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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 20

[Docket No. 2002N-0276] (formerly Docket No. 02N-0276)
RIN 0910-AC40

Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final regulation that confirms the interim final rule entitled ``Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002'' (68 FR 58894, October 10, 2003 (interim final rule) as corrected by a technical amendment (69 FR 29428, May 24, 2004), and responds to comments submitted in response to the request for

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comments in the interim final rule. This final rule affirms the interim final rule's requirement that domestic and foreign facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States be registered with FDA by December 12, 2003. The interim final rule implemented the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires domestic and foreign facilities to be registered with FDA by December 12, 2003. This final rule does not make any changes to the regulatory requirements established by the interim final rule.

DATES: The interim final rule published at 68 FR 58894 was effective on December 12, 2003. The technical amendment to the interim final rule published at 69 FR 29428 was effective May 24, 2004. This final rule, which adopts as final the interim rule as amended, is effective October 3, 2005.

FOR FURTHER INFORMATION CONTACT: Catherine L. Copp, Center for Food Safety and Applied Nutrition (HFS-004), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1589.

SUPPLEMENTARY INFORMATION:

I. Background and Legal Authority

Section 305 of the Bioterrorism Act, which was enacted on June 12, 2002, amended the Federal Food, Drug, and Cosmetic Act (the act) to require the Secretary to establish regulations requiring domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to be registered with the Secretary (section 415 of the act (21 U.S.C. 350d)). Facilities were required to be registered by December 12, 2003. Failure to register a facility in accordance with section 415 of the act is a prohibited act (section 301(dd) of the act (21 U.S.C. 331(dd))). Section 305 of the Bioterrorism Act amended the act to prohibit the importation of food from a foreign facility that is required to register, but has not done so (section 801(l) of the act (21 U.S.C. 381(l))).

The Department of Health and Human Services (DHHS) and the Department of Treasury (Treasury) jointly published the proposed registration regulation in the Federal Register on February 3, 2003 (68 FR 5378), for comment (proposed rule). On October 10, 2003, DHHS and the Department of Homeland Security (DHS) jointly issued the interim final rule\1\. The interim final rule implemented section 305 of the Bioterrorism Act, and required domestic and foreign facilities to be registered with FDA by December 12, 2003. The interim final rule responded to comments from the public on the proposed rule, and established a 75-day comment period on a limited set of issues identified in the interim final rule and also set out below. In order to ensure that those commenting on the interim final rule had the benefit of FDA's outreach and educational efforts and had experience with the systems, timeframes, and data elements of the registration system, FDA reopened the comment period on the same limited set of issues for 30 days on April 14, 2004 (69 FR 19766). FDA requested comment only on the following issues:

\1\The authorities of Treasury under section 701(b) of the act to prescribe regulations for the efficient enforcement of section 801 of the act were transferred to DHS when it was created by an act of Congress in 2002.

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1. The cost to foreign facilities of hiring and retaining a U.S. agent. Specifically, FDA invited comment, and the submission of data or other information, on the following:

<bullet> The costs to a foreign facility of hiring a U.S. agent;

<bullet> The number of foreign facilities that have hired a U.S. agent or negotiated additional duties from someone with whom they have an existing relationship in response to the interim final rule, instead of relying on an existing relationship with a person who qualifies as a U.S. agent;

<bullet> The number of foreign facilities that have ceased exporting to the United States because they have decided not to hire/retain a U.S. agent for registration purposes.

<bullet> The distribution of costs between submitting registrations and other services offered by the U.S. agent.

<bullet> The assumptions underlying FDA's estimates of the costs of hiring and retaining a U.S. agent.

2. The effects on domestic small businesses, if any, if some foreign facilities cease exporting to the United States due to the U.S. agent requirement for registration. Specifically, FDA invited comment, and the submission of data or other information, on the following:

<bullet> The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration; and

<bullet> The costs incurred by these domestic small businesses due to the loss of these trading partners.

In addition to the provisions of the act amended by section 305 of the Bioterrorism Act, FDA is relying on section 701(a) and (b) of the act (21 U.S.C. 371(a) and (b)) in issuing this final rule. Section 701(a) authorizes the agency to issue regulations for the efficient enforcement of the act, while section 701(b) of the act authorizes FDA and Treasury jointly to prescribe regulations for the efficient enforcement of section 801 of the act.

To the extent that 5 U.S.C. 553 applies to this action, the agency's implementation of this action with an immediate effective date comes within the good cause exception in 5 U.S.C. 553(d)(3) (21 CFR 10.40(c)(4)(ii)). As this final rule imposes no new regulatory requirements, a delayed effective date is unnecessary.

II. Comments on the Interim Final Rule

FDA received approximately 200 timely submissions in response to

the interim final rule. Approximately three-quarters of the comments FDA received addressed issues outside the scope of the interim final rule's request for comments. FDA did not consider nonresponsive comments in developing this final rule, and this final rule does not address comments that are beyond the scope of the issues on which FDA requested comment. Relevant comments did not cause FDA to significantly revise its economic analysis of the requirement that each foreign facility designate a U.S. agent. Because FDA's responses to the comments below do not result in any changes to the regulatory requirements published in the interim final rule, the governing regulation continues to be set out in Sec. Sec. 1.225 through 1.243 and 20.100.

All of the issues on which FDA requested comment were related to the assumptions in the economic analysis section of the interim final rule. Accordingly, FDA is responding to all comments in section III of this document.

III. Analysis of Economic Impacts Benefit-Cost Analysis

We have examined the economic implications of this final rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the

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economy of $100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. Executive Order 12866 also considers a rule as a significant regulatory action if it raises novel legal or policy issues. In the interim final rule, FDA determined that the rule was a significant regulatory action as defined by Executive Order 12866. We have determined that this final rule is not a significant regulatory action as defined by Executive Order 12866, because it is not imposing any new requirement on any entity beyond the requirements of the interim final rule.

The scope of the analysis of economic impacts for this final rule is limited to the costs associated with the U.S. agent requirement. For a full discussion of all costs and benefits associated with the registration requirement, see the proposed and interim final rules.

Summary of U.S. Agent Costs

Section 415(a)(1)(B) of the act, as established by the Bioterrorism Act, requires that the owner, operator, or agent in charge of a foreign facility submit in the facility's registration the name of the U.S. agent for the facility. Section 1.232(d) requires that all foreign facility registrations include information about the facility's U.S. agent and implements the statutory requirement. Section 1.227(b)(13) requires that the U.S. agent be a person residing or maintaining a place of business in the United States, who is designated by the owner, operator, or agent in charge of a foreign facility as the facility's agent. FDA recognizes only one U.S. agent per foreign facility for purposes of registration. (See 68 FR 58894 at 58915.) The U.S. agent acts as a communications link between FDA and the facility, and FDA considers providing information to the U.S. agent the same as providing information directly to the foreign facility (Sec. 1.227(b)(13)(ii)). A U.S. agent may submit a facility's registration to FDA if the owner, operator, or agent in charge of the foreign facility authorizes the U.S. agent (if an individual) to register on behalf of the owner, operator, or agent in charge of the facility (Sec. 1.225(c)).

In the economic analyses of the proposed and interim final rules, FDA estimated that more than 90 percent of foreign facilities did not currently have a U.S. agent and that foreign facilities currently without a U.S. agent would require 5 to 15 hours to find an agent and would pay an annual fee of $1,000 (68 FR 5378 at 5396 and 68 FR 58894 at 58943). The $1,000 fee estimated in the proposed rule was an estimate of an average fee for a U.S. agent under FDA regulations for drugs, biologics, and devices (21 CFR parts 207, 607, and 807, respectively), based on fees quoted over the phone and in Internet advertisements. During the period from the publication of the proposed rule to publication of the interim final rule, a number of companies began advertising their services as a U.S. agent for foreign food facilities on the Internet. These companies specified a range of costs, some with discounts for multiple facilities under the same ownership, fees that are a function of the number of shipments each year, or additional fees for registration updates. Based on the requirements in the proposed rule, the lowest fee quoted was $399 for representation by a U.S. agent for 1 year; other U.S. agents charged initial fees between $599 and $1,400. Many of the U.S. agents charged fees for additional registration-related services, such as registration updates or cancellations. Based on these estimates of fees, FDA concluded that $1,000 represented a reasonable estimate of a U.S. agent fee, including registering the foreign facility (68 FR 58894 at 58945). The total first year cost for foreign facilities was estimated to be $306 million, and annual costs were estimated to be $229 million with a U.S. agent fee of $1,000. However, because there was a wide range of fees charged by U.S. agents, FDA also presented in the interim final rule an estimate of the cost of the rule with a U.S. agent fee of $700. Assuming this $700 fee, FDA estimated that the total first year cost for foreign facilities would be $247.6 million and annual costs would be $164.5 million (68 FR 58894 at 58945).

To improve the analysis involving the costs of hiring and retaining a U.S. agent, FDA requested comments on a number of specific components of the cost calculations, as summarized below.

A. The Costs to a Foreign Facility of Hiring and Retaining a U.S. Agent

(Comment 1) FDA received a number of comments about the costs of hiring and retaining a U.S. agent. FDA received estimates of U.S. agent fees ranging from $95 to $1400. Many comments mentioned a very wide range of fees, with differences as large as $800 between the lowest and highest fees cited in a single comment. None of the comments stated whether there were differences in services between the low and high fee agents, other than lower fees for ``farm'' registrations. (The comments did not elaborate on the meaning of ``farm'' registrations.) The majority of the comments that estimated U.S. agent fees mentioned $700 or $750 or included $700 in the range of fees. Some comments also noted that U.S. agents charged an hourly fee for any additional, but unspecified, services provided to the foreign facility. Some comments did not provide a dollar estimate of the U.S. agent fee, but asserted that FDA had underestimated the cost of a U.S. agent, while others claimed that FDA had overestimated the cost of hiring and retaining a U.S. agent.

(Response) In the interim final rule, FDA estimated total costs using average U.S. agent fees of $700 and $1,000. Given the wide range of fees reported in the comments, we now conclude that the average fee for a U.S. agent is probably closer to $700, giving a total first year cost for foreign facilities of $247.6 million and annual costs of $164.5 million. Table 1 presents the revised present value and annualized total costs of the interim final rule for a U.S. agent fee of $700.

Table 1.--Present value and annualized costs over 20 years for a U

Discount Rate	Present Value
7%	$
3%	$

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B. The Number of Foreign Facilities That Have Hired a U.S. Agent or Negotiated Additional Duties From Someone With Whom They Have an Existing Relationship in Response to the Interim Final Rule, Instead of Relying on an Existing Relationship With a Person Who Qualifies as a

U.S. Agent

(Comment 2) FDA did not receive any comments estimating the number of facilities that have hired a U.S. agent or have negotiated additional duties from someone with whom they have an existing relationship. However, we did receive individual comments from facilities and industry representatives reporting that some facilities have hired a new U.S. agent. FDA also received comments reporting that some facilities have used U.S. business partners, U.S. customers, or U.S. brokers as U.S. agents.

(Response) From the comments we received it is clear that foreign facilities are complying with the U.S. agent requirement both by hiring new U.S. agents and by negotiating new duties with someone with whom they have an existing relationship. However, it was not possible to extrapolate from the comments how many facilities were hiring new U.S. agents or utilizing existing relationships. Therefore, FDA has not altered its analysis on this point. (See 68 FR 58894 at 58945.)

C. The Number of Foreign Facilities That Have Ceased Exporting to the United States Because They Have Decided Not to Hire or Retain a U.S. Agent for Registration Purposes

(Comment 3) FDA did not receive any estimates of the number of foreign facilities that have ceased exporting to the United States due to the U.S. agent requirement. FDA did receive comments from governmental agencies and industry groups reporting that some exporters of small value shipments may stop exporting or have stopped exporting to the United States as a result of the cost of hiring a U.S. agent. Other comments stated that they were unaware of any facilities that had stopped exporting to the United States in response to the cost of hiring a U.S. agent.

(Response) Although some comments confirmed the assumption of the interim final rule economic analysis that some facilities would stop exporting to the United States due to costs associated with hiring a U.S. agent, the comments did not provide any information to estimate how many facilities would stop exporting. Therefore, FDA has not altered this portion of its analysis. (See 68 FR 58894 at 58943.)

D. The Distribution of Costs Between Submitting Registrations and Other Services Offered by the U.S. Agent

(Comment 4) FDA received some comments separating the fee paid to a U.S. agent for registration services from fees paid for ongoing services. One comment assumed that the U.S. agent fees would be in addition to any existing fee for services the agent may be providing for the facility. Another comment stated that the fee to register a facility was $350 with an additional charge of $199 per year for acting as a facility's U.S. agent, for a total fee of $549. Most comments that provided a U.S. agent fee did not specify what services were provided for the fee.

(Response) FDA was unable to estimate based on the information in the comments the distribution of costs between submitting registrations and other services offered by the U.S. agent. Therefore, FDA has not altered this portion of its analysis. (See 68 FR 58894 at 58945.)

E. The Assumptions Underlying FDA's Estimates of the Costs of Hiring and Retaining a U.S. Agent

(Comment 5) FDA received comments questioning whether FDA had included all costs associated with hiring a U.S. agent. One comment stated that a firm had spent $1,800 per facility to register its foreign affiliates.

(Response) The comment that provided specific costs of registration included many activities that FDA considered in other parts of its analysis, such as reading and understanding the rule and understanding the implications of the requirements for their business. If only activities related to the U.S. agent were considered, the comment's cost estimates were consistent with FDA's cost estimates for a U.S. agent. (See 68 FR 58894 at 58945.)

(Comment 6) Other comments that mentioned costs stated that FDA had failed to include costs associated with entering into a legal agreement with the U.S. agent.

(Response) FDA did include an estimate of costs to find and hire a U.S. agent in the interim final rule, which would include the costs of establishing an agreement between the U.S. agent and the facility. Accordingly, FDA has not altered its assumptions about costs associated with entering into an agreement with the U.S. agent. (See 68 FR 58894 at 58945.)

F. The Effects on Domestic Small Businesses, if Any, if Some Foreign Facilities Cease Exporting to the United States Due to the U.S. Agent Requirement for Registration

Specifically, FDA invited comment, and the submission of data or other information, on the following: The number of domestic small businesses that have been adversely affected by trading partners that have ceased exporting to the United States due to the U.S. agent requirement for foreign facility registration.

FDA received no comments on the number of U.S. small businesses adversely affected by the loss of their trading partners, and thus, has not altered this portion of its analysis. (See 68 FR 58894 at 58954 to 58955.)

G. The Effects on Domestic Small Businesses, if Any, if Some Foreign Facilities Cease Exporting to the United States Due to the U.S. Agent Requirement for Registration

Specifically, FDA invited comment, and the submission of data or other information, on the following: The costs incurred by these domestic small businesses due to the loss of these trading partners.

(Comment 7) Some comments agreed that there was a potential for some foreign facilities to stop exporting to the United States as a result of the U.S. agent requirement. One comment listed the following several possible consequences for U.S. small businesses if foreign facilities stopped exporting: (1) Need to find new suppliers; (2) inability to supply existing customer base; (3) increase in cost of goods; and (4) increase in cost of goods that may be passed on to U.S. consumers. However, no comments provided any estimate of the costs of these effects.

(Response) In the economic analysis of the interim final rule, FDA considered the impacts on small businesses. Because no comment provided an estimate of the costs to domestic small businesses if some foreign facilities cease exporting to the United States due to the U.S. agent requirement, FDA has not altered its estimate of the number of facilities that will stop exporting to the United States or its expectations of possible consequences for U.S. facilities. (See 68 FR 58894 at 58954 to 58955.)

IV. Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601-612) requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. Because this final rule

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does not make any changes to existing requirements, and thus, does not impose any new costs on facilities, the agency certifies that this final rule will not have a significant impact on a substantial number of small entities. Full analysis of the effect of the registration requirement on small entities is provided in the analysis of economic impacts set out in the preceding analysis of economic impacts and in the preamble to the interim final rule at 68 FR 58894 at 58954.

V. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ``any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003)

Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any one-year expenditure that would meet or exceed this amount.

VI. Federalism Analysis

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency concludes that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions and an estimate of the annual reporting burden were provided in the interim final rule issued October 10, 2003 (68 FR 58894). Included in the estimate was the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. The final rule requires no new information collection. Individuals and organizations may submit comments on the burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the contact person identified in the FOR FURTHER INFORMATION CONTACT section of this document. The information collection provisions in this final rule have been approved under OMB control number 0910-0502. This approval expires October 31, 2006. 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.

VIII. Analysis of Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 1

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

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

PART 1--GENERAL ENFORCEMENT REGULATIONS

PART 20--PUBLIC INFORMATION

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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the interim rule amending 21 CFR parts 1 and 20, which was published at 68 FR 58894 (October 10, 2003) and amended at 69 FR 29428 (May 24, 2004), is adopted as a final rule without change.

Dated: August 28, 2005.
Michael Chertoff,
Secretary of Homeland Security.

Dated: September 20, 2005.
Michael O. Leavitt,
Secretary of Health and Human Services.
[FR Doc. 05-19730 Filed 9-28-05; 1:53 pm]

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U.S. Department of Health and Human Services
Food and Drug Administration

CFSAN(食品安全応用栄養センター)

2003年10月

本文書は、FDAが2003年の10月に発行したFact Sheet on FDA'S New Food Bioterrorism Regulation: Interim Final Rule -- Prior Notice of Imported Food Shipmentsの翻訳です。FDAによる翻訳版文書発行の目的は、幅広い国際社会の読者の役に立つ情報を提供することにあります。内容については、できるだけ正確に翻訳するように努めていますが、翻訳の過程で、類似の表現への置き換えや、不明瞭な表現、不正確な情報が生じる場合があります。FDAの正式文書は英語版となりますのでご了承ください。

FDA（食品医薬品局）新バイオテロリズム規制に関するファクトシート：暫定最終規則—輸入食品出荷に関する事前通告について

2002年の公衆衛生安全保障バイオテロリズム法（バイオテロ法）では、2003年12月12日以降、輸入業者に対してFDA（食品医薬品局）に輸入食品の内容を事前に通告することを義務付けています。暫定最終規則で定めている事前通告情報のほとんどは、従来、食品が米国に到着した際に、米国の輸入業者または代行業者によってCBP（税関国境警備局 Bureau of Customs and Border Protection）に提出されていたものですが、バイオテロ法では、同様の情報をFDAに対して輸入食品が米国に到着する前に提出することが必要になります。FDAでは、輸入食品の到着前にこの情報を検討・査定し、輸入食品の検査が必要かどうかを決定します。FDAとCBPは協力して事前通告の暫定最終規則の施行準備を進めてきました。現在輸入されている食品のほとんどは、CBPのABI/ACS（Automated Broker Interface of the Automated Commercial System）を使用して規則を遵守することができます。事前通告は、2003年12月12日以降、ABI/ACSまたはFDAのPN（事前通告 Prior Notice）システム インターフェイスを使用して提出できるようになります。

事前通告はいつ提出しなければならないのですか？ 食品到着の前、5日を超えない期間内にFDAが電子通知を受理・確認する必要があります。さらに、輸送モードごとに、次の時間数が必要になります。

1) 陸上輸送（道路）の場合は到着の最低2時間前
2) 航空輸送または鉄道輸送の場合は到着の最低4時間前
3) 海上輸送の場合は到着の最低8時間前
4) 手荷物あるいは預入れ荷物として持ち込まれる物品が事前通告の対象になる場合は、輸送モードごとに個別に設定されたタイムフレーム（この場合は、FDAの確認書(Confirmation)が必要になります。）

国際郵便として発送される食品の事前通告は、食品の郵送前にFDAが電子通知を受信・確認する必要があります。（小包にはFDAの事前通告受領確認書（Confirmation of FDA receipt of prior notice）を添付する必要があります。）

事前通告はどのような方法で提出しなければならないのでしょうか？ 事前通告は電子通知で提出してください。FDAでは、輸入食品の事前通告の80%以上が、ABI/ACSシステムを通じて送信されるものと推定しています。国際郵便や、ABI/ACSを使用できない輸送モードを使用した場合、および、連邦食品医薬品化粧品法（Federal Food, Drug, and Cosmetic Act：FFDCA）§801(m)(1)で処理を拒否された物品については、FDAのPNシステム インターフェイス www.access.fda.gov を使用して事前通告を提出してください。2003年12月12日以降、事前通告の提出についてのテクニカル サポートは下記にご連絡ください。

