



Draft Inventory of Issues
Raised by Stakeholders in
Response to the Draft IRA on
New Zealand Apples



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Acronyms

AAPGA	Australian Apple and Pear Growers' Association
AFFA	Department of Agriculture, Fisheries and Forestry - Australia
ALOP	Appropriate Level of Protection
AQIS	Australian Quarantine and Inspection Service
BA	Biosecurity Australia
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CER	The Australia New Zealand Closer Economic Relations Agreement
cfu	Colony forming unit
DEA	Designated Export Area
DNA	Deoxyribo Nucleic Acid
EA	Environment Australia
FAO	Food and Agriculture Organization
FSC	Food Standards Code
GATT	General Agreement on Tariffs and Trade
IFP	Integrated Fruit Production
IPM	Integrated Pest Management
IPPC	International Plant Protection Convention
IRA	Import Risk Analysis
ISPM	International Standard for Phytosanitary Measures
NZ	New Zealand
MAFNZ	Ministry of Agriculture and Forestry, New Zealand
NPPO	National Plant Protection Organisation
MRL	Maximum Residue Limit
NRA	National Registration Authority
PFA	Pest Free Area
PRA	Pest Risk Analysis
QFVG	Queensland Fruit and Vegetable Growers
REB	Registered Export Block
SPS	Sanitary and Phytosanitary
TPE	Tray Pack Equivalent
WTO	World Trade Organization

Explanation of Purpose

This document is a draft inventory or consolidation of all the issues Biosecurity Australia has identified in the submissions it received in response to the draft IRA on New Zealand apples. These submissions are all available on the public file (with the exception of two confidential submissions). Arrangements for viewing the public file can be made with Technical and Administrative Services (see below).

Due to the large volume of comments and the extensive interest from stakeholders in having opportunities to contribute to this IRA, Biosecurity Australia decided that the most effective way to address the comments made was to first produce an inventory. The structure of the inventory will provide the framework for Biosecurity Australia's initial response to those comments. As outlined in Plant Biosecurity Policy Memorandum 2001/11 of 24 May 2001, this response will be in the form of a Scientific Review Paper.

The purpose of circulating this draft inventory is to provide those stakeholders with an opportunity to identify any substantive issues raised in their submissions that have not been identified by Biosecurity Australia. This will enable us to finalise the inventory and prepare a Scientific Review Paper.

Please note that in many cases we have transcribed the actual text from submissions. However, in other cases we have paraphrased sections. This has resulted in a blended document that is not totally consistent in style.

If you have any comments on this draft inventory please forward them to:

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Part 1 - General

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Stakeholders' issues on the draft IRA on New Zealand apples

Agricultural chemicals

- ◆ Antibiotics were recommended without examining the health threat to the Australian community and the fact that they were not registered in Australia.
- ◆ New Zealand (NZ) and its growers must be able to prove that any fruit destined for export to Australia is known to be free from antibiotics and antibiotic resistant *Erwinia amylovora*.
- ◆ Are antibiotics used in organic production?
- ◆ No explanation is made of how normal channels of registration can be side-stepped nor how a temporary Maximum Residue Limit (MRL) can be out in place.
- ◆ Because streptomycin is not registered in Australia shouldn't we be demanding zero MRLs for streptomycin on apples coming into Australia.
- ◆ Will the Australian public be made aware of the fact that the fruit from NZ has been treated with an antibiotic?
- ◆ Residual effects of streptomycin stored in honey is a concern.
- ◆ There appears to be a degree of conflict in Biosecurity Australia's (BA's) position on streptomycin with imports of pear from Korea.
- ◆ National Registration Authority (NRA) has advised that there would be great difficulty in registering streptomycin in Australia.
- ◆ The Australian *Food Standards Code* (FSC) currently does not include an MRL for streptomycin in apples.
- ◆ The NZ (*Maximum Residue Limits for Agricultural Compounds*) *Mandatory Food Standard 1999* does not include a specific MRL for streptomycin in apples. Therefore, the default MRL of 0.1 ppm applies.
- ◆ Food imported into Australia from NZ may be produced according to either the Australian *Food Standards Code*, or to the equivalent NZ food legislation.
- ◆ Acetic acid, chlorine and sodium hypochlorite, specifically for bleaching, washing or peeling purposes, may be permitted for use on apples in the *Food Standards Code*.
- ◆ Propionic acid and benzalkonium chloride are not currently permitted for apples in the *Food Standards Code* and must not be present in unprocessed fruits.
- ◆ The *Food Standards Code* includes limits on the amount of copper that apples may contain.

Apple cultivars

- ◆ Government policy, that encouraged the planting of exportable apple varieties that are highly susceptible to fire blight, has increased Australia's vulnerability to this disease.

Apple imports from Japan

- ◆ Have phytosanitary conditions, including operational procedures, been prepared for Japanese Fuji apple and if so were stakeholders consulted?

Stakeholders' issues on the draft IRA on New Zealand apples

AQIS performance

- ◆ “34% of new incursions of pathogens were illegally imported Fruit & Vegetable Trade” (Nairn Report. Chapter 8.)
- ◆ Can you please explain how and why ‘at least 12 exotic diseases and pests have entered in the past two years’ (The Advertiser, November 1995).
- ◆ The number of establishments for plant pathogens is approximately ten times greater than for animal diseases.

BA's responsibilities

- ◆ Why place our livelihood in jeopardy by importing apples from NZ? What is the benefit to the Australian economy as a whole by importing NZ apples?
- ◆ Achieving a country's appropriate level of protection is Biosecurity Australia's role, irrespective of difficulties or costs encountered by other countries.
- ◆ The decision on whether Australia would breach WTO rules is not the responsibility of Biosecurity Australia or AQIS. The Australian Government has set guidelines for its quarantine agency that keeps them consistent with World Trade Organisation (WTO) rules.
- ◆ Any political ban of NZ apples would be a breach of WTO rules and NZ would be entitled to take countervailing action against Australia.
- ◆ It is not Australia's place to quantify the risk, which it deems acceptable to allow entry of NZ apples.
- ◆ There is no proof in the draft IRA that apples will not act as vector to fire blight if the suggested protocol is implemented. The onus of proof that NZ apples are free from fire blight should be on the exporter not the importer.
- ◆ The campaigns against imports into Australia are putting the majority of Australian farmers who depend on exports at a disadvantage.
- ◆ The competitiveness of our global market for horticultural products should be improved through negotiating the relaxation of some of the requirements from other countries.

Benefits to consumers

- ◆ If Australian community tasted a fresh, crisp NZ Pacific Rose or Braeburn, they would realise how much they were cheated.

Citing personal communication

- ◆ It is not clear whether the reference of the New Zealand Ministry of Agriculture and Forestry (MAFNZ) 2000a should be noted as personal correspondence.
- ◆ The listing of personal communications and correspondence in the reference section is not part of current scientific writing.

Compensation

- ◆ The government will have to take responsibility for the destruction of the industry if fire blight is introduced.

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- ◆ It would bring BA into reality if the budget for fire blight eradication are drawn from the same budget for hiring those responsible for the decision and as a result they would automatically lose their jobs.

Conflicting statements

- ◆ No attempt is made to reconcile several conflicting statements.

Current access bid

- ◆ What is different in NZ's 1999 application? What has changed in Australia's stand? Has Australia's ALOP changed between December 1998 and October 2000? How have the gaps in our scientific knowledge changed?
- ◆ Is cold storage data the only data that New Zealand has supplied to support the new application? In comparing the 1998 import risk analysis (IRA) document and the new draft IRA document, it is obvious that there is no new scientific evidence to support a differing opinion to that drawn in 1998.
- ◆ The responsibility of proposing an import system, which guarantee fire blight free apples, should not rest with Australia.

Datasheets

- ◆ The data sheet of fire blight is misleading as it does not indicate that in specific countries in Europe the disease has a restricted distribution.
- ◆ The data sheet for the arthropod pests was drafted by scientists of Landcare Research New Zealand Limited, not by MAFNZ as cited in the draft IRA. The way this datasheet and other relevant datasheets are cited should be changed.

Earlier access requests

- ◆ In the previous IRA (1998) it indicated that the discarded apple could be an inoculum source and transmit the disease to other host plant which are flowering.
- ◆ Wasn't the [unsuccessful] 1989 modified proposal based on a quasi 'area freedom' concept?
- ◆ Re BA's statement that 'New Zealand submitted a new application in January 1999, requesting a review of available risk management options', isn't this what was done in the 1995 application and subsequent review? Didn't AQIS reject the New Zealand proposal because it did not provide an equivalent degree of risk mitigation as Australia requires?

Fire blight; History

- ◆ The analysis of the event of outbreaks of fire blight in the world needs to be done in a transparent manner.
- ◆ Although there is no clear-cut evidence if *Erwinia amylovora* can be transmitted by the infected fruit, there are two cases of a possible pathway of dissemination that involves trade of fruit (apple cases –England, Bartlett pears – Hawaii). Significant expansion in the known distribution of fire blight has occurred where quarantine standards have been relaxed.
- ◆ In NZ the first outbreak of fire blight was in 1920 when it was thought to have entered through infected nursery stock. The disease spread to the South

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island despite quarantine regulations designed to prevent this.

- ◆ The majority of apple trade is between countries that already have the disease and are therefore not likely to report the spread of the disease.
- ◆ The draft IRA has not mentioned the trade of apples from the USA to Australia before the imposition of the general ban on apple imports.
- ◆ Historical evidence suggests that there has been no documented evidence of fire blight spread through international trade of fruit from fire blight host. Despite the movement of fruit is not controlled in Europe, there is no evidence of the disease spread into new areas.
- ◆ As far as I am aware no country that has partial freedom from fire blight imposes any restriction on the movement of fruit within or into its pest free areas.
- ◆ Fire blight has been eradicated in many countries eg. Northern Ireland and the trade of fruit from infested areas in England into non-infested areas in Ireland still continues.
- ◆ NZ scientists have tried to spread the disease using contaminated fruit and they were unable to do this.

Formation of Biosecurity Australia

- ◆ Why did the internal structure of the Department of Agriculture, Fisheries and Forestry – Australia (AFFA) change resulting in the creation of Biosecurity Australia (BA)?

General comments

- ◆ Allowing NZ apple imports would be an absolute disaster for our own fruit growers and we urge BA to reconsider this very important issue. Australia does not need NZ apples, therefore the risk should not be taken.
- ◆ Apple and pear growers have maintained that this is a quarantine issue not a trade issue.
- ◆ The draft IRA does not have public support and goodwill of Australian citizens. BA's actions on this issue are regarded as an act of treason against the future of Australia. Don't put our industry into jeopardy by importing NZ apple and make the right decision. The consequences of an error are so great with this IRA.
- ◆ The draft IRA has failed to consider a significant body of scientific evidence which has not been previously considered by BA.
- ◆ The science and research that has been undertaken is flawed and biased in NZ's favour.
- ◆ The draft IRA is deficient in its scientific data and has frequent use of statements with no reference to any source. There are several fundamental errors in the assessment of species biology. The phytosanitary steps are fundamentally flawed. The recommendations of the draft IRA is totally unacceptable.
- ◆ The claim that this protocol is the most stringent in the world is misleading. There are only a few countries in the world that are still free from fire blight:

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Japan, South Africa and Australia and are the only export target. BA prejudiced the document with the statement that "this protocol is strictest in the world".

- ◆ Claims regarding the levels of risk of pests and pathogens entering and becoming established in Australia are flawed.
- ◆ There should be a penalty on those countries that inflict fire blight on countries free of the disease.
- ◆ The Australian government's continuing ban on imports of NZ apples is unacceptable.
- ◆ Unfortunately, in the zealot drive for free trade, Australian negotiators have made unnecessary concessions without corresponding advantages for our exporters.
- ◆ WTO should initiate a directive to those countries with fire blight to eradicate the disease in their countries before it spreads to other countries such as Australia.
- ◆ A key Centre for quarantine -related risk analysis should be established to enhance Australia's standing in this field.
- ◆ Australian growers will be pleased at the prospect of going into yet another trade season without competition with NZ apples.
- ◆ There appears to be no mention in the IRA of where the distribution of the potential quarantine pests in the pest risk analysis (PRA) area was ascertained.

General comments; Additional research

- ◆ Would Biosecurity Australia be prepared to re-evaluate their position in the light of further information?
- ◆ The knowledge how fire blight spread and what are the pathways of infection should be investigated thoroughly by studying the overseas countries where fire blight has been introduced.
- ◆ Controlled trials should be conducted by AQIS to check whether bacteria can enter Australia on fruit.
- ◆ Research should be carried out from varieties of apple that will be imported from NZ.

Note: More specific comments about additional research are included under individual subject headings.

General editing

- ◆ A standard procedure is to have a manuscript read by at least one other person, who is familiar with the subject and an understanding of orchard procedure, after the author has completed it.
- ◆ Vague and meaningless statements like "the complete pest list was quite large" should be avoided. In this example, the total number of pest should have been stated.
- ◆ There is no explanation of the meaning of 'cfu' [colony forming unit] and it is not in the Glossary of Terms and Abbreviations. The use of jargon is unsatisfactory. Obscure and unfamiliar terms should be clearly defined.

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- ◆ The term “Plant part affected” in the data sheet causes some confusions. As an example a nematode may only infest a root but it could have an affect on the whole plant. I recommend that the term should be changed to plant part infected/infested.
- ◆ The columns of figures should be aligned to the right side not to left side. Percentages are given but no sample sizes are provided.

