

FDA 306 Checklist For Food Manufacturers

Introduction	<p>The following checklist is designed to help companies quickly assess their level of compliance with FDA Bioterrorism 306 laws. The user should be able to select “Yes” for all situations. Obviously a “No” response then indicates an area of likely non-compliance.</p> <p>In constructing this list Operations Technologies used the FDA 306 final document, the FDA Final Rules slide presentation, “<u>Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records (Edition 2)- Nov 10, 2005</u>”, and detailed interviews with FDA personnel. Hyperlinks(<u>underlined and in blue</u>) will route the user to the exact documentation from the FDA’s documentation No.</p> <p>FDA 306 is a supplemental regulation. It does not replace other regulations.</p> <p>Sources : FDA 306 and FDA Q&A http://www.cfsan.fda.gov/~dms/frrecord.html http://www.cfsan.fda.gov/~dms/recguid2.html#sec-f</p> <p>Full 21 CFR (code of Federal Regulations) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1</p> <p>Prohibited Acts (Penalties for noncompliance) Introduction http://www.fda.gov/opacom/laws/fdcact/fdcact3.htm</p> <p>This is an evolving document so if you spot an error, hear contradictory information, or would just like discuss this with us further – Please email or call Dave Miller at davemiller@operationstech.com , 864-787-3971 .</p> <p>This information has been gathered primarily from FDA websites and supplemented by discussions with FDA agents. Operations Technologies assumes no legal responsibilities for actions or inactions taken by the reader as a result of this checklist.</p>		
---------------------	---	--	--

Links to Definitions			
	Food		
	Farm		
	Non Transporter		
	Transporter		
	Manufacturing / processing		
	FTE – Full Time Equivalent Employee		
	“Reasonably Available Information”		

Applicability	Check List For Manufacturers ONLY	Yes	No
AP 1.0	<p>Are you a manufacturer for purpose of FDA 306?</p> <p><i>(If not a manufacturer: this check list does not apply. It does NOT attempt cover distributors or transporters)</i></p> <p>Manufacturing/processing means making food from one or more ingredients, or synthesizing, [packing], preparing, treating, modifying, or manipulating food, including food crops or ingredients. Also includes vitamins and vitamin supplements.</p> <p>Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.</p> <p>Note : Food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) are subject to this regulation</p>	<input type="checkbox"/>	<input type="checkbox"/>
	<p>Manufacturer's exemptions and partial exemptions include :</p> <p>Persons who manufacture, process, pack, [] food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions.</p> <ul style="list-style-type: none"> - Nonprofits - Manufacturers EXCLUSIVELY covered by USDA - Retail manufacturers whose PRIMARY function is to sell to end consumers - Restaurants - Fishing Vessels <p>Please refer to in Sec. 1.327 for more complete information.</p>		

Prohibited Act	Civil and Criminal Penalties	Yes	No
PA 1.0	<p>Are your management and staff aware of the consequences of non-adherence to FDA 306 ?</p> <p>Failing to collect and maintain the data required by FDA 306 is a “Prohibited Act”</p> <p>Persons committing a “Prohibited Act” are subject to one-year in jail and manufacturers are subject to a \$100,000 fine - per event or occurrence.</p> <p><i>Note : In previous FDA prosecution the cascading effects to stakeholders were often more damaging than the legal penalties. While 306 increases penalties it seems probable that <u>stockholders, customers, and staff</u> will continue to be more negatively impacted by implied risk and bad press than by the actual prosecution itself.</i></p> <p>The exact wording is :</p> <p>As per SEC. 303. [21 U.S.C. 333]</p> <p>(a)(1) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than \$1,000, or both</p> <p>(3) Any manufacturer or distributor who violates section 301(t) because of a failure to make a report required by section 503(d)(3)(E) shall be subject to a civil penalty of not more than \$100,000.</p> <p>For more detail at the FDA source -> http://www.fda.gov/opacom/laws/fdcact/fdcact3.htm</p>	<input type="checkbox"/>	<input type="checkbox"/>

Retention		Yes	No
RT 1.0	For food that is likely to spoil within 60 days, do you retain the records for 6 months? (Sec. 1.360)	<input type="checkbox"/>	<input type="checkbox"/>
RT 2.0	For food that is not likely to spoil within 60 days but likely to within 6 months, do you retain the records for 1 year? (Sec. 1.360)	<input type="checkbox"/>	<input type="checkbox"/>
RT 3.0	For food that is not likely to spoil within 6 months, do you retain the records for 2 years? (Sec. 1.360)	<input type="checkbox"/>	<input type="checkbox"/>
RT 4.0	For pet/animal food, do you retain the records for 1 year? (Sec. 1.360)	<input type="checkbox"/>	<input type="checkbox"/>

Availability		Yes	No
AV 1.0	Are all the documents dating back to the start of the required retention period (6 to 24 months) available? (Sec. 1.360)	<input type="checkbox"/>	<input type="checkbox"/>
AV 2.0	Are records on site or at a readily available location and can they be retrieved and the specific data retrieved “as soon as possible” and no later than 24 hours after request? (Sec. 1.360) Note: There is no exemption for weekend or holiday requests. The SPECIFIC data must be retrieved, not lumped in a “show box” with all data	<input type="checkbox"/>	<input type="checkbox"/>

Security		Yes	No
SC 1.0	Are backup copies of the FDA 306 documents stored in a secure location? (Not specifically required by FDA 306, however since the documentation is required, a secure copy seems advisable.) (Sec. 1.360)	<input type="checkbox"/>	<input type="checkbox"/>

<u>Receiving</u>		Yes	No
RC 1.0	Do you record and maintain name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you) ? (1.337 (6))	<input type="checkbox"/>	<input type="checkbox"/>
RC 2.0	Do you have the physical address for the transporter (vs. a PO Box) ? (QA 34.9)	<input type="checkbox"/>	<input type="checkbox"/>
RC 3.0	Do you record and maintain name of the firm, address, telephone number and, if available, the fax number and e-mail address of the supplier ? (nontransporter IPS in 306 speak) (1.337(1))	<input type="checkbox"/>	<input type="checkbox"/>
RC 4.0	Do you have the physical address for the nontransporter (vs. a PO Box) ? (QA 34.9)	<input type="checkbox"/>	<input type="checkbox"/>
RC 5.0	Do you record and maintain adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce) ? (1.337 (2))	<input type="checkbox"/>	<input type="checkbox"/>
RC 6.0	Do you record and maintain the date you received each ingredient or food ?(1.337 (3))	<input type="checkbox"/>	<input type="checkbox"/>
RC 7.0	Do you record and maintain the lot or code number or other identifier of the food (to the extent this information exists) ? (1.337 (4))	<input type="checkbox"/>	<input type="checkbox"/>
RC 8.0	Do you record and maintain the quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); etc. (1.337 (5))	<input type="checkbox"/>	<input type="checkbox"/>
RC 9.0	Are materials received (transferred) from other subsidiaries (owned by the same parent) recorded at the same level as from an independent 3 rd party (QA 35.5)	<input type="checkbox"/>	<input type="checkbox"/>
RC 10.0	Are food contact substances (packaging material that touches the food) tracked as any other raw material (lot #, etc) (QA 29.8 – part II, fyi, there were two 29.8 Q&A's)	<input type="checkbox"/>	<input type="checkbox"/>
RC 11.0	Are food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) treated as any other raw material (lot tracking, etc) ? (QA 9.5)	<input type="checkbox"/>	<input type="checkbox"/>
RC 12.0	Are the transporters of all samples recorded even if they arrive via mail, personal vehicle, taxi, etc ? (QA 9.1)	<input type="checkbox"/>	<input type="checkbox"/>
RC 13.0	If the material arrives on a pallet or other container, do you take the pallet apart to collect the information? Other options include vendors who use SupplySync or otherwise provide the container's ingredients details. (QA 32.9)	<input type="checkbox"/>	<input type="checkbox"/>
	Note: Because the date, transporter, and vendor lot (etc) must be tracked through production/shipping (QA29.5), there are two likely acceptable scenarios. 1) The information must be physically attached to the container or 2) a new internal lot number is assigned and that information is attached to the material. The internal lot is then tracked via internal systems- For businesses of any volume, the later seems the most likely approach		
	Because date and transporter are key tracking components, the vendor's lot alone can not be used for tracing (Vendors lot A sent via carrier B on date C goes through a different transportation channel than Vendor lot A via carrier B on day C+1). This item was referred to and verified by an agent at FDA.		

Production		Yes	No
PR 1.0	<p>Do you record and maintain information “reasonably available” to you to identify the specific source of each ingredient used to make every lot of finished product ? (1.345 (b)). Note : “reasonably available” has been defined as “does not require physical reconfiguration of the manufacturing facility”)</p> <p>Information should include the shipper, transporter, receipt date of the actual inventory (not just the lot), the vendor’s lot and manufacturing date.</p> <p>Note : Because the vendor’s lot number , transporter, and receipt date were required to be collected at receiving – that information is , by definition, reasonably available.</p>	<input type="checkbox"/>	<input type="checkbox"/>
PR 2.0	<p>Are you recording ACTUAL quantities and lots as opposed to using backflushing?</p> <p>(We have not seen a SPECIFIC ruling that backflushing is no longer allowed but the existing requirements seem to imply it can no longer be used for lot controlled items)</p>	<input type="checkbox"/>	<input type="checkbox"/>
PR 3.0	Is “food contact” packaging material traced as an ingredient (QA 29.8 – part II , fyi, there were two 29.8 Q&A’s) ?	<input type="checkbox"/>	<input type="checkbox"/>
PR 4.0	Do you trace “recycled” packing material that touches food and is returned for refilling (exemption may apply see QA 29.8) ?	<input type="checkbox"/>	<input type="checkbox"/>
PR 5.0	Are you recording the lots, etc of material used in manufacturing that are not ingredients? For instance the starch used in candy molding operations. The starch is not intentionally made part of the candy and the starch is reworked and replenished as needed. (QA 29.7)	<input type="checkbox"/>	<input type="checkbox"/>

Shipping		Yes	No
SP 1.0	Do you record and store the name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the customer ? (1.345 (1))	<input type="checkbox"/>	<input type="checkbox"/>
SP 2.0	Do you record and store an adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce) ? (1.345 (2))	<input type="checkbox"/>	<input type="checkbox"/>
SP 3.0	Do you record and store the date you released the food ? (1.345 (3))	<input type="checkbox"/>	<input type="checkbox"/>
SP 4.0	Do you record and store the lot or code number or other identifier (1.345 (4)) of the shipped food ?	<input type="checkbox"/>	<input type="checkbox"/>
SP 5.0	Do you record and store the quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank) ? (1.345 (5))	<input type="checkbox"/>	<input type="checkbox"/>
SP 6.0	Do you record and store name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter (1.345 (6))	<input type="checkbox"/>	<input type="checkbox"/>

<< full source at
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=1>
>>

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling,
Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology,
Reporting and recordkeeping requirements.

0

Therefore, under the Federal Food, Drug, and Cosmetic Act and under
authority delegated to the Commissioner of Food and Drugs, 21 CFR parts
1 and 11 are amended as follows:

PART 1--GENERAL ENFORCEMENT REGULATIONS

0

1. The authority citation for 21 CFR part 1 continues to read as
follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21
U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355,
360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262,
264.

0

2. New subpart J (Sec. Sec. 1.326 through 1.368) is added to part 1 to
read as follows:

Subpart J--Establishment, Maintenance, and Availability of Records
General Provisions

Sec.

1.326 Who is subject to this subpart?

1.327 Who is excluded from all or part of the regulations in this
subpart?

1.328 What definitions apply to this subpart?

1.329 Do other statutory provisions and regulations apply?

1.330 Can existing records satisfy the requirements of this subpart?

Requirements for Nontransporters to Establish and Maintain Records to
Identify the Nontransporter and Transporter Immediate Previous Sources
of Food

1.337 What information must nontransporters establish and maintain
to identify the nontransporter and transporter immediate previous
sources of food?

Requirements for Nontransporters to Establish and Maintain Records to
Identify the Nontransporter and Transporter Immediate Subsequent
Recipients of Food

1.345 What information must nontransporters establish and maintain
to identify the nontransporter and transporter immediate subsequent
recipients of food?

Requirements for Transporters to Establish and Maintain Records

1.352 What information must transporters establish and maintain?

General Requirements

1.360 What are the record retention requirements?

1.361 What are the record availability requirements?

1.362 What records are excluded from this subpart?

1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

Compliance Dates

1.368 What are the compliance dates for this subpart?

Subpart J--Establishment, Maintenance, and Availability of Records

General Provisions

Sec. 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in Sec. 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in Sec. 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

Sec. 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except Sec. Sec. 1.361 and 1.363. However, those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, ``processing'' means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in Sec. 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. The term ``consumers'' does not

include businesses.

[[Page 71652]]

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in Sec. 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

(1) For purposes of this section, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ``consumers'' does not include businesses.

(2) A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers.

(3) A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(4) A ``retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except Sec. Sec. 1.361 and 1.363. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.) are excluded from all of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to Sec. Sec. 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all of the requirements of this subpart, except Sec. Sec. 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive,

hold, or import the finished container that directly contacts the food are excluded from the requirements of this subpart as to the finished container, except Sec. Sec. 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except Sec. Sec. 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

Sec. 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term ``farm'' includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

[[Page 71653]]

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)).

Person includes individual, partnership, corporation, and association.

Recipe means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ``Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers.

(1) Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants.

(2) Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

Transporter means a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter's immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under Sec. 1.326.

Sec. 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods, juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in Sec. 11.3(b)(6) (21 CFR 11.3 (b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

Sec. 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

Sec. 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive:

(1) The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) For persons who manufacture, process, or pack food, the lot or

code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

Sec. 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

Requirements for Transporters to Establish and Maintain Records

Sec. 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following

[[Page 71654]]

records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and

transporter's immediate subsequent recipient;

- (2) Origin and destination points;
- (3) Date shipment received and date released;
- (4) Number of packages;
- (5) Description of freight;
- (6) Route of movement during the time you transported the food; and
- (7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of December 9, 2004:

- (1) Names of consignor and consignee;
- (2) Origin and destination points;
- (3) Date of shipment;
- (4) Number of packages;
- (5) Description of freight;
- (6) Route of movement and name of each carrier participating in the

transportation; and

- (7) Transfer points through which shipment moved; or

(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of December 9, 2004:

- (1) Date received;
- (2) Received from;
- (3) Consigned to;
- (4) Destination;
- (5) State of;
- (6) County of;
- (7) Route;
- (8) Delivering carrier;
- (9) Car initial;
- (10) Car no;
- (11) Trailer initials/number;
- (12) Container initials/number;
- (13) No. packages; and
- (14) Description of articles; or

(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:

- (1) Shipper's name and address;
- (2) Consignee's name and address;
- (3) Customs reference/status;
- (4) Airport of departure and destination;
- (5) First carrier; and
- (6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in Sec. 1.352(a), (b), (c), or (d). The agreement must contain the following elements:

- (1) Effective date;
- (2) Printed names and signatures of authorized officials;
- (3) Description of the records to be established and/or maintained;
- (4) Provision for the records to be maintained in compliance with

Sec. 1.360, if the agreement provides for maintenance of records;

(5) Provision for the records to be available to FDA as required by Sec. 1.361, if the agreement provides for maintenance of records;

(6) Acknowledgement that the nontransporter assumes legal responsibility under Sec. 1.363 for establishing and/or maintaining the records as required by this subpart; and

(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

Sec. 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

Sec. 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

Sec. 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in Sec. 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

[[Page 71655]]

Sec. 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under Sec. 1.352(c) to establish, maintain, or establish and maintain, records required under Sec. 1.352(a) or (b), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the act and this regulation is a prohibited act under section 301 of the act.

