



**Movement of Citrus Fruit from Citrus Canker  
Disease Quarantine Area  
Supplemental Risk Management Analysis**



**Response to peer review**

United States  
Department  
of Agriculture

Animal and  
Plant Health  
Inspection Service

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# 1 Introduction

Following Office of Management and Budget (OMB) guidance (OMB 2004), the risk management analysis published with the proposed rule for amending the citrus canker regulations to modify the conditions under which fruit may be moved interstate from a quarantined area was submitted for peer review. The analysis was reviewed by three experts in the fields of citrus diseases, plant pathogenic bacteria, and risk assessment. Each reviewer addressed specific issues raised in the peer review charge. In particular, the reviewers were asked:

1. Does the analysis clearly characterize the potential, or lack thereof, for commercially packed citrus fruit to serve as a pathway for the introduction and/or spread of *Xanthomonas citri* subsp. *citri*?
2. Are the data or other evidence complete? If not, please indicate significant references that should be included.
3. Does the analysis accurately characterize the cited literature?
4. With regard to the methodology, is the approach and process appropriate for the analysis?
5. Are all important assumptions identified and uncertainties clearly stated?
6. Is any part of the document difficult to read or understand?
7. Do the data and the evidence support the range of risk management options presented?

The charge to the reviewers, the original and revised risk analyses, and the peer review report are available at [http://www.aphis.usda.gov/peer\\_review/peer\\_review\\_agenda.shtml](http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml).

The reviewers were generally supportive of the methods, evidence, and conclusions presented by the Animal and Plant Health Inspection Service (APHIS) in the risk management analysis. They also asked a variety of questions and suggested minor refinements. We made changes to the risk management analysis in response to editorial suggestions, without noting them individually here. In this document, we respond to the content-related comments and questions raised by the reviewers. We indicate in each case whether we have amended the risk management analysis in response to the comment.

## 2 Comments and Responses

### **2.1 Does the analysis clearly characterize the potential, or lack thereof, for commercially packed citrus fruit to serve as a pathway for the introduction and/or spread of *Xanthomonas citri* subsp. *citri*?**

**Comment:** *It does not seem that characterizing the pathway was a primary purpose of this analysis. Rather, updating a previous analysis, where the pathway was characterized, was the focus. Consequently, the details of the pathway and related “Xcc introduction” scenarios are absent as is the supporting literature for this pathway. It is presumed this was intentional and it appears to me appropriate; if it was not then, no, the pathway is not clearly characterized... For the record, the potential for intentional use of commercially packed fruit for introduction or spread of Xcc was mentioned by me for completeness. There are many far more effective ways to introduce Xcc if this was an intentional desire. I do not mean to suggest this must be done, but expressing an awareness and providing at least brief consideration of this motivation would be beneficial.* (Reviewer 2)

**Response:** The reviewer is correct in his assumption that potential pathways were more thoroughly discussed in previous analyses that were available to the reviewer. All relevant previous analyses were included in the package of supporting documents supplied to the peer review contractor.

The reviewer noted that there are alternative pathways to the introduction of Xcc, such as deliberate introductions. APHIS concurs that there are more effective ways for intentional introduction of Xcc and further notes that this analysis was explicitly limited to commercially packed citrus fruit as a pathway. Deliberate introduction was outside the scope of this document.

The supplemental RMA states “This Supplemental RMA does not recreate or revise the entire body of evidence cited in the previous RMA (USDA, 2007b), but rather it evaluates those areas of evidence impacted by the new research.”

### **2.2 Are the data or other evidence complete? If not, please indicate significant references that should be included.**

**Comment:** *The data are almost exhaustive. The only missing comments or evidence that I questioned is the lack of mention of how the cull piles in the packinghouse are dealt with. They may be a source of contamination (or not), but I did not see the question addressed, which may have been done many years ago.* (Reviewer 1)

**Response:** Culls in Florida are removed from the packing stream and redirected to juicing, livestock feed, or other alternative uses that limit the opportunity for contamination. A statement to that effect occurs in the supplemental RMA in Section 3.4 Environmental and Epidemiological Conditions for Xcc Establishment. Since Florida citrus is not shipped interstate in bulk, as it must be treated and plant debris must be removed before interstate movement, no similar culling process with its resulting cull piles would occur in destination States.

