Importation of Apples from

New Zealand

Scientific Review Paper

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AGRICULTURE, FISHERIES AND FORESTRY - AUSTRALIA

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Annexes

ACRONYMS

AAPGA	Australian Apple and Pear Growers' Association Inc
AFFA	Department of Agriculture, Fisheries and Forestry — Australia
ALOP	Appropriate level of protection
ANZFA	Australia New Zealand Food Authority (renamed Food Standards Australia and New Zealand on 1 July 2002)
AQIS	Australian Quarantine and Inspection Service
BA	Biosecurity Australia
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CER	Closer Economic Relations Agreement between Australia New Zealand
cfu	colony forming unit
DEA	designated export area
DNA	deoxyribonucleic acid
EA	Environment Australia
FAO	Food and Agriculture Organization
FSANZ	Food Standards Australia and New Zealand (prior to 1 July 2002 — the Australia New Zealand Food Authority)
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
MOU	memorandum of understanding
NPPO	National Plant Protection Organisation
MRL	maximum residue limit
NRA	National Registration Authority
PBPM	Plant Biosecurity Policy Memorandum
PFA	pest free area
PRA	pest risk analysis
QFVG	Queensland Fruit and Vegetable Growers
RAP	risk analysis panel
REB	registered export block
SPS agreement	The Agreement on the Application of Sanitary and Phytosanitary Measures
TPE	tray pack equivalent
WA	Western Australia
WTO	World Trade Organization

PURPOSE

The primary purpose of this document is to provide information to stakeholders about the Import Risk Analysis (IRA) of New Zealand apples. This information is intended to assist stakeholders contribute to the risk analysis process.

This document comprises responses to submissions that were received following the release of the draft IRA in October 2000. It also includes summaries of new technical information, relevant recent international developments, changes in the domestic policy environment and the process that is being used to complete consideration of the New Zealand request for access.

This document is the first substantial response to the issues identified in the submissions stakeholders lodged in response to the October 2000 draft IRA on the Importation of Apples from New Zealand.

In all, 141 submissions were received, approximately containing 3000 individual comments. These submissions are available on the public file (with the exception of two confidential submissions[2]). Arrangements for viewing the public file can be made with Technical and Administrative Services, Plant Biosecurity (see p2).

Because of the large number of comments received, Biosecurity Australia first produced an inventory which categorised all comments into five sections and under 198 subject headings. To ensure the inventory captured all the concerns raised by stakeholders, it was first circulated as a draft under the cover of Plant Biosecurity Policy Memorandum (PBPM) 2001/13 of 2 July 2001. In addition, Biosecurity Australia wrote to all those who made submissions advising them of the subject headings under which their comments were grouped in the draft inventory. The inventory was then updated to incorporate the comments received and was circulated under the cover of PBPM 2001/23 of 20 November 2001. The final inventory is available via the AFFA web site at http://www.affa.gov.au/plantcra or in hard copy from Technical and Administrative Services, Plant Biosecurity (see page 2).

The inventory was the first step towards identifying and addressing the issues which need to be resolved to progress the IRA. As outlined in PBPM 2001/11 of 24 May 2001, Biosecurity Australia intended to respond to the issues included in the inventory via a scientific review paper. However, management of this task, along with all other work on the IRA, is now the responsibility of the risk analysis panel (RAP), that was announced in PBPM 2001/22 of 8 October 2001.

[2] These submissions raised issues consistent with those raised by major Australian pome fruit producers.

This document contains a compilation of information relevant to this risk analysis. A brief discussion of each section of the document follows.

Chronology of events

Annex 1 shows key steps in the process that has been followed to date on this issue, starting with the request received on 14 January 1999 from New Zealand. A significant event was the decision by Biosecurity Australia to form a risk analysis panel (RAP), which was announced on 13 August 2001. The RAP had its first meeting on 17 January 2002. Details of panel membership are included in annex 1.

Inventory of issues

The RAP has considered the comments received in response to the draft IRA and identified three groups of issues:

1. Those issues important to the on-going analysis. These are issues that the RAP will need to consider in detail in the risk analysis process.

2. Issues that the RAP considers are adequately dealt with in the draft IRA and which the RAP does not intend to re-examining in detail.

3. Those issues outside scope of the IRA. The RAP does not believe it is appropriate to respond to such issues.

In response to the first group of issues, the RAP has provided a brief commentary that highlights factors that the RAP will need to consider in its detailed analysis. The RAP's views on these issues will be reflected in the revised draft IRA to be issued later.

In response to the second group of issues the RAP has aimed to provide a substantial response. However, given the detailed analysis the RAP is undertaking, it is likely that many of these issues will be considered further. In many cases Biosecurity Australia assisted by drafting comments but the final comments represent the agreed RAP view on these issues.

The responses to the third group of issues are outside the scope of the IRA and the responses given have been provided by Biosecurity Australia, sometimes in consultation with other areas of AFFA and/or other government departments.

New technical information obtained since October 2000

This section alerts stakeholders to new technical information. It includes information about the International Fire Blight Conference held in New Zealand in 2001 and a summary of new relevant scientific information.

International developments since October 2000

Two Interim Commission for Phytosanitary Measures meetings have been held since the draft IRA was released. This section contains information about new standards endorsed at these meetings and information about a WTO dispute between Japan and the USA that may interest stakeholders.

Developments in domestic policy environment since October 2000

This section summarises Biosecurity Australia's review of the IRA process and the role of the environment portfolio in IRAs.

Process issues following the release of the scientific review paper

An outline of the process being followed to complete consideration of the importation of apples from New Zealand is included in this section.

COMMENTARY ON ISSUES RAISED

The order of listing in the inventory has been retained to allow the reader to reconcile the issues in the inventory against the commentary. In some cases, this may have resulted in a degree of repetition with related issues being dealt with in separate sections.

Part 1 General Issues

Grouped under this heading are approximately 130 issues that cover general (and sometimes specific) issues that do not fit under the headings of IRA process, methodology, risk assessment or risk management.

Several issues were raised about the use of antibiotics in New Zealand apple production and the fact that these are not registered in Australia for that purpose. The use of antibiotics in New Zealand, and how that might influence the likelihood of establishment of *Erwinia amylovora* in Australia from imported apples, is an issue that the RAP will consider. However, consideration of the human health or other aspects of antibiotic use are not the responsibility of the RAP, and Biosecurity Australia will continue to liaise with relevant authorities on this issue.

There were several comments about the use of chemical agents for disinfection. The RAP will consider the possible role of these agents in managing any identified risks, and the expert advice on registration and human health issues provided by the relevant authorities.

A range of comments through this section (and also in other sections) raise issues related to information sources, professional opinions, conflicting information etc. The RAP needs to consider all relevant information in forming its recommendations. As part of the process, the RAP will need to consider the value and veracity of different pieces of information.

Several comments asked what had changed between the previous risk analysis and the current one. The decision to consider the 1999 application is the responsibility of the government, and the RAP will not address this issue. The earlier application proposed that apples should be drawn from any area in New Zealand, with the only risk management measures being that apples be mature and free of trash. The current application is a request that Australia *"review available risk management options,*

with a view to allowing trade in apples that is least trade restrictive and meets Australia's level of protection."

Various comments were received on the history of fire blight. The history of the spread of fire blight can give some indications of the quarantine risks associated with the disease, but the RAP will need to consider this in the broader context of the conditions that prevailed when the disease spread.

Issues were raised about failure to consider a significant body of evidence, and deficiencies in the scientific data. The RAP has asked Biosecurity Australia to contact several stakeholders to identify any significant body of evidence that has been overlooked. The RAP asks that all stakeholders forward information to Biosecurity Australia that they feel is relevant to the risk analysis and that they believe has not been considered previously.

The issue of additional research was raised by several stakeholders and by the Senate Inquiry. The RAP has considered the need for and practicality of commissioning new research but has not yet reached a final view on this issue. In principle, experimental work to clarify some aspects of the risks appears simple but in practice it is often extraordinarily difficult. The problems flow from the difficulties of investigating events that may only occur very infrequently but are very significant in terms of the risks. Given the need to investigate the effect of different factors (such as temperature, humidity etc.) on an event and the need to provide sufficient replication to validate the results, it may be impractical to work under natural conditions. However, the alternative approach of doing the experiments under artificial conditions and extrapolating to natural conditions may not adequately reflect the real situation.

The RAP is aware that New Zealand and the USA (both countries with fire blight) export apples to Japan on the basis of a protocol to manage the risks of fire blight. Although the Japanese protocol may be a useful example of a quarantine measure related to fire blight, it does not necessarily mean that the protocol can be directly applied to Australian conditions. The RAP will consider the Japanese protocol and the record of trade under this protocol in concluding its analysis.

Several issues were raised about New Zealand's ability to comply with any inspection regime. The ability of a country to deliver the pre-export aspects of a risk management system is considered in formulating an import protocol. For example, it is usual to include the requirement that the exporting country allow audits and checks of their system. This issue will be considered by the RAP in reaching any recommendations on phytosanitary measures.

Several comments relate to differential treatment of Western Australia (WA) in the draft IRA. The draft IRA recognised that WA's status differs from that of the rest of Australia for apple pests. The RAP has agreed that the WA situation should be fully assessed and any special pest circumstances in WA taken into account.

Part 2 Process Issues

The submissions raised 50 issues related to the process of developing the draft IRA.

Ten issues focused on the justification of the IRA. They involved the grounds for initiating the IRA, its purpose, and the original choice of the routine process for the IRA.

The grounds justifying the IRA were questioned by a contention that the New Zealand government had not supplied sufficient information for Biosecurity Australia to initiate the IRA process. The RAP will consider the adequacy of available information in considering the New Zealand application and reaching its recommendations.

Some comments indicated a lack of understanding of the purpose of the risk assessment process and the draft IRA. This information is available in *The AQIS Import Risk Analysis Process Handbook*.

Five issues relate to views that the routine process should not have been followed because of the technical complexity and lack of knowledge. At the stage of the process when stakeholders were asked to comment on the choice of process, four of seven comments disagreed with the choice of the routine process, one favoured it and two did not indicate a view. Given the decision to use a RAP to complete the assessment of the New Zealand application, comments on the use of the routine process are no longer relevant.

The greatest number of issues, eighteen of the total of fifty, relate to input into the IRA, especially the adequacy of the consultation undertaken. The other issues were the adequacy of the public meetings, dissatisfaction with the cooperation from Biosecurity Australia, failure to consider some available evidence, the Senate Inquiry into importation of New Zealand apples, and issues concerning the role of the environment portfolio in the IRA.

