# INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
# DEPARTMENT OF PESTICIDE REGULATION

Title3. California Code of Regulations
Amend Sections 6000, 6188, 6742, 6746, and 6793
Pertaining to Closed Mixing Systems

This is the Initial Statement of Reasons required by Government Code section 11346.2 and public report specifics in section 6110 of Title 3, California Code of Regulations (3 CCR). Section 6110 meets the requirements of Title 14 CCR section 15252 and Public Resources Code section 21080.58 pertaining to certified state regulatory programs under the California Environmental Quality Act.

## SUMMARY OF PROPOSED ACTION/PESTICIDE REGULATORY PROGRAM ACTIVITIES AFFECTED

The Department of Pesticide Regulation (DPR) proposes to amend 3 CCR sections 6000, 6188, 6742, 6746, and 6793. The pesticide regulatory program activities that would be affected by the proposal are those pertaining to pesticide enforcement and pesticide registration. In summary, the proposed action would require a tiered mitigation scheme to establish specific closed mixing system and personal protective equipment (PPE) requirements based on a pesticide label's Human Hazards and Precautionary Statements, and amend pesticide data requirements language to be consistent with the proposed amendments to 6746.

## SPECIFIC PURPOSE AND FACTUAL BASIS

DPR's mission is to protect public health and the environment from adverse effects of pesticide use. DPR's strict oversight includes: product evaluation and registration; statewide licensing of commercial and private pesticide applicators, pest control businesses, dealers, and advisers; environmental monitoring; and residue testing of fresh produce. This statutory scheme is set forth primarily in Food and Agricultural Code (FAC) Divisions 6 and 7. Also, the FAC requires that DPR adopt regulations that provide for safe working conditions for persons handling pesticides and working in and about pesticide-treated areas, including regulations on the subject of PPE and other protective devices such as closed mixing systems.

Pesticides must be registered (licensed for sale and use) with the U.S. Environmental Protection Agency (U.S. EPA) before they can be registered in California. DPR's preregistration evaluation is in addition to, and complements, U.S. EPA's. Before a pesticide can be sold or used, both agencies require data on a product's toxicology and chemistry--how it behaves in the environment; its effectiveness against targeted pests and the hazards it poses to nontarget organisms; its effects on fish and wildlife; and degree of worker exposure.

Methods to control health hazards fall into three categories: engineering controls, administrative controls, and PPE. Engineering controls should be the first line of defense whenever feasible. Closed mixing systems are considered an engineering control method and are required when using toxicity category one pesticides. Pesticides classified as a toxicity category one are

considered highly toxic by at least one route of exposure, and identified by the signal word "Danger" on their label.

A closed mixing system reduces the skin absorption exposure to pesticide handlers who are handling category one pesticides. Closed mixing systems include removal of material from the original pesticide container; rinsing and collection of the rinsate from the original container; moving the pesticide and its rinsate into appropriate mixing/holding tanks; and finally moving the pesticide and its rinsate into the application equipment. Ideally, all this is to be accomplished without any potential for worker exposure. The use of a closed mixing system allows for the reduction in PPE that would normally be required when handling pesticides.

Currently, section 6746 requires that during the production of an agricultural commodity, employers must provide closed mixing systems for employees who mix or load liquid pesticides in toxicity category one, or load diluted liquid mixes derived from dry pesticides in toxicity category one. The primary impetus for the closed mixing system requirement was to protect handlers from systemic hazards via skin absorption. A secondary incentive was to protect workers from exposures to corrosive pesticides which potentially can cause severe eye or skin damage. Fortunately, the number of category one pesticide products with these toxicological properties has vastly decreased. However, for those remaining products, closed systems are specifically designed to mitigate skin and eye contact.

The closed mixing system design and construction is required to meet prescriptive criteria established by the Director. However, current regulation does not provide employers with clear criteria for a closed mixing system design. For clarity purposes and under changing circumstances, the current Director's prescriptive-based criteria will be converted to performance-based criteria for closed mixing system design.

Additionally, to systematically group pesticides by worker hazard(s) that can be mitigated through engineering controls such as closed system mixing and loading, DPR believes that the "Human Hazard and Precautionary Statements" on the label are a more precise indicator of potential hazard than the "danger" signal word on the label. Therefore, employee-handler protection would be based upon a "tiered" approach when the Human Hazard and Precautionary Statements indicate a specific dermal toxicity hazard such as "fatal if absorbed through skin." The proposed regulation change will establish "Tier 1" and "Tier 2" closed mixing systems based on the precautionary statements on the label.

