Cholinesterase Monitoring of Pesticide Handlers in Agriculture Report to the Legislature

As required by RCW 49.17.288

JANUARY 2007

Executive Summary

This report is prepared, as required by RCW 49.17.288, to reflect the first three years (2004-06) of implementation of the cholinesterase monitoring rule, WAC 296-307-148, (the rule) adopted by the Department of Labor and Industries (L&I) in late 2003.[1] Since the experiences of the first two years have previously been documented and reported to the legislature[2] this report will focus primarily on the data analysis presented in the 2006 Cholinesterase Scientific Advisory Committee Report to L&I. In some cases, data presented in the 2004 and 2005 reports to the legislature are repeated.[3]

During the 2006 agriculture pesticide application season, 244 employers and 1889 pesticide handlers participated in baseline (pre-exposure) cholinesterase testing. Four hundred and seventy one of these pesticide handlers were tested at least once during the application season (periodic testing). Of these 471 handlers, 50 (10.6 percent) received at least one test with a 20 percent or greater depression in cholinesterase activity requiring the employer to evaluate pesticide handling practices, and 7 (1.5 percent) were temporarily removed from exposure to cholinesterase-inhibiting pesticides because of a more significant cholinesterase depression.

The number of handlers undergoing cholinesterase testing in 2006 was significantly less than in previous years. This is thought to reflect industry pesticide use patterns, employer experience in identifying employees covered by the testing requirements of the rule, and employer actions resulting in limiting handler exposure (e.g., product substitution, spreading pesticide handling duties among employees). Even though fewer handlers underwent periodic testing in 2006 (471) than 2005 (611) the number of handlers experiencing a significant cholinesterase depression remained stable (2005=59, 2006=57).

As in 2004 and 2005, agriculture pesticide handlers with significantly depressed cholinesterase levels were generally employed in the tree fruit industry with operations located in L&I Region 5 (West Adams, Benton, Chelan, Columbia, Douglas, Franklin, Grant, Kittitas, Okanogan, Walla Walla and Yakima counties). Airblast pesticide application was most often implicated in significant cholinesterase depressions. Toxicity class I and II cholinesterase inhibiting pesticides most frequently handled prior to testing include chlorpyrifos, azinphos-methyl, phosmet, formetanate hydrochloride, and carbaryl.

Procedures and requirements for the collection of blood samples did not change from the 2005 season. The Washington State Public Health Laboratory continued as the only laboratory approved to provide cholinesterase-testing services. Testing was conducted in accordance with the laboratory Standard Operating Procedures (SOP) established in 2005. All test samples were tested within the time frames established in the SOP. In its analysis of testing services, the Cholinesterase Scientific Advisory Committee concluded that testing continued to be well within acceptable parameters.

As planned during the initial rulemaking process laboratory testing services will shift to the commercial sector beginning in 2007. L&I has selected Pathology Associates Medical Laboratories, Spokane WA, as the single approved laboratory to provide testing and data management services under the rule. Approval of a single laboratory to provide all testing will serve to eliminate test variability between laboratories.

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[1] Rulemaking was initiated pursuant to Juan Rios and Juan Farias v. Washington Department of Labor & Industries, et al., 145 Wn.2d 483, 39 P.3d 961 (2002).
[2] Cholinesterase Monitoring of Pesticide Handlers in Agriculture: Report to the Legislature (2004 and 2005)
[3] The Scientific Advisory Committee for Cholinesterase Monitoring: Report to L&I (2004, 2005, and 2006)

CHOLINESTERASE MONITORING IN AGRICULTURE

WAC 296-307-148

WASHINGTON STATE DEPARTMENT OF LABOR AND INDUSTRIES

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CONTENTS

Background

WAC 296-307-148, Cholinesterase (ChE) Monitoring (the rule) was adopted in December 2003. The rule requires agriculture employers to 1) record hours employees handle[4] toxicity class I and II organophosphate and N-methyl-carbamate pesticides, 2) provide cholinesterase blood testing to employees who handle covered pesticides for 30 or more hours in any consecutive 30 day period, and 3) take specified actions when an employee experiences a cholinesterase depression of >20% from their individual baseline.[5] RCW 49.17.288 directs the Washington State Department of Labor & Industries (L&I) to submit reports of the results of data collection, correlation, and analysis related to cholinesterase monitoring to the legislature. This is the third and final of these reports.

