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Electronic Submission
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-4187

"A New Era of Smarter Food Safety"

Western Growers, a non-profit trade association representing growers and handlers of fresh fruits, nuts and vegetables from California, Colorado, Arizona and New Mexico appreciates the opportunity to comment on FDA's "A New Era of Smarter Food Safety" workshop and initiative. Our 3,000 plus members grow, pack, process and handle approximately half of the United States (U.S.) total production of fresh fruits, nuts, and vegetables. They are both large and small companies committed to ensuring that their products are delivered safely to consumers, both here in the U.S. and abroad. As a trade association representing the fresh produce industry, Western Growers has a long history of working to lead in the development and implementation of preventive food safety programs.

Western Growers applauds FDA for advancing the use of technology and data-driven solutions as the food industry continues moving forward in implementing the Food Safety Modernization Act (FSMA). We largely agree with FDA's approach to steering the food industry into a New Era of Smarter Food Safety; however, we also believe technology-enabled traceability and transparency should be a secondary focus complimentary to a primary focus on preventing human pathogens from entering the food supply in the first place. Furthermore, we hope the agency uses its regulatory authority to ensure that the best preventive practices are being established and implemented by all segments of the supply chain without placing undue burden on one segment over another.

Western Growers believes FDA's resources should be concentrated on and prioritized for investigating pathogens in the growing, packing, and manufacturing environments over conducting random,

untargeted enforcement activities (i.e., not based on risk). A more comprehensive understanding of how pathogens are transferred from their carriers and reservoirs to the food supply provides a greater benefit to the consuming public than surveillance of those (whom we believe to be the majority) that are faithfully following best practices. As the industry becomes more digital and cloud-based, the agency should provide industry with opportunities to demonstrate food safety competency and for those who do so, there should be rewards (e.g., reduced fees, audit relief, public recognition, etc.). FDA should focus their regulatory efforts on those unable or unwilling to demonstrate food safety competency. The ability to more accurately and comprehensively demonstrate food safety competency should be a natural outcome of a data-driven approach to food safety.

Western Growers adamantly believes FDA would benefit greatly by not reinventing the wheel in their efforts to develop state-of-the-art food safety systems and policies but should look to their counterparts in the U.S. and foreign governments that have utilized new technologies to effectively established innovative systems for enhancing food safety. Western Growers recommends leaving the development of technology to private industry so FDA can focus its resources on advancing general public and background data streams that will better support predictive analyses efforts.

We offer our comments to the agency's questions in the spirit of developing proactive approaches to smarter food safety versus concentrating efforts on reactive systems after contamination has occurred. As part of our continuing commitment to collaborate and cooperate with FDA, we offer our responses to the questions raised by FDA as follows:

Western Growers Comments on the FDA's "New Era of Smarter Food Safety"

A. New and Evolving Digital Technologies Will Play a Pivotal Role in Tracing the Origin of a Contaminated Food to Its Source in Minutes, or Even Seconds, Instead of Days or Weeks

FDA lists traceability as the first area of focus in the "New Era of Smarter Food Safety", and Western Growers fundamentally disagrees with the premise that traceability is the highest priority for food safety reform or even the weakest point in today's food safety system. Yes, new technologies are emerging that will allow tracing contaminated foods to their point of origin in seconds but following a contaminated food back to its starting point remains a reactive step and does not, in and of itself, protect public health. Instead, Western Growers believes focus should be placed first and foremost on smarter tools and approaches for prevention. Establishing and implementing effective preventive controls is by far the most critical factor in protecting public health.

1. What are the most significant actions FDA could undertake to enable industry to enhance traceability across the entire global food supply chain?

