

INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Amend Section 6728
Pertaining to the Medical Supervision Program

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 requirements 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 6728. This proposal will affect pesticide regulatory program activities pertaining to pesticide worker safety. In summary, this proposed action will clarify that the physician contracted with an employer to act as a medical supervisor must be registered with the Office of Environmental Health Hazard Assessment (OEHHA), and specify that baseline red cell and plasma cholinesterase determinations, which are verified every two years, be established after a period of at least 30 days during which the employee has had no exposure to an organophosphate or carbamate (OP/CB) pesticide.

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.

FAC section 12980 requires that DPR work jointly with OEHHA to develop regulations to ensure safe working conditions for persons handling pesticides and working in and around pesticide-treated areas. FAC section 12981 requires DPR to adopt regulations to accomplish the Legislature's intent relative to ensuring pesticide safety in the workplace. DPR's current regulatory requirements for pesticide safety training, personal protective equipment, field posting, and notice of completed applications are designed to reduce the risk of pesticide exposure and injuries among pesticide handlers and workers.

The Medical Supervision Program ("Program") is a surveillance program designed to protect employees who regularly mix, load or apply OP/CB pesticides with the signal word "DANGER" or "WARNING" for the commercial or research production of an agricultural plant commodity by monitoring their cholinesterase activity levels (3 CCR section 6728). These pesticides can

inhibit acetylcholinesterase, an enzyme essential for proper neurological function, which can lead to adverse health effects ranging from blurred vision, diarrhea and tremors to seizures, loss of consciousness, and even death. Plasma and red blood cell cholinesterase activity levels are useful surrogate markers for cholinesterase inhibitor activity in the nervous system. The Program requires each employer of these employees to contract with a physician to act as a medical supervisor. The medical supervisor orders a cholinesterase test to establish baseline blood cholinesterase levels of the employees before they are exposed to OP/CB pesticides with the signal word “DANGER” or “WARNING.” If the employees handle these pesticides for more than six days in a 30-day period, then follow-up cholinesterase tests are ordered for monitoring, at intervals specified by the medical supervisor. The follow-up cholinesterase levels are then compared to the employees’ baseline levels to determine whether a depression of cholinesterase activity has occurred. If the follow-up cholinesterase levels for an individual employee are at certain levels below their baseline, the employer is then required to take certain actions to prevent further exposure.

While 3 CCR section 6728 currently requires employers to ensure their employees have baseline red cell and plasma cholinesterase determinations, there is no language specifying when the baseline values must be established under the Program. According to U.S. Environmental Protection Agency (US EPA) guidance for OPs, “enzyme depression is usually apparent within a few minutes or hours of significant absorption of organophosphate. Depression of the plasma enzyme generally persists several days to a few weeks; the RBC [red blood cell] enzyme activity may not reach its minimum for several days, and usually remains depressed longer, sometimes one to three months, until new enzyme replaces that inactivated by organophosphate” (Roberts, 2013, p. 46). Furthermore, according to US EPA guidance for CBs, “carbamate poisonings tend to be of shorter duration than organophosphate poisonings because of the reversibility of the AChE [acetylcholinesterase] binding and the more rapid metabolism of carbamates.” Additionally, the guidance states that “unless a substantial amount of N-methyl carbamate has been absorbed and a blood sample is taken within an hour or two, it is unlikely that blood cholinesterase activities will be found depressed. Even under the above circumstances, a rapid test for enzyme activity must be used to detect an effect, because enzyme reactivation occurs in vitro as well as in vivo” (Roberts, 2013, pp. 56-57). Because it takes cholinesterase between one to three weeks (plasma cholinesterase) and one to three months (red blood cell cholinesterase) to recover after inhibition, it is critical that there be an exposure-free period prior to establishing a baseline.

OEHHA’s *Medical Supervision of Pesticide Workers—Guidelines for Physicians* (GFP) recommends a 30-day exposure-free period from OP/CB pesticides before establishing a baseline. Under 3 CCR section 6728(b), physicians registered as medical supervisors must possess a copy of this document and be aware of its contents. However, while physicians can recommend a 30-day exposure-free period, under 3 CCR section 6728(c), it is the employers’ responsibility to send their employees for baseline testing when needed. Washington State has a similar cholinesterase monitoring program. Under their program, Washington State requires employers of employees handling similar pesticides to ensure a baseline is established after at least 30 days with no exposure to OP/CB pesticides (Washington Administrative Code 296-307-14820). This established exposure-free period ensures an accurate determination of an employee’s baseline red cell and plasma cholinesterase level, so the medical supervisor can

accurately determine if an employee has depressed cholinesterase levels and therefore, can provide the appropriate recommendations to the employer to protect its employees from overexposure (i.e., removal of the employee from further exposure or workplace evaluation).

Lastly, California Health and Safety Code (HSC) section 105206(a) was recently updated in 2017. It now requires the employer to contract with a medical supervisor **registered** with OEHHA. The current language in 3 CCR section 6728(b) does not require that the physician providing medical supervision be registered with OEHHA and needs to be updated for consistency with HSC section 105206.