Six issues relate to dissatisfaction that the respondents were not consulted during the development of the draft IRA, and one related to stakeholder calls for genuine and open consultation with industry. In one instance, this problem arose from inadequate communication within the stakeholder group. The other instances occurred because

the respondent had not registered with Biosecurity Australia as interested stakeholders in the IRA. Biosecurity Australia periodically advertises in the national press for interested parties to register as stakeholders for specific IRAs or interest categories. Registered stakeholders then receive information, and are consulted during the process.

Two issues relate to dissatisfaction with the public meetings held after the release of the draft IRA, one contending that the meetings were only for promotion and the other stating that the meetings were too short to deal with all the questions. These meetings were intended to familiarise the participants with the draft IRA, thereby assisting them to respond to the issues as they saw appropriate; this appears to have been misinterpreted as promotion. The meetings generally lasted several hours, and were arranged with the local industry. The RAP intends to provide as many opportunities as possible for communication with stakeholders on this issue but acknowledges the practical difficulties of satisfying all stakeholders all the time. The RAP encourages stakeholders to contact its chairman, Dr Bill Roberts, at the address on page 2, if ever they feel there is a lack of communication.

Four issues relate to dissatisfaction with Biosecurity Australia's cooperation with stakeholders. Two issues relate to dissatisfaction with the time it took Biosecurity Australia to respond to requests for information. Information in the public domain can be provided quickly when copyright restrictions do not apply, but Biosecurity Australia advises that delays did occur when permission had to be sought to release private information. The greater involvement of stakeholders in the current IRA process will facilitate rapid exchange of information among Biosecurity Australia and the various stakeholders.

One issue relates to claims that Biosecurity Australia has not considered a significant body of evidence. The RAP is determined that any evidence that was not considered previously will be included and evaluated in the current IRA process. Evidence identified by stakeholders as having not been considered is:

- *"The competence of* E. amylovora *as an epiphyte."*
- *"Ability of* E. amylovora *to over-winter in sites other than cankers including soil, dead tissue, mummified fruit."*
- *"The range of flies, quarantine pests and other vectors able to transfer inoculum from discarded fruit to host plants in Australia."*

Where it is not clear what significant body of evidence stakeholders are claiming has not been considered, the RAP has asked Biosecurity Australia to request details.

Two issues were identified in relation to the role of the environment portfolio in the preparation of the draft IRA and in the IRA process. The RAP includes expertise in environmental risk analysis, and important environmental issues related to the potential introduction of pests will be considered by the RAP.

One issue relates to the contention that the IRA should be delayed until the Government has received and accepted the findings of the Senate Inquiry. The Interim Report of the Senate Rural and Regional Affairs and Transport Legislation Committee has been tabled in Parliament and the Government is considering it. The recommendations predominantly pertain to the broader IRA process, and many are being addressed in the current process. The RAP will consider the reported deliberations of the Senate Inquiry in the current IRA.

Ten issues were identified relating to openness and transparency. These related to the public file, transparency, the public comment period, the role of State departments of agriculture, and authorship of the draft IRA.

One issue related to the contention that all responses should be on the public file, and another stated that scientific responses should be on the public file. A third issue noted that a particular consultation draft document was not on the public file. The RAP notes Biosecurity Australia's advice that all submissions are placed on the public file unless confidentiality is requested and the request accords with that status under the *Freedom of Information Act 1982*. Two stakeholders, who raised issues consistent with major Australian pome fruit producers, requested that their submissions be kept confidential, so these have not been placed on the public file. Subject to the *Privacy Act 1988*, all scientific responses are on the public file.

Transparency is most important during the IRA process. The evidence considered and the basis of the analysis must be evident to all parties. One issue related to the contention that the process has not been transparent. Another issue related to the claim that confidential discussions with State departments of agriculture early in the consultations excluded other stakeholders. The RAP is advised that Biosecurity Australia considered the confidentiality of those discussions to be essential at that time, early in the process. However, the revised process gives stakeholders better opportunity for consultation and access to information and the RAP will ensure that the IRA process is consistent with the draft revised process. A third issue related to the claim that the release of the draft IRA before the industry had opportunity to comment was prejudicial, particularly at the WTO. This latter issue is beyond the

scope of the IRA, having been considered in the review of the IRA process. Nevertheless, the RAP has undertaken to maximise transparency of the process to all parties.

Another issue related to the claim of unfairness in the process because industry had only two months to comment on the draft IRA that Biosecurity Australia had taken 18 months to prepare. Consultations in the current IRA provide stakeholders with fresh opportunity for further input.

One issue related to the contention that failure to provide names and qualifications of authors of the draft IRA attempted to hide responsibility for a deficient document. The RAP notes that the document resulted from the efforts of a team of people and that the new IRA process provides for release of information about members of the team. The subject of the IRA is very contentious and there is a risk that personnel involved can be subjected to unfair personal harassment if they are specifically identified.

Two issues challenged the impartiality of the IRA process but these originated from misunderstandings of the processes of government decision-making. One issue related to the incorrect contention that a conflict of interest arose when a judgement made by a government department was used in formulating government policy. A significant role of government departments is to contribute to the formulation of government policy, and this does not constitute a conflict of interest. Another issue related to the contention that an independent arbiter should decide the final outcome of the IRA because the Director of Animal and Plant Quarantine is closely connected with Biosecurity Australia and therefore could not make an impartial decision. The RAP notes that the *Quarantine Act 1908* vests quarantine decision-making powers in the Director of Animal and Plant Quarantine who is the Secretary of AFFA.

Five issues questioned the consistency of the IRA process as outlined in *The AQIS Import Risk Analysis Process Handbook*. One issue urged Biosecurity Australia to advise stakeholders of any significant variation to the process after the IRA had begun. The RAP notes that it is normal practice to advise stakeholders of any significant variation to the process, as indicated in the Handbook. Also, the Handbook indicates minimum procedures, and Biosecurity Australia may vary the procedures to enable greater consultation with stakeholders. In addition, the Government intends to strengthen public involvement and consultative procedures in the IRA process, and this will be reflected in the *Administrative Framework for Import Risk Analysis*, which is due to be published later this year. The RAP will ensure that the process followed is consistent with the draft revised process. One

issue questioned the validity of basing the draft IRA on a draft ISPM. This draft ISPM would have been relevant to the dispute settlement process in the WTO. Concerns on this issue have been superseded by the adoption of ISPM 11 *Pest risk analysis for quarantine pests* and ISPM 14 *The use of integrated measures in a systems approach for pest risk management* at the third (2001) and fourth (2002) sessions respectively of the Interim Commission on Phytosanitary Measures.

Four issues drew attention to the time taken by the IRA process and the uncertainty that this causes for the industry and investment decisions. The RAP shares this concern, but notes that examination of complex scientific issues with various gaps in knowledge, coupled with extensive consultation with stakeholders, is bound to take a significant time to complete. The RAP considers it most important that the issues are deliberated thoroughly with all available evidence so the best possible outcome can be delivered for the long-term benefit of Australia. One issue noted that industry was denied dollar-for-dollar funding to provide of a response to the draft IRA. Neither Biosecurity Australia nor the RAP have any role in providing or approving funding for industry in these circumstance, and the RAP considers that this issue is beyond the scope of the IRA process.

Part 3 Methodology Issues

There are 104 issues grouped under the general heading of methodology.

A range of comments concerned issues associated with Australia's appropriate level of protection (ALOP). A section of the draft IRA described Australia's approach to ALOP but from the comments that were received it is clear that there is some misunderstanding of the concept. The draft *Guidelines for Import Risk Analysis* provides an overview of Australia's Biosecurity Policy including a discussion of ALOP, and the reader is referred to this document. The Guidelines is available on the AFFA Internet site http://www.affa.gov.au[3]. The draft *Administrative Framework for Import Risk Analysis* is also available at this site. Copies are available to stakeholders (in paper or electronic form) from Biosecurity Development and Evaluation at bde@affa.gov.au, telephone 02 6272 4914 or fax 02 6272 4568.

However, a few of the basic principles are dealt with here:

- Every WTO member has the sovereign right to set its ALOP. The level of ALOP is set by each country not the WTO or any other body. In Australia's case the

[3] Follow the links "Publications", "Biosecurity Australia" and "Draft Import Risk Analysis Guidelines". "Publications" is under the heading "Tools & Services"

ALOP is government policy and is not set by Agriculture, Fisheries and Forestry, Australia, Biosecurity Australia or AQIS.

- Every WTO member has the right to apply quarantine measures to achieve the ALOP. Such measures must be justifiable on scientific and technical grounds.

- Where a range of measures is available that would meet a country's ALOP, the one/s chosen must be the least restrictive to trade, taking into account technical and economic feasibility.

- In applying quarantine measures, WTO members must avoid arbitrary or unjustifiable distinctions in the ALOP in comparable situations, where such distinctions result in discrimination or a disguised restriction on trade.

The RAP has the responsibility of analysing the risks and recommending measures that it considers are appropriate to meet Australia's ALOP.

Although the general concept of an ALOP is simple, the expression or representation of ALOP is difficult. Discussion on the best way to express or measure ALOP has been going on for many years in international forums without any agreement on methodology. The iso-risk curves, used to illustrate the concept of ALOP in the draft IRA and the draft *Guidelines for Import Risk Analysis,* have been discussed internationally at great length. However, although it is generally acknowledged that the logic behind these curves is correct, no country has used this approach in the practical implementation of its ALOP.

A recent Primary Industries Standing Committee meeting considered that the current level of definition of ALOP, as presented in the draft *Guidelines for Import Risk Analysis* adequately meets Australia's present needs, and that further work on ALOP definition should not be a priority. This was subsequently endorsed by the State/Territory and Commonwealth Agriculture Ministers at a meeting of the Primary Industries Ministerial Council.

In the WTO Salmon case, Australia stated its ALOP to be "a high or very conservative level of sanitary protection aimed at reducing risk to very low levels, while not based on a zero-risk approach". The WTO found that Australia had articulated its own ALOP and had done so with sufficient precision.

Australia's ALOP is also expressed in terms of past and ongoing quarantine decisions. The draft *Guidelines for Import Risk Analysis* contains a discussion on ALOP and

how it is used. The RAP will use the approach to the ALOP outlined in the draft *Guidelines for Import Risk Analysis*.

One issue related to contaminants associated with apples. Contaminants that may be associated with a commodity are a legitimate concern and the RAP will consider all quarantinable organisms that in the judgement of the RAP could be on, in or associated with the import of apples from New Zealand.

