

Proposed Rules

This section of the **FEDERAL REGISTER** contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 300 and 319

[Docket No. 02-023-3]

RIN 0579-AB40

Importation of Clementines From Spain

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule and notice of public hearings.

SUMMARY: We are proposing to amend the fruits and vegetables regulations to allow the importation of clementines from Spain to resume if the clementines are cold treated en route to the United States, and provided that other pre-treatment and post-treatment requirements are met. These requirements would include provisions that the clementines be grown in accordance with a Mediterranean fruit fly management program established by the Government of Spain, that the clementines be subject to an inspection regimen that includes fruit cutting prior to, and after, cold treatment, and that the clementines meet other conditions designed to protect against the introduction of the Mediterranean fruit fly into the United States. We are proposing this action based on our finding that the restrictions described in this proposed rule will reduce the risk of introduction of Mediterranean fruit fly and other plant pests associated with the importation of clementines from Spain.

DATES: We will consider all comments that we receive on or before September 9, 2002. We will also consider comments made at public hearings to be held in Oxnard, CA, on August 20, 2002; and in Lake Alfred, FL, on August 22, 2002.

ADDRESSES: You may submit comments by postal mail/commercial delivery or

by e-mail. If you use postal mail/commercial delivery, please send four copies of your comment (an original and three copies) to: Docket No. 02-023-3, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238. Please state that your comment refers to Docket No. 02-023-3. If you use e-mail, address your comment to regulations@aphis.usda.gov. Your comment must be contained in the body of your message; do not send attached files. Please include your name and address in your message and "Docket No. 02-023-3" on the subject line.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690-2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at <http://www.aphis.usda.gov/ppd/rad/webrepor.html>.

Public hearings regarding this rule will be held at the following locations:

1. Oxnard, CA: Radisson Hotel, 600 Esplanade Drive, Oxnard, CA.

2. Lake Alfred, FL: University of Florida Experiment Station, Ben Hill Griffin Hall, 700 Experiment Station Road, Lake Alfred, FL.

FOR FURTHER INFORMATION CONTACT: Mr. I. Paul Gadh, Import Specialist, Phytosanitary Issues Management Team, PPQ, APHIS, 4700 River Road Unit 140, Riverdale, MD 20737-1236; (301) 734-6799.

SUPPLEMENTARY INFORMATION:

Public Hearings

We are advising the public that we are hosting two public hearings on this proposed rule and on the documents that support it. The first public hearing will be held in Oxnard, CA, on Tuesday, August 20, 2002. The second public hearing will be held in Lake Alfred, FL, on Thursday, August 22, 2002.

A representative of the Animal and Plant Health Inspection Service

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(APHIS), U.S. Department of Agriculture (USDA or the Department), will preside at the public hearings. Any interested person may appear and be heard in person, by attorney, or by other representative. Written statements may be submitted and will be made part of the hearing record. A transcript of the public hearings will be placed in the rulemaking record and will be available for public inspection.

The purpose of the hearings is to give interested persons an opportunity for presentation of data, views, and arguments. Questions about the content of the proposed rule may be part of the commenters' oral presentations. However, neither the presiding officer nor any other representative of APHIS will respond to comments at the hearings, except to clarify or explain provisions of the proposed rule.

The public hearings will begin at 9 a.m. and are scheduled to end at 4:30 p.m., local time. The presiding officer may limit the time for each presentation so that all interested persons appearing at each hearing have an opportunity to participate. Each hearing may be terminated at any time if all persons desiring to speak have been heard.

Registration for the hearings may be accomplished by registering with the presiding officer between 8:30 a.m. and 9 a.m. on the day of the hearing. Persons who wish to speak at a hearing will be asked to sign in with their name and organization to establish a record for the hearing. We ask that anyone who reads a statement provide two copies to the presiding officer at the hearing. Those who wish to form a panel to present their views will be asked to provide the name of each member of the panel and the organizations the panel members represent.

Persons or panels wishing to speak at one or both of the public hearings may register in advance by phone or e-mail. Persons wishing to register by phone should call the Regulatory Analysis and Development voice mail at (301) 734-8138. Callers must leave a message clearly stating (1) the location of the hearing the registrant wishes to speak at, (2) the registrant's name and organization, and, if registering for a panel, (3) the name of each member of the panel and the organization each panel member represents. Persons wishing to register by e-mail must send an e-mail with the same information

described above to matthew.a.rhoads@aphis.usda.gov. Please write "Public Hearing Registration" in the subject line of your e-mail. Advance registration for either hearing must be received by 3 p.m. on Friday, August 16, 2002.

If you require special accommodations, such as a sign language interpreter, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

The regulations in "Subpart Fruits and Vegetables" (7 CFR 319.56 through 319.56-8, referred to below as the regulations) prohibit or restrict the importation of fruits and vegetables into the United States from certain parts of the world to prevent the introduction and dissemination of plant pests, including fruit flies, that are new to or not widely distributed within the United States.

The regulations do not contain any specific administrative instructions regarding the importation of clementines (*Citrus reticulata*) from Spain. However, until recently, the Animal and Plant Health Inspection Service (APHIS) authorized the importation of clementines from Spain under the regulations in § 319.56-2(e)(2). The regulations in § 319.56-2(e) provide that any fruit or vegetable, except those restricted to certain countries and districts by special quarantine and other regulations or orders now in force and by any restrictive order as may hereafter be promulgated, may be imported from any country under a permit issued in accordance with this subpart and upon compliance with the regulations in this subpart, if the U.S. Department of Agriculture, after reviewing evidence presented to it, is satisfied that the fruit or vegetable either:

(1) Is not attacked in the country of origin by injurious insects, including fruit and melon flies (Tephritidae);

(2) Has been treated or is to be treated for all injurious insects that attack it in the country of origin, in accordance with conditions and procedures that may be prescribed by the Administrator;

(3) Is imported from a definite area or district in the country of origin that is free from all injurious insects that attack the fruit or vegetable, its importation can be authorized without risk, and its importation is in compliance with the criteria of paragraph (f) of this section; or

(4) Is imported from a definite area or district of the country of origin that is free from certain injurious insects that attack the fruit or vegetable, its

importation can be authorized without risk, and the criteria of paragraph (f) of this section are met with regard to those certain insects, provided that all other injurious insects that attack the fruit or vegetable in the area or district of the country of origin have been eliminated from the fruit or vegetable by treatment or any other procedures that may be prescribed by the Administrator.

Until recently, clementines from Spain have been imported under permit, provided that they were cold treated for the Mediterranean fruit fly (*Ceratitis capitata*) (Medfly) in accordance with the treatment listed in the Plant Protection and Quarantine (PPQ) Treatment Manual, which is incorporated by reference into the regulations at 7 CFR 300.1. The treatment listed in the PPQ Treatment Manual for clementines from Spain requires fruit to be held at temperatures from 32 °F to 36 °F according to the following schedule:

Temperature	Exposure period (days)
32 °F or below	10
33 °F or below	11
34 °F or below	12
35 °F or below	14
36 °F or below	16

Clementines imported from Spain were not required to meet any additional treatment requirements in order to be imported into the United States, but were subject to inspection at the port of entry.

On November 20 and 27, 2001, live Medfly larvae were intercepted in clementines from Spain that were purchased by consumers from food stores in North Carolina and Maryland. On November 30, 2001, APHIS notified the Government of Spain that it was suspending the importation of clementines pending an investigation into the cause of the infestations. In the course of its investigation, APHIS traced the infested fruit from both locations to a single sea vessel importing clementines from Spain into Philadelphia, PA.

