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

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Re: Requirements for Additional Traceability Records for Certain Foods (Sept. 23, 2020), Docket No. FDA-2014-N-0053

Dear Sir or Madam:

Western Growers is pleased to submit comments to the Food and Drug Administration ("FDA" or "the agency") on the agency's proposed rule on "Requirements for Additional Traceability Records for Certain Foods." Western Growers is an organization that represents producers and handlers of specialty crops - fresh fruits, nuts and vegetables grown, harvested, packaged, processed, and shipped from the states of California, Arizona, Colorado, and New Mexico. Our members provide half the nation's fresh fruits, vegetables and tree nuts including locally grown produce and a third of America's fresh organic produce. Some members also farm throughout the U.S. and in other countries providing consumers with year-round access to nutritious food. For generations we have provided nutritional variety and healthy choices as the first line of defense against obesity and disease: we grow the best medicine in the world.

Western Growers supported the passage of the FDA Food Safety Modernization Act (FSMA) and supports FDA fulfilling its Congressional mandate under Section 204 of FSMA to develop a system within the agency for product tracing and to establish recordkeeping requirements for high-risk foods. Western Growers members share FDA's goal of facilitating quick traceback activities to enable swift identification of contaminated product, help prevent future public health outbreaks, and avoid sweeping public advisories. Our members have been committed to improving traceability in our industry for several years and have extensive experience with traceback investigations. They have participated in voluntary efforts to both better understand traceability challenges and enhance traceability practices such as through the Produce Traceability Initiative, compliance with GFSI standards, and the Leafy Greens Traceability Pilot. In short, we have long supported and want to promote an end-to-end traceability system.

We have reviewed the proposed rule in light of our objectives and are concerned that as drafted, it is overly complex, complicated, and burdensome, particularly for growers. As a result, it will not achieve its public health goals. In our view, for end-to-end traceability to work, it must be implementable by all entities and, therefore, must be simple and direct.

We respectfully request that FDA significantly revise the proposed rule using a framework that is as simple as possible. The simpler the rule, the better industry will be able to comply, and the more accurate information provided to FDA will be. We also note that FSMA expressly states that the public health benefits of the new recordkeeping requirements must outweigh the cost of compliance with such requirements.[1] We believe new traceability recordkeeping requirements should recognize, support, and align with voluntary industry efforts, which have shown to be effective. For instance, the California Leafy Greens Marketing Agreement (LGMA) conducted a traceability survey in 2020. The survey results showed that growers are capable of quickly tracking product in 2 hour or less, regardless of whether they had a paper-based or electronic system. In addition, more than half of the respondents confirmed they are utilizing the Produce Traceability Initiative (PTI) for labeling and traceback. The PTI effort started over a decade ago and demonstrates the ability to quickly and accurately trace products when key information is consistently maintained by each participant in the supply chain.

In our comments below, we provide feedback on the agency's proposal and offer suggestions for a more workable approach. Specifically, we recommend that the agency narrow the recordkeeping requirements to focus on the minimum elements needed to effectively trace food and protect public health. In our view, a narrowed approach will assure that key information is captured and retained by each entity participating in the supply chain. As discussed further below, we believe the key information that should be maintained and passed forward in the supply chain is the lot code, the harvest/pack date and name of the entity that assigned the lot code.

Below, we first outline key themes from our comments and provide background information on how product moves within the produce supply chain. We then share feedback on key provisions in the proposed rule, including definitions, exemptions, and key data elements (KDEs). Finally, we offer our perspective on compliance and enforcement activities related to this rulemaking.

I. Executive Summary

In our detailed comments below, we elaborate on the challenges the proposed rule presents, our suggestions for solutions to those challenges, and areas of the proposal we support. Common among our detailed comments are the following themes:

[1] FDA Food Safety Modernization Act §204(d)(1)(D).

- There are many different business models and supply chains involved in getting fresh produce from the farm to the point of service/retail. It is imperative, therefore, that any new recordkeeping requirements and the ultimate traceability framework account for all of these models.

- We believe that all produce should have traceability information associated with it.
    - From a grower perspective, it is not practical or feasible to manage different recordkeeping systems for different crops.
    - Consistent implementation of new recordkeeping requirements across the supply chain for all produce would be beneficial to all entities involved and would better protect public health.