For these reasons, DPR proposes amending section 6746 by requiring a tiered mitigation scheme to establish specific closed mixing system and PPE requirements based on the Human Hazard and Precautionary Statements specified on the label. DPR proposes to remove the definition of "closed system" in section 6000, and amend sections 6742 and 6746 for clarity.

In developing the proposed regulations, DPR discussed the proposal with representatives from groups that will be directly affected including agricultural organizations, manufacturers, applicators, and growers, as well as at DPR’s Pesticide Registration and Evaluation Committee and the Agricultural Pest Control Advisory Committee and Pest Management Advisory Committee meetings.

The proposed regulation changes are described below:

Section 6000. Definitions

DPR proposes to delete the definition of "closed system" in section 6000. The definition was part of a prescriptive process that DPR originally took when first developing the regulation. Proposed section 6746 provides a description of a closed mixing system and its capabilities. The proposed regulation would establish a performance-based standard instead of a prescriptive based standard for closed mixing systems, and therefore this definition is no longer necessary.

Section 6188. Closed System Compatibility.

DPR proposes to amend section 6188 to be consistent with the Health Hazard and Precautionary statements proposed in section 6746 and to clarify that the section only applies to those pesticide products that will be used in the production of an agricultural commodity. The change from agricultural use to production of an agricultural commodity is to make the regulation consistent with 6746. Also, in proposed subsection (a) amend an incorrect reference of section 6744 to 6746, and in subsection (b), amend the reference to section 6000 to 6746 since the definition of "closed system" is proposed to be deleted.

Section 6742. Safe Equipment.

Proposed subsection 6742(b)(5) would require that all external sight gauges be equipped with valves so the pipes or tubes connected to the sight gauge can be shut off. The protection of the external 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.

Additionally, grammatical changes being made to subsections (b)(1)-(4).

Section 6746. Closed Mixing System

DPR proposes to amend 6746 to adopt a two-tiered hazard mitigation approach based upon the Human Hazard and Precautionary Statements on the registered pesticide label instead of the signal word. The proposal defines closed mixing systems using a "performance-based" standard instead of a static prescriptive standard.

Proposed subsection (a) would continue to require employee-handlers to use a closed mixing system for products labeled for agricultural production use and require the employer to provide the appropriate closed mixing system. This is a reworded version of the original regulation text to clarify the employer’s responsibility to supply a closed mixing system.

Proposed subsection (b) introduces the Tier 1 closed mixing system. It would require employees who handle pesticides, including spray adjuvants, with a dermal hazard statement of "Fatal if absorbed through skin" or comparable language to use a Tier 1 closed mixing system.

As mentioned above, use of Human Hazard and Precautionary Statements is a more appropriate hazard indicator than the current signal word. This proposed section specifies what capabilities would be required for Tier 1 closed mixing systems. The closed mixing system must be capable of enclosing the pesticide while removing the contents from its original container, and each emptied container must be rinsed and drained while still attached to the closed mixing system. This will prevent the pesticide from contacting handlers.

The proposed subsection (c) introduces Tier 2 closed mixing system. It would require employees who handle pesticides, excluding spray adjuvants, with a dermal hazard statement of "May be fatal if absorbed through skin" or, "Corrosive, causes skin damage", or other comparable language to use a Tier 2 closed mixing system. It would require the mixing system to prevent a pesticide from contacting handlers; however, it would not require the container to be rinsed while still attached to the system. This a performance-based standard that was added to allow industry another option of a closed mixing system that does not require the container be rinsed while still attached to the closed mixing system. Pesticide illness data indicate that more people are harmed by the rinsing requirement on closed mixing systems so this section allows a simplified closed mixing system to be used for those pesticides that pose a reduced risk if dermal exposure occurs. Spray adjuvants with these dermal hazard statements are excluded because adjuvant containers are smaller (one gallon, pints, etc.) and therefore do not have the standard pesticide container openings. Attaching these containers to the closed mixing system would require that growers have access to a wide variety of container opening adapters which would be burdensome on growers.

