



Quick Guide on the FSMA Food Traceability Rule Requirements for the Mango Industry



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What is the Food Traceability Rule?

The Final Rule on Requirements for Additional Traceability Records for Certain Foods is a key component of the FDA's Food Safety Modernization Act, also known as FSMA. The Rule establishes additional recordkeeping requirements, in addition to existing ones, for persons, including farms, who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL) and requires companies subject to the Rule to establish a Traceability Plan. Mangos are included on the Food Traceability List (FTL).

The purpose of the Rule is to allow for faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and/or deaths.

To achieve this, FDA has identified important steps along the supply chain at which records must be kept. These required records will vary depending on the activities being carried out at each step of the supply chain. Although records can be kept in any form or system, and do not have to be kept electronically, if there is a food safety issue, FDA may ask that these records be provided in an electronic sortable spreadsheet within 24 hours of their request.

Additionally, the Rule establishes the use and assignment of Traceability Lot Codes at certain stages of the supply chain. These are unique descriptors, often alphanumeric, that are used to uniquely identify a traceability lot or "batch" of product within a company's records.

For the mango industry, Traceability Lot Codes must be assigned whenever they are initially packed, and if the product is ever transformed, such as through processing, but also when mangos from different lots are comingled and repacked.

Finally, if you are subject to requirements of the Traceability Rule, you must design and maintain a traceability plan that includes specific information detailed further in this guide.

For more information you can read the full Traceability Rule at:

<https://www.federalregister.gov/documents/2022/11/21/2022-24417/requirements-for-additional-traceability-records-for-certain-foods>

and

<https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-requirements-additional-traceability-records-certain-foods>

Who Needs to Comply With the Rule?

Compliance with the Rule is required for any person or company, both domestic or foreign, who manufacture, process, pack, or hold foods at some point throughout the supply chain, and that appear on the FDA’s Food Traceability List and that will be consumed within the United States. This includes farms.

What is the Food Traceability List (FTL)

The Food Traceability List is the list of foods for which additional traceability records are required to be maintained. The term “Food Traceability List” includes both the foods specifically listed and foods that contain listed foods as ingredients, provided that the listed food that is used as an ingredient remains in the same form (e.g., fresh) in which it appears on the list.

To determine which foods would be included on the Food Traceability List, the FDA developed a risk-ranking model for food tracing. The model scores commodity and hazard pairs (for example mangos and *Salmonella*), according to data and information relevant to the following criteria:

- Frequency of outbreaks and occurrences of illnesses
- Severity of illness
- Likelihood of contamination
- The potential for pathogen growth, with consideration of shelf life
- Manufacturing process contamination probability and industry-wide intervention
- Consumption rate and amount consumed
- Cost of the illness

The FDA used data going back several years and relied more heavily on more recent information. You can see all of FDA’s product-hazard pairs and their scores at:

<https://www.fda.gov/media/166880/download>



Are Mangos Included on the Food Traceability List (FTL)? *

There is one main category in which products from the mango industry are included on the Food Traceability List.

Food Traceability List*	Description
Tropical tree fruits (fresh)	Includes all types of fresh tropical tree fruit. Examples include, but are not limited to, mango , papaya, mamey, guava, lychee, jackfruit, and starfruit. Does not include non-tree fruits such as bananas, pineapple, dates, soursop, jujube, passionfruit, loquat, pomegranate, sapodilla, and figs. Does not include tree nuts such as coconut. Does not include pit fruits such as avocado. Does not include citrus, such as orange, clementine, tangerine, mandarins, lemon, lime, citron, grapefruit, kumquat, and pomelo.

*These are categories in which products from the mango industry may be included on the Food Traceability List as of 2023. This is not the full Food Traceability List.

How Often is the Food Traceability List Updated?

The Rule establishes a process for the FDA to update the Food Traceability List if the agency concludes that updates are appropriate, for example, because industry practices have changed. FDA has stated that they intend to update the Food Traceability List approximately every five years, subject to available resources.

