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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 300, 301, and 319

[Docket No. 02–071–2]

Cold Treatment of Fruits

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule as final rule.

SUMMARY: We are adopting as a final rule, without change, an interim rule that amended the Plant Protection and Quarantine Treatment Manual, which is incorporated by reference into the Code of Federal Regulations, by revising the cold treatment schedules under which fruits are treated for the Mediterranean fruit fly (Medfly) and other specified pests. Based on a review of those treatment schedules, we determined that it was necessary to extend the duration of cold treatment for Medfly. We also amended the regulations for importing fruits and vegetables to provide that inspectors at the port of first arrival will sample and cut fruit from each shipment cold treated for Medfly to monitor the effectiveness of the cold treatment. The interim rule was necessary to protect against the introduction and dissemination of Medflies into and within the contiguous United States.

EFFECTIVE DATE: The interim rule became effective on October 15, 2002.

FOR FURTHER INFORMATION CONTACT: Dr. I. Paul Gadh, Import Specialist, Phytosanitary Issues Management Team, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737–1231; (301) 734–6799.

SUPPLEMENTARY INFORMATION:

Background

The Plant Protection and Quarantine Treatment Manual (PPQ Treatment Manual), which is maintained by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), contains approved treatment schedules for agricultural commodities and is incorporated by reference into the Code of Federal Regulations at 7 CFR 300.1.

The PPQ Treatment Manual contains, among other things, cold treatment schedules for the treatment of fruits for the Mediterranean fruit fly (Medfly). Those schedules are prescribed to treat commodities for Medfly, and in some cases other pests, that occur in the regions from which the commodities originate.

In an interim rule effective and published in the **Federal Register** on October 15, 2002 (67 FR 63529–63536, Docket No. 02–071–1), we amended the PPQ Treatment Manual by extending the cold treatment schedules under which fruits are treated for Medfly and other specified pests. In addition, we amended the regulations for importing fruits and vegetables to provide that inspectors at the port of first arrival will sample and cut fruit from each shipment cold treated for Medfly to monitor the effectiveness of the new treatment.

Comments on the interim rule were required to be received on or before December 16, 2002. We received eight comments by that date. The comments were from State departments of agriculture, citrus growers, and foreign fruit shippers. While some commenters expressed general support for the actions taken in the interim rule, all of them raised specific concerns or objections regarding certain aspects of the rule. These comments are discussed below by topic.

Need for More Research

All of the commenters stated that APHIS needed to conduct more research to either support eliminating treatments of lower temperatures and shorter durations or to validate the efficacy of the new treatment schedules. Some commenters stated that APHIS had not followed a scientific procedure in developing the new treatment schedules and requested that APHIS conduct its own research to determine if adjustments to the schedules are necessary. One commenter suggested the rule be delayed for 6 months, during which time such research could be conducted.

Our analysis of the currently available data, as discussed in an analysis prepared by the USDA's Office of Risk Assessment and Cost-Benefit Analysis (ORACBA) (referred to below as the ORACBA analysis), indicates that treatments of shorter durations and lower temperatures will not be efficacious in achieving probit 9 security (*i.e.*, a survival rate of not more than 0.0032 percent of target pests). Although APHIS plans to conduct a comprehensive study involving shorter durations of exposure and a range of temperatures including lower temperatures, *i.e.*, 33 °F and lower, we do not presently have enough data available to support a probit 9 level of mortality at these temperatures and have removed them from the treatment schedule. Currently, there is no timeframe set for this study. It is a time-consuming process that will depend on the availability of resources. Until such time as this additional research is completed, we are confident that the new treatment schedule and fruit cutting provisions will appropriately mitigate the risk of introducing Medfly into the United States. Given the examination of the available cold treatment data, as discussed in the ORACBA analysis, and the fruit cutting provision as additional security, we see no need to delay implementation of the rule.

One commenter noted that the interim rule stated that APHIS was sponsoring research to address the application of cold treatment, but failed to discuss this research in detail. The commenter requested more information regarding the research APHIS indicated it would sponsor and a timeframe for completion.

APHIS's Center for Plant Health Science and Technology has contract work in progress to develop a fluid dynamics computational model of a cold treatment chamber that simulates those used in cold treatment. When completed, the model will allow us to visualize the actual flow of temperature throughout a cold treatment chamber. With the ability to visualize factors that influence temperature, such as the effects of hold construction, pallet stacking configurations, fruit variety, and hot spots (areas within the cold

treatment chamber where the temperature remains higher than other areas), we can better determine those areas within the cargo where treatment is most likely to fail in terms of reaching and maintaining target temperature. This information will provide a valid basis for determining sensor placement within the cargo and will optimize our ability to adequately monitor the treatment.

