Regulatory Alignment Study Update: Preliminary Evaluation and Listening Sessions

Summary

The California Department of Food and Agriculture (CDFA) contracted with Crowe LLP (Crowe) to facilitate the evaluation and identification of process improvements for ag-related food safety and water quality regulations and reporting requirements at CDFA and the California Environmental Protection Agency (CalEPA) by conducting a study on regulatory alignment. CalEPA's coordination is primarily through State Water Resources Control Board and Regional Water Quality Control Boards (Water Boards). Crowe prepared this update to provide details on the following milestones:

- **Evaluate Regulatory Requirements (completed June 2023) –** Crowe identified, documented, mapped, and conducted a preliminary evaluation of ag-related regulatory requirements, including reporting and compliance processes, within the areas of food safety and water quality.
- **Conduct Listening Sessions (in progress through 2023 and early 2024) –** Crowe is conducting outreach and facilitating initial listening sessions with interested parties to identify their experiences with the state's food safety and water quality programs and regulatory requirements. The feedback will inform documentation of current and potential regulatory pathways[1] guiding the study's future efforts.
- **Release Concept Paper (Early 2024) –** Crowe will release a Regulatory Alignment Concept Paper (Concept Paper) outlining preliminary regulatory pathways within the areas of food safety and water quality for consideration by CDFA, CalEPA, Water Boards, interested parties, and public commenters.
- **Hold Workshops on Concept Paper (Spring 2024) –** Crowe will engage and convene members of the agricultural community, industry, interested parties, and regulators to review and further develop regulatory pathways outlined within the Concept Paper, which will guide our efforts going forward.

Regulatory Alignment Study Objectives

In November 2022, CDFA contracted with Crowe to meet the study's five (5) objectives, outlined in **Exhibit 1.** By November 2025, Crowe will issue a final report to provide CDFA, CalEPA, and the Water Boards detailed regulatory alignment recommendations resulting from the study along with proposed implementation plans.

Exhibit 1
Regulatory Alignment Study Objectives

	Evaluate state regulatory requirements within the areas of water quality and food safety for the agricultural community and identify environmental and public health protections.
	Conduct listening sessions to gather input from the agricultural community relating to their experiences with the reporting requirements and processes in these areas.
	Convene with the agricultural community and regulators to review and map existing regulatory pathways for water quality and food safety to identify opportunities to improve efficiency and information sharing.
	Identify and prepare implementation plans for recommended process improvements to streamline reporting requirements.
	Provide recommendations to CDFA, CalEPA, and the Water Boards for technological enhancement to ease the administrative burden of the agricultural community.

[1] Regulatory pathways include considerations, options, tools, and/or recommendations for improving, streamlining, and aligning the regulatory programs in scope of the study.

Release date: January 2024

Preliminary Evaluation Outcomes

Regulatory alignment is of paramount importance to the agricultural community[2] in California, particularly concerning food safety and water quality regulations. It aims to reduce apparent discrepancies and redundancies with the goal of increasing regulatory clarity and compliance. Further, regulatory alignment supports standardizing regulatory requirements while minimizing health risks associated with foodborne illnesses and safeguarding the protection of water resources from contamination. This effort aims to achieve these objectives while fostering consumer confidence and supporting market demand and the economic vitality of the state's nearly $60 billion agricultural industry.

As of June 2023, Crowe completed the first study milestone – an evaluation of the state's ag-related regulatory requirements within the areas of food safety and water quality. At the onset of the study, CDFA, CalEPA, and Water Board staff coordinated with Crowe to confirm the regulatory programs and requirements in scope of the study, listed in **Exhibit 2.** Crowe then conducted nearly 30 interviews with CDFA and Water Boards' subject matter experts (SMEs) to document and map key practices and processes, including technologies, tools, and other inputs, to implement and monitor programs and assure compliance with associated requirements. Crowe will continue to build on the outcomes from the preliminary evaluation identified in this update to support continued engagement with CDFA, CalEPA, Water Boards, and impacted parties in an effort to identify regulatory pathways within the areas of food safety and water quality.

Identification of Regulatory Requirements

The table below summarizes the programs in scope of the study, including programmatic goals, regulatory requirements, and regulated communities. Other water quality programs considered in scope of the study, but not included for further description or evaluation include the National Pollutant Discharge Elimination System Permit (NPDES) for Stormwater Associated with Industrial Activity and Central Valley Salinity Alternatives for Long-Term Sustainability (CV-SALTS).

