## DEPARTMENT OF AGRICULTURE

### Animal and Plant Health Inspection Service

### 7 CFR Part 319

**[Docket No. 02–023–4]**

**RIN 0579–AB40**

## Importation of Clementines From Spain

**AGENCY:** Animal and Plant Health Inspection Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** We are amending 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 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. This final rule also includes restrictions on the distribution of imported Spanish clementines for the 2002–2003 shipping season. We are taking this action based on our finding that the restrictions described in this final rule will reduce the risk of introduction of Mediterranean fruit fly associated with the importation of clementines from Spain.

**EFFECTIVE DATE:** 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 20737–1236; (301) 734–6799.

**SUPPLEMENTARY INFORMATION:**

### Background

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

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). As such, clementines from Spain were imported under permit, provided that they were cold treated for the Mediterranean fruit fly (*Ceratitis capitata*) (Medfly). Clementines imported from Spain were not required to meet any additional regulatory requirements in order to be imported into the United States, but were subject to inspection at the port of entry.

Between November 20 and December 11, 2001, several live Medfly larvae were intercepted in clementines from Spain. On December 5, 2001, APHIS notified the Government of Spain that it was suspending the importation of clementines. 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.

APHIS believes, based on the available evidence, that there are several possible explanations for the survival of Medfly larvae in imported Spanish clementines during the 2001–2002 shipping season.

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

*Revised Risk Mitigation for Spanish Clementines*

On April 16, 2002, we published in the **Federal Register** (67 FR 18578–18579, Docket No. 02–023–1) a notice of availability and request for comments on 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'' (referred to elsewhere in this document as ''risk management analysis'' or ''RMA''). The RMA describes and evaluates the use of certain risk-mitigating measures associated with the importation of clementines from Spain. We solicited comments on the RMA for 30 days ending May 16, 2002.

On May 24, 2002, we published in the **Federal Register** (67 FR 36560–36561, Docket No. 02–023–2) a notice in which we reopened and extended the comment period for our risk management analysis until June 14, 2002. We received a total of 17 comments on the RMA by that date. We considered the comments and described changes made to the RMA in a revision dated July 5, 2002.

On July 11, 2002, we published in the **Federal Register** (67 FR 45922–45933, Docket No. 02–023–3) a proposal to amend 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 included provisions that the clementines be grown in accordance with a Medfly 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 Medfly into the United States. We proposed this action based on our finding that the requirements described in the proposed rule would reduce the risk of introduction of Medfly and other plant pests associated with the importation of clementines from Spain. The proposed rule also provided notice of two public hearings related to our proposal and detailed the dates, times, and locations of those hearings.

We solicited comments concerning our proposal for 60 days ending September 9, 2002. We received 33 comments by that date, in addition to testimony provided by 30 persons at the two public hearings. The comments were from officials of State departments of agriculture, officials of foreign Governments, Members of Congress, scientists, representatives of associations such as farm bureaus, marketing associations, consumer groups, and trade associations, and growers, packers, and shippers of fruits and vegetables. Twelve of the commenters supported the rule, and 40 opposed some aspect of it. Fifteen commenters noted that APHIS should ensure that its decision to proceed with a final rule is based on science, and at least 10 commenters stated that APHIS should delay action until additional information is available to eliminate uncertainty in its approach. The issues raised in the comments are discussed below, by topic.

### Determination by the Secretary

In this document, APHIS is adopting its proposal to allow the importation of clementines from Spain to resume as a final rule, with the changes discussed in this document.

Under § 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 within the United States of a plant pest or noxious weed.

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 final rule will prevent the introduction or dissemination of plant pests into the United States. The factors considered in arriving at this determination include: (1) A risk management analysis (revised October 4, 2002), (2) 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''), (3) a quantitative analysis of available data related to cold treatment for Medfly that was produced by USDA's Office of Risk Assessment and Cost Benefit Analysis (ORACBA), ''Revised Quantitative Analysis of Available Data on the Efficacy of Cold Treatment Against Mediterranean Fruit Fly Larvae'' (September 20, 2002), referred to elsewhere in this document as ''ORACBA analysis,'' and (4) the determinations of USDA technical experts.

**Discussion of Public Comments**

*Clarification of Terms*

Several commenters expressed confusion over our use of the terms ''shipment'' and ''lot.'' We discuss this issue in more detail later in this document. In response to those commenters' requests for clarification, we have defined those terms.

In our final rule, a *lot* of clementines is considered to include a number of units of clementines that are from a common origin (*i.e.*, a single producer or a homogenous production unit).[1] The definition of the term *shipment* depends on the context in which it is used. Specifically, the definition depends on whether or not fruit has been treated. The term can refer to one or more lots of clementines that are presented to an APHIS inspector for pre-treatment inspection. Such a shipment may not include more than 200,000 boxes of clementines (555 pallets). The term can also refer to one or more lots of clementines that are imported into the United States on the same conveyance. Our use of these terms in the remainder of this document is consistent with these definitions.

*General Comments*

Several commenters questioned whether Spain, in just 9 months, has taken the proper steps to ensure their product is free from Medfly, and asked what changes have taken place in Spain's production areas since the shutdown of their exports in December 2001.

The system we have designed for the resumption of imports of Spanish clementines is designed to ensure that APHIS will be able to detect infestation levels of 1.5 percent or greater with a high (95 percent) level of confidence through the pre-treatment cutting of randomly selected fruit.[2] If a single live Medfly in any stage of development is detected during pre-treatment fruit cutting, the shipment of clementines in which the Medfly is found will not be approved for export to the United States.

Conversely, if no infested fruit are detected via fruit cutting, APHIS's analysis shows that the revised cold treatment will eliminate any undetected low-level Medfly infestations. Furthermore, fruit cutting at the port of entry is designed to provide additional assurance that the revised cold treatment was successful.

For these reasons, APHIS believes the new Spanish clementine import program will prevent the introduction or dissemination of Medflies into the United States. Nonetheless, to further ensure that the program does not result in the introduction of Medflies into the United States, we have required Spanish growers, in order to be approved to export to the United States, to enter into the Government of Spain's Medfly management program, which APHIS must approve, and which must ensure low levels of infestation in clementine production areas. We believe the activities required under Spain's program, which include phytosanitary measures that must be followed in the field and at packinghouses, represent a significant improvement over Spain's efforts in 2001.

Several commenters noted that APHIS still does not know ''what went wrong'' in 2001, when there were multiple live larvae finds on Spanish clementines in several different regions of the United States. The commenters suggested that designing a solution when the problem is not fully understood is risky. Specifically, one of those commenters proposed that despite APHIS's determination that there are two possible scenarios that could explain the discovery of live larvae in clementines imported from Spain, a third scenario, that both those things occurred, is also possible.

APHIS acknowledges that the cause of last year's infestations of imported Spanish clementines has not been definitively established; however, we have responded as if the problem resulted from one or both of the following: (1) 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, or (2) the level of Medfly infestation in imported clementines simply overwhelmed the capabilities of the cold treatment process, even though the treatment was properly applied. These two scenarios have received support from State agricultural officials and domestic stakeholders. We believe the system we have designed addresses all possible explanations for the problem.

In order to address the first explanation for last year's problem, APHIS has extended cold treatment as described in this document, and is confident that the prescribed cold treatment will provide a high level of mortality of target pests (equivalent to probit 9 mortality). The extension of cold treatment also addresses concerns that the cold treatment under the previous schedule may not have provided probit 9 mortality.[3] We have conducted a thorough review of the documentation of cold treatment application and have found no evidence that cold treatment was improperly applied during the 2001 shipping season, although a long-term thermal-mapping study on the application of cold treatment is underway. That study, which was initiated before the Medfly infestations of Spanish clementines occurred in 2001, is described in more

[1] A homogeneous production unit is a group of adjacent orchards in Spain that are owned by one or more growers who follow a homogenous production system under the same technical guidance. The fruit produced by these units is pooled and packed together, and all the orchards in the group are regulated as one unit in the event that traceback of infested fruit is necessary.

[2] We will also be able to detect lower levels of infestation in clementines with varying levels of confidence as described in detail under the heading, ''Infestation Levels, Inspection, and Fruit Cutting.''

[3] A level or percentage of mortality of target pests (*i.e.,* 99.9968 percent mortality or 32 survivors out of a million) caused by a control measure.

detail later in this document under the heading ''Cold Treatment.''

Regarding the second explanation for the problem, we have required that levels of infestation of Spanish clementines presented for export be kept at low levels (levels that cannot be detected via fruit cutting) in order to ensure that high levels of infestation do not cause the treatment to be overwhelmed. Inspection and cutting of clementines prior to cold treatment will ensure that this requirement is met.

One commenter noted that shortly after the interceptions of Medfly larvae in Spanish clementines, APHIS advised that the situation would be handled with transparency, stakeholder involvement, and most critically, that science would be the only determinant relative to developing a protocol and plan for the potential resumption of Spanish clementine shipments into the United States. The commenter stated that APHIS has failed to honor its commitment as a result of a predetermined decision to allow clementines back into the U.S. market for this upcoming season.

APHIS has upheld its commitment to handle the issue of the importation of Spanish clementines with transparency and stakeholder involvement, and the Secretary has based her determination to allow the importation of clementines from Spain to resume on science, and in accordance with the requirements of the Administrative Procedure Act. We have made the documents that support this rule available for public comment, some for as long as 120 days. We have listened to stakeholder concerns in meetings and at public hearings. We have made changes to our supporting documents based on stakeholder review and comments. We have considered all comments received on our proposed rule and its supporting documents and have documented our responses in this final rule. For the reasons outlined in this document, our decision to allow the resumption of clementines from Spain is based on science.

Two commenters claimed that APHIS's characterization of the events leading to the December 5, 2001, suspension of clementine imports from Spain is questionable. They stated that at no time has APHIS produced credible and verifiable evidence of live and viable Medfly larvae in shipments of Spanish clementines.

APHIS takes quarantine action on imported commodities if a given commodity is found to be infested with a live quarantine pest, and APHIS's actions in December 2001 were based on repeated findings of live Medfly larvae in imported Spanish clementines. APHIS believes that it is often impossible and always impractical to determine the true viability of a live pest intercepted in an imported commodity, especially one that has undergone cold treatment. Therefore, APHIS has no other alternative but to take action to protect American agriculture based on the finding of a live pest in any stage of development. This course of action is consistent with our authority under the Plant Protection Act.

Determining the true viability of Medflies would require APHIS to rear them to adults, allow them to mate, lay eggs, etc., all under high security conditions to protect against the escape of the pest to the natural environment. APHIS has no doubt, based on visual inspections by field and headquarters personnel, including expert identifiers, that the larvae were indeed alive upon interception in the United States.

One commenter claimed that there has never been such a catastrophic failure of an APHIS program as there was with Spanish clementines in 2001, and APHIS has no idea what the results of that failure will be. The commenter questioned whether Medfly could be established somewhere in the United States as a result of 2001 imports of Medfly-infested Spanish clementines.

APHIS believes that if clementines imported from Spain caused the establishment of Medfly in the mainland United States, that would indeed represent a catastrophic failure of the APHIS import program. However, APHIS has no evidence to indicate that infested Spanish clementines have resulted in a Medfly establishment in the United States. Despite the events of 2001, APHIS's actions to address the situation appear to have been successful. Since October 2001, the only wild Medfly detected in the mainland United States has been a single female trapped in San Bernardino County, CA, in August 2002. The results of DNA tests to determine the origin of the Medfly were inconclusive, though they did show a banding pattern that may be consistent with Medfly from Central America, South America (except Venezuela and most of Brazil), Mediterranean countries, or Sub-Saharan Africa.[4]

One commenter questioned whether APHIS has the resources available to effectively carry out and enforce the new import program, especially given congressional proposals to transfer the 3,200 APHIS employees at ports of entry to a proposed Department of Homeland Security. The commenter stated that, given the uncertainty surrounding the move of port personnel to the Department of Homeland Security, the reentry of Spanish clementines should be delayed.

APHIS has reviewed its resources and believes it has adequate coverage in Spain and across the United States to ensure compliance with this final rule. We have no reason to believe that inspectors and preclearance personnel will be unable to continue to carry out their current responsibilities in the event that they are moved to the proposed Department of Homeland Security.

One commenter noted that APHIS states that it is imposing a combination of measures aimed at achieving probit 9 protection from entry on Medfly into the United States. These measures comprise (1) pre-export controls in orchards and inspection at point of export, (2) cold treatment, extended by 2 days compared with previous conditions, and (3) post-import inspection. This commenter asked that we explain what contribution each step makes to achieving probit 9 protection.

Probit 9 was established by A.C. Baker in 1939 as a useful concept when trying to assess mortality of commodity treatments against fruit flies.[5]

APHIS considers ''probit 9 protection'' to be relevant only to cold treatment in this case. As stated earlier in this document and in the proposed rule, the term ''probit 9'' refers to a level or percentage of mortality of target pests (i.e., 99.9968 percent mortality or 32 survivors out of a million) caused by a control measure. APHIS has historically used the term ''probit 9'' in association with the mortality rate caused by commodity treatments (including vapor heat, high temperature forced air, methyl bromide, and cold treatments) for fruit flies. We do not believe the term can be assigned generally as a measure of success of a pest-excluding regulatory approach if the term is used as a representation of the risk reduction potential of (1) a systems approach to pest management or (2) any combination of treatment and other types of safeguards other than treatment. This is to say that APHIS uses the term only as a representation of the level of mortality of pests caused by a specific treatment, in this case cold treatment.

[4] DNA tests are actually better at clarifying where Medflies did not originate, as opposed to where they did originate. In this case, DNA tests revealed that banding patterns are not consistent with Medflies in Hawaii, Venezuela, and most of Brazil.

[5] Baker, A.C.. 1939. ''The Basis for Treatment of Products Where Fruitflies are Involved as a Condition for Entry into the United States.'' Circular No. 551. US Department of Agriculture, Washington, DC.

The level of mortality called ''probit 9'' is a historical, well-recognized benchmark in the area of phytosanitary security. It has been useful as a benchmark, but recent findings[6] suggest that requiring a probit 9 treatment may or may not be sufficient in a given case (i.e., in situations where there are significant pest populations). Conversely, the use of probit 9 under other circumstances (i.e., in situations with very low or nonexistent pest populations) may be more restrictive than is necessary to protect against pest infestation of imported fruits or vegetables. In such cases, risk analysis is necessary to determine the effect and role of treatment in a given pest-management approach.

In our RMA, APHIS considered that cold treatment approximated the ''probit 9'' level. We also stated that the risk management analysis for our proposal ''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.'' Upon further consideration, this statement, and other similar statements made in our proposed rule and supporting documents require clarification. The RMA assesses the extent to which other risk-mitigating measures, in combination with cold treatment, reduce the risk that a mated pair of Medflies could enter the United States via imported Spanish clementines. Population levels have significance in the context of the RMA's calculations regarding the probability that a mated pair of Medflies could enter into the United States via Spanish clementines imported under the provisions of the proposed rule. However, the probit 9 efficacy of cold treatment is not dependent on population levels of Medflies in Spanish production areas in the sense that the same proportion of mortality is expected regardless of the Medfly population density. We have revised our RMA to clarify that fact.

To elaborate, if 32 Medflies survive out of each 1 million that are subject to a probit 9 treatment, one should expect that reducing the number of Medflies present to 500,000 would reduce the number of survivors to 16; if 100,000 are treated, then 3 will survive; and so on. We believe this clearly illustrates the relevance and effect of low pest population density, not to cold treatment itself, but to the overall success of a pest-exclusion program.

As a general rule, APHIS has required treatments for fruit flies to provide probit 9 mortality in cases where treatment is the only mitigation measure applied against the pest of concern. This is because the level of mortality represented by this benchmark is considered extremely high and stringent, especially when the field infestation rates are low.[7] In this rule, we are requiring a treatment that we are confident will provide a level of quarantine security that is equivalent to probit 9, but we are also requiring that fruit be consistently at low rates of infestation by Medflies in order to ensure that there is a very low probability that Medflies could survive cold treatment and become established in the United States.

*Appropriate Level of Protection and Level of Risk*

Several commenters claimed that, according to the court decision on APHIS's rule authorizing the importation of citrus from Argentina (*Harlan Land Company, et al.* vs. *United States Department of Agriculture, et al.*, Case #CV–F–00–6106–REC/LJO (D. Ariz. Sept. 27, 2001)) (referred to elsewhere in this document as *Harlan Land Co.*), as a matter of law, APHIS must define what it considers to be a ''negligible level of risk'' in the context of a rule authorizing the importation of fruit from a disease and pest infested area. The commenters elaborated that APHIS must define what it considers to be a negligible or acceptable level of risk (referred to by one commenter as a ''quarantine security standard''), and it must also adequately explain that determination, and claimed that the proposed rule does not do so, nor has APHIS made any attempt to articulate why the issue is not addressed. The commenters stated that without a discussion of the issue, there is no way to judge whether APHIS is meeting the congressional expectation that its regulations will prevent the movement into and through the United States of commodities that ''could present an unacceptable risk of introducing or spreading plant pests.''

The RMA does not conclude that there is negligible risk associated with such importations. Rather, it concludes that there is a very low likelihood that mated pairs of Medflies could enter the United States via clementines imported from Spain. Furthermore, APHIS does not agree that the *Harlan Land Co.* court decision requires APHIS to define what it considers to be a ''negligible level of risk'' in the context of this rule, or any other rule apart from the rule at issue in *Harlan Land Co.*

The term ''negligible'' is one that was used by APHIS in prior rulemaking and risk analysis documents unrelated to this action to describe risk in a qualitative, descriptive sense. APHIS has never intended that ''negligible level of risk'' should be interpreted as a term of art, but instead has used the term in its plain meaning. APHIS believes that its decisionmaking is tied directly to the authority given to the Secretary of Agriculture by the Plant Protection Act.

Under the Plant Protection Act, the Secretary 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 within the United States of a plant pest or noxious weed. In the case of clementines from Spain, 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. This determination is based on the finding that the application of the remedial measures contained in this rule will provide the protection necessary to prevent the introduction or dissemination of plant pests into the United States.

One commenter stated that, under the provisions of the World Trade Organization's (WTO) sanitary and phytosanitary (SPS) Agreement, as well as the standards that have been developed to implement the SPS Agreement by the International Plant Protection Convention (IPPC), a definition of the ''appropriate level of protection'' is the first step that must be taken when a country is considering allowing the importation of a commodity from another country. The commenter claimed that only after the ''appropriate level of protection'' or the ''acceptable level of risk'' is established, will the destination country be in a position to consider what phytosanitary measures, if any, need to be implemented in order to assure that its phytosanitary requirements will be met.

APHIS believes the commenter has misinterpreted provisions of the SPS Agreement and IPPC standards. The commenter appears to suggest that, under the SPS agreement and IPPC standards, the identification of an appropriate level of protection is a kind of procedural requirement that must be

[6] A detailed consideration of the shortcomings associated with any measure that uses a fixed expression of proportion of mortality (such as probit 9) may be found in: Landolt, P., D. Chambers, and V. Chew. 1984. ''Alternative to the use of probit 9 mortality as a criterion for quarantine treatments of fruit fly infested fruit.'' *J. Econ. Entomol.* 77(2): 285–287.

[7] See footnote 6.

fulfilled prior to each individual instance when the United States considers allowing the importation of a commodity from another country. Under the SPS Agreement and IPPC standards, there is no obligation to complete such a task. Furthermore, guidelines on how to implement SPS Agreement Article 5.5 reveal that an indication of a country's appropriate level of protection:

''* * * may be contained in a published statement or other text generally available to interested parties. The statement of the appropriate level of protection may be qualitative or quantitative, and should serve to guide its consistent implementation over time, and also to increase the transparency of the sanitary or phytosanitary regime. Examples might include government policy statements with regard to appropriate levels of protection in response to certain risks, or documents on animal health protection objectives or with respect to plant protection.'' [8]

For plant health in the United States, Congress has expressed the United States' ''appropriate level of protection'' in the Plant Protection Act (a text generally available to interested parties) in the specific discretion provided to the Secretary of Agriculture. The Plant Protection Act authorizes the Secretary to ''prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant, plant product, biological control organism, noxious weed, article, or means of conveyance, 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 Plant Protection Act further elaborates on the Secretary's discretion in carrying out that determination by stating that the Secretary may promulgate regulations requiring permits, or certificates for importation, and may require remedial measures that ''the Secretary determines to be necessary to prevent the spread of plant pest or noxious weeds.''

The Plant Protection Act ensures that our phytosanitary measures are transparent and implemented consistently over time, and thus is consistent with the guidelines cited above.

There is no obligation to express the ''appropriate level of protection'' quantitatively under either the SPS Agreement or IPPC standards, and Congress, in the Plant Protection Act, did not establish a quantitative expression of the ''appropriate level of protection'' or require APHIS to set such a quantitative expression. The SPS Agreement obligates members to be consistent in the level of protection they consider appropriate in similar cases. Allowing imports of clementines from Spain reflects consistency with our determinations to allow citrus imports from other countries and regions where Medfly is found. Therefore, this final rule is consistent with our obligations under Article 5.5 of the SPS Agreement.

One commenter noted that, in its Regulatory Impact Analysis (RIA) for the proposed rule, APHIS says that it ''attempts to maintain the risk of Medfly introduction at an acceptable level in order to protect U.S. agricultural resources and maintain the marketability of agricultural products,'' but the Agency does not say what an ''acceptable level'' of risk is in that document or in the RMA. The commenter also noted that the Appendix 1 to the RMA defines the term ''acceptable level,'' but it does so tautologically, stating: ''Acceptable level means the presence of a hazard that does not pose the likelihood of causing an unacceptable phytosanitary risk.'' In other words, ''acceptable'' means ''not unacceptable.''

For the reasons stated above, we do not identify an ''acceptable level of risk'' in either the RIA or the RMA because those documents are, respectively, analyses of (1) the economic effects that could occur under this final rule, and (2) the probability that a mated pair of Medflies could enter the United States via a shipment of clementines from Spain. Neither document is intended to provide a decision or judgment as to whether this final rule provides a defined acceptable or appropriate level of protection, i.e., in a qualitative or quantitative sense. The documents are intended simply to inform the decisionmaker in her consideration of whether to allow the importation of Spanish clementines.

Furthermore, Congress stated in § 402(3) of the Plant Protection Act that,

''* * * it is the responsibility of the Secretary to facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests or noxious weeds.''

APHIS believes the process it follows in evaluating risks prior to rulemaking on a given subject is consistent with the clearly stated intent of Congress.

Regarding the commenter's statement that RMA defines the term ''acceptable level'' tautologically, the SPS Agreement employs a similar approach. The SPS Agreement defines ''appropriate level of * * * phytosanitary protection'' as ''The level of protection deemed appropriate by the Member [country] establishing a * * * phytosanitary measure to protect human, animal or plant life or health within its territory.'' We believe this is further testament to the fact that APHIS has no obligation under any of its authorities or international agreements to set a quantitative level of protection that it believes is acceptable. Again, we believe the United States expresses its appropriate level of protection in the Plant Protection Act, which authorizes the Secretary to 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 within the United States of a plant pest or noxious weed.

One commenter stated that the RMA does not purport to assess the likelihood of Medfly introduction at all; it simply estimates the probability that a mated pair of Medflies will arrive at a suitable location in the United States, and while this is said to be ''directly related'' to the likelihood of introduction, it is not, according to APHIS, the same thing. The commenters further noted that the RMA does not reach any judgment as to whether the risk of Medfly introduction under the proposed rule is ''acceptable.'' Instead, it merely asserts that the mitigation activities associated with a 1.5 percent maximum infestation rate decrease the risks of introduction as compared to the baseline of cold treatment alone. The proposed rule addresses the issue by saying the Secretary has determined ''that the application of the remedial measures contained in the proposed rule will provide the protection necessary to prevent the introduction or dissemination of plant pests into the United States,'' but APHIS does not say what this necessary level of protection is, or how much risk is compatible with ''preventing the introduction'' of Medflies. The commenter stated that none of the supporting documents conclude that the mitigation measures will ''prevent the introduction'' of Medflies.