International relations

- ◆ Damage to relations with sister industry in NZ because Australian industry has to refute impractical management measures proposed by the Quarantine Service.
- ◆ New Zealand politicians and fruit growers seem to lack an of appreciation of the seriousness of the fire blight disease to Australia.

Japanese protocol

- ◆ The Japanese experience is that MAFNZ failed to comply with the requirements in both orchard inspections and fruit inspections.
- ◆ Consultation with Japan and studying their protocols prior to the release of the draft IRA would also be a logical expectation.
- ◆ The Japanese protocol is much stricter.

Lack of co-operation by BA

- ◆ BA responded to the Australian Apple and Pear Growers Association Inc (AAPGA) Freedom of Information request late.

New IRA guidelines

- ◆ A review of the IRA process is supported.
- ◆ This application should be re-assessed using the new guidelines.

NZ inspection service

- ◆ The current record for compliance to international quarantine protocols of MAFNZ is poor. The unreliability of MAFNZ inspection process was demonstrated when 60% of the certified blocks was rejected by Japanese fire blight inspectors.
- ◆ The discoveries of fire blight by the MAFNZ scientist at Melbourne Botanical Garden still left doubt and suspicions to their actions. The protocol should not allow for orchard inspections to be undertaken by MAFNZ personnel.
- ◆ MAFNZ is actively engaged in attempting to have the draft protocol weakened. It is hard to believe that they will be unbiased during the auditing process.

NZ motives

- ◆ It will be in NZ's interest to see fire blight established in Australia.

Other

- ◆ *Erwinia amylovora* can survive in pollen for at least one week and up to

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two weeks in honey at hive temperatures.

- ◆ The introduction of Western flower thrips caused an estimated crop loss of \$2,000,000.
- ◆ What other quarantine issues are involved with importation of NZ apples?

Other access requests

- ◆ This IRA will set a precedent for future IRAs, which would allow imports from countries where pests, which are not present in Australia, occur.
- ◆ If this draft IRA is implemented it will set a precedent for all other industries to be exposed to other quarantine pests.

Other reasons for excluding NZ apples

- ◆ If unresolved issues relating to fire blight was the 'primary' reason for prohibition of NZ apples previously, what were the other reasons?

Possibilities versus probabilities

- ◆ In some instances, AFFA has taken possibilities, as opposed to probabilities, into account in the risk assessment.

Production statistics

- ◆ Production statistics are only from one year, which may have been a very light or a heavy crop.

Quality of BA's work

- ◆ Scientific rigour has not been fully applied.
- ◆ BA must fulfil its obligation of due diligence and due care and ensure that apple industry is not put at any risk.
- ◆ Authors of this draft IRA are uninformed of the seriousness of the nature of fire blight disease and the devastating impact on trade and horticulture industry.
- ◆ Proper due diligence would require the original IRA (1992) with full details to be used as a reference and be included in the document.

Quarantine Act

- ◆ Draft IRA is conducted on the basis of likelihood of harm arising from introduction establishment and spread not on probabilities as defined in the *Quarantine Act 1908*.
- ◆ It would appear that Section 70 of Quarantine Proclamation 1998 and 5D of the *Quarantine Act 1908* requires the risks posed by non-plant pest species and orchard and packinghouse contaminants to be taken into account before a permit can be issued to allow the import of a specified commodity.
- ◆ Interpretation from the *Quarantine Act 1908* section 5 D Level of quarantine risk, which used the word " a disease or pest being introduced, established or spread in Australia...." the word OR indicated that the formula proposed to calculate the probability of entry, establishment and spread in the draft IRA was incorrect. The formula should be: $P(En \text{ or } Es \text{ or } Sp) = P(En) +$

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$P(Es) + P(Sp) - P(En) \times P(Es) - P(Es) \times P(Sp) - P(En) \times P(Sp) - P(En \times Es \times Sp)$.
This would result in the probability of entry, establishment and spread of fire blight to be 'High'. When this probability is multiplied with consequences, which estimated as 'extreme' the result of R would then be extreme.

Regional issues

- ◆ A revision of the inter-state quarantine policies regarding area freedom for fire blight may be required.
- ◆ The IRA has not recognised or explored the regional aspects within Australia. Regional quarantine areas in Australia should be evaluated in an IRA, using IPPC guidelines.
- ◆ The importation of apples from NZ is a national issue for Australia, it is not appropriate that WA should be treated any differently from any other state.
- ◆ The precedent already established by BA in recognising WA as a separate region in respect of its health status for apple scab must be extended to Tasmania in the light of disproportionately high risk associated with the establishment of fire blight.

Scientific basis of draft IRA

- ◆ It seemed that the decision to allow importation of NZ apple has been made before the scientific review and this document is written to confirm that decision. Biosecurity Australia seemed to be intimidated by others and has to recommend the importation of fire blight disease.
- ◆ It is of particular interest to ensure that any decision regarding the issue of fire blight is made based on genuine science and not because of political considerations or trade issues. BA is urged to recommend for the benefit and well being of Australia fruit growing communities and disregard the evident pressure from free trade advocates and the WTO.
- ◆ The turn around of the decision from 1998 by Biosecurity Australia is seen as the linkage to the trade issue.
- ◆ The draft IRA places the apple and pear industry at extreme risk in the interests of Closer Economic Relations (CER) with NZ..
- ◆ The application from NZ being viewed as a trade issue and there is not enough emphasis on quarantine issues and Australia's appropriate level of protection from fire blight.
- ◆ Overuse of personal communication destroyed the claim that the document based on sound science.
- ◆ The media has been totally unreasonable in misleading the public and generating the pressure onto organisation such as BA/AQIS.

Scientific opinions; Conflicts of interest

- ◆ The conclusions of the IRA are flawed because they are only based on informal scientific opinions, which seem to be coming from overseas scientists who may have a conflict of interest.
- ◆ Accepted practice indicated that if an individual has a potential conflict of interest, they are excluded from having any critical input into the process. Two

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of the four scientists whose opinions were used in assessing the level of risk in the IRA have a clear conflict of interest (Professor H.S. Aldwinckle of Cornell University, USA and Dr L. Pusey of USDA).

Selective quotation

- ◆ Concerned that unwarranted conclusions were drawn that are, in many cases, vastly different from those of the original authors.
- ◆ References have been partially quoted or taken out of context. Selective use of answers from responses to the questionnaire. There has been selective use of favourable science and scientific references.

Senate inquiry into salmon products

- ◆ The inquiry was critical of AQIS for relying too much on qualitative risk analysis and recommended that a more quantitative analysis be employed.
- ◆ The senate inquiry into the importation of salmon products raised issues of concern about definitions, consultation and notification procedures and the science and methodology of the IRA.
- ◆ The open publishing of the draft against the initial recommendation by the Senate Rural and transport Committee has complicated the issue.

Status of draft IRA

- ◆ As the document is so fundamentally flawed it should be withdrawn. Conduct a non-routine process with a high level of consultation with the industry.
- ◆ The current draft IRA should be down-graded to the status of a 'discussion paper'.
- ◆ BA should thoroughly review the draft IRA.
- ◆ The new process be based on sound science and appropriate international standards without reference to trade issues.

Supplementary information

- ◆ No reference are given for the “information obtained subsequently”. [Page 42 line 5]

Western Australian issues

- ◆ Biosecurity have failed to make any comment on the unique position of Western Australia which is free from Apple Scab or Codling Moth.
- ◆ Decision to import apples into mainland Australian States will impact upon a later decision about whether to import into WA.
- ◆ When will the assessment of NZ apples to WA be conducted?
- ◆ The IRA does not include all pests under official control or identify them on Table 15.

Part 2 - IRA process

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AAPGA's statistical advice

- ◆ Prior to the release of the draft IRA, AAPGA offered BA the opportunity to consult with their Biometrician. BA refused this offer.

Authors of draft IRA

- ◆ The authors name and qualification were not provided, this is totally unsatisfactory and suggests an attempt to hide a deficient document behind anonymity.
- ◆ Do personnel in Biosecurity Australia have the qualifications or experience to make judgement?
- ◆ Were Australian scientists given the opportunity to contribute to the draft IRA?

BA's lack of co-operation

- ◆ There was an initial lack of openness and timely provision of information.
- ◆ Information requested from BA had taken a significant of time to be delivered. This reflects the lack of co-operation from BA on this important matter.

Conclusion of IRA

- ◆ It is difficult to accept that a person (Director of Animal and Plant Quarantine) closely involved in with the BA could make an impartial decision. The final outcome of the new IRA should be decided upon by an independent arbiter.

Conflicts of interest

- ◆ A clear conflict of interest occurs when a government department is tasked to make independent judgements, which will be used as input to government policy.

Consultation

- ◆ Stakeholders were not consulted during the preparation of the draft IRA, therefore our input into the draft IRA was zero.
- ◆ Various elements in the protocol indicate close collaboration with MAFNZ.
- ◆ This draft IRA document should be published in an appropriate scientific journal and discussed at open forums of interested parties.
- ◆ The process should include a meaningful consultation with the industry. The next round of consultation should be genuine and open.
- ◆ BA should have a decision making process that automatically takes taxpayers' concerns into account rather than ignoring them.
- ◆ As Australian growers why don't we have opportunity to provide input to the consequence of fire blight?

Cost of process

- ◆ It cost the industry a lot of time and effort on this poor set of draft recommendations.

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- ◆ Each period of uncertainty creates delays, which place heavy burdens on the future success of the industry.
- ◆ Industry was denied dollar for dollar funding to provide a response to this draft IRA.

Delays in the IRA process

- ◆ Period of uncertainty causes delays in investment decisions.
- ◆ The time for Australia to make decision on import application has been taken too long, this has been criticised by other countries.

Failure to consider evidence

- ◆ There is a significant body of scientific evidence that has not been considered by Biosecurity Australia.

Industry reference group

- ◆ BA refused to develop issues with the industry reference group.

Initiation of this IRA

- ◆ The IRA process should not have commenced because MAFNZ has not provided sufficient information for a risk analysis process to be initiated.
- ◆ What makes the request from NZ any different to the 120 others also in front of AQIS?

IRA handbook

- ◆ BA failed to adhere to the AQIS IRA handbook. Why does AQIS/Biosecurity Australia change the rules without consulting with stakeholders?
- ◆ BA has produced a range of draft documents, as part of the process, which have not been previously presented to the stakeholders for consideration.
- ◆ Our previous input regarding the IRA process has been ignored.
- ◆ Why is this draft IRA built around a draft ISPM? Isn't it true that a 'draft' document has no legal status? Is the draft ISPM part of the AQIS IRA handbook?

Public comment period

- ◆ The process, which BA used to prepare the draft IRA is very unfair. BA spent 18 months to complete this IRA, while industry has only 60 days to respond to this IRA.

Public file

- ◆ All submissions must be made public.
- ◆ All scientific responses should be on the public record.
- ◆ The public file does not include a draft document dated 19 July 2000 for technical consultation with State and Territory Governments.

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Public meetings

- ◆ The industry meetings after the release of the draft IRA, although we appreciate this initiative from BA, tended to be in light of promotion only.
- ◆ There was a lack of time to answer all questions asked at the industry meetings, which were often confined to less than one hour.

Purpose of an IRA

- ◆ Australia does not need to import apples in any form.
- ◆ BA and their Minister are compelled to defend the draft IRA, rather than heed industry concerns.
- ◆ The draft IRA indicated the lack of knowledge on fire blight and the risk of fire blight entry with mature apple fruit.

Role of environment portfolio

- ◆ Draft IRA raises significant environmental issues and that the proposal should be formally referred to the Environment Minister under the terms of the Act.
- ◆ It is implied in the draft IRA that Environment Australia was consulted and advice was provided on development of policy. BA has suggested in at least one public meeting that Environment Australia has given in-principle support to the measures contained in the draft.

Role of state departments of agriculture

- ◆ The 'confidentiality agreements' between AQIS and representatives of the State Departments were extremely disappointing and locked stakeholders out of parts of the process.

Senate inquiry into apples

- ◆ Further work on the analysis should be held over until the findings of the Senate Inquiry have been made known and accepted by the Government.

Significant variation to process

- ◆ Advise the stakeholders of any significant variation to the process once it is under way.

Stakeholder issues

- ◆ We only became aware of this issue through the public debate and feel aggrieved that we were not routinely consulted as important stakeholders during the process.
- ◆ The Honey bee industry has not been involved with the consultation process at the early stage of this IRA.

Transparency

- ◆ The risk analysis process has not been transparent.
- ◆ Draft IRA prejudicial to final outcome particularly at WTO. Draft IRA should have been kept confidential until this industry was able to have an opportunity for input. A recent Senate Inquiry also recommended against open publicity of the draft IRAs

Stakeholders' issues on the draft IRA on New Zealand apples

Use of routine process

- ◆ BA has failed to adequately consider stakeholders' comments regarding the pathway used to consider this application.
- ◆ The non-routine process should have been followed because of: (a) the seriousness of the risk to industry, (b) the fact that two previous applications had been refused and (c) the number of stakeholders and the need for extensive consultation.
- ◆ The draft IRA hardly fits into the category of 'technically less complex'.
- ◆ The routine approach of the risk analysis excluded major industry input into the research and minimised consultation with the industry.
- ◆ BA is required to withdraw the current draft IRA and institute a new IRA utilising the non- routine pathway.