Following its development, the model will be tested in field trials. The South African Government has agreed to assist us with the validation and, if they desire, the Government of Spain could also be involved. The trials would be designed to determine whether or not the model could predict what the cooling rates and temperature fluctuations are at various selected locations during the treatment. To do this, a number of sensors would be installed in the cargo at the beginning of the treatment and, as usual, monitored throughout the voyage. Following the treatment, those data would then be compared with the data predicted by the model. Based on how closely the two data sets agree, the model might need adjustment, which would require further field validation trials.

One commenter requested that the original treatment schedules remain in place for all countries exporting fruit to the United States except Spain, until a need to modify the treatment was scientifically proven. This commenter also suggested that Spain conduct its own tests to determine if the Medfly infestation in imported Spanish clementines was the fault of the treatment schedule or some other variable that was not considered. Another commenter stated that Spain should conduct tests specifically regarding how various pests respond to cold treatment in its climate.

As a result of our examination of the currently available data, we do not believe there is evidence to support the continued use of the previous treatment schedule for the treatment of commodities from any country. Since the ineffectiveness of the previous treatment schedule may have contributed to the survival of Medfly larvae in imported Spanish clementines, we would not be appropriately mitigating the risk of Medfly introduction to the Unites States by only applying restrictions to Spain. In addition, APHIS cannot impose research requirements on other countries. We can, however, ensure that proper procedures are followed and the risk of pest introduction is appropriately mitigated. In this case, we are confident that the new treatment schedules and fruit cutting procedures at the port of first arrival effectively mitigate the risk of Medfly introduction.

Research Used by APHIS

One commenter stated that after reviewing the Australian data cited in the ORACBA analysis, there was insufficient evidence that extending the treatment period by 2 days and removing treatments at the lower temperatures would be sufficient to achieve probit 9 quarantine security for all fruits. According to the commenter, oranges or tangors (close relatives of clementines) would require 18 days of cold treatment at 35.6 °F and the Australian data indicated that 16 days at 35.6 °F is only sufficient for lemons. The commenter pointed out that in revised treatment schedule T107–a, APHIS allows 14 days at 34 °F, 16 days at 35 °F, and 18 days at 36 °F.

APHIS's decision to extend the cold treatment exposure time was not based on one particular piece of research, but rather, a number of factors including a technical panel's review, the ORACBA analysis (which uses a model to combine several different pieces of existing research), and our past experience with the interception of live Medfly larvae in cold treated clementines from Spain. The Australian work cited in the ORACBA analysis, which was primarily intended to provide the Japanese Government with data proving efficacy of cold treatment at temperatures above 33.8 °F so that Australian exported fruit that failed at 33.8 °F could meet Japanese phytosanitary requirements at higher temperatures, used only two temperature/time combinations, *i.e.*, 35.6 ± 0.9 °F and 37.4 ± 0.9 °F, in the study. The 35.6 ± 0.9 °F corresponded to at or below 36.5 °F and 37.4 ± 0.9 °F corresponded to at or below 38.3 °F. Using a high number of second-instar fruit fly larvae (the most tolerant stage), the Australians demonstrated that 18 days exposure of citrus fruit except lemons (which were exposed for 16 days) at 35.6 ± 0.9 °F was effective enough to achieve 100 percent mortality. At 37.4 ± 0.9 °F, this 100 percent mortality was achieved when citrus other than lemons was exposed for 20 days (18 days in the case of lemons). In our revised treatment schedule T107–a, we require 18 days at or below 36 °F and have not approved cold treatment above 36 °F, thus we are being somewhat more stringent than the Australians in this regard. Treatments of shorter durations are done at lower temperatures and we are confident that all treatment combinations will achieve probit 9 security.

One commenter stated that the Australian data reflect that Medfly larvae react differently to cold treatment in different types of citrus because the same cold treatment period did not result in the same mortality in various types of citrus tested. The commenter added that the ORACBA analysis included studies done only on apples and lemons. The commenter supported longer periods of cold treatment, but stated that the data provided by the ORACBA analysis did not directly address the question of whether 14 days of cold treatment at 34 °F is sufficient to provide an acceptable level of quarantine security for clementines or other varieties of oranges and tangors.

As shown in the PPQ Treatment Manual, our treatments are applicable to more than one host and are based on research performed on different hosts, not just citrus varieties or species. Hosts for which we have inadequate research data are not included in the treatment schedules. In addition, the research used in the ORACBA analysis was not conducted solely on apples and lemons. The analysis considered studies using a variety of fruits. For example, Nel (1936) used grapes, nectarines, peaches, and plums, and Hill *et al.* (1988) used Valencia and Navel oranges as host material.