- 米国内からの電話による問い合わせ：TEL 1-800-216-7331 または 301-575-0156
- 米国外からの電話による問い合わせ：TEL 301-575-0156
- ファクシミリによる問い合わせ : FAX 301-210-0247

テクニカル サポートは平日の午前7時から午後11 時（米国東部標準時）までご利用いただけます。電子メールでのお問い合わせは furls@fda.govまでメールをお送りください。 ABI/ACS 送信についてのお問い合わせは お使いのCBPのカスタマー サポートにお問い合わせください。
2003年12月12日以降、CBPシステムと FDAシステムの事前通告情報提出システムは1日24時間、週7日間、毎日使用できるようになります。

ABI/ACS が使用できない場合は、FDAの PNシステム インターフェイスを使って事前通告を提出する必要があります。PN システム インターフェイスが作動していないと思われる場合は、まず、オンラインのヘルプデスクに確認してください。システムが機能していない場合は、暫定最終規則で規定されている事前通告（FDAのWEBサイトに記載予定）を、ファクシミリまたは電子メールで提出する必要があります。事前通告の提出先のファックス番号と電子メールのアドレスについては、FDAのWEBサイト（www.fda.gov）を参照してください。

誰が事前通告を提出しなければならないのでしょうか？ 必要情報についての知識をお持ちの方であれば誰でも提出できます。主な提出者は代行業者、輸入業者、米国代理人などですが、これ以外の方でも提出できます。

事前通告の対象となるのはどのような食品ですか？ 事前通告は人および動物の食べ物として米国に輸入される食品、および輸入予定の食品が対象になります。暫定最終規則で言う食品（Food）とは、連邦食品医薬品化粧品法 §201(f) で定義されている物品、すなわち「人およびその他の動物の食用または飲用となるもの、チューインガム、およびそれらの物品の成分に使用される物品」を指します。

主な食品には次のようなものがあります。

栄養補助食品およびその成分
幼児用粉ミルク
飲料（アルコール飲料およびペットボトル ウォーターを含む）
果物および野菜類
魚および魚介類
乳製品および殻つき卵
食品または食品成分として使用される農業原材料製品(Raw agricultural commodities)
缶詰および冷凍食品
パン製品、スナック フード、キャンディ（チューインガムを含む）
生きている食用動物
飼料およびペットフード

事前通告の適用外となる食品にはどのようなものがありますか？ 事前通告の適用外となる食品は(1) 米国に到着する個人が手荷物あるいは預入れ荷物として持ち込む食品で、個人的に使用される食品（つまり、本人、家族、友人などにより消費されるもので、販売やその他の流通を目的としない食品）、(2) 輸出されるまで到着港の外に出ない食品、 (3) 連邦食用獣肉検査法(Federal Meat Inspection Act)、連邦家禽肉検査法（Poultry Products Inspection Act）、連邦卵検査法(Egg Products Inspection Act)でUSDA(農務省)の専轄に規定されている食肉類、家禽類、卵類、 (4) 個人の住居内で作られ、個人的な贈物として（非業務目的で）個人によって米国内の個人に対して送られる食品

FDAは事前通告受理の確認書を送付しますか？ はい。事前通告情報がきちんと受信された時点で送信者に対して確認書を発行します。

事前通告にはどのような情報が必要なのですか？ 事前通告は電子送信してください。必要な情報は下記の通りです。

- 事前通告の提出者を確認する情報：氏名、電話番号、ファックス番号、電子メールアドレス、会社名および住所など
- 送信者（提出者と送信者が異なる場合）を確認する情報：氏名、電話番号、ファックス番号、電子メールアドレス、会社名および住所など
- 通関タイプおよびCBP 確認情報（CBP Identifier）
- 食品の確認情報：完全なFDAの商品コード、慣用名、一般名、または市場名、最小サイズのパッケージから最大のコンテナまでを使用して記述される推定数量、ロットおよびコード番号、またはその他の食品を確認できる情報（該当する場合）
- 製造者の確認情報
- 原産者の確認情報 （既知の場合）
- FDA 原産国
- 荷主の確認情報（国際郵便の場合を除く）
- 食品の出荷元国（国際郵便の場合は、郵送予定日および郵送国）
- 到着予定情報（場所、日付、時刻）、食品が国際郵便で郵送される場合は、米国受取人（氏名および住所）
- 輸入業者、荷主、最終荷受人の確認情報（国際郵便の場合および米国内で詰め替えが行われる場合を除く）
- 運送業者の確認情報および輸送モード（国際郵便の場合を除く）
- 計画出荷情報（国際郵便の場合を除く）

運送業者の到着の際に事前通告確認書が必要ですか? 確認書を用意しておくのが賢明です。ABI/ACSインターフェイスを使用して提出された事前通告については、ファイル者が事前通知確認番号と「PN受領証（PN Received）」メッセージをABI/ACSを通して取得できるようになります。事前通告がFDAのPNシステム インターフェイスを使って提出された場合は、提出が確認され次第、送信者はオンラインで確認書を受け取ります。入港時の処理が迅速に行えるように、運送業者は確認書のコピー（事前通告確認番号を含む）を手元に用意しておく必要があります。 国際郵便小包の場合は、事前通告確認番号を小包に添付する必要があります。米国に入国する個人の持込みあるいは預入れ手荷物として米国内に持ち込まれる食品の場合は、事前通告通知確認書を食品に添付する必要があります。

不十分な事前通告は修正可能ですか？ 検証に失敗した場合は拒否されますので、内容を修正することができます。

FDA の PN システム インターフェイスにはヘルプとダイアログ形式のフィードバック機能があり、提出者をサポートしてスペリングやその他の入力ミスが最小限に押えられるようになっています。さらに、2003 年 12 月 12 日以降は、オンラインヘルプデスクもご利用いただけるようになります。ヘルプデスクには平日の午前 7 時から午後 11 時まで（米国東部標準時）担当者が待機しています。

確認書は、書面上の情報受理が完了したことを意味します。その後のシステムおよびFDA 担当者による検討の結果、食品到着時に検査が実施される場合があります。

事前通告の確認後に情報の変更があった場合はどうするのでしょうか？もし、確認後に下記の必要情報の一部またはすべてに変更があった場合は、 新しい事前通告を提出する必要があります。

- 事前通告の提出者を確認する情報：氏名、電話番号、ファックス番号、電子メールアドレス、会社名および住所など
- 送信者（提出者と送信者が異なる場合）を確認する情報：氏名、電話番号、ファックス番号、電子メールアドレス、会社名および住所
- 通関タイプおよびCBP 確認情報（CBP Identifier）
- 食品の確認情報（推定数量を除く）
- 製造者の確認情報
- 原産者の確認情報（既知の場合）
- FDA 原産国
- 荷主の確認情報
- 食品の出荷元国（国際郵便の場合は、郵送予定日）
- 食品が国際郵便で郵送される場合は、米国受取人（氏名および住所）
- 輸入業者、荷主、最終荷受人を確認する情報
- 運送業者の確認情報および輸送モード

不適切な事前通告を理由に一度拒否された食品についての事前通告には、追加の情報が必要ですか? はい。不適切な事前通知を理由に拒否された食品の事前通知には、到着地、拒否された食品が保管されている場所、その場所への到着日あるいは到着予定日、その場所における連絡担当者の確認情報が必要になります。

輸入食品の出荷において適切な事前通告をしなかった場合はどうなりますか？ 輸入される食品または輸入予定の食品の事前通告が不適切な場合は、その通関が拒否され、入港地または安全な施設に留置されます。FDA は担当職員向けに、適切な事前通告を指定時間内に提出できなかった場合の強制命令、告訴、除外等の措置および§ 801(m)(1)による拒否、§ 801(1)の留置についての FDA の方針をまとめた施行ガイダンスを用意する予定です。このガイダンスでは、移行期間を設け、その間、教育とコンプライアンス（遵守）の達成に力を入れる予定です。移行期間中にも、FDA は、事前通告違反に対して様々な行動を取る権限がありますが、この予定されている移行期間によって、リソースをより適切な状況に集中させることが可能になります。また、移行期間後に、事前通告の施行要件について、担当職員に対するガイダンスを行う予定です。FDA のガイダンス文書は一般公開される予定で、その公開は『連邦官報(*Federal Register*)』で発表されます。

この暫定最終規則についての追加コメントは受け付けていますか？ この暫定最終規則に対して、FDA は 75 日間のコメント期間を設ける予定です。さらに、この暫定最終規則にコメントされる方々がFDA の支援活動と教育努力の恩恵を受け、システム、タイムフレーム、データ要素などを実際に経験できるように、2004 年の 3 月にさらに 30 日間追加のコメント期間を設ける予定です。この日付は、タイ

ムフレームと関連したFDAおよびCBPによる計画の発行日に合せています。暫定最終規則は定期的に更新されています。更新情報とコメント方法についての情報は下記の電子アドレスからアクセスしてください。http://www.fda.gov/oc/bioterrorism/bioact.html.

コメント期間中の暫定最終規則の施行はどのようにして行われるのですか？ FDAは、最初の暫定最終規則の施行期間中もその後も、公衆衛生の保護を確実なものにする事に努め、同時に、事前通告暫定最終規則の施行について積極的かつ慎重に検討していきます。この事前通告暫定最終規則は2003年12月12日に発効となり、その時点で対象者はこの規則へのコンプライアンスを要求されます。FDAでは、2003年12月12日までに行う予定の、広範な教育・支援活動の後でも、規則の適用対象となる多くの関係者が、規則の内容とコンプライアンスの理解のために手助けを必要とする場合があるかもしれないと考えています。このような理由から、発効に続く最初の数ヶ月は、影響を受ける関係者の理解を深めるよう努力する方針を作成する予定です。FDAでは、近日中に、施行方法についての方向付けをまとめたまとめたコンプライアンス ポリシー ガイドの利用可能通知を発行する予定です。しかしながら、このガイダンスはFDAが食品の安全と保障上の懸念がある場合に検査を行ったり、連邦食品医薬品化粧品法に定められた必要な行動をを取る権限を規制するものではなく、また、CBP（税関国境警備局 Bureau of Customs and Border Protection）局が19 U.S.C. 1595a(b)に定められたペナルティを課したり他の権限のもとに必要な行動を取ることを規制するものでもありません。

本暫定最終規則の特定要求事項についての詳細な情報は暫定最終規則本文を参照してください。暫定最終規則は下記のサイトでご覧いただけます。 http://www.cfsan.fda.gov/~pn/pnfr.html.

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BILLING CODE 4160–01–C

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: Interim final rule; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is issuing an interim final regulation that requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. The interim final rule implements the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which requires prior notification of imported food to begin on December 12, 2003, even in the absence of a final regulation. The interim final rule requires that the prior notice be submitted to FDA electronically via either the Bureau of Customs and Border Protection (CBP) Automated Broker Interface (ABI) of the Automated Commercial System (ACS) or the FDA Prior Notice System Interface (FDA PN System Interface). The information must be submitted and confirmed electronically as facially complete by FDA for review no more than 5 days and no less than 8 hours (for food arriving by water), 4 hours (for food arriving by air or land/rail), and 2 hours (for food arriving by land/road) before the food arrives at the port of arrival. Food imported or offered for import without adequate prior notice is subject to refusal and, if refused, must be held.

DATES: This interim final rule is effective December 12, 2003. Submit written or electronic comments by December 24, 2003.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Deborah Ralston, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6230.

SUPPLEMENTARY INFORMATION:

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I. Background

In the **Federal Register** of February 3, 2003 (68 FR 5428), the Department of Health and Human Services (FDA) and the Department of Treasury (U.S. Customs Service) issued a joint notice of proposed rulemaking requiring submission to FDA of prior notice of human and animal food that is imported or offered for import into the United States. The events of September 11, 2001, had highlighted the need to ensure that FDA had additional tools to help prevent a food-related bioterrorism event or other public health emergency. Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107–188), which was signed into law on June 12, 2002. The Bioterrorism Act includes a provision in Title III (Protecting Safety and Security of Food and Drug Supply), Subtitle A'Protection of Food Supply, section 307, which changes when FDA will receive certain information about imported foods by requiring the Secretary of Health and Human Services (the Secretary), after consultation with the Secretary of the Treasury, to issue an implementing regulation by December 12, 2003, to require prior notification to FDA of food that is imported or offered for import into the United States. Under the Homeland Security Act of 2002 (Pub. L. 107–296), the Secretary of the Treasury has delegated all relevant Customs revenue authorities to the Secretary of Homeland Security who has, in turn, delegated them to the Commissioner of the Bureau of Customs and Border Protection (CBP or Customs). Thus, we are issuing this interim final rule jointly with the Secretary of Homeland Security.

Section 307 of the Bioterrorism Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 801(m) (21 U.S.C. 381(m)) and amending section 301 (21 U.S.C. 331). (In the regulation itself, which is codified in Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act is referred to as "the act." Thus, when the regulation is quoted in this preamble the term "the act" will be used to refer to the Federal Food, Drug, and Cosmetic Act. However, in this preamble we refer to the Federal Food, Drug, and Cosmetic Act as "the FD&C Act" in the preamble to distinguish it from the Bioterrorism Act.)

The Bioterrorism Act also requires FDA to issue regulations requiring certain food establishments to register with FDA (section 305), directs FDA to issue regulations regarding maintenance of certain records (section 306), and grants FDA the authority to administratively detain food (section 303). FDA has published proposed rules implementing section 305 of the Bioterrorism Act (68 FR 5378, February 3, 2003), section 303 of the Bioterrorism Act (68 FR 25242, May 9, 2003), and section 306 of the Bioterrorism Act (68 FR 25188, May 9, 2003). The interim final rule implementing the food facility registration requirements is published elsewhere in this issue of the **Federal Register**.

A. Current Process—Admissibility Determinations Under Section 801(a) of the FD&C Act

Section 801(a) of the FD&C Act sets out current standards and procedures for FDA review of imports under its jurisdiction. Section 801(a) provides for examination of imports and also authorizes FDA to refuse admission of imports that appear, from examination or otherwise, to be, *inter alia*, adulterated or misbranded. When an FDA-regulated product is imported, generally customs brokers submit entry information to CBP on behalf of the importers of record. CBP then provides entry information to FDA to enable admissibility decisions to be made. Under CBP authorities, entry of the merchandise can be made up to 15 days after arrival.

CBP regulations provide for different kinds of entries. Commonly, merchandise is the subject of an entry for consumption or warehouse (*i.e.*, unrestricted, general use) under a basic importation and entry bond at the port of arrival. A warehouse entry is a CBP entry procedure as described in 19 CFR part 144. It allows imported product (with some restrictions) to be entered without payment of duty, provided it is kept in a bonded warehouse and not distributed. CBP authorities also allow for an Immediate Transportation or IT entry of merchandise for transportation under a custodial bond from the port of arrival to another port where the consumption or warehouse entry will be made or the product will be admitted into a foreign trade zone (FTZ) located outside of the port area. In addition, if the merchandise is going to an FTZ in the port area, FTZ admission documents are presented to CBP. Finally, a transportation and exportation (or T&E) entry may be filed if the merchandise is to be transshipped from the port of arrival through the United States to another port for export.

FDA currently receives electronic information about entries from CBP through CBP's ABI of the ACS. FDA receives this information through its Operational and Administrative System for Import Support (OASIS). The entry types currently transmitted through the ABI/ACS interface with OASIS include consumption entries and warehouse entries but not IT entries, T&E entries, or admissions into FTZs. The customs broker or self-filer electronically submits entry information to ABI/ACS, including: The identification of the product by the Harmonized Tariff Schedule (HTS) code; the entry type; the entry number (including both the ACS line number and the FDA line number); the arrival date; the port; the port of unlading; the carrier code; the vessel name and voyage, flight or trip number; importer and ultimate consignee; the quantity; value; country of origin; bill of lading or airway bill number; the manufacturer; the importer of record; and the ultimate consignee. The HTS codes are flagged to indicate which products will require FDA review; all FDA-regulated products are covered, not just foods. The additional information that is currently transmitted through the ABI/ACS interface to FDA includes: The FDA manufacturer; the FDA shipper, the FDA Country of Production (country of origin); the complete FDA product code; a description of the food in common business terms; the quantity for each FDA line, and, as "Affirmations of Compliance," information specific to certain products, such as the Food Canning Establishment (FCE) Number.[1] CBP regulations do not mandate electronic transmission of entry information; therefore, some entries are filed in paper. If a "paper" entry is filed, it is customary for CBP to require that copies of entry documentation by submitted to FDA. The entry documents contain the same information as the electronic filing, typically the information required on CBP's Entry/Immediate Delivery (CF3461), and a copy of the foreign invoice. The paper entries may be presented at the time of arrival or after.

After information is transmitted from ABI/ACS, OASIS performs additional validations on the data. If no corrections from the customs broker or self-filer are needed, it screens the entry information against FDA admissibility criteria. If the FDA electronic review determines that further evaluation of the information or article of food is not necessary, the system transmits a message back through the FDA/CBP interface that the article of food "may proceed without FDA examination." If further evaluation is necessary, FDA staff will review the entry information and may request additional information necessary to make an admissibility determination or may examine or sample the product. Section 801(b) of the FD&C Act provides for the release of FDA regulated products to the importer or owner, under bond, before the FDA admissibility decision is made. Accordingly, FDA examination may take place at a location to which the product has been moved. Because there are no restrictions on movement, the product may be at the border, within the confines of a port, at a public storage facility in the vicinity of the importer, or at the ultimate consignee's warehouse. Finally, if the FDA electronic review indicates that the product appears "by examination or otherwise" to be subject to refusal of admission under section 801(a) of the FD&C Act (*e.g.*, appears to be adulterated or misbranded), the FDA reviewer will evaluate the entry information based on FDA guidance, take appropriate action, and notify the importer as well as the customs broker.

Under current laws and regulations, FDA may receive the information about some food imports some days after the food has arrived in the United States,

[1] Affirmations of Compliance are data elements that a customs broker or self-filer currently uses when transmitting certain information to FDA through ABI/ACS to OASIS. Each provides a mechanism to indicate (or affirm) compliance with a specific FDA regulatory requirement.

has been moved from the port of arrival, and has been delivered to the ultimate consignee. While FDA may ultimately receive electronic entry notification of IT entries when the consumption entry is later filed, FDA does not receive electronic notification with information about food entered for transshipment for export or when the food is admitted to an FTZ.

The admissibility standard in section 801(a) of the FD&C Act largely focuses on whether the article of food appears to have been safely produced, contains no contaminants or illegal additives or residues, and is properly labeled. Section 801(a) provides that an article of food is subject to refusal of admission if it "appears, from physical examination or otherwise': (1) To have been manufactured, processed, or packed under insanitary conditions; (2) to be forbidden or restricted in sale in the country in which it was produced or from which it was exported; or (3) to be adulterated or misbranded. The food adulteration and misbranding provisions (sections 402 and 403 of the FD&C Act) set out most of the FD&C Act's safety and labeling standards for foods.

B. Process After December 12, 2003—Prior Notice Determination Followed by Admissibility Determination

Section 801(m) provides that an article of food is subject to refusal of admission if adequate prior notice has not been provided to FDA. Thus, the refusal standard in section 801(m) focuses in the first instance on whether the requisite information has been provided in a timely fashion, while the refusal standard in section 801(a) focuses on whether the article was safely produced, contains no contaminants or illegal additives or residues, and is properly labeled.

By adding the prior notice requirement to the FD&C Act, Congress, in the Bioterrorism Act, changed when information about FDA-regulated food imports must be provided to FDA and what happens if the information is not provided. The prior notice provisions require that notice must be provided on imported food shipments to FDA before arrival. If adequate notice is not provided, section 801(m) of the FD&C Act provides that the food is subject to refusal, and that refused food must be held until adequate notice is given and may not be delivered to the importer, owner, or consignee. The stated purpose of requiring notice of imported food shipments before arrival in the United States is to enable FDA to conduct inspections of imported food at U.S. ports (see section 801(m)(1) of the FD&C Act). Thus, FDA intends to use prior notice information to make decisions about which inspections to conduct at the time of arrival. Currently, we intend to focus on conducting these inspections when our information suggests the potential for a significant risk to public health.

