

FINAL STATEMENT OF REASONS AND PUBLIC REPORT  
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations  
Amend Sections 6260, 6262, 6264, and 6266  
Relating to Research Authorizations

UPDATE OF THE INITIAL STATEMENT OF REASONS

As authorized by Government Code section 11346.9(d), the Department of Pesticide Regulation (DPR) incorporates by reference the Initial Statement of Reasons prepared for this rulemaking. No changes were made to the proposed regulations nor are any changes necessary to the Initial Statement of Reasons following the 45-day public comment period.

The proposed regulatory action was noticed in the *California Regulatory Notice Register* on July 10, 2015. During the 45-day public comment period, DPR received comments on the proposed text. The comments are discussed under the heading "Summary and Response to Comments Received" of this Final Statement of Reasons.

DPR has amended Title 3, California Code of Regulations (3 CCR) sections 6260, 6262, 6264, and 6266. This regulatory action pertains to research authorizations. In summary, this action will clarify the information required on the research authorization application and reporting forms, and will revise the notification requirements. These changes are intended to ensure that DPR and the county agricultural commissioners (CACs) have the necessary information to evaluate pesticides applied under the research authorization program.

PUBLIC HEARING

No public hearing was scheduled or held.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING 45-DAY COMMENT PERIOD

- Comments received from *Rachel Kubiak, Western Plant Health Association (WPHA)*.

**Comment:** A 72-hour notice of intent (NOI) is unmanageable for field researchers. The complications resulting from the increased time frame far exceed any reasonable benefit. The increase will prevent researchers from undertaking timely and effective research in situations where pests are in the optimal state of development for testing and delay bringing softer chemicals to market.

**Response:** Since the notice of application may be the first time the CAC is aware of research being conducted in his/her county, the intent of the 72-hour notice is to ensure that CACs have time to conduct pre-application inspections, identify sensitive sites, make arrangements to be at the site prior to the application, and perform any other necessary evaluations to ensure human health and the environment are adequately protected before the pesticide is applied. The

proposed regulation allows CACs to reduce the notice of application to less than 72 hours with prior approval, with no minimum amount of notice specified in regulation. Therefore, if there are concerns that 72 hours' notice may impede on conducting timely trials, the researcher is encouraged to communicate with the CAC in advance.

As part of approval process, DPR may add site specific conditions to a research authorization. In some cases, such as for field fumigants, the current minimum 24-hour notice is increased to 72 hours. DPR did not receive any comments stating that the 72-hour notice for field fumigants is unmanageable. In addition, DPR surveyed several counties and estimated that CACs will only require the increased 72-hour notice for approximately 19 percent of the research authorizations. DPR's economic analysis used this estimate along with the estimated 30 percent cost increase that WPHA provided to DPR to calculate the estimated economic impact.

**Comment:** Delaying applications will lead to multiple trials or attempts at trials being conducted to achieve satisfactory results. Aside from the added costs, the researcher will need to submit additional NOIs to the CAC and DPR, increasing workload. While this figure has been deemed negligible in the economic analysis, it should be recognized as an additional workload for research companies.

**Response:** A 72-hour notice of application would not necessarily result in delayed applications or additional trials. Since the CAC has the discretion to reduce the amount of notice, if there are concerns that 72 hours' notice may impede on conducting timely trials, the researcher is encouraged to communicate with the CAC. In fact, the proposed regulation gives CACs the authority to reduce the amount of notice to even less notice than is required in the current regulation.

**Comment:** Mis-timed applications result in significant delays in bringing products to market. This applies to providing California growers' with less-toxic alternative products. Because there are limited alternatives, production costs for efficacious products increase, which is passed along to growers. In many instances, growers must increase the amount of product applied to ensure pest management, driving costs up even further. Unfortunately, this increased cost was not captured in the economic analysis provided to DPR by the Air Resources Board's Economic Studies Section (ESS).

**Response:** A 72-hour notice of application would not necessarily result in delayed applications. Currently, DPR asks researchers using field fumigants to provide 72-hour notice as a condition of the research authorization. DPR did not receive any comments stating that 72-hour notice for field fumigants has resulted in significant impacts. Whereas the current regulations require at least 24 hours' notice prior to beginning the application, the proposed regulations allow CACs the flexibility to reduce the amount of notice from 72 hours to less than 24 hours, with prior approval. The costs associated with increased production costs for efficacious products and an increased use of pesticides to ensure pest management are not relevant to the 72-hour notice.

