Update to the Legislature Required by Health and Safety Code Section 105206(g): Effectiveness of the California Medical Supervision Program and the Utility of Laboratory-based Reporting of Cholinesterase Testing for Illness Surveillance and Prevention

Executive Summary

The California Medical Supervision Program is designed to protect workers who regularly mix, load, or apply highly toxic organophosphate and carbamate pesticides. The goal of the program is to monitor blood cholinesterase activity levels of workers in order to identify and prevent excessive pesticide exposure and resulting pesticide-related illness. In 2016, the Legislature passed AB 2892 (Statutes of 2016, Chapter 475), which directed DPR and OEHHA to prepare and publicly post an update on the effectiveness of the California Medical Supervision Program and the utility of laboratory-based reporting of cholinesterase testing for illness surveillance and prevention. This report updates the 2015 report to the Legislature as required by AB 2892. In this report, OEHHA and DPR discuss efforts conducted to improve the program, analyze laboratory-based reporting of cholinesterase test results from 2014 to 2019, evaluate the effectiveness of the Program, and propose steps to be taken to improve it.

Background

The California Medical Supervision Program ("Program") is designed to protect agricultural workers who regularly handle Type I and II organophosphate (OP) and carbamate (CB) pesticides [Title 3, California Code of Regulations (CCR), section 6728]. It requires employers to contract with a medical supervisor to monitor the blood cholinesterase (ChE) levels of their workers. ChE is critical for the normal function of the nervous system. Overexposure to OP and CB pesticides can lead to a depression in ChE activity levels, which can lead to various adverse health effects. The California Department of Pesticide Regulation (DPR) is responsible for the overall administration of the Program. The Office of Environmental Health Hazard Assessment (OEHHA) is responsible for outreach and education of medical supervisors, and the California Department of Public Health (CDPH) is responsible for approving laboratories performing ChE analysis.

The Program was established in 1974 when the use of cholinesterase-inhibiting pesticides was prevalent in California agriculture. DPR Pesticide Use Report data from 1995 to the present show the use of Type I and II OP/CB pesticides has declined by 89%. However, according to pesticide use data, Type I and II OP/CB use remained on average at approximately two million pounds per year from 2011 to 2019 (Figure 1), thus highlighting the need to continue to monitor and provide protection to workers who regularly handle these pesticides.

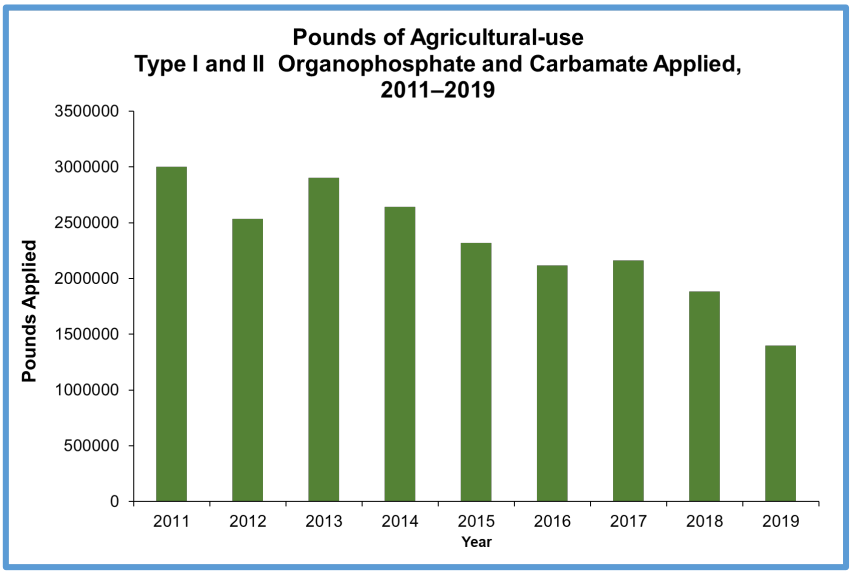

Figure 1: *Reported pounds of agricultural-use Type I and Type II OP and CB pesticides applied in California, 2011–2019.*

Assembly Bill (AB) 1963 (Statutes of 2010, Chapter 369) established the requirement for the reporting of laboratory ChE test results to DPR. Reporting of ChE test results is a series of steps that begins with the medical supervisor submitting a ChE test order to the facility drawing the employee's blood. The blood drawing facility then transmits information on the test order to the laboratory performing the ChE analysis, who then in turn sends the ChE results and other required data elements to DPR. DPR then shares this information with OEHHA who along with DPR is charged under Health and Safety Code (HSC) section 105206 with evaluating the effectiveness of the program.

