March 29, 2006

Ms. Louise Van Meurs
General Manager
Plant Biosecurity, Biosecurity Australia
Department of Agriculture, Fisheries and Forestry
Canberra Australia

Dear Ms. Van Meurs:

We appreciate the opportunity to offer our comments on Biosecurity Australia's (BA) December 1, 2005, revised draft Import Risk Analysis (IRA) for New Zealand apples. The United States is keenly interested in this analysis and the policies stemming from it, as it will affect our longstanding request for U.S. apple access to Australia. We understand from our discussions of the past year that BA will extend its policy for New Zealand apples to U.S. apple access. Of course, adjustment to BA's policy for New Zealand apples would be needed based on differences in the climatic and growing conditions between New Zealand and U.S. apples.

This IRA is one of the most comprehensive and complex commodity risk analyses we have ever seen. However, despite the extensive work, we are disappointed by what we see as a report that is severely flawed, particularly for fire blight and the other diseases for which BA developed semi-quantitative models. We encourage BA to revise the analysis, particularly for fire blight, for the following reasons:

- The IRA should be revised substantially per New Zealand's request to reflect the definition of the commodity as mature, export-quality apple fruit.
- The analysis should be revised to reflect a more accurate and appropriate volume of apples to be exported to Australia from New Zealand.
- The semi-quantitative models should be re-estimated and recalculated to reflect the internationally-recognized scientific evidence, particularly for fire blight. This restructuring should recognize that not all orchards in which *Erwinia amylovora* is present have fire blight and that the disease is not transmitted to orchards in Australia by mature, symptomless apples in commercial trade.
- BA should clearly and transparently present the final assumptions on which the statistical ranges are based for each variable of the model and the final calculations. In many cases, the defined statistical range is not supported by the internationally affirmed scientific evidence. In others, conflicting studies are presented, but no transparent linkage is established between BA's interpretations of the studies and the defined statistical range.
- When the scientific evidence indicates that the likelihood of an event occurring is "0," the model should be re-estimated to take into account that evidence.

- The model should be re-estimated to remove the additive aspects of the analysis, especially when the scientific evidence does not support this feature. This is most apparent for the variables allowing for contamination of apples during harvest, packing and export.

We found BA's use of statistical ranges to define the standard qualitative ranking factors (Negligible, Very Low, Extremely Low, Low, Moderate, and High) to be misleading when used in the disease models for fire blight and European canker, particularly when the assumptions are not clearly defined, are misdefined, are additive, or are not supported by internationally affirmed scientific evidence. It is unfortunate that BA's Appropriate Level of Protection (ALOP) and the potential need for risk mitigations are defined by these calculations.

With regard to BA's proposed risk mitigations for fire blight, we have serious concerns that the measures are not supported by the internationally affirmed scientific evidence regarding fire blight. We believe that appropriate measures for fire blight are that the apples be free of fire blight disease symptoms and be physiologically mature. We encourage BA to re-evaluate these risk mitigations.

We also encourage BA to re-evaluate its analysis of European canker and re-estimate the model for that disease.

We have addressed these issues more comprehensively in our enclosed comments on fire blight and other pests and diseases. We encourage your further review and revision of this IRA. We would be pleased to discuss our comments with you.

Sincerely,

/S/ Michael A. Guidicipietro

Michael A. Guidicipietro
Acting Assistant Deputy Administrator
Phytosanitary Issues Management
Plant Protection and Quarantine

Enclosure

Comments on Specific Sections of the Import Risk Analysis

Fireblight Analysis

General comments

We believe that this extensive analysis is severely flawed. The commodity analyzed is incorrectly identified. The factors comprising the semi-quantitative model are not supported by the scientific evidence. The ranges of the semi-quantitative estimates are not clearly and transparently linked to the scientific evidence, and the additive nature of the model compounds the errors in specification.