Examination of the literature and various standards indicates that even though the basic principles (assess likelihood of occurrence, potential consequences and determine appropriate risk management measures) are similar, there is a great deal of debate about terminology used under different risk assessment and analysis systems. The AS/NZ 4360 standard uses somewhat different terminology to that used in the International Standards for Phytosanitary Measures (ISPMs). However, the ISPMs are the international standards directly relevant to this analysis and are recognised by the Sanitary and Phytosanitary Agreement (SPS). The RAP will follow the terminology and approach in the ISPMs but will review the AS/NZ standard and ensure that the RAP analysis covers all the relevant areas and issues.

Given the wide host range of fire blight including many Rosaceous plants and the widespread occurrence of rosaceous plants in Australia, the RAP considers that there is little to be gained from detailing the specific area endangered — it is simply all areas in Australia with hosts growing or with the potential to grow hosts. This is not to conclude that the disease would be severe in all areas, but even in the dryer areas of Australia, where the severity of the disease might be expected to be lower, the use of irrigation could significantly increase the impact of the disease. The RAP will consider these issues in its analysis.

The International Plant Protection Convention (IPPC) definition of a quarantine pest is "a pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled". The key elements include the pest being either absent from the endangered area or, if it is present, being not widely distributed and subject to official control. Official control is control that is either performed or authorised by the National Plant Protection Organisation. In Australia, the National Plant Protection Organisation (NPPO) is the body responsible for national plant quarantine policy — Biosecurity Australia. However, control programs are carried out by State and Territory governments.

Fire blight is a major disease which is absent from Australia so it is clearly a quarantinable pest under the IPPC definition. Another example is apple scab. This

disease is absent from WA (but present in other areas of Australia) and under official control in that State. A disease such as this would meet the other provisions of the IPPC definition of a quarantine pest. The draft IRA proposed that because of issues such as apple scab New Zealand apples would not be permitted entry to WA until further analysis was undertaken. This action is consistent with the current action taken by WA in banning entry of apples from other states into WA. The RAP is aware of several differences in pest status in various areas in Australia, and will consider these issues in the risk analysis.

Several issues relate to likelihoods and the way they are expressed. The draft *Guidelines for Import Risk Analysis* contains a detailed discussion that is illustrated by matrix tables and worked examples for qualitative, semi-quantitative and quantitative analysis. This relates to the points raised, and the reader is referred to this document for an explanation. The RAP will use the approaches outlined in the draft Guidelines document in the risk analysis process.

There are several issues about the approach to environmental risks. The RAP is aware that there is a small number of native rosaceous plants. Although these plants do not appear to be closely related to known hosts of fire blight, and therefore are less likely to be hosts of the disease, the RAP will seek expert advice on this matter. The environment could be taken to include the use of hosts of fire blight as ornamental and street trees, and the RAP is conscious of the need to consider this in its analysis.

The draft IRA concluded that the economic consequences of fire blight establishment and spread in Australia would be extreme. This is the highest rating on the scale. Several respondents commented about the lack of detailed analysis of this point, but the RAP considers that any detailed further analysis taking into account additional factors as suggested by some respondents will simply reinforce the view that the consequence rating for fire blight would be in the highest category. Other stakeholders considered that the draft IRA overestimated the level of consequences. Also, the RAP notes the refinements Biosecurity Australia has made to the procedures for estimating consequences. Accordingly, the RAP will review the work that has been done on this issue as well as the potential consequences of other pests.

There are several issues grouped under the subject headings of General, Independence of events, Risk matrix, Quantitative vs qualitative and Probability theory in the Inventory of Issues section on Methodology. These issues raise concerns about the use of the matrices to combine values or the way that steps in the chain of events needed for fire blight establishment have been separated or grouped. The draft *Guidelines for Import Risk Analysis* document has an extensive discussion on the

issues relevant to these concerns, and readers are referred to that document. These are the procedures and the processes that the RAP will apply in its analysis.

Australia is a very active participant in developing international standards under the IPPC, and the RAP is familiar with the ISPMs developed under this convention. Several points should be kept in mind while using these standards. The ISPMs are intended to provide guidance, and it is often appropriate for interpretation to be very flexible and not prescriptive. They may also allow for different ways of achieving the same ends. Several standards have been adopted under the IPPC since the draft IRA was released, and annex 2 lists all the current ISPMs and their adoption date.

The application from New Zealand made no mention of apples produced organically, and the RAP is not aware of any subsequent request for access for organically produced apples. In the absence of any formal request, the RAP does not intend to specifically consider this issue. However, if organic growers are able to meet any conditions that may be required for export to Australia, then there would be no reason why access would not be granted. The RAP is aware that the organic industry in Australia may be unable to use sprays in an organic production system, and therefore may face special difficulties if fire blight were to establish. The RAP will consider this issue in the analysis.

Several issues concerned the possible pathways for entry of fire blight in addition to the main pathway on fruit. The RAP is aware that there are other possible pathways such as on packing material or trash with the fruit. There is also a complex distribution system in Australia that may be relevant to the assessment of the likelihood of establishment and the RAP will consider these issues in its analysis.

There are very few instances in decision making where "perfect knowledge" is available. Several issues related to uncertainty and the need to explicitly take account of uncertainty. The RAP agrees with this view, and will ensure that the analysis explicitly considers uncertainty in reaching its recommendations. The comments on the use of caution are also relevant to this issue. Australia takes a very conservative approach to quarantine decision making, which reflects an inherently cautious approach.

Several issues related to the sources of information used. Views differed with some considering that only refereed scientific journal material was relevant whereas others considered that all sources of information should be considered. The RAP has the responsibility to consider all relevant material and make a judgement on the significance and veracity of all the information available. The RAP appreciates that it is sometimes difficult for stakeholders to access material not published in a

conventional form, and will endeavour to make available all unpublished information, while taking into account the requirements of the privacy and copyright provisions.

The potential volume of trade is a relevant factor that needs to be considered in the risk analysis. The draft *Guidelines for Import Risk Analysis* deals with this by a level of protection, based on an analysis of a one year time frame, that has an inherent level of conservatism intended to take into account any risks that are associated with on-going trade. The RAP will follow the approach outlined in this document.

Part 4 Risk Assessment

Biosecurity Australia's draft *Guidelines for Import Risk Analysis* describes risk assessment as "the process of identifying pests of quarantine (or biosecurity) concern and estimating the risk (probability of introduction and spread and the magnitude of the likely consequences) associated with each." This statement is qualified to the extent that "the probability of 'introduction' for a quarantine pest represents an amalgamation of the probability of 'entry' and the probability of 'establishment'…"

In all, 206 issues related to risk assessment were identified from the submissions made by stakeholders. Of these, by far the majority of issues (140) were related to *Erwinia amylovora* and/or fire blight disease caused by this bacterium. Of the others, 6 issues related to fungal disease, 23 to arthropods and the remainder (37) to general comments and concerns about the risk assessment process.

The RAP in its assessment of part 4 of the "final inventory of issues" document, considered that analysis of the issues relating to *Erwinia amylovora* and fire blight disease were all important issues that would need to be considered by the RAP.

Of the remaining broad categories, the RAP considered that it was appropriate to form two technical working groups to assist the RAP with its deliberations. Technical working groups are being formed to advise on the technical aspects of both the fungal pathogens issues and the range of issues identified in relation to the arthropods. This will enable the RAP to focus on the assessment of *Erwinia amylovora*.

Various issues were raised in relation to the consequences of fire blight should it be introduced and become established within Australia. The RAP agrees with the draft IRA assessment that the consequences of fire blight are very significant. It is also agreed that there may be a need for a more explicit explanation of the rationale used in assessing the consequences. The possible consequences to the honey bee industry is an issue that will require consideration but is only likely to reinforce the RAP view

that the consequences of establishment of fire blight in Australia would be very significant.

Many of the issues raised by respondents relate to concerns about the scientific veracity of the various stages involved in determining the level of unrestricted risk. Besides concerns over the interpretation of the results of various scientific investigations, several respondents raised issues about the use of expert opinion by Biosecurity Australia and the subsequent interpretation of the opinions received. The RAP believes that consideration of the risks of entry and establishment of *Erwinia amylovora* is pivotal to the analysis, and requires careful analysis as part of the proposed future draft IRA document. The RAP considers that all relevant information should be considered irrespective of the source. However, the RAP will need to evaluate the significance of individual pieces of information based on a range of factors, including its source.

The issue of the use of modelling as part of the risk analysis process for fire blight was raised by several respondents. This included the use of simulation methods in relation to assessment of the uncertainty and variation of data. The RAP considers that modelling has been useful for indicative purposes but appreciates the limitations of such approaches and that the results cannot always be highly relied upon. The RAP has decided, as far as possible, to use a quantitative or semi-quantitative approach to the analysis, and is exploring different approaches, including modelling, for dealing with uncertainties in the data.

A considerable number of issues raised concerned the biology of *Erwinia amylovora*, and the RAP will investigate these. Issues included the ability of *Erwinia amylovora* to form biofilms, and its competency as an epiphyte without disease symptoms (latency/dormancy).

The overall issue of fruit infestation and in particular calyx infestation stimulated a wide range of views based upon published reports. The ability of *Erwinia amylovora* to survive in the calyces of mature fruit, and its significance, is seen by the RAP as a critical issue for further consideration.

Several respondents raised issues about the likelihood of fruit infection and the implications of this. The literature contains some reports of fruit infection, and the RAP will need to carefully evaluate these reports.

Other issues raised included assessment of the risk posed by infected trash, the level of bacteria required to provide an infective dose, the ability of *Erwinia amylovora* to be spread by apple seed, *Erwinia amylovora*'s sensitivity to ultra-violet radiation, and

the ability of the bacteria to be transferred by vectors into a registered export block and from an imported apple to initiate an infection. One respondent raised the issue of *Erwinia amylovora* being able to exist in a viable but non-culturable state as has been reported for several other bacteria.

One issue was in relation to the fire blight host status of plums, strawberries, blackberries, raspberries and cherries. The RAP will consider the likely host status of these plants in assessing the possible impact of fire blight, should it establish in Australia. The possibility that fruit from these plant species could be a pathway for introduction of fire blight to Australia is outside the scope of the RAP but has been referred to Biosecurity Australia for consideration.

The specification, of laboratory testing protocols were raised by several respondents, but the RAP considered that these standards would be inherent in any subsequent testing requirements proposed by Biosecurity Australia. There is no internationally accepted standard for testing for the presence of the fire blight bacterium.

Various comments were received about the issue of expert opinion. The RAP supports the use of expert opinion where published data are not available but the value of such opinion needs to be considered carefully by the RAP case by case. Subject to any privacy and confidentiality provisions the RAP intends to place all opinions and other relevant information on the public file.