Based on the findings of the investigation, on December 4, 2001, APHIS notified the Government of Spain that imports of clementines could resume on December 5, 2001, as we believed that the infested fruit likely were the product of improper application of cold treatment on the vessel in which they were imported. However, later that same day, APHIS inspectors intercepted live Medfly larvae in Spanish clementines during a market inspection in Louisiana. The

clementines were traced back to a shipment of clementines that were imported from Spain into Newark, NJ, on a different sea vessel than the shipment that produced the North Carolina and Maryland interceptions.

After the third Medfly interception, on December 5, 2001, APHIS notified the Government of Spain that it was suspending the importation of clementines based on interceptions of live Medfly larvae in Spanish clementines that were transported to the United States in two separate sea vessels. Beginning December 5, 2001, all shipments of clementines from Spain were refused entry into the United States. APHIS also announced restrictions on the marketing of Spanish clementines that had already been released into domestic commerce. Under those new restrictions, Spanish clementines could only be sold in northeastern U.S. States where Medfly host material was not prevalent at that time of year. Clementines distributed in the States of Alabama, Arizona, Arkansas, California, Florida, Georgia, Louisiana, Mississippi, North Carolina, Nevada, New Mexico, Oklahoma, Oregon, Puerto Rico, South Carolina, Tennessee, Texas, and Washington were required to be removed from retail shelves, and had to be destroyed or shipped to northeastern States.

After we adopted those restrictions on clementines from Spain, APHIS was notified by the California Department of Food and Agriculture (CDFA) that CDFA inspectors had intercepted live Medfly larvae in imported Spanish clementines on five occasions in three California cities between December 3 and December 7. On December 11, 2001, after the restrictions on Spanish clementines had been put in place, APHIS inspectors intercepted additional live Medfly larvae in imported Spanish clementines that were being held at Port Elizabeth, NJ.

The number of Medfly interceptions in Spanish clementines in such a short period of time in November and December 2001 was very uncharacteristic given the history of clementine imports from Spain. The U.S. Department of Agriculture (USDA) has allowed the importation of clementines from Spain since 1985. Prior to November and December 2001, there had never been multiple confirmed finds of Medflies in fruit of any kind that had been legally imported into the mainland United States from any source. Additional problems pertaining to the importation of clementines have been reported in the past (*i.e.*, consumer submissions to APHIS of (1) clementines with dead

Medfly larvae that were reported to be alive when they were found and (2) fruits that may not have been subject to treatment), but even those unconfirmed events consisted of only one or two fruits per year.

In order to get a better sense of what factors contributed to the survival of Medfly larvae in clementines that were imported from Spain, APHIS initiated a review of the Spanish clementine import program and the cold treatment protocol in general. As part of this review, an APHIS team visited Spain in mid-December 2001. The review team noted that there may have been an overwhelming presence of Medfly larvae in Spanish clementines during the early part of the 2001–2002 production season. The review team concluded that the following conditions in clementine production areas may have contributed to the overwhelming larval presence:

- Unseasonably warm weather conditions;
- Above average fruit fly populations;
- High host susceptibility of the early season clementine varieties;
- Low trap densities and inadequate bait spray applications; and
- Lack of fruit cutting activities to adequately monitor larval populations.

APHIS believes, based on the available evidence, that there are two possible explanations for the survival of Medfly larvae in imported Spanish clementines during the 2001–2002 shipping season. One is that despite the assumed mortality rate of the cold treatment (99.9968 percent), any small or partial failure in the application of the cold treatment could have allowed Medflies to survive in clementines imported from Spain due to the above average levels of Medflies in the growing areas in Spain. Alternately, it is possible that the level of Medfly infestation in imported clementines simply overwhelmed the capabilities of the cold treatment process, even if the treatment was properly applied.

In order to address this problem, since December 5, 2001, APHIS has prohibited the importation of clementines from Spain while it considers alternate approaches to mitigating the Medfly risk posed by clementines from Spain.

Determination by the Secretary

In this document, APHIS is proposing to allow the importation of clementines from Spain to resume, but only under additional conditions that we believe will prevent the introduction of Medfly into the United States in clementines imported from Spain.

Under section 412(a) of the Plant Protection Act, the Secretary of Agriculture may prohibit or restrict the importation and entry of any plant product if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination of a plant pest or noxious weed within the United States.

The Secretary has determined that it is not necessary to prohibit the importation of clementines from Spain in order to prevent the introduction into the United States or the dissemination within the United States of a plant pest or noxious weed. This determination is based on the finding that the application of the remedial measures contained in this proposed rule will provide the protection necessary to prevent the introduction and dissemination of plant pests into the United States. The factors considered in arriving at this determination include: (1) The conclusions of a risk management analysis, “Risk mitigation for Mediterranean fruit flies with special emphasis on risk reduction for commercial imports of clementines (several varieties of *Citrus reticulata*) from Spain” (Revised July 5, 2002) (referred to elsewhere in this document as “risk management analysis”), (2) the findings of a review of the existing cold treatment for clementines from Spain, “Evaluation of cold storage treatment against Mediterranean Fruit Fly, *Ceratitis capitata* (Wiedemann) (Diptera:Tephritidae)” (May 2, 2002) (referred to elsewhere in this document as “cold treatment evaluation”), and (3) the findings of USDA technical experts.

Risk Management Analysis

On April 16, 2002, we published a notice in the **Federal Register** (67 FR 18578–18579, Docket No. 02–023–1) in which we announced the availability of the risk management analysis and appendices. On May 24, 2002, we published another notice in the **Federal Register** (67 FR 36560–36561, Docket No. 02–023–2) in which we extended the comment period on the risk management analysis and appendices until June 14, 2002. Based on comments we received in response to those notices, we have made changes to the risk management analysis. Those changes are described in section X of the risk management analysis. APHIS will continue to accept comments on the risk management analysis and the other documents supporting this proposed rule throughout the comment period for the proposed rule. The revised risk management analysis and appendices can be viewed on the APHIS

Internet site at: <http://www.aphis.usda.gov/oa/clementine/index.html>. Copies are also available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

APHIS's risk management analysis evaluates the potential of remedial measures employed in this proposed rule to reduce the risk that Medflies could be imported into the United States from Spain. As part of our analysis of the risks posed by the importation of clementines from Spain, we identify critical control points in the safeguarding system which assure that risks are minimized and are subject to verification and monitoring by regulatory personnel. Identification of these critical control points permits the risk assessor to focus on those components of a system that are key to the overall effectiveness of the system.

This approach is similar to a type of risk management approach used by the Food and Drug Administration (FDA) and USDA's Food Safety and Inspection Service, called a Hazard Analysis and Critical Control Point (HACCP) analysis. HACCP analyses have been found to provide an effective and rational means of assuring food safety from harvest to consumption. Preventing problems from occurring is the paramount goal underlying any HACCP system, and seven basic principles are employed in the development of HACCP plans that meet the stated goal. These principles include hazard analysis, critical control point identification, establishing critical limits, monitoring procedures, corrective actions, verification procedures, and record keeping and documentation. Using a HACCP approach, if a deviation occurs indicating that control has been lost, the deviation is detected and appropriate steps are taken to reestablish control in a timely manner to assure that potentially hazardous products do not reach the consumer.