Compliance Dates

Sec. 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is December 9, 2005. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is June 9, 2004, for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is December 11, 2006, for very small businesses that employ 10 or fewer full-time equivalent employees.

PART 11--ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

0

3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

0

4. Section 11.1 is amended by adding paragraph (f) to read as follows:

Sec. 11.1 Scope

* * * * *

(f) This part does not apply to records required to be established or maintained by Sec. Sec. 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

Dated: November 30, 2004.

Lester M. Crawford,
Acting Commissioner of Food and Drugs.

Dated: December 2, 2004.

Tommy G. Thompson,
Secretary of Health and Human Services.
[FR Doc. 04-26929 Filed 12-6-04; 8:45 am]

BILLING CODE 4160-01-S

Guidance for Industry

Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records (Edition 2)

Table of Contents

- I. [Introduction](#)
- II. [Questions and Answers](#)
 - A. [Who is Subject to this Rule? \(Section 1.326\)](#)
 - B. [Who is Excluded From All or Part of the Regulations? \(Section 1.327\)](#)
 - C. [Definitions \(Section 1.328\)](#)
 - D. [Do Other Statutory Provisions and Regulations Apply? \(Section 1.329\)](#)
 - E. [Can Existing Records Satisfy the Requirements of this Rule? \(Section 1.330\)](#)
 - F. [What Information is Required in the Records You Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Source and Immediate Subsequent Recipients? \(Sections 1.337 and 1.345\)](#)
 - G. [Who is Required to Establish and Maintain Records for Tracing the Transportation of All Food? \(Section 1.351\)](#)
 - H. [What Information is Required in the Transportation Records? \(Section 1.352\)](#)
 - I. [What Are the Record Retention Requirements? \(Section 1.360\)](#)
 - J. [What Are the Record Availability Requirements? \(Section 1.361\)](#)
 - K. [What Records Are Excluded From this Rule? \(Section 1.362\)](#)
 - L. [What Are the Consequences of Failing to Establish and Maintain Records or Make Them Available to FDA as Required by this Rule? \(Section 1.363\)](#)
 - M. [What Are the Compliance Dates for this Rule? \(Section 1.368\)](#)
 - N. [General Comments](#)

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

On December 9, 2004, FDA issued a final rule that requires the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States. Such records are to allow for the identification of the immediate previous sources and the immediate subsequent recipients of food. The final rule implements Section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (See 69 FR 71562; December 9, 2004 (<http://www.cfsan.fda.gov/~dms/frecord.html>)).

This document is being issued as Level 1 guidance pursuant to 21 CFR 10.115 and includes answers to inquiries regarding the implementation of the Establishment and Maintenance of Records Final Rule (21 CFR Part 1, Subpart J). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate. New editions of this guidance may be issued at a later date that include additional inquiries on the implementation of this regulation.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. QUESTIONS AND ANSWERS

A. Who is Subject to this Rule? (Section 1.326)

1. General Questions

1.1 Q: A brokerage division of a shipping company handles nationwide shipping needs for several other shippers. The brokerage division does not physically take custody of the food, but negotiates the freight rates and assigns the contracts to independent carriers. Does the brokerage division have record keeping obligations under this regulation?

A: Yes. 21 CFR 1.328 defines a transporter as a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting it. For the purpose of this regulation, a person, such as the shipping company above, who enters into a contract to transport an article of food and has control over the food is considered a transporter, even if the actual transport is subsequently subcontracted to another entity. In the above example, the freight broker and the independent carrier are transporters subject to the Final Rule in accordance with §1.352. This scenario differs from that described in the response to comment 16 in the Final Rule preamble, in which FDA states that the recordkeeping requirements do not apply to brokers who act *only* to facilitate distribution, sale, or transportation of food by processing information or paperwork associated with these functions, such as customs brokers who file entry information on food imported or offered for import with U.S. Customs and Border Protection. Brokers who do not *directly* manufacture, process, pack, transport, distribute, receive, hold, or import food are not subject to the requirements of this regulation.

1.2 Q: A firm purchases bottled water for use by its employees. Does this firm have to establish and maintain records?

A: Yes. The firm must establish and maintain records of the nontransporter and transporter immediate previous sources of the bottled water in accordance with 21 CFR 1.337. However, §1.327(d) excludes persons who distribute food directly to consumers from the requirements in §1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. Therefore, the firm does not have to establish records of distribution to its employees.

1.3 Q: Drug manufacturers often compound their products using various excipients (*e.g.*, lactose, sugar alcohols, amino acids, and beta-carotene) that are obtained as food-grade material. Are the drug manufacturers who obtain these materials covered by this regulation? If another company provides one of these materials to the drug manufacturer, is that transaction covered by this regulation?

A: No. 21 CFR 1.326(a) requires that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food (including food ingredients) must establish and maintain records as required by this regulation. However, if a food ingredient is transferred to an immediate subsequent recipient who will use that substance as a drug excipient, FDA considers the substance to be a drug component regulated under applicable drug statutory and regulatory provisions. FDA is not requiring the original firm, the transporter, and the recipient (the drug manufacturer) to establish and maintain records of this transaction. Conversely, if a firm manufactured a substance intended primarily for use as a drug excipient, but sold some of that substance for use in food or feed, the firm would have to establish and maintain records of that transaction.

1.4 Q: Are over the counter vitamins covered by this regulation?

A: Yes. Food in this regulation has the same meaning as under section 201(f) (21 U.S.C. 321(f)) of the Federal Food, Drug, and Cosmetic Act. Food includes dietary supplements, such as over-the-counter vitamins (21 U.S.C. 321(ff)).

1.5 Q: Halloween candy is donated to a firm's distribution center and then distributed to the firm's retail stores to be given out to children. There is currently no record kept of the candy receipt or distribution to retail stores. Is the practice exempt from this regulation?

A: 21 CFR 1.326(a) requires that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food must establish and maintain records as required by this regulation. However, as discussed in the response to comment 13 of the Final Rule preamble, a vertically integrated company does not have to establish and maintain records of internal transactions. The distribution center must always establish and maintain records of the transporter and nontransporter immediate previous sources of the candy, but if the distribution center, transporter, and retail store are all part of the same company under identical ownership, distribution to retail stores is considered an internal transfer for the purpose of this regulation and no records of the transaction must be established and maintained. If the distribution center is not integrated with the retail store (*e.g.*, not part of the same company), or if an independent transporter carries the candy between them, then records of this transaction must be established and maintained. Finally, §1.327(d) excludes persons who distribute food directly to consumers

from the requirements in §1.345 to establish and maintain records to identify the nontransporter and transporter subsequent recipients as to those transactions. Therefore, the retail store does not need to establish records identifying the immediate subsequent recipients of the candy if those recipients are consumers.

1.6 Q: A facility manufactures fruit and vegetable salads, and the waste is removed by an outside entity that may direct it to a landfill, compost, or animal feed. Is the facility required to track the waste?

A: FDA intends to consider exercising enforcement discretion if a facility manufacturing fruit and vegetable salads releases food waste to a nontransporter immediate subsequent recipient who directs the waste to a landfill or compost facility or to a facility for consumption by animals without further manufacturing/processing. FDA does not intend to consider exercising enforcement discretion with regard to §1.345, however, if the waste will be further manufactured/processed (*e.g.*, by rendering facilities) before it is consumed by animals, or if there is more than one intermediary (transporter or nontransporter) between the manufacturing facility and the facility where the waste is disposed of at a landfill or compost facility or is consumed by animals.

1.7 Q: [Added November 2005] A nonprofit food business incubator owns a facility with kitchens, cold storage, and warehouse space. The incubator rents kitchen and storage space to many small manufacturers engaged in product development. The incubator is the receiving point for all food coming into the facility. The food is stored in the warehouse and freezers under the control of incubator employees until each manufacturer takes possession. What are the incubator's responsibilities under the recordkeeping rule?

A: The incubator is considered a nontransporter covered by this regulation. 21 CFR 1.326 states that covered persons are those who manufacture, process, pack, transport, distribute, receive, hold, or import food. In the specific case above, the incubator receives and holds food at a facility that it owns and controls before releasing it to the resident manufacturers. The incubator must establish and maintain records for food received and released that identify the nontransporter and transporter immediate previous sources and immediate subsequent recipients, as required by §§1.337 and 1.345. The incubator is not exempt as a nonprofit organization, as discussed in the response to comment 44 in the Final Rule preamble, because it is not an establishment that prepares or serves food directly to the consumer.

1.8 Q: [Added November 2005] A food laboratory/culinary school occasionally brings in ingredients and prepares food to be given to staff members and/or members of the general public. For example, some laboratories bring in ingredients to make a small batch of a certain product and offer that product for consumption to other employees and/or selected guests. These foods are not being prepared for commercial purposes. Is this type of food preparation and distribution exempt from the rule?

A: Yes. As discussed in the response to Comment 37 in the Final Rule preamble, a person who prepares and distributes food directly to consumers for immediate consumption is exempt under the restaurant exemption with respect to that food.

1.9 Q: [Added November 2005] Company A receives a call from Company C requesting a certain product. The product is not currently in Company A's warehouse. Company A calls Company B and requests that Company B ship the product directly to Company C. Company A then charges Company C for the product. Must Company A establish and maintain records of this transaction?

A: Yes. 21 CFR 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. A person who enters into a contract to hold, manufacture, process, pack, import, receive, or distribute food is considered a nontransporter, even if that person subcontracts the actual performance of the covered action to another entity. In the above example, both Company A and Company B are nontransporters subject to the final rule. Both are responsible for complying with the rule, which either may do for the other as a matter of business practice, but legal responsibility for establishment and maintenance of records and for meeting the records access timeframes specified in §1.361 remains with both parties. Company C may identify either Company A or B as its nontransporter immediate previous source.

1.10 Q: [Added November 2005] Is a winery subject to this regulation?

A: Yes. 21 CFR 1.326 states that persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are covered by this regulation. The winery is considered a manufacturer and must establish and maintain records of the food (including ingredients) that it receives as well as the food (wine) that it releases, in accordance with §§1.337 and 1.345. If the winery also grows and harvests grapes that it uses to manufacture the wine, then it would be engaged in a mixed activity. In this instance, the growing facility may qualify for the farm exemption; the manufacturing activity would remain subject to the nontransporter requirements in the final rule.

1.11 Q: [Added November 2005] Some wineries are co-located with gift shops where wine can be sampled and purchased. Are these gift shops/tasting areas exempt from the rule?

A: No. A gift shop co-located with a winery is an example of a mixed facility that engages in both manufacturing and retail activities, and therefore does not qualify for the restaurant exemption provided by 21 CFR 1.327(b). However, if the gift shop and winery are under the same ownership, they are vertically integrated, as discussed in the response to Comment 13 of the Final Rule preamble and elsewhere in this document. Records do not have to be established and maintained for transfers of wine from the winery to the gift shop. Records must be established and maintained for food received from other sources in accordance with 21 CFR 1.337. The gift shop does not have to establish and maintain records of food it releases directly to consumers, in accordance with the retail exemption provided by 21 CFR 1.327(d).

1.12 Q: [Added November 2005] An airline purchases tax-free liquor in the United States that is served strictly on international flights. Is this practice covered by this regulation?

A: The answer depends on whether the airline meets the definition of a retailer, as provided in 21 CFR 1.327(e), or a restaurant, as provided in 21 CFR 1.328. A restaurant is entirely exempt

from this regulation. A retailer is covered only with respect to those activities that occur in the United States, as specified in 21 CFR 1.326(a). A retailer, as with other covered persons, must establish and maintain records for food it receives even if that food is not consumed in the United States, as discussed in the response to Comment 22 in the Final Rule preamble.

1.13 Q: [Added November 2005] A manufacturer sells its food product on consignment in a retail store. Although the food product is delivered to a retail store under separate ownership, the manufacturer still owns the food product until it is sold to a consumer. In this situation, is the retail store required to establish and maintain records of the receipt of the food product?

A: Yes. Both the manufacturer and the retail store are nontransporters with respect to this food product and are required to establish and maintain records of receipt and release of the food in accordance with 21 CFR 1.337 and 1.345. Section 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, receives, or distributes food for purposes other than transportation. While the manufacturer owns the food, the retail store receives and holds the food. Therefore, the retail store should establish and maintain records when the food is received that identify the nontransporter and transporter immediate previous sources, in accordance with §1.337. In the case described above, the nontransporter immediate previous source is the food manufacturer.

1.14 Q: [Added November 2005] In Control State bailment warehouses, which in the beverage alcohol industry are operated by or on behalf of Control States such as North Carolina, Virginia and Washington, beverage alcohol products are owned by the manufacturer or importer until the Control State withdraws those goods from the warehouse for shipment. Beverage alcohol products in these bailment warehouses are under the physical possession and are controlled substantially by the Control State. Is the Control State subject to the recordkeeping rule requirements for product in bailment warehouses?

A: Yes. Both the Control State and the owner of the alcohol product are covered entities.

2. Intrastate (Reserved)

B. Who is Excluded From All or Part of the Regulations? (Section 1.327)

3. General Questions

FDA has addressed questions we received on this issue in the [Final Rule](#).

4. Farms

4.1 Q: [Added November 2005] Company A cools, holds in cold storage, markets and sells a raw agricultural commodity (RAC) grown on a farm land which is owned by company B and farmed by company C. The RAC is harvested by a contractor company D that places the RAC grown on the farm land leased and farmed by company C directly into unlined corrugated boxes. The boxes are marked as a product of company A and the box serves as the primary container for the RAC during distribution and wholesaling. Which companies and activities qualify for the farm exemption? Are the corrugated boxes a finished container for which records must be established and maintained?

A: Company B, C, and D are all exempt from the requirements of this regulation as provided by the farm exemption in 21 CFR 1.327(a). Company A must establish and maintain records of the food that it receives and distributes. Section 1.328 defines a farm as a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals, or both. Cooling produce is considered part of harvesting and persons that pack or hold food grown on that farm or another farm under the same ownership remain within the farm exemption but Company A is engaged in other nonexempt activities and is not within the farm exemption. Accordingly, Company A must establish and maintain records of the receipt of the food as required by §1.337 and must also establish and maintain records of subsequent release of the food in accordance with §1.345. Neither Company A nor the other companies mentioned above are required to establish and maintain records with respect to the corrugated cardboard boxes. In the above example, Company D is included in the farm exemption and is not subject to any requirements of this regulation. If Company D were not a farm, it would be subject only to the record access requirements of §1.327(j) as to the packaging, because the box serves as wholesale packaging and is not the finished container in which the food will be received by the consumer.

4.2 Q: [Added November 2005] A farm grows, dries, and chops alfalfa before releasing it to another person for use as animal feed. Is the farm still exempt from this regulation?