The RAP notes that several comments are about supposed misquotes or incorrect reporting based upon several published reports. The RAP will consider these issues as it works through the full range of scientific and technical information available.

International agreements allow for equivalence of measures in meeting the same objectives. In forming any recommendations on risk management measures, the RAP will need to consider different measures and combinations of measures that could be used to achieve the ALOP.

The RAP supports the status of *Nectria galligena* as a pathogen of quarantine concern, and has established a Technical Working Group to consider the issues raised by stakeholders in relation to both this and other fungal pathogens.

Issues were raised in relation to all eleven quarantine arthropod pests, and a specialist Technical Working Group has also been established to advise the RAP on these issues. The RAP will seek specific clarification on the status of apple leaf curling midge as a potential vector of *Erwinia amylovora*.

Part 5 Risk Management

About 300 issues relating to 55 subject headings about Risk Management measures are listed in the inventory. Almost all of these were judged by the RAP as likely to be major issues for its consideration. However, the process of addressing the issues which may reduce the assessed risk to an acceptable level (below Australia's ALOP), is the 3rd stage in the IRA process. It is axiomatic that they cannot be fully addressed until the risk assessment stage is concluded.

The RAP intends to produce a revised draft IRA based on the results of a reconsideration of all the quarantine pest risk profiles. In the case of the key pest, fire blight (the trigger for most but not all of the comments), it has been agreed to attempt a pest risk analysis that is as close to fully quantitative as is feasible.

Although Australia's preferred policy is to manage import risk offshore, some necessary onshore measures may emerge from either the pathway analysis or consequence evaluation. Australia has an obligation under its international agreements to consider different approaches to risk management for imports, and offer the least trade restrictive measures that achieve our ALOP.

New science or accrued knowledge may also affect the risk management, either directly (for example a new disinfestation process or material), or indirectly through its effect on the assessed unmanaged risk level. For example, further research into the likelihood of transfer and re-infection by *Erwinia amylovora* in Australia may reduce the uncertainty surrounding this mechanism.

Many stakeholder comments have questioned the appropriateness and security of registered export blocks for the disease fire blight. Included are the application and relevance of ISPMs for pest free areas, and the effectiveness, timing and frequency of orchard inspections. The concept of detection zones, their scientific basis, and their size have particularly attracted much comment. There is no consensus about size, with widths from 10 metres to 15 km being mentioned by respondents.

The efficacy of the chlorine disinfestation treatment, and practical use issues such as the possible use of surfactants, are also the subject of conflicting statements. The inability of the solution to disinfest the calyx cavity is a strongly made point, but two stakeholders submit that such entry could increase infestation or infection. The RAP understands that disposal of spent chlorine dip material is an environmental issue in New Zealand, but this point was not made in the draft IRA submissions.

The practical feasibility of producing a trash-free product is questioned by many stakeholders. The RAP understands that high-volume low-pressure water treatment is increasingly being used on apple export grading lines in New Zealand. The effectiveness of this equipment in trash elimination (as well as reduction of Arthropod hitchhiker pests) may require evaluation, and mandatory use may be an option.

The RAP is aware that the apple export marketing from New Zealand has recently been deregulated. This could raise some issues that were not considered in the draft IRA, or put those that were into a different light. Control of grades of fruit able to be exported and the type of packages allowed are two such issues.

The protocols for sampling and fruit inspection attract considerable comment, particularly the relationship between a fixed sample size and variable lot size. The adequacy of the option of either pre-harvest orchard inspection and enhanced on-arrival inspection, or phytosanitary inspection and enhanced on-arrival inspection is queried. The RAP will reconsider the adequacy of these measures, particularly for freedom from trash, endophytic infection by *Erwinia amylovora* and for arthropod pests that may live in the calyx of apples.

Some of the operational issues raised would normally be detailed in an Arrangement Document, rather than the IRA. Operational issues normally included in an arrangement document do not relate directly to the efficacy of the risk management measures but relate to organisational arrangements such as payment of costs, lines of reporting etc. However, the RAP will consider whether more detail should be provided in the IRA about operational issues related to risk management measures.

The view has been expressed that the risk assessment and management of pests and diseases other than fire blight was not handled in sufficient detail in the draft IRA. The RAP will consider all relevant pest and disease risks in forming its recommendations. The RAP has established two technical groups (on fungi and arthropod pests) to investigate and advise it on the need for technical working groups to provide it with specialist advice on the issues that need to be addressed.

A requirement for fumigation for arthropod quarantine pests was called for by several submissions. Fumigation is considered by exporting countries to be a very trade restrictive measure. The RAP understands that New Zealand apple exports to some destinations are fumigated before release from quarantine if apple leaf curling midge is detected by on-arrival inspection.

The draft *Guidelines for Import Risk Analysis* document outlines the principles for the identification of appropriate risk management options, and categorises the types of measures commonly applied to traded commodities and their pathways.

These include measures applied:

- to consignments
- to prevent or reduce the original infestation of the crop
- to ensure the area or place of production is free from the pest
- to prohibit commodities.

Finally, the risk assessment methodology applied to the unrestricted risk must be used to determine the managed risk for comparison with Australia's ALOP.

Conclusion

The RAP is committed to considering all the relevant information in reaching its recommendations. The issues raised by stakeholders and collated in the inventory provide a very valuable resource document to assist the RAP in its analysis. This scientific review paper has sought to provide some feedback to stakeholders on the thinking of the RAP and provide a common basis for further discussion. The IRA is by no means finished and feedback or comment from stakeholders is welcome at any time and actively sought by the RAP. All comments should be directed to:

The Chairman
Risk analysis panel
New Zealand apple IRA

C/- Plant Biosecurity
Biosecurity Australia
Agriculture Fisheries and Forestry – Australia
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RESPONSES TO ISSUES

For clarity, the responses to issues have been prepared in the same format as the inventory and are provided in Annex 3. A numbering system has been added to facilitate reference to individual issues or responses.

As indicated above, the RAP has authorised all responses except those it considered outside its scope. The response to each of these issues clearly states that the RAP considers it outside its scope.

NEW TECHNICAL INFORMATION SINCE OCTOBER 2000

Biosecurity Australia has identified numerous new research papers relevant to the IRA, and either has or is attempting to obtain copies for the RAP to use in its analysis. The titles of these publications are provided in Annex 4.

The 9th International Workshop on Fire Blight was held on 8–12 October 2001, in Napier, New Zealand. The workshop is a regular meeting of the International Society for Horticultural Science's Working Group on Fire Blight. The aim is to provide a venue and opportunity for discussion of all aspects of the biology and epidemiology of *Erwinia amylovora* and control of the disease.

The workshop was a valuable source of up-to-date information, and a large Australian contingent attended, from both government and industry. The workshop program (Annex 5) includes many of the papers, poster presentations and discussion sessions that have direct relevance to issues associated with this IRA.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

The World Trade Organization's (WTO's) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) identifies the International Plant Protection Convention (IPPC) as the organisation providing international standards for measures implemented by governments to protect their plant resources from harmful pests (phytosanitary measures). The IPPC complements the SPS Agreement by providing the international standards that help to ensure that phytosanitary measures have a scientific basis and are not used as unjustified barriers to international trade.

The New Revised Text of the IPPC (IPPC 1997) provides for the establishment of a Commission on Phytosanitary Measures that will serve as the global agreement's governing body. The contracting parties to the IPPC agreed that the commission be established on an interim basis until IPPC 1997 enters into force (which requires ratification by two-thirds of contracting parties).

International standards for phytosanitary measures (ISPMs) are endorsed by the Interim Commission on Phytosanitary Measures (ICPM), following formal country consultation. To assist this process, ISPMs are prepared by the secretariat of the IPPC as part of the United Nations' Food and Agriculture Organization's (FAO's) global program of policy and technical assistance in plant quarantine. This program publishes these standards, guidelines and recommendations to achieve international harmonization of phytosanitary measures, with the aim to facilitate trade and avoid the use of unjustifiable measures as barriers to trade. The current list of final standards is provided at annex 2.

The third session of the ICPM (3ICPM) was held in April 2001, the full report from which is available at: http://www.fao.org/waicent/FaoInfo/Agricult/AGP/AGPP/PQ/En/Publ/Cpm/ICPM3e.pdf

This session accepted the following international standards:

- Amendments to the Glossary of Phytosanitary Terms
- Pest Risk Analysis for Quarantine Pests

- Guidelines for Phytosanitary Certificates
- Guidelines for Notification of Non-compliance and Emergency Actions
- Glossary Supplement No 1: Guidelines on the Interpretation and Application of the Concept of Official Control for Regulated Pests

The fourth session of ICPM (4ICPM) was held in March 2002, the full report from which is available at: http://www.fao.org/waicent/FaoInfo/Agricult/AGP/AGPP/PQ/En/Publ/Cpm/ICPM4e.pdf

This session accepted the following international standards:

- Amendments to the Glossary of Phytosanitary Terms
- The Use of Integrated Measures in a Systems Approach for Pest Risk Management
- Guidelines for Regulating Wood Packaging Material in International Trade
- Pest Reporting
- Regulated Non-Quarantine Pests: Concept and Application

4ICPM also adopted a specification for a new standard on living modified organisms, enabling the establishment of an expert working group on the topic.

The IPPC secretariat reported on the continuing cooperation between the IPPC and the Convention on Biodiversity, to strengthen the work of the ICPM concerning the relationship of the IPPC to genetically manipulated organisms (GMOs), biosafety and invasive species.

As requested by 3ICPM, FAO regional groups of ICPM members nominated members to the new Standards Committee and Subsidiary Body on Dispute Settlement, and these were confirmed by 4ICPM. The FAO region for the South West Pacific had three possible nominees for the Standards Committee. Biosecurity Australia's Chris Hood has been confirmed to continue his work from the Interim Standards Committee onto the Standards Committee. IPPC dispute settlement focuses on resolution of technical issues and therefore complements the dispute settlement arrangements under the WTO.

The Standards Committee held its inaugural meeting in Rome 13–17 May 2002. In addition to procedural matters, the Committee considered draft standards for *Irradiation as a phytosanitary treatment* and *Analysis of environmental risks.* The latter is a draft supplement to ISPM #11 *Pest risk analysis for quarantine pests* and deals with intentionally imported plants as environmental risks rather than as pests and diseases *per se*.

WTO DISPUTE

WTO dispute settlement is legally binding and provides for significant sanctions against members found not to be fulfilling their obligations under any of the various WTO agreements. Because the SPS agreement is relatively new, there is limited case law. However, the United States requested the establishment of a WTO panel at the 22 May 2002 meeting of the WTO Dispute Settlement Body (DSB), in its complaint against Japan, about Japan's measures affecting the importation of apples. This complaint focuses on Japan's measures against *Erwinia amylovora*.

