

INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Amend Section 6400
Designating Chlorpyrifos as a Restricted Material
When Labeled for the Production of an Agricultural Commodity

This is the Initial Statement of Reasons required by Government Code section 11346.2 and the public report specified in section 6110 of Title 3, California Code of Regulations (3 CCR). Section 6110 meets the requirement of Title 14, CCR section 15252 and Public Resources Code section 21080.5 pertaining to state regulatory programs certified under the California Environmental Quality Act.

SUMMARY OF PROPOSED ACTION/PESTICIDE REGULATORY PROGRAM
ACTIVITIES AFFECTED

The Department of Pesticide Regulation (DPR) proposes to amend 3 CCR section 6400(e). The pesticide regulatory program activities that will be affected by the proposal are those pertaining to pesticide chemicals designated as state-restricted materials. In summary, the proposed action would make a pesticide product containing the active ingredient chlorpyrifos a state-restricted material when labeled for the production of agricultural commodities.

SPECIFIC PURPOSE AND FACTUAL BASIS

DPR protects human health and the environment by regulating pesticide sales and use and by fostering reduced-risk pest management. DPR's strict oversight includes: product evaluation and registration; statewide licensing of commercial and private pesticide applicators, pest control businesses, dealers, and advisers; environmental monitoring; and residue testing of fresh produce. This statutory scheme is set forth primarily in Food and Agricultural Code (FAC) Divisions 6 and 7.

Pesticides must be registered (licensed for sale and use) with the U.S. Environmental Protection Agency (U.S. EPA) before they can be registered in California. DPR's preregistration evaluation is in addition to, and complements, U.S. EPA's evaluation. Before a pesticide can be sold or used in California, both agencies require data on a product's toxicology and chemistry--how it behaves in the environment; its effectiveness against targeted pests and the hazards it poses to nontarget organisms; its effect on fish and wildlife; and its degree of worker/bystander exposure.

Chlorpyrifos is a broad-spectrum insecticide widely used in California for the control of foliage and soil-borne insect pests on a variety of food and feed crops. Chlorpyrifos is also used on non-food sites such as golf course turfs, industrial sites, and seed treatment. Chlorpyrifos products are available in several different formulations, such as liquid emulsifiable concentrate, granular, microencapsulate, and wettable powder. Chlorpyrifos belongs to a classification of chemicals known as organophosphates, which adversely affect the nervous system by inhibiting the activity of cholinesterase (ChE), an enzyme necessary for the proper functioning of the nervous system. ChE inhibition can result in overstimulation of the nervous system causing nausea, dizziness,

confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death. Additionally, exposure to chlorpyrifos has also been linked to long-term neurological effects.

In June 2000, U.S. EPA completed its "Human Health Risk Assessment for Chlorpyrifos." To address exposure concerns identified in the assessment, U.S. EPA entered into an agreement with the technical registrants of chlorpyrifos to eliminate virtually all residential uses, except ant and roach baits in child resistant packaging by December 31, 2001. Additionally, in 2000, U.S. EPA designated all chlorpyrifos products formulated as emulsifiable concentrates, and products packaged in containers smaller than 15 gallons of a liquid formulation or 25 pounds of a dry formulation as a federally restricted-use pesticide pursuant to section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Pursuant to Title 40 Code of Federal Regulations section 171.11, sales and use of these pesticides are limited to certified applicators and those under their direct supervision, thus controlling the number of persons with direct access to the chemical. In California, applicators become certified by taking an examination to demonstrate they have the knowledge and proficiency required to use restricted materials, and maintain certification by completing DPR pre-approved continuing education courses.

3 CCR section 6400(a) states that any pesticide labeled as a "restricted use pesticide" (RUP) pursuant to section 3 of FIFRA is also designated as a restricted material in California. In accordance with FAC section 14015, restricted materials can only be purchased by, possessed, or used by or under the direct supervision of, a certified private applicator or a certified commercial applicator. Generally, the purchase, possession, and use of a restricted pesticide are allowed only under a permit issued by the local county agricultural commissioner (CAC). However, 3 CCR section 6414(b) exempts those pesticides deemed state-restricted solely under section 6400(a) as an RUP from a restricted materials permit provided the pesticide is used by or under the supervision of, a certified applicator, unless otherwise required by the CAC. Therefore, the restricted materials permit requirement currently does not apply to federal RUP chlorpyrifos products.