A: No. Traditional farming activities, such as harvesting of grains, are covered under the farm exemption. However, this question implies that the drying and chopping are post-harvest activities, which would be considered manufacturing/processing and therefore are subject to this rule. Therefore, the facility drying and chopping alfalfa must establish and maintain records of the food's receipt and release as required in 21 CFR 1.337 and 1.345.

5. Restaurants

5.1 Q: Some retail stores have sushi makers on site. The sushi maker prepares sushi in a store and sells it through that store. The retailer never actually owns the sushi, but only retains a portion of the net amount received from the sushi sales. In this case, is the retailer required to keep any records regarding the sushi?

A: No. Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to this regulation, in accordance with 21 CFR 1.326(a). Section 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. In the above example, both the owner of the food (the sushi maker) and the retailer who controls the surrounding facility are nontransporters subject to this regulation with respect to the sushi, unless an exemption applies. In this case, the sushi is prepared and sold directly to consumers for immediate consumption, in accordance with the definition of "restaurant" in §1.328. As discussed in the response to comment 37 of the Final Rule preamble, all sales of food prepared and sold directly to consumers for immediate consumption fall under the restaurant exemption, regardless of whether the seller is a retailer or another type of entity. Therefore, in accordance with §1.327(b) the retailer and sushi maker are excluded from all the requirements of this regulation with respect to the food (sushi) prepared and sold directly to consumers.

6. Retail Facilities

6.1 Q: Is a retail store with an in-store bakery also a manufacturing facility that must track ingredients and lot numbers for its baked goods manufactured on-site?

A: No. 21 CFR 1.328 defines a restaurant as a facility that prepares and sells food directly to consumers for immediate consumption. The bakery in a retail store that prepares and sells food in the retail store is considered a restaurant for the purpose of this regulation. Section 1.327 excludes a restaurant from all requirements of this regulation, including the requirement to establish and maintain records of all food it receives (§1.337). Therefore, the retail store does not need to track ingredients and lot numbers for the baked goods manufactured on-site.

6.2 Q: A retailer buys bulk packs of food (*e.g.*, fish) and prepares it for resale in smaller quantities. Is the retailer considered a packager? If the food is placed in a new container, must the retailer track the packaging?

A: 21 CFR 1.327(e) states that a retail food establishment may pack food and retain its retail designation if the annual value of food sold directly to consumers is equal to more than half of its total sales. If this condition is met, the establishment still must establish and maintain records of the receipt of the finished container (packaging) that contains the food in accordance with §1.327(k), but is excluded from the requirement in §1.337(a)(4) to record the lot or code number or other identifier of the packaging. Section 1.327(d) excludes a retail establishment from the requirement to establish and maintain records for the food it releases, including the source of the finished container in which the establishment has placed the food, for those products it distributes directly to consumers.

6.3 Q: Some retail stores have sushi makers on site. The sushi maker might prepare sushi in one store and sell it through both that store and other stores. The sushi maker handles all transportation, and the retailer does not own the sushi, but only retains a portion of the net sales. Would the sushi maker be considered a central kitchen (*i.e.*, not a restaurant) with respect to the sushi that is sold in other stores?

A: No. The sushi remains in the continuous possession of the sushi maker (including transport between stores) until it is sold to consumers for immediate consumption. Therefore, the sushi maker functions as an integrated company that prepares and sells food directly to consumers and is considered a restaurant for the purpose of this regulation.

6.4 Q: In a central kitchen in one of its stores, a retailer makes a prepared salad or bakery item that it distributes for sale at multiple stores in the region. Is lot number tracking for ingredients and finished products required?

A: No, provided all of the multiple stores are under the same ownership as the central kitchen. In this situation, the retailer prepares the salad or bakery item and retains that food within its person until it is sold directly to consumers. This retailer is exempt as a restaurant from the requirements of this regulation in accordance with 21 CFR 1.327, for the food it prepares and sells directly to consumers for immediate consumption. If, however, the retailer's central kitchen is preparing and distributing the food to other retailers with different ownership, the

retailer's activities would not qualify for the restaurant exemption as to those transactions and would be subject to this regulation for that food.

6.5 Q: Some retail stores donate old produce to pig farms for free. The donated produce is eaten by the animals and reduces the waste produced by the retail store. However, the farms are not considered non-profit organizations. Does this mean that each store that donates in this way will have to document the donations?

A: Similar to [Question 1.6](#) above, FDA intends to consider exercising enforcement discretion regarding records of food waste released by a facility to a pig farm for consumption by animals without further manufacturing/processing.

6.6 Q: A retail establishment releases food to a business. Damaged goods may be sold to third-party reclamation centers or salvagers for eventual resale to consumers. The retail establishment is aware that the nontransporter immediate subsequent recipient in these transactions is not a consumer. However, there is not currently a system in place that can provide information on the specific foods released. Instead, generic descriptions are used (*e.g.*, one pallet of dented cans). 21 CFR 1.327(e) states that for retailers, the requirements in §1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available. The response to comment 38 in the Final Rule preamble states that "information is reasonably available to you if you have a system in place to capture the information. FDA does not intend to require the reconfiguration of business operations." In the situation described above, is the retail establishment required to establish and maintain records of the nontransporter and transporter immediate subsequent recipients?

A: Yes. 21 CFR 1.327(e) provides: "Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in §1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies to those transactions only to the extent that the information is reasonably available." FDA considers the information that must be "reasonably available" in this subsection to refer to the retailer's *knowledge* as to whether the recipient of the food is a consumer or a business; it does not exempt the retailer from keeping required records when the retailer knows the recipient is a business and is able to capture this information. For example, if a person buying deli meat from a grocery store owns the sandwich shop in the same shopping complex, the grocery store does not have to inquire as to whether the buyer is purchasing the meat in her individual capacity as a consumer, or purchasing the meat for use in her sandwich shop, nor does the store have to establish separate business accounts to capture the status of the buyer. If, however, the grocery store provides membership cards for buyers based on their status (*e.g.*, one type of card for consumers and another type for businesses), then this information is reasonably available to the retail store, and records of the release of food to businesses are required. In the question posed above, the retail store is aware that the recipient is a business, and the salvaged food is sold on the basis of that understanding. The retail store does not qualify for the exclusion for sales to consumers for these transactions, and must establish and maintain records of the released food as required by §1.345, including an adequate description of the food released.

6.7 Q: [Added November 2005] Is a retail food establishment (retail animal feed) that employs 10 or fewer full-time equivalent employees still exempt from the requirement to establish and maintain records (but not the record access requirements for existing records), if they sell feed to a business or the feed sold is to be used in animals that will subsequently be sold as food?

A: This establishment is exempt if it meets the definition of a retail establishment as defined in 21 CFR 1.327(e). 21 CFR 1.327(e)(1) states that a retail establishment's primary function is to sell food directly to consumers, and 21 CFR 1.327(e)(3) states that a retail establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food to all other buyers. As discussed in the response to Comment 52 in the Final Rule preamble, "food distributed directly to consumers" includes sales of bagged feed, pet food, and feed ingredients/additives over-the-counter directly to consumers and final purchasers for their own animals, unless the feed is to be used in animals that will be sold as food or used to produce food for sale. If this establishment with 10 or fewer full-time equivalent employees qualifies according to the criteria discussed above, it is exempt as provided by 21 CFR 1.327(f).

6.8 Q: [Added November 2005] A retail facility receives a returned food product from a consumer. The food product may be restocked if there is no damage or consumer complaint. Is the retail facility required to establish and maintain records of the receipt of the returned food?

A: Yes. The retail facility is assuming custody and control of food released by another person, and must establish and maintain records of the immediate previous source as required by 21 CFR 1.337. However, FDA intends to consider exercising enforcement discretion with regard to section 1.345(b) if the records indicating the source of the incoming returned food refers to "customer return" or the equivalent as the source.

7. Persons Under the Exclusive Jurisdiction of USDA (Reserved)

8. Food Contact Materials

8.1 Q: The final regulation requires the person placing a food directly into contact with its finished container to establish and maintain records on the container that contacts the food. Since the definition of food includes food ingredients, this requirement appears to apply to equally to anyone placing any food ingredient into any container as well as commercial packaging operations. This encompasses activities such as a chemical plant placing bulk oil or glycerin into a railroad tank car, placing grain into a grain silo, loading product into drums, loading a tank truck, or placing vegetables into a pick-up truck, as well as more traditional food packaging operations such as filling a bottle of ketchup or canning tomatoes. Does "finished container" apply to every container at every step in the chain of custody?

A: No. A "finished container" as described in 21 CFR 1.27(k) is the packaging in which the finished food will be received by an individual consumer (not by a business).

8.2 Q: A transporter carries items that may or may not become food contact substances (e.g., polyethylene bags). Is the transporter subject to the records access requirements?

A: In accordance with 21 CFR 1.327(j), all persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that directly contacts food are excluded from all recordkeeping requirements except §1.361 and §1.363. Under these provisions, any existing relevant records must be made available to FDA as soon as possible, not to exceed 24 hours from the time of request, if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. If a transporter can reasonably expect that some or all of its cargo may become food contact substances, then that transporter must ensure that it has the capability to provide access within the specified time limit to records it normally maintains as a matter of business practice and that may be within the scope of a records access request by FDA.

8.3 Q: Does a firm that collects reusable containers after use and then releases them to another firm that places food in the containers, such as a bottling firm that refills the bottles with water, have to establish and maintain records under this regulation?

A: No. 21 CFR 1.327(k) provides that all persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts food and do not themselves place the food in contact with the container are excluded from the requirements of this regulation, except §§1.361 and 1.363. However, the firm placing food in contact with the reusable containers does have to establish and maintain records of the received containers that identify the first firm that is collecting the reusable containers as the nontransporter immediate previous source.

8.4 Q: [Added November 2005] During a firm's manufacturing process, the food may come in contact with many substances and materials such as chemically treated water (*e.g.*, chlorine, anti-foam agent), steam which is generated from chemically treated boilers, gases, gaskets, mixing vessels, and tote liners which temporarily hold the product. Would these substances and items be considered ingredients or food contact materials subject to this regulation?

A: FDA notes that there are a wide variety of processing aids and other incidental additives that are used in the manufacture of food. If a substance is intended to have a technical effect in the food to which it is added, it is considered a food ingredient subject to this regulation, as discussed in the response to comment 96 of the final rule preamble. A manufacturing firm must therefore establish and maintain records as required by 21 CFR 1.337 for the receipt of these substances. In addition, the firm must establish and maintain records for the food it releases that include the reasonably available information on the specific source of every ingredient (including processing aids and incidental additives) used to make every lot of the finished food, as required by §1.345(b). However, persons placing food in contact with containers or surfaces other than the finished container that directly contacts the food or using other food contact substances do not have to establish and maintain records for the food contact substances and are subject only to the requirements in 21 CFR 1.361 and 1.363 for existing records with respect to those food contact substances.

8.5 Q: [Added November 2005] Within a retail establishment, are the pots and pans used in food preparation in the deli, produce plastic bags, saran wrap, foam plates and other such materials subject to this regulation as food contact items?

A: No. A facility that prepares and sells food directly to consumers for immediate consumption is considered a restaurant and is exempt from all the requirements discussed above, in accordance with §1.327(b). In addition, a facility that is a retail establishment only is required to establish and maintain records for those food contact substances it receives that serve as finished containers for the food it releases. 21 CFR 1.327(k) states that persons who place food directly in contact with its finished container are subject to all of the requirements of this regulation as to the finished container that directly contacts the food. As explained in question 8.1 of this document, the finished container is the packaging in which the food will be received by an individual consumer. Food contact substances other than the finished container that directly contacts food are excluded from all the requirements of this regulation except §§1.361 and 1.363, as provided in §1.327(j). Accordingly, those handling food contact substances will need to ensure they have procedures in place to satisfy the record access timeframes established in §1.361.

8.6 Q: [Added November 2005] Bananas in transport from a distribution center to a retail store are covered by bags. The bags are removed before the bananas are sold to the consumer. Does the store or distribution center have to establish and maintain records for the bags?

A: No. Food contact substances other than the finished container that directly contacts food are excluded from all the requirements of this regulation except 21 CFR 1.361 and 1.363, in accordance with §1.327(j). As explained in question 8.2 of this document, the finished container is the container in which the food will be received by an individual consumer. The bags contact the food, but are not present when the consumer receives the food.

9. Persons Who Manufacture, Process, Pack, Transport, Distribute, Receive, Hold, or Import Samples

9.1 Q: Samples are employed in a wide variety of ways within the business community and move between facilities in many ways, based largely on how many samples are involved. Larger quantities of samples are more likely to be mailed, shipped by a shipping service, or shipped by a carrier. Smaller quantities of samples are more likely to be hand carried, transported in an employee's personal vehicle, or even moved by taxi cab. Do businesses have to establish and maintain records for all samples, regardless of use or mode of transport?

A: Yes. As discussed in the response to comment 32 of the Final Rule preamble, food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) are subject to this regulation. Accordingly, records must be established and maintained identifying the immediate previous sources and immediate subsequent recipients of the samples in accordance with 21 CFR 1.337 and 1.345. However, §1.327(d) excludes persons who distribute food directly to consumers from the requirements in §1.345 to establish and maintain records to identify the nontransporter and transporter subsequent recipients as to those transactions. In accordance with this subsection, a firm does not need to establish and maintain records for release of samples as long as the samples are released directly to an individual consumer. For the purpose of this regulation, FDA considers a company that transfers food samples to its own employees for personal consumption to be distributing food directly to consumers as specified in §1.327(d). Conversely, distribution of samples and other feed to a farm that is raising animals for food or distribution of samples and other feed to

contract farms is not considered to be releasing food directly to consumers. In addition and as discussed in the response to comment 70 of the Final Rule preamble, a person (including an individual partnership, corporation, or association) who distributes or receives food for purposes other than transportation is not a transporter, even if the person also transports food. Therefore, if samples are transported by an employee of either the manufacturer or recipient firm, the transporter records specified by §1.352 are not required and only those records required of non-transporters are required.

9.2 Q: A firm manufactures metal and plastic closures for food products. The firm's research and development laboratory may receive food packed by a customer for performance testing by the laboratory. Excess food packages are distributed to the firm's employees at no charge. Is the laboratory subject to this regulation?

A: Yes. The laboratory must establish and maintain records of the receipt of food (including samples of food) if that food will be consumed, in accordance with 21 CFR 1.337. However, §1.327(d) excludes persons who distribute food directly to consumers from the requirements in §1.345 to establish and maintain records of the nontransporter and transporter immediate subsequent recipients as to those transactions. For the purpose of this regulation, a company that transfers food samples to its own employees for personal consumption is considered to be distributing food directly to consumers as specified in §1.327(d).

9.3 Q: Customers frequently ask manufacturers for laboratory samples of food ingredients for evaluation. It is unknown whether the company requesting samples will produce an edible food product. Must records be established and maintained for transfer of the samples sent to these immediate subsequent recipients?

