Appendix A: Background

4. Summary of Published Peer-Reviewed Literature of the Medical Supervisor Program

California's medical supervision program, as described in 3CCR §6728, has been previously reviewed. The following is a summary of selected articles evaluating the program:

- Coye *et al.* (1986) discussed the need to establish standards for agricultural workers exposed to OPs/CBs nationally and used the California medical supervision program as an example. The authors reviewed the use of biologic monitoring of agricultural workers to measure ChE activity, one of which was a colorimetric method (Ellman), the current standard[1].

- Ames *et al.* (1989) requested medical supervision records from physicians, laboratories and employers for the first 9 months in 1985. The authors also requested from the employers a list of pesticides used by employees whose ChE levels were below the "State thresholds."
  - Records from 542 agricultural workers that had at least one pre-exposure (baseline) and one post-exposure (periodic) ChE testing were analyzed.
  - At the time of this study, the State thresholds to remove workers from handling OPs/CBs were 60% or less of baseline for RBC ChE or 50% or less of baseline for plasma ChE.
  - In their analysis, 26 (4.8%) workers had ChE levels below the State threshold.
    - Eight workers were removed from work because of low ChE level.
    - **No actions were taken** for six workers because their ChE levels were within the laboratory's "normal range" even though the depressions exceed the State threshold.
    - Eight workers were tested because they were already ill from a pesticide exposure.
  - Their analysis indicated that the State thresholds at that time were set too high to prevent pesticide poisoning.
  - The authors reiterated the need to establish a baseline for each individual as there were nine workers whose ChE test results were below the State threshold but were within the laboratory "normal range" values.

- Ames *et al* (1989) published a companion article explaining the reason for the change in the California regulation in 1988 which changed the "action" threshold from 60% to 70% depression of RBC ChE activity and from 50% to 60% depression of plasma ChE activity.
  - The new levels were in line with the thresholds recommended by the World Health Organization.
  - The authors also reviewed problems with the medical supervision program and made recommendations for improvement.
    - Exposure for Program requirement – change from 30 hours in 30 days to more than six days in any 30-day period.[1] No reason was given for selecting six days as the "trigger."
    - Mandate frequency of ChE tests by state code– every 30 days for first 3 tests, then every 60 days or as specified by the medical supervisor. [1]
    - Require employers to inform CAC of the name of their medical supervisor.[1]

[1] Adopted in current regulations.

- Increase county enforcement of Program requirements.
- Use of a single analytical test method and standardization of test methodology.
- State certification of laboratories that perform ChE analysis.[2]
- Require employers to inform physician of pesticide exposure status to determine if test is for baseline or periodic testing.
- Increase physician education of the Program and revise the *Guidelines for Physicians*.[3]

- Brown *et al.* (1989) reviewed data for occupational illnesses from OPs/CBs among agricultural applicators in California between 1982 and 1985 (n=238).
  - The authors classified the exposures into five categories: chronic, short-term, accident, safety violation, and weather.
  - They concluded that counties need to include ChE monitoring results in their investigation to assist in establishing ChE inhibition and illness.
  - They also suggested that careful ChE monitoring may reduce the likelihood that persons receiving a single massive dose of OPs/CBs will develop clinical illness.

- Fillmore and Lessenger (1993) published their findings from a 1989 to 1990 retrospective cohort study of 155 employees who had ChE baselines established.
  - Only 79 of the 155 workers had ongoing ChE monitoring.
  - The authors indicated that conducting a ChE monitoring program is far more complicated than just measuring laboratory values.
  - Further, they stressed that careful attention must be paid to comparing ChE values to previous ChE test results and baselines.
  - They also identified a need for regulations to clearly indicate the testing frequency for monitoring, "especially during peak spraying periods."
  - They suggested program improvements and better enforcement of regulations.

- Ames and Menendez (2001) conducted a survey of "medical supervisors of record" in 1992.
  - The survey, based on 101 responses, indicated that medical supervisors were supportive of the Program and felt that it was effective in preventing pesticide poisoning.
  - The survey focused on the medical supervisor responsibilities and did not address the employer requirements of the program.

- Wilson *et al.* (2004) determined that commonly used clinical ChE kits (standard Ellman) were not optimal for assaying blood ChE.
  - This study led, in part, to the revision of 3 CCR §6728(f) to specify the use of the Modified Ellman method for RBC and plasma ChE activity measurement.[1]
  - The authors performed a validation study of ChE activity measurements, and the results were used, in part, for the Department of Health Services to approve nine clinical laboratories for ChE testing.

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[2] Laboratories are currently approved by CDPH but not certified.

[3] Ongoing