INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Adopt Section 6247
Spray Adjuvant Ingredient Statement Requirements

This is the Initial Statement of Reasons required by Government Code section 11346.2 and the public report specified in section 6110 of Title 3, California Code of Regulations (3 CCR). Section 6110 meets the requirement of Title 14, CCR section 15252 and Public Resources Code section 21080.5 pertaining to state regulatory programs certified under the California Environmental Quality Act.

SUMMARY OF PROPOSED ACTION/PESTICIDE REGULATORY PROGRAM ACTIVITIES AFFECTED

The Department of Pesticide Regulation (DPR) proposes to adopt 3 CCR section 6247. The pesticide regulatory program activities that will be affected by this proposal are those pertaining to the registration of spray adjuvant products. The proposed action will establish and standardize ingredient statement requirements, including principal functioning agent identification and nomenclature requirements, on spray adjuvant product labels. The proposed regulations will only apply to spray adjuvant products submitted for registration or an amendment on or after the effective date of this proposed action. Labels of currently registered spray adjuvant products will have to comply with the proposed regulations if and when an application for a label amendment is submitted.

SPECIFIC PURPOSE AND FACTUAL BASIS

Background

DPR protects human health and the environment by regulating pesticide sales and use and by fostering reduced-risk pest management. 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.

With certain exceptions, 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 evaluation. Before a pesticide can be sold or used in California, 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 effect on fish and wildlife; and its degree of worker and bystander exposure.

The purpose of the registration process is to determine whether the pesticide product can be used safely and effectively in accordance with its label directions. The pesticide product label and scientific data must be reviewed and found acceptable before the product can be registered. Pesticide product labels provide critical information about the product, and must include certain information, including an ingredient statement that identifies the name and percentage by weight of each active ingredient and the percentage by weight of other inert ingredients. Labeling requirements are generally set forth in Title 40, Code of Federal Regulations (40 CFR) section 156.10.

A "spray adjuvant" is any wetting agent, spreading agent, deposit builder, adhesive, emulsifying agent, deflocculating agent, water modifier, or similar agent, with or without toxic properties of its own, which is intended to be used with another pesticide as an aid to the application or effect of the other pesticide, and sold in a package that is separate from that of the pesticide other than a spray adjuvant with which it is to be used (FAC section 12758). Under California law, spray adjuvants are considered pesticides (FAC section 12753(a)). Therefore, DPR requires the registration of spray adjuvants, which are not considered pesticides under federal law. Because spray adjuvants are not considered pesticides under federal law, they are not covered under the labeling requirements in 40 CFR section 156.10.

Additionally, several other states also regulate spray adjuvants as pesticides and have established labeling requirements. For example, the State of Washington regulates and has a comprehensive set of requirements for spray adjuvants. Under their regulations, spray adjuvant ingredient statements are required to include the individual or total percentage of functioning agents, the percentage of "constituents ineffective as spray adjuvants," and the total percentage of all ingredients (Washington Administrative Code 16-228-1400).

California statute currently has limited requirements for spray adjuvant labeling. FAC section 12883(b) states that "a pesticide that is sold only as a spray adjuvant is not misbranded if the total percentage of the constituents ineffective as a spray adjuvant is stated on the label without mention of the terms 'active ingredient' or 'inert ingredient'." FAC section 12885 states that while the label must state the type or function and the names of the principal functioning agents, in cases where more than three functioning agents are present, only the three principal ones need be named. In addition, 3 CCR sections 6235–6243 establishes limited requirements for items that must be identified on product labeling in California. However, these sections do not address spray adjuvant nomenclature on the label ingredient statement.

Although Food and Agricultural Code contains some requirements for spray adjuvant labeling, existing statutory language lacks specificity in regard to principal functioning agent nomenclature and label ingredient statements for spray adjuvant products. These regulations are being promulgated to address this lack of specificity and provide clarity to regulated industries and the public. Additionally, DPR has the authority (FAC sections 11501 and 12824) to require

additional label language if it is determined that the omission of such label statements would pose a hazard to humans or the environment. The proposed regulations will allow many principal functioning agents to be designated by their chemical class, which provides a way to group chemicals with similar properties into distinct classes that are more meaningful and easily identifiable to end-users. However, in some instances, chemical class is not adequate to describe the properties or hazards of certain principal functioning agents. Principal functioning agents that fall under the same chemical class may have completely different physicochemical and toxicological properties, with some being more corrosive or hazardous than other substances within the same class. In these situations, it is necessary for these potentially hazardous substances to be identified by their precise chemical or common name. The language set forth in this proposal is intended to outline nomenclature requirements that will better inform the general public of potential hazards from principal functioning agents within spray adjuvants.

