March 2009

Peer Review of Supplemental Risk Management Analysis for Movement of Citrus Fruit from Citrus Canker Disease Quarantine Area

Final Report

Prepared for

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Executive Summary

The Office of Management and Budget (OMB) requires a peer review for important scientific information to ensure the quality of scientific and technical research and guide improvements in draft scientific documents before federal agencies disseminate them (OMB, 2004). The Animal and Plant Health Inspection Service (APHIS) is interested in conducting a peer review of the document *Movement of Commercially Packed Citrus Fruit from Citrus Canker Disease Quarantine Area—Supplemental Risk Management Analysis.* This scientific document is related to the effectiveness of potential measures to prevent the spread of citrus canker disease via commercially packed fruit from quarantined areas, currently the state of Florida, to areas where the disease does not occur. APHIS requested RTI International's support for conducting a peer review conforming to OMB's guidelines (OMB, 2002; 2004) under their task order contract (AG-6395-C-07-0046, Task 4).

RTI conducted the peer review according to the statement of work. We identified and selected three experts to review the Risk Management Analysis (RMA) document:

- Mani Skaria, Texas A&M University Kingsville Citrus Center—an expert in plant pathology
- Anne Vidaver, University of Nebraska—an expert in phytobacteriology
- Charles Yoe, College of Notre Dame at Maryland—an expert in risk assessment

The blinded reviews are included in no particular order as Appendices A, B, and C.

1 Background and Objective

RTI International coordinated an external peer review of the document *Movement of Commercially Packed Citrus Fruit from Citrus Canker Disease Quarantine Area—Supplemental Risk Management Analysis,* as requested by the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) under task order contract AG-6395-C-07-0046, Task 4. This scientific document is related to the effectiveness of potential measures to prevent the spread of citrus canker disease via commercially packed fruit from quarantined areas, currently the state of Florida, to areas where the disease does not occur. In this report, we present background information about the peer review, describe the review process, list key questions or the charge to the reviewers, and include the three peer review reports.

The document that was reviewed updates the risk management analysis (RMA) entitled *Movement of Commercially Packed Citrus Fruit from Citrus Canker Disease Quarantine Area: Risk Management Analysis* prepared by USDA in 2007. Research summarized in two recent publications provides additional evidence addressing key uncertainties identified in the RMA that justified revisiting the conclusions on both fruit as a pathway and subsequent risk management options. APHIS determined that the new research significantly reduces the level of uncertainty that commercially packed citrus fruit is unlikely to play a role in transmitting and establishing citrus canker disease.

Conclusions drawn from new evidence include the following:

- Postharvest treatments (including a prewash) substantially reduce bacterial populations on fruit.
- Viability of bacteria on fruit declines significantly after harvest.
- Bacteria populations in wounds declined to undetectable levels within a few weeks after harvest.
- There is a low potential for disease spread from infected fruit to susceptible hosts.
- Discarded infected fruit rinds do not spread the disease.

The supplemental RMA updates the sections pertaining to the biology and epidemiology of citrus canker disease in the original RMA and supports the findings from the previous RMA that commercially packed fresh citrus fruit is unlikely to be an epidemiologically significant pathway for the introduction and spread of the bacterium.

After reviewing the available evidence, including the new research, APHIS concluded that although citrus fruit may remain a conceptually possible pathway for transmitting and establishing citrus canker disease, research shows that extreme conditions are required to successfully transmit the pathogen from infected fruit to a susceptible host, and even under these extreme conditions, transmission is rare. APHIS concluded that commercially packed citrus fruit is unlikely to be an epidemiologically significant pathway for transmitting and establishing citrus canker disease in regions currently free of citrus canker disease.

Based on these conclusions, the supplemental RMA identifies several options for modifying APHIS regulations on the interstate movement of citrus fruit from regions quarantined for citrus canker. The risk management options evaluated are as follows:

- **Option 1:** Allow unrestricted distribution of all types and varieties of commercially packed citrus fruit to all U.S. States.
- **Option 2:** Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. States, subject to packinghouse treatment with APHIS-approved disinfectant. No packinghouse phytosanitary inspection is required.

- **Option 3:** Allow distribution of all types and varieties of commercially packed citrus fruit with minimal or no requirements to all U.S. States except commercial citrus-producing states. Allow distribution of all types and varieties of commercially packed citrus fruit to all U.S. citrus-producing States with APHIS-approved disinfectant treatment and some additional requirements (e.g., inspection).
- **Option 4:** Allow distribution of all types and varieties of commercially packed citrus fruit in U.S. States except U.S. commercial citrus-producing States with an APHIS-approved packinghouse disinfectant treatment. No packinghouse phytosanitary inspection required.
- **Option 5:** Leave the current regulations for the interstate movement of citrus fruit from citrus canker disease–quarantined areas in place and unchanged.

The analysis conducted by APHIS is scientifically important and thus warrants an external peer review as per the Office of Management and Budget (OMB) (2004) guidelines. Peer review is an important process that can help ensure that the quality of scientific information meets the standards of the technical community, and it can help strengthen and clarify the analysis. APHIS requested RTI's support in conducting a formal and independent peer review conforming to OMB's guidelines for peer review and quality of information (OMB, 2002; 2004).

