

CALIFORNIA LEGISLATURE

Informational Hearing

Senate Committee on Agriculture

Senator Cathleen Galgiani, Chair

The Federal Food Safety Modernization Act: Impact of the Proposed Produce Rule on California On-Farm Agricultural Production

Stockton, California

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SENATOR CATHLEEN GALGIANI: Good afternoon ladies and gentlemen. Welcome to the Senate Committee on Agriculture’s informational hearing titled “The Federal Food Safety Modernization Act: Impact of the Proposed Produce Rule on California On-Farm Agricultural Production.”

Food safety in California is of the utmost importance in preserving and producing a safe and abundant food supply. Over the past decade, several food safety procedures have been developed and implemented in California to the extent that California arguably produces some of the safest and highest quality fruits and vegetables.

Food safety is also of national concern, and the Food Safety Modernization Act, a comprehensive federal law, was enacted in 2011. In January of this year, the FDA released for public comment proposed rules that would implement this new law. For purposes of today’s hearing, we will focus specifically on the proposed Produce Safety Rule.

Therefore, today’s hearing will focus on issues relative to the impact that the proposed Produce Safety Rule could have on California farms and farming practices, as well as determine whether state laws and regulations will need to be amended to ensure compliance with the new rule. We will discuss the role of state government coordination with other local, state, and federal agencies in ensuring a safe food supply. We will also discuss the roles of government, scientists, and industry in

developing and implementing food safety programs. Lastly, we will examine how different commodity and production systems could be affected by the proposed rule.

Furthermore, given that the informational hearing serves the public by providing a forum to discuss the importance, please be advised that the Committee plans to share the hearing discussion with the FDA by submitting the transcript as public comment on the proposed rule.

For everyone here today, thank you for your attendance, and I look forward to our discussion.

With that, I would like to invite our first witness and panel to come forward. Mr. Rick Jensen, Director of the Inspection Services Division, California Department of Food and Agriculture.

Also, while Mr. Jensen comes forward, I would like to invite anyone interested in providing testimony during the public comment period to please sign in with the sergeants at the back of the room.

Thank you.

MR. RICK JENSEN: Well, thank you, Madam Chair. Thank you for the introduction.

My name is Rick Jensen. I'm the director for inspection services with the California Department of Food and Agriculture.

I'm going to give a little bit of history: In the early 1930's, the California Department of Food and Agriculture entered into a cooperative agreement with USDA in order to provide shipping-point inspection services. I thought about that this morning, and I realized that—I'm quickly approaching, having been in the Division and in that program for nearly half of that time—clearly, the state of California did have very liberal child labor laws at that time. And I talk about that because that gave us the foundation in 1999 when we were approached by industry to start thinking about new ways of what we do and start incorporating new services. And by that, I mean providing on-farm verification audits to producers' good agricultural and good handling practices. That was really driven from the retailers in those early days. And we approached USDA—our partners with USDA—and encouraged them to embrace that from a national standpoint. We partnered with various state agencies as well in order to get to where we needed to be. We finally did, and we implemented those programs in 2001 and began providing those services throughout the state and

throughout the country. By doing so, that allowed us to be well positioned when the 2006 spinach outbreak hit the industry here in California so that we were ready to go and provide services to the leafy greens industry and the Leafy Greens Marketing Agreement in 2007.

I want to say that we are not food scientists. We're unbiased third-party auditors and that is our role, that is what we do. We have over twenty licensed auditors throughout the state. We conduct well over 1000, 12, 13, 1400 on-farm audits annually. About half of those are for the Leafy Greens Marketing Agreement, but we also do just general good agricultural practice audits on a vast array of commodities. We also provide services to the Almond Board and the almond producers of California in the verification of their systems as well.

In 2012, the Cantaloupe California Advisory Board came forward and also adopted food safety rules—on-farm food safety rules—into their marketing order. We're also providing services to that group.

Generally speaking, food safety or on-farm food safety programs (GAPs, if we will) are really designed to minimize the potential for contamination, microbial contamination. They are not done in factories. Farms are outside, so you cannot really control all of the environmental pressures that occur on farms. There's people here, like Dr. Suslow, that can talk about that with much more intelligence than I. However, they all focus in minimizing risks, minimizing contamination points. They focus on worker hygiene, worker training, and worker health. They require the development of a food safety plan so that there's a written document that says how a farmer is going to implement these rules: what they do in documentation in terms of all of the training; whatever water tests that they may have; the results of those water tests; sanitization, whether it be of toilet facilities or farm harvesting implements; mechanisms to prevent equipment that is moved from one farm to another farm. It looks at inputs. It looks at environmental assessments, both pre-plant and pre-harvest environmental assessments, looking for potential contamination points.

I realize that the hearing today is focused specifically on the Food Safety Modernization Act. I do want to let you know that the Department is currently finalizing its comments, so we're not here to really speak directly to those comments and speak directly to that rule. However, I would say that the piece about the communication between agencies and the roles and how we carry those out, we do

have an agreement and an obligation with the Department of Public Health, so that if in the event while we are conducting any of these audits that we see something that we believe is a significant risk or imminent risk to human health, we will contact Public Health, and Public Health will then take their regulatory responsibilities to follow through on that.

And with that, my formal comments are done.

SENATOR GALGIANI: Thank you very much. I was wondering if you could share with everyone here how it was that the regulations and changes with regard to the Leafy Greens Commission came into effect following the outbreak in 2006. Maybe you can walk us through that process.

MR. JENSEN: Sure. I'll try to do it and not step on Mr. Horsfall's toes (who's with the Leafy Greens). But there's a marketing act in the Department—the Food and Agriculture—that authorizes the development and marketing orders, marketing agreements, associations, different trade groups, and that tool was used to develop the Leafy Green Marketing Agreement.

The difference is pretty technical, the difference between a marketing order and a marketing agreement. A marketing order: there's a proponent group that come to the Department, they develop those rules. There is an election. If a certain percentage, if it is approved by the rule, based upon the various rules that they have, then it becomes mandatory for every producer or handler or packer of that commodity that is petitioning for this; it becomes mandatory that they follow. So that's the California Cantaloupe Advisory Board. It is through a marketing order. So once that rule is implemented in the order and it's approved, it is mandatory that every single handler comply with that rule. A marketing agreement requires a lower threshold in terms of obtaining the authorization to enact it, and it is voluntary to join the agreement. But once you join, then the rules in that agreement are mandatory. And there's pros and cons to both.

SENATOR GALGIANI: Okay. Are you aware of any state laws or regulations that we should be looking at that perhaps might need to be changed in light of these new federal changes under FSMA?

MR. JENSEN: No, I am not.

SENATOR GALGIANI: Okay. Alright. Thank you very much.

MR. JENSEN: Thank you.

SENATOR GALGIANI: And with that, we'll call up the members of our second panel: Dr. Trevor Suslow, Extension Research Specialist with UC Davis; Dr. Michele Jay-Russell, Program Manager/Research Microbiologist with Western Center for Food Safety, UC Davis.

Thank you.

DR. TREVOR SUSLOW: Thank you very much, Madam Chair. Thank you very much for the opportunity to come at the outset.

I just want to make it clear that what I might share in terms of my experience-based observations and opinions are really offered by myself as an extension specialist in the Department of Plant Sciences at the University of California but not necessarily representing any institutional views on the subject matter of the informational hearing. I just wanted to share some brief comments to make sure that I put on the table a few things that from the many years I've been doing this seem apparent to me, at least, and I think maybe it seemed like some needs to be aware of for California.

It's really a privilege to serve the population of California in my capacity as statewide responsibilities in quality and safety of horticultural foods. And my program is really in applied problem-solving research, extension outreach, and education, and it's been dominated by issues surrounding pre-harvest through post-harvest produce safety since I joined UC Davis exactly 18 years ago. Throughout that time, I've tried to balance and provide leadership in balancing agricultural productivity and sustainability, environmental stewardship, as well as protection of the public health—sort of bringing 32 years of diverse experience within California both in the ag industry and now in academia. And for brevity, I'm just going to go through sort of a short list of expected impacts or observations due to the Produce Safety Rule on California farms and farming communities.

I guess it's my belief that for the most part, the California produce industry will not really see significant impacts of the Produce Rule for the majority in terms of the supply base as the programs they already have in place encompass much of the FSMA specifics, are generally more detailed and even more prescriptive, and will allow compliance with minimal modifications to whatever that final rule will be – and certainly are participating in comments to try to steer that for balance. Some of the proposed provisions, particularly in the ag water area, you know, I think really may expose California on-farm producers to both unnecessary liability and risk. An

example is no water quality standards for drip irrigation. There are many, many different parts and different perspectives on what should be in the final rule—knowing that there will be one—and it’s beyond, you know, the time available to go through it. But each individual one, depending on the nature of the operation and even where you are in the state, you may be challenged to comply with what those standards may be. But really, it’s those farm operations, especially small farm and limited-resource producers—who I interact with quite a bit—that don’t currently have a food safety plan, you know, and have some support resources through the UC Cooperative Extension, the Community Alliance with Family Farms, other programs, including those that will result from the products that come out of the Produce Safety Alliance developing the curriculum.

Some of the challenges and, you know, we don’t often like to, in these opportunities, talk about lack of funding, but I think we do have to face the reality that lack of resources to extend any of these programs statewide to the people that hopefully will want it and ready to embrace this, is really a barrier. How we will resolve that, you know, I don’t have an answer for that.

But what I’m really concerned about is that those that insist that produce safety expectations, including distilling down the Produce Rule to a single sheet—you know, “how-to’s”—have a high probability of ultimately making serious errors in compliance or in marketing contaminated produce. And we see many situations out there that perhaps aren’t an absolute risk but certainly have that potential. And knowing that each individual need to have a trained certified person on staff that’s gone through an FDA curriculum that’s been approved, that’s part of this Produce Safety Alliance, again, I think there is state-level support that we need somehow to help make that possible.

There is certainly a lot of confusion and concern among many in the farming community regarding the specifics of the rule and its proposed standards. Much of the language in that regulatory document doesn’t help the situation. But it seems that significant modifications will result from the public comment period. So specifically worrying about or reacting to likely impacts is harder, knowing that it’s highly probable that they will be changed in some way. But regardless, I think California really has a strong position to take advantage of the opportunities in the

Produce Rule to develop alternatives and agency-backed, agency-supported variances where they're allowable.

And really, distinct from passing an audit, I believe most farm operations are not adequately prepared to effectively conduct the type of on-farm microbial hazard analysis and prevent a risk identification. And they simply—you know, it's a daunting task. You know, both Dr. Russell and I are going to be launching a two-and-a-half day training program for food safety professionals to get them beyond some of the information barriers that they might have. Bringing that down to those with limited resources, those that, you know, perhaps need it the most, to at least have something in place is a bit of a challenge.

I know this is about the Produce Rule—and I'm wrapping up here—but I have far greater concerns for California on-farm production in regards to what may happen with the Preventative Control Rule, which really brings significant challenges and expectations to validation of risk reduction and risk management practices. And, you know, again, some very vague standards for measurable and enforceable verification at the farm level, at the packing facility level.

