Apple & Pear Australia Ltd

Response to the Biosecurity Australia Draft Import Risk Analysis Report for Fresh Apple Fruit from the United States of America Pacific Northwest States

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Contents

Executive Summary

This submission from Apple and Pear Australia Ltd (APAL) to the draft IRA for US apples from the Pacific North West (PNW), identifies a number of serious inadequacies in the draft IRA and calls on Biosecurity Australia to reassess many issues related to an underestimation of the risk posed by the entry, spread and establishment of a number of pests not present in Australia and review risk management measures to deal with pests that exceed Australia's appropriate level of protection.

This submission reflects the range of concerns that the Australian apple and pear industry has with the information presented, the manner in which that information has been assessed and the ultimate conclusions presented by Biosecurity Australia.

A number of specific and important issues are raised within this submission. Foremost is the ill-considered adoption by Biosecurity Australia of the risk assessment and management protocols that it has applied to the import of apples from New Zealand. Unlike NZ, apples from the PNW are anticipated during the spring and summer months. During this period Australian climatic conditions are such that hosts are more receptive to many pests (and especially of fire blight), insects which transmit disease are more active and numerous, and any discarded diseased seeds are more likely to germinate. These factors have not been taken into account and as a consequence Biosecurity Australia has underestimated the risk of fire blight and seed-tissue borne pests from the PNW.

Industry is also concerned that a large number (34) of pests and diseases have been assessed to be above Australia's ALOP. A further 12 have been assessed as regional pests, which, although not currently recorded in the PNW, pose a clear and present danger because of unrestricted movement of apples across continental USA. The apple industry contends that the qualitative risk estimation method used by Biosecurity Australia is calibrated to a significantly smaller number of pests than is considered in the Draft IRA. Previously finalised IRAs by Biosecurity Australia have involved a range of between 3 to 14 pest risk assessments. Given that the greater the number of possible pests or diseases means an increased chance that apples arriving in Australia will be infected/infested with a pest of concern, the industry believes that a recalibration of the risk assessment for the PNW is required.

Fire blight remains a major concern and the Australian apple industry is disappointed that Biosecurity Australia has failed to incorporate recent scientific knowledge into its risk assessment. This research indicates that the healthy appearance of fruit is not evidence that it is free of the fire blight pathogen; the cold conditions used in the long distance transport of fruit actually increases the survival ability of the pathogen in mature apple calyces; bacterium can survive within the calyx of mature apple fruit in a viable but nonculturable state; and the bacterium is able to regain its culturability and pathogenicity. The apple industry believes that this scientific knowledge must be incorporated into the risk assessment of fire blight.

The apple industry is also concerned that the risk of spread of apple maggot has been seriously underestimated because of the non-existence of effective surveillance measures in Australia. Also, Biosecurity Australia has failed to include a risk assessment for the spotted wing drosophila, which is reported to infect apples in Japan.

These oversights imply that the unrestricted risk assessment of apples from PNW entering, spreading and establishing within Australia have been seriously underestimated by Biosecurity Australia. This is compounded by the failure to incorporate the impact of commercial practices associated with the US apple industry, including the seasonal movement of honey bees and unrestricted movement of vegetative and propagation materials across states.

An underestimation of the risks posed by pests associated with PNW apples implies that the risk management measures proposed by Biosecurity Australia are inappropriate. The apple industry has also identified that the risk management measures for fire blight need to be strengthened to include a minimum of two inspections and that the proposed co-measure of chlorine treatment is ineffective and that fumigation is the only responsible action for apple curculio and apple maggot.

Independent expert advice also indicates that the efficacy of proposed sampling regimes is not statistically sound. Sample sizes and sample methodologies are inadequate to ensure that orchards are free from disease symptoms and that cartons are free of diseased apples with the required degree of confidence.

These concerns lead the apple industry to recommend that Biosecurity Australia undertake further extensive analysis to ensure that the apples sourced from the PNW do not exceed Australia's ALOP. Specifically, Biosecurity Australia should continue the draft IRA process to include new scientific research and review omissions in the current draft.

Finally, due process requires that the apple industry be afforded the opportunity to analyse and provide feedback on any further investigations undertaken by Biosecurity Australia. Any re-evaluation of the risk assessment and of the risk management options proposed by Biosecurity Australia arising from deliberations on this Draft IRA must form part of the draft IRA and should not be automatically incorporated into a final import policy.

1. Introduction

The Draft IRA for US Apples from the PNW (the states of Washington, Oregon and Idaho) was released for public comment by Biosecurity Australia on 22 October 2009. This submission was prepared on behalf of the Australian apple industry by Apple and Pear Australia Ltd (APAL) using expertise from growers as well as independent scientists with expertise in entomology, plant pathology and statistics. This submission builds upon comments provided by APAL to the Issues Paper for Fresh Apple Fruit from the US PNW (September 2008).

Industry remains extremely concerned by the large number of pests and diseases associated with US apples considered to be above the ALOP and the need for a wide range of strong and verifiable risk management measures for these pests and diseases. In particular, the presence of fire blight and *Rhagoletis pomonella* (apple maggot) pose extreme biosecurity threats to the Australian apple industry. Industry would also like to raise the possible risk posed by the recently detected *Drosophila suzukii* (spotted wing drosophila) in the PNW.

Inadequacies within the Draft report prepared by Biosecurity have been identified. These relate to both a severe underestimation of the risk posed by and consequences of the entry, distribution, establishment and spread of certain pests and to the inadequacy of the risk management measures offered as a means of attaining Australia's appropriate level of protection.

Specific comments on these issues and industry recommendations in regard to how they might be rectified are provided below.

2. Multiple Pests

A key difference between this IRA and that undertaken in recent years is the sheer volume of pests and diseases that pose a risk for Australian agriculture. Specifically, this Draft IRA involves 38 pest risk assessments, including 31 for known PNW pests and a further 7 for pests not currently recorded in the PNW states[1]. In comparison, previously finalised IRAs by Biosecurity Australia have involved a range of between 3 to 14 pest risk assessments. For example, in assessing apples from New Zealand, only 11 pests were assessed.

The apple industry contends that the qualitative risk estimation method used by Biosecurity Australia is calibrated to a significantly smaller number of pests than is considered in this Draft IRA. This is because the process focuses on identifying and ranking the risks presented by each of the various diseases or pests associated with the commodity and identifying risk management options pertinent to those pests which pose a risk above Australia's ALOP.

However the process does not explicitly identify an *overall risk* associated with the importation of the commodity, other than through the crude judgement of acceptable or unacceptable. An acceptable risk, according to the process, is one in which all identified pests or diseases that exceed the acceptable level of risk individually have suitable management measures imposed.

Specifically, the process does not reflect the magnification of risk associated with a high number of pests. Independent experts (Attachment 1) support this view. They note that for a commodity with a large number of pests, the probability that any one of them enters, establishes or spreads will be greater than for a commodity with a small number of associated pests. Put simply, the higher the number of possible pests or diseases, the greater the chance that apples arriving in Australia will be infected/infested with a pest of concern. Moreover, the experts confirm that this logic is the same as that applying to the volume of trade - a greater volume of trade will increase the probability that a pest will enter, establish and spread (see also Section 11 below). The latter proposition is acknowledged by Biosecurity Australia (p10).

[1] The 38 risk assessments relate to those 31 assessed in Sections 4.1-4.31 plus those 7 assessed in Sections 4.32-4.38.

The quantum of pests assessed and the identification of 34 pests that require a risk management measure[2] take this Draft IRA to an order of magnitude well beyond that underpinning import assessments previously undertaken by Biosecurity Australia. This new order of magnitude is inconsistent with a model that is based on a small number of pests. The apple industry believes that the qualitative risk estimation method used by Biosecurity Australia needs to be re-calibrated because the overall risk presented by the importation of apples is likely to be greater than that which was considered acceptable in previous risk assessments. Moreover, the effectiveness of the suite of risk management measures must be reduced by the quantity of pests and hence this too requires recalibration.

Recommendation: *That Biosecurity Australia undertakes a review of the model used in the import risk analysis. The objectives of this review are to a) design a new model that can, in light of a large number of pests, correctly quantify the levels of risk associated with the entry, establishment and spread of pests and correctly interpret the consequences that would flow from the unrestricted risk of imports and b) apply that new model to the PNW pests of concern and adjust the risk levels and subsequently the risk management measures accordingly.*

3. PNW parameters differ from NZ

A major weakness of the current IRA process is that outcomes from the New Zealand IRA have been applied to the importation of apples from the PNW without due consideration to the vastly different parameters that apply. This is most noticeable in the case of fire blight, but pertains to the risk assessment of a number of pests and diseases.