At the DSB meeting on 3 June 2002, a panel was established to hear this dispute. At that meeting several members, including Australia, reserved their third party rights to this dispute. Australia has joined as a third party with the sole objective of protecting its own interests. Third parties have an opportunity to make submissions at the time of the first panel meeting and to make an oral statement.

THE REVIEW OF THE IRA PROCESS

The IRA process, developed from recommendations of the Australian Quarantine Review Committee (1996) is a key element in the development and implementation of Australia's biosecurity policy. The process aims to ensure that all stakeholders have ample opportunity to contribute information and views when Biosecurity Australia is developing and reviewing policies regarding the import of animals and plants, and their products, into Australia. More than 20 IRAs have been completed using this process.

In the light of lessons from recent years, Biosecurity Australia is reviewing the IRA process to ensure that decisions continue to reflect the Government's highly conservative approach to quarantine, to strengthen opportunities for external scientific input and to enhance opportunities for public consultation. Biosecurity Australia consulted with all registered stakeholders in reviewing the process. Over 50 submissions were received. A revised draft Administrative Framework, addressing the issues raised by stakeholders was circulated for comment in September 2001 and 24 further submissions were received.

The new IRA framework will make the process more consistent, accountable, scientifically rigorous and transparent. Until the new framework is in place, the existing process, set out in *The AQIS Import Risk Analysis Process Handbook*, applies. However, in the spirit of the new process, Biosecurity Australia is committed to full consultation and increased opportunity for external scientific input for the IRA's currently underway. The IRA process will continue to comply with our international obligations. The new IRA Framework is expected to be finalised in the latter part of 2002.

DRAFT *GUIDELINES FOR IMPORT RISK ANALYSIS*

Biosecurity Australia also advised stakeholders of the completion of a working draft of the *Guidelines for Import Risk Analysis*. The Guidelines draws together AFFA's corporate experience in the conduct of IRAs, and input from risk analysts in State agriculture departments, the private sector and overseas government agencies.

The Guidelines is a technical reference document prepared specifically to assist Biosecurity Australia's scientific personnel in the conduct of IRAs. It is based on the relevant international standards for IRAs (the Office International des Epizooties (OIE) International Animal Health Code and Aquatic Code, and International Plant Protection Convention (IPPC) International Standards for Phytosanitary Measures (ISPM) Pest Risk Analysis for Quarantine Pests), and provides terminology and methodology that can be applied consistently to meet Australia's obligations under the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The Guidelines has been placed on the AFFA Internet site (http://www.affa.gov.au[4]). The draft *Administrative Framework for Import Risk Analysis* is also available at this site. Copies of both documents are available to stakeholders (in paper or electronic form) from Biosecurity Development and Evaluation at bde@affa.gov.au, telephone 02 6272 4914 or fax 02 6272 4568. The final *Administrative Framework for Import Risk Analysis* is expected to be published later this year.

MEMORANDUM OF UNDERSTANDING WITH ENVIRONMENT AUSTRALIA

Biosecurity Australia and Environment Australia (EA) are developing a Memorandum of Understanding (MOU) in relation to import risk analyses. Under the MOU, Environment Australia will be formally consulted on the scope, technical issues for consideration, timetable and composition of the team to conduct an IRA, to ensure that environmental considerations are appropriately taken into account. This is already occurring, but will be formalised through revised arrangements established under the MOU.

[4] Follow the links "Publications", "Biosecurity Australia" and "Draft Import Risk Analysis Guidelines". "Publications" is listed under the heading "Tools & Services".

PROCESS FOLLOWING RELEASE OF SCIENTIFIC REVIEW PAPER

The RAP notes that Biosecurity Australia is reviewing the IRA process and that the new IRA Framework is expected to be finalized in the latter part of 2002. The process the IRA will follow is subject to developments in the IRA process. In the spirit of the new process, Biosecurity Australia has asked the RAP to ensure full consultation with stakeholders. The RAP envisages the following:

- a consultation workshop to discuss methodology
- preparation and release of revised draft IRA
- a formal 60 day comment period on revised draft IRA
- consultation with stakeholders
- peer review
- preparation of final IRA report
- consultation with States and Territories
- release of final IRA report and provisional policy determination
- 30 day appeal period on the final IRA report
- appeal determination (if required)
- notification of final policy determination.

The objectives of the workshop to discuss methodology are:

- to allow participants to provide input on important issues that need to be considered by the Risk Analysis Panel
- to identify issues that need to be considered in analysing the risk pathways for entry and establishment of fire blight via trade in apples
- to provide an opportunity for participants to meet the Risk Analysis Panel and understand the process that is being used to analyse the quarantine risks of apple importation.

CHRONOLOGY OF KEY EVENTS – NZ APPLE IRA

1. AQIS received a formal approach from NZ Ministry of Agriculture and Forestry (MAF) on 14 January 1999, requesting a review of available risk management options for apples from New Zealand. MAF asked that the review identify phytosanitary measures that are the least trade restrictive necessary to meet the level of protection deemed appropriate by Australia.

2. The draft IRA was released on 11 October 2000 for public comment until 11 December 2000, which was later extended until 28 February 2001. Stakeholders made 141 submissions.

3. On 13 August 2001, the Secretary announced the establishment of a risk analysis panel (RAP) to help assess the request to import New Zealand apples. Only a few days after the first RAP meeting, one of the original members, Mike Kinsella, passed away. Mike's contribution to the RAP is greatly missed.

4. Membership for a risk analysis panel is:
   - Dr Bill Roberts (Chairman), Australia's Chief Plant Protection Officer;
   - Mr Ian Armour, an Australian apple grower
   - Mr Bill Hatton, a fruit producer with expertise in growing, packing and shipping a range of fruits and experience in pest and disease incursion planning;
   - Mr David Cartwright, a plant pathologist and Manager, Plant Health, Department of Primary Industries and Resources South Australia;
   - Dr Kent Williams, Ecologist and Principal Research Scientist, CSIRO Sustainable Ecosystems;
   - Dr Brian Stynes, General Manager, Plant Biosecurity, Biosecurity Australia.

5. On 20 November 2001, BA circulated a final inventory of issues raised by stakeholders in response to the draft IRA.

6. The RAP had its first meeting on 17 January 2002. The key outcome of this meeting was for the RAP to develop the following forward plan:
   - Identify the issues raised in response to the draft IRA on which it will focus most of its effort.
   - Produce a Scientific Review Paper that responds to all issues raised.
   - Conduct workshops to discuss the major outstanding issues.
   - Analyse the issues, taking into account the comments and advice received, produce a revised draft IRA and distribute it to stakeholders for comment.
   - Continue the process as set out in the administrative framework for IRA.

INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURE

ISPM 1[5]	*Principles of plant quarantine as related to international trade*	1995
ISPM 2	*Guidelines for pest risk analysis*	1996
ISPM 3	*Code of conduct for the import and release of exotic biological control agents*	1996
ISPM 4	*Requirements for the establishment of pest free areas*	1996
ISPM 5	*Glossary of phytosanitary terms 2002*	2002
ISPM 6	*Guidelines for surveillance*	1997
ISPM 7	*Export certification system*	1997
ISPM 8	*Determination of pest status in an area*	1998
ISPM 9	*Guidelines for pest eradication programmes*	1998
ISPM 10	*Requirements for the establishment of pest free places of production and pest free production sites*	1999
ISPM 11	*Pest risk analysis for quarantine pests*	2001
ISPM 12	*Guidelines for phytosanitary certificates*	2001
ISPM 13	*Guidelines for the notification of non-compliance and emergency action*	2001
ISPM 14	*The use of integrated measures in a systems approach for pest risk management*	2002
ISPM 15[6]	*Guidelines for regulating wood packaging in international trade*	2002
ISPM 16	*Regulated non-quarantine pests: concept and application*	2002
ISPM 17	*Pest reporting*	2002

[5] You can download these International Standards for Phytosanitary Measures (ISPMs) from the following web page: http://www.fao.org/ag/agp/agpp/pq/En/Publ/Ispm/ispms.htm .

[6] A key provision of this standard is the use of a mark for the certification of approved measures. Difficulties have arisen as a result of efforts by FAO to legally protect the mark for use according to the standard. The FAO Legal Office is recommending that governments temporarily suspend implementation of the standard until these legal issues are resolved. In the meantime, the IPPC Secretariat is undertaking to establish a new mark, which is anticipated in the latter part of 2002. Members will be notified immediately when the standard can be implemented again.

RESPONSES TO SPECIFIC ISSUES SET OUT IN THE FINAL INVENTORY OF ISSUES RAISED BY STAKEHOLDERS IN RESPONSE TO THE DRAFT IRA ON NEW ZEALAND APPLES

Table of Contents

Part 1 - General

1 Agricultural chemicals

1.1 Antibiotics were recommended without examining the health threat to the Australian community and the fact that they were not registered in Australia.

The draft IRA acknowledges that New Zealand apple growers are permitted to use antibiotics to control fire blight and this fact was considered during the risk assessment. However, the risk management measures proposed in the draft IRA do not include the use of antibiotics. Nevertheless, the RAP considers that stakeholders have raised important and inter-related issues in relation to antibiotics and will address these comments in its analysis.

1.2 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.

The regulation of food safety in Australia *per se* is outside the scope of this analysis. Imported apples would be required to meet appropriate Australian food standards. Food Standards Australia and New Zealand (FSANZ) has responsibility for these standards. However, the RAP considers that stakeholders have raised important and inter-related issues in relation to antibiotics and to resistant *Erwinia amylovora* and will address these comments in its analysis.

1.3 Are antibiotics used in organic production?

BA understands that streptomycin, which is the only synthetic antibiotic registered for use in New Zealand, is not used in organic production.

1.4 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.

This issue is outside the scope of the IRA. Imported fruit is required to meet appropriate Australian food standards. FSANZ has responsibility for these standards.

1.5 Because streptomycin is not registered in Australia shouldn't we be demanding zero MRLs for streptomycin on apples coming into Australia.

This issue is outside the scope of the IRA. Imported apples would be required to meet appropriate Australian food standards. FSANZ has responsibility for these standards.

1.6 Will the Australian public be made aware of the fact that the fruit from NZ has been treated with an antibiotic?

This issue is outside the scope of the IRA. Imported apples would be required to meet appropriate Australian food standards. FSANZ has responsibility for these standards.

1.7 Residual effects of streptomycin stored in honey is a concern.

This issue is outside the scope of the IRA. Imported foods are required to meet appropriate Australian food standards. FSANZ has responsibility for these standards.

