

Table 16.—Perishable Seafood From Central America

2001 Perishable Seafood Products Flown From Central America	Pounds	Dollars
Alka mackerel, fresh	14,128	22,148
Conch live, fresh	2,474,956	5,884,962
Crab live, fresh	248,580	1,125,507
Eels, fresh	207	7,520
Fish liver and roe, fresh	78,606	112,066
Flatfish flounder, fresh	6,622	7,840
Freshwater fish, fresh	211,853	354,798
Groundfish cod, fresh	1,808	2,381
Grouper, fresh	1,077,703	2,092,349
Lingcod, fresh	5,020	8,804
Lobster (Homarus spp.), fresh	104,689	1,007,256
Rock lobster, live	55,042	414,237
Mackerel, fresh	178,312	230,169
Marine fish fillet, fresh	5,840,824	12,442,031
Marine fish, fresh	21,284,450	32,628,025
Marine fish scaled, fresh	98,085	196,186
Mollusc live, fresh	7,372	14,739
Oysters live, fresh	4,629	10,380
Perch fillet, fresh	6,461	13,104
Salmon Atlantic fillet, fresh farmed	8,969	16,002
Salmon fillet, fresh	3,766	10,524
Shark, fresh	35,823	45,543
Shrimp peeled, fresh	58,384	177,434
Snapper, fresh	8,502,525	14,314,692
Squid live, fresh	5,914	2,575
Swordfish, fresh	2,272,257	6,626,692
Swordfish steaks, fresh	1,577	5,945
Tilapia fillet, fresh	11,053,830	28,080,704
Toothfish patagonian, fresh	5,636	15,574
Trout, fresh	67,795	130,844
Trout rainbow, fresh farmed	468,200	1,025,162
Tuna albacore, fresh	55,561	113,930
Tuna bigeye, fresh	2,924,770	8,348,825
Tuna bluefin, fresh	1,580	2,148
Tuna, fresh	1,070,384	2,735,066
Tuna yellowfin, fresh	2,542,404	7,652,086
Wholesale Value		\$125,898,248
Retail Value		\$231,796,496

Importers of perishable products from Canada, Mexico, and Central America may not be able to cross the border for 4 hours, which is 2.4 percent of the produce life span (4 hours out of 168 hours) and 8.3 percent of the seafood life span (4 hours out of 48 hours). Table 17 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 20 percent of imported Mexican, Canadian, and Central American perishable seafood and produce affected.

TABLE 17.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 4

Perishable Produce	Dollars (thousands)
2001 Imported Mexican produce total retail value	\$3,458,525,000
2.4% Reduction in value for 20% of Mexican produce	\$16,600,920
2001 Imported Canadian produce total retail value	\$401,826,000
2.4% Reduction in value for 20% of Canadian produce	\$1,928,765
2001 Imported Central American produce total retail value	\$217,420,000
2.4% Reduction in value for 20% of Central American produce	\$1,043,616
Total Lost Value for Produce	\$19,574,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,406
6.3% Reduction in value for 20% of Mexican seafood	\$1,863,806
2001 Imported Canadian seafood total retail value	\$1,863,267,894
6.3% Reduction in value for 20% of Canadian seafood	\$30,929,417
2001 Imported Central American seafood total retail value	\$251,768,466
6.3% Reduction in value for 20% of Central American seafood	\$4,179,822
Total Lost Value for Seafood	\$36,973,000

For this 4-hour prior notice submission timeframe and for all subsequent options with longer timeframes for submission, we also begin to include some holding time costs paid to carriers of products to be imported. We add in this cost in that at least 40 percent of food products being imported from Canada and Mexico are coming from locations located 4 hours or less from a U.S. border. For products located less than 4 hours from the U.S. border, it is quite possible that the carrier will have to be paid for additional waiting time over what had been established under the current business practices. Comments indicated that additional truck time was a real possibility for all food products being imported and not just perishable products. We therefore include a percentage of all products requiring prior notice in the cost estimate in table 18 of this document. We do not have information on the number of import entries that may use additional truck time because of prior notice submission times. Therefore, we will assume that 20 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) will pay for an additional 1 hour of truck time per entry. We use 20 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 20 percent when the prior notice submission timeframe is 4 hours before arrival.

TABLE 18.—COST OF ADDITIONAL CARRIER TIME FOR OPTION 4

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
20% of ground entries	176,923
Cost for 1 hour of carrier time (\$250 per hour)	\$250
Total cost of truck time	\$44,231,000

Table 19 of this document presents a summary of the costs associated with option 4. Also presented in table 19 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

TABLE 19.—SUMMARY OF COSTS FOR OPTION 4 (4 HOUR MINIMUM PRIOR NOTICE SUBMISSION TIME)

	Dollars (thousands)
Learning costs	\$66,240
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional Costs for BRASS users	\$48,462
Lost value for Mexican produce	\$16,601
Lost value for Canadian produce	\$1,929
Lost value for Central American produce	\$1,044
Lost value for Mexican seafood	\$1,864
Lost value for Canadian seafood	\$30,929
Lost value for Central American seafood	\$4,180
Cost for truck time	\$44,231
Total first year costs for Option 4	\$454,675
Annual costs after first year	\$348,534
Present value of costs at 7% for 20 years	\$3,791,567
Present value of costs at 3% for 20 years	\$5,288,348

TABLE 20.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 5 FOR SHIPMENTS ARRIVING BY VEHICLE (1-HOUR MINIMUM NOTICE REQUIREMENT)—Continued

	Dollars
97% of Total retail value for Canadian seafood .....	\$1,807,321,000
2.1% Reduction in value for 2.5% of Canadian seafood .....	\$948,844
Total lost value for seafood .....	\$1,006,000

(ii) *Four-hour minimum prior notice time for food arriving by rail and air.* We adjust the total retail value of highly perishable produce and seafood coming from the Central American region, we assume that 97 percent of perishable produce and seafood from Central America is shipped to the United States by air. We adjust the total retail value of the perishable products from Central America to reflect that 97 percent of the total value that arrives in the United States by air. Table 21 of this document shows the loss of value for those 20 percent of air shipments from Central America for which prior notice was resubmitted under option 5.

TABLE 21.—Loss in Value Caused by Resubmitted Prior Notice Under Option 5 for Shipments Arriving by Air and Rail (4-hour minimum notice requirement)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
3% of Total retail value for Mexican produce	\$103,756,000
2.4% Reduction in value for 20% of Mexican produce	\$498,000
2001 Imported Canadian produce total retail value	\$401,826,000
3% of Total retail value for Canadian produce	\$12,055,000
2.4% Reduction in value for 20% of Canadian produce	\$58,000
2001 Imported Central American produce total retail value	\$217,420,000
97% of Total retail value for Central American produce	\$210,897,000
2.4% Reduction in value for 20% of Central American produce	\$1,012,000
Total lost value for produce	\$1,508,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,000
3% of Total retail value for Mexican seafood	\$3,368,000
8.3% Reduction in value for 20% of Mexican seafood	\$36,000
2001 Imported Canadian seafood total retail value	\$1,863,218,000
3% of Total retail value for Canadian seafood	\$55,897,000
8.3% Reduction in value for 20% of Canadian seafood	\$928,000
2001 Imported Central American seafood total retail value	\$251,796,000
97% of Total retail value for Central American seafood	\$244,242,000
8.3% Reduction in value for 20% of Central American seafood	\$4,054,000
Total lost value for seafood	\$5,038,000

option at the OMB-recommended discount rates of 3 and 7 percent.

importers bringing food into the United States by airplane or by train are required to give prior notice a minimum of 4 hours before arrival. This timeframe is sufficient for even shorter flights from Caribbean countries and Central American countries to the United States. For example, though the actual flying time of a direct flight from the Bahamas to Miami is only 2 hours, the airplane must be loaded, taxied to the runway, cleared for take-off, and on arrival landed, taxied from the runway, and unloaded. A 4-hour minimum prior notice time will therefore seldom be constraining. A 4-hour minimum prior notice time for flights could be constraining for rush orders of food from Canada and Mexico. However, OASIS fiscal year 2002 data shows that only about 10,000 food entry lines were flown in from Canada and only about 20,000 lines flown in from Mexico. This is a very small portion, less than 1 percent, of total shipments from Canada and Mexico.

Option 5 requires that prior notice be submitted 8 hours before arrival for articles of food being imported by vessel. We do not specifically address food imported by vessel in this option because this mode of transport will not be constrained by an 8-hour minimum prior notice timeframe. The costs of this option for vessels will be the same as in the previous option. (i) *One-hour minimum prior notice time for food arriving by vehicle.* Importers of perishable products from Canada and Mexico, whose articles of food arrive in the United States by vehicle, will have to submit prior notice 1 hour before arrival. This short, minimum submission time should eliminate the probability of having to resubmit prior notice for all but 2.5 percent of those perishable products imported from Canada and Mexico. OASIS data indicates that approximately 44 percent of all

imported food shipments used land transportation to arrive in the United States for fiscal year 2002. These shipments must come from Canada and Mexico (or in some cases transhipped), as these are the countries that have land borders with the United States. OASIS data shows that only about 2 percent of imported food shipments arrived in the United States by rail in 2002, and less than 1 percent of shipments arrived from Canada and Mexico by air. Thus, at least 97 percent of all imported food shipments arriving from Canada and Mexico used vehicles as the mode of transport.

Using this 97 percent estimate, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrives in the United States by vehicle. We then use this new retail value, 97 percent of the total value, to calculate the lost product value (1 hour out of 48 hours for seafood) for the 2.5 percent of highly perishable produce and seafood from Canada and Mexico for which importers would have to resubmit the prior notice when the minimum submission time is 1 hour. Table 20 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 2.5 percent of imported Mexican and Canadian perishable seafood and produce affected.

We also do not include the cost of truck time with this option, because the minimum prior notice time for articles of food arriving by vehicle is only 1 hour. Given current border wait times and manufacturing/processing facility distance from the U.S. border, it is unlikely that articles of food will have to wait to enter the United States because of prior notice requirements.

TABLE 20.—LOSS IN VALUE CAUSED BY RESUBMITTED PRIOR NOTICE UNDER OPTION 5 FOR SHIPMENTS ARRIVING BY VEHICLE (1-HOUR MINIMUM NOTICE REQUIREMENT)

Perishable Produce:	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
97% of Total retail value for Mexican produce	\$3,354,769,000
0.6% Reduction in value for 2.5% of Mexican produce	\$903,215
2001 Imported Canadian produce total retail value	\$401,826,000
97% of Total retail value for Canadian produce	\$389,771,000
0.6% Reduction in value for 2.5% of Canadian produce	\$84,466
Total lost value for produce	\$562,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,000
97% of Total retail value for Mexican seafood	\$108,909,000
2.1% Reduction in value for 2.5% of Mexican seafood	\$37,177
2001 Imported Canadian seafood total retail value	\$1,863,218,000

option at the OMB-recommended discount rates of 3 and 7 percent.