The model's output overestimates the unrestricted risk for fire blight and, as a result, BA recommends risk mitigations that are not justified by the internationally affirmed scientific evidence. BA estimates that the probability of entry, establishment, and spread of fire blight (PEES) is Low, the Consequences are High, and the Unrestricted Annual Risk (unmitigated risk) is Moderate (Table 6, page 14 of Part A – Summary). The required mitigations – an orchard inspection and chlorine dip are neither technically justified nor the least trade restrictive.

Importation

We find that the annual probability of entry, establishment and spread (PEES) is over-estimated at 'Low'. The causal agent of fire blight, *Erwinia amylovora*, can occur in the calyx end of mature, symptomless fruit in a low percentage of fruit harvested from infected trees. However, only a small number of New Zealand or U.S. trees are infected with fire blight. More importantly, there is no evidence that bacteria in the calyx end of fruit play any role in the transmission of the disease and there is no known or demonstrated pathway by which bacteria can be transmitted from fruit calyces to fire blight infection courts. Therefore, estimating the risk of an event not known to occur in nature, or to be able to occur in nature, is highly speculative.

In our view, a more realistic estimation of PEES is 'Extremely Low" or 'Negligible", resulting in an unrestricted annual risk of 'Very Low" or "Negligible" that would require no risk management measures. We believe that the most reasonable management measure to insure that apple fruit exported from New Zealand or the United States to Australia does not result in an outbreak of fire blight in Australia is to limit export to fruit that are free of fire blight symptoms and physiologically mature.

Scope of the analysis

BA defines the scope of the analysis as mature apple fruit free of trash, either packed or sorted and graded bulk fruit from New Zealand. We understand that New Zealand has requested that the analysis should address mature, export quality fruit packed in cartons as would be the case for U.S. apple fruit to be exported to Australia. We believe that BA's misinterpretation has allowed BA to build complex scenarios around the repacking of apples that are not germane to the analysis or current commercial practices or reflective of the scientific evidence. The analysis should be revised to reflect only the risk of apples packed and exported in cartons.

Volume of trade

Our colleagues from New Zealand indicate that BA has overestimated the volume of trade by almost four times New Zealand's projected trade volume. The reduction in projected trade volumes will significantly reduce BA's multiplier for the calculation of the probability of Entry, Establishment and Spread (PEES). From our perspective, as mature, symptomless export quality fruit are not a pathway for the disease, the volume is not relevant to this analysis.

The Semi-Quantitative Model

We have substantial concerns about BA's semi-quantitative model for fire blight for the following reasons:

- BA's statistical estimates are not linked clearly to the scientific evidence presented and contradicts the evidence in a number of sections of the analysis.
- BA defines and estimates variables for the model that are not supported by the internationally affirmed scientific evidence.
- The additive nature of the model builds on the faulty estimates.
- The mapping of unsupported quantitative estimates to overestimated trade volumes raises questions about the credibility of this model as a determinant of unrestricted risk and the establishment of risk mitigations.

The Importation Steps (Model Variables)

Importation Step 1 – Likelihood that *Erwinia amylovora* (Ea) is present in source orchards in New Zealand. BA assigned a ranking of "1," a High ranking, to this factor.

We believe that the information presented by BA does not support its assignment of a High likelihood to this variable. The information presented by BA does not support BA's assumed likelihood that the fire blight bacteria, Ea, is present in all source apple orchards of New Zealand. In New Zealand and in the United States, Ea is not routinely detected in all orchards as the disease caused by the bacteria is sporadic in nature.

This variable also is misleading since the commodity to be imported is not Ea-infected plant material, but mature, symptomless apples. The United States has exported almost 60 billion apples worldwide during a period spanning nearly 40 years, including almost 25 billion apples to its top 10 fire blight-free markets without a single instance of fire blight being spread through exports of U.S. apples. We, therefore, note that this initial overestimation biases the model and should be reduced considerably.