A: As discussed in the response to comment 32 of the Final Rule preamble, food samples intended for consumption (including consumption via test marketing, tasting at trade shows, and promotional marketing) are subject to this regulation. Records must be established and maintained if there is a reasonable expectation that the ingredient samples will be used in a food product that will be consumed. If it is unclear whether the samples will be incorporated into food that is consumed, the ingredient manufacturer may wish to obtain this information from the recipient as a matter of business practice.

9.4 Q: If samples are intended for consumption by a laboratory animal (*e.g.*, a rat) are they exempt from this regulation?

A: FDA intends to consider exercising enforcement discretion with regard to records for samples if the samples are consumed by animals that: (1) are used for research purposes only, (2) are not used for food, and (3) remain under the control of the laboratory.

9.5 Q: A supermarket headquarters building receives samples that are tested. The testing may include tasting. Is recordkeeping required to track receipt of these samples?

A: Yes. If samples will be consumed by humans for testing purposes after receipt, the firm must establish and maintain records of the nontransporter and transporter immediate previous sources of the samples as required by 21 CFR 1.337.

9.6 Q: If a manufacturing firm provides one or two samples of an item to a buyer for a retail firm for immediate consumption by that buyer, does this regulation require recordkeeping?

A: In general, yes. The manufacturing firm must establish and maintain records of the immediate subsequent recipient of the samples as required by 21 CFR 1.345. However, if the transfer occurs in a venue where commercial buyers and members of the general public are both present and a specific recipient cannot be readily distinguished as belonging to one or the other of those groups (*e.g.*, at a trade show open to both industry and the public where a buyer consumes one or two samples and does not provide his or her corporate affiliation or otherwise establish commercial contact), FDA intends to consider exercising enforcement discretion regarding establishment of records of that specific transfer.

9.7 Q: A research and development laboratory creates samples and ships them to a customer who consumes them. Does the laboratory have to establish and maintain records of incoming ingredients and outgoing samples?

A: Yes. The laboratory must establish and maintain records of incoming ingredients intended for use in samples that will be consumed, including records of the transporter and nontransporter immediate previous sources, as specified by 21 CFR 1.337. The laboratory must also establish and maintain records of outgoing samples that will be consumed, including records of the transporter and nontransporter subsequent recipients, as specified in §1.345, unless the recipients are individual consumers. For the purpose of this regulation, a company that transfers food samples to its own employees for personal consumption is considered to be distributing food directly to consumers as specified in §1.327(d).

9.8 Q: If one firm engages a second firm to place samples in different geographic locations that are then given to consumers for testing, what records need to be maintained?

A: As discussed in the response to comment 32 of the Final Rule preamble, food samples intended for consumption (including consumption via test marketing and promotional marketing) are subject to this regulation. Therefore, both firms must establish and maintain records with respect to the transfer of samples between them, in accordance with 21 CFR 1.337 and 1.345. However, §1.327(d) excludes persons who distribute food directly to consumers from the requirements in §1.345 to establish and maintain records to identify the nontransporter and transporter subsequent recipients as to those transactions. Therefore, the second firm need not establish and maintain records of release of the samples if they are distributed directly to individual consumers.

9.9 Q: [Added November 2005] Are hospitals and doctors' offices required to establish and maintain records of receipt and release of food samples?

A: Yes. Hospitals and doctors' offices must establish and maintain records for the receipt of food, including food samples, as required by 21 CFR 1.337. However, §1.327(d) states that if the food is released directly to individual consumers, no record of the release is required.

9.10 Q: [Added November 2005] A firm assembles panels (consisting of employees) to assess the quality of potential new products. Organoleptic assessment is done by placing small quantities in the mouth; in most cases the sample is not swallowed. Must records be established and maintained for this activity?

A: The firm does not have to establish and maintain records when it receives samples that will not be consumed. The response to comment 32 in the Final Rule preamble states that samples used only for analysis are exempt from this regulation, and that analysis may include organoleptic examination. However, in the above example, the food is placed in the mouth, which would include consumption or absorption of some part of the sample. Accordingly, the exemption does not apply and the firm must establish and maintain records of the receipt of the samples in accordance with 21 CFR 1.337. The firm does not have to establish and maintain records of transfer of the samples to its own employees even if consumption occurs, as FDA considers this distribution directly to consumers, which is subject to the exclusion in 21 CFR 1.327(d).

10. Persons Who Distribute Food Directly to Consumers

10.1 Q: A combined airline and caterer receives foods and food ingredients with production codes and expiration dates. Is the company expected to track each product by code number through the kitchen to the customer? For example, if the company receives a gallon of olive oil, must that oil be linked to each recipe where it is used and through the facility to the customer by lot number?

A: No. In general, as discussed in the response to comment 76 in the Final Rule preamble, a caterer for interstate conveyances does not qualify for the restaurant exemption defined in 21 CFR 1.328 and must comply with both §1.337 and §1.345. Records established and maintained in accordance with §1.345 must include the information reasonably available to the caterer to identify the specific source of each ingredient used to make every lot of finished product. However, an airline that caters its own flights is vertically integrated (as long as ownership of the two companies is the same and the food is not transported independently). As discussed in the response to comment 13 of the Final Rule preamble, a vertically integrated company does not have to establish records of internal transfers of food. In accordance with §1.327(d), the airline is also excluded from the requirement to establish and maintain records of the immediate subsequent recipient when the food is ultimately released because it is being distributed directly to the consumer. However, if the airline were to prepare finished food products and sell them to another airline, the firm would be required to establish and maintain records for each food released to the other airline, including both the specific source of each ingredient used to make every lot of the finished food product (to the extent that the information is reasonably available) and lot numbers or other identifiers (to the extent they exist).

10.2 Q: [Added November 2005] (*Amended 10.2 from 1st Edition*) A bottled water company delivers to businesses, and the water is consumed by employees at these businesses. Is this considered delivery to consumers with respect to recordkeeping obligations?

A: No. 21 CFR 1.327(d) only excludes persons who distribute food directly to individual consumers from the requirements in §1.345 to establish and maintain records. This subsection expressly states that the "term 'consumers' does not include businesses." Therefore, the bottled water company is required to establish and maintain records of its water deliveries to businesses. The exemption in §1.327(n) for persons who receive or hold food on behalf of specific individual consumers is not applicable because in this case the business is the purchaser and a party to the transaction with the bottled water company, and is not simply holding the bottled water for a consumer purchaser. However, the bottled water company is performing mixed nontransporter activities, similar to the example discussed in question 37.1 of this document: (1) it is manufacturing, processing, and packing its products; and (2) it is distributing these products to businesses. In situations where the bottled water company is placing its products directly in the location where they will be consumed, it is functioning as a retailer, similar to a vending machine supplier or a direct store delivery operation. Both of these situations directly parallel the example in question 37.1. In all cases, the bottled water company must establish and maintain records for each of these two distinct functions. As required by sections 1.337 and 1.345, the bottled water company must establish and maintain records of all food (water and finished containers that will be placed in contact with the water) it receives, and all water it releases to its distribution or warehouse location, including lot number or other identifier (to the extent this information exists) as required by 21 CFR 1.345(a)(4). The company's distribution or warehouse facility must record the release of water to businesses as required by 21 CFR 1.345, but is not required to record lot numbers. Each client business is also a nontransporter who is subject to these regulations because it has custody or control of the food. Accordingly, it must establish and maintain records of all water it receives from the bottled water company in accordance with section 1.337, but it is not required to record lot numbers, as it is not manufacturing, processing or packing the food.

10.3 Q: [Added November 2005] A firm may give a selection of food products from its inventory to employees as gifts. Must records be established and maintained for this activity?

A: No. For the purpose of this regulation, the firm is distributing food directly to consumers and falls under the exclusion in 21 CFR 1.327(d).

10.4 Q: [Added November 2005] An airline loads food in a foreign country and it is served to passengers in United States airspace. Is the airline required to establish and maintain any records with respect to the food?

A: No. The final rule only applies to manufacturing, processing, packing, holding, transporting, distributing, receiving and importing activities that occur with the U.S. In the above example, the airline receives the food in a foreign country and thus, those activities are not subject to the rule. Although the distribution of food occurs in U.S. airspace, the distribution is directly to consumers and no records are required of that release, as provided in 21 CFR 1.327(d).

10.5 Q: [Added November 2005] A theme park may have a variety of restaurants, food stands, gift shops and facilities at which food is stored on its premises. Please comment on the applicability of the recordkeeping rule to these facilities. Can the theme park be viewed as a single establishment for purposes of this analysis?

A: This question is similar to the sushi example in question 5.1. Both the theme park and the restaurants, food stands, and gift shops (which may be under different and perhaps multiple ownerships from the theme park) are subject to the rule, unless an exemption applies. The park has overall custody and control of the premises, while individual facilities under different ownership have ownership of individual articles of food and/or custody and control of the food. Both sets of entities are responsible for complying with this regulation, which either may do for the other as a matter of business practice, but legal responsibility for establishment and maintenance of records and for meeting the records access timeframes specified in §1.361 remains with both parties. The theme park (or individual entities within the park if under a different ownership) may qualify for the restaurant exemption provided in 21 CFR 1.327(b) and 1.328 if sales of food it prepares and serves directly to consumers for immediate consumption are more than 90% of its total food sales. Alternatively, the theme park may qualify for the retailer partial exemption in 21 CFR 1.327(e). If it does, it would have to establish and maintain records to identify the immediate previous sources of food it receives in accordance with section 1.337, but it would be exempt from recording the release of food to consumers under section 1.327(d). Similarly, the individual restaurants, food stands, and gift shops within the theme park, if owned by different entities, may qualify for the restaurant exemption in 21 CFR 1.327(b), the small retailer exemption in 1.327(f), or the partial exemption for distribution to consumers in 1.327(d). Storage of the food in connection with any of these facilities is considered integral to the restaurant and/or retail activities and would be considered part of the same activity.

C. Definitions (Section 1.328)

11. General Questions (Reserved)

12. Person (Reserved)

13. Farm

FDA has addressed questions we received on this issue in the [Final Rule](#).

14. Food

FDA has addressed questions we received on this issue in the [Final Rule](#).

15. Manufacturing/Processing (Reserved)

16. Nontransporter

FDA has addressed questions we received on this issue in the [Final Rule](#).

17. Nontransporter Immediate Previous Source

17.1 Q: A firm receives foreign products in an overseas container and processes them on behalf of the owner, the importer of record. Who is the immediate previous source? What if the importer of record considers the source of the product confidential commercial information?

A: 21 CFR 1.328 defines a nontransporter as a person who owns food *or* who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. Section 1.328 defines a "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an

individual, partnership, corporation, and association. In the above example, both the owner of the food and the firm receiving the food are nontransporters subject to the final rule. Both are responsible for complying with the rule, which either may do for the other as a matter of business practice, but legal responsibility remains with both parties. The nontransporter immediate previous source is the foreign nontransporter that released the food to the owner and receiving firm, whether or not this information is confidential. Again, as a matter of business practice, the receiving firm and/or owner may choose to arrange to have another establish and maintain records on their behalf at the location where the food is received or at a reasonably accessible location that contains the confidential information, but legal responsibility for providing the records, including information that the importer of record considers confidential, within the timeframes specified in §1.361 remains with the owner and receiving firm.

17.2 Q: Who is the nontransporter immediate previous source of an imported food? When an imported food arrives at the port of entry, the importer of record is responsible for finding an appropriate place to store the food. If, for example, the importer places the food in a contract warehouse at the port of entry and that warehouse is owned by Company A but leased to Company B, it is not clear which company (the importer, Company A, or Company B) should be considered the nontransporter immediate previous source with respect to the next recipient. It seems the answer should not depend on who owns the warehouse. Since the importer of record is legally responsible for the food for Customs purposes, shouldn't the importer of record be the nontransporter immediate previous source?

A: The response to comment 17 of the Final Rule preamble notes that this regulation apply to persons who manufacture, process, pack, transport, distribute, *receive*, *hold*, or *import* food in the United States, unless the person qualifies for an exclusion in 21 CFR 1.327. An importer of record or an initial United States recipient that is involved in one or more of the identified activities must establish and maintain the required records for the imported food. In this case, the imported food is received and held in a warehouse. If Company B has dedicated use and physical control of the warehouse, then the imported food is in Company B's physical possession. If Company A retains physical control of the leased warehouse, then the imported food is in Company A's possession. Section 1.328 defines a nontransporter as a person who *owns* food *or* who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. The importer of record and the entity with physical possession of the food (Company B or Company A) are considered nontransporters by this definition. If the owner of the imported food is not the importer of record, then that owner is also considered a nontransporter. Section 1.328 defines a "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an individual, partnership, corporation, and association. In the above example, the importer of record, the person with physical possession of the food, and the owner (if a third party) are all nontransporters subject to the final rule. All are responsible for complying with the rule, which one may do for the other as a matter of business practice, but *legal* responsibility for establishment and maintenance of records and for meeting the records access timeframes specified in §1.361 remains with all parties. If the food is further delivered from the warehouse, the recipient's nontransporter immediate previous source is whichever company (A or B) had physical control over the warehouse.

17.3 Q: A nontransporter firm may receive a product from a vendor with multiple ship points. Currently the firm's systems cannot record the ship point. Is the firm required to record the actual ship point as the nontransporter immediate previous source, or just the contact information for the vendor?

A: 21 CFR 1.337(a)(1) requires a nontransporter to establish and maintain records for all food it receives that identify the name of the firm, address, telephone number and, if available, the fax number and email address of the nontransporter immediate previous source. Section 1.328 defines "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an individual, partnership, corporation, and association. Therefore, the nontransporter firm above must provide the specific address and other contact information of the legal person (the vendor) that released the food to them but does not need to provide information regarding particular ship points of the vendor.

17.4 Q: A supermarket receives direct store deliveries from various companies. For some of these companies, the actual product is manufactured by a franchisee or contractor. From a recordkeeping standpoint, is the nontransporter immediate previous source the brand company or the contractor?

A: 21 CFR 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. Section 1.328 defines a "nontransporter immediate previous source" as a person that last had food before transferring it to another nontransporter and "person" as including an individual, partnership, corporation, and association. A person who enters into a contract to hold, manufacture, process, pack, import, receive, or distribute food is considered a nontransporter, even if that person subcontracts the actual performance of the covered action to another entity. In the above example, both the brand company and the actual manufacturer are nontransporters subject to the final rule. Both are responsible for complying with the rule, which either may do for the other as a matter of business practice, but legal responsibility for establishment and maintenance of records and for meeting the records access timeframes specified in §1.361 remains with both parties. The supermarket may identify either the brand company or the manufacturer as its nontransporter immediate previous source.

17.5 Q: [Added November 2005] A firm purchases a food ingredient from a broker who does not take actual possession of the food. Is the immediate previous source of the food the broker or the ingredient manufacturer (from whom the broker obtains the food)?

A: The purchasing firm may identify either the broker or the ingredient manufacturer as its nontransporter immediate previous source in establishing and maintaining the records required by 21 CFR 1.337. Section 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. A person who enters into a contract to hold, manufacture, process, pack, import, receive, or distribute food is considered a nontransporter, even if that person subcontracts the actual performance of the covered action to another entity. In this example, the broker enters into a contract to distribute the food and in addition may own title to the food. For

this reason, the broker is subject to the rule and an acceptable nontransporter immediate previous source for the purchasing firm.

