

Risk mitigation for tephritid fruit flies with special emphasis on risk reduction for commercial imports of clementines (several varieties of *Citrus reticulata*) from Spain using a Phytosanitary Hazard Analysis and Critical Control Point (PHAACP) system.

United States Department of Agriculture – Animal and Plant Health Inspection Service

I. Executive Summary

This document examines risk mitigation measures to prevent the introduction of the Mediterranean fruit fly in imports of citrus from Spain. We used a Hazard Analysis and Critical Control Point (HACCP) approach adapted to phytosanitary or plant quarantine safeguards; specifically to evaluate how off site-measures coupled with cold treatments assured reduced risks compared to the use of quarantine cold treatments only. HACCP recognizes that there are multiple phases of a system. The different phases can be subject to varying kinds and levels of risk. The overall system includes the pathway (importation of citrus) that may result in pest introduction. The HACCP approach ensures a systematic examination of the hazards and the identification of controls (i.e., phytosanitary practices) of the overall system that result in mitigated risks. We analyzed the production system and characteristics of the pest; we then evaluated the different mitigation practices; finally, we identified critical control points and critical control limits. The latter clearly define how the proposed additional mitigation practices reduce overall risks. We conclude that two elements (critical control points) are fundamental to the successful reduction of risks associated with the importation of citrus from Spain: the limitation of the population of pests in the field such that the proportion of fruit infested is no greater than 1.5 percent and the application of quarantine cold treatments such that probit 9 mortality is achieved. Probit 9 refers to a treatment schedule that results in ca. 99.9968 percent mortality. This corresponds to a survival rate of 0.000032 (0.0032 percent) of all individuals exposed to a treatment that is said to achieve Probit 9 mortality. In addition, supplementary mitigation measures (e.g., surveys, port inspections, quality assurance, training, field controls, management of the pest in other hosts, US domestic fruit fly trapping, and others) provide additional safeguards that result in risk reductions that further diminish the potential effects of uncertainties and variability inherent in the system. The endpoint of our analysis showed that on average there is less than one infested fruit per shipment and less than 0.05 probability that a pair of fruit flies occurs in a given shipment. The calculation showed that even if all shipments for an entire year were combined, the likelihood of a mated pair was less than 0.27. This document concluded that proposed new mitigation practices (notably, assuring low field populations of fruit flies) reduced overall risk compared to the current system of cold treatments alone. Although this document addresses clementines specifically the risk from other citrus from Spain is comparable to that evaluated here because the pest complexes and risk mitigations practices are similar.

II. Introduction

This document evaluated the risk mitigation measures associated with the commercial importation of Spanish clementines. The approach is to first identify system components, evaluate pest attrition associated with each component, and to examine the effects of the combination of components (field practices, post-harvest treatments, and other safeguarding practices) in overall risk. We used a stochastic approach to analyze the percentage of infested fruit as it is managed with the procedures represented within each component. A stochastic approach is one that includes variability associated with a system. Variability is included by consideration of the range of possible values, in addition to mean or most likely value estimates for responses associated with each system component. The endpoint of this analysis was the average infested fruit per shipment and the probability that a pair of fruit flies occurred in a given shipment.

To emphasize components of the system that are of greatest safeguarding value and subject to control, we adopted some concepts from the area of food safety. Specifically we use concepts associated with a risk management approach developed by NASA, FDA, the Pillsbury Company and others called “Hazard Analysis and Critical Control Point” (HACCP) (Buchanan 1990, Corlett, 1991, Guzewich 1987, ICMSF 1989, NACMCF 1992, Pierson and Corlett, 1992). Thus, we identified critical control points and control limits, which we detail. The identification of these control points permits focus on those components that are key to the overall safeguards. The adoption of HACCP concepts provides a valuable framework and guidelines while not constituting a departure from existing procedures. A HACCP plan largely parallels “work plans” developed as part of regulatory procedures that allow commodities to move internationally.

Citrus from Spain has been exported to the United States for some fifteen years (Snell, personal communication). Events during 2001 (finding live larvae in shipments) led to the suspension of the rule that

allowed shipments to occur. Enhanced mitigations were outlined in an updated work plan. This work plan (D. West, personal communication), specifically limits populations of pests in the groves in Spain, in addition to existing required treatments (cold treatment). This document was motivated by revisions required to existing rules which must be based on a reassessment of the mitigations associated with this pathway. This document is part of the regulatory process; it evaluated whether the field mitigations proposed resulted in reduced risks compared to the existing (baseline) system.

III. Risk Analysis vs. Risk Management

The importation of clementines from Spain was based on evaluations of risk associated with this commodity. Regulatory authority for importation of citrus from Spain is described in 7 CFR 319.56. However, recent evidence suggests that the reliance on a single tactic, cold treatment T107, USDA 1998, which has previously been determined to provide quarantine security may not allow for some variances in the application of the tactic. This observation is based on the occurrence of live fruit fly larvae in fruit from several shipments of clementines (observed by USDA and state inspectors) in cold-treated fruit detected in shipments from Spain during 2001. The precise cause of the finds during 2001 are not well known but they may include an atypically warm year and very early season in Spain that allowed for early population buildup coupled with late season warm temperatures that exacerbated the problem. In addition to high field populations, variability in quarantine cold treatment may have also been a factor in the occurrence of live larvae after treatment. Variability in management procedures in different groves constitute yet another potential risk element. All of the known risk elements are being addressed with new mitigation practices.

The approach of USDA to address risk mitigation is multi-pronged: manage potential variation in the application of cold treatment with increased quality control at all stages but with particular emphasis on critical control points, and to address field population levels through a series of pre-harvest mitigation practices and fruit cutting with rejection of shipments if live larvae are found.

We chose a systematic approach to implement verifiable risk mitigation measures. Whereas, available risk analysis guidelines (e.g., USDA 2000) include descriptions for the assessment of risk, we have adopted and adapted additional guidelines, i.e. HACCP that specifically address risk mitigation. To distinguish our adaptation from the guidelines applicable to food safety, we use the name Phytosanitary Hazard Analysis and Critical Control Point (P-HACCP). We note that risk assessment guidelines (USDA 2000) focus on hazard identification and evaluation whereas the PHACCP procedures as adapted here emphasize control and risk mitigation. The adaptation of HACCP, described here as PHACCP is detailed in Appendix 1, most of the text was incorporated from the guidelines adopted by FDA with changes to reflect phytosanitary safeguards (<http://www.cfsan.fda.gov/~dms/hret-toc.html>).

IV. Description of Mediterranean fruit fly behavior and dynamics

The biological description of *Ceratitidis capitata*, the Mediterranean fruit fly or Medfly, presented here is not meant to be an exhaustive review but rather to emphasize characteristics of the pest that are key to understanding risk mitigation. The Medfly is a pest of fleshy fruits that occurs in tropical and subtropical area and is one of the most destructive fruit pests in the world, due to its broad host range, and its ability to survive and expand its range wherever establishment has occurred.

Medfly infests more than 250 types of fruits, flowers, vegetables, and nuts. Weems (1981) lists 42 host species as "heavily or generally infested", 15 species as "occasionally infested", 25 species as "rarely infested", 21 species as "laboratory infestations", and 153 species as "unknown importance". Liquido *et al.* (1991) report 180 genera, worldwide, as hosts for this insect.

Female Medfly oviposits up to 14 eggs below the skin of the host fruit (McDonald and McInnis, 1985), with the potential of producing up to 1000 eggs throughout its lifetime. Hatching occurs in 2-18 days, (depending upon the temperature), the three larval instars require 6-50 days, pupation occurs in soil, with adult eclosion in 6-60 days (EPPO, 1979; Weems, 1981).

Adults fly short distances but may be carried by wind for 2.4 km or more (PNKTO 18, 26; Weems, 1981). Steiner *et al.* (1962) have reported migratory movements of 40-72 km, and sustained over-water flights of 19-64 km. This insect is multivoltine, with 10-15 generations possible in warm climates (EPPO, 1979). Bodenheimer (1951) has recorded the following developmental ranges for various stadia: at 2°C: egg 9.7 days, larvae 53.6 days, pupa 79.1 days; 35°C: egg 1.0 days; larva 4.7 days; pupa 7.2 days; developmental zero occurred at 10.5°C, 9,8°C and 9.7°C, respectively, for egg, larva and pupa. Adult flies cannot live more than one to two weeks below 5°C.

In Spain, the Medfly has been known since the XIX century. Management procedures are necessary in most production areas and most years to reduce populations (Azcarate-Luxan 1996). Up to eight fly generations may occur in Spain and damage may be great if left unmanaged (Agusti 2000) but four to six are more common (Planes and Carrero, 1996). Management practices include the use of population monitoring, mass trapping, bait sprays, biological control and broadcast sprays (aerial and terrestrial) (Agusti 2000, Dominguez 1998).

V. Citrus production in Spain

Citrus production has been an important element of the Spanish economic sector since its introduction in the VII century; indeed, by the 1500s references to citrus production are common. There are records of large commercial citrus production from the area of Mallorca by the end of the nineteenth century that cite 30,000 ha of citrus, a large proportion of which were destined for exports mostly within Europe (Azcarate-Luxan 1996). Mandarins were introduced into Valencia from Italy in 1845 (Agusti 2000). Clementine varieties of mandarins have been known only since the 1950s in Spain with most of the recent varieties originating in the 1960s and 1970s (Agusti 2000).

Citrus is produced in different provinces bordering the Mediterranean Sea as shown in Figure 1. Approximately 271,000 ha are in production for both the domestic and export markets (MAPA 2001).

Production regions for citrus (in descending amount of surface area dedicated to citrus, in hectares) include (MAPA 2001): Valencia: 183,000; Andalucia: 45,000; Murcia: 33,000; Cataluna: 6,300; Baleares Islands: 2,300; Canary Islands: 1,300.

Citrus production in Spain continues to focus on a large export market. Spain exports large quantities of citrus to most of Western and Eastern Europe, Russia, Argentina, Australia, Brazil, Canada, United States, and Iceland. Exports from Spain to the United States date from 1985 (W. Snell and D. West, personal communication). Exports from the 2001 season were interrupted by reports of live larvae in fruit mostly in US distribution outlets. Exports worldwide were 1,248,515 tons in 1994 and 1,121,162 tons in 1996. Total mandarin (including clementines) exports to the United States totaled 12,848 tons in 1994; 15,172 tons in 1995, 23,107 tons in 1996 (MAPA 1999). During the 1999-2000 season, exports to the United States were approximately 80,000 tons (source: Appendix 2).

VI. Description of Medfly population dynamics

The exact date of introduction of the Medfly into Spain is unknown, however there are records of this pest from the nineteenth century (Azcarate-Luxan 1996), although its introduction likely pre-dates that period. The Medfly is reportedly common along the Mediterranean coast (Dominguez 1998). Dominguez (1998) states that reports of Medfly from the interior are largely due to the movement of produce from coastal areas. He notes that there are no damage reports from Castilla La Vieja and that the colder regions in the Central and inland portions of Spain probably are not suitable for the continuous presence of the Medfly.

Agusti (2000) reports up to eight generations possible depending on the weather. Planes and Carrero (1996) report from four to six as more common. Hosts in Spain include peaches, apricots, pears, persimmons (“caquis”), oranges, and mandarins (Agusti 2000, Planes and Carrero 1996, Dominguez 1998). Peach is the preferred host (Dominguez 1998). Clementines are not optimal hosts with maximum survival rates of Medfly in citrus being ca. 9% in late oranges and ca. 8% in clementines (Santaballa et al. 1999).