Foods on the Food Traceability List as Ingredients

Foods that contain an ingredient that is a food on the Food Traceability List (FTL) are also covered by the Rule if the ingredient remains in the form in which it appears on the list. This means that if a commodity is used as part of a multi-ingredient food without any processing or alteration that would take it out of the Food Traceability List, then the multi-ingredient food would also be covered under the final Rule. Some examples of products that use ingredients from the Food Traceability List that would still be covered:

- A fresh-cut fruit salad with fresh mango
- A prepared smoothie with fresh mango

Some examples given by FDA of products that use ingredients from the Food Traceability List that would not be covered include:

- A frozen pizza with spinach topping (because the spinach is no longer fresh)
- Trail mix with dried papaya (because the papaya is no longer fresh)

It is important to note that even though these are examples given by FDA in official documents, each case is different, and FDA may come to a different conclusion on a similar circumstance.

Who is Exempt From the Rule?

There are certain ways to be eligible for a partial or a full exemption from the requirements of the Food Traceability Rule, generally based on business size and what exactly happens to the food. FDA has developed a software tool to help you determine whether an exemption may apply to you. You can access the tool at:

<https://collaboration.fda.gov/tefcv13/>

Final Rule on Requirements for Additional Traceability Records for Certain Foods – The Basics

If you find that the Rule applies to your products and your company, you will need to understand the following key terms to comply with the Rule's requirements:

● **Critical Tracking Event (CTE)**

The path fresh mangos take from being picked all the way to the grocery store is very complex. On their path, mangos shift hands various times, and so the people responsible for ensuring their safety also change. Because of the many steps a product takes through the supply chain, tracing back a product's steps to its point of origin can be hard. This is especially true when there are points on the supply chain where the product may be transformed, processed, or comingled with other products.

The Rule defines these steps as Critical Tracking Events (CTEs), and its definition from the Rule is as follows:

“A Critical tracking event means an event in the supply chain of a food involving the harvesting, cooling (before initial packing), initial packing of a raw agricultural commodity other than a food obtained from a fishing vessel, first land-based receiving of a food obtained from a fishing vessel, shipping, receiving, or transformation of the food.”

To summarize, Critical Tracking Events (CTEs) include:

1. **Harvesting**
2. **Cooling (Before initial packing)**
3. **Initial Packing**
4. **First Land Based Receiver**
5. **Shipping**
6. **Receiving**
7. **Transformation of the product such as repacking of mangos where product is comingled from different batches or different suppliers, or during fresh cut processing.**

Not all of these Critical Tracking Events (CTEs) apply to the Mango Industry, only those that have been **highlighted**. Also, most mango companies do not carry out all these steps by themselves or in a single facility. Shipping and receiving Critical Tracking Events (CTEs) likely occur at many steps throughout the supply chain.

Put simply, a Critical Tracking Event (CTE) is a step of special importance in the supply chain, and there are many of them riddled throughout a product’s journey to the table. So, if some information related to the product is collected at each one of these points, traceability becomes much easier and any emergencies like foodborne outbreaks and recalls can be dealt with quicker and more efficiently. The records that remain, even after a product is gone, can be used by regulators to figure out exactly where a potentially contaminated product came from, without confusing it with products that aren’t contaminated. But then, what information needs to be collected and kept? This is the next key term we need to understand.

● **Key Data Element (KDE)**

The Rule defines Key Data Elements (KDEs) as: “The Information associated with a CTE for which a record must be maintained and/or provided”.

In other words, Key Data Elements (KDEs) are the bits of information collected at Critical Tracking Events. These often relate to information about where a product was, is and will be, how much product is in a given batch, dates etc. In short, Key Data Elements (KDEs) serve as “footprints”, marking the place where a specific lot or batch of product has been and how it was handled.

Let's Review some examples of Key Data Elements (KDEs) required for the different Critical Tracking Events (CTEs) found in the mango industry:

1. Product Harvesting

- a. Product description (type/variety of mango)
- b. Quantity of product
- c. A description of the location where the product was grown and harvested (name of the farm and field and their location as precise as possible)
- d. Location description for the next recipient (likely the packinghouse it is headed to)
- e. Date of harvest
- f. Reference document type and reference document number (i.e., bill of lading)



2. Initial Packing

- a. Product description (type/variety of mango)
- b. Location description of where the food was harvested
- c. Date of receiving
- d. Quantity of product
- e. Lot or batch number of the packed product (as discussed in the next section)
- f. Location description for next recipient
- g. Product description of the packed food
- h. Location description for where you initially packed the food (i.e., traceability lot code source)
- i. Date of initial packing
- j. Quantity of the packed food
- k. Reference document type and reference document number (i.e., bill of lading)