And again, working with the federal-level agencies, working within our own to improve the language that you're talking about, on-farm practices, I've always found that to be a barrier. So if they're talking about processing when they really mean packing facilities or on-farm packing is actually a significant barrier to just getting people's attention and communicating.

So, you know, overall, I think there are many aspects—that I'm sure you'll hear from the industry representatives—in potential impacts: economic, liability, environmental, negative environmental impacts potentially, but from the sort of science and extension outreach. We've been working on this for a long time. And I'd say it's more, you know, preparing and being ready to participate in whatever training and certification programs and additional research we're capable of.

Thank you.

SENATOR GALGIANI: Thank you. You mentioned that you're getting ready to have a two-and-a-half day food safety program. Is that something that UC Davis and California is just voluntarily taking the lead on or is that at federal direction?

DR. SUSLOW: No. This is something that comes out of my program and is also co-sponsored by the UC Davis Post-Harvest Technology Center.

And I'll just briefly share with you: When I first came out of industry—and it was really before microbial food safety was on the industry's horizon—and when I interviewed, I said, "I think I should make this about 10 to 15 percent of my program"—even though that's not what I was being hired for—"because it's coming." And then it came to dominate, and so I started doing a lot of training. The more advanced—the industries with more resources were participating, and we did a bunch of training. Shortly thereafter, you sort of saturated that market, if you will, and nobody would come to the others; so I haven't done one like this for at least ten years. And so we're just starting up again because looking at being part of the regulated community there's more interest and there is more need. So it should be an ongoing program for UC Davis.

SENATOR GALGIANI: Well, I commend you for doing it because obviously California, once again, is taking the lead on the whole food safety area, and this is one perfect example of how we're doing that.

Can you please describe the methods to prevent animal intrusion on fields that are currently in place?

DR. SUSLOW: I'll give you a very brief answer. Michele Jay-Russell, here, is really one of the leading experts in that. It really comes down to observation and trying to segregate crops that perhaps are more vulnerable, moving them from areas where animal intrusion would be more likely; trying to avoid—prevent putting crops between wildlife and habitat that they need to get to or a water source or things like that. Certainly, there are other things that tend to be of limited effectiveness in terms of, you know, disruptors or tracking and things like that, but really it's moved quite a bit away from the more draconian responses to, you know, selective areas or selective response through monitoring and then having standard protocols in place, knowing how to react should an intrusion event occur.

SENATOR GALGIANI: Thank you. Would you like to add to that?

DR. MICHELE JAY-RUSSELL: I was just going to add on to what Trevor said, that the approaches with animal intrusions over time, they stun—some of the research I'll talk about in a bit—have become more refined and very species and cite specific and that's why they're not as draconian; and we've been able to balance the environmental stewardship better. Also, there's been effort to connect growers with

wildlife professionals and conservationists so that there's more education on how to balance those goals.

SENATOR GALGIANI: Thank you. Thank you. And also for Dr. Suslow: Can you explain to us what it means to actually test for generic *E. coli*?

DR. SUSLOW: What it means? Let me see if I can do this.

The use of generic *E. coli* is meant to serve as an indicator of fecal contamination, not really, or not necessarily, an indicator of pathogen presence; and it can and is used in a variety of ways. Probably the most common way that it's used is in relationship to agricultural water, either for irrigation purposes, other crop management, foliar spray use, and the like. The difficulty is that research has shown over and over and over again that it is an imperfect indicator. It still can be very valuable. And I think certainly what our research and my research program has shown is that when the numbers are high and, therefore, well above the noncompliant level that are part of the current standards it is a very good indicator of likely recent fecal contamination and a good chance that you will find pathogens presence in the water source. That doesn't, though, tell you, really, anything that we've been able to determine in our Mediterranean, arid environment about probability of survival on the crop, transfer to the crop of these pathogens. So right now, it's the best tool we have in terms of feasibility, you know, lower cost and accessible and can be performed by a wide diversity of labs. But, you know, certainly research continues to work towards evaluating and bringing the cost down for those other types of indicators, which ultimately, I think, will be better indicators of a true risk of pathogen presence.

SENATOR GALGIANI: Okay. And then finally, have you had the opportunity to work with the Produce Safety Alliance?

DR. SUSLOW: Yes. I've worked with them since the beginning. I was co-chair of the harvest and post-harvest section; and I'm on the steering committee and working, looking at, and helping to help revise and streamline the curriculum that they're developing, which, you know, I do genuinely have some concerns about how they're going to get that through and get that out. Making it a mandatory requirement that, you know, every operation has somebody that's been through that accredited course and who's going to deliver it and how it's going to get funded, none of those answers are available that I'm aware of.

SENATOR GALGIANI: Yet.

DR. SUSLOW: Yet.

SENATOR GALGIANI: Thank you. Dr. Michele Jay-Russell, who, again, is Program Manager/Research Microbiologist with Western Center for Food Safety from UC Davis.

Thank you.

DR. JAY-RUSSELL: Good afternoon. Thanks for the invitation to share some of our research and outreach work.

Basically, I was going to share with you, or make you aware, of research and outreach programs that have been specifically funded to UC Davis by FDA in order to look at the Produce Safety Rule.

To give you a little bit about my background: Again, my name is Michele Jay-Russell, and I'm the program manager with the Western Center for Food Safety. This is an FDA Center of Excellence that's located at UC Davis. As far as my background: I am a veterinarian, and I also have a master's in preventive medicine and a Ph.D. in microbiology, and am board certified with the American College of Veterinary Preventive Medicine.

In my current position, I work actively in applied food safety research, outreach, and education. I work with Trevor quite a bit. We'll be at the training tomorrow and the next day and a half. My research program focuses on pre-harvest food safety of fresh produce with an emphasis in identifying and mitigating potential risks from fecal pathogen contamination of plants by domestic and wild animal intrusions, agriculture water, and animal-based soil amendments.

Prior to coming to UC Davis, I worked for the California Department of Public Health and served as a member of the CDPH-FDA Joint California Food Emergency Response Team (CalFERT). CalFERT conducted the 2006 on-farm investigation of a nationwide *E. coli* O157 outbreak that was linked to bad baby spinach ultimately traced to a single ranch in San Benito County. This spinach outbreak was a major impetus for implementation of the industry-based, voluntary on-farm food safety practices such as the Leafy Green Marketing Agreement –that will be talked about in a bit—as well as the proposed produce safety rules that are in the Food Safety Modernization Act.

So based on that background of my expertise, I'm going to talk about three bullet topic points that were sent in my invitation. The first one is "Current and future research investigating on-farm food safety practices."

Our center, the Western Center for Food Safety at UC Davis, is an academic center of excellence. We were established in 2008 as a cooperative agreement with the FDA CFSAN (Center for Food Safety and Applied Nutrition) Office of Food Safety. The center's scientists help support FDA's public health mission by conducting studies that address knowledge gaps surrounding the safe production of agriculture foods. Our center, a major goal has been to support FDA's implementation of the on-farm prevention-oriented activities outlined in the Produce Safety Rule. Western Center, in our five years that we've been in existence, has played a critical role in conducting studies that were used to inform policy, including the Produce Safety Rule that we're discussing today.

The center is co-located with Western Institute for Food Safety and Security (WIFSS) and the Center for Produce Safety (CPS), which enhances opportunities for collaborative research being co-located. Our location in California also gives FDA access to the expertise of agriculture scientists, veterinary and human health professionals, food scientists, ecologists, engineers, economists, and otherwise. Likewise, the proximity of UC Davis to over 50 percent of the U.S. fresh fruit, vegetable, and tree nut production, including California's Salinas and Central Valleys, is ideal for conducting research related to on-farm food safety practices. And FDA has often emphasized to us this is why they partnered with us.

FDA also appreciates that WIFSS is a partner with the University of California Ag and Natural Resources (UC ANR Cooperative Extension) throughout the state, which then links to an expansive boots-on-the-ground network of extension specialists and advisors in food production and ag throughout the country. The statewide presence of UC Cooperative Extension and the extensive resources of ANR have created unparalleled abilities to conduct on-farm, real-world research, technology transfer, and food safety that relates to FSMA.

I'm going to give just a few high-impact examples of some of our completed and ongoing research that specifically relates to on-farm food safety practices.

- One is field experiments, looking at the fate of *E. coli* O157 in field-inoculated lettuce, cilantro, and basil. That was in the Salinas Valley.

- Also in the Salinas Valley, we've done experiments to enhance FDA's produce risk model. We've had extensive epidemiologic studies, studying and strengthening good agriculture practices, looking at sources and risk factors.
- We've done work enhancing the safety of nut and nut products.
- And have had a small cost-effectiveness analysis of the Leafy Green Marketing Agreement in collaboration with Iowa State University economists.

In this upcoming year, 2013 to 2014, we were funded to start several new projects very specifically addressing on-farm food safety. Specifically:

- Evaluation of treatment and disinfection protocols for agriculture water and equipment.
- Determining the fate of foodborne pathogens, root crops and tree fruits.
- And validation of the proposed safety rules that relate to minimum application intervals for untreated biological soil amendments of animal origin.

So that's where we're at with the research.

The second question, related to the role of scientists in developing alternatives within FSMA, to address this issue: The Western Center and a network of collaborators created a framework for developing a research strategy and experimental design that would then generate data that could be used to support an alternative or variance to sections of the Produce Safety Rule. These framework documents, so to speak, address 1) agricultural water that has contact with fresh produce that may be consumed raw, and 2) the application of untreated soil amendments of animal origin on land used to grow produce that will likely be consumed raw. We published two peer-reviewed papers with open access in the *Journal of Food Protection*, a publication widely read by industry and other food safety professionals, to learn about these approaches for alternatives and variances.

Additionally, we partnered with the Center for Produce Safety and announced in 2013 a Request for Proposals that went out to other universities to provide data related to alternatives in ag water standards specific to the Produce Safety Rule. And as of now, four projects have been funded and are scheduled to be completed through June 1st next year, 2014.

And the third, final point was a question about our FDA funding related to education and outreach for food safety practices. And as Trevor talked about, at UC Davis a major goal of outreach, education extension has been to provide technical assistance to the farming community to adopt and comply with FSMA.

FDA has acknowledged specifically that they have a limited history with the agricultural community and seeks to use the strong relationships of academia and the relationships we have with the farming community in order to facilitate education and outreach. We have been working actively with FDA CFSAN to develop a technical assistance network to achieve this goal and have partnered with the Cornell University's Produce Safety Alliance to conduct "train-the-trainer" and "train-the-grower" programs in California and the western states. There's an expectation extension educators and county agents will assist with this effort, but as Trevor noted, there is no state or local funding to support that.

Additionally, WIFFS has a cooperative agreement with the FDA's Office of Regulatory Affairs (ORA) to assist in updating and redesigning courses for regulatory investigators and inspectors—so the other side, the people who are actually going to be doing the inspections. The largest effort they have currently pertains to the FDA and state employee course on how to conduct on-farm investigations, produce farm investigations, and this course has been given in California and several other states. As part of this new curriculum, the outreach team is standardizing the training materials so that all investigators are up to date on current farm practices and the methods for conducting on-farm investigations. The curriculum guides investigators to think about sources and routes and look for evidence of possible routes of contamination.