Importation Step 2 – Likelihood that picked fruit is infested/infected with Ea: BA assessed this step as a triangular distribution with a minimum value of 10^{-3}, a maximum value of 5×10^{-2}, and a most likely value of 3×10^{-2}. BA's estimate of this variable raised many questions for us

since BA did not present a concluding assumption to support its statistical range. BA acknowledged that there are several studies that found no evidence of the presence of fire blight bacteria on mature, symptomless apples and that some of these studies were carried out on orchards showing symptoms of fire blight. However, the BA team gave less weight to these studies than to those that confirmed the presence of fire blight bacteria on mature, symptomless fruit.

The United States asserts that fire blight is not spread by the pathway of commercial exports of mature, symptomless fruit. We emphasize that there is no scientific evidence that demonstrates that mature, symptomless apple fruit can 1) harbor endophytic infections of Ea or 2) be naturally infected with fire blight from other contaminating sources. By giving less weight to studies that did not detect fire blight bacteria on mature, symptomless fruit in calculating the risk of importation, BA overestimates the risk associated with Importation Step 2.

We therefore believe that BA overestimated Importation Step 2, the likelihood that picked fruit is infested/infected with Ea. Based on the scientific evidence ruling out the possibility of endophytic infection in mature, symptomless apple fruit, we suggest that this variable should be reestimated to allow for a "0" probability of endophytic infection as the pathway is likely broken at this point. With regard to infestation, BA's estimate of this variable and the others in the importation scenario imply that as little as one colony forming unit (cfu) of Ea bacteria is epidemiologically significant. We believe that internationally affirmed scientific evidence does not support this implied likelihood.

Endophytic bacteria: BA observed that "there is little evidence in the literature to support the occurrence of endophytic infection of symptomless, mature apple fruit." In fact, the only study which supports this hypothesis was disputed by the panel of scientific experts in the WTO dispute on Japan's measures for the import of U.S. apples. The Panel noted the following about the van der Zwet study:

"Based on the scientific evidence available to us in these proceedings, we note that the observation of the existence of endophytic populations in mature apple fruit is based essentially on one single study whose findings in this respect are not clear and are disputed: van der Zwet et al. (1990).[282] That study, although it recorded the isolation of E. amylovora from harvested fruit, did not specify the degree of maturity of the fruit or whether it was symptomless or not.[283] The study also appeared to report in a single paper different series of experiments in different locations and conditions, and not to contain a sufficiently precise description of the conditions of the experiment to allow for a precise conclusion to be drawn from them.[284] This in itself made its conclusions relatively confused, difficult to interpret or even unconvincing, as was suggested by the experts consulted by the Panel.[285] Furthermore, clarifications sought by the United States from the main authors of this study cast further doubt on conclusions that E. amylovora was found inside commercially mature fruit.[286] The Roberts et al. (1998) study cited by Japan simply reports on the findings in van der Zwet et al. (1990) and does not report on any new evidence in this regard. The fact that van der Zwet collaborated in Roberts et al. (1998) does not, in our view, affect the conclusion drawn from the experts' views and the author's comments of 16 July 2002. The Panel concluded that…there is not sufficient scientific evidence to conclude that mature, symptomless apples would harbor endophytic populations of bacteria. (Japan: Measures Affecting the Importation of Apples: Report of the Panel, 2003)

We therefore suggest that BA remove from further consideration the existence of endophytic populations of Ea in mature apple fruit, including those in Importation Steps 3 through 8 and other sections of the importation scenario. We also recommend that BA recalculate the risk in each step based only on survival of a small number of epiphytic bacteria consistent with the risk scenario described on page 48 of the IRA : "The importation risk scenario of particular relevance to Ea is one that is associated with the epiphytic (external) infestation."

We also suggest the removal of the following citations that make reference to endophytic infection and contamination of apples through endophytic infection.