Part 3 - Methodology

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Stakeholders' issues on the draft IRA on New Zealand apples

ALOP

- ◆ Australia should not have to reduce quarantine standard by being a member of WTO. Do you think any other country would accept the risks to their land should the situation be reversed?
- ◆ AQIS/BA cannot define Australia's ALOP.
- ◆ The appropriate level of protection adopted by Australia has not been defined in precise terms. Industry supports a consultative approach to developing a more definitive ALOP.
- ◆ ALOP set in the draft IRA was not high enough for such an extreme economic consequence disease such as fire blight.
- ◆ Australia's ALOP appears to have been defined quite arbitrarily and unrealistically, and it conveniently supports the conclusion that apple should be permitted.
- ◆ The view that the quarantine risk can be managed, is an acknowledgment that the risk does exist.
- ◆ ALOP is most likely to vary between pest risk areas within Australia and States require jurisdiction to determine the ALOP that meets their particular circumstances.
- ◆ The issue of resources should not be a limit to achieving as close to zero risk as possible.
- ◆ As Australia is still free from many serious plant diseases, we should have the right and responsibility to maintain strict quarantine conditions.
- ◆ Australia's ALOP should be introduced at the risk management stage of the draft IRA, and not during the risk assessment stage.
- ◆ There should be a zero risk policy and no import of NZ apples under the present protocol.

Association with apples

- ◆ The orchard and packinghouse contaminants should be treated as on pathway because the IRA defines pathway as "associated with" rather than "pests of apple".

Australian standard for risk assessment

- ◆ How can a legitimate risk assessment ignore the joint Australian and NZ Standard (AS/NZS 4360:1999)? Any other risk assessment would more closely resemble the informative guidelines provided in this standard.
- ◆ Requirements for consultation with stakeholders with regard to the criteria for characterising risk, as required by AS/NZ 4360, have not been reported in the document.

Definition of 'endangered area'

- ◆ Where are the endangered area(s) in Australia? Why are the endangered areas not listed within the draft IRA?

Stakeholders' issues on the draft IRA on New Zealand apples

Definition of a quarantine pest

- ◆ The draft IRA infers that that pests need to be under official control to meet the definition of a quarantine pest.
- ◆ Australia does not have fire blight, therefore under WTO rule we have the right to ban importation of apples from NZ. Japan already has fire blight, they cannot ban apple from NZ, therefore, they proposed a stringent protocol.

Description of likelihoods

- ◆ Where do the classifications and associated descriptions come from? Are they internationally recognised?
- ◆ Risk assessments are expressed in purely qualitative terms and distinctions between categories cannot be assessed as to acceptability.
- ◆ If the probabilities are 'normally distributed' there should be three quantitative categories below the 'moderate' and three above.
- ◆ The median values and ranges which lie behind qualitative likelihoods become critically important when a risk matrix is to be developed.
- ◆ Why use the terms primary and secondary plant species at risk, if 'primary' and 'secondary' do not indicate the magnitude of possible loss.

Environmental assessment

- ◆ Serious deficiencies in risk assessment methodology have led to an underestimation of the risk to the environment from pests.
- ◆ Poor consideration was given to Australia's environment including our flora.

Estimation of consequences

- ◆ There is no attempt made to quantify economic consequences and no consideration of environmental or social consequences in the risk estimation methodology.
- ◆ Within the area of economic consequence the classification of negligible and very low, and even low, are irrelevant and inappropriate to use. Any new pest or disease, as covered by this IRA will have an affect at 'national level' no matter where the pest/disease might be found in Australia.
- ◆ An arbitrary scale has been used for economic consequences in the risk estimation matrix.
- ◆ A different table of economic consequences must be developed for each IRA product as it will change depending on the rate of development of that particular industry.
- ◆ AFFA has introduced into pest risk assessment concepts that go beyond the internationally accepted guidelines for assessing the economic impact of a pest (eg. 'recognition', 'concern', 'values', 'wellbeing').

General

- ◆ The methodology used by BA has not been published or made available for public comments or review. A thorough review, revision and re-evaluation of

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methodology should be undertaken.

- ◆ The risk assessment ratings are related to each other through a complex and undisclosed assignment of numerical values that are then used in arithmetic operations.
- ◆ In the methodology used an underestimation of any likelihood would tend to disproportionately lower the final estimation of risk. Under the rules used, one low rating dominates the overall result.
- ◆ The matrix contained in the draft IRA overestimates risk unless it is used for combining only two probabilities.
- ◆ Each matrix is based on discrete steps of what are admitted to be continuous quantities which causes discrepancies. The errors introduced by this model should be admitted and some flexibility in interpretation of results should be allowed based on sound scientific rationale.
- ◆ Draft IRA draws on four differing methodologies for determining the probability of entry, establishment and spread.
- ◆ The assessment does not clearly focus on the risk as being in the trade in apple fruit.
- ◆ The approach to risk estimation is severely flawed and it is not appropriate to attempt to rework the economic consequences or unrestricted risk.
- ◆ [Application of] the risk analysis methodology has not been transparent or consistent.
- ◆ BA methodology of subjective assessment of each probability event is sufficiently robust and consistent with the approach used by WTO members.

Independence of events

- ◆ In splitting the probability of entry into effectively eight components, BA stated that the IPPC definition of entry is preserved. However, the model is not robust enough to withstand the mathematical outcome of this splitting. This is because the overall probability of an event is effectively determined by the lowest probability of any sub-component.
- ◆ Assumptions are made about the independence of various steps in the 'importation scenario' which has led to a questionable methodology for combining likelihoods.
- ◆ Arbitrary distinctions have been made between entry, establishment, spread and consequences which resulted in double counting of establishment and spread and artificially reduced the assessed risk.
- ◆ The rationale behind the method of combining risks is not transparent.
- ◆ The probability of importation and distribution should not be combined together. They each have a separate score eg. probability of fire blight infested/infected fruit in fruit ready for shipment in NZ –high; probability of failure to detect fire blight at the border – high; therefore distribution of fire blight around Australia is high.
- ◆ For fire blight 'entry' has been broken down to two components - 'importation' and 'distribution' but for all other pests 'entry' is treated a single

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issue.

International standards

- ◆ The factors considered to determine entry pathway were inconsistent with ISPM No. 2 (Pest Risk Analysis). In establishing criteria for economic impact, AFFA has failed to follow international guidelines.
- ◆ According ISPM No. 10, the place of production or production site should be sufficiently distant from active symptoms to enable the block to remain free over a season. The draft IRA does not allow for this.
- ◆ Before pest free production site status be granted, the growers must demonstrate a 'pest free' status, not just a symptomless status.
- ◆ The draft IRA does not deal in detail with the IPPC and the ISPM '*The principles of plant quarantine as related to international trade*'. These principles (including acceptance of risk, equivalence, non-discrimination and transparency) underpin the conduct of pest risk analysis and have been largely ignored.
- ◆ BA does not require that production areas in Japan, Korea or China be surveyed for two seasons and found free from fire blight before permitting the export of host fruit to Australia.
- ◆ The draft IRA has taken area freedom to extremes. The nature of spread of fire blight can occur long distance by insects and bees the proposed block freedom can not be justified.
- ◆ The 'quotes' from Standards (eg. ISPM 4) used are not complete and are misleading.
- ◆ It is inappropriate to use draft standards (eg 'quarantine pests' and 'systems approach') which are deficient in a number of areas.
- ◆ Australia's standard for area freedom in other import protocols is large scale "Area Freedom" eg. Korea – 15 km, Japan –disease free islands only.
- ◆ What are the internationally known management systems that are to be used in maintaining pest freedom?
- ◆ If Australia contributes to the development of ISPMs why aren't stakeholders offered opportunity to comment on the draft ISPMs prior to their final approval?

Iso-risk curve

- ◆ The iso-risk curve (figure 5) conveys absolutely no meaningful information.
- ◆ Iso-risk curve has the undesirable effect of reducing, to a smaller extent, the positive effect of an extreme consequence.
- ◆ The iso-risk curve should be 'shifted to the left' by approximately one order of magnitude for fine-tuning judgements.

Method of estimation

- ◆ Were the ratings qualitative, quantitative or personal judgements?
- ◆ Can you provide level of fire blight incidence (in percentage of infection)

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that were called severe or negligible level in NZ?

- ◆ How did you arrive at the probability of entry for fire blight and other quarantine pests and diseases.

Organic production

- ◆ The organic products are likely to have a much higher incidence of fire blight within the orchard and on fruit.
- ◆ What additional and/or new requirements will be placed on organic Registered Export Blocks to meet Australia's ALOP.
- ◆ What protocols does Biosecurity Australia recommend for organic packing facilities?
- ◆ Is chlorine certified as an approved chemical within an organic packing facility?

Pathways

- ◆ The draft IRA assumes that the only pathway by which bacteria contained within the calyx of an apple might spread to hosts within Australia is from the disposal of a waste core, but there are several other more likely pathways for potential transmission of fire blight.
- ◆ Seed is part of the infested fruit and should be identified at Step 2. Technically it is not a waste.
- ◆ Contaminated fruit packages are a potential pathway for entry of fire blight to Australia.
- ◆ Not enough weight has been put on the various methods of distribution. AQIS had not previously examined the detailed issues that arise in relation to the establishment of fire blight from the disposal of waste apples.
- ◆ The BA model defines distribution as up to 'transfer of pests from the environment to a susceptible host in the endangered area' yet it has omitted to consider identity, distribution or indeed any aspect of susceptible hosts.
- ◆ Is dried bacterial ooze another pathway for fire blight to enter Australia?
- ◆ AFFA has not considered smuggling as a pathway and the likelihood of introducing fire blight through this pathway is estimated to be higher than one introduction in 663 years.
- ◆ Draft IRA assumes simultaneous heavy infestation throughout all production areas, a scenario that is highly improbable.

Probability theory

- ◆ It has not been shown how probability theory can apply to the qualitative expressions in the draft IRA.
- ◆ No references or reasons are given for a high or extreme probability being close to one or a negligible probability being very close to zero.
- ◆ The mechanism by which Risk (R) is obtained from PxC in Table 9 is not transparent.

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Qualitative verses quantitative

- ◆ The risk assessment is subjective and not quantitative. The Nairn report recommended the quantitative approach.
- ◆ The draft IRA uses a very subjective method of assessment, therefore producing a subjective result.
- ◆ Lack of any mathematical model, data or any other evidence linking theoretical calculations to the biological complexity and variability of the systems, questions the practical validity.
- ◆ Quantitative basis for the risk estimation matrix remains a mystery.
- ◆ A quantitative approach must be developed in consultation with industry stakeholders and qualified statisticians.

Risk assessment matrix

- ◆ The Risk Estimation Matrix is highly theoretical and unproven. The source of the qualitative matrix for combining descriptive likelihoods (table 8) is not cited and such matrices are not described in the AQIS Handbook.
- ◆ A quantitative analysis of the underlying values in the risk estimation matrix used shows that the matrix is flawed. A thorough assessment of the risk matrix taking into account the inputs of independent experts in the field of risk management is required.
- ◆ The matrices combining the probabilities of independent events are methodologically and statistically flawed.

Terminology

- ◆ BA used 'importation' and 'distribution' pathways in considering Entry Potential whereas AQIS Handbook talks of Introduction Potential.
- ◆ What is the formal definition of entry?
- ◆ Isn't it true though that 'likelihood', 'consequence' and 'risk' are interrelated and linked to each other? As a result you cannot treat them in isolation of each other.

Uncertainty

- ◆ Uncertainty should be explicitly addressed so that decision-makers and the public can recognise that some hazards may not be well enough understood to be simply classified as, for example, 'very low'.
- ◆ The draft IRA suggested that there is a substantial gap in knowledge of the fire blight bacterium. It is dangerous to base the protocol on an incomplete knowledge on fire blight.
- ◆ The uncertainties involved in probability estimates, when combined to yield cumulative probabilities, gives rise to a cumulative multiplication of those uncertainties.

Use of case studies

- ◆ There are deficiencies trying to develop risk analyses and phytosanitary measures on the basis of published literature alone.
- ◆ The draft IRA cannot be completed without such case studies of other areas

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where the pest in question occurs.

Use of caution

- ◆ In the absence of relevant information a precautionary approach should be applied to decision making.
- ◆ The absence of data or knowledge on the possible impact of pests and diseases on native flora and fauna makes it essential that further evaluation be undertaken.
- ◆ The draft IRA relies on 'suggestions' and what may be considered 'plausible' rather than what has been proven through research.
- ◆ There are many deficiencies in the knowledge of pests and diseases but decisions were made. The use of 'precautionary principle' has enabled many countries to protect their industries where science does not give a complete protection.
- ◆ Where research does not exist the final draft IRA should be delayed until it can be commissioned, carried out and published in a peer-reviewed journal.

Volume and time factors

- ◆ Volume of trade and length of time over which trade may occur have not been taken into account in the draft IRA.
- ◆ The worse case scenario indicated that between 276-570 million infested apple fruits would enter Australia each year.
- ◆ There is an implied one year time scale used for considering the likelihood of early establishment and spread but no time scale for economic consideration.
- ◆ End use patterns and product distribution patterns have not been addressed in the assessment of risk.