While the RMA does not directly assess the likelihood of Medfly introduction quantitatively, it does (1) provide a discussion of the relationship between the likelihood of Medfly introduction and the probability that a mated pair of Medflies could enter the United States in a shipment of Spanish clementines, and (2) provide a baseline

[8] See *http://docsonline.wto.org/DDFDocuments/t/G/SPS/15.DOC.*

figure to which the likelihood of introduction can be compared. In order to quantitatively assess the likelihood of introduction, additional analysis would be required to evaluate the possibility that a mated pair of Medflies that has entered the United States in Spanish clementines and arrived in a suitable area can then (1) find a host, (2) find fruit that is sufficiently mature in which to oviposit, (3) oviposit viable eggs, and (4) avoid death by dessication, heat or cold, or other factors. The effect of these other variables on the ability of a mated pair to survive, reproduce, and spread would, in all cases, further reduce the likelihood that Medfly could be introduced into the United States below the already very low probability that a mated pair of Medflies could enter the United States via Spanish clementines.

One commenter stated that the *Harlan Land Co.* court decision made it clear that ''unless an agency describes the standard under which it has arrived at its conclusion, the court has no basis for exercising its responsibility to determine whether the agency's decision is arbitrary, capricious, an abuse of discretion, or otherwise in avoidance with the law.'' The commenter stated that according to the court's statement, an agency must cite information to support its position; without data the court owes no deference to an agency's line-drawing.

APHIS believes that the standard under which it has arrived at its conclusion is tied directly to the authority given to the Secretary of Agriculture by the Plant Protection Act. Under the Plant Protection Act, the Secretary may prohibit or restrict the importation and entry of any article if the Secretary determines that the prohibition or restriction is necessary to prevent the introduction into the United States or the dissemination within the United States of a plant pest or noxious weed. In the case of clementines from Spain, 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. Several analyses (the RMA the cold treatment evaluation, the ORACBA analysis, and the judgment of USDA technical experts), provide the basis for the Secretary's finding that the application of the remedial measures contained in this rule will provide the protection necessary to prevent the introduction or dissemination of plant pests into the United States. Furthermore, the Secretary's determination is consistent with the congressional charge that she ''facilitate exports, imports, and interstate commerce in agricultural products and other commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, to the extent practicable, as determined by the Secretary, the risk of dissemination of plant pests or noxious weeds.''

*Trade Issues, International Agreements, and Equivalence*

One commenter claimed that any delay that prevents the re-entry of clementines into the United States beyond the beginning of the next shipping season would constitute unreasonable delay in violation of the Administrative Procedure Act and in contravention of the U.S. Government's WTO obligations.

Under the Administrative Procedure Act, USDA's rulemaking review policy, and the requirements of several Executive Orders, APHIS must follow certain procedures in the drafting and review of rulemaking documents. This process takes time. APHIS must consider issues raised in comments submitted before the close of the comment period, and then determine what action to take on its proposal given the issues raised by commenters. It must then draft a rule that documents its response to comments, and must circulate the rule through a significant review and approval process. APHIS is committed to rulemaking based on science and according to the requirements of the Administrative Procedure Act, and will not produce a final rule until we have carefully considered the issues raised by commenters and have followed our formal review process. This is consistent with member obligations under the WTO SPS Agreement.

Three commenters stated that the proposed rule violates WTO prohibitions against discriminatory trade practices by requiring an extra 2 days of cold treatment for Spanish exports that are not required of clementine exports from other countries susceptible to Medfly infestation.

In the October 15, 2002 issue of the **Federal Register**, APHIS published an interim rule (APHIS Docket No. 02–071–1) under which all commodities, including clementines from other countries, that are subject to cold treatment for Medfly must be treated under the same treatment schedule that we are requiring for Spanish clementines.

Two commenters stated that the proposed rule violates WTO prohibitions against discriminatory trade practices by imposing a field treatment regimen for control of Medfly in Spanish clementine orchards, as well as pre- and post-treatment fruit cutting, but does not require an equivalent field treatment regimen for other countries exporting clementines to the United States from areas susceptible to Medfly infestation.

It is true that APHIS has not placed additional pre-treatment, population-limiting requirements on clementines and other Medfly-host fruits and vegetables from other areas where Medflies are present. In the event that emergency measures are required to address a pest risk, APHIS applies them to the extent they are necessary, and APHIS has no evidence to support the conclusion that clementines or other fruits and vegetables from other Medfly-infested areas pose the same risk as clementines from Spain. We have conducted extensive fruit cutting and inspection activities associated with imports of clementines and other fruits and vegetables from other areas, and have not found a single live Medfly larvae. As stated previously in this document and in the proposed rule, given that high Medfly populations in production areas in Spain in 2001 could have caused the infestations discovered that year, APHIS believes it has sufficient reason to adopt specific measures that it believes will ensure against a similar occurence in future years. If we had evidence that suggested an equivalent problem in other regions, we would require equivalent safeguards. The available evidence does not, however, support that course of action.

The interim rule for other cold treated commodities, nonetheless, provides that those commodities, like Spanish clementines, will be subject to post-treatment fruit cutting, though fewer of certain commodities will have to be inspected and cut due to their non-preferred Medfly host status.

Several commenters stated that the technical trapping protocol, type of trap, baits, frequency of inspection, *etc.,* used by the Spanish growers should mirror the same protocol that is used by APHIS within the United States. The commenters claim that should a temporary Medfly infestation occur in a U.S. production area, the citrus within the established quarantine area cannot, under any circumstances, move to market, and they note that, in contrast, APHIS has proposed to allow foreign origin fruit from permanently infested production areas to be brought into the United States with only the provisos that the pest detections in the export groves are relatively low and the fruit is cold treated. Some commenters also questioned whether cold treatment is actually available to domestic producers in the event of a Medfly outbreak in the United States.

We do not agree that the technical trapping protocol, type of trap, baits, and frequency of inspection and other requirements regarding the Spanish clementine import program should mirror the same protocol that is used by APHIS within the United States for a reason the commenter has pointed out: Different requirements are warranted for fruit moving from Medfly-free areas in which there is an outbreak than for fruit moving from generally infested areas. The Spanish are not attempting to eradicate Medfly, nor does APHIS believe they have to do so in order to export fruit to the United States, provided they can mitigate the pest risk posed to the United States by their exports.

U.S. producers and agricultural officials have a longstanding policy to eradicate Medfly infestations if they are detected in the mainland United States.[9] Spanish producers use trapping as an indicator of the presence of Medflies in production areas, and use that indicator to trigger bait spray applications that are intended to lower Medfly population densities. U.S. producers and agricultural officials employ trapping programs to monitor for the presence of Medflies in free areas. For these reasons, APHIS does not believe there is a demonstrated need for trapping and bait treatment measures to be the same in Spain as they are in the United States. APHIS would, however, require equivalent measures if the intent of the Spanish program was maintaining Medfly freedom.

Furthermore, APHIS disagrees with the commenters' statements that citrus may not move from a U.S. area that is under quarantine for Medfly. In fact, under § 301.78–10(b)(3), APHIS allows the movement of regulated articles, which include citrus fruit, from quarantined areas provided they are treated with the same cold treatment schedule that we use for the importation of Spanish clementines. There are also other treatments available, as specified in § 301.78–10.

Several commenters noted that other countries will not accept U.S. fruit if it is 1.5 percent infested with Medfly.

Some countries will not accept fruit known to be infested with Medfly, and the United States is one of those countries. To clarify, we are not allowing imported Spanish clementines to be 1.5 percent infested or less upon arrival in the United States. Rather, we are requiring inspection and fruit cutting of 200 randomly selected fruit per shipment of clementines prior to cold treatment. If a single live Medfly is found during inspection in Spain, the entire shipment of clementines will not be eligible for export. If no infested fruit is found upon inspection, that provides a very high level of confidence (95 percent) that the shipment sampled has a low level of infestation (a level that cannot be detected via fruit cutting). Furthermore, according to our RMA, fruit that is 1.5 percent infested or less and that is cold treated has a low probability of carrying a mated pair of Medflies into a suitable location in the United States. If we find one live Medfly larva in a shipment of clementines at the port of entry in the United States, we will reject that shipment.

We suspect that the commenters doubt whether other countries would adopt a similar protocol in general for U.S. exports. Such a program would not seem to be necessary, since there currently is no Medfly infestation in the mainland United States. However, we do believe that the Spanish clementine import program could serve as an effective model for exports from Medfly infested areas in the United States to other countries. In the event that such a program is necessary, we would negotiate with foreign Governments to secure export opportunities for citrus and other Medfly hosts from Medfly-infested areas under this same protocol, and we would continue to allow interstate movements of such articles under the requirements of 7 CFR 301.78 through 301.78–10.

*Cold Treatment*

Several commenters noted that the time-temperature response surface model contained in the ORACBA analysis can be read to suggest that for treatment periods less than 16 days, a probit 9 level of phytosanitary security may not be achieved even at temperatures of 32 °F, 33 °F, or 34 °F, yet APHIS's revised protocol would allow treatment for only 12, 13, and 14 days, respectively, at those temperatures. One commenter recommended that, until the uncertainty is resolved regarding the lower temperatures and durations of cold treatment, the cold treatment protocol be kept at a minimum duration of 14 days. Other commenters urged APHIS to review data relevant to this subject that were recently developed in Australia and South Africa.

APHIS has obtained and evaluated data collected in Australia by its Department of Agriculture and Horticulture Australia regarding time/temperature combinations that provide apparent complete mortality of Medfly.[10] Copies of that data are available from the person listed under **FOR FURTHER INFORMATION CONTACT.** These data have also been factored into an updated version of the ORACBA analysis. In short, the data provide evidence that the longer durations of cold treatment (16 days/35 °F, and 18 days/36 °F) are likely to provide a very high level of quarantine security (probit 9 or above).

The specific South African data cited by commenters were not submitted to APHIS by commenters. We were able to communicate with the persons conducting the study, and the information they provided supports the cold treatment we are requiring under this final rule.

Regarding the question of whether cold treatment provides probit 9 mortality at all the proposed time/temperature combinations, APHIS agrees with the commenters that additional statistical or experimental evidence is necessary to continue to support the conclusion that the 12 days/32 °F and 13 days/33 °F combinations provide probit 9 mortality. However, as evidenced clearly by Figure 3 of the ORACBA analysis, there are sufficient data available to conclude that 14 days/34 °F, 16 days/35 °F, and 18 days/36 °F treatments do provide probit 9 level quarantine security.

Given that the calculations of risk in our RMA depend on the assumption that cold treatment provides probit 9 mortality, we have removed the 12 days/32 °F and 13 days/33 °F cold treatment combinations from this final rule, due to the unavailability of sufficient data to continue to support those time/temperature combinations as providing probit 9 mortality. Thus, the revised T107-a cold treatment schedule for clementines from Spain will require fruits to be treated according to the following schedule:

| Temperature | Exposure period (in days) |
|---|---|
| 34 °F or below | 14 |
| 35 °F or below | 16 |
| 36 °F or below | 18 |

The revised ORACBA analysis provides statistical justification for our selection of the above schedule, and is based on all available data.

Some commenters noted that Spanish exporters claimed that their fruit was

[9] Hawaii is generally infested with Medfly and uses treatments to certify movements.

[10] De Lima, C.P.F, A. Jessup, and R. McLauchlan. 2002. "Cold disinfestations of citrus using different temperatures X time combinations." Horticulture Australia Ltd. Project Number: CT96020.

cooled to 32 °F for 12 to 14 days in 2001, which is as long or longer than the revised protocol would require, and yet a substantial number of Medfly larvae survived that treatment. If the previous statement is true, asked the commenters, how is APHIS's proposed approach different from 2001?

We have conducted a review of available cold treatment records for shipments of Spanish clementines into the ports of Philadelphia, PA, and Elizabeth, NJ. The results of our review are as follows: (1) There was no clear pattern for the use of specific time/temperature combinations of cold treatment; and (2) though some shipments of clementines were treated for more days than were required at various approved temperatures, there is no evidence to suggest that the treatment time/temperature combinations cited by the commenter were used on more than a few occasions. In fact, the records show that in 2001, the 10 day/32 °F treatment schedule was the least used of the five options available, perhaps because shippers were hesitant to subject the fruit to the damage that can be caused by freezing temperatures.

While our review did reveal that, in some cases, treatments were applied for longer durations (several hours to several days) than was required under the previous treatment schedule, we have no direct evidence that fruit found to be infested with Medfly were treated for more time than was required under the previous treatment schedule.

Upon the detection of Medfly in Spanish clementines in 2001, APHIS was able to trace the initial interceptions to particular sea vessels, including the M/V Japan Senator and the M/V Green Maloy. The records for the M/V Japan Senator, which arrived in Elizabeth, NJ, on November 7, 2001, show that each of the eight sea containers imported on that vessel met only the minimum time/temperature combinations provided under the previous treatment schedule. The records for the M/V Green Maloy, which arrived in Philadelphia on November 11, 2001, show that some time/temperature combinations in the 12 compartments on the vessel met only the minimum standards of the previous treatment schedule, while other compartments were cold treated for as many as 3 extra days. Since APHIS cannot trace back the fruit that was found to be infested to a specific hold on either vessel, we cannot know whether the fruit was exposed to more cold treatment than was required. We do know, however, that the infested fruit was held for at least as long as the previous treatment schedule required, which suggests a failure of the previous schedule to provide near 100 percent mortality, but not necessarily a failure of the revised schedule.

Furthermore, the approach we use in this final rule also addresses the risk posed by high levels of infestation of imported clementines. There were no such restrictions on infestation levels in 2001.

One commenter claimed that APHIS's proposal to extend cold treatment is based exclusively on the recommendation made by a panel put together by APHIS, using studies and scientific literature that are not recent and not credible enough. The commenter stated that cold treatment should not be extended, as any extension should be based upon more detailed scientific studies with internationally accepted credibility.

Upon further analysis of all the available data, as stated above, APHIS is amending the cold treatment schedule to allow cold treatment for Medfly only at the longer time/temperature combinations (14, 16, or 18 days, at the temperatures listed above). This change is based on the results of the ORACBA analysis, which essentially combines the results of available cold treatment research and uses a model to assess and show the ability of certain time/temperature combinations to provide probit 9 mortality of Medfly. The ORACBA analysis does not contradict the recommendations of the cold treatment review panel that drew up the cold treatment recommendation document that was cited in our proposed rule. Rather, the ORACBA analysis shows that data are only available to support cold treatment at the longer time/temperature combinations suggested by the panel. Given the clarity of the available data, including data recently made available by the Australian Government, we are confident that our revised cold treatment is science-based.

Two commenters questioned whether APHIS allows the use of a single fruit temperature probe in a cold treatment container or ship hold, and stated that a single data point does not allow an estimate of the variation in temperature that normally occurs, and the protocol does not incorporate the necessary treatment time adjustment associated with this temperature variation. The commenters stated that there are very little published data on temperature variation in marine shipments, so the actual level of temperature variation in some shipments may be high.

APHIS's cold treatment protocols do not authorize the use of only a single data point in the load. Multiple temperature sensors are required (in the fruit pulp, as well as in the air), and readings from these sensors must print out once an hour during the entire voyage. The larger the cargo space, the more sensors that are required, and sensors must be checked and calibrated before each treatment begins. Furthermore, all cold treatment containers and compartments must be checked and certified by APHIS, and APHIS verifies the treatment records upon arrival of the imported commodity. Given that APHIS requires the use of multiple sensors, given that we require all temperature sensor readings to meet the appropriate treatment schedule, and given the certification requirements for treatment equipment, we are confident that our existing procedure accounts for any temperature variation that may occur during cold treatment.

One commenter expressed concern that fruit subject to break bulk shipment and that is not pre-cooled will take 100 hours to reach desired temperatures. Other commenters asked exactly when cold treatment is considered to begin. Others questioned whether the cold chain is broken when fruit is brought to the port for loading onto the ship. Another commenter noted that, under break bulk shipping, cooling fans are not normally operated until 75 percent of the cargo hold is loaded, and stated that this condition further exacerbates the problem of breaking the cold chain.

Cold treatment is not considered to have begun until all temperature sensors within a particular compartment in a sea vessel or a container reach treatment temperature or below. If the cold chain is broken at any time during treatment, the treatment must start over, and must be completed in its entirety. As stated above, multiple temperature sensors are used (in the fruit pulp, as well as in the air), and readings from each sensor must be printed out once an hour during the entire voyage.

APHIS recommends that the fruit be pre-chilled before loading. However, many foreign seaports have not built cold-storage facilities, and precooling is not essential given that treatment according to the schedules described in this document provide probit 9 mortality. Loading warm fruit mandates a later starting time for the treatment, often several days after the ship has left the port. In some cases, the required number of days may not have elapsed by the time the ship reaches its destination in the United States. This delay may be minimized at the port of embarkation by loading only one compartment at a time, and running the cooling fans during loading. In cases where the treatment is not complete upon arrival, the ship must either remain in port until the cold treatment is completed in the last compartment, or the fruit is consigned to a cold-treatment warehouse on shore, where treatment can be completed or re-initiated.

Several commenters stated that APHIS should delay the final rule until additional research on the application of cold treatment is completed, as it has not established why the previous program failed. The commenters cited an ongoing APHIS study to investigate temperature distribution in cold treatment holds in ships to see whether it is necessary to increase the number of temperature sensors in the holds.

APHIS's review of the application of cold treatment to shipments of clementines that produced live Medfly larvae yielded no evidence that treatment was improperly applied. Given our analysis of available data on cold treatment, which is documented in the ORACBA analysis, we are confident that the revised cold treatment schedule for Spanish clementines will provide probit 9 mortality. Though there is a temperature mapping study underway regarding the application of cold treatment (which was underway before the 2001 Spanish clementine shipping season), we do not expect the results of the study to suggest dramatic changes to existing guidance on the deployment and placement of sensors in cold treatment compartments and containers. Given the clarity of the available cold treatment data, as discussed in the ORACBA analysis, the probit 9 mortality of cold treatment, and the other mitigating measures contained in this rule, we see no need to delay this final rule.

Two commenters stated that APHIS's cold treatment protocol should require that more temperature data be collected in each container to determine the variation in temperature of a load, as this is the only way to ensure that fruit is subject to disinfestation temperatures for the required time period. They claimed that the current protocol potentially allows significant portions of a load to be delivered without adequate treatment, and that a minimum of three temperature probes per unit of fruit are needed. One of the commenters stated that USDA research reports published in the 1980's indicate that the fruit temperature range in a refrigerated container is typically about 3 °F, and based on that figure, single temperature monitors measuring average temperatures could fail to reveal temperatures above the level permitted by the treatment schedule.

APHIS requires the use of multiple sensors, given that we require all temperature sensor readings to meet the appropriate treatment schedule, and given the certification requirements for treatment equipment, we are confident that our existing procedure accounts for temperature variation that may occur during cold treatment.

For shipping containers, we require a minimum of three temperature sensors to be placed in fruit pulp. For sea vessel compartments, we require a minimum of four temperature sensors, but the number required may be larger, depending on the size of the treatment compartment. See Chapter 6 of the Plant Protection and Quarantine (PPQ) Treatment Manual [11] for additional information.

Several commenters noted that in December 2001, when the Government of Spain proposed that APHIS extend the cold treatment on two of the vessels then docked in U.S. ports with a view to permitting the fruit to enter the United States if the treatment were successful, APHIS rejected the approach, saying it had ''no data to support the efficacy of extending the time or temperature of the approved cold treatment.'' These commenters claimed that APHIS still has no such data.

At the time of the Government of Spain's proposal, APHIS had not conducted its review of the available data on cold treatment, and would not suggest a remedial measure without a basis in science. Furthermore, for the reasons stated previously in this document, we must disagree with the commenters' conclusion. We believe there are adequate data available to support our revised cold treatment protocol.

One commenter stated that the effects of precooling on the ability of Medflies to survive cold treatment are not known and pointed out that the draft workplan for the clementine import program states that ''Additional long-term research will be needed to determine if the rate of precooling has an effect on insect tolerance of the cold treatment.''

Studies on other fruit fly species have shown that pre-cooling does not have a significant effect on fruit fly mortality. Whether pre-cooling would have a beneficial effect with respect to Medfly mortality remains to be determined. If so, it is possible that adjustment (*i.e.*, shortening) of the treatment schedule would be possible, as available evidence shows that the extended cold treatment required under this final rule already provides quarantine security equivalent to the probit 9 level.

Two commenters stated that it is possible that Medflies in Spain may be able to withstand colder temperatures than can more tropical populations of Medflies since most, if not all, cold treatment work has been done on strains of Medfly other than that found in Spain.

While it is possible that Medflies in Spain may be able to withstand colder temperatures than some other Medflies, there is no evidence available to support or verify that supposition. There is, however, evidence, which is cited in our risk mitigation analysis, that Medflies have not established in the colder inland areas of Spain where they would be expected to occur if they had become adapted to colder conditions. Indeed, the distribution of Medflies in Spain is consistent with a Mediterranean climate, not a temperate or cold environment.

One commenter stated that Medfly larvae have the capability to overwinter in freezing conditions.

Larvae may survive brief periods (*e.g.* 2 to 3 days) of exposure to freezing conditions, especially if protected from actual freezing by host fruit. Available evidence (cited in the RMA) indicates that larvae cannot survive long-term exposure (*i.e.*, 3 to 4 days) to freezing temperatures.

One commenter stated that the statement in the proposed rule that APHIS inspectors will examine the cold treatment data prior to clearing an incoming shipment is very troubling, as it infers that this might not have been occurring previously even though the PPQ Treatment Manual cold treatment protocol requires a review of the treatment logs or charts for any irregularities that might have occurred during treatment (and, time permitting, examination of the load and compartments) prior to clearance of any cold treated shipment.

APHIS always reviews the cold treatment records of each compartment or container that contains imported cold treated fruits and vegetables. For each imported shipment, an inspector reviews the treatment charts to ensure that the treatment cold chain was uninterrupted and that the time/temperature combinations meet the required treatment schedule. Our statement in the proposed rule was intended to reinforce this requirement, not to imply it had not been applied.

One commenter stated that methyl bromide fumigation is a proven treatment meeting a probit 9 standard of quarantine security with regard to Medfly infestation, and that based on

[11] See *http://www.aphis.usda.gov/ppq/manuals/pdf_files/TM.pdf.*

applications of methyl bromide to mandarin crops (a citrus fruit similar to clementines), methyl bromide treatment would have minimal aging effects on the fruit and little to no cosmetic effects provided that the fumigation was properly applied. The commenter pointed out that the established PPQ treatment schedules for citrus for methyl bromide use is listed as T101–w–1–2 in the PPQ Treatment Manual.

The treatment referred to by the commenter is listed in the PPQ Treatment Manual as an approved Medfly treatment for citrus moving interstate within the United States. However, APHIS only employs that treatment for use as a precautionary treatment for fruit moving from areas near areas where Medfly has been trapped. Treatment T101–1–2 does not provide probit 9 mortality, and there is no approved methyl bromide treatment for citrus that provides probit 9 mortality of Medfly.

*Confidence Building and Limited Distribution*

Many commenters had concerns about the potential limited distribution of Spanish clementines. The proposed rule explained that APHIS was considering restricting the distribution of imported Spanish clementines to non-citrus producing States for the first year of the program as a confidence-building measure. With limited distribution, clementines would not be eligible for distribution in California, Arizona, Texas, Florida, Louisiana, Puerto Rico, the U.S. Virgin Islands, the Northern Mariana Islands, Guam or American Samoa. Four commenters stated that such a requirement is unwarranted and unjustified given the findings of the RMA, and especially given the new stringent controls included in the proposed rule. One commenter stated that the requirement would be contrary to the provisions of the SPS Agreement, which requires measures to be based on scientific principles. Twelve other commenters stated that limited distribution was warranted, and each had different ideas as to what APHIS's limited distribution protocol should actually entail. Some commenters claimed that distribution should be allowed only in States without Medfly host material and conditions for Medfly survival. Others stated that distribution should not be allowed in citrus-producing States or States that border citrus-producing States. Other commenters agreed with APHIS's original suggestion. One commenter suggested that APHIS limit distribution for 2 years rather than 1 year to build added stakeholder confidence in the new program.

