February 8, 2021

Brian Pendleton
Office of Policy
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: 21 CFR Part 1: Requirements for Additional Traceability Records for Certain Foods; FDA-2014-N-0053-0184

Mr. Pendleton,

The Produce Marketing Association (PMA) is pleased to offer comments on the proposed FDA rule 'Requirements for Additional Traceability Records for Certain Foods.' We appreciate the Department's intention to establish recordkeeping requirements for foods on the Food Traceability List designed to improve the traceability information during foodborne illness outbreaks and to increase the speed and precision of trace-back and trace-forward investigations for recall events. The proposed requirements are informed by the challenges we have faced in obtaining critical tracing information and the advancements in traceability approaches that industry has already begun to implement. We support FDA efforts to use the proposed rule to reduce the harm to the consumers caused by foodborne pathogens and limit adverse impacts on industry sectors affected by the outbreaks by improving the ability to trace the movement quickly and efficiently through the supply chain of foods recognized as causing illness, identify and remove products from the marketplace, and develop mitigation strategies to prevent future contamination.

PMA represents more than 2,600 member companies in over 40 countries around the world. Our members operate at every level in the supply chain from growing, shipping, processing, distribution, wholesaling, retail, and foodservice. A significant portion of PMA's membership includes technology and input suppliers, including manufacturers of products that would be regulated under the proposed rule. In the United States, it is estimated that PMA members handle more than 90 percent of fresh produce sold to U.S. consumers. PMA serves its members by providing a forum to make business connections and by providing them with the information they need to make decisions that will enhance their businesses, allowing them to deliver fresh fruits and vegetables to consumers. Regardless of size or scope of operations, our members are committed at every level to improving the health and well-being of consumers.

General Comments

Overall, PMA commends the FDA on release of the proposed rule that we believe will strengthen the industry's record keeping requirements for certain foods, some of which were linked to outbreaks of foodborne illness. Furthermore, the traceability requirements will establish best practices for maintaining and quickly tracking information up and down the supply chain. The net result will be much stronger consumer confidence in products produced by the fresh produce and broader food industry.

In reviewing the proposed rule, PMA noted areas where there were outstanding questions or additional guidance needed from FDA to properly communicate and enforce the regulations. With that in mind we have posed questions and comments, section by section, in those areas that are most relevant to the fresh produce and floral supply chains.

Specific Comments

General Provisions:

§ 1.1300 Who is subject to this subpart? - PMA believes that non-registered facilities should not be exempt from record keeping. However, the reference to "apply to all persons" in non-registered facilities would appear to expand beyond the rule as intended in the Act. We would like FDA to please explain the rationale for this expansion.

§ 1.1305 What foods and persons are exempt from this subpart?

(a) *Exemptions for small originators - (1) Certain produce farms*

PMA has several questions related to the exemption of produce farms:

1. How does the downstream user know if the product is exempt or not?
2. Is there a written exemption that will be provided? Will an exempt form need to be provided to the distributor to declare?
3. Is product shipped from "the small farm" exempt throughout the entire supply chain?

(b) *Inapplicability to certain food produced and packaged on a farm*

1. What is the basis for the exemption on packaging that "maintains integrity"?
2. What is the proper process when a business field packs the same commodity in different locations? Is labeling required for each individual farm (separate farm location and contact information for each farm) or will the farm's business address suffice?

(c) Option 1 for Paragraph G – Exemption for small food retail establishments – Please provide the official definition or reference source for full-time equivalent (FTE).

(d) *Option 2 for Paragraph G – Partial exemption for small food retail establishments* - PMA would like clarification that only invoices/receipts would be required and not full traceability logs. It would be an unrealistic and unnecessary burden for restaurants to comply with full traceability logs. However, it may be realistic for small food establishments to keep copies or records for 180 days of where the items on the list were purchased to allow for proper trace-back during an outbreak investigation.

(e) *Partial exemption for retail food establishments* – PMA would like clarification that the definition of retail food establishments would not include distribution centers (DC's).

§ 1.1310 What definitions apply to this subpart?

Cooling – Please clarify as to whether cooling refers to re-cooling as well?

