November 30, 2021

Julie Henderson, Acting Director, julie.henderson@calepa.ca.gov
Karen Morrison, Acting Deputy Director, karen.morrison@cdpr.ca.gov
California Department of Pesticide Regulation
Via email

Dear Director Henderson and Deputy Director Morrison:

Thank you for meeting with us recently to discuss DPR's recently-released Risk Management Directive (RMD), pilot project, and rulemaking plans for 1,3-dichloropropene (1,3-D).

We are following up to elaborate on our discussion of the acute regulatory target concentration set in the Acute RMD and occupational bystander risk concerns, and to ask some follow-up questions about the assumptions the department plans to use in setting emission rates from the mitigation pilot study results.

Acute Regulatory Target Concentration

We support selection of 55 ppb as a reference concentration for acute effects to account for uncertainties in the intraspecies pharmacokinetic data.[i] However, for mitigating risk, we conclude that future control measures should be designed to limit 24-hour exposure to 55 ppb rather than 72-hour exposure as the RMD proposes. Reasons for basing mitigation on 24-hour exposures to 55 ppb or less include:

1) The Department's 1,3-D Risk Characterization Document (RCD)[ii] documents that body weight decrement was documented after 1 day of exposure in at least one acute toxicology study[iii].
2) The target concentration was derived from a study[iv] where the test animals were <u>first weighed</u> after 3 days of exposure, so the effect (weight gain decrement) could have occurred earlier.
3) In the 1,3-D RCD, Acute Margins of Exposure (MOEs) were calculated for residential bystanders[v] for 24-hour rather than 72-hour exposures.
4) As detailed in a DPR Memorandum responding to Dow AgroSciences comments on DPR's draft 1,3-D Risk Assessment[vi], Dow AgroSciences commented on the draft RCD: "The short-term endpoint being used by DPR did not manifest until a minimum of 3 days after exposure. Thus a 3 day average is appropriate for the endpoint used." DPR

> toxicologist Andy Rubin responded, “The toxicological effect in the inhalation study of (Stott et al., 1984) was not measured until 3 days after the dosing was initiated. The effect could conceivably have occurred earlier, before the first body weight measurement.”

In the powerpoint presentation at the DPR October 17, 2019 public workshop "Options to Mitigate Acute Exposure to 1,3 Dichloropropene”[vii], slide 5 compares the highest 24 hour measurements in Parlier and Shafter to a regulatory target of 110 ppb. In subsequent slides, estimates of required buffer zone distances are presented for acute targets of both 55 ppb and 110 ppb but the averaging time used (24-hour vs 72-hour) is not noted. We have submitted a public records request for the air modeling data used to derive these buffer zone estimates.

We also concur with CARB’s comment that a 24-hour target concentration is needed so that ambient air samples of 24 hours in duration can be used to evaluate whether the target concentration is being exceeded. Since air concentrations are only measured once a week, modeling would need to be used to estimate 3 day average air levels. However, as OEHHA has pointed out in comments on the 1,3-D Acute RMD[viii], in a few recent incidents, the results of air modeling markedly underestimated the 24-hour levels monitored.

Accounting for uncertainties when estimating emission rates from pilot study results

We appreciate DPR’s work conducting application monitoring to investigate emission rates for a number of fumigant application methods involving higher soil moisture, deeper injection, additional soil compaction and/or alternating rows of TIF tarp and bare ground. Due to constraints in resources and cooperating growers, only 5 field application studies have been completed in 4 counties, with 3 additional studies conducted with Dow and UC researchers still in process. Summary data presented to the Pesticide Registration and Evaluation Committee (PREC) seem to show that for the studies completed so far, applications conducted on small (2-5 acre) test plots resulted in lower emissions than the current 18” untarped applications and were comparable to TIF tarp emissions.