Table 22.--Summary of Costs for Option 5

	Dollars (\$ thousands)
Learning costs	\$66,240
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for produce	\$2,130
Lost value for seafood	\$6,044
Cost for truck time	\$0
Total first year costs for option 5	\$362,071
Annual costs after first year	\$255,929
Present value of costs at 7% for 20 years	\$2,810,515
Present value of costs at 3% for 20 years	\$3,910,630

e. Option 6: Minimum prior notice timeframe of 2 hours before arrival for vehicles, 4 hours before arrival for rail and air, and 8 hours before arrival for vessels; electronic submission of information; any change in information requires resubmission (interim final rule). Option 6 requires that prior notice be submitted 2 hours before arrival for articles of food being imported by vehicle and 4 hours before arrival for articles of food being imported by rail or air modes of transportation.

Option 6 requires that prior notice be submitted 8 hours before arrival for articles of food being imported by vessel. We do not specifically address food import by vessel in this option because this mode of transport will not be constrained by an 8-hour minimum prior notice timeframe. The costs of this option for vessels will be the same as in the previous options.

i. Two-hour minimum prior notice time for food arriving by vehicle. Importers of perishable products from Canada and Mexico, whose articles of food arrive in the United States by vehicle, will have to submit prior notice 2 hours before arrival. This short, minimum submission time frame should eliminate the probability of

Mexico for which importers would have to resubmit the prior notice when the minimum submission time is 2 hours. Table 23 of this document shows the loss in value caused by the cancelled and resubmitted prior notice information for the 5 percent of perishable seafood and produce affected.

We do not include the lost value for perishable seafood and produce imported from Central America in table 23 of this document since perishable products from Central America are most likely flown into the United States. We also do not include the cost of truck time with this option since the minimum prior notice time for articles of food arriving by vehicle is only 2 hours. Given current border wait times and manufacturing/processing facility distance from the U.S. border, it is unlikely that trucks will have to wait to enter the United States because of prior notice requirements. We expect that some delays will occur, but that they will be relatively rare and will impose little additional cost compared with a 1-hour minimum prior notice time. We therefore do not include any additional truck time costs for this option.

having to resubmit prior notice for all but 5 percent of those perishable products imported from Canada and Mexico. OASIS data indicates that approximately 44 percent of all imported food shipments used land transportation to arrive in the United States for fiscal year 2002. These shipments must come from Canada and Mexico (or in some cases transhipped), as these are the countries that have land borders with the United States. OASIS data shows that only about 2 percent of imported food shipments arrived in the United States by rail in 2002, and less than 1 percent of shipments arrived from Canada and Mexico by air. Thus, at least 97 percent of all imported food shipments arriving from Canada and Mexico used vehicles as the mode of transport.

Using this 97 percent estimate, we calculate the proportion of the total retail value of highly perishable produce and seafood from Canada and Mexico that arrives in the United States by vehicle. This new retail value, 97 percent of the total value, is then used to calculate the lost product value for the 5 percent of highly perishable produce and seafood from Canada and

Table 23.--Loss in Value Caused by Resubmitted Prior Notice Under Option 6 for Shipments Arriving by Vehicle (2-hour minimum notice requirement)

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
97% of Total retail value for Mexican produce	\$3,354,769,000
1.2% Reduction in value for 5% of Mexican produce	\$2,013,000
2001 Imported Canadian produce total retail value	\$401,826,000
97% of Total retail value for Canadian produce	\$389,771,000
1.2% Reduction in value for 5% of Canadian produce	\$234,000
Total Lost Value for Produce	\$2,247,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,000
97% of Total retail value for Mexican seafood	\$108,909,000
4.2% Reduction in value for 5% of Mexican seafood	\$229,000
2001 Imported Canadian seafood total retail value	\$1,863,218,000
97% of total retail value for Canadian seafood	\$1,807,321,000
4.2% Reduction in value for 5% of Canadian seafood	\$3,795,000
Total Lost Value for Seafood	\$4,024,000

ii. Four-hour minimum prior notice time for food arriving by rail and air. The 4-hour minimum submission time for prior notice applies to articles of food imported by rail and air modes of transportation. A 4-hour minimum prior notice timeframe for these modes of transportation could be constraining for products arriving from the countries bordering the United States.

Since we are assuming that 97 percent of food imported from Canada and Mexico arrives by vehicle, we are left with 3 percent that is imported by rail

or air. We adjust the total retail value of highly perishable produce and seafood from Canada and Mexico to account for this 3 percent. Table 24 of this document shows the lost value for the 20 percent of perishable products arriving by rail and air from Canada and Mexico that may have to resubmit prior notice when the minimum prior notice timeframe is 4 hours. For Central American countries, it is probable that most, if not all, of their perishable products are imported to the United States by air. Therefore, for the

highly perishable produce and seafood coming from the Central American region, we assume that 97 percent of the perishable produce and seafood from Central America is shipped to the United States by air. We adjust the total retail value of the perishable products from Central America to reflect that 97 percent of the total value that arrives in the United States by air. Table 24 of this document shows the loss of value for those 20 percent of air shipments from Central America for which prior notice was resubmitted under option 6.

For Central American countries, it is probable that most, if not all, of their perishable products are imported to the United States by air. Therefore, for the

Table 24.--Loss in Value Caused by Resubmitted Prior Notice Under Option 6 for Shipments Arriving by Air and Rail (4-hour minimum notice requirement)

	Dollars
Perishable Produce	
2001 Imported Mexican produce total retail value	\$3,458,525,000
2% of Total retail value for Mexican produce	\$103,756,000
2.4% Reduction in value for 20% of Mexican produce	\$498,000
2001 Imported Canadian produce total retail value	\$401,826,000
2% of Total retail value for Canadian produce	\$12,055,000
2.4% Reduction in value for 20% of Canadian produce	\$38,000
2001 Imported Central American produce total retail value	\$217,420,000
2% of Total retail value for Central American produce	\$210,897,000
2.4% Reduction in value for 20% of Central American produce	\$1,012,000
Total Lost Value for Produce	\$1,568,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,000
2% of Total retail value for Mexican seafood	\$3,368,000
2.4% Reduction in value for 20% of Mexican seafood	\$56,000
2001 Imported Canadian seafood total retail value	\$1,863,218,000
2% of Total retail value for Canadian seafood	\$55,897,000
2.4% Reduction in value for 20% of Canadian seafood	\$938,000
2001 Imported Central American seafood total retail value	\$251,796,000
2% of Total retail value for Central American seafood	\$244,242,000
2.4% Reduction in value for 20% of Central American seafood	\$4,054,000
Total Lost Value for Seafood	\$5,038,000

Table 25 of this document presents a summary of the costs associated with option 6, including the costs of the option at the OMB-recommended discount rates of 3 and 7 percent.

Table 25.--Summary of Costs for Option 6--Interim Final Rule

	Dollars (thousands)
Learning costs	\$66,240
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for produce	\$3,815
Lost value for seafood	\$9,062
Cost for truck time	\$0
Total first year costs for Option 6	\$366,744
Annual costs after first year	\$260,633
Present value of costs at 7% for 20 years	\$2,860,342
Present value of costs at 3% for 20 years	\$3,980,603

f. Option 7: Prior notice required 4 hours before arrival; electronic submission of information; allow changes to the prior notice submission up to 1 hour before arrival. We now take the estimates in option 4 and adjust them to account for the effects of allowing changes to the prior notice submission without requiring resubmission. Although the original submission time of 4 hours before arrival is relatively short, allowing changes to the original submission, in the form of electronic amendments and updates, would improve the flow of import traffic by reducing the notice resubmission rate. The smaller resubmission rate would reduce the loss

arrival. A more flexible entry screen that allows for updates and amendments to some notice information would reduce the likelihood that the original notice would have to be resubmitted by importers, thus lessening the time burden, and therefore the costs of prior notice. Even a 1 hour amendment and updates to prior notice would provide some flexibility for importers in industries where certain information, such as the type of the product being imported and the quantity of the article to be imported, may change or is not known until just before shipping.

It is also important to note here that we assume that the 1-hour time FDA has estimated that it takes to fill out each prior notice is sufficient for this option, even with the opportunity of amending prior notice information. This time is sufficient because amending or updating a particular item in the prior notice

submission should only take a few seconds to a few minutes in time. If prior notice can be amended and updated, fewer resubmissions would occur. For this option, then, with amendment and updates, we will assume that the number of prior notice resubmissions necessitated by changes in information on the notice would be reduced from 20 percent (as in option 4) to 2.5 percent. FDA believes that the resubmission rate for a 4-hour prior notice time with 1-hour amendment will result in about the same resubmission rate as option 2 (a straight 1 hour before arrival, prior notice timeframe). FDA believes these two timeframes will cause about the same resubmission rate, because both arrival timeframes are relatively short and both are within the timeframe of 4 hours that was suggested by Canadian, Mexican, and Central American perishable produce and seafood.

Table 26.--Loss in Value Caused by Resubmitted Prior Notice Under Option 7

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
2.4% Reduction in value for 2.5% of Mexican produce	\$2,075,115
2001 Imported Canadian produce total retail value	\$401,826,000
2.4% Reduction in value for 2.5% of Canadian produce	\$241,096
2001 Imported Central American produce total retail value	\$217,420,000
2.4% Reduction in value for 2.5% of Central American produce	\$130,452
Total Lost Value for Produce	\$2,446,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,406
2.4% Reduction in value for 2.5% of Mexican seafood	\$232,976
2001 Imported Canadian seafood total retail value	\$1,863,217,894
2.4% Reduction in value for 2.5% of Canadian seafood	\$3,866,177
2001 Imported Central American seafood total retail value	\$251,796,496
2.4% Reduction in value for 2.5% of Central American seafood	\$322,478
Total Lost Value for Seafood	\$4,621,000

Table 27 of this document compares the reduction in the costs of this interim final rule if amendments and updates to the prior notice are allowed (option 7), as opposed to the no-amendment 4-hour option 4.

Table 27.—Comparison of Option 4 With Option 7—Lost Value for Perishables

Perishable Mexican Produce Value Loss	
Option 4—4 hour minimum notice	\$16,601,000
Option 7—4 hour notice with changes	\$2,075,000
Savings with amendment and update	\$14,526,000
Perishable Canadian Produce Value Loss	
Option 4—4 hour minimum notice	\$1,929,000
Option 7—4 hour notice with changes	\$241,000
Savings with amendment and update	\$1,688,000
Perishable Central American Produce Value Loss	
Option 4—4 hour minimum notice	\$1,044,000
Option 7—4 hour notice with changes	\$130,000
Savings with amendment and update	\$914,000
Perishable Mexican Seafood Value Loss	
Option 4—4 hour minimum notice	\$1,864,000
Option 7—4 hour notice with changes	\$233,000
Savings with amendment and update	\$1,631,000
Perishable Canadian Seafood Value Loss	
Option 4—4 hour minimum notice	\$30,929,000
Option 7—4 hour notice with changes	\$3,866,000
Savings with amendment and update	\$27,063,000
Perishable Central American Seafood Value Loss	
Option 4—4 hour minimum notice	\$4,180,000
Option 7—4 hour notice with changes	\$522,000
Savings with amendment and update	\$3,658,000

Although submitters can amend prior notice information with this option, we assume that 2.5 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 4 hours of truck time per line. We use 2.5 percent as the percentage of trucks delayed to be consistent with our resubmission rate of a result of this wait time. Therefore, we will assume that 2.5 percent when the prior notice submission timeframe is 4 hours before arrival with a 1-hour amendment option. Table 28 of this document shows the costs of truck time associated with those prior notices that cannot be amended.

