

Worksheet Harvesting CTE

	KDEs for Each Traceability Lot	Example/definition	What existing records contain this information?
1	Location description for the immediate subsequent recipient (other than a transporter) of the food	Key contact information for the immediate recipient: <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) 	
2	Commodity harvested and, if applicable, variety of the food	species and/or acceptable market name	
3	Quantity and unit of measure of food	e.g., 75 bins, 200 pounds <u>add other examples:</u>	
4	Location description for the farm where the food was harvested	Key contact information for farm location: <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) 	

5	<p>Name of “container” from which the food was harvested</p> <p>or</p> <p>other information identifying the harvest location at least as precisely as the container name</p>	<p>“Container” is the specific pond, pool, tank, cage, etc. from which the food was harvested. This must correspond to the container name used by the farm.</p>	
6	<p>Date of harvesting</p>		
7	<p>Reference document type and reference document number.</p>	<p>Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.</p> <p>Reference document number means the identification number assigned to a specific reference document.</p>	
8	<p>Information to provide to initial packer of harvested food</p>	<p>KDEs 1-6 plus business name and phone number of the harvesting entity</p>	

§ 1.1325 What records must I keep and provide when I harvest or cool a raw agricultural commodity on the Food Traceability List?

(a) Harvesting.

(1) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must **maintain** records containing the following information:

- (i) The location description for the immediate subsequent recipient (other than a transporter) of the food;
- (ii) The commodity and, if applicable, variety of the food;
- (iii) The quantity and unit of measure of the food (e.g., 75 bins, 200 pounds);
- (iv) The location description for the farm where the food was harvested;
- (v) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;
- (vi) For aquacultured food, the name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;
- (vii) The date of harvesting; and
- (viii) The reference document type and reference document number.

(2) For each raw agricultural commodity (not obtained from a fishing vessel) on the Food Traceability List that you harvest, you must **provide** (in electronic, paper, or other written form) your business name, phone number, and the information in paragraphs (a)(1)(i) through (vii) of this section to the initial packer of the raw agricultural commodity you harvest, either directly or through the supply chain.

Worksheet
Initial Packing CTE

	KDEs for Each Traceability Lot	Example/definition	What existing records contain this information?
1	Commodity received and, if applicable, variety of the food	species and/or acceptable market name	
2	Date you received the food		
3	Quantity and unit of measure of food received	e.g., 75 bins, 200 pounds <u>add other examples:</u>	
4	Location description for the farm where the food was harvested	Key contact information for farm location: <ul style="list-style-type: none">• the business name,• phone number,• physical location address (or geographic coordinates),• city, State, and zip code (for US locations)• comparable information, including country (for foreign locations)	

5	<p>Name of “container” from which the food was harvested</p> <p>or</p> <p>other information identifying the harvest location at least as precisely as the container name</p>	<p>“Container” is the specific pond, pool, tank, cage, etc. from which the food was harvested. This must correspond to the container name used by the farm.</p>	
6	<p>Business name and phone number for the harvester of the food</p>		
7	<p>Date of harvesting</p>		
8	<p>Traceability lot code you assigned</p>	<p>A descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.</p> <p>Traceability lot means a batch or lot of food that has been initially packed ..., received by the first land-based receiver ..., or transformed.</p>	
9	<p>Product description of packed food</p>	<p>Description includes:</p> <ul style="list-style-type: none"> • product name (including, if applicable, the brand name, commodity, and variety), • for seafood, the product name may include the species and/or acceptable market name. • packaging size, and packaging style. 	
10	<p>Quantity and unit of measure of the packed food</p>	<p>e.g., 6 cases, 25 reusable plastic containers, 200 pounds</p> <p><u>add other examples:</u></p>	

11	<p>Location description for where you initially packed the food (which is also the traceability lot code source)</p> <p>and (if applicable)</p> <p>the traceability lot code source reference</p>	<p>Key contact information for the location where the food was initially packed (which is the same as where the traceability lot code was assigned):</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) <p>AND (if applicable)</p> <p><i>Traceability lot code source reference</i> means an alternative method for providing FDA with access to the location description for the traceability lot code source. Examples include:</p> <ul style="list-style-type: none"> • FDA Food Facility Registration Number for the traceability lot code source • a web address that provides FDA with the location description for the traceability lot code source. 	
12	Date you initially packed the food		

13	Reference document type and reference document number.	<p>Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.</p> <p>Reference document number means the identification number assigned to a specific reference document.</p>	
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§ 1.1330 What records must I keep when I am performing the initial packing of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List?

