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List of Subjects in 21 CFR Part 1

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart I is added to part 1 to read as follows:

Subparts F-G [Reserved]
Subpart I—PRIOR NOTICE OF IMPORTED FOOD
General Provisions

Sec.

1.276 What imported food is subject to this subpart?

1.277 What definitions apply to this subpart?

1.278 What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?

Requirements to Submit Prior Notice of Imported Food

Sec.

1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?

1.286 When must the prior notice be submitted to FDA?

1.287 How must you submit the prior notice?

1.288 What information must be submitted in the prior notice?

1.289 What changes are allowed to a prior notice after it has been submitted to FDA?

1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?

1.291 What is the deadline for product identity amendments under § 1.290?

1.292 How do you submit a product identity amendment to a prior notice?

1.293 What are the consequences if you do not submit a product identity amendment to your prior notice?

1.294 What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?

General Provisions

§ 1.276 *What imported food is subject to this subpart?*

(a) This subpart applies to food for humans and other animals that is imported or offered for import into the United States (U.S.), including U.S. foreign trade zones, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export.

(b) This subpart does not apply to:

(1) Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use;

(2) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(3) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(4) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.277 *What definitions apply to this subpart?*

(a) The act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article of food was shipped* means the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(3) *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 components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging 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.

(4) *Originating country* means the country from which the article of food originates. If the article of food is fresh produce or fresh aquacultured fish or seafood, the originating country is the country in which it is grown and harvested. If the article of food is wild-caught fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the originating country is the United States. Otherwise, the originating country is the country in which the article of food is produced.

(5) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(6) *You* means the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or, if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier.

§ 1.278 *What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?*

(a) If an article of food is imported or offered for import with no prior notice or inadequate (e.g., untimely, inaccurate, or incomplete) prior notice, the food shall be refused admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)).

(b) If an article of food is refused admission under section 801(m)(1), it must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with § 1.278(c).

(c) If FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a Bonded Warehouse, Container Freight Station, Centralized Examination Station, or another appropriate secure facility that has been approved by FDA.

(d) The person submitting the prior notice or the carrier must arrange for movement of the article of food, under appropriate custodial bond, within the port of entry or to the secure facility and must promptly notify FDA of the

location. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(e) (1) The article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

(2) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food that has been refused admission under section 801(m)(1) of the act is held at its port of entry or in a secure facility, it may not be delivered to any of its importers, owners, or consignees.

(f) A determination that an article of food is no longer subject to refusal under section 801(m)(1) is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

(g) Any person who imports or offers for import an article of food without complying with the requirements of 21 U.S.C. 381(m) as set out in this subpart, or otherwise violates any requirement under 21 U.S.C. 381(m), or any person who causes such an act, commits a prohibited act within the meaning of 21 U.S.C. 331 (ee). Under 21 U.S.C. section 332, the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under 21 U.S.C. section 333, the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under 21

U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

Requirements to Submit Prior Notice of Imported Food

§ 1.285 *Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?*

(a) A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer, is authorized to submit to FDA prior notice of the article of food being imported or offered for import into the United States, except as specified in paragraph (b) of this section.

(b) If the article of food is imported for in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier is authorized to submit prior notice to FDA.

§ 1.286 *When must the prior notice be submitted to FDA?*

(a) You must submit the prior notice to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

(b) You may not submit the prior notice until all of the information required by § 1.288 exists, except as provided in §§ 1.288(e)(2) and 1.290, which both relate to product identity amendments. You may not submit prior notice more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry.

§ 1.287 *How must you submit the prior notice?*

(a) You must submit prior notice, product identity amendments, and arrival updates electronically to FDA through FDA's Prior Notice System,

which is available at www.fda.gov/, except as provided in paragraph (b) of this section. ~~at~~ ~~at~~ ~~at~~ [a website that will be provided in the final rule]

(b) If FDA's Prior Notice System is unable to receive prior notice electronically, you must submit prior notice, product identity amendments, and arrival updates using a printed version of the Prior Notice Screen from FDA's Prior Notice System delivered in person, by e-mail, or fax to the FDA field office with responsibility over the geographical area in which the anticipated port of entry identified in your initial prior notice is located.

✓ § 1.288 *What information must be submitted in the prior notice?*

For each article of food that is imported or offered for import into the United States, you must submit the information listed ~~below:~~ ^{in this section/}

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(a) The name of the individual submitting the prior notice, the submitting firm's name, address, phone number, fax number, and e-mail address, and, if the firm is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(b) The entry type as designated by the U.S. Customs Service;

(c) The U.S. Customs Service's Automated Commercial System (ACS) entry number, or if the article of food is an import that is not subject to ACS, the other U.S. Customs Service identification number associated with the importation;

(d) If the article of food is under hold under § 1.278, the location where it is being held, the date the article will arrive at that location, and identification of a contact at that location.

(e)(1) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The trade or brand name, if different from the common or usual name or market name;

(iv) The quantity of food described from smallest package size to largest container; and

(v) The lot or code numbers or other identifier of the food if applicable.

(2) If all of the information required by this subsection exists by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must include it in your prior notice and you may not amend the prior notice under § 1.290. If any of this information does not exist by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must give FDA as much information as does exist at that time and tell FDA that you will amend the prior notice as required under § 1.290.

(f) The name, address, phone number, fax number, and e-mail address of the manufacturer, and if it is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(g) The name, address, phone number, fax number, and e-mail of all growers, and the growing location if different from business address, if known at time of submission of your prior notice;

(h) The originating country of the article of food;

(i) The name, address, phone number, fax number, and e-mail address of the shipper and, if it is required to register under 21 CFR part 1, subpart H,

for a facility associated with the article of food, the registration number assigned to that facility;

(j) The country from which the article of food was shipped;

(k) (1) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of entry and, if the anticipated port of entry has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of entry; and

(iii) The anticipated time of that arrival;

(2) If any of the anticipated arrival information required under this paragraph changes after you submit your prior notice, you must update your notice in accordance with § 1.294.

(l) The port where entry of the article of food will be made for purposes of the U.S. Customs Service;

(m) The anticipated date of entry for purposes of the U.S. Customs Service; and

(n) The name, address, phone number, fax number, and e-mail address of the importer, and, if the importer is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(o) The name, address, phone number, fax number, and e-mail address of the owner, and if the owner is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(p) The name, address, phone number, fax number, and e-mail address of the consignee, and if the consignee is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility; and

(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate.

(The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.)