- Any new recordkeeping requirements should emphasize the information that is absolutely necessary for traceability; and that should be the information that is passed forward in the supply chain.
    - The simpler and more straightforward the new recordkeeping requirements are, the more likely it is that the system can be implemented broadly, across the supply chain.
    - As has been demonstrated by pilot projects, the key information is the harvest date/pack date, the lot code and name of the entity that assigned the lot code. This is the information that should be required. The remainder of the data elements are supportive. It is not necessary to regulate the supportive proposed KDEs, and unnecessarily burdensome to do so.
    - FDA should use Guidance as a means of recommending other information that could be maintained by the supply chain.

- We are concerned that much of the data FDA proposes to require be recorded, maintained, and provided throughout the supply chain is intended to facilitate root cause investigations, rather than identify potentially contaminated food; which is the purpose of Section 204 and the mandate provided by Congress to FDA.
    - We appreciate FDA's challenges in conducting root cause investigations and recognize the value in understanding the cause of a particular contamination event so that corrective and preventive actions can be taken to reduce the likelihood of a reoccurrence.
    - That information, however, is not necessary to tracing food and removing it from the marketplace and those additional details have the potential of slowing down the traceback exercise.

- We recommend that FDA simplify the rule and make it goal based – with a focus on ensuring the lot code is available at the last mile. FDA has made clear that when traceability information is available at the point of service, tracebacks are most efficient. FDA should focus on that objective, without prescribing how information is shared throughout the supply chain.

Our more detailed comments follow.

II. Background Information

Before providing feedback on specific elements of the proposed rule, we thought it would be helpful to provide some background information regarding how produce may move through the supply chain. As we comment further below, the fact that both the Produce Safety Rule's definition of "farm" and this proposed rule's definition of "first receiver" are based on "ownership" causes confusion for entities that handle the product before it reaches its purchaser/owner (a.k.a. the first receiver). For fresh produce commodities, numerous entities often handle the product before it reaches the first receiver. Because the first receiver is responsible for obtaining required KDEs, it is unclear which entity or entities have the necessary information to support this requirement, which entity or entities are responsible for creating the records, and which entity or entities are responsible for passing those records to the first receiver.

In many cases the grower will not know who the first receiver will be when the product leaves the growing area following harvest. For example, after harvest, one lot of fresh produce can take numerous paths through the supply chain (see supply chain scenarios below) depending on the entity that purchased and ultimately possesses the product (the first receiver). In general, this is because:

- Harvesters can be part of a separate company and also not contracted by the grower;
- Growers / farms do not always arrange transportation; and,
- Cooling facilities are often not owned by the grower, harvester, or packer. Due to the hot growing environment, removing heat from most fresh produce commodities as soon as possible after harvest is essential for maintaining the quality. However, due to the cost of running a cooler, most cooling facilities are owned by a separate company dedicated to providing cooling services to the industry.

Below are several supply chain scenarios demonstrating how produce may move to the purchaser. In the scenarios below, the entity that purchases and takes possession of the product (depicted in red) can be at different points in the supply chain. Several entities handle the product without taking ownership prior to the buyer taking possession of the product. In addition, after the initial post-harvest cooling, products are often cooled again at other points along the supply chain. Please note that the terms "handler/shipper" refer to "the entity that places produce into commerce." (Our industry uses the term "shipper" differently than the proposed rule).

1. If a **Shipper/Handler** purchases the product and takes it into their possession (the first receiver), the supply chain may look like this:

Growing → Harvesting → Packing → Icing/cooling → cold storage → Transportation by **Shipper/Handler** → Cold storage/warehouse → End customer (retail/foodservice/broker/cooperative/distribution center)

2. If a **Processor** purchases the product and takes it into their possession (the first receiver), the supply chain may look like this:

Growing → Harvesting → Packing → Icing/Cooling → Cold storage → Transportation → Cold storage warehouse **(Processor)** → Transportation → End customer (retail/foodservice/broker/cooperative/ distribution center)

3. If a **Distributor** purchases the product and takes it into their possession (the first receiver), the supply chain may look like this:

Growing → Harvesting → Packing → Icing/cooling → cold storage → Transportation → Cold storage/warehouse → Fresh-cut processing → Cold storage finished goods → Transportation → **Distributor** → End customer (retail/foodservice)

4. If the **End Customer** (broker, cooperative, retailer, foodservice) purchases the product and takes it into their possession (the first receiver), the supply chain may look like this:

Growing → Harvesting → Packing → Cold storage → Transportation → Value-added processing facility → Cold storage → Transportation → Cold storage warehouse → Transportation → **End customer** (retail/foodservice/broker/cooperative/ distribution center)

Finally, we note that one lot of product could be divided up and go through each of these scenarios. In other words, one lot of product can have multiple, different first receivers.