2 Description of Review Process

RTI conducted the review process in accordance with OMB's guidelines (OMB, 2004). The review process consisted of selecting the reviewers, explaining the scope of the review, facilitating the review, and consolidating the reviews in a single report.

First, we selected three peer reviewers based on their expertise. We identified 27 potentially suitable reviewers after understanding the background and objectives of the peer review from APHIS. Subsequently, we finalized the list to three reviewers based on their availability and the desired overlap of expertise in the key areas of plant pathology, phytobacteriology, and risk assessment. Additionally, it was desired that one or more of the reviewers have in-depth knowledge and expertise in plant disease transmission, knowledge of citrus canker disease, knowledge of the citrus industry, and knowledge of phytosanitary procedures for citrus fruit. We also considered conflict of interest in the selection process.

We selected the following individuals to peer review the document:

- Mani Skaria, Texas A&M University Kingsville Citrus Center—an expert in plant pathology
- Anne Vidaver, University of Nebraska—an expert in phytobacteriology
- Charles Yoe, College of Notre Dame at Maryland—an expert in risk assessment

Table 2-1 provides a brief description of each of the three peer reviewers.

Table 2-1. Peer Reviewers' Summary of Experience

Mani Skaria

Professor

Texas A&M University Kingsville Citrus Center

Dr. Skaria is a Professor at the Texas A&M University Kingsville Citrus Center. Prior to this appointment, he has worked for Washington State University and the U.S. Agency for International Development. His research focus is on all citrus diseases that are caused by diverse pathogens, including diseases caused by fungi, viruses, bacteria, nematodes, and post harvest pathology. In addition, he has expertise in micro-budding of citrus for use as a disease management strategy via high density planting. He is active in numerous regional, national and international organizations, including serving as chairperson of various committees with the American Phytopathological Society and serving as President of the Rio Grande Valley Horticultural Society. He is an author on more than 100 peer-reviewed scientific publications, proceedings, book chapters, and extension publications. He has presented numerous invited talks and workshops to professional organizations, including the American Phytopathological Society, insurance industries, the National Home Builders Association, and many civic organizations and clubs. Dr. Skaria received his PhD in plant pathology from Purdue University.

Anne Vidaver

Professor

University of Nebraska

Dr. Vidaver has served as a Professor in the Department of Plant Pathology at the University of Nebraska since 1979. She served as Department Head from 1984 through 2000 and again from 2003 through 2006. Her research focuses on the biology, genetics, and management of phytopathogenic bacteria, and endophytic bacteria and their uses. She has authored or coauthored one book, 19 book chapters, 87 refereed journal articles, and 28 extension publications. Dr. Vidaver served on the National Institutes of Health (NIH) National Science Advisory Board for Biosecurity and the USDA/APHIS Quarantine Containment Committee, and was a Chief Scientist for the USDA NRI Competitive Grants Program. She is a Fellow with the American Phytopathological Society, the American Society for Microbiology, and the American Association for the Advancement of Science. Dr. Vidaver received her master's and doctorate degrees in bacteriology from Indiana University.

Charles Yoe

Professor

College of Notre Dame at Maryland

Dr. Yoe serves as both a professor of economics at the College of Notre Dame at Maryland and an adjunct professor in the Department of Nutrition and Food Sciences at the University of Maryland. He also teaches a number of risk analysis, assessment, and management courses at the Joint Institute for Food Safety and Applied Nutrition, and for government and industry clients around the world. He is internationally recognized for his leadership in risk analysis, serving on expert panels for the National Academy of Sciences, the U.S. Army Corps of Engineers, the U.S. Environmental Protection Agency, the North Atlantic Treaty Organization, and the World Health Organization. During his career, he has conducted or participated in over 40 risk assessments. Dr. Yoe has a B.S. in economics, a master's of policy sciences from the University of Maryland, an M.S. in water resources from Colorado State University, and a Ph.D. in agricultural and resource economics from the University of Maryland.

Second, we explained the scope of the review in terms of the charge to the reviewers prepared by APHIS. RTI provided the supplemental risk management analysis, the charge, and a CD containing supporting materials to the reviewers, asking them to provide potential solutions to address their comments. The charge consists of seven questions as described in Section 3. To assist the reviewers in preparing their report, we provided a template that included each question from the charge and space below each question for their response and potential solution.

Third, RTI communicated with the reviewers to ask if they had questions about the scope of the review or the document itself and to remind them of the review deadline. We communicated the progress and status of the review to APHIS regularly and ensured that the reviewers were meeting the objectives of the peer review. We also ensured that the reviewers describe possible ways to address their concerns instead of only describing the concerns.

We compiled the three reviews in a single report. We include the original peer reviews as Appendices A, B, and C. To maintain the integrity of the reviews, we present the reviews as appendices to this report instead of consolidating the comments by the charge questions. Each reviewer focused on different aspects of the charge questions depending on his/her area of expertise, and their reporting formats and writing styles also differ. Therefore, reading each review separately can help readers better understand their comments. We have corrected minor typographical errors and slightly reformatted their reports to ensure a minimum level of uniformity of presentation in this report.