Critical Tracking – PMA would recommend that 'growing' be replaced with 'harvesting' to reflect the step in the process where tracing begins. We would also recommend the addition of 'disposal' as one of the critical tracking events.

Farm – We feel that the proposed definition will make it extremely difficult for the produce industry and FDA to comply with the rule as proposed as the definition of "farm" is unclear. The lack of clarity around "secondary activity farms" is increased by FDA's definition of "first receiver," which is the first non-farm entity. The produce industry has urged FDA to align the "farm" definition with the official title of the Produce Safety Rule and the corresponding section of FSMA, which specifies that the rule is intended for the growing, harvesting, packing and holding of produce. We suggest that FDA use ownership rather than activity in all regulations in defining a "farm."

First Receiver – Does the definition of 'purchase' include 'consignment'? As an example, we note that brokers purchase the fresh produce product but do not take possession. We request clarification of the language in the regulation to reflect the information provided in the "Frequently asked questions about the food traceability proposed rule" published on January 12, 2021 in the "First Receiver" section.

Food Traceability List – We note that when the rule is finalized, industry has 24 months to implement. However, when items are added to the Food Traceability List, they become effective in 12 months. We recommend the implementation period be 24 months, the same for those items on the initial list, as well as those added to the list.

To reflect that food from the traceability list may have been transformed using a critical control step, we recommend the sentence be reworded as following: "The term 'Food Traceability List' includes both the foods specifically listed and foods that contain specifically listed foods as ingredients *unless subjected to a known kill step.*"

Physical Location – In some cases, production property may span more than one county, or the entry point may be common for multiple growing areas under different ownership. We recommend physical address be provided as an alternative to protect the confidentiality of coordinates. In the case of multiple entry points, the required information should be more clearly identified as the entry point may not be the specific growing location.

Harvesting – PMA recommends there be a distinction of 'harvesting' versus 'further processing' for raw agricultural commodities. We also note that the *first receiver* definition, 'harvested', specifically excludes produce, while the definition in this section includes produce. To clarify, we recommend the term 'harvesting' replace 'growing' under the *critical tracking* definition.

Holding –

1. We believe the reference to "such as drying/dehydrating hay or alfalfa" should be replaced with an example more directly related to the foods subject to this proposed rule.
2. We note this entire paragraph is nearly verbatim from 21CFR, but the word "could" in front of "include" was removed in this version. Please clarify as to whether the removal of "could" is intentional to narrow the scope of what could be done on a farm.

Kill Step – Further clarification is requested on the meaning of "significantly minimizes," and whether a log reduction should be considered in order to identify what is meant by significantly minimizing pathogens.

Location Identifier – PMA recommends that a Global Locator Number (GLN) or another internally assigned location number be used to assign the physical location.

Lot – PMA recommends the language be revised to 'recommended that lots consists of same product and produced under uniform conditions." It is important to reference the same product produced within a lot.

Manufacturing/processing -We note that drying alfalfa in the *Harvesting* definition is not considered manufacturing, while drying raisins in this example is. Can you please provide the basis for the two definitions?

Nonprofit food establishment – Please clarify as to whether hospitals and nursing homes would be considered non-profits.

Originating – As referenced previously, replace 'growing' with 'harvesting'. "Growing" can be complicated by the realities of the production cycle, for example, a number of crops are grown using transplants, some are grafted and then transplanted.

Packing – The proposed regulations refer to packing as a transformation. Is commingling considered a transformation under this definition? For packinghouse operators, would new lot codes be needed when re-packing?

Person – Please provide further clarification on the definition of 'person'. Would it include corporations with multiple physical locations? We request clarification of the language in the regulation to reflect the information provided in the "Frequently asked questions about the food traceability proposed rule" published on January 12, 2021 in the "Movement of the food within the same organization" section.

Physical location name – PMA believes that requiring both a 'physical location name' and a 'physical location description' is confusing. Physical location description typically means a complete physical address and other key contact information, specifically the business name, physical location name, primary phone number, physical location street address (or geographical coordinates), city, state, and zip code for domestic facilities and comparable information for foreign facilities, including country. Please clarify specifically what data fields are required (i.e., street address, zip code, county/city, state, etc.).