(a) Except as specified in paragraph (c) of this section, for each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List you initially pack, you must **maintain** records containing the following information and **linking** this information to the traceability lot:

- (1) The commodity and, if applicable, variety of the food received;
- (2) The date you received the food;
- (3) The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds);
- (4) The location description for the farm where the food was harvested;
- (5) For produce, the name of the field or other growing area from which the food was harvested (which must correspond to the name used by the grower), or other information identifying the harvest location at least as precisely as the field or other growing area name;
- (6) For aquacultured food, the name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (which must correspond to the container name used by the aquaculture farmer) or other information identifying the harvest location at least as precisely as the container name;
- (7) The business name and phone number for the harvester of the food;
- (8) The date of harvesting;
- (9) The location description for where the food was cooled (if applicable);
- (10) The date of cooling (if applicable);
- (11) The traceability lot code you assigned;
- (12) The product description of the packed food;
- (13) The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- (14) The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
- (15) The date of initial packing; and
- (16) The reference document type and reference document number.

(c) For each traceability lot of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List **you initially pack that you receive from a person to whom this subpart does not apply**, you must maintain records containing the following information and linking this information to the traceability lot:

- (1) The commodity and, if applicable, variety of the food received;
- (2) The date you received the food;
- (3) The quantity and unit of measure of the food received (e.g., 75 bins, 200 pounds);
- (4) The location description for the person from whom you received the food;
- (5) The traceability lot code you assigned;
- (6) The product description of the packed food;
- (7) The quantity and unit of measure of the packed food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- (8) The location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
- (9) The date of initial packing; and
- (10) The reference document type and reference document number.

Worksheet
First Land Based Receiver from Fishing Vessel CTE

	KDEs for Each Traceability Lot	Example/definition	What existing records contain this information?
1	Traceability lot code you assign	<p>A descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.</p> <p>Traceability lot means a batch or lot of food that has been initially packed ..., received by the first land-based receiver ..., or transformed.</p>	
2	<p>Species and/or acceptable market name for unpackaged food,</p> <p>or</p> <p>the product description for packaged food</p>	<p>Description includes:</p> <ul style="list-style-type: none"> • product name (including, if applicable, the brand name, commodity, and variety), • for seafood, the product name may include the species and/or acceptable market name. • packaging size, and packaging style. 	
3	Quantity and unit of measure of food	<p>e.g., 300 kg</p> <p><u>add other examples:</u></p>	
4	<p>Harvest date range</p> <p>and</p> <p>Harvest locations</p>	<p>Harvest locations as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard for the trip during which the food was caught</p>	

5	<p>Location description for first land-based receiver</p> <p>and (if applicable)</p> <p>the traceability lot code source reference</p>	<p>Key contact information for the land-based location where a food was received (which is the same as where the traceability lot code was assigned):</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) <p>AND (if applicable)</p> <p><i>Traceability lot code source reference</i> means an alternative method for providing FDA with access to the location description for the traceability lot code source. Examples include:</p> <ul style="list-style-type: none"> • FDA Food Facility Registration Number for the traceability lot code source • a web address that provides FDA with the location description for the traceability lot code source. 	
6	<p>Date the food was landed</p>		

7	The reference document type and reference document number.	<p>Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.</p> <p>Reference document number means the identification number assigned to a specific reference document.</p>	
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§ 1.1335 What records must I keep when I am the first land-based receiver of a food on the Food Traceability List that was obtained from a fishing vessel?

For each traceability lot of a food obtained from a fishing vessel for which you are the first land-based receiver, you must **maintain** records containing the following information and **linking** this information to the traceability lot:

- (a) The traceability lot code you assigned;
- (b) The species and/or acceptable market name for unpackaged food, or the product description for packaged food;
- (c) The quantity and unit of measure of the food (e.g., 300 kg);
- (d) The harvest date range and locations (as identified under the National Marine Fisheries Service Ocean Geographic Code, the United Nations Food and Agriculture Organization Major Fishing Area list, or any other widely recognized geographical location standard) for the trip during which the food was caught;
- (e) The location description for the first land-based receiver (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
- (f) The date the food was landed; and
- (g) The reference document type and reference document number.

First land-based receiver means the person taking possession of a food for the first time on land directly from a fishing vessel.

Fishing vessel means any vessel, boat, ship, or other craft which is used for, equipped to be used for, or of a type which is normally used for fishing or aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing, as set forth in the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1802(18)).

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

(m) *Partial exemption for owners, operators, or agents in charge of fishing vessels.*

(1) Except as specified in paragraph (m)(2) of this section, with respect to a food that is obtained from a fishing vessel, this subpart does not apply to the owner, operator, or agent in charge of the fishing vessel, and this subpart also does not apply to persons who manufacture, process, pack, or hold the food until such time as the food is sold by the owner, operator, or agent in charge of the fishing vessel.