1.8 There appears to be a degree of conflict in Biosecurity Australia's (BA's) position on streptomycin with imports of pear from Korea.

This issue is outside the scope of the IRA.

The position stated in the final IRA on pears from Korea was: "AQIS will advise NPQS that streptomycin is not an approved chemical for use in pome fruit orchards under Australia's regulations. Further, continuous use of streptomycin can lead to the development of resistant strains of the pathogen. A copy of the final IRA will be circulated to the Australian government agency responsible for monitoring chemical residues. It will take appropriate action if pear fruit imported into Australia is contaminated with streptomycin."

1.9 National Registration Authority (NRA) has advised that there would be great difficulty in registering streptomycin in Australia.

The RAP is aware of possible difficulties in the registration and use of control agents for fire blight such as streptomycin. These issues will be considered by the RAP in assessing the potential impact and spread of fire blight should it establish in Australia.

1.10 The Australian Food Standards Code (FSC) currently does not include an MRL for streptomycin in apples.

This issue is outside the scope of the IRA. The RAP notes that The Australia New Zealand Food Authority (now FSANZ), which has responsibility for these standards, was among the stakeholders which made this comment. If appropriate, the RAP will take into account the fact that imported fruit is required to meet appropriate Australian food standards.

1.11 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.

See 1.10

1.12 Food imported into Australia from NZ may be produced according to either the Australian Food Standards Code, or to the equivalent NZ food legislation.

See 1.10

1.13 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.

See 1.10

1.14 Propionic acid and benzalkonium chloride are not currently permitted for apples in the Food Standards Code and must not be present in unprocessed fruits.

See 1.10

1.15 The Food Standards Code includes limits on the amount of copper that apples may contain.

See 1.10

2 Apple cultivars

2.1 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.

The RAP is not aware of any government policy in this area. Further the RAP notes that the fluidity of world markets make it difficult to define an "exportable apple variety." Choice of cultivars is a commercial decision.

3 Apple imports from Japan

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

A protocol, including phytosanitary conditions, for Fuji apple imports agreed in 1998. Stakeholders were consulted during the risk analysis process.

No trade has taken place since 1998 and Japanese authorities have advised that Japanese growers have been unable to meet the stringent phytosanitary conditions. Nevertheless, the operational procedures necessary to fully implement the conditions set out in the final IRA have been developed.

4 AQIS performance

4.1 34% of new incursions of pathogens were in legally imported Fruit & Vegetable Trade" (Nairn Report. Chapter 8.)

There is no definitive list of pests[7] that have established in Australia. Information is scattered through various State/Territory and Commonwealth government systems and is very difficult to access. The authors of the Australian Quarantine Review Committee (Nairn) Report made this statement based on one of the scientific reports the committee commissioned, summaries of which are contained in appendix B to that report.

An assessment of section 3.1 of appendix B indicates that the report includes an assumption based on the information in the summary report, and as a result is inaccurate. This section states that 34% of exotic plant pathogens were associated with fruit and vegetables. The preceding paragraph indicates that 'plant materials' were the probable route of entry of 41% of introductions. It does not indicate whether or not the importation of the 'plant materials' was legal or otherwise. Nor does it say whether or not the fruit and vegetables, that were associated with 34% of exotic plant pathogens, were imported or locally grown.

Since that report, AFFA has undertaken further study and maintains information about incursions since 1996. This information has been placed on its web site (see http://www.affa.gov.au/ and follow these links - Product Integrity/Animal and Plant Health > Plant Health > Exotic Plant Pest/Disease and Weed > Incursion List) and is updated periodically. The Office of the Chief Plant Protection Officer (OCPPO), which was formed as a result of concerns raised in the Australian Quarantine Review, is the area responsible for this information.

The information on the web site illustrates the problem in interpreting pest incursion data. For example, detection of 4 of the thrips on the list resulted from just one collecting trip. Further, the Commonwealth, in cooperation with the States/Territories, has put in place formal reporting arrangements for all suspected plant pests (weeds, insects, pathogens). These have replaced various ad hoc arrangements in place up to the late 1990's and have resulted in an apparent increase in the rate of detections. Also, a significant number of the pests have been in Australia for some time before they are formally reported.

The Commonwealth is funding a Plant Health Australia project intended to build a database of all pests in Australia. This database, which was launched in May 2002,

[7]Use of the term "pest" conforms with the IPPC definition ie "Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products." to plants or plant products

will allow convenient access to pest records and provide a much better basis for tracking pest incursions and our border protection.

4.2 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).

See 4.1

4.3 The number of establishments for plant pathogens is approximately ten times greater than for animal diseases.

There are a far greater number of plant pathogens than there are animal pathogens. For example, a study commissioned for the assessment of the risks of importing bulk maize identified around 500 pathogens that could affect maize. There are also a far greater number of host plants. There is over 300 agriculturally important plant species and when ornamental and native plants are included there would be thousands of potential host species of plant pathogens present in Australia. There are also significant natural pathways for entry. For example, the most probable pathway of entry of sugar cane smut disease is via airborne spores carried on the wind from Asia.

5 BA's responsibilities

5.1 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?

Consideration of any benefits to the Australian economy of importing NZ apples is outside the scope of this analysis. Biosecurity Australia is undertaking this analysis consistent with the *Quarantine Act 1908*; *Quarantine Proclamation 1998* (including Section 70 of the proclamation and Section 5D of the Act); and Australia's treaty obligations.

5.2 Achieving a country's appropriate level of protection (ALOP) is Biosecurity Australia's role, irrespective of difficulties or costs encountered by other countries.

BA's primary role in developing quarantine policies is meeting Australia's ALOP. However, it is also a requirement to apply the least trade restrictive measure reasonably available - taking into account technical or economic feasibility - that would achieve this primary goal. There is also an obligation on importing countries to accept equivalent measures proposed by an exporting country if it can be scientifically demonstrated that they provide an equivalent level of protection.

5.3 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.

One of BA's primary roles in developing quarantine policies is meeting Australia's ALOP. Section 5D of the *Quarantine Act 1908*, together with section 70 of the *Quarantine Proclamation 1998* are compatible with WTO risk assessment

requirements and do not serve to prevent quarantine decision-makers from taking account of WTO obligations.

5.4 Any political ban of NZ apples would be a breach of WTO rules and NZ would be entitled to take countervailing action against Australia.

Quarantine measures need to conform with Australia's policy and be consistent with Australia's international obligations. Any WTO member has the right to mount an international legal challenge to any import conditions. Under WTO dispute settlement rules, a successful WTO challenge would give rise to a right of WTO-authorised retaliation in the event that adverse WTO findings were not acted upon within a reasonable period of time.

5.5 It is not Australia's place to quantify the risk, which it deems acceptable to allow entry of NZ apples.

In accordance with Section 70 of the *Quarantine Proclamation 1998*, the Director of Quarantine is bound to take into account certain things when deciding whether to grant a permit. As reflected in the WTO SPS Agreement, Australia retains sovereignty over the level of risk, which it may deem acceptable. WTO jurisprudence has clarified that such risk does not need to be expressed in quantitative terms. WTO disciplines apply to the measures determined by Australia to meet its ALOP. New Zealand has provided relevant data, but it is up to Australia to carry out its own risk assessment, in accordance with the requirements of Australian law.

5.6 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 RAP considers that stakeholders have raised important issues in relation to the onus of proof and will consider these comments in its analysis. However, the RAP notes that the relevant Australian law (See Section 5D of the *Quarantine Act 1908* and Section 70 of the *Quarantine Proclamation 1998*) requires the Director of Animal and Plant Quarantine to consider *inter alia* the level of quarantine risk.

5.7 The campaigns against imports into Australia are putting the majority of Australian farmers who depend on exports at a disadvantage.

The RAP considers that this issue is outside the scope of this analysis. See 5.1

5.8 The competitiveness of our global market for horticultural products should be improved through negotiating the relaxation of some of the requirements from other countries.

Biosecurity Australia has a comprehensive program to seek improvements to market access for Australian exports. A series of regionally based brochures that includes information on achievements in this area can been seen at the following web site:

http://www.dfat.gov.au/publications/quarantine_world_markets/index.html.

6 Benefits to consumers

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

Assessment of the benefits to Australian consumers is outside the scope of this analysis.

7 Citing personal communication

7.1 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 bibliography (see p 143 of the draft IRA) makes it clear that this reference was a document sent by email. This document is considered to be official correspondence.

7.2 The listing of personal communications and correspondence in the reference section is not part of current scientific writing.

The draft IRA is not a strict scientific document, rather it is a scientifically based policy document. In the interests of maximising the transparency of the draft IRA, it was decided to include as much detail as possible about personal communications and correspondence. Accordingly, except where not possible due to the constraints of privacy provisions, all personal communications and correspondence listed in the reference section are included on the public file.

8 Compensation

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

The purpose of the IRA process is to develop appropriate conditions to meet Australia's ALOP. There are long standing arrangements that are activated in response to incursions of all exotic pests. Under these arrangements response action is the responsibility of State and Commonwealth Governments. Plant Health Australia is currently working to establish new arrangements that include industry on a partnership basis with government.

8.2 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.

The RAP considers that this issue is outside the scope of this analysis.

9 Conflicting statements

9.1 No attempt is made to reconcile several conflicting statements.

9.2 The RAP has noted the concerns raised about conflicting statements. The RAP has the responsibility to consider all relevant information in forming its recommendations.

10 Current access bid

10.1 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?

The decision taken by BA to consider the 1999 New Zealand application was based on the request by New Zealand for Australia to set conditions for imports of apples which meet Australia's level of protection, but in doing so are least trade restrictive. This contrasts with the previous application that sought access for mature apple fruit, produced under New Zealand conditions and free from trash, with no other conditions.

10.2 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 RAP considers that stakeholders have raised important issues in relation to new information available and will address these comments in its analysis. See also 10.1

10.3 The responsibility of proposing an import system, which guarantees fire blight free apples, should not rest with Australia.

In accordance with Section 70 of the *Quarantine Proclamation 1998*, the Director of Quarantine is bound to take into account certain things when deciding whether to grant a permit. As reflected in the WTO SPS Agreement, Australia retains sovereignty over the level of risk, which it may deem acceptable. WTO jurisprudence has clarified that such risk does not need to be expressed in quantitative terms. WTO disciplines apply to the measures determined by Australia to meet its ALOP. New Zealand has provided relevant data, but it is up to Australia to carry out its own risk assessment, in accordance with the requirements of Australian law.

11 Datasheets

11.1 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 RAP considers that stakeholders have raised important issues in relation to the spread of fire blight in Europe and will address these comments in its analysis.

11.2 *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.

This change will be made.