So in summary, much of the FSMA-related training and outreach material related to on-farm food safety practices is based on research that was done by UC Davis scientists, including myself, my colleagues in Western Center, Trevor's research program, and others. The close alignment of our centers and allied food safety programs on campus allows new research to then immediately be incorporated into training and outreach materials.

SENATOR GALGIANI: Thank you very much. You spoke about the methods that are used to prevent animal intrusion. Can you explain to us what is meant by co-management?

DR. JAY-RUSSELL: The idea of co-management is—there is an actual formal definition that I don't think I can remember word for word, but the basic idea is that 1) you have to manage food safety risks in an on-farm produce environment, and 2) you also have to manage conservation and water resources. And so, the co-management of the environment and the food safety risks is a common, common goal. And it's balancing concerns about wildlife habitat, water quality, soil health, nutrient runoff with also the important concerns of protecting the public health from contamination of fresh produce.

SENATOR GALGIANI: Okay. You described some of the research that is currently being done. In your opinion, what are the most important food safety issues right now and are they being addressed by the research that's currently being done or are there specific areas that you can point to that we should be looking at as policymakers?

DR. JAY-RUSSELL: Because I used to work in outbreak investigations, I often look back at what we learned from outbreak investigations. And, obviously, in the major areas of workers, worker hygiene, animal intrusions, animal risks, soil amendments, and water, all of those areas have specific research-related needs. Probably what we are hearing the most is, as Trevor mentioned, not finding a good indicator of water contamination, given the pathogen testing is very expensive and labor intensive and *E. coli* doesn't always correlate well. So I think water will continue to be a very important area of research.

And I mentioned a study that we're doing looking at the use of raw animal manure or stacked untreated animal manure. And the proposed rule has a nine-month interval between placement of the manure on the soil and harvest of a covered crop, and that is potentially in conflict with the National Organic Standard of 120 days. And so that's an area that we're looking to ramp up our research.

SENATOR GALGIANI: Okay. And how are these research studies actually funded? Generally, where does that come from?

DR. JAY-RUSSELL: For my program in particular, but also our colleagues', we do quite a bit of leveraging with Center for Produce Safety. So through this Western Center for Food Safety, FDA will give us seed money each year of kind of a base funding, with research priorities that they set in collaboration with us based on what we're learning from outbreaks in particular and also previous projects. As far as other

funding, we typically will take those projects and see if we can leverage them with Center for Produce Safety or USDA NIFA-type grants and at least match the funds to have a broader study. We have been, in doing that, expanding to collaborations outside of California and sharing some of what we've learned—especially in the Salinas Valley with our field trials and epidemiologic studies—bringing that to Arizona, Georgia, and other states, since we are probably ahead of everyone else in terms of dealing with some of the produce safety research and outreach.

SENATOR GALGIANI: And in California, do you have the opportunity to partner with others in the private sector to further some of this research?

DR. JAY-RUSSELL: Yeah. When we do receive Center for Produce Safety funds, they're often partially through industry boards, like the Pistachio and Almond Board. We've had private farmers give donations to support the Center for Produce Safety projects and the Produce Marketing Association and others. And then there have been specific—Trevor could speak more—but emergency response, rapid response-type projects that industry has helped out on when they need our expertise and lab assistance in particular.

SENATOR GALGIANI: Do you want to add to that? Would you like to add to that?

DR. JAY-RUSSELL: I put you on the spot.

DR. SUSLOW: No. That's okay. That pretty much sums it up. That really, you know, for me, came out of my interactions and the support that—very grateful for—from the California Leafy Green Research Program and the California Melon and Cantaloupe Advisory Boards in dealing with things that happen on the farm. And there's a real knowledge of gaining opportunity, and you have to sort of drop everything, assemble a crew, and go down to take advantage of that, as well as try and provide support and some answers to help in their decision making, help, you know, an informed decision. The Center for Produce Safety has picked up on that, and there have been a few, now, where an opportunity that is sort of out of sync with their normal funding cycle comes up and then the industry helps fund part of it. The Center uses some of its discretionary funds to fund the rest. And they're all typically short term projects, you know, six months, eight months, and really, you know, develop some actionable results. That's the point.

If I might stretch that a little bit and indulge: One thing. I made some scribbly notes listening to Rick Jensen talk that I didn't want to be overlooked and that actually revolves around one of the rapid response efforts that I currently have that the Center for Produce Safety is helping with. One of the impacts that's been going on for a long time, since produce safety sort of got greater attention, but because of the proposed Produce Rule a lot of misguided or ineffectual technologies are being pushed out to growers, shippers, and handlers that really add cost and no benefit. And it's, you know, our collective responsibility to try and help inform and provide data to substantiate or to maybe potentially make effective that technology, but there may also be a role for agencies to provide some oversight for some of these things. And I will just go ahead and say that there are, really, food safety predators, and we spend a lot of time working to try and prevent those negative impacts.

SENATOR GALGIANI: Thank you. Thank you, both of you, for your time today.

DR. JAY-RUSSELL: Thank you.

DR. SUSLOW: Thank you.

SENATOR GALGIANI: Our third panel has been asked to provide information about the potential impact of the proposed Produce Rule on California on-farm ag production and food safety. So at this point in time, I would like to welcome Scott Horsfall, CEO of the California Leafy Green Marketing Agreement; Hank Giclas, Senior Vice President, Western Growers Association; and Jamie Johansson, Second Vice President, California Farm Bureau Federation.

Thank you.

MR. SCOTT HORSFALL: Thank you, Madam Chairwoman.

My name is Scott Horsfall. I am the CEO of the California Leafy Greens Marketing Agreement. I thought I'd give you a little background. You've heard about us this morning already, but I'll fill you in a little bit on the background, where we came from, and then talk about what we see as some of the major issues with the Produce Rule as proposed.

As you've heard this morning, in the fall of 2006, there was an outbreak of *E. coli* that sickened over 200 people and tragically killed four. That outbreak was eventually traced to California-grown spinach from San Benito County. At the time of the outbreak, or at the peak of the outbreak, the FDA issued a "Do not eat spinach"

order, which saw sales plummet virtually overnight to virtually nothing, and our industry has never been the same since.

Following that outbreak, in 2007, the California Leafy Greens Marketing Agreement was created, commonly referred to as the LGMA. We are an instrumentality of the state of California, so we operate under the authority of the state, as Rick Jensen explained it this morning. But our organization is a little different than most marketing orders and marketing agreements in that we were created to verify through mandatory government audits that leafy greens farmers and handlers are following a set of accepted food safety practices. The idea, obviously, was to address the issues that came to light through the outbreak in 2006 and to create a program that would help the entire industry raise the bar for food safety.

We've seen the program become something of a model for other industries. In Arizona they created a leafy greens marketing agreement as well. The tomato farmers, cantaloupe farmers, and others have adopted the basic model in their efforts to improve food safety practices as well. And we created the program, or we created this model program by requiring mandatory government audits which are based on—and by having a program that's based on sound science and best practices and, really, the work on driving continuous improvement on the farm. Our goal is to change the culture of food safety on the farm and those are the tools that we use to get there. The marketing agreement is voluntary to join—as was explained earlier—but handlers who represent roughly 98, 99 percent of all the leafy green production in the state are members, and so when they do join, they're obligated by the law to follow the rules that we set down.

The LGMA has been very interested in the Food Safety Modernization Act, particularly the Produce Rule, because that covers on-farm food safety, which is also the area that we are involved in.

In general, the LGMA supports the proposed Produce Rule. You know, our farmers understand that—at least with our product—we're dealing with products that are consumed in large quantities by a lot of people in the home and restaurants and those products are seldom cooked. And so, we recognize that leafy greens absolutely must be safe. And so, we recognize the critical importance of food safety practices on the farm. We do believe that the proposed standards will help protect public health and create a safer food supply.

We were actually pleased to see that the proposed rule pretty closely aligns with the food safety practices that we enforce in the leafy greens industry, although most of our requirements go quite a bit further than what is proposed in the Produce Rule. But there are elements in the proposal that we believe can be improved or that should be changed before they're finalized. And much of the input that we're providing the FDA is kind of based on the last six or seven years that we've been in business because we've overseen the implementation of the set of practices that is very similar to what is being proposed.

We will be offering comments to the public record, but I'm happy to share a little bit of what we've identified as some key issues today.

One big issue specific to us—but it does have wider implications—is that FDA has provided a list, a definitive list, of products that are exempted from the provisions of the rule because they are seldom consumed raw. They had a database that they referred to in order to make that list. And one of the products on the list is kale. As you may know, kale is enjoying something of a boom in popularity because of its nutritional value, and it is decidedly a product that is being consumed raw. We think that its inclusion on that list is inappropriate. We want kale to be covered. We're going to continue to cover it, but it also kind of highlights a problem with even having such a list because as markets change growers will adjust their production accordingly, and what is consumed one way today may be totally different five years down the road. And we're concerned that if you enshrine a list of exempted products in regulation it may be impossible to change it when it needs to get changed.

Second big issue for us has already been raised this morning and that's some of the proposed regulations for agricultural water, particularly the requirement that surface waters be tested on a weekly basis for contamination. We will be submitting data both from the Center for Produce Safety and from our own audit records showing that a weekly water test is both excessive and unnecessary based on our history over the last seven to ten years. Water tests are not inexpensive and requiring them on that frequent a basis could create a very heavy burden for farmers and really wouldn't result in corresponding increase in food safety.

Another big area of concern for us has to do with definitions. It was touched on a little bit earlier I think in Trevor's comments. All of the proposed rules include

definitions that are confusing and at times contradictory, and we will be offering a number of suggestions for clarifications.

For us, one of the most problematic has to do with definitions of “processing” and “manufacturing.” In the proposed rule, the FDA has included a new definition of processing that lists several practices that they will consider as being “processing” or “manufacturing” and then would thus conceivably come under the Preventive Practices Rule. The activities listed include among many other things: washing; trimming of outer leaves; stickering; cutting; and coring. Our concern is that defining common harvest activities as “manufacturing” could make all ranches and fields subject to the Preventive Practices Rule rather than the Produce Rules. These things ought to be covered by food safety rules. We absolutely agree with that. We just think they should be covered by the Produce Rule. And as written, there’s an awful lot of confusion and contradictory information.

One part of the rule that we strongly support has to do with training and education. Our program places a very high priority on training workers, and we believe that changing the culture on the farm is not possible without regular and thorough training of everybody involved in growing, harvesting, and transporting produce. So we support the FDA’s call for comprehensive training. What we will be encouraging them to do, however, is to recognize industry-specific training programs, like those in our industry and others, as meeting the requirements of the rule. I think Trevor touched on this a little bit earlier as well. We’re involved with the PSA as well, and there will be a curriculum that emerges from that, but we believe there should be some mechanism to recognize existing programs or programs that can be tailored to that curriculum as meeting the requirements of the rule.

And then finally, the most important thing for us is that we are asking the FDA to utilize food safety programs that already exist to verify compliance with the new rules once they’re finalized. Programs like ours and the Arizona Leafy Greens Marketing Agreement, the California Cantaloupe Advisory Board Program; these are all perfectly positioned to fulfill this role.