Part 4 - Risk assessment

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Fire blight; Consequences

- ◆ A thorough assessment is required of the possible economic impact of fire blight including not only the pear and apple industry but also the impact on the recreational and amenity areas of horticulture and the native plants, societal values or social wellbeing etc.
- ◆ AFFA has not clearly assessed the effect of fire blight on the economic stability, or specified the meaning of 'significance at the national level'.
- ◆ BA must give due consideration to the developing organic industry, advantages that the current 'clean green' environment has for the further expansion of the organic industry and economic consequence to that industry from an outbreak of fire blight or any other pest/disease coming from NZ.
- ◆ What other control do organic growers have to deal with an outbreak of fire blight within their orchard?
- ◆ Who would develop resistant varieties if fire blight become established in Australia?
- ◆ The economic consequence of fire blight on Australia should be ranked 'moderate' rather than 'extreme'. At no point does the draft IRA provide a rationale for why such an extreme scenario should be regarded as likely. It is more appropriate to consider the most likely scenario, rather than the worst case.
- ◆ The risk of streptomycin to human health and environment would be so extreme that it would not be a practical option for management of fire blight outbreaks in Australia.
- ◆ Australia's reputation for quality produce and freedom from disease will be lost if apples are imported from NZ and fire blight disease is transferred to Australian fruit and horticulture. As we already struggle to maintain our global market, the introduction of fire blight will add a significant cost to the phytosanitary arrangement. This could end up destroying the industry.
- ◆ Australia produces many export apple variety-rootstock combinations which are extremely susceptible to fire blight. The climate in various parts of Australia is more suitable to fire blight than NZ.
- ◆ Streptomycin resistant strains of the pathogen already exist in NZ.

Fire blight; Risk level

- ◆ Fire blight disease is far too great a risk for Australia, the risk must be prevented completely.
- ◆ If the probability of entry of fire blight were determine as low, the overall restricted risk would then become moderate, that would be above the Australian ALOP.
- ◆ There is a negligible probability of the unrestricted importation of apple fruit resulting in the entry, establishment and spread of fire blight in Australia and no specific phytosanitary measures are necessary to manage that level of risk.
- ◆ The draft IRA estimated that the outbreak of fire blight could occur as one in 1.6 –160 years and as one in 114 years. The risk of the outbreak of disease

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that could wipe out the pome fruit industry within one to three generations is unacceptable.

- ◆ Although BA stated that there is a lack of good scientific evidence that fire blight can be transmitted through apple fruit, it still concluded that there is a low risk of fire blight establishing in Australia via infested fruit.
- ◆ Considering that BA estimated that the chance of an insect spreading the disease from an infected apple core to a suitable host plant was 0.01-0.1%, this estimation equates to a very high probability of establishment because of the potential large volume of import.
- ◆ Due to the uncertainty and the lack of this information, if the probability of entry for fire blight moves from negligible to low, the restricted risk for fire blight changes to low, which is above the ALOP.

Fire blight; Probability of Introduction

- ◆ The conclusion of a low probability of introduction is scientifically flawed, demonstrably contradictory and should be rejected.
- ◆ Data used to estimate the probability of entry should take into account the environmental conditions under which the data was obtained.
- ◆ There does not appear to be a rational relationship between the scientific evidence and the determined risk when addressing the probability of entry.

Importation

- ◆ Unable to understand why BA concludes that the probability of entry should be ranked as low rather than very low or negligible. Disagreed with the statement that 'unrestricted likelihood that imported apple fruit would be either infested or infected with *Erwinia amylovora* was considered high....', given that published evidence indicated that the detection of bacteria was very low or may not be sufficient to cause further re-infection.
- ◆ Importation potential is overestimation of probability due to the misinterpretation of the literature, and failure by BA to consistently apply its methodology each step along the importation pathway. An objective review of data strongly suggest calyx infestation is a rare phenomenon. The importation potential should be rated as 'very low' rather than 'high'.
- ◆ 'It is considered likely that the importation of apples from NZ would lead to the arrival in Australia of infected fruit'. This should be the first likelihood used in the matrix.

Distribution

- ◆ There needs to be an assessment of the effect of waste disposal patterns and to incorporate this into the risk analysis.
- ◆ The draft IRA lacks adequate information on import volumes, end use patterns and product distribution patterns. All of which are essential to make informed decisions. In fact, BA has shown a total lack of understanding of the marketing of apples/pears within Australia.
- ◆ There is a lack of information on which to base a judgement either way that *Erwinia amylovora* would be transferred to an appropriate site on a susceptible

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host. We believe the probability of entry is at least high if not extreme.

- ◆ The draft IRA has not demonstrated with sufficient confidence that the transfer of epiphytic *Erwinia amylovora* to the PRA area by quarantine, non-quarantine pest species and non-pest species present on the pathway is an event that would almost certainly not occur.
- ◆ The published literature (or lack of it) and expert opinion supports a conclusion that there is negligible risk of transfer of bacteria from an imported apple to a receptive host.
- ◆ The IRA has not given sufficient significance to the widespread nature of potential fire blight hosts in its assessment of the potential for distribution. The rating of the distribution potential phase and thus probability of entry should be increased from 'low' to 'moderate'.
- ◆ Dumping of fruit with no commercial value could easily occur close to orchards, greatly increasing the risk of spread of fire blight. Some supermarkets have a 'nursery section' where young plants are sold next to fruit. These could easily become infected/infested by cross contamination.
- ◆ 'Infested' apple waste in contrast to endophytically 'infected' apple waste will not support the multiplication of *Erwinia amylovora* bacteria is questioned.
- ◆ Many studies have shown that whilst the risk of transmission of *Erwinia amylovora* via mature fruit is low there can be significant transmission of the disease.
- ◆ If a bacterium gets into the country it will always find a means of finding a host and producing an infection.

Fire blight; Models

- ◆ Although some progress has been made in the modelling of epidemics and has been applied to control methods, the application of these models to the Australian production system should be viewed with caution.
- ◆ It is undesirable to place undue reliability on the probabilities of entry, establishment and spread of *Erwinia amylovora* based on published predictive models.
- ◆ The experience of the outbreak in Melbourne would suggest that the disease may not be as severe as predicted by Australian scientists.
- ◆ Fruit from any orchards where the Firework predictive model is used and results in the recommendation of using antibiotic spray should not be allowed to export.

Fire blight; Establishment

- ◆ Most of the Australian population, who will consume imported apples, live along the coastline where environmental conditions are likely to assist establishment of the disease.
- ◆ No assessment is made on the effect of different climates on the establishment and spread of the disease.
- ◆ In estimating the risk of establishment it is necessary to first determine whether the establishment is likely to result from a single or multiple

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introduction.

- ◆ What qualitative rating was given to each factor to achieve a high probability for establishment? We believe that 'moderate' is a more accurate assessment of likelihood of establishment.
- ◆ The probability of establishment should not be high but instead should be negligible considering that the only bacterial population level likely to enter Australia is $x < 50$ cfu (colony forming unit), and that this epiphytic population is not likely to survive exposure.

Fire blight; *Monte Carlo simulation*

- ◆ Data to input into Monte Carlo simulation are not available for the majority of steps involved in imported apples from NZ.

Fire blight; *Quantitative risk assessment*

- ◆ The mathematics behind the prediction for how long the infection is likely to occur within Australia was not given, therefore it cannot be checked. The statement that 'AQIS estimates that the mechanical transfer of *Erwinia amylovora* from an apple core to a suitable host has a probability between 1 in 1000 and 1 in 10,000, ...', this estimation is not acceptable. Does this mean that if 10,000 apples are imported from infested blocks, we will get fire blight? Actually the number of apples to be imported will be many times more than 10,000 fruit.

Fire blight; *Consequences to honey-bee industry*

- ◆ The impact of fire blight on the honey-bee industry has not been taken into account in the draft IRA.
- ◆ Surveys for managed bee hives and feral bees will be required within a 3 km radius of infected premises should a fire blight outbreak occur.

Fire blight; *Spread*

- ◆ Probabilities of establishment and spread should be changed to 'extreme' considering the favourable environment conditions, availability of susceptible host and flowering habits.
- ◆ BA has made no attempt to estimate the rate of spread of fire blight from either single or multiple introductions. There seems to be a view that a single introduction of fire blight will result in the disease instantaneously spreading to all pome fruit growing areas of Australia.
- ◆ Fire blight appears to have been present in the Royal Melbourne Botanic Gardens for a number of years without spreading.
- ◆ In assessing the probability of spread, BA has not taken into account the activities that would be taken to prevent spread after the disease was first detected.
- ◆ The draft IRA did not mention filaments as a mechanism of spread of fire blight and it should be further investigated.
- ◆ BA confused the issue by estimating that the probability of spread is high from contaminated fruit.

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- Fire blight;**
A 'second line of defence'
- ◆ There are no protocols or activities that reduce risk of establishment and/or spread to create a 'second line of defence'.
- Fire blight;**
Streptomycin registration
- ◆ Streptomycin is not registered for use here in Australia and will never be registered for use in other than an emergency eradication program for fire blight.
- Fire blight;**
Incidence in New Zealand
- ◆ Can you provide level of fire blight incidence (in percentage of infection) that were called severe or negligible levels in NZ?
- Fire blight;**
Biofilms and dried bacterial ooze
- ◆ No consideration has been given to 'biofilms' of bacteria, how they survive and how they might be controlled.
 - ◆ BA has failed to consider the issue of 'dried ooze' and/or 'latent epiphytic' colonies of fire blight and the possibility of spreading the disease.
- Fire blight;**
Latent infection
- ◆ Fire blight bacteria can survive in a tree in a latent form for an indeterminate time.
- Fire blight;**
Competent epiphyte
- ◆ Steiner (1998) has observed that *Erwinia amylovora* remained viable for periods of up to 10 months on wood and 4 months on plastic. Full consideration of the characteristics of *Erwinia amylovora* and its ability to survive in a range of environments is required.
- Fire blight;**
Dormancy
- ◆ There is insufficient scientific evidence on dormancy and disease outbreaks.
- Fire blight;**
Cross contamination
- ◆ BA has not assessed the risk of cross contamination or provided justification for disinfestation of fruit and sanitation of the packing line. There is no literature demonstrating that cross contamination occurs.
- Fire blight;**
Infestation of immature fruit
- ◆ Infestation of immature apples is irrelevant to the importation of mature, healthy fruit since immature apples are not shipped.
- Fire blight;**
Fruit infestation
- ◆ Although infestation of mature fruit is known to occur, this is much less common than suggested in the draft IRA.
 - ◆ An objective review of the data cited in the draft IRA strongly suggested that calyx infestation is a rare phenomenon. A more accurate assessment is that infestation of immature apple fruit has a very low probability.

Stakeholders' issues on the draft IRA on New Zealand apples

- ◆ It is obvious that fire blight can be present in the calyx. Moreover, the bacterium can survive on plastic for four months and on timber for 10 months. Therefore apple fruit can harbour the disease.
- ◆ The research work carried out by the NZ indicated that only 3% apple are found positive, this was suggested by McManus and Jones (1996), who found an infection of 27%, that the NZ's work may be an underestimate of the level of *Erwinia amylovora* infection [sic] on fruit.

Fire blight; **Fruit infection**

- ◆ Anecdotal evidence of 'ooze' from fire blight being observed on mature fruit out of long term controlled atmosphere storage in USA.
- ◆ Van der Zwet (1990) also found that apple harvested from apparently healthy trees developed rot during storage and found to be infected by *Erwinia amylovora*. This confirms that apple fruit can carry the bacteria even harvested from the healthy looking tree.
- ◆ Possibility exists for endophytic infection of fruit to occur from trees which do not show any symptoms of fire blight.
- ◆ If symptomless fruit is harvested from orchards where fire blight occurs, or where fire blight symptoms are present in nearby orchards, then it cannot be assumed that none of these will be infested or infected.
- ◆ Core of fruit taken from 2 m from infected shoots may be infected with *Erwinia amylovora*.
- ◆ If bacteria could move into growing shoot tips there is no reason why they cannot move into developing fruit.
- ◆ No discussion as to how blighted orchards nearby could be accounted for when assessing the likelihood of orchard infection.
- ◆ Endophytically infected mature, symptomless fruit, at most, is a rare event or non-existent to date according to Aldwinckle.
- ◆ There are no literature reports to support the multiplication of *Erwinia amylovora* in discarded apple tissues.
- ◆ As stated in the draft IRA, endophytic infections are associated with the development of disease symptoms. As a result, the infected fruit will be rejected during the commercialisation process.

Fire blight; **Infected trash**

- ◆ BA needs to undertake an assessment of the risk of trash being infected with *Erwinia amylovora*.

Fire blight; **Infective dose**

- ◆ A small amount of inoculum on and/or in apples should not be taken as unimportant as there are many areas in Australia that have ideal environmental conditions favouring fire blight.
- ◆ Bacterial multiplication is time, host and climate dependent, and a low dose such as that likely to be present on an infested apple fruit ($<10^2$ cfu) is very unlikely to be sufficient to result in infection of a host.