TABLE 28.—COST OF ADDITIONAL CARRIER TIME FOR OPTION 7

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
2.5% of ground entries	22,115
Cost for 4 hours of carrier time (\$250 per hour)	\$1,000
Total cost of truck time	\$22,115,000

Table 29 of this document presents a summary of the costs associated with option 7. Also presented in table 29 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 29.—Summary of Costs for Option 7 (4 hour minimum submission time, 1 hour amendment)

	Dollars (thousands)
Learning costs	\$66,420
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for Mexican produce	\$2,075
Lost value for Canadian produce	\$241
Lost value for Central American produce	\$130
Lost value for Mexican seafood	\$233
Lost value for Canadian seafood	\$3,866
Lost value for Central American seafood	\$522
Cost for truck time	\$22,115
Total first year costs for Option 7	\$383,079
Annual costs after first year	\$276,938
Present value of costs at 7% for 20 years	\$3,033,077
Present value of costs at 3% for 20 years	\$4,223,181

**E. Option 8: Minimum prior notice timeframe of 8 hours before arrival; electronic submission of information; any change in information requires resubmission (statutory default option).**

Option 8 is to issue an interim final rule that incorporates the default minimum timeframe for prior notices as provided in the Bioterrorism Act. Pre-proposal information and comments on the proposed rule indicated that Canadian and Mexican produce growers and seafood processors are concerned that the longer the minimum time required for the prior notice, the less fresh their products will be when they reach U.S. customers. Less-than-optimal fresh (i.e., lower quality) products would result in a lower price paid for the imported produce or seafood shipments, or possibly even the loss of a customer's business to a domestic producer.

For importers of perishable products such as seafood and produce, the 8-hour minimum time for prior notice is expected to change business practices. How much importer produce grower, and seafood processor business practices will be affected by prior notice requirements will depend on how early the orders are received compared with

how early prior notice must be submitted. Also, as the prior notice submission time increases, the location of the exporter in relation to the U.S. border becomes a more important factor in determining whether changes in business practices are needed.

If the prior notice time for submission is 8 hours instead of 4 hours, the probability of having to resubmit prior notice information will be greater. Now, instead of 20 percent of the importers of perishable products from Canada, Mexico, and Central America having to resubmit their notices, we will assume that the 8-hour submission timeframe means that 30 percent will have to resubmit their notices.

As explained in option 2, we based the resubmission rate percentages for perishable products coming from Canada and Mexico on comments FDA received indicating that 40 to 100 percent of the products from these two countries are shipped from locations no more than 4 hours from the border. For shorter prior notice timeframes, starting with the 4-hour option and moving downward in minimum prior notice time, we halved the resubmission rate because every hour decrease in required

prior notice submission time will eliminate a significant number of prior notice resubmissions for those facilities close to the border. For options with longer timeframes, however, instead of doubling the resubmission rate, we begin to add an additional 10 percent resubmission rate for each additional 4 hours of required prior notice minimum submission time. We do this because, aside from perishable products and rush orders, most foods are ordered in advance of shipping and the quantities of such foods are easily identifiable; these are orders that will not change and thus will not require resubmission of prior notice.

Carriers of products requiring prior notice may not be able to cross the border for 8 hours or longer, instead of 4 hours. This time for prior notice represents 4.8 percent of the produce life span (8 hours out of 168 hours) and 16.7 percent of the seafood life span (8 hours out of 48 hours). Table 30 of this document shows the loss in value caused by the resubmitted prior notice information for the 30 percent of imported Mexican, Canadian, and Central American perishable seafood and produce affected.

Table 30.--Loss in Value Caused by Resubmitted Prior Notice Under Option 8

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
4.8% Reduction in value for 30% of Mexican produce	\$49,802,760
2001 Imported Canadian produce total retail value	\$401,826,000
4.8% Reduction in value for 30% of Canadian produce	\$5,786,294
2001 Imported Central American produce total retail value	\$217,420,000
4.8% Reduction in value for 30% of Central American produce	\$3,130,848
Total Lost Value of Produce	\$58,720,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,406
16.7% Reduction in value for 30% of Mexican seafood	\$5,625,098
2001 Imported Canadian seafood total retail value	\$1,863,217,894
16.7% Reduction in value for 30% of Canadian seafood	\$93,347,216
2001 Imported Central American seafood total retail value	\$251,796,496
16.7% Reduction in value for 30% of Central American seafood	\$12,615,004
Total Lost Value for Seafood	\$111,587,000

For this 8-hour prior notice submission timeframe, we include holding time costs paid to carriers of products to be imported. We add in this cost in response to comments indicating that for longer submission timeframes and for products located less than 8 hours from the U.S. border, it is quite possible that the carrier would have to be paid for additional waiting time over what had been established under the current business practices. We do not have information on the number of import entries that may use additional truck time because of prior notice submission timeframes. We will assume that 30 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal

year 2002 (based on OASIS data) would pay for an additional 2 hours of truck time per entry. We use 30 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 30 percent when the prior notice submission timeframe is 8 hours before arrival. These costs are summarized in table 31 of this document.

Table 31.--Cost of Additional Carrier Time for Option 8

2001 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
30% of ground entries	265,385
Cost for 2 hours of carrier time (\$250 per hour)	\$500
Total cost of truck time	\$132,692,500

Table 32 of this document presents a summary of the costs associated with option 8. Also presented in table 32 of

this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 32.--Summary of Costs for Option 8 (8-hour minimum prior notice submission time)

	Dollars (thousands)
Learning costs	\$66,420
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for Mexican produce	\$49,803
Lost value for Canadian produce	\$5,786
Lost value for Central American produce	\$3,131
Lost value for Mexican seafood	\$5,625
Lost value for Canadian seafood	\$93,347
Lost value for Central American seafood	\$12,615
Cost for truck time	\$132,693
Total first year costs for Option 8	\$656,897
Annual costs after first year	\$550,756
Present value of costs at 7% for 20 years	\$5,933,909
Present value of costs at 3% for 20 years	\$8,296,901

h. *Option 9: Prior notice required 8 hours before arrival; electronic submission of information; allow changes to the prior notice submission up to 1 hour before arrival.* We now take the estimates in option 8 and adjust them to account for the effects of allowing changes to the prior notice submission. With an original submission time of 8 hours before arrival, it is likely that allowing changes to the original submission, in the form of electronic amendments and updates, would improve the flow of import traffic—especially since comments indicated that between 40 and 100 percent of products coming from Canada and Mexico are within 4 hours of a U.S. border. Regardless of when the order is placed, if the exporting facility of the product is located less than 8 hours from a U.S. border, allowing amendments and updates to prior notice would reduce the notice resubmission rate, and also reduce the loss of value for perishable foods that might

otherwise have to wait extra time before crossing the U.S. border. Again, we note with this option, we assume that the FDA 1-hour time estimate for filling out each prior notice is sufficient, even with the option of amending prior notice information. This time is sufficient because amending or updating a particular item in the prior notice submission should only take a few seconds to a few minutes in time. For this option, with amendment and updates, we will assume that the number of prior notice resubmissions necessitated by changes in information on the notice will be reduced from 30 to 5 percent. Although the amendment will eliminate the need for notice resubmission for many entries, the uncertainty associated with some shipment information increases as the prior notice minimum submission timeframe increases. Thus, for an 8-hour original submission time frame, it is unlikely that the allowance of an amendment will reduce the prior notice

resubmission rate to 2.5 percent as presented in option 7. Instead, we assume that an 8-hour prior notice submission timeframe with a 1-hour amendment will reduce the prior notice resubmission rate to 5 percent.

Option 9 saves 8 hours of wait time per entry for prior notices that can be amended or updated. The 5 percent of imports for which the prior notice cannot be amended, however, will end up waiting at the border or at the manufacturing/processing facility an additional 8 hours before arriving in the United States, which is 4.8 percent of the perishable produce life span (8 hours out of 168 hours) and 16.7 percent of the perishable seafood life span (8 hours out of 46 hours). Table 33 of this document shows the costs of submitting prior notice for an 8-hour minimum time, with a 1-hour amendment and updates, for Canadian, Mexican, and Central American perishable produce and seafood.

Table 33.--Loss in Value Caused by Resubmitted Prior Notice Under Option 8

Perishable Produce	Dollars
2001 Imported Mexican Produce total retail value	\$3,458,525,000
4.8% Reduction in value for 5% of Mexican produce	\$8,300,460
2001 Imported Canadian produce total retail value	\$401,826,000
4.8% Reduction in value for 5% of Canadian produce	\$964,382
2001 Imported Central American produce total retail value	\$217,420,000
4.8% Reduction in value for 5% of Central American produce	\$521,808
Lost Value for Produce	\$9,786,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,406
16.7% Reduction in value for 5% of Mexican seafood	\$937,516
2001 Imported Canadian seafood total retail value	\$1,863,217,894
16.7% Reduction in value for 5% of Canadian seafood	\$15,557,869
2001 Imported Central American seafood total retail value	\$251,796,496
16.7% Reduction in value for 5% of Central American seafood	\$2,102,501
Total Lost Value for Seafood	\$18,599,000

Table 34 of this document compares the reduction in the costs of this interim final rule if an amendment and update to prior notice is allowed (option 9) as opposed to the no-amendment option 8.

Table 34.--Comparison of Option 8 With Option 9--Lost Value for Perishables

Perishable Mexican Produce Value Loss	
Option 8--8 hour minimum notice	\$41,502,000
Option 9--8 hour notice with changes	\$8,300,000
Savings with amendment and update	\$33,202,000
Perishable Canadian Produce Value Loss	
Option 8--8 hour minimum notice	\$4,822,000
Option 9--8 hour notice with changes	\$964,000
Savings with amendment and update	\$3,858,000
Perishable Central American Produce Value Loss	
Option 8--8 hour minimum notice	\$3,131,000
Option 9--8 hour notice with changes	\$522,000
Savings with amendment and update	\$2,609,000
Perishable Mexican Seafood Value Loss	
Option 8--8 hour minimum notice	\$4,688,000
Option 9--8 hour notice with changes	\$938,000
Savings with amendment and update	\$3,750,000
Perishable Canadian Seafood Value Loss	
Option 8--8 hour minimum notice	\$77,789,000
Option 9--8 hour notice with changes	\$15,558,000
Savings with amendment and update	\$62,231,000
Perishable Central American Seafood Value Loss	
Option 8--8 hour minimum notice	\$12,615,000
Option 9--8 hour notice with changes	\$2,103,000
Savings with amendment and update	\$10,512,000

Although submitters can amend prior notice information with this option, we assume that those 5 percent of entries that cannot use the amendment, but instead have to wait an additional 8 hours before arriving in the United States would incur at least some truck costs as a result of this wait time. We will therefore assume that 5 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 8 hours of truck time per prior notice submission. We use 5 percent as the percentage of trucks delayed to be.

consistent with our resubmission rate of 5 percent when the prior notice submission timeframe is 8 hours before arrival with a 1-hour amendment option. Table 35 shows the costs of truck time associated with those prior notices that cannot be amended.