**Comment:** Based upon conversations with crop protection product researchers and private consultants, it is estimated that the cost of managing the proposed 72-hour regulation would add approximately 30 percent to the cost of an individual research trial. The additional cost includes

time for additional paperwork, travel time locating suitable trials, and other overhead expenses including meals and lodging should the researcher need to stay at the proposed site until the NOI hours are met. This would be common when a trial is in a remote location, making driving back and forth to the trial area unmanageable.

**Response:** There is no requirement to submit the 72-hour notice in person. As indicated in the comment, the additional costs associated with travel and per diem would occur when the trial is in a remote location, but not necessarily when the trial is local or if the notice can be submitted electronically. Regardless, DPR used WPHA's cost estimate of 30 percent to account for potential additional costs associated with 72-hour notice.

**Comment:** As a general measure of trial costs, there are 8 to 10 trials needed to develop adequate efficacy data to support a *California* registration. The average cost of a research trial is \$8,000 to \$10,000 depending upon the pest and the number of treatments in the trial. Average cost of an efficacy program for a single crop with all pest components is \$80,000 to \$100,000.

If trial costs are increased by 30 percent to cover added costs for 72 hour wait times, total cost of each trial will increase by \$2,400 to \$3,000. Adding 2-3 additional research trials at \$10,400 to \$13,000 (now 10-13 trials), increases the total cost to \$104,000 to \$169,000. This increase cost will ultimately be passed on to the grower.

**Response:** The proposed regulation does not impact the number of trials needed to develop adequate efficacy data. DPR's economic analysis accounts for WPHA's estimated 30 percent increase in cost for a portion of the research authorizations that would be subject to the 72-hour notice.

**Comment:** The analysis fails to address the addition of 2-3 research trials if the researcher misses the window of opportunity when the pest is in optimal state of development. This very realistic scenario can be verified by anyone involved in product research. The estimated 462 research trials provided in the ESS are based on a five-year average that does not account for an increase in trial numbers resulting from mis-timed applications that will require the trial to be re-run. This could double or triple the number of research trials being run over time. Even a 50 percent increase in the number of trials from 462 to 693 would push the figures provided in the total cost estimate from \$237,000 to \$355,500 per year.

**Response:** A 72-hour notice of application would not necessarily result in delayed applications. Whereas the current regulations require at least 24 hours' notice prior to beginning the application, the proposed regulations allow CACs the flexibility to reduce the amount of notice, with prior approval, to less than 72 hours, with no minimum amount of notice specified in the regulations. DPR's economic analysis accounts for a 30 percent increase in cost based on the estimates WPHA provided to DPR. If there are concerns that 72-hour notice may impede on conducting timely trials, the researcher is encouraged to communicate with the CAC.

**Comment:** DPR estimates the expected percent of research authorizations subject to the 72-hour notice to be 19 percent. The estimate fails to recognize that 72 hours will become the default unless the research manager, who may be responsible for multiple research trials throughout the

state during the year, requests that the time frame be reduced. While it is unlikely that 100 percent of the research trials going forward would be subject to the 72-hour notice, it is difficult to estimate what that percentage will be and 19 percent appears to be very arbitrary. According to the ESS, DPR's entire estimate is based on a survey DPR conducted in January 2015 of eight CACs who indicated whether they would request the 72-hour NOI or maintain the 24-hour NOI currently in place. Again, the regulation requires the researcher to submit the NOI 72-hours in advance. The discretion of the CAC does not come into play until the researcher requests a reduced time frame and can't be predicted in advance.

**Response:** DPR calculated the 19 percent estimate based on a representative survey of eight counties located throughout the state. The first five counties were selected because they historically fall within the top ten counties for the highest number of research authorizations closed out each year. The three other counties were selected to represent counties that historically fall within the middle range of research authorizations closed out each year. As already discussed with WPHA and CACs, researchers are encouraged to communicate in advance with the CACs of the counties in which they anticipate doing research if they feel that less than 72 hours' notice is appropriate for their trials.

**Comment:** It is arguable that the 19 percent estimate could be much higher. Taken into consideration, increasing the estimate from 19 to 50 percent would raise the current total cost of the 72-hour NOI from \$237,000 to \$623,000 per year. That's an increase of over \$10,000 per company per year versus the \$2,576 estimate by ESS. We have provided potential cost estimates in an attachment labeled Appendix A.

**Response:** DPR calculated the 19 percent estimate based on a survey of eight counties located throughout the state, including five counties that historically fall within the top ten counties for the highest number of research authorizations closed out each year. It is unclear the basis for how the 50 percent increase was derived.