17.6 Q: [Added November 2005] The Prior Notice Rule requires the reporting of specific data elements for the shipper of the food item. FDA defines the shipper as "the owner or exporter of the article of food who consigns and ships the article from a foreign country or the person who sends an article of food by international mail to the U.S." For direct imports, is the immediate non-transporter the person noted as the shipper on the Prior Notice submission?

A: The nontransporter immediate previous source for food is defined by 21 CFR 1.328 as the person that last had food before transferring it to another nontransporter. See question 17.1 in this document.

18. Nontransporter Immediate Subsequent Recipient

FDA has addressed questions we received on this issue in the [Final Rule](#).

19. Perishable Food (Reserved)

20. Recipe (Reserved)

21. Restaurant

FDA has addressed questions we received on this issue in the [Final Rule](#).

22. Retail Facility

FDA has addressed questions we received on this issue in the [Final Rule](#).

23. Transporter

FDA has addressed questions we received on this issue in the [Final Rule](#).

24. Transporter's Immediate Previous Source

FDA has addressed questions we received on this issue in the [Final Rule](#).

25. Transporter's Immediate Subsequent Recipient

FDA has addressed questions we received on this issue in the [Final Rule](#).

D. Do Other Statutory Provisions and Regulations Apply? (Section 1.329)

26. General Questions (Reserved)

E. Can Existing Records Satisfy the Requirements of this Rule? (Section 1.330)

27. General Questions

FDA has addressed questions we received on this issue in the [Final Rule](#).

F. What Information is Required in the Records You Must Establish and Maintain to Identify the Nontransporter and Transporter Immediate Previous Source and Immediate Subsequent Recipients? (Sections 1.337 and 1.345)

28. General Questions

28.1 Q: [Added November 2005] An animal food manufacturer receives commingled product from three different facilities and produces an animal feed finished product. The product is sold directly to farmers as feed, and also to subsequent animal food manufacturers who commingle it

with other food ingredients and make a final saleable product. What information must the records established and maintained by the original manufacturer contain?

A: The firm manufactures a product that is both a finished feed and a feed ingredient. As discussed in the response to comment 61 in the Final Rule preamble, "food" includes food ingredients. For the purpose of this rule, the only difference in the record requirements therefore concerns the container of the product. If the manufacturer is placing the product in contact with a finished container in which it will be received by an individual consumer (not a business), the manufacturer must establish and maintain records of the receipt of the finished container in accordance with 21 CFR 1.327(k) and must identify the specific source of the finished container in the record of release of the finished food as specified by §1.345(b). With respect to all other ingredients incorporated in the product, the manufacturer must always establish and maintain records of receipt that include the information specified in §1.337, including the lot or code number or other identifier if it exists. When the manufacturer releases the finished product, it must establish and maintain records of release to any person who is not an individual consumer, including farms. Although farms themselves are exempt from all requirements as provided by §1.327(a), records must be established and maintained by the nontransporter (including the original manufacturer) and transporter immediate previous source of food released to farms.

28.2 Q: [Added November 2005] A firm sells byproducts from its manufacturing process, but the rights to a certain quantity of byproduct may be resold several times. Is the immediate subsequent recipient the original buyer of the byproduct, or the entity who actually is the owner at the time the byproduct leaves the firm's possession?

A: The manufacturing firm may identify either the original buyer or the actual recipient as the immediate subsequent recipient. Similar to the response to Question 17.4 of this document, both the original buyer and the actual recipient are considered nontransporter immediate subsequent recipients, and both are responsible for complying with this regulation.

28.3 Q: [Added November 2005] In the course of normal business practice, packages occasionally break during transportation or distribution. The remaining, undamaged units are often repacked with other units for sale. Must records be established and maintained for this type of occasional repacking?

A: Generally yes, unless an exemption applies. The Final Rule applies to persons who pack food, which includes repacking. Similar to the definition of "packing" in the Registration of Food Facilities Final Rule, 21 CFR 1.227(b)(9), FDA considers "packing" for purposes of this rule to be placing food in a container other than the finished container that directly contacts the food and is received by the consumer. The person repacking the food must establish and maintain records of the lot or code number or other identifier of the food it releases in accordance with 21 CFR 1.345(a)(4) if the person manufactures, processes, or packs food. However, if the person qualifies as a retailer in accordance with 21 CFR 1.327(e), that person is exempt from this requirement. Other persons who do not engage in manufacturing, processing, or packing are not required by 21 CFR 1.345 to record lot numbers as part of their records, but still need to establish and maintain records identifying the immediate previous source of all food

received and immediate subsequent recipient of all food released in accordance with 21 CFR 1.337 and 1.345.

28.4 Q: [Added November 2005] How detailed must the record of repaired cases due to breakage (discussed in question 28.3 be? If a company repairs a case with one bottle from a previous production lot, will that company be required to trace the one bottle, as well as the other 11 bottles in the case, or does that one bottle become part of the production batch of the new repaired case? The bottle has a unique identifier on it so that the company can work backward; however, going forward to find where the bottle ultimately was shipped is difficult.

A: The company must record the lot or code number of all food that it packs and releases. If the company releases a case that contains bottles with two distinct identifiers, the company should be able to link both identifiers to that case. See questions 32.1 and 32.4 in this document.

28.5 Q: [Added November 2005] A person may engage in a number of different types of activities (such as transporting, distributing, etc.), one of which is repacking of beverage alcohol products. The repacking is subject to the requirement to establish and maintain records, including an existing lot or code number or other identifier. Please confirm that the recordkeeping requirement applies only to that person's repackaging activity and does not extend to all of the person's activities unless those activities separately are covered by the recordkeeping requirement.

A: The person is required to establish and maintain records for all covered activities as required in the Final Rule. A person both packing and performing other subsequent activities with respect to that food must establish and maintain records when it releases the food it has packed, including the lot or code number or other identifier, if it exists, unless an exemption applies. (*e.g.*, see 37.1 and 37.2 in the document if the person is performing direct store deliveries.)

28.6 Q: [Added November 2005] Under the Act, it is our understanding that "repackaging" that only involves transfer of the package from one secondary container (case) to another or adding something to a secondary case (a promotional item) is not considered packing and therefore is not subject to the lot number requirements. Is this correct?

A: No. As discussed in 28.3 above, FDA considers packing to be placing food in a container other than the finished container that directly contacts the food and is received by the consumer. The example above describes repacking and is a covered activity subject to this regulation, including the lot code requirement of 21 CFR 1.345(a)(4), except as discussed in question 28.3 above.

28.7 Q: [Added November 2005] During the course of daily business, a wholesaler/distributor of wine and spirits ships both full cases and single bottles to customers. The bottles contained in each case box are sealed prior to receipt by the wholesaler/distributor. In the process of distributing individual bottles to retail customers, it is most efficient to separate these individual sealed bottles from their original shipment packing (case box) and combine them in separate boxes destined for the customer. Given that there is no contact with the actual food product in this process, do these types of activities change the status of a wholesaler/distributor as a non-

transporter who does not manufacture, process or pack goods as defined in Sections 1.337 and 1.345 of the Final Rule on Establishment and Maintenance of Records (69 FR 71561)?

A: Yes. The activity described above is considered "packing" because it involves placing food in a container other than the finished container that directly contacts the food and is received by the consumer. In the example described above, the covered entity is subject to the lot code requirement of 21 CFR 1.345(a)(4) with respect to food that is repacked, if a lot or code number or other identifier exists for that food.

28.8 Q: [Added November 2005] Is the status of a wholesaler/distributor as a non-transporter who does not manufacture, process or pack goods as defined in Sections 1.337 and 1.345 of the Final Rule on Establishment and Maintenance of Records (69 FR 71561) changed if that wholesaler/distributor combines two sealed products into one box in order to create a promotional item? If a wholesaler/distributor contracts with a third party to repack these sealed products, does that contract change its status as a non-transporter who does not manufacture, process or pack goods? Similarly, does the status of a wholesaler/distributor change in the event that they received a product packed for promotional purposes (*i.e.*, a holiday packaging outer box) and that wholesaler/distributor is required to remove the sealed bottle from this holiday packaging in order to sell it?

A: If a wholesaler or distributor packs sealed food products that entity is also a packer and must establish and maintain records that include the lot or code number or other identifier of the packed food it releases as required by 21 CFR 1.345, if that information exists. If the wholesaler or distributor releases the sealed food products to a third party for packing, that third party is a packer subject to this regulation who must establish and maintain records of the food it receives and releases, including the lot or code number or other identifier of the food if that information exists. A wholesaler or distributor who only unpacks food and does not repack it is not considered a packer with respect to this regulation.

29. Information Reasonably Available to Identify the Specific Source of Each Ingredient

29.1 Q: A bulk grain elevator receives many small lots from individual farmers, aggregates them, and blends them to whatever specifications are required. What records and degree of lot specificity are required for the grain elevator?

A: The grain elevator is required to establish and maintain records for each incoming shipment of grain, including a lot number if it exists, in accordance with 21 CFR 1.337. When blended grain is released by the facility, it must also establish and maintain a record, including both the lot number if one is assigned and information to identify the specific source of each component grain, to the extent that the information is reasonably available, in accordance with §1.345. In the response to comment 94 in the Final Rule preamble, FDA acknowledges that the degree of specificity may be limited by the current physical configuration of the facility. For example, the facility may place thirty lots from farmers into a single storage bin, place another thirty lots into a second bin, and draw from both bins to create a blended product that is transferred to an immediate subsequent recipient. The record created for the outgoing blended product should indicate all immediate previous sources for the component grain; in this example there may be as many as sixty.

29.2 Q: A feed mill receives ingredients and commingles individual shipments into bins which are never completely empty. Over the course of a year, a hundred or more lots could theoretically be part of any food drawn from a bin. Would the feed mill have to provide all these lot numbers for food it releases?

A: Yes. Manufacturers are required to establish and maintain records for each food received, including the lot number if it exists, in accordance with 21 CFR 1.337. When a food is released by a manufacturer, the firm must establish and maintain records that include information reasonably available to identify the specific source of each ingredient used to make every lot of finished product in accordance with §1.345. In the response to comment 94 in the Final Rule preamble, FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with specificity to the outgoing product, and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. Because shipments of incoming material are commingled in the storage bin, the record created for every lot of food released by the manufacturer that incorporates material from the bin would include all possible sources of the material placed in that bin.

29.3 Q: A firm uses raw agricultural commodities to manufacture its products. What are the recordkeeping requirements: (1) if the firm receives its ingredients directly from farms and commingles them in storage bins on site, and (2) if the firm receives ingredients that already have been commingled by a distributor?

A: The source of each shipment that enters a particular storage bin must be recorded in accordance with 21 CFR 1.337. If the commodities are commingled on site, there will be more sources for a given bin. In both cases, incoming sources of ingredients must be linked to finished products leaving the site to the extent that the information is reasonably available in accordance with §1.345. For example, if a lot of a product incorporated an ingredient from a particular bin and that bin was filled with a commodity derived from five immediate previous sources, then those five sources would be the reasonably available information for that ingredient. If the bin was refilled before being emptied and now may contain ingredients from up to ten immediate previous sources, then this is the information that is reasonably available. If the firm receives ingredients that already have been commingled by a distributor, the firm only has to record the lot numbers of the food, as received, to the extent that information exists, and link incoming sources of ingredients to finished products leaving the site to the extent that the information is reasonably available in accordance with §1.345.

29.4 Q: A manufacturing firm may handle over a thousand different ingredients on the same day, and three or four lot codes of the same ingredient from the same supplier may be used on a particular day. Assuming the ingredients arrive at the manufacturing facility with lot codes, does the manufacturer have to track each lot code and link it to a finished product?

A: Yes. The manufacturer is required by 21 CFR 1.337(a)(4) to establish and maintain records for each ingredient it receives, including the lot codes of each ingredient received if they exist. When the manufacturer releases a food, it must also establish and maintain records for that food. The records must include both the lot code of the finished product if it exists and the

specific source of each ingredient used to make every lot of finished product, to the extent that information is reasonably available, as required by §1.345(b).

29.5 Q: A firm manufactures many varieties of ice cream and sorbet, and delivers these products directly to restaurants and scoop shops. Do the incoming sources (including lot codes) of each ingredient have to be linked to the specific outgoing products?

A: Yes. As a manufacturer, the firm must establish and maintain records for the ingredients that it receives, including lot codes if that information exists, in accordance with 21 CFR 1.337. The firm must also establish and maintain records when it releases each article of food, including information reasonably available to identify the specific source of each ingredient in every lot of ice cream or sorbet, in accordance with §1.345.

29.6 Q: A manufacturing firm has multiple suppliers of particular ingredients and packaging materials. Is it sufficient to simply record all the potential suppliers that an ingredient or packaging material might have come from?

A: Persons who manufacture, process, or pack food are required to establish and maintain records regarding receipt of the lot or code number or other identifier of each ingredient and any finished container that they place in contact with food, if a lot or code number or other identifier exists, in accordance with 21 CFR 1.337 and 1.327(k). When the food is released, records must be established and maintained that include the specific source of each ingredient used to make every lot of finished food and any finished container placed in contact with food, to the extent that the information is reasonably available (e.g., does not require physical reconfiguration of the manufacturing facility), in accordance with §1.345. "Packaging" is defined in § 1.328 as "the outer packaging of food that bears the label and does not contact the food." The manufacturer, processor, or packer does not have to establish and maintain records for any packaging or for finished containers that it does not place in contact with the finished food, as stated in §1.327(j). All existing relevant records must be made available as soon as possible to FDA on request, not to exceed 24 hours, as required by §1.361 and §1.363, if FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. If information is reasonably available when food is released to narrow the possible sources of an ingredient, it is not sufficient to record all potential suppliers that an ingredient or packaging material *might* have come from if there is no expectation that that supplier's product would be in the finished product (e.g., no shipments have been received from a vendor for months and onsite supply has been depleted).

29.7 Q: A candy manufacturer has a starch molding operation in which a candy is deposited into a starch that has impressions. The starch is used to form the candy and remove the moisture. After a period of time the candy is removed from the starch and sent to packaging. The starch is dried, cooled and placed back into the starch trays for the deposit of more candy. In the manufacturing operation some starch is lost due to spillage and dusting. New starch is added to replace the lost starch. It is possible that the starch in the system could have been in the system for many months. The manufacturer only replaces 300-400 pounds a day and the entire system has over 40,000 pounds. How should the company track this?

A: FDA considers the starch a food ingredient, as defined and discussed in the response to comment 61 in the Final Rule preamble. However, 21 CFR 1.345(b) only requires nontransporters to identify the specific source of each ingredient that was used to make every lot of finished product to the extent that such information is reasonably available. In this case, information about the source of starch from which daily additions to the system are made should be reasonably available, and thus it should be possible to define a length of time (and series of lots of candy) during which a specific source of starch is being used to replenish the supply. Depending on the size of each lot of starch relative to the size of the entire system and the number of suppliers, the manufacturer might reasonably identify multiple sources of starch that contribute to the system. The manufacturer would not need to identify sources of starch received prior to the compliance date established in the Final Rule.