Table 35.--Cost of Additional Carrier Time for Option 9

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
5% of ground entries	44,231
Cost for 8 hours of carrier time (\$250 per hour)	\$2,000
Total cost of truck time	\$88,462,000

Table 36 of this document presents a summary of the costs associated with option 9. Also presented in table 36 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 36.—Summary of Costs for Option 9  
(8-hour prior notice minimum submission time, 1-hour amendment)

	Dollars (thousands)
Learning costs	\$66,420
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for Mexican produce	\$8,300
Lost value for Canadian produce	\$964
Lost value for Central American produce	\$522
Lost value for Mexican seafood	\$938
Lost value for Canadian seafood	\$15,558
Lost value for Central American seafood	\$2,103
Cost for truck time	\$88,462
Total first year costs for Option 9	\$470,744
Annual costs after first year	\$364,603
Present value of costs at 7% for 20 years	\$3,961,802
Present value of costs at 3% for 20 years	\$5,527,415

i. *Option 10: Prior notice received by 12 noon of the calendar day before arrival; electronic submission of information; any change in information requires resubmission.* This option requires that prior notice be submitted no later than 12 noon of the calendar day before the expected day of arrival. Under this option, prior notice submitters will have to let FDA know of the incoming food shipment at least 12 hours before the shipment reaches the U.S. port of arrival. This option would likely cause a change in importer business practices and the business practices of their clients in much the same way as option 8, but the potential loss of product value is higher because the minimum prior notice time has increased.

Again, how business practices would be affected by prior notice requirements depends on how early the invoice orders are received, when the truck is loaded, and when prior notice is submitted. As before, we assume that as the minimum notice time increases, the likelihood of a resubmission also increases. Instead of 30 percent of the importers of perishable products from Canada and Mexico having to cancel their original prior notices and resubmit, we will assume that the 12-hour submission timetable means that 40 percent will have to cancel and resubmit their notices. We increase the percentage of resubmission this time by 10 percent because as the prior notice time frame

increases relative to the time of arrival, it becomes more likely that the prior notice information will change after the notice is submitted to FDA, thus requiring resubmission of the notice. The transporters of products with resubmitted prior notices may then have to wait as long as 12 hours, which affects 7.1 percent of the produce life span (12 hours out of 168 hours) and 25 percent of the seafood life span (12 hours out of 48 hours).

Table 37 of this document shows the loss in value caused by the resubmitted prior notice information for the 40 percent of imported Mexican, Canadian, and Central American perishable seafood and produce that might be affected.

Table 37.—Loss in Value Caused by Resubmitted Prior Notice Under Option 10

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
7.1% Reduction in value for 40% of Mexican produce	\$98,222,110
2001 Imported Canadian produce total retail value	\$401,826,000
7.1% Reduction in value for 40% of Canadian produce	\$11,411,858
2001 Imported Central American produce total retail value	\$217,420,000
7.1% Reduction in value for 40% of Central American produce	\$6,174,728
Total Lost Value for Produce	\$115,809,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,406
25% Reduction in value for 40% of Mexican seafood	\$11,227,741
2001 Imported Canadian Seafood total retail value	\$1,863,217,894
25% Reduction in value for 40% of Canadian seafood	\$186,321,789
2001 Imported Central American seafood total retail value	\$251,796,496
25% Reduction in value for 40% of Central American seafood	\$25,179,650
Total Lost Value for Seafood	\$222,730,000

For option 10, we also include the costs of additional carrier time that may be necessary due to the longer minimum prior notice submission timeframe. For option 8 we had included the cost of an additional 2 hours of truck time for 30 percent of ground-based import entry lines; for this option we will include the cost of an additional 4 hours of truck time for 40 percent of ground-based import entry lines. We expect the percentage of imported shipments that

need extra truck time, and the truck time itself, to increase as the prior notice submission timeframe increases. These costs are summarized in table 38 of this document.

Table 38.—Cost of Additional Carrier Time for Option 10

2001 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
40% of ground entries	353,846
Cost for 4 hours of carrier time (\$250 per hour)	\$1,000
Total cost of truck time	\$353,846,000

Table 39 of this document presents a summary of the costs associated with option 10. Also presented in table 39 of

this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.



Table 39.—Summary of Costs for Option 10  
(12 noon the calendar day before arrival minimum submission time)

	Dollars (thousands)
Learning costs	\$66,420
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for Mexican produce	\$98,222
Lost value for Canadian produce	\$11,412
Lost value for Central American produce	\$6,175
Lost value for Mexican seafood	\$11,228
Lost value for Canadian seafood	\$186,322
Lost value for Central American seafood	\$25,180
Cost for truck time	\$353,846
Total first year costs for Option 10	\$1,046,282
Annual costs after first year	\$940,141
Present value of costs at 7% for 20 years	\$10,059,060
Present value of costs at 3% for 20 years	\$14,089,967

j. Option 11: Prior notice received by 12 noon of the calendar day before arrival; electronic submission of information; allow changes to the prior notice submission up to 1 hour before arrival. We now take the estimates in option 10 and adjust them to account for the effects of allowing changes to the prior notice submission. Since prior notice must be submitted by 12 noon on the calendar day before arrival, it is reasonable to expect that not all the information required on a prior notice would be final.

The prior notice requires the addresses of the submitter, importer, owner, and consignee, as well as the carrier, manufacturer, and grower if known. Required information also includes the identity of the article of food, its PDA Country of Production, the country from which the food is shipped, its CBP entry identifier, the date, time, and anticipated port of arrival, and planned shipment information.

Increasing the number of required fields that can be changed in the prior notice before arrival reduces the likelihood that the information would have to be completely resubmitted by importers. This change would lessen the time burden, and therefore, the cost of

having to submit prior notice. Allowing a 1-hour amendment and updates to prior notice would provide some flexibility for importers in industries where some of the required information, such as the specific type of food (i.e., codfish instead of fish) of the product being imported, may change or is not known until just before shipping. Again we note that we assume that 1-hour time each prior notice is sufficient, even with the option of amending prior notice information. This time is sufficient because amending or updating a particular item in the prior notice submission should only take a few seconds to a few minutes.

For this option with amendment and updates, we assume that the number of prior notice resubmissions necessitated by changes in information on the notice would be reduced from 40 percent (as in option 10) to 10 percent. The notice resubmission rate for this option is expected to be higher than previous options with amendments because the original submission must be given by 12 noon on the calendar day before arrival. The lengthening of the minimum prior notice time period from 8 hours with amendment (option 9) to 12 noon the

calendar day before arrival with amendment (this option) suggests that there would be significantly more prior notices initially submitted for which all required information has not been completely determined. Less-than-final information on original prior notice submissions increases the likelihood that the notice will require revision, either in the form of an amendment or in the form of a total resubmission of the original prior notice.

Option 11 saves 12 hours wait time per entry line that can be amended or updated for the prior notice over the time used in option 9. Those shipments, whose prior notice must be completely resubmitted, would wait an additional 12 hours at the manufacturing/processing facility or at the U.S. border; 7.1 percent of the perishable produce life span (12 hours out of 168 hours) and 25 percent of the perishable seafood life span (12 hours out of 48 hours). Table 40 of this document shows the costs of submitting prior notice for a 12-hour minimum time, with a 1-hour timeframe for amendment and updates before arrival, for Canadian, Central American, and Mexican perishable produce and

Table 40.—Loss in Value Caused by Resubmitted Prior Notice Under Option 11

Perishable Produce	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
7.1% Reduction in value for 10% of Mexican produce	\$24,555,528
2001 Imported Canadian produce total retail value	\$401,826,000
7.1% Reduction in value for 10% of Canadian produce	\$2,852,965
2001 Imported Central American produce total retail value	\$217,420,000
7.1% Reduction in value for 10% of Central American produce	\$1,543,682
Total Lost Value for Produce	\$28,953,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,406
25% Reduction in value for 10% of Mexican seafood	\$2,806,935
2001 Imported Canadian seafood total retail value	\$1,863,217,894
25% Reduction in value for 10% of Canadian seafood	\$46,580,447
2001 Imported Central American seafood total retail value	\$251,796,496
25% Reduction in value for 10% of Central American seafood	\$6,294,912
Total Lost Value for Seafood	\$55,682,000

Table 41 of this document compares the reduction in the costs of this rule if an amendment and update to prior notice is allowed (option 11) as opposed to the no-amendment option 10.

Table 41.—Comparison of Lost Value for Perishables Between Option 10 With Option 11

Perishable Mexican Produce Value Loss	
Option 10–12 hour minimum notice	\$98,222,000
Option 11–12 hour notice with changes	\$24,556,000
Savings with amendment and update	\$73,666,000
Perishable Canadian Produce Value Loss	
Option 10–12 hour minimum notice	\$11,412,000
Option 11–12 hour notice with changes	\$2,853,000
Savings with amendment and update	\$8,559,000
Perishable Central American Produce Value Loss	
Option 10–12 hour minimum notice	\$6,175,000
Option 11–12 hour notice with changes	\$1,544,000
Savings with amendment and update	\$4,631,000
Perishable Mexican Seafood Value Loss	
Option 10–12 hour minimum notice	\$11,228,000
Option 11–12 hour notice with changes	\$2,807,000
Savings with amendment and update	\$8,421,000
Perishable Canadian Seafood Value Loss	
Option 10–12 hour minimum notice	\$186,322,000
Option 11–12 hour notice with changes	\$46,580,000
Savings with amendment and update	\$139,742,000
Perishable Central American Seafood Value Loss	
Option 10–12 hour minimum notice	\$25,180,000
Option 11–12 hour notice with changes	\$6,295,000
Savings with amendment and update	\$18,885,000

Although submitters can amend prior notice information with this option, we assume that those 10 percent of entry lines that cannot be amended, but instead have to wait an additional 12 hours to arrive in the United States would incur at least some truck costs corresponding to this wait time.

Therefore we will assume that 10 percent of the 2.3 million lines that entered the United States by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 12 hours of truck time per line. We use 10 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 10 percent when the prior notice submission timeframe is noon the calendar day before arrival with a 1-hour amendment option. Table 42 of this document shows the costs of truck time associated with these prior notices that cannot be amended.

TABLE 42.—COST OF ADDITIONAL CARRIER TIME FOR OPTION 11

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
10% of ground entries	88,462
Cost for 12 hours of carrier time (\$250 per hour)	\$3,000
Total cost of truck time	\$265,386,000

Table 43 of this document presents a summary of the costs associated with option 11. Also presented in table 43 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 43.—Summary of Costs for Option 11 (12 noon the calendar day before arrival minimum submission time with amendment option 1 hour before arrival)

	Dollars (thousands)
Learning costs	\$66,420
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for Mexican produce	\$24,556
Lost value for Canadian produce	\$2,853
Lost value for Central American produce	\$1,544
Lost value for Mexican seafood	\$2,807
Lost value for Canadian seafood	\$46,580
Lost value for Central American seafood	\$6,295
Total truck time	\$265,386
Total first year costs for Option 11	\$703,918
Annual costs after first year	\$397,777
Present value of costs at 7% for 20 years	\$6,432,050
Present value of costs at 3% for 20 years	\$8,996,455

k. *Option 12: Prior notice received by 12 noon of the calendar day before arrival; electronic submission of information; allow changes to the prior notice submission up to 2 hours before arrival (proposed rule)* Option 12 is the option that was originally proposed by FDA. This option requires prior notice submission by noon on the calendar day before arrival, with updates and amendments that can be submitted up to 2 hours before scheduled arrival at a U.S. port. We re-present the option here for comparison, as the costs attributable to each option have changed significantly since the proposed rule was updated for the prior notice over the stages.