Detailed discussions of occupational cholinesterase monitoring and history of the rule can be found in the *2004 Cholinesterase Monitoring of Pesticide Handlers in Agriculture Report to the Legislature,* and the *Washington State Cholinesterase Testing: Guidelines for Health Care Providers Manual* (http://www.lni.wa.gov/Safety/Topics/AtoZ/Cholinesterase/default.asp).

In 2006 the Washington State Public Health Laboratory (PHL) continued to be the sole laboratory approved by L&I to provide cholinesterase-testing services. Blood sample collection and laboratory testing procedures remained unchanged from 2005.[6] Analysis of Laboratory performance conducted by the Cholinesterase Monitoring Scientific Advisory Committee (SAC) concluded that laboratory performance remained well within acceptable limits.[7]

Test data continued to be collected and managed by the PHL and Department of Health Non-Infectious Conditions Epidemiology program (DOH). DOH maintains the Cholinesterase Monitoring Data System (CMDS), notifies L&I of cholinesterase depressions exceeding 20 percent[8], and provides a variety of data reports. .

Due to stakeholder concerns regarding employee access to health care provider recommendations the following amendments to the cholinesterase monitoring rule were adopted for 2006:

The employer must:

- *Provide a completed CHOLINESTERASE MONITORING HANDLING HOURS REPORT (F413-065-000) to the physician or other licensed health care professional (LHCP) for each employee receiving a periodic cholinesterase blood test and make sure the report is submitted to the laboratory with each periodic cholinesterase test.*

- *Obtain a written recommendation from the health care provider for each employee's blood test and evaluation (including baseline tests) and make sure that the employee receives a copy of the health care provider's written recommendation within 5 business days after receipt.*

[4] Pesticide handling is defined in WAC 296-307-11005
[5] Employer requirements for response to significant cholinesterase depression are found in WAC 296-307-14825
[6] Standard Operating Procedures for the Determination of Red Blood Cell and Serum Cholinesterase (2005)
[7] The Scientific Advisory Committee for Cholinesterase Monitoring: Report to L&I (2006)
[8] Bodies such as the World Health Organization, American Conference of Governmental Hygienists, and the state of California have identified a 20% decrease in cholinesterase activity as indicative of pesticide overexposure.

- *Instruct the health care provider to not reveal in writing or in any other communication with you any findings or diagnoses unrelated to occupational exposure.*

- *Make sure that any employee declining participation in the cholinesterase testing program receives a copy of the signed declination statement within 5 business days after receipt.*

The legislature has authorized annual expenditures of up to 1.6 million dollars from the L&I Accident Fund to cover the costs of laboratory testing, and to reimburse employers for other clinical and related administrative costs incurred. Employer reimbursement policies and protocols a can be found at http://www.lni.wa.gov/Safety/Topics/AtoZ/Cholinesterase/files/413062af.pdf . Testing, data collection, and employer reimbursement costs for calendar year 2006 totaled ~$253,170.00.

Laboratory program

The PHL continued to provide exemplary services in 2006. The addition of a laboratory technician 3, provided by L&I, bolstered resources dedicated to the program.

Both internal and external (blind sample submissions) quality control programs were utilized to monitor testing competency. Cholinesterase Scientific Advisory Committee (SAC) analysis of quality control data showed good agreement between internal and external QC data, demonstrating a lack of bias in internal laboratory measurements**.** A detailed discussion of laboratory data quality can be found in the 2006 SAC report to L&I (http://www.lni.wa.gov/Safety/Topics/AtoZ/Cholinesterase/default.asp).

As planned, and as consistent with medical surveillance programs required by other DOSH rules, the PHL will no longer be providing testing services and testing will move to the commercial sector in 2007. L&I has worked with interested private laboratories to identify a single laboratory to provide testing services beginning in 2007. Use of a single laboratory serves to eliminate test variability between laboratories.