III. Proposed Definitions

In order to bring clarity to the rule and make it easier to implement, we recommend revisions to several of the key definitions and terms proposed. Many of our suggestions are intended to better reflect the supply chain for the produce industry and better account for how produce is handled and moves from the farm to the consumer.

- **Farm**

As we have previously commented, we are concerned that FDA has not revised the farm definition under the Produce Safety Rule and yet is proposing to use that definition in this rulemaking as well.

Specifically, the current definition of "farm," specifically the definition of "secondary activities farm," is based on ownership and management. This is incredibly confusing because there are often complex business relationships managing the growing, harvesting, and distribution and sale of produce. A definition of "farm" that focus on ownership and sales cannot account for these complexities and makes compliance more burdensome than is necessary for regulated entities. In our view, a definition of "farm" that is based on activity, will make more sense. We support a definition of "farm" based on activity for purposes of the Produce Safety Rule and for this rule. Consistency between these two rules is important to avoid confusion and ensure ease of implementation.

- **First Receiver**

As noted above, the concept of the "first receiver" is very confusing, both to growers and receivers alike. Notably, in recent guidance, FDA explained that there can be "receivers" before there are "first receivers." Nonetheless, as current proposed, receivers and shippers cannot assign a traceability lot code if one has not already been assigned. It is unclear to us how this will work in practice and how information will be shared downstream if a lot code has not already been assigned to the food.

Adding to the complexity of this concept and the role of the first receiver is that often, who is the first receiver can change, based on the business transaction. As outlined above, produce can be purchased at many different points in the supply chain. For example, it can occur before or after growing. Significantly, often the farm will not know who the first receiver is (or which entity fills this role), as the farm may sell to a broker. Brokers are not covered by the rule because they do not take possession of the food. Yet, brokers are the entity that often arranges for the transportation of the produce and knows who is purchasing and taking possession of the product.

To address this issue, we suggest that FDA remove the first receiver concept from the rule. As discussed further below, we do not think that there is additional information that should be provided to or maintained by first receivers of produce.

If FDA decides to retain the first receiver concept in the final rule, FDA should make clear in the text of the regulation that covered entities can rely on other parties to establish and maintain records on their behalf. In addition, FDA should require that when the farm and broker (or other entity) have a written agreement that the broker will be responsible for providing shipping information regarding a product, the broker is responsible for carrying out the responsibilities for "shippers" and "receivers" (as may be appropriate) and are subject to the rule's requirements for those entities.[2]

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[2] We note that FDA took a similar approach in the rulemaking for the Sanitary Transportation of Human and Animal Food rule. There, carriers are subject to certain responsibility under the rule when they enter into contracts with shippers. See 21 C.F.R. § 1.908(e). Similarly, Congress recognized the need to hold importers accountable for the safety of the foods they import, regardless of whether they took physical possession or not, when they authored the Foreign Supplier Verification Programs requirement.

We also note that FDA does have the authority under the Bioterrorism Act to impose recordkeeping requirements on distributors, importers, and transporters (among other entities). These entities are not required today to maintain lot code information. FDA has the ability to amend these provisions under its existing authority in 21 U.S.C. §350c. We suggest the agency considers ways to combine the requirements of Subpart J and proposed Subpart S to enhance traceability.

Furthermore, if FDA does not change the definition of "farm" in this rulemaking, then it is important that FDA de-link the definition of first receiver to a farm. The first receiver should be the first registered facility to hold the food (regardless of ownership).