The accurate transfer of all data elements under HSC § 105206 requires each party to be able to collect and submit the information to the next party in the data chain. The quality of the data received by DPR is entirely dependent on successful submission by the ordering physician, and the ability of the laboratories to capture and transfer all of the required data elements.

DPR and OEHHA, in consultation with CDPH, submitted a report to the Legislature in December 2015 evaluating the effectiveness of the Program. The ChE test results included in the 2015 Report were collected from 2011–2013, and the departments determined that "overall the Program appears effective in protecting agricultural workers handling cholinesterase-inhibiting pesticides." However, the evaluation of the utility of laboratory-based reporting of ChE test results was difficult due to certain challenges identified in the report. Recommendations for future directions to address these challenges were also included in the report.

Acting on the recommendations in the 2015 Report, the Legislature passed AB 2892 (Statutes of 2016, Chapter 475) to amend HSC § 105206, requiring:

- Employers to contract only with physicians registered with OEHHA as medical supervisors.
- Changes in terminology for "purpose" of ChE test to be entered by the medical supervisor, consistent with that in OEHHA's *Guidelines for Physicians Who Supervise Workers Exposed to Cholinesterase-inhibiting Pesticides* (*Guidelines for Physicians*).
- Medical supervisors to report any worker with ChE depression indicating pesticide exposure to the local health officer pursuant to HSC § 105200.

- An update prepared and posted by DPR and OEHHA on the effectiveness of the medical supervision program and the utility of laboratory-based reporting of ChE testing for illness surveillance and prevention, by January 1, 2021.
- Continued reporting of ChE test results to DPR until January 1, 2021. In 2020, the Legislature passed Assembly Bill 3220, which extended the reporting of ChE test results to DPR until January 1, 2023.

Effectiveness of the Program and Utility of Laboratory-Based Reporting

Following the recommendations from the 2015 Report, OEHHA and DPR have taken a series of actions in an attempt to improve the data quality of the ChE test results submitted by the reporting laboratories and/or the Program itself. OEHHA and DPR used the ChE data reported in the 2014–2019 period and other efforts to evaluate the effectiveness of the program and utility of laboratory-based reporting.

Physician Registration and Outreach to Medical Supervisors

Since AB 2892 was enacted in 2016, OEHHA has developed a registration process[1] and in 2018 adopted that process in regulation (17 CCR § 98201 et seq.). OEHHA annually registers[2] physicians as medical supervisors pursuant to this process. To identify potential medical supervisors under the Program, OEHHA used ChE test results submitted by the laboratories from previous years and informed all physicians who ordered at least 10 ChE tests about the new mandatory registration. A continuously updated list of currently registered physicians is posted on OEHHA's website with a map to help employers identify medical supervisors by proximity. OEHHA also contacts registered physicians on an annual basis to inform them of the need to renew their registration and to report any ChE test result depression indicative of pesticide exposure.

OEHHA communicated with registered physicians to share new or updated materials and created a training video on the Program so physicians and other health care professionals interested in the Program can learn the main responsibilities of medical supervisors. Links to these materials are sent to physicians at the time of registration.

OEHHA and DPR found that most physicians who regularly ordered ChE tests under the auspices of the Program were medical supervisors. Although an assumption can be made that ChE tests ordered by physicians on OEHHA's registry or confirmed by DPR are for employees under the Program, it is important to note that medical supervisors often work in occupational clinics and may order ChE tests for other employment purposes (e.g., HAZMAT).

[1] Health and Safety Code § 105206(f): The OEHHA shall establish a procedure for registering and deregistering medical supervisors for the purposes of outreach and training and may establish reasonable requirements for performance.
[2] A registration form developed by OEHHA is available online for physicians to download https://oehha.ca.gov/media/downloads/pesticides/document/medsuperegforma5.pdf.