**Comment:** *An RMA is different in purpose from a risk assessment, and its requirements are likewise different. The data and evidence in a risk assessment is bound to differ from the evidence in an RMA. I expect a risk assessment to focus narrowly on matters of science. I expect an RMA to reflect the judgments and findings of that assessment, along with the most relevant and significant uncertainties, and the social values of importance to decision makers.*

*It is unclear from the SRMA what the APHIS decision process is.*

*Risk management is the decision-making component of the risk analysis process. Most decision science suggests that clearly articulated objectives are essential to a good decision. The objectives of this SRMA seem to consist of reducing uncertainty about the commercially packed fruit pathway and revisiting the risk management options under consideration. Those strike me more as tasks than objectives or goals.*

*If decision criteria beyond the scientific evidence introduced by Gottwald and Shiotani will be used in the risk management decision then no, this analysis is not complete.*  
(Reviewer 2)

**Response:** This differs from the IPPC definition of risk management. In the phytosanitary definition, risk management is about evaluation of the effectiveness of measures. So whereas the reviewer is correct about risk management including social and policy level factors in other disciplines, such factors are not within the scope of phytosanitary risk management analysis. The ISPM 11 definition (stage 3 of the risk analysis process) is: "Pest risk management (in the analytical sense) is the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions, and identifying the most appropriate options." Thus, the definition used by the reviewer is much broader than the IPPC definition used by the analysts.

For this reason, this Supplemental RMA has a much more limited scope than the prototypical risk management documents from other disciplines that the reviewer refers to; it focuses on scientific evidence and the operational feasibility of the management options. As such, this document does not address social or economic issues; these are addressed in separate analyses that are part of the regulatory docket. The sum of all these analyses and the decision process is then summarized elsewhere in the proposed rule itself. That said, additional language was added to the section describing the purpose and scope of the supplemental RMA to clarify these points.

APHIS would characterize reducing uncertainty about the commercially packed fruit pathway and revisiting the risk management options under consideration as objectives and not tasks. As noted above, additional language was added to the section describing the purpose and scope of the Supplemental RMA to explicitly state the objectives of the analysis.

### **2.3 Does the analysis accurately characterize the cited literature?**

**Comment:** *The literature cited section is inaccurate, little of the literature included is actually cited in the SRMA. Either whittle the list down to what was cited or provide a more accurate title for the list. (Reviewer 2)*

**Response:** The document was written using software with a “cite while you write” interface that only adds references to the literature cited when those references are cited in the document. A manual check of each of the 40 + citations in the literature cited section confirmed that every one was cited in the document.

### **2.4 With regards to the methodology, are the approach and process appropriate for the analysis?**

**Comment:** *The only area in which I found some discrepancy was in the sanitation of the fruit in the packinghouse (i.e. the newest publications [Cantero; Gottwald] provided data indicating that the combined use of chlorine and SOPP [sodium orthophenyl phenate] were superior to the use of either alone). Further studies on the combined treatment may or may not be warranted: if the cost and time involved in treatment are not an issue (costs were not addressed, as far as I could tell), then recommend or require both be used. (Reviewer 1)*

**Response:** APHIS did not intend the RMA to include final decision-making, rather the purpose of this document was to evaluate new research and place it in context with the existing body of scientific evidence, then provide risk management options for decision makers to evaluate. The supplemental RMA examined the new evidence regarding a pretreatment detergent wash in the context of the other evidence available; the decision on whether to require the pretreatment detergent wash was reserved for the proposed rule