The Patagonia Region

Some commenters from shipping organizations within the Patagonia region of South America expressed concern that the interim rule did not take into account the phytosanitary practices that are employed in that region. These commenters stated that the region has been shipping fruit to the United States under the previous treatment schedules for the past 20 years without a single detection of fruit fly larvae—dead or alive—and should not have to comply with the increased requirements of the new treatment schedule.

A few commenters stated that the Patagonia region should be recognized as an area free from fruit flies and should therefore not be subject to the revised treatment schedules. Some stated that the region has an effective fruit fly control and eradication program in place. In addition, recent trapping programs in the region have verified the total absence of all species of *Anastrepha* spp. fruit flies.

Prior to live Medfly larvae being intercepted in clementines from Spain in November and December 2001, there had never been multiple confirmed finds of live Medfly larvae in fruit of any kind that had been legally imported into the mainland United States from

any source since the previous cold treatment schedule was implemented more than 40 years ago. These interceptions forced us to reexamine the effectiveness of our cold treatment schedules. After an evaluation, a panel concluded that the previously approved cold treatment schedule provided a high level of Medfly mortality, but did not achieve a probit 9 level quarantine security in all cases. The panel's recommendation, which was supported by a quantitative analysis of available data, was that there was uncertainty as to whether treatments of less than 14 days and at temperatures in the 32–33 °F range would achieve the probit 9 level of security. Therefore, in order to protect the United States against the introduction of Medfly, we revised our Medfly treatment schedules based on the available scientific evidence in order to achieve a probit 9 level of security.

We have received data suggesting that certain areas in the Patagonia region are free of fruit flies. We are presently reviewing the information and working with Argentine officials to establish the boundaries of such areas. If, upon completion of our review, we determine that a change in the status of this region is warranted, we will initiate the necessary regulatory actions to recognize the fruit-fly-free status of the region.

General Comments

One commenter questioned APHIS's actions in implementing the new treatment schedule and resuming imports of Spanish clementines when APHIS acknowledged it did not know if the Medfly outbreak was due to faults in the cold treatment application process or with the treatment schedule itself. The commenter stated that both levels of larval infestation and an inadequate treatment schedule may have been responsible for the Medfly larvae discovery in Spanish clementines, and lengthening the treatment schedule only addressed one of these factors. Another commenter asked if APHIS planned to conduct any research on the point at which cold treatment fails, *i.e.*, if the level of larval infestation could overwhelm cold treatment.

We made revisions to the cold treatment schedules based on the recommendations of our technical panel and after considering the ORACBA analysis, which analyzed the available information in support of a probit 9 level of mortality. We also excluded those temperature/duration combinations from the revised treatment schedules for which enough scientific support was not available for probit 9 mortality. As an additional precaution in the Spanish clementine final rule (*see* 67 FR 64702–64739, Docket No. 02–023–4, published October 21, 2002), we required fruit cutting pre- and post-treatment in order to assess the effectiveness of the treatment. In the cold treatment interim rule that is the subject of this affirmation, we required only post-treatment fruit cutting to evaluate the effectiveness of the new treatment schedules. If during the post-treatment fruit cutting process we consistently find a number of dead larvae in a particular treated article or in treated articles from a particular region, we will reexamine if there is a need for fruit cutting prior to cold treatment taking place. For these reasons, we do not believe it is necessary to conduct the type of research suggested by the commenter. In addition, our inspections of cold treated fruit at the ports of arrival and past interception records (or lack thereof) demonstrate that cold treatment has been effective over the years in preventing Medfly introduction into the United States.

One commenter stated that the USDA should provide shippers with a written treatment verification protocol and shippers should be required to provide USDA documentation to demonstrate that cold treatment is administered as prescribed.

The regulations in § 319.56–2d, ''Administrative instructions for cold treatments of certain imported fruits,'' contain detailed requirements regarding the application and verification of cold treatments. The requirements for commodities cold treated in transit include maintaining a continuous, automatic temperature record under lock from at least four locations in each refrigerated compartment, providing charts from the temperature recording apparatus to an inspector at the port of arrival as proof the appropriate treatment schedule was followed, and requiring the responsible ship's officer to sign the temperature chart at least once during every 24-hour period.

One commenter stated that it was inappropriate for APHIS to resume imports of Spanish clementines based on the interim rule, which was made effective before the public had an opportunity to comment. In doing this, the commenter stated, APHIS did not follow a sound scientific process.