Biosecurity Australia contends that the unrestricted risk of fire blight (*E. amylovora)* entering, spreading and establishing in Australia as a result of the importation of apples from the PNW is the same as the risk posed by apples imported from New Zealand. As a consequence, Biosecurity Australia has adopted the risk assessment and protocols for *E.*

[2] This includes the 34 pests identified in Table 5.1 that require a specific pre-border risk management measure. It excludes a further 12 pests that require an annual declaration that they are still not present within the PNW.

amylovora that apply to apples from New Zealand and applied them to PNW apples. Similarly, the same risk assessments (and often the same risk management measures) that pertain to European Canker, Leafroller moths and ALCMs associated with apples from New Zealand were also judged to apply equally to apples from the PNW.

The apple industry strongly disagrees with Biosecurity Australia's proposition that the probability of entry, establishment and spread of *E. amylovora* will be the same for apples imported from the USA as those sourced from New Zealand. This is because the timing of apple imports from the PNW will differ markedly from that of New Zealand. For example, shipments of apples from the PNW are expected during the August to November period, which broadly coincides with their harvest - from mid August to end of October, depending on cultivars and climatic conditions within specific production areas.

The arrival of PNW apples during the Australian spring and summer months poses a number of serious threats, in relation to both E. *amylovora* and seed borne rots and pathogens. Specifically:

(i) The chances of discarded infected seeds germinating are greater in spring and summer than in winter. Many rots and pathogens, for example, are seed borne and infections are hard to identify through visual inspection. If an infected apple was to enter Australia it is possible that germination could take place if the fruit and seeds were discarded. The spring and summer months would provide the ideal conditions for the germinated plant to develop and the subsequent seedlings would provide the basis for the establishment of the pathogen in Australia. The likelihood of that event rises dramatically with the onset of favourable germination conditions – the spring months when apple shipments from the PNW are anticipated. In comparison, it is likely that NZ apples will arrive in direct competition to the harvested Australian product when conditions for germination are less likely (though nevertheless possible).

(ii) Biosecurity Australia has noted Thomson's (2000) observation that the timing of apple imports from the US coincides with the flowering period of rosaceous hosts in Australia, a particularly receptive stage for *E. amylovora* infections. This is because the appearance of new shoots, buds and flowers during the spring and summer months provides an ideal environment for the establishment of the pathogen. Biosecurity Australia has not, however, applied this scientific observation to the risk assessment of E. *amylovora* and assumes the unrestricted risk estimates is the same as that for imported NZ apples. Clearly the chances of hosts to E. *amylovora* being in optimal condition for the transmission and establishment of the pathogen are much higher in spring and summer when apples from the PNW are anticipated. The industry therefore contends that it is not possible to adopt the existing (ie NZ) pest risk assessment for *E. amylovora* - the unrestricted risk estimates cannot be the same.

(iii) The spring and summer months also provide a more attractive environment for larvae and insects to establish and develop. This is significant because:

i. The chance of a prohibited insect or larvae surviving and flourishing in Australia is much greater should it enter with fruit imported in the spring and summer months. For example, if an infested apple core were discarded, the eggs or larvae would have a greater chance of developing into mature adults able to continue the life cycle. The chances of this occurring are greatest during spring and summer when Australian climatic conditions are more conducive to insect development. This suggests that the likelihood of pests spreading and establishing as a result of imports from the PNW is greater than estimated by Biosecurity Australia.

ii. The chance of insect transmitted diseases that enter with fruit imported in the spring and summer months being transmitted to receptive plants is much greater during these seasons because of the higher level of domestic insect activity. For example, discarded apples or apple cores will attract a greater level of visitation by native insects during the spring and summer months simply because of the greater level of insect activity and larger insect numbers during those months. However, should that apple contain an infestation within the tissue or calyx, the higher visitation levels imply a greater chance of transmission of insect borne disease. Again, this would suggest that the likelihood of pests spreading and establishing as a result of imports from the PNW is greater than estimated by Biosecurity Australia.

The apple industry believes that these issues have not been adequately considered by Biosecurity Australia. The unrestricted risk estimates for E. amylovora for apples imported from the PNW cannot be the same as that for apples imported from NZ. The industry also contends that the risk of spread and establishment of many other diseases has been vastly underestimated and a further assessment is required.

Recommendation: *That Biosecurity Australia a) re-examine the import risk assessment for fire blight and all other seed and flesh borne pests. This analysis should demonstrate how the anticipated timing of apple imports from the PNW might impact upon the unrestricted risk of such pests entering, spreading and establishing within Australia. The most recent scientific research with regard to the impact of seasonal conditions upon the life cycle of pests and diseases should be outlined. b) develop stricter risk management measures to reflect the higher risks associated with PNW apples compared with New Zealand apples and c) ensure that these matters form part of the Draft IRA process and industry is afforded an opportunity to respond to the analysis and outcomes.*

4. Commercial production practices

The apple industry contends that the likelihood of pests entering Australia has been seriously underestimated because the consequences of commercial practices associated with apple production in the US have not been adequately taken into account. These practices relate to the unrestricted movement of bees as well as bud wood, rootstock, nursery trees and trash across continental US.

For example, Biosecurity Australia correctly notes that “honey bees are used to promote pollination and that the bees are transported from California to Oregon then Washington, following the cycle of the bloom” but then underplays the role that this practice plays in spreading pests, including *Erwinia amylovora.* The *s*tatement that “this practice *may* (italics added) aid the spread of some pests” is at odds with Biosecurity Australia’s deliberations of in 2006. Specifically, in the Final Import Risk Analysis Report for apples from New Zealand, Biosecurity Australia noted that honey bees are *the most effective carriers* of *E. amylovora* from infected or infested blossoms to non-infested blossoms.

Biosecurity Australia (2006, p114) further noted that:

> Bees are recognized as important agents of disease transmission from flower to flower…. Foraging bees visited about 400 blossoms per hour… The estimated efficiency of bees to disperse *E. amylovora* from infested hives to pome fruit blossoms averaged 20 blossoms per hour of foraging activity… The flight range of bees in each foraging area is quite variable and is influenced primarily by the resource distribution, population levels of bees that are competing in the respective areas and the productivity of the plant… In general, bees have a strong tendency to forage at the nearest source for each floral species in the area… It has been observed that honey bees can readily fly 4 km in all directions of their hive…{and}… the possibility of in-hive pollen transfer from bee to bee… has implications in the transfer of *E. amylovora* from contaminated pollen in the hive to blossoms. Experiments have demonstrated that honey bees were able to disseminate *E. amylovora* from beehives to healthy pear flowers for less than 48 h after initial contamination of the beehives …. Bees from hives in a desert will fly as much as 13.7 km to a food source….

It would appear that the PNW IRA has failed to take account of this important area of scientific research. When combined with the knowledge that beekeepers move unrestricted from state to state to pollinate species which flower at different times, the potential for disease to manifest within PNW apples is increased. More importantly, the transmission of disease by bees has significant implications for the number and timing of orchard inspections required as part of risk management strategies. This is because bee-transmitted diseases, which will infect plants at the time of flowering, may be latent and not exhibit symptoms for some time (8 to 10 days in the case of fire blight). Inspections at the time of flowering or immediately post flowering may give false negatives if symptoms are latent, reducing the effectiveness of this type of risk management tool.

The apple industry considers that the risk of pests, and especially of fire blight transmission, on mature apple fruit from the PNW should be reconsidered in light of the commercial pollination route and the role that bees play in disease transmission. Additionally, the minimum number of inspections and the timing of inspections aimed at pest and disease discovery should be reviewed.

Recommendation: *That Biosecurity Australia re-examine the import risk assessment for fire blight and all other pests known to be transferred by honey bees. The analysis should demonstrate how the unconstrained movement of honey bees across the US impacts upon the unrestricted risk of pests entering Australia. The analysis should also demonstrate how the unconstrained movement of honey bees across the US impacts upon the proposed risk management measures required to attain Australia's ALOP and how these measures might be altered to take account of the practices of the US pollination industry. These matters should form part of the Draft IRA process and industry should be provided with details of the analysis as part of that process.*

The apple industry is also concerned that Biosecurity Australia has not given due consideration to the absence of measures which restrict the movement of vegetative material such as budwood, rootstock and nursery trees across the US. The unrestricted movement of vegetative (trash) and propagation material across states increases the risk of transmission of fire blight, apple maggot, and other pests. As a consequence, the overall risk of entry and establishment of exotic pests may have been underestimated by

Biosecurity Australia. The apple industry seeks to have these issues clarified, including details of the risk assessment analysis, as part of the draft IRA.