CALIFORNIA USE PATTERNS

Chlorpyrifos is used on more than 60 different agricultural commodities in California. Since 2004, one to two million pounds of chlorpyrifos have been applied each year in more than 20,000 applications. Currently, 30 products containing the active ingredient chlorpyrifos are registered by DPR for agricultural use on agricultural commodities. In addition, section 24(c) of FIFRA allows states to register additional uses of a registered product if there is a demonstrated "special local need" for the product. As of July 2014, there are eight section 24(c) special local need registrations for use on various agricultural commodities in California that would also be subject to the proposed regulation. From 2009-2011, 67 percent of all agricultural applications of chlorpyrifos were conducted via ground application methods (ground boom or air blast sprayer) and 32 percent of all agricultural applications were conducted aerially (helicopter or fixed wing) to a wide range of agricultural commodities. Chlorpyrifos also is used for purposes other than production of agricultural commodities, such as applications to golf courses, rights of way, landscape areas, non-residential structures, and livestock housing. However, these other uses comprise less than one percent of chlorpyrifos use.

HUMAN HEALTH CONCERNS

Chlorpyrifos is a semi-volatile organic compound with a vapor pressure of 1.87×10^{-5} mm Hg (millimeter mercury). Due to its wide use, toxicity, and semi-volatile nature, DPR and the California Air Resources Board (ARB) monitored ambient and off-site levels in air for chlorpyrifos. The results of the most recent studies are described below.

- Ambient Air Concentrations

DPR and ARB conducted several California monitoring studies for chlorpyrifos and other pesticides in air. In the absence of standards or formal DPR risk assessments, DPR developed health screening levels as part of an initial evaluation of monitoring results. Health screening levels are calculated air concentrations based on a chemical's toxicity that are used to evaluate the possible health effects of exposure to the chemical. A measured air concentration below the screening level for a given pesticide would not be considered a significant health concern and would not generally undergo further evaluation. A measured concentration that is above the screening level would not necessarily indicate a significant health concern, but would indicate the need for a further, more refined evaluation. Significant exceedance of the screening levels could be a health concern and may indicate the need to explore the imposition of mitigation measures. The air monitoring studies show that chlorpyrifos is one of the most frequently detected agricultural pesticides in California, but few of the detections have exceeded the screening levels.

In 2006, DPR and ARB conducted a joint 12-month air monitoring study in Parlier, California. Chlorpyrifos and/or its breakdown product were detected in 64 percent of the samples and was one of the pesticides most often detected. Collectively, detections of chlorpyrifos and other organophosphates posed the highest sub-chronic/non-cancer risk among the pesticides detected.

In 2011, as part of DPR's mandate for "continuous evaluation" of currently registered pesticides, DPR implemented a multi-year statewide air monitoring network for measuring pesticides in various agricultural communities. The Air Monitoring Network was the first long-term air monitoring study conducted by DPR with the intent of using the data collected to estimate seasonal pesticide exposures and local concentrations as well as more accurately estimate chronic pesticide exposures. In 2011 and 2012, chlorpyrifos was one of the most frequently detected chemicals. Chlorpyrifos was detected in 32 percent of the samples collected in 2011, and 28 percent of the samples collected in 2012. All ambient air detections were at low concentrations relative to their screening levels.

- Exposure Incidents Related to Agricultural Use

Based on the California Pesticide Illness Surveillance Program, between 2001 and 2011, 35 different agricultural chlorpyrifos applications were identified as "possibly," "probably," or "definitely" associated with chlorpyrifos use alone, or in combination with other pesticides in which 136 people were exposed due to drift. Of the drift exposures, 126 people were exposed as a result of ground applications and 10 people were exposed as a result of aerial applications. Of the 35 separate applications where drift occurred, 9 met DPR's criteria for a "priority

investigation" due to the fact that more than 5 people became ill as a result of a single application event.

OFF-SITE SURFACE WATER MOVEMENT CONCERNS

In addition to air monitoring, DPR conducts surface water sampling to monitor for potential environmental contamination of water bodies due to pesticides. DPR's surface water monitoring data indicate chlorpyrifos is frequently detected in rivers and streams in agricultural areas in California, often at concentrations that exceed water quality benchmarks for aquatic invertebrates.

In 2004, DPR placed all chlorpyrifos products labeled for agricultural use into reevaluation based on 2002–2003 monitoring data from 73 agriculturally dominated river and tributary sites. In 2006, DPR adopted regulations restricting pesticide applications during the dormant season to tree crops to address frequent detections of chlorpyrifos at concentrations that could impact aquatic life. However, surface water monitoring studies continued to show elevated concentrations of chlorpyrifos occurring during the non-dormant season in regions with tree crops and throughout the year in regions with vegetable commodities.

