

EFFICACY DATA FOR ADJUVANTS & CA REGISTRATION REQUIREMENTS

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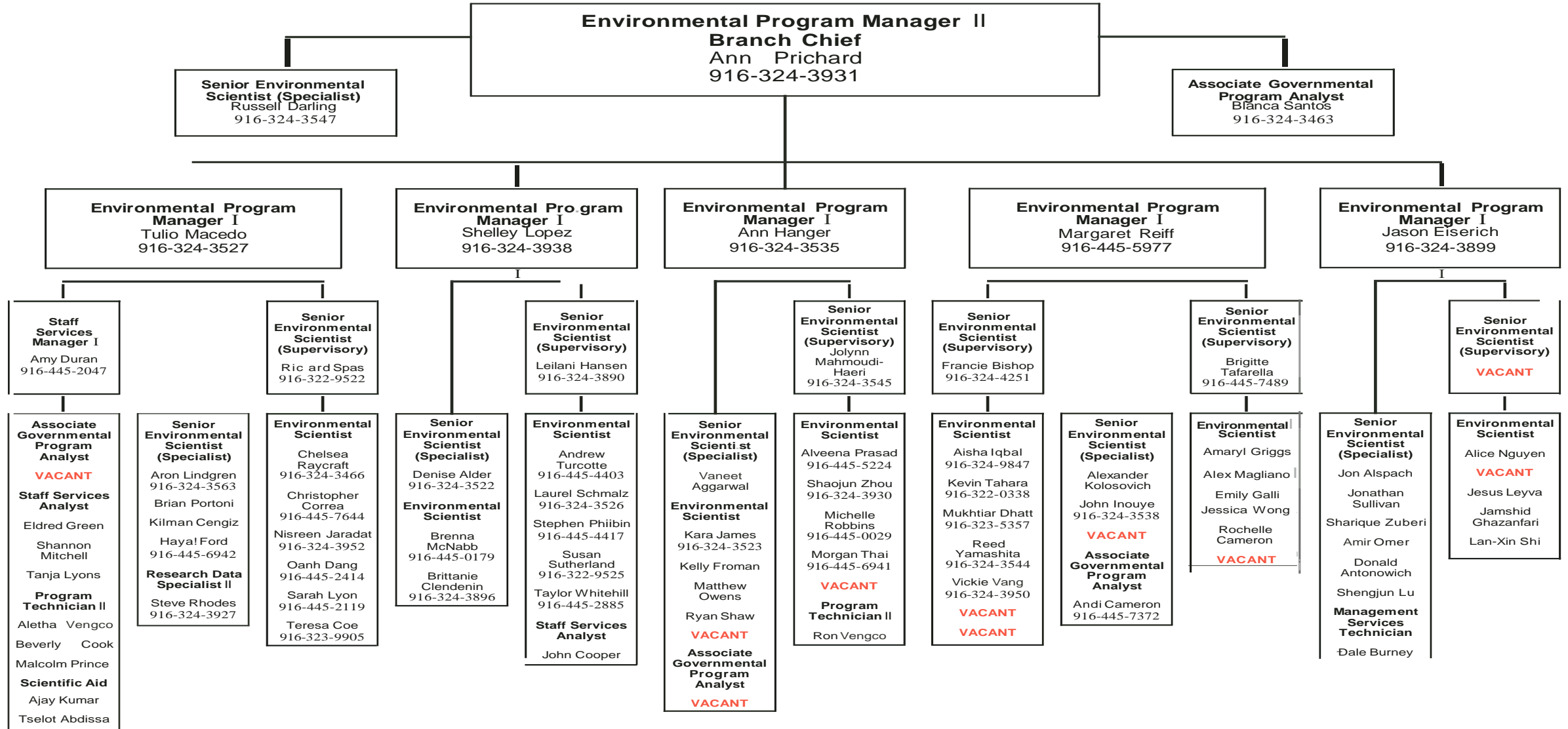
R3 Ag Consulting, LLC

CPDA Meeting August 20, 2019

CPDA Proactive Approach to New Regulations

- ▶ CPDA Task Force meets with CA DPR Chemistry Group to explore ways to use ASTM or other standard methods to support registrations
- ▶ Task Force develops survey for CPDA members to comment on use of ASTM or equivalent standards to support registration
- ▶ Survey results sent to CA DPR Chemistry for use in their developing registration standards that comply w/CEQA
- ▶ Goal: Keep review of adjuvants that do not require field trials in Chemistry group only w/o requiring full review and the new NOD standards

PESTICIDE REGISTRATION BRANCH
Pesticide Programs Division



Why Require Efficacy Studies?