As explained in greater detail in the following paragraphs, FDA and CBP are coordinating FDA's new prior notice requirements with CBP's and FDA's existing entry requirements to the greatest extent possible. Thus, the interim final rule allows prior notice to be submitted electronically to FDA through either ABI/ACS or the FDA Prior Notice (PN) System Interface. The HTS codes will be flagged within ABI/ACS to indicate which HTS codes contain foods subject to prior notice requirements. In addition, the ABI/ACS interface will provide a new transaction for transmission of prior notice information on IT and T&E entries, and FTZ admissions, *e.g.*, the types of entries of which FDA was not aware or did not know about until many days after arrival in the United States. This will allow for FDA electronic screening and FDA staff evaluation of the information so that FDA can assess, before the food arrives, whether to inspect and to be prepared to conduct that inspection upon arrival.

FDA expects approximately 90 percent of prior notice submissions for all importations of foods to be transmitted by a customs broker or self-filer through the ABI/ACS interface to FDA. FDA estimates that only 10 percent (or less) of the total importations cannot be accommodated by the ABI/ACS interface and, therefore, will be submitted via the FDA PN System Interface.

In addition to requiring submission of the information currently sent to FDA for admissibility determinations, information identifying the grower (if known), the country from which the article is shipped, and anticipated arrival information is also required for prior notice. If all of the prior notice information is transmitted through the ABI/ACS interface, no additional transmission of information for admissibility determinations under section 801(a) of the FD&C Act will be necessary. If prior notice is submitted through the FDA PN System Interface, additional transmission through ABI/ACS may be necessary for CBP purposes and FDA's admissibility evaluation.

Regardless of the mode of transmission, the prior notice information will undergo both a validation process and screening in OASIS for food safety and security criteria. After the validation step is complete, the prior notice will be confirmed by FDA for review and a reply message sent to the transmitter indicating the prior notice has been received and confirmed for FDA review. The form of this reply messaging depends upon the mode of initial transmission: ABI/ACS or FDA PN System Interface. The clock starts for determining if prior notice was timely when this prior notice confirmation message is sent by FDA.

If the FDA system does not indicate that further evaluation of or action on the notice or article of food is necessary for prior notice purposes, the system will transmit a message back through the OASIS to ABI/ACS interface for CBP that the article of food "may be conditionally released under section 801(b) of the act." However, if additional evaluation of the prior notice information is necessary, FDA headquarters staff, operating 24 hours a day, 7 days a week, will review and assess the information and may initiate an examination or other action by FDA or CBP of the article of food at the port of arrival or elsewhere, or in the case of rail shipments, within the confines of the closest appropriate examination site.

In addition, the OASIS system review will determine if further staff evaluation of the article of food is necessary for admissibility determinations under section 801(a) of the FD&C Act (*e.g.*, subject to the guidance in an import alert). If so, FDA staff in the appropriate district office will take action, which, in addition to the review and evaluation of the submitted information or other documentation, could include an examination of the article of food for admissibility purposes. This admissibility examination may take place at the border but may also take place at an examination site, a public warehouse, or other appropriate locations. If FDA determines that refusal under section 801(a) of the FD&C Act is appropriate, it will follow appropriate procedures.

II. Overview of the Interim Final Rule and Significant Changes Made to the Proposed Rule

The highlights of this interim final rule are described briefly in the following paragraphs and are discussed in more detail later in the preamble.

A. "What Definitions Apply to This Subpart?" (Section 1.276 Proposed as § 1.277)

- The term "the act" was not changed.
- The term "calendar day" was not changed.

- The term "country from which the article originates" was added and defined as "FDA Country of Production."
- The term "country from which the article of food was shipped" was revised to "country from which the article is shipped."
- The term "FDA Country of Production" replaces the term "originating country." For an article of food that is in its natural state, the FDA Country of Production is the country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is in its natural state was grown, including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States. For an article of food that is no longer in its natural state, the FDA Country of Production is the country where the article was made; except that, if an article of food is made from wild fish aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in a Territory, the FDA Country of Production is the United States.
- The term "food" has been redefined. The new definition excludes "food contact substances" as defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) and "pesticides" as defined in 7 U.S.C. 136(u).
- The term "grower" has been added to the interim final rule. It means a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.
- The term "international mail" has been added to the interim final rule. The term "international mail" means foreign national mail services, but not express carriers, express consignment operators, or other private delivery services.
- The term "no longer in its natural state" has been added to the interim final rule. The term means that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state 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. However, crops that have been cleaned (*e.g.*, dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of the prior notice interim final rule. Likewise, whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of the prior notice interim final rule.
- The term "port of entry" has been defined, as having the meaning given in 19 CFR 101.1.
- The term "port of arrival" has been added to the interim final rule. The interim final rule defines "port of arrival" to mean "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 the article of food first arrives in the United States."
- The term "registration number" has been added to the interim final rule. Registration number refers to the registration number assigned by FDA under section 415 of the FD&C Act, 21 U.S.C. 350d, and 21 CFR part 1, subpart H.
- The term "shipper" has been added to the interim final rule. The interim final rule defines "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 United States."
- The term "United States" has been added to the interim final rule. It defines "United States" as the Customs territory of the United States, *i.e.*, "the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico."
- The term "you" has been revised to reflect the removal of limitations on who is authorized to submit prior notice.

B. "What is the Scope of This Subpart?" (Section 1.277 Proposed as § 1.276)

This provision has been revised. Section 1.277(a) clarifies that the interim final rule applies to all food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, and includes food for gifts, trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. FTZ. Section 1.277(b) sets out the exclusions from prior notice. It excludes food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States (*i.e.*, for consumption by themselves, family and friends, not for sale or other distribution); food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (*i.e.*, for nonbusiness reasons) to an individual in the United States; food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg 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.*), 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.*).

C. "Who Is Authorized to Submit Prior Notice?" (Section 1.278 Proposed as § 1.285)

This provision has been revised. The interim final rule has been revised to remove the restriction that the submitter be the U.S. importer or purchaser. The interim final rule provides that any person with knowledge of the required information may submit prior notice or have it transmitted on their behalf.

D. "When Must Prior Notice Be Submitted to FDA?" (Section 1.279 Proposed as § 1.286)

This provision has been revised. FDA had proposed that all information required in the prior notice be submitted to FDA no later than 12 noon of the calendar day before the day the article of food arrived at the border crossing in the port of entry. Under the interim final rule, prior notice must be submitted to FDA and confirmed for FDA review no less than 2 hours before arrival by land via road, no less than 4 hours before arrival by air and land via rail, and no less than 8 hours before arrival by water. If the article of food is arriving by international mail, the prior notice must be submitted before the food has been sent to the United States and the parcel must be accompanied by confirmation of FDA receipt of prior notice. With the exception of prior notice for international mail, prior notice may not be submitted more than 5 calendar days before the anticipated date of arrival at the anticipated port of entry. When an article of food that is carried by or otherwise accompanies an individual is subject to prior notice, the prior notice must be submitted within the timeframe established for the mode of transportation, and the food must be accompanied by a copy of the FDA confirmation including the PN Confirmation Number. Because we

reduced the timeframes for submitting prior notice in the interim final rule to the minimum amount of time that we need to meet our statutory responsibility to receive, review, and respond to prior notice submissions, the interim final rule does not provide for amendments or updates to the prior notice. However, as discussed in more detail in section D, FDA and CBP will be actively exploring ways to reduce prior notice timeframes, while fulfilling the Bioterrorism Act mandates.

E. How Must You Submit Prior Notice? (Section 1.280 Proposed as § 1.287)

FDA proposed that prior notice, amendments, and updates be submitted electronically to FDA through the FDA PN System. The interim final rule provides that prior notice must be submitted electronically, in English (except an individual's name, the name of a company, or the name of a street), through either CBP's ABI/ACS or the FDA PN System Interface. All information must be submitted using the Latin (Roman) alphabet. The interim final rule eliminates submission of duplicative information to FDA by those who can file import entry information through ABI/ACS. FDA and CBP are upgrading and interfacing their respective electronic systems so that information required for prior notice can be submitted through ABI/ACS. Information required by the interim final rule also can be submitted through the FDA PN System Interface. The interim final rule also provides that if a customs broker's of self-filer's system is not working or if ABI/ACS is not working, prior notice must be submitted through the FDA PN System Interface. If the FDA PN System Interface or OASIS is not operating, prior notice information must be submitted by e-mail, or by fax to the FDA, but not in person.

F. What Information Must Be in a Prior Notice? (Section 1.281 Proposed as § 1.288)

The interim final rule requires the following information to be submitted in the prior notice:

- Submitter (name of individual, individual's telephone, fax, e-mail, name/address of submitting firm);
- Transmitter, if different than submitter (name of individual, individual's telephone, fax, e-mail, name/address of transmitting firm);
- Entry type;
- CBP entry identifier, such as the CBP entry number or in-bond number;
- The identity of the article of food as follows: The complete FDA product code; the common or usual name or market name; the estimated quantity described from largest container to the smallest package size; and the lot or code numbers or other identifier of the food if required by the FD&C Act or FDA regulations;
- Manufacturer, for food no longer in its natural state (name, address, registration number, except that the requirement to provide registration number does not apply to an article of food that is imported for transshipment or other export;
- Grower, if known, for an article of food that is in its natural state (name and growing location);
- Consolidator may voluntarily be provided by the submitter, at the submitter's option, if the grower is not known (name and address);
- FDA Country of Production;
- Shipper (name, address, registration number; except that the requirement to provide registration number does not apply to an article of food that is imported for transshipment or other export;
- The country from which the article is shipped;
- Anticipated arrival information (port of arrival and crossing location within that port, date, and time) or, if the food is imported by international mail, the anticipated date of mailing;
- The name and address of the importer, owner, and ultimate consignee, unless the shipment is imported or offered for import for transshipment through the United States under a T&E entry, or, if the food is imported by international mail, the U.S. recipient (name and address);
- Mode of transportation;
- Carrier (SCAC/Standard Carrier Abbreviated Code or IATA/International Air Transportation Association code or, if codes are not applicable, the name and country of the carrier) (except for food imported by international mail);
- Planned shipment information as applicable (except for food imported by international mail), including 6-digit HTS code; and
- If the article of food is under hold for failure to submit prior notice or submit an adequate prior notice, the location where it is being held, the date the article has arrived or will arrive at the location, and the name of a contact individual at the location.

FDA eliminated from the interim final rule telephone and fax numbers and e-mail addresses for most firms, entry line numbers, trade or brand name, and consumption entry information (port of entry/anticipated date of entry for Customs purposes). FDA revised information requirements regarding the quantity, lot/code identifier, manufacturer, grower, and carrier in the interim final rule. FDA added mode of transportation and planned shipment information to the interim final rule. In the interim final rule, registration numbers are required only for manufacturer and shipper, if the shipper is a facility that is required to be registered under section 415 of the FD&C Act (21 U.S.C. 350d) and 21 CFR part 1, subpart H, for that article of food. For clarity, the interim final rule segregates the information required for food arriving by international mail (§ 1.281(b)) and also segregates the information required for food refused under section 801(m) of the FD&C Act (§ 1.281(c)).

Table 1A, which appears later in this preamble, describes the information required in prior notice.

G. "What Must You Do If Information Changes After You Have Received Confirmation of a Prior Notice From FDA?" (Section 1.282 Proposed as §§ 1.289 to 1.294)

This provision has been revised in the interim final rule. The proposed rule allowed one product identity amendment for certain product identity information that was not known at the time of submission and for arrival updates. Product identity amendments could be submitted up to 2 hours before arrival at the border. Arrival updates were required if the port of entry changed or if the time of arrival was expected to be more than 3 hours later or 1 hour earlier than the anticipated time of arrival.

The interim final rule does not provide for product identity amendments or arrival updates. Because we reduced the timeframes for submitting prior notice in the interim final rule to the least amount of time that we need to meet our statutory responsibility to receive, review, and respond to prior notice submissions, the interim final rule does not provide for amendments or updates. The interim final rule requires that if required information (except estimated quantity, anticipated arrival information including the anticipated date of mailing, and planned shipment information) changes after FDA has confirmed prior notice for review, the prior notice should be cancelled and a prior notice with the correct information must be submitted.

H. "What Happens to Food That Is Imported or Offered for Import Without Adequate Prior Notice?" (Section 1.283 Proposed as § 1.278)

FDA revised the proposed rule to provide for more specificity, to clarify the status of refused food, and to provide a mechanism for FDA review after refusal. In the interim final rule, FDA identifies the consequences and procedures for the following situations:

1. Inadequate Prior Notice (No, Inaccurate, or Untimely Prior Notice)

Unless immediately exported with CBP concurrence, an article of food that is refused for inadequate prior notice shall be held in accordance with § 1.283.

2. Status and Movement of Refused Food

- A refused food is considered general order merchandise under section 490(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1490(a)).
- The refused food must be moved under an appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved within 24 hours of refusal. If the food is held, it must be taken directly to the designated location within 48 hours, shall not be entered, and shall not be delivered to any importer, owner, or ultimate consignee.

3. Segregation of Refused Foods

If a refused food is part of a shipment that contains other articles, the refused food may be segregated from the rest of the shipment within the port of arrival or at the hold location if different.

4. Costs

Neither FDA nor CBP are liable for transportation, storage, or other expenses resulting from refusal.

5. Export After Refusal

A refused food may be exported with CBP concurrence and supervision (unless CBP or FDA has administratively detained or seized the article under other authority).

6. No Post-Refusal Submission or Request for Review

If no prior notice submission or request for FDA review is submitted in a timely fashion after a food is refused, the food will be dealt with as set forth in CBP regulations relating to general order merchandise. It may only be sold for export or destroyed as agreed to by CBP and FDA.

7. Food Carried by or Otherwise Accompanying an Individual

For food that is not for personal use, if the article of food is refused because prior notice is inadequate or the individual cannot provide FDA or CBP with a copy of the PN confirmation, the article may be held at the port or exported. If the individual cannot make arrangements for holding or export, the food may be destroyed.

8. Post-Refusal Prior Notice Submissions

If an article of food is refused for no or inaccurate prior notice, the prior notice must be submitted or corrected and resubmitted to FDA and confirmed by FDA for review.

9. FDA Review After Refusal

After refusal, only the submitter, importer, owner, or ultimate consignee may submit a written request asking FDA to review whether the article is subject to the requirements of this subpart under § 1.276(b)(5) and § 1.277, or whether the prior notice submission is accurate. The interim final rule also sets out procedures and timeframes for the review process.

10. International Mail

In the case of food arriving by international mail, if prior notice is inadequate or if the PN Confirmation Number is not affixed, the article will be held by CBP for 72 hours for FDA inspection and disposition. If refused and there is a return address, the parcel may be returned to sender. If there is no return address or the food in the shipment appears to present a hazard, FDA may dispose of or destroy the parcel at its expense. If FDA does not respond within 72 hours of the CBP hold, CBP may return the parcel back to the sender or, if there is no return address, destroy the parcel, at FDA expense.

11. Prohibitions on Delivery and Transfer

A refused article of food may not be delivered outside of the port where the article is held and may not be delivered to the importer, owner, or ultimate consignee or transferred by any person from the port or secure facility until FDA has examined the prior notice, determined the adequacy of the prior notice, and notified CBP and the transmitter that the article is no longer refused. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

12. Relationship to Other Admissibility Provisions

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

I. What Are the Other Consequences of Failing to Submit Adequate Prior Notice or Otherwise Failing to Comply With This Subpart? (Section 1.284 Proposed as § 1.278)

The interim final rule provides that failure of a person who imports or offers to import an article of food to submit prior notice is a prohibited act under section 301(ee) of the FD&C Act (21 U.S.C. 331(ee)) and sets out the civil, criminal, and debarment actions that the United States may bring against persons who are responsible for the commission of a prohibited act.

J. What Happens to Food That Is Imported or Offered for Import From Unregistered Facilities That Are Required to Register Under 21 CFR Part 1, Subpart H? (Section 1.285)

The interim final rule also sets out the consequences concerning what happens at the border to food from facilities that are not registered as required under section 415 of the FD&C Act and 21 CFR part 1, subpart H. These are similar to provisions in the interim final rule for dealing with food that is refused for inadequate prior notice.

Table 1A of this document shows the information required by sections 1.281(a), (b), and (c). For clarity, the table also identifies under what circumstances certain information is not required, *e.g.*, registration numbers when the article of food is imported or offered for import for transshipment, storage and export, or further manipulation and export.

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Table 1A.--Prior Notice Information Required by Category

Information	Transshipment, Storage and Export, Manipulation and Export	Carried by or Accompanies an Individual	Food Not in Natural State	Food in Natural State	Mail	After Section 801(m) Refusal
§1.281 paragraph(s)	(a) and (c)	(a) and (c)	(a), (b), and (c)	(a), (b), and (c)	(b)	(c)
Submitter	Y	Y	Y	Y	Y	Y
Transmitter	Y	Y	Y	Y	Y	Y
Entry Type	Y	Y	Y	Y	Y	Y
Entry Identifier	Y	Y	Y	Y	Y	Y
FDA Product Code	Y	Y	Y	Y	Y	Y
Common, usual, or market name	Y	Y	Y	Y	Y	Y
Estimated Quantity	Y	Y	Y	Y	Y	Y[2]
Lot/Code #	Y	Y	Y	N	Y	Y
Manufacturer	Y	Y	Y	N	Y/N	Y
Manufacturer Registration #[1]	N	Y	Y/N	N	Y/N	Y
Grower, if known	Y	Y	N	Y	Y	Y
Cty of Production	Y	Y	Y	Y	Y	Y
Shipper	Y	Y	Y	Y	Y	Y
Shipper Registration #[1]	N	Y	Y	Y	Y	Y
Country Shipped	Y	Y	Y	Y	Y	Y
Port of Arrival	Y	Y	Y	Y	N	Y[2]
Date of Arrival	Y	Y	Y	Y	N	N
Time of Arrival	Y	Y	Y	Y	N	N
Date of Shipment	N	N	N	N	Y	N
Importer	N	Y	Y	Y	N	Y
Owner	N	Y	Y	Y	N	Y
Ultimate Consignee	N	Y	Y	Y	N	Y
U.S. Recipient	N	N	N	N	Y	Y
Mode of Transport	Y	N	Y	Y	N	Y
Carrier	Y	Y	Y	Y	N	Y
Airbill or Bill(s) of Lading	Y	N	Y	Y	N	Y[2]
Vessel/Voyage	Y	Y	Y	Y	N	Y[2]
Flight #	Y	Y	Y	Y	N	Y[2]
Trip #	Y	Y	Y	Y	N	Y[2]
Container #	Y	N	Y	Y	N	Y[2]
Car #	Y	N	Y	Y	N	Y[2]
License Plate #	Y	Y	Y	Y	N	Y[2]
HTS code	Y	Y	Y	Y	N	Y
Hold Location	N	N	N	N	N	Y

[1] Registration numbers are required only if the firm is required to register for a facility associated with the article of food under section 415 of the FD&C Act, 21 U.S.C. 350d and 21 CFR part 1, subpart H; if registration number is provided, city and country can be provided instead of the full address.

[2] After arrival, therefore, no longer anticipated or planned.

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III. Comments on the Proposed Rule

FDA received approximately 470 timely responses containing one or more comments in response to the proposed rule. To make it easier to identify comments and responses to the comments, the word "Comments" will appear before the description of the comment, and the word "Response" will appear before our response. A summary follows which includes a description of the appropriate section in the interim final rule.

A. General Comments and Outreach

(Comments) Some comments suggest revision of section 307 of the Bioterrorism Act. Other comments recommend that FDA repropose the rule or not implement the rule.

(Response) Changes to the statute are beyond the scope of this rulemaking. Postponing implementation of or not implementing the rule is not viable under section 307(c) of the Bioterrorism Act, which not only directs the FDA to "promulgate proposed and final regulations for the requirement of providing notice in accordance with section 801(m)" by December 12, 2003, but also provides that an 8 hour prior notice requirement takes effect on this date even if FDA has not promulgated regulations that are in effect by this deadline. However, we are publishing this rule as an interim final rule and are, accordingly, soliciting comment on its provisions.

(Comments) Most comments generally support the protections of the food supply provided under the Bioterrorism Act. Although comments recommend that the final rule be amended to reflect more accurately industry practices, other comments suggest the regulation should be strengthened to ensure that FDA has all of the information required to identify foods that may pose a health or security threat. Some comments argue that FDA already has access to information currently submitted to CBP to allow for identification and quick interdiction of foods that may pose a health or security threat. Other comments question how the final rule would enhance FDA's ability to improve food safety and whether the benefits outweigh the costs.

