

FINAL STATEMENT OF REASONS AND PUBLIC REPORT (REVISED)
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Amend Sections 6000, 6188, 6742, 6746, and 6793
Pertaining to Closed Mixing Systems

UPDATE OF THE INITIAL STATEMENT OF REASONS

The proposed regulatory action was noticed in the *California Regulatory Notice Register* on December 26, 2014. Two requests were made to extend the close of the comment period. A Notice of Extension of the Public Comment Period was issued on January 22, 2015 extending the comment period for an additional 16 days.

During the public comment period, the Department of Pesticide Regulation (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.

As authorized by Government Code section 11346.9(d), DPR incorporates by reference the Initial Statement of Reasons (ISR) prepared for this rulemaking. No changes were made to the proposed regulations nor are any changes necessary to the ISR following the public comment period. Nonsubstantive changes were made to section 6746 subsections (b) and (c) to improve grammar, and in (b), (e), and (h)(1) and (5) added "pesticide product" before the word "label" for clarification. Also, a nonsubstantive change has been made to section 6746(e). Subsection (e) makes reference to section 6738. Since the noticing of this regulation on December 26, 2014, DPR has adopted regulations pertaining to personal protective equipment (Office of Administrative Law File No. 2015-0305-04S). Those regulations, in part, renumbered numerous sections including section 6738. Therefore, the section referenced within 6746(e) should now be section 6738.4(c). The text was revised to align with the existing language in the California Code of Regulations (CCR).

DPR has amended 3 CCR sections 6000, 6188, 6742, 6746, and 6793. In summary, this regulatory action requires a tiered mitigation scheme to establish specific closed mixing system and PPE requirements based on a pesticide label's Human Hazards and Precautionary Statements, and amends data requirement language to be consistent with the proposed amendments to section 6746.

PUBLIC HEARING

No public hearing was scheduled or held.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING COMMENT PERIOD

Comments were received from the following: (1) Joel Nelsen, California Citrus Mutual; (2) Roger Isom, California Cotton Ginners and Growers Associations; (3) Kay Pricola, Imperial Valley Vegetable Growers Association; (4) Richard H. Collier, Agricultural Handler Exposure

Task Force, LLC; (5) Eddy Greynolds, Kern County Department of Agriculture and Measurement Standard; (6) Christopher Valadez, California Fresh Fruit Association; (7) Bob Blakely, California Citrus Mutual; (8) Nat DiBuduo, Allied Grape Growers; (9) Richard D. Gupton, Agricultural Retailers Association; (10) Anne Katten, California Rural Legal Assistance Foundation; (11) John Aguirre, California Association of Winegrape Growers; (12) Paul Wenger, California Farm Bureau Federation; (13) Rachel Kubiak, Western Plant Health Association; and (14) Laura L. Whatley, BASF

No.	Comment/Response	Commenter
1	Request extension of the public comment period. <i>DPR extended the public comment period for an additional 16 days beyond that required by regulation.</i>	1, 2
2	The proposed language creates confusion and will lead to interpretation rather a clear definitive requirement. Lack of a uniform label language for suppliers/manufacturers will lead to misinterpretation by user and regulators. In areas where, which is most of California agricultural, employees using the chemicals, may not have the strong enough English reading skills to decipher the labels without standard text to determine appropriate usage. <i>Employers are currently responsible for knowing safe use requirements in regulations and labeling, and communicating these to employees in a language they understand (3 CCR section 6702). Further, 3 CCR section 6724 currently requires that the employer shall assure that employees who handle pesticides have been trained, including the safety requirements and procedures for closed systems. While transition to the new regulation requires additional attention to these responsibilities, effectively implementing these regulations should not be problematic.</i>	3
3	We understand that the U.S. Environmental Protection Agency (U.S. EPA) is working on closed system requirements to apply to all states. We strongly encourage DPR to revise the proposed language to be more definite, and until, in conjunction with U.S. EPA, language for labels can be developed for use by the manufacturers. By doing so, the regulation will be stronger and have a greater impact on employee safety. <i>DPR understands that U.S. EPA may not go forward with their proposed changes to the closed system requirements after learning that DPR is modifying its closed system regulations.</i>	3
4	DPR should incorporate the latest advancements in risk assessment methodology into the revisions rather than relying on a hazard-based approach as proposed. <i>As stated in the ISR, the purpose of this regulation is to protect handlers from hazards occurring via skin absorption and to protect workers from exposure to corrosive pesticides. DPR agrees that risk assessment is useful</i>	4, 6, 7, 8, 9, 11, 12, 14