Stakeholders' issues on the draft IRA on New Zealand apples

- Fire blight;**
Infection and infestation
- ◆ There is a failure to differentiate between the risk presented by infection and infestation.
- Fire blight;**
Orchard freedom
- ◆ There are no orchards free of fire blight in NZ, although at specific time, there may be orchards free from symptoms of fire blight. Van der Zwet studied in orchards free of fire blight and this affects the interpretation of these results.
- Fire blight;**
Other hosts
- ◆ There are claims that plums, strawberries, blackberries, raspberries and cherries are infected by fire blight.
- Fire blight;**
Spread by seed
- ◆ The analysis has ignored the possibility of apple seed being part of the pathway for fire blight.
- Fire blight;**
Apple varieties
- ◆ Van der Zwet studied delicious apples only. The apple fruits from NZ are unlikely to be varieties of Delicious apples.
- Fire blight;**
Vectors of
- ◆ Van der Zwet (1979) lists 77 genera of Arthropods that have been associated with the transmission of fire blight. Of these 27 genera are present in Australia. The transfer of fire blight from the pathway to the PRA area by quarantine, non-quarantine pest species and non-pest species present on the pathway appears not to have been considered.
 - ◆ Relationship between apple leaf curling midge and spread of fire blight has been clearly demonstrated.
 - ◆ Many flies have a 'regurgitating and sponging' mode of feeding and carry large amounts of bacteria in their alimentary canal, which makes them ideal vectors for spread of the pathogen. Queensland fruit flies, *Bactrocera tryonii* are dedicated bacterial feeders. They contaminate fruit and leaf surfaces and also inject bacteria into interior of fruit along with eggs when ovipositing.
 - ◆ Honey bees are a major vector, especially at flowering time when trees are most vulnerable to *Erwinia amylovora*.
 - ◆ Because of the lack of vectors or means of transfer, the risk posed by imported apple fruit is negligible.
 - ◆ Packing line provides another vector for the infection of fruit with pest organisms.
- Fire blight;**
UV radiation
- ◆ Page 77 line 22 '*Erwinia amylovora* is sensitive to ultraviolet light....' No references are given to support this statement and the experts consulted have given diverse opinions about it.

Stakeholders' issues on the draft IRA on New Zealand apples

Fire blight; *Viable but non-culturable*

- ◆ Consideration has not been given to viable but non-culturable *Erwinia amylovora* within the draft IRA.
- ◆ Pulawska et al. (1997) evaluated the ability of pesticides (commonly applied to apples) to inhibit the PCR reaction for *Erwinia amylovora*.

Fire blight; *Laboratory testing*

- ◆ The protocols make no allowance for monitoring of inoculum levels in symptomless orchards or in the fruit exported to Australia.
- ◆ Method of testing of endophytically infected fruit is not specified.
- ◆ There is serious concern that testing, without stringent protocols to eliminate infested fruit and dead fire blight colonies, would result in an unnecessary suspension of trade.
- ◆ Concerned over the proper supervision of laboratory tests.

Fire blight; *Experts opinions*

- ◆ Establishing risk of infection is almost entirely dependent upon unpublished expert opinion given in response to a biased questionnaire issued by BA. BA does not explain how the experts were selected for the questionnaire. Scientific questioning and opinions should have been requested in writing and formally documented. Verbal questioning can be loaded to gain desired answers.
- ◆ Who are these international experts? And how many were consulted? How were these experts chosen? Are there any other world experts on this subject whose opinions has not been obtained and not published or disclosed here?
- ◆ It appears that not all the experts are asked the same questions. It seemed that if the answers received did not support the low risk, then they were sent a set of refined question that led them to answer in a way that suited the outcomes BA wished to conclude.
- ◆ BA/AQIS was dishonest in claiming that it has consulted 15 experts when in fact 8 did not reply. Did BA follow up and find out why half of the scientists asked did not respond?
- ◆ It is generally agreed that published information is more credible and open to scrutiny than personal communication. For the scientific opinion to be worthwhile it should have three principles: impartiality, openness and defensibility.
- ◆ The names, qualifications and comments of the fire blight experts from whom AQIS sought the opinion should be given in the appendix.
- ◆ JP Paulin, when asked to describe the risk, said that the risk should not be taken by a country free of the disease.
- ◆ Comments of one scientist have been misinterpreted and therefore the accuracy of views expressed by other scientists as personal communication is questionable.
- ◆ BA should consult with Professor Ted de Jong from the USA, a leading world expert in growing pears and other fruit, who is very knowledgeable on fire blight.
- ◆ Both the probability and consequences of entry, establishment and spread have been over-estimated due to misinterpretation of published literature and

Stakeholders' issues on the draft IRA on New Zealand apples

selective citation of expert opinion.

Fire blight; Misquotes

- ◆ BA incorrectly reports that 'bacterial numbers exceed 10^3 cfu/fruit in the calyxes of fruit harvested from blight free orchards'. The level of infestation was <50 cfu.
- ◆ Hale *et al.* (1987) recovered *Erwinia amylovora* from 3% of the calyxes of mature apples from severely blighted orchard by isolation (not PCR).
- ◆ In the datasheet BA reports an 8% recovery, however this is from all parts of fruit. It is important that the affected part is clearly identified.
- ◆ It is stated that Covey (1975) recovered *Erwinia amylovora* from mature apple fruit. This is incorrect.
- ◆ The reference to Sholbeger *et al.* (1988) recovery of fire blight from 100% of the mature fruit is mistaken, Sholbeger *et al.* (1988) recovered the bacteria from the leaves not from mature fruit.
- ◆ AFFA has perpetuated a typographical error in Clark *et al.* (1993). The 87% reported is actually 8.7%.

Fire blight; Equivalence

- ◆ AFFA should apply equivalent measures for this pest on apples as it does on other crops from New Zealand.

Pathogens; European canker; Consequences

- ◆ Economically, *Nectria galligena* is of equal importance to fire blight.
- ◆ Low is an over-estimate of risk of *N. galligena*. Economic impact is moderate and the likelihood of entry is very low.
- ◆ The argument that *Nectria galligena* is unlikely to be spread to pome fruit trees or forest trees from core infections or storage rots is unconvincing. Long distance dispersal of conidia and ascospores has been demonstrated. The probability of entry should be 'high' (or at least 'moderate') and consequently overall unrestricted risk should be 'high'.

Pathogens; Data sheets

- ◆ No data sheet or any information has been presented in the IRA to demonstrate to stakeholders that *P. maculans* and *P. cava* have no *potential* economic importance and therefore do not meet this element of a quarantine pest.
- ◆ Data sheets should be compiled for each pathogen identified up to the Genus (Table 15) to show they have no potential economic significance and thus are not regarded as quarantine pests.

Arthropods; Leaf rollers

- ◆ Larvae readily invade calycine sinuses on apples and can be difficult to detect by inspection of fruits. Establishment of these leaf rollers in Australian orchards will have high rather than moderate economic consequences because they not only affect a wide range of crops but also will adversely affect IPM management programs.

Stakeholders' issues on the draft IRA on New Zealand apples

- ◆ *Pygotis plagiatana*: The conclusion reached for this species is erroneous and requires consideration in more detail, in particular in relation to the impact it may have on Australian flora.

Arthropods; *Apple blister mite*

- ◆ Agreement with BA about the pest having a low overall probability of entry. However a conclusion that the pest will be of high, not moderate, economic significance if it were to establish in Australia. This is because it is likely to be difficult to control and may disrupt IPM programs in orchards.

Arthropods; *Apple leaf-curling midge, consequences*

- ◆ Apple leaf curling midge is the major determinant of organo-phosphate pesticide usage in NZ. There is also evidence that apple leaf curling midge has developed chemical resistance in New Zealand and IPM programs would be disrupted if the pest were to establish in Australia.
- ◆ It has been described by Gouk and Boyd (1999) as a vector for the spread of fire blight.
- ◆ If apple leaf curling midges were a significant pathway for the distribution (entry 2) or spread of fire blight bacteria, the economic consequences of its establishment in Australia would rise from high to extreme.
- ◆ Economic consequence should be extreme (fire blight should be beyond extreme).

Arthropods; *Apple leaf-curling midge; likelihood of entry and establishment*

- ◆ It is unclear why, given the advice provided in the draft IRA, the probability of entry and subsequent establishment were both considered moderate. It seems more appropriate that the probability is high.
- ◆ The United States' Department of Agriculture (USDA) has intercepted apple leaf-curling midge in NZ apple consignments exported to the USA.

Arthropods; *Mealybugs*

- ◆ The estimation for probability of entry given for *Pseudococcidae* spp. does not seem to be supported by the text given, from the text it seems appropriate that the estimated probability of entry of this pest should be high.
- ◆ BA should remove any reference to *Pseudococcidae* spp. from the draft IRA, as these records almost certainly refer to one of the mealybugs species found on apple fruit (all of which are present in Australia).

Arthropods; *NZ flower thrips*

- ◆ The probability of establishment be classified as high, economic consequence high and unrestricted risk estimate high.
- ◆ The risk of entry under the proposed BA protocol would be moderate since thrips eggs and insects are very small and difficult to detect in apple calyces.

Stakeholders' issues on the draft IRA on New Zealand apples

- Arthropods;**
Carpophilus
species
- ◆ Page 60 line 4 ‘...long distance spread is likely to be low....’ Line 7 ‘...some species are strong fliers (one species has been reported to fly 3 km). These statements are contradictory and no attempt is made to reconcile them. Furthermore, the 3 km would encompass a number of properties in most fruit growing districts.
- Arthropods;**
Noctuid moth
- ◆ The economic consequences of *Graphania mutans* to the wheat industry should be thoroughly assessed.
- Arthropods;**
Black lyre moth
- ◆ Page 62 line 7, 8, ‘...it would be likely to have effects on native plants if it is established in Australia as it is polyphagous’. The species, genera or family of native plants likely to be affected should be stated.
- Arthropods;**
Oecophorid
moth
- ◆ The probability of entry should be classified as moderate-high, not low. The economic consequences should be rated high and unrestricted risk estimate also be high.
- General issues;**
Requirements
for a valid risk
assessment
- ◆ It is not acceptable for BA to rely on personal comments of scientists that cannot be scrutinised.
 - ◆ There is significant lack of consensus between scientists on the likelihood of fire blight becoming established in Australia.
 - ◆ Substantial amount of scientific evidence in the references in the draft IRA that disputes the conclusions arrived at by BA.
 - ◆ The proposed protocol has not been tested, Australia should not be used as a test case to prove or disprove this untested protocol.
 - ◆ No attempt is made to combine the losses of all pests.
 - ◆ Relevant ecological and environmental conditions should be taken into consideration when assessing risk.
 - ◆ BA needs to recognise that absence of evidence is not evidence of absence.
 - ◆ The draft IRA appears to place the industry in a position of guilty until proven innocent, which leaves the industry to prove that there is a possibility of fire blight entering our country.
- General issues;**
Assessing data
- ◆ The gaps in science for fire blight are too great to make decision to allow importation of NZ apples.
 - ◆ The draft IRA has cited too many lighter weight references. Of the 284 citations there are only 120 from refereed journals and only approximately 58 of these related to fire blight.
 - ◆ The draft IRA cited many publications, which are considered outdated because they are published before modern technology was established to facilitate the detection of fire blight.
 - ◆ Most of these scientific publications were based on red delicious which is the resistant variety to fire blight.

Stakeholders' issues on the draft IRA on New Zealand apples

- ◆ Data from trials in which only one strain of *Erwinia amylovora* has been utilised should be treated with caution.
- ◆ “Roberts *et al.* (1989): Mature healthy apple fruit do not appear to be an economically suitable substrate for the survival of epiphytic *Erwinia amylovora*...” How can this quote be included in the draft IRA as it is shown to contradict other publications?
- ◆ Evidence in Hale *et al.* (1996) paper on the inoculum dose required for infection of blossoms should be treated with caution.
- ◆ Clark *et al.* (1993) comment that the lack of blossom spread of fire blight may have been due to the size of the sample and a season not conducive to natural spread of the disease.
- ◆ If there have been many experiments that do not show a result, the experiments that have shown a result should not be disregarded.
- ◆ BA has failed to take into account the lack of research on some issues because of the fact that those countries already having fire blight will not invest time and money on research on the infection/infestation of apples.

General issues; Insufficient science

- ◆ The draft IRA lacks scientific analysis to support that the risk over time is indeed negligible.
- ◆ There is no unanimous support from the scientists.
- ◆ There is not enough scientific work to demonstrate that fire blight cannot spread from fruit to a suitable host.

General issues; Additional pests

- ◆ A range of arthropod pests, predators, parasites and plant pathogens associated with NZ apples were not assessed in the IRA.

General issues; Pests, general consequences

- ◆ There is the risk of importing other pests, which are not present in Australia and could result in having to use more pesticides to control any new pests entering the country. In turn this may affect our environment and our market access status.

General issues; Taxonomic resolution

- ◆ What does distinct taxonomic entity mean?
- ◆ BA has failed to adequately isolate the particular species of *Carpophilus*, *Pseudococcidae* and *Tortricinae* and as a result the unrestricted risk for these pests must be extreme.
- ◆ It appears that some pathogens, were not retained on the list as ‘potential quarantine pests’ for further consideration, despite ‘doubt or contention regarding the distribution, occurrence or species level identity of a given pest’.