The extended treatment schedule first appeared in our proposed rule for Spanish clementines (*see* 67 FR 45922–45933, Docket No. 02–023–3, published March 22, 2002) as a result of comments made on the risk assessment that was prepared for that proposed rule and made available for comment in a notice published April 16, 2002, in the **Federal Register** (67 FR 18578–18579, Docket No. 02–023–1). A panel of experts subsequently concluded that there was uncertainty as to whether treatments of less than 14 days and at temperatures in the 32–33 °F range will achieve the probit 9 level of security; we therefore eliminated the two shortest duration treatments from the treatment schedule in the interim rule that is the subject of this affirmation. While we acknowledged that further research was needed, we implemented the new treatment schedule in addition to fruit cutting immediately in order to mitigate the risk of introducing Medfly into the United States. The changes to the cold treatment schedules, which were supported by the panel's research, were promulgated in an interim rule in order for those treatment schedules to be effective prior to the commencement of the Spanish clementine shipping season. However, the revised treatment schedules apply to all commodities cold treated for Medfly, not only Spanish clementines, as recommended by the panel based on its findings.

One commenter stated that APHIS should reassess its willingness to consider import requests for fresh fruits and vegetables from disease and pest-infested areas of the world. The commenter stated that a tremendous burden exists on the enforcement personnel of the Agency with having to deal with possible illegal importation of pests, and that by limiting importation to commodities grown where pests or diseases are present in small numbers, or not at all, would greatly reduce this burden.

APHIS has stated in the past that if zero tolerance for pest risk were the standard applied to international trade in agricultural commodities, it is quite likely that no country would ever be able to export a fresh agricultural commodity to any other country. There will always be some degree of pest risk associated with the movement of agricultural products; APHIS's goal is to provide the protection necessary to prevent the introduction and dissemination of plant pests into the United States. In this case, we believe that the revised treatment schedule and the fruit cutting provisions will achieve that goal.

One commenter suggested that APHIS review all cold treatment schedules in light of the discovery of at least one live larva of false codling moth in clementines from South Africa in 2002. There has been no overall review of the efficacy of cold treatment protocols in light of the interceptions of live insects following treatment.

In general, when pests are intercepted following treatment, APHIS investigates possible causes and responds appropriately. In the specific case of multiple live Medfly interceptions in clementines from Spain, APHIS halted clementine imports until we evaluated the situation, and the Secretary subsequently determined that it was no longer necessary to prohibit the importation or interstate movement of the fruits if a lengthened cold treatment was applied, along with other safeguards. In conducting our evaluation, we reviewed the cold treatment protocols for Medfly. APHIS' review of the cold treatment focused on the clementine shipments that contained live Medfly larvae and yielded no evidence that the treatment was improperly applied.

In response to interceptions of the false codling moth in cold treated citrus from South Africa, we have taken three actions to help ensure fruit with false codling moth do not enter the United States with cold treated fruit. First, fruit entering through preclearance programs will be rejected before treatment if false codling moth is found. Second, additional fruit cutting is being instituted in the preclearance program. Third, at the ports of entry, fruit cold treated for false codling moth has been moved to the highest risk level—the number of fruit being cut on arrival is 150 per container or 1,500 for bulk shipments. The interception noted by the commenter was an isolated event and is not reflective of failure of the cold treatment.

Other Comments

In addition to the comments discussed above, one commenter questioned the effectiveness of APHIS's enforcement of the limited distribution of Spanish clementines. We consider this comment to be outside the scope of this rulemaking because the requirements governing the distribution of Spanish clementines were not part of the interim rule.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule without change.

This action also affirms the information contained in the interim rule concerning Executive Orders 12866 and 12988 and the Paperwork Reduction Act.

Further, for this action, the Office of Management and Budget has waived its review under Executive Order 12866.

Regulatory Flexibility Act

This rule affirms an interim rule that amended the PPQ Treatment Manual, which is incorporated by reference into the Code of Federal Regulations, by revising the cold treatment schedules under which fruits are treated for Medfly and other specified pests. Based on a review of those treatment schedules, we determined that it was necessary to extend the duration of cold treatment for Medfly [1] in order to protect against the introduction or dissemination of Medfly into and within the United States.