Proposed changes

DPR proposes to amend 3 CCR section 6728(b) to require that the physician be “registered as a medical supervisor with OEHHA” to be consistent with HSC section 105206, which states the employer shall contract with a medical supervisor registered with OEHHA.

In addition, DPR proposes to amend 3 CCR section 6728(c)(1) to specify that baseline values verified every two years shall be established after a period of at least 30 days during which the employee has had no exposure to OP/CB pesticides. This regulation relates to and enhances worker safety by ensuring continuous monitoring of cholinesterase levels of employees handling OP/CB pesticides with the signal word “DANGER” or “WARNING.” As described above, establishing a baseline when employees have not been exposed to OP/CB pesticides is necessary to ensure an accurate determination of their depression levels and help determine if any additional protective measures are needed. Requiring the baseline to be established after a period of at least 30 days during which the employee has had no exposure to OP/CB pesticides is consistent with the recommendation in OEHHA’s GFP and with Washington State’s regulations regarding cholinesterase testing. DPR’s proposed regulatory amendment is necessary to ensure the employers’ responsibility to send their employees for baseline red cell and cholinesterase testing after a specified time period aligns with the 30-day exposure-free period recommended in OEHHA’s GFP, and would ensure the establishment of the most accurate baseline and level of depression.

COLLABORATION WITH OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT (OEHHA) PURSUANT TO FAC SECTIONS 12980 AND 12981

As discussed above, 3 CCR section 6728 is a regulation relating to pesticide worker safety. Therefore, DPR and OEHHA jointly and mutually developed the proposed regulations as specified in FAC sections 12980 and 12981. DPR and OEHHA have set forth the rulemaking process used to meet these statutory requirements in a Memorandum of Agreement dated August 13, 2008.

CONSULTATION WITH OTHER AGENCIES

DPR consulted with the California Department of Food and Agriculture during the development of the text of the proposed regulations, as specified in FAC section 11454 and the Memorandum of Understanding updated on January 15, 2019, that was developed per FAC section 11454.2.

DPR consulted with the University of California and the Department of Industrial Relations pursuant to FAC sections 12980 and 12981.

DPR has also consulted with the several county agricultural commissioners.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION [GOVERNMENT CODE SECTION 11346.2(b)(4)]

DPR has not identified any feasible alternatives to the proposed regulatory action that would achieve the purpose of the regulation with fewer possible adverse economic impacts, including any impacts on small businesses, and invites the submission of suggested alternatives. The proposed regulations will amend 3 CCR section 6728 to add language requiring that physicians be registered with OEHHA as medical supervisors and to make mandatory OEHHA's current recommended exposure-free period for baseline red cell and plasma cholinesterase testing for employees who handle OP/CB pesticides with the signal word "DANGER" or "WARNING." In accordance with Government Code sections 11346.2(b)(1) and (b)(4)(A), a performance standard was considered but is not appropriate for the proposed requirement as the specific time period of at least 30 days is necessary to ensure the establishment of the most accurate baseline red cell and plasma cholinesterase determination and level of depression.

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

The proposed action 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 proposed action will amend 3 CCR section 6728 by adding language consistent with HSC section 105206, and only requires that physicians contracted with a covered employer be registered with OEHHA (at no cost). It will also specify when employers need to send their employees for baseline red cell and plasma cholinesterase testing. The proposed action should not impact employers or pesticide applications as employers should be able to send their employees for baseline red cell and plasma cholinesterase testing during low-spraying seasons.

The document relied upon to make this determination is the "Economic and Fiscal Impacts of Proposed Medical Supervision Program Regulations." This document 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)

The proposed action would not create or eliminate jobs in California; result in the creation of new businesses or the elimination of existing businesses within the State of California; or result in an expansion of businesses currently doing business with the State of California. Employers covered by the Program are already required to send their employees who regularly handle cholinesterase-inhibiting pesticides for cholinesterase baseline testing. This proposed action will simply add language to an existing program to clarify the period when baseline red cell and plasma cholinesterase testing shall be performed. Moreover, employers are already required to

contract with a medical supervisor under HSC section 105206. This amendment adds language specifying that physicians contracted as a medical supervisor must be registered with OEHHA. These amendments will not have an economic impact on established businesses and medical practices, as there is no cost for physicians to register as medical supervisors with OEHHA.

The Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: This proposed action will amend an existing program by adding language making it consistent with HSC section 105206, requiring medical supervisors to be registered with OEHHA, and specifying the period for which employers must send their employees for baseline red cell and plasma cholinesterase testing. The proposed amendment will establish consistency amongst employers regarding when to send their handlers for baseline red cell and plasma cholinesterase testing, resulting in more accurate baseline red cell and plasma cholinesterase determinations for employees. This proposed action will benefit and enhance worker safety by ensuring accurate determinations of an employee's baseline red cell and plasma cholinesterase levels during an exposure-free period. Accurate baselines will enable registered medical supervisors to continuously monitor cholinesterase levels of an employee and recommend additional protective measures if cholinesterase depression occurs. This will further protect employees by ensuring the most accurate baseline and subsequent testing, helping determine if additional protective measures are needed to protect employees from overexposure (i.e., removal of the employee from further exposure or workplace evaluation).