Exhibit 2
Scope of the Regulatory Alignment Study
Food Safety and Water Quality Programs, Goals, Requirements, and Regulated Community

Program	Goals	Requirements	Regulated Community
Food Safety			
Produce Safety Program	To ensure that California produce farmers understand how to comply with the requirements of the Produce Safety Rule (PSR) under the Food Safety Modernization Act (FSMA).	PSR under FSMA (21 CFR, Part 112) requirements in scope of the study: • Personnel Qualification and Training • Health and Hygiene • Agricultural Water[3] • Biological Soil Amendments of Animal Origin and Human Waste • Domesticated and Wild Animals • Growing, Harvesting, Packing, and Holding Activities • Equipment, Tools, Buildings, and Sanitation	Applies to approximately 4.4 million (harvested) acres of farms that grow, harvest, pack, or hold covered produce totaling nearly $40 billion in value. This includes roughly 20,000 covered farms encompassing large and medium-scale commercial farms and smaller, diversified operations.

[2] For the purposes of the study, Crowe will utilize the term "agricultural community" to account for the full spectrum of interested parties that will likely be impacted by the study's outcomes, including but not limited to producers, farmers, ranchers, dischargers, growers, food processors, coalitions, associations, environmental groups, environmental justice groups, health advocates, and others.

[3] Proposed Rule.

Program	Goals	Requirements	Regulated Community
Water Quality			
State Winery Order	To minimize groundwater quality degradation and protect beneficial uses of waters of the state from discharges of wastes to land for reuse or disposal from wineries or other similar facilities.	Waste Discharge Requirement (WDR, CWC §13263) for the program generally includes the following requirements: • Enrollment • Design, Construction, and Operation • Monitoring • Maintenance • Reporting	Applies to an estimated 2,100 wineries and other similar facilities (collectively referred as wineries) in California with activities related to producing wine or grape juice that generate winery waste and discharge it to land for reuse or disposal.
Irrigated Lands Regulatory Program[4] (ILRP)	To prevent discharges of wastes from commercial irrigated lands from impairing surface and groundwater for their beneficial uses.	WDR and Waivers of WDRs (Waivers, CWC § 13269) for the program generally include the following requirements: • Enrollment • Farm Plan/Evaluation • Sediment and Erosion Control, if applicable • Irrigation and Nitrogen Management • Education • Surface and Groundwater Monitoring • Drinking Water Well Monitoring, if applicable • Reporting	Applies to approximately 36,000 operations on 6 million acres of commercial irrigated lands (unless they are exempt), including nurseries and managed wetlands, in California.
Confined Animals Facilities (CAF) Program	To prevent discharges of wastes from confined animal facilities from impairing surface and groundwater for their beneficial uses.	National Pollutant Discharge Elimination System (NPDES) permits under the Clean Water Act (CWA, 33 USC § 1251 et seq.), WDRs, and Waivers for the program generally include the following requirements: • Enrollment • Nutrient Management, if applicable • Riparian Management, if applicable • Grazing Management, if applicable • Waste Management, if applicable • Monitoring • Reporting	Applies to approximately 1,950 commercial confined animal facilities in California, with roughly 83.1 million non-dairy animals and 1.6 million mature cows covered; where confined animal facilities are any place where cattle, calves, sheep, swine, horses, mules, goats, fowl, or other domestic animals are corralled, penned, tethered, or otherwise enclosed or held and where feeding is by means other than grazing.

[4] Includes the Drinking Well Monitoring Program, which is intended to protect communities that rely on groundwater for their drinking water from impacts of nitrate concentration.

Common Regulatory Processes Across Programs

Crowe identified common regulatory processes, shown in **Exhibit 3,** across the key programs based on a preliminary evaluation of the regulatory requirements in scope of the study. These common regulatory processes across programs will support the identification of potential regulatory pathways that may likely improve administrative, reporting, and data-collection efforts. While these common regulatory processes are not exhaustive, they do represent an initial assessment of potential pathways for further exploration with CDFA, CalEPA, Water Boards, and impacted members of the agricultural community. Below is a summary of these processes from the perspective of a farmer[5]:

- **Verify Farm or Facilities:** Farmer and regulators verify eligibility to the regulatory program.
- **Enroll in Program:** Farmer submits Notice of Intent (NOI) and/or permit registration documents to enroll.
- **Pay Regulatory Fees:** Farmer pays application fees and/or annual permit fees.
- **Complete Training and Education:** Farmer participates in training and/or obtains required certifications.
- **Maintain and Monitor Farms:** Farmer maintains required facility standards and upkeep.
- **Prepare and Implement Plans:** Farmer prepares, maintains, and implements various required management plans.
- **Prepare and Submit Reports:** Farmer prepares, maintains, and submits reports.
- **Maintain Records:** Farmer keeps records of documents, such as training logs, copies of plans, equipment logs, etc.
- **Monitor for Continuous Improvements:** Farmer conducts ongoing monitoring activities for continued compliance with regulations.
- **Prepare for Inspections:** Farmer prepares for regulatory inspections of facilities, operations, and farms.
- **Implement Corrective Actions:** Farmer implements corrective actions if facility is not in compliance.

Exhibit 3
Common Regulatory Processes Across Programs

Programs	Verify Farm or Facilities	Enroll in Program	Pay Regulatory Fees	Complete Training and Education	Maintain and Monitor Farms	Prepare and Implement Plans	Prepare and Submit Reports	Maintain Records	Monitor for Continuous Compliance	Prepare for Inspections	Implement Corrective Actions
Food Safety											
1. Produce Safety Program	●	●		●	●		●	●	●	●	●
Water Quality											
2. Irrigated Lands Regulatory Program	●	●	●	●		●	●	●	●	●	●
3. Confined Animal Facilities Program	●	●	●		●	●	●	●	●	●	●
4. State Winery Order	●	●	●		●	●	●	●	●	●	●

[5] Crowe will often refer to "farmer" to encompass members of the regulated community within scope of the study; other terms used within regulatory requirements may include producers, ranchers, dairy farmers, vintners, dischargers, and others.

Listening Sessions Update

Over the course of the last year, Crowe has conducted nearly 70 listening sessions with the agricultural community. Crowe met with interested parties from various groups and backgrounds within the agricultural community including but not limited to: farmers and ranchers, dairies, industry and commodity associations, water quality coalitions, environmental advocates, environmental justice advocates, non-profit groups, and researchers.

We listened and learned about their experiences with the state's food safety and water quality regulatory programs and requirements. Our goal was to understand any existing challenges and to identify streamlining efforts that meaningfully reduce the agricultural community's regulatory burden and support the state's reporting and data collection efforts while maintaining human health and environmental protections.

Preliminary Outcomes from Listening Sessions

Crowe has documented interested parties' input throughout the year. A synopsis of key input for the Produce Safety Program and Water Quality Programs in scope of the study is below. Crowe plans to use interested parties' input to support the development of the Concept Paper. For context, listening sessions focused on:

- **Interested Parties' Experiences:** Experiences with the regulatory programs and associated requirements in scope of the study.
- **State Regulatory Staff Experiences:** Experiences implementing the regulatory programs and associated requirements in scope of the study.
- **Proposed Improvements:** Input on administrative and reporting streamlining opportunities (e.g., improvements associated with data collection and information sharing, improvements to administrative, reporting, and compliance processes, and improvements to programs' effectiveness).
- **Costs:** General costs of regulatory compliance (e.g., direct, indirect, opportunity, other costs).
- **Benefits:** General benefits of regulatory compliance (e.g., human health, environmental, economic vitality, other).

Input on the Produce Safety Program

- **Producers understand the purpose of the Produce Safety Program.** In general, producers across all commodities and regions understand that the Produce Safety Program is responsible for ensuring that California produce farmers understand how to comply with "science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption," as defined by the PSR under FSMA. Producers understand the PSR aims to reduce and prevent foodborne illnesses caused by contaminated produce.
- **PSR requirements are feasible and seen as less complex than market driven third party audits.** Many producers expressed that they are likely already meeting PSR requirements through compliance with market driven third party audits (i.e., food safety audits required by produce buyers and retailers). Some producers expressed that CDFA should consider pursuing a regulatory pathway that allows market driven third party audits, such as the GLOBALG.A.P. Integrated Farm Assurance – All Farm Base-Crops Base – Fruit and Vegetables Checklist, Leafy Greens Marketing Agreement (LGMA) Full Scope Audit Checklist, USDA Harmonized GAP Plus+ Standard and Checklist, and more, to satisfy PSR requirements to minimize the associated costs and time to plan for on-farm produce safety inspections.
- **PSR requirements align with producers' business incentives and practices.** Most producers shared that PSR requirements align with existing business incentives and farming practices. However, many producers noted that the PSR requirements were duplicative and could be met by market driven third party audits. Many producers expressed the notion of "audit fatigue" indicating that individually the program requirements are feasible but become challenging when combined with other regulatory programs, such as air quality, pesticide usage, and water quality.