Laboratory evaluation criteria included;

- Licensure under the Washington State Laboratory Quality Assurance Office or the Clinical laboratory Improvements ACT (CLIA).
- Ability to perform red blood cell (acetylcholinesterase) and serum (butyrylcholinesterase) cholinesterase testing utilizing the Ellman Method. Test protocols must be reviewed and approved by the Washington State Public Health Laboratory.
- Demonstration of a robust quality assurance program including, but not limited to;
    - Participation in the College of American Pathologists cholinesterase proficiency testing program
    - Submission of a quality assurance plan with approval by the Public Health Laboratory
    - Routine review of quality assurance data by the Public Health Laboratory.
- Ability to report test results within 5 days of sample collection.
- Maintenance of test results and related demographic information in an Aggregate electronic data base with transfer of surveillance data to L&I on a scheduled basis.

L&I has chosen Pathology Associates Medical Laboratories (PAML), Spokane WA, to provide all testing services beginning January 15, 2007. Ongoing approval will be dependent of factors including 1) demonstrated laboratory capacity to manage and process samples as dictated by standard operating procedures, 2) maintenance of formalized QC programs, 3) competency of data management systems, and 4) customer service programs.

Summary of the 2006 Medical Monitoring Experience

As in 2004 and 2005 the vast majority of employers participating in the medical monitoring program had operations located in L&I Region 5 (West Adams, Benton, Chelan, Columbia, Douglas, Franklin, Grant, Kittitas, Okanogan, Walla Walla and Yakima counties.) L&I Regions 1 (Island, San Juan, Skagit, Snohomish, and Whatcom) and 4 (Clark, Cowlitz, Grays Harbor, Klickitat, Lewis, Mason, Pacific, Skamania, Thurston and Wahkiakum) accounted for the remainder of the samples submitted

Table 1. Monthly blood samples submitted 2004-06 (2006 SAC report)

Time Period	Number of Samples Per Month & Year		
Month	**2004**	**2005**	**2006**
January	22	74	22
February	1039	1127	239
March	1338	1376	1076
April	459	144	612
May	331	97	296
June	105	35	257
July	75	23	80
August	40	70	*
Total Blood Samples	3409	2946	2582

* 2006 analysis included data collected from January through July

During the 2006 pesticide application season, 244 employers and 1889 employees submitted cholinesterase baseline tests. The number of samples submitted to the lab from January through July totaled 2582 (Table 4.1) The total number of samples decreased 12-13% each year of the program, presumably (at least in most cases) because their exposure levels remained below 30 hours in any one 30-day period and employer actions resulting in decreased use of cholinesterase inhibiting pesticides.

Of the 471 employees who received at least one periodic test, 50 employees (10.6 percent) received at least one periodic test result with a 20 percent or greater cholinesterase depression, requiring the employer to evaluate pesticide handling practices for possible deficiencies. Of those same 471 employees, 7 (1.5 percent) were temporarily removed [9] from exposure due to a more significant depression (at least 30 percent depression in red blood cell [RBC] cholinesterase or at least 40 percent depression in serum cholinesterase (Table 2.). The 57 total employees who experienced a significant cholinesterase depression in 2006 worked for 30 different employers. Only two employees experienced an RBC ChE depression with one of these

[9] Employees may return to handling covered pesticides when cholinesterase levels return to within 20% of baseline. While medically removed from exposure to covered pesticides employee pay, seniority and other benefits are maintained at the pesticide handler level for a maximum of 3 months.

employees experiencing both an RBC and serum ChE depression. No employees were identified, through the monitoring program, with symptomatic pesticide illness.

Table 2. Comparison of employer and employee cholinesterase testing and significant cholinesterase depressions in 2004-06

	2004	2005	2006
Employers participating in testing	380	316	244
Employees submitting baseline tests	2630	2263	1889
Employees with at least 1 periodic test	580	611	471
Periodic tests	911	970	692
Employees with ChE depression to work evaluation level	97 (16.7%)	49 (8.0%)	50 (10.6%)
Employees with ChE depression to exposure removal level	22 (3.8%)	10 (1.6%)	7 (1.5%)

In adopting RCW 49.17.285, the Legislature required employers to submit pesticide handling hours to L&I on each employee who received a periodic test. The SAC analyzed handling hours in relation to change in cholinesterase levels. No significant relationship was found for RBC cholinesterase. A small relationship was found for serum cholinesterase. The current 30 hour exposure threshold will remain in place in light of the SAC finding no conclusive evidence supporting a change.