For the purposes of our risk management analysis, APHIS has applied the HACCP approach to the analysis of phytosanitary measures; i.e., we consider the critical control points employed by HACCP approaches as being equivalent to critical control points employed in the area of phytosanitary safety. We emphasize that our application of the HACCP approach does not represent a departure from existing guidelines for the phytosanitary risk analysis, but rather, is a refinement that reflects more emphasis on certain risk mitigating elements of a set of phytosanitary measures (e.g., the critical control points). A more detailed description of how HACCP principles can be applied to phytosanitary risk

management is shown in appendix 1 of the risk management analysis.

As stated above, the risk management analysis considers the risk that Medflies could be introduced into the United States via Spanish clementines. We only consider Medflies in this analysis because we have conducted a review of the pests known to infest clementines in Spain, and have found that all other pests except Medflies are readily detectable by visual inspection, and therefore do not require additional risk mitigation. This pest list review is documented in appendix 4 of the risk management analysis. The information provided in the risk management analysis and its appendices meets applicable risk analysis standards adopted by the International Plant Protection Convention.

The risk management analysis, among other things, notes that two elements (critical control points) are fundamental to the successful reduction of risks associated with the importation of clementines from Spain:

1. The limitation of the population of Medflies in clementine production areas in Spain such that the proportion of infested fruit is no greater than 1.5 percent.

2. The application of cold treatment such that a Probit 9 level of quarantine security is approximated.¹

The risk management analysis concludes that the risk of Medfly introduction via Spanish clementines would be significantly reduced if cold treatment is applied to fruit that have been subject to the proposed Medfly population reduction measures, rather than if fruit is simply subject to cold treatment alone. With this in mind, we have drafted a revised regulatory approach for the importation of clementines from Spain that would allow the underlying goals of both elements to be met if imports of clementines from Spain resume. The phytosanitary measures employed in the regulatory approach described in this document would also provide additional safeguards resulting in risk reductions that further diminish the potential effects of uncertainties and variability inherent in the commodity import system.

¹ A system that ensures at least 99.9968 percent mortality of target pests provides Probit 9 quarantine security. Probit 9 quarantine security allows for a survival rate of no more than 0.0032 percent of target pests. The risk management analysis does not assume that cold treatment alone provides a defined level of quarantine security (i.e., probit 9 quarantine security). Rather, the analysis considers other risk-mitigating measures as necessary to ensure that cold treatment has the potential to provide approximately a probit 9 level of quarantine security.

Proposed Requirements

As discussed in detail below, the remedial measures contained in this proposed rule are intended: (1) To prevent high Medfly infestation levels of the sort that occurred in 2001 through the use of fruit fly trapping, bait treatment procedures, and record keeping requirements, (2) to permit the detection of high levels of Medfly infestation through pre-shipment inspection procedures, and (3) to prevent the introduction of Medflies into the United States through modified cold treatment and post-shipment inspection procedures.

We are proposing to add a new § 319.56-2jj, "Administrative instructions; conditions governing the importation of clementines from Spain," to the regulations. Section 319.56-2jj would list the conditions under which the importation of clementines from Spain into the United States could resume. Those conditions are described in detail below.

Trust Fund Agreement

Paragraph (a) of proposed § 319.56-2jj specifies that clementines will only be allowed to be imported into the United States from Spain if the Government of Spain or its designated representative (e.g., an association of exporters of Spanish clementines) enters into a trust fund agreement with APHIS before each clementine shipping season. The agreement would require the Government of Spain or its designated representative to pay in advance all costs that APHIS expects to incur through its involvement in those elements of the proposed Spanish clementine regulations that must take place in Spain. The requirements regarding activities in Spain can be found in paragraphs (b) through (g) of proposed § 319.56-2jj.

Costs that would have to be paid in advance include administrative expenses incurred in conducting the required services in Spain and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by the inspectors in performing these services. The regulations and trust fund agreement would require that the Government of Spain or its designated representative deposit a certified or cashier's check with APHIS for the amount of those costs, as estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement would further require the Government of Spain or its designated representative

to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before the services could be continued. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the Government of Spain or its designated representative or held on account until needed.

These requirements regarding the trust fund agreement would be necessary to ensure that APHIS is able to cover all costs resulting from its participation in the approval of clementines for export to the United States.

Mediterranean Fruit Fly Management Program

Paragraph (b) of proposed § 319.56-2jj specifies that persons who produce clementines in Spain for export to the United States must be registered with the Government of Spain and that they enter into the Government of Spain's Mediterranean fruit fly management program.

The Government of Spain's Mediterranean fruit fly management program is a new program that was designed to reduce the presence of Medflies in areas that produce clementines for export to the United States to levels that are conducive to successful treatment of the fruit (i.e., a target infestation rate of 1.5 percent or less). Under paragraph (c) of proposed § 319.56-2jj, the Government of Spain's Mediterranean fruit fly management program would be required to contain certain fruit fly trapping and recordkeeping requirements, and program operations in general would have to be approved by APHIS as adequate to ensure that the areas where clementines are produced for export to the United States indeed do have low infestation rates. The proposed regulations would also require that clementine producers allow APHIS inspectors access to clementine production areas in order to monitor compliance with the Mediterranean fruit fly management program.

Specifically, the regulations and the Mediterranean fruit fly management program would require that, in areas where clementines are produced for export to the United States, fruit fly traps be placed in preferred Medfly host plants at least 6 weeks prior to the harvest of the clementines. This requirement would ensure that growers in Spain are able to determine the extent of the presence of Medflies in clementine production areas, so that appropriate control methods could be applied prior to harvest of fruit.

In addition, bait treatments using malathion, spinosad, or another pesticide approved by APHIS would have to be applied in the production areas at a rate appropriate to maintain the level of infestation of clementines by Medflies at 1.5 percent or less. This proposed requirement would help ensure that the majority (98.5 percent) of fruit intended for exportation to the United States is not infested with Medfly larvae prior to cold treatment and that the Spanish Medfly management program reduces populations of Medflies to levels that allow for effective cold treatment of fruits exported to the United States.

In addition, the proposed regulations would require that the Government of Spain or its designated representative keep records that document all fruit fly trapping and control activities that are conducted under the Government of Spain's Medfly management program. All trapping and control records kept by the Government of Spain or its designated representative would have to be made available to APHIS upon request. APHIS would require access to these records in order to verify that clementine production areas in Spain meet the requirements of the Government of Spain's Medfly management program and APHIS regulations.

Phytosanitary Certificates

Under paragraph (d) of proposed § 319.56–2jj, clementines from Spain would have to be accompanied by a phytosanitary certificate that states that the clementines meet the conditions of the Government of Spain's Mediterranean fruit fly management program and applicable APHIS regulations. This requirement would provide APHIS with the Government of Spain's assurance that imported clementines have been grown under conditions designed to reduce the level of infestation of the fruit by Medflies.

Labeling

Paragraph (e) of proposed § 319.56–2jj specifies that cartons in which clementines are packed would be required to be labeled with a lot number

that provides information to identify the orchard where the fruit was grown and the packinghouse where the fruit was packed. The lot number would have to end with the letters "US," and the labeling would have to be large enough to clearly display the required information and be located on the side of cartons to facilitate inspection by APHIS.

Pre-Treatment Sampling

Clementines that are produced under the Government of Spain's Medfly management program should have low levels (i.e., 1.5 percent or less) of infestation with Medflies prior to cold treatment. In order to ensure that the efficacy of the cold treatment is not undermined by high levels of infestation, paragraph (f) of proposed § 319.56–2jj would require that, prior to beginning cold treatment of a shipment of clementines, APHIS inspectors will cut and inspect a designated number of fruit that are randomly selected from throughout the shipment. A shipment could include as little as one shipping container of clementines (approximately 166,000 fruit) or could be a bulk shipment of approximately 972,000 clementines (a maximum of 120 pallets, with each pallet containing approximately 8,100 fruit). A shipment is basically a group of fruit from one packinghouse that is presented for inspection by APHIS. A shipment from a single packinghouse could include fruit from many different orchards.