(Response) Through section 307 of the Bioterrorism Act, Congress amended the FD&C Act to require the submission to FDA of a notice providing information regarding food before its importation into the United States. Congress also required FDA to issue implementing regulations to be effective not later than December 12, 2003. Thus, a postponement of the rule is not an option. Although FDA is aware that the prior notice regulation will affect industry, Congress determined the need for prior notice by passing the Bioterrorism Act. Prior notice of imported food will give FDA better information about the food earlier, enabling FDA to review and respond to the information before the arrival of the food at the border. Prior notice also will give FDA information with which it will be able to better focus its inspection resources. Section V of this preamble, Analysis of Economic Impacts, discusses the benefits of this interim final rule in detail. To address many of the concerns raised by the comments, FDA has made significant modifications in the interim final rule. However, we are publishing this rule as an interim final rule and are, accordingly, soliciting comment on its provisions.

(Comments) Some comments ask that FDA provide clear guidance and training to industry and agency field personnel about the procedures for implementing the regulation.

(Response) FDA conducted extensive outreach on the proposed prior notice rule, including having relevant FDA staff attend 6 international meetings and over 100 domestic meetings to ensure that affected parties were aware of the Bioterrorism Act prior notice requirements. On January 29, 2003, FDA held a public meeting (via satellite downlink) to discuss both the registration and prior notice proposed rules (*see* 68 FR 1568, January 13, 2003) or *http://www.accessdata.fda.gov/scripts/oc/ohrms/advdisplay.cfm.* Nearly 1,000 participants in North and South America and the Caribbean viewed that live broadcast. The meeting was later re-broadcast to Europe, Asia, Africa, and the Pacific. FDA has also posted transcripts of the broadcast in English, French, and Spanish on the agency's Web site.

FDA plans similar outreach efforts directed to both domestic and international stakeholders after publication of the interim final rule implementing the registration and prior notice provisions of the Bioterrorism Act. Outreach will include many methods of communication:

- Dissemination of materials to guide affected domestic and international food facilities through the new processes established to implement the registration and prior notice requirements;
- Domestic outreach meetings to State regulators and industry;
- A satellite downlink video broadcast and a series of videoconferences to various regions of the world;
- Materials and events for the media;
- International outreach to food trading partners;
- Presentations by FDA officials and exhibits at professional and trade conferences and meetings to inform industry and state and local government representatives of the new requirements; and
- Cooperative arrangements with CBP and other Federal agencies to ensure that information on the interim final regulations and their requirements is disseminated to affected companies and individuals.

More specifics regarding each of these will be included in FDA's Web site at *http://www.fda.gov.* In addition, FDA also plans training in new or revised procedures for its field personnel, as well as CBP field personnel. FDA will also provide guidance on enforcement to its staff containing the agency's policies on injunctions, prosecution, and debarment related to failure to provide timely and accurate prior notice, as well as the agency's policies regarding refusals under section 801(m)(1) of the FD&C Act and holds under section 801(l). As described in greater detail later, FDA intends to include a transition period in this guidance, during which it will emphasize education to achieve compliance. Guidance documents are available to the public, and FDA will shortly publish a notice of availability in the **Federal Register.**

FDA will notify the World Trade Organization (WTO) of this interim final rule. Shortly after publication of this interim final rule, FDA will begin disseminating at U.S. ports flyers and posters summarizing the new requirements and informing representatives of affected entities how to provide prior notice to FDA. Online assistance and a help desk will be available when the interim final rule becomes effective.

B. Foreign Trade Issues

(Comments) Some comments questioned the consistency of the proposed regulation with U.S. obligations under various WTO agreements, NAFTA, and other international agreements.

(Response) FDA is aware of the international trade obligations of the United States and has considered these obligations throughout the rulemaking process for this regulation and the interim final regulation is consistent with these international obligations.

(Comments) Some comments asserted that the proposed regulation is burdensome, confusing, costly, disproportionate, discriminatory, and will have a negative impact on foreign trade.

(Response) In drafting the proposed rule, FDA considered how best to structure the proposed rule consistent with the statutory mandates of the Bioterrorism Act and, at the same time, to reduce the costs associated with compliance. As discussed in more detail in the following paragraphs, FDA has carefully considered comments received regarding the burden imposed by the proposed rule, including its effects on international trade. Furthermore, based on the comments received on the proposed requirements, FDA has made a number of significant changes that minimize the impact of prior notice requirements on the food industry. These changes include removing restrictions on who can submit prior notice; allowing submission to be made either through ABI/ACS (the existing mechanism for filing entry information with CBP) or the FDA PN System Interface (the FDA PN Web system described in the proposed rule); reducing the timeframes for submission of prior notice and tying them to mode

of transport; and streamlining the information requirements.

C. "What Definitions Apply to This Subpart?" (Section 1.276 Proposed as § 1.277)

1. The Act (§ 1.276(a))

The proposed rule defined "the act" as the Federal Food, Drug, and Cosmetic Act. The proposed rule also applies the definitions of terms in section 201 of the act (21 U.S.C. 321) to such terms as used in the proposed rule.

(Comments) FDA did not receive comments on the definition of "the act."

(Response) We did not change the definition in the interim final rule. We have clarified that the definitions in the FD&C Act do not apply if a term is defined differently in the interim final rule.

(Interim final rule) Section 1.276(a) of the interim final rule defines "the act" as the Federal Food, Drug, and Cosmetic Act. Section 1.276(b) provides the definitions in the FD&C Act apply unless a term is defined differently in the interim final rule.

2. Calendar Day (§ 1.276(b)(1))

The proposed rule defined "calendar day" as "every day shown on the calendar."

(Comments) FDA did not receive comments on the definition of "calendar day."

(Response) We did not change the definition in the interim final rule.

(Interim final rule) "Calendar day" is defined in § 1.276(b)(1) of the interim final rule as "every day shown on the calendar."

3. Country From Which the Article Originates (§ 1.276(b)(2))

Section 801(m)(1) of the FD&C Act requires that "the country from which the article originates" be identified in a prior notice. The proposed rule used the term "originating country" and defined it as "the country from which the article of food originates."

(Comments) Comments were received on the proposed definition of "originating country." These comments are addressed under "FDA Country of Production," which is the term that FDA has chosen in the interim final rule to replace "originating country."

(Response) The term "the country from which the article originates" has been added to the interim final rule to refer back to the statutory language.

(Interim final rule) "Country from which the article originates" is defined as "FDA Country of Production."

4. Country From Which the Article Is Shipped (§ 1.276(b)(3))

The proposed rule defined "country from which the article of food was shipped" as "the country in which the article of food was loaded onto the conveyance that brings it to the United States." A conveyance is the means of transportation, *e.g.*, ship, truck, car, van, plane, railcar, *etc.*, not the shipping container that can be moved from a ship to a truck to a train. FDA requested comment on whether the phrase "country from which the article of food was shipped" should include the countries of intermediate destination.

(Comments) Several comments support identifying countries of intermediate destination, noting that it would be desirable to have this information to support product tracing. One states that even if a food product were merely shipped through another country without further manufacturing/processing, the potential for tampering would still exist. This comment is concerned that, without information on every intermediate country, FDA would lack the ability to trace food for potential contamination back through the distribution chain. Another comment supports providing the countries of intermediate destination. It states that, except in the case of sealed containers, the manufacturer cannot control manipulation that occurs in countries of intermediate destination.

Several comments state that the information required in a prior notice should not include countries of intermediate destination. Other comments note that: An imported article may pass through a number of ports or stops in a variety of countries and never be unloaded; a U.S. importer in most cases has no control of which ports or stops a carrier may make; and exporters cannot guarantee which ports the ship will enter or pass through on its way to a U.S. port. Another comment states the information would not be necessary for sealed containers because alteration or absence of a seal alerts the owner to tampering, but it may be necessary for bulk or unpackaged products. Most of the comments that object conclude that submission of additional countries of intermediate destination would be unreasonable and burdensome and would not improve the safety and security of the food supply.

(Response) Section 801(m)(1) of the FD&C Act uses the singular "country" when it directs submission of the identity of the country from which the article is shipped, not the plural "countries." Thus, FDA has concluded that the text of the statute dictates that the definition be singular. The interim final rule thus retains the proposed definition of the term "country from which the article was shipped."

(Comments) One comment states that the proposed definition of "country from which the article of food was shipped" is clear and suggests that it be maintained. Several commenters suggest that "country from which the article of food was shipped" should be defined as the country from which the goods were "exported" to the United States as that phrase is used in the CBP regulations defining "country of export."

Other comments suggest that FDA's definition failed to take into account the following considerations: That ocean and air carriers routinely use "feeder" vessels/aircraft to move cargo from the country of origin to a "gateway" for transfer to a larger vessel or aircraft that will transport the cargo to its final destination; and that ocean vessels frequently discharge containers destined for the United States in Canada where they are transferred to a motor carrier for transport to the United States. The comments conclude that the proposal, if implemented, would confuse importers and require them to attempt to obtain the cargo routing from master carriers. They suggest that FDA require instead the reporting of the last country in which a product was stored if that is different from the country in which it was produced (the country of production).

(Response) Section 801(m)(1) of the FD&C Act requires that prior notice submissions identify "the country from which the article is shipped." "Country of export" is not a term formally defined in CBP's regulations.

We acknowledge that food may pass through more than one country before it reaches the United States. However, we do not believe that this practice changes the definition dictated by the statutory language. Several examples may be helpful. In one scenario, a shipper in country A arranges for a food manufactured in country B to be transported to the United States via country C. The food arrives in country C on an ocean vessel and is transferred to a truck that brings it to the U.S. port of arrival. In this first scenario, the country from which the article is shipped is country C.

In a second scenario, a shipper in country A arranges for a food manufactured in country B to be transported to the United States by a ship that is loaded in country B but stops in country C and then continues to the United States where the food is discharged. In this second scenario, the country from which the article is shipped is country B. In a third scenario, if the food was transferred to a different vessel in country C, the country from which the article is shipped is country C.

(Interim final rule) Section 1.276(b)(3) of the interim final rule defines "country from which the article is shipped" as "the country in which the article of food is loaded onto the conveyance that brings it to the United States." We changed the term from "country from which the article was shipped" to "country from which the article is shipped" to accurately reflect the language of the statute.

5. FDA Country of Production and Originating Country (§ 1.276(b)(4))

The proposed rule defined "originating country" as "the country from which the article of food originates," which means the country where the article of food was grown and harvested, or if processed, where the article of food was produced.

(Comments) Many comments regarding the definition of "originating country" suggest that FDA use the "country of origin" definition used by CBP, or the standard rules of origin used by CBP, USDA, and associations such as the WTO.

(Response) Section 801(m)(1) of the FD&C Act requires prior notice submissions to FDA identify "the country from which the article originates."

We have not changed the definition of "originating country" to align it with "country of origin" as that term is defined by CBP. CBP defines "country of origin" at 19 CFR 134.1(b) as follows:

> the country of manufacture, production, or growth of any article of foreign origin entering the United States. Further work or material added to an article in another country must effect a substantial transformation in order to render such other country the "country of origin" within the meaning of this part; however, for a good of a NAFTA country, the NAFTA Marking Rules will determine country of origin.

In rulings, CBP has further defined "country of origin" and substantial transformation to identify the country of growth of the main ingredient in a processed food rather than the country of production of "the *article [of food]*" (emphasis added) in the form it is being imported into the United States. For example, a CBP ruling identified the country of origin as the United States where beans were rehydrated and canned in the Dominican Republic, but grown and dried in the United States (Ref. 1). For purposes of the prior notice provisions of the FD&C Act, the "article of food" is canned beans, not dried beans. From a food safety standpoint, FDA is most interested in knowing where the article of food was processed and canned. We believe that it best serves the language and the purposes of section 801(m)(l) of the FD&C Act to define the term to focus on the country of production of the specific article of food that is being shipped to the United States. To avoid confusion between FDA's prior notice requirements and CBP requirements, the interim final rule uses the term "FDA Country of Production" instead of the term "originating country" or "country from which the article originates." "FDA Country of Production" is already familiar to customs brokers and self-filers using ABI/ACS interface with OASIS.

(Comments) One comment suggests that "EU" (European Union) be acceptable for use as an originating country.

(Response) FDA disagrees. Section 801(m) of the FD&C Act requires identification of "the *country* from which the article originates" (emphasis added). Accordingly, for purposes of this provision, each sovereign country must be identified when declared as part of the prior notice submission.

(Comments) Several comments suggest that the definition of "country of origin" for fish be the country in which the vessel is flagged or in which the fish was last processed. Another comment asks FDA to use the definition of "country of origin" being used by USDA's Agricultural Marketing Service for fish and seafood.

(Response) We generally agree. The proposed rule relied in part on USDA's proposed definition as set out in USDA guidance published in the **Federal Register** on October 11, 2002, and is based on the Farm Security and Rural Investment Act of 2002 (commonly known as the 2002 Farm Bill), as amended. As set out in § 1.276(b)(4) of the interim final rule, if an article of food is wild fish that is still in its natural state and was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. If the article of food is made from wild fish aboard a vessel, the FDA Country of Production is the country in which the vessel is registered.

(Comments) Several comments express concern that the proposed definition, "[o]riginating country means the country from which the article of food originates," does not take into consideration the producer, processor, vessel or common carrier feeder and consolidation practices in which components of the shipment may be composites or commingled from more than one country. One comment asks that FDA describe when the country of canning would be the originating country, and when it would not. One comment suggests that decaffeinating or blending coffee be considered processing and that decaffeinated or blended coffee be considered as processed food for the purposes of prior notice.

(Response) Some of these comments appeared to confuse the proposed definition of "country from which the article of food was shipped" with the proposed definition of "originating country," another reason why we decided to use the term "FDA Country of Production." As explained above in the discussion of "the country from which the article is shipped," the two countries will sometimes be different. When determining which country is the FDA Country of Production, the focus should be on the production of the specific article of food. For example, if the article of food is raw, whole, unpeeled carrots, the FDA Country of Production is the country where the carrots were grown and harvested. If the article of food is raw peeled and chopped carrots or canned carrots, the FDA Country of Production is the country where the carrots were peeled and chopped or canned. As a general matter, for canned foods, the FDA Country of Production should be the country where food was canned. Similarly, we consider decaffeinated coffee to be no longer in its natural state and the FDA Country of Production would be the country in which the coffee was decaffeinated.

(Interim final rule) Section 1.276(b)(4) of the interim final rule defines the "FDA Country of Production" for an article of food that is in its natural state, as country where the article of food was grown, including harvested or collected and readied for shipment to the United States. If an article of food is wild fish, including seafood, that was caught or harvested outside the waters of the United States by a vessel that is not registered in the United States, the FDA Country of Production is the country in which the vessel is registered. For an article of food that is no longer in its natural state, the FDA country of production is defined as the country where the article was made; except that, if an article of food is made from wild fish, including seafood, aboard a vessel, the FDA Country of Production is the country in which the vessel is registered. If an article of food that is no longer in its natural state was made in

a Territory, the FDA Country of Production is the United States.

6. Food (§ 1.276(b)(5))

The proposed rule defined "food" as having the meaning given in section 201(f) of the FD&C Act. The proposed rule provided examples of food including:

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 (such as hogs and elk), bakery goods, snack foods, candy, and canned foods.

a. *Food packaging and other food contact substances.*

(Comments) We received several comments on the subject of food contact substances, including packaging. The comments ask that FDA clarify the definition of "food" because the proposed rule included as examples of food not only those items traditionally understood as food, but also items that come into contact with and may migrate into food during processing or packaging. In particular, the comments ask that food packaging and components of food packaging, other food contact articles (such as food processing equipment and components of such equipment, glassware, dishware, cutlery, kitchen appliances), and so-called indirect additives (including those applied to food contact surfaces) be excluded from the final rule's definition of "food."

In support, the comments contend the legislative history of the prior notice provisions establish that Congress did not intend to apply prior notice requirements to these substances even though they can be food within the meaning of section 201(f) of the FD&C Act. In addition, some point to language in section 415 of the FD&C Act (21 U.S.C. 350d) relating to registration and language in section 414(b) of the FD&C Act relating to recordkeeping (21 U.S.C. 350c). Finally, some comments argued that an overly broad definition of "food" would dilute the government's resources, thereby hampering the government's opportunity to achieve the protective goals of the Bioterrorism Act.

(Response) We expressly included food packaging and other food contact materials in the proposed definition, with the result that prior notice would have been required for food packaging and other food contact materials and their components (see 68 FR 5428 at 5430). The breadth of the proposed definition of "food" was based on both the statutory definition in section 201(f)(3) of the FD&C Act, which defines articles used as components of food as "food," as well as the case law interpreting the definition, including *Natick Paperboard* v. *Weinberger,* 525 F.2d 1103 (1st Cir. 1975) (paperboard containing PCBs intended for food use is adulterated food; *U.S.* v. *Articles of food * * * 688 Cases * * * of Pottery (Cathy Rose),* 370 F. Supp. 371 (E.D. Mi. 1974) (ceramic pottery that leaches lead is adulterated food).

The comments on food contact substances raise the question of what Congress intended "food" to mean for purposes of prior notice. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? ("*Chevron* step one") *Chevron, U.S.A., Inc.* v. *NRDC, Inc.,* 467 U.S. 837, 842 (1984). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young* v. *Community Nutrition Institute,* 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent (*Chevron,* 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of "food," FDA may define "food" in a reasonable fashion ("*Chevron* step two"); *Chevron,* 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 132 (2000)).

The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did not speak directly and precisely to the meaning of "food." As noted, the FD&C Act has a definition of "food" at section 201(f). It may be a reasonable assumption that, when the term "food" is used in the FD&C Act, section 201(f) applies. However, although there may be "a natural presumption that identical words used in different parts of the same act are intended to have the same meaning [citation omitted], * * * the presumption is not rigid * * *." (*Atlantic Cleaners & Dyers, Inc.* v. *U.S.,* 286 U.S. 427, 433 (1932); (*accord: U.S.* v. *Cleveland Indians Baseball Co.,* 532 U.S. 200, 213 (2000)). Thus, the same word may be given different meanings, even in the same statute, if Congress intended different interpretations or if such different interpretations are reasonable (at step 2) (*Atlantic Cleaners & Dryers, Inc., supra*).

Even before the Bioterrorism Act amendments, the term "food" was not defined identically throughout the FD&C Act. For example, in construing the parenthetical "(other than food)" in section 201(g)(1)(C) of the FD&C Act, the Seventh Circuit Court noted that Congress meant to exclude only "articles used by people in the ordinary way that most people use food—primarily for taste, aroma, or nutritive value" and not all substances defined as food by section 201(f) (*Nutrilab, Inc.* v. *Schweiker,* 713 F.2d 335, 338 (7th Cir. 1983)). Similarly, section 409(h)(6) of the FD&C Act defines a "food contact substance" as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding *food* if such use is not intended to have any technical effect in *such food*" (emphasis added). This definition makes sense only if "food" in this context excludes materials that contact food because components of food contact materials are plainly intended to have a technical effect in such materials.[2]

Thus, in this larger statutory context, FDA has evaluated section 801(m) of the FD&C Act to determine whether the meaning of the word "food" is ambiguous. In conducting this *Chevron* step one analysis, all of the traditional tools of statutory interpretation are available to determine whether the language Congress used is ambiguous (*Pharmaceutical Research & Manufacturers of America* v. *Thompson,* 251 F. 3d 219, 224 (D.C. Cir. 2001)). Beginning with the language of the statute, in section 801(m) of the FD&C Act, "food" is used to describe which subset of FDA-regulated articles are subject to prior notice:

> In the case of an article of *food* that is being imported or offered for import into the United States, the Secretary, after consultation with the Secretary of the Treasury, shall by regulation require, for the purpose of enabling such article to be inspected at ports of entry into the United States, the submission to the Secretary of a notice * * * (emphasis added).

The Bioterrorism Act is silent as to the meaning of "food." Congress did not specify whether it intended the definition in section 201(f) of the FD&C Act to apply, one of the other possibilities noted above, or another meaning. Where, as here, the statutory language on its face does not clearly establish Congress's intent, it is appropriate to consider not only the particular statutory language at issue, but also the language and design of the statute as a whole (*Martini* v. *Federal Nat'l Mortgage Association,* 178 F. 3d 1336, 1345 (D.C. Cir. 1999), *citing K Mart Corp.* v. *Cartier, Inc.,* 486 U.S. 281 (1988)). Indeed, the analysis should not be confined to the specific provision in isolation, because the meaning or ambiguity of a term may be evident only when considered in a larger context (*FDA* v. *Brown & Williamson Tobacco Corp., supra* at 132 (2000)).