3 CCR section 6724 requires an employer to assure that employees are trained before being allowed to handle any pesticides. The training covers areas such as understanding and recognizing the information on the pesticide label that relates to human health hazards, medical supervision, employee rights, and safety requirements and procedures including engineering controls such as closed systems. Proposed subsection (d) would require the employer to train the employee in the proper use of the closed mixing system pursuant to section 6724, as well as how to operate the closed mixing system in accordance with its written operating instructions. This strengthens the training requirements specific to closed mixing system use.

DPR's current PPE regulatory requirements (3 CCR section 6738) are designed to reduce the risk of pesticide poisonings and injuries among pesticide handlers and other agricultural workers exposed to pesticides. DPR proposes in subsection 6746(e) to identify the sources of PPE requirements – the pesticide product labeling, restricted material permit conditions or regulation – and to specify that the PPE must be at the worksite and in proper condition to provide protection to the employee. It will also require that protective eyewear be worn while using a closed mixing system. This is consistent with section 6738 where specific PPE requirements are found. This proposed subsection was added to ensure that in the event of a system failure the proper PPE is immediately available on site to protect the employee. The eyewear requirement was also added because the closed mixing system is always under pressure and the eyewear will provide a safeguard against eye damage should a system failure occur.

Proposed subsection (f) specifies the design and proper construction criteria for a closed system and Tier 1 rinsing requirement. This is a performance-based standard to ensure that the closed

mixing system is capable of handling the material that is being used. Some materials can be acidic or corrosive and this standard is being put in place to make sure that the system will not deteriorate or fail while used.

Proposed subsection (g) requires that closed mixing systems have written operating instructions that include restrictions, limitations, and incompatibilities. The instructions must be legible and available with the system. This proposed subsection also requires the system be cleaned and maintained as specified by the operating instructions. Commercially produced systems currently provide instructions; this proposed subsection would also require growers who design and build their own systems to have those operating instructions available for their employees who are operating these systems.

Proposed subsection (h) would exempt the following from the requirements of section 6746:

(1) Mixing pesticides using a method or mixing device required by the label. The label must be followed if there is a direct conflict between the label and a regulation. This proposed exemption would ensure that the regulation would not create any conflict with the product labeling.

(2) Opening of a container by removal of the manufacturer's original sealing device without removing any of the contents before re-closing it with a liquid-tight sealing device. This proposed exemption would clarify that removal of the aluminum seal on a pesticide container is allowed before attaching it to the closed mixing system.

(3) Regulatory personnel collecting samples of pesticides. Due to the small size of the sample taken for verification and the likelihood of sample contamination of the pesticide, the use of closed mixing system is not feasible. This proposed exemption is currently located in sections 6746(b)(1) and 6793(d)(1) and revised for clarification.

(4) The rinsing of refillable pesticide containers that are required to be returned to a pesticide dealer, pesticide registrant, or manufacturer. This proposed exemption is intended to ensure that the refillable pesticide container is not contaminated.

(5) An employee required to use a Tier 2 closed mixing system if the employee handles a daily maximum of one gallon or less. Currently section 6746(b)(2) exempts employees from the requirement to use a closed system for category one pesticides if they handle a total of one gallon or less per day. The proposed regulation would no longer allow Tier 1 pesticides to be exempt from the closed mixing system requirement since these pesticides are highly toxic. Instead the proposed exemption would only apply to Tier 2 pesticides which have lower health risks than do Tier 1 pesticides. Additionally, the exemption would continue to allow applicators to have access to small amounts of Tier 2 pesticides without the burden of setting up a closed mixing system. Nonetheless, if a closed system is not used as provided by this proposed exemption, appropriate PPE must be worn. This is consistent with section 6738.

Section 6793. Minimal Exposure Pesticide Safety Use Requirements.

Minimal exposure pesticides listed in 3 CCR section 6790 are pesticides subject to minimal exposure pesticide safety use requirements pursuant to section 6793. Section 6793 was adopted in 1990, before many product labels required any substantial PPE or engineering controls measures. Since then, label requirements for products currently registered specify the use of a closed mixing system (for liquid formulations, sometimes under specific use situations and water-soluble packaging for dry formulations) as well as several other worker safety use requirements. Therefore, DPR proposes to delete subsection (d) since the label requirements mitigate the need for this subsection. The exceptions to proposed subsection 6793 (d)(1) and (2) have been relocated to 6746 subsection (h)(3) and (5).

Propose to reorder current subsections (e), (f), and (g) to (d), (e), and (f), respectively.