Stakeholders' issues on the draft IRA on New Zealand apples

- General issues;**
Pests, general risk
- ◆ The unrestricted risks for all pests are much higher than the BA's assessments.
- General issues;**
Supplementary information
- ◆ “The ‘step-level likelihoods’ were based on the conclusions of the 1998 IRA (AQIS, 1998b) but supplemented with information obtained subsequently”
What additional information has been ‘obtained subsequently’?
- General issues;**
Assessment of managed risks
- ◆ Draft IRA lacks a risk analysis of managed risks.
- General issues;**
Consequences; General
- ◆ Australian apple growers are working hard to develop a sustainable orchard and would be devastated to see new pests and diseases invade our country.
 - ◆ Changes in policy at Federal or State level that reduces company's supply options will have a direct impact on the financial stability of the company, it's employment levels and the multiplier effect it has within the local, state and national economy.
- General issues;**
Australian exports
- ◆ The various species of fruit fly can cause much more damage to horticulture internationally than fire blight does, yet Australian horticulturists expect to continue to export their products all over the world.
 - ◆ It is inappropriate for the inspection to be 600 pieces of fruit when inspection of Australian product leaving the country is far greater.
- General issues;**
Consistency
- ◆ The proposed protocol is contradictory when one considers: the prohibition of the importation of any plant material including seed (fruit) that are hosts of Dutch elm disease; recent decisions by the Australian government to ban the importation of meat-containing products from Europe because of the BSE risk; the risk of the introduction of fire blight through illegal means due to increasing trade and travel between the two countries; and the importation conditions for vegetative material of apple and pear for propagation.
- General issues;**
Detail of analysis
- ◆ The PRA on insect pests has not been carried out with sufficient rigour. The rationale used in the draft IRA for fire blight has not been used for the other pests analysed.
 - ◆ Why weren't significant investigations undertaken for all of the other quarantine pests such as the contaminants, and their potential to be carriers of fire blight [bacteria]?

Part 5 - Risk management

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Stakeholders' issues on the draft IRA on New Zealand apples

Fire blight; Area freedom

- ◆ Apples for export must come only from fire blight free areas with a buffer zone of 15 km (area freedom).
- ◆ The use of block freedom as the basis of the draft protocols is outside standard international protocols. Where the pest or disease is considered to be one that cannot be killed, the international standard is to adopt a policy of 'area freedom'.
- ◆ Area freedom from fire blight should be required as a minimum or at very least – property freedom; block freedom is not acceptable.
- ◆ Three risk mitigation strategies based on high, medium or low risk districts, rated annually, according to prevalence of fire blight should be considered.

Fire blight; Block freedom

- ◆ The concept of block freedom is unreliable as it uses freedom from disease symptoms as the indicator of freedom from disease.
- ◆ Why is Biosecurity Australia recommending 'block freedom for New Zealand while adopting area freedom for Japan'?
- ◆ Consulting ISPM No. 10, it is very clear that the draft IRA falls considerably short of international guidelines on the establishment of pest free production sites.
- ◆ The draft IRA did not establish an acceptable delimited boundary considering the biology of *Erwinia amylovora* as stated in the ISPM No. 4.
- ◆ Area freedom- page 104 the draft IRA stated that 'Disinfestation and area freedom would require considerable resources to implement and are therefore considered more trade restrictive' (than block freedom). However, is block freedom adequate to ensure that disease such as fire blight does not enter Australia?
- ◆ A number of registered export blocks in New Zealand established for export apple to Japan has been withdrawn. This indicated that the establishment of Pest Free Areas (PFA) is not possible and that a Pest Free Production Site would be very difficult to maintain.
- ◆ NZ cannot meet area freedom requirement as fire blight is endemic there.

Fire blight; Bee hive management

- ◆ REBs should be in quarantined bee-free areas.

Fire blight; Detection zone

- ◆ The draft IRA did not give the definition of 'detection zone'.
- ◆ The research of Clark *et al.* (1993) would also support the introduction of 500m buffer zone.
- ◆ 50 m buffer zone is totally inadequate, unacceptable and does not conform to relevant International Standards for Phytosanitary Measures (ISPMs).
- ◆ 50 m detection zone is ineffective in stopping the spread of bacteria by

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insects, rain, wind, birds and aerial strands. The 500 m required by Japan has been shown to be an insufficient safeguard (12% registered areas rejected for fire blight in 1996/97).

- ◆ A significant number of registered export blocks for Japan were found to be infected with fire blight even in cooler low risk areas. This indicated that even 500 m detection zone required by the Japanese is not effective.
- ◆ 15 km zone was required when fire blight was found in the Royal Botanic Gardens in Melbourne. Australia's standard for a disease similar to fire blight in other import protocols is area freedom (Korea-15 km, Japan-disease free island).
- ◆ Independent sources indicated that a buffer zone of 5-10 km was required or implied a larger distance.
- ◆ According to American knowledge an area of 8 km radius should be quarantined, all host plants of the disease should be removed and root grubbed and burnt on site, Quarantine area should not be planted with host plants.
- ◆ In Italy, they have 1 km detection zones and in case fire blight is detected within these areas, the nurseries in the areas will not be approved.
- ◆ A 200 m buffer zone would at least help to minimise the risk factor posed by fire blight.
- ◆ Biosecurity Australia should reconsider the size of the proposed disease detection zone to a minimum of 100 m.
- ◆ A 25 m zone of susceptible apple trees immediately around the REB should be left untreated (sentinel zone) with antibiotics or other suppressants at least during the blossom period.
- ◆ If there is no host surrounding the REBs, then from where are the bacteria to be splashed?
- ◆ Irrespective of the width of the buffer zone, alternative hosts should be absent from within 250 m of the REB.
- ◆ A 500 m buffer zone with no susceptible hosts should be the minimum requirement.
- ◆ Biosecurity Australia moves away from International Standard by allowing host within the small detection zone. Buffering and detection of infection are two separate functions, which tend to be mutually exclusive.
- ◆ The detection zones are unlikely to be of any value as an 'early detection mechanism' because fire blight does not infect the edges of an orchard before any other part of the orchard.
- ◆ Biosecurity Australia stated that 'The wider detection zone would be of disadvantage in that it would be difficult to monitor ...' Is Biosecurity Australia responsible for making New Zealand inspector's job easier?
- ◆ No data have been presented by Biosecurity Australia to link the requirement for a 50 m detection zone with epiphytic infestation of the calyx of mature fruit.
- ◆ Given that *Erwinia amylovora* has not been recovered from fruit located

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more than 15 cm from infection sites, we cannot establish any rational link between the establishment of a buffer zone and the assessed risk posed by either fruit infections or epiphytic infestation of the calyx of mature fruit. A distance no greater than 10 m would ensure an area is free of fire blight.

- ◆ The requirement should include thorough inspections including laboratory testing as a requirement for export accreditation.
- ◆ There is no provision for the checking of host plants within the 50 m detection zone or disqualification if fire blight is found on these plants.
- ◆ Why would we accept 50 m? If accepted, this would result in industry (presently only Tasmania) being unable to export to Japan, as the protocol would be breached indirectly.

Fire blight; Orchard surveys

- ◆ What are the elements of the system that will address the risk of infection/infestation from long distance spread?
- ◆ Biosecurity Australia needs to consider revisions to survey timing.
- ◆ A further inspection prior to or at leaf fall is considered essential.
- ◆ Shouldn't at least one orchard inspection take place in the dormant period, when it is much easier to see the wood of the tree and therefore spot the symptoms?
- ◆ A canker can be as small as 2 mm – how can this be found in the orchard?
- ◆ A representative sample of all fire blight host plants should be included in district surveys.
- ◆ AAPGA submitted a report on the number of Designated Export Areas (DEA) in New Zealand registered for export to Japan and subsequently withdrawn from the program. The rejections were based on the visible symptom of fire blight found in the DEA and the detection zone. This indicates the difficulty of maintaining an orchard block free of fire blight in New Zealand.
- ◆ All publications indicated that the absence of fire blight symptoms in an orchard is not evidence of the absence of fire blight. Yet, the draft IRA proposed visual orchard inspection. What research has been done to quantify the effectiveness of this method?
- ◆ Fire blight sometimes cannot be seen by the naked eyes, therefore, the orchard inspection may not be effective.
- ◆ Bacteria can survive for more than two years as dried ooze and it may lead to infestation and infection of apples without visual symptoms on which the phytosanitary inspections will be relied upon.
- ◆ If cankers can remain viable for 2-4 years as said in the draft IRA, why shouldn't the length of time free of fire blight be four years, not two?
- ◆ Symptoms are not necessary for bacteria to be present in the detection zones and REBs.
- ◆ A more intense scrutiny, than would be afforded by 'walk past' inspection,

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proposed in the IRA, of 10% of trees is required.

- ◆ The proposed protocol does not take into account the history of fire blight outbreaks in the REBs.
- ◆ Systems should be established that increases the intensity of surveys in the warmer area eg. Hawkes Bay in NZ.
- ◆ As fire blight has no cure, once established the disease is there forever. How can the same trees which have shown symptoms of the disease be allowed to be included in export blocks just because no symptoms have been detected in inspections over two growing seasons?
- ◆ Twig cankers are inactive by the harvest period (Dueck, 1974), so an inspection at harvest is not relevant.
- ◆ van der Zwet *et al.* (1990) found that from apples harvested within 120 cm of a blighted shoot or in close proximity to cankers, up to 15% of blighted apples occurred following storage ranging from 37 to 121 days. Similar consequences (although at a lower incidence) could be expected if symptoms are missed at inspections. This possibility increases the likelihood of fire blight arriving in Australia as infestation and infection.
- ◆ Laboratory based disease diagnosis will be necessary to identify the cause of many suspect disease symptoms.
- ◆ What is the 'appropriate laboratory test' to confirm absence of *Erwinia amylovora* (draft IRA pg 117)? Please detail.
- ◆ Why are additional inspections for orchards affected by hail or severe storms to be considered only after pre-harvest? Why not after any and all hail or other severe storm?
- ◆ If REB has been affected by hail then a further inspection should be undertaken.
- ◆ Based on the biology of fire blight one year of pest free status and only one inspection prior to harvest should be sufficient to address the risk.
- ◆ 'A detection zone would lower the risks of wind or water borne inoculum drops that could cause secondary spread of the disease, which is of particular concern after blossoming and before fruit formation'. Inspection at harvest would not, then, contribute to risk reduction.
- ◆ Australia did not conduct two years of surveillance (at appropriate times for detection) in order to declare freedom from fire blight following the confirmation of *Erwinia amylovora* in the Royal Botanic Gardens, Melbourne.
- ◆ If fire blight symptoms are found, the status of REB should be removed.
- ◆ Inspection procedures for small or symptomless infestations are relatively ineffective in reducing the likelihood of entry of *Erwinia amylovora*.
- ◆ Is secondary blossom important? Can it extend the possibility of infection of an orchard?
- ◆ Is the variation in full bloom across varieties going to be taken into consideration?

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Fire blight; REB management

- ◆ All handling equipment used to pick the fruit should be steam cleaned and sterilised between uses. Biosecurity Australia needs to develop an orchard equipment disinfection program.
- ◆ Apples or alternate hosts which have been managed in such a way as to mask visual symptoms of fire blight by use of antibiotics, copper sprays, pruning etc. do not comply with ISPM 10, 2.1.1.
- ◆ It can be argued that removal of symptomatic, infected material is helping to decrease the risk by reducing inoculum levels but the infestation/infection of fruit may have already occurred.
- ◆ The question still remains as to whether all bacteria will be removed when cankers and blighted shoots are pruned out.
- ◆ Branches showing the disease can be removed before the orchard is registered for export, despite scientific evidence that the disease remains in the rest of the tree. Biosecurity Australia needs to specify restrictions on orchard pruning relative to the requested official inspection program.
- ◆ Pruned storm damage limbs in the REB and detection zone should be left adjacent to the tree until after inspection is completed.
- ◆ Cutting out blighted tissues during the season can induce formation of overwintering cankers that provide inoculum for the next season.
- ◆ It must be mandatory for MAFNZ to provide the list of REBs prior to the commencement of any growing season.
- ◆ The inspection dates can be anticipated, therefore visual symptoms can be removed beforehand. Supervision of orchard production by MAFNZ will not be sufficient to overcome the problem of masking of symptoms.
- ◆ The draft IRA does not have controls set in place for the movement of 'pest free propagating material' or require growers to notify the National Plant Protection Organisation (NPPO) of any suspected or actual occurrence of fire blight.
- ◆ The fire blight economic consequence is so extreme that the presence of fire blight in one sample should be sufficient to exclude the REB from further supply of export fruit.
- ◆ Multiple apiaries should be required in the REB as part of a protocol to limit the transfer of *Erwinia amylovora* by bees.
- ◆ Will all growers supply aerial photographs of their properties with the boundaries of the REBs appropriately marked? If not, how will AQIS know what the boundaries are?
- ◆ Burning fire blight material has been known in the USA to reinfest because the bacteria were carried in the smoke air stream.

Fire blight; Harvest management

- ◆ There appears to be no practical method of ensuring that fruit from a detection zone and any other part of the orchard are excluded from export.
- ◆ There are concerns with practical application of audit of REBs e.g.

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segregation of fruit at row ends.

- ◆ What policing of labelling bins 'For Australia' would be enforced as well as keeping them segregated from ineligible bins?

Fire blight; Harvest bins

- ◆ Harvesting bins must be subjected to either steam cleaning or hot high-pressure washing before they are treated by dipping in chlorine solution.
- ◆ The strength of the chlorine solution should be increased from 100 ppm to 200 ppm for at least one minute.
- ◆ Chlorine dip should be the only option, since its effectiveness is independent of the orientation of the bin.
- ◆ All bins should be treated before use and between uses.
- ◆ Wooden harvesting bins should not be permitted.
- ◆ No evidence is presented for the efficacy of disinfection measures (use of chlorine, steam or high-pressure water) to eradicate *Erwinia amylovora* in fruit bins.
- ◆ 'For Australia' bins should be stored in an area physically separated from that used for the storage of other bins.
- ◆ The imposition of phytosanitary measures must be based on the probability of risk, not the mere possibility of risk. Therefore, Biosecurity Australia should explain the need for disinfection of harvesting bins with data.