Recommendation: *That Biosecurity Australia clarifies the degree to which consideration was given to the unconstrained movement of vegetative and propagative material across the US. Specifically, Biosecurity Australia should clarify how this influences the unrestricted risk of pests entering Australia and what impact it has upon the proposed risk management measures required to attain Australia's ALOP.*

5. Fire Blight – Risk Assessment

The adoption of the New Zealand pest risk assessment for fire blight (*E. amylovora)* for the importation of apples from the PNW also implies that scientific knowledge has not advanced since 2006. In reality scientific understanding of E. *amylovora* continues to evolve and it is important that the implications of new research are understood and incorporated into government policy.

For example, the recent work of Ordax *et al.* (2009) clearly indicates that E amylovora revealed a remarkable ability to survive under different conditions and over a long period (35 days) in mature apple calyces without showing fire blight symptoms. As Ordax *et al.* conclude this means that " *E. amylovora* could go unnoticed in the fruit, which means that its healthy appearance is not evidence that it is free of the pathogen, as concluded by other authors (Tsukamoto et al. 2005; Azegami et al. 2006)." In addition, Ordax *et al* have shown that "cold conditions, used in the long distance transport of fruit, increase the survival ability of the pathogen in mature apple calyces." This implies that infected imported apples from the PNW and New Zealand could be a potential carrier of E. *amylovora* and thereby contribute to the entry, spread and establishment of fire blight disease into Australia.

While Biosecurity Australia acknowledge the research undertaken by Ordax *et al.* the implications of the research do not appear to have been incorporated into the unrestricted risk assessment of fire blight entering, spreading and establishing as a result of the importation of apples. Specifically, Biosecurity Australia continues to maintain that the overall probability of entry, establishment and spread is very low. The apple industry believes that by demonstrating that the *E. amylovora* bacterium can survive within the calyx of mature apple fruit in a viable but nonculturable state and that the bacterium is able to regain its culturability and pathogenicity, the Ordax *et al.* research implies that the risk of entry is much higher and that the probability of spread and establishment is much greater than previously thought and adopted for the NZ IRA.

The apple industry also refers Biosecurity Australia to the evidence presented in the World Trade Organisation (WTO) dispute hearing (June 2009) in regard to the importation of New Zealand apples. When questioned by the panel in regard to potential risks that were not taken into account in the NZ IRA the technical experts of fire blight pointed to three risk areas:

- Hosts in close proximity to known infections
- Potential transfer via the VBNC condition
- Hail events post flowering and before harvest

Recommendation: *That Biosecurity Australia review the unrestricted risk estimates in light of the latest scientific research and adopt further protocols that reduce the unrestricted risk to below Australia's ALOP. Biosecurity Australia's deliberations on these matters should be made available before finalising the IRA report to enable the industry to comment upon Biosecurity Australia interpretation of the research and its implications.*

6. Fire Blight – Risk Management Measures

The apple industry also contends that the protocols proposed by Biosecurity Australia to manage the risks posed by fire blight - chlorine disinfections and the establishment of areas free from disease symptoms - are inadequate.

Biosecurity Australia suggests that areas free from disease symptoms can be established through a single inspection of the trees within an area (an orchard or a block within an orchard) and carried out 4 – 7 weeks after full bloom. The apple industry believes that a single inspection is insufficient and that infected plants and fruit would remain undetected. Biosecurity Australia itself acknowledges that it is extremely difficult to confirm absolute freedom from symptoms using visual inspections of orchards. Moreover, the inspection of areas as defined - as an orchard or block- is too narrow and ignores potential infections that later spread from neighbouring blocks.

Recommendations: *To help overcome the inadequacies of these risk management measures the apple industry proposes that the system of inspections be widened to include:*

- *A minimum of two inspections: one at full flowering or immediately post flowering and one prior to harvest*
- *Potential further orchard inspections after damaging climatic events which could include hail, rain and/or wind storms.*
- *No removal of symptoms prior to inspections*
- *Exclusions of export orchards in close proximity to Fire Blight hosts showing symptoms*
- *Exclusion of orchards that have exhibited symptoms in the two previous years*

Biosecurity Australia also contends that including chlorine treatment as a measure additional to the establishment of areas free of disease symptoms would reduce the risk estimate for E. *amylovora* to "very low", thereby meeting Australia's ALOP. However the inadequacy of chlorine treatment as a risk management strategy is highlighted by the fact that fruit sourced from infected orchards have the potential to carry epiphytic bacteria in the remnant flower parts present at the calyx-end of the fruit (Hale et al. 1987). That chlorine treatment would not be fully effective against *E. amylovora* bacteria protected in the tissue and the calyx and is fully acknowledged by Biosecurity Australia (p267).

Recommendations: *That Biosecurity Australia evaluate other options that might be used in conjunction with the establishment of areas free of disease symptoms to achieve Australia's ALOP. The assessment of options that are more effective than chlorine treatment should be* *made as part of this draft IRA and opportunities should be afforded to the apple industry to assess the adequacy of proposed measures.*

7. Apple curculio – (Anthonomus quadrigibbus)

Anthonomus quadrigibbus is a beetle of the weevil family *Curculionidae* and larvae are internal feeders on the apple pulp and seed. The scientific literature suggests that a large portion of the infested fruit drops from the tree to the ground. However, some apples remain on the tree where larvae continue to develop successfully (CABI/EPPO 1997). The probability of importation was assessed to be low, despite the fact that this pest is an internal feeder and would not be detected by visual inspection. Further, the unrestricted risk of this pest was considered to be negligible and below Australia's ALOP. As a result, Biosecurity Australia concluded that a risk management measure was not required for this pest.

The apple industry, however, contends that Biosecurity Australia's assessment is a severe underestimate of the risk posed by this quarantine pest. A rating of negligible is inconsistent with ratings in previous risk assessments for internal pulp or seed feeders associated with other commodities and with other weevils.

The apple industry believes that additional risk management measures are required for this pest. Further the industry believes that only two risk management measures would be sufficient to reduce the risk estimate sufficient to achieve Australia's ALOP. These are:

- The inspection of a minimum of 3000 pieces of fruit taken by random sample from each lot to determine for freedom from this weevil must be undertaken. Detection would result in rejection of the lot or a treatment such as fumigation. Alternatively,
- Fumigation treatment for all export lots must be undertaken.

Recommendation: *That Biosecurity Australia a) re-evaluates the risk assessment for Anthonomus quadrigibbus to adequately account for the status of the larvae being internal* *feeders; and b) the risk management regime be changed to include either the inspection of a minimum of 3000 pieces of fruit (taken by random sample from each lot) or fumigation treatment for all export lots.*

8. Apple maggot- (Rhagoletis pomonella)

Rhagoletis pomonella is a serious pest of apples within the US PNW. Biosecurity Australia acknowledges that there is a high risk of entry of apple maggot eggs and larvae accompanying apples imported into Australia.

However, the apple industry believes that the risk of this pest spreading within Australia has been underestimated. This is because traps designed to detect *R. Pomonella* are not available in Australia and for economic reasons unlikely to be developed. Existing Australian fruit fly monitoring efforts would also prove to be ineffective as a surveillance measure for apple maggot. As a result, the pest could spread widely and in great numbers before being detected. The economic consequences of wide distribution also need to be acknowledged.

The apple industry therefore believes that Biosecurity Australia has underestimated the overall unrestricted risk posed by apple maggot.

Recommendation: *That Biosecurity Australia re-evaluates the risk assessment for Apple maggot to adequately account for the probability and consequence of undetected and extensive spread should the pest enter the country.*

Biosecurity Australia proposes that the risks posed by apple maggot can be managed either by the establishment of pest free areas or by treatment of all lots. The apple industry, however, contends that the establishment of pest free areas or pest free areas of production is an inadequate measure for this pest. As apple maggot larvae feed internally, fruit with low rates of infestation would not, as Biosecurity Australia (p59) notes, "show obvious signs of damage, allowing infested fruit to pass through the harvesting process undetected". Surveys and monitoring processes associated with the establishment of pest free areas are unlikely to be effective for apple maggot.

The apple industry therefore recommends that fumigation of all export lots is the only acceptable method of reducing the risk of this pest.

Recommendation: *That Biosecurity Australia change the proposed risk management measure for apple maggot to fumigation as the only means of achieving Australia's ALOP.*

9. Spotted wing drosophila - Drosophila suzukii

Drosophila suzukii is a recently introduced pest fruit fly species into the US. Data on host status and distribution within the US is currently being accumulated. Host records currently suggest that most soft skinned fruits may be susceptible to this fruit fly pest. Berries, strawberries and stone fruit have been confirmed as hosts. Unofficial reports indicate that this pest infests apples in Japan.

It is imperative that Biosecurity Australia includes a full risk assessment of *Drosophila suzukii* as part of the IRA process for apple imports from the PNW. Procedural fairness requires that the apple industry is afforded the opportunity to understand the details of any assessment made by Biosecurity Australia and is able to provide its own comments on conclusions.