- The first step is to break the data and information silos which have been created by the current one-up / one-back PTI methods and require product information to be digitized at the lot level and stored 'in the cloud' so it is accessible to those who need it.
- Secondly, retailers and foodservice distributors should be required to track lot level details through their distribution centers and into stores, first in their internal ERP/WMS systems (enabling precise one-up/one-back trace, i.e., days to trace the supply chain), and second, also in the cloud (i.e., enabling a <1 second trace). There are numerous ways to accomplish this: scanning PTI labels is one option; another option is ASNs and the utilization of PTI Voice Pick Code that doesn't require the retailers to buy expensive scanners and devote extra time to scanning cases.
- Clarify for the industry that blockchain is one traceability data storage option but is not a traceability solution and not the only option for traceability data storage. Other good options exist that don't have blockchain's scalability and performance limitations.

2. How could FDA make it more likely that companies utilize new technologies to enhance the traceability of their products?

The majority of grower-shippers currently follow PTI guidelines. These companies need to hear positive validation from FDA that the PTI investments they have made are the foundation of the future, and that getting retail and foodservice tracking lot-level details is a priority for FDA followed by end-to-end supply chain traceability data in the cloud. Western Growers believes that to move industry forward in adopting cloud-based product tracing technologies in a constructive fashion, FDA should develop specifications for industry systems and communicate those specifications to the industry as "performance standards" that, if met, would facilitate rapid traceback. Communicating these specifications (and possibly timelines) as performance standards would provide industry with the flexibility to design programs that meet FDA specifications and would inform developers of the precise expectations of the agency. In establishing performance standards, we would expect FDA to establish what type of information should be available at what points in the supply chain and recommend how quickly it should be delivered. Western Growers does not believe FDA should prescribe the format in which the information will be delivered as we believe the industry is better equipped to make those business decisions. If FDA's performance standard expectations are clear, it sets a clear path for industry innovation and performance while avoiding one-size-fits-all programs that might unnecessarily add cost and negate industry efforts and investments to-date. This would also leave room for industry initiatives like the PTI to continue moving forward but provide companies the ability to select programs based on a variety of factors including ease and efficiency of adoption, costs, and maximized return on investment.

The fresh produce industry has traceability programs in place today, and many companies are working to enhance and improve their programs by adopting electronic systems. We have consistently demonstrated that we can effectively trace fresh produce products from the distributor back to the

supplier and ultimately back to the farm and field where the fresh produce originated. In moving forward, the industry needs direction from FDA so companies can tailor their individual systems and confidentially provide appropriate information to a larger data stream. Western Growers appreciates that FDA is engaging stakeholders from the various industries involved in providing a safe food supply in order to develop more comprehensive data-distribution systems. The questions posed in the Federal Register will hopefully provide FDA with information that will be useful in developing an approach to enhancing traceability that recognizes and allows for the best practices of industry without dictating the manner in which electronic product tracing must be achieved.

3. What can FDA do to facilitate and expedite outbreak-related communications between government agencies, industry, and consumers?

- Encourage the industry to digitize their lot-level harvest and food safety information as opposed to keeping it in analog formats or even spreadsheets.
- Encourage industry to provide FDA and state health department investigators access to this digital information through appropriate user roles and permissions.
- Encourage those in the supply chain that have typically been the weakest link to maintain all product information (e.g., pallet-level, lot-level).

4. Are there mechanisms FDA could employ to incentivize adoption of real-time, end-to-end food traceability throughout the food sector?

- FDA should use its "bully pulpit" to push the industry forward in this area. The message must be clear that this is the direction regulation is moving and getting on board the train is essential for not being left behind. This message must be consistent within the agency and repeated often by agency representatives in industry forums. Deputy Commissioner Yiannas and others must broaden their discussion of traceability solutions beyond tracing mangos through Walmart blockchain to other tangible examples of how real-time, cloud-based systems improve traceability and benefit the bottom line of companies across the supply chain.
- The produce industry has demonstrated that existing technologies are adequate if each player in the supply chain participates. The agency could improve transparency by helping to publicize who in the supply chain is participating and who is not. Similar to FSIS ranking of poultry facilities, FDA could publish inspection results. They could also publicly recognize and incentivize industry participants that are investing in food safety technology to set them apart from those that are reluctant to invest. This information can be used to influence business relationships within the industry, i.e. suppliers may put pressure on non-participants by establishing a preference or only selling to customers that are participating as they are.