I’m sure you’ve heard this, but in our world audit fatigue is a very real problem. People are being audited on the same farms, the same documentation, the same paperwork over and over again, and we really do not want to see a situation where yet another layer of audits and inspections gets layered on top of what they’re already

dealing with. Just by utilizing the existing marketing agreements for leafy greens in California and Arizona, the FDA can be assured that over 90 percent of the leafy greens grown in the country are being grown under a set of food safety practices and that are meeting the specific standards that are required under the law.

So by embracing food safety standards to the Leafy Greens Marketing Agreement, our industry has raised the bar for food safety, and we are changing the culture of food safety on the farm. Since our programs have been implemented, over 300 billion servings of leafy greens have gone to the marketplace grown under auspices of either the LGMA program here or in Arizona. We believe that the requirements under FSMA once improved through the comment process can help change the culture of food safety for the entire produce industry, and that's why we, in general, support the rule as proposed.

Thank you.

SENATOR GALGIANI: Thank you. You mentioned that the testing that occurs for the Leafy Greens Marketing Agreement with regard to ag water pretty closely is in line with what's being proposed under FSMA, and you said that you will be submitting documents for the proposed new rule saying basically that the weekly requirement for testing is overly burdensome and won't necessarily produce additional better results. Can you give us a simple explanation about how the testing does occur under LGMA?

MR. HORSFALL: Sure. In our program—and I will clarify something if I said it earlier—the requirements in the proposed rule are not—well, in some ways they're aligned with our program in the sense that the water standard being looked at is the same for what they talk about. They call agricultural water what we call foliar applications. So the water requirement is the same level. We also have requirements that are not in the Produce Rule for testing of other water used in agriculture, water that doesn't touch the product, so there are more requirements in that regard. But as far as the water testing that goes on, we require a monthly water test of all water sources. Now, you can get exemptions for six months for some sources of water. We're not even saying that that's necessarily what should be the national standard; that's what exists in our program; and that has led to the collection of a huge number of data points over the last six or seven years that shows to a very, very high extent that the water supplies being used, at least in California and in Arizona, are very, very clean. And so, you're not going to move the needle any further by requiring a weekly

test. And we can document that the testing that's already been done has painted a very clear picture of the quality of the water in California. We do believe regular testing is important according to local conditions and risk analysis, but requiring a weekly water test we believe is excessive.

SENATOR GALGIANI: Okay. And with regard to audits, do you anticipate that the federal government might be implementing some changes requiring federal audits on top of the audits that are already occurring?

MR. HORSFALL: Well, we don't know. The rules are silent on the question of verification. What we're saying is that where there are industry programs that are already in place that can verify that our members are, in fact, in compliance with the rule it makes sense for the FDA to work with us. So we're proposing through a memorandum of understanding or something like that, but, you know, we don't know what approach they're going to take overall for verification, but we stand ready to work with them to verify that our industry...

SENATOR GALGIANI: And it may be that they don't have an approach yet, but they're waiting to see what California does and perhaps use what we already have in place, hopefully, rather than creating a new program.

MR. HORSFALL: But hopefully, we'd use what is already in place, not just in California in other states as well.

SENATOR GALGIANI: Yes. Okay. Thank you. Thank you very much.

MR. HORSFALL: Sure.

SENATOR GALGIANI: Next, Mr. Hank Giclas, Senior Vice President, Western Growers Association.

MR. HANK GICLAS: Thank you, Madam Chairwoman. And thank you for the opportunity.

As background, Western Growers is a trade organization that, since 1926, has represented local, regional family farmers of all sizes that are growing fresh produce in California and Arizona. Our members provide half the nation's fresh fruits, vegetables, and tree nuts, including a third of America's fresh organic produce.

For all intents and purposes, our entire membership is subject to the Food Safety Modernization Act and the companion rules that are required to implement this law. The Produce Rule, the topic today, will for the first time mandate preventive practices in the field. We have found through conversations with our members that

you can't really generalize the impacts of the proposed rule; each operation is different. The food safety programs in place today are at varying levels of sophistication and will require varying levels of change in order to conform to the Produce Rule as it's proposed. For some operations, what FDA is contemplating will not change their current practices or increase their cost. For others, the proposal may require significant change and corresponding increases in operational costs.

Regardless of what FDA does or does not formalize in the final rule, it's important to note that the consumers in the marketplace are also demanding improved food safety on the farm. And it's Western Growers' strong assertion that every agricultural operation who sells fresh fruits and vegetables for human consumption should have a strong food safety program in place that is geared towards preventing contamination in the field. That does not mean that "one size fits all" or that these programs should be required to address all risks equally. It does mean that individual operators, regardless of the size of their operation or the commodity they produce, should conduct a hazard identification and analysis of their unique operation in their unique setting and design and implement preventive practices to address the risks that may be presented in that setting. In this regard, we believe the FDA got their proposal for standards correct, and they focused on key areas of risk. The key areas are water, animals, biological soil amendments of animal origin, workers, and equipment. These have been understood and recognized by farmers and food safety practitioners alike for decades as potential points for introduction of contaminants into a produce operation. In fact, almost 20 years ago, Western Growers offered the first ever good agricultural practice document to help producers sharpen their preventive practices in the field around these key areas.

I would like to focus the rest of my remarks on the areas in the Produce Rule where Western Growers will be focusing some of our comments. We plan to comment on every subpart in each rule, but there are a few things that are notable for this hearing today.

First and most significant area where we think change is needed, as has been alluded to by many of the other speakers, is in FDA's proposal in their provisions relating to water. The basic requirement in this section is that all agricultural water must be safe and of adequate sanitary quality for its intended use. This overarching

tenet has been embedded in food safety guidance for over 20 years. The struggle is: how do you demonstrate that the water is safe?

In recent years, a large cross section of the industry has worked to develop a combination of qualitative and quantitative checks to ensure that water is safe. Visual inspections coupled with testing of water were first formally used by the leafy greens industry when the California Leafy Greens Marketing Agreement was formed. At the time, we were prompted by the marketplace and the California Legislature. Industry worked with FDA, the California Department of Public Health, and the academic community to develop metrics for agricultural water. Metrics for water sources and uses have to consider which microorganisms to test for and the test methods, the action levels to apply, and appropriate responses.

An ideal test method would detect all pathogenic organisms present, but this is not scientifically or economically feasible for many reasons. Concentrations and pathogenic microbes can vary widely in fecal matter. Existing test methods may not be able to detect a wide variety of pathogens that might contaminate water, and for these reasons, as well as guidance from various regulatory agencies, we opted for the use of an indicator microbe, determined to be the most effective and efficient testing approach. Generic *E. coli* is generally nonpathogenic, thus using it as an indicator organism results in action levels that are not necessarily health-risk based, but the action levels based on generic *E. coli* concentration should not be considered as separating safe or unsafe levels. They're only to be considered as indicators of fecal contamination or increasing bacteriological densities. FDA has approached water much in the same way, and as such, many in California are used to and will not have much difficulty complying with or understanding the proposed standards. That said, there's a lot of criticism over the use of generic *E. coli* as an indicator.

Western Growers believes that a metric for water is an important part of assuring water quality, and we believe the marketplace will continue to require water testing regardless of what FDA does. When another, better indicator is developed or identified, we will embrace and extend it to industry programs, but right now, generic *E. coli* is the best we have. So the major questions for us now surround how frequent to test and what to do when you identify numbers that exceed action levels.

What Western Growers will be advancing is a whole system concept for water quality in our comments.

We would like to encourage folks to look at the system design and construction. Does it minimize the potential for the introduction of contaminants?

We want them to take into account system maintenance. Are things like dredging avoided? Are conveyances cleaned prior to this season? Is access controlled?

System monitoring is important. Is a sanitary survey conducted? Are there visual inspections?

And then look to testing to verify that water is within the system specs.

We'll also emphasize more risk-based testing, such as after storms, approximate to sources of potential contamination.

Our comments in this area are intended to point out the need for a better, more holistic way to assure water quality. We think there's way too much rote, calendar-driven testing today. And Scott talked about the seven-day example that's in the proposed rule. But even with the California Leafy Greens Marketing Agreement, we know in advance of doing the test in many of these water systems what the result of the test is going to be already. So in our minds, that's money that could be better spent in other areas to prevent contamination.

I think FDA agrees. They've already acknowledged publicly that their proposal for water can be improved. They've reached out to industry, and they've asked for better suggestions, as well as initiated the research that Dr. Russell talked about to better inform their decisions. In the meantime, the water provisions will not impact anyone for four or five or six years from the effective date of the rule. So if the rule goes into effect in 2015 as mandated by the court, the soonest that the individual companies will have to comply with water standards is 2019. We remain confident that by that time we'll have a more practical, protective system in place. And then in the meantime, what we are currently doing here in California is best in class.

The second area I wanted to discuss briefly is the area of biological soil amendments. FDA set up standards for treatment and application intervals for biological soil amendments of animal origin that Western Growers has some concerns with.

The first is for untreated biological soil amendments of animal origin or raw manure. FDA is allowing its use in the field with no waiting period if it will not contact the crop during or after application and after a nine-month waiting period if it does not

contact the crop during application and minimize the potential for contact after application. There are numerous pathogen studies in the field environment that show organisms such as *Salmonella*, *E. coli* O157, and other pathogens may be present in manure can survive for very long periods of time in the soil. Nine months may or may not be an adequate waiting period, but Western Growers will continue to discourage the use of raw manure in a fresh produce operation.

We recognize the benefits the manure brings to things like tith and its source of nutrients for agricultural commodities. We know it's a critical input in organic systems where synthetic fertilizers are not allowed, and we're supportive of the use of properly treated—not raw—manures. FDA's proposed rule allows for the use of treated manure and only requires additional application intervals when composted manures will be applied in a manner where compost may contact that covered commodity during or after application. A 45-day application interval has been part of the Leafy Greens Marketing Agreement since its inception, and both organic and conventional growers who are growing under the LGMA have been following this without an issue.

Finally, I want to talk about what we believe is necessary to ensure that the rule is flexible, adaptable, and scalable for the diversity of regions, commodities, and growers throughout California: that's an expansion of the alternatives and variance allowances in the proposed rule. The proposed rule allows farms to establish alternative practices or alternative standards for certain specified requirements of the rule. The specified areas are: requirements for testing ag water, composting treatment processes, and the minimum application intervals for untreated biological soil amendments of animal origin. In these cases, the proposed rule would allow farms to use alternative practices or standards to those proposed if adequate scientific data or other information demonstrates those alternatives provide the same level of public health protection as the proposed rule and would not increase the likelihood that covered produce will be adulterated.

Western Growers believes that the FDA should open up the alternatives allowances beyond the narrow specifics that are outlined in the proposed rule. Any practice or standard that can be demonstrated by scientific data or other information as being protective should be allowed by FDA. In addition, we believe that FDA should communicate clear criteria on which these alternatives will be judged and deemed

protective; and the growers who want to review of their alternative should have an opportunity, even through FDA or a credible third party, to submit alternatives for peer review. This is similar to a request for a variance wherein a state or a foreign government can petition on behalf of a region, commodity, group of growers, et cetera, for relief from the proposed standard based on their local growing conditions, procedures, processes, practices followed under the variance are reasonably likely to ensure that produce is not adulterated.