Consistent with this instruction, FDA has considered other parts of the Bioterrorism Act in assessing whether the meaning of "food" in section 801(m) of the FD&C Act ambiguous. In particular, FDA has considered the language of section 415 of the FD&C Act. The Bioterrorism Act's registration provision is one piece of several enacted by Congress to enhance the safety of the U.S. food supply. Registration is designed to work in concert with prior notice. This is reflected in the Bioterrorism Act's amendment of section 801 of the FD&C Act to provide that food from an unregistered foreign facility be held at the port when imported or offered for import (section 801(l) of the FD&C Act). The information provided by registration will allow FDA to cross-check prior notice submissions against registration data to confirm the identity of manufacturers and others who are required to register. Furthermore, the information provided by prior notice submissions can serve as a cross-check as to whether firms are registered as required and have been providing the necessary updates.

As explained in the preamble to the interim final registration rule published elsewhere in this issue of the **Federal Register**, FDA has concluded that the meaning of the term "food" in section 415 of the FD&C Act is ambiguous. First, the use, in section 415(a)(1) of the FD&C Act, of the phrase "for consumption" after the word "food" creates an ambiguity because it could be read to suggest that "food" within the context of the section 415 registration requirement only refers to food that is ordinarily thought of as "consumed." By modifying the term "food," Congress apparently intended to limit the term "food" to something less than the broad definition in section 201(f) of the FD&C Act. In addition, in section 415(b)(1) of the FD&C Act, when defining "facility" for purposes of section 415, Congress expressly exempted "farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared for or served directly to the consumer * * *." These exemptions do not make clear whether Congress intended them to cover only food that is ordinarily eaten at some point by consumers primarily for taste, aroma, or nutritive value or whether, for example, a retail food establishment could include retailers of food contact materials, such as retail cookware stores.

The legislative history of section 415 of the FD&C Act also supports the conclusion that Congress did not speak directly to the meaning of "food" in that Bioterrorism Act provision. Such history is appropriately consulted at *Chevron* step one (*Atherton* v. *FDIC,* 519 U.S. 213, 228–29 (1997)). In particular, the Conf. Rept. to H.R. 3448, which became the Bioterrorism Act, explains what Congress intended by "retail food establishments," which is used to create an exemption from registration.

> The Managers intend that, for the purposes of this section, the term 'retail food establishments' includes establishments that store, prepare, package, serve, or otherwise provide articles of food directly to the retail consumer for human consumption, such as grocery stores, convenience stores, cafeterias, lunch rooms, food stands, saloons, taverns, bars, lounges, catering or vending facilities, or other similar establishments that provide food directly to a retail consumer.

(H. Conf. Rept. No. 481, 107th Cong., 2d Sess., 133 (2002)). Similarly, the Conf. Rept. notes that the term "non-profit food establishments" includes not-for-profit establishments in which food is prepared for, or served directly to the consumer, such as food banks, soup kitchens, homebound food delivery services, or other similar charitable organizations that provide food or meals for human consumption" (*Id.* at 133–34). Notably, the examples provided by Congress for both types of exempt food establishments are not those that generally sell or distribute food contact materials. Accordingly, the legislative history of section 415 of the FD&C Act creates additional ambiguity as to the meaning of "food."

This ambiguity in the word "food" is further underscored by the legislative history of section 801(m) of the FD&C Act. For example, the Conf. Rept. states that the prior notice provision is to be construed not to apply to "packaging materials if, at the time of importation, such materials will not be used for or in contact with food * * *" (see H. Conf. Rept. No. 481, 107th Cong., 2d Sess., 136 (2002)). This statement implies that Congress was not relying on the definition of food in section 201(f) of the FD&C Act. For example, the statement could be read to mean that the term "food" does not include packaging or other materials that contact food.

Having concluded that the meaning of "food" in section 801(m) of the FD&C Act is ambiguous, FDA has considered how to define the term to achieve a "permissible construction" of the prior notice provision (*Chevron, USA, Inc.* v. *NRDC, Inc., supra* at 843). In conducting this *Chevron* step two analysis, the agency has considered the same information evaluated at step one of the analysis (*Bell Atlantic Telephone Co.* v. *FCC,* 131 F. 3d 1044, 1049 (D.C. Cir. 1997); *Chevron U.S.A., Inc.* v. *FERC,* 193 F. Supp. 2d 54, 68 (D.D.C. 2002)). FDA has determined that it is permissible, for purposes of the prior notice provision, to exclude food contact materials from the definition of "food."

Restricting "food" to substances other than food contact materials is consistent with the legislative history of the prior notice provision relating to food packaging and other food contact substances. In addition, it is consistent with the "food for consumption" language in section 415(a)(1) (FD&C Act) of the registration provision. That is, foods that are "consumed" are generally those eaten for their taste, aroma, or nutritive value. In addition, excluding food contact materials from "food" in this regulation is consistent with the exemptions in section 415(b)(1) of the FD&C Act, as well as the legislative history of section 415.

As discussed in the following paragraphs in responses to other comments, FDA has also interpreted "food" for purposes of section 801(m) of the FD&C Act to exclude pesticides as that term is defined under 7 U.S.C. 136(u). Accordingly, FDA has determined that a reasonable interpretation of "food" for purposes of section 801(m) of the FD&C Act is as follows and has revised § 1.276(b)(5) of this interim final rule to provide:

> Food has the meaning given in section 201(f) of the act, except for purposes of this subpart, it does not include food contact substances as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)); or pesticides as defined in 7 U.S.C. 136(u). Examples of food include fruits, vegetables, fish (including seafood), dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, 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.

[2] FDA's long-standing interpretation of the FD&C Act's definition of color additive, section 201(t), is an additional example of where "food" is used more narrowly than as defined in section 201(f). A color additive is defined in section 201(t) of the FD&C Act as a substance that "when applied to a food * * * is capable * * * of imparting color thereto * * *." The agency's food additive regulations distinguish between color additives and "colorants," the latter being used to impart color to a food-contact material (21 CFR 178.3297(a); see also 21 CFR 70.3(f)). Thus, "food" as it appears in the statutory definition of color additive, necessarily excludes food contact materials.

Importantly, FDA still considers food packaging and other food contact substances to be "food" within the meaning of section 201(f) of the FD&C Act when they, or their components, migrate into other food. Therefore, these items are still "food" for purposes of the other provisions of section 801 of the FD&C Act (with the exception of section 801(l), which shares the same definition of food as section 801(m)). Accordingly, although not subject to the section 801(m) of the FD&C Act requirement of prior notice, food packaging materials and other food contact substances will remain, as they have been, subject to determinations of admissibility under section 801(a) of the FD&C Act.

b. *Food processing aids.* (Comments) One comment argues that food processing aids and "indirect food additives" should not be considered food for purposes of section 801(m) of the FD&C Act. According to the commenter, these substances resemble food contact substances, which Congress, as evidenced by the prior notice legislative history of food contact substances, did not expect FDA to subject to prior notice.

(Response) Whether a food processing aid or "indirect additive" is subject to prior notice depends upon whether such a substance is "food" under this rule. As noted, for purposes of the interim final rule, "food" excludes "food contact substances" as defined at section 409(h)(6) of the FD&C Act. Among other things, unlike food processing aids and "indirect additives," "food contact substances" are not "intended to have any technical effect in food," section 4091(h)(6) of the FD&C Act. In addition, "food" excludes pesticides as defined at 7 U.S.C. 136(u). Thus, if the substance is not a pesticide and is intended to have a technical effect in the food being processed, the substance is not exempt from the definition of "food" under § 1.276(b)(5) in the interim final rule. This is a reasonable result in that such processing aids are intentionally and directly added to "traditional" foods.

c. *Antimicrobial pesticides.* (Comments) One comment expresses concern about including antimicrobial pesticides within the scope of this regulation. The comment states that pesticides are imported pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), not the FD&C Act, and are subject to Environmental Protection Agency (EPA) approval before they are admitted to the United States. The comment asks that FDA clarify that this regulation is not applicable to antimicrobial pesticides with FDA and/or EPA approved food contact uses. The comment states that including antimicrobial pesticides within the scope of this regulation would impose unnecessary burdens on antimicrobial pesticide registrants, without enhancing the protection of the food supply.

(Response) As discussed previously, the meaning of "food" in section 801(m) of the FD&C Act is ambiguous. Therefore, FDA may define "food" in a reasonable manner. FDA believes that excluding pesticides from the definition of food is reasonable. Pesticides, including those used in or on food for human or animal use, are comprehensively regulated by the Federal Government. Under FIFRA, 7 U.S.C. 136 *et seq.*, all pesticides (both food and nonfood use) are registered with EPA. As part of the registration process, establishments in which pesticides are produced must register with EPA (40 CFR 167.3 and 167.20). As part of the importation process, prior notice of pesticide shipments must be provided to EPA (19 CFR 12.112).

Importantly, the Federal regulatory scheme for pesticides was substantially revised in 1996 by the Food Quality Protection Act (FQPA) (Pub. L. 104–170), and EPA's authority over pesticides was consolidated and expanded. As a result of FQPA, pesticides and their residues are subject to substantial and comprehensive regulation by EPA. Where another Federal agency has the types of specific and comprehensive authority described previously to regulate the safety of a substance, FDA believes that it is appropriate to interpret "food" in section 801(m) of the FD&C Act as not including that substance. Accordingly, FDA has revised the definition of "food" in § 1.276(b)(5) to exclude pesticides as defined by FIFRA.

d. *Chemicals* (Comments) One comment seeks clarification as to whether chemicals are considered "food." The comment expects that chemicals intended for human consumption will likely be included in the requirements for prior notice.

(Response) We are not sure exactly what substances or products the comment refers to; "chemicals" is a very broad term. Unless excluded because they are food contact substances or pesticides, chemicals that are "used for food or drink" or are "used for components of any such articles" are "food" under section 201(f) of the FD&C Act and the definition in the interim final rule (§ 1.276(b)(5)). If the substance is used in some applications that make the substance "food" and some that do not, the principles applicable to further processing and multi-use substances, set out in the following paragraphs, apply.

e. *Live animals.* (Comments) Two comments address inclusion of live animals. One comment urges FDA to exempt live food animals from this regulation, as it will have far-reaching impacts on all Canadian farmers who export live food animals to the United States. The other comment asks for clarification as to how prior notice applies to live food animals imported for further processing, such as finishing.

(Response) As discussed previously, the meaning of "food" in section 801(m) of the FD&C Act is ambiguous. Therefore, FDA may define "food" in a reasonable manner. FDA believes that it is reasonable to interpret "food" in section 801(m) of the FD&C Act to include live animals. Such inclusion is consistent with the explicit reference to animals in the statutory standard, "serious adverse health consequences or death to humans or animals" in section 801(m)(2)(B)(ii) of the FD&C Act—the provision that relates to FDA review of prior notices submitted for food refused for lack of adequate prior notice. In addition, it is consistent with the legislative history of section 801(m) of the FD&C Act that refers only to the exclusion of food contact substances. Moreover, the products of live food animals are an integral part of the food consumed in the United States, and thus, it is logical to protect the raw materials (*i.e.*, the live animals) by including them under the Bioterrorism Act's safeguards. Finally, the inclusion of live animals in the definition of "food" is consistent with the reasonable interpretation of the registration provision, section 415 of the FD&C Act. Accordingly, the interim final rule's definition of "food" includes live food animals. Defining "food" to include live animals is also consistent with the case law interpreting the term "food" in the broader context of the FD&C Act. See *United States* v. *Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995).

f. *Articles for further processing or capable of multiple uses.* (Comments) Some comments ask that FDA clarify that the definition of "food" does not include substances that are not edible, but may be further processed to be rendered edible, for example, crude vegetable oils, crude petroleum, and minerals such as phosphates which may be refined and processed into food ingredients such as glycerin and phosphoric acid. The comments state that where bulk commodities have potential food and nonfood uses, there should be an exemption from import notification where these commodities have not been sufficiently refined to be directly used as food ingredients without further processing or refining.

Another comment notes that gelatin is used for food, pharmaceutical, and technical applications and seeks assistance with establishing a labeling protocol to distinguish between edible gelatin, pharmaceutical gelatin, and technical gelatin. Some comments state FDA should require prior notice only for food intended for consumption and ask FDA to specify the articles that would be considered "food." The comments also state that some imports have both food and nonfood uses and that prior notice should only be required for imports that will be used as a food. In addition, one comment strongly urges FDA to remove indirect food contact colors (*i.e.*, material used to color food contact material) from the requirements of prior notice. The comment indicates that food contact colors are often prepared in bulk and then shipped to companies that can use these pigments in both food and nonfood applications. The process of manufacturing color pigments could be many steps removed from the process of actually using these products in food packaging. Therefore, the decision to use the product in food may not be made until after the pigment has entered commerce.

(Response) For purposes of the interim final rule, "food" has the definition in section 201(f) of the FD&C Act except that "food contact substances" as defined at section 409(h)(6) of the FD&C Act and "pesticides" as defined at 7 U.S.C. 136(u) are excluded from "food." Under section 201(f) of the FD&C Act, "food" means "articles used for food or drink" (section 201(f)(1)) and articles "used for components of any such article" (section 201(f)(3)). The determination of whether a substance is "food" is not a question of intended use (*Nutrilab* v. *Schweiker*, 713 F.2d. 335, 337 (7th Cir. 1983); *U.S.* v. *52 Drums Maple Syrup*, 110 F.2d 914, 915 (2d Cir. 1940); *U.S.* v. *Technical Egg Products*, 171 F.Supp. 326, 328 (N.D. Ga. 1959)). Courts interpreting the "food" definition in the FD&C Act have held that articles at both ends of the food continuum are "food" for purposes of the FD&C Act (*U.S.* v. *O.F. Bayer & Co.*, 188 F.2d 555 (2d. Cir. 1951); *U.S.* v. *Tuente Livestock*, 888 F. Supp. 1416 (S.D. Ohio, 1995) (live animals for food use are "food" under the FD&C Act); *U.S.* v. *Technical Egg Products, supra*, 171 F.Supp. at 328 (rotten eggs are "food")). Thus, FDA believes that an item may be food even if the food is not yet in the form in which it will be used for food. FDA will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (*e.g.*, submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use.

If the substance can be used in some applications that make the substance "food" and some that do not, the same principles apply. With respect to gelatin and other substances that may exist in multiple grades, including food grade, FDA will consider an article one that will be used for food if any of the persons involved in importing or offering the product for import (*e.g.*, submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use.

Finally, as set forth previously, the interim final rule excludes food contact substances from the definition of "food." Thus, when substances to color food contact substances or their components are imported, they are not subject to prior notice. However, colors used in such substances are still subject to regulation as food under section 201(f) of the FD&C Act for purposes of other provisions of the FD&C Act.

(Interim final rule) In the interim final rule (§ 1.276(b)(5)), "food" has the meaning given in section 201(f) of the FD&C Act, except for purposes of this rule, it does not include "food contact substances" as defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)) or "pesticides" as defined in 7 U.S.C. 136(u). Examples of food include fruits, vegetables, fish (including seafood), dairy products, eggs, raw agricultural commodities for use as food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, 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.

7. Grower (§ 1.276(b)(6))

Although the statute and proposed rule used the term grower, the proposed rule did not define the term. However, FDA solicited comments on whether the term "grower" includes a harvester or collector of wild products, *e.g.*, some fish and botanicals.

(Comments) A comment states that although harvesters or collectors of wild botanicals do not grow botanicals and should be differentiated from growers for certain purposes, these can be included in the term "grower" consistent with the congressional intent in § 307 of the Bioterrorism Act to identify the direct source of the agricultural raw commodity.

(Response and interim final rule) FDA agrees. Accordingly, we have defined "grower" to mean a person who engages in growing and harvesting or collecting crops (including botanicals), raising animals (including fish, which includes seafood), or both.

8. International Mail (§ 1.276(b)(6))

Although the proposed rule applied to food imported or offered for import by mail, see, *e.g.*, 68 FR 5436, the proposed rule did not define "international mail."

(Comments) There were no comments received concerning any definition of "international mail."

(Response and interim final rule) The interim final rule imposes slightly different requirements relating to prior notice for food arriving by international mail. Thus, FDA determined that a definition of "international mail" would be helpful. The interim final rule defines "international mail" to mean "foreign national mail services." It also expressly excludes express carriers, express consignment operators, or other private delivery services from this definition.

9. No Longer In Its Natural State (§ 1.276(b)(8))

Section 801(m)(1) of the FD&C Act requires that the identity of the manufacturer be submitted as part of a prior notice. However, the proposed rule did not define "manufacturer" or address what constituted the product of a manufacturer versus the product of a grower.

(Comments) Comments raised questions concerning when a manufacturer must be identified for an article of food.

(Response) These comments are discussed under the heading "What Information Must be in a Prior Notice." However, as a result of the comments, we determined that a definition of when food would be "no longer in its natural state" would be helpful to clarify when the identity of a manufacturer versus the identity of a grower must be provided in a prior notice.

(Interim final rule) The interim final rule (§ 1.276(b)(8)), defines the term "no longer in its natural state" to mean that an article of food has been made from one or more ingredients or synthesized, prepared, treated, modified, or manipulated. Examples of activities that render food no longer in its natural state 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. However, crops that have been cleaned (*e.g.*, dusted, washed), trimmed, or cooled attendant to harvest or collection or treated against pests, waxed, or polished are still in their natural state for purposes of the prior notice interim final rule. Likewise, whole fish headed, eviscerated, or frozen attendant to harvest are still in their natural state for purposes of the prior notice interim final rule.

10. Port of Arrival (§ 1.276(b)(9)) and Port of Entry (§ 1.276(b)(10))

The proposed rule defined "port of entry" as "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."

(Comments) Many comments suggest harmonizing with, or adopting, the CBP definition for "port of entry." In the opinion of two comments, the CBP definition is consistent with congressional intent and the FDA departure from the CBP definition is unsupported. Many of these comments state the two definitions would cause confusion in the import community and could delay proper prior notice. Other comments suggest changing the FDA definition of "port of entry" to the "port of arrival." Another comment suggests defining "port of entry" as the entering point of a country where the merchandise is checked by official authorities. Two comments state that defining "port of entry" as the port of arrival would change business practices by essentially stopping the use of CBP "in-transit" (*i.e.*, IT) entries under bond to inland ports.

(Response) Section 801(m)(2)(A) of the FD&C Act states that FDA's implementing regulations must require that the notice "be provided by a specified period of time in advance of importation of the article involved * * *." The stated purpose of section 801(m)(1) is "enabling [articles of food] to be inspected at ports of entry into the United States * * *." Moreover, the overall purpose of the Bioterrorism Act is "[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." (Pub. L. 107–188.) The ability to examine or, if necessary, hold a suspect article of food when it first arrives at a port of entry in the United States, rather than later at the port where CBP will process the entry, will most effectively serve this overall purpose. Thus, to ensure that there is clarity that prior notice must be provided in advance of arrival, we are defining the term "port of arrival" as 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 the article of food first arrives in the United States.

In addition, we are adopting the CBP definition of "port of entry" to allow flexibility when designating where refused merchandise will be held. The CBP "Port of entry" definition states:

The terms "port" and "port of entry" refer to any place designated by Executive order of the President, by order of the Secretary of the Treasury, or by Act of Congress, at which a Customs officer is authorized to accept entries of merchandise to collect duties, and to enforce the various provisions of the Customs and navigation laws. The terms "port" and "port of entry" incorporate the geographical area under the jurisdiction of a port director. (The Customs ports in the Virgin Islands, although under the jurisdiction of the Secretary of the Treasury, have their own Customs laws (48 U.S.C. 1406(i)). These ports, therefore, are outside the Customs territory of the United States and the ports thereof are not "port of entry" within the meaning of these regulations) (19 CFR 101.1).

This flexibility will ensure that food that has been refused may move to the port of destination where, for example the consumption or warehouse entry will be filed, unless directed by CBP or FDA. Generally, we do not intend to hold shipments at the border unless our assessment of the situation leads us to believe it is warranted, *e.g.*, the food may present a serious risk to public health or that the prior notice violation is egregious. We intend to implement prior notice, both in terms of determining what warrants a refusal in the first place, and in terms of determining which shipments may move to the port of destination, in a risk-based way.

(Comments) Other comments state rail transportation would be especially affected because inbound trains often are not required to stop at the U.S. border but proceed to inland terminals.