Agusti (2000) summarized the dynamics of the Medfly in Spain noting that a first generation may occur during the winter developing in late season oranges and mandarins, especially in more protected sun-warmed areas. In spring, a subsequent generation (second) attacks apricots and peaches. The third generation appears at the beginning of summer in peaches. Two more generations (fourth and fifth) may develop during August and September on peaches, pears, figs, and persimmons at the same time that it may also attack the earliest varieties of oranges and mandarins. During the fall, another generation (sixth) develops on oranges and mandarins. Additional generations are possible if fall and winter temperatures are warm. Dominguez (1998) presents a similar description of host phenology. In practice, Agusti (2000) reports that Medfly does not attack citrus before September-October. First because other preferred hosts are present and second, because the condition of citrus at this time (color and hardness) are not adequate for Medfly oviposition. Dominguez (1998) notes that the colder months are most likely spent in the soil in the pupal stage.

VII. Review of control practices (up to 2001)

Field controls. Control practices against the Medfly in Spain reported in the nineteenth century included collecting fallen fruit and burying it after covering with lye (“cal viva”) (Azcarate-Luxan 1996). More recently, integrated pest management methods have included the use of classical biological control,

mass trapping, pesticide bait sprays, population monitoring, and others (Agusti 2000, Planes and Carrero 1995). At this time the main control tactics include the use of bait sprays triggered by a threshold amount of flies caught in “Nadel” traps baited with an attractant, usually Trimedlure[®]. The threshold that triggers bait sprays is 0.5 flies/trap/day (Planes and Carrero 1995). The use of traps as a mechanism of control (without bait sprays) is also cited. With relatively high densities of traps the percentage of fruit that is infested remains 0 to 20% (Planes and Carrero 1995). Planes and Carrero (1995) cite the placement of traps in preferred hosts and before citrus begins maturation (e.g. in apricots and peaches in April) to allow for management of the pest population such that subsequent population build-up and economic damage are avoided.

Culling and Packing house Controls. Culling occurs during many phases beginning at harvest when blemished fruit is usually removed. Direct inspection and culling for quality control then occurs during at least two other phases (quality control and packing) (APHIS site visit report 2001).

Cold Treatment. The use of cold temperatures to destroy fruit flies has been long the subject of research (e.g., Back and Pemberton 1916; Yothers and Mason 1930; Petty and Griffiths, 1931; Mason and McBride 1934; Nel 1936, 1937). More recent research has refined and expanded the use of cold treatment to many more species and with a variety of equipment and conditions that all result in mortality close to 100% (e.g., Sproul 1976; Hill et al., 1988; Santaballa et al. 1999). Nearly one century of experience in the movement of different commodities from infested to non-infested areas attest to the effectiveness of cold treatments. However, the experiences during 2001 with Spanish clementines (i.e., the occurrence of live larvae in US markets after cold treatment) suggest that variability in the application of this control may be responsible for less than probit 9 mortality. Probit 9 refers to a treatment schedule that results in ca. 99.9968 percent mortality. This corresponds to a survival rate of 0.000032 (0.0032 percent) of all individuals exposed to a treatment that is said to achieve Probit 9 mortality. Prior to 2001, port inspections after cold treatment suggested that densities of dead larvae were below 1% in most inspected cargo (W. Thomas, personal communication) during most years.

Regulatory and phytosanitary practices in Spain. The use of national regulatory programs has a long history in Spain. There exist detailed reports of national control programs dating back to the XVI century focusing on locust management (Azcarate-Luxan 1996).

The current (2002) Spanish production and agricultural regulatory system has some elements that are similar to the American system of state autonomy and federal coordination of some export programs, among others. Specifically, the Spanish Ministry of Agriculture, Fisheries, and Nutrition (MAPA) has coordination responsibilities for phytosanitary issues, especially related to export systems and the management of invasive species. However, the implementation of recommendations and domestic programs lies with regional administrative units called “Comunidades Autonomas”. These autonomous communities (AC) roughly correspond to the divisions presented in figure 1.

As part of its responsibilities and according to specific regulations associated with citrus management, the ACs directly monitor some 800 Medfly traps in Valencia (ca. 1 trap per 200 Ha) distributed in the citrus production regions. Additional traps are managed at the farm level. MAPA also issues recommendations regarding field controls, packinghouse quality control and cold treatments. Actual field activities are monitored and carried out by the administration of the ACs and exporters. In addition to field controls (especially aerial sprays), individual farmers may also use additional traps and ground applications to manage specific problems. Close contacts with academia assure the application of newer research activities (Artolachipi, Cortina and Esteruelas, personal communication).

VIII. Risk reduction

Spanish clementines have been imported into the United States under CFR 7-319.56. However, the events of 2001 (live larvae reported in several shipments) have motivated the establishment of additional safeguards and the addition of several new quality control activities to the program. Key elements of the revised work-plan are detailed below.

Key phytosanitary measures

- Traps will be used to monitor adult populations and placed in preferred hosts at least six weeks before harvest.
- Bait sprays will be triggered when a maximum 0.5 flies/trap/day are detected.
- A preharvest field certification/management plan is implemented to control the field Medfly populations to reduce the infestation rate of fruit to below detectable levels of 1 1/2 % after harvest. Fruit cutting at the inspection site and prior to cold treatment (in Spain) will include the cutting of

sufficient fruit to allow detection of densities 1 ½ % or greater of infested fruit). This step is intended to allow a maximum 1½ % level of infestation (percent infested fruit) with a confidence level of 95%.

- All fruit will be traceable to its originating farm throughout the entire system.
- Cold treatment as per schedule T107 (USDA, 1998) will be implemented.
- Upon arrival at the United States, fruit will be sampled at the rate of 1490 fruit per shipload or 149 fruit per sea container at the discretion of PPQ.

In addition to the work plan safeguards, domestic safeguards (USA) include the expansion of trapping protocols to five states considered at highest risk from Medfly introduction. This increased domestic monitoring began in 2001. To assure quality control over the long term, harvest crews, quality control personnel and others involved in this safeguarding system, especially in Spain will be trained in the identification of fruit fly punctures and other Medfly evidence. Training is already part of PPQ's New Officer Training (NOT) program. This document does not contemplate beginning a new training system since one already is in place, it does however emphasize the need for periodic retraining and updates.

Quality Control. Quality control procedures will be integrated into standard operating procedures. Quality control will be co-developed by USDA and MAPA and managed by the ACs for the on-site QA procedures related to trapping and survey in Spain; Packing house culling and sampling; and other field activities. Quality control procedures will be managed by PPQ and will include stringent review of cold treatment and port of entry inspections. As per language noted in Appendix 1 (description of PHACCP), we equate the work plan that details requirements for importation of fruit into the United States with a PHACCP plan.

IX. Assessment of risk reduction and evaluation of overall system risks with emphasis on PHACCP Critical Control Points

Figure 2 outlines the main components of the system. Circles in figure 2 include the main control points. Circles with bold lines identify critical control points. The first circle in the system represents all fruit destined for export. The next circle represents field pest population (fruit flies) after different management practices (e.g., bait sprays, fallen fruit removal, ground spot treatments, mass trapping, and others) have been implemented. The next circle indicates the density of infested fruit in the harvest bin after field culling (i.e., rejection of infested, blemished or otherwise unacceptable fruit), the next circle identifies all other post-harvest quality control and culling processes that result in reductions in infested fruit. This circle ("Post harvest Exclusion") constitutes a critical control point. The next circle ("Cold Treatment") refers to the flies in fruit after in-transit cold treatment. The next circle identifies port inspections at US ports of entry as another filtering mechanism where fruit will be inspected and rejected if live larvae are found. The next circle acknowledges that there is natural mortality associated with Medfly, especially developing in citrus. The next circle includes the effect of dilution away from susceptible areas. That is, not all citrus that is imported ends up in states where susceptible hosts occur or where conditions for establishment prevail. Medfly is not likely to become established in an area where citrus does not grow. Areas that have winter temperature too cold for citrus are also too cold for the pest and citrus is generally the only good host available in subtropical or Mediterranean climates during the late winter or early spring (Miller 1992). The final circle assesses the likelihood that a population becomes established.

PHACCP analysis. We used PHACCP to concentrate on the behavior of the critical components to establish values for critical limits associated with these components. The multi-component system is evaluated below with emphasis on critical control points.

Component 1. Number of Fruit Shipped

Exports from Spain to the United States date from 1985 (W. Snell and D. West, personal communication). Export totals worldwide were ca. 1,248,515 tons in 1994 and 1,121,162 tons in 1996 (MAPA, 1999). Total mandarin (including clementines) exports to the United States totaled 12,848 tons in 1994; 15,172 tons in 1995, 23,107 tons in 1996 (MAPA 1999). During the 1999-2000 season, exports to the United States were ca. 80,000 tons (Appendix 2). There may be 20-25 clementine fruit per 2.5 kg carton (W.Thomas, personal communication; Santaballa, personal communication). That indicates eight to ten fruit per kg. There are 1000 kg in one metric ton, so there are 8,000 to 10,000 fruit per metric ton. Fruit is transported domestically usually with 40 ft containers. One such container may carry 20 to 21 fruit pallets of 360 cartons per pallet. If each carton weighs 2.5 kg, then there are up to =360 cartons/pallet * 25 fruit per

carton * 21 pallets = 189,000 (maximum) fruit in each container. The minimum number of fruit (assuming 22 fruit per carton) would be 166,320.

In terms of total fruit shipped per year, there were ca. 80,000 tons shipped during 2000; there are 1000 kg per ton and eight to ten fruit per kg. Thus, 80,000 tons * 1000 kg * 10 fruit per kg = total fruit per year (the value is 640,000,000 to 800,000,000 for eight and ten fruit per kg, respectively).

Landolt et al. (1984) proposed shipments (e.g., commercial containers) as a reasonable unit for which risk could be assessed. They stated: “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 mating 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 mating 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 mating pair occurring. The risk of an introduction should then be calculated as the probability of one or more mating pairs per shipment surviving quarantine measures”.

Thus, we assessed the probability of mated pairs in individual shipments (one container) and for all shipments in one year.

Component 2. Fruit Infested with Larvae in the Field (*Critical Control Point 1*)

The mitigations associated with the system (that is, fruit fly management in the field) result in a maximum tolerable amount of pest density, which is reflected in a critical limit for this critical control point. The critical limit is the “post harvest exclusion” which should be a maximum 1.5% infested fruit. This maximum threshold (critical control limit) is assured by a hypergeometric sampling system that uses fruit cutting and visual inspections at the packinghouse that result in 95% confidence that populations are less than or equal to (but no greater than) 1 ½ % (AQIM 2001). The minimum expected pest infestation proportion is 0% infested fruit. The reports from the expert panel (Santaballa, Moner, personal communication) and the experience from the PPQ pre-clearance inspectors in Spain and in the United States (W. Thomas, personal communication) suggest that the most common infestation proportion is 0.5% or lower. A triangular distribution was constructed to represent our knowledge about this component. The minimum value was zero, the most likely value is 0.005 and the maximum value is 0.015 (1½ %). A closely related distribution is the Pert distribution (Vose, 1996), it is considered to more accurately represent biological phenomena and was also used.

Component 3. Larvae per fruit

The number of larvae per infested fruit is estimated from the evidence in PNKTO (18,26); Santaballa et al. 1999; and W. Thomas, personal communication) as 1 to 200 per fruit (minimum and maximum, respectively). In order to determine a most likely value, we reviewed interception records and interviewed port inspectors (W. Thomas, personal communication). The most common number of larvae (dead) found in fruit was ca.15. We thus used 15 as the most likely value.