Request for variance is submitted by a state or foreign government and reviewed by FDA prior to being approved, or not, for the affected state, region, or growers. This process gives us confidence that the practices, region, et cetera, have been examined by FDA and deemed reasonably likely to ensure the produce is safe. A similar process should serve for alternatives. In addition, we believe the third-party organizations, such as Western Growers, should be eligible to seek a variance on behalf of members or groups of members if we can meet the same standard of reliable scientific data or other information to support the request.

In closing, the proposed standard will have some impact on every California produce operation. But the public and the marketplace are demanding it along with a large cross section of industry. The proposed rule needs work to ensure that it is not only protective but practical. The FDA needs assistance to ensure that their rule is finalized in a way that is reachable for all firms.

Western Growers will continue to work with the agency, the academic community, and other ag groups to make sure every serving of California fresh fruits, nuts, and vegetables is safe at the plate.

Thank you.

SENATOR GALGIANI: Thank you, Mr. Giclas. Is Western Growers looking into getting a variance at this point?

MR. GICLAS: At this point, we're still trying to sift our way through the multiple rules that are on the docket, so we have not necessarily been approached by any individual commodity group who's thinking about a variance.

SENATOR GALGIANI: Is there anything that jumps out to you that looks like it could be problematic or warrant the request of a variance?

MR. GICLAS: Well, there's been a lot of conversation about water. There's certainly a lot of data that shows that large areas of water, both surface and

groundwater, meet the standards that have been proposed by FDA. But we have heard anecdotally from people in California—and we certainly are aware of other areas of the country—where water will not meet the standard routinely that FDA has proposed. But we also know that produce has been coming out of those areas for years and years without incident or without, you know, contamination. So one of the things that's being looked at is what is going on between the last irrigation and the actual shipment of the product. There's potential for die off if there is any contamination on the product itself between that last irrigation and shipment, right. So some of the commodities are looking at either establishing an alternative to the water standard or a variance based on their area by conducting studies that show there is effective pathogen die off between the use of substandard water and shipment. And that would be one of the areas that we know that here in California there is certain commodity groups that are interested in pursuing as well.

SENATOR GALGIANI: To whom do you currently turn to for expert help and advice, and who would you say that your members turn to, as well, for expert help?

MR. GICLAS: I think it depends largely on the issue and maybe secondarily a little bit on where they are. I mean, the UC system is recognized as—including the folks who are in the room are recognized as among the best in terms of food safety expertise in the country.

SENATOR GALGIANI: Agree.

MR. GICLAS: But there are others in other areas of the country and in Arizona where we have members who also have expertise in food safety. That's from the academic standpoint.

There is a huge investment of industry, you know, intelligence and capital, that's constantly working on advancing food safety in entities like the Leafy Greens Marketing Agreement and the Cantaloupe Marketing Order where, you know, food safety experts from industries and academics and, you know, regulatory entities come together and sort of put their collective minds to how to do the right thing.

SENATOR GALGIANI: Okay. Thank you very much.

And now if we can turn to Jamie Johansson, Second Vice President to the California Farm Bureau Federation.

MR. JAMIE JOHANSSON: Thank you, Madam Chair, for the invite to be here today. I do serve as second vice president of the California Farm Bureau, but I also

farm up in Butte County and also serve. But again, thank you for this opportunity to comment.

The California Farm Bureau Federation is California's largest farm organization, comprised of 53 county farm bureaus representing over 74,000 agricultural, associate, and collegiate members. The grower-members of farm bureau are committed to producing the safest food in the world. It is our passion; it is our livelihood. The mission of farm bureau is to promote agricultural interests throughout the state of California and to find solutions to the problems of the farm through responsible stewardship of California's resources.

The Farm Bureau appreciates the heightened attention given to food safety in recent years by federal officials, most notably beginning with President Obama's Food Safety Working Group. We believe measures can be taken at the federal level to further enhance the goal of improving the safety of our food. We have a strong record, encouraging continued collaboration between the FDA, USDA, and industry, applying the best available science in order to achieve our collective food safety goals. Throughout the deliberation of FSMA in Congress, the Farm Bureau expressed strong opposition to the idea of creating mandatory, enforceable regulations that define how farmers grow and harvest their crops. Our position against such enforceable regulations is best expressed in the policy statement adopted by our state and national membership. We support efforts to develop food safety guidelines to help prevent microbial contamination of fresh produce. The guidelines must take the form of good agricultural practices rather than federal or state mandates. Our policy is not just saying what we don't want. We have a long list of food safety principles that includes, for example, adequate funding of government's food and feed safety and protection functions, increased education and training for inspectors, and research and development of scientifically based rapid testing procedures and tools.

Additionally, we expect the government will provide accurate and timely responses to outbreaks that identify contaminated products and then to remove them from the market and to minimize disruption to producers. And as a check against unnecessary or unwarranted regulatory intrusion, we support indemnification for producers who suffer marketing losses due to inaccurate government-advised recalls or warnings. While the issue of indemnification is not included in the Produce Safety

Rule, we see it as an important discussion item when discussing new mandatory rules and standards.

We look to the California Leafy Greens Marketing Agreement as a model for creating food safety standards that reflect our position on guidelines. The LGMA is a voluntary agreement with a government oversight component. It was formed with significant input from California's leafy green growers and handlers and food safety scientific experts.

The administration and the FDA should be aware that the federal regulation requiring farmers to grow and harvest crops is unprecedented. In our view, a broad overreach of executive power. Under a regulatory scheme, the science would have to be foolproof, but it is clear there are still many unanswered scientific questions related to food safety. The unintended consequences of well-intentioned rules create a climate of overregulation, unnecessary civil or criminal penalties, competitive disadvantage with our trading partners, and serve to drive the market away from growing regulated or covered crops. In a time of tightened budgets, it is well understood that FDA will not have sufficient funds for oversight of this rule. We fear that the California Department of Food and Agriculture will be left to carry the burden of these oversight requirements, and CDFA is not equipped with enough funding to enforce this rule.

Since the Produce Rule was introduced in January 2013, industry and growers have asked for extensions as each deadline loomed. Currently, industry and growers are almost unanimously asking that the FDA release a follow-up produce rule that will be available for another round of public comment. We also note that the proposed rule amounts to hundreds of pages of numerous subparts. We ask that a second proposed rule be simplified and reviewed by farmers before publication so that its requirements are clear and not open to interpretation. For example, the word "adequate" is used 221 times in the proposed rule; the terms "reasonably likely" is used 80 times, and "reasonably necessary" is used 50 times. The words and terms are very important in advising growers of the standards with which they must comply; yet, we believe they are not reflective of the statutory requirements of the standard to be science-based minimum standards. A simplified rule in each of these key areas: water, hygiene, et cetera, would encourage increased public comment and more of a collaborative environment for the regulated community and the regulator to work together. As American Farm Bureau Federation noted in formal comments submitted

three years ago prior to FSMA, the Farm Bureau urged FDA to focus any produce safety regulations on those commodities or commodity groups that have been associated with human foodborne illnesses. Despite congressional intent in directing FDA to concentrate FSMA rulemaking on these commodities, FDA rejected this approach. The FDA should follow congressional intent in their second proposed rule.

We cannot overemphasize that regulating low- to no-risk commodities will place undue hardships on thousands of California growers. We support variances and/or exemptions of commodities that are examples of raw agricultural commodities with no known foodborne illness outbreaks. We ask that the FDA eliminate the blanket approach taken in the Produce Rule and instead do what Congress intended: to exempt low-risk fruit and vegetables. California's producers are proud of their food safety record, and their actions show a willingness to adopt innovative food safety practices.

As noted earlier, farmers are very much aware that their livelihood depends on the safety of the food they produce. We are accomplishing a great deal as we evolve and enter voluntary agreements. In light of these concerns, we look forward to working closely with you in the future on food safety matters, especially as it impacts California's fresh produce growers.

Thank you again for the opportunity put these comments on the record.

SENATOR GALGIANI: Thank you very much.

In your view, what are the big challenges to complying with FSMA?

MR. JOHANSSON: Well, the biggest challenge right now is the uncertainty facing farmers. And as a farmer, what are we going to be required to do? How is that going to vary region to region? Is it going to be a blanket approach which, you know, obviously from the technical people here, is not advisable? With the diversity of California agriculture, comes a complexity that the rest of the country, basically—in my travels—can't quite comprehend. And even in California, that complexity escapes a lot of us. And so applying a rule back in Washington, D.C. that applies anywhere else really is going to have different ramifications for California producers. Certainly, again, I think all of us in farming, we recognize the duplication of documents and all the paperwork that's going to be required in ensuring that that is streamlined, that accessibility of training and education is available for all farmers. We're proud at the California Farm Bureau of our close relationship and our historical relationship with

the UC Extension offices, a natural place. But, again, it's going to be achieving that funding level in a day and in an economic time that we live in to ensure that all farmers and ranchers have access to education necessary to comply with the rule, whatever that may be.

SENATOR GALGIANI: Thank you. Thank you very much.

And for our next panel, if we could call up Judith Redmond who is a partner with Full Belly Farm and a member of the California Certified Organic Farmers; Christopher Valadez, Director, Environmental and Regulatory Affairs, California Grape and Tree Fruit League; and Bob Blakely, Director of Industry Relations, California Citrus Mutual. Thank you.

Good afternoon. Thank you.

MS. JUDITH REDMOND: Good afternoon. Thank you.

As you mentioned, I'm an organic farmer. I'm from western Yolo County. I own a 350-acre farm that grows a diverse mix of certified organic fruits, vegetables, herbs, and nuts, the majority of which would be covered, I believe, by the proposed rule. We've been in operation as an organic farm since 1985, and we sell our produce at farmers' markets, to CSA members, restaurants, stores, and wholesale distributors. Because we know many of our customers as individuals—we interact with them on a weekly basis—I can say in all sincerity that nobody has more interest in safe food than farmers.

So thank you very much for the opportunity to comment on the proposed rule, and thank you very much for your time in considering our concerns.

Overall, I think that there are several requirements of the rule that aren't, in fact, unfortunately, science based and that may not address food safety problems. I think that the proposed rule doesn't address some of the most risky parts of the food system and, conversely, also does not encourage some very beneficial practices. So I had a few examples that I was going to give. One of them was the water element of the rule which has been discussed quite a bit already. But I think that I could, you know—and I agree with the comments that the other panelists have made about the water standard that—we have concerns actually that the standard itself is based—it doesn't have a clear correlation with pathogens in an agricultural situation and also, that because it's a generic *E. coli* and not—if it's just an indicator, that it's not really clear how it would relate to serious human pathogens. And all of that has been

mentioned here already and researchers like Trevor Suslow and Michele Jay-Russell are going to be doing some work on that hopefully to shed light upon it.