(Response) As explained later, rail shipments that have been refused admission per section 801(m)(1) of the FD&C Act are considered to have the status of general order merchandise. In many cases, it will be operationally difficult to stop an entire train because an article of food on it has been refused admission because of inadequate prior notice. Under CBP regulation, general order merchandise may be stored by the carrier or as the CBP port director may direct (see 19 CFR 123.10(f)). Moreover, in situations involving shipments by rail, FDA and CBP have the discretion to allow the movement of the cargo from the border crossing to the nearest point where it can be safely and securely held. We intend, whenever possible, to examine articles of food arriving by rail at the appropriate examination site closest to the border. However, if the shipment might pose an immediate danger to public health and safety, an article of food arriving by train may be held at the border pending resolution of the situation.

(Interim final rule) The interim final rule, § 1.276(b)(9) defines "port of arrival" as "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 the article of food first arrives in the United States," (§ 1.276(b)(9)). This port may be different from the port where consumption or warehouse entry or FTZ admission documentation is presented to CBP. The interim final rule (§ 1.285(b)(10)) also defines port of entry as follows:

11. Registration Number (§ 1.276(b)(11))

Although the term appears in several places in the proposed rule, the term "registration number" was not defined.

(Comments) No comments addressed the definition or meaning of "registration number."

(Response) To clarify that the term refers to registration of food facilities, the interim final rule defines "registration number" as the registration number assigned by FDA under section 415 of the FD&C Act and 21 CFR part 1, subpart H, § 1.276(b)(11). Specific comments addressing when a registration number is required and other aspects of providing registration numbers as information submitted in prior notice are addressed later in this preamble—see "What Information Must be in a Prior Notice?'.

12. Shipper (§ 1.276(b)(12))

Section 801(m)(1) of the FD&C Act requires that the "shipper of the article" be provided in a prior notice submission. The proposed rule included the shipper as required information in a prior notice, but did not define the term "shipper."

(Comments) FDA received no comments concerning the meaning of this term.

(Response) In the proposed rule, we described the "shipper" as "the person who arranges for a shipment to get to its first destination in the United States * * *. The shipper is usually a foreign firm that is located or maintains an address in the country from which the article was shipped." (68 FR 5437). However, in drafting the interim final rule, we have realized that this description was not written in a way that was useful in identifying the shipper in the case of food imported by international mail. Accordingly, we have revised the description of the "shipper" and included it in the definitions to make it easier to find.

The definition is based on the description of "shipper" used by CBP in their proposed rule, "Required Advance Electronic Presentation of Cargo Information," published in the **Federal Register** on July 23, 2003 (68 FR 43574 at 43577), which is similar to, but clearer than, the description we used in the preamble to the proposed prior notice rule.

(Interim final rule) The interim final rule (§ 1.276(b)(12)), defines "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 United States."

13. United States (§ 1.267(b)(13))

Although the term appears in several places in section 801(m) of the FD&C Act itself, the proposed rule did not contain a definition of "United States."

(Comments) A comment seeks clarification whether the prior notice regulation applies to food imported into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories.

(Response) This comment raises the question of what the term "United States" means for purposes of section 801(m) of the FD&C Act. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? ("*Chevron* step one") (*Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984)). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent (*Chevron*, 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of "United States," FDA may define "United States" in a reasonable fashion ("*Chevron* step two"); (*Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000)). The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did not speak directly and precisely to the meaning of "United States."

The FD&C Act does apply to Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories. Section 201(a)(1) of the FD&C Act (21 U.S.C. 321 (a)(1)) defines the term "State" to mean any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico. The term "Territory" is defined to mean any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone, section 201(a)(2) of the FD&C Act (21 U.S.C. 321(a)(2)). However, the terms "State" and "Territory" are not used in section 801(m) of the FD&C Act.[3] Instead, section 801(m) of the FD&C Act deals with "articles imported or offered for import into the United States," (section 801(m)(1)).

The term "United States" is not defined in the FD&C Act's general definitions in section 201. Nor is it defined in section 801(m) of the FD&C Act. It is defined for purposes of section 702(a) of the FD&C Act (21 U.S.C. 372(a)), which provides:

> In the case of a food packed in the Commonwealth of Puerto Rico or a Territory [FDA] shall attempt to make inspection of such food at the first point of entry within the United States * * *. For the purposes of this subsection, the term 'United States' means the States and the District of Columbia.

This definition in section 702(b) seems to imply that, in other places in the FD&C Act, the term "United States" would include all Territories. However, in section 801(m) of the FD&C Act, the term "United States" appears as part of the phrase "for purposes of enabling inspection of such [food] articles at *the ports of entry* into the United States" (emphasis added). As defined by CBP, "port of entry" means ports within the part of the United States that has been denominated as the "Customs territory of the United States." (19 CFR 101.1 and 101.3). Notably, though, the Territories are not considered part of the Customs territory of the United States. CBP defines "Customs territory of the United States" to "include[] only the States, the District of Columbia, and Puerto Rico." (19 CFR 101.1).

Because of this reference to "the ports of entry into the United States," FDA has concluded that the term "United States" is best interpreted in section 801(m) of the FD&C Act to be the Customs territory of the United States and include only the 50 States, the District of Columbia, and Puerto Rico, but not the U.S. Territories and possessions. Defining the "United States" to be the Customs territory of the United States will maximize FDA's ability to coordinate prior notice with the CBP entry process, as CBP entry is made for articles from the Territories when they arrive in the Customs territory of the United States. Thus, section 801(m) of the FD&C Act does not apply to articles of food imported or offered for import into Guam, the U.S. Virgin Islands, the Northern Mariana Islands, and other U.S. Territories; section 801(m) does apply, however, when articles of food are imported or offered for import from the Territories into the United States as defined by § 1.276(b)(11) of the interim final rule.

(Interim final rule) The interim final rule (§ 1.276(b)(13)), defines "United States" to mean the Customs territory of the United States, *i.e.*, the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico, but not any other part of the United States.

14. You (§ 1.276(b)(14))

The proposed rule defined "you," based on who was authorized to submit prior notice, as "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 the arriving carrier * * *" or, if known, the in-bond carrier.

(Comments) No comments were received concerning the definition of "you." However, comments were received about who may submit prior notice.

(Response) Discussion of those comments and our responses are found in the section "Who is Authorized to Submit Prior Notice?" FDA decided, based on revisions to who may submit prior notice, to revise the definition of "you." The interim final rule clarifies that "you" means the persons (*i.e.*, individuals and firms) submitting or transmitting the prior notice. The submitter is responsible for the prior notice. The persons who send the prior notice are transmitters. If the submitter sends the prior notice, he or she is both

[3] The terms "State" and "Territory" are key to the FD&C Act's definition of "interstate commerce," which is, in turn, key to many of the FD&C Act's general inspection and enforcement provisions, see, *e.g.*, sections 301, 304, and 704 (21 U.S.C. 331, 334, and 374). However, while articles that "are imported or offered for import into the United States," section 801(m)(1) of the FD&C Act, are in "interstate commerce," see, *e.g.*, *U.S.* v. *2,998 Cases * * * First Phoenix Group, Ltd, 64 F.3d 884 (5th Cir. 1995), the term* "interstate commerce" does not appear in section 801(m).

the submitter and transmitter. FDA notes that all messages sent via the FDA PN System Interface will be sent to the transmitter. If prior notice is submitted via ABI/ACS, all messaging goes to the customs broker or self-filer via ABI/ACS.

(Interim final rule) The interim final rule (§ 1.276(b)(14)), defines "you" as the person submitting the prior notice (the "submitter") or the person transmitting prior notice information on behalf of the submitter (the "transmitter").

13. Summary of the Interim Final Rule

The interim final rule defines the following terms:

- The act;
- Calendar day;
- Country from which the article originates;
- Country from which the article is shipped;
- FDA Country of Production;
- Food;
- Grower;
- International mail;
- No Longer in Its Natural State;
- Port of arrival;
- Port of entry;
- Registration Number;
- Shipper;
- United States; and
- You.

D. "What Is the Scope of This Subpart?" (Section 1.277 Proposed as § 1.276)

FDA proposed that the prior notice requirements apply to food for humans and other animals that is imported or offered for import into the United States. The proposed rule specified that this included food that is imported or offered for import into U.S. FTZs, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export. The proposed rule said that prior notice did not apply to food carried by an individual in that individual's personal baggage for that individual's personal use, meat food products, poultry products, and egg products that are subject to the exclusive jurisdiction of USDA.

(Comments) Some comments state that the prior notice requirements should not apply to food that is brought across the U.S. border but not for consumption in the United States. In particular, the comments focus on food exported from the port of arrival, food imported for transshipment and export from another port, and food imported for further processing and export. The comments argue that Congress did not envision that the prior notice requirements would cause importers to give notice of food not for consumption within the United States and that notice of such food would not give FDA any useful or actionable information. One comment states that the Bioterrorism Act repeatedly refers to "offered for import into the United States" and concludes, based on this phrase, that prior notice should apply only to food for consumption by the citizens of the United States. One comment points to statutory language that stipulates "for human and animal consumption." Based on this language, the comment argues that FDA would exceed its statutory authority by requiring prior notice for shipments not intended for consumption within the United States. Another comment states that prior notice should not apply to food of U.S. origin, especially if it was simply transshipped through another country then "re-imported" into the United States.

(Response) These comments on scope raise the question of what Congress intended the phrase "imported or offered for import into the United States" to mean for purposes of section 801(m) of the FD&C Act. In construing the prior notice provision of the Bioterrorism Act, FDA is confronted with two questions. First, has Congress directly spoken to the precise question presented? ("*Chevron* step one"). (*Chevron, U.S.A., Inc.* v. *NRDC, Inc.*, 467 U.S. 837, 842 (1984)). To find no ambiguity, Congress must have clearly manifested its intention with respect to the particular issue (*Young* v. *Community Nutrition Institute*, 476 U.S. 974, 980 (1986)). If Congress has spoken directly and plainly, the agency must implement Congress's unambiguously expressed intent (*Chevron*, 467 U.S. at 842–843). If, however, the Bioterrorism Act is silent or ambiguous as to the meaning of "imported or offered for import into the United States," FDA may interpret the phrase in a reasonable fashion ("*Chevron* step two"); (*Chevron*, 467 U.S. at 842–843; *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000)).

The agency has determined that, in enacting section 801(m) of the FD&C Act, Congress did not speak directly and precisely to the meaning of "imported or offered for import into the United States." For the reasons in the following paragraphs, FDA has determined that, for purposes of section 801(m) of the FD&C Act, the phrase "imported or offered for import into the United States" can reasonably be interpreted to apply to articles that are brought into the United States for consumption in the United States, for transshipment through the United States and export to another country, for further processing in the United States and export, and articles of U.S. origin that are "re-imported" back into the United States. We have also determined that the phrase "imported or offered for import into the United States" can reasonably be interpreted to exclude articles that are brought to the United States for the purpose of being exported without ever leaving the port of arrival until export.

Neither the Bioterrorism Act nor the FD&C Act defines this phrase. Moreover, courts that have considered the meaning of "import" or similar terms in other statutes have not always arrived at the same conclusions: Sometimes "import" means simply to bring in, but other times "import" means to bring in with the intent to unlade or enter (*Procter & Gamble Manufacturing Co.* v. *U.S.*, 19 C.C.P.A. 415, 422 (C.C.P.A. 1932) (to import "may mean to bring goods within the jurisdictional limits of the country * * *; or it may mean the time when it is withdrawn from the warehouse and enters the commerce of the country"); *compare, e.g., Canton R. Co.* v. *Rogan*, 340 U.S. 511, 514–15 (1951) ("to import means to bring into the country"); *Brown* v. *Maryland*, 25 U.S. 419, 426, 437–38 (1827) ("What, then, are 'imports'? The lexicon informs us, they are 'things imported.' If we appeal to usage for the meaning of the word, we shall receive the same answer. They are the articles themselves which are brought into the country.") *with United States* v. *Watches, Watch Parts, Calculators & Misc. Parts*, 692 F. Supp. 1317, 1321 (S.D. Fla. 1988); *United States* v. *Commodities Export Co.*, 14 C.I.T. 166, 169–70 (Ct. Int'l Trade 1990) ("once goods are within the jurisdictional limits of the United States with the intent to discharge, they are imports under this definition"); *United States* v. *Boshell*, 14 U.S. Cust. App. 273, 275–77 (Ct. Cust. App. 1922) ("The common ordinary meaning of the word 'import' is to bring in. Imported merchandise is merchandise that has been brought within the limits of a port of entry from a foreign country with intention to unlade, and the word 'importation' as used in tariff statutes, unless otherwise limited, means merchandise to which that condition or status has attached")).

In considering what is a reasonable interpretation, we considered the language and purpose of section 801(m) of the FD&C Act, as well as the other provisions of the Bioterrorism Act and section 801 of the FD&C Act. Section 801(m)(1) of the FD&C Act states, "In the case of an article of food that is being imported or offered for import into the United States, the Secretary * * * shall by regulation require * * * the submission to the Secretary of a notice * * *." FDA notes that Congress did not explicitly limit this provision to articles of food that are intended for consumption in the United States. However, such limiting language does appear in section 415 of the FD&C Act, which requires certain food facilities to register with the agency. This shows that when Congress crafted the Bioterrorism Act, it knew how to impose the limitation sought by the comments. But neither section 801(m) of the FD&C Act nor its legislative history contains language suggesting this limitation.

The purpose of the Bioterrorism Act is "to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies." The prior notice provision furthers this goal by enhancing the agency's ability to inspect imported food upon arrival in the United States. Excluding from prior notice food that is brought into the United States for transshipment or further processing, rather than consumption, would run counter to the purpose of the Bioterrorism Act. Articles entered at the port or arrival under T&E entries with the stated intent to transship and export may be diverted for consumption in the United States and thus remain here rather than leave from another port. Some of this diversion is legitimate; under CBP regulations, importers may change their minds and file a superseding consumption entry. In addition, unscrupulous importers may file a T&E entry instead of a consumption entry to avoid paying duties on foods for consumption in the United States. Unscrupulous importers may also file a T&E entry instead of a consumption entry to try to avoid FDA review of their merchandise: generally, FDA does not receive any notice of these kinds of entries from CBP because these entries are not filed through ABI/ACS.

If we were to interpret "imported or offered for import" to exclude those entries, we could be creating a significant potential gap in section 801(m) of the FD&C Act's coverage. An importer could simply bring in an article of food under a T&E entry without giving prior notice and then, as allowed by CBP regulations, file a consumption or other entry. Thus, this exclusion would create a loophole that could be exploited by those who want to avoid giving prior notice, even for articles of food that are for consumption in the United States. Given the stated purposes of the Bioterrorism Act and of section 801(m) of the FD&C Act, FDA has concluded that it is reasonable to interpret "imported or offered for import into the United States" to include articles of food entered for transshipment and exportation.

Section 801(a) of the FD&C Act sets out the basic admissibility procedure and standards for foods, drugs, devices, and cosmetics, "which are being imported or offered for import into the United States." As with section 801(m) of the FD&C Act, nothing in section 801(a) limits its requirements just to articles that are intended for consumption in the United States. Indeed, section 801(d)(3) of the FD&C Act exempts from section 801(a)'s admissibility standards certain drugs, devices, food additives, color additives, and dietary supplements if these items are intended at the time of "importation" for further processing or incorporation into a product that will be exported. This exemption is only necessary if the phrase "imported or offered for import" in section 801(a) includes the bringing into the country of some types of goods that are for processing but not consumption in the United States. Thus, in the context of section 801(a) of the FD&C Act, "imported or offered for import into the United States" applies to more than food intended for consumption in the United States. Finally, section 801(d)(1) of the FD&C Act, which limits the circumstances under which U.S.-made drugs can be imported back into the United States, makes it clear that the phrase "imported or offered for import" in section 801(a) applies to items made in the United States, exported, and then "re-imported."

In light of the text of section 801(m) of the FD&C Act, its purpose, and these other provisions in section 801, we believe it is reasonable that this interim final rule applies to food that is brought into the United States for "consumption" (immediate or otherwise) in the United States, for transshipment through the United States and export, or for further processing in the United States and export (often referred to as "import for export"), and to food that is "re-imported." In addition, FDA has concluded in this interim final rule that there are compelling policy reasons for adopting this reasonable definition of "imported," "offered for import," and "importation."

However, when it comes to articles that are imported then exported directly from their port of arrival, we have concluded that it is reasonable to interpret the term "imported or offered for import" to exclude them from the prior notice requirements.

Food that is brought to a U.S. port but is then directly exported from that port of arrival is entered under a CBP IE entry and subject to the limitations of an IE bond. In essence, this food may not leave the port of arrival until export. These imports are thus subject to almost identical restrictions as food that is refused under section 801(m)(1) of the FD&C Act—foods that are imported under an IE entry may not leave the port of arrival unless exported. Given that controls already exist to ensure that these articles are not released from the port of arrival, FDA believes that it is reasonable to interpret 801(m) as excluding these imports from section 801(m) of the FD&C Act's prior notice requirements.

(Comments) One comment asks that other products covered by USDA programs (such as products included in "CFR(Q37)") be exempt from prior notice in the same manner as foods under the exclusive jurisdiction of USDA.

(Response) The comment did not provide more detail concerning what program is referred to by "CFR(Q37)." As set out in section 801(m)(b)(3)(B) of the FD&C Act, the interim final rule provides that meat food products, poultry products, and egg products that are subject to the exclusive jurisdiction of the 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 not subject to FDA's prior notice requirements. With regard to other USDA programs, section 315 of the Bioterrorism Act states that no part of Title III should be construed to alter the jurisdiction between USDA and FDA. Notably, under current practice, FDA may have jurisdiction over an imported food under the FD&C Act and USDA may have jurisdiction over an imported food under one or more statutes that it administers, or the two agencies may have joint jurisdiction over an imported food. Under its section 315, the Bioterrorism Act does not change this structure. Accordingly, only imported food that is regulated exclusively by USDA is exempt from prior notice.

In addition, we believe that the statute requires prior notice to be submitted to FDA. As described elsewhere in greater detail, we are working with CBP to modify our existing ABI/ACS and OASIS systems to permit additional data sharing to satisfy prior notice. Although it is theoretically possible for FDA to obtain information from agencies other than CBP, the stringent

timeframes for issuing this interim final rule do not provide FDA adequate time to reconcile the different information required or to work with the other agencies to have them amend their existing requirements to capture all the information FDA needs. Merely obtaining existing information about the food from other agencies would not guarantee that FDA has the information required by section 801(m) of the FD&C Act's prior notice requirements because there is wide variation in the purposes and information required by other government programs. We would also need to work with other agencies to ensure the confidentiality of nonpublic prior notice information under relevant information disclosure laws, *e.g.*, 21 CFR 20.85 (Federal), 20.88 (State), and 20.89 (foreign). Because a purpose of providing prior notice to FDA is to assist FDA in responding to bioterrorism incidents or other food-related emergencies, FDA must have the required information readily accessible. If FDA has to coordinate with other agencies or governments to obtain from them the information necessary to respond to such an emergency, FDA may be prevented from responding to the emergency in a timely manner.

FDA notes that it is dedicated to increasing information-sharing capabilities with other agencies even after this interim rule is in effect, and we will continue to work with other government agencies to further streamline the prior notice process, consistent with our statutory obligations.

(Comments) Several comments suggest that exclusion for baggage in the proposed rule should be broadened in the final rule to include all food in baggage, even food that is not for the traveler's personal use. For example, one comment reasons that samples carried in the baggage of company representatives (or sent unaccompanied) generally do not enter commercial trade.

(Response) FDA disagrees. Except as already provided for, section 801(m) of the FD&C Act does not authorize an exclusion from prior notice for all food imported or offered for import into the United States in baggage. In the preamble to the proposed rule, we explained that the information that section 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (*i.e.*, consumption by themselves, family or friends, not for sale or other distribution). We reasoned that when travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended for us to characterize such travelers as "shippers" for purposes of section 801(m) of the FD&C Act.