If inspectors find a single live Medfly in any stage of development during an inspection, the entire shipment of clementines would be rejected. While a single Medfly interception in a shipment of Spanish clementines may not be proof that the shipment is highly infested, such a detection provides a statistical basis by which to infer that fruit could be 1.5 percent infested or more. Conversely, if no Medflies are intercepted during an inspection of a shipment of fruit, there is a statistical basis upon which to assume that the fruit sampled is less than 1.5 percent infested.

Further, if a live Medfly in any stage of development is found in any two

shipments of fruit from the same orchard during the same shipping season, that orchard would be removed from the export program for the remainder of that shipping season.

Rates of Pre-Treatment Sampling

For the first clementine shipping season that occurs under the regulations described in this proposed rule, inspectors would cut 200 randomly selected fruit per shipment. We chose 200 as a sample size because, according to hypergeometric sampling rates, this sample size provides a 95 percent chance of finding one or more infested fruit when the infestation rate (percent of fruit infested) in the shipment sampled is 1.5 percent, provided that the size of the shipment sampled falls within the range described earlier in this document (between one container and 120 pallets). Since the regulations would require shipments in which Medflies are detected to be rejected, we are confident that only clementines with very low levels of infestation with Medflies would proceed to the next step in the import process.

The proposed regulations also contain provisions that would allow the sample size for pre-treatment fruit cutting to be adjusted for subsequent shipping seasons based on the number of rejections of shipments that occur during the previous shipping season. For the purposes of this proposed rule, a shipping season would include the period beginning approximately in mid-September and ending approximately in late February of the next calendar year. This is to say that if our experience with fruit cutting suggests that the majority of Spanish clementines presented for exportation to the United States are not infested with Medflies, we would decrease the number of fruit that need to be cut and inspected. Conversely, the sample size could be returned to higher levels if the number of rejections of shipments rose above a specified percentage of the shipments. The sample size adjustments and their triggers are shown in the following table:

If the sample size for a given season is—	... and the rejection rate during that season is—	... then the sample size for the next season is—
200	≤5 percent	¹ 100
100	>5 percent	200
76	≤2 percent	² 76
	>2 percent but ≤5 percent	100
	>5 percent	200
	≤2 percent	76
	>2 percent but ≤5 percent	100

If the sample size for a given season is—	... and the rejection rate during that season is—	... then the sample size for the next season is—
	>5 percent	200

¹ According to hypergeometric sampling rates, this sample size provides a 95 percent chance of finding one or more infested fruit when the infestation rate (percent of fruit infested) in the shipment sampled is 3 percent.

² According to hypergeometric sampling rates, this sample size provides a 90 percent chance of finding one or more infested fruit when the infestation rate (percent of fruit infested) in the shipment sampled is 3 percent.

These potential changes in the sample size for shipments of clementines that have not yet been cold treated would provide for responsive changes in inspection protocols based on the success Spanish growers and exporters have in maintaining low Medfly infestation levels in clementines, as indicated by Medfly interceptions during fruit cutting. However, if APHIS determines that fruit presented for inspection and treatment appear to be highly infested during a shipping season in which 100 or 76 fruit are cut per shipment, APHIS would reserve the right to increase the required sample size during the shipping season. At no time would more than 200 fruit be required to be cut, but the sample size could be raised to that level at APHIS's discretion, depending on the number of Medfly interceptions.

The sample rates described above are each designed to ensure that, prior to cold treatment, APHIS can ensure that the level of Medfly infestation in clementines is sufficiently low to provide for effective treatment of the fruits.

Cold Treatment

Cold treatment of imported fruit is often conducted while the vessel carrying the fruit is en route to the United States, as cold treatment requires several days to cause mortality of target pests. Clementines from Spain are typically held in a refrigerated hold of cargo ship or in a refrigerated shipping container, and records are kept during transit to verify that the treatment for Medfly is successfully completed.

As stated earlier in this document, after the interceptions of Medflies in clementines from Spain in December 2001, APHIS undertook a review of activities associated with the production and treatment of Spanish clementines. As part of this review, APHIS is sponsoring additional research on the application of cold treatments for imported fruits and vegetables. In addition, APHIS asked a panel composed of APHIS regulatory personnel and USDA technical experts on fruit flies to conduct a review of available scientific literature related to the efficacy of the cold treatment for

Medfly described earlier in this document, with the intention of using the panel's findings as guidelines on the future application of cold treatment. The panel found that the existing cold treatment schedule, while providing a very high level of Medfly mortality, does not provide Probit 9 level quarantine security in all cases. The panel also found that the high numbers of larvae present during the early part of the 2001–2002 growing season overwhelmed the ability of the cold treatment to provide quarantine security, and concluded that the present cold treatment schedule is insufficient for controlling high larval populations of Medflies and may result in Medfly survivors. The panel's findings are corroborated by an additional quantitative USDA analysis, "Quantitative Analysis of Available Data on the Efficacy of Cold Treatment Against Mediterranean Fruit Fly Larvae" (July 5, 2002).

Based on its review of the available scientific literature and of all factors involved in quarantine cold treatments against Medfly eggs and larvae, the panel recommended increasing the length of the required cold treatment at each temperature by 2 days. The cold treatment evaluation and the quantitative analysis referred to above can be viewed on the APHIS Internet site at: <http://www.aphis.usda.gov/oa/clementine/index.html>. Copies are also available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Based on the panel's recommendation, we are proposing to amend the PPQ Treatment Manual by revising the Medfly treatment listed for clementines from Spain.²

The revised treatment schedule would require clementines from Spain to be held at temperatures from 32 °F to 36 °F according to the following schedule:

² The current cold treatment used for clementines from Spain is also applicable to a number of other commodities imported from several different countries. We are only proposing to amend the cold treatment for clementines from Spain in this document, and we intend to make changes to the treatments for the other commodities in a separate rulemaking.

Temperature	Exposure period (days)
32 °F or below	12
33 °F or below	13
34 °F or below	14
35 °F or below	16
36 °F or below	18

There should be no effect on fruit quality due to the increased holding times, based on anecdotal information from New Zealand's Ministry of Agriculture and Forestry.

In conjunction with this revised treatment protocol, the proposed rule would require that, upon arrival of clementines at a port of entry into the United States, APHIS inspectors will examine the cold treatment data for each shipment³ to ensure that the cold treatment was successfully completed. If the cold treatment has not been successfully completed, the shipment would be held until appropriate remedial actions have been implemented.

Appropriate remedial actions would depend on the circumstances of the treatment failure, but could include retreatment, extension of treatment, destruction, disposal, or reexportation of fruit. For instance, if the treatment records for a vessel reveal that a single cargo hold did not maintain the appropriate cold treatment temperature during the first 2 days of a 13-day treatment, inspectors could require that the fruit in that hold be held at the appropriate temperature for an additional 2 days prior to allowing the fruit to be removed from the vessel and inspected. In the event that temperature is not maintained during the middle of the treatment period, an inspector could allow the fruit to be containerized and retreated according to the appropriate treatment schedule prior to release into domestic commerce. Alternately, the inspector could allow the shipment to be reexported to a country that does not require treatment of fruits for Medflies, or the fruit could be destroyed or disposed of according to certain conditions.