But I thought it would be interesting, even though it's already been discussed, just to talk a little about the costs of those tests because it may be possible that the FDA doesn't have a sense of how it would play out on the ground, on a farm. We irrigated our farm, a combination of both surface water and ground water. And as you know, the proposed rule would require the weekly testing of surface water but quarterly testing, I believe, of groundwater during irrigation system—excuse me, during the irrigation season. So we go all 12 months of the year, year-round. And let's say that it's a year where we have some rain—let's pray that it's a year that we have some rain—and that we're only irrigating from these sources for about 36 weeks of the year. We have pumps that pull surface water out of Cache Creek in four different places, and we have ten different wells that pump groundwater. So our very conservative calculation is that the proposed rule would require us to do at least 174 annual microbial water tests in a wet year where we were irrigating 36 weeks. That's with these four surface water weekly tests and the ten groundwater wells doing quarterly tests.

We do test our water regularly already. We do have a good agricultural practices food safety program at our farm, and so we know what would be involved. And quite recently, there is a local lab that has made it easier for us to do these tests, less time consuming. But if this one part of the Produce Rule did become law, we calculate it would cost our 350-acre farm almost \$12,000 in labor and laboratory costs—and we can document that for you—and that's just for the testing alone. And the proposal is that this would be repeated by every single farm along our creek and along the aqueducts. We've talked to the irrigation district locally about having it done regionally instead of by every single farm, and they have some concerns about that that I think are very, very interesting to know about. But I think a similar calculation could be done for a number of the requirements in the proposed rule, and all of that. You know, there's the maintaining the paperwork, implementing the system, implementing different systems and activities, working with auditors and inspectors, and I think that would all be really great and fine if it were very certain that these requirements would result in decreased levels of food contamination. So that's—it's

very, very important that if you're going to have these increased costs that it actually is effective.

SENATOR GALGIANI: You said—excuse me. You said that it would be \$12,000?

MS. REDMOND: That's for labor, our labor—which we're very, very hard working and efficient—that's for our labor, plus it's \$50 a test. So there's 174 annual tests. This new lab that does it is much, much better than what we were using previously. So it's \$50 for each of those 174 annual tests plus our time. So I think in the Salinas Valley, the calculations might show that it's a little less expensive because they've been doing so many tests. There may be a greater number of labs there. But that's what it would cost us in Yolo County, for sure, because we're doing it already on a quarterly basis.

But the second issue, one that hasn't come up a lot today that I wanted to mention and to raise: the new requirements imposed on the use of compost. Like many farms, Full Belly Farm's fertility program includes the use of compost on every field a minimum of once a year but usually about three times a year. And I'd like to note that few organic farmers in California use raw manure despite statements that you might have heard to the contrary. Most certifiers have been really encouraging it, implementing [sic] people to use compost, not raw manure. Raw manure is used very rarely on organic farms in California.

Now in FSMA, Congress made it clear that the rules should not conflict with or duplicate National Organic Program standards. That's the federal law that regulates organic agriculture. And current NOP regulations do not subject compost to any waiting period between application and harvest, while the proposed rule requires a 45-day wait. Compost that's manufactured, according to NOP (National Organic Program) rules, is subject to rules about how hot it gets, how often it's turned, and how long it sits before it can be delivered to the farmer. In addition, before it's delivered, it has to be tested for at least three human pathogens.

So just one idea: if there is really clear evidence that a 45-day interval improves the quality of compost, I think the FDA should consider other options. For example, why don't they require the compost manufacturer to hold the compost for an additional 45 days? There are a lot fewer compost manufacturers than there are farmers; why must the burden be on the farmers? But, really, contrary to all of that

and contrary to the FDA's apparent concern about human pathogens and any association that they might have with the use of compost, there's a wealth of data that shows that using compost in your soil contributes to a very healthy microbial balance and makes your soil much more suppressive of human pathogens than otherwise. So we, as organic farmers, suggest that the FDA should not only drop the 45-day waiting period but they should be advising farmers to use compost. It's a beneficial practice. It makes your soil more suppressive of human pathogens, and there's a lot of data and science to back that up. There's absolutely no scientific support for the 45-day waiting period. And so by discouraging the use of compost, the rules may again be defeating their original purpose.

The third area, the final, the last area that I just wanted to briefly mention is that in the preamble to the rule the FDA asks if the type of supply chain used by a farm makes a difference. And our experience at Full Belly Farm argues that short supply chains can potentially have advantages for food safety and perhaps that that could be considered by the FDA. In the case of our farmers' markets and community-supported agriculture program, fresh fruits and vegetables are harvested at our farm directly from the field on one day and get to the consumer's kitchen the next, and that's a short interval and I think has obvious benefits in terms of limited potential growth of pathogens between harvest and the kitchen. That's one advantage.

Another advantage of the short food supply chains used by not just Full Belly Farm but many farms that are a part of this whole local foods movement is their transparency regarding both production methods and the provenance of the food. This transparency is a fundamental building block of the local foods movement. And, again, I think it has clear advantages in terms of food safety.

CSA members and farmers' market customers know all the time where their food comes from. But that transparency in terms of the provenance of the food and the production practices of the food isn't just limited to farmers' markets and CSAs because the stores that we sell to have labels showing where the farm, where the food was from in the store, and the wholesale distributors that we sell to. They work very, very hard to provide accurate information on their availability and price lists to their customers. And I think that is a contrast to some segments of the food system where food from various different farms and even from various different regions is mixed together. And in fact, sometimes the food manufacturers resist efforts to provide

transparency to their customers, so it's possible that there are some advantages to short supply chains.

One last thing that I think is interesting to think about in that regard is that many of the diverse vegetable growers like us and those others, many others, that I know—on our farm the produce is harvested by hand by really well-trained crews. And if there were signs of animal intrusion or quality problems related to animal contamination, our crews have been trained and would know not to harvest from those areas. I think an assessment like that would be difficult for crews harvesting with machines.

So in closing, I think that those concerns kind of scratch the surface of what is really a very complicated subject, and I wanted to make four suggestions—because this is a federal rule and we're here in California—about what we could do here in California.

So the first one is that I've heard that the National Association of State Departments of Agriculture is trying to get the FDA to issue another draft rule—and several other panelists mentioned this—before the final rule is issued. I think that might be a good idea because it will allow an analysis to see how and if California agriculture's concerns have been addressed. And I do think the diversity and complexity of the farms here does make it difficult for the FDA to address our concerns.

The second suggestion is, as Scott Horsfall said, the rules are silent on the verification process. I think there's a question whether the Department of Public Health or CDFA will really be in charge of implementation and inspection. And it could be that it would be better for California agriculture if CDFA was in charge because of their close relationship to—closer relationship—to farmers.

Third—no one's really spoken about this yet—it's very important to defend California regulations for sales of products within the state, such as the Cottage Food law—which has been very, very popular—the new CSA law that just was passed this session, and others. If those California regulations are not defended, FSMA could preempt them and define all farms, as someone mentioned, including those that only sell direct through CSAs as food facilities. So I think the interrelationship between those California—very popular—California regulations and FSMA should be looked at.

And then finally—and this was also mentioned briefly—food safety auditors and inspectors in California should be made aware of the importance of conservation practices on farms. No more habitats should be destroyed in the name of food safety. California legislators should seek to protect practices like installing native plant buffers for pollinator habitat that benefit both wildlife and food safety. Unfortunately, as we know, there are handlers, buyers, and inspectors in California that have asked farmers to remove wildlife habitat on or near their farms, and I think that practice can be very damaging to water quality in California. And so California auditors and inspectors should be trained that it's important to protect habitat on farms and co-manage for both food safety and conservation.

So thank you very much again for the opportunity to meet with you and discuss this important subject.

SENATOR GALGIANI: Thank you very much.

We spoke earlier about the difference between the farmers that use raw manure and compost. It's my understanding that some farmers in between harvests allow for cattle grazing and grazing of other animals on their land. So in your view with what's being proposed by FSMA, will this impact—will their proposed rules impact the practice of allowing grazing between harvests?

MS. REDMOND: Yes. The National Organic Program is unclear and doesn't make it clear whether grazing animals is considered the application of raw manure because usually the amount of raw manure on the field is so much less than it would be if there was a specific application of raw manure. So regulations around the application, but around grazing animals, are a little bit unclear. But most farmers that we know consider the 120 days of National Organic Program to be the rule for both application of raw manure and for raw—for grazing animals.

So let's say—because it is the common assumption—that most farmers if they are grazing animals, as Full Belly does, between crops use the 120-day rule. The Produce Safety Rule of the FDA, again, is not totally clear. In the preamble, it mentions a nine-month interval, but it doesn't exactly say that it requires a nine—did I say three month?—I meant to say nine-month interval [sic]—it doesn't actually require it. If it does, it needs to make that clear, what it does require. But if it were to require a nine-month interval, it would mean that grazing animals would no longer be part of agriculture, of produce farms. And there may be some folks that think that

that's a good idea. We've been grazing animals between harvest on cover crops and when there is a crop that is done. We put animals on that field, and we have them graze briefly and then we take them off, and we till the field and do whatever preparation we need. And so then we wait 120 days before harvesting a crop. We've been doing it for 25 years, and we think that it's how we have a really healthy soil. We think that it's a very important part of healthy agriculture, and obviously, we need more science to prove that we're right. But we also would say that if you take all the animals off the farm and put them in a confined animal feeding operation—which seems to be the way that we're moving in terms of animal agriculture—you create many, many problems. And really the origin of some of the most serious human pathogens like O157 is in animals that are eating only grain; whereas, the animals in our system are eating pasture. They're grazing on pastures.

So all of these are important questions. I know there's a lot of disagreement around many of them. But the FDA proposed Produce Rule potentially would mean that animals would have to completely be removed from grazing because you can't afford to fallow your fields for nine months, basically.

SENATOR GALGIANI: Okay. Thank you.

MS. REDMOND: You're welcome.

SENATOR GALGIANI: Thank you very much.

SENATOR GALGIANI: Next.

MR. CHRISTOPHER VALADEZ: Good afternoon, Senator. My name is Chris Valadez, and I represent the California Grape and Tree Fruit League. We're a voluntary, nonprofit trade association representing fresh table grapes and deciduous tree fruit growers, packers, and shippers throughout California. And to start out, I'd like to focus my comments on the, I think, the outset of the scope you and your staff have provided to us as participants in terms of potential areas where we see or can foresee state government participation as the Produce Safety Rule is rolled out and ultimately put into action here in the state of California. And as a result of state government participation, what are some potential concerns, gray area, and/or opportunity. And so with that, I'd refer back to a comment that we agree with that was made by Mr. Scott Horsfall today regarding his concern with an apparent inconsistency where under the Preventive Controls Rule FDA has identified activities such as washing, trimming, and in an additional case, packing of a raw agricultural

commodity, as activities which would qualify under a specific definition which would be regulated under Preventive Controls Rule; yet, those same activities identified are also identified under the Produce Safety Rule. So what gives for these farming operations?