Component 4. Cold Treatment (*Critical Control Point 2*)

The fruit is treated with refrigeration that achieves probit-9 mortality (second critical control limit). The evidence from cold treatment studies shows that at most 32E-6 (32 in a million) individuals will survive. As per requirements detailed in USDA’s Treatment Manual (USDA 1998), both the Medfly and species of *Anastrepha* can be controlled using a combination of different temperatures and periods that all result in the required mortality. These treatments (T107a for Medfly and T07b,c for species of *Anastrepha*) require different temperatures if different periods are used. Specifically, at a temperature setting of 32°F or below the required exposure period is ten days; at 33°F or below the period is 11 days; at 34°F or below it is 12 days; at 35°F or below it is 14 days; at 36°F or below it is 16 days. These requirements imply the existence of critical limits, which are related to the period of exposure. Therefore, critical limits are to be understood as the temperature settings for a given period of exposure. The critical temperature limits are set at a specific temperature or a temperature below that setting. Variances in the system (the regulations require that settings be set at a given value or below with no acceptance or allowance for temperatures above the specified setting). This implies that if a specific equipment has a variability of ± 0.1 degrees, the setting (critical control limit) required to achieve regulatory treatment for the combination “32°F for ten days”, will be 31.9°F for ten days. The setting lower than 32°F will allow for variability associated with specific equipment. USDA maintains lists of approved vessels and approved cold treatment equipment that satisfies its requirements. These lists

may be found in USDA (1998). That reference also includes descriptions of the requirements and instructions used to verify the accurate delivery and application of cold treatment.

Treatment schedules are designed to have a probit 9 (99.9968 percent) mortality and were based on a demonstrated large-scale conformation tests that shows that the treatment kills about 100,000 insects with no survivors. The conformation tests gives a statistical inference of a survivor rate of either 30 or 32 survivors or less with a binomial distribution with a mode of zero. This distribution does not allow for error in operational protocol (i.e., hot spots in the compartment not detected by temperature leads) which would have a mode greater than zero, nor does it consider that most treatments continue on ship even after the required number of days are completed, simply because the travel time from port to port is greater than the required treatment time. This increases the mortality. Given the above, a lognormal distribution with a mean of 0.0001, standard deviation of 0.00011 was used (Liquido et al 1995; C.E. Miller,)

Treatment schedules were based on demonstrated efficacy of probit 9 (99.9968 percent) mortality. This corresponds to a survival rate of 0.000032 (0.0032 percent) and was represented as a lognormal distribution with a mean of 0.0001 and a standard deviation of 0.00011. This standard deviation was chosen because the resulting distribution has a mode (peak of the distribution) at 0.00003. The lognormal distribution is biased towards zero. This distribution is consistent with the mortality patterns in the evidence cited in the previous paragraph, and with insect control mortality in general (Robertson and Preisler, 1992).

The result from this step is that a proportion of at most .000032 larvae will survive treatment. That value represents the proportion of survival for fruit flies. Supporting evidence for this value is provided by Back and Pemberton (1916a,b); Fares (1973); Flitters (1958); Hill et al. (1988); Mason and McBride (1934); Pettey and Griffiths (1931); and Nel (1936).

Component 5. Viability

The survival of eggs to viable adults in citrus was reviewed by Santaballa et al. (1999) under optimal temperature conditions. Even at optimal conditions, the survival did not reach 10%. *To simulate this characteristic we used a minimum of 8% and a maximum of 10% with a uniform distribution.* The observation that citrus is not an optimal host is consistent with findings reported by Leyva et al. (1991) who also report 3.13 average viable adults of a related tephritid fruit fly (*Anastrepha ludens*) emerging from infested oranges.

Component 6. Arrives at susceptible area

USDA (1993) has analyzed the portion of the United States is at risk from *C. capitata* or the likelihood that a suitable host will be found in the southern portions of the continental United States. This likelihood incorporates both the likelihood that suitable hosts are in the area and the likelihood that an adult fly emerging from imported fruit will find the host material before dying.

Fruit that arrives in the United States does not arrive at a single State. Rather, the fruit is distributed according to market demands. The distribution channels reduce the number of fruit that end up in regions susceptible to pests. U. S. demographics and distribution of markets are strong indicators of the ultimate destination of fruit. The distribution of U.S. population according to the 2000 U.S. Census is shown in figure 3 (<http://www.census.gov/>) and describes the likely patterns of fruit destined for human consumption. Fruit that enters is mostly directed away from susceptible areas with a likely maximum 34 percent of imported fruit reaching states with citrus production. The US population varies between censuses and shows increasing trends towards higher densities in southern states. By 2025, the population that lives in the South and West (which includes states that have susceptible hosts) may be 44% of the total US population (<http://www.census.gov/>). *We thus used 30% as the minimum, 50% as the maximum with the midpoint, 44%, as the most likely value.*

The distribution of susceptible hosts does not cover an entire state for any given hosts or combination of hosts (<http://www.usda.gov/nass/aggraphs/>) (figure 4a-c) and that county level description would be more appropriate. Such descriptions were not available at the time of this analysis. Further, the likelihood that an entire shipment that is intended for consumption as fresh fruit ends up in, as susceptible grove is known to be lower than indicated by the population indicators used here. However, we did not have specific information on the fate of fruit to refine our estimates at this time. We used the estimates in the paragraph above for both the Current (Baseline) and New Proposed Mitigations (Program) scenarios

Integrating the Components

We combined the components as follows to estimate the number of live larvae that arrive at a suitable location every year:

$$\begin{aligned}
 &\text{Number of Fruit in shipments (from C1), multiplied by,} && (1) \\
 &\text{Infested Fruit (From C2), multiplied by,} && (2) \\
 &\text{Number of larvae per infested fruit (from C3), multiplied by,} && (3) \\
 &\text{Larvae that survive cold treatment (live larvae/total larvae, from C3), multiplied by,} && (4) \\
 &\text{Fruit that arrives at a suitable location (from C4)} && (5) \\
 & \\
 &= \text{Live adults at suitable location per year} && (6)
 \end{aligned}$$

That number (6) of Medflies exists within all shipments of fruit (Adults/All fruit that arrive in a suitable location in one year) and we can use the predicted values to estimate a rate of infestation of live adults within the commodity that arrives in the susceptible location.

The rate is estimated as: Live adults in the fruit that arrives at a suitable location per year, that is given by,

$$\text{Infestation Rate} = (6) / [(1) * (5)] \quad (7)$$

The probability of introduction is directly linked to the likelihood that a mated pair (one male and one female) will occur from a shipment of fruit. This probability has been studied by several researchers (Landolt 1984; Baker et al, 1990; Mangan et al. 1997; Liquido et al. 1996; Liquido et al. 1997); key findings are applied here.

The Probability of a mated pair in a shipment = $P = [1 - e^{-NR/2}]^2$, as described below.

Specifically, the occurrence of 1 or more reproductive pairs surviving in a single shipment can be estimated as:

$$P_m = \sum_{x=2}^{x=\infty} (e^{-NR} (NR)^x / X!) \bullet (1-0.5)^{x-1}, \quad (\text{Landolt 1984; Baker et al, 1990; Mangan et al. 1997; Liquido et al. 1996; Liquido et al. 1997})$$

Where,

P_m is the probability of 1 or more mating pairs occurring in a given shipment

N is the number of fruit, R is the rate of infestation, e is the base of natural logarithms, and X is the number of flies

Vail et al (1993) simplified the above to estimate the probability (P) of a surviving pair as:

$$P = [1 - e^{-NR/2}]^2 \quad (8)$$

Where,

P is the probability of a surviving pair, and the other variables are as defined above. R is given by (7) and N is given by (1) * (5).

The likelihood that a given fruit arriving in a suitable location is infested is shown in Table 1c. This likelihood was lower in the mitigated (inclusion of both cold treatment and field controls) than in the baseline scenario (cold treatment) only. Further, table 1c shows that 29 adults may result from the baseline system contrasted with 3.6 adults in the Mitigated system. The last column shows that there is a significant reduction in the overall probability that a mated pair will occur over an entire year ($P < 0.27$) compared to the baseline system ($P < 0.99$). If we use a “per shipment” calculation. That is, if we consider that a shipment contains at most 189,000 fruit then the probability of a mated pair is less than 0.05 per year (Appendix 3).

The variability associated with each component was explored using a Monte Carlo simulation procedure that combined all the possible values for all the components considered into an expression of overall probability and associated distribution of probable values. This combined probability then represents the overall pathway. In a typical Monte Carlo simulation, the endpoint value is calculated many times and is meant to produce a distribution of values, in addition to a single point estimate.

The risk analysis software package, @Risk™ for Excel was used to evaluate the effect of variability in our conclusions. Simulations for each component were run for 10,000 iterations. Input values for the calculations were drawn from the specified input distributions during each iteration (i.e., input values were drawn from the basic values like the maximum and the minimums specified in table 1a and 1b), and the computer program randomly selected a value from each of the input distributions. After the specified number of iterations, the software generated a combined distribution, expressed in terms of the annual distribution of chances of the occurrence of infested fruit. Results of the simulation are summarized in Table 1c. The characterization of the variability is presented in Appendix 3. The variability associated with the components did not change our assessment of the likelihood of entry of infested fruit from earlier risk assessments that proposed that cold treatment provided significant reductions in risks. That is, the level represented by the Baseline values has been associated with an appropriate level of protection for several decades. However, this document does not assess what constitutes an appropriate level of protection; it merely points out that the baseline values in the past have provided a particular level of protection and that the mitigated values (Table 1c) further decrease the risks associated with the importation of clementine fruit from Spain.

The distributions chosen were triangular (or the very closely related Pert distribution) and were parameterized based on our knowledge of the maximum, minimum, and most likely values that characterized the range of possible values. Our justification for using the triangular distribution is that it correctly captures the range and most expected values as indicated by our evidence (Vose 1996). Whereas we acknowledge that this distribution is not a 100% accurate reflection of underlying mechanisms, we also used other possible distributions (binomial, lognormal, normal) and obtained results that were very close to the results obtained with the triangular distribution. We thus note that our findings (that is the endpoint expression of probability of a mated pair in a shipment and proportion of infested fruit in shipments) are not sensitive to the use of alternative distributions given the same evidence (parameter values).

Conclusions

Our analysis shows that the combination of population control in production fields with cold treatment results in reduced risks compared to the use of quarantine cold treatments alone. Previously other citrus fruit from Spain has been allowed entry into the United States with cold treatment for Medfly. These include sweet oranges (*Citrus sinensis*), other varieties of *Citrus reticulata*, ortaniques (*Citrus sinensis* x *Citrus reticulata*), and ethrogs (*Citrus medica*). Lemon, sour limes and under certain conditions, ethrogs, are allowed entry without treatment because of non-host status. Although this document addresses clementines specifically, the risk from other Medfly host citrus from Spain is comparable. The other fruit are similar or larger thus less fruit would be in the shipment and the number of pests per shipment would be similar.

The critical control points (cold treatment and field population control) are being addressed by both existing (e.g., USDA, 1998- Treatment Manual) and new procedures (field controls are now part of the Spanish workplan as required by USDA). These quality control procedures will assure that the risk mitigations will be maintained as evaluated in this document.

