



Department of Pesticide Regulation



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MEMORANDUM

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TO: Marylou Verder-Carlos, Assistant Director
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FROM: Teresa Marks 
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916-445-4000

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SUBJECT: DIRECTIVE FOR INTERIM MITIGATION MEASURES TO ADDRESS
HEALTH RISKS FROM CHLORPYRIFOS

The Department of Pesticide Regulation's (DPR's) draft health risk assessment released in December 2015 identified several scenarios with potentially unacceptable risk, primarily from exposure through ingestion and dermal exposure. Since then, DPR has made revisions to the risk assessment based on the statutorily mandated peer review comments from the Office of Environmental Health Hazard Assessment (OEHHA) and other reviews. There remains a difference of opinion between DPR and OEHHA scientists on elements of the risk assessment analysis that would impact the final regulatory target.

The revised risk assessment identifies additional scenarios with potentially unacceptable risk which will require additional review, including inhalation exposures to the public. These potential inhalation exposures require that DPR initiate the review of the current August 2017 draft of its risk assessment analysis under the process outlined in Food & Agricultural Code section 14023 for potential listing and mitigation of chlorpyrifos as a toxic air contaminant (TAC). However, as explained below, to protect public health DPR believes the appropriate path forward is to develop interim mitigation measures as soon as possible to address bystander exposure.

Section 14023 requires an additional review by the Scientific Review Panel (SRP) of chlorpyrifos as a potential TAC. The SRP will evaluate the potential inhalation exposures to the public and provide an additional opinion on the scientific issues that have been raised during the initial peer review process. The SRP TAC process may be lengthy, however, so to provide protection of the public during this process, DPR will develop interim mitigation based upon its revised draft risk assessment. Mitigation will be revised and strengthened if necessary as part of the TAC process. In addition, DPR will continue to review and evaluate relevant scientific studies on the potential hazards of chlorpyrifos on human health or the environment, including developmental neurotoxicity.



This document outlines DPR's management decisions based on the August 2017 risk assessment to set the regulatory goals necessary to initiate and guide the development of interim mitigation measures. The mitigation measures will focus on the exposures of greatest risk, short-term acute exposures to children one to two years old.

Background

Chlorpyrifos is a widely used pesticide to control a variety of insects in numerous crops, including alfalfa, almonds, broccoli, cotton, citrus, and walnuts. Major use areas include the Central Valley, Central Coast region, and Imperial County. Use occurs year-round, with peak use during the summer. There are several dozen chlorpyrifos products, registered by approximately 20 different companies. Methods of application allowed by labels include aerial, airblast, ground boom, chemigation, and others.

Chlorpyrifos can cause cholinesterase inhibition. Acetylcholinesterase (AChE) is an enzyme that is required to break down the neurotransmitter acetylcholine in nerve junctions. Chlorpyrifos and other organophosphate pesticides block this enzyme, and high exposures can cause sweating, salivation, vomiting, diarrhea, low blood pressure and heart rate, muscle twitching, and even seizures. Chlorpyrifos also affects multiple neurological functions that may or may not be associated with cholinesterase inhibition. Epidemiological studies have shown some evidence of associations between maternal or childhood exposure to chlorpyrifos and delays in mental and psycho-motor development in infants, attention deficits, autism, and other effects in young children. Some of these developmental neurotoxic effects appear to occur at lower levels than those that cause cholinesterase inhibition although a mechanism of action and the critical timing of exposure have not been determined.

Both DPR and the U.S. Environmental Protection Agency (U.S. EPA) have been evaluating the potential health and environmental effects of chlorpyrifos for several years. In 2015, U.S. EPA proposed to revoke all food tolerances to mitigate potential exposures, based on its 2014 draft risk assessment. This action would have ended most, if not all uses of chlorpyrifos. In November 2016, U.S. EPA issued a revised draft risk assessment, indicating greater health risk than the 2014 draft evaluation due to its potential developmental neurotoxicity. However, this assessment was not finalized, and in March 2017, U.S. EPA denied a 2007 petition by environmental groups to revoke the food tolerances and indicated more information will be necessary before U.S. EPA will be able to set tolerances. DPR issued its draft risk assessment in 2015, and a revised draft risk assessment in August 2017. Both of DPR's risk assessments identify cholinesterase inhibition as the critical endpoint.