- **Fresh Cut Fruits and Vegetables**

Fresh cut fruits and vegetables are identified as a commodity on the Food Traceability List. Neither the Food Traceability List nor the proposed rule defines "fresh cut." The Food Traceability List simply explains that it covers all types of "fresh cut fruits and vegetables." We respectfully request additional clarity regarding the meaning of "fresh cut" for purposes of understanding which foods are covered under this commodity. Existing FDA Guidance on controlling for microbial contamination in fresh cut produce contains a definition,[3] but its application remains unclear. For example, it is unclear which activities are considered part of harvesting, such as trimming, field coring, and washing, and which activities are considered to take place after harvesting. We ask FDA to further define "fresh cut" and outline how processing activities that result in "fresh cut" produce differ from those that are part of traditional harvesting, such as trimming and cutting. Consistent with the overall theme of our comments, the definition of "fresh cut" should be simple and easy to understand and interpret.

- **Originating**

FDA proposes that "originating" involves the growing, raising, or catching of a food or the harvesting of a non-produce commodity. As discussed below, FDA proposes that a traceability lot must be assigned at "originating" and therefore at "growing." However, for traceability purposes, produce does not exist as a traceability lot until it is harvested. There is no meaningful lot code assigned to produce when it is still

[3] "Fresh cut produce" means any fresh fruit or vegetable or combination thereof that has been physically altered from its whole state after being harvested from the field (e.g., by chopping, dicing, peeling, ricing, shredding, slicing, spiralizing, or tearing) without additional processing (such as blanching or cooking). Fresh-cut produce may or may not undergo a wash or other treatment before being packaged for use by the consumer or a retail food establishment. Fresh-cut produce can be a single commodity or two or more mixed in the same package, such as coleslaw or fruit salads, and sometimes called "ready to use," "precut," or "value added" produce. Fresh-cut produce also does not include produce that has been processed by freezing, cooking, canning, or packing in a juice, syrup, or dressing. Guide to Minimize Food Safety Hazards of Fresh-cut Produce: Draft Guidance for Industry (2018) at: https://www.fda.gov/media/117526/download.

in the field. Accordingly, we recommend that "harvesting" be considered "originating" food. Alternatively, harvesting should be a separate critical tracking event where the lot code is assigned.

- **Traceability Lot**

FDA proposes to define a "traceability lot" as a lot of food that has been originated, transformed, or created. As noted above, because there is no lot when produce is grown, only once it is harvested, FDA should amend the definition of originating to include harvesting.

In addition, FDA should include the activity of "packing" produce as an event at which a lot code can be assigned.

- **Transformation**

FDA proposes that transformation includes "repacking." In addition, FDA proposes that when food has been transformed, it must be assigned a new traceability lot code. Further, during transformation, records must be maintained "linking" the incoming lot to the outgoing lot.

In the produce industry, often farms will repack produce from within the same lot. This product does not receive a new lot code (as would be required under the rule), because the product has not changed. It has simply been resorted for grading or size or other quality purposes (e.g., color). FDA should clarify that these activities do not constitute "repacking" and are not considered transformation under the rule. For example, FDA could clarify that "repacking" only takes place at "facilities" and not at "farms." It is appropriate for this repacked product to retain the same lot number as that facilitates traceability back to the growing farm. If the produce were required to receive a new lot code, it would actually hinder traceability efforts.

FDA also proposes that transformation involves "changing a food's label (regarding the traceability lot code or traceability product identifier)." We support a narrow interpretation of changes to a food label. These should be those changes that result in a change to the commodity, not just the brand name, for example.

- **Retail Food Establishment**

FDA proposes to define a "retail food establishment" as one that sells food products directly to consumers as its primary function. The definition explains that retail food establishment "includes grocery stores, convenience stores, and vending machine locations." In the preamble, FDA explains that it regards "restaurants, online food retailers, and meal kit delivery companies as other examples of such establishments." We recommend that FDA revise the regulatory definition of "retail food establishment" to identify these entities, consistent with the preamble. This is very important, as these entities are the last stop in the supply chain before the consumer and are critical for traceback investigations.

IV. Exemptions

Western Growers has historically opposed exemptions related to food safety. However, we feel that with few exceptions, the proposed exemptions and limitations in this proposed rule will not substantially limit FDA and industry's ability to trace food. We offer our feedback on ensuring the proposed exemptions are workable, below.

- **Small Originators**

FDA proposes to exempt certain originators of food based on size. As noted, above, although we historically have not supported exemptions because we believe all entities should engage in practices relevant to food safety, in this instance, we expect that this exemption will not hinder traceback efforts, because the rest of the supply chain would still be subject to subpart S and these new recordkeeping requirements.