3 Charge to the Peer Reviewers

APHIS asked the reviewers to focus and structure their reviews on the specific questions listed below. APHIS wants to confirm that the scientific information is sufficiently complete to support the results, that the results are consistent with the evidence, and that the rationale supporting conclusions is clear and convincing.

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, are 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?

References

The Office of Management and Budget (OMB). 2002. "Information Quality Guidelines." Washington, DC: The Office of Information and Regulatory Affairs, Office of Management and Budget, Executive Office of the President.

The Office of Management and Budget (OMB). 2004. "Final Information Quality Bulletin for Peer Review." A Memorandum for Heads of Departments and Agencies. M-05-03. Washington, DC: Office of Management and Budget, Executive Office of the President.

Appendix A:
Review #1

Peer Review of:

Revised Risk Management Analysis for Movement of Citrus Fruit from Citrus Canker Disease Quarantine Area

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*?**

The analysis is extremely comprehensive, including not only information on the Florida situation but elsewhere in the world. The several hundred pages are packed with experimental protocols, data, and appropriate interpretation. The concurrence of studies in three countries (Argentina, Japan, and U.S.A.) is quite compelling because the strains of the bacterium are presumably all different, the conditions of growth of the host plant differ, and environments and weather differ, etc. Moreover, since the studies encompass multiple years, strain variation, though not discussed (or the lack thereof), is apparently not an issue. Thus, the conclusion that fruit of various citrus species and varieties is not a likely source of introduction and/or spread is valid. This conclusion is backed up by extension experimentation, reports, and statistical analyses.

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

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.

3. **Does the analysis accurately characterize the cited literature?**

The analysis is comprehensive and highly informative. Both experimental and statistical analyses are presented in multiple references that essentially reinforce one another. The exception is noted below.

4. **With regard to the methodology, are the approach and process appropriate for the analysis?**

All the methodology approaches, and processes appeared appropriate for gaining an understanding of a very difficult

problem. 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 orthopehnyl 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.

5. Are all important assumptions identified and uncertainties clearly stated?

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.

6. Is any part of the document difficult to read or understand?

For all the government documents I reviewed for this assignment, they are exceedingly well done and clear. The questions are posed, the data presented, the interpretations given, and the conclusions drawn. The conclusions are reasonably presented, and the options for oversight given with rationale for each possibility.

7. Do the data and the evidence support the range of risk management options presented?

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.

Appendix B:
Review #2

Peer Review of:

Revised Risk Management Analysis for Movement of Citrus Fruit from Citrus Canker Disease Quarantine Area

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*?**

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.

Such a characterization would require an expanded discussion of the means by which commercially packaged fruit could be used intentionally (this does not seem to have been considered) or unintentionally to introduce or spread Xcc. Those details are presumed to have been adequately addressed in the risk assessment and previous RMA. (Neither was made available with my supporting materials CD.)

Given the stated purpose of the Supplemental Risk Management Analysis (SRMA), and absent the comprehensive detail noted above, the characterization was quite clear. It needs to be noted that the contextual focus of this SRMA was intentionally narrow. This reviewer accepts the stated purpose without judging it. In essence the SRMA says that in the original RMA there was too much uncertainty to preclude the possibility of introduction/spread of Xcc via the commercially packed citrus fruit pathway. This SRMA says that new evidence now provides the credible basis for considering this introduction unlikely and to warrant reconsideration and expansion of the risk management options. This was clearly and effectively stated and supported.

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.

The SRMA does establish the unlikely nature of introducing Xcc via commercially packed citrus to a reasonable degree of certainty, subject to successfully establishing that the expected/required postharvest procedures are followed and the reasonableness of extrapolating the Gottwald and Shiotani results to all citrus (these two points are detailed in my response to subsequent questions).

Recommendations

1. Provide specific mention/citation of the documents where the details on the pathway can be found.

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

I lack the qualifications to comment on the Xcc-specific scientific evidence presented. The review of Gottwald and Shiotani appeared adequate in intent, purpose, and execution.

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. So I approach my answer to this question through the filter of the lens (i.e. I look for more than science). This additional information was generally not presented.

Decision Context/Problem Identification

APHIS has done a good job of establishing the decision context. The purpose of this SRMA is clear and well identified. I have some issue with whether it is complete enough in terms of the handling of uncertainty, but that point will be made in response to subsequent questions.

Decision Process

The process by which a risk management decision is made is often the most opaque part of a long and rigorous analytical

process. It is unclear from the SRMA what the APHIS decision process is. Two questions of obvious interest in any decision making context are as follows: 1) Do you have a process and 2) Did you follow your process?

It is unclear from the SRMA how APHIS would answer these questions. That is not to argue for a detailed explanation but to suggest that a paragraph and figure or other supporting material that explains the general process by which a decision will be reached would aid transparency and a structured decision-making process. It would also enable reviewers to better judge the completeness of the information herein.

Risk Management Objectives

What is it that APHIS is ultimately trying to accomplish (i.e., what are the desired outcomes of this decision problem?)? This is neither clearly stated in terms of broad general agency responsibilities and mission nor in specific terms of this Xcc issue. It should be. 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.