Scope of Interim Mitigation Measures and Regulatory Target

Consistent with DPR's August 2017 draft risk assessment, the goal of the interim mitigation measures is to reduce acute aggregate exposures to bystanders so that they do not exceed a regulatory target margin of exposure (MOE) of 100.¹ Aggregate exposure to chlorpyrifos includes exposures through inhalation, dermal, and ingestion. The regulatory target air concentration of 23.7 micrograms per cubic meter is based on cholinesterase inhibition after 21 consecutive days of repeated inhalation exposure to chlorpyrifos². The mitigation measures should focus on the populations with highest risk (one to two year old children and 13-49 year old females) and the two major routes of exposure (inhalation and ingestion), as described in the August 2017 draft risk assessment. The use restrictions to meet this regulatory target will address potential health effects from cholinesterase inhibition. DPR will more fully address potential developmental neurotoxicity and longer term exposures, if needed, after DPR completes the TAC review and finalizes the risk assessment.

Also consistent with the August 2017 draft risk assessment, gaps in the available data require us to make two assumptions as we evaluate potential mitigation measures. First, we will assume that the estimated air concentrations for ground applications are the same as aerial applications. Since there is a lack of data for air concentrations resulting from airblast and ground boom applications, we are using aerial applications as a surrogate. Second, because the available data comes from an AGDISP Model, we will assume that all of the chlorpyrifos in air may be inhalable and potentially inhibit cholinesterase. There are potentially two forms of chlorpyrifos in air: aerosols and vapor. Since product labels require the use of application equipment spray nozzles that produce medium or coarse droplets, not all of the chlorpyrifos aerosols have sizes that are inhalable and chlorpyrifos in vapor form has less potential to inhibit cholinesterase. Nevertheless, the only information we have comes from the AGDISP model, version 8.28,

¹ The regulatory target was determined by first using a computer model to estimate the amount of chlorpyrifos that causes cholinesterase inhibition in humans. This amount was then adjusted by a 10-fold reduction to address variability within the human population and a 10-fold reduction to address potential developmental neurotoxicity. The combined 100-fold adjustment is a margin of exposure of 100. Using the model eliminates the need for the default 10-fold factor to address potentially different sensitivity to chlorpyrifos between test animals and humans; animal data were not used for this part of the risk assessment.

² This regulatory target concentration is more stringent than the typical acute target, because repeated exposures generally result in more cholinesterase inhibition at a given concentration. Computer modeling indicates that cholinesterase inhibition stabilizes, and continued exposures at the target concentration past 21 days do not result in greater cholinesterase inhibition. DPR chose this 21-day regulatory target in order to account for the cumulative nature of cholinesterase inhibition not only from inhaling airborne chlorpyrifos, but also from other exposures potentially occurring on the same day (e.g., consuming food and drinking water with chlorpyrifos residues).

which was used to estimate the air concentrations in the August 2017 draft risk assessment. Since U.S. EPA recently approved version 8.29 of the model, DPR staff will evaluate the feasibility of using it for developing mitigation measures.

The mitigation measures will address chlorpyrifos applications to agricultural commodities (production agriculture use) because they constitute more than 99 percent of the use.

Measures to Achieve Regulatory Goals

In 2015, DPR designated chlorpyrifos as a restricted material when labeled for the production of an agricultural commodity, and developed mitigation measures in the form of recommended permit conditions that included the following based on best practices.

Minimum distances to sensitive sites:

Application Method	Minimum Setback Distance
Ground Boom	25 feet
Chemigation	25 feet
Airblast	50 feet
Aerial (fixed wing or rotary)	150 feet

Current recommended permit conditions require that all applications must take place with a wind speed of three to 10 miles per hour.

Current recommended permit conditions for airblast applications:

- Spray the outside crop row from outside in, directing the spray into the treatment area and shutting off nozzles on the side of the sprayer away from the treatment area.
- Shut off top nozzles when treating smaller trees, vines, or bushes to minimize spray movement above the canopy.

DPR staff should update these recommended permit conditions and consider including the following:

- additional restrictions on application methods,
- limits on size of applications, and
- larger setbacks that are based on the August 2017 risk assessment.