- FDA should look to what other agencies in the U.S. government and abroad have successfully implemented to incentive companies in the private sector. For instance, FDA could develop an incentive program modeled after USDA's *Salmonella* program where companies that collect and aggregate data that is subsequently made available to the agency are rewarded with exemptions from sampling programs, lower fees, fewer inspections, etc.

5. What are the challenges to creating a more digital, traceable global food supply, and how might FDA approach this in a manner that creates shared value for all participants?

The challenges are many, but not insurmountable. Keeping systems simple and establishing a common language or data conversion tools and standard practices (e.g., global identification) around the systems will help industry have the confidence to buy in and individually invest. Western Growers has helped to coordinate a system which digitizes lot-level harvest and food safety information and makes it available on the cloud using established PTI standards for end-to-end traceability. Too often the traceability chain breaks down at the distribution center and store levels if product lot details are not tracked. FDA can use its regulatory authority to encourage weak links in the supply chain to participate in electronic data collection and transfer systems.

B. To Fully Realize a Preventive Controls System That Rapidly Incorporates New Knowledge, We Must Also Ask if We Can We Make Processes and Communications More Effective, Efficient, and in Some Cases, Simpler

1. What are the most significant actions FDA could undertake to promote and support the use of smarter tools for prevention?

There are several actions FDA can undertake to promote and support the use of smarter tools for prevention. Ensuring a safe food supply is the responsibility of multiple federal agencies including the FDA. FDA will make the greatest impact on prevention if they continue to partner with these other federal agencies to collectively promote and support the development and use of smarter tools. Some of these "tools" are quite advanced and others are basic and simple preventive measures. Along with their collaborative partners, FDA could channel more research monies to providing basic scientific information such as background pathogen levels, areas of sequestration, common carriers, survival and growth conditions, and how pathogens are transferred in food production environments. Smarter food safety involves better use of what we know as much as it means adopting new technologies. Basic data and information about how human pathogens survive, grow and move around in the environment as well as how they enter the food supply chain will enable researchers and industry to conduct more accurate quantitative microbial risk assessments (QMRA) and develop better predictive analysis models. Basic scientific data and information would also greatly enhance the effectiveness of new

technologies developed to prevent the transfer of pathogens into the food supply (i.e., pathogen detection sensors, kill steps, etc.) during harvest, packing, processing, and manufacturing operations.

At the retail level, FDA could require use of disposable gloves – both for retail employees and customers. This is currently being practiced in some European countries to help prevent the spread of human pathogens when customers are touching produce while making purchasing decisions.

2. What predictive analytical tools and data streams are best suited to helping identify a potential contamination event?

There are many obstacles to the government gaining access to and using industry's data. With the establishment of operational incentives and appropriate user roles and permissions, these obstacles may be overcome. In the meantime, FDA should focus on making use of public data sources, including but not limited to:

- background levels of pathogens in the non-agricultural environment
- local water quality data i.e., irrigation district microbial level data
- weather and climate data
- pathogen prevalence in native animal populations
- wildlife and human traffic patterns

FDA should work with researchers to develop algorithms to predict increased contamination risk due to risk factors such as climatic conditions and weather. These models can be developed regionally across the globe and used to inform industry when there is increased contamination risk in their region.

3. What further steps can be taken to advance the safety of domestic and foreign commodities that have been the subject of frequent contamination incidents?

FDA should first and foremost prioritize researching and understanding the root causes of these outbreaks. The advancement of food safety will not come through increased or ongoing punitive approaches to industry such as recent broad advisories to consumers. While we understand and wholly support the need to protect public health – recent consumer and market advisories have been broader than necessary. FDA should recognize industry expertise and allow for novel approaches such as tracing forward from the farm to narrow the scope of advisories when necessary and place a much higher emphasis on collaborating with industry to discover root causes. Through these efforts we expect fewer repetitive contamination events.