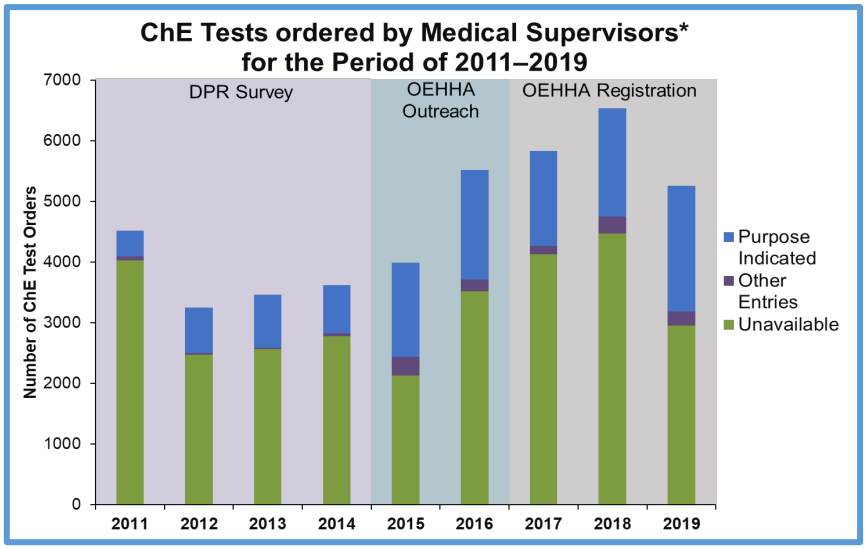

Figure 2: *Number of ChE tests ordered for known and likely agricultural employees by medical supervisors from 2011 to 2019. Purpose of the test was either not indicated (green), not fully indicated (purple), or indicated (blue) by the Medical Supervisor on the test order and provided with the results by the laboratory.*

Based on the data in Figure 2, there have been improvements in ChE tests ordered by medical supervisors. First, though use of type I and II pesticides have been steadily decreasing since 2014, the number of tests that can be associated with the program have substantially increased, along with the identification of the purpose of the test. These improvements follow DPR's Medical Supervisor Survey that took place from 2011–2014 and OEHHA's outreach and registration efforts from 2015–2019 to identify and register medical supervisors.

Outreach to Employers, Handlers of OPs/CBs, and CACs

Another effort undertaken to improve the effectiveness of the Program since the 2015 Report to the Legislature involved updating and developing new outreach materials for employers, OP/CB handlers, and County Agricultural Commissioners (CACs). Briefly, DPR conducted surveys and completed inspections of growers and pest control businesses with high OP/CB use in 2014 and 2017, as well as developed outreach materials for handlers, employers, and CACs in 2018. These efforts may have helped to improve the understanding of the Program by employers, and led to better compliance.

Outreach to Laboratories

ChE test results reporting is a complex mechanism that necessitates a thorough understanding of the Program's requirements by all individuals involved in each step of the ChE reporting process. The data provided by the ordering medical supervisor, the transfer of data from the blood-drawing facility to the laboratory performing ChE analysis, and the reporting by the laboratory to DPR all have to work in union in order to provide the data required under HSC § 105206. In 2016, DPR coordinated with CDPH on outreach efforts to the laboratories in order to improve the quality of reporting required in HSC § 105206. As a result, CDPH updated the application forms used by laboratories seeking approval to perform ChE analysis for occupational health surveillance.

Evaluation of ChE Tests Ordered during 2014–2019 Period

DPR and OEHHA independently analyzed the over 140,000 ChE test results from the reporting laboratories DPR received between 2014 and 2019. As with previous years, a majority of the reported tests were ordered for clinical reasons unrelated to the Program,

such as pre-operative testing, Alzheimer's drug monitoring, liver disease screening, and occupational monitoring not under the Program (e.g., HAZMAT, patients treated with ChE inhibitors), as indicated on the ChE reports. When the test is performed under the Program, the purpose of the ChE test is a data element required under HSC § 105206. The purpose includes whether it is a baseline pre-pesticide exposure vs a follow up during pesticide exposure or during a recovery period after the worker has been removed from exposure to Type I and II pesticides because of ChE depression.