APHIS has determined that, in order to ensure the success of our new approach, it is necessary to limit the distribution of Spanish clementines to non-citrus producing States during the upcoming (2002–2003) Spanish clementine shipping season. This means that, under § 319.56–2jj(i) of this final rule, the importation and distribution of Spanish clementines will not be allowed in Arizona, California, Florida, Louisiana, Texas, Puerto Rico, the U.S. Virgin Islands, the Northern Mariana Islands, Guam and American Samoa [12] during the 2002–2003 shipping season, and all boxes of Spanish clementines will be required to bear the following statement: ''Not for distribution in AZ, CA, FL, LA, TX, Puerto Rico, and any other U.S. Territories.'' All labeling must be large enough to clearly display the required information and must be located on the side of the cartons to facilitate inspection. APHIS has determined that this measure is necessary to provide added protection to areas in the United States that are most vulnerable to Medfly establishment.

Our strategy is limited to fewer States than some commenters would have preferred because we do not believe it is necessary, especially given the RMA's characterization of the likelihood that a mated pair could enter the United States via imported Spanish clementines, for us to temporarily prohibit the distribution of Spanish clementines in any States except those where Medfly could become established for the long term. We acknowledge that Medfly attacks many crops other than citrus, and that those crops are produced in some non-citrus producing States, but those States do not have favorable climatic conditions and sufficient host material present throughout the year to support Medfly establishment. APHIS is adopting this requirement on a temporary basis to protect the most sensitive agricultural production areas of the United States from infestation with Medfly. Therefore, we are confident that we are well within our rights as a WTO member country.

Several commenters stated that limited distribution is not good regulatory policy and does not work, as shipments of commodities entering California from other States have been found to contain live Medfly larvae. The commenters noted that the California Department of Food and Agriculture routinely finds exotic pests in parcels handled by the U.S. Postal Service and commercial delivery firms at various locations in California and stated that USDA cannot implement a 100-percent effective program to stop transshipment of clementine fruit from other States into California.

APHIS has had success with compliance systems for limited distribution of fruits and vegetables. The keys to this success have been communication, labeling, trade verification, and enforcement. Communication of regulations for limited distribution has been made via public notice, APHIS Industry Reports, internet websites, direct mailings to members of the Produce Marketing Association and American Trucking Association, and issuance of compliance agreements and permits.

Distribution statements are required on the shipping boxes for all limited distribution commodities, as will be the case for Spanish clementines. These statements inform the importer, shipper, or market owner of the areas in which the products are prohibited from being distributed. Verification of commodity and required labeling takes place at the initial port of entry and at internal markets within the United States. Commodities found to have been moved in violation of limited distribution requirements are recalled and/or destroyed. Reports of illegal movement are investigated and civil penalties are issued to violators as appropriate.

For example, APHIS has monitored importation and compliance with the limited distribution of Mexican avocados since 1997. Compliance has been 98 to 99 percent by volume during the past 5 shipping seasons. In spite of an increased volume of imports, the 2001–2002 season saw a notable decline in violations over past years. In the 2001–2002 shipping season, APHIS had three violations under investigation for illegal transshipment to Tennessee and Georgia. Approximately 85 boxes were found in several unapproved markets, of which 80 (1 shipment) were reported to agricultural officials by the receiver in Georgia and returned.

We are confident that limited distribution of Spanish clementines can be enforced and can work, as shown by past experience.

Two commenters stated that APHIS should consider a trial period during which limited volumes of clementines would be allowed to be imported to northern-tier States for a minimum of one shipping season, so as to ensure that the system works.

[12] Hawaii produces citrus, but is generally infested with Medfly, and therefore is not included in the list of citrus-producing States where distribution of Spanish clementines will be prohibited for the 2002–2003 shipping season.

As stated in previous responses, APHIS is confident that limiting distribution to non-citrus producing States should be adequate to provide confidence that the new approach works, especially given the very low probability of a Medfly infestation identified in the RMA, which does not even consider limited distribution as a mitigation measure.

*Operational Workplan*

Several commenters stated that, in order to truly understand whether or not the risk mitigation measures chosen will provide an appropriate level of protection, APHIS's analysis must contain the workplan that will be used to implement the mitigation strategy chosen. The commenters said that, without the workplan, there is no way for any cooperator or other stakeholder to ascertain if the measures chosen will be effective.

The workplan referred to by commenters is, in essence, an operational agreement between APHIS and other parties (the Spanish Government and a group representing clementine exporters) as to the responsibilities of each for the operation of the preclearance program. The provisions of the workplan intertwine with the regulations and are more detail-oriented.

When APHIS designs a regulatory approach for a particular issue, it places or proposes to place all measures deemed to be necessary according to risk analysis in the Code of Federal Regulations. If a specific measure is not relevant to our calculations of risk, that measure may be included in the regulations, and it may not. There is no bright line between what is included in a workplan and what is included in the regulations, save that the regulations must include all provisions necessary to properly enforce the approach evaluated by risk analysis.

As a longstanding matter of policy, APHIS does not make preclearance workplans available for public comment, nor does it have the intention of doing so in this case, though APHIS has, on some occasions, consulted stakeholders (who are not signatories of the workplan) on the contents of such workplans. In fact, at the request of stakeholders, APHIS has met with several State plant health officials as to the content of the preclearance workplan for this rulemaking. Nonetheless, APHIS does not believe that the contents of the workplan should be included in the rulemaking at hand.

To elaborate, APHIS has received a number of comments urging specific handling of trapping and monitoring activities in Spain—*i.e.*, commenters have suggested the use of a certain fruit fly traps, and certain spacing of trap locations. APHIS believes that such points do not have to be included in the rulemaking at hand, given that the rule is designed to provide for a measure of performance that will be demonstrated primarily via inspection and fruit cutting. Moreover, regardless of what trap is used and how the traps are spaced, under this rule, growers of Spanish clementines must ensure that products submitted for export to the United States have a low Medfly infestation level (a level that cannot be detected via fruit cutting). If they do not meet this standard, clementines intended for treatment will be rejected. APHIS will reject a shipment of fruit presented for export if it is found to contain live larvae upon fruit cutting. In short, if the fruit is found to be infested, it will be rejected. If fruit is not found to be infested, the extended cold treatment will provide that the fruit can be safely imported.

One commenter stated that without the workplan, there is no way for any cooperator or other stakeholder to ascertain if there is sufficient APHIS oversight planned in Spain. The commenter stated that the workplan should allow APHIS unfettered access to production areas and packing and shipping facilities, regular auditing of Spanish records, and other procedures to ensure that APHIS personnel verify compliance with the terms and conditions of the operational workplan.

The requirements described in the proposed rule and this rule clearly state that the Spanish Medfly management program must provide that clementine producers allow APHIS inspectors access to clementine production areas in order to monitor compliance with the Medfly management program, and that all trapping and control records kept by the Government of Spain or its designated representative must be made available to APHIS upon request. APHIS will have inspectors working full time in Spain on the verification of the Spanish clementine import protocol-including inspections at the port of export and production area monitoring. The inspectors will be present to conduct and monitor fruit cutting at the exporting port, and will be able to review records kept by the Government of Spain regarding its management program. Only APHIS personnel and personnel of Spain's Plant Protection Service will be allowed to conduct fruit cutting, and any fruit cutting performed by the Government of Spain will be supervised by APHIS.

*Infestation Levels, Inspection, and Fruit Cutting*

Several commenters expressed concern or confusion over our reference to a 1.5 percent level of infestation. One commenter stated that allowing 1.5 percent of imported Spanish clementines to be infested is unacceptable, and that 1.5 percent is a high level of infestation of any pest, even in the field, while several other commenters claimed that our selection of that level of infestation is not supported by science.

We recognize that our reference to a 1.5 percent level of infestation of Spanish clementines may have caused confusion among commenters. To clarify, under this rule, the detection of a single live Medfly during any sampling of clementines will result in the rejection of the shipment sampled. Hence our actual target infestation level of fruit is zero, not 1.5 percent. However, as a practical matter, it is impossible to sample a sufficient number of fruit to arrive at a statistically valid conclusion that the fruit sampled is Medfly-free. Therefore, we have selected a sampling rate (200 fruit per shipment) that provides a high level of confidence that we will be able to detect low levels of Medfly infestation in clementines from Spain. This particular level of inspection was selected because inspection and fruit cutting at lower rates would provide decreased confidence in our ability to detect low-level infestations of fruit, and because inspection and fruit cutting at higher rates would either not be practical from an operational standpoint or would not measurably improve confidence in our ability to detect such infestations. While this sampling rate was represented in the proposed rule as a measure that provided 95 percent confidence that we could detect Medfly in fruit that were no less than 1.5 percent infested, the same sampling rate will also provide a relatively high degree of confidence that even lower levels of Medfly infestation could be detected. For example, based on established hypergeometric sampling rates shown in the table below, we would still have a relatively high level of confidence (75 percent) that we could find an infested fruit if the unit sampled is only 0.70 percent infested with Medflies.

| Percentage of fruit infested with Medflies | Confidence in detection, assuming 200 fruit sample [1] (in percent) |
|---|---|
| 0.05 | 9.52 |
| 0.10 | 18.13 |

| Percentage of fruit infested with Medflies 0.05 9.52% | Confidence in detection, assuming 200 fruit sample [1] (in percent) |
|---|---|
| 0.11 | 19.76 |
| 0.12 | 21.36 |
| 0.20 | 32.99 |
| 0.30 | 45.17 |
| 0.40 | 55.15 |
| 0.50 | 63.32 |
| 0.60 | 70.00 |
| 0.70 | 75.47 |
| 0.80 | 79.95 |
| 0.90 | 83.61 |
| 1.00 | 86.61 |
| 1.10 | 89.06 |
| 1.20 | 91.06 |
| 1.30 | 92.70 |
| 1.40 | 94.04 |
| 1.50 | 95.14 |
| 1.60 | 96.03 |
| 1.70 | 96.76 |
| 1.80 | 97.36 |
| 1.90 | 97.85 |
| 2.00 | 98.24 |

[1] Assuming shipments of clementines are within the maximum and minimum sizes described in this final rule (166,000 to 4.5 million fruit).

While this sampling rate (200 fruit per shipment) provides a high level of confidence that we can detect low levels of infestation, we acknowledge that some small percentage of infested fruit may be missed during sampling. However, as discussed elsewhere in this document, the calculations of our RMA suggest that the application of cold treatment to such fruit would result in a very low probability that such fruit could serve as a pathway for Medfly to enter the United States into a suitable area.

If exporters of Spanish clementines are to avoid having shipments of clementines routinely rejected by inspectors, they must ensure that the infestation level of fruit is below detectable levels. Furthermore, given that APHIS may shut down the export program if shipment rejection rates rose above 20 percent in a given month, we believe that an appropriate target maximum infestation level for fruit presented for export would have to be well below 1.5 percent.

Again, we did not intend to identify a 1.5 percent level of infestation as a target infestation level for the fruits in the field. Given this fact, and the confusion expressed by commenters, we believe it is necessary to clarify and revise part of our proposal. Specifically, § 319.56–2jj(c)(1) of our proposed rule required that ''* * * bait treatments * * * 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.'' This proposed language was inappropriate, because maintaining levels of infestation at 1.5 percent would result in the majority of shipments of clementines being rejected. In addition, the responsibility for operating the Medfly management program in Spain resides with the Spanish Government, and this rule contains no provisions for APHIS or any other party to verify levels of infestation of clementines in the field. Rather, this rule provides for such verification through examination of clementines at the port of export. Therefore, we are amending § 319.56–2jj(c)(1) in this final rule to require that ''* * * bait treatments * * * be applied in the production areas at the rate specified in Spain's Medfly management program.'' We are making this revision because, while we do believe bait treatments need to be applied in order to ensure low levels of infestation of fruit that are presented for export to the United States, we do not believe it is necessary or appropriate for APHIS to specify the level of infestation that must be maintained in production areas via those bait treatments. We are confident, however, that we can appropriately monitor the infestation level of fruit presented for export via inspection and fruit cutting of 200 randomly selected fruit.

One commenter stated that APHIS last surveyed the Spanish clementine growing regions in December 2001 and has no more recent data. The commenter stated that, given the age and unreliability of Spanish Government data on trapping and pest populations, APHIS cannot determine with any confidence the type of spraying required and the duration and frequency of the treatments necessary to reach the 1.5 percent desired level.

APHIS believes that a well-maintained trapping program can be used as an accurate indicator of the localized prevalence of Medflies. We do not believe that trapping is precise enough to accurately determine infestation levels of fruit, though it is useful as an indicator for when bait treatment applications are necessary. APHIS believes that inspection and fruit cutting provide a more effective means to determine the level of infestation in fruit submitted for cold treatment than can trapping. For this rule, we use inspection and fruit cutting as a means of determining the level of infestation of Spanish clementines.

Two commenters claimed that APHIS has presented no data showing that an infestation rate of 1.5 percent or less, combined with cold treatment, will successfully prevent mated pairs of live Medfly larvae from entering the United States. The commenters noted that direct sampling data compiled by APHIS inspectors from vessels unloaded at ports of entry in 2001 showed an overall average infestation rate (0.16 to 0.18 percent) that is an order of magnitude lower than the maximum infestation rate (1.5 percent) contemplated under the proposed rule, yet there were multiple finds of live Medfly larvae in Spanish clementines last year. The commenters questioned the particular significance of a 1.5 percent infestation level, asked why it is a critical control point, and stated its selection appears to be arbitrary.

As stated in this document, we believe it is highly likely that infestations of imported Spanish clementines were due to the inability of the cold treatment schedule to provide probit 9 mortality. We are confident that the revised treatment schedule, in combination with the reduction in Medfly infestation levels ensured via fruit cutting, provide that needed quarantine security.

Regarding the infestation levels in 2001, APHIS acknowledges that all samples taken after the initial infestations of 2001 were detected revealed low level infestations. It was not possible to randomly (that is, in an unbiased manner) sample fruit from shipments that had already been distributed and/or sold through retail outlets; given that those early-season shipments are the origin of first interceptions of live Medfly larvae in 2001, APHIS is unconvinced that the level of infestation observed in samples taken later in the shipping season are representative of the level of infestations of early season shipments. The unprecedented, numerous reports of live larvae from retail outlets and ports suggest that high densities of live larvae were indeed associated with early season shipments.

As stated earlier in this document, the sampling rate used for inspecting clementines presented for export was selected primarily because it provides a high level of confidence of detecting low level infestations of clementines. For this reason, we do not agree that its selection was arbitrary. We believe that the RMA provides ample evidence that the level of Medfly mortality caused by cold treatment (probit 9 or above), in conjunction with the low levels of pest infestation ensured via fruit cutting reveal that there is an extremely low likelihood that a viable mated pair of Medflies would enter the United States with imported Spanish clementines.

Furthermore, as discussed earlier in this document, APHIS is unconvinced that the level of infestation observed in samples taken later in the shipping season (presumably, the samples referred to by the commenter) are representative of the level of infestation of early season shipments. APHIS has assumed that the infestations associated with early season shipments were higher than average. This is a reasonable assumption based on the available evidence, which includes the unprecedented and numerous reports of live larvae, the higher than average trap captures in Spain during the growing season, and the higher than average temperatures in Spain during the growing season.

One commenter stated that the 1.5 percent value was chosen not because it was shown to provide any particular level of phytosanitary security, but because 200 fruit per shipment was the maximum amount APHIS felt it was capable of inspecting in a reasonable amount of time and at reasonable expense.

As stated in response to the previous comment and others, the 200 fruit per shipment sample size was selected primarily because it provides a practical means to verify with a high level of confidence that fruit is infested at low levels. We stated in our proposed rule that we consider fruit cutting (200 randomly selected fruit per shipment) to provide a statistical basis on which we can infer whether the shipment inspected is 1.5 percent infested or greater. The use of this measure in combination with cold treatment will result in a very low probability that a viable mated pair of Medflies would enter the United States with imported Spanish clementines.

Several commenters noted that after the first shipping season, the pre-treatment sampling rate would not ensure with 95 percent confidence that sampled fruit is 1.5 percent infested or less, but rather that is 3.0 percent infested or less. The commenters also noted that in future years, the sampling rate could be reduced to 76 fruit per shipment, and the sampling would provide only a 90 percent confidence level that the infestation rate is no greater than 3 percent. The commenters questioned how the findings of the risk management analysis are affected by changing the sample size from 200 to 100 to 76 fruit. Some of the commenters noted that the lower sampling amounts are inconsistent with USDA's Pre-Clearance Program Guidelines, which define ''quarantine security'' as ''a level of control which assures a 95 percent confidence level that a pest population will not become established based on the inspection/treatment certification procedure(s) used when considering the biology and ecology of the pest species.'' Commenters stated that there is no biological justification for reducing the sampling rate in one year based on rejection rates of shipments in the previous year since infestation rates in one year may differ substantially from rates a year earlier, and stated that APHIS has provided no evidence that there is any correlation between infestation rates in different years.

APHIS does not necessarily agree with the commenters' assertion that there is no biological justification for reducing the sampling rate in one year based on rejection rates of shipments in the previous year, though we do acknowledge that we did not provide a clear justification for such a measure in the proposed rule. To elaborate, if orchards in Spanish clementine productions areas are well managed for Medfly on an ongoing basis according to specific measures contained in a pest management program, then there would be a clear connection between the Medfly populations in those areas from one year and the next. Nonetheless, given that the RMA does not consider the effect of decreasing the pre-treatment fruit cutting sample size from one year to the next, in the final rule we are simply requiring that fruit be cut at a rate of 200 fruit per shipment, as that level of inspection is the only one evaluated in the RMA.

Two commenters stated that the maximum size of a shipment or lot should be set according to the number of boxes, not the number of pallets, and noted that the maximum lot size specified in the rule appears to be smaller than that specified in discussions regarding the program workplan. Several commenters expressed concerns over our explanation for what constitutes a ''shipment'' of clementines under the proposed rule. Those commenters suggested that the rule needs a clear definition of the term ''shipment'' as it relates to cutting requirements, and argued that the proposed rule does not specify how it will be made clear, in advance of an inspection, what constitutes the particular ''shipment'' when fruit is presented for inspection.

As pointed out by one commenter, the maximum size of shipment described in the proposed rule was 120 pallets (approximately 43,243 boxes). This figure was incorrect, as we allow a maximum size shipment of 200,000 boxes (555 pallets) under the operational workplan. We have corrected this error in this final rule.[13] Further, due to the confusion caused by our use of the terms ''shipment'' and ''lot,'' we are making changes in the final rule based on these comments. In our final rule, a *lot* of clementines is considered to include a number of units of clementines that are from a common origin (*i.e.*, a single producer or a homogenous production unit [14]). The definition of the term *shipment* depends on the context in which it is used. Specifically, the definition depends on whether or not fruit has been treated. The term can refer to one or more lots of clementines that are presented to an APHIS inspector for pre-treatment inspection. Such a shipment may not include more than 200,000 boxes of clementines (555 pallets). The term can also refer to one or more lots of clementines that are imported into the United States on the same conveyance. These definitions are included in a revised § 319.56–2jj(k). Furthermore, inspectors must be able to easily distinguish one shipment from the next, and exporters are required to present their shipments for inspection in an orderly manner to facilitate inspection.

One commenter stated that the proposed rule does not say what is meant by the term ''orchard,'' and requested that APHIS clarify the term's meaning. The commenter noted that it is unclear how APHIS will determine whether two shipments with infested fruit are from the same ''orchard'' or how APHIS will determine the bounds of the ''orchard'' that is to be removed from the export program.

We have added a definition for the term ''orchard'' to § 319.56–2jj(k). For the purposes of this rule, the term ''orchard'' refers to each plot on which clementines are grown that is separately registered in the Spanish Medfly management program. Some orchards could be owned by one person, and some could be owned by several persons (in Spain, such cooperatives are called ''homogenous production units''). Some orchards could be less than an acre in size, while others could include hundreds of acres. APHIS will be able to determine the origin of infested fruit via box markings that are required

[13] This change has no effect on calculations of risk, as the same level of confidence (95 percent) is provided by inspection and cutting 200 fruit out of either 120 pallets or 555 pallets, according to hypergeometric sampling rates.

[14] A homogeneous production unit is a group of adjacent orchards in Spain that are owned by one or more growers who follow a homogeneous production system under the same technical guidance. The fruit produced by these units is pooled and packed together, and all orchards in the group are regulated as one unit in the event that traceback of infested fruit is necessary.

under this final rule. The box markings will provide a means to identify the particular orchard owner or homogeneous production unit from which infested fruit originated. In order to confirm that fruit are eligible under the export program, APHIS checks the box markings on cartons submitted for cold treatment to verify the orchard's status in the export program.

One commenter noted that the pretreatment fruit cutting sample size represents too small a percentage of the actual sample itself. The commenter noted that the samples represent .0012 percent of the smallest shipment of fruit, and .0002 percent of the largest shipment respectively. The commenter stated that inspecting and cutting a small random sample of fruit does not ensure the shipment is clean prior to cold treatment.

These sampling techniques are not designed to ensure that fruit is pest-free. Rather, sampling is intended to provide confidence that the infestations levels in fruit are low enough to ensure a low probability that a viable mated pair of Medflies would enter the United States via imported Spanish clementines. As stated in response to the previous comment, the maximum size of a shipment would be 200,000 boxes, containing approximately 4.5 million fruit. Even so, according to established hypergeometric sampling rates, whether cutting 200 fruit out of (1) a 166,050 fruit sample or (2) a 4.5 million fruit sample, if samples are randomly selected, the negative results would provide 95 percent confidence that the unit sampled is less than 1.5 percent infested.

One commenter stated that if Medflies at any stage of development are discovered in two or more shipments in one season from the same orchard, the orchard should be removed from the export program until it can certify compliance with Medfly management and commodity export programs, rather than only being removed for the remainder of the shipping season.

APHIS believes that fruit cutting is the most effective means to determine the infestation level of fruit presented for cold treatment, and thus does not agree that such a review is needed to qualify an orchard for re-entry into the export program. If the orchard is not managing Medfly populations effectively, that fact will be evident in fruit cutting required under this rule.

One commenter stated that APHIS should specify the cutting rates and procedures that will be used once the fruit reaches the United States or the basis on which the rates will be determined.

Post-treatment fruit cutting is not considered as a mitigation measure in the calculations of risk of the RMA. Since the RMA estimates a very low probability that a viable mated pair of Medflies would enter the United States with imported Spanish clementines under the other provisions of this rule, we see no need to specify the level of post-treatment fruit cutting in the rule itself. We will continue to require post-treatment fruit cutting of clementines, and will cut 1,500 fruit per bulk shipment and 150 fruit per shipping container for the first shipping season. Sample sizes may decrease in future years based on the success of the program.

Two commenters claimed that the reliability of fruit cutting as a sampling technique is questionable, at best. One of those commenters cited studies indicating that, on average, inspectors will identify only 35 percent of infested fruit, noted that the infestation rate of Spanish clementines could actually be as high as 4.3 percent during the first shipping year when the 1.5 percent limit applies (1.5 percent ÷ 0.35 = 4.3 percent), and argued that cutting a statistically determined sample will not ensure that the infestation rate on fruit accepted for shipment does not exceed 1.5 percent. The other commenter stated that the effectiveness of inspection is dependent on both the skill and qualifications of the personnel carrying out the exercise and the standardization of the activity. The commenter stated that without assurances that the fruit cutting will be undertaken in a uniform, standardized manner and by fully qualified inspectors, there can be no confidence that these procedures, whether applied pre-or post-cold treatment, can accurately measure whether the infestation level in the groves is 1.5 percent or less, or that the Medfly control program, including cold treatment, has been effectively applied.

Inspection is a measure used worldwide to mitigate the risk posed by pests that may be present in imported agricultural commodities. APHIS inspectors are trained to find pests in agricultural commodities, and our pest interception records for the past 17 years support this. Since 1985, we have intercepted 485 fruit flies in *Citrus reticulata*, with 38 of those being Medflies.