For this option with amendment and prior notice resubmissions necessitated by changes in information on the notice would be reduced from 40 percent (as in option 10) to 15 percent. The notice resubmission rate for this option is expected to be higher than previous options with amendments because the original submission must be given by 12 noon on the calendar day prior to arrival and the minimum amendment timeframe before arrival is now 2 hours instead of 1 hour. Option 12 saves 12 hours wait time per entry line that can be amended or updated for the prior notice over the

time used in option 10. Those shipments whose prior notice must be completely resubmitted however, would wait an additional 12 hours at the manufacturing/processing facility or at the U.S. border; 7.1 percent of the perishable produce life span (12 hours out of 168 hours) and 25 percent of the perishable seafood life span (12 hours out of 48 hours). Table 44 of this document shows the costs of submitting prior notice for a 12-hour minimum time, with a 2-hour timeframe for amendment and updates before arrival, for Canadian, Central American, and Mexican perishable produce and seafood.

Table 44.--Loss in Value Caused by Resubmitted Prior Notice Under Option 12

Perishable Products	Dollars
2001 Imported Mexican produce total retail value	\$3,458,525,000
7.1% Reduction in value for 15% of Mexican produce	\$36,833,000
2001 Imported Canadian produce total retail value	\$401,826,000
7.1% Reduction in value for 15% of Canadian produce	\$4,279,000
2001 Imported Central American produce total retail value	\$217,420,000
7.1% Reduction in value for 15% of Central American produce	\$2,316,000
Total Lost Value for Produce	\$43,428,000
Perishable Seafood	
2001 Imported Mexican seafood total retail value	\$112,277,000
25% Reduction in value for 15% of Mexican seafood	\$4,210,000
2001 Imported Canadian seafood total retail value	\$1,863,218,000
25% Reduction in value for 15% of Canadian seafood	\$69,871,000
2001 Imported Central American seafood total retail value	\$251,796,000
25% Reduction in value for 15% of Central American seafood	\$9,442,000
Total Lost Value for Seafood	\$83,523,000

Although submitters can amend prior notice information with this option, we assume that those 15 percent of entry lines that cannot be amended, but instead have to wait an additional 12 hours to arrive in the United States would incur at least some truck costs corresponding to this wait time.

Therefore we will assume that 15 percent of the 2.3 million lines that entered the U.S. by ground transportation in fiscal year 2002 (based on OASIS data) would pay for an additional 12 hours of truck time per line. We use 15 percent as the percentage of trucks delayed to be consistent with our resubmission rate of 15 percent when the prior notice submission timeframe is noon the calendar day before arrival with a 2-hour amendment option. Table 45 of this document shows the costs of truck time associated with those prior notices that cannot be amended.

Table 45.--Cost of Additional Carrier Time for Option 12

2002 OASIS import entry lines by ground transportation (truck or train)	2,300,000
Average number of lines per entry	2.6
Total number of ground entries	884,615
15% of ground entries	132,692
Cost for 12 hours of carrier time (\$250 per hour)	\$33,000
Total cost of truck time	\$398,076,000

Table 46 of this document presents a summary of the costs associated with option 12. Also presented in table 46 of this document are the present values of the costs associated with this option using the OMB-recommended discount rates of 3 and 7 percent.

Table 46.--Summary of Costs for Option 12 (12 noon the calendar day before arrival minimum submission time with amendment option 2 hours before arrival)

	Dollars (thousands)
Learning costs	\$66,420
Coordination costs	\$31,095
Computer acquisition costs	\$7,600
FDA prior notice system cost	\$13,000
Annual costs to fill out prior notice screens	\$187,500
Additional costs for BRASS users	\$48,462
Lost value for Mexican produce	\$36,833
Lost value for Canadian produce	\$4,279
Lost value for Central American produce	\$2,316
Lost value for Mexican seafood	\$4,210
Lost value for Canadian seafood	\$69,871
Lost value for Central American seafood	\$9,442
Cost of truck time	\$398,076
Total first year costs for Option 12	\$878,924
Annual costs after first year	\$772,783
Present value of costs at 7% for 20 years	\$8,286,066
Present value of costs at 3% for 20 years	\$11,600,102

4. Summary of Options

Table 47 of this document gives a summary of the costs associated with the prior notice rule for each option presented. The costs associated with the prior notice requirements are included for each option for all modes of

transportation. These costs include the following items: Learning the rule, coordinating the required information, acquiring computer equipment, and annual submission costs for all imported food shipments. The cost of lost value for perishable products is

included in each option calculation depending on mode of transportation and minimum prior notice submission time. Lost truck time is included for options with longer timeframes.

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**Sensitivity analysis.** We estimate that the costs of the interim final rule (option 6) will be about \$367 million in the first year and \$261 million in later years. At a 7 percent discount rate, the present value of the costs of the interim final rule, discounted 20 years into the future, would be about \$3 billion; for a discount rate of 3 percent, the present value costs would be \$4 billion. These estimates rely on several important assumptions:

- In option 6, for perishable products from Canada, Mexico, and Central America: 5 percent of prior notices will need to be resubmitted if the notice must be submitted 2 hours before arrival for vehicles; 20 percent of prior notices will need to be resubmitted if the notice must be submitted 4 hours before arrival for air and rail.
- The minimum entry time for food shipments imported over land and by air is a constraining factor for those importers who use these modes of transportation. The additional costs for

shipments made over land and by air are greater for a specified minimum prior notice time, the closer the facility is to the U.S. border. Shipments arriving by sea are not likely to be affected by a specified minimum prior notice time.

- The retail value of imported fresh seafood and produce is 100 percent higher than its wholesale value.
- The number of entry lines requiring prior notice will increase 3 percent per year.
- Prior notice does not need to be submitted for informal food entries, i.e., international mail.
- BRASS is not compatible with submitting prior notice.
- We now present a sensitivity analysis, which shows how our estimates of costs for the interim final rule change if we use different assumptions. We substitute the following assumptions for those used previously:
- In option 6 for perishable products from Canada, Mexico, and Central America: 10 percent of prior notices will need to be resubmitted when the prior rate of discount.

notice time is 2 hours before arrival for vehicles; 40 percent of prior notices will need to be resubmitted if the prior notice must be submitted 4 hours before arrival for shipments arriving by rail and air.

- The retail value of imported fresh seafood and produce is 200 percent higher than its wholesale value.
- The number of entry lines requiring prior notice will increase 3 percent per year.
- Prior notice does not need to be submitted for informal food entries, i.e., international mail.
- BRASS is compatible with submitting prior notice.
- Tables 48 and 49 of this document show the results of the sensitivity analysis. The tables show that the estimated cost of the interim final rule is most sensitive to the assumed fraction of prior notices that will need to be changed. The present value of the interim final rule is most sensitive to the rate of discount.

Table 48.--Sensitivity Analysis for Assumptions Made for Option 6 (interim final rule)

Test	First Year Cost Under Base Assumption		First Year Cost Under Test Assumption		Percent Change in Cost
	(\$ millions)		(\$ millions)		
10 and 40% prior notices changed	\$367	\$367	\$380	\$13	4
Retail value is 200% of wholesale value	\$367	\$367	\$380	\$13	4
Prior notice entries increase 3%	\$367	\$367	\$372	\$5	1
Informal entries do not submit prior notice	\$367	\$367	\$329	-\$38	-10
BRASS is compatible with submitting prior notice	\$367	\$367	\$318	-\$49	-13

Table 47.--Summary of Costs Associated With Each Option

Description of Option	No Regulation	Costs (thousands)											
		Licensing costs	Coordination costs	Computer acquisition costs	FDA prior notice system cost	Annual costs to fill out prior notice	BRASS users	Least value for perishable foods	Cost for truck time	First year cost of each option	Present value total cost of each option at 7% for 20 years	Present value total cost of each option at 3% for 20 years	
Option 12	Prior notice 12 noon the calendar day before arrival with 2 hour amendment (proposed rule)	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 11	Prior notice 12 noon the calendar day before arrival with 1 hour amendment	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 10	Prior notice 12 noon the calendar day before arrival	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 9	Prior notice 8 hours before arrival with 1 hour amendment	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 8	Prior notice 8 hours before arrival	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 7	Prior notice 4 hours before arrival with 1 hour amendment	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 6	Prior notice 2 hours before arrival for vehicles, 4 hours for arrival for planes and (interim final rule)	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 5	Prior notice 1 hour before arrival for planes and (interim final rule)	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 4	Prior notice 1 hour before arrival for vehicles, 4 hours for arrival for planes and (interim final rule)	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 3	Prior notice 2 hours before arrival	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 2	Prior notice 2 hours before arrival	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	
Option 1	Prior notice 1 hour before arrival	66,420	31,095	7,600	13,000	187,500	48,462	126,951	398,976	878,924	772,783	8,966,455	



businesses as defined by the Small Business Administration. Because most of the importers affected are small, all options considered in the Benefit-Cost Analysis in section IV.A of this document are regulatory relief options.

A few comments stated that FDA's analysis of the impact of prior notice on small businesses was inadequate. The comments also wished to see a breakdown of costs of the rule per small business by industry sector.

Unfortunately, FDA does not have detailed information on which businesses subject to this interim final rule are small, nor did comments provide such information. Therefore, FDA cannot perform a detailed analysis of the costs per small business by industry sector. With limited data, FDA can estimate an average cost per importer for some of the prior notice cost categories, estimate some costs of the rule per retail establishment, and provide an average estimate of cost per establishment if the costs of the rule were evenly distributed across the supply chain.

2. Costs per Entity

This interim final rule requires FDA be notified of incoming products

electronically before the food arrives at a U.S. port. The annual cost of doing so is about \$2,400 per submitter (based on \$187.5 million in notification costs/77,427 U.S. importers). This calculation is presented in table 52 of this document. Also presented in table 52 is the cost per importer to learn about the prior notice interim final rule and to coordinate the information that needs to be submitted; the costs per importer of these two activities are about \$850 and \$400, respectively.

As discussed and shown in tables 1B and 2 of this document, about 3,100 U.S. importers are estimated to not have electronic transmitting capacity and will have to obtain computer equipment (at a cost of about \$2,000 per importer) and Internet access (at a cost of about \$240 annually) in order to comply with this interim final rule. FDA could not provide flexibility for those importers who do not have electronic transmitting capacity, because paper notices could not be submitted in the prior notice timeframe and would therefore actually be more burdensome to importers, and because FDA would not be able to receive, review, and respond to paper prior notices that are submitted on a routine basis.

This interim final rule will cause some loss of product value if the prior notice requirement causes perishable products to have to wait any length of time before arriving at a U.S. port. The costs of lost product value vary with the required notice time. FDA does not have information on the subset of importers who will be affected by these costs; therefore, we cannot calculate a cost per importer for these potential losses. We do discuss the various costs associated with this possibility in the options outlined previously.