The rule allows covered pesticide handlers to decline participation in the testing program. The 2003 Agriculture Cholinesterase Monitoring Cost Benefit Determination (http://www.lni.wa.gov/wisha/p-ts/Cholinesterase/ChE-BCD-Final.pdf) estimated that the declination rate would be approximately 15%. In an attempt to assess the proportion of handlers offered participation in the program but declining testing from the health care provider, L&I surveyed the five health care clinics performing the majority of baseline cholinesterase tests. Each clinic was asked how many handlers were referred to the clinic and of those, how many declined participation. All clinics had a less than 15% declination rate, well within the expected rates (Table 3.). There are no comparable data for 2004.

Table 3. Declination rates at the five clinics providing the most baseline cholinesterase blood samples. (2006 SAC report)

Provider	Baselines		Declinations		Declination Rate	
	2005	**2006**	**2005**	**2006**	**2005***	**2006**
1	559	576	65	89	10.4	13.4
2	117	87	1	5	>0.1	5.4
3	73	118	10	34	12.0	22.3
4	106	61	14	5	11.7	7.6
5	701	623	120	51	14.6	7.6
Total	1556	1465	210	184	11.9	11.2

The rule allows employees to either choose to participate or decline participation in the employer's cholinesterase testing program. The option is consistent with other WISHA rules that contain medical surveillance provisions. As an additional protection against potential coercion regarding the employee's decision to participate in the program the rule includes the requirement that this decision is made in conversation with the health care provider. There have been no cases of potential coercion identified. L&I believes that adding additional employer requirements and dedicating program resources to track employee declinations is not justified.

L&I Consultation and Compliance Activities

In 2006, L&I transitioned to use of standard consultation and compliance programs in response to significant cholinesterase depressions (ChE depression >20% from baseline). WISHA Regional Directive 33.27, Cholinesterase Depression (http://www.lni.wa.gov/Safety/Rules/Policies/PDFs/WRD3327.pdf), provides consistent enforcement policy. Employers with employees who experienced significant cholinesterase depressions were contacted and offered field consultation services. Compliance referrals are made under the following circumstances:

- The employer declines the offer of consultation services for a second time.
- An employer has received at least 2 consultations as a result of cholinesterase depressions but continues to have additional employees with a significant cholinesterase depression.
- Consultation identifies circumstances that warrant a compliance referral, e.g. hazards are not abated in a timely manner.
- DOSH Technical Services identifies trends or circumstances that indicate employer safety program deficiencies, e.g. cholinesterase depression clusters or ongoing employee cholinesterase depressions.

The ChE field consultations and enforcement investigations were performed by one of five DOSH consultation and compliance staff. DOSH consultants collected surveillance information using a standard series of questions (see WRD 33.27). The questions included worker name, birth date, primary language and number of years as a handler. The employer name was recorded along with additional information regarding the number of acres, crop types, the types of ChE inhibiting pesticides handled, the number of handling hours, handler training, types of pesticide handling activities, use of personal protective equipment (PPE), decontamination facilities, handler symptom history, and identification of the potential cause of exposure. The investigator summarized the reports for use by the scientific advisory committee. Employers who received a ChE consultation or compliance inspection from DOSH are required by state law to correct any serious job safety and health hazards or deficiencies found.

Twenty-one of the 30 employers who had employees with ChE depression received consultation visits. Two additional employers received compliance visits due to having multiple workers with depressed cholinesterase levels.

The vast majority of consultations revealed that over-exposures occurred in tree fruit operations. There was one employee working in a field crop operation (onions, beets, green beans, grass seed) applying pesticides to the ground from tractor mounted spray booms. Air blast application of the covered pesticides may not be the sole contributing exposure factor for the workers with depressed cholinesterase levels. Other exposure hazards found include not properly decontaminating before meal or bathroom breaks and not wearing appropriate personal protective equipment, e.g., the use of leather boots when the pesticide label required the use of protective footwear.

Common rule violations found during consultation visits include:

- WAC 296-307-6005 – Develop and maintain written respiratory protection program.
- WAC 296-307-13050 – Provide decontamination supplies (e.g. water, soap, disposable hand towels, and an emergency change of clothing).
- WAC 296-307-13025 – Provide effective pesticide safety training.
- WAC 296-307-60805 – Provide effective training on the use and maintenance of respirators.
- WAC 296-307-13045(3)(f) – Ensure use of appropriate personal protective equipment
- WAC 296-307-14835 – Conduct and document work practice evaluations of employees experiencing significant ChE depression.