In addition, we amended the regulations for importing fruits and vegetables to provide that inspectors at the port of first arrival sample and cut fruit from each shipment cold treated for Medfly to monitor the effectiveness of the cold treatment. If a single live Medfly in any stage of development is found, the shipment will be held until an investigation is completed and appropriate remedial actions have been implemented. If APHIS determines at any time that the prescribed cold treatments do not appear to be effective against Medfly, APHIS may suspend the importation of fruit from the originating country and conduct an investigation into the cause of the deficiency. The Plant Protection Act (7 U.S.C. 7701–7772) authorizes the Secretary of Agriculture to prohibit or restrict the importation, entry, and interstate movement of any plant, plant product, article, or means of conveyance if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction or dissemination of a plant pest into or within the United States.

In accordance with 5 U.S.C. 603, we performed an initial regulatory flexibility analysis for the interim rule, which was included in the interim rule and which invited submission of comments and data to assist in a comprehensive analysis of the economic effects of the interim rule on small entities. More specifically, we requested information on the number and kind of small entities that may incur benefits or costs from the implementation of the interim rule. No such information was submitted in the comments that we received. Based on the information we have, there is no basis to conclude that adoption of this rule will result in any significant economic impact on a substantial number of small entities. For this document, we have prepared a final regulatory flexibility analysis, which is set out below.

Fruit cutting and inspection charges associated with the interim rule will more than likely be small. APHIS, in a regulatory impact analysis (RIA) conducted for a rulemaking related to the importation of clementines from Spain (referred to below as the clementine RIA),[2] indicates that bulk shipments of fruit will more than likely pass inspection because the proportion of fruit infested with live Medfly will more than likely be extremely low after the application of the revised cold treatment schedules. In addition, the amount of fruit that is cut in the United States will more than likely be low relative to the value of imports, amounting to between 0.24 percent and 0.31 percent of gross import value. As a result, we state at the outset that costs associated with cutting and inspecting fruit will not have a significant negative economic impact on a substantial number of small importers.

The United States Small Business Administration (SBA) defines a small fruit importer (NAICS 424480, Fresh Fruit and Vegetable Merchant Wholesalers) as one with 100 or fewer employees. According to the most recent information available from the SBA's Office of Advocacy, a total of 5,403 firms comprised the ''Fresh Fruit and Vegetable Merchant Wholesalers'' category in 1999.[3] Seventy-eight percent of these firms (4,227) employed 20 or fewer individuals, and 99 percent of the firms had 500 or fewer employees. Clearly, the majority of fruit and vegetable wholesalers are small entities, having 100 or fewer employees. Although we lack specific information regarding the number of entities, large or small, that are likely to be affected by the rule (*i.e.*, U.S. importers of fruits from countries where Medfly is known to exist), we expect that the majority of those entities are small. However as we demonstrate below, economic impacts associated with the rule are not expected to be significant.

Import data for 1996–2000 for fruits that require cold treatment for Medfly under the revised schedule T107–a are shown in table 1. Import data are not reported separately for all of the fruits

[1] Certain commodities that are subject to the extended cold treatment, *i.e.*, commodities that are subject to treatment for Medfly and *Anastrepha* spp. (except *Anastrepha ludens*), will not necessarily be subject to additional days of cold treatment due to the fact that treatment for *Anastrepha* spp. is already longer than the extended Medfly treatment requires. Thus, such commodities may be subject to 1 additional day of treatment, or none at all, depending on the temperature at which they are held. Nevertheless, for the purposes of this analysis, we assume that all commodities will be subject to additional days of treatment.

[2] ''Amending Import Rules for Clementines from Spain: Final Regulatory Impact Analysis.'' Animal and Plant Health Inspection Service, Riverdale, MD. Available on the Internet at *http://www.aphis.usda.gov/lpa/issues/clementine/clementines.html*.

[3] *See http://www.sba.gov/advo/stats/us99_n6.pdf.*

that are subject to cold treatment for Medfly, so similar fruits are combined into categories in table 1.[4] Import data for litchis, pomegranates, and carambola are not available, and there were no imports of mountain papaya and very few imports of cherries that required cold treatment for Medfly during 1996–2000; therefore, data for these fruits are not included in table 1.

In order to estimate costs associated with extending Medfly cold treatment periods, it is necessary to estimate 2002 import levels, because additional cold treatment expenses vary with the amount of imported fruit. We base the 2002 import level for ethrogs on the 5-year average, because annual growth rates were extremely volatile during 1996–2000. We base the 2002 import level for pears and quinces on the 2000 import level because the import data provided little guidance regarding a likely value for 2002. We base the 2002 import level for clementines, ortaniques, and tangerines on the 2000 import level and annual import growth in 2000 because growth rates were highly volatile during the preceding years and imports apparently leveled off in 1999.[5] We report estimates of 2002 import levels for these and the remaining fruits in table 1.