Point of contact – As there may be continuous changes in persons that may have familiarity with an entity, we recommend changing the reference to 'an entity's designated individual(s).

Receiving – We recommend changing the reference to 'customer' to 'received by a different facility'.

Reference record – PMA believes the records should correspond to 'critical tracking events' and not just 'an event'.

Retail food establishment – Please clarify if retail food establishments include restaurants, cafeterias and commissary be added to the definition of a retail food establishment. In addition, please clarify as to whether operations that prepare and serve food without selling it that are not non-profits would be included in the scope (i.e., company-owned cafeterias)?

(i) At a roadside stand – Is there a revenue cap that would apply to roadside stands? We note that most roadside stands either sell their own produce, or re-sell produce they packaged in bulk.

Shipping – Please clarify if retailers that are donating food would need to capture traceability information.

Traceability product description – We recommend the addition of a Global Trade Item Number (GTIN) to the product description. Please also clarify if the category code or term needs to be printed on the package.

Traceability product identifier – We recommend that an example of a unique identification code be provided, such as GTIN, Internal Item Number, etc.

Transformation – Please clarify if the same lot number must stay in effect if product is regraded/sized and put back in original cases.

Traceability Program Records:

§ 1.1315 What traceability program records must I have for foods on the Food Traceability List that I manufacture, process, pack, or hold?

(2) List of foods – Is this information required for every individual SKU, or just per commodity?

§ 1.1320 When must I establish and assign traceability lot codes to foods on the Food Traceability List?

(b) New traceability lot code –

We request clarification of the language in the regulation to reflect the information provided in the in the "Traceability Lot Code" section of the "Frequently asked questions about the food traceability proposed rule" published on January 12, 2021 and state that lot numbers cannot change if product is shipped and or received only with no transformation occurring.

Records of Growing, Receiving, Transforming, Creating and Shipping Food:

§ 1.1325 What records must I keep when I grow a food on the Food Traceability List? – If a grower is producing product for a shipper, must the grower retain records in addition to the shipper? Note that in most cases, the packer/shipper assigns the lot number and not the grower.

(a) Growing area coordinates – Does the coordinate information need to be shared with trading partners? We request clarification of the language in the regulation

to reflect the information provided in the "*Frequently asked questions about the food traceability proposed rule*" published on January 12, 2021 in the "Growing" section.

(b) Sprouts – A specific definition of sprouts should be included in the final regulations.

(c) Date of seed harvesting – Is this the date of seed harvest, or *sprouted* seed harvest?

§ 1.1330 What records must I keep when I am the first receiver of a food on the Food Traceability List? - As an overall comment, we would ask for further explanation as to the objective with this requirement. PMA is concerned that the effort to exchange the data will turn out to be ineffectual as there is no mechanism to ensure accuracy. The additional first receiver information to be captured and stored by the first receiver would be difficult to be verified for accuracy by the first receiver as it does not directly relate to the process of receiving. Who will be held accountable if the data is found to be inaccurate? In addition, the receiver has no way of knowing if they are the first receiver in advance of receiving the shipment, due to the variability in roles, ownership and practices in the fresh produce supply chain and within supplier companies. One shipment of the exact same product with different traceability lot numbers could have different record keeping requirements as the receiver could be considered "first receiver" on one traceability lot and not the "first receiver" on the second.

This section raises some additional questions/points:

1. We recommend using the case-level GTIN lot number to identify the originator.
2. We feel there could be some data privacy and corporate confidentiality concerns generated by asking the first receiver to share data that is not their own. In addition to the accuracy concerns noted above, the relationships at issue may be subject to contractual confidentiality provisions that restrict parties from sharing certain information. The proposed requirement could run afoul of those contractual terms.

   (i) Location identifier – Please clarify that GLN will be sufficient versus using latitudinal/longitudinal coordinates.

   (ii) Business name, point of contact and phone number – Please provide further information as to the benefit of this information in a traceability investigation.