It is our general understanding that DPR will use data on air concentrations, soil characteristics, weather data and soil moisture from the field studies to refine computer modeling of air emissions. However, it is not evident how DPR will incorporate real-world uncertainties when extrapolating emission rates from small field studies to much larger applications conducted under real world conditions where water application may be uneven, rocks may impede deep injection and time pressure may lead to cutting of corners. We request that DPR disclose how such uncertainties will be taken into account so that emission rate estimates are realistic.

Mitigations needed for occupational bystanders

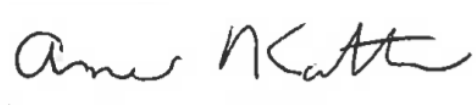
The need to reduce 1,3-D emissions in rural California is urgent, especially in areas where untarped applications are the norm. Risk calculations in the Department’s 1,3-D RCD[ix] show that exposures need to be reduced for both residential and occupational bystanders and as noted by OEHHA, recent air monitoring results in Shafter and Parlier show that the air modeling can markedly underestimate exposures. The RCD points out that the lack of any buffer zone for

occupational bystanders[x] increases exposure but fails to account for the fact that farmworkers can be exposed both as residential and occupational bystanders.

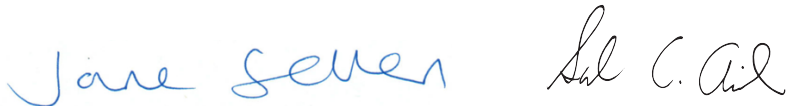
We remain convinced that reducing reliance on soil fumigation is the best approach. In the meantime it is crucial to thoroughly evaluate the emissions from new fumigation methods under real world conditions.

We request a written response or a follow up meeting to discuss these points at your earliest convenience.

Sincerely,



Anne Katten, MPH, Pesticide and Work Health and Safety Specialist
California Rural Legal Assistance Foundation



Jane Sellen and Sarah Aird, Co-Directors
Californians for Pesticide Reform

Caroline Cox
Retired Scientist
Californians for Pesticide Reform Steering Committee, honorary member.

CC: Lauren Zeiss, OEHHA, lauren.zeiss@oehha.ca.gov
Dave Edwards, OEHHA, david.edwards@oehha.ca.gov
Richard Corey, CARB, richard.corey@arb.ca.gov
Lynn Baker, CARB, lynn.baker@arb.ca.gov
Ouahiba Laribi, OEHHA, ouahiba.laribi@oehha.ca.gov
Jared Blumenfeld, CalEPA, jared.blumenfeld@calepa.ca.gov
Nan Singhasemanon, DPR, Nan.Singhasemanon@cdpr.ca.gov

ENDNOTES:

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[i] DPR derived an acute reference concentration of 110 ppb in the 2015 1,3 D RCD. In peer review comments, OEHHA recommended an additional 2x uncertainty factor for a derived reference concentration of 55 ppb.

[ii] 1,3 D RCD https://www.cdpr.ca.gov/docs/risk/rcd/dichloro_123115.pdf

[iii] 1,3 D RCD pg.4, pg 102, "The body weight effects, which were likely generalized expressions of animal stress, occurred early in the treatment period (ie. within 1-13 days)."

[iv] Stott et al (1984) 13 week rat study, 1,3 D RCD pg 103: "Study was chosen because the 3 day time period more closely approximated an acute exposure regime than the other studies."

[v] 1,3 D RCD pg.120: "The short-term air concentration is defined as the daily 1,3 D breathing zone concentration of the workers (8 hour TWA) for up to one week or the residential bystander (24 hour TWA) for up to one week."

[vi] DPR Memorandum. November 8, 2016. Response to comments by Dow AgroSciences on DRP-HHAB's draft 1,3-Dichloropropene Risk Characterization Document dated August 31, 2015.

[vii] https://www.cdpr.ca.gov/docs/whs/pdf/1,3-d_options_mitigate_acute_exposures.pdf

[viii] https://www.cdpr.ca.gov/docs/whs/pdf/1,3-d_directive_mitigation_exposure_response.pdf

[ix] 1,3 D RCD pg. 160, 168, 169, 200

[x] For Telone II and other formulations that don't contain chloropicrin