TABLE 1.—FRUIT IMPORTS THAT ARE SUBJECT TO T107 COLD TREATMENT FOR MEDFLY *

Commodity	Average import level (1,000 kg)	Weighted import level ($/kg)	Average import value ($1,000)	Percentage of world imports	Expected imports 2002 (1,000 kg)
Apple	4,128	$0.86	$3,550	2.52	[1] 4,128
Apricot	4	2.48	10	0.23	[1] 4
Clementine, ortanique, and tangerine	52,176	1.43	74,354	86.32	[2] 95,952
Ethrog	160	2.79	446	32.17	[1] 160
Grape	33,399	426.18	14,234	3.29	[3] 52,369
Grapefruit and pummelo	356	0.91	323	3.31	[1] 356
Kiwi	6,080	1.05	6,384	6.91	[1] 6,080
Orange	6,361	1.07	6,776	8.34	[1] 6,361
Peach and nectarine	10	0.95	10	0.02	[3] 17
Pear and quince	35,915	0.96	34,478	44.81	[4] 58,228
Plum, loquat, persimmon, and plumcot	124	0.99	123	0.54	[4] 513

* Imports, prices, and percentages of world imports are averages for 1996–2000. Prices are weighted averages converted to 2002 dollars, using the consumer price index for fresh fruit (from U.S. Bureau of Labor Statistics). Data are from USDA-FAS, ''U.S. imports and import values for various fruit,'' except for grapes, which are from Bureau of Census data: 080610, U.S. fresh grape imports. Quantity data for grapes are in cubic meters; grape prices are in dollars per cubic meter.

[1] Five-year average.

[2] Based on the 2000 import level and annual import growth for 2000.

[3] Based on the 2000 import level and average annual import growth for 1999 and 2000.

[4] The 2000 import level.

As shown in table 1, very low percentages of apple, apricot, cherry, grape, grapefruit and pummelo, kiwi, mountain papaya, orange, peach and nectarine, and plum, loquat, persimmon, and plumcot imports undergo cold treatment for Medfly; as a result, the interim rule will likely not affect a substantial number of small importers of these fruits. Thirty-two percent of ethrogs, 44 percent of pears and quinces, and 86 percent of clementines, ortaniques, and tangerines must be cold treated for Medfly. Therefore, the interim rule may affect a substantial number of U.S. importers of these fruits, and we estimate economic impacts for these fruits. We do not estimate economic impacts for the remaining fruits because it is unlikely that a substantial number of small importers of those fruits will be significantly affected by the interim rule. Furthermore, economic impacts for ethrogs, pears and quinces, and clementines, ortaniques, and tangerines can be considered as representative of the economic impacts for the other fruits.

The overwhelming majority of cold-treated fruit imports are treated aboard ship while in transit to the United States, although treatment can also be carried out at authorized ports. When cold treatment is conducted in transit, the treatment period must be met before unloading. For countries with sailing times to the United States longer than the extended treatment periods, the interim rule will only lead to increases in cold treatment costs. For countries with sailing times to the United States shorter than the extended treatment periods, the interim rule will lead to increases in cold treatment and shipping costs. To account for the extended treatment periods in these instances, vessels will either adjust sailing times to coincide with the length of the treatment period, sit at the dock, or go into anchorage near the U.S. port. As a result, labor, fuel, and opportunity costs associated with delaying shipments of other cargoes will more than likely be added to shipping charges.

Costs associated with extending treatment periods have been estimated for clementine imports from Spain in the clementine RIA cited earlier in this analysis. We use the same parameters and methods to estimate additional cold treatment expenses for clementines, ortaniques, and tangerines. It costs approximately $0.50 per day to cold treat a pallet of fruit at U.S. ports. This provides an approximate upper bound on cold treatment costs because most fruits are cold treated in transit, which may be less expensive on average. We therefore use this as our unit cost to calculate cold treatment expenses in the analysis.

Historically, Spain has exported clementines, ortaniques, and tangerines to the United States under the 11 day (33 °F) or 12 day (34 °F) cold treatment schedules. As a result, Spanish clementines, ortaniques, and tangerines shipped to the United States will undergo at least 2 to 3 days (34 °F) of

[4] USDA–FAS, ''U.S. imports and import values for various fruit.'' Available through the U.S. Trade Internet System at: *http://www.fas.usda.gov/ustrade/*.

[5] In particular, expected imports for 2002 are given by $x(1 + y)^2$, where x denotes the import value for 2000 and y denotes import growth for 2000.

extra cold treatment. We assume the average bulk shipment will undergo an additional 2.5 days of cold treatment. The following daily charges will likely be added to the cost of shipping clementines, ortaniques, and tangerines to the United States: $10,000 chartering fee (although this fee is highly variable depending on the availability of bulk ships); $2,160 docking fee ($0.27 per metric ton with an average ship size of 8,000 metric tons); $990 fuel at anchorage fee (five to six tons at $180 per ton); and $0.50 per pallet cold treatment fee.

