



Department of Pesticide Regulation



Brian R. Leahy
Director

MEMORANDUM

Edmund G. Brown Jr.
Governor

TO: Teresa Marks
Chief Deputy Director

FROM: Brian R. Leahy *Original Signed By*
Director
916-445-4000

DATE: August 24, 2018

SUBJECT: DIRECTOR'S PROPOSED DETERMINATION CONCERNING
CHLORPYRIFOS AS A TOXIC AIR CONTAMINANT

Attached is a public notice of the proposed determination concerning my response to the Scientific Review Panel's findings on chlorpyrifos as a toxic air contaminant. My response has been made in accordance with all authorities and requirements stipulated in the Food and Agricultural Code and California Code of Regulations that mandate this determination. The Scientific Review Panel's findings were received on August 15, 2018. Therefore, my response has been made within the ten-day statutory deadline.

I thank you, staff, and all the members of the Scientific Review Panel for the excellent work.

Attachment

cc: Richard Corey, ARB, Executive Officer (w/Attachment)
Lauren Zeise, OEHHA, Director (w/Attachment)
Scientific Review Panel (w/Attachment)
James Behrmann, Scientific Review Panel ARB Liaison (w/Attachment)
Jesse Cuevas, Assistant Director (w/Attachment)
Marylou Verder-Carlos, Assistant Director (w/Attachment)
Daniel Rubin, Acting Chief Counsel (w/Attachment)
DPR Program Branch Chiefs (w/Attachment)

August 24, 2018

Post Until September 24, 2018

NOTICE OF PROPOSED DETERMINATION CONCERNING
THE DIRECTOR'S DECLARATION OF
CHLORPYRIFOS AS A TOXIC AIR CONTAMINANT

Section 14023 of the Food and Agricultural Code (FAC) requires the Director of the Department of Pesticide Regulation (DPR) to determine if a pesticide is a toxic air contaminant (TAC) after receiving the findings of the Scientific Review Panel (SRP), a panel of experts representing a range of scientific disciplines. Based on the findings of the SRP's assessment of the report entitled "Evaluation of Chlorpyrifos as a Toxic Air Contaminant" and the criteria given in Title 3, California Code of Regulations (CCR) section 6864(b), the Director proposes to declare chlorpyrifos as a TAC.

Background

With the enactment of California's Toxic Air Contaminant Act (Assembly Bill 1807, Tanner, Chapter 1047, Statutes of 1983; amended by Tanner, Chapter 1380, Statutes of 1984), the Legislature created the statutory framework for the evaluation and control of chemicals as TACs. The statute defines TACs as air pollutants that may cause or contribute to increases in serious illness or death, or that may pose a present or potential hazard to human health. DPR is responsible for the evaluation of pesticides as TACs.

In general, the law focuses on the evaluation and control of pesticides in ambient community air. In implementing the law, DPR must: (1) conduct a review of the physical properties, environmental fate, and human health effects of the candidate pesticide; (2) determine the levels of human exposure in the environment; and (3) estimate the potential human health risk from those exposures. The law requires DPR to list in regulation those pesticides that meet the criteria to be TACs.

For each pesticide, FAC section 14023 requires the preparation of a report, in consultation with Office of Environmental Health Hazard Assessment, that includes: the environmental fate and use of the pesticide, an assessment of exposure of the public to air concentrations of the pesticide, and a health assessment. The report is reviewed by the Air Resources Board, and is made available for public review. Based on the results of these reviews, the draft report is revised as appropriate. The draft undergoes a rigorous peer review for scientific soundness by the SRP. Based on the results of this comprehensive evaluation, the DPR Director determines whether the candidate is a TAC. If the Director determines the pesticide meets the criteria to be a TAC, DPR declares the pesticide a TAC in regulation, and adds it to the TAC list.

Once a candidate pesticide has been declared a TAC, it enters phase two of the program--the mitigation, or control, phase. In the mitigation phase, DPR investigates the need for, and appropriate degree of, control measures for the TAC. If reductions in exposure are needed,

DPR must develop control measures to reduce emissions to levels that adequately protect public health.