## COLLABORATION WITH OEHHA PURSUANT TO FAC SECTIONS 12980 AND 12981

DPR and OEHHA jointly and mutually developed the proposed regulation as specified in FAC sections 12980 and 12981, utilizing OEHHA's health-based recommendations as a factor in setting DPR's regulatory target level related to pesticides and worker safety. DPR and OEHHA have set forth the rulemaking process used to meet these statutory requirements in a Memorandum of Agreement dated August 13, 2008.

## CONSULATATION WITH OTHER AGENCIES

DPR consulted with the California Department of Food and Agriculture during the development of the text of proposed regulations, as specified in FAC section 11454, and the August 20, 2013, Memorandum of Understanding that was developed per FAC section 11454.2.

DPR consulted with the University of California and the Department of Industrial Relations.

DPR has also consulted with the California Agricultural Commissioners and Sealers Association at a Pesticide Regulatory Affairs Committee meeting.

## ALTERNATIVES TO THE PROPOSED REGULATORY ACTION [GOVERNMENT CODE SECTION 11346.2(b)(5)]

DPR has not identified any feasible alternatives to the proposed regulatory action that would lessen any adverse impacts, including any impacts on small businesses, and invites the submission of suggested alternatives.

ECONOMIC IMPACT ON BUSINESS PURSUANT TO [GOVERNMENT CODE SECTION 11346.2(b)(5)(A)]

The proposed regulations will not have a significant economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The document relied upon to make this determination is listed in the "Documents Relied Upon" section of this initial statement of reasons and is available from DPR.

ECONOMIC IMPACT ASSESSMENT PURSUANT TO SECTION 11346.3(b)

Creation or Elimination of Jobs within the State of California: It is unlikely that the proposed action would create or eliminate jobs within the State of California because closed mixing systems are currently required when using certain pesticides. However, manufacturers of closed systems could design newer models under the performance-based criteria, but any model re-design could likely be handled by existing staff.

Creation of New Business or the Elimination of Existing Businesses within the State of California: Although new businesses developing new closed mixing systems could be created, it is unlikely that the proposed regulatory action will impact the creation or elimination of existing businesses within the State of California.

The Expansion of Businesses Currently Doing Business within the State of California: There is the potential for existing businesses to develop new closed mixing systems in addition to current inventory but it is unlikely that the proposed regulatory action will impact the expansion of businesses currently doing business within the State of California.

The Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: Implementation of the regulation would benefit persons who handle pesticides with specific Human Hazards and Precautionary Statements on the label--primarily employees of agricultural businesses and farms--and would protect them from potential exposures to pesticides.

IDENTIFICATION OF ANY SIGNIFICANT ADVERSE ENVIRONMENTAL EFFECT THAT CAN REASONABLY BE EXPECTED TO OCCUR FROM IMPLEMENTING THE PROPOSAL

DPR’s review of the proposed action showed that no significant adverse environmental effect to California’s air, soil, water, plants, fish, or wildlife could reasonably be expected to occur from implementing the proposal. Therefore, no alternatives or mitigation measures are proposed to lesson any significant adverse effects on the environment.

EFFORTS TO AVOID UNNECESSARY DUPLICATION WITH FEDERAL REGULATIONS

The proposed action does not duplicate or conflict with the Code of Federal Regulations.

DOCUMENTS RELIED UPON

1. Fong, Harvard R., CIH, Senior Industrial Hygienist, Worker Health and Safety Branch, DPR. An Overview of Closed System Use in California 2001-2002, HS-1849, June 2003.

2. Giles, Ken, and Billing, Ryan. University of California, Davis. Design and Improvements in Closed Systems. February 25, 2013; Operating Instructions for User-Built Closed System Handling System for Agricultural Pesticides (April 2013).

3. Agricultural Pest Control Advisory Committee Minutes, August 13, 2013.

4. County Agricultural Commissioner and Sealers Association's Pesticide Regulatory Affairs Committee, Minutes, October 8, 2013.

5. Pesticide Registration and Evaluation Committee Minutes, November 15, 2013 and August 15, 2014.

6. Economic Analysis of Proposed Closed Mixing Systems. California Environmental Protection Agency, Agencywide Economic Studies Section, Air Resources Board. Memorandum from Stephen Storelli to Linda Irokawa-Otani, Regulations Coordinator, DPR. May 29, 2014.