A large proportion of the ChE test results reported by the laboratories to DPR do not include this information. The laboratories reported that this information was often left out because 1) the laboratories do not know if the ChE test order was for an individual in the Program, 2) the purpose of test was not indicated by the ordering Medical Supervision physicians, or 3) the purpose of test was not transmitted to the laboratory. ChE data submitted by the reporting laboratories were reviewed by DPR to identify and remove duplicates, correct formatting errors, identify missing information, and correct typographical errors. OEHHA used "R" software to identify test results likely associated with the Program. OEHHA improved its methodology, including automatically assigning unique identifiers to individuals and analyzing the data at a regional level. In order to improve the confidence in the results, OEHHA also contacted some physicians of individuals with significant ChE depressions.

Participation of workers in the program

Figure 3 shows the geographic distribution of ChE test results OEHHA found associated with the Program and agricultural use of Type I and II OP and CBs in the state. Both the total number of ChE tests and ChE depressions (data not shown) significantly correlated with average pesticide usage per county.

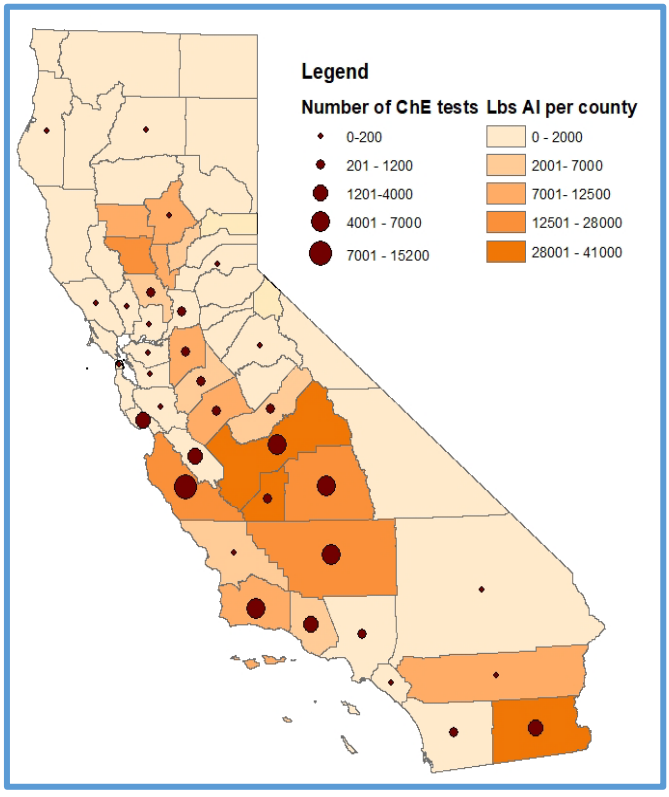

Figure 3: *Geographic distribution of Type I and II OP and CB pesticides and number of ChE tests by county across California (2014–2019).*

In order to gain insight on program compliance and the testing of handlers during spraying seasons, following 3 CCR 6728 requirements, OEHHA analyzed correlations between the temporal distribution of ChE test results and agricultural use of Type I and II OP and CBs in high-use area groups, such as the Coast area (as defined by the California Agricultural Commissioners and Sealers Association).

As an example, Figure 4 (left side) shows for the Coast area the monthly numbers of identified "follow-up" tests ordered – that is the tests during the time workers are being exposed - on the same plot as the pounds of active ingredient applied. It shows for the Coast area the number of identified follow-up ChE tests correlated with monthly use of Type I and II OP and CBs.

Figure 4 (right side) also show that the number of estimated significant ChE depressions derived from 14-day baseline estimates correlated with monthly use of Type I and II OP and

CBs for the same area group. Thus, as expected, ChE depressions occurred when pesticide usage was high.