3. Shipping

- a. Traceability lot code of the food (as discussed in the next section)
- b. Quantity of product
- c. Product description (type/variety of mango)
- d. Location description for the next recipient
- e. Location description for the location from which you shipped the food
- f. Date of shipment
- g. Location description for the traceability lot code source or the traceability lot code source reference
- h. Reference document type and reference document number (i.e., bill of lading)



4. Receiving

- a. Traceability lot code of the food (as discussed in the next section)
- b. Quantity of product
- c. Product description (type/variety of mango)
- d. Location description for the previous source of the food (other than transporter)
- e. Location description for the location where the food was received
- f. Date on which the food was received
- g. Location description for the traceability lot code source or the traceability lot code source reference (e.g., the initial packer)
- h. Reference document type and reference document number (i.e., bill of lading)



5. Transformation – Repacking

For each traceability lot used as an “ingredient” in the repacked product:

- a.** Traceability lot code(s) of the food(s) being mixed/comingled
- b.** Quantity of product
- c.** Product description (type/variety of mango)

(Note: you will have captured other information as part of the receiving CTE)



In addition, for the NEWLY transformed product:

- a.** The NEW traceability lot code for the food that YOU assign
- b.** Product description for the NEW product (type/variety of mango)
- c.** Location description for where you transformed the food (i.e., the traceability lot code source)
- d.** Quantity of transformed product
- e.** Date of transformation/repacking
- f.** Reference document type and reference document number (i.e., work order number)

Notice how Key Data Elements (KDEs) generally link a product to a previous and/or future step in the supply chain whenever it is applicable. But keeping all this information is useless if you can’t link the information to the specific product to which it belongs. This is why you also need to include a Traceability Lot Code (TLC).

You should also consider what the Rule defines as a location description, since it includes some important information that should be included. According to the Rule, location description means: “key contact information for the location where a food is handled, specifically the business name, phone number, physical location address (or geographic coordinates), and city, State, and zip code for domestic locations and comparable information for foreign locations, including country.”

You should also consider that while FDA does consider repacking without the mixing or comingling of products from different lot codes as a transformation, it does not require the creation of a new traceability Lot Code (TLC) since the repacking is “like into like”. However, a new “traceability lot code source” must be identified, since the warehouse performed a transformation.

Traceability Lot Code (TLC)

A Traceability Lot Code (TLC) is a special identifier that helps us recognize any single lot of product on its journey through the supply chain. You can think of it as an “ID number”, as it is unique for every batch of product. These codes are often alphanumeric but can take different forms.

A Traceability Lot Code (TLC) is only assigned at certain Critical Tracking Events and once assigned, it accompanies the product through many steps in the supply chain. However, a new Traceability Lot Code (TLC) may have to be assigned if certain transformations occur, such as repacking with comingling, where product from various batches are mixed together.

When to Assign Traceability Lot Codes (TLCs)

The Rule requires that Traceability Lot Codes (TLCs) be established whenever a raw agricultural commodity (Mango) is initially packed, and whenever it is transformed (for example when there is comingling and repacking). While there are other steps established by the Rule in which a Traceability Lot Code (TLC) would need to be assigned (for example fresh-cut), these generally do not apply to the fresh mango industry.

It's important to understand that the purpose of this code is to make traceability easy, and as such having a single Traceability Lot Code (TLC) identify the product throughout most of the supply chain is essential. It should not be changed unless the product is transformed in a way that may affect traceability. As such, do NOT establish a new Traceability Lot Code (TLC) when you conduct other handling activities for a food on the Food Traceability List (FTL). For example, if you are only storing and then shipping a product, without any transformation or repacking of said product, you must NOT establish a new Traceability Lot Code for the food; you must use the Traceability Lot Code (TLC) that was already assigned.



So, What Does This All Mean?

If You Are a Grower/Harvester

Once you have identified Critical Tracking events (CTEs) in your operation, you need to record the required Key Data Elements (KDEs) and send this information along with your business name, phone number and the product to the next recipient of the product. The Rule does not require this information to be sent electronically but doing so electronically will be much faster than writing on paper, and it will be easier to find the records later, if asked.