When food is not being carried by or otherwise accompanying an individual for his or her personal use, there is a "shipper"—the person or entity on whose behalf the traveler is bringing in the food. Thus, by its terms, section 801(m) of the FD&C Act requires that food carried by or otherwise accompanying an individual arriving in the United States that is not for personal use be subject to prior notice. In addition, were we to adopt such an exemption, it would create a potentially significant loophole, which could defeat the purpose of prior notice. For example, travelers coming from Latin America sometimes carry local soft cheeses for sale in the United States (Ref. 16). In fact, these travelers often are not staying in the United States for any period of time, but are merely transporting cheese to sell in the United States in their luggage or baggage. These cheeses have been tested by FDA and found positive for listeria, salmonella, and other pathogens associated with raw milk and insanitary conditions. Consumption of such contaminated cheese has been associated with illnesses and deaths. Another example is travelers arriving by automobile who carry cases of shellfish from unapproved foreign growing locations. These shellfish may be contaminated with a variety of illness-causing pathogens including vibrio cholerae or Norwalk virus. These shellfish are often not destined for personal consumption but for sale directly to the public or for consumption by the public at restaurants. Finally, trade samples are imported or offered for import to generate sales, which is a commercial, not personal, use. Thus, there is a "shipper" when these samples are brought to the United States.

FDA notes that it is changing the proposed rule by removing the term "baggage" and referring instead to food carried by or otherwise accompanying an individual. This change clarifies that the exclusion applies to food that might not be regarded as "baggage" but, nonetheless, accompanies the traveler. For example, food in the trunk of a car is not in baggage, but it accompanies the driver and any passengers.

(Comments) Comments ask that any food imported for personal use which arrives in the country by common carrier (*e.g.*, express carrier, truck, plane) should be treated the same as food imported for personal use and carried with a traveler.

(Response) FDA disagrees. Section 801(m) of the FD&C Act does not authorize a broad exclusion from prior notice for all food imported or offered for import for personal use. In the preamble to the proposed rule, we explained that the information that section 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to food that travelers bring into the United States in their personal baggage for personal use (*i.e.*, consumption by themselves, family or friends, not for sale or other distribution). We reasoned that when travelers bring food back from their travels in their personal baggage for their own use, we do not believe that Congress intended to characterize such travelers as "shippers" for purposes of section 801(m) of the FD&C Act. However, when food is shipped by an individual or business in another country to a consumer in the United States for his or her personal use (or otherwise), there is a "shipper" as that term is used in section 801(m)(1) of the FD&C Act and defined in § 1.276(b)(10). Accordingly, there is no basis in section 801(m) of the FD&C Act for concluding that Congress did not intend prior notice to apply to articles sent (as opposed to carried) to the United States for the recipients' personal use.

(Comments) One comment asked that FDA address the issue of noncommercial family food shipments and to add these to the list of exemptions from prior notice. Another comment stated that a food shipment consisting of one noncommercial shipper sending food to another noncommercial recipient (*e.g.*, a friend abroad shipping cookies to a friend in the United States) should be outside the scope of the prior notice requirement.

(Response) FDA agrees in part and we have added a provision that excludes personal gifts of homemade food from prior notice. Although we believe that this food is imported into the United States, the information that § 801(m)(1) of the FD&C Act requires in a prior notice, in conjunction with the purpose of the provision, demonstrates that Congress did not intend prior notice to apply to homemade food sent as a personal gift by the maker to a recipient in the United States. In particular, under § 801(m)(1) of the FD&C Act, a prior notice must contain the identity of the manufacturer of the food. When an individual makes a food in their home as a gift for a relative or friend, we do not believe that Congress intended for us to characterize such cooks as "manufacturers" for purposes of § 801(m) of the FD&C Act.

(Comments) Several comments suggest that the final rule should not apply to foods that arrive by international mail or express carriers.

(Response) FDA disagrees. Except for the exclusions already described for food for personal use that is carried by or otherwise accompanying a traveler and homemade gifts, section 801(m) of the FD&C Act applies to food regardless of the method of importation. Thus, foods that arrive by international mail and by express carriers (*e.g.*, Federal Express, United Parcel Service, *etc.*) are subject to section 801(m)'s prior notice requirements. Indeed, FDA notes that foods, drugs, devices, and cosmetics that arrive by mail or express carriers are currently subject to admissibility determinations under section 801(a) of the FD&C Act, which also uses the phrase "imported or offered for import." Finally, were we to adopt such an exemption, it would create a potentially significant loophole, which could defeat the purpose of prior notice. Those who did not want to or could not comply with prior notice requirements would be able to bring articles of food in by mail or express carrier. While this might not be practical for all kinds of foods, many foods are regularly imported by mail or express carrier, *e.g.*, dietary supplements and specialty foods ordered by U.S. consumers from foreign firms. For example, one commenter states its company provides, through Internet sales, special dietary foods and fresh baked foods that are shipped via express carriers directly to consumers at the rate of around 1,000 home deliveries per week.

(Comments) Several comments suggest that the final rule should not apply to various kinds of samples, including trade and market research samples (*i.e.*, samples sent or carried in for the purpose of selling products or conducting market research), trade show samples, samples for testing for nutritional, safety, quality control, or quality assurance reasons, and samples for basic research. These comments reason that samples used for marketing are not intended for retail consumption and generally do not enter commercial trade and, thus, are not intended for use as food. In the case of samples for testing, comments reason that these samples are for the individual's specific and limited personal use and not for further distribution to others and should be exempted as samples are under federal poultry and meat inspection regulations.

(Response) FDA agrees in part. If the samples are items that are in such early stages of research and development that they cannot yet be considered food under § 1.276(b)(5) of the interim final rule, they would not be subject to prior notice requirements. An example of such an item is a substance being tested for possible preservative qualities before being tested in any food. However, samples of food, including those for test marketing, are clearly subject to prior notice as they are "articles of food imported or offered for import" as stated in section 801(m) of the FD&C act. For example, in the summer of 2003, FDA received a report from a poison control center in country T concerning the acute poisoning of 9 men (one died) from ingestion of an herbal fermented wine. Symptoms occurred within minutes. Reports indicated that this product may have been exported to the United States in small quantities for test marketing in restaurants. This underscores the importance of FDA receiving prior notice of all food imported or offered for import.

(Comments) One comment suggests that food for research and development purposes sent directly to facilities that are registered under section 415 of the FD&C Act should be exempt.

(Response) If the item is indeed food under this subpart and it is not otherwise excluded under § 1.277(b), prior notice is required. There is no basis in the statute for an exemption based on the fact that an article of food is being sent to registered facilities.

(Comments) Comments ask that articles of food that are of *de minimis* value (*i.e.*, less than $200) be exempt from prior notice. The comments argue that such small shipments for personal use could hardly qualify as a risk to the domestic food supply. They also point out that enforcing prior notice on such articles would be difficult and burdensome to FDA. In addition, they state that prior notice for these items would be a burden on consumers as they usually do not have an agent in the United States to represent them.

(Response) FDA notes that it has removed the restrictions on who can submit prior notice. Thus, foreign sellers or shippers can file prior notices for these kinds of shipments under the interim final rule. Low-value food items are clearly subject to the terms of section 801(m) of the FD&C Act as they are "articles of food imported or offered for import" as stated in section 801(m). Moreover, we do not agree that low value shipments are always imported for personal use or would present only *de minimis* risks, such that an exemption can be justified under the *de minimis* doctrine. First, a low value is not necessarily a good indication that the article is for personal use. Many food items (*e.g.*, produce) can have a low invoice value at importation, especially if the shipment is not large. Moreover, in our experience, many specialty, gourmet, ethnic, and exotic foods are often imported for commercial purposes in very small amounts. Thus, a shipment of bottled cooking oil or a beverage contaminated with toxic chemicals may be represented as low-value or low-volume but could have a wide, and very negative, public health impact. In addition, we note that misdeclaration of value of articles of food at entry can be a problem. Finally, any burden such an exemption might relieve would likely be offset by the burden of administering it.

(Comments) Comments ask for an exemption for food imported into the United States for sale in duty free stores.

(Response) FDA disagrees. Unless the food is imported and exported without leaving the port of arrival until export, as set out in § 1.277(b)(2), there is no basis in section 801(m) of the FD&C Act for such an exemption.

(Comments) Some comments recommend that prior notice be waived for foods in situations that they characterize as "low risk." These situations were identified in the comments as any one of the following:

- Exported from U.S.-owned foreign companies;
- Transferred between commonly owned facilities (intra-company transfers);
- Subject to high quality control standards and/or produced in highly-regulated businesses;
- Shipped under seal or in bond;
- Entered as high-volume, repetitive shipments;
- Processed through CBP's Border Release Advanced Selectivity Screening (BRASS); and
- Associated with a program of assessment of low risk, such as the Customs-Trade Partnership Against Terrorism (C–TPAT); Free and Secure Trade program (FAST); or food safety and security programs of foreign government regulatory authorities.

(Response) FDA disagrees. As explained previously, section 801(m) of the FD&C Act applies to all food imported or offered for import into the United States except as outlined in § 1.277(b). Nothing in section 801(m) of the FD&C Act authorizes an exemption for articles of food that are "low risk" or covered by programs of other agencies, such as CBP or foreign government regulatory authorities.

Summary of the Interim Final Rule

Section 1.277(a) provides that the interim final rule applies to food for humans and other animals that is imported or offered for import into the United States. This covers food for use, storage, or distribution in the United States, including food for gifts, trade and quality assurance/quality control samples, food for transshipment through the United States to another country, food for future export, and food for use in a U.S. FTZ. Section 1.277(b) sets out the exclusions from prior notice. It excludes food carried by or otherwise accompanying an individual arriving in the United States for that individual's personal use (*i.e.*, consumption by the individual or his or her family or friends, not for sale or other distribution); food that was made by an individual in his or her personal residence and sent by that individual as a personal gift (*i.e.*, for nonbusiness reasons); food that is imported then exported without leaving the port of arrival until export; and meat food products, poultry products, and egg products subject to the exclusive jurisdiction of 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.*).

E. "Who Is Authorized To Submit Prior Notice?" (Section 1.278 Proposed as § 1.285)

The proposed rule (§ 1.285) provided that a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent thereof was authorized to submit prior notice. FDA noted that a broker/filer would be authorized to be a submitter if it was the U.S. agent of the U.S. importer or U.S. purchaser.

FDA further proposed that if the article of food is imported for in-bond movement through the United States for export, the prior notice must be submitted by the arriving carrier or, if known, the carrier making the in-bond entry.

(Comments) Many comments object to the limitation that only a person who resides or maintains a place of business in the United States can submit the prior notice. Some comments state that foreign-based companies that sell food directly to U.S. individuals for their own use, including companies that sell via the Internet, cannot expect their individual customers to submit prior notice. In addition, comments point out that, under some circumstances, the U.S. importer or purchaser or carrier would not have all the information required by prior notice, but that other entities, *e.g.*, the foreign manufacturer/processor, shipper, or exporter, would have the required information. Many comments state that entities other than U.S. firms or carriers should be allowed to submit prior notice.

(Response) FDA agrees and has removed this restriction on who can submit prior notice. Accordingly, § 1.278 of the interim final rule provides that any person with knowledge of the required information may submit prior notice to FDA. Thus, any person may now take responsibility for submitting prior notice for a particular article of food, as long as that person can provide all the required information. This person is referred to as the submitter in the interim final rule. The interim final rule also states that the submitter may use another person to transmit the required information to FDA. For ease of reference, the person who transmits the prior notice is referred to as the transmitter in the interim final rule. If the submitter submits and transmits the prior notice, he or she is both the submitter and the transmitter. FDA notes that all reply messages sent by the FDA PN System Interface will be sent to the transmitter. If prior notice is submitted via ABI/ACS, all reply messaging goes to the customs broker or self-filer. FDA has also revised the definition of "you" accordingly.

(Comments) Comments from customs brokers noted that, although they are responsible for timely submission of all documentation required for import entry, they are not responsible for verifying the accuracy of information provided to them from their customer. Comments ask FDA to clarify in the final rule that the customs broker is merely an agent for the filing of information obtained from the importer and is not responsible for either the adequacy or accuracy of the data submitted. Comments assert that the responsibility of the customs broker is to accurately submit the information provided by his or her client in correct form and in a timely manner.

(Response) The submitter of prior notice information, regardless of the method of or person transmitting the information, is responsible for the accuracy of that information. If the transmitter is not the submitter, we expect the transmitter, whether he or she is a licensed customs broker or other kind of agent, to exercise diligence and care to transmit the information provided by the submitter accurately.

(Interim final rule) Proposed § 1.285 has been changed in the interim final rule to § 1.278, "Who is authorized to submit prior notice?" The interim final rule states that any person with knowledge of the required information may submit prior notice. This person is the submitter. The submitter may also use another person to transmit the required information on his or her behalf. The person who transmits the information to FDA is the transmitter. The submitter and the transmitter may be the same person. The interim final rule also defines "you" to mean the submitter or transmitter (§ 1.276(b)(12)).

F. "When Must Prior Notice Be Submitted to FDA?" (Section 1.279 Proposed as § 1.286)

FDA proposed that the prior notice must be submitted to FDA no later than 12 noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry. As described in the proposal, this was based on FDA's assessment of what time was needed to meet its statutory mandate of receiving, reviewing, and responding to prior notice.

(Comments) Generally, the comments recommend that FDA adopt a shorter, rolling prior notice submission timeframe to reduce the burden of the prior notice requirement on the smooth flow of commerce. Many comments recommend a specific timeframe for submission of prior notice. These recommendations ranged from submission of an annual report for repetitive shipments, to submission of the notice at the time of distribution of the food after it arrives in the United States.

Many comments recommend that the prior notice submission timeframe be linked to a mode of transportation or type of port of entry, and others recommend that it be linked to the type of food. Many comments recommend a specific timeframe and associated that timeframe with either a mode of transportation/type of port or with a type of food or both. Comments recommend that prior notice be submitted 8 hours before arrival; some associate the 8 hours timeframe with a water mode of arrival only, while others associate the 8 hours timeframe with nonperishable foods. Many comments recommend that prior notice be submitted 4 hours before arrival; some associating the 4 hours timeframe with land and air modes of arrival only and some associating the 4 hours timeframe with perishable foods (produce and seafood) and live animals only.

(Response) FDA agrees that the time for submission of prior notice should be a rolling timeframe. FDA has determined that the time can be shortened to reduce the effect on the smooth flow of trade while still providing FDA with sufficient time to receive, review, and respond to the information. FDA also agrees that timeframes should be different for different modes of transport. As such, FDA has revised the rule to require that the timing of submission will be no more than 5 days (except in the case of international mail) and that the prior notice submission be confirmed by FDA for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water.

When food carried by or otherwise accompanying an individual is subject to this rule, the timeframe associated with the manner of the individual's arrival applies. If the individual and article of food are arriving by land via road, the prior notice must be submitted and confirmed at least 2 hours before arrival. If the individual and article of food are arriving by air or by land via rail, the prior notice must be submitted and confirmed at least 4 hours before arrival. If the individual and article of food are arriving by water, the prior notice must be submitted and confirmed at least 8 hours before arrival.

Two major agreements between CBP and FDA allow FDA to reduce significantly the time necessary to receive, review, and respond to prior notice information. First, FDA and CBP have agreed to commission or use CBP staff to perform examinations for FDA when FDA is not present at the port of arrival. Since CBP staff generally will be available where FDA is not, this means that FDA no longer needs lead-time to travel significant distances to conduct inspections. In addition, CBP agreed to modify ABI/ACS to receive, transmit, and communicate prior notice information electronically between CBP and FDA for most entries of imported foods by the statutory deadline in the Bioterrorism Act of December 12, 2003. CBP's assistance with prior notice means that FDA needs far less time to respond to prior notices.

In considering how to modify the timeframes, FDA concluded that setting them by mode of transportation would be the best approach. Mode of transportation is clear and easy to apply and administer, so there is likely to be little confusion about what timeframes apply. If we were to set timeframes based on type of food, *e.g.*, perishable versus nonperishable, we would have to develop and implement a system for determining which articles of food were which. In addition, different articles of food in the same conveyance would be subject to different prior notice timeframes, which would subject all items in the conveyance to the longest timeframe and add an additional layer of complexity that could cause confusion and delays at the border. Moreover, many comments recommended mode of transportation, which suggests that many stakeholders, including industry, believe such a system is workable.

In determining the actual timeframes for submission of prior notice for each mode of transportation, FDA considered the need to provide sufficient time for the agency to review and respond to the information submitted, as well as the current ability of the food industry to provide the information required within the stated timeframe given the differences in lead time before arrival among different modes of transportation. We determined that information for shipments whose transport time is measured in days or weeks (*e.g.*, ocean shipments) is available further in advance of arrival than shipments whose transport time is measured in hours (*e.g.*, land and air shipments.) Staggered prior notice submission timeframes will allow FDA reviewers to direct additional resources to shipments with short transport times and to defer review of shipments with longer transport times. Based on these considerations, FDA established the prior notice timeframes in the interim final rule to associate with the mode of transportation.

FDA is committed to exploring ways to increase integration and reduce the prior notice timeframes further. Accordingly, FDA and CBP will continue working together to determine what is needed to achieve this goal. No later than March 12, 2004, the Commissioners of FDA and CBP will publish a plan, which will include an implementation schedule, to achieve the goal of a uniform, integrated system and to coordinate timeframes for import prior notice information while fulfilling the Bioterrorism Act mandates for air and truck modes of transportation with timeframes finalized by CBP when they finalize the rule entitled "Required Advance Electronic Presentation of Cargo Information," published in the **Federal Register** on July 23, 2003 (68 FR 43574).

For imported food arriving via international mail, the interim final rule requires that prior notice be submitted before the food has been sent. This timeframe allows the FDA PN Confirmation Number to accompany the package, which is necessary to establish that prior notice has been submitted and to match the prior notice submission to the package upon arrival.

(Comments) Some comments recommend that the prior notice submission timeframe be waived for foods exported from U.S.-owned foreign companies. Other comments recommend that a different timeframe be established for foods associated with a program of assessment of low risk, such as the C–TPAT.

(Response) The interim final rule does not provide for a waiver of the timeframe for foods imported by U.S.-owned firms. Nor does the rule provide for a different timeframe for foods or firms covered by programs of other agencies, such as C–TPAT. The interim final rule provides for greatly reduced timeframes for foods based on mode of transportation. These timeframes are what FDA has determined are the minimum timeframes necessary to allow it to satisfy the statutory mandate that the timeframes give the agency the time it needs to "receive, review, and respond" to prior notices. However, FDA is also interested in exploring flexible alternatives for submission of prior notice for foods or firms covered by programs of other agencies, such as C–TPAT, or imported by other agencies.

(Interim final rule) Section 1.279(a) in the interim final rule has been revised to require submission of the prior notice to FDA and the submission must be confirmed by FDA for review no less than 2 hours before arriving at the port of arrival by land via road, no less than 4 hours before arriving at the port of arrival by air and land via rail, and no less than 8 hours before arriving at the port of arrival by water. Under § 1.279(b), prior notice may not be submitted more than 5 calendar days before arrival, except in the case of food imported or offered for import by international mail.

Under § 1.279(c), if the article of food is arriving by international mail, the prior notice must be submitted before the food is sent to the United States.

Section 1.279(d) provides that the time of submission is fixed and the prior notice time will start for purposes of determining if prior notice is timely when the prior notice submission is confirmed by FDA for review. FDA will confirm a prior notice once all required information has been submitted and confirmed as facially complete. For example, if the information submitted were to include a registration number, name, city, and country for the manufacture of an article of food, and the system review were to reveal that the registration number does not exist or does not match the name, city, and country of the facility, the FDA PN

System Interface will not provide a confirmation for that prior notice. The transmitter will have an opportunity to correct the rejected information. When the information is corrected, transmitted, and determined to be facially valid, the system will then notify the transmitter and provide the PN Confirmation Number. As set out in § 1.279(d), FDA will notify the transmitter that the prior notice has been confirmed for review with a confirmation that contains a PN Confirmation Number. The prior notice will be considered submitted and the prior notice time will start when FDA has confirmed the prior notice for review.

Under § 1.279(e), the PN Confirmation Number must accompany any article of food arriving by international mail. Under § 1.279(f), a copy of the confirmation (with the PN Confirmation Number) must accompany any article of food carried by or otherwise accompanying an individual (unless excluded under § 1.277(b)(1)), and be provided to CBP or FDA upon arrival.

Additionally, under § 1.279(g) the PN Confirmation Number must accompany any article of food for which the prior notice was submitted through the FDA PN System Interface when arriving in the United States and must be provided to CBP and FDA upon arrival.