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§ 1.289 *What changes are allowed to a prior notice after it has been submitted to FDA?*

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

§ 1.290 *Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?*

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete product identity information by the deadline specified in § 1.291.

(b) You may only amend your prior notice once.

(c) You may not change the general identity of the article of food that is the subject of the prior notice by amendment. However, if the article is fresh produce or fresh, wild-caught fish, you may amend the last two digits of the product code when you do not know the specific identity of the article at the time of initial prior notice. If your initial prior notice submission identifies the product by the FDA product code for “fresh peppers, refrigerated,” when you amend your submission, you must give the product code that identifies with specificity the type of pepper—“fresh green bell peppers, refrigerated.” You may also include more than one article in your amendment if the industry and class and process (of the FDA product code) are the same. A prior notice for “refrigerated fresh fish” may be amended as “refrigerated fresh cod” and “refrigerated fresh salmon,” but not “refrigerated fresh cod” and “canned shrimp.” You may not amend the product identity to refer to another food, e.g., apples, or another process, e.g., canned.

(d) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you submit a product identity amendment to your prior notice, you must include in your amendment: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

§ 1.291 *What is the deadline for product identity amendments under § 1.290?*

Your product identity amendment must be submitted no later than 2 hours prior to the time of arrival.

§ 1.292 *How do you submit a product identity amendment to a prior notice?*

You must submit product identity amendments in accordance with § 1.287.

§ 1.293 *What are the consequences if you do not submit a product identity amendment to your prior notice?*

(a) If you informed FDA in your prior notice that you would be submitting a product identity amendment but you do not amend your prior notice completely, the prior notice is inadequate for the purposes of § 1.278(a).

(b) If you informed FDA in your prior notice that you would be submitting a product identity amendment and you submit your amendment after the deadline provided in section 1.291, the prior notice is inadequate for the purpose of § 1.278(a).

§ 1.294 *What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?*

(a) If any of the anticipated arrival information required under § 1.288(k)(1) changes after you submit a prior notice to FDA, you must submit an arrival update updating the information in your prior notice in accordance with § 1.287. Your arrival update must provide the following information:

(1) If the anticipated port of entry changes, provide the updated port of entry;

(2) If the time of arrival is expected to be more than 3 hours later than the anticipated time of arrival, provide the updated time of arrival;

(3) If the time of arrival is expected to be more than 1 hour earlier than the anticipated time of arrival, provide the updated time of arrival.

(b) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you update your prior notice, you must include in your update: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

(c) You must update the information in accordance with the requirements of §§ 1.291 and 1.292.

(d) If you do not submit an arrival update when one is required by paragraph (a) of this section, the prior notice is inadequate for the purposes of § 1.278(a).

Dated: _____





DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration PRIOR NOTICE SUBMISSION		Form Approved: OMB No. 0910-____ Expiration Date: _____	
Paperwork Reduction Act Statement An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Public reporting burden for this collection of information is estimated to average 0.5-1.0 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:		Food and Drug Administration Center for Food Safety and Applied Nutrition <i>Office to be Determined</i> 5100 Paint Branch Parkway College Park, MD 20740-3835	
<input type="checkbox"/> Initial	<input type="checkbox"/> Held	<input type="checkbox"/> Amendment Product Identity	<input type="checkbox"/> Update Arrival Info
<input type="checkbox"/> Cancel			
Mandatory Information		Mandatory if applicable	
Submitter			
First Name			
Last Name			
Submitting Firm			
<input type="checkbox"/> U.S. Purchaser		<input type="checkbox"/> U.S. Importer	
<input type="checkbox"/> U.S. Agent of Purchaser		<input type="checkbox"/> U.S. Agent of Importer	
<input type="checkbox"/> Carrier		<input type="checkbox"/> In-bond Carrier	
Name of Firm			
FDA Registration Number		<input type="checkbox"/> N/A	#
Street Address			
City			
State			
Zip			
Phone			
FAX			
E-mail address			
Entry Type			
<input type="checkbox"/> Consumption	<input type="checkbox"/> T & E	<input type="checkbox"/> IE	<input type="checkbox"/> Mail
<input type="checkbox"/> Warehouse	<input type="checkbox"/> TIB	<input type="checkbox"/> Baggage	<input type="checkbox"/> Other
Entry Type Customs Code			
Customs Entry Number/Customs Line Number/FDA Line Number			
Article held under FDA direction		<input type="checkbox"/> No	<input type="checkbox"/> Yes
Name of Location			
Street Address			
City			
State		Zip	
Contact Name		Phone	

Date available at Location mm/dd/yy																								
Product Identity																								
FDA Product Code																								
Common/usual/market name																								
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Quantity					Number					Measure														
Identifiers										<input type="checkbox"/> Lot number					<input type="checkbox"/> Production Code									
1																								
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Growing Location State/Province																								
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Growing Location Zip/Mail code																								
ADDITIONAL GROWERS										<input type="checkbox"/> No					<input type="checkbox"/> Yes					How Many?				
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Name of Firm																								
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City																								

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Growing Location State/Province			
Growing Location Country			
Growing Location Zip/Mail code			
<u>GROWER 3</u>			
Name of Firm			
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State/Province			
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Zip/Mail code			
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FAX			
E-mail address			
Growing Location street			
Growing Location City			
Growing Location State/Province			
Growing Location Country			
Growing Location Zip/Mail code			
<u>Originating Country</u>		ISO code	
<u>Shipper</u>			
Name of Firm			
FDA Registration Number	<input type="checkbox"/> N/A	#	
Street Address			
City			
State/Province			
Country			
Zip/Mail code			
Phone			
FAX			
E-mail address			
<u>Country from which the article was shipped</u>		ISO code	
<u>Anticipated Arrival Information</u>			
Name of Crossing			

City of Crossing												
State of Crossing					Port of Entry Code							
Anticipated Date of Crossing mm/dd/yy												
Anticipated Time of Crossing												
											<input type="checkbox"/> am	<input type="checkbox"/> pm
Port of Entry for Customs Purposes (port code)												
Date of Entry for Customs Purposes mm/dd/yy												
<u>Importer</u>												
Name of Firm												
FDA Registration Number												
											<input type="checkbox"/> N/A	#
Street Address												
City												
State												
Zip												
Phone												
FAX												
E-mail address												
<u>Owner</u>												
Name of Firm												
FDA Registration Number												
											<input type="checkbox"/> N/A	#
Street Address												
City												
State												
Zip												
Phone												
FAX												
E-mail address												
<u>Consignee</u>												
Name of Firm												
FDA Registration Number												
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Street Address												
City												
State												
Zip												
Phone												
FAX												
E-mail address												
<u>Carrier 1</u>												
Standard Carrier Abbreviation Code												
Name of Firm												
Street Address												