Recommendations: That Biosecurity Australia a) undertake, as part of this Draft IRA process, a full assessment of the overall unrestricted risk for the spotted wing drosophila to enter, establish and spread as a result of imports from the PNW; b) analyse risk management options to achieve Australia's ALOP in regard to this pest; and c) provide the details and conclusions arising from these assessment to industry for feedback prior to the completion of the draft IRA process.

10. Pests not currently recorded in the PNW states

The Draft IRA considers quarantine risks associated with the importation of fresh mature apple fruit, free of trash, from the US PNW states of Washington, Oregon and Idaho. It also includes an assessment of pests and diseases not currently recorded in the PNW. Their inclusion rightly reflects the risks associated with the lack of official control measures to prevent the spread of such pests into states that might supply apples to Australia. In responding to this risk, Biosecurity Australia indicates that:

- it will require an annual declaration from the US stating that the 7 pests (28 species) listed in table 4.1b are not present in the PNW prior to each year of trade;
- the US Animal and Plant Health Inspection Service (APHIS) will be asked to provide comprehensive information on how the PNW states maintain freedom from those pests.

The apple industry considers that freedom from pest declarations are a critical link in the approval to import decision-making chain. Specifically,

(a) Annual declarations should be accompanied with a continuous flow of 'evidence of absence' documentation. Declarations made once a year are an insufficient means of validating pest monitoring and surveillance processes.

(b) An assessment of the adequacy of the proposed methods form part of any approval to import process. It is imperative that the apple industry is provided the opportunity to scrutinise the scientific reasoning underpinning any measures proposed by the US to verify PNW freedom from the 7 pests (28 species) of concern. This is fundamental to assuring the Australian apple industry that the US possesses tools and processes that are based on sound science and that such measures will adequately ensure that the PNW states are free from pests found elsewhere in continental USA. Natural justice for the apple industry would be denied should access to details regarding the proposed verification methods not be provided prior to the finalisation of the IRA;

(c) Any future change to the 'approved' method used by the US to verify PNW freedom from the 7 pests (28 species) of concern be subject to consultation between Biosecurity Australia and the apple industry so that each has an opportunity to examine the sufficiency of the science generating the change. Again, procedural fairness would be denied if Biosecurity Australia failed to provide industry with access and an opportunity to influence any changes to the processes applied in verifying PNW freedom from the 7 pests (28 species) of concern.

The apple industry also believes that the documentation supporting the continuous flow of 'evidence of absence' should be made available to the industry in a timely manner and on a regular and on-going basis. This information will provide both confidence that commitments are being met and approved processes are being applied and will enable opportunities to scrutinise surveillance results.

Recommendations: That, in regard to the 7 pests (28 species) pests of concern, Biosecurity Australia a) undertake an assessment of the adequacy of the methods of verifying disease free status that are proposed by APHIS and that the assessment form part of the approval to import process – that is, it form part of the draft IRA process rather than a consequence of any final import determination; b) provide the apple industry an opportunity to scrutinise the scientific reasoning underpinning the measures proposed by the US; c) seek a continuous flow of 'evidence of absence' documentation from APHIS and supply this information to industry in a timely manner and on a regular and on-going basis; and d) liaise with industry in regard to any future change to the 'approved' method used by the US to verify PNW freedom from the 7 pests of concern so that each party has an opportunity to examine the sufficiency of the science generating the change.

11. Volume of trade

As Biosecurity Australia is aware, a key element of the IRA process is an assessment of the likely volume of trade, as part of both the likelihood of entry and the economic consequences analyses. The volume of trade from the PNW has been estimated at approximately 20% of the domestic fresh apple market, the same as that estimated for apples from NZ (Biosecurity Australia 2006) and the Draft Import Risk Analysis for Apples from China (Biosecurity Australia 2009).

A fundamental flaw associated with the IRA process is that each is conducted in isolation so that cumulative impacts cannot be considered. However, as acknowledged by Biosecurity Australia (p9), the likelihood of pests entering Australia increases as the overall volume of trade expands. Taken alone, the expected volume of imports from New Zealand may not force the risk of pest entry above Australia's Level of Protection. But adding in expected imports from the PNW magnifies this threat and challenges the Level of Protection afforded to the Australian industry. For example, Australia is likely to see apple imports soar from zero today to over 92,000 tonnes within five years[3]. The magnitude of the increase must intensify the risks of entry of exotic pests and policy makers should acknowledge and address this issue in a more comprehensive and strategic manner. Moreover, this warrants urgent attention.

Biosecurity Australia confirms that it has an obligation to review the risk analysis and provide updated policy advice if there are substantial changes in the volume and nature of the trade in specific commodities. The apple industry therefore seeks, as a matter of priority, an explanation of the mechanisms that Biosecurity Australia has established to monitor volumes of trade and the processes it has created to reassess risks as import volumes exceed those acceptable to maintain Australia's ALOP.

[3] Based on an annual domestic fresh apple market of 231,000 tonnes and assuming a 40% replacement by imports from NZ and the PNW.

Recommendations: That Biosecurity Australia undertake, as part of this Draft IRA process, a full assessment of the expected expansion of imports resulting from trade with the PNW taking into account the expected flow of imports from other suppliers. This should include an assessment of whether the model currently employed by Biosecurity Australia to measure risk and design risk management strategies is appropriate given the significant expansion expected in the trade of apples. Using a model calibrated to the volume of trade, Biosecurity Australia should then reassess its estimates of the risk of pests entering, spreading and establishing within Australia. A re-examination of the economic consequences should follow, as should reconsideration of the risk management strategies required to achieve Australia's ALOP. Finally, due process requires that full details of these assessments are provided to the apple industry for their feedback as part of the draft IRA.

12. Pest risk management measures and phytosanitary inspections

The apple industry has a number of concerns relating to the efficacy of the risk management measures, including the sampling regimes, proposed by Biosecurity Australia in relation to a number of pests: fire blight, European canker, apple maggot, leafcurling midge, codling moth, oriental fruit moth, cherry fruitworm and the lesser appleworm. Specifically, the Draft IRA:

- Does not take into account, in an appropriate statistically sound way, the effect of inspection sampling on the proportion of infected/infested fruit entering Australia;
- Ignores the impact of clustering;
- Assumes a 100% detection rate of pests and diseases and human error is not taken into account;
- Recommends AQIS use pre-clearance and on-arrival phytosanitary inspection levels that are too lenient;

The apple industry contends that all these factors lead to underestimation of the risk of these diseases entering, spreading and establishing within Australia. Therefore more stringent risk management measures should be imposed to achieve Australia's ALOP.

Our concerns are outlined in greater detail below.

9.1 Prevalence of the pest

Independent analysis (Attachment 1) demonstrates that the Draft IRA does not take into account, in an appropriate statistically sound way, the effect of inspection sampling on the number of infested/infected fruit.

Sampling schemes have been proposed by Biosecurity Australia as part of the risk management measures to ensure that areas are free of disease (say for fire blight) or that cartons are free of infected/infested apples (say, for the leaf curling midge). However, as independent experts note (Attachment1) inspection sampling schemes do not in themselves change the number of infected trees in an orchard or the number of infected/infested apples in a lot (carton/container). What changes is that as the proportion of trees or apples with the pest increases, the probability that the nominated sample will contain at least one tree or apple with the pest increases. Sampling has absolutely no effect on the proportion of trees or apples infested with the pest.

Put another way, the greater the confidence required that a tree which is infected/infested is identified by the sampling technique, the higher the number of samples that must be taken, given any degree of infestation/infection (eg 1% of the orchard). Fewer samples will provide less confidence that a diseased tree will be identified. But the number of diseased trees remains unaffected by the sampling regime.

As a result, the Draft IRA underestimates the number of infested/infected fruit that might enter Australia. The proposed risk management regimes will therefore fail to attain Australia's ALOP.

Recommendations: *That the (a) inspection sampling schemes for fire blight, apple maggot, leafcurling midge, codling moth, oriental fruit moth, cherry fruitworm and the lesser* *appleworm be made more stringent than proposed in the Draft IRA in order to meet Australia's ALOP; and, (b) specific details of the sampling schemes for fire blight and aforementioned pests be provided so that its efficacy and its robustness can be measured against imperfect visual inspection (c) Assessments of the efficacy of the sampling regimes by Biosecurity Australia are provided to industry for input and comment as part of the draft IRA process; (d) these issues be addressed and the apple industry consulted prior to the finalisation of the IRA.*

9.2 Clustering

The apple industry is concerned that the proposed sampling scheme does not take into account the clustering of diseased trees. This concern relates to fire blight as well as other pests.

A standard sampling approach assumes that the trees with symptoms are randomly distributed throughout the orchard and sampled trees are selected at random. However, it is expected that infected trees tend to cluster in locations in the orchard, for example, due to varying exposure to wind and rain and varying visitation by (transmitting) insects.