Furthermore, because the federal government does not register spray adjuvants, 40 CFR section 156.10 does not contain labeling requirements specific to spray adjuvant ingredient statements, including requirements for principal functioning agent nomenclature. Because California requires registration of stand-alone spray adjuvant products, spray adjuvant labeling requirements are necessary to establish clear ingredient statement requirements for principal functioning agents separate from active and inert ingredients covered by federal regulations. In addition, labeling requirements for spray adjuvants, which are considered pesticides under California law, will ensure some consistency among ingredient statements of all pesticides and with spray adjuvant labeling requirements in other states.

Proposed Regulations

- Article 11

DPR proposes to adopt "Spray Adjuvant Labeling" as the title of Article 11 to better reflect the content of proposed section 6247, the sole section within the article.

- Section 6247

The title of section 6247, "Spray Adjuvant Ingredient Statement," is being adopted to align with the proposed changes throughout section 6247.

- Section 6247(a)

DPR proposes to adopt section 6247, adopting new subsection (a) to establish ingredient statement requirements for spray adjuvant product labeling. As spray adjuvants are not registered by U.S. EPA, they are exempt from federal labeling requirements in 40 CFR section 156.10. There are also limited requirements for spray adjuvants in FAC Divisions 6 and 7. These regulations are necessary to outline spray adjuvant-specific ingredient statement requirements that provide clarity to spray adjuvant registrants as well as end-users.

DPR's proposed regulations establish requirements for spray adjuvant product ingredient statements. In order to streamline implementation, the proposed regulations will apply only to those products submitted for registration or an amendment on or after the effective date of this proposed action. DPR further proposes specific ingredient statement requirements in subsections (a)(1) through (a)(4).

Subsection (a)(1) establishes that the ingredient statement must include the name of each principal functioning agent, as specified in new proposed subsection (b). This is necessary to align with FAC section 12883, which requires the name of each active ingredient (or principal functioning agent). Additionally, as mentioned above, FAC section 12885 currently requires only the three 'principal' functioning agents to be named on the label. However, the term "principal" is not properly defined and would allow registrant's sole discretion in the functioning agents that are disclosed on the label. The proposed regulation reiterates existing statutory allowances in FAC section 12885 and specifies that only the three most abundant by weight are considered principal and must be named on the label. Abundance by weight is an objective measure of determining principality and provides clarity to registrants of spray adjuvant products about what is considered principal for purposes of listing functioning agents on the label. Listing the most abundant *by weight* will ensure consistency with how functioning agents are being measured and reported on pesticide labels. Additionally, this is consistent with the current common practice for registrants to include the three functioning agents that are most abundant by weight on spray adjuvant labels.

Subsection (a)(2) establishes that each ingredient statement must include the percentage by weight of each principal functioning agent or the total percentage by weight of all functioning agents. This is necessary to align with the options presented in FAC section 12883. FAC section 12883(a) states that a pesticide is misbranded when the pesticide label fails to state the name and percentage of each active ingredient (or principal functioning agent) together with the total percentage of the inert ingredients. Alternatively, FAC section 12883(b) states that a pesticide is misbranded when the label fails to state the name of each active ingredient (or principal functioning agent) along with the name of each and total percentage of the inert ingredients. DPR proposes to require either individual listing of principal functioning agent percentages consistent with FAC section 12883(a) or the total percentage by weight of all functioning agents to be stated on the label. Although FAC section 12883(b) does not require listing the total percentage of active ingredients (or principal functioning agents), this information can be easily derived from the total percentage of inert ingredients (or constituents ineffective as a spray adjuvant), thus, the proposed option to list the total ensures this information is easily available to end-users. Like California, the State of Washington regulates and has a comprehensive set of requirements for spray adjuvants. Under their regulations, the individual or total percentage of functioning agents must be stated on the label (Washington Administrative Code 16-228-1400). DPR is proposing these same labeling requirements for spray adjuvants. Additionally, requiring the percentage by weight of each principal functioning agent is necessary for consistency with labeling requirements for conventional pesticides in 40 CFR section 156.10(g)(3), which requires percentage by weight to be included in the ingredient statement. Since spray adjuvants are

considered pesticides under California law, having consistency in labeling requirements with conventional pesticides is appropriate.