Well, as my colleagues and I have discussed in the past and I think what most of us are prepared to comment on is an apparent—in our case, a point that we disagree with would be the use by FDA in relying on the Food Facility Registration requirement where going back to the 2002 Bioterrorism Act, which was a food security issue, identified the facilities that handle, process, manufacture, pack food, et cetera, where these facilities essentially by FDA are required to be identified in case there is a terrorist, a similar type of event which affects the domestic food supply. Well, that got carried over into FDA's interpretation in their initial or this current proposed draft under the Preventive Controls Rule; therefore, it creates a problem for many fresh produce operations and that is this: If we in California have a fresh produce operation—let's say a peach operation, a grower and a packer—and all they do is grow and pack their own produce, well they're under the Produce Safety Rule, there's not a problem there. However, if a different operation which is similar—they're similar in that they grow peaches, they pack peaches—but they also handle packed peaches that come from someone else's farm—they have a contract to pack and so they pack for a grower who doesn't have their own packing operation—well, they're handling someone else's produce. Well, under the identification by FDA for Food Facility Registration Requirement eligibility, that operation would have been required for handling produce other than those at which they own or co-located on the same facility or the same farming grounds—they're under the Preventive Controls Rule. So for us, there's a clear distinction where they've used a food facility registration requirement to basically separate but cover all of these farming operations, those which handle their produce and those which handle other produce or their produce plus others' produce. We believe that's extreme inconsistency. But as a result, what we're preparing to do in our comment is to ask that all of those operations to receive coverage under the Produce Safety Rule as the rule that is more appropriate for those operations. But where we think the state of California may have a role by default as a result of this distinction, if not fixed in a future iteration of these rules, is the involvement of the California Department of Public Health.

I've talked to California Department of Public Health officials regarding a state of California's similar food facility registration requirement. And unlike the registration requirement at the feds where there is no fee associated, there are fees associated with the California registration requirement. Now, I can't cite them today. But why that becomes a concern for a fresh produce operation—so I don't believe they should receive regulatory coverage under the Preventive Controls Rule—is that could be a mechanism by which FDA looks to the state of California to help with enforcement and/or oversight of those operations under the Preventive Control Rule. And guess what? There's a funding mechanism there if there's a fee tied to the registration requirements. So that's one concern for our members that could get tied up into that either/or Produce Safety Rule or Preventive Controls Rule. We think that can be a big concern and kind of an unanalyzed funding consequence, economic consequence, that was yet to be considered by FDA. And so that's something that we are making comment towards to FDA in various meetings we've discussed with them.

Another area, not to double back over the ag water testing comments—and you've received a lot of information today in a relatively short amount of time regarding ag water. But in looking at a specific example, kind of a scenario that could impact the fresh table grape industry: when you look at agricultural water—and it's been described as water that when used during the growing season is intended or is likely to come in contact with the covered produce itself—it would touch the produce and in theory carry with it, or could carry with it, a pathogen of human health concern that could make its way into the hands of a consumer and the consumer could become sick. Well, most table grape farms in the state of California are irrigated by either drip or some are still flood irrigated. And so FDA had analyzed in its qualitative risk assessment irrigation methods and looked at, well, what's a more or less risky method to irrigation [sic] in terms of the likelihood of a pathogen being carried through a water source in the irrigation method and ultimately attaching itself onto a piece of produce? Well, for us, we would tend to think that the risk is low because of the way they're irrigated and that the water is not intended or likely to come into contact with the actual berries itself. However, let's look at an example where we know water will come in contact with the grape berry and that is through, as an example, crop spray.

So if we think about the table grape growing season here in the state of California, it goes for quite some time nowadays with many new varieties that have

become popular with consumers. So we're harvesting through November and ending, you know, relatively early December, depending on weather and other pressures. And so what we find now is a potential scenario where a growing operation who relies upon surface water and untreated surface water—so this would kick in that every seven-day growing season testing requirement—well they can find themselves in a very concerning scenario where, given a scheduled harvest—and knowing that there are tight harvest windows—if there's a spray event that is going to lead up into the harvest or just come a couple of days before because, let's say, later in November there's more moisture in the air and so there's the need to apply fungicides just before you go into harvest, and there are fungicides that you can apply that have relatively short re-harvest or reentry intervals in a 24- or 48-hour period, so a day out, two days out before harvest, you spray. Now if you filled up your sprayer from a surface water source, well, depending on the timing of when your test came or if you tested within a seven-day window, that can potentially jeopardize that next step which is pulling the grapes off the vine to harvest itself. So what do you do?

Well, the rule doesn't necessarily say that your produce is adulterated. You know your produce is adulterated. What it says is, well, you have to discontinue the use of the water, at least for now. Stop, re-inspect, see if anything within your farming operation within the water system that you can see, control, or manipulate—whether there's a problem—check it out. If there is, remove it and retest. And even if you can't find any problem with the water system, retest anyways. And so this sets up a scenario in this very... what we would think would be an unworkable situation where you're essentially beholden to a test and test, after test, after test to test your way to clean water. I wouldn't say—let me rephrase that—test your way to water which meets the standards identified in the Produce Safety Rule. And there's going to be waters, as was discussed today, which in some areas given different environmental conditions, there's going to be waters that tests are going to reveal that the samples pulled will exceed the water standard being relied upon in the Produce Safety Rule. In other areas, that may not be the case. And it may not be area specific; it may be time specific. Again, we're talking about samples and we're talking about “snapshots in time” tests. So can you pull multiple samples from the same day from the general same location and come up with different numbers? Sure, you can. So what does that mean?

What it means for us as an industry, we are faced with an ag water section in a Produce Safety Rule which could have very real impacts in addition to a cost impact to our growers. Now, for those who can get away from the ag water definition for irrigation events in that it doesn't come in contact with produce—and that's going to be some of our members as well—it's not a concern. Where it becomes a concern are those instances where, if you have a spray event and the water source that you use—because maybe you're not as flexible with your water so you just can't go to our groundwater which is deemed less risky because there are fewer points of infiltration for pathogens because it's groundwater—so for those concerns, in that sort of scenario, that becomes highly concerning for us.

So what are some alternatives? What do we think that, either as industry or as produce in general or table grapes specific, are there alternatives? We think FDA would be likely to consider alternatives, knowing that they do recognize there are challenges with the ag water standard as it presently exists. One thing to look at is your general history. If you're already testing at least annually—and these operations generally are due to third-party audits, buyer agreements—they're testing already, at least annually. So if annually is... if you're performing an annual test and you're taking that test as an attempt to characterize the water quality of the farm water being used, are there holes there? Sure, it's once a year. When was that poll, that's, again, behold to that snapshot test in time? Every seven days? Probably overkill.

So is there any middle ground? We don't know. But things that we suggest could be looked at, particularly if there's data and science and future studies to support, is how about if there were testing regimes perhaps in response to events which are likely or reasonably likely to have contributed to contamination of the water source which is at your discretion? Maybe in the middle of November you had a heavy storm event and you had runoff and there's runoff that you couldn't control getting into the water delivery system that delivers to your farm. Well, that runoff could have carried with it fecal contamination and could have increased your generic *E. coli* counts as pulled from a future sample. Well, okay, that may make more sense. Again, these are imperfect ideas, but it may make more sense to test in response to an event or events that could, if identified through science in either present data or future studies, as a testing regime, which would not tie you to kind of a calendar testing date, it would tie you to a real-world event that science has established is likely to

contribute it to, perhaps an increase in generic *E. coli* in your water. That's one suggestion that could be made to FDA.

I think in another area—going back to the original question I visited—and that was the role of state government. My colleagues and I are working on a parallel water... on a water quality issue with the regional water quality board for Region 5 for the growers in the region which I represent by and large. And in that regulatory structure, we're looking at the question of nitrates and nitrates in groundwater for public health uses. Okay. And we're not talking about pathogenic indicators, but we're talking about nitrates in groundwater. And agriculture is being looked at kind of the prime generator of those nitrates, so you're guilty until proven innocent. So while agriculture, unfortunately, is going to have to spend a lot of money in the very near future designing studies to show its management practices, the implication of its management practices, and how, when employing current management practices, what are the trends that are set up in terms of groundwater or water moving from surface to just below the root zone to when it encounters groundwater and what's the nitrate concentration there?

Well, one of the regulatory—how would I term it? I think one of the methods for compliance for growers that they will utilize in their farm evaluation, planning processes is going to be, well, demonstrate that you are limiting direct avenues, direct infiltration points to groundwater. Well, how can you do that? Well, capping off unused wells. You can, you know, identify that you have unused wells on your farm; cap them off. Do you have backflow prevention vises? Again, we're looking at what the state of California is presently doing for something different. This is, again, a water quality issue, but it's a nitrates water quality issue. Perhaps that could have a parallel here for farmers that are going to have to employ those measures if they're not doing it already in the state of California for protecting water quality because, again, we're looking at not water being dirty but water being a carrier of a pathogen. So perhaps that's another area where we're not going to ask for the state of California to take any primacy over that, over pathogenic indicators in water, that's going to come under the federal regime through FDA. However, I think it is important to highlight that there are programs that are coming underway that are dictated by the state of California that are going to have an impact and/or an overlaying effect onto California agriculture when they're employing the Produce Safety Rule, and specifically, the ag

water requirement, as we relate to the groundwater testing issue, which, as of right now, is every three months. So those are two general areas where I see there are potential infiltration points with the state of California government and the work that is being undertaken through FDA.

You know, moving forward, from our perspective and looking at our crops—table grapes and deciduous tree fruit—we think FDA moved down a path that was afforded to it under FSMA and that was essentially to say, hey, you're allowed to take a risk-based analysis of the roots of contamination—which have been identified—and employ or adopt minimum standards so that everyone has to abide by these minimum standards—essentially, a “one size fits all” regulation. I think there are some areas which are going to be problematic for us. Other areas, it's not, because that's what we're already doing. But we also think FDA kind of took a shortcut and only saw one side of the risk-based calculation because under FSMA it also asked FDA to look at, account for risk-based differences between commodities, between the foods itself. So you can look at risk-based differences between the commodities, but they've also asked them to minimize the number of standards. So you kind of put FDA into this—well, we have to do something which is risk based, but what's something that we think we can accomplish?

Well, there's a reason why FDA performed its qualitative risk assessment and didn't do its quantitative risk assessment: because they couldn't have done a quantitative risk assessment for all commodities. So for us—and I think moving forward—whether it's partnerships with CDFA and keeping close to your committee, it allows us as commodity representatives to move forward whether we want to explore the alternative option process or we want to explore the variance process to establish that there are perhaps alternative measures underway in the ag water section, whether it's the soil amendment section or the other sections—it could be the building, tools, equipment section—where we think there are alternative methods of employing or being or recognizing that we are regulated without creating any new or undue burden.

In sum, we're still developing our comments, but it's important that we all recognize, and as a commodity representative, this is something that we can necessarily say, but it's much harder for those in the sales world to get into, and there's no such thing as zero risk—there is no such thing as zero risk. So there's the

other area: whether it's the continuing studies, what is an acceptable risk level that we believe; whether it's a tolerance; whether it's commodity studies looking at commodity characteristics—such as, you know, a crop surface area, distance to ground, the survivability of an indicator organism—these are the commodity characteristics that I think we would look to explore within these rules to hopefully carve out an area where our membership is covered under these rules but in a manner which we believe could be less burdensome to their operations. Thank you.

SENATOR GALGIANI: Thank you. Thank you very much.