If clustering does occur, the standard sampling approach may fail to identify diseased trees and false negatives may be granted - that is, the orchard may incorrectly be granted freedom from pest symptom status. The apple industry therefore believes that the operating characteristics of the sampling scheme have to be designed to take the strong probability of clustering into account to obtain the required statistical specification.

Recommendations: *That the (a) the Draft IRA should develop a statistically sound means of taking into account clustering of diseased trees as part of the process of developing a sampling scheme for inspections to establish orchards declared free of visible disease symptoms; (b) specific details of the statistically sound approach be assessed by Biosecurity Australia and provided to industry for comment as part of the draft IRA process.*

9.3 Human Fallibility

The apple industry is concerned that the proposed risk management schemes assume a 100% detection rate of pests and diseases and that the potential for human error is not taken into account.

For example, the risk management measure proposed by Biosecurity Australia for *E. amylovora* requires that orchards be inspected 4 to 7 weeks after flowering – spring or summer depending upon the variety. Those inspectors will return to the orchards after leaf fall but before winter pruning to conduct inspections for European canker. The two inspections will be conducted in very different light conditions, neither of which is ideal. Because winter is associated with lower levels of light, especially in the higher latitudes of the PNW states, sight detection of pests is made more difficult and false negative results may be recorded. The possibility of human error is similarly raised by sun-glare during the spring and summer months. False negative readings of pest free or symptom free trees through human error is also much more likely to occur with larger trees because height and foliage reduces visibility.

The apple industry believes that the Draft IRA needs to specify the conditions for inspection to ensure that inspection errors are minimised to take account of poor light conditions in winter and also for the inspection of larger trees.

Recommendations: *As part of the Draft IRA process, Biosecurity Australia should specify the conditions for inspection to ensure that human errors are minimised and false negative recordings are eliminated. Specific conditions should not be generalised. Rather, the conditions should be tailored for each pest or disease that requires an inspection (pre-border or at border; of orchards, blocks or trees; and, of bins or cartons) as part of the risk management regime.*

9.4. Pre-clearance and on-arrival phytosanitary inspection by AQIS

The apple industry also contends that the pre-clearance and on-arrival phytosanitary inspection schemes operated by AQIS are too lenient and therefore the Draft IRA underestimates the overall risk associated with pathogens entering Australia from the PNW.

Biosecurity Australia indicates that the pre-clearance and on-arrival phytosanitary inspection schemes for apples from the PNW will be conducted on the basis of the standard AQIS inspection protocol. This implies an inspection rate of 100 per cent of the consignment for consignments of 1–450 apples; a sample of 450 apples for consignments of 451–1000 apples; and, a sample of 600 apples for consignments of 1001 apples or more.

However independent analysis (Attachment 1) indicates that the AQIS acceptance scheme would, assuming consignments of 1000 apples, lead to about 66,000 infested or infected apples being imported into Australia each year (assuming US imports of 44,000 tonnes per year). Tripling the size of consignments to 3000 apples and inspecting a sample of 600 apples would still mean that 42,000 diseased apples would enter Australia.

The apple industry is therefore concerned that the AQIS sampling scheme is not sufficiently stringent in terms of the sample size of the number of apples taken from consignments.

Recommendation: *That Biosecurity Australia change the protocol for apple imports to 100% inspection rates for consignments of less than 3000 apples and a sample of size 3000 apples for consignments with size greater than 3000.*

13. Finalisation of Import Requirements

Biosecurity Australia has indicated that, 'in some cases, detailed efficacy data on the proposed treatments is not available and that such data will need to be provided by the US before these treatments can be finalised and final import conditions developed. Finalisation of the quarantine conditions may be undertaken with input from AQIS and the Australian states and territories as appropriate.'

The apple industry is extremely concerned that it has been excluded from providing input to the finalisation of import conditions. It is the industry's view that an assessment of the scientific data provided by the US to support treatment options forms a critical part of the IRA process and has all stakeholders have an essential role to play in scrutinising the effectiveness of risk management strategies prior to their finalisation and adoption as policy. The apple industry therefore seeks access to data and documentation provided by the US and an opportunity to present an assessment of that documentation to Biosecurity Australia prior to the IRA being finalised.

Recommendation: *That Biosecurity Australia provides the apple industry access to the data and documentation provided by the US and an opportunity to present an assessment of that documentation as part of this draft IRA process.*

14. Managing the Complexity

The apple industry is concerned that the cumulative risks associated with the extremely high pest and disease load, managed by a complexity of risk management measures, will inevitably raise the probability of the entry, establishment and spread of a pest from the PNW.

Apple imports from the PNW will present a significant operational challenge to those charged with monitoring and enforcing compliance with the complex array of risk management strategies that will be required to achieve Australia's ALOP. The proposed risk management measures are numerous, varied and multifaceted and range from visual inspection, fruit cutting, physical treatments, pests free areas, pest free places of production, establishment of areas free of disease symptoms, areas of low pest prevalence and systems approaches. The application of a large number of risk management strategies will inevitably require human intervention on many complex fronts and this can only escalate the potential of human error.

The apple industry contends that the draft IRA has not adequately addressed the potential of human error arising from the multiplicity of risk management strategies proposed for apples from the PNW. It is, therefore, likely that the risk posed by the importation of apples from the PNW has been underestimated.

Recommendations: That the overall risk assessment for apples from the PNW be re-evaluated in light of the multiplicity of risk management strategies required given the type and number of potential pests.

15. Conclusion

The apple industry has identified a number of serious inadequacies within the Draft IRA for apples from the PNW. These fall into two broad areas. The first relates to the underestimation by Biosecurity Australia of the risk posed by the entry, spread and establishment and consequential impact, of the pests and diseases associated with PNW apples. These issues include:

- Adoption of NZ assessments and protocols even though very different parameters apply;
- Magnitude of the number of pests and diseases that pose a risk;
- Failure to take account of the most recent scientific research on fire blight;
- Spotted wing drosophila is not assessed;
- Lack of surveillance tools for apple maggot not considered;
- Impact of commercial practices such as honey bee pollinators not incorporated;
- Unrestricted movement of vegetative and propagation materials across states not assessed
- Anticipated significant volume of trade, on top of potential Chinese and New Zealand imports, not assessed.

The second set of issues relates to the inadequacy of the risk management measures posed by Biosecurity Australia to deal with pests that have been identified as exceeding Australia's appropriate level of protection (ALOP). These issues include, but are not limited to:

- Efficacy of proposed sampling regimes;
- Ineffectiveness of chlorine treatments for fire blight;
- Too few orchard inspections for fire blight;
- Fumigation the only responsible response to apple maggot;

- Requirement for a minimum 3000 fruit inspection or fumigation for apple curculio;

The apple industry has provided a number of recommendations to overcome these issues. Most of these suggest that Biosecurity Australia should re-examine the risk assessment for specific pests and/or the risk management measures required to afford an appropriate level of protection. In such cases, Biosecurity Australia is asked to demonstrate how the specific new information or previously ignored information affects the risk assessment or risk management proposal. The apple industry also suggests that Biosecurity Australia seek certain information from APHIS and that this be made available and form part of this decision-making process. It is recommended that Biosecurity Australia also review the model used in the import risk analysis. The objectives of this review are to a) design a new model that can, in light of a large number of pests, correctly quantify the levels of risk associated with the entry, establishment and spread of pests and correctly interpret the consequences that would flow from the unrestricted risk of imports and b) apply that new model to the PNW pests of concern and adjust the risk levels and subsequently the risk management measures accordingly.

Finally it is recommended that the issues raised by the apple industry within this review be addressed by Biosecurity Australia as part of the Draft IRA. Due process requires that the apple industry be afforded an opportunity to respond to further analysis undertaken by Biosecurity Australia.

16. References

Biosecurity Australia (2006) Final Import Risk Analysis Report for Apples from New Zealand. Biosecurity Australia, Canberra, Australia.

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17. Attachment 1

Draft Import Risk Analysis Report for Fresh Apple Fruit from the United States of America Pacific Northwest States, October 2009

Statistical Methodology and Modelling

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11th December 2009

EXECUTIVE SUMMARY

This report was commissioned by Apple and Pear Australia Limited to examine the statistical methodology and modelling of the Draft IRA, October 2009 (BA 2009b). In particular the report was commissioned to examine the efficacy of the risk management schemes, in terms of the inspection schemes proposed, and the number of pests for which risk management has to be proposed.

We are concerned that the Draft IRA does not take into account in an appropriate statistically sound way the effect of inspection sampling so that the proposed risk management in the Draft IRA does not attain Australia's ALOP by not reducing the proportion of infected/infested fruit entering Australia by the amount expected by the Draft IRA; that a 100% detection rate of pests and diseases is assumed and human error is not taken into account and therefore the Draft IRA underestimates the overall risk; and that the pre-clearance and on-arrival phytosanitary inspection by AQIS is too lenient and therefore the Draft IRA underestimates the overall risk. We consider that all these factors lead to underestimation of the risk and therefore more stringent risk management measures should be imposed to achieve Australia's ALOP. We make suggestions how the inspection sampling should be more stringent in order to achieve Australia's ALOP.