City				
State/Province				
Zip/mail code				
Country				
Phone				
FAX				
E-mail address				
Additional Carriers	<input type="checkbox"/> No	<input type="checkbox"/> Yes	How Many?	
<u>Carrier 2</u>				
Standard Carrier Abbreviation Code				
Name of Firm				
Street Address				
City				
State/Province				
Country				
Zip/Mail code				
Phone				
FAX				
E-mail address				
<u>Carrier 3</u>				
Standard Carrier Abbreviation Code				
Name of Firm				
Street Address				
City				
State/Province				
Country				
Zip/Mail code				
Phone				
FAX				
E-mail address				
Amendment to follow				
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
Cancel this submission				
	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
<i>This form must be submitted by the U.S. Importer or U.S. Purchaser, or U.S. Agent of the importer or purchaser, of the article of food being imported or offered for import. Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.</i>				

REVISIONS

JAN 27 2003

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 02N-0278]

RIN 0910-AC41

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is proposing a regulation that would require U.S. purchasers or U.S. importers or their agents to submit to FDA prior notice of the importation of food. The proposed regulation implements ^Q of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin by December 12, 2003. The Bioterrorism Act requires FDA to issue final regulations that specify the period of advance notice by this date or a statutory notice provision requiring not less than 8 hours prior notice and not more than 5 days prior notice will take effect until a final rule is issued. ✓

DATES: Submit written or electronic comments by *[insert date 60 days after date of publication in the Federal Register]*. Submit written or electronic comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

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the prior notice to the corresponding U.S. Customs entry in order to assess the adequacy of the prior notice when shipments arrive and are presented for review. FDA believes that these numbers can be obtained by the proposed deadline for prior notice. We seek comment on this issue.

d. *The location where the food is being held under proposed § 1.278, if applicable.* FDA is proposing to require that, if the article of food has been refused admission due to inadequate prior notice and thus is required to be held at the port of entry or in a secure facility, the submitter of the prior notice must inform FDA both that the article is under hold, and the location where the shipment is being held (proposed § 1.288(d)). Additionally, FDA is proposing to require the date that the article will arrive at that location as well as the identification of a contact at that location. This information is necessary to ensure FDA can locate the food for inspection and to ensure that the hold requirement is being complied with.

e. *The product identity.* Section 801(m)(1) states that a prior notice must contain the identity of the article of food being imported or offered for import. FDA is proposing the following data elements to ensure that each prior notice adequately and completely identifies the food being imported or offered for import.

i. The complete FDA product code. FDA is proposing to require the submission of the complete FDA product code as an element of the identity of the product (proposed § 1.288(e)(1)(i)). The FDA product code is a unique code currently used for classification and analysis of merchandise. The FDA product code is currently available via the Internet at www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm as a “buildable” code which is used to describe the food by industry, industry class, subclass, container/packaging, process, and

solicits comment on this standard and whether it is sufficiently flexible to achieve our goals.

ii. The Common or usual or market name. FDA is proposing to require the submission of the common or usual or market name of the article of food as an element of the identity of the product (proposed § 1.288(e)(1)(ii)). This is a description, in common terms, detailed enough to allow the kind of product to be identified. (See 21 CFR § 102.5 for additional information about common or usual names.) The filer currently submits the common or usual or market name to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS for each entry line. This information is necessary to confirm the accuracy of the product code.

iii. The trade or brand name. FDA is proposing to require the submission of the trade or brand name of the article of food, if it is different than the common or usual or market name, as an element of the identity of the product (proposed § 1.288(e)(1)(iii)). For example, the brand name of canned tuna would be XYZ brand tuna. This information is necessary to ensure that FDA knows the brand identity of the product, which is often a critical piece of information when making inspection decisions. The filer currently submits the trade or brand name to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS for each entry line.

iv. The quantity. FDA is proposing to require the submission of the quantity of food described from smallest package size to largest container as an element of the identity of the product (proposed § 1.288(e)(1)(iv)). The number of container units and units of measure are to be submitted in decreasing size of packing unit (starting with the largest). Some examples of quantity descriptions are: 100 cartons of 48/6 oz. cans each of tuna; 100 pallets

of 2/100 lb. totes each of frozen tuna loins for a total of 20,000 pounds; 100 pallets of 2/100 lbs. cartons each of dehydrated pig ears for a total of 20,000 lbs.; and 100 cartons of 20 lbs. of fresh watermelons each for a total of 2000 lbs. The filer currently submits the quantity of each line entry to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS. FDA requests comment on whether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes usually are.

v. The lot or code numbers or other identifier. FDA is proposing to require the submission of the lot or code numbers or other identifiers that are specific to the article of food, if applicable, as an element of the identity of the product (proposed § 1.288(f)(1)(v)). These numbers are the identification number or code of a production lot and are needed to more specifically identify a product. Currently, there may be more than one identifier represented in an entry line. The prior notice system will be developed to accept more than one lot identifier per article.

f. *The manufacturer*. As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the manufacturer of each article of food (proposed § 1.288(f)). The filer currently submits the identity of the manufacturer to U.S. Custom's ACS when entry is made, and it subsequently is transmitted to FDA's OASIS.

g. *The growers, if known*. As required by section 801(m)(1), FDA is proposing to require the submission of the identity of all growers of each article and the growing location if different from the grower's business address, if known at the time of submission of the prior notice (proposed § 1.288(g)). If the submission is amended, the proposed rule provides that the identity of

j. *The country of shipping.* As provided for in section 801(m)(1), FDA is proposing to require the submission of the identity of the country from which the article of food was shipped (proposed § 1.288(j)). This term is defined in proposed § 1.277(c)(3).

k. *Anticipated arrival information.*

i. The anticipated port of entry. As provided for in section 801(m)(1), FDA is proposing to require the submission of the anticipated port of entry at which the article of food will arrive in the United States (proposed § 1.288(k)(1)(i)). “Port of entry” is defined in proposed § 1.277(c)(5).

ii. The anticipated date of arrival. FDA is proposing to require the submission of the anticipated date when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(ii)). FDA believes that this information is necessary to plan inspections.

iii. The anticipated time of arrival. FDA is proposing to require the submission of the anticipated time when the article of food will arrive at the port of entry in the United States (proposed § 1.288(k)(1)(iii)). FDA believes that this information is necessary to plan inspections.