These cost figures are based on recent charges quoted by a representative from Lauritzen, a company that specializes in the bulk shipment of fruit. Ninety percent of clementines, ortaniques, and tangerines shipments come into the United States in bulk shipments. Using a bioeconomic model, which incorporates variation in clementines designated for export to the United States and fruit cutting and rejection of shipments in Spain according to farm-level variation in numbers of fruit infested with Medflies, additional shipping and cold treatment expenses averaged $1.23 million (± $15,000, with 95 percent confidence). U.S. imports of clementines averaged 88,461 metric tons (± 1,042 metric tons). As a result, total regulatory expenses were $13.92 per metric ton, or $5.57 per metric ton per day. Average import price in the United States was $1.05 per kilogram, thus import value averaged $92.65 million. Total regulatory expenses were therefore 1.33 percent of gross value.

These estimates can be used to estimate regulatory costs associated with shipments of clementines, ortaniques, and tangerines from Spain, Morocco, Israel, and Italy. Applying the $13.92 per metric ton fee to 95,952 metric tons (table 1), total regulatory costs, assuming fruits are cold treated for an additional 2.5 days on average, are $1.34 million. To determine whether these costs are significant, we estimated the value of clementine, ortanique, and tangerine imports for 2002 using the Spanish clementine import demand curve estimated in the clementine RIA. Plugging in the expected 2002 import level and converting the price to 2002 dollars using the consumer price index for oranges, including tangerines,[6] gives a price of $0.84 per kilogram.[7] Using this expected price, the expected value of imports for 2002 is approximately $78.47 million. Additional treatment expenses associated with the interim rule amount to only 1.7 percent of this total and, as a result, the interim rule will likely not have a significant negative economic impact on small importers of clementines, ortaniques, and tangerines, even in the unlikely event that importers bear the entire economic burden.[8]

We use the same parameters and methods to estimate additional cold treatment expenses for ethrogs, pears, and quinces under the assumption that these fruits and clementines, ortaniques, and tangerines have roughly the same dimensions. For ethrogs, assuming an additional 2.5 days of cold treatment and shipping expenses, total regulatory costs for 2002 came to $2,227. This amounts to only 0.5 percent of the estimated value of ethrog imports for 2002 ($446,400), which is based on the estimated import level (160 metric tons) and the weighted average price ($2.79 per kilogram) during 1996–2000 (*see* table 1). As a result, the interim rule will more than likely not have a significant negative economic impact on small importers of ethrogs.

For pears and quinces, additional cold treatment expenses for 2002 came to $1.3 million, which amounts to 2.32 percent of the estimated value of pear and quince imports for 2002 ($56 million), based on the estimated import level (58,228 metric tons) and weighted average price ($0.96 per kilogram) during 1996–2000 (*see* table 1). During 1996–2000, 95 percent of the pear and quince imports from regions with Medfly came from Argentina, and the remainder came from China, South Africa, and Spain. The direct sailing time from Argentina is approximately 10 days, which is 4 days less than the shortest treatment period. As a result, the interim rule will add an additional 4 days of cold treatment and shipping charges for shipments of pears and quinces to the United States from Argentina. Total regulatory expenses for 2002 are $1.30 million, which amounts to 2.32 percent of the estimated value of pear and quince imports for 2002 ($56 million), based on the estimated import level (58,228 metric tons) and weighted average price ($0.96 per kilogram) during 1996–2000 (table 1).

Countries that import citrus from the United States may change their cold treatment guidelines to reflect the changes being made to our cold treatment requirements; however, such changes would only affect U.S. exporters in the event of a Medfly outbreak in the continental United States. Indirect impacts of the interim rule, therefore, are highly uncertain and depend on the probability that Medflies are introduced and become established, as well as the regional extent of outbreaks and the efficiency with which they are controlled and eradicated. Because potential economic impacts on U.S. fruit importers are low relative to import values and because Medfly outbreaks within the United States will more than likely be confined to particular areas and eradicated efficiently, the interim rule will likely not have a significant negative economic impact on a substantial number of small exporters in the United States. However, in the event of a Medfly outbreak, exporters who wish to export affected commodities from areas quarantined for Medfly should expect to pay an additional $5.57 per metric ton per day of extra cold treatment. For example, exports from quarantined areas on the U.S. west coast to Asia would have to undergo an additional 2.5 days of cold treatment; therefore, each metric ton of affected produce would cost an additional $13.92 to ship. The same cost schedule applies to affected commodities on the U.S. east coast destined for European markets. Because shipment times from the U.S. west coast to Europe and from the U.S. east coast to Asia are longer than the revised cold treatment periods, the interim rule would have no impact on the cost schedules associated with those exports.