Department Conclusions

Title 3, CCR section 6864 states, "A pesticide shall be identified as a toxic air contaminant if its concentrations in ambient air are greater than the following levels (for the purposes of this section, a threshold is defined as the dose of a chemical below which no adverse effect occurs):

- (a) For pesticides which have thresholds for adverse health effects, this level shall be ten-fold below the air concentration which has been determined by the Director to be adequately protective of human health.
- (b) For pesticides which do not have thresholds for adverse health effects, this level shall be equivalent to the air concentration which would result in a ten-fold lower risk than that which has been determined by the Director to be a negligible risk."

In its December 2015 Draft Risk Assessment, DPR's Human Health Assessment Branch initially adopted the points of departure (PoDs) from the 2014 US EPA Revised Human Health Risk Assessment for Chlorpyrifos (US EPA, 2014) which utilized an Acetylcholinesterase (AChE) inhibition endpoint. The PoDs were human estimates derived from physiologically based pharmacokinetic-pharmacodynamic (PBPK-PD) modeling of 10 percent AChE inhibition in red blood cells. It was in the December 2015 draft that the potential human exposure to spray drift (via inhalation or deposition) first became a concern. As such, chlorpyrifos entered the formal process to evaluate the scientific evidence for listing as a pesticide TAC (FAC §14021-14027).

In a December 2017 revision of the Draft TAC Evaluation, the critical no-observed effect level (NOEL) for evaluating oral, dermal, and inhalation exposure to chlorpyrifos was a PBPK-PD derived PoD based on 10 percent inhibition AChE after an acute (single day, 24 hr.) or steady-state (21-day) exposure. The PBPK-PD model includes parameters that account for human-specific physiology and metabolism and can be used to derive age, exposure duration, and route specific PoDs.

Risks were calculated as a margin of exposure (MOE) for infants, children, youths, and non-pregnant adults. The MOE equals the critical PoD divided by the estimated human exposure level. DPR considered a MOE of 100 to be protective of human health for all exposure scenarios. The target of 100 included uncertainty factors of 1x for interspecies sensitivity, 10x for intraspecies variability, and 10x for potential neurodevelopmental effects. Exposures resulting in MOEs lower than the target of 100 were considered to be of potential health risk to humans. Dividing the AChE PoD by the MOE of 100 resulted in a reference concentration (RfC) of 28.5 µg/m³ for children 1-2 years old.

After further review of the PBPK-PD modeling parameters, and in consultation with the SRP, DPR's Human Health Assessment Branch subsequently increased the interspecies

uncertainty factors for model insufficiencies, thus adjusting the target MOE from 100 to 300, and a RfC of 9.5 µg/m³ for children 1-2 years old.

Following the recommendation of the SRP, in the final July 2018 TAC evaluation of chlorpyrifos, DPR thoroughly evaluated developmental neurotoxicity (DNT) as a critical endpoint for risk assessment. HHA conducted a comprehensive review of recently available animal studies and focused on the evidence of DNT at low dose levels. Critical PoDs were established from animal studies reporting effects at dose levels that were approximately 10-fold lower than those that inhibit red blood cell AChE. A target MOE of 100 was selected to be protective of human health for the DNT endpoint and is comprised of 10x for interspecies sensitivity and 10x for intraspecies variability. Dividing the DNT PoD by a MOE of 100 results in a RfC of 4.05 µg/m³ for children 1-2 years old.

DPR estimated exposures from spray drift using computer modeling. If using a fixed-wing aerial application of chlorpyrifos with 2 gallons/acre finished spray volume and 2 lbs/acre application rate as its standard exposure scenario (the most common aircraft used for aerial applications in California and a reasonable “worst case” scenario), the modeled air concentration at 100 feet from the treated area was 35 µg/m³. (For aerial applications, chlorpyrifos labels require a setback distance of 50 – 80 feet, depending on the application rate and type of nozzle.)

A pesticide is defined as a TAC if its air concentrations, either measured or modeled, exceed the RfC divided by 10. Chlorpyrifos meets the criteria of TAC designation.

The SRP agrees with the science presented in the Risk Characterization Document and recommends that the Director identify chlorpyrifos as a TAC.

Department Actions

DPR proposes to adopt a regulation designating chlorpyrifos as a TAC. DPR proposes to add chlorpyrifos to the list of pesticides in Title 3, CCR section 6860(a).

DPR will conduct a public hearing concerning the proposed regulation.

APPROVED BY: Original Approved By Date: 08/24/18
Brian R. Leahy, Director