FDA is proposing to require the prior notice to be updated if any of the anticipated arrival information changes after the submission of the prior notice (proposed § 1.288(k)(2)). Updates are necessary so FDA can change its plan when anticipated arrival information changes. The conditions appropriate for updates are provided in proposed § 1.294.

l. *The port where entry will be made for U.S. Customs purposes.* FDA is proposing to require the submission of the identification of the port where entry will be made for U.S. Customs purposes (proposed § 1.288(l)). Often, this port will be different than the port where the article of food arrived in the

transport in tanker trailers that previously had carried non-pasteurized eggs.

There were 150 confirmed cases of salmonellosis associated with the outbreak in Minnesota. However, ice cream produced during the contamination period was distributed to 48 states. To calculate the total number of illnesses associated with the outbreak, researchers calculated an attack rate of 6.6 percent. This attack rate was extrapolated to the population that consumed the ice cream, giving a total number sickened of 224,000 (Ref. 11).

Salmonellosis most commonly causes gastrointestinal symptoms. Almost 91 percent of cases are mild and cause one to three days of illness with symptoms including diarrhea, abdominal cramps, and fever. Moderate cases, defined as requiring a trip to a physician, account for 8 percent of the cases. These cases typically have duration of two to 12 days. Severe cases require hospitalization and last 11 to 21 days. In addition to causing gastroenteritis, salmonellosis also can cause reactive arthritis in a small percentage of cases. Reactive arthritis may be short or long term and is characterized by joint pain. Just over one percent of cases develop short-term reactive arthritis and two percent of cases develop chronic, reactive arthritis.

In table 21, FDA estimated the costs associated with salmonellosis, including medical treatment costs and pain and suffering. Pain and suffering is measured by lost quality adjusted life days (QALDs). QALDs measure the loss of utility associated with an illness. A QALD is measured between zero and one, with one being a day in perfect health. The total loss of a Quality Adjusted Life Year (QALY), or the loss of a year of life is valued at \$100,000, based on economic studies of how consumers value risks to life (Ref. 12). Thus, an entire lost QALD would be valued at \$274 and fractions of QALDs are a fraction of the day's value. FDA presents two estimates of values of pain and

suffering associated with arthritis, one based on physician estimates (Ref 13) and another based on a regression analysis approach (Ref 14). This gives a range of costs for the average case of salmonellosis between \$14,231 and \$25,133.

TABLE 21.—THE COST OF AN AVERAGE CASE OF SALMONELLOSIS

Severity	Case Breakdown	Total QALDs Lost per Illness	Health Loss per Case (Discounted)	Medical Costs per Case (Discounted)	Weighted Dollar Loss per Case	
Illness						
Mild	90.7%	1.05	\$660	\$0	\$599	
Moderate	8.1%	3.68	\$2,310	\$283	\$209	
Severe	1.2%	9.99	\$6,266	\$9,250	\$188	
Arthritis						
<i>Regression Approach</i>						
Short-Term	1.26%	5.41	\$3,391	\$100	\$44	
Long-Term	2.40%	2,613.12	\$452,554	\$7,322	\$11,048	
<i>Direct Survey Approach</i>						
Short-Term	1.26%	10.81	\$6,778	\$100 \$87		
Long-Term	2.40%	5,223.15	\$904,573	\$7,322	\$21,906	
Death	0.04%		\$5,000,000		\$2,143	
Total Expected Loss per Case					Regression Approach Direct Survey Approach	\$14,231 \$25,133

To estimate the economic cost due to illness associated with this outbreak, FDA used the range for the average cost per case. For 224,000 people, this is a total cost of between \$3,187,744,000 and \$5,629,792,000 from this accidental food disaster.

Shigella sonnei in tofu salad

In 1988, a tofu salad at an outdoor music festival was contaminated with *Shigella sonnei* and sickened an estimated 3,175 people. Over 2,000 volunteer food handlers served communal meals at the festival. (Ref 15) Shigellosis causes similar symptoms and is of similar duration to salmonellosis. It also is associated with short term and chronic reactive arthritis; thus, FDA assumed the average case of shigellosis has the same cost as salmonellosis. This gives a total cost of \$45,183,000 to \$79,797,000.

Nine affected workers went to the emergency room, four of whom were hospitalized (Ref. 17).

To estimate the cost of this outbreak, FDA assumed that the eight cases that required consultation with a doctor, but did not require hospitalization, had the same cost as a moderate case of salmonellosis. The four cases requiring hospitalization were estimated to have the same cost as a severe case of gastroenteritis resulting from salmonellosis. This gives a cost of \$82,808 for illnesses associated with the event.

TABLE 22.—SUMMARY OF COSTS FOR AN OUTBREAK OF SHIGELLOSIS

Severity	Number of cases	Cost per case	Total cost
Mild	0	\$0	\$0
Moderate	8	\$2,593	\$20,744
Severe	4	\$15,516	\$62,064
Total	12		\$82,808

Cyclospora cayatanensis in imported raspberries

In 1996, 1,465 cases of cyclosporiasis were linked to consumption of raspberries imported from Guatemala. Nine hundred and seventy eight of these cases were laboratory confirmed. No deaths were confirmed and less than 20 hospitalizations were reported (Ref. 18). Case control studies indicated that raspberries imported from Guatemala were the source of the illnesses. Fifty-five clusters of cases were reported in 20 states, two Canadian provinces, and the District of Columbia (Ref. 19).

Cyclosporiasis typically causes watery diarrhea, loss of appetite, weight loss, and fatigue. Less common symptoms include fever, chills, nausea, and headache. The median duration of illness associated with the outbreak was more than 14 days and the median duration of diarrheal illness was 10 days (Ref 20). We estimated the cost of a mild case of cyclosporiasis as two and one half times higher than the cost of a mild case of gastroenteritis from

salmonellosis due to the longer duration. The reports of cyclosporiasis outbreaks did not include information on the number of physician visits. We assumed that the percentage of total cases that result in physician visits would be larger than the corresponding percentage for salmonellosis illnesses, due to the longer duration of illnesses. We assumed, therefore, that 40 percent of those infected with cyclosporiasis visited a physician. Less than 20 hospitalizations were reported from the cyclosporiasis outbreak. No deaths were confirmed.

TABLE 23.—SUMMARY OF COSTS OF AN OUTBREAK OF CYCLOSPORIASIS

Severity	Number of cases	Cost per case	Total cost
Mild	879	\$1,650	\$1,450,000
Moderate	586	\$3,748	\$2,196,000
Severe	19	\$15,516	\$294,000
Total	1,465		\$3,941,000

B. Small Entity Analysis (or Initial Regulatory Flexibility Analysis)

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities consistent with statutory objectives. The analysis below, together with other relevant sections of this document, serves as the agency’s initial regulatory flexibility analysis under the Regulatory Flexibility Act.