In the Draft IRA an unusually large number of pest risk assessments (39) are considered compared with other risk assessments finalised to date by BA (these number in the range 3 to 13). We consequently consider that the Draft IRA should be re-calibrated and therefore more stringent risk management measures should be imposed to achieve Australia's ALOP.

INTRODUCTION

This report was requested by Apple and Pear Australia Limited to examine the statistical methodology and modelling of the Draft IRA, October 2009 (BA 2009b), in particular to examine the efficacy of the risk management schemes, in terms of the inspection schemes proposed and the number of pests for which risk management has to be proposed.

We consider risk management proposed for Fire blight, European canker disease, leafcurling midge**,** apple maggot, codling moth, oriental fruit moth, cherry fruitworm and lesser appleworm. We have concerns about the following aspects of risk management and the IRA's assessment of risk:

- the risk reduction effect of acceptance sampling for orchards declared as free from fire blight symptoms;
- the assumed inspection detection rate of 100% for pests and disease symptoms;
- the effect of clustering on the performance of acceptance sampling scheme for reducing risk; and
- the risk reduction effect of the pre-clearance and on-arrival phytosanitary inspection by AQIS.

Consequently we make recommendations that the inspection sampling schemes should be more stringent in order to meet Australia's ALOP.

We also note that the Draft IRA involves 39 pest risk assessments whereas previously finalised IRAs by BA have involved a range of 3 to 14 pest risk assessments. Thus we believe that the qualitative risk estimation method used by BA is calibrated to a significantly smaller number of pests than is considered in the Draft IRA. Because of this, the overall risk presented by the importation of apples with the risk management measures in place is likely to be greater than that which is considered acceptable for other commodities. Consequently we make recommendations that the risk management should be more stringent in order to meet Australia's ALOP.

The report addresses these issues and has 11 concerns.

FIRE BLIGHT

The risk reduction effect of acceptance sampling for orchards declared free from fire blight symptoms

On page xiv and page 260 of the Draft IRA details are given of a risk management procedure to maintain orchards free from fire blight symptoms. The Draft IRA specification is as follows.

> *Orchard inspections undertaken for fire blight symptoms at an inspection intensity that would, at a 95% confidence level, detect visual symptoms if shown by 1% of the trees. This inspection should take place between 4 and 7 weeks after flowering when conditions for fire blight disease development are likely to be optimal. Orchards with any visual symptoms of fire blight would be disqualified from export.*

For this to be implemented the sampling scheme needs to have a 95% chance that at least one tree with symptoms would be found if 1% of tress had symptoms. For example, for large orchards with at least 3000 trees, this specification is satisfied by taking a sample of 300 trees and assuming that any tree with any visual symptoms is detected with certainty.

The two values of 95% and 1% can be used to work out the sample size required for an inspection. The standard modus operandi is to assume a binomial distribution, where trees are independently showing symptoms (that is, no clustering). This assumes the block size is large, say more than 3000 trees, and trees are selected at random for inspection (or symptoms occur randomly or both). In this case, the probability of showing symptoms for each tree is p=0.01, N is the number of trees in a sample, which we need to find, and x is the number of trees in the sample showing symptoms. If we detect symptoms in the sample, then $x \geq 1$ and the 95% confidence level statement can be expressed as

$$pr(\text{detection}) = pr(x \geq 1) = 1 - pr(x = 0) = 1 - (1 - 0.01)^N = 1 - 0.99^N \geq 0.95$$

where we must select the sample size N so that detection occurs with at least 95% confidence. Some algebra then allows us to solve for N and rounding up, we would expect that a sample of 300 trees would be needed to satisfy this standard.

The point about such inspection or acceptance sampling schemes is that they do not in themselves change the number of infected trees in the orchard, this remains at the same proportion. What changes, as the proportion of infected trees increases, is the probability that the sample of 300 trees will contain at least one infected tree. If all orchards had 1% of trees displaying visible symptoms then the sampling scheme would eliminate 95% of the orchards whilst 5% of orchards would be declared symptom free, but the proportion of trees with symptoms would still be 1%.

Sampling would affect the percentage of trees displaying visible symptoms on average as follows. If for example half the orchards had 1.5% of trees displaying visible symptoms and half had 0.5% displaying visible symptoms (an average of 1%) then the effect of sampling would change the average proportion displaying visible symptoms to

$$\frac{0.015\times(0.985)^{300}+0.005\times(0.995)^{300}}{(0.985)^{300}+(0.995)^{300}}$$

$$=0.0052\,,$$

or 0.52%. That is, most of the accepted orchards declared free from visible symptoms would be orchards with 0.5% of trees infected and the remaining small proportion with 1.5% of trees infected. The effect of sampling in this example for orchards that are declared free from visible symptoms is to reduce the average percentage of trees displaying visible symptoms from 1% to 0.52%, that is to halve the proportion of visibly infected trees not to reduce it to zero.

We can argue a similar situation for when the orchard has a small number of trees. Suppose it has 600 trees, about one hectare. In this case, in order to obtain a 95% confidence level that the proportion of trees with symptoms is no more than 1%, we require a sample of size 235 trees. In the table below we give the probability that orchards will be accepted with a given proportion of trees with symptoms. This amounts to the probability of the sample of size equal to 235 containing no trees and the trees with symptoms being in the remaining 600 – 235 = 365 trees not sampled.

Proportion of trees with symptoms	**Number of trees with symptoms in orchard of 600 trees**	**Probability orchard accepted as symptom free**
0.5%	3	22.4%
1.0%	6	5%
2.0%	12	0.2%

Thus if the proportion of trees with symptoms were 0.5%, 22.4% of orchards would be accepted as being "symptom free" even though 0.5% (or 3 in 600) trees have symptoms. There is no reduction in the proportion of trees with symptoms just that some orchards would be accepted and some rejected leaving just under a quarter of the orchards with the status of 'orchard free of visible symptoms'. This quarter of orchards from which exports would be allowed would have 3 infected trees per 600 in the orchard. Thus if there were originally 1000 orchards each with 600 trees of which 3 had symptoms, then apple exports would come from 224 orchards and 672 trees with symptoms.

In order to quantify the effect of the proposed inspection sampling on the average proportion of trees, which are free from symptoms in an orchard which is declared to be free from symptoms, it is necessary to have good information about the number of trees with Fire blight symptoms. This is lacking in the Draft IRA. It is not sufficient to define the inspection scheme as it is in the Draft IRA as below

> *Orchard inspections undertaken for fire blight symptoms at an inspection intensity that would, at a 95% confidence level, detect visual symptoms if shown by 1% of the trees.*

The definition requires additional specification.

Concern (1). We are concerned that the Draft IRA does not take into account in an appropriate statistically sound way the effect of inspection sampling (to declare an orchard symptom free) on reducing the number of imported infected fruit and consequently overestimates the risk reduction. This reduces the capacity of the risk management measures in the Draft IRA to meet Australia's ALOP.

Detection rate less than 100%

The performance of the sampling schemes is dependent upon the detection rate of the inspectors involved. This could be less than 100% with error being present. Two different errors can be defined as a false positive and a false negative. The former would incorrectly declare a tree to have Fire blight symptoms whilst the latter occurs when a tree with symptoms is incorrectly declared to be symptom free. We will only consider the possibility of a false negative (less than 100% sensitivity) and assume that the probability of a false positive is zero (or 100% specificity). The occurrence of error could depend on various factors such as the lighting and other environmental conditions such as noise; the size of the tree; personal factors such as skill level and tiredness; and the difficulty of detecting the disease symptoms. The detection rate could become less than 100% if the tree had the disease and was yet to produce visual symptoms or produced symptoms which were difficult to determine as symptoms. If there were such errors in the visual inspection, then the detection rate could become 50% rather than 100%. With larger, older trees the error rate is more likely to be greater than with smaller younger trees.

The Draft IRA sampling scheme specification referred to above has to be changed so that less than 100% sensitivity is accommodated. For example, the sampling scheme needs to have a 95% chance that at least one tree with symptoms would be found if 1% of tress had symptoms and there were a 50% chance of detection. To take account of such possibilities the scheme has to be rewritten to assume that only 0.5 % of the trees have symptoms that would be detected. If this were the case then the scheme above with a sample size of 300 trees assuming perfect detection would need to have a sample of 600 trees. Govindaraju (2007) addresses this issue.