IDENTIFICATION OF ANY SIGNIFICANT ADVERSE ENVIRONMENTAL EFFECT THAT CAN REASONABLY BE EXPECTED TO OCCUR FROM IMPLEMENTING THE PROPOSAL

The Secretary of Natural Resources determined that DPR's pesticide regulatory program, including the adoption, amendment, and repeal of pesticide regulations, qualifies as a certified regulatory program under Public Resources Code section 21080.5 and 14 CCR section 15251(i). This determination means DPR's pesticide regulatory program is functionally equivalent to the California Environmental Quality Act's (CEQA) requirements for preparing environmental impact reports (EIRs), negative declarations, and initial studies, and is therefore exempt from such requirements. This initial statement of reasons serves as the public report required under 3 CCR section 6110 and satisfies the requirements of DPR's CEQA certified regulatory program for rulemakings at 3 CCR sections 6110-6116.

DPR's public report must include a description of the proposed activity, and either (A) alternatives to the activity and mitigation measures to avoid or reduce any significant effects that the project might have on the environment, or (B) a statement that DPR's review of the project showed that the project would not have any significant effects on the environment and therefore no alternatives or mitigation measures are proposed to avoid or reduce any significant effects on the environment. (3 CCR section 6110.) DPR shall not adopt a regulation that would cause a significant adverse environmental impact if there is a feasible alternative or mitigation measure that would substantially lessen those significant adverse environmental impacts. (3 CCR section 6116.)

Under DPR's existing regulations, employers must contract with a physician to provide medical supervision of pesticide workers, and must have certain employees obtain baseline red cell and plasma cholinesterase determinations. Existing law requires that the physician be registered with OEHHA. These laws and regulations do not have any environmental impacts. The proposed regulations would clarify that the physician must be registered with OEHHA, as required by statute, and specify that the baseline testing occur after a period of at least 30 days during which the employee has had no exposure to OP/CB pesticides.

The proposed regulations do not have any possible environmental effect, positive or negative. Specifically, DPR considered the following potential environmental effects:

- Human Health
- Flora (Plants)
- Fauna (Fish & Wildlife)
- Water
- Air

DPR did not consider potential environmental effects to flora, fauna, water, or air because the proposed regulations would only clarify the certification required for a physician and specify when baseline testing occurs, neither of which would have any effect on these other environmental aspects.

DPR considered the potential effects the proposed regulations would have on human health. The requirement for the physician to have OEHHA certification is consistent with existing law and would not result in any impact, positive or negative. The proposed revision to require a period of at least 30 days during which the employee has had no exposure to OP/CB pesticides before baseline testing does not impact pesticide use. The 30-day timeframe is already recommended in existing guidance from OEHHA. However, because the 30-day timeframe is not currently mandatory, employers may use a shorter timeframe that could result in an inaccurate baseline against which to measure potential human health effects from pesticide exposure. The proposed regulation would specify the requirements for baseline testing, resulting in more accurate baseline determinations, and would therefore potentially result in positive impacts to human health. The proposed regulation is not expected to have cumulative effects, as no other projects are proposed that interact with this project.

Because the proposed regulations do not have any possible environmental effect, positive or negative, it is not considered a "project" under CEQA. Because it is not a "project," no alternatives or mitigation measures are proposed to lessen any significant adverse effects on the environment.

EFFORTS TO AVOID CONFLICT OR DUPLICATION OF FEDERAL REGULATIONS

The proposed regulatory action does not duplicate or conflict with the Code of Federal Regulations.

DOCUMENTS RELIED UPON

1. Laribi, O., & Ngai, W. (2017). *Medical Supervision of Pesticide Workers - Guidelines for Physicians Who Supervise Workers Exposed to Cholinesterase Inhibiting Pesticides*. Office of Environmental Health Hazard Assessment.
<https://oehha.ca.gov/media/downloads/pesticides/document-pesticides/physicianguidelines.pdf>
2. Roberts, J. R., & Reigart, J. R. (2013). *Recognition and Management of Pesticide Poisonings* (6th ed., pp. 43-62). United States Environmental Protection Agency.
https://www.epa.gov/sites/production/files/2015-01/documents/rmpp_6thed_final_lowresopt.pdf
3. Make cholinesterase testing available. Washington Administrative Code 296-307-14820 (2004). <https://app.leg.wa.gov/wac/default.aspx?cite=296-307-14820>
4. Memorandum from Shafeesha Ali to Lauren Otani, California Department of Pesticide Regulation. 2021. Economic and Fiscal Impacts of Proposed Medical Supervision Program Regulations.