1. Number of establishments affected

FDA finds that this proposed rule would affect the 77,427 U.S. importers. Most of these importers have fewer than 500 employees, thus making them small businesses according to the definitions of the Small Business Administration. Because most of the importers affected are small, all options

considered in the Benefit-Cost Analysis in section IV.A above are regulatory relief options.

2. Costs per entity

Small businesses will be affected by this proposed rule in a couple of ways. First, this proposed rule requires importers to notify FDA of incoming products electronically before the food arrives at the U.S. border. The annual cost of doing so is about \$770 per importer (see tables 1, 2, and 17 of this document). As discussed above and shown in tables 1 and 2, about 3,100 U.S. importers do not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about \$2,000 per importer) and Internet access (at a cost of about \$240 annually) in order to comply with this proposed rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, as paper notices could not be submitted and processed in the proposed prior notice timeframe and would therefore actually be more burdensome to importers because paper notices would need to be submitted earlier.

Second, this proposed rule will potentially cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before crossing the U.S. border. The costs of lost product value vary with the required notice timeframe. We discuss the various costs associated with this possibility in the options previously outlined. FDA requests comments on the effect of this proposed rule on small entities.

3. Additional flexibility considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the rule on small entities, including granting an

information that the prior notice is required to contain, the method of submission of the notice, and the minimum and maximum period of advance notice required. Section 801(m)(1) of the Act states that the Secretary shall require submission of notice providing the identity of each of the following: the article of food; the manufacturer; the shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of entry. Section 801(m)(2)(A) of the Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed five days. FDA's prior notification of imported food shipments proposed regulation would implement these statutory provisions.

FDA estimates the burden for this information collection as follows:

TABLE 24.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Part 1, Subpart I	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.285–1.290, 1.294 ¹	77,427	23.3	1,807,692	1–2	\$6,194,000	\$743,280	1,888,216
1.278(d) ¹	90,385	1	90,385	0.5	\$0	\$0	45,193
1.278(d), 1.285–1.290, 1.294 ²	77,427	23.8	1,844,116	0.5–1	\$620,000	\$817,680	1,833,822
Total hours for first year							1,888,216
Total recurring hours							1,833,822

¹ First year burden.

² Recurring burden.

Burden Estimate

Number of Establishments Affected

Using 2001 FY information from FDA's OASIS system (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food

requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice, 7,433 of whom are estimated to have Internet access and 310 of whom do not.

Submitting Prior Notice

To estimate the repetitive effort of submitting a prior notice, and updating and amending the information, as needed, FDA will assume the activity takes one hour each time an entry (based on an average of 2.6 lines, and therefore notices, per entry) must be submitted. This includes 45 minutes of an administrative worker's time to fill out the screen, including updating, and then 15 minutes of the manager's time to verify the information. FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 1,807,692 prior notices will be submitted annually (based on FY 2001 OASIS information); we can take this number and divide by the 77,427 importers to get an average response frequency per importer of 23.3 notices.

Secure storage and notifying FDA

If an article of food is imported or offered for import with no prior notice or inadequate (e.g. untimely, inaccurate, or incomplete) prior notice, the food must be held at the port of entry or in a secure facility. In these cases, the submitter or carrier must promptly notify FDA of the location where the goods are held.

It is quite likely that more imported products will be held during the first year that the prior notice is required than in subsequent years as importers will learn from experience. Therefore, FDA estimates that imported products with insufficient prior notice will be held or sent to secure storage about 5 percent of the time during the first year and 2 percent of the time thereafter.

by this date, FDA still must receive prior notice of food imported or offered for import into the United States by December 12, 2002, of no less than 8 hours and no more than 5 days, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the United States government's need to prepare to respond to bioterrorism and other food-related emergencies and FDA's need to have the final rule in place, tested, and fully operational by December 12, 2003. This means that the final rule must publish in early October 2003.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act's requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Compilation of food entry documents, with corresponding invoices and screens, taken from FDA's Operational and Administrative System for Import Support (OASIS).
2. Bureau of Economic Analysis, <http://www.bea.doc.gov>
3. United States Department of Labor, Bureau of Labor Statistics, National Compensation Survey: Occupation Wages in the United States, 2000, Summary 01-04. Available at <http://www.bls.gov/ncs/ocs/sp/ncbl0354.pdf>.

4. USDA Agricultural Marketing Service (March 2002) Fresh Fruits and Vegetable Shipments. www.ams.usda.gov

5. Kasmire, Dr. Robert F. Vegetable Marketing Specialist, www.thepacker.com/rbcs/handbookarticles/properis.htm Accessed on ^{September} 9/16/02.

6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002 and September 16, 2002. www.ams.usda.gov

7. Florida Department of Agriculture and Consumer Services (FDACS) www.ffva.com/rps.htm.

8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, www.st.nmfs.gov accessed September 2002.

9. Florida Department of Agriculture and Consumer Services, <http://doacs.state.fl.us/press/1999/090999.html> and www.ffva.com/rps.htm

10. Center for Food Safety and Applied Nutrition, <http://www.cfsan.fda.gov/~dms/qa-sto8.html>

11. Hennessy TW, Hedberg CW, Slutsker L, White KE, Besser-Wiek JM, Moen ME, Feldman J, Coleman WW, Edmonson LM, MacDonald KL, Osterholm MT, and the Investigation Team, "A National Outbreak of Salmonella enteritidis infections from ice cream," The New England Journal of Medicine (May 16, 1996) 1281-1286.

12. Cutler, D., Richardson E., 1999, "Your Money and Your Life: The Value of Health and What Affects It," Working Paper 6895, National Bureau of Economic Research.

13. Zorn, D., Klontz K., 1998, Appendix: "The Value of Consumer Loss to Foodborne Reactive Arthritis", **Federal Register**, 63, May 1, 1998. ^{FR 24292-24299}

14. Scharff R, and A. Jessup, "Valuing Chronic Disease for Heterogenous Populations: the Case of Arthritis," 2002, Mimeo.

15. Lee LA, Ostroff SM, McGee HB, Johns DR, Downes FP, Cameron DN, Bear NH, and PM Griffin, An Outbreak of shigellosis at an outdoor music festival, American Journal of Epidemiology, 133:6:608–615.