Table 1a. Values used in the Estimation of Mitigated Risk

C1	C2	C3	C4	C5	C6
Fruit [/]	Infested fruit	Flies per Infested Fruit	Cold treatment Survivors	Viability [/]	Reaches Susceptible area
Maximum 800,000,000	Maximum 0.015	Maximum 200	Maximum 32E-6*	Maximum 0.1	Maximum 0.1
Minimum 640,000,000	Minimum 0	Minimum 1	Minimum 0*	Minimum 0.08	Minimum 0.1
Most Likely -	Most Likely 0.001	Most Likely 15	Most Likely -	Most Likely -	Most Likely 0.1
Distribution Uniform	Distribution Pert (Triangular)	Distribution Pert (Triangular)	*Lognormal (0.000001,0.0001)	Distribution Pert(Triangular)	Distribution Pert (Triangular)

Units Summary:

c1 Number of Fruit (total) (including all shipments for entire season)

c2 Infested Fruit/Total Fruit

c3 Larvae / Infested fruit.

c4 Live larvae / Larvae

c5 adults/larvae

c6 Suitable host location/US all host Locations

Table 1b. Values used in the Estimation of Baseline Risk

C1	C2	C3	C4	C5	C6
Fruit [/]	Infested fruit	Flies per Infested Fruit	Cold treatment Survivors	Viability [/]	Reaches Susceptible area
Maximum 800,000,000	Maximum 0.15	Maximum 200	Maximum 32E-6*	Maximum 0.1	Maximum 0.1
Minimum 640,000,000	Minimum 0	Minimum 1	Minimum 0*	Minimum 0.08	Minimum 0.1
Most Likely -	Most Likely 0.001	Most Likely 15	Most Likely -	Most Likely -	Most Likely 0.1
Distribution Uniform	Distribution Pert (Triangular)	Distribution Pert (Triangular)	*Lognormal (.000001,.0001)	Distribution Uniform	Distribution Pert (Triangular)

Units Summary:

c1 Number of Fruit (total)

c2 Infested Fruit/Total Fruit

c3 Larvae / Infested fruit.

c4 Live larvae / Larvae

c5 adults/larvae

c6 Suitable host location/US all host Locations

Table 1c. Evaluation of control points associated with Spanish clementines imports

Scenario	Proportion of ¹ Fruit Infested	Adults Per Year over All Suitable Locations	P[Mated Pair] All Year All Suitable locations
Mitigated (field controls plus cold)	1.28778E-09	3.6	0.27
Baseline (cold only)	1.04378E-08	29.4	0.99

/1 Calculated as: $c2*c4*c6$ /2 Calculated as: $c1*c2*c3*c4*c5*c6$

/3 Calculated using equation (8)

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XI. Team

The following PPQ groups participated in the development or provided input for this document: CPHST, PPD, IS, PIM, ARS, Regions and ports (especially Port of Philadelphia), SITC. Additional information was received from IPPC and the Spanish Ministry of Agriculture, Fisheries, and Nutrition. The information presented regarding HACCP was adapted from procedures published by FDA and based on previous research and development by the Pillsbury Company, NASA and others.

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Figure 1. Commercial citrus production areas in Spain (yellow), numbers indicate approximate total area for a region.

Components of the Spanish Clementine Pathway

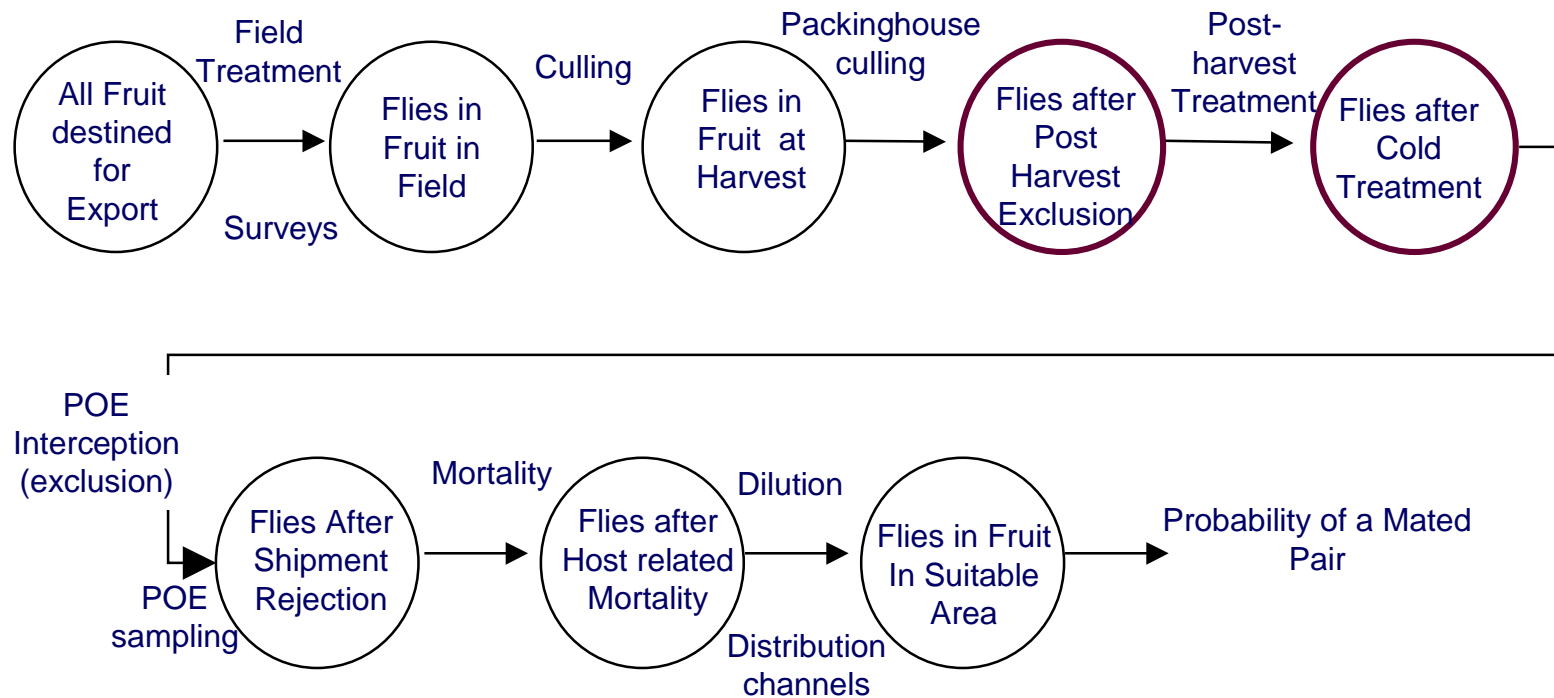


Figure 2. Components of the citrus pathway

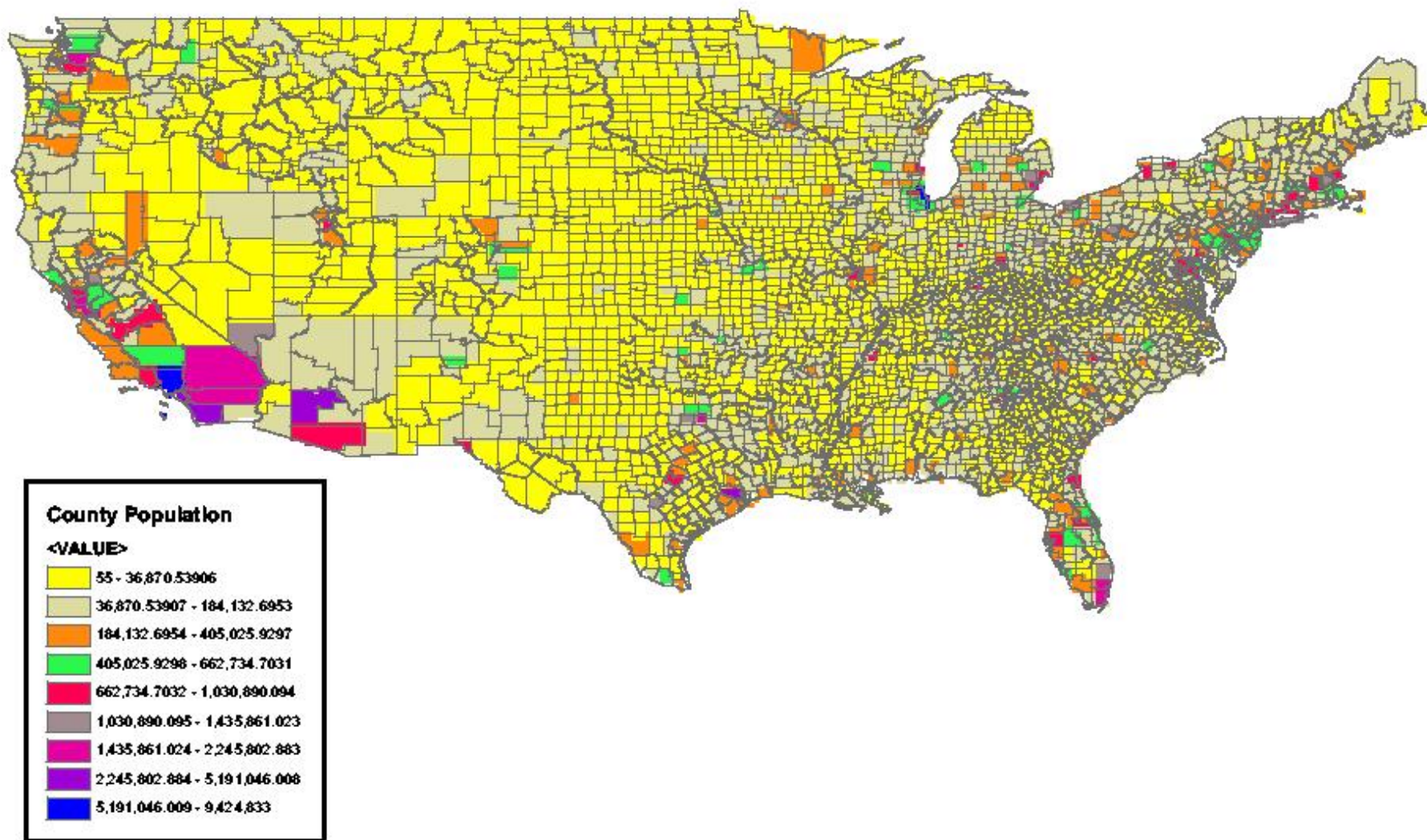


Figure 3. US population density, by county (US Census 2000)

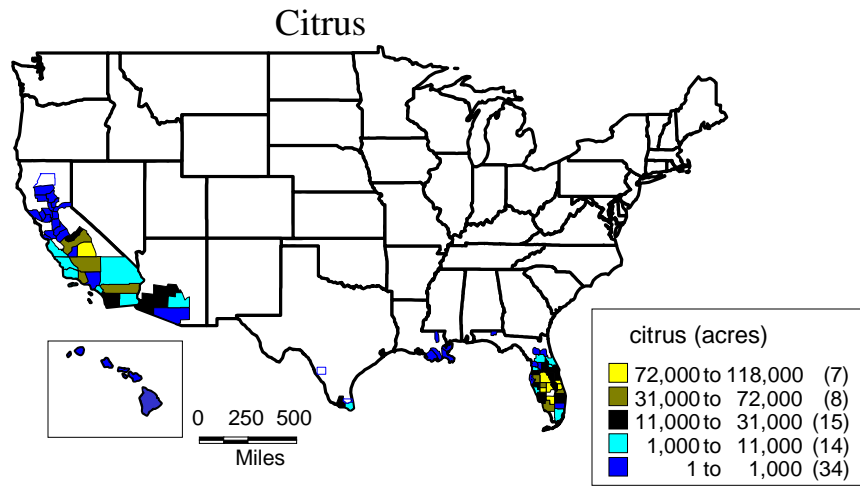


Figure 4a. Distribution of Citrus grove acreage in the United States (all commercial species and cultivars).