Table 52 of this document shows the average costs per importer to learn the rule, coordinate information, and submit prior notice. Table 52 also shows the average costs to the importer to absorb the costs of not being able to use BRASS and to absorb costs of lost value of perishable products. Table 52 also shows these average costs per retail establishment and per establishment across the supply chain. Numbers for establishments come from the County Business Patterns, U.S. Census, and Non-Employer statistics. A complete discussion of these establishment numbers can be found in the FDA Registration of Food Facilities interim final rule (Ref. 20).

Table 52.—Costs per Importer and per Establishment

Activity	Total Costs	Cost per importer (n=77,427)
Learning costs	\$66,240,000	\$856
Coordination costs	\$31,095,000	\$402
Annual costs to fill out prior notice screens	\$187,500,000	\$2,422
Costs for BRASS users	\$48,462,000	\$626
Lost value for perishables	\$12,877,000	\$166
Total estimated average costs per importer		\$4,472
Total estimated average costs per retail establishment (n= 238,697)		\$1,450
Total estimated average costs per establishment in the distribution chain (n= 454,968)		\$761

3. Additional Flexibility Considered

Because of the requirements of the Bioterrorism Act, FDA is precluded from selecting some of the options that typically would be considered to lessen the economic effect of the interim final rule on small entities, including granting an exemption to small entities. FDA concludes that it would be inconsistent with section 307 of the Bioterrorism Act to allow small entities a later effective date, since the Bioterrorism Act establishes an effective date for prior notice that applies to FDA-regulated food imported or offered

for import into the United States, whether or not FDA has issued a final rule by this deadline. Thus, FDA concludes that Congress intended for prior notice to apply to FDA-regulated food by the effective date established in the Bioterrorism Act.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires cost-benefit and other analyses before any rulemaking if the rule would include a "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 or more (adjusted annually for inflation) in any 1 year." The current inflation-adjusted statutory threshold is \$113 million. FDA has determined that this interim final rule is significant under the Unfunded Mandates Reform Act. FDA has carried out the cost-benefit analysis in preceding sections (see table 47 of this document for the total costs). The other requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on the following factors:

and papayas are not grown in significant quantities in the United States; if the time of notification; the originating country; the shipping country; and the anticipated port of arrival. Section 801(m)(2)(A) of the FD&C Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed 5 days. FDA's prior notification of imported food shipments interim final rule implements these statutory provisions.

D. SBREFA Major Rule

The Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (Pub. L. 104-121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this interim final rule is a major rule for the purpose of congressional review.

VI. Paperwork Reduction Act of 1995

This interim final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). A description of these provisions is given below with an estimate of the annual reporting burden. The estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information, i.e., each prior notice.

Title: Prior Notice of Imported Food.

A. Description

Section 801(m) of the FD&C Act (21 U.S.C. 381(m)) requires prior notice to the Secretary of Health and Human Services (the Secretary) of an article of food that is being imported or offered for import into the United States. Section 801(m)(1) of the FD&C Act states that the Secretary shall require submission of notice providing the identity of each of the following: The article of food; the manufacturer; the

shipper; the grower, if known at the time of notification; the originating country; the shipping country; and the anticipated port of arrival. Section 801(m)(2)(A) of the FD&C Act states that the Secretary shall by regulation prescribe the time of submission of the notification in advance of importation or the offering of the food for import, which period shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification, but may not exceed 5 days. FDA's prior notification of imported food shipments interim final rule implements these statutory provisions.

1. Comments on the Burden of Information Collection

Some comments on the proposed burden of information collection stated that the information collection would not be necessary if ABI/ACS could be used to submit the required information. Other comments stated that the information collection was unproductive and unduly burdensome for the benefits it would provide. Still other comments stated that FDA had underestimated the hours associated with the reporting burden.

FDA's agreement with CBP to allow most prior notices to be submitted through ABI/ACS will greatly reduce the burden of this new collection of information.

A few comments were concerned that FDA had underestimated the proposed burden because they did not understand that FDA had calculated the submitting burden based on import entries, not entry lines. For each import entry, the prior notice or notices are expected to take about an hour to file. The prior notice or notices for each import entry would cover approximately 2.6 lines, with each line representing a different article of food to be imported. For this interim final rule burden of information analysis, FDA has clarified how the estimates were calculated to allay the comments' concerns.

2. Information Collection Burden Estimate

FDA estimates the burden for this information collection as follows:

Table 53.—Estimated Annual Reporting Burden

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Capital Costs	Operating and Maintenance Costs	Total Hours
1.279-1.285 <sup>1</sup>	77,427	1	77,427	40	\$6,194,000	\$743,000	3,097,080
1.279-1.285 <sup>1</sup>	7,743	1	7,743	40	\$620,000	\$74,400	309,715
1.280-1.281 <sup>2</sup>	77,427	84	6,500,000	0.384	\$0	\$0	2,500,000
1.282 <sup>2</sup>	77,427	3.36	260,000	0.5	\$0	\$0	130,000
1.283(a)(2)(iv), (a)(6)(iv), 1.285(c)(4) <sup>2</sup>	77,427	0.168	13,000	0.25	\$0	\$0	3,250
1.283(a)(5)(ii) <sup>2</sup>	77,427	1.26	97,500	1	\$0	\$0	97,500
1.283(a)(7) <sup>2</sup>	77,427	0.105	8,125	0.25	\$0	\$0	2,031
1.283(a)(6)(i), (a)(6)(iv), 1.285(f)(1)-(4) <sup>2</sup>	77,427	0.168	13,000	8	\$0	\$0	104,000
Total one time burden hours							3,406,795
Total recurring burden hours							2,836,781

<sup>1</sup> One time burden.

<sup>2</sup> Recurring burden.

**B. Hour Burden Estimate**

1. Number of Establishments Affected  
Using 2001 fiscal year information from OASIS (industry codes 02 through 52, 54, and 70 through 72), FDA has determined that there are approximately 77,427 importers and consignees who receive shipments of food imported or offered for import into the United States. FDA does not have specific information on who will submit prior notice since there are no restrictions on who can submit prior notice. Therefore, FDA estimates prior notice submission information based on the 77,427 importers of food in OASIS.

**2. New and Closing Importers**

In addition to the U.S. importers currently in existence, in future years new import businesses will open and some existing import businesses will close. These new businesses would have to become familiar with the FDA prior notice system and possibly obtain computer equipment and Internet access to comply with prior notice requirements.

According to the Small Business Administration Office of Advocacy, in 2001, about 10 percent of all businesses were new and 10 percent of businesses closed. Using the 10 percent opening and closing business statistic, and given that there are currently 77,427 U.S. importers, FDA assumes that on a yearly basis 7,743 importers will leave the

market and 7,743 importers will enter the market.  
3. Hour Burden Estimate Researching the Prior Notice Requirement  
a. Learning the interim final rule. To become familiar with the requirements for this interim final rule, FDA estimates that one manager and two subordinates from each importing business will attend an 8-hour training session on the prior notice regulation. This one-time research burden for the existing importers is about 1,858,248 hours (3 people per firm x 8 hours x 77,427 importers). This portion of the estimate is for 21 CFR part 1, subpart I, through 1.285 and is shown in row 1 of table 53 of this document.

In the years that follow the startup year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. In addition to the first year burden to research prior notice, it is expected that 185,832 hours will be spent annually researching the prior notice requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice (3 people per firm x 8 hours x 7,743 new importers). This portion of the estimate is for 21 CFR part 1, subpart I, 1.285 and is shown in row 2 of table 53 of this document.

b. Coordinating the information. FDA assumes it will take about 2 business days (16 hours) for an administrative employee of the prior notice-submitting

entry, on average, constitutes 2.6 different articles of food; a prior notice must be submitted for each article of food. Therefore we estimate that submitting prior notice for each article (23 minutes per line = 60 minutes/2.6 lines per entry). On an annual basis, 2.9 million hours (23 minutes or 0.384 hours) per prior notice x 6.5 million notices). This estimate is for 21 CFR part 1, subpart I, 1.280 through 1.281 and is shown in row 3 of table 53 of this document.

FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 6.5 million prior notices will be submitted annually based on fiscal year 2002 OASIS information and estimates of prior notice capacity. We divide 6.5 million lines by the 77,427 importers to get an average annual response frequency per importer of 84 notices.

5. Changes to a Confirmed Prior Notice  
The annual total number of changes made by importers to confirmed prior notices will vary depending on the minimum prior notice submission time required. For example, more confirmed prior notices will likely have to be changed if the minimum prior notice submission time is noon the calendar day before arrival as opposed to a minimum submission time of 2 hours before arrival. FDA's interim final rule requires a minimum prior notice submission time for each of the following situations: 2 hours before arrival for articles of food imported by vehicle, 4 hours before arrival for articles of food imported by rail and air, and 8 hours before arrival for articles of food imported by vessel.  
By combining the percentages by mode of transport and taking into

account the location of the exporting country, we assume that about 4 percent of all prior notices (260,000 notices) will have to be resubmitted after confirmation is received from FDA. We assume that changes in the prior notices will be minor adjustments; therefore, both the cancellation of the original notice and the resubmission of the new notice are estimated to take about 30 minutes. This estimate is for 21 CFR part 1, subpart I, 1.282 and is shown in row 4 of table 53 of this document.

6. Refused Admission  
Although FDA at this time does not have enough information to estimate a percent of refusals under the new prior notice program, for the purposes of this analysis FDA estimates the reporting

burden assuming a 2 percent refused admission rate.

An imported food product is subject to refusal under section 801(m)(1) of the FD&C Act if it arrives at the port of arrival with untimely, inaccurate, or no prior notice. FDA estimates that about 130,000 of the annual prior notices will be subject to refusal (2 percent of 6.5 million prior notices).

If an article of food is refused under section 801(m)(1) of the FD&C Act, the food must be held until the prior notice has been correctly submitted or until the product is exported. FDA must be notified of the location where the food has been or will be moved within 24 hours of refusal.

In many cases, the location notice will be given as part of a correction and resubmission, as described in the next section. FDA estimates that 13,000 out of the 130,000 annual refusals will give the location notice separately and that it will take about 15 minutes per prior notice to notify FDA of the shipment's location. This will result in about 3,250 hours (13,000 notices x 0.25 hours). (This estimate is for 21 CFR part 1, subpart I, 1.283(a)(2)(iv) and 1.285(c)(4) and is shown in row 5 of table 53 of this document.)

7. Correction and Resubmission of Prior Notice  
FDA estimates that 97,500 out of the 130,000 annual refusals will be because of inaccurate prior notice requiring resubmission, or because no prior notice was submitted. FDA estimates that it will take an hour to cancel, correct, and resubmit, or submit (in the case of no notice) each of these 97,500 notices. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(5)(ii) and is shown in row 6 of table 53 of this document.