- **Certain Food Produced and Packaged on a Farm**

Consistent with FSMA, FDA proposed to exempt produce in packaging that maintains the integrity of the product and prevents subsequent contamination and alternation until it reaches the consumer, provided it is labeled with the name and address of the farm on which it was produced and packaged. We suggest that FDA clarify the meaning of "integrity." We believe that in this context, Congress was referring to packaging that maintains the food as a distinct unit, rather than packaging that prevents exposure to the environment. All produce is packaged in breathable packaging to prevent deterioration. Because this rule is about identifying the commodity, rather than about food safety, exposure to the environment (e.g., clam shells with holes), is irrelevant. Further, when produce is transported, it is further protected by an outer container (e.g., cardboard case) and shipped directly to a retail food establishment. At the same, we are concerned that simply requiring consumer level labeling with the farm information (which will likely be discarded upon consumption) provides limited value for a traceback. While this allows consumers to identify a product in the event of a recall, given the perishability of produce we are doubtful of the public health benefit. Accordingly, we encourage FDA to recommend additional voluntary practices in guidance that would focus on maintain and providing the lot code through the supply chain.

- **Partial Exemption for Retail Food Establishments**

FDA has proposed a partial exemption for retail food establishments for food produced on a farm and sold directly to a retail food establishment, provided the retail food establishment maintains a record documenting the name and address of the farm that was the source of the food for 180 days. It is unclear what it means for food to be sold directly to a retail food establishment, such as whether brokers could be used and whether the food could be shipped to a warehouse or distribution center

that is part of the retail food establishment's network and still be exempt. We request additional clarification regarding the scope of this exemption.

Further, in addition to maintaining the name and address of the farm that sold the food; we also recommend that the retail food establishment maintain the lot code and date (harvest/pack) associated with the food. We maintain that this is the most important information for traceability purposes.

- **Partial Exemption for Farm to School and Farm to Institution Programs**

FDA proposes a partial exemption for food produced on a farm and sold to farms and institutions, provided the food is "sold directly to the school or institution" and states that a "school or institution…purchases a food directly from a farm." We are concerned that as currently proposed, this partial exemption will not apply to the distributors who play a critical role in implementing the farm to school/institution programs. As written, we interpret this partial exemption to also exclude food purchased, for example, by USDA in support of such feeding programs, because strictly speaking, the food is not "sold directly to the school or institution." We encourage FDA revise the regulatory language to account for these distribution practices. We also suggest that FDA consider expanding this section beyond food that is sold and purchased, to include food that is donated by the farm to a school or institution operating an authorized child nutrition program.

- **Produce that Receives Commercial Processing**

FDA proposes that produce that receives commercial processing adequate to reduce the presence of microorganisms of public health significance should be completely exempt, provided the produce is accompanied by a written disclosure that it has not been grown in accordance with the Produce Safety Rule. We recommend FDA remove the proposed requirement that produce intended for commercial processing must be accompanied by a written disclosure to be exempt from the traceability requirements. Written disclosures are not common because even if produce is grown and intended for commercial processing, it is grown in compliance with the Produce Safety Rule. In other cases, the farm does not know the intended use of the produce it grows, and so it is grown in compliance with the Produce Safety Rule. To us, it does not make sense to tie a requirement that is related to food safety practices to a rule about recordkeeping and tracebacks. Further, we note that the processing facility will have records under the Bioterrorism Act and the Preventive Controls Rule that address the receiving and processing of the food.

- **Modified Requirements for Food that Are Subject to a Kill Step**

FDA has proposed modified recordkeeping requirements for foods that are subject to a kill step. Once the kill step is applied, additional recordkeeping requirements do not apply to the subsequent shipping

and receipt of the food, or subsequent transformation. Although we appreciate FDA's attempt to lessen the recordkeeping burden imposed on covered entities, as a practical matter we view this proposed exemption as having limited affect. It will be challenging for receivers to know whether a food has undergone a kill step. For example, some mangos are irradiated, yet this may not be known to entities in the supply chain. We consider the complications that arise with trying to understand whether a food has undergone a kill step as further evidence that the rule needs to be simplified so that it can be broadly implemented from end to end.