It is possible that as a principally internal decision document the objectives are well understood by all but the outside reviewer. Best practice necessitates a clear statement of the objectives of the risk management analysis.

Decision Criteria

Closely related to the previous point is the absence of discussion about decision criteria. When a decision is made about which risk management option is to be implemented how will that decision be made? Will it be solely based on the likelihood of introduction/spread of Xcc? Will it include the costs of implementation? Will it include any consideration of how this domestic decision might affect subsequent international trade decisions? Are there jobs and income concerns in the current economic environment? Any, all or other than these could be legitimate considerations for a decision. None of these are identified in this document. It would be wise to do so.

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.

Recommendations

1. Provide some discussion of or link to APHIS's decision-making process.
2. Include a simple statement of objectives.
3. Identify the decision criteria.

3. Does the analysis accurately characterize the cited literature?

The literature cited in the SRMA was limited and appropriately so. This analysis built on and evolved the work done in previous analyses. The bulk of the literature is really cited in those resources. The Gottwald and Shiotani articles seem to have been accurately characterized, although this science is not part of my personal expertise.

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.

Perhaps a more germane question is does the analysis cite enough literature? Specifically, is there literature germane to potentially significant uncertainties that have not been formally identified? For example, is there literature that documents practice of postharvest procedures in the field? Is there literature that addresses the susceptibility of different citrus varieties to Xcc? More is said about these uncertainties in response to Question 5.

I have no specific expertise in the biology of Xcc or citrus fruit and am unable to contribute to the literature in these areas.

Recommendations

1. Change name of literature cited or whittle the list down.
2. Consider adding literature on postharvest behaviors in the field and extrapolating the Gottwald and Shiotani results to all citrus.

4. With regard to the methodology, are the approach and process appropriate for the analysis?

There is no widely recognized, generally prescribed approach for risk management. There are many models in circulation. If APHIS has a risk management model or standard operating procedure (SOP), it is not made known to the reader, so it is unclear if they have a process and if they do whether it has been followed or not. In general, the approach is appropriate for the analysis, but there are opportunities for improving it.

The IPPC is one source of general guidance on the practice of risk analysis for plant pests. It promulgates international guidance, however, and that is in no way binding although it is of general interest.

ISPM No. 11 Pest Risk Analysis for Quarantine Pests Including Analysis of Environmental

Risks and Living Modified Organisms (2004) offers basic guidance on pest risk management (Stage 3). It says in part (page 130, emphasis added):

"The conclusions from pest risk assessment are used to *decide whether risk management is required* and the strength of measures to be used. Since zero-risk is not a reasonable option, the guiding principle for risk management should be to manage risk to *achieve the required degree of safety that can be justified* and is feasible within the limits of available options and resources. 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*. The *uncertainty noted in the assessments of economic consequences and probability of introduction should also be considered and included in the selection* of a pest management option."

Referring to the emphasized tasks above, this analysis has quite effectively addressed the need for risk management. Likewise it has identified a number of ways to act in response to the assessed risk. The required degree of safety is left implicit rather than made explicit. The SRMA could be strengthened to the extent this degree of safety is described or made explicit, but the implicit judgment is evident.

It was judged that there was too much uncertainty remaining in the original RMA to allow movements of commercially packed citrus to citrus-producing states. This SRMA presents evidence that lessens this uncertainty. 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.

IPPC document ISPM No. 14 The Use of Integrated Measures in a Systems Approach for Pest Risk Management (2002) is more germane to systems approaches to risk management. ISPM No. 14 defines a systems approach as:

“A systems approach requires two or more measures that are independent of each other, and may include any number of measures that are dependent on each other. An advantage of the systems approach is the ability to address variability and uncertainty by modifying the number and strength of measures to meet the appropriate level of phytosanitary protection and confidence.”

The current analysis is to be commended for considering a tiered approach, which while not formally a system, it captures the spirit of independent measures functioning together to achieve risk management goals.

In my experience, best practice risk management includes a minimum of the following steps:

- Option formulation

- Evaluation and comparison of options
- Decision making including adaptive management as appropriate
- Implementation
- Monitoring, evaluation, modification

On these points the SRMA has a mixed performance. The SRMA has done an excellent job, with noted exceptions, on formulating risk management options. The evaluation of these options has been restricted to the consideration of the risks and even that remains vague. My own bias is to consider risk management as the integration of science and social values in decision making; thus, I would find a broader evaluation as well as formal judgment of the options' efficacy to be useful.

It is unclear if this document was intended to proceed to the decision step. If so, it has failed to do so. I also have discussed the shortcomings in considering uncertainty in the next response. If there are remaining uncertainties that could require an anticipated change in the risk management strategy, this should be accompanied by an adaptive management component in the risk management option. This would provide an explicit recognition of a key uncertainty, a plan for reducing it, and a plan for adapting risk management to what is learned as that uncertainty is reduced.

It is recognized that implementation and subsequent steps are not appropriate to this analysis.

Recommendations

1. Identify the APHIS risk management process, if only by hyperlink.
2. Provide more explicit identification of the specific range of the risk management process covered by this analysis.
3. Include some evaluation and/or comparison of risk management options in the discussion of options.