12 Earlier access requests

12.1 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.

The RAP considers that stakeholders have raised important issues in relation to discarded apple being an inoculum source and leading to transmission of the disease to other host plant, which are flowering. This prospect was considered in great detail in the draft IRA (see pages 84-87) and it will be considered further in the current analysis.

12.2 Wasn't the [unsuccessful] 1989 modified proposal based on a quasi 'area freedom' concept?

The 1989 proposal was essentially as systems approach, based on block freedom, in orchards situated in low risk areas. The low risk areas were to be determined by the Billings predictive model using climatic data and block freedom was to be verified by DNA testing of immature fruit. Block freedom was to be supported by a requirement that no non-commercial hosts be within 250 m of apples sourced for Australia and a post harvest dip in 100 ppm of chlorine.

12.3 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?

The decision taken by BA to consider the 1999 New Zealand application was based on the request by New Zealand for Australia to set conditions for imports of apples which meet Australia's level of protection, but in doing so are least trade restrictive. This contrasts with the previous application that sought access for mature apple fruit, produced under New Zealand conditions and free from trash, with no other conditions.

13 Fire blight; History

13.1 The analysis of the event of outbreaks of fire blight in the world needs to be done in a transparent manner.

The RAP considers that stakeholders have raised important issues in relation to outbreaks of fire blight around the world and will address these comments in its analysis.

13.2 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.

The RAP considers that stakeholders have raised important issues in relation to the role of infected fruit in the international spread of fire blight and will address these comments in its analysis.

13.3 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 island despite quarantine regulations designed to prevent this.

The RAP considers that stakeholders have raised important issues in relation to spread of fire blight within New Zealand and will address these comments in its analysis.

13.4 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 RAP considers that stakeholders have raised important issues in relation to the international spread of fire blight and will address these comments in its analysis.

13.5 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.

The RAP considers that stakeholders have raised important issues in relation to the role of fruit in the international spread of fire blight and will address these comments in its analysis.

13.6 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.

The RAP considers that stakeholders have raised important issues in relation to the role of fruit in the international spread of fire blight and will address these comments in its analysis.

13.7 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.

The RAP considers that stakeholders have raised important issues in relation to the role of fruit in the international spread of fire blight and will address these comments in its analysis.

13.8 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.

The RAP considers that stakeholders have raised important issues in relation to the role of fruit in the international spread of fire blight and will address these comments in its analysis.

13.9 NZ scientists have tried to spread the disease using contaminated fruit and they were unable to do this.

The RAP considers that stakeholders have raised important issues in relation to the role of fruit in the international spread of fire blight and will address these comments in its analysis.

14 Formation of Biosecurity Australia

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

Management structures within the department were aligned more closely to a defined set of required outputs to enhance its efficiency and effectiveness. As part of this structural re-alignment, the import risk analysis functions, which were formerly part of the Australian Quarantine and Inspection Service (AQIS), were moved to a separate area within the department called Biosecurity Australia. Biosecurity Australia continues to conduct science-based risk analyses on access requests for commodities from other countries within the framework of government policy and WTO rules.

15 General comments

15.1 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.

The purpose of the IRA process is to develop biosecurity policy for Australia's protection from the entry, establishment and spread of unwanted pests and diseases which may cause social, economic or environmental damage, while minimising restrictions on the entry of agricultural commodities. The trade impact of imports is outside the scope of the quarantine decision-making process.

Also see 5.1 regarding Australia's obligation to consider this issue.

15.2 Apple and pear growers have maintained that this is a quarantine issue not a trade issue.

The RAP agrees with this view.

15.3 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.

Biosecurity Australia has a responsibility for considering all applications to import plant products. Biosecurity Australia is undertaking this analysis consistent with the *Quarantine Act 1908* and *Quarantine Proclamation 1998* (including Section 70 of the

proclamation and Section 5D of the Act) and consistent also with Australia's international treaty obligations

15.4 The draft IRA has failed to consider a significant body of scientific evidence, which has not been previously considered by BA.

Evidence that has not been considered will be assessed on a case-by-case basis. Scientific evidence brought to the attention of RAP will be considered in the revised IRA. The RAP requests all stakeholders to provide any new technical information they have or any that they feel has not been considered previously to the RAP. Where appropriate, the RAP has asked BA to contact stakeholders concerned to identify the evidence they claim was not considered.

15.5 The science and research that has been undertaken is flawed and biased in NZ's favour.

The RAP considers that stakeholders have raised important issues in relation to the validity of research results and will address these comments in its analysis.

15.6 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 are totally unacceptable.

The RAP considers that stakeholders have raised important issues in relation to data used and their assessment and will address these comments in its analysis.

15.7 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: 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".

The RAP considers that stakeholders have raised important issues in relation to the efficacy of the measures proposed in the draft IRA and will address these comments in its analysis.

15.8 Claims regarding the levels of risk of pests and pathogens entering and becoming established in Australia are flawed.

The RAP considers that stakeholders have raised important issues in relation to the levels of risk of pests and pathogens and will address these comments in its analysis.

15.9 There should be a penalty on those countries that inflict fire blight on countries free of the disease.

The RAP considers that this issue is outside the scope of this analysis. Current international agreements place the emphasis on the importing country's government conducting an appropriate risk analysis and putting in place appropriate arrangements to protect its country from pests.

15.10 The Australian government's continuing ban on imports of NZ apples is unacceptable.

Quarantine measures need to conform with Australia's policy and be consistent with Australia's international obligations.

15.11 Unfortunately, in the zealot drive for free trade, Australian negotiators have made unnecessary concessions without corresponding advantages for our exporters.

Quarantine measures need to conform with Australia's policy and be consistent with Australia's international obligations.

15.12 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.

The RAP considers that this issue is outside the scope of this analysis. Current international agreements place the emphasis on the importing country conducting an appropriate risk analysis and putting in place appropriate arrangements to protect itself from pests.

Fire blight, is endemic and widespread in many countries and there would be little prospect of eradication.

15.13 A key Centre for quarantine -related risk analysis should be established to enhance Australia's standing in this field.

The RAP considers that this issue is outside the scope of this analysis.

The principal requirements for comprehensive risk analysis include expertise in modelling, epidemiology, statistics, economics and communications. The Government believes that this is best achieved by the current practice of drawing upon as wide as possible a pool of expertise, including experts within government (both Commonwealth and State), within academia and industry, and in the private sector (both in Australia and overseas).

15.14 Australian growers will be pleased at the prospect of going into yet another trade season without competition with NZ apples.

The RAP considers that this issue is outside the scope of this analysis.

Government policy is to conduct a comprehensive risk analysis in consultation with stakeholders. Given the range of issues and the level of stakeholder interest, this is a lengthy process. Nevertheless, Biosecurity Australia has committed significant resources to ensure that this IRA is completed in a timely manner, regardless of the outcome.

15.15 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.

The assessment of distribution potential for potential quarantine pests other than *Erwinia amylovora* is included under the heading of probability of entry. For *Erwinia amylovora* a separate heading was included.

16 General comments; Additional research[8]

16.1 Would Biosecurity Australia be prepared to re-evaluate their position in the light of further information?

Evidence that has not been considered will be assessed on a case-by-case basis. Scientific evidence brought to the attention of RAP will be considered in the revised IRA.

16.2 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.

The RAP considers that stakeholders have raised important issues in relation to pathways of infection and will address these comments in its analysis.

16.3 Controlled trials should be conducted by AQIS to check whether bacteria can enter Australia on fruit.

The RAP considers that stakeholders have raised important issues in relation to pathways for infection and will address these comments in its analysis.

16.4 Research should be carried out from varieties of apple that will be imported from NZ.

The RAP considers that stakeholders have raised important issues in relation to the validity of research data and will address these comments in its analysis.

17 General editing

17.1 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.

All BA documents are rigorously edited for technical veracity. Since publication of the draft IRA Biosecurity Australia has strengthened its documentation process by engaging a full time scientific editor to assist in the preparation of policy documents such as draft IRAs.

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

17.2 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.

This 'example' was taken from line 31 page 35 of the draft IRA, and refers to the rationale for undertaking the pest categorisation in two stages. Although the use of imprecise terms should be avoided, in this context Biosecurity Australia cannot see a real need for greater precision.

17.3 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.

Agreed.

17.4 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.

Biosecurity Australia notes this comment and will make the necessary changes to its risk assessment documentation.

17.5 The columns of figures should be aligned to the right side not to left side. Percentages are given but no sample sizes are provided.

Tables 3 and 4 conform to the style of the other 14 tables in the draft IRA. Biosecurity Australia notes that these tables may have been clearer if the numbers were aligned to the right.

18 International relations

18.1 Damage to relations with sister industry in NZ because Australian industry has to refute impractical management measures proposed by the Quarantine Service.

Biosecurity Australia is undertaking this IRA consistent with the *Quarantine Act 1908* and *Quarantine Proclamation 1998* (including Section 70 of the proclamation and Section 5D of the Act) and consistent also with Australia's international treaty obligations

18.2 New Zealand politicians and fruit growers seem to lack an of appreciation of the seriousness of the fire blight disease to Australia.

This is not relevant to Biosecurity Australia's consideration of the risk involved.

19 Japanese protocol

19.1 The Japanese experience is that MAFNZ failed to comply with the requirements in both orchard inspections and fruit inspections.

The RAP understands that Biosecurity Australia has investigated a range of such claims. This included obtaining confirmation from the Japanese authorities that media report about rejections on arrival in Japan. The investigation found no basis for

such claims and that the media reports were false. Biosecurity Australia also advises that Australia's experience has been one of proper compliance by MAFNZ.

Nevertheless, the RAP considers that stakeholders have raised important issues in relation to the integrity of phytosanitary protocols and will address these comments in its analysis.

19.2 Consultation with Japan and studying their protocols prior to the release of the draft IRA would also be a logical expectation.

The RAP understands that Biosecurity Australia referred to published literature which included information on the Japanese requirements. Nevertheless, the RAP considers that stakeholders have raised important issues in relation to New Zealand's exports to Japan and will address these comments in its analysis.

19.3 The Japanese protocol is much stricter.

The RAP considers that stakeholders have raised important issues in relation to New Zealand's exports to Japan and will address these comments in its analysis.

20 Lack of co-operation by BA

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

Biosecurity Australia complied with all requirements of the *Freedom of Information Act 1982* in respect to the two requests made by the AAPGA in relation to this issue. In one case an initial decision to refuse access to a draft document was reviewed and access granted, because at the time of the review, the circumstances that initially prevented release no longer applied. In the other case, which was a request for a very large amount of information, Biosecurity Australia considered that the estimated work required to retrieve the information would unduly disrupt its current work program. As a result Biosecurity Australia refused the request in its original form. Biosecurity Australia then provided assistance to the AAPGA in framing a request that would meet the association's needs without unduly disrupting Biosecurity Australia's current work program.