Potential exposure routes identified during consultation visits include:

- Cotton ball cap (bill exposed) worn under protective head gear
- Lack of chemical resistant footwear
- Improper maintenance and storage of respirators
- Improper decontamination of personal protective equipment, incl. respirators
- Exposure to contaminated equipment
- Overuse of respirator cartridges
- Use of cotton gloves under rubber gloves,

Two employers were referred for compliance investigations. Both employers had clusters of five employees with cholinesterase depressions greater than 20% from baseline. In the first compliance investigation, the employer was cited for two serious violations: 1) not ensuring handlers' head gear (hats) were chemical resistant and 2) not ensuring emergency eyewash was available on every tractor used to spray pesticides. There were no serious violations found on the second compliance investigation. However, the compliance officer noted potential exposure routes: 1) not washing hands before and after using the bathroom, 2) wearing hooded cotton sweat shirts under rain gear, and 3) not showering or changing clothes after applying pesticides.

In addition to the compliance investigations, L&I conducted scheduled investigations with a group of employers who had participated in the ChE monitoring program in 2005 but had not participated in the program in 2006. One hundred twenty-four employers were identified and thirty-one (~25%) were chosen to receive a compliance visit. A focus of the inspection was to determine compliance with the cholinesterase monitoring rule. Based on a review of handling records by DOSH compliance inspectors all of the inspected employers were in compliance with the ChE monitoring rule. Employers made the following engineering or administrative controls to mitigate worker exposure to covered pesticides:

- The owner applied the covered pesticides.
- The employer eliminated the use of cholinesterase-inhibiting pesticides.
- The farm was converted to organic farming.
- The employer hired additional pesticide applicators to decrease the number of exposure hours.
- The employer monitored and restricted handling hours to keep workers under the 30 hour threshold.
- The employer switched from Guthion to Assail for coddling moth.
- The employer increased spray rate per acre to limit exposure time.
- The employer increased use of integrated pest management techniques.

The majority of significant cholinesterase depressions occurred during the beginning of the tree fruit application season (dormant season spraying). Later depressions tended to coincide with orchard activities such as application of fruit thinning and post bloom cover sprays. During dormant season spraying, the organophosphate insecticide Lorsban (chlorpyrifos) is used. The fact that the majority of significant cholinesterase depressions were due to depression of serum cholinesterase is consistent with the use of chlorpyrifos as it has an affinity to bind with serum cholinesterase. Other cholinesterase inhibiting pesticides handled by these employees include Guthion (azinphos-methyl), Carzol™ (formetanate hydrochloride), Imidan™ (phosmet.), and Sevin (Carbaryl).

2007 Program Highlights

The 2004-06 experience has demonstrated the feasibility of a state wide occupational cholinesterase monitoring program. The rule has provided clear direction and support to employers, employees, and health care providers. The cholinesterase monitoring program continues to demonstrate improved function and has reached a level of self sustaining maturity. The Cholinesterase Monitoring Benefit-Cost Determination listed the following probable benefits of a cholinesterase monitoring rule:

- Greater certainty about the frequency of pesticide overexposure
- Avoidance of serious pesticide illness
- Improved compliance with the pesticide worker protection standard
- Identification of any existing PPE, work practice and engineering control requirements that are not sufficient to protect pesticide handlers from exposure
- Greater awareness of chemical and exposure hazards

The information gathered over the last three years has shown that these benefits are being realized. There is an increased awareness in the agriculture industry of the hazards inherent in pesticide handling, causes of overexposure are being identified, handler pesticide training programs have been bolstered and educational opportunities expanded, and laboratory blood cholinesterase testing has shown itself to be an effective method to identify overexposure prior to the onset of illness. While much data has not been available to allow for precise quantification of benefits it is apparent that the goals of increased knowledge and improved worker health protection have and are being achieved.