³ Cold treatment records and data must be made available to APHIS under § 319.56–2d(b)(3)(i).

Port of Entry Sampling

Under paragraph (h) of proposed § 319.56–2jj, clementines imported from Spain would be subject to inspection by an inspector at the port of entry into the United States. This includes inspection for hitchhiking pests that could be present in shipments of clementines, in addition to fruit cutting inspections for Medflies.

In order to ensure that the proposed cold treatment, in combination with other proposed requirements, is working correctly, APHIS inspectors would cut and inspect randomly selected fruit at a sampling rate determined by the Administrator. The number of fruit to be cut could be adjusted based on the historical success of the treatment.

For the first clementine shipping season that occurs under the regulations described in this proposed rule, APHIS would cut 1,500 randomly selected fruit per shipload or 150 randomly selected fruit per shipping container.⁴ We chose these particular sample sizes because, according to hypergeometric sampling rates, they provide a 95 percent chance of finding one or more infested fruit when (1) the infestation rate (percent of fruit infested) in the shipload sampled is 0.2 percent, or (2) the infestation rate (percent of fruit infested) in the shipping container sampled is 2.0 percent.

For future shipping seasons, APHIS may reduce the amount of fruit to be cut at the port of entry as our confidence in the effectiveness of the cold treatment increases. However, if inspectors detect a single live Medfly in any stage of development in a shipment of Spanish clementines, the shipment of clementines would be held until an investigation is completed and appropriate remedial actions have been implemented. Further, regardless of the level of inspection applied at that time, any further inspections would be subject to increased rates of inspection not to exceed 1,500 randomly selected fruit per shipload or 150 randomly selected fruit per shipping container, and inspections would remain at that level until APHIS is able to determine the cause of infestation and apply appropriate remedial measures.

Appropriate remedial actions would depend on the circumstances of the infestation, but could include retreatment, destruction, disposal, or reexportation of fruit. For instance, if

fruit cutting reveals infestation of clementines with Medflies, and APHIS determines that the infestation is limited to fruit imported in a specific cold treatment hold or container in the vessel, APHIS could require that the infested fruit be reexported or destroyed. If APHIS is unable to link the infestation to a particular treatment hold or container, an inspector could refuse entry of the clementines and require them to be reexported or destroyed. Furthermore, if APHIS determines at any time that the required cold treatment or other safeguards contained in the proposed regulations are not protecting against the introduction of Medflies into the United States, APHIS may suspend the importation of clementines from Spain and conduct an investigation into the cause of the deficiency.

Definitions

Paragraph (i) of proposed § 319.56–2jj would clarify that, as stated earlier in this document, for the purposes of the proposed regulations, a shipping season would be considered to include the period beginning approximately in mid-September and ending approximately in late February of the next calendar year.

Limited Distribution

We are considering instituting a limited distribution plan that would delay the entry of Spanish clementines into citrus-producing areas in the United States for up to 1 full shipping season. This would mean that clementines could not be distributed in or imported into California, Arizona, Texas, Florida, Louisiana, Puerto Rico, the U.S. Virgin Islands, the Northern Mariana Islands, Guam, and American Samoa as an additional precaution against the introduction of Medflies into those areas, whose citrus industry could be severely harmed if Medflies were introduced into commercial production areas. This delay would provide an opportunity for the efficacy of the proposed regulations to be demonstrated under actual production and distribution conditions for 1 full shipping season before Spanish clementine imports would be allowed to enter citrus-producing areas of the United States. We invite the public to submit information demonstrating whether or not this confidence-building measure is warranted.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be significant for the purposes of Executive Order

12866 and, therefore, has been reviewed by the Office of Management and Budget.

For this proposed rule, we have prepared an economic analysis. The economic analysis provides a cost-benefit analysis as required by Executive Order 12866, as well as an analysis of the potential economic effects of this proposed rule on small entities, as required under 5 U.S.C. 603. The economic analysis is summarized below. See the full analysis for the complete list of references used in this document. Copies of the full analysis are available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**, or on the Internet at <http://www.aphis.usda.gov/oa/clementine/index.html>.

Under the Plant Protection Act (7 U.S.C. 7701–7772), the Secretary of Agriculture is authorized to regulate the importation of plants, plant products, and other articles to prevent the introduction of injurious plant pests.

Summary of Economic Analysis

Our analysis estimates expected benefits and costs associated with lifting the ban on the importation of Spanish clementines by the beginning of the next shipping season (mid-September 2002). Expected benefits and costs are estimated relative to the current ban and relative to the previous import program. Benefits and costs are estimated relative to the ban, because the ban is currently in effect. Benefits and costs are estimated relative to the previous import program, because this provides a useful benchmark for measuring relative benefits and costs. Potential benefits associated with lifting the ban include increased profits for importers and wholesalers and increased clementine supplies for retail consumers in the United States. Potential costs include eradication and other expenses that might be borne by taxpayers and fruit and vegetable producers in the United States in the event live Medflies are introduced.

Under the most likely scenario examined in the analysis, expected welfare gains relative to the current ban are approximately \$210 million for marketing season 2002, which includes \$120, \$60, and \$30 million in estimated welfare gains for importers, wholesalers, and retail consumers, respectively, with practically no increase in expected costs to U.S. taxpayers and fruit and vegetable producers. In addition, under the most likely scenario, expected welfare gains relative to the previous import program are over \$26 million for marketing season 2002. This includes \$15, \$8, and \$4 million in relative gains for

⁴ A shipload could contain approximately 2,509 metric tons of clementines—equivalent to approximately 22.6 million fruit at a rate of 9,000 fruit per metric ton. As stated earlier in this document, a shipping container could contain approximately 166,000 fruit.

importers, wholesalers, and retail consumers, respectively, and approximately \$50,000 in gains to U.S. taxpayers and fruit and vegetable producers in the United States arising from improved Medfly management.

Clementine Market

Clementines are not grown domestically in significant quantities; therefore, U.S. consumption during the last 15 years (Snell 2002) has depended on imports from Spain, which contributed 90 percent of total U.S. imports during 1996–2000 (FAS 2002). Between 1991 and 2000, Spain's annual production of clementines averaged slightly over 1.1 million metric tons. During 1991–2000, Spain exported most of its clementines to Germany, France, the United Kingdom, and the Netherlands; however, exports to the United States grew 45 percent per year during this period, even though clementine production in Spain grew only 2 percent per year (FAS 1996–2001, MAPA 1999). The phenomenal growth in exports to the United States has been due to increased demand, leading to high import prices in the United States relative to import prices in the rest of the world. During 1989–2000, prices offered by U.S. importers averaged 20 percent higher than prices offered by all other importing countries, providing incentives sufficient for exporters to ship an average annual 6 percent of total exports to the United States in 1999 and 2000.

Spain exports clementines to the United States during mid-September to late February. Morocco, Italy, and Israel also export clementines to the United States during this marketing period; however, during 1996–2000, only 2 and 0.1 percent of U.S. clementine imports were from Morocco and Italy, respectively, and during 1998–2000, only 0.4 percent of U.S. clementine imports were from Israel. This suggests that exporters in these countries have not established export market infrastructures sufficient to allow for massive increases in shipments to the United States in the short run. In addition, clementines from these countries are typically of lower quality as reflected in lower average prices paid by U.S. importers. As a result, it is assumed that exports from Morocco, Italy, and Israel will not be able to fill the void left by the ban on Spanish clementines in the short run.