- **Intracompany Shipments**

To help reduce the burden of the rule, we recommend FDA clarify that intracompany shipments do not constitute "shipping" even if the product changes locations, provided the company has traceability procedures in place. The requirement to produce an electronic sortable spreadsheet of all CTEs would be incredibly burdensome if the movement of food through a vertically integrated supply chain needs to be accounted for. To address this, the regulations could provide that "entities that are under the ownership or operational control of a single legal entity may establish and maintain traceability records in conformance with common, integrated, written procedures."

V. Key Data Elements

As we noted at the outset, any new recordkeeping requirements should emphasize the information that is absolutely necessary for traceability; and that should be the information that is passed forward in the supply chain. Based on our members experience voluntarily implementing enhanced traceability procedures, the simpler and more straightforward the new recordkeeping requirements are, the more likely it is that the system can be implemented broadly, across the supply chain.

Several pilot projects and initiatives have demonstrated that the key information for traceability is the harvest date/pack date, the lot code, and the business name of the entity who assigned the lot code. We recommend that FDA streamline the proposed recordkeeping requirement to focus on this information. This is the information that should be required to be maintained and passed forward in the supply chain.

All other information such as quantity, unit of measure, product identifier, product description, location identifier, transporter, etc. are not necessary.[4] The other information becomes redundant and imposes costs on covered entities without an accurate and enhanced outcome. In addition, the systems that maintain the additional pieces of information or data elements are not always linked together and, in

[4] We understand that FDA has proposed certain KDEs because the lot code is rarely, if ever, available when a consumer is ill. We appreciate that challenge, but do not believe that the burden of the additional KDEs will outweigh their value. In our view, consistent with the 80/20 principle, if FDA requires less information, it will achieve significant success in improving traceability because the critical data will be maintained and available to the agency.

particular, are not linked to shipping records. Maintaining these additional data elements also would be prone to error, further reducing their value. Through Guidance, FDA can recommend the maintenance of information that is helpful, such as the remaining KDEs, but this data should not be required to be maintained or passed through the supply chain.

In our view, the more data that is required, the likelihood of having convergence decreases. For example, if a distribution center provides product to ten retail stores, that product could have come from a variety of different supply chains. The common information, and the information necessary to tracking which product was received by which retail store, is the lot code. Again, the simpler the requirements, the easier it will be for covered entities to comply and the easier it will be for FDA to enforce.

Below, we offer our feedback on a few of the proposed KDEs in particular.

- **Growing area coordinates:**

FDA proposes to require farms to maintain records linking the traceability lot code to the growing area coordinates for the entry point of the location where the food was grown. This information is not necessary to identify potentially contaminated food and remove it from the marketplace, as the growing area coordinates are not used to assign a lot code to a food or trace it. Rather, this information is only useful during a regulatory investigation into the potential source of cause of contamination. We also note that there may be multiple entry points to a farm; as well as growing area coordinates that designate entry points to different farms at the same location. We maintain that the key piece of information for traceability purpose is the physical address for the farm. As such, this requirement should be removed from the final rule.

- **Point of contact for the traceability lot code generator:**

Full contact information including name, phone number, and email address are not necessary to trace food. Instead of full contact information, only the business name of the traceability lot generator should be required. Again, if the lot code and harvest/pack date are available, this is more than sufficient. Alternatively, we submit that FDA could require covered entities to maintain contact information regarding the traceability lot code generator, but not be required to pass that information forward when shipping the food.

- **Information regarding the harvester and date/time of harvesting; location and date/time of cooling; and location and date/time the food was packed:**

FDA proposes that farms maintain and provide to first receivers information regarding harvesting, cooling and packing. We maintain that this information is not relevant and is unnecessarily burdensome to maintain and provide. For example, the name of the harvester and the time of harvesting are not

material to identifying the lot of food. Cooling can happen more than once and at multiple locations. Further, the cooling event is not important from a traceability perspective because the lot does not change as the product is cooled. Moreover, we note that cooling information is maintained by the cooler, not the farm. This information is maintained in a separate system, and not provided as the product is moved.[5] Similarly, although the date of packing is relevant, the location where the food was packed is not. Again, the lot code is the key piece of information that should move forward with the product.