16. Trook TJ, Tauxe RV, Wise RP, Livengood JR, Sokolow R, Mauvais S, Birkness KA, Skeels MR, Horan JM, and LR Foster, A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars, JAMA The Journal of the American Medical Association, 278:5:389–397.

17. Kolavic SA, Kimura A, Simons SL, Slusker L, Barth S, and CE Haley, An outbreak of Shigella dysenteriae type 2 among laboratory workers due to intentional food contamination, JAMA The Journal of the American Medical Association, 278:5:396–403.

18. Colley DG, Widespread Foodborne Cyclosporiasis Outbreaks Present Major Challenges (letter), Emerging Infectious Diseases, 2:4:354–356.

19. Herwaldt BL, Ackers ML, and Cyclospora Working Group, An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries, New England Journal of Medicine. May 29, 1997, 1548–1556.

20. Small Business Administration Office of Advocacy, “Small Business by the Numbers”, May 2002, <http://www.sba.gov/advo/>

List of Subjects in 21 CFR Part 1

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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

1.294 What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?

General Provisions

§ 1.276 *What imported food is subject to this subpart?*



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(a) This subpart applies to food for humans and other animals that is imported or offered for import into the United States (U.S.), including U.S. foreign trade zones, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export.

(b) This subpart does not apply to:

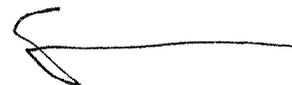
(1) Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use;

(2) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(3) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(4) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.277 *What definitions apply to this subpart?*



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(a) The act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article of food was shipped* means the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(3) *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 components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging 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.

(4) *Originating country* means the country from which the article of food originates. If the article of food is fresh produce or fresh aquacultured fish or seafood, the originating country is the country in which it is grown and harvested. If the article of food is wild-caught fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the originating country is the United States. Otherwise, the originating country is the country in which the article of food is produced.

(5) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(6) *You* means the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or, if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier.

§ 1.278 *What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?*

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(a) If an article of food is imported or offered for import with no prior notice or inadequate (e.g., untimely, inaccurate, or incomplete) prior notice, the food shall be refused admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)).

(b) If an article of food is refused admission under section 801(m)(1), it must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with § 1.278(c).

(c) If FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a Bonded Warehouse, Container Freight Station, Centralized Examination Station, or another appropriate secure facility that has been approved by FDA.

(d) The person submitting the prior notice or the carrier must arrange for movement of the article of food, under appropriate custodial bond, within the port of entry or to the secure facility and must promptly notify FDA of the

location. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(e) (1) The article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

(2) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food that has been refused admission under section 801(m)(1) of the act is held at its port of entry or in a secure facility, it may not be delivered to any of its importers, owners, or consignees.

(f) A determination that an article of food is no longer subject to refusal under section 801(m)(1) is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

(g) Any person who imports or offers for import an article of food without complying with the requirements of 21 U.S.C. 381(m) as set out in this subpart, or otherwise violates any requirement under 21 U.S.C. 381(m), or any person who causes such an act, commits a prohibited act within the meaning of 21 U.S.C. 331 (ee). Under 21 U.S.C. section 332, the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under 21 U.S.C. section 333, the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under 21

U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

Requirements to Submit Prior Notice of Imported Food

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§ 1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?

(a) A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer, is authorized to submit to FDA prior notice of the article of food being imported or offered for import into the United States, except as specified in paragraph (b) of this section.

(b) If the article of food is imported for in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier is authorized to submit prior notice to FDA.

§ 1.286 When must the prior notice be submitted to FDA?

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(a) You must submit the prior notice to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

(b) You may not submit the prior notice until all of the information required by § 1.288 exists, except as provided in §§ 1.288(e)(2) and 1.290, which both relate to product identity amendments. You may not submit prior notice more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry.

§ 1.287 How must you submit the prior notice?

(a) You must submit prior notice, product identity amendments, and arrival updates electronically to FDA through FDA's Prior Notice System, which is available at www.fda.gov/__, except as provided in paragraph (b) of this section.

(b) If FDA's Prior Notice System is unable to receive prior notice electronically, you must submit prior notice, product identity amendments, and arrival updates using a printed version of the Prior Notice Screen from FDA's Prior Notice System delivered in person, by e-mail, or fax to the FDA field office with responsibility over the geographical area in which the anticipated port of entry identified in your initial prior notice is located.

§ 1.288 What information must be submitted in the prior notice?

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~~For each article of food that is imported or offered for import into the~~
United States, you must submit the information listed below:

(a) The name of the individual submitting the prior notice, the submitting firm's name, address, phone number, fax number, and e-mail address, and, if the firm is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(b) The entry type as designated by the U.S. Customs Service;

(c) The U.S. Customs Service's Automated Commercial System (ACS) entry number, or if the article of food is an import that is not subject to ACS, the other U.S. Customs Service identification number associated with the importation;

(d) If the article of food is under hold under § 1.278, the location where it is being held, the date the article will arrive at that location, and identification of a contact at that location.

(e)(1) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The trade or brand name, if different from the common or usual name or market name;

(iv) The quantity of food described from smallest package size to largest container; and

(v) The lot or code numbers or other identifier of the food if applicable.

(2) If all of the information required by this subsection exists by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must include it in your prior notice and you may not amend the prior notice under § 1.290. If any of this information does not exist by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must give FDA as much information as does exist at that time and tell FDA that you will amend the prior notice as required under § 1.290.

(f) The name, address, phone number, fax number, and e-mail address of the manufacturer, and if it is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(g) The name, address, phone number, fax number, and e-mail of all growers, and the growing location if different from business address, if known at time of submission of your prior notice;

(h) The originating country of the article of food;

(i) The name, address, phone number, fax number, and e-mail address of the shipper and, if it is required to register under 21 CFR part 1, subpart H,

for a facility associated with the article of food, the registration number assigned to that facility;

(j) The country from which the article of food was shipped;

(k) (1) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of entry and, if the anticipated port of entry has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of entry; and

(iii) The anticipated time of that arrival;

(2) If any of the anticipated arrival information required under this paragraph changes after you submit your prior notice, you must update your notice in accordance with § 1.294.

(l) The port where entry of the article of food will be made for purposes of the U.S. Customs Service;

(m) The anticipated date of entry for purposes of the U.S. Customs Service; and

(n) The name, address, phone number, fax number, and e-mail address of the importer, and, if the importer is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(o) The name, address, phone number, fax number, and e-mail address of the owner, and if the owner is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(p) The name, address, phone number, fax number, and e-mail address of the consignee, and if the consignee is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility; and

(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate.