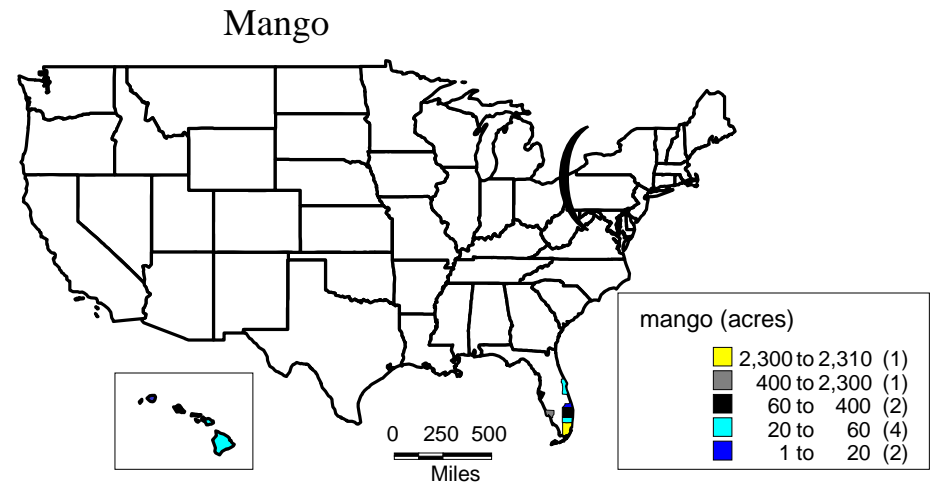


Figure 4b. Distribution of mango grove acreage in the United States (all commercial cultivars).

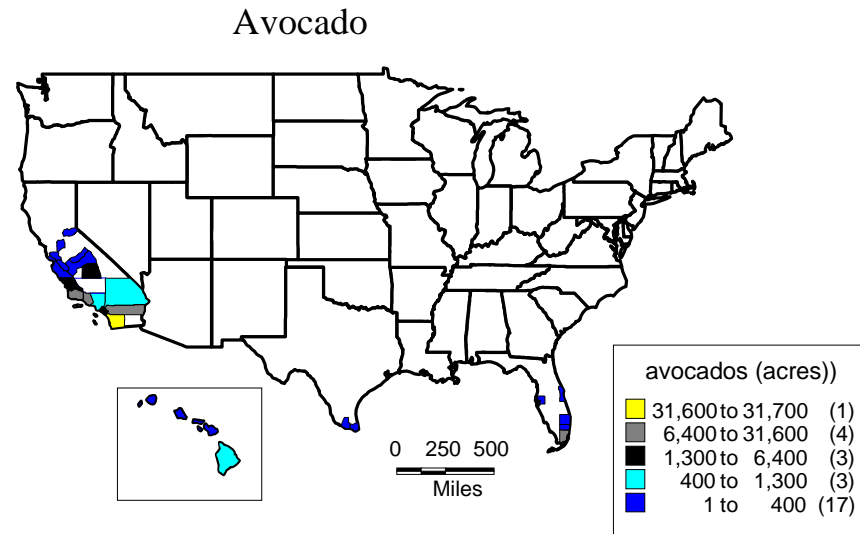


Figure 4c. Distribution of avocado orchard acreage in the United States (all commercial cultivars).

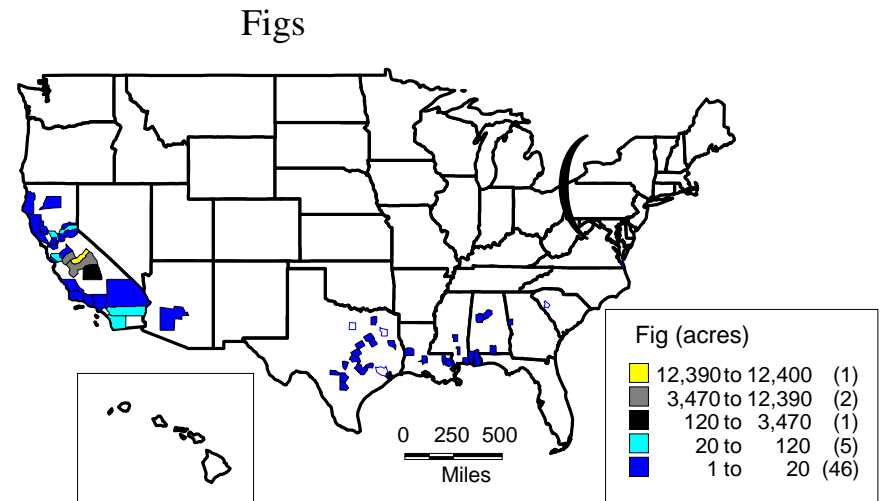


Figure 4d. Distribution of fig orchard acreage in the United States (all commercial cultivars).

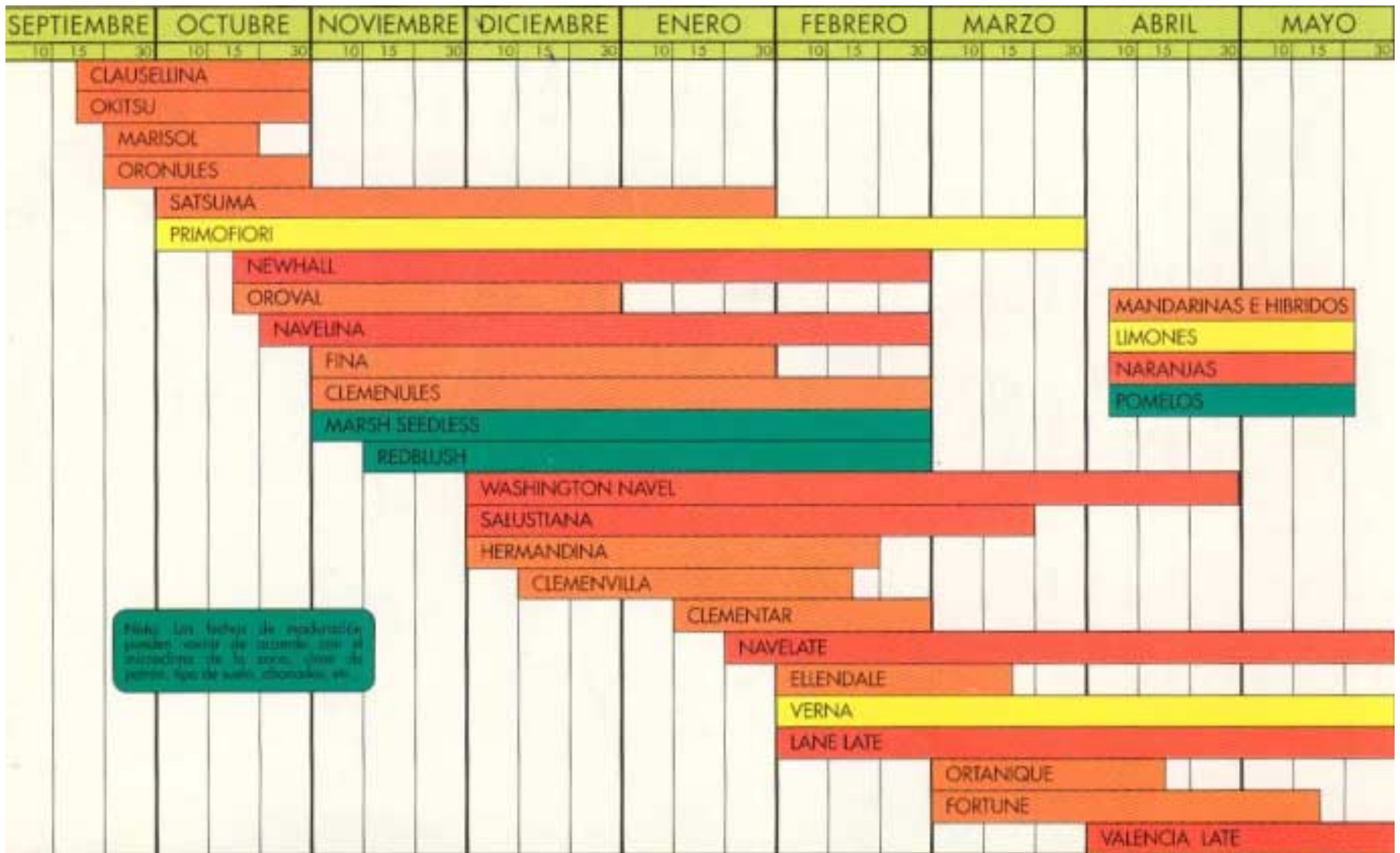


Figure Appendix 1. Phenological timing of all citrus in Spain. Source: Santaballa, personal communication 2002.

Appendix 1.

The text presented here is an adaptation of the procedures recommended by FDA and described in www.fda.gov and www.foodsafety.gov.

Phytosanitary Hazard Analysis and Critical Control Point. PHACCP is a systematic approach in identifying, evaluating and controlling hazards. HACCP was developed in the area of food safety. However, its phases (principles) are broadly applicable and are used here with adaptations as appropriate to the area of quarantine safety or quarantine security.

A PHACCP system is designed to emphasize prevention and control over reaction and remediation. Our intent is to implement PHACCP systems are designed to prevent pest introduction and provide quarantine security. As in the area of food safety, USDA-APHIS-PPQ has been achieving this goal through a combination of regulatory and cooperative programs domestically and internationally. Whereas the purposes are indeed similar (prevention and reduction of the risk of a hazard), USDA-APHIS recognizes the value of the PHACCP framework in assuring that key safeguarding elements are addressed. Hereafter, the guidelines for PHACCP are discussed as applicable to USDA-APHIS-PPQ. Elements that are redundant with existing USDA-APHIS procedures and guidelines (e.g., PRA guidelines) are not detailed.

Safeguarding (from pest introductions) is achieved by assessing the inherent hazards attributable to the importation of a commodity or other initiating action, determining the necessary steps that will control the identified hazards, and implementing active phytosanitary control practices to ensure that the hazards are eliminated or minimized.

Essentially, PHACCP is a system that identifies and monitors specific phytosanitary hazards – exotic pest species – that can adversely affect natural ecosystems and agricultural productivity. This hazard analysis serves as the basis for establishing critical control points (CCPs). CCPs identify those points in the process that must be controlled to ensure appropriate safeguards. Further, critical limits are established that document the appropriate parameters that must be met at each CCP. Monitoring and verification steps are included in the system, again, to ensure that potential hazards are controlled. The hazard analysis, critical control points, critical limits, and monitoring and verification steps are documented in a PHACCP plan. Seven principles have been developed which provide guidance on the development of an effective PHACCP plan.

- (1) Acceptable level means the presence of a hazard that does not pose the likelihood of causing an unacceptable phytosanitary risk.
- (2) Control point means any point in a specific pathway at which loss of control does not lead to an unacceptable phytosanitary risk.
- (3) Critical control point, as defined here, means a point at which loss of control may result in an unacceptable phytosanitary risk.
- (4) Critical limit, as defined here, means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified phytosanitary hazard may occur.
- (5) Deviation means failure to meet a required critical limit for a critical control point.
- (6) PHACCP plan, as defined here, means a written document that delineates the formal procedures for following the HACCP principles developed by The National Advisory Committee on Microbiological Criteria for Foods and modified for phytosanitary applications here.
- (7) Hazard, as defined here, refers to an exotic pest that may cause an unacceptable phytosanitary risk.

