



California Environmental Protection Agency
Department of Pesticide Regulation

Overview of Draft Evaluation of Chlorpyrifos as a Toxic Air Contaminant

December 2017

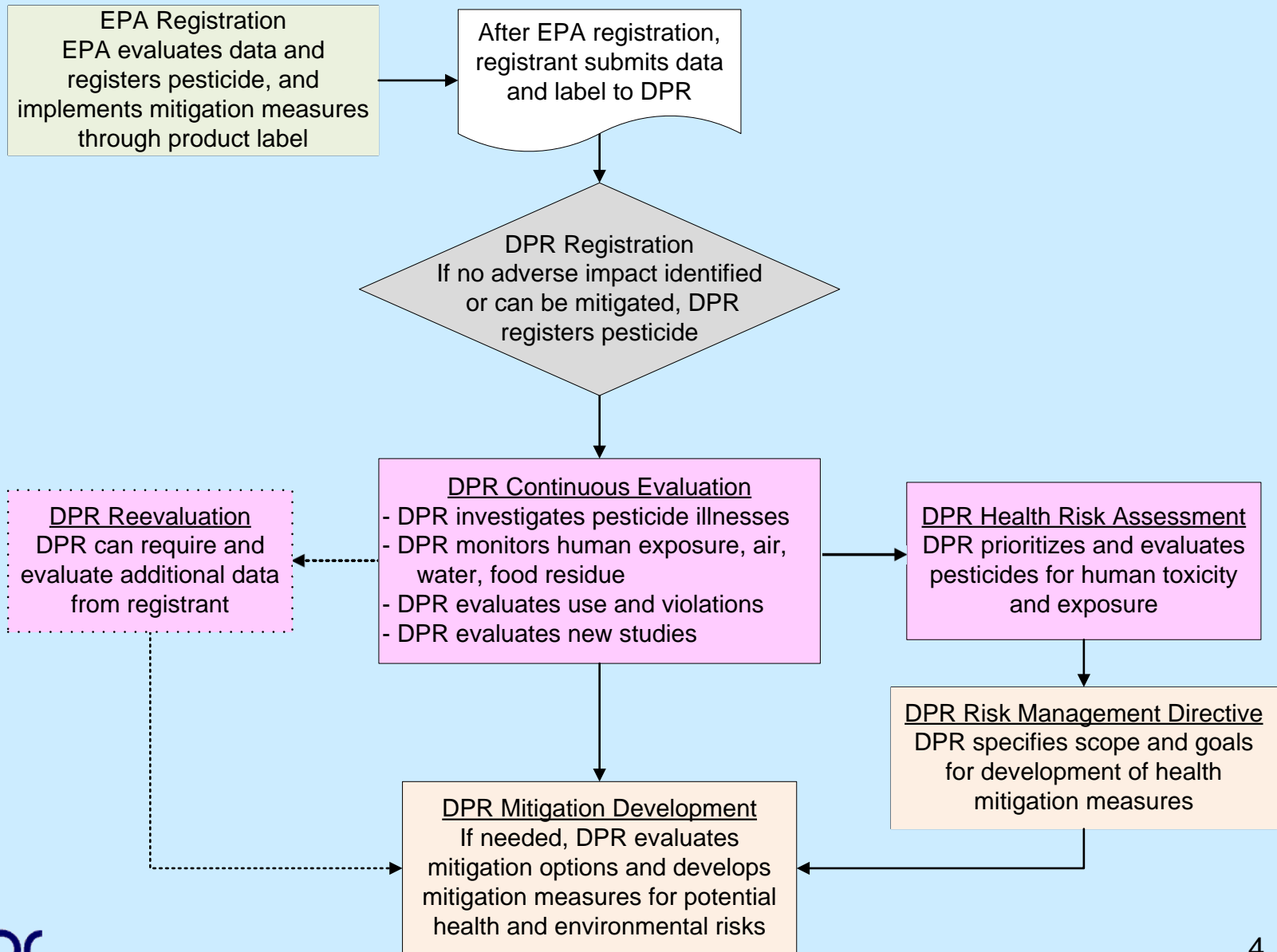
Overview

- Background on pesticide regulation and toxic air contaminant requirements
- Background on chlorpyrifos
- Overview of draft evaluation for chlorpyrifos and charge questions to the Panel

