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SUBJECT: ENDOSULFAN REREGISTRATION ELIGIBILITY DECISION, MITGATION MEASURES PROPOSED FOR OCCUPATIONAL EXPOSURE

USEPA made their Reregistration Eligibility Decision (RED) available on their website August (USEPA, 2002), following a closure conference call on July 31. The Special Review and Reregistration Division representative, Stacey Milan, stated in a phone call this morning that USEPA intends to release the full RED, including appendices, about September 30. At that time, an announcement will be published in the Federal Register, and the 60-day comment period will commence.

Some mitigation measures proposed in the closure call and the RED are potentially of concern to DPR. In particular, USEPA proposed formulation-based restricted entry intervals (REIs) for several crops, with longer REIs following application of wettable powder (WP) than emulsifiable concentrate (EC) products. DPR has objected in the past to multiple REIs because of potential confusion among users that might result in inadequate protection of workers. Thus, DPR may also choose to comment on formulation-based REIs. In this memo, proposed measures to mitigate occupational risks are summarized, with special emphasis on REIs.

In the RED (p. 65), USEPA expressed a preference to avoid multiple REIs:

> "In general, EPA prefers to set a single REI for all activities related to a crop or crop group without additional activity-based labeling. This approach is favored because handlers and workers are more likely to understand and comply with simpler labels. Also, permitting entry for some activities during the REI could cause confusion and compromise the effectiveness of the Worker Protection Standard (WPS). However, when the consideration of risks and benefits indicate that a single REI is unworkable, EPA may consider either setting an REI with early entry exceptions for one or more critical tasks or establishing an entry prohibition for a specific task after the REI has expired. For endosulfan, no critical activities have been identified to warrant the use of an activity-based exception or prohibition. However, during the 60-day comment period for this RED, EPA will accept further comments from growers regarding needs for additional REI exceptions for specific activities, and will consider such exceptions where needed if there are adequate MOEs and/or benefits associated with such activities."

Mitigation measures proposed in the RED avoided activity-based REI, although as stated in the last sentence above, USEPA will consider activity-based REI requested by commenters.

The RED proposed formulation-based REI, however. In several crops (see below), longer REI were proposed following treatment with WP products than with EC products. Interestingly, a rationale for multiple REIs was stated in the notes distributed for the closure call (under mitigation measures for occupational risk in melons cucumber and squash), but was omitted from the RED: "Endosulfan appears to possess a bi-phasic dissipation quality. This is especially evident in the first several days following application. Evidence of this bi-phasic property leads the Agency to believe that the MOE at 3 days is likely to be greater than 86 and may exceed 100." This statement is omitted from the RED; in fact, no reference is made in the RED to the "bi-phasic property" of endosulfan's DFR dissipation. Instead, the RED simply notes (p. 29): "In general, post-application risks were higher for the wettable powder formulation versus the emulsifiable concentrate."

Occupational mitigation measures

Occupational risks were to be mitigated by the following proposed measures (pp. 59-60 and 63-85):

Handler:

1. All wettable powders must be in water-soluble packaging. Intended to mitigate risks for M/L. Also, as noted by USEPA (p. 65), this packaging "will effectively preclude the use of WPs" for M/L/A using backpack sprayers or high pressure handwands.

2. Uses of wettable powder (WP) were canceled in the following crops: alfalfa (seed), carrots, sweet corn, cotton, dry beans, dry peas, small grains, sweet potato, pineapple, tomato, and tobacco.

3. Aerial applications of WP were canceled in the following crops: pome fruits, stone fruits, citrus, blueberry, strawberry, collard greens (for seed), kale (for seed),mustard greens (for seed), radish (for seed), turnip (for seed), rutabaga (for seed), broccoli (for seed), cabbage (for seed), cauliflower (for seed), kohlrabi (for seed), filberts, walnuts, almonds, and macadamia nuts.

4. Closed M/L systems required for aerial applications of the emulsifiable concentrate (EC) to all crops in which WP aerial uses were canceled, and to most crops in which WP uses were canceled completely. Crops: pome fruits, stone fruits, citrus, blueberry, strawberry, collard greens (for seed), kale (for seed), mustard greens (for seed), radish (for seed), turnip (for seed), rutabaga (for seed), broccoli (for seed), cabbage (for seed), kohlrabi (for seed), filberts, walnuts, almonds, macadamia nuts, alfalfa (seed), sweet corn, cotton, small grains, sweet potato, and tomato. (Exceptions: carrots, dry beans and peas, pineapple and tobacco).

5. Maximum application rate, seasonal application rate and/or number of applications were reduced on most crops. See Table 1 for a list of crops and changes. Many of these changes were proposed to mitigate environmental risks, but would also result in decreased occupational exposure.

6. Closed cab required for airblast applications to tree crops. Crops: pome fruits, stone fruits, citrus, filberts, walnuts, almonds, and macadamia nuts.

7. High-pressured handwand and right-of-way sprayer (greenhouse and bark treatments): maximum application rate reduced to 0.005 lbs AI/gal.