The RMA discusses the reliability of fruit cutting, and discusses the effect of that variability on its calculations. Given the characteristics of clementines-they are small, easy to peel and cut, and their pulp is translucent-we believe our inspectors will be able to detect Medfly infestations in imported clementines with a high level of confidence. Further, we wish to clarify again that we are not attempting to determine the level of infestation of fruit in the groves where they grow. We are simply attempting to ensure that fruit presented for treatment is infested with Medflies at low levels (*i.e.*, levels that cannot be detected via fruit cutting), as discussed earlier in this document.

**Remedial Measures**

Two commenters stated that if live larvae are detected in imported Spanish clementines, the investigation should be performed jointly by APHIS and Spain. The commenters requested that APHIS ensure that access to all relevant data and samples is provided to the importer and the Spanish authorities to permit independent verification of the findings of the U.S. inspectors.

APHIS is not opposed to Spain participating as appropriate in an investigation that may be necessary if Medflies are found in imported Spanish clementines, and we will share data relevant to such findings with the Spanish. However, APHIS will not delay any part of such an investigation based on the availability, or lack thereof, of Spanish Government personnel.

Several commenters stated that fruit should not be destroyed if it arrives at a U.S. port and (1) treatment has not been properly applied or (2) fruit are found to be infested. The commenters expressed concern that the proposed rule allows for the destruction of improperly treated or infested fruit, and suggested that APHIS apply the least drastic measures necessary at the port of entry in the event that Medfly is detected in Spanish clementines.

APHIS gives fruit importers the choice of what to do with shipments of fruit that are found to be infested with pests, unless the exporter's choice poses a risk that pests could be introduced into the United States. For instance, APHIS would not require the destruction of fruit that is found, upon inspection, to be infested with Medflies if the fruit can safely be reexported.

One commenter asked if APHIS has ever considered requiring exporting countries to put up a performance bond to ensure against the devastation of American agriculture in the event that legally imported fruit introduce serious agricultural pests into this country.

The idea of a protective bond to be paid by a foreign region to U.S. producers in the event that imported fruit causes a catastrophic pest emergency in the United States is not a new idea, nor is it a practical one. Such ''insurance'' against pest infestation and loss of agricultural production has been determined to be contrary not only to the will of foreign exporters, but to the will of domestic exporters, who would be expected by other countries to put up similar bonds for their exports. The matter is further complicated by the fact that it is very difficult to tie an outbreak to a specific source, as per past experience. For these reasons, the use of such bonds is considered impractical.

One commenter stated that the handling of potentially infested cargo at ports of entry is subjective and criteria for suspension of the program is ambiguous.

The regulations do not cite specific courses of action to be followed in the event that infested fruit are intercepted at the port of entry, as each such situation could require a unique reaction. APHIS believes that decisionmaking related to such events is best handled on a case by case basis, and we believe our position is well within the authority given to the Secretary by Congress.

One commenter questioned whether APHIS, upon finding live Medflies in imported Spanish clementines, would allow consignments which are en route to be inspected, possibly at a higher rate, with appropriate action taken on a case by case basis.

As stated in the proposed rule and in this final rule, if a single live Medfly in any stage of development is found in a shipment of clementines being imported into the United States, 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 the regulations 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.

*Risk Analysis*

One commenter stated that the RMA is not (and does not purport to be) a risk assessment, and noted that, according to the IPPC standard, a pest risk assessment—which evaluates the probability of the introduction and spread of a pest—should be performed as a predicate to conducting a risk mitigation analysis to select the most appropriate pest risk management options. The commenter claimed that APHIS has not performed a pest risk assessment as a predicate to conducting the RMA, and thus commenters do not know what APHIS believes to be the probability of the introduction of Medfly under the baseline or mitigated scenario, and it is not possible to determine whether APHIS has selected the most appropriate management options to mitigate the identified pest risk.

The events of the 2001 Spanish clementine shipping season suggested that a review of risk mitigation for Medflies was justified, and the risk mitigation document is such a review. Based on the updated decision sheet [15] contained in Appendix 4 of the RMA, and based on more than 20 years of previous imports of Spanish clementines, we have no reason to believe that there are other pests of quarantine significance that require additional risk mitigation, and therefore disagree with the commenter's claim that we have not conducted a pest risk assessment. Indeed, we evaluated the risk posed by all known pests of clementines, and our analysis is documented in the decision sheet, which was made available to the public when the original draft of the RMA was released for public comment on April 16, 2002.

The decision sheet notes that the following insect pests are known to occur in Spain and are also associated with clementine fruit, and may be imported with the commodity:

*Ceratitis capitata* (Medfly) (Wiedemann) (Diptera: Tephritidae)
*Ceroplastes rusci* (L.) (Homoptera: Coccidae)
*Ceroplastes sinensis* Del Guercio (Homoptera: Coccidae)
*Cryptoblabes gnidiella* (Milliere) (Lepidoptera: Pyralidae)
*Parlatoria cinerea* Hadden (Homoptera: Diaspididae)
*Parlatoria ziziphi* (Lucas) (Homoptera: Diaspididae)
*Prays citri Milliere* (Lepidoptera: Plutellidae)

The decision sheet concludes that, even though the seven quarantine pests listed above have the potential of being imported with clementines, all pests listed except Medfly would be easily detected by visual inspection during preclearance procedures.

The scale insects, *Ceroplastes rusci*, *Ceroplastes sinensis*, *Parlatoria cinerea* and *Parlatoria ziziphi*, are relatively large and are located on the surface of the fruit. The larval stages of both Lepidopteran pests, *Cryptoblabes gnidiella* and *Prays citiri*, reside in or adjacent to the rind of the fruit. However, these two pests create large entrance holes in the fruit that are easily detected during even a cursory inspection. This is not the case with the larvae of Medfly, which require a careful analysis of the fruit pulp because they feed inside the fruit and the oviposition entrance holes are usually not readily visible. The decision sheet also noted that, of the 20 plant pathogens or the 4 parasitic nematode pests identified, none are of quarantine significance.

Furthermore, we also disagree with the commenter's claim that it is not possible to determine whether APHIS has selected the most appropriate management options to mitigate the identified pest risk, since our RMA is intended to evaluate the risk reduction potential of our approach.

One commenter noted that the ORACBA analysis is not referenced in the RMA, and its conclusions and the conclusions used in the RMA are not the same.

We agree that we did not cite the ORACBA document in the RMA, though we have done so in the October 4, 2002 revision. For the reasons discussed earlier in this document, we are confident that the ORACBA document supports the extension of cold treatment described in this rule, and that its findings provide support the conclusion that the revised treatment will provide the requisite probit 9 mortality assumed in the RMA.

One commenter stated that the RMA should include a qualitative analysis that describes and characterizes the risk elements that are analyzed quantitatively. The commenter noted that, whereas the quantitative analysis allows for any variability, it does not capture the analyst's view of what the variability he/she believes might exist.

We believe that the quantitative analysis captures the variability associated with the clementine pathway. Several of the steps that make up the pathway were evaluated using maximum, and therefore, most conservative, estimates. These conservative estimates isolate the conclusions of the RMA from the effects of variability.

For example, the RMA assumed that the distribution of imported clementines in the United States would, over time, follow population demographic trends that suggest human population levels will increase in southern States where the risk of Medfly establishment is greater. This to say that the RMA assumes exaggerated current and near-

[15] Before we began routinely preparing pest risk assessments to inform our decisionmaking relative to commodity import requests, APHIS based its decisionmaking on documents called "decision sheets." Such documents contained relatively the same information that is contained in modern pest risk assessments, but without the standardized format. We have updated the decision sheet for Spanish clementines to reflect all available pest information and modern pest risk assessment structure, and are confident it considers the risks posed by all pests of Spanish clementines.

term distribution of clementines to southern States, as it evaluates risk based on projected population levels in southern States that will not be realized until approximately 25 years from now. The RMA assumes that an additional 30 percent of clementines are shipped to those areas than is currently the case, to account for population trends assumed to occur in the future.

The RMA also assumed that every shipment of clementines that arrives in a suitable location is equally likely to arrive in an area where suitable hosts for Medfly are present; however, during the fall and winter (when most clementines are shipped) this is a conservative assumption. By assuming conservative values, we were able to account for additional variability beyond that expressed explicitly in the RMA's simulation model (quantitative analysis).

We would, however, like to note that a qualitative analysis of the risk of Medfly introduction into the United States is provided in the RMA under the heading ''Likelihood of Introduction.''

One commenter stated that using the likelihood of the movement of a single container of fruit to a susceptible grove as a means to assess the likelihood of successful invasion is uncharacteristic of Medfly invasion patterns. The commenter noted that clementines are imported for consumption, and historically, infestations have been detected in urban settings where a variety of residential plantings provide fruit year round. Thus, the commenter concluded that infestation of commercial production areas is most likely to occur via natural spread or artificial movement of infested fruit from a residential area to a commercial production area.

We agree with the commenter and have revised our analysis such that it no longer assumes that an entire container is likely to be released into suitable conditions. Rather, we used evidence provided by Wearing *et al.* 2001 and Roberts *et al.* 1998[16] which suggests that a maximum of 5 percent of fruit that ends up in a given region is discarded. Since fruit that is not discarded is assumed to be consumed, we used the value suggested by Wearing *et al.* 2001 and Roberts *et al.* 1998 (the range provided was 0.5 percent to 5 percent) to estimate the actual amount of fruit that is not consumed and therefore, presents risks. Although we used the most conservative estimates (the maximum value for discards), our estimate of the overall probability of a mated pair in shipments was reduced. This is because, prior to consideration of this comment, the RMA's estimates treated all fruit as if it was not going to be consumed, and that all fruit, therefore, was likely to constitute hazards. This was clearly an overestimate, and the available evidence, as suggested by public comments, provided good reason for us to refine our estimates.

One commenter stated that the RMA's statistical calculations are incomplete, and fail to take into account more than one container of clementines. Consideration has not been given to additional shipments.

The RMA estimated the risk associated with (1) a single shipment moving to suitable areas and (2) multiple shipments moving to suitable areas. The probability of a mated pair in a shipment of Spanish clementines arriving in a suitable area was estimated to be low. According to published evidence,[17] a shipment that includes a single container is already a conservative estimate of risk. Landolt *et al.* states:

''The most practical point to assess the risk of an introduction occurring is the probability of a potential mating pair or gravid female * * * getting through quarantine. A potential mated pair might be defined as a nonsterile male and a nonsterile female occurring in the same area during the same period such that mating is possible. For our purposes, a pair of fruit flies emerging from the same shipment would be considered a potential mated pair. The additional problems of survival, feeding, dispersal, mate finding and host finding are unknown but add a large degree of safety beyond the probability of a mated pair occurring. The risk of an introduction should then be calculated as the probability of one or more mated pairs per shipment surviving quarantine measures.''

These statements clearly support our approach to using single shipments as the unit of risk. Nonetheless, the effects of multiple shipments (cited above) were still estimated using methods obtained from peer reviewed methodologies cited in the RMA.[18]

One commenter stated that the calculation of the overall probability for a ''mated pair'' relies on a formula that combines the effects of many U.S. domestic shipments, but that formula uses as an input the probability for a mated pair in just a single shipment, whereas APHIS has already indicated that the probabilities differ for different shipments. The commenter claimed that the calculation cannot be correct if it just uses a single value, because that value does not represent all shipments, and therefore does not account for variability.

Our calculations regarding the risk posed by a single shipment use the maximum risk posed by a single shipment, thus causing the figure to represent a worst-case scenario. For instance, we made assumptions regarding the Medfly populations in shipments that would be consistent with relatively high levels of infested fruit. Available evidence (*e.g.*, Agusti, M. 2000. Citricultura. Ediciones Mundi-Prensa. Madrid, Spain. 416 pp. and Ministerio de Agricultura, Pesca y Alimentacion de Spain Trapping records) indicates that as fall arrives, the population levels of Medfly drop precipitously in Spain, thus making late season shipments much less likely to harbor Medfly than assumed by our baseline (maximum) value. Our approach has addressed some of the elements of variability as such via the use of maximum values, as discussed previously in this document.

One commenter stated that, according to the RMA, the chances of live mated pairs of Medfly being introduced into the United States via every imported shipment going at the same time to the same suitable location is an unrealistic scenario. However, the commenter noted, it appears that the RMA calculates the probability for mated pairs of Medfly from any shipment going to any suitable location at any point in time, which is actually a fairly realistic scenario. Why did APHIS choose the scenarios it evaluated, and why did it not use real world scenarios?

As stated earlier in this document, based on scientific research and published evidence, a single shipment is already a conservative unit for which to estimate risk. We estimated the likelihood that a mated pair of fruit flies would be present in a shipment (of 166,050 fruit) in the RMA. However,

[16] Wearing, C.H., J. Hansen, C. Whyte, C.E. Miller, J. Brown. 2001. ''The potential for spread of codling moth (Lepidoptera: Tortricidae) via commercial sweet cherry fruit: a critical review and risk assessment.'' *Crop Protection* 20: 465–488 and Roberts, R.C. Hale, T. van der Zwet, C. Miller, S. Redlin. 1998. ''The potential for spread of Erwinia amylovora and fire blight via commercial apple fruit; a critical review and risk assessment.'' *Crop. Prot.* 19–28.

[17] Landolt, P., D. Chambers, and V. Chew. 1984. ''Alternative to the use of probit 9 mortality as a criterion for quarantine treatments of fruit fly (Diptera: Tephritidae)-infested fruit.'' *J. Econ. Entomol* 77: 285–287.

[18] Wearing, C.H., J. Hansen, C. Whyte, C.E. Miller, J. Brown. 2001. ''The potential for spread of codling moth (Lepidoptera: Tortricidae) via commercial sweet cherry fruit: a critical review and risk assessment.'' *Crop Protecton* 20: 465–488 and Whyte, C.F., R. Baker, J. Cowley, and D. Harte. 1996. ''Pest establishment, a quantitative method for calculating the probability of pest establishment from imported plants and plant products, as a part of pest risk assessment.'' NZ Plant Protection Centre Publications, No. 4, ISSN 1173–6704. Lynfield, NZ.

comments received from stakeholders on the draft RMA requested that we estimate alternative scenarios (for example, millions of fruit being deposited in close proximity such that flies from different shipments and shipped during different times would be assumed to find each other). These scenarios are clearly unrealistic, as the chance that the entirety of one shipping season's Spanish clementines going unconsumed, and ending up in close proximity to each other in a location that has available host material and the right environmental conditions is not likely. The figure calculated, does, however, provide an upper theoretical threshold. Analysts estimated these upper thresholds and noted that if there is a low probability of Medfly entry into a suitable area associated with extreme scenarios (such as those just described), then the probability of Medfly entry under more realistic, constrained scenarios is clearly lower.

Nonetheless, again in response to comments, in our final RMA, we have estimated risk associated with a single container arriving in a suitable location and multiple containers moving to suitable locations.

One commenter stated that it is very difficult to follow where some of the input values used in the RMA originated and why they were chosen, particularly since, in a number of cases, the values selected seem to be inconsistent with the referenced data. The commenter noted that:

- The most likely values for the number of fruit shipped are not shown in Tables 4a and 4b of the RMA, and the volumes that are shown are inconsistent with the volumes assumed in the Regulatory Impact Analysis.
- The evidentiary basis and rationale for selecting the shape of the probability distributions are not transparent.
- In many cases, ''personal communications'' are referenced as the source of information without the precise contents of those communications being disclosed.

To summarize some of the key values of concern to the commenter, we briefly review them here. The values chosen for the different components assume that:

- Approximately 166,050 clementines may be associated with a single shipment,
- A maximum 1.5 percent of fruit will be infested with flies prior to cold treatment,
- No more than 8 flies emerge as viable adults from infested fruit,
- Cold treatment approximates the probit 9 level,
- 44 percent of fruit imported go to States where suitable hosts and conditions are found,
- 5 percent of all fruit imported is discarded and not consumed, and
- More than 6,400 total shipments will arrive in the United States each year.

Our rationale for selecting the above values is detailed in the RMA is also summarized as follows:

The maximum number of clementines was based on the number of fruit that fit in a box (from 20 to 25), the number of boxes contained in a pallet (360), and the number of pallets (20–21) that can fit into a forty-foot ground transport container. This information was obtained through a review of shipping and packing documents and was confirmed via personal communications with experienced port inspectors.

In addition to the total number of fruit in a container, we also estimated the total number of containers that could be exported to the United States. We used historical data and shipping records through 2001 to determine the maximum number of containers shipped to the United States (6,408 shipments). The RIA for this rule, however, considers a maximum number of shipments based on the historical evidence cited above, but also considers future trends. For consistency, we have updated the final RMA to reflect the same maximum number identified in the RIA.

As stated earlier in this document, the 1.5 percent level of infestation was derived from our ability to determine maximum infestation levels of fruit via sampling. Based on a sampling rate of 200 randomly selected fruit per shipment of clementines, APHIS can verify with a high level of confidence (95 percent) that the fruit sampled is 1.5 percent infested or less, based on negative results of sampling. Support for this approach can be found in standard statistical texts.[19]

The maximum level is further supported by evidence from shipping during a presumably ''high density'' year such as 2001. As stated elsewhere in this document, sampling data for 2001 did not provide evidence that infestation levels were above 1.5 percent; however, sampling was not unbiased, and therefore was not representative of the level of infestation of fruit imported during the early part of the shipping season.

In addition to purely statistical evidence, we also consulted with port inspectors and Spanish scientists. There was agreement that, as a practical matter, it was possible to limit the the proportion of infested fruit using the measures required by this rule.

We also used evidence to support our minimum estimated values. The minimum expected pest infestation proportion is 0 percent infested fruit. Prior to 2001, port inspections had never found multiple live Medfly larvae in commercial shipments of citrus from Spain. This level was the minimum value for infestation most commonly cited by inspectors, and was used a minimum value for the purposes of the RMA.

The maximum number of larvae per fruit that are viable (i.e., that grow to fully functional, potentially reproductive adults) was estimated as eight and the minimum was estimated as zero. The values noted were supported by evidence from direct laboratory experiments[20] on clementine fruit. We also used additional evidence from other studies on other related fruit flies[21] because tephritid flies share many common traits, because some family generalizations are appropriate, and because USDA scientists agreed that the commonalities between other tephritid fruit flies and the Medfly would allow us to make some comparisons. We concluded from a review of the evidence that a maximum eight larvae and a most likely three larvae would successfully develop and lead to viable adults from each clementine fruit under typical field conditions such as those studied.

We based our cold treatment parameters on the assumption that the revised treatment schedules, as proposed, would provide a ''probit 9'' level of quarantine security or better. This assumption is supported qualitatively by the cold treatment recommendation and quantitatively by the ORACBA analysis. However, as discussed in detail elsewhere in this document, and as evidenced by the quantitative analysis of available data in the ORACBA analysis, not all of the cold treatment time/temperature combinations suggested in the cold treatment recommendation document will provide probit 9 mortality. As a result, in this final rule, based on the findings of the ORACBA analysis, we are only allowing cold treatment of

[19] See Steel, R. and J. Torrie. 1980 ''Principles and Procedures of Statistics.'' McGraw Hill, Inc. New York, NY. 633 pp.

[20] Santaballa, E., R. Laborda, M. Cerda. 1999. ''Informe sobre tratamiento frigorifico de cuarentena contra *Ceratitis capitata* (Wied.) para exportar mandarinas clementines a Japon.'' Univ. Polytecnica de Velencia. 25 pp.

[21] Leyva, J.L., H. Browning, and F. Gilstrap. 1991. ''Development of *A. ludens* in several hosts.'' Environ.Entomol 20(4): 1160–1165.

clementines at the 14 day/34 °F, 16 day/35 °F, and 18 day/36 °F combinations, as these are the only time/temperature combinations for which there is sufficient evidence available to support a finding that they provide probit 9 mortality.

We only estimated the risk posed by fruit that would arrive at a suitable location where Medflies could become established. We assumed that there are two factors that affect the amount of fruit imported that will arrive at suitable locations; One is tied to the distribution of people who consume clementines, and the other is tied to the rate at which they discard fruit.

For the purposes of our analysis, we assumed that there is small number of States where Medfly could become established. This includes South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, New Mexico, Arizona, and California. According to U.S. Census data, some 34 percent of the population currently lives in those States. Furthermore, according to the U.S. Census Bureau, in 25 years, some 44 percent of the population will live in those same States. We used this higher value (44 percent) to estimate how much of the population lives in suitable areas, and assumed that clementines would follow market patterns that are driven by population (i.e., that clementines are distributed evenly with population). For reasons explained in detail elsewhere in this document, we believe the value we used (44 percent) is a conservative estimate.

Further, fruit is intended for consumption, and a large portion can be assumed to be eaten. We therefore assume that fruit that is consumed does not pose risks of Medfly introduction. We investigated the number of fruit that goes unconsumed and provide evidence in the RMA for the fact that, at most, 5 percent of fruit is discarded by consumers in a way such that it might lead to pest introduction.[22] It is this discarded fruit in a suitable area that was the focus of our analysis.

One commenter stated that the understandability and transparency of the RMA's outputs leave much to be desired, and that despite extensive comments provided during the comment period on the draft RMA, there have been no changes to the methodology of risk mitigation, and no justification given for why comments were used or not used. The commenter claimed that despite recommendations made during the comment period for the draft RMA, Table 4D, which intended to reflect the risks of introduction of Medfly under three different scenarios, is still completely incomprehensible.

APHIS believes that, given the detailed technical comments we have received on the proposed rule and its supporting documents, persons who are knowledgeable in the field of risk analysis were certainly able to understand what the RMA's inputs were derived from, and how we calculated its outputs. All calculations contained in the RMA were presented to the public in the actual spreadsheet used by APHIS, and the spreadsheet includes all the input values we used. We have, however attempted to make the outputs in Table 4D easier to understand in response to commenters' concerns, and have made some changes to our methodology where appropriate as described elsewhere in this document and in the RMA. We have also provided evidence and documentation for the scientific basis of our findings and for the use of specific methods that we used throughout the analysis. The changes made in response to comments do not change our conclusion that the combination of cold treatment and the limitation of Medfly infestation in Spanish clementines will result in a minimal likelihood that mated pairs of Medflies will arrive in shipments of Spanish clementines.

One commenter stated that a key holding of the court in *Harlan Land Co.* was that the risk assessment should be transparent, with ''complete and transparent documentation of data used in the assessment,'' and claimed that the risk mitigation analysis that has been prepared for the Spanish clementine import proposal does not meet that test. The commenter claimed that even informed experts are not able to comprehend the analysis contained in that document.

Based on the lengthy and substantive comments we received on the proposed rule and supporting documentation, we believe the documents were sufficiently comprehensible. These comments were considered and helped to strengthen the RMA as described in detail in this document and in the RMA itself.

Several commenters stated that limiting the RMA to citrus is a gross underestimation of the potential economic and social impact that could occur if Medfly is introduced into both agricultural communities and residential communities. The commenter noted that Medfly is not just a citrus pest, but a pest of many agricultural commodities.

The RMA does not assume that the Medfly poses a threat to only citrus. To the contrary, throughout the RMA, APHIS fully acknowledges the multiple hosts and seriousness of this pest. The RMA does, however, focus on the likelihood that this serious and multiple-host pest would occur in association with clementines after they were treated in the field and after harvest, and it does evaluate risk based on the likelihood that the mated pairs of fruit flies enter the United States and arrive in a suitable area. For the purposes of our analysis, we consider citrus-producing States to be the most suitable areas for Medfly establishment because those are the only States that have the climatic conditions and year-round host availability to support an established Medfly population.

One commenter stated that, despite the fact that phytosanitary security in Spanish clementine production areas has been nonexistent, USDA has not required that Spain follow a systems approach to risk mitigation.

We did not refer to our approach regarding the importation of clementines from Spain as a formal ''systems approach,'' though our approach, by definition, could constitute a systems approach by virtue of its two critical control points (Medfly population control and cold treatment). Given that clementines were imported for upwards of 20 years with no significant problems despite only being subject to cold treatment, in this rulemaking, we attempted to simply resolve some of the uncertainty associated with the events of 2001 by tightening existing restrictions, and did not see the value in referring to the revised protocol as a systems approach.