And our last presenter: Mr. Bob Blakely, Director of Industry Relations with California Citrus Mutual.

MR. BOB BLAKELY: Thank you, Senator. I do appreciate your time this afternoon and for allowing us this opportunity to comment on the proposed Food Safety Rule.

California Citrus Mutual is a citrus producer's trade association representing over 2,200 primarily small family farmers who represent and comprise about 75 percent of California's \$2 billion citrus industry. The primary role of Citrus Mutual is to represent the citrus producers on matters that affect their economic livelihood and provide them with the necessary information to enhance their ability to profit from their work. Our efforts include working in the area of state and federal regulatory affairs, legislative matters, marketing and trade issues, education, and any other areas that would assist the growers in better providing a better economic environment for them to operate in.

We strongly support a safe and reliable food supply and the intent of FSMA to assure that America's fresh produce is as safe as it possibly can be. The surest way to effectively achieve these objectives that Congress intended is to establish scientifically sound regulations that are commodity specific and based on real, quantifiable risk.

As the leading organization representing the citrus industry, California Citrus Mutual, in conjunction with our industry, has developed good agricultural practices for growing and harvesting citrus, and these were prepared as specific guidelines and in harmony with a harmonized standard for fresh produce that has been developed with broad industry participation from the U.S. produce industry, buyers, auditing agencies, and the USDA.

The citrus GAPs established food safety practices that are adhered to by our growers, and these GAPs address the areas of water quality, soil amendments, domestic and wild animals, sanitation, worker health and hygiene, traceability, and the use of pesticides. The GAPs describe the best practices for producing fresh citrus which is grown off of the ground on a tree and which has a naturally protective inedible peel. The fresh citrus industry has never been associated with a foodborne illness outbreak, and our industry is committed to maintaining that precedent and to ensuring safe and wholesome citrus to U.S. consumers as well as our trading partners abroad.

CCM has submitted comments expressing our concern that FDA has failed to follow the legislative intent of FSMA to provide a true risk-based approach that recognizes the diversity of the fruit and vegetable industry. FDA in the proposed rule has applied the same prescriptive requirements to all commodities despite significant variations in the risk between the commodities. This places a tremendous economic burden on low-risk producers that will have little or no impact on risk or illness reduction.

We maintain that adherence to best practices during production and harvesting combined with the cleaning and sanitizing that takes place at the packing house during the grading and packing operation are a perfect example of a systems approach to food safety which assures our product is safe when it comes into the distribution channels. We've proposed to FDA on numerous occasions during the development of the proposed regulations and again in our formal comments that FDA should approve the Citrus GAPs as an accepted alternative to a one-size-fits-all regulation.

In addition to the GAPs for citrus, CCM worked with industry to develop a standardized citrus-specific written food safety plan template for both growers and harvesters to ensure that the standards that our industry espouses are followed through. We believe that documentation is essential for successful implementation of the GAPs and that to the regulators and the retail auditors and to our customers food safety practices are not considered implemented unless they're documented.

Citrus growers are utilizing this food safety plan for citrus to assure their customers that the fruit from their farms is safe. Audits of the operations utilizing the citrus food safety plan have repeatedly shown extremely low potential for bacterial contamination and continue to substantiate the inherent low risk associated with

fresh citrus. In the unlikely event that a contaminated orange does find its way to the packinghouse, it will be cleaned up during the packing process.

It could be that FDA's decision to use an integrated approach to the regulations rather than the commodity-specific approach as intended is deemed to be a way to meet the arbitrary deadlines that have been imposed upon the agency by legal actions. We believe a better approach would be for FDA to work with the low-risk commodity groups, such as California Citrus and other low-risk commodities, to finalize effective systems approaches such as we have described, and this would free up the agency to focus then on the tougher, riskier commodities which I think was the original intent of Congress, as already been mentioned. It also would relieve the low-risk commodities of the burden of unnecessarily more stringent and costly regulations. And most importantly, it would still assure the consumers of receiving a fresh product.

We've conducted an exhaustive data and literature review, including statistics from the Center for Disease Control, and have not uncovered a single documented case of fresh citrus being linked to a foodborne illness. In our view, FDA's conclusion that at-risk pathways apply almost universally to all fresh produce commodities, we believe, ignores the science and is a contradiction of FSMA and FDA's stated intention to regulate produce based on commodity-specific risk factors.

The California citrus industry believes that basing produce food safety risk on production practice alone is not really appropriate. We believe that commodity characteristics are relevant indicators of risk, and the Qualitative Assessment of Risk prepared by FDA addresses specific commodity characteristics that might serve as a basis for exemption of commodities or alternative standards and then argues that none are adequate to base risk on a commodity-specific basis. These points include absence of outbreaks, inedible peel, and growing off of the ground. FDA looks at each of these parameters independently rather than considering the cumulative effect of all of these for a specific commodity, such as fresh citrus and other tree crops. We believe that it is more appropriate to evaluate the risk based on the cumulative effect of the safety factors—as we have suggested in our comments to FDA—and that these cumulative effects of a systems approach should be taken into account.

In its current form, the proposed rule, in our view, is inequitably restricting the use of alternative methods of managing risk factors to only those primarily associated with water, composting processes, and application intervals for untreated soil

amendments. We believe that the same option for using alternative methods should be applicable to any prescribed requirement for any of the five risk factors. And further, we recommend that individual producers or commodities where there is commonality should be able to rely upon commodity board and trade association publications and research that establish such alternative measures. We reiterate that we feel strongly that this general issue should be addressed in commodity-specific guidance rather than its specific underlying rules. The rule as written is inadequate in restricting the ability to petition for a variance to state and foreign governments. We propose that commodity boards and trade associations specifically be recognized as having standing to request variances under the rules as they're proposed.

Just in closing, it goes without saying that buyers of fresh fruit and citrus are demanding that growers have a food safety plan in place and in some cases are requiring food safety audits down to the field level. FDA will eventually implement regulations that will govern food safety practices, but these may not go even as far as what growers are already doing on a voluntary basis and at the request of their customers. We don't feel that in this environment that there is a need for additional state legislatures to pass more laws and impose another layer of regulation on top of what customers and FSMA are and will require.

That concludes my comments.

SENATOR GALGIANI: Perhaps you can speak to us about how you clean citrus prior to packing.

MR. BLAKELY: When citrus is harvested—of course it's harvested in bins—it goes on a truck to the packinghouse. That fruit is then typically dumped into a hot chlorine bath to clean the fruit, to kill bacteria. From there, it moves through pressure washers where, again, it's hot treated with chlorinated water at high pressure to remove any additional dirt. Sometimes it's a means of removing certain insects that may adhere to the outside of the fruit. So at that point, it's been cleaned twice. It then goes through high-temperature dryers before it even goes onto the grading table. Additionally, there's additional fungicides and waxes that are applied then to the exterior of the fruit after it's been cleaned.

SENATOR GALGIANI: Could this same process be applied to other tree fruits?

MR. BLAKELY: It depends on the different commodity. Some are conducive to being washed, others are more tender and not. I think maybe Mr. Valadez can speak more to what some of the tree fruit processes are, but I know what we do for citrus.

MR. VALADEZ: Similarly, in the packinghouse, there's a process. After it's harvested in a tote and brought into the packinghouse, it goes through a wash, generally a dump tank of wash water with chlorination solution in there. And then from that, it moves down along the packing line. It's also washed with spray water that has a chlorine solution, the difference being the temperature. It's not—the temperature is not a hot temperature. It's a cool temperature because you have to maintain the cool chain, because after all of that, it's also graded and sorted. It's packed and then moved into cold storage.

SENATOR GALGIANI: Thank you.

Well, thank you to our third panel, and thank you to all of our panelists.

At this time, we would like to open it up for public comment. Do we have anybody that would like to... Okay.

Is Kelly Covello still here? Thank you.

MS. KELLY COVELLO: Thank you. My name is Kelly Covello. I am president of the Almond Hullers & Processors Association, the almond industry's trade association representing 90 percent of the industry based on volume. I want to first thank you for the opportunity to comment on the proposed Produce Safety Rule under FSMA.

The California almond industry supports efforts to ensure that consumers receive the safest food possible. In that vein, we employ a number of food safety practices from farm to fork, including good agricultural practices, good manufacturing practices, and HACCP programs.

It is imperative that any regulations placed on growers are risk based and do not place growers at an economic disadvantage relative to other growers or at an economic disadvantage to food produced overseas. One hundred percent of the U.S. commercial almond production is in California. This production also represents over 80 percent of the global supply. All almonds grown in California are subject to the Federal Marketing Order under USDA and administered through the Almond Board of California. Requirements of the Federal Marketing Order are considered federal law.

One of the mandatory outgoing requirements under the federal marketing order is a minimum 4-log pasteurization treatment of almonds sold in North America, which includes the U.S., Canada, and Mexico. Processes and equipment under this program are validated through a third-party technical expert review panel, and audit functions are in place. As the Produce Safety Rule is currently drafted, only a state or a foreign country may request a variance from one or more requirements of the Produce Safety Rule or the state determines that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that produce is not adulterated and provides the same level of public health protection as requirements of the rule.

We are requesting that FDA acknowledge other regulatory frameworks—which has been discussed by some of the other groups here today—and such as our program, since it’s overseen by USDA at a federal level. Additional requirements would be redundant and costly with no significant health benefits. Although, I would say, if that is not granted by FDA, we would be looking to the state agencies for support and help getting those variances.

We share similar concerns that were expressed earlier about harvest processes and activities that may be subject to preventative controls. As currently drafted, the intermediary harvest steps, such as almond hulling and shelling, can fall under produce safety, preventative controls, or even under both rules, depending on the registration requirements that were discussed earlier and whose product the operation is processing, so their own—well, ag commodities versus another growers raw ag commodities. We feel that all harvest activities should fall under the Produce Safety Rule, regardless of the registration requirement or whether they’re performing that activity on another grower’s racks.

In the terms of hulling and shelling of almonds, FDA has acknowledged that on-farm it is a low-risk food activity combination. It is also included in their harvest definition. The concern that we run into is the fact that most hulling and shelling operations are not going to be harvest—or processing only their own raw ag commodities. Due to the cost of running a huller-sheller, many growers band together to form grower-owned cooperatives or they hull and shell other growers’ racks to capitalize on the economies of scale. When they do that, they’re going to be automatically subject to preventative controls, and this is not based on risk.

Lastly, we would ask that the state support a second comment period within the parameters of finalizing the rule by 2015. FDA has requested comments on a wide range of issues that will have a considerable impact on the preparation of final rules. Having the opportunity for further comments will enable stakeholders to understand how FDA viewed the responses to the key questions that were posed, to comment on sections that have been revised, and to clarify any key elements prior to the issuance of final regulations. Most importantly, an additional review comment and opportunity will enable stakeholders to address sections that were previously redlined and, therefore, not in the body of the current Federal Register Notification that may be reintroduced into the final rules as a result of this comment period.

Thank you.

SENATOR GALGIANI: Would anyone else like to make any public comment for the record?

That concludes our hearing for today. Thank you so much for all of the participants. Thank you for those who attended. We will see you, some of you, back next year when we reconvene the Agriculture Committee. Thank you.

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