	<i>in determining the level of protection occurring during normal handling activities. DPR adjusts exposure estimates in a risk assessment when a closed system is required. Over the years DPR has evaluated pesticide illness data independent of the risk assessment process and determined that additional protective measures were necessary to address exposures. In addition, DPR has not completed risk assessments for all of the pesticides impacted by this rulemaking, and therefore has determined that a closed system requirement should be maintained.</i>	
5	DPR currently has available to it the exposure data from the Pesticide Handlers Exposure Database (PHED). The data development involves the monitoring of mixer/loader exposure during both open pouring and the use of engineering controls such as a range of closed loading systems and water soluble packaging. It would be a disservice to agricultural employers and employees not to incorporate these data into the closed loading decision-making process proposed for this regulation. <i>See response to comment no. 4.</i>	4, 6, 7, 8, 9, 11
6	With current risk assessment methodology, the toxicology data base contains much more sensitive potential endpoints including developmental, reproductive, and neurotoxicity endpoints as examples. The toxicity endpoints obtained from the comprehensive evaluation of the toxicology data are often orders of magnitude lower than the hazard triggers proposed by the revised regulation. A formulation that may not meet the triggers for a closed loading system based on only the acute dermal toxicity or skin irritation may indeed require some level of risk mitigation based on a risk assessment that involves the evaluation of the comprehensive toxicology data. Conversely, a formulation that meets the trigger for the closed loading system may not really need to mitigate exposure based on a comprehensive risk assessment. <i>See response to comment no. 4.</i>	4, 6, 7, 8,
7	While the proposed hazard-based approach would impose the closed loading system requirement on both operations, a risk assessment could reasonably determine that a closed loading system is only necessary for the aerial operation. This could be a source of confusion to growers in California because the label, based on U.S. EPA risk assessment, would specifically state that a closed loading system is required only when mixing and loading for aerial applications. <i>See responses to comment no. 2 and 4.</i>	4, 7, 8,
8	An exposure and risk assessment based on the PHED data could determine that a personal protective equipment (PPE) requirement as simple as water proof gauntlets to protect the forearms in addition to the existing requirement for protective gloves could be sufficient to mitigate risk at much less cost and complexity.	4, 7, 8, 9, 11

	<i>As noted in the ISR and from an Industrial Hygiene standpoint, the methods to control health hazards fall into three categories: engineering controls, administrative controls, and PPE. The preferred order of these controls is as listed. A key to this premise is that, practicable speaking, realization that "engineering controls should be the first line of defense whenever feasible." (Fundamentals of Industrial Hygiene Plog, B.A. – 1996 as cited in HS-1489. Also, see response to comment no. 4.</i>	
9	Use the proposed human hazard precautionary statements as a means of prioritizing a requirement for an exposure and risk assessment to be submitted to DPR specific to mixing and loading activities for products currently on the market or pending registration in California. Based on the risk assessment, the requirement for a closed loading system or other method of mitigation would be determined and appropriate handler requirement statements would be required on the formulation label. <i>See responses to comment no. 4 and 8.</i>	4, 7, 8
10	For products proposed for registration in the future with either the "fatal if absorbed through skin" or "may be fatal if absorbed through skin" human precautionary statement, a quantitative risk assessment based on accepted U.S. EPA and DPR policy would be required prior to DPR making a registration decision. Based on the risk assessment, the requirement for a closed loading system or other method of mitigation would be determined and appropriate handler requirement statements would be placed on the formulation label. <i>See responses to comment no. 4 and 8.</i>	4, 7, 8
11	For currently registered products with the "corrosive, cause skin damage " human precautionary statement, require the refinement of the acute skin irritation potential by utilizing analysis of the California PISP database or other incident reporting data that are sufficiently robust to determine whether dermal irritation based illness are not likely under actual use of the formulation during mixing and loading. <i>See response to comment no. 4.</i>	4, 7, 8
12	Rely on the proposed hazard-based approach only in circumstances where it is not possible to conduct the risk-based assessments. <i>See response to comment no. 4.</i>	4, 7, 8
13	Have there been incidents or illnesses that involved broken or leaking sight gauges that necessitate the change in section 6742(b)(5)? <i>There have been some incidents where sight gauges have broken-- especially with glass sight gauges. The protection of the sight gauge will be a performance-based measure with the shut-off valves as a secondary measure to limit spillage and exposure to people and the environment, and only applies to sight gauges that protrude from the tank wall. This</i>	5