One commenter stated that the Hazard Analysis and Critical Control Point (HACCP) approach to calculating the potential for a Medfly to be exported to the United States from Spain is a risk mitigation tool that is invaluable perhaps in a food safety program, but must be fully considered for its appropriateness when dealing with invasive pests. The commenter claimed that until our trading partners concede or provide reciprocity to such a HACCP-like approach, it seems inappropriate to use this as a tool, and certainly in this instance.

We did not incorporate new risk management paradigms as part of this rulemaking. Rather, in the RMA, we noted that our procedures are consistent with other procedures such as HACCP. HACCP was cited to establish parallels, not as an effort to integrate new procedures into our approach. The mitigations considered by APHIS are supported by scientific evidence, decades of successful experiences, and expert panel recommendations, and, in this case, the mitigations and system

[22] Wearing *et al.,* 2001; Roberts *et al.* 1998.

used by APHIS happen to be consistent with other well-known monitoring programs such as HACCP. As stated in our proposed rule, our analysis 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).

One commenter suggested the RMA include a third critical control point. The commenter stated that the additional critical control point could be (1) the review of cold treatment records prior to release of any shipment on arrival, or (2) a program review every 3 to 5 years.

We agree with the commenter that there is a need for stringent oversight of the program, and we intend to conduct program reviews on similar timeline to the one suggested by the commenter. Review of cold treatment records prior to release of any shipment is considered as part of our analysis, and making it a critical control point would have no meaningful effect on our calculations of risk or the actual enforcement of the requirement.

One commenter stated that the RMA fails to define what it means by ''variability.'' The commenter stated that, while certain variabilities are described, such as variations among different populations and carton-to-carton variability in the number of clementines, the key variability—the variation expected in the number of surviving Medflies in each shipment to the United States—is missing. The commenter stated that the modeling has to correctly account for the different pest populations for which the variabilities are defined, and claimed that the RMA currently does not do that.

We have generally discussed the topics of variability and uncertainty in detail in Appendix 3 of the RMA, and elsewhere in this document. Regarding variation expected in the number of surviving Medflies in each shipment to the United States, we believe that is addressed by the parameters of the cold treatment. This is to say that we assumed that cold treatment assures levels of mortality that are equivalent to, or greater than, the probit 9 level. This assumption is supported by recent large scale tests, as evaluated in the ORACBA analysis, and as discussed elsewhere in this document. The recent tests of cold treatment show that, at certain time/temperature combinations, the observed mortality of cold treatment was 100 percent, and additional data support the other approved time/temperature combinations. Again, the ORACBA analysis considers available data, and provides an assessment of where the proposed cold treatment schedule provides probit 9 level quarantine security, and where it does not. We do consider variation in survivors of cold treatment, and this variation is documented in Appendix 3 of the RMA, which cites the minimum, maximum, mean, and 95th percentile values of the distribution used for variation in a shipment. As for the proportion of infested fruit and number of larvae in a shipment, this is explored by multiplying single fruit estimations (*i.e.,* number of Medfly larvae per fruit, which varies from zero to eight) by the proportion of fruit that is infested (varies from zero to 1.5 percent).

One commenter stated that the RMA does not take into account how certain we can be that the calculated results correspond to reality, particularly the calculation concerning the probability that mated pairs of Medflies reach susceptible areas of the United States.

We address the question of how our results correspond to reality by questioning the validity of our assumptions. APHIS believes that the maximum number of shipments of clementines is well described by the values used (6,408 per year), that the number of infested fruit can be realistically kept below 1.5 percent, that the number of viable larvae associated with clementines is low (zero to eight per fruit), that the cold treatment is effective (approximating probit 9), that not all fruit is discarded (most fruit will be consumed), and that the majority of fruit will not be shipped to areas suitable for Medfly development. APHIS strongly believes that these fundamental assumptions are correct.

We also further believe that, by using a system that assures low population densities in fruit prior to cold treatment, and then applying a cold treatment schedule that kills more than 99.9 percent of the Medflies that are present, there is a very low likelihood that a mated pair will be associated with any given shipment of fruit.

We address uncertainty by considering the effects of maximum values of inputs for the system. In essence, the investigation of maximum values helps us establish if our assumptions are realistic and whether the model used is realistic. As such, multiplication of maximum values results in conservative estimates of risk. Though such estimates may not always be realistic, they provide a point of comparison for mean values, and allow us to identify areas of uncertainty in the system.

One commenter stated that the RMA incorrectly compares the effects of two systems—one with field controls in place, and the ''baseline'' without such field controls. The commenter stated that the difference evaluated in the RMA should not be between two inventions of the analysts. Instead, the RMA should start with the baseline scenario, and then add the effect of the controls. The commenter stated that this would modify the baseline distribution for infestation rates by the likelihood of non-detection due to the controls added, and that with such an approach, the effect of the controls can actually be evaluated, not just the inventiveness of the analysts.

The key difference between the two scenarios (the baseline-cold treatment only—and the mitigated scenario employed by this rule) considered in the RMA was the addition of field population limits in the mitigated scenario. These scenarios do not reflect a contrived system but represent USDA's understanding of the key elements that are being refined and that will increase its ability to safeguard against Medfly risks. The parameters used were, therefore, not contrived but linked to the evidence presented. Whereas the values of specific parameters may be subject to refinement, the final conclusions are robust. They are robust because changes in the assumptions and exploration of the effect of changing values (*e.g.*, decreasing the effectiveness of cold treatment, increasing the proportion of infested fruit) did not change our findings that the probability that a mated pair of Medflies could enter into the United States via Spanish clementines is very low. Whereas a comparison to a baseline is useful, the estimation of the likelihood of introduction even without reference to a baseline is valid. That is, if we were to consider a single scenario (cold treatment plus limitation of field populations) we would not find otherwise. Indeed, we would conclude that, the probability that a mated pair of Medflies arrives in a suitable location in the United States as part of multiple shipments is low.

One commenter stated that the RMA fails to track the effect of new controls when everything else is equal. The commenter noted that the RMA compares the difference between averages with and without controls; when what is really required is calculation of a distribution of the differences with and without controls. This requires a single Monte Carlo analysis that evaluates the baseline and new scenario simultaneously, and with such analysis, it is clearer when the new controls have an effect and the extent of the effect.

We tested two scenarios independently; one scenario included a simulation that used what we termed ''baseline'' input values. Those values were associated with no field controls, which are the only difference between the baseline and the second ''mitigated'' scenario. Both scenarios included cold treatments. The baseline scenario assumed that there could be higher populations (up to a maximum 15 percent infested fruit) than what is allowable in the mitigated scenario. A comparison of the output from these two simulations allowed us to obtain a relative estimate of the impact of the proposed mitigation measures (namely, the addition of field controls as the single key additional mitigation measure).

One commenter noted that the RMA does not consider the possibility of mated Medfly pairs coming from a source other than Spanish clementines. The commenter stated that, if the probability for a Medfly from another source is higher than the probability from a given clementine shipment, it is the single Medfly per shipment, not the probability of a male/female pair within a shipment that will matter most.

Given that Medfly is not established in the mainland United States, we see no need to assess the scenario posed by the commenter.[23] Indeed, the RMA is based on the assumption that Medfly is not established in the mainland United States. The probability that a Medfly from another source would mate with a Medfly from Spanish clementines is even lower than the probability that a mated pair could enter the United States via a shipment of clementines from Spain.

One commenter stated that the RMA evaluates the probability for a mated pair at all locations, and for all suitable locations, using a formula that corresponds to Medflies from different shipments being unable to get together and mate. The commenter claimed that the calculations actually performed do not correspond to the ''worst case'' as APHIS implies; they are not upper bounds on the probabilities, but instead assume the best possible case. Therefore, they are lower bounds.

The possibility that 9 tons of produce (a single container) are distributed within a small area such that output from many containers could in effect coalesce and allow for Medflies from many different containers to emerge, fly to suitable hosts, find their mates, mate, oviposit, etc. is not realistic given the evidence considered in the RMA. The RMA uses a formula that evaluates the probability of a mated pair in any of multiple, independent containers. That probability does not represent a lower bound, but rather a conservative estimate of the likelihood of Medfly entry to a suitable location. Assumptions such as (1) All containers to all suitable locations will find suitable conditions, (2) emerging flies will find suitable hosts at any given time, and (3) that the maximum amount (5 percent) of fruit is discarded by consumers are all conservative assumptions. Our estimates and the formula we used are based on peer reviewed evidence (*i.e.*, Wearing *et al.*).

*Trapping, Bait Treatments, Monitoring*

A number of commenters raised concerns about the content of the Spanish Medfly management program. One commenter noted that the first of the ''minimum criteria'' for a measure that is a required component of a systems approach is that the measure be ''clearly defined.'' The mitigation requirements of the proposed rule do not meet this standard. The proposed rule does not say what kinds of traps are to be used, or how many, or by whom, or how the traps should be baited and rotated, or what kind of records must be kept. Another commenter claimed that without assurance that trapping activities are adequate to determine the current pest population in Spain, the effectiveness of a spraying program cannot be evaluated.

The Plant Protection Act defines a systems approach as defined set of phytosanitary procedures, at least two of which have an independent effect in mitigating pest risk associated with the movement of commodities. While the regulatory approach employed by this rule could constitute a systems approach by virtue of its two critical control points (Medfly population control and cold treatment), in a simple sense, the measures referred to by the commenter have no real bearing on the calculations of risk contained in the RMA. For this simple reason, we do not agree that these measures should be more clearly defined than they already have been in the proposed rule. To elaborate, we do not believe that a continuing debate about an issue such as what fruit fly trap the Spanish use would result in any significant improvement to the approach we have chosen. As stated previously in this document, details of the Spanish Medfly program, such as the type of trap and bait used, the type of bait sprays required, the spacing of Medfly traps, and the triggers for bait sprays have no connection to our calculations of risk. We also believe that fruit cutting is the best available indicator of the level of Medfly infestation of Spanish clementines, and the success of this measure is not dependent on any of the other measures cited by commenters.

Three commenters stated that APHIS should delay resumption of shipments of Spanish clementines until an aggressive, comprehensive, and consistent trapping program fully operated, monitored, and documented by Spanish Government officials has been in place through a full shipping season.

The operation of such a program for a full year would have little or no bearing on the ability of the safeguards we have chosen to provide the risk reduction identified by our analysis. This is to say that, regardless of pest populations, trap types, and bait spray applications, if Medfly infestations of Spanish clementines are not kept at low levels, APHIS will confirm as much via inspection and fruit cutting and will refuse to allow those clementines to be exported to the United States. If Medfly populations are maintained at low levels (levels that cannot be detected via fruit cutting), we are confident that cold treatment will ensure a low probability that a viable mated pair of Medflies could enter the United States via imported Spanish clementines.

Several commenters expressed concern over servicing and monitoring of Medfly traps, application of bait treatments, and recordkeeping activities associated with these activities. Some of those commenters stated that APHIS should not allow the Spanish citrus industry to service and monitor the traps in the production areas or apply bait treatments, and argued that the Government of Spain should be given those tasks to better ensure compliance with the regulations. Others noted that according to the report of the APHIS Technical Review from the trip made in December of 2001, Spain has not kept the type of records on trapping and bait spraying programs that the work plan required them to keep. The commenters questioned why U.S. stakeholders should now have confidence that there will be a new commitment by the Spanish industry to actually follow an updated protocol when there was a failure to follow the previous protocol, and urged APHIS to insist on scrupulous adherence to the work plan and regulations, and issue steep penalties for not doing so.

[23] Hawaii is generally infested with Medfly, but all Medfly host commodities moving interstate from Hawaii to the mainland must be treated for Medfly prior to movement into a State on the mainland.

Under this rule, the Government of Spain or its designated representative must keep records that document fruit fly trapping and control activities conducted under the Government of Spain's Medfly management program. These records must be kept for all 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. APHIS inspectors may review those records at any time, and therefore, will be able to determine whether the conditions of the regulations and Spain's Medfly management program are being complied within areas that produce clementines for export to the United States. We agree with the commenter that APHIS should be able to insist on compliance with these requirements, and we are clarifying in this final rule that APHIS may suspend the importation of clementines in any case if we determine there is a failure to follow the program requirements. This requirement is reflected in the revised § 319.56–2jj(j).

APHIS has received full cooperation from its Spanish counterparts in this matter, and is confident that they will ensure compliance with all aspects of this new regulatory approach. To clarify, during its site visit in December 2001, APHIS was not able to obtain documentation on trapping and bait sprays in clementine production areas not because the documentation did not exist, but because there was no central repository for the documentation, and because it took some time for the Spanish to assemble the appropriate records and forward them to APHIS. In January/February 2002, during a second site visit, APHIS received all documents requested and these were incorporated into the risk management analysis.

Furthermore, given that we believe trapping is not precise enough to accurately determine infestation levels of fruit, while fruit cutting is, we do not agree that there is a need for the Government of Spain to service and monitor all traps and apply bait treatments. The Government of Spain is, however, responsible for maintaining trapping records for the program.

One commenter stated that the rule does not say how that bait treatment application rate gets determined, or by whom, or when the treatments will be applied. The commenter noted that, according to the RMA, the practice in Spain has been to spray when trapping results reach a rate of 0.5 flies/trap/day, yet APHIS has provided no justification for the 0.5 flies/trap/day trigger for spraying and the rule itself does not require it.

This final rule does not include a trigger for bait sprays in Spain because APHIS believes it is the responsibility of Spanish producers to provide a product that is minimally infested with Medflies. They may accomplish this through whatever bait spraying regimen that they deem appropriate, as we have designed a regulatory approach that simply requires fruit to be infested at low levels upon inspection prior to treatment. The RMA identified the 0.5 fly per trap per day trigger as a ''key phytosanitary measure,'' however, this designation is not appropriate, as the measure has no bearing on the calculations of risk contained in the RMA. We have revised the RMA to clarify this fact.

One commenter noted that the proposed rule specifies that traps must be placed in preferred Medfly hosts at least 6 weeks prior to the harvest of clementines. The commenter suggested that APHIS remove the word ''preferred.''

We agree with the commenter, as preferred hosts may not be available in all areas where trapping may occur, and we have removed the word ''preferred'' from § 319.56–2jj(c)(1) in this final rule.

Several commenters urged APHIS to maintain strict oversight of the Spanish clementine import program at all points in the system, and requested that industry representatives, university researchers, and State Government officials be included in the on-site review process.

As stated earlier in this document, the Spanish Medfly management program must provide that clementine producers allow APHIS inspectors access to clementine production areas in order to monitor compliance with the Medfly management program, and that all trapping and control records kept by the Government of Spain or its designated representative must be made available to APHIS upon request. APHIS will have inspectors working full time on the verification of the Spanish clementine import protocol—including inspections and production area monitoring. The inspectors will be present to conduct and monitor fruit cutting at the exporting port, and will be able to review records kept by the Government of Spain regarding its management program. Only APHIS personnel and personnel of Spain's plant protection service will be allowed to conduct fruit cutting. The salaries of APHIS inspectors are paid by APHIS, but the Government of Spain reimburses APHIS for those costs under the requirements of § 319.56–2jj(a).

APHIS does not see the necessity of including representatives of industry, university researchers, and State Government officials in site visits. We will, however, make it known to stakeholders when we are conducting a site visit, and will invite questions and suggestions that we will follow up on in Spain. Upon our return, we will make a report of our visit available to interested persons.

One commenter stated that APHIS should review documentation of the execution of Medfly trapping and population reduction sprays before fruit is moved into export channels.

APHIS is confident that review of documentation prior to the movement of fruit into export channels is not necessary because our risk management measures are designed to protect against the arrival of a mated pair of Medflies in the United States regardless of the actual infestation level in Spanish production areas. For this reason, we will monitor for compliance with Spain's Medfly management generally, but will not review the control activities of a given production area as a condition of export. As stated previously, we believe that fruit cutting is more accurate indicator of the population of Medflies in production areas than trapping.

Two commenters stated that the rule should require the establishment of buffer zones in Spain.

There is no scientific justification for requiring the establishment of buffer zones in Spain under this rule, as the clementine production areas in Spain are not Medfly-free areas. The approach that APHIS has designed accounts for the presence of Medflies in the production areas in Spain, and is intended to ensure that the prevalence levels remain low, so that fruit presented for export is minimally infested. Buffer zones would only be useful if Spain were trying to establish and maintain pest-free areas.

One commenter noted that the APHIS review team found that no fines or penalties were issued for noncompliance with the ''mandatory'' fruit fly detection and control program in place in 2001, yet the proposed rule does not specify any penalties for non-compliance with the proposed Medfly management program and does not require that the Spanish authorities impose them. The commenter questioned that, given their past record, why should the Spanish regulatory officials be relied on to enforce compliance with the Medfly management program?

APHIS agrees that it should have the authority to suspend growers from participating in the Spanish export program if the grower is not in compliance with our regulations, which, by extension, also require compliance with Spain's Medfly management program. To provide for this, we have added the following statement to paragraph (c) of the regulations: ''If APHIS determines that an orchard is not operating in compliance with the regulations in this section, it may suspend exports of clementines from that orchard.''

One commenter stated that the proposed rule does not require all orchards in a defined area to participate in the Medfly management program, yet individual clementine orchards in Spain are very small (0.5–2.0 hectares in size), and ''physical barriers to segregate [them] are limited to a ledge about 4 inches wide and 6 inches tall.'' The commenters noted that adult Medflies may be carried by the wind for 2.4 km or more, are reported to have migratory movements up to 72 km, and are known to fly up to 40 miles, and thus, can easily move from one grove to the next; these commenters stated that APHIS has not considered what happens when one grower plans to sell fruit to the United States and participates in the Medfly management program, while a neighboring grower does not.

As stated previously in this document, our regulatory approach is designed to ensure that clementines subjected to cold treatment are minimally infested with Medflies. Since all fruit submitted for export is sampled, and since fruit cutting will provide a means to reject fruit that is found to be infested, we do not believe that the proximity of approved orchards to nonapproved orchards is relevant to our calculations of risk.

One commenter stated that there should be an incentive to encourage Spanish growers to keep Medfly populations in check, such as requiring a previous season average of 1.5 percent infestation, or less, to ship to the United States.

The incentive for the Spanish to keep populations in check is simple: If they do not do so, APHIS will determine as much via fruit cutting, and will reject shipments intended for export to the United States.

One commenter requested that APHIS approve a pesticide for use in the Spanish export program.

We are considering the commenter's request, and will advise the commenter of our findings when our review is complete.

One commenter stated that APHIS should not specify the pesticides to be utilized in Spain's Medfly management program without consulting Spain's Ministry of Agriculture, especially considering that the use of this type of pesticide changes over time. The commenter stated that the regulations should simply state that acceptable pesticides are those approved by both APHIS and Spain's Ministry of Agriculture.

We agree with the commenter that any pesticide used in the Spanish Medfly management program should be approved by both APHIS and the Government of Spain, and have amended § 319.56.2jj(c)(1) in this final rule to reflect this change.

*Traceback*

Several commenters stated that APHIS's proposal to traceback to the orchard in the event of Medfly detection during fruit cutting is likely to be ineffective because (1) Spanish clementine production is comprised of thousands of small growers who often commingle their fruit with fruit of other small growers at the packinghouse which prevents any reliable traceback to the individual grower; and (2) the season for Spanish clementines is only a few months, so remedial action that would remove a grower from the export program for the remainder of that year would have few consequences for the grower, since the grower would have already shipped all or most of his fruit for the season by the time remedial action was taken. The commenters suggested that remedial action should be taken against the packinghouse, not the grower, and should affect the packinghouse's ability to export for the present and next shipping season, unless the packinghouse provides evidence that controls are in place to prevent further failure of the quarantine measures.

We disagree with the commenter. Under the new Spanish export program, packinghouses are required to ensure that fruit from one orchard is not commingled with fruit from others. In the odd event that traceback of an infested fruit does not lead to a single orchard (a single producer or a homogenous production unit), APHIS will continue traceback to next largest traceable unit. If this means that traceback can only go so far as a group of producers who have shipped fruit to the same packinghouse, then that entire group of producers will be subject to suspension from the program for the shipping season in the event that another infested fruit is traced to their orchard or their group of producers. It is therefore in the interest of Spanish producers to facilitate the accurate traceback of infested fruit to the orchard where it was produced. We believe it is appropriate to suspend only orchards from the program, and not packinghouses, as suggested by the commenter, because packinghouses have no significant role in mitigating any Medfly risk posed by exports. Orchard managers, however, are responsible for maintaining low levels of Medfly infestation in their orchards.

One commenter stated that if fruit is sampled before it is packed in cartons, carton labeling will not help in tracing back infested fruit.

Sampling typically occurs at the port of export, and in some cases, at the packinghouse after fruit have been boxed.

One commenter questioned whether, upon detecting live Medflies in clementines submitted for treatment, it is sufficient to remove just the single orchard (perhaps just a few acres in size) from the export program for the balance of the shipping season since adjacent orchards likely have the same Medfly problems.

As stated in response to previous comments, given our ability to determine infestation levels of fruit via fruit cutting, there is no need to penalize orchards that happen to be adjacent to orchards with higher pest populations. Adjacent orchards may employ very different Medfly treatment regimens, and we believe that inspection and fruit cutting provides sufficient evidence to determine that fruit is minimally infested, even if it is from an orchard adjacent to a highly infested orchard.

*Eradication*

One commenter stated that the Spanish clementine industry should be required to eradicate Medfly, not simply control it.

As stated earlier in this document, APHIS does not believe the Spanish have to be required to eradicate Medfly from their clementine production areas in order to export fruit to the United States, provided they can adequately mitigate the pest risk posed to the United States by their exports. The RMA supports the Secretary's determination that it is not necessary to prohibit the importation of clementines from Spain, provided that the clementines are subject to the requirements contained in this final rule.

Two commenters stated that, in the event of a Medfly outbreak, eradication strategies used in previous years will not be possible. The commenters suggested that APHIS has to take that into consideration in its analysis, as ''the next Medfly infestation in the

United States may end agriculture as we know it in the infested location.''

APHIS believes that it has sufficient tools to eradicate any new Medfly outbreaks. New technologies, including the use of sterile insects, make it possible to eradicate Medfly infestations in areas where chemical treatments are not acceptable.

*Regulatory Impact Analysis*

Several commenters noted that, in the Regulatory Impact Analysis (RIA), APHIS states that the ''probability of a Medfly introduction per forty-foot container equivalent is * * * 1.3E–12,'' and it references the RMA as the basis for this estimate. The commenters stated that the RMA shows the mean probability per shipment (or forty-foot container equivalent) to be 2.5E–5, and thus, in the RIA, APHIS incorrectly used a probability value that appears to be off by almost seven orders of magnitude—*i.e.*, the probability estimate used in the RIA is low by a factor of almost 10 million. The commenter claimed that as a result of this discrepancy, the RIA cannot support a finding that the rule would not have a significant economic impact on a substantial number of small entities. The commenters further stated that the RIA also incorrectly interprets the RMA as showing that the most likely infestation rate (based on the 5-percentile infestation rate from the Monte Carlo simulations) is 3.3E–3 percent (0.003 percent).

APHIS believes these comments highlight the fact that the discussion in the economic analysis regarding the infestation rate needs clarification. The first number mentioned by the commenter is the expected number of introductions [24] under the default model (see Table 4 of the RIA). It is not appropriate to compare the mean mated pair probability per shipment reported in the RMA, 2.50E–5, with the expected number of introductions. The RIA does not report a mean mated pair probability. However, the assumptions made in the RIA having to do with risks associated with potential Medfly introductions under the proposed rule are in scientific agreement with the information, data, and parameters reported in the RMA.