In California, most chlorpyrifos was applied in the Central Valley, Central Coast, and Imperial County regions during 2006-2012. For the Central Valley during this period, chlorpyrifos was detected in 12 percent of the 3,529 samples collected. Chlorpyrifos detections occurred at high enough concentrations to exceed the U.S. EPA's chronic invertebrate aquatic life benchmark in six percent of the samples. This benchmark represents a concentration that when exceeded, is expected to cause toxicity to aquatic invertebrates over a period of chronic exposure. For Imperial County and three Central Coast watersheds, chlorpyrifos use was lower than the Central Valley, but displayed a relatively high detection frequency of 47 percent in the 565 samples collected. In addition, chlorpyrifos concentrations exceeded the U.S. EPA's chronic invertebrate aquatic life benchmark in 30 percent of the samples. Imperial County and the Central Coast regions tend to have multiple croppings per year, and therefore are subjected to repeated chlorpyrifos applications resulting in higher use intensity.

Once applied to the field, chlorpyrifos can move off-site in runoff water or become attached to sediment. Factors such as climate, soil characteristics, field slope, and water/ irrigation management influence the off-site movement of chlorpyrifos. Drift is another pathway for direct deposition into waterways in some cases.

The California Regional Water Quality Control Boards (CRWQCBs) established a number of Total Maximum Daily Loads (TMDLs) for agriculturally-dominated waterways, predominantly in the Central Valley and central coast watersheds, to address contamination caused by elevated concentrations of chlorpyrifos. Users of chlorpyrifos (e.g., growers) are designated as dischargers by CRWQCBs and must comply with the load allocations established in TMDLs. To coordinate their TMDL efforts, the two CRWQCBs that have authority over the Central Valley and central coast watersheds have formally requested DPR's assistance in addressing the contamination of waterways from chlorpyrifos use.

OFF-SITE AIR MOVEMENT CONCERNS

In 2011, as part of the registration review process, U.S. EPA published the memorandum "Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration." This memorandum identified the potential for bystander exposure to spray drift and/or volatilization as public health concerns. In 2012, U.S. EPA addressed these concerns by requiring registrants to reduce application rates and establish mandatory buffers around sensitive sites to protect children and other bystanders who live, attend school, play, or otherwise spend time next to sites where chlorpyrifos is applied. The buffer distances are greatest for aerial applications which pose the highest risk. By adopting the new mitigation measures, applicators can effectively lower spray drift levels and reduce risks to bystanders. After taking these actions, U.S. EPA subsequently identified additional potential risks from drift.

As described above, chlorpyrifos is a widely used pesticide in California with more than 20,000 applications to several dozen crops each year. U.S. EPA's registration review evaluates concerns associated with typical use patterns nationwide. However, much of California's agricultural environment is uncommon to other states due to its wide variety of crops, application sizes, application methods, microclimates, and other factors which may influence the off-site movement of chlorpyrifos in ways U.S. EPA's review does not consider.

PROPOSAL FOR RESTRICTING USE

Existing law (FAC sections 14004.5 and 14005) authorizes the Director to adopt, by regulation, a list of restricted materials based upon criteria including danger of impairment of public health; hazards to pesticide applicators, farmworkers, and domestic animals; hazards to the environment from pesticide drift onto streams, lakes, and wildlife sanctuaries; and hazards to wildlife and other crops through persistent residues in the soil. Listing a pesticide as a state-restricted material allows the additional regulatory control provided by the requirement to obtain a time and site specific permit before use.

Based on DPR's and U.S. EPA's findings that chlorpyrifos has the propensity to move off-site in both air and surface water, and has caused illnesses and surface water contamination due to off-site movement, DPR proposes to designate chlorpyrifos as a California-restricted material when used for the production of an agricultural commodity, adding it to the listing in section 6400(e).

As mentioned above, federal RUP chlorpyrifos products can only be sold to, purchased by, possessed, and used by or under the direct supervision of, a certified private applicator or a certified commercial applicator. However, some chlorpyrifos products packaged in "large containers" are exempt from the federal RUP designation. Currently not all chlorpyrifos products used for the production of an agricultural commodity are RUPs, and therefore those products can be used by noncertified applicators. This proposed action will limit the purchase and use of all chlorpyrifos products used in the production of an agricultural commodity to only certified applicators regardless of container size.