- Page 63 – (Summary of Step 2) – "This range allows for fruit to be infected at picking through wounds as well as surface contamination that may occur by contact with contaminated bins, pickers' hands, leaves, twigs, etc……"

- Page 63 (Pre-cooling) – "If Ea were present in internal tissues, their numbers would not be reduced during pre-cooling…"

- Pager 63 (Pre-cooling): "These conditions may occur during pre-cooling and packing house operations, which will reduce epiphytic populations of bacteria but not those in internal tissues."

- Page 66 – (Brushing) – "Brushing would not remove bacteria present in internal tissues…"

- Page 66 – (Sorting and Grading) – "If such infections [internal] do occur on mature fruit they are unlikely to be detected during sorting and grading."

- Page 70 – (Burnett et. Al) – "If Ea gets into the core in the dump tank, one would expect some internal infection to develop but this has never been reported."

- Page 71 – (Step 7) – "Surface contamination of clean fruit can occur only if bacteria ooze out from internally infected fruit."

- Page 71 – (Step 8) – "Bacteria present on the surface, in the calyx or internally will not be detected at on-arrival border procedures…."

- Page 73 – (Consumers) – "Such infested or infected waste could act as a potential source of inoculum."

- Page 77 – (Viability) – "Spoiled whole fruit, partially consumed fruit and fruit peels and cores infested or infected with Ea will enter the Australian environment through the disposal of waste."

Epiphytic bacteria: The United States observes that the presence of low levels of epiphytic bacteria on the calyx of mature apples harvested from heavily blighted orchards is very rare.

However, the apple calyx is not an environment that supports the growth or survival of Ea (Roberts et al, 1998).

Populations of Ea in the apple calyx are in a state of continuous decline. Ea from calyxes of maturing fruit declined from 50 percent of fruit sampled for fruitlets to 3 percent for mature fruits (Hale et al, 1987). Populations of Ea in calyxes of inoculated and naturally infested apples declined in cold storage and did not increase to detectable levels when incubated at room temperature (Taylor, 1999). The populations of Ea associated with calyxes of apple fruit while stored at 2 degrees C decreased from 10^6 to 10^2 colony forming units (cfu) over a 20-day cold storage period (Taylor and Hale, 2003). Discarded apple fruit with calyxes infested with 10^6 cfu decreased to 10^2 cfu per calyx (Taylor et al., 2003).

Populations of Ea that are associated with calyxes of mature fruit at harvest are unlikely to be of epidemiological significance. Several studies indicate that numbers of bacteria found on calyxes from mature, export quality apples at harvest are less than 10^4 cfu per calyx and decrease exponentially over time. In the IRA, page 59: "Bacterial numbers in the calyces of mature orchard fruit are likely to be similar to these (101.8 cfu per calyx on day 0 from an experiment of artificial inoculation of pears) and such small numbers are unlikely to be physically accessible to allow contamination to occur during picking and transport." (Ceroni, 2004) Also on page 59, BA states that "All of the above studies demonstrate poor epiphytic survival of Ea, except occasionally in small numbers in the calyx."

Ea has the ability to grow epiphytically only on the stigma of flowers and, if climatic conditions are not conducive for infection to occur, these flowers can develop into healthy fruit with the bacterium localized only in the calyx end of the fruit. Thomson and Gouk (2003) demonstrated that flowers more than 4-5 days old did not support the growth of Ea. From this point on, populations of Ea are in a constant state of decline.

The panel of scientific experts in the WTO dispute on Japan's measures for the import of U.S. apples concluded that, "on the basis of the information made available to the Panel, there is not sufficient scientific evidence to conclude that mature, symptomless apples are likely to harbour epiphytic populations of bacteria capable of transmitting *E. amylovora*." (Japan: Measures Affecting the Importation of Apples: Report of the Panel, 2003). Therefore, we request that the IRA conclude that, given the apples being considered for importation, there is no pathway for establishment and spread.

Importation Steps 3 through 8

Contamination: We note the many instances in the model for fire blight where BA creates the potential for contamination of fruit where such contamination is highly unlikely and the United States believes is even less probable. In these cases, it is not clear why BA's estimates did not reflect the possibility that contamination could be "0."