5. Are all important assumptions identified and uncertainties clearly stated?

This is the one substantive area where improvement would be most valuable. Assumptions are either not recognized or not explicitly identified in this document. The manner in which uncertainty has been considered is unclear and appears to be incomplete.

Assumptions

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. A list has value for at least two very important reasons. First, it requires the analysts to identify their assumptions. This increases awareness in ways that can produce better decisions. Second, it makes the reader aware of the more subjective aspects of the analysis.

A document search on all words related to "assumptions" produced one hit on page 13:

"Implicit in all these regulations has been the assumption that fruit represents a potentially important pathway for the long-distance dissemination of Xcc."

This assumption forms the primary basis for this SRMA action.

No attempt has been made to comprehensively identify the assumptions made by the analysts; this is best done by the analysts. However, there are implicit assumptions in the document that need to be explicitly recognized for the sake of transparency. These include the following:

1. One hundred percent compliance with APHIS regulations, procedures, and processes appears to be implicitly assumed. There seems to be a common assumption that symptomatic infected fruit and other plant materials are not coming out of the packinghouses, that postharvest treatments like prewashes and disinfecting steps are successfully concluded, all fruit is transported and stored at sufficiently low (5-8 C°) temperatures, and so on. Many behaviors by growers, packers, and the distributors are assumed without supporting evidence that such practice has been verified in the field. This reviewer has no evidentiary reason to quarrel with such an assumption, but it would be desirable for the agency to state these assumptions explicitly and to provide whatever supporting evidence for them that is available. If these assumptions do not hold true, that needs to be addressed in the decision-making process and could affect the formulation of risk management options.

2. It appears to be implicitly assumed that all citrus fruits are well represented by the studies on ruby red grapefruits and Satsuma mandarins. If other citrus are more susceptible to Xcc than these types of fruits, the risk management options may not be adequately formulated. It is essential that this extrapolation assumption be supported with evidence or reasonable argument.

With regard to my first identified assumption (1), the document does say:

"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.

Uncertainty

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. The Executive Summary says in part:

"Research summarized in two recent publications provides additional evidence addressing key uncertainties identified in the RMA which justifies revisiting our conclusions on both fruit as a pathway and subsequent risk management options. APHIS determined that new research by Gottwald *et al.* (2009) and Shiotani *et al.* (2009) significantly reduces the level of uncertainty that commercially packed citrus fruit is unlikely to play a role in transmitting and establishing citrus canker disease (USDA, 2009)."

It is unclear from documents provided in support of this review whether and what key uncertainties were identified in the RMA (not available to me at the time of this review). It is clear that no such list was reproduced anywhere in the Supplemental RMA. This would seem an essential bridge from the original RMA to the SRMA, identifying the key uncertainties in a simple

list, if transparency is desired. The point being that it is not clear from any narrative in the SRMA what the key uncertainties are and whether they have been addressed.

It is, however, very clear in the SRMA that APHIS considers uncertainty about the likelihood of packed citrus fruit in transmitting Xcc to have been significantly and substantially reduced. What is not known from this document alone is what other key uncertainties may still exist.

This reviewer would prefer to see a list of key assumptions and a list of key uncertainties prominently displayed in the front matter of a report that is based in large part on the reduction of uncertainties identified in previous analysis.

Page 3 says in part:

"The new evidence and reduced uncertainties relate to several events identified as necessary for the pathogen to be introduced into a new area on commercially packed citrus fruit and incite a disease outbreak."

This clearly suggests multiple circumstances/events that have been considered uncertain. A list that identifies these uncertainties has potential value in spurring research and in encouraging adaptive learning and adaptive management. It is suggested these uncertain events be clearly, specifically and explicitly identified. One good example of this is found on page 20:

"What was lacking were direct experiments to explore the potential for harvested infected or contaminated citrus fruit to act as the inoculum source for transmission of the bacterium to healthy trees under field conditions. "

More of this kind of direct identification of uncertainties is desired. Some remaining uncertainties are incidentally identified on page 16:

"APHIS notes, however, that uncertainties remain regarding the epidemiological significance of untreated fruit. In the Gottwald *et al.* (2009) study, this uncertainty is linked to the relatively small number of experimental units. This increases the uncertainty and variability of statistical inferences, especially in the single case where transmission occurred in a simulated wind/rain dispersion experiment."

It is fair to say that this uncertainty has been reduced but not eliminated. It is unclear what the third sentence above means when it refers to "increases." The single incidence of transmission raises a question about what could happen in extreme weather events like Hurricanes Katrina, Rita, and Ivan, which have recently ravaged citrus-producing coastal states.

Several times the SRMA quotes the following:

"…cull pile experiment was a highly contrived situation designed to provide every possible opportunity for dispersal of *Xcc* and would be unlikely to occur in most areas, except those locations where hurricanes or tropical storms are common occurrences" (Gottwald *et al.*, 2009)

While it is granted that the confluence of events required for transmission is unlikely (whatever that word is intended to mean), the key piece of new evidence (Gottwald) clearly seems to exempt the very kinds of areas that characterize several of the citrus-producing states. It would seem hurricane and extreme weather events might remain a source of uncertainty that should be addressed at least by recognition and discussion.

