CPMA ACDFL

February 19, 2021

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

RE: Requirements for Additional Traceability Records for Certain Foods (Docket ID #: FDA-2014-N-0053-0056)

Mr. Pendleton,

On behalf of our members, the Canadian Produce Marketing Association (CPMA) respectfully submits the following comments to the proposed rule "Requirements for Additional Traceability Records for Certain Foods" [Docket No. FDA-2014-N-0053].

Based in Ottawa, Ontario, CPMA is a not-for-profit organization that represents a diverse membership made up of every segment of the produce industry supply chain who are responsible for ~90% of the fresh fruit and vegetable sales in Canada. CPMA is fortunate to represent a sector that is both a significant economic driver for communities and that also improves the health and productivity of Canadians. To provide context to our comments, approximately 25% of CPMA's members are based in the U.S. and many of the others have operations in both nations. To learn more about CPMA, please visit www.cpma.ca.

In January of 2019, Canada's Safe Food for Canadians Regulations (SFCR) came into force and as of January 15, 2021 all of the fresh produce sections were enforceable. Fresh produce traceability, SFCR, Part 5 - Traceability, was a new regulatory provision on which CPMA actively consulted with the Canadian Food Inspection Agency (CFIA) during the development of the new statutes.

As an industry, fresh fruit and vegetable chain participants have expended thousands of hours and millions of dollars to better understand and mitigate risks throughout the produce supply sector. Traceability requirements were being implemented by industry prior to both the SFCR and FDA Traceability Rule. Supplier adherence to industry developed programs including the Produce Traceability Initiative (PTI), Leafy Green Products Handler Marketing Agreement (LGMA) and the Global Food Safety Initiatives (GFSI), are standard requirements for the majority of large buying organizations.

CPMA asks that FDA and CFIA continue working together to streamline and/or standardize regulatory requirements and minimize those which place unnecessary regulatory burdens on the industry. CPMA will continue to liaison with both governments to assist in the creation of efficiencies throughout the fresh produce supply chain.

General Comments

Overall, CPMA commends the FDA on the 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.

CPMA works very closely with its counterparts in the U.S. (e.g. Produce Marketing Association and United Fresh Produce Association) and our comments in many instances are reflective of their comments which we anticipate being sent to FDA. These include a number of areas where there are 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 supply chain and our members.

While we understand FDA's interest in understanding as much as possible about impacted product, and the need to quickly identify product implicated in an event, not all information needs to be shared amongst trading partners to accomplish this. The use of a lot number in combination with other data such as the company name and product identification provide the keys to "unlock" information available with the lot originator – sharing information such as growing area coordinates or transporter along the supply chain is not necessary to ensure efficacious traceability and may be confidential or sensitive information that parties have concerns sharing. In addition, requiring information unnecessary for traceability needlessly complicates information sharing and adds complexity and burden to the supply chain. To ensure KDEs are being shared, the goal should be to simplify the process to ensure mass implementation of traceability regulations.

We agree with the themes developed by United Fresh Produce Association and included below:

1. Foundational prerequisites, including solid epidemiology, well scoped request for records, and a clear farm definition, must be in place for the rule to have the intended benefits.
2. Additional detail and definitions are needed regarding foods proposed on the Food Traceability List. Further, parameters should be developed to determine when foods containing foods on the FTL are also subject to the rule requirements.
3. Several terms and definitions are new, subject to interpretation, and create confusion. Further, many of the "new" data elements proposed to be required provide little value to traceability and simply increase the compliance burden.
4. Based on interpretation of terms and definitions, it appears that there is redundancy in the information required. We suggest that minimal information such as lot code on the product and brand owner is required to trace foods through the supply chain, regardless of the mechanism by which that information gets there.
5. Clarity is sought regarding records and information that must be shared through the supply chain, versus kept internally and shared with FDA upon request.
6. We urge FDA to leverage existing standards and industry initiatives, and work with other agencies in the US and abroad to provide resources (both training, as well as financial resources) that will support the changes to systems and processes that will be required to comply with the rule within the proposed timeline. Given the global nature of the fresh fruit and vegetable industry, we encourage FDA to, as much as possible, harmonize traceability regulations and guidance with major trading partners of the U.S.

Specific Comments

Part 1 – General Enforcement Provisions

General Provisions

§ 1.1300 Who is subject to this subpart? - CPMA supports full chain traceability but believes that internal traceability (within an organization) is outside the scope of the regulations and the spirit of one-up/one-down traceability.

§ 1.1305 What foods and persons are exempt from this subpart?
(a) Exemptions for small originators - (1) Certain produce farms
CPMA has several questions related to the exemption of produce farms but, in general, we would urge consideration to remove any exemption of farms, regardless of size of operation, as size of the operation does not impact the potential for a food safety event to occur at that facility.
In addition, if the exemption is maintained:

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 proper process when a business field packs the same commodity in different locations?
2. Is labeling required for each individual farm (separate farm location and contact information for each farm) or will the farms business address suffice?

(d) Option 2 for Paragraph G – Partial exemption for small food retail establishments - CPMA 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 of where the items on the list were purchased for 180 days to allow for proper traceback during an outbreak investigation.

§ 1.1310 What definitions apply to this subpart?

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

Critical Tracking – CPMA 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’ or ‘donation’ 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 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 – CPMA 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.

Lot – CPMA 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?

Non-profit 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 – CPMA 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 – CPMA believes the records should correspond to 'critical tracking events' and not just 'an event'.

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

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.

<u>Traceability Program Records</u>

§ 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 "Frequently asked questions about the food traceability proposed rule"

published on January 12, 2021 in the ”Traceability Lot Code” section 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. CPMA is concerned that the effort to exchange the data will turn out to be in vain as there is no mechanism to ensure accuracy. The first receiver additional 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?

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.

(1) Location identifier – Please clarify that GLN will be sufficient versus using latitudinal/longitudinal coordinates.
(2) 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 – CPMA recommends that all reference to the transporter be deleted. If FDA chooses to keep references to the Transporter, they 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 – CPMA recommends that all reference to the transporter be deleted. If FDA chooses to keep references to the Transporter, they 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, lease explain the purpose/benefit of providing the entry number(s) for the imported food.
(4) Location identifier and location description of the originator – CPMA recommends focusing on the outcome and not dictating how the information gets there or who must share it. 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.

<u>Special Requirements for Certain Persons and Foods</u>

§ 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.

<u>Procedures for Modified Requirements and Exemptions</u>

§ 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? – CPMA 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 within 24 hours of request by an authorized FDA representative. We recommend some flexibility with this requirement, as a large and wide investigation may require more time during certain periods of the year. In addition, food under consideration which originates in another country may require longer time periods to access information given time zones, national holidays, etc. 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 – having gone through a very rigorous process in Canada during the development of Part 5 Traceability in the Safe Food for Canadians Regulations, we have spent a great deal of time determining the balance between efficacious traceability and practicality for industry implementation – our comments above reflect some of our learnings. Please let us know if I can provide additional information or explanation.

Regards,

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