(2) With respect to any person who receives the partial exemption set forth in paragraph (m)(1) of this section, if such person is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years..

Worksheet Receiving CTE

	KDEs for Each Traceability Lot	Example/definition	What existing records contain this information?
1	Traceability lot code	<p>A descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.</p> <p><i>Traceability lot</i> means a batch or lot of food that has been initially packed ..., received by the first land-based receiver ..., or transformed.</p>	
2	Quantity and unit of measure of food in shipment	<p>e.g., 6 cases, 25 reusable plastic containers, 200 pounds</p> <p><u>add other examples:</u></p>	
3	Product description of food	<p>Description includes:</p> <ul style="list-style-type: none"> • product name (including, if applicable, the brand name, commodity, and variety), • for seafood, the product name may include the species and/or acceptable market name. • packaging size, and packaging style. 	
4	Location description for the immediate previous source recipient (other than a transporter) of the food	<p>Key contact information for the immediate previous source:</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) 	

5	Location description for where the food was received	<p>Key contact information for receiving location:</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) 	
6	Date you received the food		
7	<p>Location description for the traceability lot code source,</p> <p>or</p> <p>the traceability lot code source reference</p>	<p>Key contact information for the place where a food was assigned a traceability lot code:</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) <p>OR</p> <p><i>Traceability lot code source reference</i> means an alternative method for providing FDA with access to the location description for the traceability lot code source. Examples include:</p> <ul style="list-style-type: none"> • FDA Food Facility Registration Number for the traceability lot code source • a web address that provides FDA with the location description for the traceability lot code source. 	

8	Reference document type and reference document number.	<p>Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food.</p> <p>A reference document may be established by you or obtained from another person.</p> <p>Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.</p> <p>Reference document number means the identification number assigned to a specific reference document.</p>	
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§ 1.1345 What records must I keep when I receive a food on the Food Traceability List?

(a) Except as specified in paragraphs (b) and (c) of this section, for each traceability lot of a food on the Food Traceability List you receive, you must **maintain** records containing the following information and linking this information to the traceability lot:

- (1) The traceability lot code for the food;
- (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);`
- (3) The product description for the food;
- (4) The location description for the immediate previous source (other than a transporter) for the food;
- (5) The location description for where the food was received;
- (6) The date you received the food;
- (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
- (8) The reference document type and reference document number.

(b) For each traceability lot of a food on the Food Traceability List you receive from a person to whom this subpart does not apply, you must maintain records containing the following information and linking this information to the traceability lot:

- (1) The traceability lot code for the food, which you must assign if one has not already been assigned (except that this paragraph does not apply if you are a retail food establishment or restaurant);
- (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- (3) The product description for the food;
- (4) The location description for the immediate previous source (other than a transporter) for the food;
- (5) The location description for where the food was received (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
- (6) The date you received the food; and
- (7) The reference document type and reference document number.

(c) This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).

Worksheet Shipping CTE

	KDEs for Each Traceability Lot	Example/definition	What existing records contain this information?
1	Traceability lot code	<p>A descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.</p> <p>Traceability lot means a batch or lot of food that has been initially packed ..., received by the first land-based receiver ..., or transformed.</p>	
2	Quantity and unit of measure of food in shipment	<p>e.g., 6 cases, 200 pounds</p> <p><u>add other examples:</u></p>	
3	Product description of food	<p>Description includes:</p> <ul style="list-style-type: none"> • product name (including, if applicable, the brand name, commodity, and variety), • for seafood, the product name may include the species and/or acceptable market name. • packaging size, and packaging style. 	
4	Location description for the immediate subsequent recipient (other than a transporter) of the food	<p>Key contact information for the immediate recipient:</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) 	

5	Location description for the location from which you shipped the food;	<p>Key contact information for shipping location:</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) 	
6	Date you shipped the food		
7	<p>Location description for the traceability lot code source,</p> <p>or</p> <p>the traceability lot code source reference</p>	<p>Key contact information for the place where a food was assigned a traceability lot code:</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) <p>OR</p> <p><i>Traceability lot code source reference</i> means an alternative method for providing FDA with access to the location description for the traceability lot code source. Examples include:</p> <ul style="list-style-type: none"> • FDA Food Facility Registration Number for the traceability lot code source • a web address that provides FDA with the location description for the traceability lot code source. 	

8	The reference document type and reference document number.	<p>Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food.</p> <p>A reference document may be established by you or obtained from another person.</p> <p>Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.</p> <p>Reference document number means the identification number assigned to a specific reference document.</p>	
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§ 1.1340 What records must I keep and provide when I ship a food on the Food Traceability List?