The two (numbered) assumptions identified above produce additional sources of uncertainties if we consider any form of negating these assumptions as a possibility, that is, if the behaviors of assumption 1 do not hold in fact. This seems to be a point recognized as a possibility when risk management options are discussed, for example, on page 17 where it says:

"Recognizing the evidence that fruit is an unlikely pathway to introduce Xcc and acknowledging uncertainties regarding untreated fruit, Option 2…"

And again on page 18:

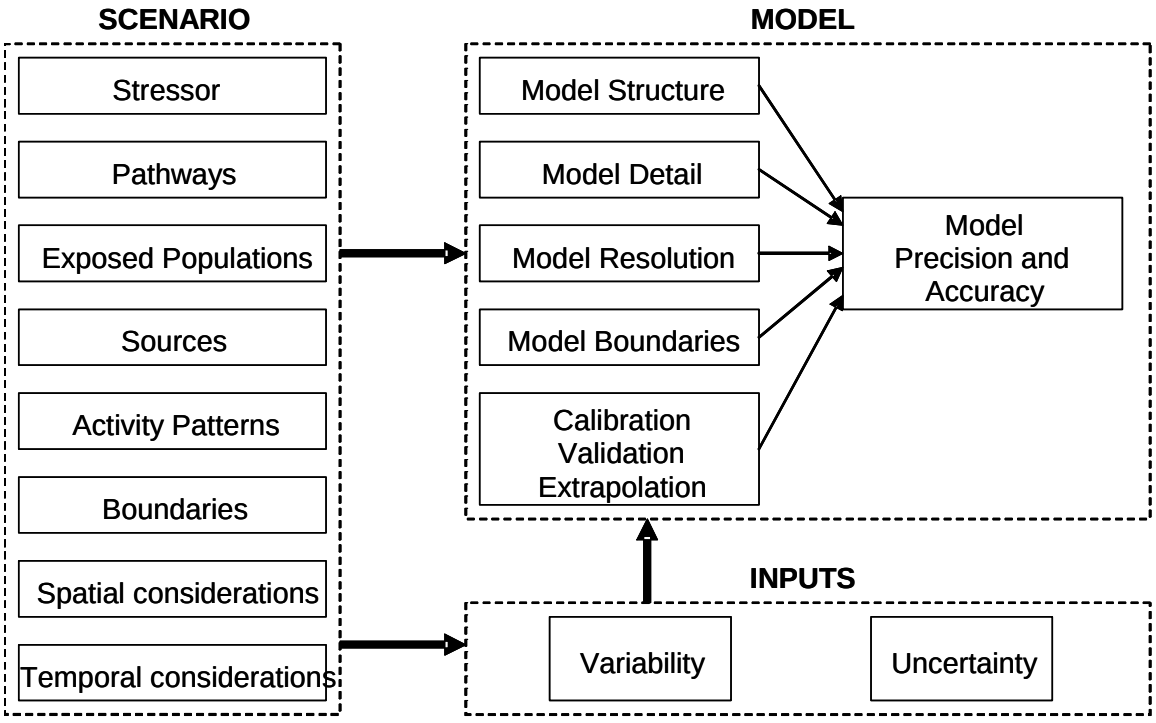
"The uncertainty that remains is the determination of whether a prewash has any epidemiological significance."

This reviewer is not a scientist with an in-depth knowledge of bacterial plant pathogens including Xcc or related Xanthomonads. Nonetheless, it is apparent that the rich diversity of citrus fruit types and varieties can be expected to vary in their susceptibility to Xcc. The new evidence presented was limited to two specific sources of Xcc and a similarly limited consideration of host fruits.

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.

Understanding that policy issues are not in the purview of this review, a seemingly important uncertainty still arises. How will this finding affect international movements of commercially packed citrus into the U.S.? While it is clearly understood this decision focuses on interstate movements of domestically grown fruit, it seems an opportune moment to consider if there are any uncertainties or unintended consequences looming on the horizon.

A final point on the identification of uncertainty is offered, perhaps more for future efforts than this one. This reviewer finds the identification and handling of uncertainty in general to be an area for improvement. Perhaps reliance on a generic scheme, such as suggested below, might aid the organization and discussion of uncertainty.



The scenario for introducing Xcc via movements of commercially packaged fruits has numerous elements as suggested by the figure. This SRMA has done a good job of identifying uncertainty about the stressor (Xcc). It has also considered variability in the data inputs to the decision model in use. But many of the other areas have been unaddressed if not unexamined. It is noted that this does not mean they were overlooked or ignored, simply that uncertainty is nowhere discussed in a comprehensive manner that satisfies either the interested reader or, it is imagined, the decision maker.

Adaptive Management

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. Absent a more complete treatment of the uncertainties in the SRMA, it is not known whether an adaptive management component is necessary in any of the risk management options.