Subsection (a)(3) establishes that the ingredient statement must include the total percentage by weight of inert ingredients or constituents ineffective as a spray adjuvant. This is necessary to align with FAC section 12883, which requires the percentage of inert ingredients to be stated on the label and allows use of the term "constituents ineffective as a spray adjuvant" in lieu of "inert ingredient." Additionally, it is necessary to specify that the percentage by weight be stated on the label for the same reasons provided above regarding the similar proposed provision requiring total percentage in subsection (a)(2).

Subsection (a)(4) establishes that the ingredient statement must include the total percentage by weight of all ingredients and specifies that the total must equal 100%. As spray adjuvants are considered pesticides under California law, this is necessary to ensure consistency among ingredient statements of all pesticides by aligning with 40 CFR section 156.10(g)(3). Additionally, this is consistent with Washington's spray adjuvant ingredient statement regulations and is already currently common practice for registrants to include this information on spray adjuvant labels. This is also necessary for consistency with what is required on page 5 of the Application for Pesticide Registration DPR-REG-030 (Rev. 10/21), a form incorporated by reference in section 6170.

- Section 6247(b)

New proposed subsection (b) further requires principal functioning agents to be identified by either chemical or substance name, common name, or chemical class, with specific exceptions outlined in proposed subsections (b)(1) and (b)(2). Requiring a principal functioning agent to be identified by its chemical or substance name, or common name is consistent with labeling requirements for active ingredients in conventional pesticides as outlined in 40 CFR section 156.10(g)(3). Since spray adjuvants are considered pesticides under California law, this is necessary to ensure consistency with conventional pesticide labels. In contrast to the federal requirements, in which the chemical or common name is required, the proposed regulation will allow the use of chemical class to identify principal functioning agents. Chemical class generally provides basic physicochemical and toxicological properties of principal functioning agents; providing the chemical or common name would not supply additional information to end-users on the properties and safety of a product. Many principal functioning agents used in spray adjuvant formulations are polymers or mixtures that lack common names that would be more easily identifiable to the general public. Such chemicals often have long and complex chemical names that do not provide readily identifiable information regarding chemical structure and general physicochemical properties. The use of chemical class is necessary as it provides a way to group chemicals with similar properties into distinct classes that are more meaningful to end-users. In cases where chemical class is inadequate in distinguishing properties among members of a class, the proposed regulation requires the use of the chemical or common name to better protect the public and the environment. DPR also proposes to list examples of acceptable chemical classes to further clarify what is permitted in the ingredient statement.

Chemical class is not always adequate to describe the properties or hazards of certain principal functioning agents. Subsection (b)(1) lists the types of principal functioning agents that must be identified by chemical or common name on the spray adjuvant label. Such agents include acids (proposed subsection (b)(1)(A)) and bases (proposed subsection (b)(1)(B)). Using a chemical class to identify an acid or base is deemed too generic and could be misleading to workers or pesticide applicators using spray adjuvants. Different acids and bases that fall under the same chemical class may have completely different physicochemical and toxicological properties. For example, phosphoric acid and sulfuric acid are both mineral acids but differ considerably in their strength. Phosphoric acid is a weak acid used in many soft drinks to impart acidity, while sulfuric acid is a very strong acid that is extremely corrosive, even in more dilute solutions. Likewise, sodium hydroxide and magnesium hydroxide are both inorganic hydroxides and strong bases. However, magnesium hydroxide is safely used in antacids because of its low solubility in water, while sodium hydroxide is very water soluble and extremely corrosive. For these reasons, it is necessary for these potentially hazardous substances to be identified by their precise chemical or common name. DPR also proposes to list examples of acids and bases to further clarify what is permitted in the ingredient statement.