The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.

§ 1.289 What changes are allowed to a prior notice after it has been submitted to FDA?

no ital and bold

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

please do the same for the following circled heading

§ 1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete product identity information by the deadline specified in § 1.291.

(b) You may only amend your prior notice once.

(c) You may not change the general identity of the article of food that is the subject of the prior notice by amendment. However, if the article is fresh produce or fresh, wild-caught fish, you may amend the last two digits of the product code when you do not know the specific identity of the article at the time of initial prior notice. If your initial prior notice submission identifies the product by the FDA product code for “fresh peppers, refrigerated,” when you amend your submission, you must give the product code that identifies with specificity the type of pepper—“fresh green bell peppers, refrigerated.” You may also include more than one article in your amendment if the industry and class and process (of the FDA product code) are the same. A prior notice for “refrigerated fresh fish” may be amended as “refrigerated fresh cod” and “refrigerated fresh salmon,” but not “refrigerated fresh cod” and “canned shrimp.” You may not amend the product identity to refer to another food, e.g., apples, or another process, e.g., canned.

(d) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you submit a product identity amendment to your prior notice, you must include in your amendment: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

§ 1.291 What is the deadline for product identity amendments under § 1.290?

Your product identity amendment must be submitted no later than 2 hours prior to the time of arrival.

§ 1.292 How do you submit a product identity amendment to a prior notice?

You must submit product identity amendments in accordance with § 1.287.

§ 1.293 *What are the consequences if you do not submit a product identity amendment to your prior notice?*

(a) If you informed FDA in your prior notice that you would be submitting a product identity amendment but you do not amend your prior notice completely, the prior notice is inadequate for the purposes of § 1.278(a).

(b) If you informed FDA in your prior notice that you would be submitting a product identity amendment and you submit your amendment after the deadline provided in section 1.291, the prior notice is inadequate for the purpose of § 1.278(a).

§ 1.294 *What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?*

(a) If any of the anticipated arrival information required under § 1.288(k)(1) changes after you submit a prior notice to FDA, you must submit an arrival update updating the information in your prior notice in accordance with § 1.287. Your arrival update must provide the following information:

(1) If the anticipated port of entry changes, provide the updated port of entry;

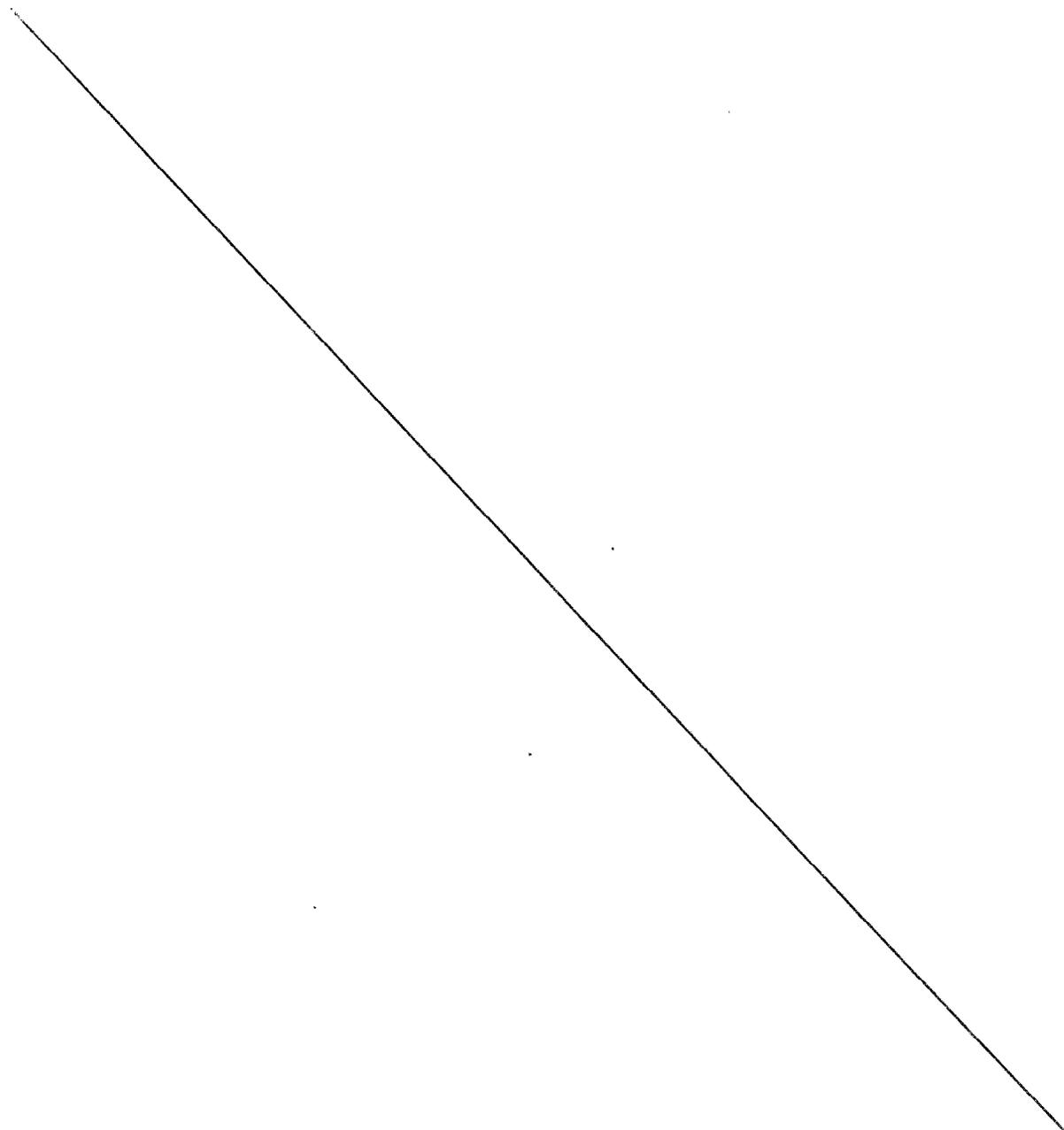
(2) If the time of arrival is expected to be more than 3 hours later than the anticipated time of arrival, provide the updated time of arrival;

(3) If the time of arrival is expected to be more than 1 hour earlier than the anticipated time of arrival, provide the updated time of arrival.

(b) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you update your prior notice, you must include in your update: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

(c) You must update the information in accordance with the requirements of §§ 1.291 and 1.292.