Table 1. Changes to maximum application rates of endosulfan products proposed as mitigation measures in Reregistration Eligibility Decision

	Maximum rate (lbs AI/acre)		Maximum seasonal rate (lbs AI/acre)		Maximum no. of applications	
Crop	**Old**	**New**	**Old**	**New**	**Old**	**New**
Melon, cucurbit, lettuce, cauliflower, Brussels sprouts, peppers, eggplant, carrot			3	2		
Filbert, walnut, almond, macadamia nut			3	2	2 [a/]	1 [a/]
Pome fruit, stone fruit	3	2	3	2.5		
Cotton (aerial)	2.0	0.75	3 [a/]	1.5 [a/]	6 [a/]	2 [a/]
Cotton (ground)	2.0	1.5	3 [a/]	2 [a/]	6 [a/]	2 [a/]
Celery			3	1		
Tomato, potato			3	2	6 [a/]	4 [a/]
Sweet corn			3	1.5	3	1
Sweet potato, dry beans, dry peas			3	2	3 [a/]	2 [a/]
Kale	1.0	0.75				
Broccoli, cabbage, kohlrabi	2.0	1.0	3	2		
Blueberry	2.0	1.5	3	1.5		
Strawberry	2.0	1.0	3	2	3 [a/]	2 [a/]
Small grains					2 [a/]	1 [a/]
Ornamental trees/shrubs	3.0	2.5				
Tobacco (no use in CA) [b/]			3 [a/]	2 [a/]	6 [a/]	2 [a/]

[a/] Change intended to mitigate environmental risks, but will affect worker exposure.
[b/] Use restricted to the following states to mitigate environmental risks: IN, KY, OH, PA, TN.

Reentry:

1. Increase base REI to 48 hours (due to eye irritation). Current base REI is 24 hours.

2. Increase WP REI in several crops. Crops and REI are listed in Table 2.

3. Increase EC REI above the baseline 48 hours in the following crops: sweet corn, sweet potato, broccoli (for seed), cabbage (for seed), kohlrabi (for seed), broccoli, cauliflower, brussel sprouts, cabbage, kohlrabi, and blueberries. See Table 2.

4. Reduced maximum application rates are expected to mitigate some reentry risks. These changes are given in Table 1. However, USEPA noted that registrants are expected to submit information that may result in increased maximum application rates to some crops (e.g., cotton).

Table 2. Formulation-specific Restricted Entry Intervals (REIs) proposed in endosulfan Reregistration Eligibility Decision [a/]

	REI (days)	
Crop	**WP**	**EC**
Melons, cucurbits	3	2
Lettuce, celery, pome fruit, stone fruit, citrus, collard greens, kale, mustard greens, radish, turnip, rutabaga, ornamental trees and shrubs	4	2
Collard greens (seed), kale (seed),mustard greens (seed), radish (seed), turnip (seed), rutabaga (seed)	5	2
Blueberry	9	6
Broccoli, cauliflower, kohlrabi, cabbage, Brussels sprouts	9	4
Broccoli (seed), cabbage (seed), cauliflower (seed), kohlrabi (seed)	12	7
Sweet potato	NA	3
Sweet corn	NA	17
[a/] Base REI will be increased to 48 hours (from 24 hours) for other crops, and will be the same for both wettable powder (WP) and emulsifiable concentrate (EC) products.		

Summary of Labeling Changes

In the RED, proposed label changes were listed in Table 12 (pp. 95-106). All of the proposed mitigation measures discussed above were included in this table, along with environmental

changes. Additionally, increased requirements for PPE and engineering controls for handlers are to be listed on the label. Double notification (oral warning in addition to posted signs) will be required for all endosulfan products.

Comments

In the RED, formulation-based REIs were proposed in several crops, based on different risk estimates for reentry into crops treated with the WP and EC formulations. The RED did not discuss the basis of exposure estimates, nor were the exposure estimates directly reported in the RED. Risks were reported rather than exposures; this is typical for REDs. Exposure estimates can be derived from risk estimates in the RED by dividing the appropriate NOEL by each MOE; they may also be obtained from the occupational exposure assessment prepared by USEPA (2001). In USEPA (2001), exposure estimates for reentry workers WP and EC were based on different DFR dissipation equations.

The decision to use formulation-specific exposure estimates is unusual, and raises a serious question. Reentry exposure estimates are based on generic transfer coefficients (TCs) that are considered to be activity-specific and crop-specific. Like DFR, TC values have generally been considered to be independent of formulation. Generic TCs are derived from limited numbers of studies using a few surrogate compounds and crops, and TC variability under varying conditions is not well-characterized.

Dissipation is an aggregation of several physical processes, such as evaporation and adsorption, as well as chemical processes such as degradation. If DFR is formulation-specific, which appears to be the case with endosulfan, then one or more of the physical or chemical processes differ between formulations. If DFR differs between the formulations because of different adsorption of endosulfan to leaf surfaces, for example, then the transfer of residues to workers might be expected to be affected as well.

To ensure that exposures are not under-estimated, and workers inadequately protected, the effect of formulation on TC should be understood. Without this understanding, USEPA should base risk estimates on the higher of the two exposure estimates.

References:

Beauvais, S., Sanborn, J. and Powell, S. (2001). Human Exposure Assessment for Endosulfan. Report no. HS-1647. Draft dated November 2. Sacramento, CA: Worker Health and Safety Branch, Department of Pesticide Regulation, California Environmental Protection Agency.

US EPA. (2001). Occupational and Residential Exposure and Risk Assessment and Recommendations for the Reregistration Eligibility Decision Document for Endosulfan. Second Revision, dated January 2. Washington, DC: Health Effects Division, U.S. Environmental Protection Agency.

US EPA. (2002). Reregistration Eligibility Decision for Endosulfan. Case No. 0014. Washington, DC: Health Effects Division, U.S. Environmental Protection Agency.