Concern (2). The Draft IRA needs to stipulate a sampling scheme more precisely than in terms of the specification given on pages xiv and 252. It needs to take account of the following:

- the error of detection being as large as 50%. This can be accommodated by increasing the sample size from 300 to 600 trees for an orchard with over 3000 trees and requiring no trees with symptoms detected in the sample.
- Detection error rates are likely to increase with the size of the tree. Therefore orchards with larger trees should have sample sizes increased accordingly to allow for higher error rates. The sample size should be increased from 300 to 900 trees to allow for 33% detection rates.

In the circumstances the Draft IRA should give details of the sampling scheme that will be implemented so that its efficacy can be measured and its robustness against imperfect visual inspection assessed.

Sampling scheme

Further details for the sampling specification need to be given. A standard approach assumes that the trees with symptoms are randomly distributed throughout the orchard and trees are selected at random. It is to be expected that infected trees tend to cluster in locations in the orchard, for example, due to varying exposure to weather types (wind, rain) through the orchard and varying exposure to insects. The Draft IRA pages 35 and 36, states, that

> *Erwinia amylovora infects flowers, fruit, leaves, stems and woody plant parts. …*
>
> *The bacterium is readily spread by wind, rain, insects and human activities, including dissemination through planting material (Beer 1990; Douglas 2006) …*
>
> *Erwinia amylovora overwinters almost exclusively in previous season's cankers (Beer and Norelli 1977). In spring, it multiplies at the margins of cankers and the adjacent bark tissues giving rise to primary inoculum. Rain or insects can disseminate the bacterium to infection courts, typically open flowers, growing vegetative shoot tips or young leaves (Beer 1990).*

The operating characteristics of the sampling scheme have to be designed to take the probable strong clustering into account to obtain the required specification. The area subject to sampling should be restricted in terms of the number of trees so that clusters of trees with symptoms are sampled. We suggest clusters of no more than 10 trees are defined and then at least one tree per cluster is sampled. So that with a total sample size of 600 trees, the sample is a spatial systematic at-least-one-in-at-most ten tree sample. This implies that the size of the orchards considered to be declared free from visible Fire blight symptoms should have no more than 6000 trees.

The trees in PNW are planted in densities that range between 500 per ha and over 800 per ha (in communication from the USDA to BA dated 5/9/20008 an average density of 743 trees/ha for red delicious and 583 trees/ha for tress planted before 1986). If the orchard is kept to 6000 trees in size this suggests that the orchards that might be 'declared free from visible symptoms' are no larger than 10 ha in area.

Concern (3). The Draft IRA should develop and give details of the sampling scheme for orchard inspections to establish orchards declared free of visible Fire blight symptoms in order that the clustering of diseased trees is soundly taken into account in a statistical manner.

EUROPEAN CANKER DISEASE

On pages xiv and 261 of the Draft IRA details are given of a risk management procedure and its specification is as follows:

> *Inspection of all host trees in export orchards after leaf fall, during winter, for freedom from European canker disease. Orchards with any symptoms of European canker would be disqualified from export.*

This specification requires inspection of all trees for disease in winter. Human inspection errors are quite likely to occur in winter with lower levels of light that occur in higher latitudes and this has a high chance of being unsuccessful at detecting trees in orchards with European canker disease. Human error is more likely to occur with larger trees.

Concern (4). The Draft IRA needs to specify the conditions for inspection to ensure that inspection errors are minimised to take account of poor light conditions in winter and larger trees. For example, inspections should be independently repeated and carried out with good artificial lighting.

LEAFCURLING MIDGE.

The effect of acceptance sampling on detection

On pages xiv and 244 of the Draft IRA details are given of a risk management procedure and its specification is as follows.

Establishment of area freedom for apple leafcurling midge. If area freedom could not be established, inspection in the PNW of a random sample of 3000 fruit from each lot for freedom from this pest must be undertaken. Detection of apple leafcurling midge would result in rejection of the lot or a treatment such as fumigation. Alternatively, an effective treatment could be used for all export lots.

A sample of size of 3000 would provide a sampling scheme which in the Draft IRA's terms of defining of such a scheme

would at a 95% confidence level detect a lot with the pest if present on 0. 1% of the apples in the lot.

The remarks relating to Concern (1) above for Fire blight apply here. The point about such inspection sampling schemes, and here it applies to 3000 apples in a lot, is that the schemes do not in themselves change the number of infected apples in the lot, this remains at the same proportion. What changes, as the proportion of apples with the pest increases, is the probability that the sample of 3000 apples will contain at least one apple with the pest. If all lots had 0.1% of apples having the pest, then the sampling scheme would eliminate 95% of lots whilst 5% of lots would be declared pest free because no pests would be detected in the 3000 apple sample, but the proportion of lots with pests would still be 0.1%. Rejected lots could be returned for acceptance sampling until the 5% probability event of acceptance was satisfied. That is, the sampling has absolutely no effect on the proportion of apples infested with the pest.

Concern (5). We are concerned that the Draft IRA does not take into account in an appropriate sound statistical way the effect of acceptance sampling on reducing the proportion of fruit infested with leafcurling midge, and hence reducing the capacity to meet Australia's ALOP.

Effect of clustering on acceptance sampling scheme.

The calculations here have assumed that the sample is a random sample of apples in the lot. There is the possibility of pests being clustered within cartons. Assuming that apples are packed into cartons of 100 apples, it is quite possible that the 3000 sample size is taken as 30 cartons of 100 apples each. If the prevalence of 0.1% of apple leafcurling midge occurs at the carton level, with all apples in the carton infested then the sample size becomes effectively 30 and not 3000. If this were the case then the conclusions about the effectiveness of the 3000 size inspection sampling for reducing the risk to meet Australia's ALOP would not be correct.

Concern (6). We are concerned that the Draft IRA has not prescribed a sampling plan that draws its sample from the maximum number of cartons to obtain 3000 apples from the lot so that the effects of clustering are minimised.

Effect of human error

As with Fire blight above, there is the issue of human error on detection of the pest. That is, the inspectors are searching for a pest with a very small prevalence so that the expectation is that any apple may have a very small chance, 1 in a 1000 using the above illustration, of being infested with the pest. Such circumstances are likely to increase the chance of human error, giving a false negative. Thus an inspection scheme has to be specified by the Draft IRA which takes into account inspection error.

Concern (7). We are concerned that the Draft IRA has not taken into account in a sound manner the human error involved in inspecting for a rare attribute. Consequently, there is concern that Australia's ALOP has not been met by the Draft IRA for the pest.

APPLE MAGGOT

On page xiv of the Draft IRA details are given of a risk management procedure and its specification is as follows.

> *Establishment of area freedom for apple maggot. Alternatively, an effective treatment could be used for all export lots*.

The establishment of areas free of apple maggot requires the same cautious statistical approach as described above for acceptance sampling so that Australia's ALOP is met. Areas have to have 100% compliance with freedom of visual symptoms.

Concern (8). In order to establish areas free of apple maggot, the following need to be taken into account in a sound manner in designing statistical sampling schemes:

- the prevalence of the pest;
- the human error involved in inspection; and
- clustering of pests and sample design,

so that Australia's ALOP can be met for the pest. This is not the case at present in the Draft IRA.

CODLING MOTH, ORIENTAL FRUIT MOTH, CHERRY FRUITWORM AND LESSER APPLEWORM

On page xiv of the IRA details are given of a risk management procedure and its specification is as follows:

Establishment of areas of low pest prevalence for codling moth, oriental fruit moth, cherry fruitworm and lesser appleworm. Alternatively, an effective treatment could be used for all export lots.

Concern (9). In order to establish areas of low pest prevalence, the following need to be taken account of in designing statistical sampling schemes:

- the prevalence of the pest;
- the human error involved in inspection; and
- clustering of pests and sample design,

so that Australia's ALOP can be met for the pest. This is not the case at present in the Draft IRA.

PRE-CLEARANCE AND ON-ARRIVAL PHYTOSANITARY INSPECTION BY AQIS

On page 264 of the Draft IRA the following is stated:

The objective of this procedure is to verify that the required measures have been undertaken. A phytosanitary inspection of lots covered by each phytosanitary certificate issued by APHIS will be undertaken by AQIS either in the US (mandatory or voluntary) as a pre-clearance, or on arrival of the consignment in Australia. The inspection will be conducted using the standard AQIS inspection protocol for the type of commodity using optical enhancement where necessary. The sample size for inspection of apple fruit is given below.

