FINAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

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

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. In the text of the proposed regulations, DPR proposed to adopt Title 3, California Code of Regulations (3 CCR) section 6247. No changes were made to the proposed regulations following the 45-day public comment period.

On pages 4 and 5 of the Initial Statement of Reasons, DPR made a typographical error when citing the federal requirement concerning percentage by weight in the ingredient statement. The citation in the Initial Statement of Reasons is Title 40, Code of Federal Regulations (40 CFR) section 156.10(g)(3). The correct citation is 40 CFR section 156.10(g)(4). Additionally, on page 6 of the Initial Statement of Reasons, DPR made a typographical error in the citation to 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)). The correct citation is 21 U.S.C. section 321(qq).

The proposed regulatory action was noticed in the *California Regulatory Notice Register* on November 4, 2022. 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 During 45-Day Comment Period" of this Final Statement of Reasons.

DPR has adopted 3 CCR section 6247. In summary, this action establishes and standardizes ingredient statement requirements, including principal functioning agent identification and nomenclature requirements, on spray adjuvant product labels. The 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 regulations if and when an application for a label amendment is submitted.

PUBLIC HEARING

No public hearing was scheduled or held, and none was requested.

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

- ***Scott Rawlins, Council of Producers and Distributors of Agrotechnology***

Comment no. 1: In some cases, DPR's labeling guidance as put forth in the Notice [California Notice 2020-13] and now in the proposed regulation, will explicitly reveal a registrant's proprietary formula and Confidential Business Information.

Response: Disclosure of the top three principal functioning agents by name on spray adjuvant product labels is a statutory requirement in California. Food and Agriculture Code (FAC) section 12885 requires the label to 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 functioning agents need to be named. The proposed regulations and the preceding California notice will not explicitly reveal information about a product's principal functioning agents above and beyond current statutory labeling requirements. Moreover, the proposed regulations do not solely require the label to state the percentage of each principal functioning agent. Rather, registrants may opt to state the total percentage of all the functioning agents combined. Registrants are also not required to list the individual inert ingredients or constituents ineffective as a spray adjuvant, or the percentage of each individual inert ingredient or constituent ineffective as a spray adjuvant. Therefore, the proposed regulations do not require disclosure of a product's proprietary formula.

Comment no. 2: The California Notice 2020-13 guidance requires registrants to list Principal Functioning Agents (PFAs) on the Product Formulation Information page of the application. This includes identifying and providing "all chemical ingredients, including the complete composition of proprietary blends, mixes, tradenames, etc." In addition, the precise chemical names of PFAs listed on the PFI form, as well as the Constituents Ineffective as Spray Adjuvants, must be adequate for DPR to understand the precise chemical composition of the proposed formulation. This means that registrants must provide Chemical Abstracts Service (CAS) numbers for each ingredient in the formulation and that the contents of the formulation must sum to a total of 100%.

Response: No response needed.

Comment no. 3: The California Notice 2020-13 guidance and proposed regulations also stipulate that only the three most abundant PFAs need to be listed on the label and that they may be listed in any order with the overall percentage indicated as a sum of all PFAs in the adjuvant formulation.

Response: No response needed.

Comment no. 4: The requirement to specifically identify the ingredients in the formulation can be enough information to give competitors the "road map" to copying the formulation. An experienced formulation chemist would have little trouble uncovering a company's proprietary formula because the new regulation, in some cases, will explicitly identify the ingredients in a registrant's recipe. This will allow a competitor to enter the California market with an identical product for free after the original registrant has spent millions of dollars in research, development, and testing. This will eliminate the introduction of new, novel, and innovative technologies now that DPR is proposing that companies must immediately share the formula with others who have invested nothing.

Response: Registrants of spray adjuvant products must identify the top three principal functioning agents on the product label according to statutory requirements. In most cases, these principal functioning agents can be identified on the label by their chemical class and not their precise chemical or common names. It is only for acids, bases, ingredients not allowed for use on food or feed crops, food commodity allergens, and ammonium sulfate that registrants must specify the chemical or common name and not the chemical class. 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. Additionally, a chemical class can contain principal functioning agents that are both allowed and not allowed for food or feed use. End-users of spray adjuvant products must 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 to prevent inadvertent contamination of a food or feed crop. 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. Lastly, ammonium sulfate must be identified as ammonium sulfate and not by its chemical class or other chemical or common name. Many conventional pesticide products have label directions regarding the use of adjuvants containing ammonium sulfate. Identifying ammonium sulfate on the spray adjuvant label is necessary for pesticide applicators to determine if they are complying with pesticide label directions regarding ammonium sulfate.