Pesticide regulation

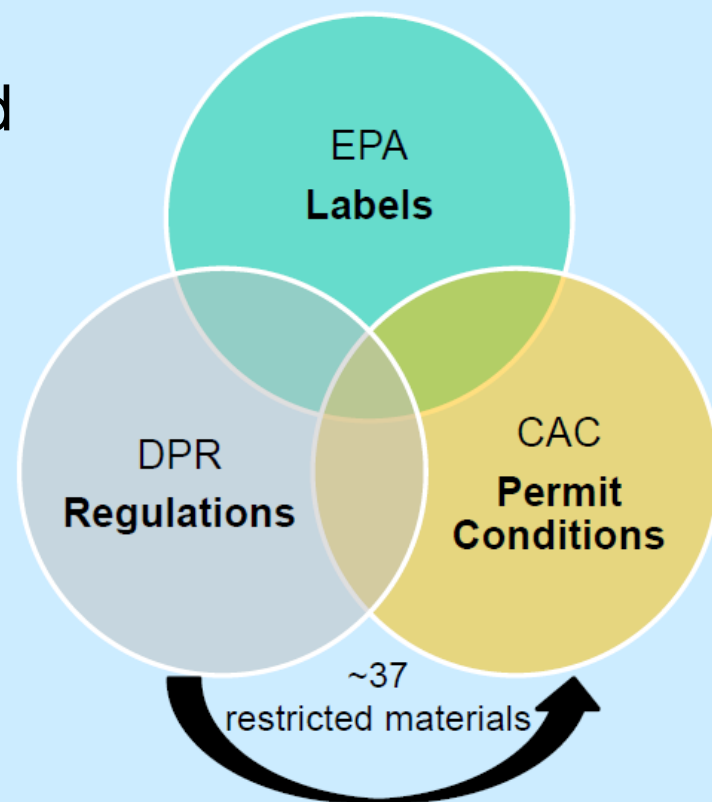
- Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and other laws, 3 agencies regulate sales and use of pesticides in California
 - U.S. Environmental Protection Agency (EPA)
 - Department of Pesticide Regulation (DPR)
 - Part of Cal/EPA
 - Includes 6 pesticide program branches
 - Approximately 400 employees
 - County agricultural commissioners (CACs)

