Free Checklist

FSMA 204 KDE and CTE Checklist

Food Traceability Rule record check for manufacturers and exporters supplying the US

Use this checklist to work through each critical tracking event (CTE) that applies to your site, confirm the key data elements (KDEs) you record, and check your traceability plan covers every required element. It covers all seven tracking events and sits alongside FDA's free sortable spreadsheet template and exemptions tool, and does not replace them.

This checklist supports record keeping. It does not make a site FSMA 204 compliant and gives no exemption advice. Recheck the FDA rule page and Federal Register before use.

Document Control

Field	Entry
Site	
Prepared by (role)	
Version	
Date	
Review date	
FDA position on timing at date of use	Originally due 20 January 2026; FDA will not enforce the rule before 20 July 2028 (Pub. L. 119-37). Check the FDA rule page on the day of use. Last checked: _____

1. Scope Check

Confirm which of your products are on the FDA Food Traceability List (FTL), including foods that contain an FTL food as an ingredient that stays in the same form (for example fresh). Check exemptions with FDA's free exemptions tool; this checklist gives no exemption advice.

Product	On FTL or contains FTL ingredient in same form? (Y/N)	FTL food	Checked with FDA exemptions tool? (Y/N, date)	Notes

2. Traceability Plan (21 CFR 1.1315)

Required element	In place? (Y/N)	Location of record	Owner (role)
Procedures for keeping required records, including format and location			
How FTL foods are identified on site			
How traceability lot codes are assigned			
Point of contact for traceability questions			
Farm map (growers of listed foods other than eggs)			

Demo template is for illustrative purposes. Not intended for legal advice. Adapt to your site.

3. Critical Tracking Events and Key Data Elements

Mark which tracking events apply to your site, then use the matching table in section 4 to confirm each record you keep. The table reference for each event is shown below.

CTE	Applies? (Y/N)	Records to keep (section 4 table)	Where recorded	Owner (role)	Gap or action
Harvesting		4.5			
Cooling (before initial packing)		4.6			
Initial packing		4.7			
First land-based receiving (seafood)		4.8			
Shipping		4.1			
Receiving		4.2			
Transformation		4.3 and 4.4			

4. Key Data Elements (KDEs) by Tracking Event

Status: Originally due 20 January 2026; FDA will not enforce the rule before 20 July 2028 (Pub. L. 119-37). The record lists below follow 21 CFR Part 1, Subpart S (eCFR text as of 1 Oct 2026) and use the rule's own item numbers. Manufacturers mainly need Shipping, Receiving and Transformation, so those come first. Tick each record you keep in the Recorded? column. This checklist is not a complete compliance list: exemptions (21 CFR 1.1305) and the traceability plan (21 CFR 1.1315) also apply.

Terms used in these tables

Location description (21 CFR 1.1310): business name, phone number, physical address (or geographic coordinates) and city, state and zip code, or the equivalent for foreign locations, including country.
Reference document (21 CFR 1.1310): a business transaction document, record or message, such as a bill of lading, purchase order or advance shipping notice. Each record notes its type and number.
TLC: traceability lot code. TLC source: the place where the TLC was assigned.

4.1 Shipping (21 CFR 1.1340)

Applies to anyone shipping an FTL food, including manufacturers.

#	Key data element	Pass to next party? (Yes/No)	Recorded? (Y/N)
1	Traceability lot code	Yes	
2	Quantity and unit of measure	Yes	
3	Product description	Yes	
4	Location description of the immediate subsequent recipient (other than a transporter)	Yes	
5	Location description of where shipped from	Yes	
6	Date shipped	Yes	
7	Location description of the TLC source, or the TLC source reference	Yes	
8	Reference document type and number	No	

Does not apply to shipping a raw agricultural commodity (RAC) before it is initially packed (21 CFR 1.1340(c)).

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4.2 Receiving (21 CFR 1.1345)

Applies to anyone receiving an FTL food, including manufacturers.

#	Key data element	Recorded? (Y/N)
1	Traceability lot code [1]	
2	Quantity and unit of measure	
3	Product description	
4	Location description of the immediate previous source (other than a transporter)	
5	Location description of where received	
6	Date received	
7	Location description of the TLC source, or the TLC source reference	
8	Reference document type and number	

[1] Exempt supplier (21 CFR 1.1345(b)): if the food comes from a person the rule does not apply to, you must assign a TLC if none has been assigned. Retail food establishments and restaurants are excepted.

4.3 Transformation: Inputs (21 CFR 1.1350(a))

Applies to manufacturing or processing, commingling, repacking or relabelling where the output is an FTL food. Record for each FTL food used.

#	Key data element	Recorded? (Y/N)
1(i)	Traceability lot code	
1(ii)	Product description	
1(iii)	Quantity and unit of measure used from each lot	

4.4 Transformation: Outputs (21 CFR 1.1350(a))

Record for the new food produced.