The objective of the RMA was to examine how the offshore risk mitigation measures in the proposed rule coupled with cold treatment might reduce mated pair probabilities per shipment in comparison to cold treatment alone. As such, the RMA employed wide ranges for several key parameters, including the infestation rate (the proportion of fruit infested with Medflies). The RMA estimated annual introductions under a worst case scenario, one in which fruit cutting and rejection of shipments did not occur and one in which parameters of the infestation rate distributions were specified conservatively. However, the regulations impose powerful economic incentives that will more than likely lead Spanish growers and exporters to manage Medfly populations and select fruit for export to the United States more effectively than was assumed in the risk analyses.

The other major difference between the RMA and the RIA was that the RMA simulated levels for the biological model's parameters, including the infestation rate, number of larvae per infested fruit, cold treatment survival rate, proportion of larvae reaching a suitable area, and larval viability, by drawing random numbers from probability distributions parameterized using available data (See Tables 4a through 4c in the RMA.) The RIA used expected values for all of the biological model's parameters and therefore employed a certainty-equivalence framework. The certainty-equivalence framework (values for biological and economic parameters were based on expected values) was used to estimate regulatory benefits and costs, based on the RMA and economic incentives facing Spanish parties from the proposed regulations.

The main difference between the RIA and the RMA was that the former estimated regulatory costs and benefits for a typical year and the latter estimated mated pair probabilities under a worst case scenario. In addition, the RIA incorporated the fruit cutting and inspection program in the estimation of mated pair probabilities and relevant information for use in specifying the infestation rate. If Medflies are detected in clementine shipments under the proposed preclearance program, shipments will be diverted to other cheaper markets and growers may lose the ability to take advantage of the much more lucrative U.S. market, which typically offers prices 20 percent higher than prices offered in the rest of the world. In addition, if too many shipments are rejected, the entire clementine import program may be suspended. As a result, exporters will more than likely choose shipments designated for the United States from regions in which growers experience below average infestation rates and in which growers manage Medflies very well.

Although the RIA uses a lower infestation rate, the two mated pair probabilities are not directly comparable, and the divergence is completely consistent with the assumptions of the RMA, the economic incentives facing clementine growers and exporters in Spain and the regulations.

Two commenters stated that the economic and social impacts associated with the proposed rule are not to growers alone, and that APHIS must consider the social and economic impacts to farm workers and their families, packinghouses and their employees, canneries and their employees, the trucking industry and their employees, ports of entry and their workers, and local rural economies.

The economic analysis for the proposed rule did not incorporate Medfly introduction costs on other industries that derive income from Medfly host crops because (1) there were no data to estimate these costs as most Medfly introductions occur in urban areas far removed from commercial agricultural production, and (2) the probability that a mated pair of Medflies could enter the United States via imported Spanish clementines is so low. The analysis for the final rule incorporates costs on these related industries.

One commenter stated that it is critical that USDA evaluate the numerous economic impacts of a Medfly infestation in addition to those impacts on the citrus industry. The commenter claimed that the economic impact analysis should address the fact that other crops are negatively affected by the Medfly, and estimate State eradication costs, quarantine costs, loss of domestic and foreign markets, and producer cultural impacts if Medfly is discovered on U.S. crops.

The economic analysis for the proposed rule incorporates these costs (See section 3.1 Costs Associated with the Proposed Rule, pp. 11–12). Mean costs of eradicating six recent Medfly introductions in 1997 and 1998, $10.93 million in 2000 dollars, which includes Federal and State expenditures, were used to estimate the impact of a potential Medfly introduction on U.S. Federal and State taxpayers. In addition, the analysis incorporates the expected impact of potential Medfly introductions on producers of Medfly hosts crops in the United States. In particular, the $3 million dollar economic impact on producers, during an introduction, includes individual monetary estimates associated with additional field sprays, post-harvest treatments, fruit losses due to yield loss

[24] Refer to the RIA (Sec. 2.1.4) for a discussion of the difference between mated pair probabilities per shipment and Medfly introductions.

and post-harvest treatments, and loss of export markets. The economic analysis did not take into account cultural impacts on producers, because such costs are difficult to quantify.

One commenter stated that the RIA does not specifically consider the effects of a Medfly outbreak on growers who employ IPM practices, and noted that the analysis focuses solely on the cost to the Federal Government should a mistake occur and the benefit to the consumer without any consideration to the impact on farmers, farms, farm workers, families, communities, and the industry.

The analysis incorporated eradication expenditures of Federal and State Governments, which are borne by U.S. Federal and State taxpayers, as well as costs borne by producers of Medfly host crops associated with additional field sprays, post-harvest treatments, fruit losses, post-harvest fruit losses, and loss of export markets during an introduction (See section 3.1 Costs Associated with the Proposed Rule, pp. 11–12). The economic analysis did not take into account potential disruptions of integrated pest management (IPM) programs, because the likelihood of such disruptions is small on average, though it may be large to individual growers. Most Medfly outbreaks in the United States occur in urban areas with little if any commercial crops present. In addition, APHIS uses environmentally friendly eradication techniques, including use of beneficial-insect friendly cover sprays and mass release of sterile adult male Medflies, practices which are completely compatible with IPM practices, and in emergency situations, malathion bait sprays, which are much friendlier to the environment than malathion cover sprays. As a result, current eradication programs, which are extremely successful in eradicating the Medfly, would more than likely not greatly impact the IPM programs of producers of Medfly host crops. The economic analysis for the proposed rule did not incorporate Medfly introduction costs on other industries that derive income from Medfly host crops. The economic analysis for the final rule discusses these costs and points out that, even if every dollar of farmer sales of Medfly host crops generated an additional 10 dollars in associated industries, inclusion of these additional costs does not affect the conclusions of the economic analysis, because the probability that a mated pair of Medflies could enter the United States via imported Spanish clementines is so low.

One commenter noted that the economic analysis for the rule states that the clementine export season runs from mid-September to late February, and stated that the season could actually extend beyond February.

Economic impacts associated with the proposed rule were based on annual data, which are independent of the length of actual shipping seasons. As a result, the fact that the shipping season could extend beyond February will not affect the analysis as written.

One commenter stated that the RIA cites sources and data indicating that imported clementines do substitute for domestic tangerines and that the price for tangerines is sensitive to clementine import volumes—*i.e.*, the price for tangerines goes up when clementine imports are stopped. That being the case, the commenter noted, it seems reasonable to expect that the converse would hold true as well—*i.e.*, the price for tangerines will go down when clementine imports resume, and this should be reflected in the RIA's analysis of competitive impact.

The analysis of the rate of substitution between Spanish clementine (clementine) imports and domestically produced tangerines (tangerines) conducted in the RIA indicates that clementines do not substitute for tangerines in a statistically significant sense (See 3.3.1 Domestic Tangerine Market, p. 17–19). Data examined from the Citrus Advisory Committee indicated that tangerine prices were higher in 2001 relative to 2000, during a period in which clementines were imported in 2000 but were not imported in 2001 due to the ban, but that price differences were not statistically significant. In addition, the coefficient estimate on clementine imports in the inverse demand curve for tangerines was negative, indicating clementines and tangerines may be substitutes; however, the coefficient estimate again was not statistically different from zero. That is, substitutability between clementines and tangerines was only apparent and potentially due to chance variation in the data. As a result, the substitutability between clementines and tangerines could not be confirmed scientifically. Because the substitutability could not be confirmed, more tangerines are consumed than clementines in the United States, and clementines have been imported historically, the RIA did not estimate economic impacts on domestic tangerine producers associated with lifting the ban on clementines under the new import program.

One commenter stated that the RIA's assumption that the total cost of a Medfly introduction to taxpayers and growers would be only $14 million ($11 million for taxpayers and $3 million for growers) is questionable. The commenter noted that an independent analysis by a University of California, Berkeley, economist estimated that a Medfly introduction in California would impose increased production and post-harvest treatment costs ranging from $316 million to $500 million, and that if Japan, Korea, Hong Kong, and Taiwan imposed an embargo on shipments of fresh produce from the affected areas, it would cost the California agricultural industry an additional $564.2 million in lost revenues.[25] The commenter noted that, due to multiplier effects, the independent analysis estimates the impact on the California economy would "amount to a $1.2 billion loss in income and a loss of 14,190 jobs," and stated that this estimate is consistent with historical experience: Twenty years ago, the 1980–1982 Santa Clara Medfly infestation cost $100 million to eradicate and an additional $100 million in lost sales due to embargoes on commodities grown within the quarantined zone.

Mean costs of eradicating six recent Medfly introductions in 1997 and 1998 ($10.93 million in 2000 dollars, which includes Federal and State expenditures) were used to estimate the impact of a potential Medfly introduction on U.S. Federal and State taxpayers. In addition, the RIA incorporates economic impact associated with a large Medfly introduction on producers of Medfly host crops in the United States. The $3 million economic impact on producers during a large introduction includes individual monetary estimates associated with additional field sprays, post-harvest treatments, fruit losses due to yield losses and post-harvest treatments, and loss of export markets (See 3.1 Costs Associated with the Proposed Rule, p. 11–12). The RIA did not incorporate potential impacts in other industries that derive income from Medfly host crops, including processors, canners, shippers, and export operations, because per introduction estimates of these costs were not available; however, the overall conclusions of the analysis are not affected when introduction costs are increased ten-fold from the $14 million specified in the RIA.

The independent analysis referred to by commenters estimates costs associated with Medfly becoming established in California, including those associated with additional

[25] Siebert, J. 1999. Update on the economic impact of Mediterranean Fruit Fly on California agriculture. Subtropical Fruit News. 7(1):16–18.

pesticide use, post-harvest treatments, loss of export markets, and losses in industries that derive income from Medfly host crops. As such, the analysis points out the devastating impacts Medflies can have on producers of Medfly host crops and related industries in California, as well as other regions that can sustain Medfly populations, in the event Medflies become established. APHIS also recognizes the fact that the Medfly is an extremely damaging pest of fruit and vegetable crops and that, if left unchecked, could potentially wreak enormous damages on agricultural producers and related industries. This is why APHIS has developed and instituted the Fruit Fly Cooperative Eradication Program.

However, we do not believe the costs identified in the independent analysis should be used to calculate expected losses to producers of Medfly host crops and associated industries resulting from a single introduction under the new clementine import program. This is because most Medfly introductions occur in urban areas and typically do not lead to long-run establishments that affect large agricultural production regions. Six recent Medfly introductions in Florida and California in 1997 and 1998, the same six introductions that were used to estimate Federal and State taxpayer eradication expenses in the RIA, were eradicated in an average 9.33 months, measured from the initial detection of Medflies to the release of affected areas from quarantine, and affected on average only 2.67 counties[26] Long-run establishments adversely affecting large production regions did not result from these recent introductions.

In addition, the eradication program has been improved considerably since the 1980–1982 Santa Clara Medfly infestation. The primary reason why the Santa Clara infestation was so expensive to eradicate, and expensive for agricultural producers, was because sterile males and sterile females were released and a required 100:1 sterile-to-fertile Medflies ''overflooding'' ratio was not met. Using the current Sterile Insect Eradication Technique (SIT), which has been greatly improved since 1982, careful population monitoring and use of cover sprays are used to reduce populations in quarantined areas to the required 100:1 sterile-to-fertile ratio before the release of sterile males only. APHIS is modifying its rearing facilities to only produce sterile males to allow for a more efficient and effective SIT system to reach the required 100:1 ''overflooding'' ratio. Sterile females are no longer released with sterile males in order to increase the likelihood that only sterile males mate with fertile females. Aerial cover sprays with spinosad, an environmentally- and beneficial-insect friendly compound, are used over affected agricultural production regions to reduce Medfly populations; ground applications of spinosad with backpack sprayers are used in urban areas. In emergency situations, APHIS may use malathion bait sprays, both aerially and using backpack sprayers and may release sterile males in amounts appropriate to achieve an expected 100:1 sterile-to-fertile individual ''overflooding'' ratio. As a result, Medfly introductions, should they occur in the future, will more than likely not lead to the devastating economic losses experienced in 1980–1982.

One commenter stated that the RIA has taken no account of the impacts that pesticide application would have in a variety of areas, including destroying beneficial insects used as part of IPM programs, creating farm worker safety issues, and raising concerns about pesticide residues on the treated produce. For example, the commenter noted, because many export markets have not set residue tolerance limits for newer (less toxic) pesticides like spinosad, growers interested in exporting their product would have to use older, more toxic pesticides (such as organophosphates). The RIA also fails to consider the impacts that would result from an erosion of consumer confidence in the quality and security of the U.S. food supply.

The RIA did not take into account potential disruptions of IPM programs because these costs will more than likely be small, on average. Most Medfly outbreaks in the United States occur in urban areas with little if any commercial crops present. In addition, APHIS coordinates the Medfly eradication program, uses environmentally friendly eradication techniques, including use of beneficial-insect friendly cover sprays (spinosad) and mass release of sterile adult male Medflies, practices which are completely compatible with IPM practices, and in emergency situations, malathion bait sprays, which are much friendlier to the environment than malathion cover sprays. As a result, current eradication programs, which are extremely successful in eradicating the Medfly, would more than likely not adversely affect the IPM programs of producers of Medfly host crops and create farm worker and environmental safety issues.

However, only the parent compound spinosad has been registered for use by organic farmers. The compounds needed to dilute the parent compound into a foliar mixture have not been registered for use by organic farmers. As a result, organic farmers would not be able to market their crops as organic in the event of a Medfly outbreak that required the use of a spinosad cover spray, even though the IPM program would not be adversely affected. The pesticide industry is currently working to get the compounds needed to dilute spinosad into a foliar mixture registered for use by organic growers.

The RIA incorporates costs associated with fruit losses due to yield loss, fruit losses due to post-harvest treatments, and losses of export markets in the calculation of losses potentially borne by agricultural producers in the event of a Medfly introduction. Because spinosad is registered for use by organic growers, spinosad residues will more than likely not affect market access for Medfly host crops in foreign markets, however, such crops might not be marketed as ''organic.'' The RIA does not incorporate ''impacts that would result from an erosion of consumer confidence in the quality and security of the U.S. food supply.'' Instead, the RIA incorporates costs associated with the value of affected commodities lost due to yield and post-harvest treatment losses. As for quality effects, we are aware of only two studies that estimate levels of pesticide residues on fruits and vegetables consumed in the United States, both of which report extremely low pesticide residues on produce (See ''The future role of pesticides in U.S. agriculture.'' (2000) National Research Council. National Academy Press. Washington, D.C., and a reference therein). Unfortunately, we are not aware of any studies that have examined quality impacts on food associated with Medfly introductions and, as a result, cannot incorporate quality impacts quantitatively. The economic analysis for the final rule discusses these costs.

One commenter stated that because of concerns by the U.S. Environmental Protection Agency (EPA) and opposition from the public, it is far from clear that growers and State officials would be permitted to undertake the aerial spraying of pesticides necessary to wipe out a Medfly infestation. If that proved to be the case, Medflies could become established in growing areas on a long-term basis, with enormous cost implications that the RIA does not even begin to consider.

[26] See APHIS. 1999. Exotic fruit fly infestations and eradications in the continental United States. Revised November 9, 1999. Riverdale, MD. P. 15–21.

Aerial spraying of spinosad is approved by EPA for use in production agriculture. In addition, ground application of spinosad using backpack sprayers is approved for urban areas. Further, the EPA has approved malathion bait sprays for emergency situations. Use of these technologies, in concert with the mass release of sterile adult males, has proven extremely effective in eradicating recent Medfly introductions, and APHIS is continuously striving to develop better more environmentally friendly eradication techniques. Because current technologies have proven so effective in eradicating recent Medfly introductions, it is likely that future introductions will not lead to long-run establishments of the Medfly. As such, the RIA incorporates costs potentially borne by Federal and State taxpayers and agricultural producers during an introduction under the assumption that the introduction is eradicated successfully.

Moreover, the RIA assumes that, should an introduction occur, it would occur in an agricultural production area, even though most introductions occur in urban areas. As a result, the RIA estimates Medfly introduction costs conservatively.

*Environmental Documentation*

One commenter noted that APHIS did not prepare an environmental impact statement (EIS) or an environmental assessment (EA) for the proposed rule, nor did it make a specific finding of no significant impact (FONSI). The commenter stated that since the RIA vastly underestimates the probability of a Medfly introduction, a finding of no significant impact based on the RIA would not be supportable. The commenter further stated that, because of the significant flaws in the RIA, there are serious questions as to the adequacy of APHIS's compliance with the requirements of the Regulatory Flexibility Act and the National Environmental Policy Act (NEPA).

We disagree with the commenter that our RIA is flawed, for reasons stated earlier in this document. APHIS did not prepare and EIS, EA, or FONSI for this rule because we have determined that this action fits within the class of actions identified in 7 CFR 372.5(c) as categorically excluded from further environmental analysis.

As noted in § 372.5(c), categorically excluded actions share many of the same characteristics as the class of actions that normally require EA's but not necessarily EIS's. The major difference between categorically excluded actions and actions that require EA's is that the means through which adverse environmental impacts may be avoided or minimized have actually been built right into the actions themselves.

We believe that this standard is applicable to the importation of Spanish clementines. In this case, we have designed a regulatory approach that results in a very low probability that a mated pair of Medflies could enter the United States via imported Spanish clementines. The only adverse environmental impacts that could be associated with the importation of Spanish clementines relate to the potential introduction of a pest via that commodity. As stated elsewhere in this document, we have determined that risks posed by all pests associated with Spanish clementines are mitigated via the measures employed in this rule. Hence, the means through which adverse environmental impacts are avoided has been built into the rule itself.

Nonetheless, APHIS has considered the environmental impacts associated with eradicating Medflies and other fruit flies from the United States in the event that they are introduced. This analysis can be found in: ''Fruit Fly Cooperative Control Program, Final Environmental Impact Statement'' (2001). (Available on the Internet at: *http://www.aphis.usda.gov/ppd/es/ppq/fffeis.pdf.)*

One commenter stated that APHIS has not discussed the expected economic and environmental impact of its proposal on Spain. The commenter claimed that there is no indication whether Spain would have the necessary resources to carry out an effective eradication and control program and no discussion of the environmental impacts that would occur in Spain in association with the requirements of the rule.

APHIS is not requiring Spain to eradicate Medfly, and therefore, there is no need to assess Spain's ability to carry out an eradication program. The RIA discusses expected economic impacts on Spain in sections 2 (Background) and 3.1 (Costs Associated with the Proposed Rule). The Spanish already have an extensive Medfly management program in place, and according to the RIA, the additional costs associated with following the new risk mitigations called for under the proposed rule were small when compared to the value of clementine exports. This indicates that Spain will have the necessary resources to carry out an effective control program.

We have also considered this rulemaking under the provisions of Executive Order 12114, ''Environmental Effects Abroad of Major Federal Actions,'' which ''represents the United States Government's exclusive and complete determination of the procedural and other actions to be taken by Federal agencies to further the purpose of the National Environmental Policy Act, with respect to the environment outside the United States, its territories and possessions.'' Inasmuch as virtually all impact-generating activities associated with this rulemaking will occur outside the United States, the provisions of this executive order may be said to apply. We believe, however, that this rulemaking is exempt from the procedural requirements of the executive order by virtue of the fact that Spain is participating with the United States and is otherwise involved in the action (see § 2–3(b) of the executive order) and because the action will not have a significant effect on the environment outside the United States (§ 2–5(a)(i)).

*Additional Specific Comments on the RMA and ORACBA Analysis*

One commenter provided a detailed critique of the RMA and the ORACBA analysis. The commenter's submission included analysis of some of the same data used in the ORACBA analysis to evaluate cold treatment and other elements of the model it uses. Several other commenters paraphrased or otherwise cited these comments in their own comments, so some of the points raised by the commenter have already been discussed in detail earlier in this document. We have made changes to the RMA in response to some of the commenter's points, as noted in detail below and elsewhere in this document. The net effect of these changes was an approximate 10-fold decrease in our original estimates of risk, suggesting that our original analysis overestimated the risk. The main reasons for the reduction in the revised risk estimates were due to initial overestimates of the effect of variability and due to overestimates in the proportion of a shipment that constitutes a hazard. Specific comments are addressed below.

**Failure To Correctly Account for Variability**

The commenter stated that the RMA fails to properly account for variability and uncertainty.

Conceptually, the difference between variability and uncertainty is clear. Variability refers to random variation that cannot be reduced through acquisition of additional information. Uncertainty refers to our state of knowledge and may be reduced through additional information. A number of leaders in the field of risk analysis have drawn attention to cases where maintaining a rigorous distinction between uncertainty and variability, if possible, may be helpful in risk management decisonmaking. For example, if the statutory decisional criteria is ''reasonable certainty of no harm,'' and this is administratively interpreted to mean protecting a hypothetical individual at the 99th percentile of the distribution of exposure to an environmental contaminant, then it may be useful to consider the uncertainty associated with estimating this percentile in the exposure variability distribution. In this context, performing so-called 2-dimensional uncertainty analysis in which variable and uncertain model inputs are separated can lead to statements such as, ''We are 95 percent confident that the individual at the 99th percentile in the exposure distribution does/not confront serious risk of illness.'' For evaluating the expected risk reduction potential of different risk management strategies, however, it is not clear that such a distinction between variability and uncertainty would be useful.

Furthermore, while the conceptual distinction between uncertainty and variability is clear, the separation can be somewhat artificial or vague in practice. Morgan [27] cautions that while variability and uncertainty are different and sometimes require different treatments, the distinction can be overdrawn. In many contexts, variability is simply one of several sources of uncertainty.[28] The National Research Council Committee that produced *Science and Judgment in Risk Assessment* [29] acknowledged complications that arise because uncertainty and variability work in tandem: Variability in one quantity can contribute to uncertainty in another, and the amount of variability is generally itself an uncertain parameter. Furthermore, this committee recognized that the lack of ''identifiability'' can frustrate efforts to partition variability and uncertainty. In the statistical sense, unidentifiability means that the parameters of a model cannot be estimated from the available information. For example, a single observation consists of a variability component (how this individual varies from the population mean) and an uncertainty component (*e.g.*, measurement error). If there are no matching replicates, a common problem in spatial or time series data, then it is impossible to empirically estimate the separate variability and uncertainty components. This problem has long been recognized, for example, in the field of geostatistics where it is referred to as the ''nugget effect,'' where geological variation at a scale finer than the separation between measurement sites cannot be distinguished from uncertainty due to the survey protocol. Although various procedures have been developed in an effort to partition the ''nugget'' into variability and uncertainty, these procedures are themselves subject to uncertainty. Attempts to model ''uncertainty about uncertainty'' can lead to infinite regress. More recently, the National Research Council [30] observed, ''[a]lthough the distinction between natural variability and knowledge uncertainty is both convenient and important, it is at the same time hypothetical. The division of uncertainty into a component related to natural variability and a component related to knowledge uncertainty is attributable to the model developed by the analyst * * * Modeling assumptions may cause ''natural randomness'' to become knowledge uncertainties, and vice versa.''

Nevertheless, an effort was made to determine whether there was substantial informational value of a two-dimensional uncertainty analysis in the case of the risk management analysis for Spanish clementines. The two-dimensional uncertainty is represented by a figure that is contained in Appendix 3 to the RMA, which includes more detailed discussion of this matter.

As indicated in the figure (and in the Summary Statistics table of Appendix 3 of the RMA report), the 95th percentile of the 1-dimensional analysis is approximately $2 \times 10^{-5}$ (1.99E–05). Given modeling results of the same order of magnitude ($10^{-5}$) and the presence of additional, unquantified uncertainties (*e.g.*, the probability of establishment of a Medfly colony, given one or more mated pairs arriving in a suitable location), the difference between the results is probably insubstantial and suggests that, at least in this case, the 2-dimensional analysis provides little more than additional complexity.

Inadequacy of the Chosen Model and Appropriateness of Assumptions

The commenter claimed that the model used to represent the movement of clementines to market appears to be oversimplified to the extent that it is likely to give misleading results. The commenter pointed out that many assumptions used in RMA may not be appropriate.