Pesticide regulation – registration to mitigation



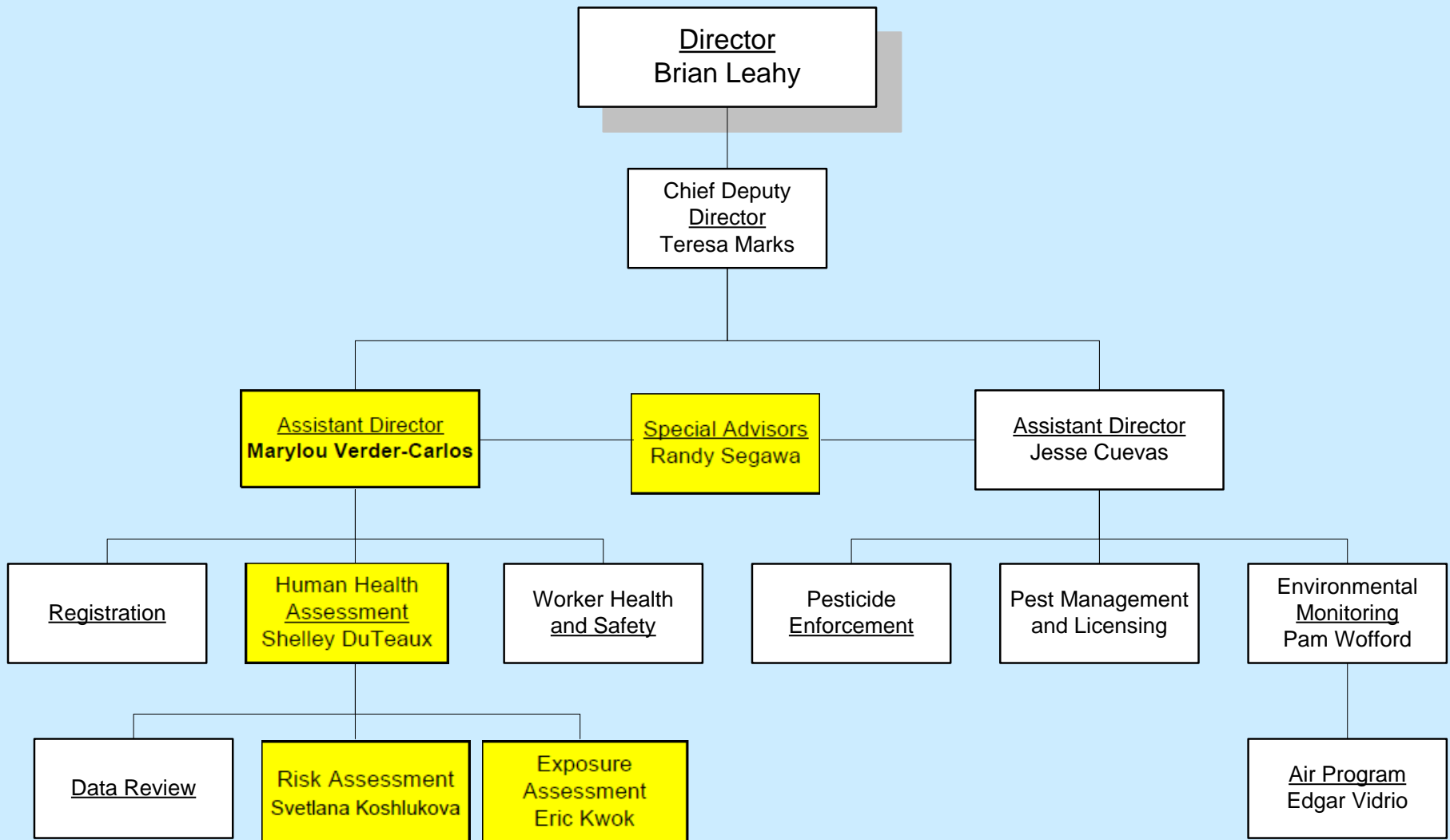
Pesticide regulation – use requirements

- EPA, DPR, and CACs implement and enforce mitigation measures as use requirements
- DPR designates some pesticides (including chlorpyrifos) as restricted materials, requiring:
 - Applications made or supervised by a certified applicator
 - A permit from CAC before purchase and use
 - CAC to evaluate application site and date, then approve, deny, or condition permit



Department of Pesticide Regulation

(primary scientific review panel contacts are highlighted)



California Toxic Air Contaminant Act

Food and Agricultural Code sections 14021-14027

- Air Resources Board (ARB) is required to monitor pesticides at DPR's request
- DPR is required to assess human health risks from pesticide air exposure
 - California Code of Regulations specifies the criteria to list a pesticide as a toxic air contaminant (TAC)
- DPR is required to mitigate health risks from pesticide air exposure

Pesticide TAC monitoring

- Application-site monitoring occurs near specific applications to estimate acute exposures
- Ambient monitoring occurs in regions of high use during periods of high use to estimate seasonal exposures

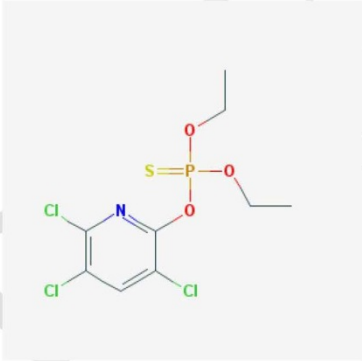


Pesticide TAC risk assessment

- DPR risk assessment must evaluate
 - Potency
 - Mode of action
 - Levels that may cause adverse effects
 - Office of Environmental Health Hazard Assessment (OEHHA) provides its findings to the SRP for their consideration

**Draft Evaluation of Chlorpyrifos
as a Toxic Air Contaminant:**

**Risk Characterization of Spray Drift, Dietary, and
Aggregate Exposures to Residential Bystanders**



The image shows the chemical structure of Chlorpyrifos, a pyridinyl phosphorothioate. It consists of a pyridine ring with chlorine atoms at the 2, 4, and 6 positions, and a diethyl phosphorothioate group at the 3 position. The phosphorus atom is double-bonded to a sulfur atom and single-bonded to two ethoxy groups and one oxygen atom that is part of the pyridine ring.