(8) Monitoring means a planned sequence of observations or measurements of critical limits designed to produce an accurate record and intended to ensure that the critical limit maintains product safety. Continuous monitoring means an uninterrupted record of data.

(9) Preventive measure means an action to exclude, destroy, eliminate, or reduce a hazard and prevent recontamination through effective means.

(10) Risk means an estimate of the likely occurrence of a hazard.

(11) Verification means methods, procedures, and tests used to determine if the PHACCP system in use is in compliance with the PHACCP plan.

A PHACCP system will emphasize the industry's role in continuous problem solving and prevention rather than relying solely on periodic facility inspections by regulatory agencies.

HACCP offers two additional benefits over conventional inspection techniques. First, it clearly identifies importers and exporters as the final party responsible for ensuring the phytosanitary safety of commodities in trade. PHACCP requires industry to analyze its production and pest management methods in a rational, scientific manner in order to identify critical control points and to establish critical limits and monitoring procedures. A vital aspect of industry's (or as represented by NPPOs) responsibility is to establish and maintain records that document adherence to the critical limits that relate to the identified critical control points, thus resulting in continuous self-inspection. Secondly, a PHACCP system allows the regulatory agency to more comprehensively determine industry's level of compliance. Use of PHACCP in an import/export program requires development of a plan to address safeguards from pests. This plan must be shared with the regulatory agency because it must have access to CCP monitoring records and other data necessary to verify that the PHACCP plan is working. Using conventional inspection techniques, an agency can only determine conditions during the time of inspection which provide a "snapshot" of conditions at the moment of the inspection. However, by adopting a PHACCP approach, both current and past conditions can be determined. When regulatory agencies review PHACCP records, they have, in effect, a look back through time. Therefore, the regulatory agency can better ensure that processes are under control.

Traditional inspection is relatively resource-intensive and inefficient and is reactive rather than preventive compared to the PHACCP approach for ensuring phytosanitary safeguards. Regulatory agencies are challenged to find new approaches to safeguarding that enable them to become more focused and efficient and to minimize costs wherever possible. Thus, the advantages of transparent guidelines including regulatory inspections are becoming increasingly acknowledged by the regulatory community.

HACCP (and PHACCP) background. Established in 1988, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is an advisory committee chartered under the U.S. Department of Agriculture (USDA) and comprised of participants from the USDA (Food Safety and Inspection Service), Department of Health and Human Services (U.S. Food and Drug Administration and the Centers for Disease Control and Prevention), the Department of Commerce (National Marine Fisheries Service), the Department of Defense (Office of the Army Surgeon General), academia, industry and state employees. NACMCF provides guidance and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services regarding the microbiological safety of foods.

(B) Development of HACCP Principles

In November 1992, NACMCF defined seven widely accepted HACCP principles that were to be considered when developing a HACCP plan. In 1997, the NACMCF reconvened the HCCP Working Group to review the Committee's November 1992 HACCP document and to compare it to current HACCP guidance prepared by the CODEX Committee on Food Hygiene. From this committee, HACCP was defined as a systematic approach to the identification, evaluation and control of food safety hazards based on the following seven principles:

Principle 1: Conduct a hazard analysis.

Principle 2: Determine the critical control points (CCPs).

Principle 3: Establish critical limits.

Principle 4: Establish monitoring procedures.

Principle 5: Establish corrective actions.

Principle 6: Establish verification procedures.

Principle 7: Establish record-keeping and documentation procedures.

Description of PHACCP stages (principles).

Principle 1

Flow Diagram

A flow diagram that delineates the steps in the production system and transport pathway forms the foundation for applying the seven principles. The significant hazards associated with each step in the flow diagram should be listed along with preventative measures proposed to control the hazards. This tabulation will be used under Principle 2 to determine the CCPs. The flow diagram should be constructed by a PHACCP team that has knowledge and expertise on the commodity and associated pests, pest management, and the likely hazards. Each step in a process should be identified and observed to accurately construct the flow diagram.

Developing Preventive Measures

The preventive measures procedure identifies the steps in the process at which hazards can be controlled.

After identifying the hazards industry and regulatory agencies must then consider what preventive measures, if any, can be applied for each hazard. Preventive measures are phytosanitary and other pest control tactics that can be used to control an identified phytosanitary hazard. More than one preventive measure may be required to control a specific hazard and more than one hazard may be controlled by a specified preventive measure.

Principle 2

PRINCIPLE #2: IDENTIFY THE CRITICAL CONTROL POINTS (CCP) IN the pathway

A CCP is a point, step, or procedure at which control can be applied and a phytosanitary hazard can be prevented, eliminated, or reduced to acceptable levels. Points in pathway that may be CCPs include hot treatment, cold treatment, fumigation, pest eradication, low prevalence, etc,

Principle 3

PRINCIPLE #3: ESTABLISH CRITICAL LIMITS FOR PREVENTIVE MEASURES

Associated with Each Identified Critical Control Point

This step involves establishing a criterion that must be met for each preventive measure associated with a CCP. Critical limits can be thought of as boundaries of safety for each CCP and may be set for preventive measures such as temperature, time, pest densities, or number of bait sprays. Critical limits may be derived from sources such as regulatory standards and guidelines, scientific literature, experimental studies, and consultation with experts.

(a) Critical Limit

A critical limit is defined as a criterion that must be met for each preventive measure associated with a CCP. Each CCP will have one or more preventive measures that must be properly controlled to ensure prevention,

elimination, or reduction of hazards to acceptable levels. Industry is responsible for using competent authorities to validate that the critical limits chosen will control the identified hazard.

(b) Target Level

In some cases, variables involved in the implementation of a phytosanitary measure may require certain target levels to ensure that critical limits are not exceeded. For example, a preventive measure and critical limit may be an internal fruit temperature of 2°C () during one stage of a process. The ship hold temperature, however, may be $2 \pm 2^\circ\text{C}$ (); thus a ship hold target temperature would have to be less than -0°C () so that no product receives a cold treatment of more than 2°C ().

Principle 4

(a) Observations and Measurements

Monitoring is a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for use in future verification procedures. There are three main purposes for monitoring:

- (i) It tracks the system's operation so that a trend toward a loss of control can be recognized and corrective action can be taken to bring the process back into control before a deviation occurs;
- (ii) It indicates when loss of control and a deviation have actually occurred, and corrective action must be taken; and
- iii) It provides written documentation for use in verification of the HACCP plan.

Principle 5

(a) Purpose of Corrective Action Plan

Although the HACCP system is intended to prevent deviations from occurring, perfection is rarely, if ever, achievable. Thus, there must be a corrective action plan in place to:

- (i) Determine the disposition of any commodity that arrives at a port when a deviation occurred;
- (ii) Correct the cause of the deviation and ensure that the critical control point is under control; and
- (iii) Maintain records of corrective actions.

Principle 6

PRINCIPLE #6: ESTABLISH PROCEDURES TO VERIFY THAT THE PHACCP SYSTEM IS WORKING

(a) Establishing Verification Procedures

- (i) The first phase of the process is the scientific or technical verification that critical limits at CCPs are satisfactory.
- (ii) The second phase of verification ensures that the facility's PHACCP plan is functioning effectively.
- (iii) The third phase consists of documented periodic revalidations and modification, as necessary.
- (iv) The fourth phase of verification deals with the regulatory agency's responsibility and actions to ensure that the establishment's PHACCP system is functioning satisfactorily.

(b) The following are some examples of PHACCP plan verification activities that should be used as a part of a PHACCP program:

(i) Verification procedures may include: Establishment of appropriate verification inspection schedules; Review of the PHACCP plan; Review of CCP records; Review of deviations and their resolution, including the disposition of commodities; Visual inspections of operations to observe if CCPs are under control; Random sample collection and analysis; Review of critical limits to verify that they are adequate to control hazards; Review of written record of verification inspections which certifies compliance with the PHACCP plan or deviations from the plan and the corrective actions taken; Validation of PHACCP plan, including on-site review and verification of flow diagrams and CCPs; and Review of modifications of the PHACCP plan.

(ii) Verification inspections should be conducted:

- + Routinely or on an unannounced basis, to ensure that selected CCPs are under control;
- + When it is determined that intensive coverage of a specific commodity is needed because of new information concerning new pests or new hazards associated with known pests; When treated commodities have been implicated as a means of entry of exotic pests;
- + When requested on a consultative basis and resources allow accommodating the request;
- + When established criteria have not been met; and
- + To verify that changes have been implemented correctly after a PHACCP plan has been modified.

(iii) Verification reports should include information about:

- + Existence of a PHACCP plan and the person(s) responsible for administering and updating the PHACCP plan; The status of records associated with CCP monitoring;
- + Direct monitoring data of the CCP while in operation; Certification that monitoring equipment is properly calibrated and in working order;
- + Deviations and corrective actions;
- + Any samples analyzed to verify that CCPs are under control. Analyses may involve physical, chemical, microbiological, or visual methods;
- + Modifications to the PHACCP plan; and
- + Training and knowledge of individuals responsible for monitoring CCPs.

(c) Training and Knowledge

(i) Focus and Objective

Training and knowledge are very important in making PHACCP successful in phytosanitary system. HACCP works best when it is integrated into each employee's normal duties rather than added as something extra. The depth and breadth of training will depend on the particular employee's responsibilities within the establishment. Management or supervisory individuals will need a deeper understanding of the PHACCP process because they are responsible for proper plan implementation and routine monitoring of CCPs such as cold treatment temperatures, pre-cooling, and treatment times. The training plan should be specific to the commodity being inspected rather than attempt to develop PHACCP expertise for broad application.

The inspector's training should provide an overview of PHACCP's prevention philosophy while focusing on the specifics of the employee's normal functions. The CCPs such as proper equipment calibration and fruit inspection should be stressed. The use of Standard Operating Procedures (SOPs) which include the critical limits of treatments and treatment details, should be included.

For all employees, the fundamental training goal should be to make them proficient in the specific tasks that the PHACCP plan requires them to perform. This includes the development of a level of competency in their decision-making about the implementation of proper corrective actions when monitoring reveals violation of the critical limit. The training should also include the proper completion and maintenance of any records specified in the establishment's plan.

(ii) Reinforcement

Training reinforcement is also needed for continued motivation of the phytosanitary employees. Some examples might include:

- + A PHACCP video training program such as PPQ's Safeguarding Video;

- + Changing reminders about PHACCP critical limits such as "No more than 2 degrees assures safe trade!" printed on employee's time cards or checks; and
- + Work station reminders such as pictorials on how and when to monitor temperatures or inspect fruit.

Every time there is a change in pest management or quarantine systems within the industry, the PHACCP training needs should be evaluated. The employees should be made sensitive to how the changes will affect phytosanitary safety

The PHACCP plan should include a feedback loop for employees to suggest what additional training is needed. All employees should be made a part of the continuous phytosanitary safety improvement cycle because the statement is very true: "The health of America's agriculture and natural systems is in their hands". This helps maintain their active awareness and involvement in the importance of each job to the safety of the traded commodities.

