and inhalation were below the acceptable threshold for M/L and applicators (Silva 2008). Limiting the amount of acreage treated to lower short-term exposure rates for handlers supporting groundboom applications will prohibit high-acreage applications.

Reentry Workers

2008 RCD

All reentry worker scenarios evaluated in the RCD had STADD rates that were of concern (occupational MOEs less than 100). Of the fifteen considered scenarios, three are still compatible with currently allowed uses: Potato Scouting, Hand Harvesting Strawberry, and Hand Harvesting Tomato. Due to an error in adjusting for the surrogate crop DFR, values used to estimate exposure for half of the RCD reentry scenarios underestimated the exposure rate and therefore over-estimated the associated MOE values (including Potato Scouting, Strawberry Hand Harvesting, and Tomato Hand Harvesting). Based on the other RCD assumptions, maximum label rates using the WP formulation, two-day REIs, and corrected surrogate application rates (Whitmyre *et al.* 2004), the corrected MOEs for Potato Scouting, Strawberry Hand Harvesting, and Tomato Hand Harvesting are 11, 8, and 17, respectively.

Interim mitigation established by 2010 MOA

The 2010 MOA between registrants and U.S. EPA (U.S. EPA 2010b) established the following mitigation measures to cover the interim until final cancellation. Compared to the RCD reentry worker assumptions, the application rate for strawberries is halved and REIs were increased from two days for all crops to four days for tomatoes and seven days for potatoes and strawberries. The WP formulation cannot be applied to tomatoes. Only perennial and biennial strawberries can be treated with endosulfan.

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Mitigation outlook

Even with longer REIs, decreased application rates and use restrictions, reentry workers are still potentially exposed to unacceptable DFRs levels. However, endosulfan use on these crops is minimal (Table A1). On average, only 123 acres of tomatoes are treated annually with endosulfan (PUR 2007–2011, “Tomato” site code). In addition, the endosulfan phase-out dates are July 31, 2015, for potatoes and tomatoes, and July 31, 2016 for strawberries.

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