We urge BA to revise its model to take note of the way that the likelihoods are estimated for fire blight, their scientific justification, the way that these likelihoods are added to establish BA's qualitative ranking factors, and the internationally affirmed scientific evidence from the WTO

decisions. BA's quantitative overestimation of the likelihoods is compounded in the model to justify a set of mitigations which are not supported by the scientific evidence.

Importation Step 3 – Likelihood that clean fruit is contaminated by Ea during picking and transport to a packing house

BA estimates this likelihood as a triangular distribution with a minimum value of 10^{-3}, a maximum value of 3×10^{-2}, and a most likely value of 10^{-2} based on the likelihood that Ea bacteria on the plant surface (epiphytic or ooze from cankers and other infections) and any bacteria on the soil, on harvesting bins, or picking bags are possible sources for contamination during picking and transport.

Contamination of clean fruit at harvest would be unlikely as the likelihood that populations of bacteria on leaf and fruit surfaces at harvest is negligible. Ea on leaf and plant surfaces have very short survival rates when exposed to Ultraviolet light, weather, and other elements. With regard to epiphytic contamination, "Ea is generally not considered a very good epiphyte. Populations of Ea usually decline rapidly on most flowers or leaves within a few hours or days" (Thomson, 2000) Regarding potential contamination by bacteria in the soil, BA also cites Thomson as stating that "soil is of little epidemiological significance in the spread of fire blight in orchards."

In previous discussions, we suggested the removal of references to infection in mature, symptomless apple fruit since such infection is not supported by internationally affirmed scientific evidence. With this in mind, the reference to infections above as a basis for BA's calculations should be eliminated.

Again, we believe that the likelihood of contamination by Ea during picking and transport to a packing house is negligible and should reflect a "0" possibility as the bottom of a lower range of values.

Importation Step 4: Likelihood that Ea survives routine processing procedures in the packing house.

BA estimates this likelihood as a triangular distribution with a minimum value of 0.3, a maximum value of 0.7, and a most likely value of 0.65. We believe that BA overestimated the risk of Ea surviving the packing house procedures because it did not fully account for their effects or for the biology of Ea.

The period of cold storage could have a significant impact on epiphytic populations of Ea in the apple calyces, the only place that Ea has been demonstrated to reside on apple fruit at harvest. Hale and Taylor (1999) and Taylor and Hale (2003) demonstrated that populations of Ea on apple fruit significantly decline in the first few days of cold storage.

Importation Step 5 through 8: Likelihood that 1) clean fruit is contaminated by Ea during processing in the packing house; 2) Ea survives palletisation, quality inspection, containerization and transportation to Australia; 3) clean fruit is contaminated by Ea during palletisation, quality inspection, containerization, and transportation; and 4) Ea survives and remains with the fruit after on-arrival minimum border procedures.

BA greatly overestimates these likelihoods which are dependent on epiphytic survival of Ea in the calyx of apples.

Probability of importation: BA combined the estimates from the eight importation steps and concluded that 3.9 percent of the total proposed apples imported from New Zealand annually would be infested with Ea. We urge BA to recalculate the Importation steps and model in light of the lack of risk of endophytic bacteria, rare likelihood of small numbers of epiphytic bacteria in the calyx, the proven decrease in colony forming units (cfu's) likely to survive through each step of the process, and our other prior comments.

Probability of transfer or spread: BA indicates that there is no specific dispersal mechanism for the fire blight bacteria. BA hypothesizes that the EA bacteria could be vectored as ooze on active cankers or by birds or bees.