**Comment:** *I raise the concern about how applicable this new evidence is to all citrus. Unless the reasonableness of extrapolating from the experimental citrus to all citrus can be established, it is fair to question whether the most appropriate options have been identified. As argued elsewhere in this review, it may be advisable to consider risk management options for specific citrus types and varieties. I must stress that I have no experience or evidence to think this is necessary, I simply note the advisability of*

*addressing this uncertainty in an explicit fashion. That is not done anywhere in the document.*

*There is no apparent systematic effort to evaluate the efficacy of these risk management options. Neither is there an effort to evaluate them against other decision criteria. I consider this a weakness of the analysis. It diminishes the utility of this SRMA in supporting decision making. If the efficacy is not explicitly considered due to a lack of data, then this needs to be identified and highlighted as a relevant uncertainty in the analysis.*

*It is unclear if this document was intended to proceed to the decision step. (Reviewer 2)*

**Response:** APHIS believes that its inferences (“extrapolation”) are appropriate based on the evidence since the citrus varieties used ranged from susceptible (grapefruit) to less susceptible (lemon) to relatively resistant (mandarins). We have, in response to the comment, added language to the RMA paragraph on assumptions to explicitly state our position.

The RMA provides evidence regarding the efficacy of various risk mitigation measures contained within each of the proposed risk management options. The efficacy is evaluated from the standpoint of the degree to which current restrictions should be adjusted in light of new information.

APHIS did not intend the RMA to include final decision-making, rather the purpose of this document was to evaluate new research and place it in context with the existing body of scientific evidence then provide risk management options for decision makers to evaluate based on this and other analyses (*e.g.*, environmental, economic).

**Comment:** *One other pathway I can think of is by introducing insects to lesions to pick up Xcc on body parts and to expose them to sensitive citrus host issue. In natural situations, all cull piles are known to attract flies. (Reviewer 3)*

**Response:** APHIS is unaware of any scientific evidence that flies are capable of vectoring Xcc.

## **2.5 Are all important assumptions identified and uncertainties clearly stated?**

**Comment:** *I could not find any issues not addressed, except the cull pile disposition from the packinghouses. Where are they located? How are they handled? What time frame is used to manage their disposal, or are these used for juice? This may or may not be an issue, since the fruit is very clean. All the data and numbers are very impressive, as well as the description of the phytosanitary inspections, under the conditions imposed for shipment and inspection. (Reviewer 1)*

**Response:** See our response to the cull pile comment above.

**Comment:** *This reviewer is partial to a formal list of key assumptions. No such list is presented in this document. In fairness to the authors, such treatment of assumptions remains in the conceptual realm of best practice. Few risk documents have implemented this practice but that does not excuse its absence... “The previous RMA (USDA, 2007b) concluded that routine procedures applied in packinghouses for cleaning and disinfecting fruit, along with culling and grading, reduce the prevalence of Xcc and the amount of Xcc inoculum associated with harvested fruit, thereby reducing phytosanitary risk. New evidence suggests improvements in packinghouse processes that may further reduce Xcc inoculum levels on fruit.” This, however, only suggests that when these procedures are used they are effective. It is desirable to offer evidence of their usage... It is difficult to constrain the discussion of uncertainty to this document because it is unclear if and what uncertainties may have been identified as critical in previous documents... A list that identifies these uncertainties has potential value in spurring research and in encouraging adaptive learning and adaptive management... Granted, it may well be unreasonable to expect experiments of every possible type and variety of fruit transmitting to every type and variety of host. However, it is essential that APHIS make the strongest case possible for the reasonableness of assuming that the experimental results from two fruit types and varieties can be generalized to all citrus fruits. This is not done... How will this finding affect international movements of commercially packed citrus into the U.S.?*

*To the extent there is significant analytical uncertainty, the risk management strategy should in best practice include an adaptive management plan to reduce such uncertainties and, as needed, modify the execution of the strategy over time. (Reviewer 2)*

**Response:** APHIS concurs that a more explicit statement of assumptions and uncertainties was missing from the document and has added sections explicitly summarizing both. A list of key uncertainties was identified in the previous Xcc documents specifically the previous PRA (USDA, 2007). APHIS concurs that statements better linking this document to the key uncertainties identified in previous documents is warranted and has added such linkage as well as an explicit discussion of uncertainties.