Fire blight; Packing line requirements

- ◆ Details need to be provided on the efficacy of sanitation of the packing line.
- ◆ How is packing line sanitation to be done? What procedure must be followed? The sanitation of the packing sheds cannot be achieved due to the nature of the equipment being used.
- ◆ Packing house equipment should be cleaned to remove organic material (bio-film) before using an alternative disinfectant such as chlorine dioxide.
- ◆ What is the process to be implemented to ensure that the packing house is 'hygienically maintained'?
- ◆ There is no mention in this requirement of culling the damaged or significantly blemished fruit.
- ◆ The protocol did not mention barriers in packing sheds.
- ◆ Disinfection of packing line should be eliminated in the absence of any documented evidence.

Fire blight; Fruit inspection

- ◆ Inspection of 600 fruit per one 'lot' harvested for one day does not seem to be enough.
- ◆ A rejection of one 'lot' from a REB requires suspension of that REB for at least two years, until fire blight free status is re-established.
- ◆ Detection of fire blight in packed fruit would appear to be impossible.

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- ◆ It is not clear whether any tests for calyx infestations would be made or whether any monitoring for the disease would be undertaken in Australia.
- ◆ Phytosanitary inspection does not decrease the risk of endophytically infected fruit being exported and is an impediment to trade.
- ◆ Fruit harbouring endophytic infection but not showing visible symptoms would not be detected in the packinghouse is based only on a bold assertion.
- ◆ Why cut open only the ones showing damage, rot or punctures and not the total 600 fruit?
- ◆ What will happen if the fruit have been rejected during the inspection?
- ◆ The inspection of waste should be included in the protocol. If fire blight is identified in the culled fruit, then the consignment should be disqualified as should the growers and region.

Fire blight; *Calyx* *infestation*

- ◆ Due to the inefficiency of chlorine dip treatment, it is essential for Biosecurity Australia to re-examine the disinfestation aspect of the IRA with a view to introducing one or more phytosanitary measures specifically aimed at control of calyx infestation.

Fire blight; *Chlorine dip*

- ◆ It is difficult to maintain the concentration of chlorine because of the effect of organic matter contaminating the dip. How often would the concentration and pH of chlorine solution be checked?
- ◆ Chlorine dipping will not kill the bacteria on the fruit surface and will not reach the bacteria at the base of the peduncle or in the calyx-end.
- ◆ Chlorine cannot kill *Erwinia amylovora* as it forms a polysaccharide which protects it from the chemical.
- ◆ More effective post-harvest treatments than chlorine are available and should be tested before the final decision. Efficacy of chlorine treatment could be enhanced by the use of surfactants in the dump tank.
- ◆ Fruit from REBs will be transported in open bins by tractor through detection area trees and other blocks, risking contamination.
- ◆ The recommendation strength of the chlorine should be 200 ppm instead of 100 ppm.
- ◆ Draft IRA stated that chlorine dip is not effective, fumigation and cold treatments are therefore recommended as recognised and more effective methods of disinfestation.
- ◆ 100 ppm chlorine and pH of 5.0 to 6.5 would virtually assure the total elimination of all external contamination of fire blight bacteria.
- ◆ There is no justification for requiring disinfestation of fruit harvested from disease-free orchards.
- ◆ The question of whether or not a disinfectant dip has access to the calyx-end of every fruit is not significant, because of the effect of the other management strategies.

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- ◆ What if, through poorly managed wash-water, new bacterial cells can be forced into the calyx-end of the fruit?

Fire blight; *Disinfestation* *alternatives -* *Water*

- ◆ Biosecurity Australia should review the efficacy of water as a measure to reduce epiphytic populations of bacteria on the surface of fruit.

Fire blight; *Disinfestation* *alternatives -* *Cold*

- ◆ The effect of cold storage on the viability of *Erwinia amylovora* has been offered as a method of reducing the spread of the bacteria. The results are inconclusive and in fact the research suggests cool temperatures may be important in the pathogenicity of the disease.

Fire blight; *Disinfestation* *alternatives -* *Irradiation*

- ◆ Currently irradiation of apples is not permitted in either Australia or New Zealand.
- ◆ The mandatory use of irradiation would be a more effective form of disinfestation for apples from New Zealand.
- ◆ Use of radiation sensitising chemicals to improve the effectiveness of disinfestation of calyx-end populations of *Erwinia amylovora* should be examined.

Fire blight; *Fruit injury*

- ◆ The protocol does not mention the allowance of stem punctures in fruit being exported to Australia.

Fire blight; *Trash*

- ◆ Experience in the packing house indicates that it is not possible to eliminate all trash from the packed fruit, especially in late maturing varieties. The elimination of trash should occur at orchard level and not at the shed or packing house.
- ◆ With regard to freedom from trash, what is practically free? Why not totally free?
- ◆ The proposed inspection regime is insufficient to ensure that trash is not in cartons.
- ◆ International accepted method of inspection for trash is to take samples throughout the day, thus ensuring that it is a representative overview of the total day's packing.
- ◆ Where are the results of the trials conducted by New Zealand with a prototype of a low pressure, high volume fruit washer that indicate this fruit washer has any value in removing/reducing fire blight on fruit?
- ◆ Who is going to monitor and ensure that fruit entering the packing line in the packing house is free from plant trash?

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Fire blight; On-arrival inspection

- ◆ Visual inspection on arrival is not adequate. Will fruit be pathologically tested for fire blight?
- ◆ Is other fruit from New Zealand tested for bacteria and/or fungi?
- ◆ Who is going to conduct the on-arrival inspection? Do these people have the qualifications to detect infected apples?
- ◆ Biosecurity Australia needs to establish a system approach for response to the detection of a critical quarantine disease during the inspection process.
- ◆ The proposed on-arrival inspection measure has no justification. On-arrival inspections for endophytic *Erwinia amylovora* does not add to phytosanitary security and is potentially very trade restrictive.

Fire blight; Cross contamination or substitution

- ◆ No detail is provided as to the strategy to prevent cross contamination or substitution with apples outside the program.
- ◆ Will inspectors ensure that the fruit from each orchard is segregated at the packing shed? If so, how will this be done?

Fire blight; General management issues

- ◆ Support the view that '*with current state of knowledge and the unresolved uncertainty about the possibility of apple fruit acting as a vector for fire blight, any risk management measures should be based on arrangements that provide to a high degree of certainty that imported apples are not carrying fire blight pathogen Erwinia amylovora*'. However, the measures proposed in the draft IRA are insufficient to achieve this.
- ◆ It requires only one of the risk parameters used in the fire blight analysis to be raised one level, i.e. negligible to low, and this would deliver a restricted risk outcome above the Australian ALOP.
- ◆ Each step in the management protocol depended on the other steps to uphold the integrity of the entire protocol. If one step is flawed, then the entire protocol is useless.
- ◆ As New Zealand has no apple growing districts which are free from fire blight, when there are no symptoms in the orchards, it means that *Erwinia amylovora* is waiting for a suitable climate condition before the symptoms can be shown? The proposed systems approach to manage the risk did not address this concern.
- ◆ A candidate block should be no less than 500 m from the boundary of a surveyed district; as justification, this distance is supported by New Zealand data.
- ◆ Adopt a block registration scheme similar to that required by Japan for apple fruit from New Zealand and USA.
- ◆ Biosecurity Australia protocol provides for a very low, but not a negligible, probability of entry which would mean that the required ALOP of very low is not met.
- ◆ Overall, there should be published expert opinion, with a majority agreeing

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on the conclusion. At present there is not unanimous support as we are aware that most state departmental plant pathologists disagree with IRA protocol.

- ◆ None of the strategies will eliminate endophytic infections.
- ◆ IFP is only a management tool that does not stop outbreaks of fire blight nor does it control the severity of an outbreak.
- ◆ Inspections should be carried out by AQIS both in New Zealand and Australia for a minimum period of five years.
- ◆ It is important that some mechanism is put in place to effectively detect infected fruit.
- ◆ The alternative risk management option of 'Limit Distribution at the Destination' must be considered in a revised IRA.
- ◆ The Japanese protocol should be adopted.
- ◆ Overestimation of unrestricted risk estimate for fire blight resulted in the adoption of inappropriately stringent measures to prevent its entry.
- ◆ Questions whether any mitigation measures are justified since Roberts *et al.* risk analysis identified that the minimal risk is reduced even more if there are minimal safeguards.
- ◆ Several of the measures identified are not based on the risk assessment and should be reviewed (eg. six inspections, a 50 m detection zone, segregation, disinfestation of fruit by chlorine dipping, disinfestation of packing houses, 1 m separation of product within cold stores).
- ◆ Even if a minute amount of the bacteria were to come in on apples, which is very unlikely, the chance of that particular apple being discarded in a way that would transfer the disease to an Australian orchard is negligible. There are very strong grounds for relaxing the protocols considerably.
- ◆ What are the New Zealand quality standards and quality control audits for fire blight?

Fire blight; Prohibition

- ◆ The need to make the protocol the 'least trade restrictive' has overridden all other concerns and has resulted in BA taking the 'soft option' rather than 'erring on the side of caution'.
- ◆ In the absence of measures to reduce the risk to an acceptable level, the final option may be to prohibit importation.

European canker; General

- ◆ The probability of entry of *Nectria galligena* is rated as low (not, 'very low') and suggests that additional measures are needed to achieve a very low ALOP.
- ◆ No further 'lots' should be accepted from REBs for that season if *Nectria galligena* is detected.
- ◆ After a thorough consultation of the reference (Swinburne, 1975) it can not be concluded that 'infection of apple fruit by *Nectria galligena* occurs only if active cankers are present on the same tree.'

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- ◆ Biosecurity Australia has used published opinion in the case of fire blight but not in the case of European canker.

European canker; Orchard inspection

- ◆ The buffer zone for European canker should be 125 m or greater.
- ◆ The first inspection for European canker should be performed prior to bud burst (mid to late winter) rather than at bloom, to allow easy observation of cankers.
- ◆ Orchard inspection and pre-export fruit inspection will not pick up latent infection of *Nectria galligena*.
- ◆ Crotch cankers are not easily detected and will be difficult to remove.
- ◆ REB freedom does not necessarily mean there will be no infection of fruit by European canker as ascospores and conidia can be carried up to 125 m.

European canker; Latent infection

- ◆ Latent infection of *Nectria galligena* will not be detected at either the phytosanitary or on-arrival inspections.
- ◆ No measures have been put in place to assess whether there is any latent infection caused by *Nectria galligena* and to what extent.
- ◆ There is bound to be latent infection of *Nectria galligena* as only one inspection in a season will not be adequate to pick out diseased plants/fruit.
- ◆ The only way to reduce the incidence of storage infection by latent inoculum of *Nectria galligena* in the fruit is an application of postharvest fungicidal dips.

European canker; Incidence

- ◆ If the incidence of the pathogen increases will Biosecurity Australia review the measures for *Nectria galligena*?

Arthropods; Apple blister mite

- ◆ Is 40x magnification sufficient to identify eggs, nymphal stages and/or adults? Are inspectors qualified? When will sampling be conducted, 20, 10, 5 or 1 day/s before harvest?
- ◆ The only way to guarantee the reduction of the risk of apple blister mite from 'low' to 'very low' is to fumigate with methyl bromide, or an equivalent treatment as the mites have proven notoriously difficult to detect.

Arthropods; Apple leaf-curling midge

- ◆ California requires apple fruit from New Zealand to be fumigated with methyl bromide and it would be appropriate to explore some form of post harvest treatment for this pest.
- ◆ Reduction of the entry of apple leaf-curling midge from 'moderate' to 'very low' on the basis of survey is unconvincing, given the pest is very hard to see.
- ◆ The requirement for enhanced hand-lens inspection for *Dasineura mali* is not justified because the life stage that may occur on fruit is easily recognisable without magnification.

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Arthropods; Leafrollers

- ◆ Orchard survey conducted to maximise the chances of detecting leafrollers and their damage should be a mandatory component of the risk management strategy for leafrollers. This could be combined with either strategy 2 or 3.
- ◆ The quarantinable tortricids are similar in behaviour and activity to light brown apple moth (*Epiphyas postvittana*). Further, it is understood that the USA and Japan currently require fumigation and/or cold treatment to Probit 9 for this pest.

Arthropods; Mealybugs

- ◆ All *Pseudococcidae* spp. on apple fruit from New Zealand are non-quarantine pests and therefore no management procedures are required.

Arthropods; New Zealand flower thrips

- ◆ Additional risk mitigation steps for New Zealand flower thrips are necessary to reduce the moderate entry risk to low.

Arthropods; Hitchhikers

- ◆ Some pests on the list, although they are not on the fruit pathway, are real threats to the environment e.g. scarab beetle. How do you propose to deal with them?

Pests; General

- ◆ There are insufficient details offered to allow a proper examination of the effectiveness of the proposed strategies.
- ◆ The restricted risk estimate is much higher than very low.
- ◆ The use of pre-harvest orchard surveys, enhanced on-arrival inspection and phytosanitary inspection must be used as a total program. The use of two out of three does not offer the necessary appropriate level of protection.
- ◆ The proposed control methods for fire blight would not prevent other insects and fungi from persisting in the calyx end of apple fruit.
- ◆ There is not enough emphasis on the management of other quarantine pests.
- ◆ What are the management procedures for these pests that have been operated for many years? Are these procedures harmonised with those proposed in this protocol?
- ◆ What rate of interceptions of these pests has been recorded by Biosecurity Australia from other imported commodities? Are the operational procedures for these pests currently acceptable?
- ◆ *Cnephasia jactana*, *Carpophilus* spp., *Graphania mutans*, *Graphania* sp., *Pyrgotis plagiata* and *Stathmopoda horticola* all need to be treated in the same manner as the other insects and mites.
- ◆ Details of pre-harvest orchard survey and enhanced on-arrival inspection is lacking and need to be part of the IRA.