(c) First receiver of food – The proposed regulations state that if you are a first receiver of a food on the Food Traceability List which has not already been assigned a lot code, you must establish a traceability lot code for the food

and maintain a record of the code linked to the information specified in paragraph (a) or (b) of this section. Does this assume at no point in the supply chain has a lot number been assigned? And is other information required for lot originators?

§ 1.1335 What records must I keep when I receive a food on the Food Traceability List?

(b) The entry number assigned – Please explain the purpose/benefit of providing the entry number(s) for the imported food.

(c) Location identifier date and time – Please clarify whether the date and time is the starting or completion of the receiving process of the food.

(f) The location identifier, location description, and point of contact for the traceability lot code generator; – We recommend identifying the brand owner through case GTIN and lot number. We would also point out that the code originator contact information being required to be captured and stored all the way through the supply chain is not necessary. The product identifier/brand owner information along with the lot number would be a more effective option. The point of contact should be the person authorized to speak to regulators. The lot code generator may not be that authorized person.

(h) Transporter – PMA recommends that all reference to the Transporter be deleted. If FDA chooses to keep references to the Transporter, please clarify if it is the Broker(s) or Transportation Company.

§ 1.1340 What records must I keep when I transform a food on the Food Traceability List?

(a) (iii) Quantity of each lot – Is this the quantity used in this transformation, or the entire quantity of that particular lot?

§ 1.1350 What records must I keep and send when I ship a food on the Food Traceability List?

As stated above, we feel there could be some data privacy and corporate confidentiality concerns generated by asking the first receiver to share data that is not their own. In addition to the accuracy concerns noted above, the relationships at issue may be subject to contractual confidentiality provisions that restrict parties from sharing certain information. The proposed requirement could run afoul of those contractual terms.

(1) Entry numbers for imported food – As stated in the previous section, what is the purpose of providing the entry numbers for imported foods?

(8) Name of the transporter – PMA recommends that all reference to the Transporter be deleted. If FDA chooses to keep references to the Transporter, please clarify if it is the Broker(s) or Transportation Company.

(8)(b) Sending records (electronic and other written form) – Will a link to this information electronically be sufficient?

(8)(b)(1) The information in paragraphs (a)(1) through (6) of this section

(1) The entry number(s) assigned to the food (if the food is imported) As stated above, please explain the purpose/benefit of providing the entry number(s) for the imported food.

(4) Location identifier and location description of the originator – PMA recommends focusing on the outcome and not dictating how the information gets there or who must share it. Perhaps an alternative is a central repository where the information is uploaded. If the information can be sent to the retail food establishment, does each entity need to share it?

(5) *Location identifier and description for the immediate subsequent recipient* – Please explain the purpose of providing information on the immediate subsequent recipient to the receiver of the product.

Special Requirements for Certain Persons and Foods:

§ 1.1355 What recordkeeping requirements apply to foods on the Food Traceability List that are subjected to a kill step?

(a) Kill step – Please clearly define kill step as it relates to fresh produce, including any pathogen specific requirements.

Procedures for Modified Requirements and Exemptions:

§ 1.1360 Under what circumstances will FDA modify the requirements in this subpart that apply to a food or type of entity or exempt a food or type of entity from the requirements of this subpart? – PMA requests FDA consider the financial impacts to the industry when modifying the requirements under this section.

Records Maintenance and Availability:

§ 1.1455 How must records required by this subpart be maintained?

(3) When necessary to help FDA prevent or mitigate a foodborne illness outbreak– The proposed regulations require persons subject to the subpart S requirements must make available, within 24 hours of request by an authorized FDA representative, an electronic sortable spreadsheet containing the information in the records they are required to maintain under subpart S, for the foods and date ranges specified in the request.

We recommend some flexibility with this requirement, as a large and wide investigation may require more time during certain periods of the year. We recommend

the insertion of ‘unless otherwise agreed to’. Furthermore, would this be a written request or a verbal request?

Thank you for the opportunity to submit comments. Please let us know if I can provide additional information or explanation.

Regards,

Ed Treacy
Vice President, Supply Chain & Sustainability
Produce Marketing Association