Citrus fruit, once in a commercial packinghouse, are subjected to cleaning and sanitizing processes to minimize surface contaminants and pathogens, and produce clean and attractive fruit for the fresh market. Diseased, damaged, disfigured, and blemished fruits are culled in the packinghouse. These post-harvest measures are largely voluntary, but APHIS provides guidance on their use in the Citrus Health Response Plan, without mandating their application. Although commercial citrus packinghouses in Florida vary in size, scale, and level of mechanization, most employ some or all of the following post-harvest measures which can reduce survival of Xcc inoculum associated with fruit. All registered commercial packinghouses shipping citrus fruit interstate are required to sign compliance agreements with APHIS ensuring that they will comply with the requirements of citrus regulations. An informal survey of 134 Florida packinghouses

conducted by APHIS personnel indicated that all of the establishments employed some form of fruit washing/disinfection. This system for ensuring regulatory compliance is widely used across APHIS domestic quarantine programs and has been effectively used for decades in the citrus canker program.

APHIS believes that inferences based on the evidence (“extrapolations”) are appropriate since the citrus varieties used in the experiments ranged from susceptible (grapefruit) to less susceptible (lemon) to relatively resistant (mandarins). APHIS concurs that this argument can be more explicitly stated in the document and has added language to that effect.

The RMA considers solely the risk associated with this particular action (the domestic movement of fresh citrus fruit). Before we would consider using an approach similar to those considered in the RMA to allow the importation of citrus fruit from canker-affected areas in another country, the national plant protection organization of such a country would need to submit a request that we do so. A country requesting to be able to use this framework to export citrus to us would have to demonstrate the ability to perform the required phytosanitary measures; it would also be required to have a bilateral workplan in place with APHIS. In addition, there may be other citrus pests in foreign citrus production areas whose risk would need to be mitigated separately from the risk posed by citrus canker. We would complete a separate pest risk analysis for such an action.

APHIS notes that this supplemental RMA is itself an example of the Agency’s adaptive management strategy, inasmuch as the RMA was conducted in response to changes in the state of technical knowledge regarding citrus fruit as a pathway for the introduction of Xcc. This is also consistent with international guidelines that note that changes in the state of scientific knowledge are appropriate justification for updating risk analyses and regulations, as appropriate APHIS is committed to continue to adapt to future changes in our knowledge of this disease.

## **2.6 Is any part of the document difficult to read or understand?**

**Comment:** *There is a difficulty with repetitious material. The analysis is relatively brief, and much of the material is repeated at least once (often in the description of risk management options). Some phrases, facts, and quotes appear far too many times for a document of this length. Several phrases are repeated to the point of distraction. The document reads as if it were written by several authors with each careful to quote the same material. As a small, illustrative example the phrase “packinghouse-disinfested...” is quoted five times (Reviewer 2)*

**Response:** While APHIS notes that there is repetition in the document, we feel that given the regulatory nature of this document, it is important to maintain consistent language not only throughout this document, but among the various Agency documents related to this proposal and previous regulatory documents on this issue. This inevitably results in a certain level of redundancy.

## **2.7 Do the data and the evidence support the range of risk management options presented?**

**Comment:** *In general, yes. But one could make the argument that shipments to CA and AZ be less stringently overseen because the climates in both citrus-producing states are not conducive to the establishment of the citrus canker pathogen, even if it were to be introduced by a commercial infected or contaminated fruit. It would, however, be prudent to watch climate change predications, because the U.S. has seen some highly improbable disease situations occur, perhaps most notable recently the entry and establishment of the fungal soybean rust pathogen. (Reviewer 1)*

**Response:** APHIS concurs that climate studies have suggested that the climates of CA and AZ are not generally well-suited to support Xcc outbreaks and we concur with the reviewers that climate change may have future impacts (though we do not agree with the characterization of the entry and establishment of soybean rust as highly improbable). If natural climate were the only risk factor that distinguished the States, then we could qualitatively conclude that potential susceptibility to citrus canker is less in California than in Louisiana or Texas. However, variations in the amount of rainfall within each State, and the use of irrigation in areas with less rainfall blur that conclusion.