29.8 Q: A bottling firm that bottles water and delivers it to various consumers receives returned bottles for reuse from these customers. Does this regulation require that the outgoing refilled bottles that are released by the bottling manufacturing firm must be linked to the source of the incoming bottles returned by the firm's customers (*i.e.*, the individual consumers)? Does the bottling firm have to record the lot numbers or other identifiers of the empty bottles collected from these customers?

A: 21 CFR 1.337 requires that nontransporters identify the immediate previous source of all food received. Section 1.327(k) states that persons who place food directly in contact with the finished container must establish and maintain records for the packaging. When the bottling firm receives new bottles from the bottle manufacturer for first time use, the record of receipt must include the lot or code number or other identifier (if it exists) as required by §1.337(a)(4). When bottled water is released to businesses (but not individual consumers), §1.345(b) requires the nontransporter who releases that food to establish and maintain records that include information reasonably available to identify the specific source of every ingredient used to make every lot of finished product. This includes the specific source of the finished container that contacts the food (*e.g.*, bottle) if the nontransporter is the one who placed the finished food (*e.g.*, water) in contact with the finished container. When the firm receives returned bottles from customers, the response to comment 21 in the Final Rule preamble states that the immediate previous source for returned water bottles is the customer. FDA intends to consider exercising enforcement discretion with regard to the name of the specific customer who returned each empty bottle if the bottling company establishes records when used empty bottles are received from multiple customers (businesses or individual consumers) indicating "customer return" or equivalent as the source, provided the bottles are returned as is (*i.e.*, without further manufacturing/processing, such as cleaning, by a third party). When the bottles are refilled and released to customers, FDA intends to consider exercising enforcement discretion with regard to §1.345(b) if the records indicating the source of the incoming returned bottles indicate "customer returns." If, however, a third party firm collects reusable containers after use from customers (in this example empty water bottles), and then releases them to the manufacturing firm that refills them, FDA does not intend to consider exercising enforcement discretion regarding the manufacturing firm's (in this example, the bottling company's) immediate previous source of the reusable containers. After reusable bottles are used for the first time, FDA intends to consider exercising enforcement discretion regarding the requirement in §1.337(a)(4) for lot numbers or other identifiers.

29.8 Q: [Added November 2005] During food processing and manufacturing production, non-traditional ingredients such as food contact packaging are used. Under the recordkeeping regulation, food processors and manufacturers are required to identify the lot code number or other identifier associated with the ingredients that go into a product. Food contact packaging in many cases will have lot code numbers or other identifiers. During packaging, packaging components may be commingled. For example, during a bottle capping operation, it is common to add bottle caps from a variety of lots to a capping hopper and during the capping operations the ability to associate a particular cap's lot code with a specific final product is completely lost. In the event that an FDA inspector requests information, under section 306 authority, regarding the immediate previous sources of the ingredients (including food contact packaging) in a specific finished product, is it acceptable in this example to inform the inspector that the cap came from any one of a specified set of lot codes associated with what the facility has received into its inventory and that no reasonable information is available which would allow the food processor or manufacturer to narrow down the list to a single lot code or small set of codes?

A: Yes. In the response to comment 94 in the Final Rule preamble, FDA acknowledges that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. 21 CFR 1.345(b) only requires information reasonably available to identify the specific source. As discussed in response to comment 97 in the Final Rule, what is reasonably available depends on the particular circumstances. Further, 21 CFR 1.345(b) does not require the lot code of each ingredient used in the released food, although the firm may choose to track lot numbers of ingredients through the manufacturing, processing, or packing process as a matter of business practice in order to determine the specific source of each ingredient. Under the circumstances described above, the lot codes of the caps are only necessary to the extent that they allow the firm to identify the specific source or sources of the caps. Depending on the facility's physical configuration, there may be multiple possible sources of the caps for each lot of food released. It is not acceptable, however, to simply identify all caps received by the facility if it is possible to determine more specific information given the facility's physical configuration.

29.9 Q: [Added November 2005] All manufacturers of spirits and wines use water as an element of their finished product. How much detail is required in the records the manufacturer establishes and maintains to comply with 21 CFR 1.337(a)(4) and 1.345(b)? Is it sufficient to say the water was sourced from the local water company on a specific date, or that water was pulled from a local natural source and purified on-site?

A: Yes. See the response to Comment 100 in the Final Rule preamble. 21 CFR 1.337(a)(4) only requires manufacturers to establish and maintain records that include the lot or code number of the food ingredient if that information exists.

30. Adequate Description of Type of Food

30.1 Q: A warehouse receives imported food that is stored in shipping containers. Upon receipt, the warehouse only records the container numbers of the containers it receives and holds. Is this sufficient information?

A: A person, such as the warehouse above, who manufactures, processes, packs, distributes, receives, holds, or imports food must be able to provide to FDA records containing sufficient

information to satisfy the requirements of 21 CFR 1.337 and 1.345 as soon as possible upon request, not to exceed 24 hours, as specified by §1.361 and §1.363. Records that only list the container number do not contain sufficient information to meet the requirements for an adequate description of the food, its quantity, and how the food is packaged.

30.2 Q: How much detail is required in describing a food (*e.g.*, different types of commodity grains, different varieties of a particular grain)?

A: Descriptions of commodity grains and produce must be as specific as possible (*e.g.*, Roma tomatoes versus cherry tomatoes, sweet corn versus feed corn), as required by 21 CFR 1.337 and 1.345. As discussed in the response to comment 64 in the Final Rule preamble, this type of description saves time and resources during a tracing investigation because it allows FDA to narrow its focus to the appropriate product during the investigation.

30.3 Q: Many food manufacturing/processing facilities have storage vessels in which out-of-specification, outdated, returned and/or damaged food products are commingled and stored pending transfer to animal farming operations where the commingled products are used as animal feed or are otherwise reprocessed into an ingredient used in animal/pet food products. The composition of the contents of the storage vessel varies from day to day in terms of the products and quantities. Lot codes of product transferred to the storage vessel and the specific products themselves and their quantities are not recorded and it would be burdensome to do so. Is the food processor or manufacturer required to establish and maintain records of the food released to farms or reprocessors for use as animal feed that include the specific products, quantities and lot codes of the immediate previous sources of the contents (or ingredients) in the storage vessel?

A: As discussed in the answer to Question 1.6 above, FDA intends to consider exercising enforcement discretion regarding establishment of records by food manufacturing/processing facilities for food waste or byproducts they release to farms that is fed directly to animals without further manufacturing/processing. If food manufacturing/processing facilities release food that is processed further prior to consumption by animals, FDA does not intend to consider exercising enforcement discretion regarding sections 1.345(a)(1), (3) and (6). However, FDA intends to consider exercising enforcement discretion regarding 21 CFR 1.345(a)(2), (4), (5) and (b) if the food being released is appropriately described as 'facility waste' or by reference to all the substances in production during a specific time period in lieu of identifying the specific source of each ingredient used to make every lot of finished product.

31. Date Food Received or Released

FDA has addressed questions we received on this issue in the [Final Rule](#).

32. Lot or Code Number/Other Identifier

32.1 Q: A food processor records the lot codes on pallets of food, which are then delivered to customers by truck. Currently, the processor does not link lot codes with specific customers. Is this required by this regulation?

A: Yes. Persons who manufacture, process, or pack food are required by 21 CFR 1.345 to identify the lot or code number or other identifier of the food that they release to each immediate

subsequent transporter and nontransporter recipient, if that information exists. If there is a lot code on both the pallet and the food, and only the lot code of the pallet is recorded, the processor must be able to link each pallet to the lots of food it contains. However, as discussed in the response to comment 112 in the Final Rule preamble, food placed directly on the shelves of a retail store by a manufacturer, processor, or packer upon delivery (direct store delivery) is excluded from the requirement to record lot or code numbers.

32.2 Q: If a manufacturer receives ingredients that have a lot number but that lot number is not provided to the manufacturer by the ingredient supplier, is the manufacturer required to actively obtain the lot number for each ingredient?

A: Yes. 21 CFR 1.337 requires that persons who manufacture, process, or pack food must establish and maintain records that include the lot or code number or other identifier for all food they receive, if that information exists. The manufacturer must obtain the lot numbers for each ingredient received from the ingredient supplier.

32.3 Q: A company owns retail stores and receives multiple shipments of the same item into its stores. Currently, the company would be able to identify all of the transporters that delivered a specific product to a particular store over the last several months. However, the company could not identify the specific transporter who delivered a particular lot to that store. For example, the company's records would show that on a given date, ABC Trucking Company delivered 25 cases of Brand X 1.2oz chocolate bars to a specific store. However, the company could not link a specific box of those bars on the store shelf to a specific carrier, because there were other deliveries of that item from other carriers on other dates, and those chocolate bars are now commingled on the shelf. Would the company's current capabilities be in compliance with this regulation?

A: 21 CFR 1.337 requires that nontransporters establish and maintain records that identify the transporter and nontransporter immediate previous sources for all food they receive. Only persons who manufacture, process, or pack food are required by §1.337(a)(4) to include lot or code numbers or other identifiers in the records they establish and maintain, if the information exists. Therefore, a retail store receiving 25 cases of Brand X chocolate bars must create at the time of receipt a record that includes the specific transporter and nontransporter sources of the food, an adequate description of the food, the date of receipt, the quantity of food, and how the food is packaged. The record does not have to include the lot or code number or other identifier of the product.

32.4 Q: If a firm is a manufacturer, processor, and packer of a single product, would all lot numbers associated with this process (*e.g.*, lot numbers for individual cans, lot numbers for pallets, etc) have to be tracked?

A: 21 CFR 1.345 requires persons who manufacture, process, or pack food to establish and maintain records when releasing the food to another person that include the lot or code number or other identifier (to the extent this information exists). FDA recommends that a vertically integrated company which generates several lot or code numbers or other identifiers in the course of its operations use the most specific one. As explained in the preamble to the Final

Rule, more specific information about the food helps FDA narrow its investigation and increase the speed of the trace in the event that there is a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. However, another acceptable alternative would be for the firm to record identifiers of larger packages (such as pallets) but retain the ability to link these to lots of cans when necessary.

32.5 Q: [Added November 2005] A firm manufactures many varieties of ice cream and sorbet, and delivers these products directly to restaurants and scoop shops. Do the deliveries have to be tracked by lot code?

A: Yes. The firm functions as a manufacturer and must, when it releases food, establish and maintain records that include the lot or code number or other identifier if it exists, in accordance with 21 CFR 1.345(a)(4). However, if the company is performing direct store delivery (placing food products directly within the restaurant) the lot number requirement is modified as discussed in question 37.1.

32.6 Q: [Added November 2005] Manufacturers and processors are required to track the lot codes associated with the products they manufacture or process when they are released. If a manufacturer brings finished product into its manufacturing facility to be combined (in orders or shipments) with the finished products it sends to its customers, is the manufacturer only responsible for tracking the lot codes associated with the finished products it manufactures and not the lot codes associated with third party finished products?

A: No. 21 CFR 1.337(a)(4) requires manufacturers, processors, and packers to record the lot or code number or other identifier of all food received, to the extent it exists. In this example, the manufacturer also is functioning as a packer for finished food it receives and finished food it manufactures. 21 CFR 1.345(a)(4) requires it to record the lot number or other identifier of the combined packaged product; 21 CFR 1.345(b) also requires the manufacturer to include in its records information identifying the specific source of each ingredient (including received finished products) used to make every lot of finished combined product.

32.7 Q: [Added November 2005] A firm manufactures frozen sandwiches that bear the manufacturing date on the packaging, but no lot number. Each category of sandwich does have a product code. The sandwiches are released to an independent transporter. The transporter delivers the sandwiches to frozen storage sites also controlled by the manufacturer. The manufacturer then transports the sandwiches from the storage sites to convenience stores with its own transport fleet. The manufacturer currently tracks its products by product code. Does the manufacturer have to establish and maintain records for the sandwiches it releases that include the manufacturing date?

A: Yes. The manufacturing date associated with a set of frozen sandwiches is considered a "lot or code number or other identifier" and must be included in the record of release of the food because it exists, as specified by 21 CFR 1.345(a)(4). The manufacturer must establish and maintain this record of the released food when it is transferred to the independent transporter at the manufacturing facility. The records the manufacturer establishes and maintains when it

reassumes control of the food at the storage site in accordance with §1.337, and when it subsequently releases the food to convenience stores in accordance with §1.345 do not have to include the manufacturing date. At this stage, the manufacturer is functioning as a distributor, rather than a vertically integrated manufacturer. However, if the manufacturer transports the food from the manufacturing facility to the storage site with its own fleet, the release of food to the convenience stores is now made by a vertically integrated manufacturer and manufacturing date must be included in the record of release to the stores.

32.8 Q: [Added November 2005] If a lot or code number or other identifier exists, but is not being used by a manufacturer, processor, or packer as part of current business practice, is this business required to include that identifier in the records it establishes and maintains?

A: Yes. 21 CFR 1.337(a)(4) and 1.345(a)(4) require the inclusion of a lot or code number or other identifier if it exists, regardless of its use in current business practice.

32.9 Q: [Added November 2005] Is a food processor required to physically examine each food product it receives in order to obtain the lot or code number information required under 21 CFR 1.337(a)(4), or can the processor rely on information provided by its immediate previous source? If the processor's immediate previous source fails to provide this information, must the processor obtain it by physical inspection of the food?

A: Manufacturers, processors, and packers are required to record lot or code numbers or other unique identifiers of the food they receive if this information exists, as provided by 21 CFR 1.337(a)(4). These persons must ensure that they meet the requirement regardless of whether the information is provided by their nontransporter immediate previous source. FDA does not intend to specify the manner in which these persons ensure that they have the required information, which may be obtained in various ways including direct physical inspection and contractual obligations.

33. Quantity and How the Food is Packaged

FDA has addressed questions we received on this issue in the [Final Rule](#).

34. Name, Address, Telephone Number, Fax Number, E-Mail Address of Transporters Who Transported the Food To You and From You

34.1 Q: A manufacturer loads a container that is being exported via ocean freight out of the United States. The ocean carrier contracted by the manufacturer is responsible for handling the inland drayage from the manufacturer to the port. For the purpose of this regulation, is the manufacturer's transporter immediate subsequent recipient the ocean carrier or the drayage company that is subcontracted by the ocean carrier?

A: 21 CFR 1.345(a)(6) defines the transporter immediate subsequent recipient as the transporter who transported the food from the nontransporter. In this case, the manufacturer may identify the transporter immediate subsequent recipient as either the ocean carrier with whom they contracted or the drayage company that directly receives the container from the manufacturer. Either choice complies with the requirements of §1.345(a)(6).

34.2 Q: A nontransporter firm contracts with an ocean carrier to bring imported food to the firm's facility. The ocean carrier subcontracts with a trucking firm to transport the food from the port to the facility. Who is the transporter immediate previous source for the firm?

A: 21 CFR 1.337(a)(6) defines the transporter immediate previous source as the transporters who transported the food to the nontransporter. In the example given above, the nontransporter firm may identify the transporter immediate previous source for the food as either the ocean carrier with whom they contracted or the trucking firm who physically delivers the food to the firm's facility. Either choice complies with the requirements of §1.337(a)(6).

34.3 Q: What are the manufacturer's and transporter's recordkeeping obligations for a food product that is transported intracompany by a contract transporter? For example, a manufacturing firm may contract with a transporter to move food product, intracompany, from its manufacturing facility to its distribution center.