	<i>standard was in the Director's criterion for closed systems and is being moved to a more appropriate code section.</i>	
14	<p>What constitutes "protected against breakage" in this proposed regulation? (Would a sight gauge consisting of clear plastic hose that is in good condition and not brittle be considered protected or would some type of guards need to be installed to protect all external sight gauges?)</p> <p><i>Clear plastic tube would be considered adequate in meeting this requirement. Also, metal guards around the sight gauge would also meet this requirement. The intent of this regulation package is to make these requirements performance-based and not prescriptive-based.</i></p>	5
15	<p>Have you reached out to pesticide equipment manufacturers (besides closed system suppliers) growers and pest control businesses about this specific proposed change? This change has little to do with closed system requirements. Industry is unaware of this part of DPR's overall proposal.</p> <p><i>As mentioned in the ISR, DPR discussed the proposal with representatives from groups that are directly affected including agricultural organizations, manufacturers, applicators, and growers. Based on the closed mixing system survey conducted by DPR in which the proposed regulations criterion was evaluated, some systems either did not have safety shut off valves or the sight gauge was not protected. In one instance, the sight gauge was not protected nor had safety shut off valves. DPR has determined it is necessary to require a secondary measure to limit spillage and exposure to handlers and the environment.</i></p>	5
16	<p>We are not aware of any basis in fact that engineering controls are superior or that they should be the first line of defense. PPE is an equally effective control.</p> <p><i>DPR disagrees with this assertion. As noted in the ISR and from an Industrial Hygiene standpoint, the methods to control health hazards fall into three categories: engineering controls, administrative controls, and PPE. The preferred order of these controls is as listed. A key to this premise is that, practicable speaking, realization that "engineering controls should be the first line of defense <u>whenever feasible.</u>" (Fundamentals of Industrial Hygiene Plog, B.A. – 1996 as cited in HS-1489.</i></p>	7
17	<p>PPE also reduces or eliminates the skin absorption exposure to pesticide handlers. Closed mixing system may not be the best control in every situation. We agree with objective to transition from prescriptive-based criteria to performance-based criteria. If performance is the measure and handler protection the goal, then the method of control need not be limited to a closed mixing system.</p> <p><i>See response to comment no. 16.</i></p>	7
18	DPR should revise the proposed regulation to include PPE that meets the	7

	<p>performance-based criteria to include provisions for PPE to be an approved alternative to closed systems.</p> <p><i>See response to comment no. 16.</i></p>	
19	<p>DPR may want to consider requiring both goggles and a face shield be worn when mixing or loading a material with the Health Hazard and Precautionary statements that would require an additional layer of protection.</p> <p><i>Protective eyewear is required to be worn when using a closed mixing system. However, because of the additional protection a closed mixing system provides, 3 CCR section 6738.4(c) allows for the reduction in PPE that would normally be required if using a closed mixing system. Requiring both goggles and a face shield is unnecessary and would not add to the safety of the pesticide handler.</i></p>	7
20	<p>The ISR appropriately states that engineering controls should be the first line of defense when feasible and that closed pesticide mixing systems are specifically designed to protect handlers from systemic hazards of skin absorption and mitigate skin and eye contact.</p> <p><i>DPR agrees.</i></p>	10
21	<p>Improved closed systems should be developed which allow rinsing without risk of injury. The design and operating system documents from University of California (UC), Davis in fact reference simpler rinsing systems developed by UC Davis and Cornell. In addition, it is unclear why these systems are appropriate for the highest toxicity pesticides if the rinsing process is poorly controlled. A more detailed accounting of pesticide illnesses resulting from closed system rinsing should have been provided with the ISR.</p> <p><i>The results of DPR's closed system field survey conducted in 2012-2013 showed that an acceptable device rinsing component was noted in 79 percent of the observations. For those devices capable of rinsing, users often complained container rinsing was difficult and/or time consuming. Many systems had complex design features which required the user to be familiar with the operation for opening and closing valves, most often without the assistance of written instructions or decals. Section 6684 requires the container to be rinsed and that engineering controls are still the preferred method (see response to comment no. 8) when dealing with the most toxic chemicals (Tier 1 pesticides). With the requirements of written operating instructions [section 6746(g)] and the requirement that operators be trained on the closed mixing systems according to the operating instruction [section 6746(d)], DPR believes that this should resolve rinsing issues that were seen in the past.</i></p>	10
22	<p>Object to the exclusion of adjuvants from the Tier 2 requirements.</p>	10