The rule functioned well in 2006 and is quickly moving to a level of self sustaining maturity. No immediate rule or enforcement policy changes are immediately anticipated for 2007. While the rule will remain intact, program changes that will occur are:

- Laboratory services will transition from the Public Health Laboratory to Pathology Associates Medical Laboratories (PAML). The transition to the private sector was anticipated and is consistent with the provision of medical surveillance services contained in other rules, e.g. lead, cadmium. All employer testing costs will continue to be reimbursed through existing structures.

- In previous years L&I often had knowledge of test results prior to the health care provider. Due to this situation L&I elected to notify the health care provider by telephone of all significant cholinesterase depressions. In 2007 all test results will be reported electronically (web based, fax) by the laboratory to the health care provider eliminating the need for telephone reporting.

- Laboratory surveillance and data management will begin transitioning from the Department of Health (DOH) to PAML. In order to ensure that appropriate data management systems are in place DOH will continue to operate the Cholinesterase Monitoring Data System (CMDS) through 2007 and in parallel with PAML. CMDS will be operated out of the DOH Office of Environmental Assessments Pesticide Program.

  L&I will continue to collect and manage laboratory test and field surveillance data gathered during consultation and compliance activities. This data will be available for analysis and used to direct rule and related program improvements.

At the time of this writing L&I has not had sufficient time to thoroughly consider the recommendations provided in the 2006 SAC report (Appendix). While many of the recommendations are specifically provided for long term consideration it may be practical to take more immediate action on some recommendations. L&I will continue to work with stakeholders in order to make these determinations**.**

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L&I appreciates the work of the Scientific Advisory and Stakeholder Committees and thanks their respective employers for making them available to assist in evaluating the rule and its implementation.

APPENDIX

2006 Cholinesterase Scientific Advisory Committee Recommendations

The following recommendations are contained in the 2006 *Scientific Advisory Committee Report to the Department of Labor & Industries*
http://www.lni.wa.gov/Safety/Topics/AtoZ/Cholinesterase/files/2004-06ChESACreport.pdf

General recommendations for program improvement

1. ***Continue retrospective evaluation of program results, and consider future changes to the rule.*** The SAC feels that there would be scientific merit in narrowing the scope of the rule, at a point when it could be established that the current rule includes handlers for whom the risk of significant cholinesterase depression is categorically less than for the handler population as a whole. This will require expanded data collection and ongoing review of program results.

2. ***Continue central data collection for the life of the program.*** The SAC suggests strongly that a centralized data collection system similar to CMDS continue and DOSH analyze these data annually and compare them across years. Sufficient resources need to be assigned to the program to assure that data quality is consistent and that important trends in cholinesterase depressions are identified and appropriate responses taken.

3. ***Collect additional data with each periodic test***. Continued collection of handling hours might be useful if other information regarding workplace conditions and practices was also collected for each handler. Examples of additional questions might include type of crop, product applied, method of application. This would be important for considering rule changes based on patterns of exposure by any of these factors. Absent this additional detail, it is doubtful if compiling handling hours as a routine feature of the monitoring program is justified, so long as those data are maintained by each employer.

4. ***Establish a provider certification or other provider quality assurance program*** . The SAC believes that role of the health care provider and clinic staff in informing the handler about the program, in obtaining medical and related information from the handler, and in interpreting ChE values is critical to the quality of the program. There is an ongoing need to provide training and update information to the staff that actually counsel handlers and carry out other monitoring program functions. The SAC recommends that L&I develop a mechanism for assuring quality in this role, particularly as medical and clinic personnel change, and as the program moves from a start-up phase with relatively close oversight to an ongoing program. Ideally, each handler would have a designated health care provider who would be certified by L&I and would participate in annual training. In addition to provider certification, L&I should develop a system to certify participating clinics. The certification programs need to pay ongoing attention to the training and guidance materials on how to conduct cholinesterase monitoring. Periodic or ongoing web based training opportunities could be made available and should be a requirement for participation for new and continuing clinic participants. These should be periodically updated based on information obtained through the systematic reviews of monitoring program results, field consultations or inspections, and through

consultation with national experts and the participating clinics. These updates should incorporate advances in communication and laboratory technology. This activity could be assigned to the Office of the Medical Director of L&I or could be a shared responsibility between DOHS and the University of Washington Occupational Medicine Program.