- **Small farms may need the most technical assistance to comply with PSR requirements.** Some producers noted that the PSR requirements are likely more costly for small, family-owned farms given that resources are often limited by farm size. Small farms would likely benefit the most from streamlining regulatory pathways (e.g., minimizing regulatory touchpoints, additional technical assistance, and outreach) to minimize overall regulatory pressures. Producers expressed that the Produce Safety Program has the opportunity to continue to coordinate efforts with the FDA, USDA, and state/local partners to provide grants to cover eligible costs associated with PSR compliance and to support compliance with PSR through continued education and training opportunities through programs such as the CDFA's Technical Assistance Program (TAP).
- **PSR requirements may not adequately consider local and cultural practices associated with specialty crops.** Some producers and other interested parties expressed concerns that the PSR, as a federal regulation, does not adequately consider local and cultural practices associated with specialty crops mostly grown in California. Some producers and interested parties recommend that CDFA continue to develop culturally appropriate regulatory processes (e.g., inspection scheduling through various methods rather than by phone, allowance for alternative documentation, bilingual Produce Safety Alliance training).
- **Producers are uncertain on the direction of the agricultural water rule.** Many producers noted that they were unsure what the potential impacts of the proposed agricultural water rule will be (especially producers already inspected by the Produce Safety Program) given that the rule has yet to be finalized by the FDA. Uncertainty surrounding the rule will likely impact producers' ability to properly prepare for and comply with the regulatory requirements of the rule once it's finalized. Crowe will continue to assess the state's ag-related water quality data collection efforts to identify potential regulatory pathways associated with this component of the PSR.

Input on Water Quality Programs

- **Industry feels expected to address legacy water quality issues.** Many farmers expressed frustration with the requirements related to legacy water quality issues that will likely require decades to remediate.
- **Cost and complexity may pose a challenge to compliance.** Many farmers subject to the water quality programs expressed that complying with these requirements is costly and complex, especially for small and family-owned operations with limited resources. In many cases, these small farmers grow multiple crops per year or may lease their land several times throughout the year to other farmers. This can create additional reporting effort for farmers with limited resources.
- **Improved communication is needed to connect the regulatory objectives and program implementation.** Many farmers perceived a disconnect between program goals and how programs are designed, implemented, and enforced. Many farmers indicated difficulty in translating how the requirements of the programs achieve the objectives to protect water quality. In some cases, farmers mentioned that implementation of the program through the requirements does not always translate well to actual farming practices.
- **Concerns over the level of publicly facing data at the farm/ranch level.** Many farmers expressed ongoing concern over publicly facing data at the individual farm or ranch level. This concern was mainly driven by apprehension that it exposes them to harmful litigation that would jeopardize their businesses, especially for small and family-owned operations. On the other hand, environmental groups expressed concern with a lack of data transparency that could impede enforcement and potentially limit the ability of impacted communities to adequately identify the source of water quality contamination.
- **Potential openness to data sharing if data is aggregated and would lead to less reporting.** Some farmers expressed openness to potentially sharing data at the aggregate level if the threat of litigation was removed and it would lead to less reporting or other regulatory incentives. In many cases for the ILRP, data is already aggregated through water quality coalitions. However, readily available reports from water quality coalitions are not always easily accessible to members of the public.
- **Requirements are always changing.** Some farmers conveyed that water quality requirements are constantly changing and expanding, making it difficult to refine and develop efficient processes to comply. For example, farmers noted that in some water quality programs they are asked to monitor for new contaminants that were not previously included in the program. Other farmers noted a steep learning with requirements to use new technologies, likely causing up-front challenges to adjust to new reporting methods and processes.