It is unclear whether clementine imports and domestically produced tangerines (*Citrus reticulata*) may be substitutes. Pollack and Perez (2001) have suggested that the two types of citrus may be substitutes; however, they

did not estimate a substitution rate. We estimated the rate of substitution using a linear relationship between tangerine prices received by U.S. producers, a constant, wholesale tangerine consumption, and U.S. clementine imports. Although the coefficient estimate on clementine imports from Spain was negative, indicating clementines and tangerines may be substitutes, the coefficient estimate was not statistically different from zero. As a result, it is not clear whether clementines and tangerines are substitutes. Because only 12 annual observations were available, we request information and data from the public relevant to the estimation of the rate of substitution between domestically produced tangerines and Spanish clementine imports. In addition, we request information and data from the public relevant to the estimation of the rate of substitution between other domestically produced citrus fruit and Spanish clementine imports. In particular, we are interested in weekly or monthly price and quantity data for the relevant markets (Spanish clementine and domestically produced tangerines and other citrus fruits) during the clementine marketing season, mid-September to late February.

In addition, there are differences between Spanish clementines and domestically produced tangerines, which may be important to U.S. consumers. In particular, clementine imports are seedless and are packaged in small wooden boxes; whereas domestically produced tangerines are generally not seedless and are marketed in bulk quantities. Tangerine wholesalers are apparently considering alternative marketing strategies based on the clementine model; however, it is not clear if or when wholesalers will adopt this marketing strategy (Pollack 2002). Moreover, consumption of domestically produced tangerines (233,147 metric tons) was almost three times higher than consumption of clementines (83,631 metric tons) in the United States in 2000. Finally, the proposed rule would permit the re-entry of Spanish clementines which, until the ban in the fall of 2001, have been imported into the United States for 15 years.

Because it is not clear if tangerines substitute for clementines in the aggregate, more domestically produced tangerines are consumed in the United States relative to clementines, and clementines from Spain have been imported historically the proposed rule would likely not have a significant impact on U.S. tangerine producers. As a result, we do not estimate impacts associated with the proposed rule on

U.S. tangerine producers in the current analysis. However, if U.S. demand for clementines continues to grow under the proposed rule and clementines substitute for domestically produced tangerines, then the proposed rule would lead to downward pressure on tangerine prices and profit losses for U.S. tangerine producers.

Costs Associated With the Proposed Rule

Additional costs include direct cost increases for local and federal governments in Spain, exporters in Spain, and Spanish clementine producers associated with producing and exporting clementines to the United States. We assume that Spanish clementine export supply is perfectly inelastic with respect to U.S. import prices and, as a result, that marginal production and export costs associated with the proposed rule borne directly by Spanish parties are not passed on to U.S. importers, wholesalers, and retail consumers. The assumption of perfectly inelastic supply is appropriate for a short-run analysis such as this and does not substantially affect the results of the analysis. Cost increases also include potential reductions in clementine import levels due to rejections of clementine shipments in Spain and in the United States in the event APHIS inspectors detect live Medflies in fruit inspections. Because rejected shipments must be diverted to other markets, clementine import quantities may be reduced leading to reductions in the economic benefits received by U.S. importers, wholesalers, and consumers. Finally, cost increases also include potential costs associated with the introduction of live Medflies into the United States.

Note that initial export quantities are referred to as "designated" in the analysis. This is because not all of the clementines initially designated for export to the United States will be exported to the United States. Some fruit will be cut and discarded in Spain and in the United States, and some of the quantities inspected (inspectional units) might be rejected and therefore not allowed to be exported to the United States. Increases in clementine production costs associated with the mandatory Medfly management program in Spain include purchases of additional traps for producers, purchases of baits for the traps, monitoring and recordkeeping costs, additional bait spray costs, additional cold treatment costs, and trust fund expenses. These additional costs will likely be borne by the Government of Spain, local governments, and

exporters. It is assumed that production decisions and designated export quantities will not be affected by these additional costs.

Total trap and bait expenses for Spanish growers are estimated to be very small (less than \$1,000) for the first year, or 0.0013 percent of the average value of Spanish clementine exports to the United States for 1999 and 2000 (\$78.69 million, FAS 2002), the majority of which will be spent on traps that can typically be used for several years. As a result, additional trap and bait expenses will represent very minor increases in fixed and variable costs, respectively, which will likely not affect production decisions regardless of who pays for them. Annual trust fund expenses for the Government of Spain or its agent are estimated to be at least \$90,000, including 16.15 percent administrative overhead (West 2002). These costs represent a more substantial increase in fixed costs, 0.1144 percent of average export value for 1999 and 2000. However, because the increase in fixed costs is small relative to the value of exports, we assume that production decisions and designated export quantities will not be affected.

The additional 2 days of cold treatment may add anywhere between \$92,000 and \$128,000 in annual expenses for all exporters (0.1627 percent of average export value for 1999 and 2000); however, because this also represents a minor fraction of the total value of exports, we assume that designated export quantities are not affected by these cost increases. We were unable to estimate additional costs associated with monitoring and recordkeeping in Spanish groves, which producers will be required to pay; however, these costs may be low as well, because the auditing agencies responsible for monitoring and recordkeeping are already in place for the U.S. Food and Drug Administration's pesticide residue program. It is not clear if or by how much annual bait sprays and spray costs may increase; however, these costs may be borne entirely by federal and local governments in Spain and therefore not affect production decisions or initial designated export quantities.

Fruit cutting and rejection of inspectional units in Spain and in the United States will reduce U.S. clementine imports by approximately 0.0069 percent, because it is assumed in the analysis that exporters do not adjust initial designated export quantities to the United States in the event inspectional units are rejected. Therefore, these costs are measured in terms of lost revenues for importers and

wholesalers and lost consumer benefits in the United States. Fruit will be cut in Spain at a rate of 200 clementines per inspectional unit, which might range in size from one 40-foot container (166,050 clementines) to 5.85 forty-foot container equivalents (972,000 clementines). Losses will include fruit that is cut and discarded, a relatively small cost that declines with inspectional unit size. Losses may also include rejections of inspectional units, where the rejection rate will depend on the proportion of fruit that is infested with Medflies (the infestation rate), the sample rate, and inspectional unit size.

Expected costs associated with potential Medfly introductions are based on estimated import levels and the infestation rate. For a given infestation rate, the expected number of introductions per year is given by the number of forty-foot container equivalents imported multiplied by the probability a typical container will lead to an introduction. The introduction probability is given by the probability that mating pairs (adult male and female Medflies) survive the export process and are delivered to an area suitable for the development of their offspring. We use the methods discussed in APHIS (2002) to estimate the introduction probability.

Expected costs associated with potential Medfly introductions are given by the product of the expected number of introductions and an estimate of the cost of one introduction. The mean cost of eradicating the last six Medfly introductions is \$10.93 million in 2000 dollars (APHIS 1999). We use this as the estimate of U.S. taxpayer costs associated with a Medfly introduction. Additional costs borne by U.S. producers during an introduction (e.g. additional field sprays, post-harvest treatments, fruit losses, post-harvest fruit losses, and loss of export markets) are estimated at approximately \$3 million per introduction. Expected Medfly introduction cost estimates under the proposed rule are calculated for the range of designated export quantities examined in the analysis. Under the most likely infestation rate examined in the analysis, expected costs associated with Medfly introductions are almost non-existent for each designated export quantity (1.12e-07 percent of average export value for 1999 and 2000). This is because the probability of a Medfly introduction per forty-foot container equivalent is extremely low (1.31e-12). For purposes of comparison with the previous import program, a calculation was also made of the expected Medfly introduction cost estimate under the previous import program. The expected cost under the

previous import program amounted to nearly \$50,000 (0.06 percent of average export value for 1999 and 2000).