Principle 7

PRINCIPLE #7: ESTABLISH EFFECTIVE RECORD KEEPING SYSTEMS THAT DOCUMENT THE PHACCP SYSTEM

(a) Written PHACCP Plan

This principle requires the preparation and maintenance of a written HACCP plan by the regulatory organizations and industry. The plan must detail the hazards of each individual or categorical product covered by the plan. It must clearly identify the CCPs and critical limits for each CCP. CCP monitoring and record keeping procedures must be shown in the establishment's PHACCP plan. PHACCP plan implementation strategy should be provided as a part of the producers/exporter's documentation.

(b) Record Keeping

The principle requires the maintenance of records generated during the operation of the plan. The record keeping associated with PHACCP procedures ultimately makes the system work. One conclusion of a study of HACCP performed by the U.S. Department of Commerce is that correcting problems without record keeping almost guarantees that problems will recur. The requirement to record events at CCPs on a regular basis ensures that preventive monitoring is occurring in a systematic way. Unusual occurrences that are discovered as CCPs are monitored or that otherwise come to light must be corrected and recorded immediately with notation of the corrective action taken.

The level of sophistication of the record keeping necessary for the producers is dependent on the complexity of the production operation. Greenhouse operations will be in general more information intense than field operations.

(c) Contents of the Plan and Records

The approved PHACCP plan and associated records must be on file at the packinghouse or production area. Generally, the following are examples of documents that can be included in the total HACCP system:

- (i) Listing of the PHACCP team and assigned responsibilities;
 - (ii) Description of the commodity and its intended distribution, destination and use;
 - (iii) Flow diagram for the pathway indicating CCPs;
 - (iv) Hazards associated with each CCP and preventive measures;
 - (v) Critical limits;
 - (vi) Monitoring system;
 - (vii) Corrective action plans for deviations from critical limits;
 - (viii) Record keeping procedures; and
 - (ix) Procedures for verification of HACCP system.
- (d) Format for HACCP Information

Appendix 2. Production of Clementines in Spain
[Document provided by MAPA's Dr. E. Santaballa.]

1.- GENERAL INFORMATION OF CLEMENTINE MANDARINS
CULTIVATED ECONOMICALLY IN SPAIN

1.1.- Characteristics of Clementine mandarin varieties

The Clementine mandarin varieties highly cultivated in Spain are:

Marisol, Oroval, Clemenules, Fina, Hernandina

The general characteristics of Clementine mandarins are

Medium sized, of a bright reddish colour and round or slightly flattened in shape. The skin is easily separated from the flesh, which is divided into about 11 large-celled sections. The Clementine is sweet and pungent and usually free from pips. It ripens from early November to mid-March.

The characteristics of different varieties of Clementine are

MARISOL

This most promising of Clementine selections originated as a bud mutation on Oroval in 1970 at Bechi in Castellon Province. Tree and fruit characteristics are indistinguishable from Oroval, with one significant exception: Marisol matures at least two weeks earlier than Oroval and is therefore as early as the Owari satsuma and seems destined to make inroads into these two varieties. This is already evident from its current popularity, with plantings of around 250.000 trees per year throughout Spain (or 15 per cent of all mandarins).

OROVAL

Oroval, a bud mutation of Fina, was found in 1950 at Quart de les Valls in Valencia Province, Spain. The trees are vigorous, well developed but thorny, although this characteristic declines with age. The fruit is only slightly larger than Nules and matures fully three weeks earlier. However, it has two important disadvantages from a production point of view: poor hanging ability because the rind, which has a somewhat more pebbly texture than Nules, becomes excessively puffy with delayed harvest; secondly, a rind which is susceptible to what is known locally as "water spot" following heavy rains, which causes the fruit to drop to the ground.

Although the flesh is reasonably tender and even more juicy than Nules, it is more acidic despite having good sugar levels. The urgency with which producers harvest the Oroval is sometimes reflected in poorer than optimum quality. This and other shortcomings have been noted by producers and are reflected in current plantings: only 1 per cent of all Clementines are of this variety. However, there are an estimated 7,000 ha in production at the present time.

CLEMENULES

The most popular Clementine selection in Spain where it constitutes around half of current plantings, Nules was discovered near the town of the same name in Castellón Province as a bud mutation on a Fina.

Like the Fina, Nules trees are vigorous, attain large size, and are very productive, out yielding the Fina by about 10 per cent. Moreover, the fruit is significantly larger (although somewhat smaller than the Oroval), maturing only a few days later than the Oroval), maturing only a few days later than Fina, in late November. An important characteristic of Nules is the extended period over which the fruit to be harvested until the end of January, if climatic conditions are favourable.

The extended harvesting period is made possible by up to three fruit sets, the fruit becoming more coarse and larger with each ser. Picking selectively is therefore an essential part of good management of Nules orchards. Packers and shippers will commonly pay a 15 to 20 per cent premium for Nules over Oroval, so much better is the quality.

FINA

First introduced into Spain in 1925, probably from Algeria, the Fina laid the foundations on which the country's Clementine industry developed. Until the early 1960s only Fina Clementine was grown on any scale in Spain. All other Spanish Clementines are derived from the Fina either directly or via one generation.

Fina trees are vigorous, dense and large and have good productivity. Although relatively later maturing by as much as four weeks compared with the early selections such as Marisol and Oroval, it is still the finest quality Spanish Clementine and is the one against which others are compared. Unfortunately the fruit is very small, much of the crop being below 60 mm in diameter (averaging 50 mm), with the result that market returns on a high proportion of smaller fruit cannot compete with other selections which produce larger is somewhat inferior fruit.

The rind is particularly smooth, and the fruit has excellent organoleptic characteristics: high juice content, very tender and sweet with good acid level but high sugar to acid ratio. It has the strong, pleasant aroma which typifies the Clementine.

Fruit may be left on the tree for relatively long period without noticeable quality deterioration. It is recommended for planting only in areas where soil and climate permit large size fruit. The Fina is no longer planted in Spain because of fruit size problems but around 10,000 ha are in production. Along with Nules, it is still the most extensively grown Clementine variety in Spain.

HERNANDINA

Discovered in 1966 as a bud mutation of Fina at Picasent in Valencia Province, the Hernandina is an exciting selection at present being extensively planted in the late areas of Spain.

Tree characteristics are almost the same as Fina, and so too are those of the fruits, with one important exception: the Hernandina's external colour develops two months later than the Fina. It is not harvested until mid-January and can be held in good condition and without quality deterioration until late February or early March.

Colour development is characteristically incomplete on a significant percentage of fruit with a small but acceptable area of the rind at the stylar-end remaining slightly green. Somewhat surprisingly the internal maturity is reached not more than one or two weeks later than the Fina and remains outstanding for an additional three months.

The Hernandina does not store well after harvest and may develop granulation if held on the tree past peak maturity. Nevertheless, price realisations on European markets

have been most rewarding and have encouraged current planting rates of over 100,000 trees per year.

1.2.- Annual cultivating schedule of mandarin varieties and harvest time.

In Spain the cultivating schedule is very similar for all the varieties. The main cultural practices are:

Fertilization:

It is usually made in two times. The first one in March, and N, P, K and microelements are supplied. This one will be the only supply of P and K for the entire year. The amounts provided will depend on soils characteristics. The N will be provided in ammonia form. The quantity provided this time would be the 60 % of the whole year.

In the second supply only N, as N nitric, will be provided. Occasionally microelements can be provided, depending on trees.

The annual amounts of N are variable, but, as average, it can be provided 0,5 kg N / tree.

Pruning:

In Spain the pruning is made yearly, in March-April, when the risks of low temperatures have disappeared. The entire pruning in Spain is manual.

Irrigation:

The entire surface dedicated to mandarin cultivating is placed in irrigation areas.

The most commonly used method is trickle irrigation (70%), the rest (30%) by flood irrigation. When flood irrigation is used, 8 to 10 irrigations are given, starting in March - April and finishing in October - November.

Phytosanitary treatments:

They are detailed at point 6

Other cultural practices

They are usually started in March and finished in September

Harvest periods

Marisol: 15 Sep. – 15 Oct.

Oroval: 15 Oct. – 30 Dec.

Clemenules: 1 Nov. – 28 Feb

Fina: 1 Nov. – 30 Jan.

Hernandina: 1 Dec. – 28 Feb.

FIGURE 1.- Maturation table of citrus fruits in Spain

1.3.- Major producing area of Clementine mandarin varieties and map.

The zones of higher production in Spain are located in the Comunidad Valenciana (provinces of Castellon, Valencia and Alicante) with 45.000 ha (87,5%) Murcia 2,2%), and Andalucia (provinces of Huelva, Sevilla and Cordoba) with 2300 ha.(4,5%) and Cataluña (Tarragona province) 3000 ha (5.8%).

The location of the production zones are represented in the figure 2

1.4.- Yield of each mandarine varieties.

The yield for trees at full production (10 years of plantation) oscillates in the 5 varieties among 25 and 30 tm/ha.

Figure 2.- Major Clementine producing areas in Spain

2.- INFORMATION OF PRODUCTION OF CLEMENTINE MANDARINS IN THE LAST SEVERAL YEARS.

The production (in tm) of Clementine mandarins in Spain in the last years has been the following, according to the data provided by Comité de Gestión de Frutos Cítricos.

Table 1.- Production of Clementine mandarins (in tm)					
Variety	1996-97	1997-98	1998-99	1999-00	2000-01
Marisol	101.947	171.143	207.696	149.703	273454
Oroval	177829	195.465	181.769	174.254	142.730
Clemenules	447671	631.994	525.970	652.832	516.708
Fina	62240	67.573	61.140	74.493	55.262
Hernandina	95318	109.313	104.114	135.901	100.066
TOTAL	885.005	1.175.488	1.080.689	1.286.183	1.088.220

TABLE 2.-PRODUCTION OF MANDARINS IN THE DIFFERENT AREAS (IN TM)							
<u>SEASON 2000/2001</u>							
SPECIE/ VARIETY	Comunidad Valenciana	Región of Murcia	Comunidad Andaluza	Prov. de Tarrago na	Baleares	Others	TOTAL
**MANDARIN							
*GROUP SATSUMAS	278.859	2.870	7.738	9.801	70	365	299.703
Clausellina- Okitsu	131.239	870	700		70		132.879
Satsuma	147.620	2.000	7.038	9.801		365	166.824
*GROUP CLEMENTINA	942.567	26.000	55.986	62.337	830	500	1.088.220
C. Marisol	259.554	13.900					273.454
C. Oroval	132.232	2.500	6.640	1.358			142.730
C. de Nules	444.831	6.000	19.100	46.447	830	500	516.708
C. Fina	26.624	2.100	12.006	14.532			55.262
C. Hernandina	80.326	1.500	18.240				100.066
*HYBRID MANDARIN	351.690	16.870	56.737	5.711	200	150	431.358
Clemenvilla Nova	126.342	3.440	4.599				134.381
Fortuna	123.063	11.000	17.815	1.164			153.042
Others	102.285	2.430	34.323	4.547	200	150	143.935
TOTAL MANDARIN	1.573.116	45.740	120.461	77.849	1.100	1.015	1.819.281