- **Issues complying with water quality requirements are compounded by other regulatory areas.** Many farmers noted that water quality requirements are often compounded by other regulatory areas such as labor, water usage, air quality, and pesticide use. Specific regulatory compliance areas that were identified as a challenge varied across programs. For example, ILRP farmers mentioned pesticide use more than other groups and CAF ranchers mentioned air quality and composting. However, farmers across all programs noted that water quality is only a piece of the entire regulatory landscape. Farmers noted that it is difficult to disentangle one regulatory program from another as they generally view regulatory compliance through a systematic lens.

Proposed Focus Areas

Crowe's preliminary evaluation of the regulatory requirements along with input from the agricultural community highlights opportunity for regulatory alignment. To effectively move forward and meet the study's objectives, a systematic approach concentrating on addressing proposed key focus areas, listed in **Exhibit 4,** is necessary. In the Concept Paper, Crowe plans to build on these proposed focus areas to outline proposed regulatory pathways within the areas of food safety and water quality for consideration by CDFA, CalEPA, Water Boards, and interested parties.

Exhibit 4
Regulatory Alignment Study – Key Focus Areas

Data and Information Sharing
Identify opportunities to improve the exchange of selected data and information between state regulatory agencies and programs.

Efficiencies
Identify opportunities to simplify and expedite regulatory administrative, reporting, and compliance processes.

Effectiveness
Identify opportunities to measure regulatory performance objectives and goals.

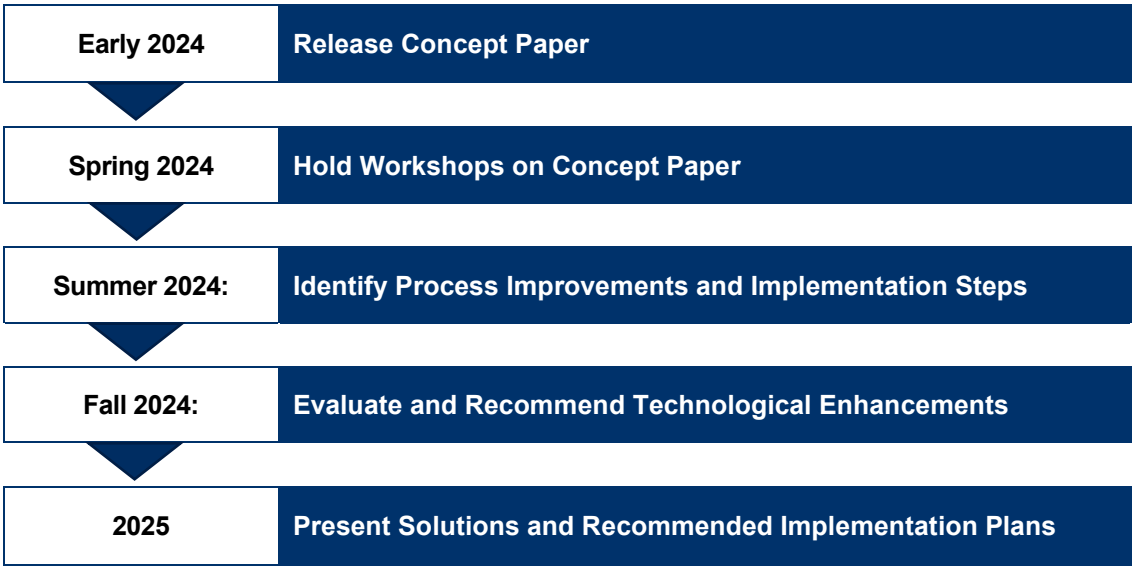
Equity
Identify opportunities to ensure the inclusion of socially disadvantaged farmers and ranchers[6] in the development, implementation, and enforcement of regulations.

[6] As defined by the Farmer Equity Act of 2017.

Next Steps

In **Exhibit 5,** we outline study milestones through 2025. In early 2024, Crowe will hold a public webinar and release an interim report on regulatory alignment (i.e., the Concept Paper) to provide proposed regulatory pathways within the areas of water quality and food safety. In Spring 2024, Crowe will conduct a series of public workshops in coordination with CDFA, CalEPA, and Water Board staff to review and obtain feedback on the Concept Paper. Crowe will utilize the feedback from CDFA, CalEPA, Water Boards, and interested parties to inform the development of recommended process improvements to streamline reporting requirements, implementation plans, and technological enhancements to ease regulatory burden for the agricultural community.

Exhibit 5
Regulatory Alignment Study – Upcoming Milestones



For More Information

Additional information about the study can be found at the following link: https://www.cdfa.ca.gov/RegulatoryAlignment/