In subsection (b)(1)(C), DPR proposes to establish that ingredients not allowed for use on food or feed crops must be identified by their chemical or common name, and not by chemical class. A chemical class can contain principal functioning agents that are both allowed and not allowed for food or feed use. This could result in inadvertent contamination of a food or feed crop, so it is critical for end-users of spray adjuvant products containing these ingredients to be able to distinguish a principal functioning agent that is not allowed for food-use from other members of the same chemical class that have food-use allowances. Therefore, requiring these principal functioning agents to be identified by chemical or common name by providing the specific name of the agent is necessary to prevent confusion, improper use, and to protect food and feed from contamination.

DPR proposes to establish that food commodity allergens (proposed subsection (b)(1)(D)) must be identified by their chemical or common name, and not by chemical class. Since food allergens represent a public health danger to sensitive groups, it is necessary for these allergens to be fully identified and recognizable to the general public. Proposed subsection (b)(1)(D)(i) specifies that food allergens include milk, eggs, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. Subsection (b)(1)(D)(ii) further specifies that food allergens include food ingredients that contain proteins derived from a food specified in (b)(1)(D)(i), except for any highly refined oils derived from a food specified in (b)(1)(D)(i) and any ingredient derived from such highly refined oil. The listed food commodity allergens are consistent with the United States Food and Drug Association, Section 203 of the Food Allergen Labeling and Consumer Protection Act of 2004 (21 U.S.C. section 203(qq)).

Lastly, ammonium sulfate (proposed subsection (b)(2)) must be identified as ammonium sulfate and not by its chemical class or other chemical or common name. Identifying ammonium sulfate

as anything other than ammonium sulfate on the spray adjuvant label will make it more difficult for pesticide applicators to determine if they are complying with pesticide label directions regarding ammonium sulfate. Many conventional pesticide products, including some glyphosate herbicides, suggest tank mixing with spray adjuvants containing ammonium sulfate to tie up calcium and magnesium ions in hard water. This requirement is necessary to ensure pesticide applicators can easily determine whether the spray adjuvant contains ammonium sulfate so they can follow the mixing instructions regarding ammonium sulfate on the conventional pesticide product label.

CONSULTATION WITH OTHER AGENCIES

Establishing spray adjuvant principal functioning agent labeling requirements was an agenda item discussed at the July 16, 2021 meeting of the Pesticide Registration and Evaluation Committee (PREC). This committee includes representatives from public agencies who have jurisdiction over activities or resources that may be affected by the use of pesticides. A copy of the PREC minutes is contained in the rulemaking file.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION [GOVERNMENT CODE SECTION 11346.2(b)(4)]

DPR has not identified any feasible alternatives to the proposed regulatory action that would achieve the purpose of the regulation with less possible adverse economic impacts, including any impacts on small businesses. DPR invites the submission of suggested alternatives.

ECONOMIC IMPACT ON BUSINESSES [GOVERNMENT CODE SECTION 11346.2(b)(5)(A)]

This regulatory action will not have a significant adverse economic impact on businesses. The proposed regulations clarify nomenclature requirements for spray adjuvant principal functioning agents listed on the label and do not impose additional data requirements. The proposed regulations will only apply to labels of spray adjuvant products submitted for registration or an amendment on or after the effective date of this proposed action. Multiple states regulate spray adjuvants as pesticides, with California and Washington having the most comprehensive spray adjuvant labeling requirements. The proposed regulations are consistent with existing Washington regulations (Washington Administrative Code 16-228-1400) and will not create an additional economic burden.

The document relied upon to make this determination is the “Economic and Fiscal Impacts of Proposed Spray Adjuvant Ingredient Statement Requirements Regulations.” This document 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)

The proposed action would not create or eliminate jobs in California; result in the creation of new businesses or the elimination of existing businesses within the State of California; or result in an expansion of businesses currently doing business with the State of California. This action is consistent with current law and will not significantly restrict or increase the use of spray adjuvant products in California. The proposed action will specify ingredient statement requirements, including nomenclature that must be used to identify principal functioning agents on new and amended spray adjuvant labels.