(d) If you do not submit an arrival update when one is required by paragraph (a) of this section, the prior notice is inadequate for the purposes of § 1.278(a).



Dated: _____

Dated: _____

Note: The following form is an appendix that will not appear in the Code of Federal Regulations.

[INSERT GLOSSY]

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

Requirements to Submit Prior Notice of Imported Food

§ 1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?

(a) A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer, is authorized to submit to FDA prior notice of the article of food being imported or offered for import into the United States, except as specified in paragraph (b) of this section.

(b) If the article of food is imported for in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier is authorized to submit prior notice to FDA.

§ 1.286 When must the prior notice be submitted to FDA?

(a) You must submit the prior notice to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

(b) You may not submit the prior notice until all of the information required by § 1.288 exists, except as provided in §§ 1.288(e)(2) and 1.290, which both relate to product identity amendments. You may not submit prior notice more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry.

§ 1.287 How must you submit the prior notice?

(a) You must submit prior notice, product identity amendments, and arrival updates electronically to FDA through FDA's Prior Notice System. ✓

at [a website that will be ¹⁰⁸ provided in the final rule] which is available at ~~www.fda.gov~~, except as provided in paragraph (b) of this section.

(b) If FDA's Prior Notice System is unable to receive prior notice electronically, you must submit prior notice, product identity amendments, and arrival updates using a printed version of the Prior Notice Screen from FDA's Prior Notice System delivered in person, by e-mail, or fax to the FDA field office with responsibility over the geographical area in which the anticipated port of entry identified in your initial prior notice is located.

Reprint pls. search the preamble for this change

§ 1.288 What information must be submitted in the prior notice?

For each article of food that is imported or offered for import into the United States, you must submit the information listed ^{in this section} below.

(a) The name of the individual submitting the prior notice, the submitting firm's name, address, phone number, fax number, and e-mail address, and, if the firm is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

place parenthetical from p. 111 here

(b) The entry type as designated by the U.S. Customs Service;

(c) The U.S. Customs Service's Automated Commercial System (ACS) entry number, or if the article of food is an import that is not subject to ACS, the other U.S. Customs Service identification number associated with the importation;

(d) If the article of food is under hold under § 1.278, the location where it is being held, the date the article will arrive at that location, and identification of a contact at that location.

(e)(1) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The trade or brand name, if different from the common or usual name or market name;

(iv) The quantity of food described from smallest package size to largest container; and

(v) The lot or code numbers or other identifier of the food if applicable.

(2) If all of the information required by this subsection exists by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must include it in your prior notice and you may not amend the prior notice under § 1.290. If any of this information does not exist by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must give FDA as much information as does exist at that time and tell FDA that you will amend the prior notice as required under § 1.290.

(f) The name, address, phone number, fax number, and e-mail address of the manufacturer, and if it is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(g) The name, address, phone number, fax number, and e-mail of all growers, and the growing location if different from business address, if known at time of submission of your prior notice;

(h) The originating country of the article of food;

(i) The name, address, phone number, fax number, and e-mail address of the shipper and, if it is required to register under 21 CFR part 1, subpart H, for a facility associated with the article of food, the registration number assigned to that facility;

(j) The country from which the article of food was shipped;

(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate.

(The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.)

move to
p. 108

§ 1.289 What changes are allowed to a prior notice after it has been submitted to FDA?

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

§ 1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete product identity information by the deadline specified in § 1.291.

(b) You may only amend your prior notice once.

(c) You may not change the general identity of the article of food that is the subject of the prior notice by amendment. However, if the article is fresh produce or fresh, wild-caught fish, you may amend the last two digits of the product code when you do not know the specific identity of the article at the time of initial prior notice. If your initial prior notice submission identifies

entry lines of food were entered in fiscal year (FY) 2001. Port locations are established by U.S. Customs and, under the statute, FDA cannot limit ports at which food may be imported or offered for import. Thus, FDA must have enough time, on a daily basis, to process the information in the approximately 20,000 prior notices we expect to receive and to send inspectors to any port in the United States if necessary. FDA believes that the minimum amount of time necessary to ensure it can plan and that its staff can travel to the arrival point is noon of the calendar day before the day the article arrives at the border crossing. FDA believes that this timeframe will give it the minimum time it needs to conduct its assessments and provide the information to its field offices so they can allocate their inspectional resources on a daily basis and plan any necessary travel.

Before proposing this deadline FDA also considered its potential effects on imported food. FDA believes that in most circumstances information regarding imports is generated when the article to be imported is ordered or purchased, not when it is shipped to the United States. FDA has examined a selection of imported food documents and compared dates of these documents with the dates of arrival in the United States and U.S. Customs entry. FDA asked several field offices to send entry documents with invoices covering imported foods. Sixty-four packages of entry documents were received in response to this request. The dates ^{of} the invoices were compared to the dates of arrival and receipt in OASIS. In 48 cases (75 percent), the invoice date or date of sale preceded the arrival date by least 1 day. In 31 cases (48 percent), the invoice or sale date preceded the arrival date by 2 or more days. In 16 cases (25 percent), the invoice date was the same as the arrival date. FDA invites comment on the representativeness of this sampling. Based

15. Lee, L.A., S.M. Ostroff, H.B. McGee, D.R. Johns, F.P. Downes, D.N. Cameron, N.H. Bean, and P.M. Griffin, "An Outbreak of Shigellosis at an Outdoor Music Festival," *American Journal of Epidemiology*, 133:6:608–615.

16. Trook, T.J., R.V. Tauxe, R.P. Wise, J.R. Livengood, R. Sokolow, S. Mauvais, K.A. Birkness, M.R. Skeels, J.M. Horan, and L.R. Foster, "A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars," *The Journal of the American Medical Association*, 278:5:389–397.

17. Kolavic, S.A., A. Kimura, S.L. Simons, L. Slusker, S. Barth, and C.E. Haley, "An Outbreak of *Shigella Dysenteriae* Type 2 Among Laboratory Workers Due to Intentional Food Contamination," *The Journal of the American Medical Association*, 278:5:396–403.

18. Colley, D.G., Widespread Foodborne Cyclosporiasis Outbreaks Present Major Challenges (letter), *Emerging Infectious Diseases*, 2:4:354–356.

19. Herwaldt, B.L., M.L. Ackers, and Cyclospora Working Group, "An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries," *New England Journal of Medicine*, May 29, 1997, 1548–1556.

20. Small Business Administration Office of Advocacy, "Small Business By the Numbers," May 2002, <http://www.sba.gov/advo/>.

List of Subjects in 21 CFR Part 1

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

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