Additionally, chlorpyrifos, designated as a state-restricted material under section 6400(e), can only be sold to, purchased by, possessed or used by, a person who holds a restricted material permit issued by the local CAC. The permit requirement will provide an effective mechanism to facilitate

CAC oversight of chlorpyrifos use by certified applicators. CACs will be able to evaluate chlorpyrifos use in the specific local conditions of each application site. This permit process is unique to California. The permit process has the advantage of allowing restrictions tailored to the unique characteristics of each use site, which may be difficult and too diverse to address in a general rule. The restrictions required to address problems unique to a site may not be necessary for every use site and may place unnecessary burdens on other applications. Restricted material permits enable CACs to assess local conditions at permit issuance and establish site-specific requirements or restrictions over and above state regulations as needed. Being closest to the pesticide-handling operations, the CAC is most qualified (and required by regulation), to issue and/or condition restricted materials permits based on their knowledge of the local conditions at the application site. This information can also be used by the CACs in their compliance monitoring activities to ensure label restrictions are followed.

Furthermore, users of restricted materials listed in section 6400(e) are required to submit a "Notice of Intent" (NOI) to the CAC 24 hours prior to each application of a restricted material. The NOI is required to provide site and time specific application information to allow the CAC to evaluate the proposed application to determine if any additional protections are necessary.

Off-site movement in the air could result in acute exposure effects of ChE inhibition to bystanders as well as increasing the risk of long-term neurological effects. Furthermore, chlorpyrifos is toxic to freshwater fish, aquatic invertebrates and estuarine and marine organisms. In summary, designating this chemical a restricted material will provide an effective mechanism to implement appropriate mitigation measures, including specific training and certification requirements, and facilitate CAC on-site evaluation to ensure worker safety and environmental protections, thereby preventing possible exposures when these chemicals are used for the production of agricultural commodities.

At this time, DPR is not proposing to designate chlorpyrifos as a state-restricted material when used for purposes other than production of agricultural commodities. These applications are much smaller and have lower health and environmental risk compared to agricultural commodity applications, and these applications comprise less than one percent of chlorpyrifos' use.

In developing the proposed regulations, DPR discussed the proposal with representatives from groups that will be directly affected including registrants, agricultural commodity organizations, pest control advisers, applicators, and environmental organizations.

CONSULTATION WITH OTHER AGENCIES

DPR consulted with the California Department of Food and Agriculture during the development of the text of proposed regulations, as specified in FAC section 11454, and the August 20, 2013, Memorandum of Understanding that was developed per FAC section 11454.2.

Potentially restricting chlorpyrifos was an agenda item and discussed at the August 15, 2014 meeting of the Pesticide Registration and Evaluation Committee (PREC), a committee whose members include representatives from public agencies who have jurisdiction over activities or resources that may be affected by the use of pesticide. Copy of the PREC minutes are contained in the rulemaking file.

The Agricultural Pest Control Advisory Committee, established by statute in the FAC, advises the DPR Director in all matters concerning the licensing, certification, and regulation of persons and firms providing pest control advice and services in California. DPR shared the intent of the regulation at the September 11, 2014 meeting.

Additionally, DPR consulted with other agencies including CACs, U.S. EPA, ARB, the Office of Environmental Health Hazard Assessment, the State Water Resources Control Board, and University of California during the development of the proposed regulations.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION [GOVERNMENT CODE SECTION 11346.2(b)(5)]

DPR has not identified any feasible alternatives to the proposed regulatory action that would achieve the purpose of the regulations with less possible adverse economic impacts, including any impacts on small businesses, and invites the submission of suggested alternatives.

ECONOMIC IMPACT ON BUSINESSES [GOVERNMENT CODE SECTION 11346.2(b)(5)(A)]

The proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The document relied upon to make this determination is listed in the "Documents Relied Upon" section of this initial statement of reasons and is available from DPR.

ECONOMIC IMPACT ASSESSMENT PURSUANT TO SECTION 11346.3(b)

Creation or Elimination of Jobs with the State of California: DPR has determined that it is unlikely that the proposed regulatory action will impact the creation or elimination of jobs within the State of California. Licensed pest control businesses could potentially have more customers if growers choose to hire a pest control business to apply chlorpyrifos, but any additional demand could likely be handled by existing staff.

Creation of New Business or the Elimination of Existing Businesses with the State of California: DPR has determined that it is unlikely that the proposed regulatory action will impact the creation or elimination of existing businesses with the State of California. Some businesses may choose to hire a licensed pest control business to apply chlorpyrifos. This additional cost should not significantly affect business operations or have a significant adverse economic impact on the sector. This workload would be handled by existing pest control businesses and would not result in the creation of new businesses or the elimination of existing businesses.

The Expansion of Businesses Currently Doing Business within the State of California: For the 28 growers who are currently using non-federal RUP chlorpyrifos products associated with the production of an agricultural commodity that want to continue applying chlorpyrifos and do not use any other federal or state restricted material, they have the option of hiring a licensed pest control business. There is a potential that this could create more business for those pest control business in the State of California.

The Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: Designating chlorpyrifos as a restricted material, when labeled for the production of an agricultural commodity, should provide an effective mechanism to implement appropriate mitigation measures, including specific training and certification requirements, and facilitate CAC on-site evaluation to ensure worker safety and environmental protections, thereby preventing possible unintended exposures when using chlorpyrifos.

EFFORTS TO AVOID CONFLICT OR DUPLICATION OF FEDERAL REGULATIONS

The proposed action does not duplicate or conflict with federal regulations because there are no federal regulations contained within the Code of Federal Regulations that address this issue.

DOCUMENTS RELIED UPON

1. George Lew, Cynthia Castronova, and Kevin Mongar, California Air Resources Board Engineering and Laboratory Branch. Report for the Application and Ambient Air Monitoring of Chlorpyrifos (and the oxon analogue) in Tulare County During Spring/Summer, 1996. April 7, 1998.
2. Deborah C. Smegal, M.P.H., Risk Assessor, U.S. EPA Office of Pesticide Programs Health Effects Division. Human Health Risk Assessment Chlorpyrifos. June 8, 2000.
3. Pamela Wofford and Randy Segawa, Environmental Monitoring Branch, DPR; Jay Schreider, Ph.D., Medical Toxicology Branch, DPR. Pesticide Air Monitoring in Parlier, CA. December 2009.
4. Danette Drew, Wade Britton, David Soderberg, Negron-Encarnacion, Carol Christensen, and William U.S. EPA Health Effects Division, Office of Pesticide Programs. Memorandum to Tom Myers and Mary Manibusan, U.S. EPA Risk Management and Implementation Branch, Pesticide Reevaluation Division. Chlorpyrifos: Preliminary Human Health Risk Assessment for Registration Review. June 30, 2011.
5. Keith Starner and Xuyang Zhang, Environmental Monitoring Branch, DPR. Analysis of Pesticide Detections in California Surface Waters, 1991-2010: Identification of Detections Exceeding U.S. EPA Aquatic Life Benchmarks. November 21, 2011.
6. Xuyang Zhang, Keith Starner, and Frank Spurlock, Environmental Monitoring Branch, DPR. Analysis of Chlorpyrifos Agricultural Use in Regions of Frequent Surface Water Detections in California, USA. April 24, 2012.
7. Jefferey L. Dawson and Wade Britton, U.S. EPA Risk Assessment Branch, Health Effect Division, Rochelle Bohaty, U.S. EPA Environmental Risk Branch Environmental Fate and Effects Division; Nikhil Mallampalli, U.S. EPA Biological Analysis Branch; Arthur Grube, U.S. EPA Economic Analysis Branch Biological and Economic Analysis Division. Memorandum to Joel Wolf, U.S. EPA Pesticide Reevaluation Division. Chlorpyrifos, Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures. July 13, 2012.

8. Richard P. Keigwin, Jr., Director, U.S. EPA Pesticide Reevaluation Division. Spray Drift Mitigation Decision for Chlorpyrifos. July 2012.
9. Edgar Vidrio, Pamela Wofford, and Randy Segawa, Environmental Monitoring Branch, DPR, and Jay Schreider, Ph.D., Medical Toxicology Branch, DPR. Air Monitoring Network Results for 2011 Volume 1. March 2013.
10. Keith Starner and Kean S. Goh, Environmental Monitoring Branch, DPR. Chlorpyrifos-Treated Crops in the Vicinity of Surface Water Contamination in the San Joaquin Valley, California, USA. June 9, 2013.
11. Edgar Vidrio, Pamela Wofford, and Randy Segawa, Environmental Monitoring Branch, DPR, and Jay Schreider, Ph.D., Medical Toxicology Branch, DPR. Air Monitoring Network Results for 2012 Volume 2. October 2013.
12. Xuyang Zhang, Environmental Monitoring Branch, DPR. Analysis of Recent Chlorpyrifos Monitoring Data in Two Water Quality Coalitions of the San Joaquin Valley. Revised January 23, 2014.
13. Pesticide Registration and Evaluation Committee Meeting Minutes. August 15, 2014.
14. Agricultural Pest Control Advisory Committee Meeting Draft Minutes. September 11, 2014.
15. Economic Analysis of Proposed Regulations. California Environmental Protection Agency, Agencywide Economic Studies Section, Air Resources Board. Memorandum from Steve Storelli to Linda Irokawa-Otani, DPR Regulations Coordinator. August 21, 2014.