Identification of spray adjuvant ingredients on the label is limited to the top three principal functioning agents by weight. The proposed regulations do not solely require the label to state the percentage of each principal functioning agent. Rather, registrants may opt to state the total percentage of all the functioning agents combined. No information on the constituents ineffective as a spray adjuvant are required on the label, other than the summed percentage of all such ingredients. This is consistent with the statutory requirements in FAC section 12885 and its legislative history and does not disclose the product's proprietary formula.

Comment no. 5: These new requirements will force companies who sell adjuvants throughout the U.S. to leave California in order to protect their products in other states. No other state in the U.S. has this requirement.

Response: The Department disagrees with this comment. Washington has substantially similar requirements outlined in Washington Administrative Code [WAC 16-228-1400(3)(c)]. This section stipulates that the label ingredient statement shall include up to three principal functioning agents "listed by chemical name in descending order of composition with either individual or total percentage(s)." The ingredient statement shall also list the percentage of "constituents ineffective as spray adjuvants" and the total percentage of all ingredients, which must equal 100%. Furthermore, Washington State Department of Agriculture has published a "Spray Adjuvant Guidance Document" on their website. This document directs registrants to use the chemical name for acids and ammonium sulfate and the chemical name or synonym for an ingredient not allowed for use on food crops. The Department's proposed regulations differ primarily in the additional directions to use the precise chemical or common name for bases and food commodity allergens.

Comment no. 6: DPR's proposed regulations will unintentionally reveal CBI. We urge DPR to amend the regulation to protect CBI and our members proprietary formulas.

Response: This rulemaking updates and provides clarification to existing statutory and regulatory requirements. The proposed regulations protect confidential business information while working within the bounds of current statutory requirements. DPR acknowledges that the confidential statement of formula, which lists the name and percentage of each principal functioning agent and inert ingredient or constituent ineffective as a spray adjuvant in the product, is protected confidential business information used by DPR as a part of its registration process.

- ***Todd Sanders, California Apple Commission, California Blueberry Association, California Blueberry Commission, Olive Growers Council of California***
  Ruthann Anderson, California Association of Pest Control Advisers
  Casey Creamer, California Citrus Mutual
  Roger Isom, California Cotton Ginners and Growers Association, Western Agricultural Processors Association
  Ian LeMay, California Fresh Fruit Association
  Mike Montna, California Tomato Growers Association
  Robert Verloop, California Walnut Commission
  Joani Woelfel, Far West Equipment Dealers Association
  Manuel Cunha, Jr., Nisei Farmers League
  Matthew Allen, Western Growers Association
  Renee Pinel, Western Plant Health Association

Comment no. 7: We are concerned that the proposal, as currently written, could compromise registrant's Confidential Business Information (CBI), which ultimately could then impact adjuvant availability in California.

Response: See response to comments #1, #4, #5, and #6.

Comment no. 8: Our original understanding was that CA Notice 2020-13 would be added to the California Code of Regulations Section 6247. Our organizations did not find that proposal problematic, so we did not see a need to comment. However, the revised proposal DPR 22-004 does propose additional changes that are of concern. DPR proposes the disclosure of a product's Principal Functioning Agents (PFAs) not only by their Chemical Abstract Service (CAS) number, but by their common or chemical name. Chemical names are already provided as part of a registrant's CBI submission along with acute toxicity studies, so is readily available to DPR scientists without it being provided publicly where CBI could be compromised.

Response: The proposed regulations closely follow the label ingredient statement guidelines of California Notice 2020-13 except for the removal of the requirement to use chemical class on mineral oils, paraffinic oils, and petroleum distillates. The proposed regulations do not require disclosure of Chemical Abstract Service numbers on the label ingredient statement.

Comment no. 9: DPR suggests that a list of common names is available on the State of Washington's website and the use of common or chemical names will provide commonality to the State of Washington regulations. However, this system and list is not being utilized by the State of Washington and is not present on the Washington State Department of Agriculture (WSDA) website. If DPR's intent is to better notify the public, Global Hazardous Statements are currently required on the label and include the signal words "None," "Warning," and "Danger" so the public can be aware of risk.