5. ***Maintain Laboratory Services.*** In 2004 and 2005, the SAC expressed concern that changing the laboratory or moving to multiple labs providing monitoring services would threaten the validity and comparability of the test data. Given the high degree of acceptance, and objective measures of reliability demonstrated in 2004-2006, purely technical considerations would indicate that the safest course would be to continue to use the PHL for program support. At this writing, there is active procurement to identify a commercial laboratory to replace the Public Health Lab as the provider of testing services. SAC reasserts the scientific value of having a single lab of known quality supporting this program. The transition to a new lab carries inherent risks: data quality and user confidence in it may suffer as a transitional effect, or might fail to be adequate for multiple years. This would not only risk increasing the number of false negative results (leaving handlers unprotected) and/or false positive results (wasting state and employer resources), but could affect overall program sustainability if participation rates are then affected. Specific recommendations for how risks might be minimized in this transition are offered in the next section.

6. ***Continue active L&I Consultation Services follow-up with employers when there are ChE depression alerts***. The SAC recommends that there be a response time goal set for consultation field visits before the start of each monitoring season, and that this be kept as short as is practical (bearing in mind that as little as 9.5 days was demonstrated to be achievable in 2005 for response to exposure removal alerts, but also that employer scheduling constraints affect this). Additionally, the SAC recommends that L&I clearly communicate the roles of consultation and compliance groups when there are repeated ChE depressions for a handler or multiple ChE depressions for handlers at a single grower.

7. ***Develop new or better methods for disseminating information on exposure reduction***. The SAC encourages L&I to develop systems that allow for timely sharing of information gathered during field activities including consultation or compliance visits in order to communicate new findings within a growing season to the various state agencies and other groups that are involved in conducting and developing farm worker and agricultural employer training, outreach and pesticide license testing related to agricultural pesticide use. This system would likely be more effective if it could be operated jointly with other groups involved in agricultural worker safety issues.

8. ***Continue to assess program performance and impact.*** Systematic review of the program should include an assessment of the participating clinic practices, satisfaction surveys of handlers and employers, review of quality assurance practices of the participating laboratory or laboratories, response time for notification of depressions, the nature of employee response to notifications of depressions and effect of the cholinesterase monitoring rule on chemical choices, and handler assignments. Although this program is becoming more established and routine, there are several important aspects of it that are as yet poorly understood or need continued tracking. These include:

Effectiveness of educational outreach efforts (for providers, handlers, and employers). This includes efforts to inform program participants about changes in program aspects, providing basic information about the program to new participants, and ongoing efforts to educate employers and handlers regarding the exposure risks.

Handler perception. As the handlers are the primary beneficiaries of this program, their continued participation and thus satisfaction with the program should be assessed and optimized. The SAC cannot determine why some handlers decline to participate in the program. This information could be important for assessing how employers and providers present the program, how handlers perceive the program, and the effectiveness of educational outreach efforts (to growers, pesticide handlers, and to health care provider groups). Given that the population presently participating is largely Hispanic, many of who speak English as a second language, particular attention needs to be paid to the understanding that this population has of the potential benefits of this program.

In addition, a related (research) question that has not been evaluated under the present system is the effect of the program on the attitude of handlers toward the risks they face in handling covered pesticides. The initiation of a medical test in response to a handler exposure emphasizes the importance of this exposure to the handler and the employer. The effect on knowledge, attitudes, and behaviors of handlers and employer due to the existence of this program is a dimension of program that would be valuable to understand and describe for the benefit of future such programs.

Employer participation. The SAC recommends that compliance investigations (checking "drop-out" employers or other spot checks of employer compliance) as an active part of the overall cholinesterase monitoring program be continued. Active investigation of other agricultural operations not currently under the rule which use organophosphate and N-methyl-carbamate pesticides might also be considered

Handler notification of routine results. The failure of handlers to get their results back in a timely way could be a significant disincentive for future participation. The SAC as well as Stakeholders unanimously support timely feedback to handlers, even for results that do not indicate overexposure to pesticides. Currently, the employer is required by L&I to provide timely interpretation of tests to each handler. Routine assessment of this aspect of employer compliance with the rule is needed. This could be added as a question on each periodic blood draw (e.g., "Have you been notified of your results from the prior month?"). The establishment of a central call in number and a unique identifier provided to the handler is another way to resolve this problem.