8. Exportation of Products Refused Admission  
Some importers of articles of food that have been refused admission into the United States will decide to export their product rather than try to submit or resubmit prior notice. FDA estimates that this will occur for only about 25 percent of the 130,000 articles refused admission for inaccurate, untimely, or no prior notice. If an article of food is refused admission under section 801(m)(1) of the FD&C Act and exported, FDA requests, but does not require, that prior notice be cancelled. FDA estimates that for these 32,500 articles of food, prior notice will be cancelled 25 percent of the time and that this cancellation will take 15 minutes per article. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(7) and

is shown in row 7 of table 53 of this document.

9. FDA Review Request  
If an article of food to be imported is refused under section 801(m)(1) of the FD&C Act or placed under hold under section 801(l), a request may be submitted asking for an FDA review. FDA estimates that of the 130,000 articles of food that are refused admission under section 801(m)(1) of the FD&C Act or placed under hold under section 801(l) of the FD&C Act yearly, 10 percent will request an FDA review (13,000 reviews). FDA estimates that it will take the requestor about 8 hours to prepare the factual and legal information necessary to request a review. Thus, importers will spend about 104,000 hours on review requests annually. This estimate is for 21 CFR part 1, subpart I, 1.283(a)(6)(f) through (a)(6)(iv) and 1.285(f)(1) through (f)(4) and is shown in row 8 of table 53 of this document.

**C. Capital Cost and Operating and Maintenance Cost Burden**

Since all prior notices must be submitted electronically, we assume that the 3,097 responsible parties without Internet access (4 percent of the 77,427 importers) will have to purchase the appropriate computer equipment and gain Internet access to transmit the information. Assuming computer equipment costs each firm \$2,000 and yearly Internet access costs each firm \$240 (\$20 per month for 12 months), this results in a one-time computer cost for these facilities of \$6,194,000 and a recurring Internet access cost of \$743,000. This estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is included in row 1 of table 53 of this document.

For the 7,743 new firms that enter the import market each year, we expect 310 of them to need to purchase computer equipment and obtain Internet access. On an annual basis we expect new importers to spend \$620,000 on computers and \$74,400 on Internet access to be able to submit their prior notice information. This estimate is for 21 CFR part 1, subpart I, 1.279 through 1.285 and is included in row 2 of table 53 of this document.

The information collection provisions of this interim final rule have been submitted to OMB for review. Prior to the effective date of this interim final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this interim final rule. 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.

**VII. Analysis of Environmental Impact**

The agency has carefully considered the potential environmental effects of this action. FDA has concluded 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.

**VIII. Federalism**

FDA has analyzed this interim final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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 has concluded that the 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.

**IX. References**

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

1. Ruling NY G98921 (June 12, 2001). U.S. Bureau of Customs and Border Protection, <http://rulings.customs.gov>
2. Bureau of Economic Analysis, <http://www.bea.doc.gov>
3. U.S. Department of Labor, Bureau of Labor Statistics, "National Compensation Survey: Occupation Wages in the United States, 2000, Summary 01-04," available at <http://www.bls.gov/news.release/wage/0324.pdf>.
4. USDA, Agricultural Marketing Service, March 2002, "Fresh Fruits and Vegetable Shipments," <http://www.ams.usda.gov>.
5. Kassaris, Dr. Robert F. Vegetable Marketing Specialist, <http://www.thefreshconnection.com/book/articles/properties.htm>, 9/16/02.
6. USDA, Agricultural Marketing Service produces price reports for various border listings for the dates September 12, 2002, and September 16, 2002, <http://www.ams.usda.gov>.

including harvested or collected and readied for shipment, in a Territory, the FDA Country of Production is the United States.

(9) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the article of food first arrives in the United States. This port may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the United States Bureau of Customs and Border Protection (CBP).

(10) *Port of entry*, in sections 801(m) and 801(l) of the act, means the port of entry as defined in 19 CFR 101.1.

(11) *Registration number* refers to the registration number assigned by FDA under section 415 of the act (21 U.S.C. 3504) and 21 CFR part 1, subpart H.

(12) *Shipper* means 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* means the Customs territory of the United States (i.e., the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.

(14) You means the person submitting the prior notice, i.e., the submitter, or the person transmitting prior notice information on behalf of the submitter, i.e., the transmitter.

(15) *What is the scope of this subpart?* (a) The act applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and 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. Foreign Trade Zone.

(b) Notwithstanding paragraph (a), this subpart does not apply to: (1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States; (2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; (3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the prior notice time will start when FDA has confirmed your prior notice for review.

(5) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(6) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(7) Notwithstanding paragraph (a), this subpart does not apply to: (1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States; (2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; (3) Food that is imported then exported without leaving the port of arrival until export;

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(5) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(9) *Port of arrival* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where the article of food first arrives in the United States. This port may be different than the port where consumption or warehouse entry or foreign trade zone admission documentation is presented to the United States Bureau of Customs and Border Protection (CBP).

(10) *Port of entry*, in sections 801(m) and 801(l) of the act, means the port of entry as defined in 19 CFR 101.1.

(11) *Registration number* refers to the registration number assigned by FDA under section 415 of the act (21 U.S.C. 3504) and 21 CFR part 1, subpart H.

(12) *Shipper* means 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* means the Customs territory of the United States (i.e., the 50 states, the District of Columbia, and the Commonwealth of Puerto Rico), but not the Territories.

(14) You means the person submitting the prior notice, i.e., the submitter, or the person transmitting prior notice information on behalf of the submitter, i.e., the transmitter.

(15) *What is the scope of this subpart?* (a) The act applies to all food for humans and other animals that is imported or offered for import into the United States for use, storage, or distribution in the United States, including food for gifts and 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. Foreign Trade Zone.

(b) Notwithstanding paragraph (a), this subpart does not apply to: (1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States; (2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; (3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the prior notice time will start when FDA has confirmed your prior notice for review.

(5) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(6) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(7) Notwithstanding paragraph (a), this subpart does not apply to: (1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States; (2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; (3) Food that is imported then exported without leaving the port of arrival until export;

(4) Meat food products that at the time of importation are subject to the prior notice time will start when FDA has confirmed your prior notice for review.

(5) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

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(4) Meat food products that at the time of importation are subject to the prior notice time will start when FDA has confirmed your prior notice for review.

(5) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

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(4) Meat food products that at the time of importation are subject to the prior notice time will start when FDA has confirmed your prior notice for review.

(5) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(6) The FN Confirmation Number must accompany any article of food

reviewed and confirmed for review with a reply message that contains a Prior Notice (PN) Confirmation Number. Your prior notice will be considered submitted and the prior notice time will start when FDA has confirmed your prior notice for review.

(7) Notwithstanding paragraph (a), this subpart does not apply to: (1) Food for an individual's personal use when it is carried by or otherwise accompanies the individual when arriving in the United States; (2) Food that was made by an individual in his/her personal residence and sent by that individual as a personal gift (i.e., for non-business reasons) to an individual in the United States; (3) Food that is imported then exported without leaving the port of arrival until export;







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

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

(a) The importing or offering for import into the United States of an article of food in violation of the requirements of section 801(m), including the requirements of this subpart, is a prohibited act under section 303(ee) of the act (21 U.S.C. 351(ee)).

(b) Section 301 of the act (21 U.S.C. 331) prohibits the doing of certain acts or causing such acts to be done.

(1) Under section 302 of the act (21 U.S.C. 332), the United States can bring a civil action in federal court to enjoin persons who commit a prohibited act.

(2) Under section 303 of the act (21 U.S.C. 333), the United States can bring a criminal action in Federal court to prosecute persons who are responsible for the commission of a prohibited act.

(c) Under section 306 of the act (21 U.S.C. 335a), FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States or any person who has engaged in a pattern of importing or offering adulterated food that presents a threat of serious adverse health consequences or death to humans or animals.

**§ 1.285** 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?

(a) If an article of food from a foreign manufacturer that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H is imported or offered for import into the United States, the food is subject to refusal of admission under section 801(m)(1) of the act and § 1.283 for failure to provide adequate prior notice. The failure to provide the correct registration number of the foreign manufacturer, if registration is required under section 415 of the act and 21 CFR part 1, subpart H, renders the identity of that facility incomplete for purposes of prior notice.

(b) Unless CBP concurrence is obtained for export and the article is immediately exported from the port of arrival, if an article of food is imported

or offered for import from a foreign facility that is not registered as required under section 415 of the act and is placed under hold, it must be held within the port of entry for the article unless directed by CBP or FDA.

(c) Status and movement of held food. (1) An article of food that has been placed under hold under section 801(l) of the act shall be considered general order merchandise as described in section 490 of the Tariff Act of 1930, as amended (19 U.S.C. 1490).

(2) Food under hold under section 801(l) must be moved under appropriate custodial bond. FDA must be notified of the location where the food has been or will be moved, within 24 hours of the hold. The food subject to hold shall not be entered and shall not be delivered to any importer, owner, or ultimate consignee. The food must be taken directly to the designated facility.

(d) Segregation of refused foods. If an article of food that has been placed under hold under section 801(l) is part of a shipment that contains articles that have not been placed under hold of the act, the food under hold may be segregated from the rest of the shipment. This segregation must take place within the port of arrival where the article is held, if different. FDA or CBP may supervise segregation. If FDA or CBP determine that supervision is necessary, segregation must not take place without supervision.

(e) Costs. Neither FDA nor CBP will be liable for transportation, storage, or other expenses resulting from any hold. (f) Export after refusal. An article of food that has been placed under hold under section 801(l) of the act may be exported with CBP concurrence and under CBP supervision unless it is seized or administratively detained by FDA or CBP under other authority.

(g) No Registration or Request for Review. If an article of food is placed under hold under section 801(l) of the act and no registration or request for FDA review is submitted in a timely fashion or export has not occurred in accordance with subsection (g), the food shall be dealt with as set forth in CBP regulations relating to general order merchandise, except that the article may only be sold for export or destroyed as agreed to by CBP and FDA.

(h) Food carried by or otherwise accompanying an individual. If an article of food carried by or otherwise accompanying an individual arriving in the United States is placed under hold under section 801(l) of the act because it is from a foreign facility that is not registered as required under section 415 of the act, 21 U.S.C. 350d, and subpart H, the individual may arrange to have

the food held at the port or exported. If such arrangements cannot be made, the article of food may be destroyed.

(k) Post-refusal and post-hold submissions. (1) Post-refusal. To resolve the refusal if an article of food is refused under § 1.283(a) because the facility is not registered, the facility must be registered and a registration number has been obtained, you should cancel the prior notice and must resubmit the prior notice in accordance with § 1.283(c). (2) Post-hold. To resolve a hold, if an article of food is held under § 1.285(b) because it is from a foreign facility that is not registered, the facility must be registered and a registration number must be obtained.

(f) FDA must be notified of the applicable registration number in writing. The notification must provide the name and contact information for the person submitting the information. The notification may be delivered to FDA by mail, express courier, fax, or e-mail. The location for receipt of a notification of registration number associated with an article of food under hold is listed at <http://www.fda.gov>—see Food Facility Registration. The notification should include the applicable CBP identifier.

(g) If FDA determines that the article is no longer subject to hold, it will notify the person who provided the registration information and CBP that the food is no longer subject to hold under section 801(l) of the act.

(h) FDA review after hold. (1) If an article of food has been placed under hold under section 801(l), a request may be submitted asking FDA to review whether the facility associated with the article is subject to the requirements of section 415 of the act. A request for review may not be submitted to obtain a registration number.