Consignment size	*Sample size*
1–450 apples	*100 per cent of the consignment*
451–1000 apples	*450 apples*
1001 apples or more	*600 apples*

The sample will be drawn proportionally from each grower contributing to the inspection lot. The detection of live quarantine pests, or dead pests from pest free areas, pest free places of production, pest free production sites or areas of low pest *prevalence, or other regulated articles, will result in the failure of the inspection lot. Detection of pests from pest free areas, pest free places of production, pest free production sites or areas of low pest prevalence will also result in the loss of the relevant pest status.*

These AQIS sampling schemes are designed to have a small probability of acceptance, less than 0.25% or 1 in 400, when the proportion of infested/infected apples is 1% or more. Below we give details of probabilities of acceptance of the scheme when 1000 apples are in the consignment and a sample of 450 is taken. Probabilities are calculated using the hypergeometric distribution. It is important to note that when the number of pest infested/infected apples in the consignment is 5, or 0.5%, the probability the consignment is accepted is 5.5%. If all consignments were of size 1000 and had 5 pest infested/infected apples and US imports amounted to 44,000 tonnes of apples per year (220,000 tonnes domestic fresh apple market, imports 20% of market, 5500 apples per tonne) then the AQIS acceptance scheme would allow about 66,000 infested/infected apples per year to be imported into Australia.

Proportion of apples with pest	**Number of apples with pests in consignment of 1000 apples**	**Probability consignment accepted, sample =450**
0.5%	5	5.5%
1.0%	10	0.24%
2.0%	20	0.0005%

Slightly smaller numbers are obtained as given below when the consignment is of size 3000 and a sample of size 600 is taken. The AQIS scheme would allow about 42,000 infested/infected apples per year to be imported into Australia.

Proportion of apples with pest	**Number of apples with pests in consignment of 3000 apples**	**Probability consignment accepted, sample =600**
0.5%	15	3.5%
1.0%	30	0.1%
2.0%	60	0.00013%

Similar numbers to the first scenario with a consignment of 1000 apples are obtained when the consignment is of size 10,000 (see table below). The AQIS scheme would allow 60,000 infested/infected apples per year to be imported into Australia.

Proportion of apples with pest	**Number of apples with pests in consignment of 10000 apples**	**Probability consignment accepted, sample =600**
0.5%	50	5.0%
1.0%	100	0.25%
2.0%	200	0.0006%

The AQIS sampling scheme is not sufficiently strong in terms of rejecting consignments when the proportion of apples infested/infected with the pest is as large as 0.5%. A sample size of 3000 for consignments of size greater than 3001 apples and 100% inspection of consignments of less than 3000 apples is recommended. The probability an assignment is accepted when the proportion of apples infested/infected with the pest is as large as 0.5% is 1.7 e-8 which is negligible, as shown in the table below.

Proportion of apples with pest	**Number of apples with pests in consignment of 10000 apples**	**Probability consignment accepted, sample =3000**
0.5%	50	1.7 e-8

Information about the proportion of apples infested/infected with the pest at the AQIS sampling stage is important to obtain in order to develop appropriately stringent sampling schemes in order to achieve Australia's ALOP.

Concern (10). We are concerned that the AQIS sampling scheme is not sufficiently stringent in terms of the sample size of the number of apples taken from consignments. We recommend 100% inspection for consignments of less than 3000 apples and a sample of size 3000 apples for consignments with size greater than 3000.

We recommend the sample is found as originally stated in the Draft IRA:

> *The sample will be drawn proportionally from each grower contributing to the inspection lot. The detection of live quarantine pests, or dead pests from pest free areas, pest free places of production, pest free production sites or areas of low pest prevalence, or other regulated articles, will result in the failure of the inspection lot. Detection of pests from pest free areas, pest free places of production, pest free*

production sites or areas of low pest prevalence will also result in the loss of the relevant pest status.

ASSESSMENT OF MULTIPLE ITEMS OF RISK.

The Draft IRA follows a qualitative methodology that estimates risk in a Pest Risk Assessment for each identified pest of concern. The risk associated with each pest is determined by qualitatively estimating the likelihood of entry establishment and spread, and qualitatively assessing the consequence of the pest's entry, establishment and spread. A risk estimation matrix then combines the consequence level and the likelihood to give an indication of risk. If the risk is above "very low", a determination is made that management measures will be required to reduce the risk associated with the pest to an acceptable level.

In this process, the focus is on identifying and ranking the risks presented by the various diseases or pests associated with the commodity, so that those which are considered too high can be reduced through appropriate management measures. This approach is consistent with standard methods of qualitative risk analysis, where the object is to identify and manage the risks associated with a course of action. However the process does not explicitly identify an overall risk associated with the importation of the commodity, other than through the crude judgement of acceptable, or unacceptable. An acceptable risk, according to the process, is one in which all identified pests or diseases which exceed the acceptable level of risk individually, have suitable management measures imposed.

This process may lead to inconsistencies in judgement of overall risk. For example, for a commodity with a large number of pests, the probability that any one of them establishes will be greater than for a commodity with a small number of associated pests, in the same way that a greater volume of trade will increase the probability that a pest will establish. More items arriving in Australia with a pest of concern equals greater risk, whether that is due to increased trade, or a greater number of possible pests or diseases.

Keith Hayes (2003) criticises qualitative risk assessment methods for their inability to appropriately estimate overall, or "pathway" risk. He makes the point that risks are approximately additive, which supports our view that the overall risk can be substantially greater when more pests of quarantine concern are present, even when the risk for each pest is managed down to an acceptable level. Richard Orr (2003) in a review of risk analysis methods for aquatic organisms, stresses that risks for individual organisms must be combined by some method to give an overall pathway risk. This step is omitted in the qualitative assessment process adopted by Biosecurity Australia, with the consequence that the pathway risk is likely to be greater than in other IRAs applying the same qualitative methodology, but with fewer quarantine pests.

It is accepted that the volume of trade is a key determinant of risk in the qualitative assessment method, because this increases the number of infected units arriving which may result in the pest establishing and spreading. The Draft IRA states on p 9:

> *Time and volume of trade*
>
> *One factor affecting the likelihood of entry is the volume and duration of trade. If all other conditions remain the same, the overall likelihood of entry will increase as time passes and the overall volume of trade increases*.

On page 10 it states

> *The use of a one year volume of trade has been taken into account when setting up the matrix that is used to estimate the risk* ..

This figure is taken to be 20% of the domestic fresh apple market, and the document also states that later on page 10:

> *if there are substantial changes in the volume and nature of the trade in specific commodities then Biosecurity Australia has an obligation to review the risk analysis…*

However, if volume of trade is to be considered a factor, then by the same logic, we must consider the number of pests associated with the commodity. For each additional pest of concern, we have additional infested units arriving in Australia, equal to the number of imported units per year times the prevalence of the disease in the imported commodity, assuming that pests/diseases occur independently.

The probability of entry establishment and spread is directly proportional to the number of infected units which arrive in the country. If we take as our viewpoint the probability of establishing any one of these potential diseases, this probability, and hence the risk, must increase with the number of pests/diseases of concern.

The individual benchmark for assessing acceptable risk for each pest/disease, must therefore be lower when there are a large number of pests, otherwise the overall risk assessments are not comparable between commodities with few and many pests.

Following this line of reasoning, qualitative risk estimates should be "calibrated" to a particular number of pests. If the number of pests are fewer than this calibration number, then the risk analysis presents no additional risk to industry. However, if the actual number of pests significantly exceeds this calibration number, then the method will inadequately characterise the overall risk, and the risk estimation matrix would need to be recalibrated.

The numbers of pest risk assessments constituting recent finalised IRAs which follow the same methodology to the Draft IRA are tabulated in the table below. In some cases below, a single pest risk assessment applies to a cluster of related pests which may be expected to behave in the same way, and respond to the same management measures. In other qualitative risk assessments performed to date, there have been between 3 and 13 pest risk assessments considered. In comparison, 31 pest risk assessments are conducted in the Draft IRA, with a further 8 pest risk assessments for pests which occur in the USA, but not in the Pacific North West.

The total risk associated with the apple imports, with management measures in place, therefore will likely be substantially greater than that posed by the importation of these other commodities.

IRA	Number of Pest Risk Assessments
Capsicums from Korea (BA 2009a)	4
Tahitian Limes from New Calidonia (BA 2006)	6
Longan and Lychee from China and Thailand (BA 2004)	13
Mangos from India (BA 2008)	11
Mangosteens from Thailand (DAFF 2004)	3
Pineapples – generic (BA 2002)	6
Table Grapes from Chile (BA 2005)	10
Unshu Mandarins from Japan (BA 2009c)	11

The number of Pest Risk Assessments in recently completed plant IRAs which follow the same methodology as the Apple IRA.

Concern (11). The qualitative risk estimation method used by BA is calibrated to a significantly smaller number of pests than is considered in the Draft IRA. Because of this, the overall risk presented by the importation of the commodity with risk management measures in place, is likely to be greater than what is considered acceptable for other commodities.

Because of the greater overall risk, it would be appropriate to make management measures more stringent for each pest or disease, in order to maintain the overall risk at the same acceptable level as in other similar qualitative IRAs.

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