**TABLE 3.-PRODUCTION OF MANDARINS IN THE DIFFERENT AREAS (IN TM)
SEASON 1999/2000**

SPECIE/ VARIETY	Comunidad Valenciana	Región of Murcia	Comunidad Andaluza	Prov. de Tarragona	Baleares	Others	TOTAL
**MANDARIN							
*GROUP SATSUMAS	287.197	3.280	8.380	11.138	70	365	299.292
Clausellina-Okitsu	121.518	880	600		70		123.068
Satsuma	165.679	2.400	7.780			365	176.224
*GROUP CLEMENTINA	1.123.520	28.770	57.553	75.010	830	500	1.286.183
C. Marisol	233.833	15.570	300				149.703
C. Oroval	162266	2.300	8.258	1.430			174.254
C. de Nules	579.400	6.600	13.894	51.608	830	500	652.832
C. Fina	38170	2500	15.101	17.722			74.493
C. Hernandina	109.851	1.800	20.000	4.250			135.901
*HYBRID MANDARIN	378.115	18.690	58.481	1.200	200	150	456.836
Clemenvilla Nova	140.380	3.320	4.549				148.249
Fortuna	159.018	13.290	20.563	1.200			194.071
Others	78.717	2.080	33.369		200	150	114.516
TOTAL MANDARIN	1.788.832	50.740	124.414	87.348	1.100	1.015	2.042.311

TABLE 4.-PRODUCTION OF MANDARINS IN THE DIFFERENT AREAS (IN TM)
SEASON 1998/1999

SPECIE/ VARIETY	Comunidad Valenciana	Región of Murcia	Comunidad Andaluza	Prov. de Tarragona	Baleares	Others	TOTAL
**MANDARIN							
*GROUP SATSUMAS	262.364	3.980	6.155	7.605	70	365	280.539
Clausellina- Okitsu	116.253	980	200		70		117.503
Satsuma	146.111	3.000	5.955	7.605		365	163.036
*GROUP CLEMENTINA	975.588	34.960	35.819	32.992	830	500	1.080.689
C. Marisol	188.896	17.800	1.000				207.696
C. Oroval	168.914	3.500	8.371	984			181.769
C. de Nules	479.879	7.200	15.528	22.033	830	500	525.970
C. Fina	41.845	4.300	5.020	9.975			61.140
C. Hernandina	96.054	2.160	5.900				104.114
*HYBRID MANDARIN	349.707	16.370	21.706	4.852	200	150	392.985
Clemenvilla Nova	115.363	3.270	3.625				122.258
Fortuna	161.495	13.100	5.273	832			180.700
Others	72.849		12.808	4.020	200	150	90.027
TOTAL MANDARIN	1.587.659	55.310	63.680	45.449	1.100	1.015	1.754.213

TABLE 5.-PRODUCTION OF MANDARINS IN THE DIFFERENT AREAS (IN TM) SEASON 1997/1998							
SPECIE/ VARIETY	Comunidad Valenciana	Región of Murcia	Comunidad Andaluza	Prov. de Tarragona	Baleares	Others	TOTAL
**MANDARIN							
*GROUP SATSUMAS	293.515	5.074	7.218	6.041	50	200	312.098
Clausellina- Okitsu	87.739	1.200	1.230		50		90.219
Satsuma	205.776	3.874	5.988	6.041		200	221.879
*GROUP CLEMENTINA	1.078.069	24.319	31.928	39.125	1.750	300	1.175.491
C. Marisol	159.554	10.833	756				171.143
C. Oroval	182.739	2.400	9.301	1.028			195.465
C. de Nules	582.372	6.750	12.877	27.945	1.750	300	631.994
C. Fina	50.851	2.436	4.134	10.152			67.573
C. Hernandina	10.2553	1.900	4.860				109.313
*HYBRID MANDARIN	274.286	12.350	15.233	4.153	400	100	306.522
Clemenvilla Nova	108.556	2.800	3.625				114.981
Fortuna	121.211	9.300	5.525	691			136.727
Others	44.519	250	6.083	3.462	400	100	54.814
TOTAL MANDARIN	1.645.870	41.743	54.379	49.319	2.200	600	1.794.111

3.- AMOUNT OF SPANISH CLEMENTINE MANDARINS FOR EACH USAGE AND AMOUNT OF EXPORT FOR EACH IMPORTING COUNTRY FOR THE LAST SEVERAL YEARS

3.1.- Usage of the Spanish Clementine mandarins

The distribution of this production, was the following (Table6):

Table 6.- Usage of the S Spanish Clementine mandarins (1000 tm)					
Season	Production	Exports	Domestic consumption		Withdrawal and wastes
			Fresh	Processing	
				g	
1996-97	885*	730,8	150	99	5,2
1997-98	1175*	895,9	261	156	88,7
1998-99	1080*	36,3	223	170	36,3
1999-00	1286,2	925,3	167,9	130	63
2000-01	1088	760	190	115	23
AVERAGE	1103*	669,66	198,38	134	43,24
%		56,19	16,64	11,24	3,63

**Author's (Santaballa) values corrected to correspond to Table 1.*

3.2.- Importing country of Spanish citrus

The exports of Clementine mandarins per importing country is shown in the table 7

4.- THE NUMBER OF PACKING HOUSES AND PRODUCING GROUPS.

In Spain there are around 600 citrus exporters. From these, around 500 (350 private exporters and 150 cooperative societies) export Clementine mandarins

However and because of technical and logistical complexities to export mandarines to U.S., it is estimated that only around 125 of these exporters have the capability to reach this objective

COUNTRIES	SEASON				
	95-96	96-97	97-98	98-99	99-00*
FRENCH	205,0	194,2	211,4	162,1	195,1
GERMANY	265,0	239,8	287,4	229,1	260,2
NEDERLAND	34,3	42,4	53,5	40,5	47,6
BELGIUM	22,7	29,2	36,8	25,1	27,3
U. K. - IRELAND	52,2	53,9	62,6	50,1	66,4
DENMARK	8,8	10,8	16,3	13,2	15,5
SWEDEN	3,2	3,6	3,1	3,5	5,1
FINLAND	2,3	2,1	3,6	3,4	5,4
AUSTRIA	4,5	7,7	12,5	10,3	9,5
ITALY	3,5	25,3	29,0	33,4	47,5
PORTUGAL	0,8	1,0	2,4	5,6	1,8
TOTAL EEC	601,5	610,0	718,6	584,4	681,4
SWITZERLAND	24,4	25,2	28,8	25,5	18,3
NORWAY	4,0	3,8	9,2	9,9	9,2
TOTAL EUR. OC. OUSIDE EEC	28,4	29,0	38,0	35,4	27,5
USA	14,4	26,3	33,9	45,0	79,3
CANADA	7,1	8	8,2	7,5	8,9
ORIENTAL EUROPE	45,8	57,2	96,3	92,7	127,5
ANOTHER COUNTRIES	0,1	0,3	0,9	0,4	0,7
TOTAL OUTSIDE EU. OC	66,8	91,8	139,3	619,8	216,4
TOTAL	696,7	730,8	895,9	765,4	925,3

5- MAIN MANDARINS PESTS: DISTRIBUTION.

The most important pests (11) and diseases (1) of the Clementine mandarins in Spain, and the periods of occurrence are shown in the figure 7.

6.- CONTROL METHOD.

In the table 8 are shown the recommended products to treat the mentioned pests

Table 8.- Recommended products

Twospotted mite <i>Tetranychus telarius</i>	dicofol, dicofol+tetradifón, dicofol+exythiazox, fenbutatin, pyridaben, tebuphenpirad
Citrus red mite <i>Panonychus citri</i>	amitraz, dicofol+tetradifon, dicofol, exythiazox, fenbutatin, fenazaquin, flufenoxuron
Black scale <i>Saissetia oleae</i>	chlorfenvinphos, fenoxycarb, phosmet, methidathion, azinphos-methyl, piriproxyphen
Diaspine scales <i>Parlatoria pergandei</i> <i>Lepidosaphes spp</i> <i>Aonidiella aurantii</i>	Mineral oils, chlorpiriphos, azinphos-methyl, methidathion, omethoate, quinalphos, pirimiphos-methyl, piriproxyphen
Aphids <i>A. ciotricola, A. Gossypii</i> <i>M. persicae, T. aurantii</i>	Benfuracarb, carbosulfan chlorpiriphos dimethoate, ethiofencarb, metomyl, oxidemeton-methyl, pirimicarb,
Green bug <i>Calocoris trivialis</i>	dimethoate, malathion
Citrus leafminer <i>Phyllocnistis citrella</i>	abamectine, azadiractine benfuracarb, diflubenzuron, flufenoxuron hexaflumuron, imidacloprid
Woolly Whitefly <i>Aleurothrixus floccosus</i>	buprofecin, butocarboxim, fenazaquin, fenotiocarb, flufenoxurón Mineral oils + ethion
Medfly <i>Ceratitis capitata</i>	malathion
Phytophthora Root Rot	Copper compounds, Fosetyl-Al, Metalaxyl
Brown Rot <i>Phytophthora spp</i>	Copper compounds, Fosetyl-Al

For the U.S., only the products in bold must be used

Appendix 3. Variability and Distribution of Input and Outputs

The table below details the simulation results after running 10,000 iterations of Monte Carlo sampling of the distributions described in tables 1a and 1b.

The outputs summarize the endpoints for the model. The values for the endpoints are described with the minimum, mean, and maximum values after 10,000 iterations. The inputs are similarly described.

The 95% confidence interval (last column) is interpreted as the value for which there is 95% confidence that values are equal to or below the number indicated. For example, in terms of the first row, Number of adult flies under the mitigated scenario that arrive each year at a suitable location, the mean value is 3.29 and further, 95% of the values associated with different iterations of this model will result in values equal to or less than 6.16E-05. Alternatively, there are less than 5% of all values likely to be greater than 6.16E-05.

Type	Variable	Minimum	Mean	Maximum	95%
Output 1	Mitigated Number Flies per year at a Suitable Location	5.25E-08	3.29	10518.82	6.16E-05
Output 3	Baseline Number Flies per Year at a Suitable Location	6.4E-08	29.2	106395.9	4.26E-04
Output 2	Mitigated Number Flies per Year at all locations	1.31E-07	7.8	23786.09	1.53E-04
Output 4	Baseline Number Flies per Year at all locations	1.52E-07	69.2	234360.3	1.03E-03
Output 5	Mitigated Mated Pairs in all shipments	1.10E-16	0.04	1	1.53E-10
Output 7	Baseline Mated Pairs in all shipments	1.87E-16	0.13	1	7.1E-09
Output 6	Mitigated Mated Pairs in one shipment	9.16E-23	8.7E-05	0.70	1.13E-16
Output 8	Baseline Mated Pairs in one shipment	1.46E-22	7.2E-04	1	5.21E-15
Input c1	Fruit in shipments	6.4E+08	7.2E+08	7.99E+08	6.48E+08
Input c2	Mitigated - infested fruit	1.31E-06	3.17E-03	1.34E-02	3.34E-04
Input c3	Mitigated - Larvae per fruit	1.02	43.50	180.4	5.59
Input c4	Mitigated - Cold treatment	4.1E-14	8.96E-07	1.48E-03	6.78E-11
Input c5	Mitigated - Larvae viability	7.85E-04	8.67E-02	0.2	2.78E-02
Input c6	Mitigated - reaches suitable area	0.34	0.41	0.49	0.36
Input c1b	Fruit in shipments	6.4E+08	7.2E+08	7.999891E+08	6.48E+08
Input c2b	Baseline - infested fruit	1.38E-06	2.57E-02	0.1305593	1.68E-03
Input c3b	Baseline - Larvae per fruit	1.0	43.5	182.7133	5.59
Input c4b	Baseline - Cold treatment	8.08E-14	9.60E-07	1.95E-03	6.78E-11
Input c5b	Baseline - Larvae viability	2.02E-03	8.67E-02	0.2	2.78E-02
Input c6b	Baseline - reaches suitable area	0.34	0.41	0.49	0.36