**Comment:** *Some of the risk management options appear incomplete. Completeness would seem to be an essential attribute of any and every risk management option. Option 2 on page 18 says in part: “If Option 2 is selected, APHIS would determine whether to continue to require the currently approved disinfectant treatments ...or apply modifications based on recent research.” This comes up again for Option 3, page 19.*

*Of greater concern is the fact that until the uncertainty about packer and distribution behavior and extrapolation of the Gottwald/Shiotani experimental results to all citrus are addressed, it is unclear if the risk management options are complete. Consider this excerpt from page 20: “The Shiotani et al. (2009) ... studies were limited to Satsuma mandarins, a citrus variety highly resistant to citrus canker disease.” Unless and until APHIS provides evidence or a reasonable argument for assuming these experimental results are applicable to all fruits, it may be desirable to consider risk management options that treat different citrus fruits differently. For example, resistant varieties may be treated differently than less resistant varieties.*

*In a similar manner, once it has been established that compliance with postharvest procedures and other assumed compliance behaviors is widespread and conscientious, the five formulated options represent a reasonable range of risk management options. (Reviewer 2)*

**Response:** As noted previously, APHIS did not intend to take this analysis through to decision making, rather the purpose of this document was to evaluate new research and place it in context with the existing body of scientific evidence, then provide risk

management options for decision makers to evaluate. The supplemental RMA examined the new evidence regarding a pretreatment detergent wash in the context of the other evidence available; the decision on whether to require the pretreatment detergent wash was reserved for the proposed rule.

As also noted above, APHIS believes that extrapolation is appropriate research since the citrus varieties used in the conducted ranged from susceptible (grapefruit) to less susceptible (lemon) to relatively resistant (mandarins). APHIS concurs that this argument can be more explicitly stated in the document and has added language to that effect.

All packers shipping interstate are currently required to sign compliance agreements with APHIS agreeing to comply with the requirements of the canker regulation. This includes periodic monitoring of the packinghouse disinfection solutions. This will not change even if the proposed regulation changes are made. This system for ensuring regulatory compliance is widely used across APHIS domestic quarantine programs and has been effectively used for decades in the citrus canker program.

### **3 Summary**

The three reviewers generally agreed that the analysis presented in the document clearly characterizes the potential of commercially packed citrus fruit as a pathway for the introduction and spread of citrus canker. Each reviewer identified additional areas to address in the analysis, for example, the extrapolation of the new research to all types and varieties or the explicit discussion of assumption and uncertainties. APHIS has addressed these concerns and others by changes to the final RMA or by providing clarification in this response.

The reviewers agreed that the document was generally well organized and clearly written. One reviewer offered suggestions for improving the document by reducing the repetition and explicitly discussing uncertainties, assumptions and objectives.

The three reviewers think that the five risk management options presented were logical ones to consider given the evidence available.

## 4 References

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USDA (2006). Evaluation of asymptomatic citrus fruit (*Citrus* spp.) as a pathway for the introduction of citrus canker disease (*Xanthomonas axonopodis* pv. *citri*)- March 2006. Raleigh, NC, U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Plant Epidemiology and Risk Analysis Laboratory

Sheryl Cates Catherine Viator, "Citrus Canker Peer Review: Final Report", July 2007, RTI International Health, Social, and Economics Research, Research Triangle Park, NC. (available at [http://www.aphis.usda.gov/peer\\_review/peer\\_review\\_agenda.shtml](http://www.aphis.usda.gov/peer_review/peer_review_agenda.shtml))