Human Health Assessment Branch
Department of Pesticide Regulation
California Environmental Protection Agency
Revised December 11, 2017

Pesticide TAC risk assessment review

- OEHHA and ARB review
- DPR must release a draft risk assessment to the public
- TAC scientific review panel (SRP) must review the risk assessment to determine if it is seriously deficient based upon a review of the scientific data, the procedures and methods used to support the data, and conclusions
- DPR finalizes risk assessment after reviews

SRP legal requirements

Food and Agricultural Code sections 14023(b)-(c)

- “(b) ...The panel shall review, as appropriate, the scientific data on which the report is based, the scientific procedures and methods used to support the data, and the conclusions and assessments on which the report is based. The panel shall submit its written findings to the director within 45 days after receiving the report, but it may petition the director for an extension of the deadline, which may not exceed 15 working days.
- (c) If the scientific review panel determines that the health effects report is seriously deficient, the report shall be returned to the director who shall revise and resubmit the report, within 30 days following receipt of the panel’s determination, to the panel before development of emission control measures.”

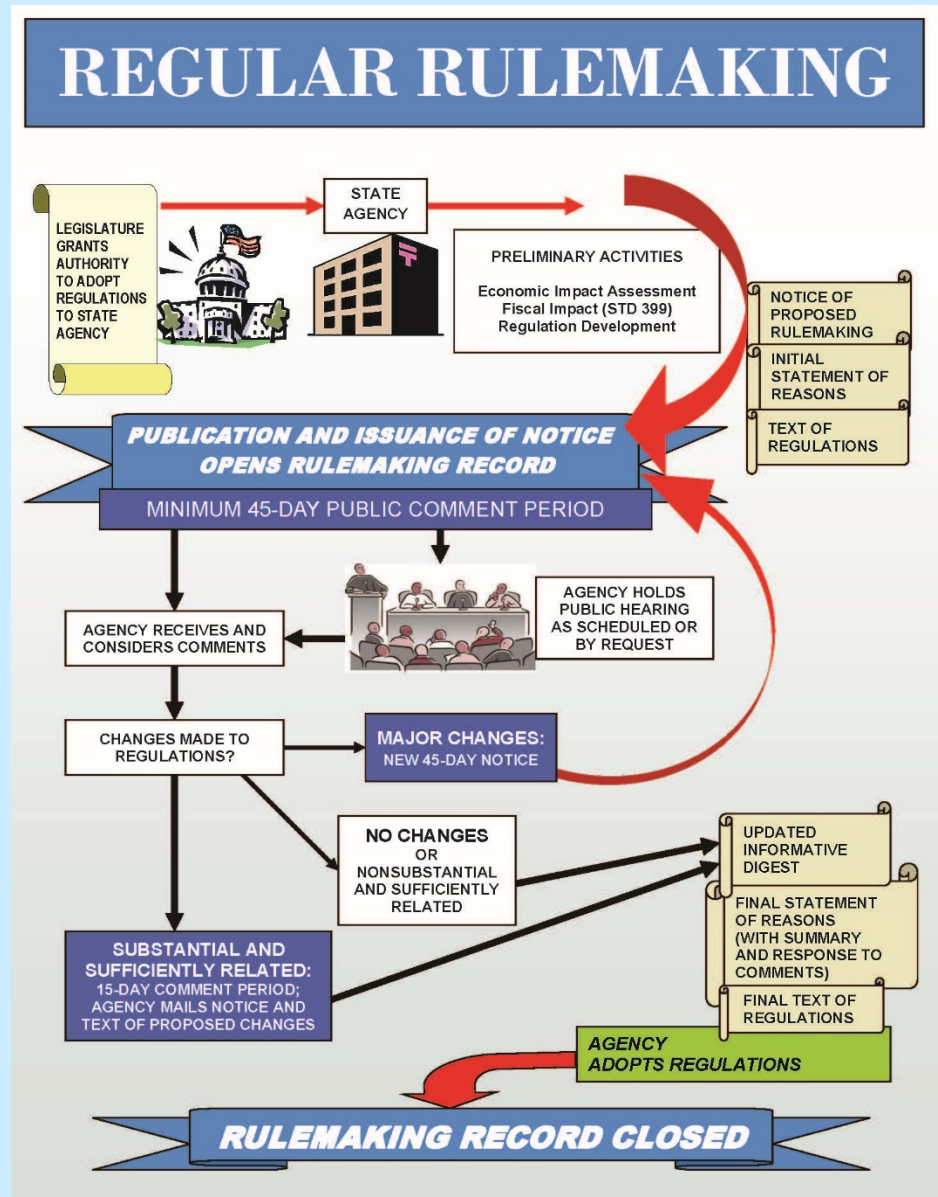
Pesticide TAC listing criteria

California Code of Regulations, Title 3, section 6864

- For non-cancer effects, threshold level is 10x below the air concentration which has been determined by the director to be protective of human health, for example
 - 2010 TAC risk assessment for chloropicrin included a 1-hour reference concentration of 4.4 ppb
 - DPR listed chloropicrin as a TAC because air concentrations exceeded 0.44 ppb
- Pesticides with cancer effects have a similar criterion

Pesticide TAC listing process

- If criteria met, DPR must follow formal rulemaking process to list
 - Federal Hazardous Air Pollutants must also be listed as TACs
- TAC listing triggers risk management evaluation



Pesticide TAC risk management and mitigation

- DPR must determine the need for and the appropriate degree of mitigation
- If mitigation is needed, DPR issues a risk management directive, including regulatory target concentrations
- DPR must develop mitigation measures within 2 years, or submit a report to the Legislature
- DPR must consult with certain agencies

TAC list

California Code of Regulations, Title 3, section 6860

- 8 pesticides have been listed as TACs through evaluation process
 - Chloropicrin
 - Endosulfan
 - Ethyl parathion
 - Methidathion
 - Methyl isothiocyanate
 - Methyl parathion
 - S,S,S-tributyl phosphorotrithioate
 - Sulfuryl Fluoride
- 38 pesticides have been listed as TACs because they are Hazardous Air Pollutants