California Code of Regulations, section 6186

Each application for registration or amendment to the labeling of a pesticide shall be accompanied by data supporting each efficacy claim. If data supporting such claims are in the public domain and copies of the data are provided, the submission of such data may satisfy the requirement of this section. Such data shall be obtained under California or similar environmental use conditions and shall take into consideration differences in plants, soils, climate conditions, and application techniques.

DPR Authority- Products Needing Testing

- ▶ **3 CCR 6192. Other Data**
- ▶ Each applicant to register a pesticide product shall submit to the director any **other data** determined by the director to be necessary to carry out the provisions of Section 12824 of the Food and Agriculture Code.
- ▶ Each data request pursuant to this section shall include the director's reason for the request. Such data **may include, but is not limited to the following:**
 - ▶ Pesticide drift
 - ▶ **Phytotoxicity**

Trial Requirements - Additional Factors

- ▶ Phytotoxicity -
 - ▶ Combine with efficacy study
 - ▶ Include phytotoxicity evaluations or observations to establish crop safety
- ▶ Herbicides -
 - ▶ Evaluate percent control at various intervals
- ▶ PGRs -
 - ▶ Establish a rate/response relationship
 - ▶ Evaluate yield or other primary effect
- ▶ Adjuvants -
 - ▶ Basics apply
 - ▶ Type of study depends on type of product

Adjuvant Data Requirements

Revisions in Progress

- ▶ Label guidelines document being prepared
- ▶ Developing clear expectations for required data
- ▶ Separating data requirements into two categories:
 - ▶ Activator adjuvants
 - ▶ Utility adjuvants
- ▶ Utility adjuvant data to be evaluated by chemistry
- ▶ Working with external stakeholders (CPDA)

Adjuvant Data Requirements - Examples

Activator Adjuvants: *Enhance pesticide performance*

- Surfactants
- Spreaders
- Wetting agents
- Deposition aids and stickers

Utility Adjuvants: *Alters physical properties of Spray Solutions*

- Drift control/reduction agents
- Buffers/pH modifiers
- Water conditioning agents
- Defoaming agents

Adjuvant Data Requirements - Categories

Activator Adjuvants: *Enhance pesticide performance*

Field Product Performance Studies
for Efficacy and Phytotoxicity

Utility Adjuvants: *Alters physical properties of
Spray Solutions*

Laboratory-based Studies and Phyto

Adjuvant Data Requirements - Activators

Field Performance Guidelines for Efficacy and Phytotoxicity

- ▶ Proper experimental design
 - ▶ Randomized complete block design
 - ▶ Use of proper treatment controls
 - ▶ Endpoints clearly specified
 - ▶ Proper number of replicate studies (at least three)
- ▶ Data must be statistically analyzed
- ▶ Phytotoxicity data required
- ▶ Data shall be developed under California or similar env. use conditions
- ▶ Efficacy data from the public domain (published papers) acceptable