Recommendations

1. Produce a list of assumptions employed in this analysis.
2. Produce a list of significant uncertainties APHIS began the SRMA with as well as those that remain.
    a. At a minimum address the question of postharvest behaviors and the extrapolation from two varieties of citrus to all varieties of citrus.
3. Address the need for adaptive management components of the risk management options as warranted, or not, by the uncertainty.

6. Is any part of the document difficult to read or understand?

The SRMA is clear and generally well written. It has a very effective executive summary that provides a useful overview of the decision context. That decision context is well presented in the body of the report.

The document provides a textbook example of adaptive learning and adaptive management from the risk assessment and RMA to the SRMA; this is a credit to the process and its documentation.

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.

The discussion of risk management options beginning on page 15 to a great extent repeats the information presented earlier. The report would benefit from the services of a professional editor. Finding a satisfactory way to make the important points once and to serve the various arguments building on those points would make a more concise and readable document.

I find the description of Option 4 in the executive summary to be confusing. It needs some commas or perhaps another sentence added.

"Allow distribution of all types and varieties of *commercially packed* citrus fruit in U.S. States **except** U.S. commercial citrus-producing States with an APHIS approved packinghouse disinfectant treatment. No packinghouse phytosanitary inspection required."

The description on page 20 is crystal clear, but I cannot derive one from the other.

Continued movement to a more user-friendly documentation style is strongly encouraged. The consistent use of headings and subheadings is desirable. For example, Section 3.3 and others use some paragraph headings, while Section 3.2 and others do not. Be consistent.

Other user-friendly features to expand include bullet list summaries and text box presentation as support materials useful to some (but not all) readers. Pathway graphics, event tree structures, and more creative use of figures will aid transparency in future efforts.

Recommendations

1. Edit to reduce repetition, producing a more readable document.
2. Add user-friendly features as appropriate.

7. Do the data and the evidence support the range of risk management options presented?

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 varies 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.

If there are insufficient data to establish these points as matters of fact, that lack of information needs to be identified as a significant source of uncertainty.

Having said that, APHIS is to be commended for the genuine effort to identify a range of risk management options.

Recommendations

1. Completely identify all components of every plan or spell out the means and schedule by which these missing details will be provided.

2. Identify and address the uncertainty about postharvest behaviors and extrapolation from two varieties to all varieties through evidence/argument or the formulation of behavior/variety sensitive management options.

Appendix C:
Review #3

Peer Review of:

Revised Risk Management Analysis for Movement of Citrus Fruit from Citrus Canker Disease Quarantine Area

Citrus Canker: A bacterial disease caused by *Xanthomonas citri* subsp.*citri* (Xcc)

Canker Quarantine Area: As shown in http://www.doacs.state.fl.us/pi/chrp/ArcReader/CC_HLB.pdfne

Regulated (= quarantined) fruit may be moved interstate, except to citrus-producing states, if all the specified conditions specified below are met.

1. Canker inspections of every tree no more than 30 days before harvest and the grove thus being found to be free of citrus canker. In the case of limes, reinspection has to be every 120 days or less thereafter as long as harvest continues. About 75% of the commercial citrus in Florida is within 5 miles of canker detection, and the entire state of Florida is a citrus quarantine area.
2. Fruit from canker affected areas should have a limited permit and the boxes and other containers in which it is packaged must be clearly marked with the statement, “Not for distribution in AZ, CA, HI, LA, TX, and American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands of the United States.”

Documents Reviewed:

1. Federal Register, Vol. 71, No. 147, pp. 43345-43352, August 1, 2006
2. Federal Register, Vol. 72, No. 222, pp. 65172-65204, November 19, 2007
3. Citrus Canker: The Pathogen and Its Impact. Gottwald, et al. Online. Plant Health Progress doi:10.1094/PHP-2002-0812-01-RV.
4. Graham, J. H. and T. R. Gottwald. 1997. Research perspectives on eradication of citrus bacterial diseases in Florida. Plant Dis. 75:1193-1200
5. Civerolo, E.L. 1984. Citrus bacterial canker disease: An overview. 1981. Proceedings of the International Society of Citriculture. 1: 390-394.
6. H. Shiotani, et.al. Survival and dispersal of *Xanthomonas citri* pv. *citri* from infected Satsuma mandarin fruit. Crop Protection 28: 19-23.

7. T. Gottwald, et.al. The edimedemiological significance of post-packinghouse survival of *Xanthomonas citri* subsp. *citri* for dissemination of Asiatic citrus canker via infected fruit. Crop Protection 28: 19-23.

Answers to Eight Specific Review Questions

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*?

My Response: The analysis clearly shows that commercially packed citrus fruit does not serve as a pathway for the introduction and/or spread of Xcc.

My Justifications: T. Gottwald et al. had studied the Xcc survival and potential of the bacterium as a source of inoculums for further spread. Semiselective agar medium and grapefruit leaf bioassay were the tools the investigators used, in repeated studies in Florida and Argentina, using grapefruit and lemon, respectively, over a period of 2 years. The authors had shown three aspects related to the Xcc survival: 1) survival of Xcc in lesions and on fruit prior to and after packing line, 2) survival of Xcc in wounds, and 3) survival of Xcc to enter susceptible host via wind or rain (both natural and simulated) and even when an infected fruit is hit with a baseball bat. This 14-author study in two countries had clearly demonstrated that Xcc on packinghouse-disinfected fruit is unlikely to infect susceptible host tissue. The results of the Gottwald et al. study referenced here is in line with a recent study by H. Shiotani et al. in Japan on the survival of Xcc in canker-infected Satsuma mandarin.