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- **Background on chlorpyrifos**
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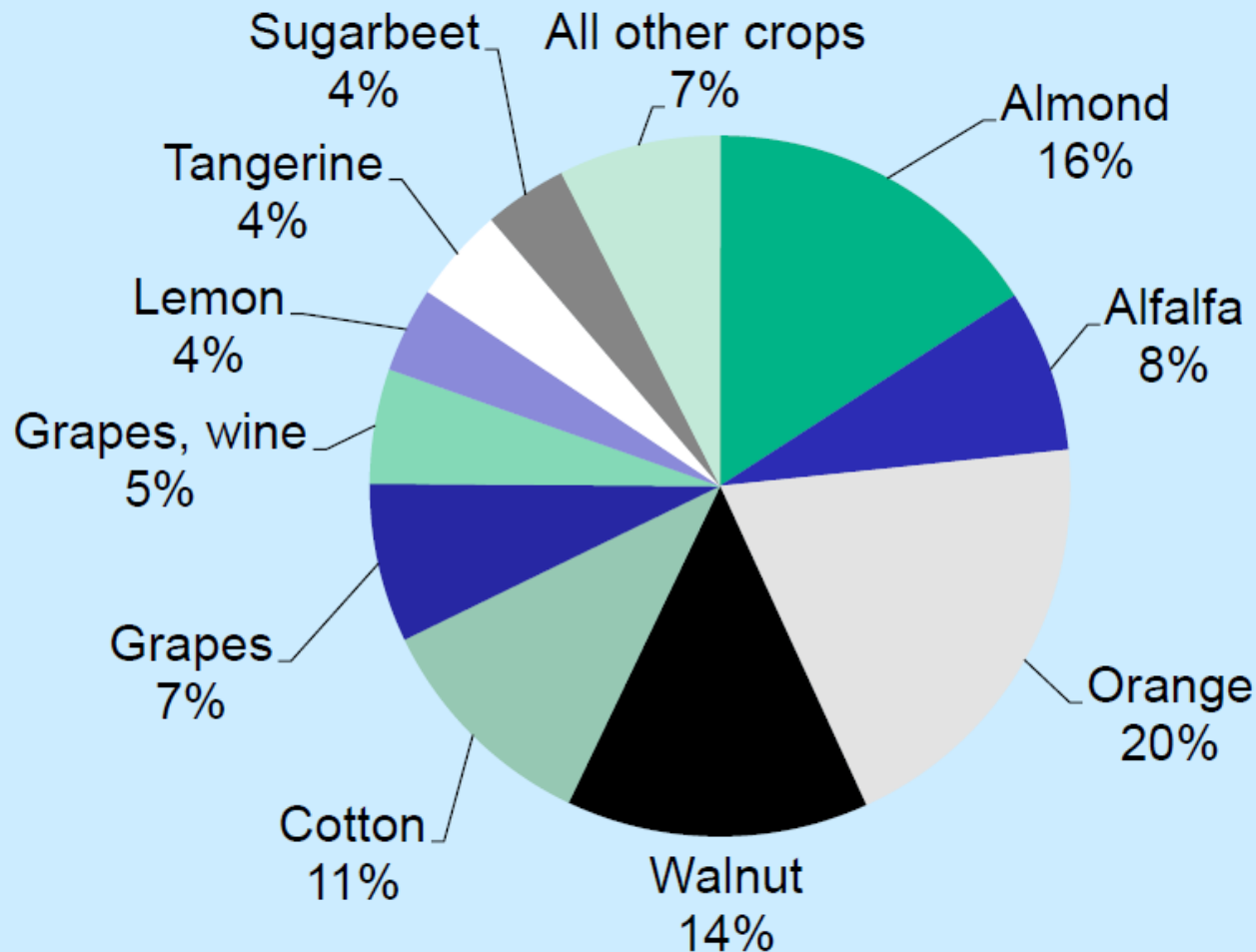
Background on chlorpyrifos

- Chlorpyrifos is an organophosphate insecticide primarily used for agricultural crops
- Dow AgroSciences is the registrant for most commonly used products

Site type	CA Chlorpyrifos Use (pounds)				