	<p>Manufacturers should be required to supply the adjuvant container opening adapter compatible with closed systems.</p> <p><i>Problems with the "Non-standardized container interfaces" and "Problems with container rinsing" identified in HS-1489, have long been recognized. On August 16, 2009, U.S. EPA's "Pesticide Container and Containment Regulations" became effective. As part of this rule certain "Container Design Standards" established the requirement that non-refillable "rigid" containers holding liquid agricultural pesticides must have one of four specified "standard closures" [ref. 40CFR 165.25(d)]. U.S. EPA does not register adjuvants. As such, adjuvants do not undergo the same rigorous registration review process at the Federal level which often results in inconsistent label precautionary language as contrasted to products that undergo U.S. EPA registration review. Furthermore, not all adjuvants are packaged in standardized containers nor is there such a requirement as there is for U.S. EPA-registered products.</i></p>	
23	<p>Agree it is better to include closed system performance and/or criteria in regulation. However, given the complexity of closed system design, the consequences of system failure and limited inspection oversight, we would prefer a combined performance and design criteria standard which references a list of commercial systems and design plans which meet DPR's approval.</p> <p><i>When county agricultural commissioners' staff conduct mix/load inspections, verification of compliance with closed mixing system requirements (if applicable) is always addressed. DPR maintains a listing of closed mixing systems that demonstrate compliance with the proposed regulation http://www.cdpr.ca.gov/docs/whs/ind_hygiene_eng_cont.htm. However, this listing is not an endorsement or recommendation by DPR.</i></p>	10
24	<p>The design criteria need to specify that hoses must have shut off devices or reverse action pumps at exit ends or disconnect points.</p> <p><i>Section 6742 addresses this concern. In part, this section requires shut-off devices to be installed on the exit end of all hoses carrying liquid pesticides in toxicity category one or two, or as an alternative, a reversing action pump or similar system may be used. DPR does not believe that additional language to the regulation is necessary.</i></p>	10
25	<p>The regulation should specify that chemical resistant gloves must be worn in addition to chemical protective eyewear when operating a closed system for protection in the event of malfunction or use errors.</p> <p><i>3 CCR section 6738.1(b) does require employees to wear chemical-resistant gloves as well as protective eyewear pursuant to section 6738.1(a). However, because of the additional protection a closed mixing system provides, 3 CCR section 6738.4(c) allows for the reduction in PPE that would normally be required if using a closed mixing system.</i></p>	10
26	<p>Slight revision is needed to make it clear that operating instructions are</p>	10

	<p>required for all closed systems in section 6746(g)(1): Any employee using a closed mixing system must have written operating instructions <u>and make them available to any employee using the system.</u></p> <p><i>DPR believes that the proposed regulation adequately addresses this issue.</i></p> <p><i>Under the proposed regulation:</i></p> <p><i>(g) <u>Written Operating Instructions and Maintenance Requirements.</u></i></p> <p><i>(1) Any employee using a closed mixing system must have written operating instructions.</i></p> <p><i>(3) The written operating instructions must be clearly legible <u>and available</u> with the closed mixing system and available for inspection by the Director or commissioner upon request.</i></p>	
27	<p>Some materials that have been safe to use without a closed mixing system will now be inadvertently required to utilize a closed mixing system without any real risk to the applicators mixers or loaders. Prior to developing a final rule, DPR should consider grandfathering existing products that have had their worker protection standards developed under the existing guidelines, to continue to be utilized under current guidelines. At the very least, significant time should be granted to give registrants the ability to conduct additional testing to meet the new standards.</p> <p><i>DPR does not agree that existing products should be grandfathered and continue to be used under the current guidelines. DPR is revising the regulation because there are no clear criteria for a closed mixing system design and pesticide illness data shows that the current regulation does not protect handlers adequately. Additionally, by basing the regulations on a hazard-based approach, DPR is able to provide pesticide handlers the most protection from potential exposures to pesticides.</i></p>	12
28	<p>Concerned that specific language provided as criteria and guidance in proposed sections 6188 and 6746 will lead to confusion amongst users and handlers. Federal regulations suggests companies use the language, "Corrosive, causes eye and skin damage [or skin irritation]," for toxicity category one human hazard irritation effects. According to the criteria for DPR's proposed regulation, a label that reads, "Corrosive, causes skin damage," would qualify that product for use through a closed system. While the difference between these two statements is minimal, some users may interpret them as having different meanings.</p> <p><i>DPR does not agree that there will be confusion between skin damage and skin irritation. See response to comment no. 29.</i></p> <p><i>Employers must train handlers in compliance with 3 CCR 6724(b)(1). The training shall cover format and meaning of information, such as precautionary statements about human health hazards, contained in pesticide product labeling.</i></p>	9, 13