**Comment:** ESS fails to recognize that companies set their research budgets months prior to the research being conducted. Decisions including how many trials will be run, where the trials will be run, and for which chemicals are based largely on cost estimates. Since the proposed regulation requires a 72-hour NOI, cost estimates will have to be based on the assumption that the 72-hour NOI will be required in every case.

Cost estimates resulting from the proposed regulation could dramatically shift which trials a company decides to run in California, resulting in delays in bringing new products or new uses to California growers and limiting product availability. CACs currently have the discretion to increase the 24-hour NOI in place. The negative result of reversing how that discretion is applied clearly outweighs any perceived value it may have.

**Response:** If companies have an indication of how many trials will be run and where the trials will be located in advance, they are encouraged to communicate with the CACs early in the process in order to establish an appropriate amount of notice. The 72-hour notice is a starting point to ensure that CACs have enough time to properly evaluate the site to ensure that human health and the environment are adequately protected.

**Comment:** DPR should retain the 24-hour NOI because the 72-hour NOI is unmanageable. However, we recommend that the research authorization application form be amended to allow the applicant to document the specific counties where the applications will be made. Once the research authorization is submitted to DPR and approved, DPR could forward the research authorization to the CAC as part of the process. This will allow the CAC advanced notice of research to be performed in their county, while allowing the researcher to conduct trials as needed. We believe this alternative will mitigate concerns by CACs with respect to advanced notice of research to be performed in their county, but will retain the researcher's ability to manage their research trials.

**Response:** The proposed application form asks the researcher for information about the county of use, if known. However, specifying the county on the application form does not take the place of submitting a time-specific notice of application which is intended to give CACs an opportunity to evaluate the local conditions closer to the time of the actual application.

**Comment:** We are concerned that the current policy to exclude new product uses from trade secret protections would infringe on the trade secret rights of many research projects. There are many types of research performed under approved authorizations that, if known to the applicant's competitors during the periods when research and development of the pesticide products are still underway in the field, could cause significant impacts on the ability to bring these new uses into the marketplace, at no advantage to either public health or the environment. These include but are not limited to the addition of a crop; the addition of a pest; new formulations; and new application methods. The estimated economic impact to business is deemed negligible in the ESS. This estimate however, takes only into account the administrative cost for submission of an additional form. It does not account for millions of dollars in research and development costs that could be compromised if a competitor's company obtains trade secret information.

**Response:** The proposed regulation protects the identity of products containing active ingredients that are not currently registered by U.S. EPA (or not currently registered by DPR in the case of spray adjuvants). However, for products containing active ingredients already registered at U.S. EPA, the current regulations already require researchers to provide DPR with the U.S. EPA registration number, method of application, type of site or commodity, and type of data sought. Therefore, disclosing this information is an existing requirement and does not need to be factored into the economic analysis. Also, see response below.

**Comment:** DPR should retain the long-held privacy of research authorization programs as they have in the past, recognizing the need for trade secret protection in the marketplace. This can be accomplished by maintaining the need for full disclosure to DPR staff while protecting confidential information from inappropriate public disclosure, consistent with applicable law, including the Public Records Act.

**Response:** If the research authorization is for a product containing an active ingredient currently in a registered product, it is already known that the active ingredient can be used as a pesticide. The identification of the inert ingredients and the percentage of inert and active ingredients (the

confidential statement of formula) of the research product are not disclosed and remain protected. Knowledge that the applicant is developing a new use or method of application using a known active ingredient has limited economic value to a competitor warranting treatment as a trade secret. If they were to learn through a Public Records Act request of the applicant's research, in order to register a competitive product similar to the applicant's research product, they would still have to engage in the process of developing a product containing the active ingredient, conduct and pay for their own research to submit to support the registration of their product, or wait for the applicant to register the new product, and pay the applicant a share of the cost incurred to conduct the research. The potential need for a new use or method to address a particular problem would be knowledge equally available to both.

- Comments received from *Anne Katten, California Rural Legal Assistance Foundation*.

**Comment:** We support the proposed requirement that the registrant must provide the identity of the pesticide active ingredient on the application form and are dismayed to learn that this is not already required. We do not think that the registrant should be allowed to keep the identity of the active ingredient off the application form because the public needs to know what pesticide active ingredients are being used under research authorizations in California, and once a pesticide is registered the active ingredients must be disclosed anyway. Also in order to do an adequate evaluation, DPR in fact needs to get information on all ingredients in the pesticide product.

**Response:** DPR agrees, however we also recognize the legal requirement to maintain certain information confidential as trade secret, therefore we are requiring researchers to provide all active ingredients to DPR while allowing them to leave that detail off the application form in certain circumstances as previously described.