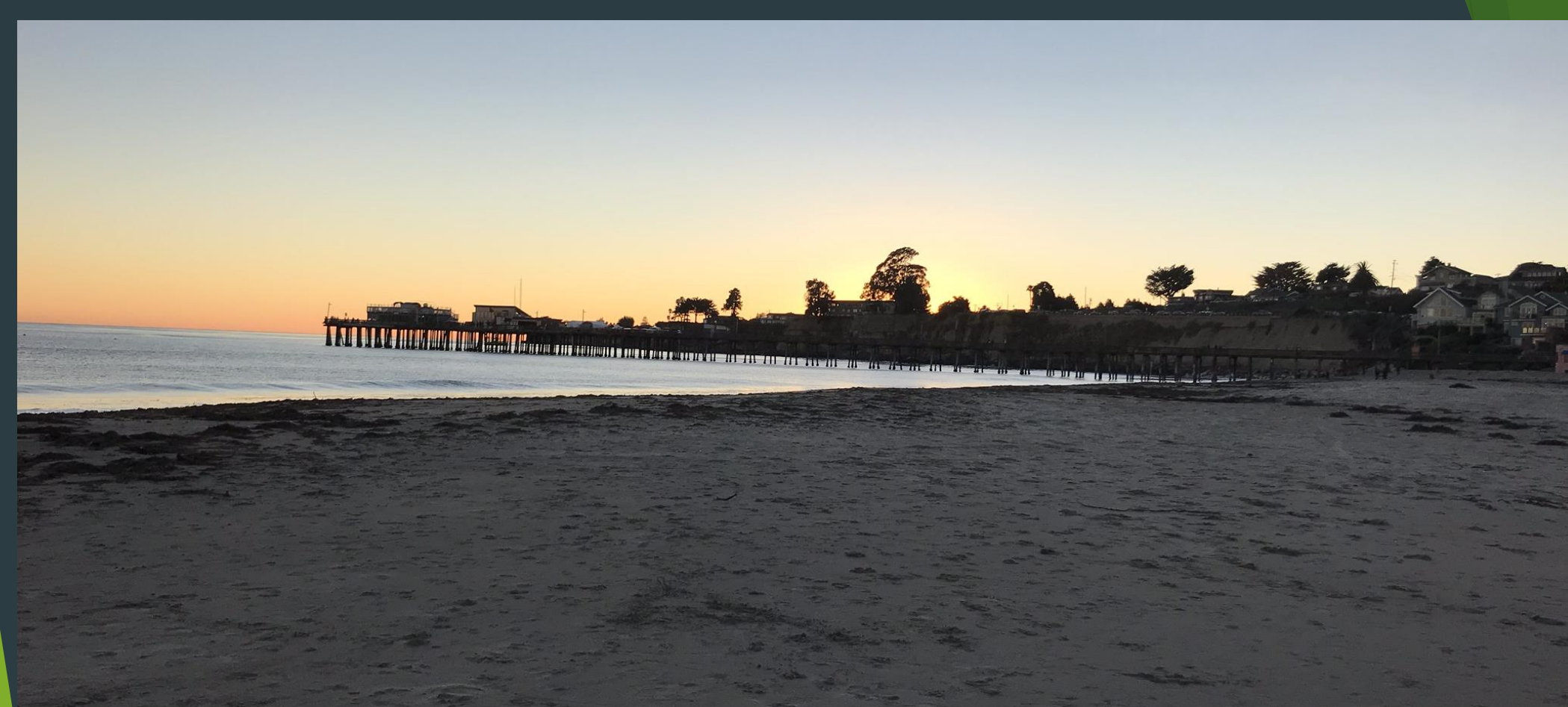
Adjuvant Data Requirements - Utility

Laboratory-based Studies Evaluated by Chemistry

- ▶ Acceptable laboratory studies are being developed
- ▶ Incorporating the use of standard methods
 - ▶ ASTM, etc.
 - ▶ Alternative methods can be submitted for approval
- ▶ Chemistry to be evaluating most utility adjuvant data
- ▶ Phytotoxicity data still needed
- ▶ Increased turnaround of evaluations

Action Items CDPR Efficacy Requirements Adjuvants

- ▶ DPR indicates revisions to adjuvant efficacy data requirements are: **“In Progress”**
- ▶ Schedule meeting with Jason Eiserich (new program mgr. DPR) to discuss possible other revisions to adjuvant efficacy
- ▶ Suggest presentation to demonstrate how drift, deposition, canopy penetration and other physical measurements can be done in the lab rather than in the field



QUESTIONS??