#	Key data element	Recorded? (Y/N)
2(i)	New traceability lot code	
2(ii)	Location description of where transformed (the TLC source), and the TLC source reference if applicable	
2(iii)	Date transformation completed	
2(iv)	Product description	
2(v)	Quantity and unit of measure	
2(vi)	Reference document type and number	

21 CFR 1.1350(b): when transforming a RAC that was not initially packed first, record the 21 CFR 1.1330 items instead. 21 CFR 1.1350(c) sets out exceptions; check the rule text.

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Farm, Packing and Seafood Events

These events apply to farms, packers, coolers and the first land-based receivers of seafood. They are included because FTL foods reach manufacturers through these steps.

4.5 Harvesting (21 CFR 1.1325(a))

Applies to farms harvesting an FTL RAC, other than one from a fishing vessel.

#	Key data element	Pass to next party? (Yes/No)	Recorded? (Y/N)
i	Location description of the immediate subsequent recipient (other than a transporter)	Yes	
ii	Commodity and, if applicable, variety	Yes	
iii	Quantity and unit of measure	Yes	
iv	Location description of the farm where harvested	Yes	
v	For produce: field or growing area name (or equally precise location)	Yes	
vi	For aquaculture: container name, for example pond or tank (or equally precise location)	Yes	
vii	Date of harvesting	Yes	
viii	Reference document type and number	No	

The harvester must also give the initial packer its business name and phone number (21 CFR 1.1325(a)(2)).

4.6 Cooling Before Initial Packing (21 CFR 1.1325(b))

Applies to anyone cooling an FTL RAC before it is initially packed.

#	Key data element	Pass to next party? (Yes/No)	Recorded? (Y/N)
i	Location description of the immediate subsequent recipient (other than a transporter)	Yes	
ii	Commodity and, if applicable, variety	Yes	
iii	Quantity and unit of measure	Yes	
iv	Location description of where cooled	Yes	
v	Date of cooling	Yes	
vi	Location description of the farm where harvested	Yes	
vii	Reference document type and number	No	

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4.7 Initial Packing of a RAC (21 CFR 1.1330(a)) [2] [3]

Applies to the first packer of an FTL RAC (not from a fishing vessel). This is where the TLC is assigned.

#	Key data element	Recorded? (Y/N)
1	Commodity and, if applicable, variety received	
2	Date received	
3	Quantity and unit of measure received	
4	Location description of the farm where harvested	
5	For produce: field or growing area name	
6	For aquaculture: container name	
7	Harvester's business name and phone number	
8	Date of harvesting	
9	Location description of where cooled (if applicable)	
10	Date of cooling (if applicable)	
11	Traceability lot code assigned	
12	Product description of the packed food	
13	Quantity and unit of measure of the packed food	
14	Location description of where initially packed (the TLC source), or the TLC source reference	
15	Date of initial packing	
16	Reference document type and number	

[2] Sprouts (21 CFR 1.1330(b)) add 7 seed elements: seed grower, conditioner, packinghouse and supplier details with their lot codes, a seed description, the date seeds were received, and the reference document.
[3] RAC received from an exempt supplier (21 CFR 1.1330(c)) has a shorter 10 item list. Check the rule text.

4.8 First Land Based Receiving of Seafood (21 CFR 1.1335)

Applies to the first person on land to take a food from a fishing vessel. A TLC is assigned here.

#	Key data element	Recorded? (Y/N)
a	Traceability lot code assigned	
b	Species and/or acceptable market name (unpackaged), or product description (packaged)	
c	Quantity and unit of measure	
d	Harvest date range and locations for the trip (NMFS Ocean Geographic Code, FAO Major Fishing Area or another widely recognised standard)	
e	Location description of the first land-based receiver (the TLC source), or the TLC source reference	
f	Date landed	
g	Reference document type and number	

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5. KDE Spot Check (One Recent Lot)

Pick one recent lot of an FTL food, choose the tracking event to test, and confirm each KDE in the matching table in section 4 can be found.

Tracking event	Item #	Key data element (from section 4)	Found? (Y/N)	Record reference	Time to find

6. 24 Hour Records Test (21 CFR 1.1455)

FDA can request records within 24 hours, or a reasonable time FDA agrees to. When needed for an outbreak, recall or other threat, an electronic sortable spreadsheet is required unless you are exempt. Log your own timed test here.

Request issued (date and time)	Sortable file produced (date and time)	Elapsed	Complete? (Y/N)	Issues

7. Gaps and Corrective Actions

Gap	Action	Owner (role)	Due date	Closed (date)

Sign Off

Role	Signature	Date
Technical or Quality lead		
Site manager		

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