"With regard to the first possibility, Ea is not known to multiply in rotting mature fruit. We believe that this scenario is highly speculative and not likely to occur. With regard to the evidence that the disease could be transmitted by insects, we note that the panel of scientific experts in the WTO dispute on Japan's measures for the import of U.S. apples "confirmed the assertion of the United States that the Tsukamoto et al study (2005b) does not establish that flies would serve as a vector which would complete the pathway. In particular, the conditions of the experiment are too removed from natural conditions. Conversely, we note that the study by Taylor et al (2003), carried out in natural conditions, did not recover bacterium from insects. (Japan: Measures Affecting the Importation of Apples: Recourse to Article 21.5 of the Dispute Settlement Understanding by the United States, June 23, 2005)

In this regard, the IRA posits that the statistical range for the transfer of the bacteria is $(0, 10^{-6})$ "based on the IRA team's views on both mechanical and insect mediated transmission, and explicitly acknowledges that in some circumstances the chances of exposure would be zero." We would like to emphasize that statistical range indicates a Negligible risk of transfer, well below Australia's Acceptable Level of Protection which is 10^{-3} to 5×10^{-2}

Probability of Establishment and Spread: "Commercial fruit crops- Establishment (0.7, 1) Spread (0.7, 1)" Given that BA determined that it is highly unlikely that the bacteria will be transferred to Australia via mature, symptomless apple fruit and attributes a statistical distribution of $(0, 10^{-6})$ to this likelihood, we do not believe that the fruit to be imported into Australia poses a risk of establishment and spread of the bacteria.

Environmental conditions within the USA are at least as favorable for establishment and spread of fire blight as those in Australia. Based upon the probabilities presented in this IRA for the distribution (1), establishment and spread of fire blight, fire blight would occur in 70-100% of U.S. orchards in any given year. This greatly overestimates the occurrence of fire blight within the United States. Similarly, the probability of establishment and spread is over-estimated for nursery plants, household and garden plants, and wild and amenity plants on p.87.

We strongly urge BA to reduce the likelihoods of establishment and spread to take into consideration that the bacteria is highly unlikely to be transmitted to Australia from mature, symptomless apple fruit.

Risk Mitigations: BA determined that the risk of entry, establishment, and spread of fire blight on New Zealand apples would exceed its ALOP. BA will require that New Zealand apples be subjected to an orchard inspection and chlorine dip.

With regard to BA's proposed risk mitigations for fire blight, we have serious concerns that the measures are not supported by the internationally affirmed scientific evidence regarding fire blight. We believe that appropriate measures for fire blight are that the apples be free of fire blight disease symptoms and be physiologically mature. We encourage BA to re-evaluate its risk mitigations accordingly.

European canker (*Nectria galligena*)

We also question BA's application of a semi-quantitative model to its analysis of European canker for New Zealand apples. BA determined that 95 percent of New Zealand apple production comes from orchards in areas where the disease has never been recorded or occurs only sporadically in very wet seasons. We question why BA represents this conclusion with a distribution (10^{-2} to 6 X 10^{-2} with a most likely probability of 3 X 10^{-2}) when BA's conclusion for this key factor factor appears to indicate a ranking of Negligible, Low or Very Low (10^{-3} to 5 X 10^{-2})

In assessing the risk of *N. galligena*, it has been well documented that the disease expression will only occur where rainfall is greater than 1000mm (Dubin, H. J. and English, H. 1975. Epidemiology of European apple canker in California. Phytopathology 65,542). BA observes that this disease has not been recorded in production areas accounting for 95 percent of New Zealand apple production. Apple production areas in most areas of New Zealand and in the apple growing States of Washington, Oregon and Idaho are therefore very likely to be free of this disease as they do not have the moisture required for its establishment.

We also would like to note that the transfer scenario of this disease from mature, export quality apple is also highly unlikely. For successful infection from mature, export quality apple fruit, there must be a coincidence of sporulating apple, duration of wetness and susceptible host. We believe that this is an unlikely event.

We therefore encourage BA to revise its semi-quantitative model for European canker to take into consideration this unlikely transfer mechanism.

We also believe that BA's proposed mitigation of an orchard inspection for European canker is not supported by the unlikely transfer mechanism. We request that BA remove this requirement.