G. "How Must You Submit Prior Notice?" (§ 1.280 Proposed as § 1.287)

FDA proposed that prior notice and any amendments and updates must be submitted electronically to FDA through a new Web interface. The proposed rule also required submission of hard-copy prior notice, in person or by e-mail or fax, if the FDA system was not operating. Before issuing the proposed rule, FDA consulted with CBP, which was then the U.S. Customs Service of the Department of the Treasury, about the proposed rule and the feasibility of modifying ABI/ACS to accommodate the new prior notice requirement. During these consultations, CBP advised that ABI/ACS could not be modified to accommodate the data requirements of the prior notice regulation by the December 12, 2003, statutory deadline.

(Comments) Many comments focus on the proposed method of submission of prior notice. These comments fall into four broad categories. The first category, which includes the largest number of comments, suggests that FDA work more closely with other agencies, and in some cases other countries, to eliminate redundancies or conflicts in the method of submission. The majority of these comments urge the FDA to work more closely with CBP. A second group of comments addresses the viability of the proposed Web-based system for submission of prior notice. The third category includes suggestions about the prior notice form that was included in the proposed rule. The final category of comments asserts that existing systems and procedures provide adequate defense against a bioterrorism threat and that the proposed regulation is unnecessary.

1a. Work With Other Agencies To Eliminate Redundancies

(Comments) Most comments recommend that FDA and CBP work together to reduce the adverse impact of submission of information in both prior notice and CBP entries. Most of these comments suggest that the existing ACS–OASIS interface between CBP and FDA be used to accept prior notice information. Other comments suggest that much of the information required for prior notice was available in CBP's Automated Manifest System (AMS). Although many comments suggest that the existing systems contained sufficient information to meet the statutory requirements, others recognize that modifications were needed to meet the Bioterrorism Act's requirements.

(Response) FDA and CBP agree with many of the comments made about inter-agency cooperation as well as with the recommendation that we provide a single point of data entry for CBP and FDA for as many kinds of entries as possible. FDA and CBP are committed to the joint implementation of an automated approach to prior notice that will meet the following objectives: (1) Reduce submission of redundant data to the extent possible; (2) build on current operational procedures; and (3) implement the law with minimal disruption to current entry practices.

The interim final rule requires prior notice to be submitted electronically to FDA through CBP's ABI/ACS or the FDA PN System Interface. Prior notice may be submitted through ABI/ACS for all food imports subject to this interim final rule except food imported by international mail or other transactions that cannot be submitted through ABI/ACS and food that has been refused under section 801(m) of the FD&C Act. The proposed rule was based on an initial review by both FDA and CBP of the feasibility of implementing new operational procedures and enhancing existing systems. After further review of the potential technical, legal, and operational impacts, FDA and CBP have determined that the prior notice information required for most types of CBP entries of foods can be submitted through the existing ABI/ACS and provided to FDA. The existing ABI/ACS–OASIS interface allows for communication both between FDA and the customs broker or self-filer (necessary for the submission of prior notice to FDA as required by section 801(m)(1) of the FD&C Act), and between FDA and CBP (necessary for followup at the border). However, although much of the information required for prior notice currently existed in some automated form in ABI/ACS, not all the necessary data were available in the right sequence or at the right time to meet prior notice requirements. Thus, FDA and CBP have been working closely together and enhancing, ABI, ACS, and OASIS to craft operational procedures and systems that meet the requirements of the Bioterrorism Act with minimal impact on existing processes.

Since prior notice is required for some of imported food for which electronic transmission of information to CBP is not available via ABI/ACS and since submission of information through ABI/ACS is not mandatory, an alternative means to submit prior notice will still be needed. Although a CBP entry is not normally submitted in ABI/ACS for T&E entries and IT entries and FTZ admissions, a new transaction format, similar to the existing ABI transactions, will be available for submitting prior notice for these imports through ABI/ACS. The FDA PN System Interface will also be available for international mail, food refused under section 801(m) of the FD&C Act, and those who choose not to submit prior notice through ABI/ACS.

1b. CBP AMS

(Comments) Several comments note that some of the information FDA required for prior notice was already being submitted to AMS and suggested that FDA could retrieve data from AMS rather than ask for a separate submission for prior notice.

(Response) AMS is a module of ACS through which carriers, port authorities, or service bureaus transmit electronically the cargo declaration portion of the inward foreign manifest to CBP. The information submitted to AMS is not sufficient to satisfy section 801(m)(1) of the FD&C Act's requirements. For example, the identities of the manufacturer, grower, FDA product code, and quantity of each article are not submitted to AMS. FDA and CBP have consulted about interfacing with AMS for manifest data and determined that the general cargo data in AMS were simply not suitable to accommodate the detailed information requirements of section 801(m) of the FD&C Act. In addition, no interface currently exists between AMS and the existing interface with OASIS through the ABI/ACS entry processes, which means FDA does not have any access to AMS data. However, section 801(m) of the FD&C Act requires that prior notice be submitted to FDA. Given the implementation date of December 12, 2003, CBP and FDA concluded that it was not practical to attempt to modify AMS to accommodate the new prior notice requirements when we could enhance the existing ABI/ACS–OASIS interface.

2a. Viability of a Web-Based System

(Comments) A common concern expressed by commenters is the viability of the FDA PN System Interface for the volume of data traffic and the time-sensitive nature of prior notice information. Multiple comments address system availability, the time needed to enter and process the data, and the need for confirmation.

(Response) FDA agrees that implementation of a new FDA PN System Interface as the primary means of data submission for 25,000 plus transactions a day would be challenging, particularly considering the effect on the food industry if the system were not responsive. That concern has been substantially addressed as a result of the commitment by CBP and FDA to work together to enhance the existing ABI/ACS–OASIS interface to accommodate the prior notice requirements. The decision includes the development of a new ABI/ACS "transaction type" that will accommodate prior notices for IT entries, T&E entries, and food shipped directly to an FTZ. This new feature further reduces the number and type of transactions that must be submitted through the FDA PN System Interface.

FDA anticipates that less than 10 percent of the total submissions will be submitted through the FDA PN System Interface. The FDA PN System Interface will be available 24 hours a day, 7 days a week. FDA has taken steps to ensure that the FDA PN System Interface can provide adequate response times to support data entry and return of confirmation by reply messaging.

2b. Contingency System

(Comments) FDA received several comments on the need for a contingency plan or backup plan in case of FDA Web system failure. The severity of the consequences if FDA were to fail to receive a prior notice, and the common experience with Web system failures, was of great concern to many of the system's potential users. Many suggestions were made for contingency plans, *e.g.*, information on what FDA plans to do if the automated system is unavailable.

(Response) FDA agrees that plans for contingencies are needed, even with the reduced volume of traffic on the FDA PN System Interface and the existence of two modes of submission. FDA does not plan to exempt any specific categories of food articles from prior notice if systems are not performing; FDA and CBP are working together to develop contingency plans for when the system(s) are not working. The interim final rule, § 1.279(b) through (d), sets out how we will handle prior notice in four "down-time" situations: The customs broker's or self-filer's access to ABI/ACS is not working; the ABI/ACS interface is not working; the FDA PN System Interface is not working; and OASIS is not working. In all these situations, an alternative form of prior notice information is required. If access to ABI/ACS is not available, prior notice must be submitted via the FDA PN System Interface. If FDA determines that FDA PN System Interface is not working, prior notice must be submitted manually by those who do not use ABI/ACS. If FDA determines that OASIS is not working, all prior notices must be submitted manually. FDA will issue notification through notices on the FDA Web site at *http://www.fda.gov*, at *http://www.access.fda.gov*, and through messages in ABI/ACS. Once FDA issues this notification, prior notice information must be submitted to FDA by e-mail or by fax.

Manual submissions must be submitted by e-mail or fax. Because all review is being done in a centralized location, we will not accept manual submissions in person. The FDA Web site at *http://www.fda.gov* will have a list of the information required for prior notice submission and the fax number(s) and e-mail address(es) where prior notice can be sent. The list of the information required can be printed. It can also be downloaded to the submitter's or transmitter's word processing system and used as a basis for submitting prior notice information to FDA. Because the FDA PN System Interface at *http://www.access.fda.gov* and FDA's Web site at *http://www.fda.gov* are located on independent platforms, this information will be available even when the FDA PN System Interface is not working. This fax number and the e-mail address will not be activated to accept prior notice information unless FDA determines that the FDA PN System Interface or OASIS is not working. Additional information about the down-time, *i.e.*, confirmation that the FDA PN System Interface or OASIS is down and estimated down-time will be posted at *http://www.fda.gov*—see "prior notice" and will be available from the help desk.

2c. Alternate Methods

(Comments) Several comments suggest more than one path for submission of prior notice information. Some comments ask that FDA allow for manual submission, either as a backup, or as an alternate path. Others suggest that some types of "safe" products be allowed to bypass prior notice if the system were not performing. Still others suggest that the potential for catastrophic system failure requires FDA to implement 2 interfaces for prior notice data, often implying that ACS was an appropriate alternative system.

(Response) FDA does not agree that a process for manual transmission is needed, except on a contingency basis. FDA believes that, in 2003, persons engaged in international commerce have, or can get, access to the Internet. If the Internet is not accessible by the submitter, he or she can use a customs broker to submit prior notice through ABI/ACS or another person to transmit prior notice through the FDA PN System Interface. As the primary mode of submission, manual transmission would not give adequate time for FDA personnel to receive, review, and respond, unless the timeframes for prior notice in the interim final rule were greatly extended. Thus, manual transmission will be used only as a contingency alternative. FDA also notes that the data quality of manual systems is usually less than satisfactory, because no automated data validation takes place during data entry. The U.S. Government has a strong commitment to reducing paper-based processes and moving toward e-commerce for all business transactions. Accordingly, under the interim final rule, paper-based submissions will not be allowed, except as set forth in § 1.280(c) and (d), by e-mail and fax. However, FDA and CBP do not expect system failures to be a common occurrence.

2d. Security of System

(Comments) Several comments question the security of the system and suggested that the system must have extraordinarily stringent security protocols in place to protect sensitive commercial information and prevent potential terrorists from obtaining information capable of providing cover.

(Response) FDA agrees the information must be secure. Any fraudulent or inadvertent changes in data could affect FDA response and thus affect the health and welfare of

consumers in the United States. FDA has determined that the data security and data integrity requirements of the prior notice data are on par with entry data currently submitted through ABI/ACS to OASIS. Prior notice data submitted through ABI/ACS will have the same security and access controls as entry data currently received through ABI/ACS. Adequate and effective security controls will be placed on the FDA PN System Interface through user account management and authentication processes, and password controls, to ensure data security and integrity.

A number of statutes, regulations, and policies address protection of sensitive information from unauthorized disclosure. Some that are relevant to prior notice include the Clinger-Cohen Act of 1996, the Computer Security Act of 1987, the Trade Secrets Act, 21 CFR 20.61 (Trade Secrets and Commercial or Financial Information Which Is Privileged or Confidential), OMB Circular A–130 (Management of Federal Information Resources), and FDA Staff Manual Guide 3250.15 (Information Technology Security, Data Security—Data Confidentiality). For example, Appendix III to OMB Circular No. A–130 establishes a minimum set of controls to be included in an agency's information security program and requires security controls to be commensurate with the risk and magnitude of the harm resulting from the loss, misuse, or unauthorized access to or modification of information.

3a. Prior Notice Form

(Comments) Several comments suggest changes to the proposed form. Most of these recommend changes in the order of items in the form.

(Response) The draft form that was provided as an attachment to the proposed rule was intended only to provide a graphic summary of the information to be collected by the FDA PN System Interface (68 FR 5334). The form was an illustration, intended to help potential users to visualize the data requirements and to better analyze their relationship and impact. FDA did not intend the draft form to be a sample of the screens that will be available to the user on the proposed FDA PN System Interface. Nor was it intended to be a draft paper form, since paper-based submission will not be acceptable, except as a contingency if the system is not operating.

The actual screens of the FDA PN System Interface are based on standard Web design principles, with primary attention to support of anticipated data entry. The screens will incorporate extensive use of "pull-down" lists to assist users in entering their data. For example, transmitters will use a predefined pull-down list of International Standards Organization (ISO) codes for countries to enter the country from which the article is shipped. Screen design places critical data entry items at the beginning of the submission process and uses those items to drive later processes. Data entry processing will also include robust and user-friendly data validation to ensure that transmitters enter data correctly and do not fail prior notice because of inadvertent errors in their data entry screens. Additional description of the FDA PN System Interface is included in the discussion of the interim final rule at the end of this section.

3b. Form Processing

(Comments) Several comments make suggestions about the way the form should be processed, requesting self-populating fields, the ability to change information without redoing the whole form, confirmation after submission, and other features that would make submission easier.

(Response) As noted previously, FDA did not intend the draft form in the proposed regulation to suggest processing sequences. Submitters or transmitters using the ABI/ACS interface to submit prior notice data to the FDA will be able to make full use of the capabilities of their particular ABI software's automation features. The FDA PN System Interface will permit initial partial data entry and will allow the user to save the information entered until all data are available for submission. The FDA PN System Interface is designed to accept "header" information that will permit repeated information to be automatically entered. This "header" would contain information consistent across several articles of food within the same submission, *e.g.*, date and time of arrival for several articles of food in one shipment. This will reduce the amount of data entry and potentially reduce typing and transcription errors. FDA has developed the FDA PN System Interface to allow submitters to automatically repeat information already entered in the submission where appropriate (*e.g.*, all information is the same except for the identity of the article or the manufacturer).

The order of information required in prior notice is displayed to best support user input. For example, the first information required is the identification of the submitter and transmitter, if applicable. The next information is the common information that may apply to all articles of food for which prior notice is being submitted at the same time, such as the manufacturer, shipper, carrier, etc. For example, when a manufacturer is identified for the first article of food, the submitter will be able to indicate, using a check box, that the manufacturer is the same for all articles of food in the shipment.

3c. Clarification of Fields

(Comments) A few comments ask for clarification on the meaning of specific fields.

(Response) Elsewhere in this rule FDA sets out the information that must be submitted in a prior notice (see § 1.281). In addition, online help will be available, which will include descriptive information on data fields, and their relationship to other required information and references to the requirements. FDA will also provide a help desk with staff who will answer questions that are not specifically answered by the online help. Information on how to contact the help desk will be available on both the FDA PN System Interface at *http://www.access.fda.gov* and the FDA Web site at *http://www.fda.gov*—see "prior notice."

4. Existing System Adequate

(Comments) Several comments suggest that the regulations proposed were unnecessary and that FDA already had the data required, so prior notice would not provide any additional security. These comments conclude that the proposed regulation is therefore functionally redundant.

(Response) Congress mandated prior notice when it enacted the Bioterrorism Act. FDA disagrees with the assertion that prior notice will not provide any additional security because similar information about food is already available. Current systems do not provide all of the information required by the Bioterrorism Act. Nor do they ensure that FDA is provided with the required information before arrival, as required by Congress when it passed the Bioterrorism Act.

5–11. Description of the Prior Notice Submission Systems

Prior notice submission and electronic review will be accomplished through several new or enhanced components of FDA's and CBP's existing electronic systems.

a. *ABI/ACS interface.* The existing ABI/ACS interface, which sends data from customs brokers or self-filers through ACS to OASIS, will be enhanced to support the prior notice requirement. For customs brokers or self-filers providing prior notice as part of their CBP entry through the ABI/ACS interface, the process for submission and response will be similar to the current process for submitting entry information about FDA-regulated products. A customs broker or self-filer will enter and transmit the information currently required in a CBP entry, along with any additional information required in prior notice, using the software that currently supports submission of data through the ABI interface. (Changes will be required to the existing software to support the additional information required in the prior notice.) As it does currently, ACS will validate the submission to ensure that data required by CBP and FDA is entered. The existing validation will be enhanced to include validation of some prior notice information. If errors or deficiencies are found, the transmission will be rejected and the customs broker or self-filer can resubmit after correcting the errors or deficiencies.

Once ACS determines a submission is valid, the prior notice information and other data will be transmitted to OASIS. OASIS will perform additional data checks and validations. Validation is the process by which the data are checked for completeness and self-consistency by the system. It is a rapid process that does not include screening the data for potential public health concerns. That screening occurs after data validation. If the submission is determined to be facially valid, FDA will transmit a message through ACS to the customs broker or self-filer. The message will provide the Prior Notice Confirmation Number (PN Confirmation Number), which verifies that the prior notice has been confirmed by FDA for review.

If errors are found, OASIS will reject the submission and generate a message(s) identifying where the error occurs. No PN confirmation number will be issued. After the customs broker or self-filer is notified of the errors, the customs broker or self-filer can correct the errors and resubmit the entire entry using the same entry number through the existing CP transaction process (which is the existing transaction for brokers or self-filers to resubmit FDA-specific data through ACS). This process only allows FDA-specific data to be corrected for resubmission, and not CBP-specific data.

A new ABI/ACS-OASIS interface, modeled after the existing process, will be available to submit prior notice for an article of food entering the United States as an IT or T&E entry, or an FTZ admission. This new transaction will not require all of the information currently submitted to CBP at the time a consumption entry is filed, but will require complete prior notice information. Processing of these prior notices will be similar to that described for consumption entries. However, prior notice will be submitted by a new transaction type that will require only the information needed for prior notice and to support messages to CBP regarding the adequacy of the prior notice.

If CBP entry is later filed, the PN Confirmation Number for the article must be entered as an affirmation of compliance for OASIS purposes as evidence that prior notice for the product was submitted and confirmed before arrival. Depending on the capabilities of a customs broker's or self-filer's software, a copy of the ABI Cargo Release Summary will also show that the prior notice has been received, though not necessarily confirmed, by FDA.

The following list identifies the types of entries, with accompanying CBP description, for which prior notice may be submitted through ABI/ACS at the submitter's option:

"Consumption entries"—products entered for use or consumption in the United States;

"Warehouse entries"—products subject to duty but for which payment of duties is deferred. Merchandise entered into a warehouse may be stored, repacked, cleaned, manufactured, smelted, refined, or sold for export. Food must remain in the warehouse until withdrawn for consumption in the United States (and any applicable duty paid);

"IT entries"—in-bond transportation entries for merchandise that arrives at a Customs port of entry but is transported without appraisement to another Customs port of entry where it may be entered for consumption or warehouse, admitted into a FTZ or may be the subject of another transportation entry;

"T&E" entries"—in-bond transportation entries for merchandise which arrives at a Customs port of entry and is to be transported without appraisement through the Customs territory and then exported; and

"FTZ admissions"—are for merchandise to be used in manufacturing or exhibition or to be manipulated in a FTZ. Merchandise admitted into the zone is not subject to the payment of duties. Merchandise may be withdrawn from the zone for consumption, warehousing, or exportation. There are various categories of merchandise in a zone.

b. *FDA PN System Interface.* The new FDA PN System Interface will be available for international mail and other transactions that are not accepted by ABI/ACS, food refused under section 801(m) of the FD&C Act, and those who choose not to submit prior notice through ABI/ACS. The FDA PN System Interface is available at *http://www.access.fda.gov*. FDA expects that less than 10 percent of transactions will be routinely submitted through the FDA PN System Interface. We estimated the number of informal entries that are not currently captured by ABI/ACS and international mail submissions based on discussions with CBP.

The FDA PN System Interface will allow the user to view and print a prior notice confirmation, including a PN Confirmation Number, the time the prior notice was confirmed, and a record of the information received and validated by FDA.

To submit prior notice information electronically by the FDA PN System Interface, the transmitter must establish a prior notice account. FDA's Unified Registration and Listing System (FURLS) at *http://www.access.fda.gov* will manage the issuance of user accounts for both food facility registrations and prior notice submissions. FURLS will be available 24 hours a day, 7 days a week, and will provide end-users access to the systems. After successfully logging in using the account password, FURLS will pass the user account credentials to the FDA PN System Interface. If the transmitter has not established a prior notice account, the transmitter will be directed to establish a prior notice account the first time he or she accesses the FDA PN System Interface. Subaccounts can also be created, at the discretion of the primary account, to allow more than one person associated with a prior notice to access the prior notice information.

A submitter or transmitter who elects to use the FDA PN System Interface will enter information online, using a series of screens designed to lead the submitter through the prior notice submission process. Data will be subject to the same validation criteria used in the ABI/ACS–OASIS interface, but the validation will be performed on-line, in real time. When the prior notice submission has been validated, the transmitter will receive a message showing that the prior notice has been received by FDA for review and accepted as facially complete. This message will include a unique PN Confirmation Number as well as the date and time of the submission and confirmation. The message will confirm that the prior notice is facially complete and has been received by the FDA for review. Capability will also be provided