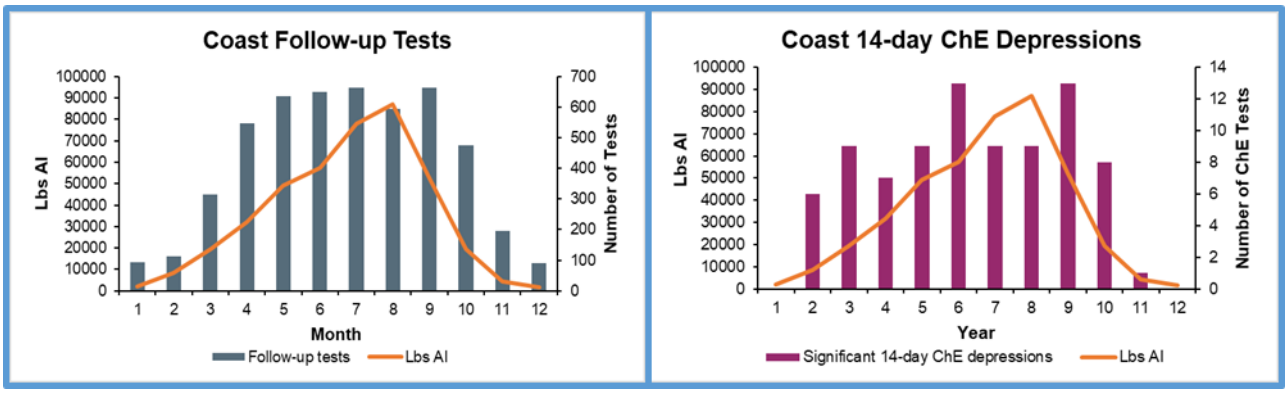

Figure 4: *ChE follow-ups (left) and 14-day ChE depressions (right) from the Coast area group correlated with monthly average PUR data.*

The above spatial and temporal correlations corroborate the likelihood that ChE tests identified as program related, using the R methodology OEHHA applied, were indeed related to the Program. Nonetheless, similar to what was observed in the 2015 Report, in several California counties, OP and CB use did not correlate with the number of tests received. One possibility is that individual workers in some of the higher use counties might not regularly handle these pesticides, and the handling is spread over a number of individuals. This would be consistent with DPR's findings from inspections of growers in a given area, as noted in the 2015 report. Similar observations were also identified in the 2017 PCB Survey. OEHHA is following up on this issue.

ChE depressions requiring action

Following the recommendations from the 2015 Report, OEHHA and DPR have taken a series of actions in an attempt to improve the data quality of the ChE test results submitted by the reporting laboratories and/or the Program itself. OEHHA also used the ChE data reported in the 2014–2019 period to evaluate the effectiveness of the program and utility of laboratory-based reporting.

Figure 5 shows by year the percent of individuals OEHHA estimated to have significant ChE depressions (>20%) for the 2014 –2019 period. Of the pool of individuals with 14-day baseline estimates (n=1,399) reported for the 2014–2019 period, 9.5% of individuals (n=133) experienced significant depressions and fewer than 2% (n=25) had ChE depressions that exceeded the workplace removal thresholds. Less than 1% of individuals experienced multiple depressions, only nine of whom experienced multiple depressions outside of a single spraying season. Interestingly, from 2014 to 2015 there was a more than 3-fold decline in the estimated percentage of individuals with significant ChE depressions. This reduction has persisted in subsequent years. It should be noted that OEHHA and DPR initiated several outreach

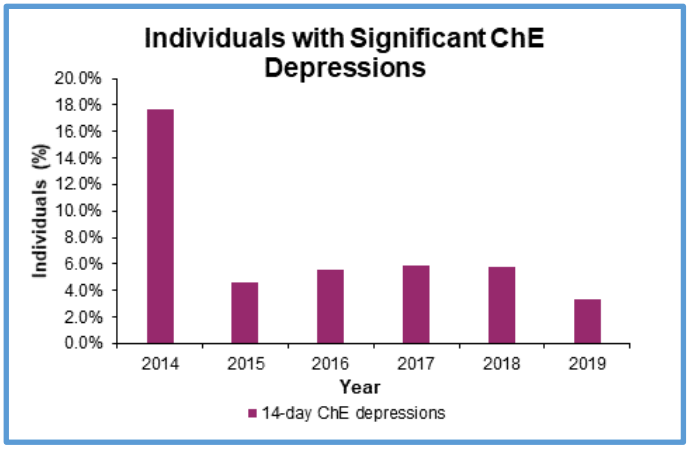

Figure 5: *Percent of individuals estimated to have over 20% ChE depressions.*

activities in 2015.