**Comment:** We support the proposed requirement for the researcher to provide a notice of application to the CAC at least 72 hours before pesticide application under a research authorization, in place of the existing 24 hour notification but do not think that the CAC should be given the discretion to decrease the notification period.

**Response:** The notice of application is intended to provide CACs with enough time to evaluate local site conditions and assess the potential impacts of the application to ensure that the conditions and limitations of the research authorization are adequately met. If the CAC determines that less notice is adequate to evaluate the intended application, then DPR believes the CAC should have the discretion to decrease the notification period.

**Comment:** We support the requirement for submission of a map or aerial photograph designating the location and identity of all known areas that could be adversely impacted by use of the pesticide. However, this list should be expanded to also include individual residences, day care facilities, and work places and should specify minimum buffer or protection zone. We recommend a minimum protection zone of five miles for research authorizations, for pesticides that are not currently registered in California, and a minimum protection zone of at least one mile for trials of unregistered uses of currently registered pesticides.

**Response:** The proposed regulation requires the map or aerial photograph to designate the location and identify of all known areas that could be adversely impacted by the use of the pesticide. This includes, but is not limited to, residential areas (including labor camps), schools, and playgrounds. CACs may identify other potential sensitive sites near the application area. Based on the information provided during the application process, DPR can determine if additional restrictions should be imposed on the research to protect human health and the environment, including buffer zones, if necessary. We do not believe that a standard minimum buffer zone of one or five miles is necessary for all products used and would be overly restrictive and even more costly to researchers to find such locations in which they may conduct research.

**Comment:** The Initial Statement of Reasons states that in 2014, 89 percent of research authorization trials were conducted on plots of one acre or less. We think that all research authorization trials for pesticides not currently registered in California should be limited to plots of one acre or less.

**Response:** While current law limits such trials to 10 acres or less, and this restriction was not changed by the proposed regulation, this is something we could consider for future regulation changes. This comment addresses an issue outside the scope of the proposed regulation, which focuses on clarifying information required on the application and reporting forms, and revising the notification requirements.

**Comment:** We are very concerned to learn that 3 CCR section 6268 exempts pesticide registrants from the requirement to apply for research authorizations if the registrant is the operator of the property upon which the research is to be conducted and continues to be the operator until the crop is destroyed or harvested or if the trial is being conducted by university or college employees operating under an institution's policy for pesticide use and experimentation. We urge DPR to rescind these exemptions because harmful levels of exposure to employees and contamination of air and water and other forms of damage to health and the environment could result from these research trials.

**Response:** While these exemptions exist in current regulations and remain unaffected by this proposed regulation, this is something we could consider for future regulation changes. This comment addresses an issue outside the scope of the proposed regulation, which focuses on clarifying information required on the application and reporting forms, and revising the notification requirements.

**Comment:** The Initial Statement of Reasons states that DPR consulted with CACs, Western Plant Health Association, and the University of California in developing the regulation. At minimum, DPR should also have consulted with Office of Environmental Health Hazard Assessment (OEHHA) because research authorizations can impact worker exposures, and with the State Water Resources Control Board (SWRCB), Air Resources Board (ARB), and Department of Fish and Game because these research authorizations can impact water, air, and wildlife.

**Response:** Although consultation is not required under 3 CCR section 6252, DPR gave a presentation summarizing the proposed regulation to the Pesticide Registration and Evaluation

Committee (PREC) on July 17, 2015, while the comment period was still underway. OEHHA, SWRCB, ARB, and the Department of Fish and Wildlife all have members on PREC and were given the opportunity to comment on the proposed regulation.

#### MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS

DPR has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts requiring reimbursement by the State pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a "new program or higher level of service of an existing program" within the meaning of section 6 of Article XIII B of the California Constitution. DPR has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action.

#### ALTERNATIVES DETERMINATION

The Director has determined that no alternative considered by DPR would be more effective in carrying out the purpose for which this regulation is proposed, or would be as effective and less burdensome to affected private persons or businesses than the adopted regulations, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of the law.

#### POSTING REQUIREMENT

Title 3, California Code of Regulations, section 6110, states in part that, "The public report shall be posted on the official bulletin boards of the Department, and of each commissioner's office, and in each District office of the DPR [Division of Pest Management, Environmental Protection and Worker Safety] for 45 days." DPR has posted its Initial Statement of Reasons and Public Report on its official bulletin board, which consists of the Department's Internet Home Page <<http://www.cdpr.ca.gov>>. In addition, copies were provided to the offices listed above for posting.