Calculation of Benefits and Costs

Expected benefits and costs associated with the proposed rule vary with the amount of clementines imported into the United States and the proportion of clementines infested with Medflies in Spain (infestation rate). Because prices offered by U.S. importers are typically 20 percent higher than prices offered in the rest of the world, because the proposed rule provides significant incentives for Spanish growers to manage Medfly populations effectively, and because exporters will be able to choose clementines from regions in Spain with relatively low Medfly population levels the infestation rate will likely be low for marketing season 2002. In the risk mitigation analysis for the proposed rule, APHIS (2002) simulated infestation rates under the proposed rule and under the previous import program. We base the most likely infestation rates examined in the analysis on their simulation results.

Benefits and costs are estimated for a range of likely designated export quantities for marketing season 2002, under the assumption that export supply is perfectly inelastic with respect to U.S. prices. We examine a minimum quantity based on the import quantity for marketing season 2000 (83,631 metric tons), a most likely quantity based on the rate of growth in imports between marketing seasons 1999 and 2000 (90,032 metric tons), and a maximum quantity based on the average annual rate of import growth from 1989–2000 (116,406 metric tons). The minimum level is examined because costs associated with the proposed rule may reduce the designated export quantity. It is assumed, however, that the impact will not be so large as to diminish designated exports below the 2000 import quantity, because exporters will likely attempt to maintain established export market infrastructures.

There was a significant increase in U.S. clementine imports from Spain between 1998 and 1999 that may have been due, in part, to the establishment of market infrastructures in 1999. It is not clear what effect the proposed rule may have on the future development of this infrastructure; however, for the short run we assume that the most likely scenario involves no change from 2000 levels. As a result, our most likely quantity for designated exports in 2002 is based on the rate of growth in U.S. imports between 1999 and 2000, approximately 7.65 percent. Finally, we

examine a maximum quantity for designated exports based on the average annual rate of growth of imports during 1989–2001, at approximately 39 percent.

Benefits to importers, wholesalers, and retail consumers associated with the proposed rule are estimated using areas under demand curves bounded by prices paid, assuming wholesalers purchase all clementines purchased by importers and retail consumers purchase all clementines purchased by wholesalers. Demand curves for each sector have not been estimated in the literature, and available data were not sufficient to estimate precisely demand curves for any of the sectors. Therefore, an iterative procedure is used to specify linear demand curves for each sector to obtain approximate measures of economic welfare. A detailed discussion of the methodology for estimating demand curves can be found in the economic analysis accompanying the proposed rule.

For marketing season 2000, estimates of gross revenues minus payments on clementines for importers and wholesalers in the United States are approximately \$105 million and \$53 million, respectively. The estimate for retail consumer benefits in 2000 is an additional \$26 million. Benefits associated with lifting the ban under the proposed rule for marketing season 2002 are estimated in a similar manner, except the provisions of the proposed rule are used to estimate final import quantities and prices. Expected imports are given by designated exports minus expected fruit loss due to fruit cuttings and rejected shipments in Spain and in the United States. Given expected import levels, we estimate import prices and benefits, wholesale prices and benefits, and retail prices and consumer benefits. For the most likely designated export quantity (90,032 metric tons), estimates of gross revenues less payments on clementines for importers and wholesalers are \$120 million and \$60 million, respectively. The estimate for retail consumer benefits is an additional \$30 million.

Net Impact of the Proposed Rule

Relative to the current ban, net welfare impacts associated with the proposed rule are positive for each designated export quantity. Under the most likely designated export quantity, expected welfare gains associated with the proposed rule are approximately \$210 million for marketing season 2002, which includes approximately \$120, \$60, and \$30 million in estimated welfare gains for importers, wholesalers, and retail consumers, with practically

no increase in expected costs to U.S. taxpayers and fruit and vegetable producers.

Estimated net welfare effects relative to the previous import program are approximately \$26 million under the most likely designated export quantity scenario. In this case, importers, wholesalers, and retail consumers are expected to be better off under the proposed rule, because the expected amount of clementines ultimately imported into the United States during marketing season 2002 exceeds the amount imported in 2000. These results indicate that net welfare effects associated with the proposed rule will likely be positive relative to either baseline. If clementine imports increase and clementines substitute for domestically produced tangerines; however, benefits would be reduced due to profit losses experienced by U.S. tangerine producers.

Analysis of the Economic Effects on Small Entities

There are approximately 15 Spanish clementine importers in the United States, three of which import the majority of clementines (Sibley 2002). In addition, individuals in foreign countries own at least two of the import companies in this list. The U.S. Small Business Administration defines a small clementine importer (NAICS 42248 Fresh Fruit and Vegetable Wholesalers) as one with annual sales receipts of \$100 million or less. As a result, approximately 13 small importers may be affected by the proposed rule. The number of small wholesalers potentially affected by the proposed rule is not known. These entities include supermarkets and other grocery stores (NAICS 445110) with annual sales receipts of \$23 million or less, warehouse clubs and superstores (NAICS 452910) with annual sales receipts of \$23 million or less, and fruit and vegetable markets (NAICS 445230) with annual sales receipts of \$6 million or less.

Because the percentage of income derived from the sale of clementines by wholesalers is likely to be low, the proposed rule will not likely have a significant negative impact on a substantial number of small wholesalers relative to either baseline. In addition, small importers and wholesalers will likely be better off under the proposed rule relative to the current ban and, when designated exports are at or above the most likely value, better off under the proposed rule relative to the previous import program as well. As a result, the proposed rule will not have a significant impact on any small

importers and wholesalers in the United States relative to the current ban, and the proposed rule will likely not have a significant negative impact on a substantial number of small importers relative to the previous import program.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule would allow clementines to be imported into the United States from Spain. If this proposed rule is adopted, State and local laws and regulations regarding clementines imported under this rule would be preempted while the fruit is in foreign commerce. Fresh clementines are generally imported for immediate distribution and sale to the consuming public and would remain in foreign commerce until sold to the ultimate consumer. The question of when foreign commerce ceases in other cases must be addressed on a case-by-case basis. If this proposed rule is adopted, no retroactive effect will be given to this rule, and this rule will not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB). Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. Please state that your comments refer to Docket No. 02-023-3. Please send a copy of your comments to: (1) Docket No. 02-023-3, Regulatory Analysis and Development, PPD, APHIS, Station 3C71, 4700 River Road Unit 118, Riverdale, MD 20737-1238, and (2) Clearance Officer, OCIO, USDA, room 404-W, 14th Street and Independence Avenue SW., Washington, DC 20250. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this proposed rule.

We are soliciting comments from the public (as well as affected agencies) concerning our proposed information collection and recordkeeping requirements. These comments will help us:

(1) Evaluate whether the proposed information collection is necessary for

the proper performance of our agency's functions, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the information collection on those who are to respond (such as through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology; e.g., permitting electronic submission of responses).

Estimate of burden: Public reporting burden for this collection of information is estimated to average 0.014 hours per response.

Respondents: Full-time, salaried plant health officials of Spain's plant protection service, and growers and shippers of clementines.

Estimated annual number of respondents: 37.

Estimated annual number of responses per respondent: 216,303.

Estimated annual number of responses: 8,003,200.

Estimated total annual burden on respondents: 113,200 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Copies of this information collection can be obtained from Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734-7477.

List of Subjects

7 CFR Part 300

Incorporation by reference, Plant diseases and pests, Quarantine.