9. Support the research value of the monitoring program. The opportunity to recognize common factors leading to pesticide overexposure and cholinesterase depression has not been realized as yet. New understanding of the underlying causes of exposure or failures of protective measures are not likely to arise from routine monitoring effort per se, but can benefit from monitoring activities and data. The SAC recognizes that research is not the primary objective of ChE monitoring, and that L&I / DOSH are regulatory programs. The SAC recommends that research uses of the program by third parties be encouraged by L&I, through cooperation and, where feasible, through selective opportunities for research support. Beyond sharing of program data as they currently exist, "cooperation" might include adopting modified practices to assist research, where such modifications are not intrusive. Some

possibilities for how this might be done include:

- The Department could organize and support an annual meeting to allow interested non-L&I groups to obtain and share analysis of program results. A related activity would be for Stakeholders to confer with L&I to identify priority issues where investigation is needed for program assessment or improvement purposes.
- The Department could support (either financially, or by cooperation) periodic studies conducted by third parties such as WSU or UW, that explore the causes of cholinesterase depression, the rate of participation among eligible employers and the reasons for non-participation of both handlers and employers. These projects could be in response to solicitations from L&I, or unsolicited research ideas, or both.
- The SAC feels that L&I should be directive in research that it funds, and that there should be a significant Agency need justifying funded projects.

Recommendations for maintaining program quality in 2007

Based on information from L&I, the SAC expects that the ChE monitoring program will undergo significant changes for the 2007 growing season. Notable potential changes include use of a single commercial laboratory and decreased involvement of L&I and the DOH in system function. It is unclear whether these changes will impact the effectiveness of the program.

The SAC recommends evaluation of the program for at least one additional year to assess

- Laboratory accuracy and timeliness for running the assay, matching baseline and periodic tests, calculating percent depression, and notifying providers.
- Provider timeliness and accuracy in matching baseline and periodic tests, calculating percent depression, and notifying growers and handlers.

To accomplish this evaluation, L&I needs access to participant identifiers and test results from the laboratory and from providers.

Manual matching of periodic samples to a single handler continues to require significant effort and could be a source of error in the future. As this task is reassigned to a commercial provider, the SAC recommends that L&I and stakeholders consider the feasibility of issuing unique identifier codes to each handler to be used by the health care provider in collecting and submitting samples.

The SAC has considered the arguments for and against continuation of the RBC ChE testing. Arguments against continuing to perform this test are that the RBC test does not detect very much exposure and added only one “work practices” alert in 2006. It is therefore potentially a case of significant cost and effort for little return. The performance on this test is inherently less robust than for the serum ChE, and no appropriate control material is available for QC purposes. Arguments for continuing to perform this test are that the marginal savings of dropping this test would be small (an example cited by L&I staff was that private labs would charge $25/sample for one test and $30/sample for both tests); the response of RBC ChE compared to serum ChE could change if the pesticides in use change, and the failing to know about RBC ChE depression is more significant than for serum ChE depression, as the RBC enzyme is

biologically closer to the health effect of concern (depression of AChE in the central nervous system). Our recommendation is that L&I determine the cost differential of one test versus both tests as part of its lab selection process, and that if the differences are not large, that both tests be continued for the present.

To assure quality of the laboratory tests, the SAC recommends that L&I, in consultation with stakeholders provides oversight of laboratory operations by establishing definitions and processes for which the laboratory can provide documentation. These include definitions and processes for assuring:

- Data validity on a batch or submission basis.
- Laboratory capacity to receive sample submissions at their peak seasonal rates and to complete analyses without exceeding holding times.
- Laboratory ability to store samples at –70°C for up to 6 months in order to respond to any questions arising from patterns in results across the monitoring season.
- Extra-lab quality control testing (operated by L&I or by health care providers under L&I direction) to serve as an adjunct to within-lab QC efforts and capture possible sources of variability related to sample collection and shipment.
- Lab certification by external bodies based on performance testing, such as the College of American Pathologists (CAP) program, is an important qualification of the lab providing ChE testing.
- Interlab comparison programs and the development and use of reference or benchmark samples (particularly for the membrane-bound form of ChE detected in the RBC assay) are highly desirable

An annual audit of lab performance according to these standards and criteria is recommended. If the audit is conducted by L&I staff, disclosure of the findings and recommendations to stakeholders is also recommended.