If You Are an initial Packer

You will receive information for the harvesting Key Data Elements (KDEs) along with the product. You will then need to add to this information any Key Data Elements (KDEs) from the Critical Tracking events (CTEs) in your facility and establish a Traceability Lot Code (TLC) for the product. This information, along with a way to contact your company, as the originator of the TLC, will need to be sent to the next recipient of the product along with the product. Again, the Rule is flexible, and you can use any system to capture and send this information, but some buyers may have preferences for how they receive this information. You'll also want to think about how you'd provide this information to FDA in an electronic sortable spreadsheet within 24 hours of a request.

If You Are Anywhere Else in the Supply Chain

You will receive information for the Key Data Elements (KDEs) regarding initial packing, and the immediate previous handler of the product, along with the product. You will also receive a Traceability Lot Code (TLC) for the product, and information about the originator of the Traceability Lot Code. You will then need to add to this information any Key Data Elements (KDEs) from the Critical Tracking Events (CTEs) in your facility. You must NOT change the product's Traceability Lot Code (TLC) UNLESS you transform the product, such as when there is repacking through comingling with product with different Traceability Lot Codes (TLCs). This information will need to be sent to the next recipient of the product along with the product.

The Food Traceability Plan

If you determine that your mangos are subject to the requirements of the Final Rule on Requirements for Additional Traceability Records for Certain Foods, you will also be required to establish and maintain a Food Traceability Plan.

This plan needs to include a description of the procedures you use to maintain the records required for compliance with the Food Traceability Rule, including the format and location of these records. You are also required to include a description of the procedures you used to determine if the products that you work with are on the Food Traceability List.

The plan must also include a procedure describing how your operation assigns Traceability Lot Codes to your products that require it because they are on the Food Traceability List; it must also include a statement identifying a contact within your company responsible for replying to any questions regarding your traceability plan and records.

Lastly, if you are a grower, your traceability plan needs to include a map of the farm showing the areas in which you grow mangos. This map must show the name and location of each field, as well as any other growing areas where you grow food on the Food Traceability List. The map needs to include the field's geographic coordinates and any other information needed to identify its location.

Once you have your Food Traceability Plan in compliance with the Rule, you will need to make sure it is always kept up to date and that it reflects the practices followed in your facility. Whenever you update your Food Traceability Plan, remember that the previous plan needs to be stored and kept for at least two years after you update it.



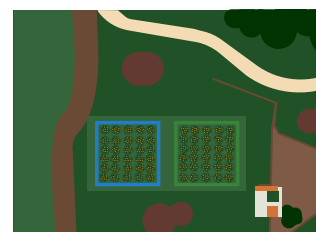
Toto's Mango Farm

Field 1 – Los Manglares

(28.643305580591512,
-106.10512393792253)

Field 2 – Doña Berta

(28.635259678965838,
-106.06748920869542)



Records and Recordkeeping

Anyone covered by the Rule must keep records regarding their Critical Tracking Events for foods on the Food Traceability List for at least 2 years. Depending on the Critical Tracking Events that take place as you handle the product, you may need to keep different records or Key Data Elements.

You are required to provide this information to the immediate subsequent recipient of each lot that you ship (not including transporters). You also need to provide your business name and phone number. This information can be provided either directly to the subsequent recipient or through the supply chain as a paper or electronic document, or through any other written form.

Remember, although records can be kept in any form or system, and do not have to be kept electronically, if there is a food safety issue, FDA may ask that these records be provided in an electronic sortable spreadsheet within 24 hours of their request. For this reason, it is important to keep an updated electronic sortable spreadsheet such as a Microsoft Excel File updated with any current Critical Tracking Elements and Traceability Lot Codes.

When do I Need to Comply?

The Rule establishes a single compliance date for everyone regardless of company size, product, or if compliance with the Rule is required in its entirety or only partially. Compliance with the rule will be mandatory on Tuesday, January 20, 2026, for any person or company, including farms, both domestic or foreign, who manufacture, process, pack, or hold foods at some point throughout the supply chain, and that appear on the FDA's Food Traceability List and that will be consumed within the United States.

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