	2013	2014	2015	DRAFT 2016	Average
Agricultural crops	1,465,618	1,310,114	1,102,952	899,326	1,194,503
Other uses	3,680	2,247	3,656	2,438	3,005
Total	1,469,298	1,312,361	1,106,608	901,764	1,197,508

Chlorpyrifos use by crop, 2013-2016

- Chlorpyrifos is used on more than 60 crops in CA, but a few crops account for most use



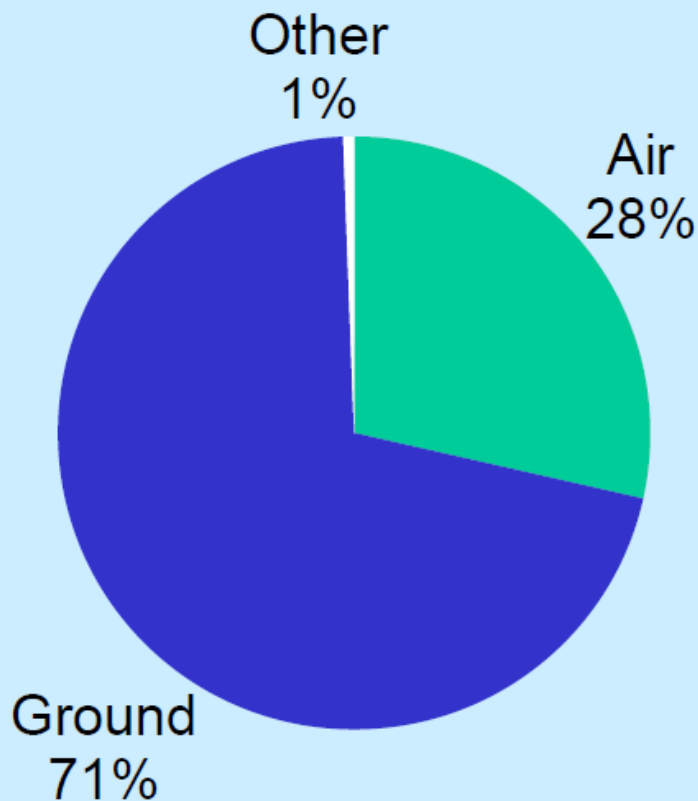
Chlorpyrifos use by application method in CA, 2013-2016