That is not to say that companies that are not making food safety a priority and following best practices do not need to be held accountable. In the short term, FDA should exercise its regulatory authority and conduct more unannounced audits of companies that grow and pack high risk commodities and have not demonstrated implementation of a robust food safety program. Adding the

threat of an unannounced audit would help provide incentive for doing the right thing. That said, long-term efforts should focus on providing supportive research for development of new technologies that can identify and/or destroy human pathogens on food. Human pathogens will arguably always be a food safety risk, and the most effective solutions involve detecting and eliminating them before they enter the food supply. Current testing methods are statistically ineffective and methods that "scan" all product is technologically feasible and needs to be developed. Better pathogen detection technologies would be a major safety advancement for the food industry, and the FDA could further the effort by providing incentives for technology development and adoption.

4. In what ways can FDA support the use of environmental assessments and root cause analyses in industry prevention efforts?

The produce industry has been conducting environmental assessments (EA) for several decades now so there's plenty of expertise within the industry and in the supporting consulting and academic communities. Root cause analysis (RCA) is a newer concept for the industry, and agreement on guiding principles and method standardization would be particularly helpful for the industry -- i.e., a "Guidance to Industry" publication. Additionally, it would be helpful for FDA to reach out to industry through agency and/or industry workshops to educate and promote RCA principles and methods as well as actively engage in RCA when opportunities present themselves.

5. Are there changes that FDA can and should make in the way in which it conducts environmental assessments and root cause analyses, and reports its findings to industry, to better facilitate their use in industry prevention efforts?

When conducting EAs and RCA, FDA needs to make better use of industry knowledge. If, during an outbreak investigation, FDA must maintain distance from industry, then there should be subject matter experts (e.g., academics, cooperative extension specialists, trade associations) with whom FDA can consult in order to more effectively conduct EAs and RCA. It's frustrating for industry when they have relevant information about an outbreak that would benefit the FDA's investigation and the FDA is unable or unwilling to accept the information. Developing liaisons (e.g., academics, cooperative extension specialists, trade associations) between the agency and industry for the purpose of transferring relevant information may be a method of bridging the legal divisions in place during an investigation.

Timeliness of publicizing the agency's EA and RCA findings would also go a long way in making them useful for the industry. Even before publication, it would be helpful to have industry briefing where EA and RCA findings are presented – especially if they are directly relevant to and would affect how companies are currently operating.

C. Evolving Business Models Present Food Safety Challenges as Well as Novel Considerations Around Regulatory Framework and Oversight at the Federal, State, Territorial, and Local Level

1. What are the most significant actions FDA could undertake to help ensure the safety of foods delivered under a variety of new business models, such as e-commerce?

Lack of regulatory oversight is the significant factor separating food delivery businesses (e.g., retail, home delivery services, etc.) from the rest of the supply chain. The most significant action FDA could undertake to help ensure the delivery of safe food to consumers is to require all food businesses, without exception, to follow the same best food safety practices. General food safety concepts such as maintaining the cold chain, separation of raw meat from fresh produce products, etc. are the same for all types of retail businesses.

2. What research is available or should be conducted to understand the potential health risks posed by foods provided by new business models, such as e-commerce?

Very little research is available for food that is sold under e-commerce. Although food safety concepts are generally the same and should be practiced by all retail establishments regardless of their business model, volume certainly plays a part in the potential health risk that direct-to-consumer and other e-commerce type businesses pose. Again, Western Growers believes that FDA will best contribute to the safety of these products by conducting and/or funding basic research on how human pathogens can gain access to food and subsequently survive and grow. This type of research provides invaluable information and data to these business for use in conducting QMRA to evaluate and validate their business models.

3. Are there specific collaborations between FDA and industry that would help to ensure the safety of these foods?

Public / private partnerships such as the Center for Produce Safety (CPS) have played a significant role in furthering food safety knowledge across the fresh produce supply chain. Within the past two years, CPS has funded research projects looking at practices used and conditions found in retail establishments. These types of partnerships could serve as a conduit for FDA to provide funding for food safety researchers to conduct studies of new business practices.

4. What are the most significant actions that FDA, state, territorial, and local agencies, and industry could take to change practices in the retail food industry that present risks to public health?