A: 21 CFR 1.345 requires that persons who manufacture, process, pack, distribute, receive, hold, or import food establish and maintain records whenever they release food to another person. As discussed in the responses to comments 13 and 71 in the Final Rule preamble, intracompany transfer of food is not subject to additional recordkeeping requirements, provided that the food is not released to another person. In this example, the manufacturing firm temporarily releases the food to another entity (person), the contract transporter. The manufacturing firm would be required to establish and maintain records of the transfer of food (including lot numbers if they exist) from the facility to the transporter and nontransporter (the distribution center) immediate subsequent recipients.

34.4 Q: Transporters may deal with brokers who only provide a location and time to pick up a product, but do not provide other contact information. Does this regulation require a transporter to identify contact and other information for the nontransporter immediate previous source, or can the broker be used as the immediate previous source?

A: This regulation provides transporters multiple options to comply with the records requirements for each article of food transported. The information required by the Department of Transportation and described in 21 CFR 1.352(b) or 1.352(c) will satisfy the requirements of this regulation, as will information meeting the requirements of the Warsaw convention under §1.352(d). The transporter likely already has this information. The transporter may also meet its obligation by complying with §1.352(a) (identifying specific information that must be kept) or §1.352(e) (providing for the transporter to enter into an agreement with the nontransporter immediate previous source) but if the broker is not considered the immediate previous source than these options require the transporter to obtain information in addition to the broker and location and time of pick up. Whether the broker is considered an immediate previous source as defined in §1.328 depends on the broker's role, as discussed in response to Question 1.1.

34.5 Q: A warehouse has information about the brokers who arrange deliveries and releases of food products, but not about the actual contract drivers and trucks that transport the products. Is this information required under this regulation?

A: No. 21 CFR 1.328 defines a transporter as someone who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food. For the purpose of this regulation, FDA considers a transporter to include a person who enters into a contract to transport food, even if that action is subsequently subcontracted to another entity. In this case, the warehouse may identify as their transporter immediate previous source or immediate subsequent recipient either the freight broker or the contract driver in compliance with §1.337(a)(6) and §1.345(a)(6).

34.6 Q: Some items that arrive at a distribution center from an independent supplier are cross-docked. In other words, they are not formally received at the warehouse, but transferred to a company-owned truck for delivery to one of the company's stores. For these items, no detailed item records are kept in the distribution center and we do not currently have a mechanism in place for identifying the transporter immediate previous source. The store invoice for the goods from the supplier is the only timely method to acquire the supplier immediate previous source, although there is not a current software solution for this. However, this invoice does not identify the transporter immediate previous source that brought the goods to the warehouse. Can the company use the invoice from the supplier to the store as a track-back document? The supplier should be able to identify their transporter immediate subsequent recipient (the company's transporter immediate previous source).

A: No, in most circumstances. The recordkeeping requirements in 21 CFR 1.337 and 1.345 of this final rule apply to persons who "hold" food for purposes other than transportation. As defined in 21 CFR 1.328 and explained further in the response to Comment 20 in the preamble to the Final Rule, "holding" means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. In the above example, if the distribution center is a warehouse, then it must establish and maintain records that identify the immediate previous source of the food received (the independent supplier) and the transporter that brought the food to it, as required by 21 CFR 1.337, as well as the records required by 21 CFR 1.345. It cannot simply rely upon the invoice, because the invoice does not identify the transporter. In the rare circumstance that an independent facility, most likely a truck terminal, merely provides a location for trucks to transfer possession, custody, or control to another entity and does not itself take possession, custody, or control, even briefly (*e.g.*, the terminal provides a location for one truck to transfer goods directly to another truck when both trucks are present at the terminal at the same time), then the independent facility is not subject to these regulations. If the facility is not independent but instead is owned by a transporter, then the transporter must maintain records that include the identity of the person from whom the transporter received the food, the person to whom the transporter delivered the food, and the route of movement of the food, which will include the terminal, as required by 21 CFR 1.352(a) or 21 CFR 1.352(b), depending on which option the transporter selects for compliance.

34.7 Q: [Added November 2005] A public warehouse releases food to a nontransporter immediate subsequent recipient who makes its own arrangements for transporting the food from the warehouse to the recipient. The receiving firm sometimes does not provide details about the carrier who will transport the food from the warehouse. Is the warehouse now required to obtain information about the carrier?

A: FDA intends to consider exercising enforcement discretion with regard to § 1.345(a)(6) if the warehouse identifies the receiving firm that made the contractual arrangement for transport of the food as the transporter immediate subsequent recipient.

34.8 Q: [Added November 2005] An animal feed manufacturer purchases a feed ingredient from a vendor. The vendor arranges transportation of the ingredient to the manufacturing facility. Does the feed manufacturer have to establish and maintain records that identify the actual transporter of the feed ingredient?

A: FDA intends to consider exercising enforcement discretion with regard to § 1.337(a)(6) if the feed manufacturer identifies the vendor that made the contractual arrangement for transport of the feed as the transporter immediate previous source.

34.9 Q: [Added November 2005] Is it acceptable to use a post-office box as the address of an immediate previous source or immediate subsequent recipient?

A: No. Section 306 (a) of the Bioterrorism Act (codified at 21 USC 414(a)) states that a person shall grant access to FDA to records "upon presentation of appropriate credentials and a written notice to such person. . . ." For FDA to present credentials and written notice, the person to whom the request is being made must be present. Because such persons are not physically present at post office boxes, FDA needs a physical address where the immediate previous source or immediate subsequent recipient is located so that FDA may make a records access request if necessary.

35. Vertically Integrated Companies

35.1 Q: If Company Z owns Facilities 1, 2 and 3, must it also own the trucks that transfer product from Facility 1 to Facility 2 and from Facility 2 to Facility 3 in order to be considered a vertically integrated company?

A: Yes. A vertically integrated company, as described in the responses to comments 13 and 71 in the Final Rule preamble, is defined by continuous possession of an article of food. Once a covered person receives food and keeps information on its immediate previous source, that person does not need to keep additional records until it releases the food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. Therefore a company is no longer integrated if the food passes out of its control and is released to another person before returning to the company's possession. For example, if an independent transporter takes possession of the food in order to transport it between two facilities owned by the same company, the company must establish and maintain records identifying the transporter and nontransporter immediate previous sources and immediate subsequent recipients.

35.2 Q: Does mode of transportation matter in cases of vertically integrated companies?

A: No. A vertically integrated company, as described in the responses to comments 13 and 71 in the Final Rule preamble, is defined by continuous possession of an article of food rather than

its mode of transport. A person or company must establish and maintain records whenever it releases the food to another person or company, including a transporter.

35.3 Q: If a nontransporter has a transporter subsidiary and uses that subsidiary to transport food to others, is the transfer from the nontransporter to the transporter subsidiary considered an internal transfer?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. A subsidiary is a distinct legal person and records of the transfer of possession from the nontransporter to the transporter subsidiary must be established and maintained.

35.4 Q: Are two corporate entities part of the same vertically integrated company if they have the same controlling parent?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. If the two corporate entities are legally distinct persons, they are not considered part of the same vertically integrated company, and records of transfers of food between them must be established and maintained.

35.5 Q: If subsidiaries are legally distinct but are managed operationally as a single entity, are they a single entity for the purpose of this regulation?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. The exemption for vertically integrated companies only applies to distinct legal persons.

35.6 Q: A grain testing company operates on its customer's property. The customer owns the facilities, but testing company employees sample grain trucks and rail cars and then perform grade testing while the truck or rail car waits. Some of the sample is destroyed by the test. The rest of the sample is collected in a grain wagon owned by the customer. Once the wagon is full, the testing company sells the grain back to the customer. Is the testing company exempt from this regulation?

A: No. 21 CFR 1.328 defines a nontransporter as a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation. Although in this case the testing operation occurs within the customer's facility and the sampled grain never leaves the site, the grain testing company has ownership of the sampled grain and sells it back to the customer. This would be considered release of the food to another person and both companies must establish and maintain records of this transfer as required by §1.337 and §1.345.

35.7 Q: Does a franchisor's warehouse that delivers to a franchisee's store comprise a vertically integrated operation?

A: No. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. The franchisee's store is a legally distinct person and records of movement of food products from warehouse to franchise store must be established and maintained. If the franchise store is a restaurant, the franchise store does not need to establish and maintain records because restaurants are exempt from all requirements in accordance with §1.327(b).

35.8 Q: A retail grocery store chain contracts exclusively with a wholesale company for distribution. Does that wholesaler, under specific contract, have to track to which stores the particular product went?

A: Yes. As described in the response to comment 71 in the Final Rule preamble, a person must establish and maintain records whenever it releases food to another person. "Person" as defined in 21 CFR 1.328 includes individuals, partnerships, corporations, and associations. The wholesaler is required to establish and maintain records of the movement of food to the warehouse in accordance with §1.337 and from the warehouse to the grocery stores in accordance with §1.345, because it is releasing food to another legal person. The retailer is required to establish and maintain records of the receipt of food in accordance with §1.337.

35.9 Q: If a vertically integrated manufacturer, packager, and distributor contracts with a second firm for dedicated use of the second firm's warehouse, would this qualify as a being vertically integrated? In this case the first firm may have control of the warehouse but not ownership of the warehouse.

A: Yes. A vertically integrated company, as described in the responses to comments 13 and 71 in the Final Rule preamble, is defined by continuous possession of an article of food. In the example above, because the integrator has "dedicated use" of the second firm's warehouse, it has retained continuous and sole possession of the food within its "person."

35.10 Q: A combined airline and caterer retrieves and reuses unused soda, coffee, peanuts, and pretzels. The company currently does not link incoming unused food products intended for reuse to outgoing ones on restocked planes. Is the company expected to trace all inbound products through recordkeeping?

A: No. As discussed in the responses to comments 13 and 71 in the Final Rule preamble, a company is vertically integrated to the extent that it does not release food to another person. Capture of unused food products from one flight and restocking on another by an airline that caters its own flights does not involve release of the food to another person. Since the products never leave the possession of the company, records do not have to be established and maintained regarding movement of the food. If the airline and caterer were distinct persons, they would be required to record any movement of food between them in accordance with 21 CFR 1.337 and 1.345. Such records must include the immediate previous source or immediate subsequent

recipient of the food, an adequate description of the food, the quantity of food, and how the food is packaged. However, records showing distribution of food to consumers are not required.

35.11 Q: Can a legal entity select a subset of facilities in the chain of custody to be a vertically integrated operation, and if so, under what conditions? For example, can legal entity "T," who manufactures, packages and distributes product "M," designate the manufacturing facility and warehouse used to store newly made inventory 10 miles away as a one vertically integrated operation but exclude 4 T-owned regional warehouses that product will be subsequently shipped though before delivered to retailers?

A: As discussed in the response to comment 13 in the Final Rule preamble, a vertically integrated operation must establish and maintain records that identify the immediate previous sources of all food it receives, but does not have to establish and maintain records identifying immediate subsequent recipients of the food until that food is released to another person (including a transporter). However, the vertically integrated operation may choose to maintain records of some or all internal transfers of food as a matter of business practice. Sections 414(a) and 704(a) of the Act provide FDA access to existing records relating to manufacture, processing, packing, transportation, distribution, receipt, holding, or importation of food when the records access requirements of the Bioterrorism Act are satisfied.

35.12 Q: [Added November 2005] If a firm administers a distribution center for a retailer under contract, are records required for transport between the distribution center and the various retail outlets?

A: Yes. The distribution contractor, a person distinct from the retailer, has custody and control of food products at the distribution center and releases them to the retail outlets under control of the retailer. The distribution center and retail outlets are therefore not vertically integrated for the purpose of this regulation and records of release of food from one facility and receipt at the other must be established and maintained in accordance with 21 CFR 1.337 and 1.345.

35.13 Q: [Added November 2005] A vertically integrated company bottles a product and distributes it to retail outlets directly. Does the route truck distributing the product have to record lot numbers delivered to each retail outlet?

A: Yes. The company must establish and maintain records in accordance with 21 CFR 1.345 when it releases the food to another person. In this case, that release occurs when the food is delivered to retail stores. As a manufacturer, the company must establish and maintain records for the food it releases that include lot numbers if they exist, in accordance with §1.345(a)(4). However, if the company is performing direct store delivery (placing food products directly within the retail store) the lot number requirement is modified as discussed in question 37.1.

35.14 Q: [Added November 2005] A food manufacturer releases frozen sandwiches to an independent transporter. The transporter delivers the sandwiches to frozen storage sites also controlled by the manufacturer. The manufacturer then transports the sandwiches from the storage sites to convenience stores with its own transport fleet. Is the manufacturer required to

establish and maintain records of the release of the food to the independent transporter as well as subsequent receipt from that transporter and release to the convenience stores?

A: Yes. For the purpose of this rule, the manufacturer/distributor is not a vertically integrated entity, as discussed in question 35.1 of this document. The manufacturer must establish and maintain records when it releases food to the independent transporter in accordance with 21 CFR 1.345. These records must include the lot or code number or other unique identifier of the food, if it exists, as required by §1.345(a)(4). The manufacturing firm also must establish and maintain records in accordance with §§1.337 and 1.345 when the food is received from the independent transporter at its storage site and upon its subsequent release to convenience stores. At this stage, the manufacturing firm functions as a distributor, and the record of subsequent release to the convenience store does not have to include lot numbers.

35.15 Q: [Added November 2005] If a company (*e.g.*, a Control State or a privately-owned business) makes a transfer between two of its own retail stores or between two of its own warehouses using an outside transporter (*e.g.*, UPS or a non-owned trucking company), shouldn't the company be exempt under the rule from maintaining records of the transfer?

A: No. As explained in question 35.1 of this document, the company is no longer vertically integrated for the purpose of this regulation if it releases food to another person as part of a transfer from one facility owned by the company to another.

35.16 Q: [Added November 2005] Two subsidiaries share the same facility. Does this regulation require the establishment and maintenance of records when food is transferred from the possession of one subsidiary to the other?

A: Yes. Legally distinct persons must establish and maintain records when food is transferred between them.

36. Reclamation Centers

36.1 Q: A supermarket chain processes food product returns through a reclamation center. Some products go from the center to donations, some back to stores in the chain, some goes back to the vendors, and some is sold to salvagers for resale. What are the recordkeeping requirements for these products?

A: As described in the response to comment 44 in the Final Rule preamble, a reclamation center owned by the supermarket chain will be treated as if it is part of the supermarket for the purpose of this regulation. The response to comment 44 also states that the release of food to nonprofit organizations is considered equivalent to direct distribution to a consumer and is exempt from recordkeeping requirements. However, if the food is returned to the manufacturer or sold to another nonconsumer, the reclamation center must establish and maintain records identifying the immediate subsequent recipient of the food, to the extent this information is reasonably available. If the reclamation center is an independent entity, then both the supermarket and the reclamation center must establish and maintain records of product movement between them. The other transactions are treated as described above.

37. Direct Store Delivery

37.1 Q: The final regulation requires persons who are manufacturers to keep production code/lot data. The final regulation also provides certain exemptions (*i.e.*, from lot control) to persons who directly place their products into a retail establishment. For a vertically integrated company that encompasses both activities, it is not clear which requirements apply. Can such an operation maintain lot tracking from the processing/packaging facility through receipt at the last company owned distribution center prior to delivery to a retail outlet?