Ground-rig sprayer
from theecologist.com



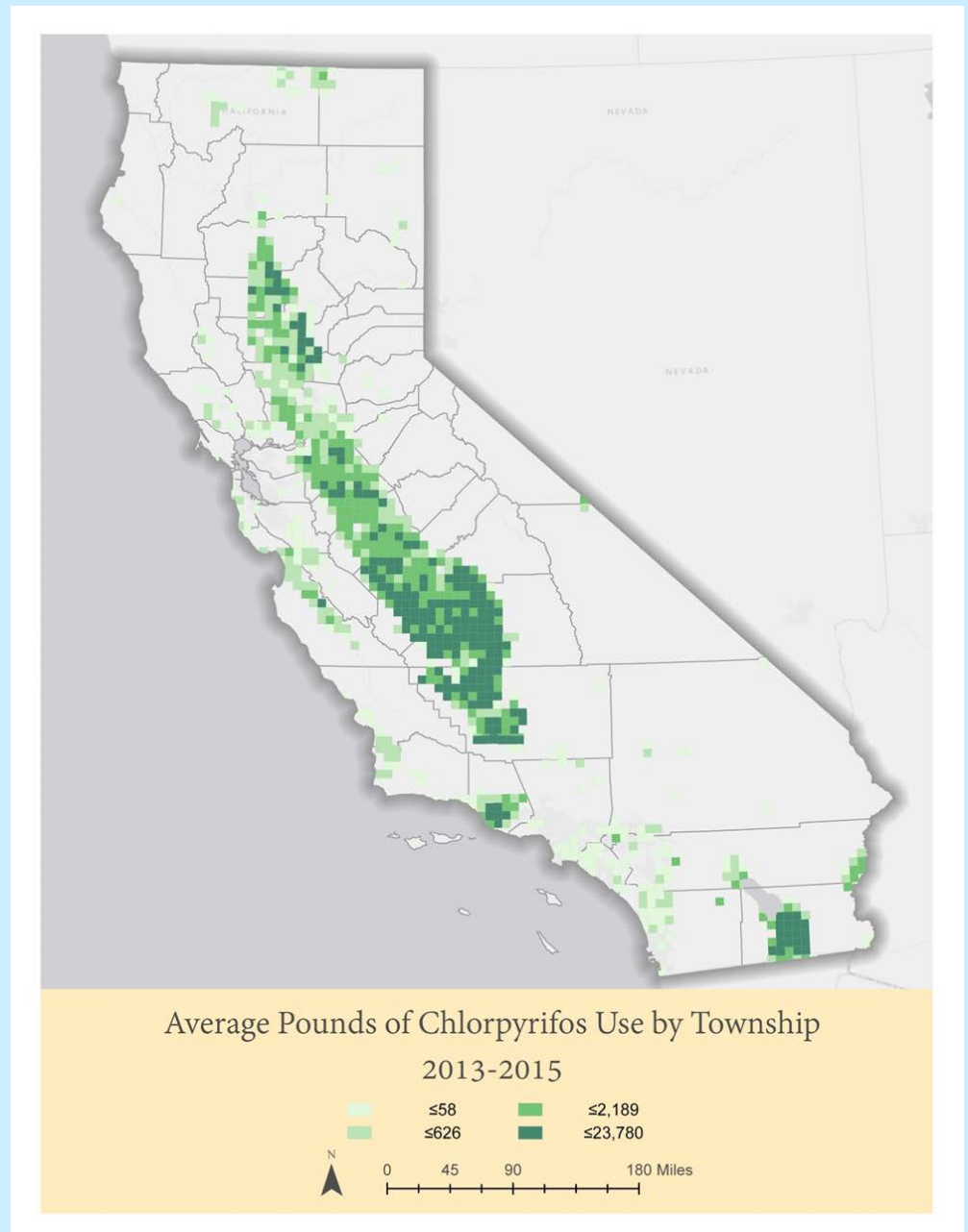
Airblast sprayer
from Virginia Tech



Aircraft
from FreshFruitPortal.com

Chlorpyrifos use by township (6x6 mile area), 2013-2015

- Most use occurs in the Central Valley, Central Coast, and Imperial regions



Chlorpyrifos use restrictions

- Chlorpyrifos is a restricted material and requires CAC permit
- EPA labels and CAC permit conditions include requirements to address bystander exposures, including
 - Application method restrictions
 - Setback distance from sensitive site to application that varies with application rate and application method
 - Aircraft: 250 – 500 feet
 - Sprinkler or ground rig: 150 – 400 feet
 - Orchard/vineyard airblast sprayer: 150 – 500 ft

Overview

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- **Overview of draft evaluation for chlorpyrifos and charge questions to the Panel**

Chlorpyrifos risk assessment history

Year	US EPA	DPR
1992		Dietary assessment
1993		Occupational & indoor assessment
2006	Reregistration Eligibility Decision	
2011	Preliminary assessment	
2014	1 st revised assessment	
2015*		1 st draft risk assessment
2016	US EPA issue paper and 2 nd revised assessment	
2017*		2 nd & 3 rd revised draft TAC assessments

*In 2015, DPR designated chlorpyrifos as a restricted use material.

**In 2016, US EPA proposed to revoke all chlorpyrifos food tolerances.

Withdrew the proposal in March 2017. October 2017, DPR restricted use further.

Scope of DPR chlorpyrifos risk assessment

- Short-term, acute exposure
- Aggregate exposure – combined inhalation, dermal, oral exposure
- Bystander exposure
- *DPR's risk assessment reflects its most current scientific understanding and comprehensive data review of potential for toxicity to humans*

Chlorpyrifos risk calculations summary

- Risks were calculated as margins of exposure (MOE)
- DPR generally considers a target MOE of at least 100 as health protective
- MOE's were calculated from route specific points of departure (PoDs)
- The risk assessment evaluated aggregate MOE's

DPR's draft risk assessment conclusions