Retail food businesses including e-commerce should be included in food safety regulations. Food can be handled safely through the supply chain, but if a retail employee places fresh produce in the same bag with raw meat products, all food safety efforts could be for nothing if the meat is contaminated and the cross-contaminated fresh produce item is then consumed raw.

Also, at the retail level, customers hands may transfer contamination from meat products to fresh produce. Currently there are no preventive measures in place at the retail level to prevent this from happening. Requiring retail establishments to train their employees in food safety practices would be a

simple preventive measure that would go a long way to reducing food safety risk to consumers within the retail food industry.

D. We Want To Do More To Use and Leverage Proven Organizational Culture and Behavioral Science Principles and Techniques To Enhance Organizational and Employee Compliance With Desired Food Safety Practices and Behaviors

1. What are the most significant actions FDA could undertake to foster and support the development of food safety cultures globally?

Unlike the CDC with its robust educational component, FDA is a regulatory agency, which naturally creates a chasm in its relationship with industry. Instead of ignoring or trying to breach the chasm, FDA may have the most significant effect on food safety culture within companies if they continue to foster and nurture a collaborative and cooperative relationship with industry trade associations. Western Growers and its industry partners work tirelessly to educate, support, and assist companies in establishing and maintaining a robust food safety culture. We firmly believe food safety culture is a top-down phenomenon within companies and make it a priority to challenge company owners and management to ensure they are supporting their food safety personnel in communicating that food safety is every worker's responsibility.

2. How can FDA encourage and support companies in the development of food safety cultures throughout the supply chain?

For many developing a food safety culture involves a learning curve. Data and information drive the learning curve when it is effectively used to educate the industry. FDA can most effectively participate in the educational process by collaborating with trusted partners such as industry trade associations and cooperative extensions. As a regulatory agency, FDA should reserve severe punitive action for those who show a blatant disregard for the law and for consumer safety and otherwise direct their resources to research and educational efforts.

FDA should also consider recognizing firms that have strong food safety culture and preventive programs. During outbreaks there are many companies who are not part of the potential problem, FDA should work quickly and with industry to clear these companies and one way to do that is to recognize them early and often as being "best in class".

3. What are the obstacles to creating food safety cultures throughout the supply chain?

Obstacles range from the lack of education to a perceived lack of resources, and, for a very minor fraction - willful neglect. Another major obstacle is an unintended consequence of audits where food safety "culture" becomes centered around passing the audit. Western Growers and their counterparts

in the fresh produce industry are working to combat the notion that passing an audit is equivalent to a robust food safety culture.

For the retail side of the supply chain, the obstacle has been a focus on the upstream suppliers. This has allowed retailers to deflect responsibility from their practices to their suppliers. As retailers consolidate, this issue is getting more and more difficult to address. Large retailers need to be held accountable for educating their workforce and maintaining an "everyone's responsible for food safety" mentality in their operations.

4. Are there changes that FDA can and should take in how it approaches food safety to place further emphasis on prevention?

Western Growers firmly believes there can never be too much emphasis on prevention. Technology holds much promise in developing the means to identify and prevent human pathogens from entering the food supply. Until those technologies are commercially available, industry must do everything they can to prevent contamination. Commercialization and market forces incentivizes the private sector to develop technological solutions for detecting pathogens. FDA can better support industry by committing more resources to investigating where pathogens are sequestered and how best to prevent them from spreading to the food supply. This basic knowledge will help drive more accurate and useful technology for the entire supply chain. In addition, FDA could prioritize and fund research and development of effective technology, industry practice, kill steps and other meaningful tools that will strengthen preventive programs.

In conclusion, Western Growers is appreciative of the opportunity to provide these comments on a New Era of Smarter Food Safety for consideration by FDA. Western Growers is actively advancing efforts consistent with FDA themes and is happy to share our work as we remain committed to working collaboratively with FDA to improve and enhance both industry and agency efforts to prevent, detect, identify, trace, and isolate pathogen-contaminated product that may threaten the consuming public's health.

Respectfully submitted,

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