Response: Neither the proposed regulations nor the associated Initial Statement of Reasons indicate that a list of common names is available on the Washington State Department of Agriculture website. The Initial Statement of Reasons does indicate that multiple states regulate spray adjuvants as pesticides and that Washington and California have similar statutory and regulatory requirements. While the Globally Harmonized System of Classification and Labeling of Chemicals provides useful signal words to alert pesticide users to potential risk, this practice is not a substitute for disclosure of the top three principal functioning agents by name on spray adjuvant product labels, which is a statutory requirement in California (FAC section 12885). Moreover, the Globally Harmonized System for Classification and Labeling of Chemicals does not provide end users with important information about whether the product contains food commodity allergens or ingredients not allowed for use on food or feed crops.

Comment no. 10: DPR 22-004 would require that only the three most abundant PFAs be listed on the label in any order preferred by the registrant, with an overall percentage indicated as a sum of the PFAs. We support this requirement as it should not contribute to the disclosure of CBI.

Response: No response needed.

Comment no. 11: We understand that DPR is concerned that many PFAs used in adjuvant formulation are polymers or mixtures that lack common names that would be easily identifiable by the public. However, this proposal poses serious threats by explicitly revealing a registrant's proprietary formula. The requirement to specifically identify the ingredients in the product's formulation can provide competitors enough information to effectively copy a formulation. That exposure of trade secrets is not acceptable as adjuvant registrants spend millions of dollars in research and development on new innovative products. We are very concerned that these new requirements will force companies who market products throughout the U.S. to leave the California market to protect their formulations, thereby leaving California farmers with even fewer tools to protect their crops.

Response: See response to comments #1, #4, #5, and #6.

Comment no. 12: We appreciate that DPR is trying to address disclosure issues being raised by some stakeholders. Again, this information is available as part of a registrant's CBI submittal, so safety is already being addressed by DPR which leads us to believe that allegations of safety are misplaced.

Response: See response to comment #1 and #4. Issues of safety being addressed by submittal and subsequent DPR evaluation of Product Formulation Information is not a substitute for listing principal functioning agent names on the label ingredient statement as required by statute.

Comment no. 13: The fact is that adjuvants provide multiple benefits in agriculture, mosquito abatement, other public health settings, and other applications. In agriculture, they help farmers and applicators reduce spray tank foaming and adjust spray water pH by providing acidification. Importantly, adjuvants improve pesticide spreading, wetting, canopy and leaf penetrations, and adhesion which in turn helps reduce pesticide use. The use of adjuvants provides an additional safeguard by helping make sure a pesticide application will stay where it is applied and not impact non-targeted pests or fauna or move off-sight where residents may be present. This is important in agricultural uses and for control efforts that protect the public from pests like mosquitos that spread disease. Adjuvants also improve worker and bystander safety by reducing the risk of pesticide drift.

Response: No response needed.

Comment no. 14: In conclusion, we ask that DPR remove the requirement that PFAs be publicly identified by common or chemical name. This requirement will impact the viability of proprietary formulations and expose CBI.

Response: See response to comment #4.

Comment no. 15: As DPR moves to implement Sustainable Pest Management systems, the use of adjuvants will play an important role in achieving more sustainable practices that better protect the public and environment. These products can help reduce the use of pesticides and protect workers and the public by preventing drift and improving the efficacy of newer products.

Response: No response needed.

Comment no. 16: If CBI is compromised as we fear this proposal will result in, companies will not bring their new technologies to California, leaving greater barriers to achieving California's Sustainable Road Map to the future.

Response: See response to comments #1, #4, #5, and #6.

- ***Suzanne M. Hume, CleanEarth4Kids.org***
  Vanessa Forsythe RN MSN, California Nurses for Environmental Health and Justice, Trusted Health Care Providers for Climate Justice

Comment no. 17: CleanEarth4Kids.org supports the establishment and standardization of ingredient statements on all pesticide and related products. These requirements must apply to all adjuvants, not just spray adjuvants, and must also apply to currently registered adjuvant products as well.

Response: A "spray adjuvant" is defined as "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). By this definition, spray adjuvant includes all adjuvants that are registered by the Department of Pesticide Regulation. Currently registered spray adjuvants are already subject to the labeling requirements contained in FAC section 12885, which requires that the product label bear the names of the principal functioning agents. The proposed regulations reiterate those existing statutory requirements and provide additional clarity on principal functioning nomenclature.