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

My Response: The data and scientific evidence are complete and scientifically valid.

My Justifications: T. Gottwald et al. tried to find answers to all uncertainties surrounding the spread of Xcc from packinghouse-processed citrus fruit. The new scientific information that they tried to obtain are given above (see Question 1, My Justification).

My suggestion: I believe, Ron Sparks, Commissioner of Agriculture of Alabama had decided not to honor the USDA's

citrus quarantine that would exclude Florida fresh citrus from Alabama. He had opted to allow Alabama residents the opportunity to enjoy fresh Florida citrus fruit. Alabama has a border with Florida. Satsuma mandarins are a growing commodity in Baldwin and Mobile counties but not large-scale operations.

I suggest that the following data be collected from Alabama.

1. How much fresh Florida fruit has been shipped from Florida to Alabama since the USDA canker quarantine?
2. Was there any evidence of Xcc infection in Alabama as a result of Florida-imported fruit?
3. Trace the origin of new Xcc findings in Alabama, if any.
4. What is the Xcc status in Alabama in general, with or without Florida fruit?

I consider this as a significant piece of information that should be included with the USDA analysis, because it will provide important new scientific information on risk assessment and risk management. Moreover, this information will bring public acceptance.

3. Does the analysis accurately characterize the cited literature?

My Response: I believe, yes.

My Justifications: The analysis show a total of 41 references and the analysis is based heavily on two references by Gottwald et al. and H. Shiotani et al. I have read both Gottwald et al. and H. Shiotani et al. in detail. I am familiar with the work reported in most of the other journal and proceedings publications listed in the document. I am familiar with the *Federal Register*, 2006 and 2007.

4. With regard to the methodology, are the approach and processes appropriate for the analysis?

My Response: I believe, yes.

My Justifications: The analysis show a total of 41 references and the analysis is based heavily on two references by Gottwald et al. and H. Shiotani et al.

T. Gottwald et al. had studied:

a. They studied Xcc survival and its potential as a source of inoculum.

b. They studied the survival of Xcc in lesions and Xcc on fruit prior to and after packing line process.

c. They studied the survival of Xcc to enter susceptible host via wind or rain and used both natural and simulated situations.

d. They also studied a likely situation of hitting an Xcc-infected fruit with a baseball.

e. They did the work in Florida and Argentina.

f. They used Xcc-sensitive grapefruit and lemon.

g. The study was repeated over a 2-year time.

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. Moreover, the artificial inoculation studies they have done are sufficient enough for their studies.

The study conducted by H. Shiotani et al. in Japan with Satsuma mandarin had used more than 3,000 fruit in 2005 and 2006.

5. Are all important assumptions identified and uncertainties clearly stated?

My Response: I believe, yes.

My Justifications: The assumptions in the T. Gottwald et al. study were based on creating situations where the Xcc, if any, from packing line-processed fruit were exposed to Xcc-sensitive host tissue. The study was done over 2 years in two countries.

Note: My citrus pathology experience covers 24 years. My responsibilities as a citrus pathologist cover all aspects of citrus diseases that are caused by 1) fungi, 2) bacteria, 3) viruses, 4) nematodes, 5) insect-vectored, 6) graft-transmissiblem and 7) packinghouse-induced diseases. I cannot think of a situation(s) or assumption(s) that the authors have ignored. However, I have made some suggestions in association with

a. Question 2 above

b. Question 7 below

c. Question 8 below

6. Is any part of the document difficult to read or understand?

My Response: No

My Justifications: The document is easy to read and understand.

7. Do the data and the evidence support the range of risk management options presented?

My Response: The risk management options lack an important aspect.

Risk management options discussed are:

4.1 Option 1—Unrestricted Movement

4.2 Option 2—Unlimited distribution, disinfectant

4.3 Option 3—Two-tier distribution requirements

4.4 Option 4—Limited distribution (all varieties) to non-citrus producing states, disinfectant

4.5 Option—No change

My Response: Lacks a monitoring plan—an important aspect

My Justifications: I believe that with an economically and politically important disease such as citrus canker, the risk management should include three aspects: 1) an assessment of the risk, 2) mitigation of the risks to an acceptable level, and 3) monitoring of risks.

The level of risk with respect to Xcc can be influenced by natural calamities such as hurricanes, human activity and other uncertain activity threats. There should be a risk monitoring plan.

I have not seen a specific plan to monitor the consequences of the new option. To my understanding, Option 2 is a logical one. However, if Option 2 is implemented, there should be a plan to monitor Xcc in citrus-producing states, at least for a period of 2 years. This should be done in all citrus-producing counties outside of Florida to where citrus fruit from Xcc-quarantined areas is shipped.

The monitoring should be done in dooryard citrus (not necessarily in commercial groves) since the pathways are via citrus fruit purchased by people.