29	<p>Many companies use the statement, "Corrosive, causes eye damage and skin irritation," as suggested by federal regulations. It is highly probable that users will interpret this statement and the statement, "Corrosive, causes skin damage," as not being equal. DPR's guidance language in the proposed regulation ties the irritation effect, "corrosion," to the skin damage. Our concern is that some user may assume that the corrosive nature of the product only applies to the eye, and that skin irritation is not synonymous with skin damage.</p> <p><i>With this regulation, it is DPR's intent to protect handlers against the dermal hazards associated with acute toxicity (label precautionary statement "Fatal if absorbed through skin" or "May be fatal if absorbed through skin") and corrosiveness to skin. In general, skin irritation is <u>not</u> synonymous with skin damage as the commenter suggests. Skin damage is a general term; whereas skin irritation is more specific. (Skin damage could mean skin burn, damage, injury.) U.S. EPA distinguishes degrees of "skin irritation" (the context in the Federal regulation cited used as a general term) as "Corrosive" (Toxicity Category I), "Severe irritation" (Toxicity Category II), "Moderate irritation" (Toxicity Category III) and "Mild or slight irritation" (Toxicity Category IV) (see Table 1). These regulations address Category I toxicants – corrosives – and not the non-corrosive toxicants in Categories II-IV. DPR believes the use of appropriate PPE mitigates non-corrosive skin irritation hazards.</i></p>	9, 13
30	<p>The problem is compounded when toxicity category two irritation effects are considered. The federal suggested language for such products is, "Causes eye [and skin] irritation," which reads very similar to the language of a category one product. WPHA recommends that DPR provide more clarity on this issue to ensure users and handlers can apply the criteria in the field.</p> <p><i>DPR disagrees. See response to comment nos. 2 and 29.</i></p>	9, 13
31	<p>If the proposed regulations are adopted as written, we recommend DPR regard these regulations as an intermediary step for continued discussion. Since this state-specific regulation is based on federal labeling requirements that cannot be altered by DPR, we recommend that DPR consider the inclusion of an appeal process. An appeal process would provide registrants and users the ability to work with DPR if they felt the closed system criteria and designation was not warranted.</p> <p><i>There is no statutory framework for an appeal process. In the future, any consideration to alter the requirement to use a closed mixing system will require regulation change.</i></p>	9, 13
32	<p>Certain documented circumstances may support the use of PPE as an alternative to the closed system requirement. Growers believe they can</p>	9, 13

	<p>demonstrate that effective PPE can be an alternative to a closed system. When properly used and once approved by DPR, operators should have the option of using the one best suited to their operation. As an example, when determining appropriate PPE, DPR may want to consider requiring both goggles and a face shield be worn when mixing or loading a material as an alternative to a closed system.</p> <p><i>See response to comments no. 4 and 19.</i></p>	
33	<p>The requirement for use of closed systems for minimal exposure pesticides was adopted to mitigate chronic and delayed toxicity and should be retained.</p> <p><i>DPR does not agree that the closed system minimal exposure requirements should be retained. In the ISR, it was stated that minimal exposure pesticide products currently registered are mitigated by label requirements and thus it is not necessary to repeat the requirements in regulation. Since section 6746(h)(1) would exempt pesticide products that have closed mixing system requirements on their label, it would be redundant to pesticide applicators by maintaining the minimal exposure pesticide closed system requirement in section 6793(d).</i></p>	10

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.

Some commenters suggest to incorporate the latest advancements in risk assessment methodology in to the revisions rather than relying on a hazard-based approach. The purpose of this regulation is to protect handlers from hazards occurring via skin absorption and to protect workers from exposure to corrosive pesticides. DPR agrees that risk assessment is useful in determining the level of protection occurring during normal handling activities. DPR adjusts exposure estimates in a risk assessment when a closed system is required. Over the years DPR has evaluated pesticide illness data independent of the risk assessment process and determined

that additional protective measures were necessary to address exposures. In addition, DPR has not completed risk assessments for all of the pesticides impacted by this rulemaking, and therefore has determined that a closed system requirement should be maintained.

POSTING REQUIREMENT

3 CCR 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.