7 CFR Part 319

Bees, Coffee, Cotton, Fruits, Honey, Imports, Incorporation by reference, Nursery Stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

Accordingly, we propose to amend 7 CFR parts 300 and 319 as follows:

PART 300—INCORPORATION BY REFERENCE

1. The authority citation for part 300 would continue to read as follows:

Authority: 7 U.S.C. 7701-7772; 7 CFR 2.22, 2.80, and 371.3.

2. In § 300.1, a new paragraph (a)(5) would be added as follows:

§ 300.1 Materials incorporated by reference.

(a) * * *
(5) Treatment T107-a, dated _____.
* * * * *

PART 319—FOREIGN QUARANTINE NOTICES

3. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 166, 450, 7711-7714, 7718, 7731, 7732, and 7751-7754; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

4. A new § 319.56-2jj would be added to read as follows:

§ 319.56-2jj Administrative instructions; conditions governing the importation of clementines from Spain.

Clementines (*Citrus reticulata*) from Spain may only be imported into the United States in accordance with the regulations in this section.

(a) *Trust fund agreement.* Clementines from Spain may be imported only if the Government of Spain or its designated representative enters into a trust fund agreement with the Animal and Plant Health Inspection Service (APHIS) before each shipping season. The Government of Spain or its designated representative is required to pay in advance all estimated costs that APHIS expects to incur through its involvement in overseeing the execution of paragraphs (b) through (g) of this section. These costs will include administrative expenses incurred in conducting the services enumerated in paragraphs (b) through (g) of this section and all salaries (including overtime and the Federal share of employee benefits), travel expenses (including per diem expenses), and other incidental expenses incurred by the inspectors in performing these services. The Government of Spain or its designated representative is required to deposit a certified or cashier's check with APHIS for the amount of the costs estimated by APHIS. If the deposit is not sufficient to meet all costs incurred by APHIS, the agreement further requires the Government of Spain or its designated representative to deposit with APHIS a certified or cashier's check for the amount of the remaining costs, as determined by APHIS, before the services will be completed. After a final audit at the conclusion of each shipping season, any overpayment of funds would be returned to the Government of Spain or its designated representative or held on account until needed.

(b) *Grower registration and agreement.* Persons who produce clementines in Spain for export to the United States must:

(1) Be registered with the Government of Spain; and
(2) Enter into an agreement with the Government of Spain whereby the producer agrees to participate in and follow the Mediterranean fruit fly management program established by the Government of Spain.

(c) *Management program for Mediterranean fruit fly; monitoring.* The Government of Spain's Mediterranean fruit fly management program must be approved by APHIS, and must contain the fruit fly trapping and recordkeeping requirements specified in this paragraph. The program must also provide that clementine producers must allow APHIS inspectors access to clementine production areas in order to monitor compliance with the Mediterranean fruit fly management program.

(1) *Trapping and control.* In areas where clementines are produced for export to the United States, traps must be placed in Mediterranean fruit fly preferred host plants at least 6 weeks prior to harvest. Bait treatments using malathion, spinosad, or another pesticide approved by APHIS must be applied in the production areas at a rate appropriate to maintain the level of infestation of clementines by Mediterranean fruit flies at 1.5 percent or less.

(2) *Records.* The Government of Spain or its designated representative must keep records that document the fruit fly trapping and control activities in areas that produce clementines for export to the United States. All trapping and control records kept by the Government of Spain or its designated representative must be made available to APHIS upon request.

(d) *Phytosanitary certificate.* Clementines from Spain must be accompanied by a phytosanitary certificate stating that the fruit meets the conditions of the Government of Spain's Mediterranean fruit fly management program and applicable APHIS regulations.

(e) *Labeling.* Cartons in which clementines are packed must be labeled with a lot number that provides information to identify the orchard where the fruit was grown and the packinghouse where the fruit was packed. The lot number must end with the letters "US." Such labeling must be large enough to clearly display the required information and must be located on the side of the cartons to facilitate inspection.

(f) *Pre-treatment sampling; rates of inspection.* For each shipment of clementines intended for export to the United States, prior to cold treatment,

APHIS inspectors will cut and inspect fruit that are randomly selected from throughout the shipment at a rate designated in this paragraph. If inspectors find a single live Mediterranean fruit fly in any stage of development during an inspection, the entire shipment of clementines will be

rejected. If a live Mediterranean fruit fly in any stage of development is found in any two shipments of fruit from the same orchard during the same shipping season, that orchard will be removed from the export program for the remainder of that shipping season.

(1) For the first clementine shipping season that occurs after the effective date of this rule, inspectors will cut 200 randomly selected fruit per shipment.

(2) For all further shipping seasons, inspectors will cut fruit according to the following table, except as noted in paragraph (f)(3) of this section:

If the sample size for a given season is—	... and the rejection rate during that season is—	... then the sample size for the next season is—
200	≤5 percent	100
100	>5 percent	200
76	≤2 percent	76
	>2 percent but ≤5 percent	100
	>5 percent	200
	≤2 percent	76
	>2 percent but ≤5 percent	100
	>5 percent	200

(3) If APHIS determines that fruit presented for inspection and treatment appear to be highly infested during a shipping season in which 100 or 76 fruit are cut per shipment, APHIS reserves the right to increase the required sample size during the shipping season. At no time will more than 200 fruit be required to be cut, but the sample size could be raised to that level at APHIS's discretion.

(g) *Cold treatment.* Clementines must be cold treated in accordance with the Plant Protection and Quarantine (PPQ) Treatment Manual, which is incorporated by reference at § 300.1 of this chapter. Upon arrival of clementines at a port of entry into the United States, APHIS inspectors will examine the cold treatment data for each shipment to ensure that the cold treatment was successfully completed. If the cold treatment has not been successfully completed, the shipment will be held until appropriate remedial actions have been implemented.

(h) *Port of entry sampling.*

Clementines imported from Spain are subject to inspection by an inspector at the port of entry into the United States. At the port of first arrival, an inspector will sample and cut clementines from each shipment to detect pest infestation according to sampling rates determined by the Administrator. If a single live Mediterranean fruit fly 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 safeguards contained in this section are not protecting against the introduction of Medflies into the United States, APHIS may suspend the importation of clementines and conduct an

investigation into the cause of the deficiency.

(i) *Shipping season.* For the purposes of this section, a shipping season is considered to include the period beginning approximately in mid-September and ending approximately in late February of the next calendar year.

Done in Washington, DC, this 8th day of July 2002.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs, USDA.

[FR Doc. 02-17431 Filed 7-8-02; 3:26 pm]

BILLING CODE 3410-34-U

DATES: Written or electronic comments must be received by October 9, 2002. Requests to speak and outlines of topics to be discussed at the public hearing scheduled for Tuesday, November 5, 2002, must be received by Tuesday, October 15, 2002.

ADDRESSES: Send submissions to: CC:ITA:RU (REG-165868-01), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to CC:ITA:RU (REG-165868-01), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments to the IRS Internet site at www.irs.gov/regs. The public hearing will be held in Room 4718, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Betty J. Clary, (202) 622-6080; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Regulations Unit Paralegal (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collections of information contained in this notice of proposed rulemaking have been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collections of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-165868-01]

RIN 1545-BA47

10 or More Employer Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that provide guidance regarding whether a welfare benefit fund is part of a 10 or more employer plan. The regulations reflect changes to the law made by the Deficit Reduction Act of 1984. The regulations will affect certain employers that provide welfare benefits to employees through a plan to which more than one employer contributes. This document also provides notice of a public hearing on these proposed regulations.