This proposal benefits the health and welfare of California residents, worker safety, and the State's environment by defining consistent and meaningful methods of identifying principal functioning agents on spray adjuvant product labels. Many principal functioning agents used in spray adjuvant formulations are polymers or mixtures that lack common names that would be more easily identifiable to the general public. Such chemicals often have long and complex chemical names that can be confusing to interpret chemical structure and general physicochemical properties. The use of chemical class provides a way to group chemicals with similar properties into distinct classes that are more meaningful to end-users. In cases where chemical class is inadequate in distinguishing properties among members of a class, the proposed regulation requires the use of chemical or common name to better protect the public and the environment.

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

The Secretary of Natural Resources determined that DPR's pesticide regulatory program, including the adoption, amendment, and repeal of pesticide regulations, qualifies as a certified regulatory program under Public Resources Code section 21080.5 and title 14, California Code of Regulations (14 CCR) section 15251(i). This determination means DPR's pesticide regulatory program is functionally equivalent to the California Environmental Quality Act's (CEQA) requirements for preparing environmental impact reports (EIRs), negative declarations, and initial studies, and is therefore exempt from such requirements. This initial statement of reasons serves as the public report required under 3 CCR section 6110 and satisfies the requirements of DPR's CEQA certified regulatory program for rulemakings at 3 CCR sections 6110–6116.

DPR's public report, as the substitute document satisfying CEQA functional equivalency requirements, must include a description of the proposed activity, and either (A) alternatives to the activity and mitigation measures to avoid or reduce any significant effects that the project might have on the environment, or (B) a statement that DPR's review of the project showed that the project would not have any significant effects on the environment and therefore no alternatives or mitigation measures are proposed to avoid or reduce any significant effects on the environment. (3 CCR section 6110.) DPR shall not adopt a regulation that would cause a

significant adverse environmental impact if there is a feasible alternative or mitigation measure that would substantially lessen those significant adverse environmental impacts. (3 CCR section 6116.)

Under existing law, spray adjuvants are required to be registered as pesticides in California. However, because they are not considered pesticides under federal law, the labeling requirements in 40 CFR section 156.10 do not apply to these products. Currently California statutes contain very limited requirements for spray adjuvant labeling. The entirety of guidance for registrants of spray adjuvant products is contained in FAC section 12883(b) and FAC section 12885. In addition, Article 10 of 3 CCR establishes limited requirements for items that must be identified generally on product labeling in California.

The proposed regulations would establish additional guidance on labeling requirements for spray adjuvants. The proposed regulations require an ingredient statement and what specific information should be included: names of each principal functioning agent (and how to identify the top three principal functioning agents if there are more than three); acceptable alternative nomenclature for principal functioning agents; and percentage by weight of the principal functioning agents and inert ingredients or constituents ineffective as a spray adjuvant.

The proposed changes to the regulations would not have any adverse environmental effects. DPR considered and dismissed potential environmental effects on human health, flora (plants), fauna (fish & wildlife), water quality, and air quality because the proposed regulations do not change the rate, timing, or use for spray adjuvants, and so would have no effect on these environmental factors. Given the minimal nature of these added conditions, DPR has no evidence and no reason to believe that these regulations would result in either an increase or decrease in the availability or use of spray adjuvants.

Rather, the proposed regulations provide guidance on labeling requirements for spray adjuvants resulting in more consistency and clarity for end product users. Therefore, while there is a potential for the proposed regulation to result in human health benefits, no possible significant adverse effect to California's environment can reasonably be expected to occur from implementing these changes to the labeling requirements. Therefore, the proposed regulations are categorically exempt from environmental review under 14 CCR section 15061(b)(c).

Because no significant adverse effect to California's environment can reasonably be expected to occur from implementing the proposed regulations, no alternatives or mitigation measures are proposed to lessen any significant adverse effects on the environment.

EFFORTS TO AVOID CONFLICT OR DUPLICATION OF FEDERAL REGULATIONS

The proposed action does not duplicate or conflict with federal regulations because U.S. EPA does not regulate spray adjuvants as pesticides.

DOCUMENTS RELIED UPON

1. Eiserich, Jason P. Economic and Fiscal Impacts of Proposed Spray Adjuvant Ingredient Statement Requirements Regulations. Department of Pesticide Regulation. Memorandum dated December 17, 2021.