We agree that some assumptions used in the RMA are a simplification of the real system; however, we did not try to replicate the real system but rather to model it. We aimed to capture key elements that represent the system such that our analysis can be informative for decisionmaking. For example, the commenter notes that we assume, among other things, that all clementines are exactly the same. We acknowledge that not all clementines are the same, that not all larvae are the same, and that biological systems in general rarely come in identical sets. However, our intent was to describe the system in terms of its key elements (listed as C1 to C5 in the RMA model), and characteristics of these elements, while a simplification, were sufficiently descriptive to allow for rational, science-based decisionmaking.

Again, not all clementines are exactly the same, not all shipments are exactly the same, and there are no two boxes of fruit that are identical. However, we believe we have captured the key elements of variability in our simulation. That is, just because fruit are different, it does not follow that such will result in more or less fruit in a container, and thus, APHIS believes it has correctly described the variation associated with fruit in a container. Further, despite the fact that fruit are not the same and may be less or more suitable for a larva to complete development, APHIS believes that it correctly captures this interaction in its stated variation of survival of larvae in fruit to vary from zero to eight.

We agree with the commenter that the system itself and the marketing of fruit has been simplified in our model. We do not agree, however, that the system we used is an oversimplification, because we believe we have captured those elements that are essential to understanding risks posed by imported Spanish clementines. We further believe that additional specification and description of the system will result in lowered estimates of risk.

For example, the commenter stated that the division of the United States into areas that are strictly suitable and

[27] Morgan, G. 1998. Uncertainty Analysis in Risk Assessment. Human and Ecological Risk Assessment 4:25–39.

[28] Morgan, M.G., M. Henrion, and M. Small. 1990. Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis. Cambridge University Press, Cambridge.

[29] National Research Council. 1994. Science and Judgment in Risk Assessment. National Academy Press, Washington, DC.

[30] National Research Council. 2000. Risk Analysis and Uncertainty in Flood Damage Reduction Studies. National Academy Press, Wash., DC.

unsuitable was an oversimplification. We disagree. It is indeed a simplification, but it allows us to correctly and conservatively capture the essence of the risk. For example, the State of Texas as a whole is considered suitable (as are the entire States of Arizona, Alabama, Georgia, South Carolina, Florida, California). However, the northern part of Texas (*e.g.*, the ''Panhandle'') does not have conditions suitable for Medfly development. That area is arid, winters are cold, there are very few hosts available, and conditions are not suitable for Medfly to establish. Indeed, it is likely that only the areas of Texas that will support Medfly populations are areas where citrus [31] occurs.

The RMA's inclusion of the entire state of Texas (and other States with similarly diverse climatic conditions) as a ''suitable area'' is indeed a simplification. It is not, however, a simplification that would result in USDA's underestimation of risk. This and other similar simplifications employed by the RMA result in conservative estimates, not otherwise. For these reasons, we disagree that we have oversimplified the system.

The commenter stated that the RMA assumes that all areas can be exactly divided into exactly two classes: One hospitable to Medfly, the other completely inhospitable.

We believe the commenter's assessment is correct, but it fails to note that our assumption results in conservative expressions of risk. For example, most of the State of Texas is considered suitable for Medfly development. Yet this is likely an overestimate because suitable hosts do not commonly occur in northern Texas where fruit production is secondary and because the conditions in northern Texas are not climatically suitable for the development of Medflies. Texas is illustrative because large populations of another fruit fly, the Mexican Fruit Fly (*Anastrepha ludens*)(Mexfly) are common and have been trapped in large numbers in southern Texas for the past decade. The Mexfly is also considered more tolerant of cold than the Medfly. Despite its occurrence in south Texas, there never have been establishments (or damages of any kind) recorded outside of the southernmost tip of Texas where citrus is produced. This is empirical evidence, but there is the additional evidence that Medflies have never become permanently established in areas where citrus does not occur. Thus, the partitioning of the United States into areas suitable and unsuitable is an approach that results in conservative estimates because we have identified entire States as suitable areas, when, in reality, only small portions of those States have all the conditions that would provide for the establishment of Medfly.

The commenter also suggested that Medflies might emerge during shipment or transportation. We did not consider this a likely scenario because clementines are stored under refrigeration. Typical refrigeration dramatically slows or stops the development of these insects and thus the emergence during refrigerated storage and transport is not considered a significant system component.

**Shapes of Distributions/Construction of Distributions**

The commenter suggested that the shapes or constructions of certain distributions require refinement.

We agree with the commenter that one distribution and several parameters could be refined. However, our refinements reduced our estimates of risk. As such, we reviewed the distribution for component 1 (number of fruit in shipments). We had previously assumed that the fruit in a container would vary uniformly. The assumption of a normal distribution is better supported by the evidence. We thus changed the distribution used from a Uniform to a Normal, and that change is reflected in our final RMA.

We also chose to simplify our treatment of component 5 of the RMA (amount of fruit that ends up in suitable areas) in response to suggestions by the commenter. We had previously used a Pert distribution. In the final version, we used constants. We selected maximum values based on evidence. Constant values were used instead of distributions for component 5 because demographic trends represented by a maximum will make our analysis valid (in terms of demographic expectations) for at least a quarter of a century. Other distributions chosen for other components were considered appropriately described by the Pert distribution, as specified previously and were not changed. Changes were made to some of the values used.

For example, we previously had estimated that up to 15 larvae could occur in each fruit. We revised this value to eight maximum larvae based on the evidence provided by Santaballa 1999 and others. We also included the evidence from the proportion of fruit that is not consumed and is discarded from Wearing *et al.* and Roberts *et al.* This evidence was suggested by commenters and APHIS agreed that indeed most fruit is not discarded but is consumed and that it is important to analyze the fruit that constitutes a hazard. By virtue of being eaten, most fruit does not pose a risk of Medfly introduction. For that reason, we used the maximum value of discarded fruit (5 percent) reported in the evidence to determine what proportion of fruit that is shipped to suitable areas actually gets discarded.

We also agreed that our text noted that in estimating the probability of a mated pair in multiple containers, these had to ''coalesce'' in a given area. Whereas, we still believe that all containers of interest (because they may lead to fruit fly introductions) are limited to areas suitable to the Medfly, we clarified in our text that containers do not have to coalesce within a specific or relatively limited area. The estimated probability of a mated pair simply estimates the probability of a mated pair in multiple, independent containers. The commenter provided alternative ways to estimate the probability of a mated pair in multiple containers. In our final draft we continue to use the formula cited in the July 20, 2002, RMA because it is supported by several peer-reviewed scientific articles (*e.g.* Wearing *et al.*).

Finally, several commenters were reportedly confused by our presentation of multiple results. In the final version of our analysis, we present two endpoints: probability of a pair of flies in a single shipment and probability of a mated pair in multiple shipments to suitable areas. A third estimate (probability of a mated pair in all shipments to all areas) presented in the previous draft was eliminated because it did not contribute to our explanation.

**The Effects of Mitigation Efforts**

The commenter stated that separate Monte Carlo simulations are not representative of the modeled systems. He also noted that the separate simulations ''might be adequate, if the outputs computed are related to quarantine security.''

This comment implies that our approach is only appropriate if we pre-specify a given level of quarantine security or appropriate level of protection and compare our results to that level. As stated elsewhere in this document, that was not the intent of the RMA. The simulations modeled two independent situations; one represents a baseline and employs cold treatment but not field controls, and the other employs cold treatment and field controls.

[31] Citrus is used here as an indicator species, and we acknowledge that it is not the only Medfly host.

We did not attempt to relate our output to pre-set levels of quarantine security in the risk mitigation document. That is, in examining the probability that a mated pair of flies could be associated with single or multiple shipments, we did not have in mind a pre-set level that would be considered appropriate. We simply conducted the analysis, used the simulation process to express our understanding of the variability, and reported our results in terms of the probability of a mated pair in containers of clementines (single and multiple).

**Cold Treatment—Extrapolations From Available Evidence**

The commenter states that Baker (1939) and Phillips *et al.* (1997) show that under different conditions (*e.g.*, in different fruit) different treatments are required to achieve the same mortality. This is speculative, however. Baker (1939, Fig. 3) indicates different probit slopes for the response of larvae in all fruits tested vs. the response of larvae in all fruits except kamani nut, but the statistical discussion is insufficient to determine whether the differences are statistically significant. The reported differences also may be due to the failure to control for the differential cooling rates among fruits. This factor is controlled for by the T107-a treatment schedule, which requires that treatment time begins once the internal temperature of the fruit has reached the designated temperature. Phillips *et al.* (1997) raises the possibility that ''host fruit may influence mortality of fruit flies exposed to cold treatments,'' but provides no test of this hypothesis. The hypothesized host effect ignores the possibility that variation in larval response to cold treatment within fruit species is comparable to the variation between fruit species. It is equally plausible that reported differences among studies are due to variation among Medfly populations used in different studies or due to different rearing or inoculation methods used prior to cold treatment. The situation is also clouded by the inability—at treatment efficacy levels in the neighborhood of probit 9—of empirically separating variability in response due to different experimental methods and materials (which are unique for each trial) from the uncertainty in the true but unknown proportion of survival. The RMA plausibly assumes that uncertainty dominates variability under the treatment conditions and commodities relevant to T107-a.

The commenter also indicated that the ORACBA analysis has ''probably included'' a 2-day cooldown time. The analysis assumes compliance with the T107-a treatment schedule, which specifies that the duration of treatment begins once the internal fruit temperature has reached the specified treatment temperature.

**Outputs and Metrics Used for Comparison**

The commenter noted that our analysis evaluates the wrong outputs. Specifically, the commenter argues that a realistic estimate would evaluate the risk that all containers are shipped to all areas.

We disagree that risk is posed by containers sent anywhere in the United States. Most fruit that is directed away from suitable areas will encounter conditions that will not support Medfly development and establishment. We have however, reassessed our presentation of outputs in the final version of the risk mitigation analysis. We have clearly indicated that our output is expressed in terms of the mean and 95th percentile of the distributions. We have also noted that our output emphasizes an endpoint describing the probability of a mated pair in a container or in multiple containers to suitable areas.

**Unjustified Extrapolation**

The commenter noted that the RMA states that the risk posed by other Spanish citrus may be similar to that of clementines. The commenter claimed that the findings of the RMA might not be applicable to other commodities.

APHIS believes that although the RMA addresses clementines specifically, the risk from other Medfly host citrus from Spain may be comparable, though there are some specific differences. Other citrus are similar, but larger, and thus fewer fruit would be contained in shipments, though the number of pests per shipment may be similar.

Regardless, as a matter of policy, before allowing the importation of another type of citrus from Spain, APHIS would conduct additional risk analyses in support of such a proposal. A new commodity import request would be subject to the rulemaking process.

**Analysis of Cold Treatment Data**

The commenter questioned the kind and nature of data used in the ORACBA analysis.

The time-temperature response surface model presented in the ORACBA analysis was based on data reported by Back and Pemberton [32] (Table 1). The cold treatment temperatures directly relevant to the T107-a cold treatment schedule are in the 32–36 °F range. The ORACBA analysis correctly listed the cold-storage temperature levels that were included in the analysis, with the temperature data coded as indicated in parentheses: 32 °F (0 °C), 32–33 °F (0.28 °C), 33–34 °F (0.83 °C), 34–36 °F (1.67 °C), 36 °F (2.22 °C), and 36–40 °F (3.33 °C). The ORACBA analysis also indicates that the final storage temperature level (36–40 °F) was included to inform the high temperature and long duration regions of the response surface.

The commenter points out, however, that the ORACBA analysis was unclear about the data that were used in this portion of the analysis. Six—not five, as indicated by the ORACBA analysis—cold storage temperature levels were included in the analysis.

The ORACBA analysis indicated that data from the 40–45 °F treatment level were excluded from the analysis but failed to indicate that data from the 38–40 °F treatment level were also excluded. The ORACBA analysis indicates that the rationale for excluding these data from the analysis was to limit the effect of independent variable measurement error (*i.e.*, treatment temperature) on the multiple regression analysis. Therefore the data used in the response surface analysis remain unchanged and are limited to the temperate range most relevant to the T107-a treatment schedule.

**Analysis Methods**

The commenter stated that the ORACBA analysis did not describe the procedure used to empirically estimate the extra-binomial dispersion about the cold treatment response surface model.

The extra-binomial dispersion was estimated to relax the default logit regression assumption that the errors about the model are binomially distributed. This estimate was obtained by dividing the deviance goodness of fit statistic by its degrees of freedom. Incorporating the extra-binomial dispersion does not affect the maximum likelihood estimates obtained for the regression model parameters; therefore, the model predictions are unaffected. Failing to correct for over-dispersion, however, causes underestimation of the standard error of the parameter estimates and would have resulted in overstating the statistical significance of

[32] Back, E.A. and C.E. Pemberton. 1916. Effect of cold-storage temperatures upon the Mediterranean fruit fly. Journal of Agricultural Research 5:657–666.

the model inputs. The ORACBA analysis (Table 2) indicates that the response surface model inputs of time and temperature remain statistically significant after allowing for extra-binomial dispersion.

**Observed Trends in Data**

The commenter, after re-examining cold treatment data, stated that ''binomial uncertainties are insufficient to explain the variations from the proposed model.''

Using the same logit model used in the ORACBA analysis, the commenter indicates a slightly longer predicted time to achieve the probit 9 level of security than presented is presented in Figure 1 of the ORACBA analysis. This difference appears to be due to the inclusion by the commenter of the data reported by Back and Pemberton for 38–40 °F treatment level that was excluded by the ORACBA analysis for the reasons indicated above. (Note that the commenter's analysis represents the logit of probability of survival evaluated using base 10 logarithms so that the probit 9 level of security (a $3.2 \times 10^{-5}$ probability of survival) takes a value of $^{-}4.5$ logits.)

Based on Figure 3.1 of his comment, the commenter judges that the binomial confidence bounds are insufficient to explain the variations from the proposed logit model. As indicated above, however, the ORACBA analysis estimated the extra-binomial dispersion about the logit model. Figure A below presents the Back and Pemberton data with the model fit according to the ORACBA analysis and extra-binomial confidence bounds. Therefore, not only was the model statistically significant, but based on Figure A, the fit also appears reasonably good. Note that the confidence bounds in Figure A represent uncertainty about the true mean response only (*i.e.*, logit model parameter uncertainty). The confidence interval for the mean response is a range of plausible values for the average of all responses at a given treatment level. The bounds in Figure A do not represent a prediction interval for an individual response, *i.e.* a range of plausible values for any single observation at a given treatment level. The latter is typically much broader than the former because it must account not only for uncertainty about the mean but also for individual random variation about the mean response for the population. Therefore a prediction interval for Figure A would envelope more of the raw data. Only approximate methods are available to estimate prediction intervals for non-linear models, however. The y-axis in Figure A represents the logit of the probability of survival evaluated using the natural logarithm so that the probit 9 level of security takes a value of $^{-}10.3$ logits. As indicated by Figure 3.1 provided by the commenter, one way of graphically presenting zero and 100 percent observed responses is to represent them by error bars that run off the bottom and top of the graph, respectively. Zero and 100 percent responses reported by Back and Pemberton have been omitted from Figure A below to ease visualization. The curves presented in Figure A have also been truncated to avoid extrapolation beyond the range of experimental observation.

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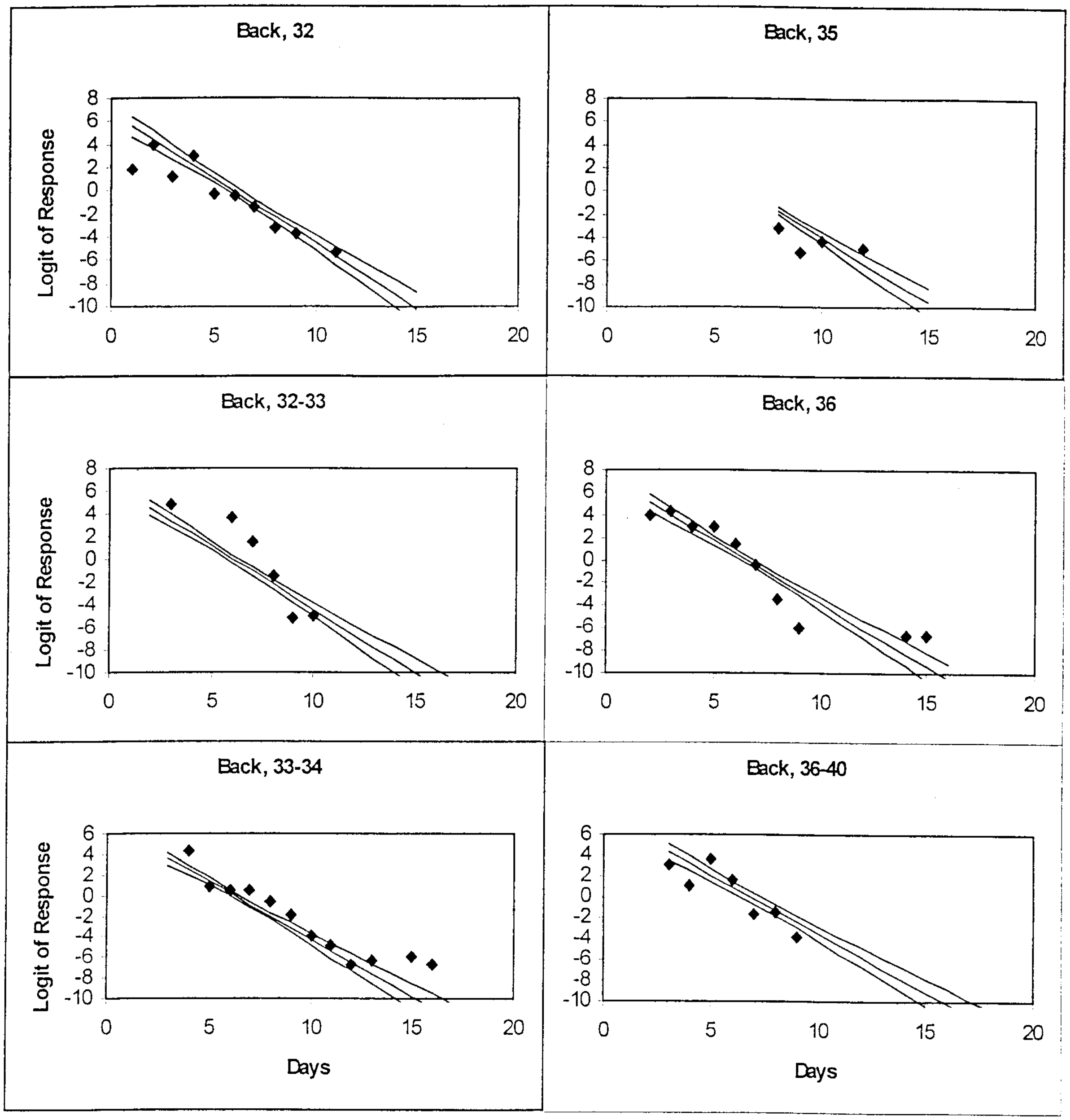
Figure A. Back and Pemberton(5) data, with model fit and confidence bounds.

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Models for Time and Temperature Response

The commenter seems to suggest that only one model form was considered in the ORACBA analysis (in equation 1), and that other link functions and data transformations were not entertained. The ORACBA analysis states, however, that in developing the response surface model, it considered three generalized linear model link functions: The logit, normit, and complementary log-log. Each was fit with and without a logarithmic transformation of time and temperature. Among the models considered, the model based on the untransformed data and the logit link function in equation 1 was selected on the basis of statistical goodness-of-fit criteria.

The commenter suggests that the response surface model developed for the ORACBA analysis is flawed because it fails to take account of both variability and uncertainty. The response surface model, however, represents only a portion of the quantitative analysis of the efficacy of cold treatment. As indicated, the response surface model based on the Back and Pemberton data is not intended to elaborate the definitive model of Medfly larval response to cold treatment. Instead, the primary aim of the analysis was to corroborate whether the existing cold treatment schedule fails to achieve the intended level of protection. To that end, the robustness of the model was assessed. To do this, response surface model predictions (point estimates omitting the unexplained variance consisting of variability and uncertainty) were compared with confidence intervals constructed about the independent results of more recent Medfly larvae cold treatment trials conducted under similar time-temperature combinations, as well as recent surveillance of shipping operations. In this manner, the complete quantitative analysis did take into account both variability and uncertainty regarding the response of Medfly larvae to cold treatment.

As indicated above, the inclusion of the Back and Pemberton data for the 38–40 °F treatment level explains the lack of correspondence between the parameter estimates obtained by the commenter and those reported in the ORACBA analysis.

The commenter stated that it is unclear why a linear effect of temperature was chosen in the response surface model used in the ORACBA analysis. The logit regression analysis assumes a linear relationship between the independent variables and the logit of the observed response. A separate (unreported) analysis testing this assumption rejected the hypothesis of no linear relationship between the logit of survival and temperature. This is consistent with the finding of the commenter that a linear variation between temperature and the logit of response may not be ruled out.

The commenter presents analysis of ‘‘the published data of Baker’’ on Medfly; however, Baker [33] only presents figures summarizing data analysis, not raw data. Therefore, it is unclear how the commenter acquired and analyzed the data. Furthermore, Baker seems to have excluded data from treatments where no larvae survived on the basis that the lack of survival was regarded as ‘‘not valid experimental information.’’ Without full disclosure of all data, it difficult to judge the analysis.

Based on a regression analysis of data reported by Santaballa *et al.*,[34] the commenter estimates that more than 18 days of cold treatment at 2 °C (35.6 °F) would be required to achieve the probit 9 level of security. This result, however, derives from the assumed statistical model form. Both Figure 3.5 provided by the commenter and Figure 3 of the ORACBA analysis indicate a high level of confidence that a 16-day cold treatment at 2 °C (35.6 °F) provides a high level of confidence of achieving the probit 9 level of security. This observation illustrates that for the purposes of revising the regulatory cold treatment schedule, elaborating a regression model relating time and temperature to survival needs to be interpreted cautiously. The ORACBA analysis notes that uncertainty remains regarding what statistical model form best describes the observed cold treatment data. The biological mechanism of larval mortality due to low temperature is not well understood, but if a critical physiological point exists (*e.g.*, beyond which cell walls rapidly lose integrity), this might suggest using a discontinuous (*e.g.*, splined) model form. Many discontinuous surface modeling approaches suffer, however, from a distinctly ad hoc flavor.

The regression modeling approach employed by the commenter, however, is not the only valid approach to evaluating the efficacy of phytosanitary risk reduction measures. Instead of relying exclusively on a regression results that are contingent on the assumed model form being correct, the ORACBA analysis provides an approach whereby the efficacy of discrete time-temperature combinations (more recent experimental trial and surveillance results) are characterized by constructing confidence intervals obtained assuming only that the probability of larval survival is beta distributed (*i.e.*, arises from a binomial process, as assumed by the commenter's analysis). This approach makes no assumption about the underlying form of the relationship between cold treatment response and time or temperature (*e.g.*, it does not assume that a logit, normit, or complementary log-log data transformation will be linearizing). Thus, limiting the analysis to discrete treatments within the range of time-temperature combinations relevant to regulatory decisionmaking has the advantage of relaxing or simply avoiding the far more numerous statistical assumptions inherent to regression analysis methods. This is of particular concern because predictions at the extremely low survival levels relevant to phytosanitary programs may be dominated not by the observed data but by the assumed statistical model form. For example, a heavy-tailed distribution may fit the data as well as a light-tailed distribution, but the predictions at very low survival levels will differ substantially due to differences in the assumed model form. In this case, therefore, simple data analysis making modest, justifiable assumptions may be preferable to elaborate regression modeling which inherently invokes numerous, often untestable, statistical assumptions.

**Miscellaneous Points**

The data presented in the ORACBA analysis (Table 4) correctly identify the data for more mature or cold-tolerant larvae used in the analysis. Note the discussion in that analysis regarding the indeterminate evidence regarding the most cold-tolerant larval stage.

Regarding the methods used in the ORACBA analysis for obtaining the beta distribution parameter estimates, both the method of matching moments and the parameterization suggested by the commenter are commonly used in the peer-reviewed literature. Some analysts prefer the method of moments because it obtains a beta distribution with an expected value equal to the sample mean and does not require specifying a subjective prior distribution, which is implicit in the parameterization

[33] Baker, A.C. 1939. ‘‘The Basis for Treatment of Products Where Fruit flies are Involved as a Condition for Entry into the United States.’’ Circular No. 551 US Department of Agriculture, Washington, DC.