A: Yes. Sections 1.337 and 1.345 require persons who manufacture, process, or pack food to record the lot number or other identifier of the food (to the extent this information exists) for food they receive or release, respectively. A vertically integrated company that also does direct store deliveries (DSD) is performing mixed nontransporter activities: (1) it is manufacturing, processing, packing, holding, transporting, receiving, and distributing its products; and (2) it is acting as a retailer (Retailer A) that is essentially renting shelf space from another retailer (Retailer B) when it stocks its products on Retailer B's store shelves. Accordingly, the vertically integrated company must establish and maintain records for each of these two distinct functions. As required by sections 1.337 and 1.345, the manufacturer must establish and maintain records of all food it receives, and all food it releases to its distribution or warehouse location, including lot number or other identifier (to the extent this information exists) as required by 21 CFR 1.345(a)(4). The DSD (Retailer A) must record the release of food to Retailer B as required by 21 CFR 1.345, but is not required to record lot numbers. Retailer B also is a nontransporter who is subject to these regulations because it has custody or control of the food. Accordingly, it must establish and maintain records of all food it receives from the DSD in accordance with section 1.337, but it is not required to record lot numbers, as it is not manufacturing, processing or packing the food. (*See Question 6.1 for another example of a person performing mixed activities - in that case, an in-store bakery within a retail store.*)

37.2 Q: A company manufactures a food product (*e.g.*, a gallon of milk) and places that milk on a truck owned either by the company or by a third party for delivery to a warehouse/distribution facility. Does the company have to keep records that contain the lot or code number or other identifier of that gallon of milk (in addition to the normal immediate previous source and immediate subsequent recipient information.)? If instead the same company places the gallon of milk on a truck owned either by the company or by a third party and delivers it directly to a retail store, does the company need to keep records that contain the lot or code number or other identifier of that gallon of milk?

A: Yes. Sections 1.337 and 1.345 require persons who manufacture, process, or pack food to record the lot number or other identifier of the food (to the extent this information exists) for food they receive or release, respectively. In both examples, the company is a manufacturer that is releasing the food to another person. In the first situation, the immediate subsequent recipient is the warehouse/distributor and the transporter taking the food to the warehouse/distributor is either the manufacturer or the third party. In the second case, the release from the manufacturer is to the retailer directly. Accordingly, section 1.345(a)(4) requires the manufacturer to include the lot number or other identifier of the food *to the extent this information exists*. If the manufacturer does not provide lot numbers or other identifiers, the rule does not require it to create one. The warehouse/distributor is not required to record the lot numbers or other

identifiers, even if they exist, unless it is subsequently packing (including repacking) the milk after receipt. The retailer also is not required to record the lot numbers or other identifiers, even if they exist, as it is not manufacturing, processing, or packing the milk.

G. Who is Required to Establish and Maintain Records for Tracing the Transportation of All Food? (Section 1.351)

38. General Questions

38.1 Q: There are ship owners that simply haul freight where the transporter is the owner of the container. The vessel owner is not considered the transporter; the owner of the container has the bill of lading and other information about the container's contents and destination. Does the owner of the vessel now need to establish and maintain records?

A: A transporter is defined as a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. This definition also includes a foreign person that transports food in the United States, regardless of whether the foreign person has possession, custody, or control of the food for the sole purpose of transporting the food. In the situation described above, the vessel owner has physical possession of the food container for the sole purpose of transporting the food and is considered a transporter. 21 CFR 1.352 requires that each transporter establish and maintain records that identify the immediate previous source and the immediate subsequent recipient of an article of food, regardless of whether the immediate previous source and immediate subsequent recipient are transporters or nontransporters. The relevant records must be created at the time of each transfer of the food. The transporter may enter into an agreement in which the nontransporter immediate previous source or immediate subsequent recipient establishes, maintains, or establishes and maintains, the required information as described in §1.352(e). The vessel owner is therefore required to establish and maintain records as specified in §1.352, as long as that vessel is transporting the food in the United States.

38.2 Q: [Added November 2005] Must a foreign transporter (transporting within the United States) have a place of business in the United States to comply with this regulation?

A: No. However, the transporter must be able to comply with the record availability requirements of 21 CFR 1.361 for the records they have established and maintained in accordance with §1.352. The records must be made available as soon as possible following an appropriate request by FDA, not to exceed 24 hours.

38.3 Q: [Added November 2005] A firm's freight brokerage division negotiates freight rates and assigns shipping to independent carriers. Is the brokerage division held liable if an independent carrier under contract is not in compliance with this regulation?

A: No. Both the freight brokerage and the independent carrier are transporters subject to this regulation. Both are responsible for complying with this rule, which either may do for the other as a matter of business practice, but legal responsibility for establishment and maintenance of records and for meeting the records access timeframes specified in §1.361 remains with both parties. For the purpose of this regulation, a person, such as the freight brokerage above, who

enters into a contract to transport an article of food and has control over the food is considered a transporter, even if the actual transport is subsequently subcontracted to another entity. If the brokerage is relying on the independent carrier under contract or business practice to satisfy the brokerage's duty to comply with this regulation and the carrier fails to keep the requisite records, the brokerage is liable for the *brokerage's* failure to comply.

H. What Information is Required in the Transportation Records? (Section 1.352)

39. General Questions

39.1 Q: A transporter picks up a container from a pier; what information is the transporter required to have about the contents of the container?

A: The transporter must establish and maintain records that contain the information specified in 21 CFR 1.352(a), (b), (c), or (d) unless there is a pre-existing agreement with the immediate previous source or immediate subsequent recipient to establish, maintain, or establish and maintain that information as described in §1.352(e).

39.2 Q: [Added November 2005] An independent transporter makes multiple deliveries of food from a single distribution center to multiple retail stores owned by a single company. Does the transporter have to establish and maintain records for each separate delivery along its route to stores in the retail chain?

A: Yes. 21 CFR 1.352 provides multiple ways in which a transporter of food may establish and maintain records to comply with this regulation. However, §1.352(a), (b), (c), and (d) all include the requirement that the transporter identify the food's destination. Each physical location that receives food is considered a destination. The transporter may also enter into an agreement with the nontransporter immediate subsequent recipient to establish, maintain, or establish and maintain the required information in accordance with §1.352(e). In the example above, the nontransporter could enter into an agreement with the retail chain or the nontransporter immediate previous source to establish and maintain the required information.

39.3 Q: [Added November 2005] When bottled water is delivered to a single commercial account with several physical locations, what records need to be kept? When delivered to several buildings at the same location?

A: The answer depends on whether the person delivering the water is a nontransporter or transporter. A nontransporter is required by 21 CFR 1.345(a)(1) to establish and maintain records for all food it releases that identify the name of the firm, address, telephone number and, if available, the fax number and email address of the nontransporter immediate subsequent recipient. Similar to the nontransporter receiving product from a vendor with multiple ship points discussed in the related question 17.3 of this document, the nontransporter delivering the water must identify the address and other contact information of the legal person (the commercial account) receiving the water but does not need to provide information on each physical location. A transporter must instead establish and maintain records as specified in §1.352, which provides multiple options to comply with the records requirements for each article of food transported. Sections 1.352(a), (b), (c), and (d) all include the requirement that the

transporter identify the food's destination. Each physical location that receives food is considered a destination. The transporter may also enter into an agreement with the nontransporter immediate subsequent recipient to establish, maintain, or establish and maintain the required information in accordance with §1.352(e).

39.4 Q: [Added November 2005] 21 CFR 1.352(a)(6) states that transporters must establish and maintain records that include the route of movement of an article of food in their possession. How detailed should this record of the route be?

A: Transporters complying with 21 CFR 1.352(a)(6) should record every transfer of the food between different vehicles owned by the firm while the food remains in that firm's possession, including the location of each transfer. If no internal transfer of the food occurs, the origin and destination points at which the transporter received and released the food are sufficient to characterize the route of movement.

39.5 Q: [Added November 2005] Certain express delivery firms are able to track domestic shipments and can identify the shipper and recipient of every shipment. However, the current system does not include descriptions of the freight. If FDA made a records access request to one of these firms, the agency would presumably already know the identity of the shipment. Given this, do these firms have to include descriptions of the freight in the records they establish and maintain?

A: Yes. An express delivery firm described in this example that transports food must comply with record retention requirements of 21 CFR 1.360(f) and the record availability requirements of §1.361. The firm will not be aware of its legal responsibilities under this regulation unless it is aware that it is transporting food, and to what degree the food is perishable. In addition, if FDA is conducting a traceback or traceforward investigation, the agency may know the identity of the food that was transported but not the quantity. Such information may allow FDA to rapidly determine whether some of the food was diverted or whether multiple transporters carried food between two nontransporters.

I. What Are the Record Retention Requirements? (Section 1.360)

40. General Questions

40.1 Q: A facility receives a product with two-year record retention requirement, holds it for three years, and then releases it. Is the facility required to retain the incoming records until or some time after the product is released, regardless of the holding period?

A: The facility is not required to maintain any record for longer than two years after its creation at the time of the transaction it describes, because Section 306 of the Bioterrorism Act explicitly limits the retention of records to two years or less. Records created when a food subject to the two year record retention requirement is received may be discarded after two years, even if the product remains in the facility. The facility still must establish and maintain records identifying the transporter and nontransporter immediate subsequent recipient when the food is released in accordance with 21 CFR 1.345, even if the retention period for the record identifying the immediate previous source has expired. If a facility anticipates that it may hold food for longer

than two years, it may wish to retain records of receipt for more than two years as a matter of business practice. Such records could be helpful to both the facility and FDA in the event of a trace back or trace forward investigation.

J. What Are the Record Availability Requirements? (Section 1.361)

41. General Questions

41.1 Q: The regulation requires each nontransporter to establish and maintain records onsite or at a reasonably accessible location. The recordkeeping requirements may be a burden for smaller businesses that assist in product development and product sample testing. Can a larger firm that hires a smaller one for food development and testing maintain the records on behalf of the smaller firm?

A: 21 CFR 1.360 requires each nontransporter to establish and maintain records at the location where the covered activities described in the records occurred, or at a reasonably accessible location. FDA does not intend to specify the method or system by which this is done. In this case, in the event that FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, relevant records must be made accessible onsite at the testing facility or at a reasonably accessible location as soon as possible upon request by FDA, not to exceed 24 hours, as required by §1.361 and §1.363. Regardless of the specific arrangements, the legal responsibility for establishing and maintaining records, and for producing them in a timely fashion, would remain with the testing facility.

41.2 Q: It is possible that an investigation may lead FDA to suspect that a product may have been tampered with inside a vertically integrated operation, for example en route between two facilities. If company systems are set up to establish records as a vertically integrated operation, what would be FDA's expectations if intra-company records were requested?

A: Sections 414(a) and 704(a) of the Act provide access for existing records relating to manufacture, processing, packing, transportation, distribution, receipt, holding, or importation. If FDA requests intra-company records under the Bioterrorism Act, FDA expects a vertically integrated operation to provide access to such existing records as soon as possible, not to exceed 24 hours from the time of receipt of the official request, as required by 21 CFR 1.361.

41.3 Q: [Added November 2005] A large firm may produce large amounts of data in response to a records access request by FDA (15 boxes of printed material or 3-4 gigabytes of electronic data, or more). How should these data be supplied to FDA?

A: As discussed in the response to comment 1 of the Final Rule preamble, this regulation does not specify the form or type of system in which records must be established and maintained. FDA's intent is to have as little impact as possible on current recordkeeping practices if those records can meet the requirement of this regulation. However, the firm must have a system to retrieve the records and be able to meet the record availability requirements of 21 CFR 1.361 by producing, in response to an appropriate request from FDA, the desired information as soon as

possible, not to exceed 24 hours. It is not sufficient to simply produce all records from a given time period or facility in response to a more specific request for information.

41.4 Q: [Added November 2005] A nontransporter establishes and maintains records at the site where covered activities are performed. The site is operated seasonally in a remote location and the nontransporter's representatives may not be able to reach the site within 24 hours of FDA's request for records access. Alternatively, the nontransporter's representatives may be able to reach the site within 24 hours to present the records but FDA's representatives are unable to reach the site in that time. Is the nontransporter failing to comply with the record availability requirements of 21 CFR 1.361?

A: Yes. 21 CFR 1.361 requires that in the appropriate circumstances, any applicable records must be made readily available for inspection and photocopying or other means of reproduction as soon as possible, not to exceed 24 hours from the time of receipt of the request. A seasonally operated remote location that may not be reachable within 24 hours by either the nontransporter or FDA is not a readily available repository for records. Under these circumstances, the nontransporter should consider maintaining the records on-site or at a reasonably available offsite location as provided by 21 CFR 1.360(g) to avoid noncompliance with this regulation.

K. What Records Are Excluded From this Rule? (Section 1.362)

42. General Questions (Reserved)

L. What Are the Consequences of Failing to Establish and Maintain Records or Make Them Available to FDA as Required by this Rule? (Section 1.363)

43. General Questions

FDA has addressed questions we received on this issue in the [Final Rule](#).

M. What Are the Compliance Dates for this Rule? (Section 1.368)

44. General Questions

44.1 Q: Some multinational companies have subsidiaries which may not be food oriented (*e.g.* trucking lines, barge companies, industrial products). These subsidiaries may be located in many countries around the globe. Should the total number of employees from all the subsidiary companies be included in the total count for the purpose of determining the compliance date for this regulation, or should the count be of those employees within the corporate subsidiary manufacturing (or otherwise associated with) the food article?

A: The employee count is limited to the individual company performing covered activities in the United States. 21 CFR 1.368 specifies that all full-time employees in the individual company (*i.e.*, a single legal person) are to be counted, whether or not those employees are engaged in activities related to food subject to this regulation. 21 CFR 1.327(h) provides that foreign persons (except foreign persons who transport food in the United States) are not covered by this regulation.

44.2 Q: A company is foreign-owned and has refineries in 3 other countries. The company's only U.S. location has approximately 60 full-time employees. Worldwide, we have nearly 1000 full-time employees. For the purposes of complying with this regulation, are we considered to have 60 or 1000 employees?

A: The company has 60 employees for the purpose of determining the compliance date for this regulation. 21 CFR 1.327(h) provides that foreign persons (except foreign persons who transport food in the United States) are not covered by this regulation.

44.3 Q: [Added November 2005] In cases where a state agency is the vendor for liquor, is the compliance deadline based on the number of employees in the agency or in the entire state government?

A: The compliance deadline is based on the number of employees in the state government. As discussed in question 44.1 of this document, 21 CFR 1.368 specifies that all full-time equivalent employees of a single legal person are to be counted, whether or not they are engaged in activities related to food subject to this regulation.

44.4 Q: [Added November 2005] How does the definition of employees in the final rule (the total number of hours a store is open divided by number of hours worked by all employees in one year, 40 hours x 52 weeks) apply to a store that may be open more than 40 hours a week?

A: 21 CFR 1.328 of the Final Rule specifies that the number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in one year (2080 hours = 40 hours x 52 weeks). This is not related to the number of hours per week that a store is open for business.

N. General Comments