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- ◆ Will trapping be established in the REBs during the season to determine the level of infestation?
- ◆ Propose that certification strategies be altered to include: either (a) orchard (REB) inspection and, either phytosanitary inspection or on-arrival inspection; or (b) disinfestation (fumigation) and, either phytosanitary inspection or on arrival inspection.
- ◆ Due to the overestimation of risk, the measures which Biosecurity Australia proposes to implement would achieve a higher ALOP against risks associated with apple imports from New Zealand than that achieved in other comparable situations (for a number of arthropod pests, Australia requires only a phytosanitary inspection of hosts such as stone fruit and kiwifruit, but is proposing more rigorous inspection or orchard survey for the same pests when they occur on apple).
- ◆ AQIS inspections have found some of the pests on other fruit coming from New Zealand including *Cnephasis jactatana*, *Ctenopseustis herana*, *C. obliquana* and *Planotortrix excessana* on apricots, avocados, cherries, nectarines and peaches, *Thrips obscuratus* on many commodities and *Eriophyes mali* on cherries.

Pests; *Orchard inspections*

- ◆ Pre-harvest orchard survey should be a mandatory component of the risk management for all arthropod quarantine pests.
- ◆ What level of quarantine pests found, would lead to the elimination of the REB?
- ◆ Will the fire blight inspectors look for other pests at the same time?
- ◆ 'A statistically based sample of trees' should be defined.
- ◆ How will AQIS know that an REB has been rejected?

Pests; *Fumigation*

- ◆ Apples should require a post-harvest treatment in addition to inspection requirements against potential insect vectors of fire blight that shelter in the calyx cavity.
- ◆ Japan requires fumigation to prevent the introduction of quarantine insect pests on New Zealand apples.
- ◆ There are important questions of efficacy of fumigation for different species of pests of quarantine concern that have to be addressed, especially mites and leafrollers.

Pests; *Fruit inspection*

- ◆ It could be questionable if the suggested inspection of 600 fruit would be consistently and effectively undertaken as this would take in excess of 6 hours.
- ◆ Is a hand lens of sufficient magnification to find the insects, larvae, pupae and eggs of apple leaf-curling midge?
- ◆ Inspection methods being proposed as part of the protocol have not been adequately detailed.

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- ◆ Inspection of apples can only occur with laboratory testing for insects, fungi, mites and bacteria.
- ◆ Phytosanitary inspection is a mandatory requirement yet is offered as an alternative; why?
- ◆ It should be mandatory for inspectors to cut a proportion of suspect fruit (eg. 10%) and microscopically examine calyces and peduncles and record the results of these inspections.
- ◆ The 600 fruit samples must be highly representative of 'lots' and all fruit in each sample should be microscopically examined.

Pests; On-arrival inspection

- ◆ What happens to a rejected consignment? Will it be destroyed? Will it be returned to New Zealand? Will it be repacked?
- ◆ The use of microscopes for direct inspection of every fruit in a standard sample is a significant change to current AQIS operational practice.
- ◆ Biosecurity Australia needs to establish a response plan in the event of the detection of a critical quarantine pest during the inspection process.

Post harvest requirements; Packaging requirements

- ◆ Only plastic bins be used for fruit to be exported to Australia.
- ◆ The risks involved with exports in bins or open tray packs are unacceptable.
- ◆ The draft IRA did not mention about how to protect the packing material from infection by fire blight.

Post harvest requirements; Storage requirements

- ◆ A one metre buffer between fruit destined for Australia and other fruit is not sufficient to provide isolation from insects in cool store or CA store.
- ◆ Fruit stored in open bulk bins are likely to be cross contaminated by insects. Therefore, bins must be kept in separate cool rooms or CA stores.
- ◆ The cartons must not only be separated by at least one metre, but all openings in the cartons should be covered with gauze to prevent insect penetration.
- ◆ The mode of cross contamination between boxes of packed fruit, supposed to occur, is not established and is hard to envisage. Therefore, segregation should either be eliminated as a measure or justified in the final IRA.

Post harvest requirements; Definition of a pallet

- ◆ What do you define as a pallet?

Post harvest requirements; Sampling

- ◆ Advice from Bio mathematicians is that inspection of 600 fruit per 'lot' is totally inadequate. Particularly trash would need more intensive rates.
- ◆ Is there evidence in the form of refereed research results to confirm that the

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proposed 600 fruit sample, irrespective of 'lot' size, provides a 95% level of confidence that the 'lot' is free of a quarantine pest.

- ◆ The critical introduction potential method ($V_{\text{critical}} = 5.0 \times 10^{-11}$) is a more sensitive sampling method.
- ◆ The 600 fruit sample is not representative for the whole consignment. The consignment could be 500,000 fruit. The inspection rate is less than 0.12%.
- ◆ The proposed inspection level of 600 pieces of fruit is poorly detailed. Is it 6 or 7 boxes, or one piece of fruit from each of 600 boxes?
- ◆ Lot size should be limited to 600 Tray Pack Equivalents per 'lot'.
- ◆ Inspection levels of 600 fruit per 'lot' are well below comparable protocols e.g. New Zealand/Japan (5%), Australia/USA (2.95%) for apples. International standards for inspection of apple and pear set by USA ranged from 2-6%.
- ◆ The validity of this sample size is critically dependent on 'lot' homogeneity. Lot homogeneity is critically dependent on the REB inspections. For the 'lot' to be homogeneous, it should only consist of fruit taken from one orchard and therefore any REB should consist of only one orchard.
- ◆ Random or sequential inspection should take place pre-export, as on-arrival it is impractical as only rear of containers is accessible.
- ◆ The 'lot' [inspection unit] should be defined as a carton not the fruit.
- ◆ The sample size should be increased to 3%.
- ◆ On arrival inspection should be 600 fruit per individual 'lot' within each consignment where a consignment is made up of a number of 'lots' (ie not 600 fruit per consignment).
- ◆ Audit sampling in Australia would be necessary.

Post harvest requirements; Fruit security; Post packing

- ◆ Sequential numbering of cartons is required to maintain the integrity of a 'lot'.
- ◆ Security of fruit in storage is insufficient and if the audit process fails, the entire 'lot' or 'lots' must be disqualified from the export program.
- ◆ This is a normal storage procedure and would have no measurable effect in reducing risk.

Post harvest requirements; Pre-clearance

- ◆ Pre-clearance will minimise the risk of consignments being held up on arrival pending diagnosis of suspect quarantine pests or diseases and will help ensure the risk is kept offshore.

Standard AQIS inspection

- ◆ There are no references given where the standard on-arrival inspection can be studied.

Fruit labelling

- ◆ Every imported fruit should be identified as non-Australian.

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Marketing

- ◆ Biosecurity Australia must demand that the proposed method of marketing be established and agreed upon as 'overseas' and not 'domestic' to ensure the highest standard of protocols and processes can be considered further by industry.

Traceback

- ◆ The protocol should provide the method which is able to trace back each and every shipment right back to the offending source.
- ◆ Protocols need to take into account the need for appropriate disposal of 'waste New Zealand apples' from repacking operations and/or the wholesale/retail supply chain.
- ◆ One measure, which has not been used by Biosecurity Australia, is the use of limited distribution at the destination or adaptation to regional conditions of the importing country.

Non-compliance

- ◆ Biosecurity Australia should not allow the export country a second chance by submitting the second 'lot' if the first 'lot' was rejected.
- ◆ It is impossible to believe that a grower with the strong interest to export fruit to Australia will volunteer to admit the presence of fire blight in his or her orchard.
- ◆ Detection of trash in a sample of carton at phytosanitary or on-arrival inspection should result in rejection of the 'lot' or consignment respectively, but further detection in fruit from the same REB should disqualify the REB for the rest of the season.
- ◆ Trade should be suspended, pending an investigation, if fire blight or European canker were to be detected at phytosanitary inspection in a number of REBs in one export season.
- ◆ How long will an exporter be deregistered? To ensure compliance the period should be at least twelve months.
- ◆ If more than one 'lot' from a REB is rejected the REB should be disqualified from the export program for the current season and the next season.
- ◆ There should be permanent disqualification of REBs that show symptoms of fire blight on three occasions in any ten-year period.
- ◆ Any packing house or exporter who is deregistered three times in a ten-year period be permanently deregistered.
- ◆ The discovery of infected fruit means that the proposed protocols are not satisfactory and that the whole import program be stopped and the IRA be started again.

Audit provisions

- ◆ It is not clear from the IRA how the measures could be audited and the effectiveness of the audit process.

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- ◆ Concern with the practical application of the auditing process for Registered Export Blocks (REBs).
- ◆ It would not be possible to guarantee with any degree of confidence by audit that fruit was sourced from the REB and not from detection zone.
- ◆ The audit and 'trace back' requirements are not rigorous enough.
- ◆ Why aren't all components audited particularly in the first two years of orchard inspection and the first two years of exporting?
- ◆ Surely an inspection prior to the first movement of fruit is also required.
- ◆ How will the inspectors assure that the fruit packaged in the 'lot' is from only one orchard?
- ◆ Biosecurity Australia should review the requirement for two full audits of MAFNZ systems so that it is consistent with AQIS requirements for other countries.

Systems approach

- ◆ Biosecurity Australia has utilised a 'systems approach' based on a draft document but this approach has not been validated. Biosecurity Australia requires relevant validation data for the proposed 'systems approach'.
- ◆ The system approach discussed here is totally inappropriate for fire blight which is a bacterial disease not an insect pest.
- ◆ Auditing in no way results in a measurable reduction in the risk.
- ◆ Registration of exporters and packing houses; and maintenance of fruit security in storage are dependent on robustness of strategy 1, and in no way do they independently reduce the risk of fire blight.
- ◆ Each strategy should be assessable on its own strengths or weaknesses.
- ◆ It is not acceptable that the utilisation of a number of options will effectively 'reduce the probability of entry' from medium to very low as per Australia's ALOP.

Integrated fruit production

- ◆ The application of an integrated fruit production system, which includes the management of fire blight, is only mentioned briefly.

Arrangement document

- ◆ What is an arrangement document? Where is this document? Why isn't it part of the Draft IRA? When will it be prepared?
- ◆ A grower representative (eg. from AAPGA) should be involved in the development of the arrangement document.
- ◆ 'The appropriate laboratory test' should be described.
- ◆ The entire sections of the protocol on packing line and pack house hygiene and sanitation are vague and undefined.
- ◆ Details of handling rejected consignments would be required to be specified in detailed work plans.
- ◆ No guidelines are proposed about how cross-contamination or substitution

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is to be overcome.

- ◆ There is no methodology proposed for identifying or confirming the presence of *Erwinia amylovora* infection.
- ◆ What are 'specific operational procedures'?

Respective roles of AQIS and MAFNZ

- ◆ MAFNZ will benefit from fire blight outbreak in Australia. Biosecurity Australia places undue reliance on MAFNZ for the management of quality control of packing house / fruit handling arrangements, with limited auditing by AQIS.
- ◆ To address the possible conflict of interest, all IRA phytosanitary requirements should be supervised and audited by Australian government employees, both in New Zealand and Australia. Associated costs should be paid for by New Zealand.
- ◆ AQIS must be integrally involved with both audit and inspection in the first five years.
- ◆ How can Biosecurity Australia ensure that an inspector will be able to recognise pests and diseases that he [or she] is monitoring?
- ◆ The protocol for export of Tasmanian Fuji apples to Japan appears to be such that Japan requires their own inspectors at critical stages to verify procedures and at the exporters' cost. In addition to the fact that Japan does the inspection, requirements are quite strict in regard to arranging inspections etc.
- ◆ Who is responsible for developing and maintaining the appropriate skills of MAFNZ personnel checking adherence to phytosanitary requirements?
- ◆ Who are MAFNZ accredited certifying agents? What are their skills and qualifications?
- ◆ Re "All fruit harvested from one REB in one day would constitute an inspection 'lot' unless otherwise agreed by AQIS and MAFNZ"; this process of making changes to the rules is not acceptable.
- ◆ If MAFNZ is the NPPO managing the pest free area, what rights and roles does AQIS have?
- ◆ The requirement for AQIS to be notified of all changes in registration of exporters and pack houses should be modified to a requirement for MAFNZ to maintain a register of blocks.
- ◆ Rejection of NZ consignments of apples in Japan suggest that quality system applied in NZ have been inadequate.

Risk management; Organic production

- ◆ What controls are in place to deal with organic and conventional orchards?
- ◆ The draft IRA did not offer the appropriate level of protection required by the organic industry.

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Risk management; Expert opinions

- ◆ Biosecurity Australia completely ignores the expert opinions in the formulation of the proposed protocols.

Risk management; General

- ◆ The proposed management procedures will not provide Australia's ALOP.
- ◆ There is some concern about the practicability in implementing some of the management strategies, and therefore the overall success.
- ◆ In proposing measures to manage risk it is necessary for an importing country to demonstrate a rational relationship between the risk and the proposed measure. The phytosanitary measures proposed are not the least trade restrictive measures available and do not bear an objective, rational relationship to the risks identified.

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