Comment no. 18: Any product that impacts our food, water, air and lands must be tested for safety and regulated without exception. We must put people before profits.

Response: These regulations outline requirements for the ingredient statements of spray adjuvant product labels. This comment is therefore outside the scope of this rulemaking action.

Comment no. 19: Any and all ingredients, "inert" or otherwise, must be listed on product labels and safety data sheets in order to inform and protect the public and workers. We have the right to know what is being used.

Response: The listing of ingredients on spray adjuvant labeling is covered by FAC sections 12883 and 12885. FAC section 12883 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" in lieu of one of the options required by this section." Additionally, FAC section 12885 requires the label to 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 to be named. Inert ingredient information is considered to be confidential business information and is protected from disclosure under federal and state law.

Comment no. 20: DPR and other agencies must prioritize the health and environmental effects from the combination of pesticides, adjuvants, and "inert" ingredients. Adjuvants and "inert" ingredients must meet the same safety standards as active ingredients.

Response: These regulations outline requirements for the ingredient statements of spray adjuvant product labels and not the scientific evaluation of the products required for registration. This comment is therefore outside the scope of this rulemaking action.

Comment no. 21: Research shows the most widely pesticides used in the US are not listed on product labels. An evaluation by Beyond Pesticides found 37 of the most widely used pesticides in California are adjuvants. Used in over 150 adjuvants in California, APNOHO is sprayed on almost 12 million acres of farmland every year and is an endocrine disruptor.

Response: These regulations outline requirements for the ingredient statements of spray adjuvant product labels. This comment is therefore outside the scope of this rulemaking action.

Comment no. 22: Studies have also shown that "inert" ingredients can be fatal to bees.

Response: These regulations outline requirements for the ingredient statements of spray adjuvant product labels and not the scientific evaluation of pesticide products required for registration. This comment is therefore outside the scope of this rulemaking action.

Comment no. 23: There are PFAS which are considered "inert" ingredients by the EPA.

A Nov 2022 study found PFOS in 6 out of 10 commonly used insecticides and found other PFAS in 7 out of 10. PFOS is on the Prop 65 list because it can cause cancer, birth defects and reproductive harm. PFAS as a class are linked to liver damage, thyroid disease, decreased fertility, high cholesterol, obesity, hormone suppression and several types of cancer.

All PFAS must be banned as any ingredient in pesticides and manufacturers must be required to test every registered pesticide product and certify that they do not contain any PFAS.

Response: These regulations outline requirements for the ingredient statements of spray adjuvant product labels and not the scientific evaluation of pesticide products required for registration. This comment is therefore outside the scope of this rulemaking action.

Comment no. 24: It is critical to protect human health, biodiversity and the environment. The complete product must be evaluated, not just the active ingredient.

An example of this is Round Up and glyphosate. Research clearly shows RoundUp is more toxic than just glyphosate, the combination of all the ingredients causing cancer and other health problems like Alzheimer's and other neurological disorders. It was also found to be far more deadly to aquatic life than just glyphosate alone.

Other studies of commonly used herbicides and insecticides found the complete formula was far more toxic than just the active ingredients.

Response: These regulations outline requirements for the ingredient statements of spray adjuvant product labels and not the scientific evaluation of pesticide products required for registration. This comment is therefore outside the scope of this rulemaking action.

Comment no. 25: DPR must take action and require all ingredients to be listed on product labels and fully test and evaluate the complete formula of all pesticides for safety.

Response: See response to comment #19 regarding the request to require all ingredients be listed on product labels. The request for full testing and evaluation of the complete formula of all pesticides is outside the scope of this regulatory action.

Comment no. 26: We call on DPR and all other agencies to put people before profit and stop the use of toxic pesticides and chemicals.

Response: No response needed.

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.

ALTERNATIVES DETERMINATION

The Director has determined that no alternative considered by DPR would be more effective in carrying out the purpose for which these regulations are proposed; as effective and less burdensome to affected private persons or businesses than the adopted regulations; or more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. These regulations are necessary to provide clarity to regulated industries and the public on the requirements for the label ingredient statement of spray adjuvant products.

POSTING REQUIREMENT

3 CCR section 6110, states in part that, “The public report shall be posted on the official bulletin boards of the Department 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>.