- MOE's greater than 100 for children and women of childbearing age include
 - Dietary exposure (residue in food and drinking water)
 - Dermal exposure resulting from spray drift

DPR's draft risk assessment conclusions

- MOE's less than 100 include
 - Hand-to-mouth exposure to children
 - Inhalation exposure to children and women of childbearing age
 - Various aggregate exposures from combined media (food, drinking water, deposition from spray drift)
 - Exposure to aerosols in the air near application sites was the main driver when the aggregate MOEs <100

Charge questions to the SRP: Please comment on the following:

- Choice of acetylcholinesterase (AChE) inhibition as a toxic endpoint
- Choice of uncertainty factors used
 - 1x for interspecies because physiologically-based pharmacokinetic-pharmacodynamic modeling used
 - Rodent data is also available
 - 10x for intraspecies
 - 10x for neurodevelopmental effects
- How to use the human epidemiological data to qualitatively or quantitatively inform the dose-response relationship

Charge questions to the SRP: Please comment on the following:

- Choice of using the 21-day steady state PoD values to evaluate the risk associated with dermal, inhalation and non-dietary oral exposure from spray drift
- Choice of using AGRicultural DISPersion (AGDISP) modeling to estimate air concentrations for fixed wing aerial applications as a surrogate for air concentrations from ground boom and airblast applications
- Choice of adjusting air concentrations for inhalable fraction. How will those adjustments be made?

Concluding remarks

- Risk assessment evaluated aggregate exposure although inhalation exposures are criteria for TAC
- DPR will make an in-depth presentation on the risk assessment at the SRP meeting on January 23, 2018
- DPR can provide original studies to SRP, but need signed data handling responsibilities form for registrant studies

Additional information

Web Page: www.cdpr.ca.gov

Click on “Air” under Quick Finder

Click on “Toxic Air Contaminant Program”

SRP questions and requests for additional information should be sent to:

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916-445-3984