[34] Santabella, E., R. Laborda, and M. Cerda. 1999. ‘‘Informe sobre tratamiento frigorifico de cuarentena contra Ceratitis capitata (Wied) para exportar mandarinas clementinas a Japon.’’ Valencia, Spain, Universidad Politecnica de Valencia.

recommended by the commenter. The method of moments is limited, however, in that it cannot handle zero values for r, the number of survivors observed after treatment. Therefore, the ORACBA analysis employed the method of moments except in the case where r=0.

The commenter criticized the treatment of zero proportion observations as ''bizarre'' and ''misleading,'' but they follow directly from the beta distribution parameterization that he recommends. Zero value observations in the ORACBA analysis (Figure 4), for example, are presented as the median of a beta distribution parameterized as $\alpha$=r+1, $\beta$=n − r+1. It is well recognized that estimated proportions of 0 and 1 pose special difficulties for variance estimation and calculation of confidence intervals. The commenter takes a bounding estimation approach to the problem that handles the ''special case'' of r=0 or 1 by logical reasoning. This reasoning becomes more compelling, however, as the sample size (n) grows larger.

For the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

**Incorporation by Reference**

This final rule requires clementines from Spain to be cold treated in accordance with treatment T107-a of the PPQ Treatment Manual, which is incorporated by reference at 7 CFR 300.1. On October 15, 2002, we published in the **Federal Register** an interim rule (APHIS Docket No. 02–071–1) that revises treatment T107-a and other cold treatment schedules and updates the incorporation by reference for those treatments.

**Effective Date**

This is a substantive rule that relieves restrictions and, pursuant to the provisions of 5 U.S.C. 553, may be made effective less than 30 days after publication in the **Federal Register**.

We are taking this action in response to a request from the Government of Spain and after determining that the restrictions described in this final rule will reduce the risk of introduction of Mediterranean fruit fly and other plant pests associated with the importation of clementines from Spain.

Immediate implementation of this rule is necessary to provide relief to those persons who are adversely affected by restrictions we no longer find warranted. The shipping season for Spanish clementines begins approximately in mid-September. Making this rule effective immediately will allow interested persons to begin shipping Spanish clementines to the United States as soon as possible after that time. Therefore, the Administrator of the Animal and Plant Health Inspection Service has determined that this rule should be effective upon signature.

**Executive Order 12866 and Regulatory Flexibility Act**

This 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 final 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 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**

In our analysis, we report estimates of regulatory benefits and costs for importers, wholesalers, retail consumers, federal and state taxpayers, and Medfly host crop producers in the United States. Regulatory benefits associated with U.S. imports of Spanish clementines and regulatory costs associated with potential Medfly introductions are estimated using an economic model, which incorporates salient features of Medfly biology, Medfly field control in Spanish groves, and fruit cutting and inspection procedures in the regulations. We estimate regulatory benefits and costs with and without limited distribution imposed, while focusing on the latter under the assumption that limited distribution will not be imposed after the first shipping season during a typical year. Regulatory benefits and costs for a typical year in the near future are estimated relative to the ban (baseline one), because the ban is currently in effect, and relative to the previous import program (baseline two), because this provides a useful benchmark for measuring relative benefits and costs.

The economic analysis for the proposed rule (APHIS 2002a) used a certainty-equivalence framework (values for biological and economic parameters were based on expected values) to estimate regulatory benefits and costs, which was based on the risk analysis for the proposed rule (APHIS 2002b), the proposed regulations, and economic incentives facing Spanish parties. Because key biological and economic parameters will likely vary from expected values on an intra- and inter-seasonal basis and, more importantly, because the model is nonlinear in these parameters, we use Monte Carlo simulation to examine benefits and costs in the current analysis, following the approach taken in the risk analyses. Other than this change, as well as some changes in additional default biological parameters, the current analysis is very similar to the economic analysis for the proposed rule. As such, the model used in the current analysis draws heavily from the economic analysis for the proposed rule and the risk analysis for the final rule (APHIS 2002c). In addition, public comments received on the economic analysis for the proposed rule indicated that the methods used to estimate annual Medfly introductions were not adequately explained. Therefore, we provide a detailed discussion of the biological model in the analysis accompanying the regulations, where, in the interest of transparency, we also provide the computer program used to estimate regulatory benefits and costs under the default model.

The results of our analysis indicate that regulatory benefits will outweigh regulatory costs relative to both baselines. Expected regulatory gains per year are roughly $207 million relative to the current ban (baseline one), including $118, $59, and $30 million in expected gains for importers, wholesalers, and consumers, respectively, with practically no increase in expected costs for federal and state taxpayers and agricultural producers in the United States associated with Medfly introductions. In addition, the regulations save an estimated $47,000 in annual Medfly introduction costs potentially incurred under the previous import program. Because import levels under the regulations will more than likely exceed import levels under the previous import program, net welfare associated with international trade in Spanish clementines under the regulations is expected to exceed net welfare under the previous import program by an average $23 million per year. That is, net regulatory welfare relative to the second baseline is $23 million per year.

*Regulatory Costs in Spain*

Regulatory costs in Spain include purchases of additional Medfly traps for producers, purchases of baits for the traps, monitoring and record keeping costs, additional bait spray costs, additional cold treatment costs, and trust fund expenses. Total annual trap and bait expenses for all Spanish growers under the regulations are only $660, or 8.39E–04% of average export market value during 1999 and 2000 ($78.69 million, FAS 2002). Total annual trust fund expenses for the Spanish government, or its agent, are estimated to be at least $90,000, including 16.15% administrative overhead (West 2002), or 1.14E–01% of average export market value during 1999 and 2000. Total annual cold treatment expenses for all exporters average $1.12 million (± $13 thousand) per year, which is 1.42% of average export value during 1999 and 2000, representing a significantly larger cost on exporters. Because the U.S. market is lucrative relative to markets in the rest of the world and because dramatic price declines in Europe associated with the Spanish clementine ban in the United States indicate that European markets are saturated at recent export levels, we assume that additional cold treatment expenses will not affect supply in the short run.

We were unable to estimate additional costs associated with monitoring and record keeping in Spanish groves, which producers will be required to pay; however, these costs will likely be low. 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. Because the preceding regulatory costs are low relative to the gross value of the U.S. market and because alternative foreign markets for Spanish clementine growers appear to be saturated at recent export levels, we assume that export supply is perfectly inelastic with respect to U.S. import prices. As a result, marginal production and export costs borne 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. Furthermore, assuming inelastic supply allows us to estimate clementine import levels and therefore Medfly introduction costs conservatively, the latter of which increase with import levels.

**Fruit Cutting and Rejection Costs**

Fruit cutting and rejections of inspectional units in Spain and fruit cutting in the United States reduces U.S. clementine imports by an average 4.91% under the default model (0.99% of average export value for 1999 and 2000), leading to reductions in revenues for importers and wholesalers, consumer benefits, and expected Medfly introduction costs. Fruit will be cut and inspected in Spain at a rate of 200 clementines per inspectional unit, which can include as many as 555 pallets, with exporters choosing the size of the inspectional unit. Losses may also include rejections of inspectional units, where the rejection rate will depend on the proportion of fruit that is infested with Medflies in inspectional units (the infestation rate). A fruit cutting and rejection program occurs at the U.S. port. The economic model incorporates the effects of the fruit cutting and inspection programs in Spain and in the United States, including the rejection of inspectional units, on U.S. import levels and therefore on regulatory costs and benefits.

**Medfly Introduction Costs**

Because current techniques and technologies used by APHIS have proven safe and effective in eradicating recent Medfly introductions and because most introductions occur in urban areas, we assume that introductions associated with Spanish clementine imports will not lead to long-run Medfly establishments in the United States. Annual Medfly introduction costs are given by the product of the expected number of introductions and an estimate of the cost of one introduction. We use the mean cost of eradicating six recent Medfly introductions in California and Florida during 1997 and 1998 in 2000 dollars, rounded up to $11 million, as our measure of federal and state taxpayer costs per introduction (APHIS 1999). Additional costs borne by producers of Medfly host crops during an introduction (additional field sprays, post-harvest treatments, fruit losses, post-harvest fruit losses, and loss of export markets) are based on producer cost estimates for a large introduction ($2.56 million) rounded up to $3 million (Vo and Miller 1993). Total taxpayer and industry costs associated with a potential Medfly introduction are therefore $14 million in the default model.

Because eradication technologies are safe and effective and because most introductions occur in urban areas, Medfly introductions resulting from the importation of clementines from Spain will more than likely not lead to long-run establishments adversely affecting agricultural production regions in the United States. As a result, we do not incorporate all of the potential costs associated with a potential Medfly introduction for four reasons. First, we do not have data to estimate all of the potential costs. Second, in the aggregate these additional costs will likely not, on average, increase total regulatory costs significantly. At the same time, however, we recognize that some of these costs may be substantial for individual growers. Third, although most Medfly introductions occur in urban areas, we assume, for the purpose of estimating Medfly introduction costs, that any introduction occurs in a Medfly host production region in the United States. As a result, we may be overestimating Medfly introduction costs in the current analysis. Finally, even if we were to increase Medfly introduction costs by a factor of ten, regulatory costs would not increase significantly and the conclusions of the economic analysis would not be affected. (Please see subsection 2.1.3 Medfly Introduction Costs in the economic analysis accompanying the regulations for more detail on the specification of Medfly introduction costs.)

**Medfly Introductions**

The number of Medfly introductions per year is given by the product of the number of forty-foot containers imported into areas in the United States suitable for the development of Medfly offspring and the probability that at least one adult male and one adult female (mated pair) survive the export process, in discarded fruit, per forty-foot container. We recognize the fact that, for a Medfly introduction to occur, it will be necessary for mated pairs to survive in their new environments long enough to find suitable hosts, for females to oviposit eggs in fruits that are sufficiently mature, for eggs to survive heat, cold, parasitism and disease, and for the eggs to develop into larvae that survive to adulthood and reproduce successfully. The effect of these other variables on the ability of a mated pair to survive, reproduce, and spread would, in all cases, further reduce the likelihood that Medflies could be introduced into the United States. Because data were not available to estimate the effects of these variables on Medfly introductions, our estimates may overstate the number of Medfly introductions that may actually occur, leading to conservative estimates of Medfly introduction costs under the regulations and under the previous import program.

We estimate the probability that at least one mated pair survives the export process, in discarded fruit, for each forty-foot container that passes fruit cutting and inspection in Spain and in the United States, using the biological model reported in the risk analyses (APHIS 2002b, c). Importantly, the simulations incorporate likely variability in Spanish clementine export levels to the United States, which will contribute to variability in mated pair probabilities per shipment and therefore regulatory costs associated with Medfly introductions. Specifically, designated export quantities are drawn from a probability distribution with a minimum value of 83,631 metric tons, a most likely value of 90,032 metric tons, and a maximum value of 116,406 metric tons. The minimum value is based on the import quantity for marketing season 2000, the most likely value is based on the rate of growth in imports between marketing seasons 1999 and 2000, and the maximum value is based on the average annual rate of import growth during 1989–2000.

The risk analyses (APHIS 2002b, c) examined how the difference in maximum infestation rates under the regulations and under the previous import program reduces the probability of a mated pair entering the United States, specifying a very wide range for the infestation rate under the regulations and a relatively wider range under the previous import program. The risk analyses estimated annual introductions under a worst case scenario, one in which fruit cutting and rejection of inspectional units did not occur and one in which parameters of the infestation rate distributions were specified conservatively. However, the regulations impose powerful economic incentives that will more than likely lead Spanish growers and exporters to manage Medfly populations and select fruit for export to the United States more effectively than was assumed in the risk analyses.

If Medflies are detected in clementine shipments under the new preclearance program, shipments will be diverted to other cheaper markets and growers may lose the right to take advantage of the much more lucrative U.S. market, which typically offers prices 20% higher than prices offered in the rest of the world. In addition, if too many shipments are rejected, the import program will likely be suspended, leading to significant reductions in clementine prices received worldwide. As a result, exporters will more than likely choose shipments designated for the United States from regions in which growers experience below average infestation rates and in which growers manage Medflies very well. Further, although the risk analyses set the maximum infestation rate in Spanish groves at 1.50E–02 under the regulations in order to estimate mated pair probabilities conservatively, the infestation rate that suspends the import program is 1.60E–03 (0.16% fruit infested with Medflies) when the effectiveness of inspectors in identifying infested fruit is fixed at 75%. Because we estimate regulatory costs and benefits in the current analysis during a typical year, as opposed to regulatory costs and benefits under a worst case scenario, we set the maximum infestation rate at 1.60E–03, under the assumption that APHIS inspectors correctly identify an infested fruit 75% of the time. We believe that this specification of the maximum infestation rate is consistent with Spanish grower and exporter profit maximization under the regulations and therefore more appropriate for use in the current analysis. An implicit assumption made in the risk analyses is that APHIS inspectors never correctly identify an infested fruit in order to provide a conservative estimate of the number of potential Medfly introductions under the regulations. We base the 75% inspection efficacy on data reported in the risk analyses. (See subsection 2.1.2 Fruit Cutting and Rejection Costs in the economic analysis accompanying the regulations for information on the specification of inspection efficacy.)

In addition, according to sources cited in the risk analyses, the infestation rate in fruit received by Spanish packinghouses ranged between zero and 1.50E–03, with the latter being associated with poorly managed fields. The most likely infestation rate in the risk analysis was set at 1.00E–03, which is only 33 and 38% lower than the infestation rate associated with poorly managed fields (1.50E–03) and the infestation rate that suspends the import program (1.60E–03), respectively. In addition, the risk analyses state that the most likely infestation rate could have been set at zero, because live Medflies were never observed in Spanish clementine shipments during 1985–2000. Because the regulations provide strong profit incentives for Spanish growers to manage Medfly populations effectively and for exporters to choose clementines from Spanish groves that are not poorly managed, the most likely infestation rate will more than likely be lower than the specification in the risk analyses, which was chosen conservatively. We therefore set the most likely infestation rate equal to the most likely infestation rate specified in the risk analyses, 1.00E–03, multiplied by (1.60E–03/1.50E–02), the proportional difference between the infestation rate that leads to suspension of the import program and the maximum infestation rate specified in the risk analyses. (See subsection 2.1.4 Medfly introductions in the economic analysis accompanying the regulations for a more detail.) Again, we believe that this specification of the most likely infestation rate is consistent with Spanish grower and exporter profit maximization under the regulations and therefore an appropriate specification for the current analysis. However, we also estimate regulatory benefits and costs using the infestation rate distribution specified in the risk analyses in order to ensure the reader that the same biological models are used in the current analysis and the risk analyses and in order to examine regulatory welfare under the more conservative distributional specification.

Under the default model, that is, under typical Medfly pressure and effective field control in Spain, annual Medfly introduction costs in the United States average less than $10 per year, because the expected number of introductions is very low. Even when the infestation rate distribution is taken from the risk analyses (which do not consider economic incentives facing Spanish growers and exporters under the regulations and which set fruit cutting and inspection efficacy at 0%), introduction costs average less than $300 per year, with expected introductions per year remaining very low. Under the previous import program, Medfly introduction costs average roughly $47 thousand per year, which is 5.93E–02% of average export value during 1999 and 2000. These results indicate that expected Medfly introduction costs increase with the average infestation rate. However, the percent change in Medfly introduction costs for every percent change in the infestation rate (the infestation rate elasticity of introduction costs) declines as the infestation rate increases, because the rate inspectional units are rejected in Spain increases with the infestation rate. In addition, introduction costs stop increasing with infestation rates at or above the rate that leads to rejection of 100% of the inspectional units in Spain. Because the rate inspectional units are rejected increases rapidly with the infestation rate and because the import program will likely be suspended if too many units are rejected, the regulations will likely be effective in terms of preventing Medfly introductions into the United States, regardless of how high the average annual infestation rate may be.

**The 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% 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% per year during this period, even though clementine production in Spain grew only 2% per year (FAS 1996–2001, MAPA 1999). The phenomenal growth in exports to the United States has been due to increased demand, leading to higher 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% higher than prices offered by all other importing countries, providing incentives sufficient for exporters to ship an average annual 6% of total exports to the United States in 1999 and 2000.

Spain typically exports clementines to the United States during mid-September to mid-March. Morocco, Italy, and Israel also export clementines to the United States during this period; however, during 1996–2000, only 2 and 0.1% of U.S. clementine imports were from Morocco and Italy, respectively, and during 1998–2000, only 0.4% of U.S. clementine imports were from Israel. This suggests that exporters in these countries have not established export market infrastructures sufficient to enable significant 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 not clear whether clementine imports and domestically produced tangerines (*Citrus reticulata*) may be substitutes for U.S. consumers. Pollack and Perez (2001) have suggested that the two types of citrus may be substitutes; however, they did not estimate a substitution rate. We estimate 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. Substitutability between clementines and tangerines could not be confirmed statistically; that is, the analysis showed little substitution between domestic tangerines and clementines. In addition, there are differences between Spanish clementines and tangerines, which may be important for U.S. consumers. In particular, clementines are seedless and packaged in decorative wooden boxes; whereas domestically produced tangerines are generally not seedless and are marketed in bulk quantities. Moreover, U.S. consumption of domestically produced tangerines (233,147 metric tons) was almost three times higher than consumption of clementines (83,631 metric tons) in 2000. Finally, until the ban in the fall of 2001, clementines had been imported into the United States for 15 years. As a result, we do not estimate regulatory impacts on U.S. tangerine producers.

**Results of the Economic Analysis**

The results of the analysis indicate that regulatory benefits will likely outweigh regulatory costs relative to both baselines. Expected regulatory gains are roughly $207 million relative to the current ban (baseline one), including $118, $59, and $30 million in expected gains for importers, wholesalers, and consumers, respectively, with practically no increase in expected costs for federal and state taxpayers and agricultural producers in the United States. As a result, expected regulatory gains are much higher than expected regulatory costs relative to the current ban, because imports are positive and introduction costs are minimal under the regulations. In addition, due to the trend exhibited in the import data during 1989–2000, import levels under the regulations will more than likely exceed import levels under the previous import program. Furthermore, expected Medfly introduction costs under the previous import program are much higher than expected Medfly introduction costs under the regulations. As a result, net gains under the regulations are expected to exceed net gains under the previous import program by an average $23 million (baseline two), which is due almost entirely to higher imports under the former. (See chapter 3 in the economic analysis accompanying the regulations for a more complete discussion of regulatory welfare impacts.)

**Regulatory Effects on Small Entities**

The U.S. Small Business Administration defines a small agricultural producer as one with annual sales receipts less than or equal to $750,000. We do not know whether the majority of producers of Medfly host crops (NAICS 111310 Orange Groves, NAICS 111320 Citrus (except Orange) Groves, NAICS 111331 Apple Orchards, NAICS 111332 Grape Vineyards, NAICS 111333 Strawberry Farming, NAICS 111334 Berry (except Strawberry) Farming, NAICS 111335 Tree Nut Farming, NAICS 111336 Fruit and Tree Nut Combination Farming, and NAICS Other Noncitrus Fruit Farming) in the United States are designated as small entities. However, regulatory costs on producers of Medfly host crops will more than likely not be significant, because Medfly introduction costs are low under the regulations, regardless of Medfly pest pressure and field control in Spain. As a result, the regulations will likely not have a significant economic impact on a substantial number of small Medfly host crop producers in the United States.

There are approximately 15 Spanish clementine importers in the United States, three of which import the majority of clementines. In addition, individuals in foreign countries own at least two of the import companies in this list. It is not clear if the majority of U.S. clementine importers are designated as small entities by the SBA. These entities include fresh fruit and vegetable wholesalers (NAICS 422480) with 100 employees or less. In addition, the number of small wholesalers potentially affected by the regulations is not known. Small wholesalers include wholesalers 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 regulations will likely not have a significant negative impact on any small wholesalers relative to either baseline. In addition, small importers and wholesalers will likely be better off under the regulations relative to the current ban and, during growing seasons characterized by typical Medfly pressure in Spanish groves and effective field control, better off under the regulations relative to the previous import program.

As a result, the regulations will likely not have a significant negative impact on small importers relative to either baseline. Further, because import levels will more than likely increase under the regulations, the effect of the average 2.5 days of additional cold treatment expenditures borne by Spanish exporters, which recall amount to 1.42% of average export value during 1999 and 2000, will likely not lead to a significant price increase, even under the unlikely situation in which all of the additional cost is borne by U.S. importers. Because historical markets for Spanish clementines in Europe appear to be saturated at recent import levels, export supply to the United States may not be extremely elastic, at least in the short run, because U.S. prices will remain higher than prices in European markets under the regulations, and Spanish exporters will not be able to divert supplies to other markets in response to the extra cold treatment costs without experiencing concomitant price declines in those markets. As a result, Spanish exporters will likely export similar and increasing quantities of clementines to the United States, until such time that Spanish clementine production has a chance to respond to changes in the world market associated with the regulations. Finally, during growing seasons in which Medfly pressure is atypically high and field control is ineffective, a higher percentage of shipments designated for export to the United States may be diverted to other markets, reducing import levels, raising import prices, and reducing regulatory gains for small importers relative to the previous import program. In addition, because clementine imports will more than likely be lower during the first shipping season, small importers and wholesalers will likely not realize regulatory gains equal to the previous import program, as imports will more than likely be lower than earlier levels.

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

**Executive Order 12988**

This final rule allows clementines to be imported into the United States from Spain. State and local laws and regulations regarding clementines imported under this rule will be preempted while the fruit is in foreign commerce. Fresh clementines are generally imported for immediate distribution and sale to the consuming public, and 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. 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 the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0203.

**List of Subjects in 7 CFR Part 319**

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

Accordingly, we are amending 7 CFR part 319 as follows:

## PART 319—FOREIGN QUARANTINE NOTICES

1. The authority citation for part 319 continues 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.

2. A new § 319.56–2jj is 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 host plants at least 6 weeks prior to harvest. Bait treatments using malathion, spinosad, or another pesticide that is approved by APHIS and the Government of Spain must be applied in the production areas at the rate specified by Spain's Medfly management program.

(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.

(3) *Compliance.* If APHIS determines that an orchard is not operating in compliance with the regulations in this section, it may suspend exports of clementines from that orchard.

(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.* Boxes 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.'' For the 2002–2003 shipping season, boxes must also be labeled with the following statement ''Not for distribution in AZ, CA, FL, LA, TX, Puerto Rico, and any other U.S. Territories.'' All labeling must be large enough to clearly display the required information and must be located on the outside of the boxes 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 200 fruit that are randomly selected from throughout the shipment. 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 lots 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.

(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.

(i) *Limited distribution.* For the 2002–2003 shipping season, clementines from Spain may not be imported into, or distributed within, the following U.S. States and Territories: Arizona, California, Florida, Louisiana, Texas, Puerto Rico, the U.S. Virgin Islands, the Northern Mariana Islands, Guam, or American Samoa.

(j) *Suspension of program.* 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.

(k) *Definitions.*

*Lot.* A number of units of clementines that are from a common origin (*i.e.,* a single producer or a homogenous production unit [1]).

*Orchard.* A plot on which clementines are grown that is separately registered in the Spanish Medfly management program.

*Shipment.* (1) *Untreated fruit.* For untreated fruit, the term means one or more lots (containing no more than a combined total of 200,000 boxes of clementines) that are presented to an APHIS inspector for pre-treatment inspection.

(2) *Treated fruit.* For treated fruit, the term means one or more lots of clementines that are imported into the United States on the same conveyance.

*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.

(Approved by the Office of Management and Budget under control number 0579–0203.)

Done in Washington, DC, this 15th day of October 2002 .

**James G. Butler,**

*Acting Under Secretary for Marketing and Regulatory Programs, USDA.*

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BILLING CODE 3410–34–P

[1] A homogeneous production unit is a group of adjacent orchards in Spain that are owned by one or more growers who follow a homogenous production system under the same technical guidance.