Among all the ChE test results submitted by registered medical supervisors, OEHHA identified five individuals with ChE tests containing the term “recovery” under the purpose of test field (some had multiple tests). All ChE tests that indicated recovery were preceded by tests with “baseline” or “follow-up” under the purpose of test field. This suggests these may have been workers under the Program whose ChE activity levels exceeded the workplace removal action threshold. Some of these individuals’ ChE activity levels gradually recovered to levels above the 80% threshold level indicating actions were taken to protect these workers from excessive exposure.

Pesticide Illness Reporting

Since AB 2892 was adopted, DPR and OEHHA have not received any pesticide illness reports due to ChE depression from local health officers. Our analyses indicated a small number of workers with levels that exceeded workplace action thresholds, and five of these individuals had follow-up test results labeled as "recovery," which indicate post ChE-depression recovery. OEHHA and DPR are following up with medical supervisors and will gather more information that could help determine why none of these were reported as pesticide illnesses.

Further improvements

Gaps remain in the information that laboratories receive from ordering medical personnel, and errors can be introduced from the laboratories. DPR is proactively working to address:

- Missing information on the test purpose and other required data elements that limit the utility of ChE test results for evaluating the effectiveness of the Program.
- Improvements in data quality (e.g., data entry errors, discrepancies).
- Medical supervisor and employer information to definitively determine if the ChE tests were related to the Program.

Related to this, ChE test reports from laboratories have been useful in identifying which ordering physicians are medical supervisors in order to inform them about the Program’s registration process and conduct targeted outreach and training. Every year, prior to registration renewal deadline, OEHHA follows up with physicians to determine whether additional medical supervisors can be identified.

The reporting laboratories submit their ChE test results in batches, at times several months after the blood specimen has been analyzed. Therefore, due to the frequency of the submission of the ChE test reports by the laboratory and level of processing required of the data, real-time analysis and detection of individuals with depressed ChE activity levels are not feasible. DPR continues to be proactive in monitoring data submitted by reporting laboratories and working with their personnel to obtain accurate data and information as required by law. Reporting laboratories have been responsive to DPR inquiries and have corrected information when possible. Identifying the missing information can help OEHHA focus its effort in training registered medical supervisors.

Summary of Findings and Future Directions

Overall, similar to the 2015 Report, the Program appears effective in protecting agricultural workers handling cholinesterase-inhibiting pesticides. Although there were some improvements in the data quality observed since 2014, the utility of the data analysis continues to be hampered by the inclusion of thousands of records from individuals who are not in the Program. While accurate information has been difficult to obtain, the analysis of the ChE data indicates that most individuals identified as part of the Program did not have significantly depressed ChE activity levels. The Program was able to identify individuals whose ChE activity was significantly depressed enough to necessitate their removal from the workplace, thereby protecting these workers from excessive exposures. Moreover, most of the physicians who regularly ordered ChE tests were medical supervisors, a marked improvement from 2014.

In general, outreach efforts by DPR and OEHHA to Program participants since the last report have resulted in improvements in the quality of the ChE reports received, and their understanding of the Program. Further enhancement of educational materials and outreach efforts to improve communications among all Program participants would strengthen efforts to monitor the Program's effectiveness and enhance protection of California's agricultural workers.

Although the recommendations proposed in the 2015 Report were carried out and provided some useful information, similar shortcomings were identified in this update report. Along with current ongoing activities, DPR and OEHHA plan to take the following steps to help enhance the Program's effectiveness and utility of laboratory-based reporting:

DPR/OEHHA – Future Directions	Leads/ *Participants*	Requires Legislation?
• Focus the next evaluation on counties with high OP/CB use and conduct monitoring study. *Rationale: to evaluate the components of the Program on a smaller scale to better assess its effectiveness*.	Leads: DPR, OEHHA	No
• Amend CCR Title 3 § 6728(c)(1) to add the recommended time frame for performing ChE baseline testing for workers under the Program to be consistent with OEHHA's *Guidelines for Physicians*. *Rationale: to align the requirements for employers with OEHHA's Guidelines for Physicians.*	Lead: DPR	No
• Amend HSC § 105206 to request additional data elements from reporting laboratories to better identify workers and ordering physicians. *Rationale: to help better identify individuals under the Program.*	Leads: DPR, OEHHA	Yes