(a) For each traceability lot of a food on the Food Traceability List you ship, you must **maintain** records containing the following information and linking this information to the traceability lot:

- (1) The traceability lot code for the food;
- (2) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds);
- (3) The product description for the food;
- (4) The location description for the immediate subsequent recipient (other than a transporter) of the food;
- (5) The location description for the location from which you shipped the food;
- (6) The date you shipped the food;
- (7) The location description for the traceability lot code source, or the traceability lot code source reference; and
- (8) The reference document type and reference document number.

(b) You must **provide** (in electronic, paper, or other written form) the information in paragraphs (a)(1) through (7) of this section to the immediate subsequent recipient (other than a transporter) of each traceability lot that you ship.

(c) This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).

Worksheet Transformation CTE

	KDEs for Each Traceability Lot	Example/definition	What existing records contain this information?
<i>For Food Traceability List Food(s) used in the transformation</i>			
1	Traceability lot code(s)	<p>A descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.</p> <p><i>Traceability lot</i> means a batch or lot of food that has been initially packed ..., received by the first land-based receiver ..., or transformed.</p>	
2	Product description of food	<p>Description includes:</p> <ul style="list-style-type: none"> • product name (including, if applicable, the brand name, commodity, and variety), • for seafood, the product name may include the species and/or acceptable market name. • packaging size, and packaging style. 	
3	Quantity and unit of measure of food used from each traceability lot		

For Food Traceability List Food produced through transformation

4	Traceability lot code(s)	<p>A descriptor, often alphanumeric, used to uniquely identify a traceability lot within the records of the traceability lot code source.</p> <p>Traceability lot means a batch or lot of food that has been initially packed ..., received by the first land-based receiver ..., or transformed.</p>	
5	<p>Location description for where you transformed the food,</p> <p>and (if applicable)</p> <p>the traceability lot code source reference</p>	<p>Key contact information for the place where a food was transformed (which is the same as where the new traceability lot code was assigned):</p> <ul style="list-style-type: none"> • the business name, • phone number, • physical location address (or geographic coordinates), • city, State, and zip code (for US locations) • comparable information, including country (for foreign locations) <p>AND (if applicable)</p> <p>Traceability lot code source reference means an alternative method for providing FDA with access to the location description for the traceability lot code source. Examples include:</p> <ul style="list-style-type: none"> • FDA Food Facility Registration Number for the traceability lot code source • a web address that provides FDA with the location description for the traceability lot code source. 	
6	Date transformation was completed		

7	Product description of food	Description includes: <ul style="list-style-type: none"> • product name (including, if applicable, the brand name, commodity, and variety), • for seafood, the product name may include the species and/or acceptable market name. • packaging size, and packaging style. 	
8	Quantity and unit of measure of food produced	e.g., 6 cases, 200 pounds <u>add other examples:</u>	
9	Reference document type and reference document number for the transformation event	<p>Reference document means a business transaction document, record, or message, in electronic or paper form, that may contain some or all of the key data elements for a critical tracking event in the supply chain of a food. A reference document may be established by you or obtained from another person. Reference document types may include, but are not limited to, bills of lading, purchase orders, advance shipping notices, work orders, invoices, database records, batch logs, production logs, field tags, catch certificates, and receipts.</p> <p>Reference document number means the identification number assigned to a specific reference document.</p>	

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

(a) Except as specified in paragraphs (b) and (c) of this section, for each new traceability lot of food you produce through transformation, you must **maintain** records containing the following information and linking this information to the new traceability lot:

(1) For the food on the Food Traceability List used in transformation (if applicable), the following information:

- (i) The traceability lot code for the food;
- (ii) The product description for the food to which the traceability lot code applies; and
- (iii) For each traceability lot used, the quantity and unit of measure of the food used from that lot.

(2) For the food produced through transformation, the following information:

- (i) The new traceability lot code for the food;
- (ii) The location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference;
- (iii) The date transformation was completed;
- (iv) The product description for the food;
- (v) The quantity and unit of measure of the food (e.g., 6 cases, 25 reusable plastic containers, 100 tanks, 200 pounds); and
- (vi) The reference document type and reference document number for the transformation event.

(b) For each traceability lot produced through transformation of a raw agricultural commodity (other than a food obtained from a fishing vessel) on the Food Traceability List that was not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and, if the raw agricultural commodity is sprouts, the information specified in § 1.1330(b).

(c) Paragraphs (a) and (b) of this section do not apply to retail food establishments and restaurants with respect to foods they do not ship (e.g., foods they sell or send directly to consumers).