- **Time:**

FDA proposed that covered entities maintain information on the time each critical tracking event takes place. When the lot code is available, the time the event occurred does not add value, and only increases the recordkeeping burden. Further, it is unclear whether this is the time an activity commenced, or the time completed. This confusion shows how this information does not add value for traceability purposes.

VI. Compliance and Enforcement

Even with the changes to the proposed rule we have recommended above, implementation of a new recordkeeping regime will be a substantial undertaking. We offer the following comments and recommendations concerning the proposed rule's compliance and enforcement provisions, which will help to facilitate adherence to the rule and a smoother implementation process.

- **Education and Outreach**

Despite our industry's experience with voluntary traceability initiatives, implementing a new a recordkeeping regime that uses terminology and new to industry will be time- and resource-intensive. In addition to updating their recordkeeping practices, farms will need to train their employees and, in many cases, purchase and implement new technologies. FDA will need to provide guidance, training materials, and sufficient time for compliance.

In addition, given the global nature of the food supply chain, we anticipate that educating the international community about the proposed rule will be imperative to ensuring a smooth implementation process, and we encourage FDA to lay out its plans for providing resource materials in multiple languages and educating the international community about the rule.

- **Focus of Enforcement Efforts**

[5] We note that in Guidance, FDA could recommend that coolers maintain information about the product they cool and make that information available to FDA upon request.

As FDA develops its enforcement strategy, we encourage the agency activities on the point of the supply chain that provides product to consumers – the last mile. If enforced at the "last mile," this rule will have impact on improving the traceability of very short shelf-life products. In addition, we ask FDA to find ways to ensure that brokers and importers facilitate compliance for other entities under the rule and are partners in traceability efforts. Finally, we believe FDA should focus on the purpose of the rule – effective traceability – rather than identifying custody of product for enforcement of other statutory and regulatory obligations.

- **Compliance Date**

We note that the ability of covered entities to comply with this rule is contingent upon how complex it is and how much it differs from existing practices. Accordingly, we encourage FDA to simplify the requirements and ensure that they align with voluntary industry efforts.

- **FDA's Time and Cost Estimates**

We are concerned that FDA's time and cost estimates for the Proposed Rule in its Paperwork Reduction Act and Preliminary Regulatory Impact Analysis are too conservative, underscoring the need for FDA to simplify the rule to help reduce the burden on covered entities. For instance, we anticipate that many of our growers will produce far more than 1,000 FTL lots per year, and therefore will be required to spend more time creating and maintaining records than FDA estimates. FDA's predictions for the time to read and understand the rule also are far too low. Our members already have spent far more than 3 hours per company reading and analyzing the Proposed Rule and assessing its potential impacts on their business. Indeed, our members have closely assessed the ways in which they would be required to change their recordkeeping systems from their current practices, and the agency's estimates for the time and cost associated with updating current recordkeeping systems, as well the cost of corresponding capital investments needed to achieve those changes, are much too conservative. Because of the complexity of the Proposed Rule, corresponding training times and costs also will far exceed FDA's estimates. Our substantially higher time and cost estimates reinforce the need for FDA to simplify the Proposed Rule to reduce the time and cost for compliance.

VII. Conclusion

Western Growers and our members have been actively engaged in efforts to improve traceability to protect consumers from potentially contaminated food and remove it from the marketplace. We have thoroughly considered the proposed rule, and based on our experience, we believe that the proposed rule would be too burdensome to implement broadly. Therefore, we request that the agency narrow the recordkeeping requirements to focus on the minimum elements required. We have long supported and want to promote an end-to-end traceability system and believe that clear, simple, and consistent

requirements along the supply chain should facilitate the adoption and implementation of traceability. We stand ready to work with FDA to achieve our common goal.

Therefore, we respectfully request that FDA take the time to work with the industry to find a practical and effective way forward, then issue a Supplemental Proposed Rule, which takes into account our and other industry members' comments. Issuing a supplemental proposed rule will allow FDA to engage further with industry to understand better the ways in which the Proposed Rule could be simplified or made more flexible to accommodate industry practices, and we would be pleased to participate in this collaborative process.

Thank you for the opportunity to comment on this important topic. We hope our comments are helpful. Please do not hesitate to contact us if we can provide any further information.

Sincerely,

De Ann Davis

SVP, Science
Western Growers Association