(2) A request may be submitted only by the prior notice submitter, importer, owner, or ultimate consignee of the article. A request must identify which one the request is.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5 calendar days of the hold. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415, it will

notify the requestor and CBP that the food is no longer subject to hold under section 801(l) of the act.

(k) International mail. If an article of food that arrives by international mail is from a foreign facility that is not registered as required under section 415 of the act (21 U.S.C. 350d) and subpart H, the parcel will be held by CBP for 72 hours for FDA inspection and disposition. If the article is held under section 801(f) of the act and there is a return address, the parcel may be returned to sender stamped "No Registration—No Admission Permitted." If the article is under hold and there is no return address or FDA determines that the article of food is in the parcel 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 to the sender stamped "No Registration—No Admission Permitted" or, if there is no return address, destroy the parcel, at FDA expense.

(l) Prohibitions on delivery and transfer. (1) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), an article of food that has been refused under section 801(m)(1) of the act may not be delivered to the importer, owner, or ultimate consignee until prior notice is submitted to FDA in accordance with this subpart. FDA has examined the prior notice and has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act.

(2) During the time an article of food that has been refused under section 801(m)(1) of the act is held, the article may not be transferred by any person from the port or the secure facility location until prior notice is submitted to FDA in accordance with this subpart. FDA has examined the prior notice and has determined that the prior notice is adequate, and FDA has notified CBP and the transmitter that the article of food is no longer refused admission under section 801(m)(1) of the act.

(3) A request must be submitted in writing to FDA and delivered by mail, express courier, fax or e-mail. The location for receipt of a request is listed at <http://www.fda.gov>—see Prior Notice. A request must include all factual and legal information necessary for FDA to conduct its review. Only one request for review may be submitted for each article under hold.

(4) The request must be submitted within 5 calendar days of the hold. FDA will review and respond within 5 calendar days of receiving the request.

(5) If FDA determines that the article is not from a facility subject to the requirements of section 415, it will

under section 801(m)(1) of the act. After this notification by FDA to CBP and transmitter, entry may be made in accordance with law and regulation.

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

Dated: October 2, 2003.  
Tommy G. Thompson,  
Secretary of Health and Human Services.

Dated: October 9, 2003.  
Tom Ridge,  
Secretary of Homeland Security.  
[FR Doc. 03-25877 Filed 10-9-03; 8:45 am]

BILLING CODE 4160-01-P

interim rule, despite our request in the interim rule for such information. The interim rule contained no new information collection requirements under the Paperwork Reduction Act.

**List of Subjects**

7 CFR Part 300

Incorporation by reference, Plant diseases and pests, Quarantine.

7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

7 CFR Chapter III

Accordingly, we are adopting as a final rule, without change, the interim rule that amended 7 CFR parts 300, 301, and 319 and that was published at 67 FR 63529-63536 on October 15, 2002.

Authority: 7 U.S.C. 166, 450, and 7701-7772; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75-15 also issued under Sec. 204, Title II, Pub. L. 106-113, 113 Stat. 1501A-2933; sections 301.75-15 and 301.75-16 also issued under Sec. 203, Title II, Pub. L. 106-224, 114 Stat. 400 (7 U.S.C. 1421 note).

Done in Washington, DC, this 27th day of January, 2004.

Kevin Shea,  
Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 04-2023 Filed 1-30-04; 8:45 am]

BILLING CODE 3160-34-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

21 CFR Part 1

[Docket No. 2002N-0278]

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

**ACTION:** Interim final rule; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting an interim final rule that appeared in the Federal Register of October 10, 2003 (68 FR 58974). The document issued 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 document was published with some errors. This document corrects those errors.

DATES: Effective February 2, 2004.

**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:** In FR Doc. 03-25877, appearing on page 58974 in the Federal Register of Friday, October 10, 2003, the following corrections are made:

§ 1.276 [Corrected]

1. On page 59070, in the third column, in § 1.276(b)(3), at the end of the sentence, remove the phrase "in which the article will be mailed" and replace it with the phrase "from which the article is mailed".

§ 1.279 [Corrected]

2. On page 59072, in the first column, in § 1.279(f), in the first sentence, after "A copy of the confirmation", insert a comma.

§ 1.280 [Corrected]

3. On page 59072, in the first column, in § 1.280(a), in the fourth sentence, remove the phrase "paragraph (d) of this section applies" and replace it with the phrase "paragraphs (c) and (d) of this section apply".

4. On page 59072, in the first column, in § 1.280(c), in the first sentence, remove the phrase "and FDA Web site at <http://www.fda.gov>—see Prior Notice" and replace it with the phrase "or <http://www.cfsan.fda.gov/~furls/issat.html>, whichever FDA determines is available".

5. On page 59072, in the first column, in § 1.280(d), in the first sentence, remove the phrase "is listed at <http://www.fda.gov>—see Prior Notice—FN System Interface" and replace it with the phrase "will be listed at <http://www.access.fda.gov/issat.html>, whichever FDA determines is available".

6. On page 59072, in the second column, in § 1.280(d), in the first sentence, remove the phrase "or <http://www.fda.gov>" and replace it with the phrase "<http://www.cfsan.fda.gov/~furls/issat.html>" and, in the third sentence, remove the phrase "is listed at <http://www.fda.gov>—see Prior Notice—FN System Interface" and replace it with the phrase "will be listed at <http://www.access.fda.gov/issat.html>, whichever FDA determines is available".

7. On page 59072, in the first column, in § 1.283(a)(1)(ii), in the second sentence, insert the word "or" after the word "port".

8. On page 59075, in the first column, in § 1.283(a)(3), in the first sentence, remove the word "underhold" and replace it with the words "under hold" and revise the second sentence to read "This segregation must take place where the article is held".

9. On page 59075, in the second column, in § 1.283(a)(6), in the first full sentence, remove the phrase "paragraph (a)(7)" and replace it with the phrase "paragraph (a)(5)".

19. On page 59075, in the second column, in § 1.283(b)(1), where it appears, and insert the words "does not" and remove the word "shall" and replace it with the word "may".

20. On page 59075, in the second column, in § 1.283(c), italicize the paragraph heading "Post-Retusal Prior Notice Submissions".

21. On page 59075, in the second column, in § 1.283(d), italicize the paragraph heading "FDA Review After Refusal".

22. On page 59075, in the second column, in § 1.283(d)(1), in the first sentence, remove "§ 1.276(b)(4)" and replace it with "§ 1.276(b)(5)".

23. On page 59075, in the third column, in § 1.283(g), italicize the phrase "International Mail" and, in the second sentence, remove "section 801(m)" and replace it with "section 801(m)(1)".

§ 1.284 [Corrected]

24. On page 59076, in the first column, in § 1.284(b)(1), capitalize the first letter of the word "federal".

§ 1.285 [Corrected]

25. On page 59076, in the second column, in § 1.285(b), insert the phrase "under section 801(l) of the act" after the word "hold".

26. On page 59076, in the second column, in § 1.285(d), in the paragraph heading, remove the word "refused" and replace it with the word "held"; in the first sentence, insert the phrase "of the act" after the phrase "section 801(j)" and delete the phrase "of the act" after the word "hold"; and, in the second sentence, revise the phrase "within the port of arrival where the article is held, if different" to read "where the article is held".

27. On page 59076, in the second column, in § 1.285(f), in the heading, remove the word "refusal" and replace it with the word "hold".

28. On page 59076, in the second column, in § 1.285(g), in the first sentence, remove the phrase "subsection (g)" and replace it with the phrase "subsection (f)".

29. On page 59076, in the third column, in § 1.285(j)(1), insert the word "after" following the words "the facility must be registered and".

30. On page 59076, in the third column, in § 1.285(j)(1), in the first sentence, insert the phrase "of the act" after the phrase "section 801(j)".

31. On page 59076, in the third column, in § 1.285(j)(3), remove the phrase "see Prior Notice" and replace it with the phrase "see Food Facility Registration".

32. On page 59077, beginning in the second column, in § 1.285(l)(1) and (2),

remove the phrase "refused under section 801(m)(1)", where it appears, and replace it with the phrase "placed under hold under section 801(l)" and remove the phrase "refused admission under section 801(m)(1)", where it appears, and replace it with the phrase "subject to hold under section 801(l)".

Dated: January 17, 2004.

Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-1592 Filed 1-30-04; 8:45 am]

BILLING CODE 4160-01-S

**ENVIRONMENTAL PROTECTION AGENCY**

40 CFR Part 52

[TN-257-200402(a); FRL-7616-2]

**Approval and Promulgation of Implementation Plans—Tennessee; Knoxville County Maintenance Plan Update**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

**SUMMARY:** The EPA is approving revisions to the Tennessee State Implementation Plan (SIP) submitted by the Tennessee Department of Environment and Conservation (TDEC) on August 20, 2003. This SIP revision satisfies the requirement of the Clean Air Act as amended in 1990 (CAA) for the 10-year update of the Knoxville County 1-hour ozone maintenance plan.

**DATES:** This direct final rule is effective April 2, 2004 without further notice, unless EPA receives adverse comment by March 3, 2004. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the Federal Register and inform the public that the rule will not take effect.

**ADDRESSES:** Comments may be submitted by mail to: Anne Marie Hoffman, Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960.

Comments may also be submitted electronically, or through hand delivery/courier. Please follow the detailed instructions described in sections I.B.1 through 3 of the

**SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Anne Marie Hoffman, Air, Pesticides & Toxics Management Division, Air Planning Branch, Regulatory Registration.

§ 2. On page 59077, beginning in the second column, in § 1.285(l)(1) and (2),

Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960. Ms. Hoffman's phone number is 404-562-9074. She can also be reached via electronic mail at [hoffman.annemarie@epa.gov](mailto:hoffman.annemarie@epa.gov) or Lynora Benjamin, Air, Pesticides & Toxics Management Division, Air Planning Branch, Air Quality Modeling and Transportation Section, Environmental Protection Agency Region 4, Atlanta Federal Center, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960. Ms. Benjamin's phone number is 404-562-9040. She can also be reached via electronic mail at [benjamin.lynora@epa.gov](mailto:benjamin.lynora@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

A. How Can I Get Copies of This Document and Other Related Information?

1. The Regional Office has established an official public rulemaking file available for inspection at the Regional Office. EPA has established an official public rulemaking file for this action under TN-257. The official public file consists of the documents specifically referenced in this action, any public comments received, and other information related to this action.

Although a part of the official docket, the public rulemaking file does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public rulemaking file is the collection of materials that is available for public viewing at the Regulatory Development Section, Air Planning Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency Region 4, 61 Forsyth Street, SW, Atlanta, Georgia 30303-8960. EPA requests that if at all possible, you contact the contact listed in the FOR FURTHER INFORMATION CONTACT section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 9 to 4:30, excluding federal holidays.

2. Copies of the State submittal and EPA's technical support document are also available for public inspection during normal business hours, by appointment, at the State Air Agency, Tennessee Department of Environment and Conservation, Division of Air Pollution Control, J & C Annex, 401 Church Street, Nashville, TN 37243-1531.

3. **Electronic Access.** You may access this Federal Register document electronically through the Regulation.gov web site located at <http://www.regulation.gov>