Summary

In our analysis, we estimate additional treatment expenses associated with the interim rule as being between 0.5 percent (for ethrogs) and 2.32 percent (for pear and quince) of the expected value of imports for 2002. Similarly, the amount of fruit that is cut in the United States will more than likely be low relative to the value of imports, amounting to between 0.24 percent and 0.31 percent of gross import value. Based on our analysis, we have no reason to expect that the requirements of the interim rule will have a significant economic impact on a substantial number of small U.S. fruit importers, including small importers of ethrogs, clementines, ortaniques, pears, quinces, and tangerines. We are unable to definitively state that this will be the case, however, because we lack specific information on the number and kind of small entities that may incur benefits or costs from the implementation of the

[6] U.S. Bureau of Labor Statistics, ''Consumer price index—oranges, including tangerines, not seasonally adjusted.'' Available on the Internet at *http://data.bls.gov/labjava/outside.jsp?survey=cu.*

[7] The y-intercept of the demand curve is $3.71 and the coefficient on kilograms of imports is −3.01E–08.

[8] This would be the case, for example, if import demand was perfectly inelastic and export supply was perfectly elastic. Available data indicate that import demand is elastic and that export supply is not perfectly elastic.

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–293; 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 3410–34–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 mail'' 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/fisstat.html*, whichever FDA determines is available'' and, in the third sentence, remove the phrase ''is listed at *http://www.fda.gov*—see Prior Notice—PN System Interface'' and replace it with the phrase ''will be listed at *http://www.access.fda.gov* or *http://www.cfsan.fda.gov/~furls/fisstat.html*, whichever FDA determines is available''.

■ 5. On page 59072, in the second column, in § 1.280(d), in the first sentence, remove the phrase ''*http://www.fda.gov*'' and replace it with the phrase ''*http://www.cfsan.fda.gov/~fulrs/fisstat.html*'' and, in the third sentence, remove the phrase ''is listed at *http://www.fda.gov*—see Prior Notice'' and replace it with the phrase ''will be listed at *http://www.access.fda.gov* or *http://www.cfsan.fda.gov/~furls;fisstat.html*, whichever FDA determines is available''.

§ 1.281 [Corrected]

■ 6. On page 59072, in the third column, in § 1.281(a)(6), in the second sentence, remove the comma after the word ''storage''.

■ 7. On page 59072, in the third column, in § 1.281(a)(7), in the second sentence remove the comma after ''consolidated'' and insert the phrase ''and the submitter does not know'' after the phrase ''if the article has been consolidated''.

■ 8. On page 59072, in the third column, in § 1.281(a)(9), in the second sentence, remove the comma after the word ''storage''.

■ 9. On page 59072, in the third column, in § 1.281(a)(12), in the third sentence, remove the word ''owner'' and replace it with the word ''importer''.

■ 10. On page 59073, in the first column, in § 1.281(a)(13), in the third sentence, remove the word ''importer'' and replace it with the word ''owner''.

■ 11. On page 59073, in the first column, in § 1.281(b), italicize the phrase ''Articles arriving by international mail''.

■ 12. On page 59073, in the second column, in § 1.281(b)(6), remove the comma after ''consolidated'' and insert the phrase ''and the submitter does not know'' after the phrase ''if the article has been consolidated''.

■ 13. On page 59073, in the third column, in § 1.281(c), in the third full sentence, remove ''§ 1.283(a)(ii)'' and replace it with ''§ 1.283(a)(1)(ii)''.

■ 14. On page 59074, in the first column, in § 1.281(c)(7), in the second sentence, remove the comma after the word ''consolidated'' and insert the phrase ''and the submitter does not know'' after the phrase ''if the article has been consolidated''.

■ 15. On page 59074, in the first column, in § 1.281(c)(13), in the first sentence, remove the phrase ''if different from the owner'' and replace it with the phrase ''if different from the importer'' and in the third sentence, remove the word ''owner'' and replace it with the word ''importer''.

§ 1.283 [Corrected]

■ 16. On page 59075, in the first column, in § 1.283(a)(1)(ii), in the second sentence, insert the word ''of'' after the word ''port'' the second time it appears.

■ 17. 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''.

■ 18. 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)''.