21 New IRA guidelines

21.1 A review of the IRA process is supported.

Biosecurity Australia has circulated Draft Administrative Framework for Import Risk Analysis to stakeholders for comment.

The RAP will continue the process as set out in the administrative framework.

21.2 This application should be re-assessed using the new guidelines.

Biosecurity Australia has also produced a working draft of *Guidelines for Import Risk Analysis*.

The RAP will produce a revised draft IRA consistent with these guidelines.

22 NZ inspection service

22.1 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 were rejected by Japanese fire blight inspectors.

The RAP considers that stakeholders have raised an important general issue in relation to what can be expected of off-shore risk management and will address this in its analysis.

22.2 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.

The RAP considers that stakeholders have raised an important general issue in relation to what can be expected of off-shore risk management and will address this in its analysis. However, it should be noted that no MAFNZ employee was involved in the incident and this event has little relevance to any proposed orchard inspection process.

22.3 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.

The RAP considers that stakeholders have raised important issues in relation to the structure of auditing programs for any off-shore risk management and will address this in its analysis.

23 NZ motives

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

The RAP considers that this issue is outside the scope of this analysis.

24 Other

24.1 Erwinia amylovora can survive in pollen for at least one week and up to two weeks in honey at hive temperatures.

The RAP considers that stakeholders have raised important issues in relation to survival of *Erwinia amylovora* on pollen and will address these comments in its analysis.

24.2 The introduction of Western flower thrips caused an estimated crop loss of $2,000,000.

The RAP considers that stakeholders have raised important issues in relation to the potential importance of pests and will address these comments in its analysis.

24.3 What other quarantine issues are involved with importation of NZ apples?

The RAP will consider all relevant quarantine issues in relation to the importation of apples from NZ in its analysis.

25 Other access requests

25.1 This IRA will set a precedent for future IRAs, which would allow imports from countries where pests, which are not present in Australia, occur.

Each new request is subjected to an import risk analysis and a decision on import conditions taken based on Australia's ALOP and consistent with Australia's international obligations.

25.2 If this draft IRA is implemented it will set a precedent for all other industries to be exposed to other quarantine pests.

Each new request is subjected to an import risk analysis and a decision on import conditions taken based on Australia's ALOP and consistent with Australia's international obligations.

26 Other reasons for excluding NZ apples

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

Prior to the full implementation of the IRA process, the approach to conducting plant quarantine risk assessments was to seek to resolve the major issues first. Hence the responses to the applications made in 1986 and 1989 did not fully consider other pests, which on the information available at that time, may have been of sufficient concern to reject the application.

27 Possibilities versus probabilities

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

The RAP considers that stakeholders have raised important issues in relation to the need to consider realistic scenarios not theoretical possibilities and will address these comments in its analysis.

28 Production statistics

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

The intention was to provide a snapshot of the production bases in each country as part of the introduction to the draft IRA.

29 Quality of BA's work

29.1 Scientific rigour has not been fully applied.

The IRA process followed by BA is designed to ensure through technical analysis and stakeholder consultation that all relevant information is considered. A final decision is taken by the Director of Quarantine taking into account the IRA process, Australia's ALOP and Australia's international obligations.

29.2 BA must fulfil its obligation of due diligence and due care and ensure that apple industry is not put at any risk.

The IRA process followed by BA is designed to ensure through technical analysis and stakeholder consultation that all relevant information is considered. A final decision is taken by the Director of Quarantine taking into account the IRA process, Australia's ALOP and Australia's international obligations.

29.3 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.

This statement is not correct. The draft IRA rated fire blight in the highest category for disease impact.

29.4 Proper due diligence would require the original IRA (1992) with full details to be used as a reference and be included in the document.

There was no IRA produced in 1992. In November 1990, AQIS circulated a position paper, which refers to a Bureau of Rural Resources (BRR) risk assessment. It is clear that the risk assessment being referred to is an assessment of a protocol proposed by New Zealand. By today's standards it is not an appropriate risk assessment. In addition, since 1990 there have been significant advances in both scientific knowledge about *Erwinia amylovora* and systems designed to control the disease. Accordingly, judgements made in 1990 need to be completely reassessed within the current policy context, with the benefit of current scientific knowledge. Therefore, Biosecurity Australia did not think it relevant to refer to this work. In addition, the 1990 work is part of an evolving policy development process, and it was considered in the preparation of the 1998 IRA. This document was in turn considered in the development of the 2000 draft IRA.

30 Quarantine Act

30.1 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.

The RAP considers that stakeholders have raised important issues in relation to legal requirements and will address these comments in its analysis.

30.2 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.

The RAP considers that stakeholders have raised important issues in relation to non-plant pest species and orchard and packinghouse contaminants and will address these comments in its analysis.

30.3 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 or Es or Sp) = P(En) + P(Es) + P(Sp) – P(En)xP(Es) – P(Es)xP(Sp) – P(En) x P(Sp) –P (En x Es x 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. [Note: There is an error in the equation but it is reproduced here as given by the stakeholder.]

The RAP considers that stakeholders have raised important issues and will address these comments in its analysis.

31 Regional issues

31.1 A revision of the inter-state quarantine policies regarding area freedom for fire blight may be required.

The RAP considers this issue is outside the scope of the IRA. However, the Commonwealth, State and Territory governments are considering the internal consistency of Australia's quarantine arrangements, under the Primary Industries Standing Committee.

31.2 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 RAP considers that stakeholders have raised important issues in relation to regional aspects and will address these comments in its analysis.

31.3 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 RAP considers that stakeholders have raised important issues in relation to the exclusion of WA specific issues in the draft IRA and these issues will be included in its analysis.

31.4 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.

The RAP considers that stakeholders have raised important issues in relation to the prediction of the severity of fire blight and will address these comments in its analysis

32 Scientific basis of draft IRA

32.1 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.

The RAP notes that Biosecurity Australia strongly refutes this assertion. The RAP will re-consider the relevant science in its analysis.

32.2 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 RAP considers that stakeholders have raised important issues in relation to the scientific basis of the draft IRA and that these have been addressed by the formation of the RAP. The RAP will re-consider the relevant science in its analysis.

32.3 The turn around of the decision from 1998 by Biosecurity Australia is seen as the linkage to the trade issue.

The decision taken by BA to consider the 1999 New Zealand application was based on the request by New Zealand for Australia to set conditions for imports of apples. This contrasts with the earlier application that was assessed on the basis that mature healthy apple fruit should be imported from New Zealand with no specific conditions.

32.4 The draft IRA places the apple and pear industry at extreme risk in the interests of Closer Economic Relations (CER) with NZ.

BA has a responsibility to conduct a risk analysis process consistent with Australia's ALOP and international obligations.

See 32.3

32.5 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.

BA has a responsibility to conduct a risk analysis process consistent with Australia's ALOP and international obligations.

32.6 Overuse of personal communication destroyed the claim that the document based on sound science.

The RAP considers that stakeholders have raised important issues in relation to use of personal communication and will address these comments in its analysis.

32.7 The media has been totally unreasonable in misleading the public and generating the pressure onto organisation such as BA/AQIS.

The RAP considers this issue is outside the scope of the IRA. There has been considerable media coverage of this issue, with arguments both for and against permitting trade in apples being aired.

33 Scientific opinions; Conflicts of interest

33.1 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.

The RAP considers that stakeholders have raised important issues in relation to the use of expert opinions and will address these comments in its analysis.

33.2 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 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).

The RAP considers that stakeholders have raised important issues in relation to the use of expert opinion and will address these comments in its analysis. It should be noted that the Senate Rural and Regional Affairs and Transport Legislation Committee (2001) consulted Professor Aldwinckle during the course of its inquiry, and found no basis for concluding that he had conflict of interest.

34 Selective quotation

34.1 Concerned that unwarranted conclusions were drawn that are, in many cases, vastly different from those of the original authors.

The RAP considers that stakeholders have raised important issues in relation to assessment of the literature and will address these comments in its analysis.

34.2 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.

The RAP considers that stakeholders have raised important issues in relation to assessment of the literature and will address these comments in its analysis.

35 Senate inquiry into salmon products

35.1 The inquiry was critical of AQIS for relying too much on qualitative risk analysis and recommended that a more quantitative analysis be employed.

The RAP considers that stakeholders have raised important issues in relation to the type of analysis that should be applied to its assessment of NZ apples and will address these comments in its analysis. However, the RAP notes the international consensus is that both quantitative and qualitative approaches to quarantine risk analysis are valid, with the circumstances of the individual analysis determining the appropriate approach in each case.

Quarantine risk analyses are commonly qualitative and have traditionally been presented in a narrative form. Analyses presented in such a way have been criticised for a lack of objectivity. To improve the transparency and objectivity, Biosecurity Australia adopted a structured approach to the qualitative risk analysis of New Zealand apples in the original draft IRA.

35.2 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 RAP considers that stakeholders have raised important issues in relation to the conduct of the IRA on NZ apples and will address these comments in its analysis.

The government is yet to respond to the Senate report on salmon. Nevertheless, many of the concerns expressed have been addressed in the review of the IRA process. See comments under sub-heading *21 New IRA Guidelines*, above

35.3 The open publishing of the draft against the initial recommendation by the Senate Rural and transport Committee has complicated the issue.

This issue is outside the scope for the RAP. This issue was considered in the revision of the IRA process. The RAP will follow the revised process.

36 Status of draft IRA

36.1 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.

Biosecurity Australia does not accept that the draft IRA is fundamentally flawed. The revised IRA process has removed the distinction between the routine and non-routine processes. A RAP has been formed to progress consideration of New Zealand apples

36.2 The current draft IRA should be down-graded to the status of a 'discussion paper'.

There is no provision in the IRA process for a draft IRA to be downgraded to a discussion paper.

The RAP has notified stakeholders of its intention to prepare a revised draft IRA.

36.3 BA should thoroughly review the draft IRA.

This review is in progress under the direction of the RAP.

36.4 The new process be based on sound science and appropriate international standards without reference to trade issues.

The import risk analysis (IRA) on apples from New Zealand will continue to be carried out in accordance with the IRA process. This science-based administrative process is politically independent and was developed in consultation with stakeholders. It is consistent with both government policy and Australia's international obligations.

37 Supplementary information

37.1 No references are given for the "information obtained subsequently". [Page 42 line 5]

This comment is made against the methodology section. References to information used in the risk assessment are included in the risk assessment section of the draft IRA.

See pages 53-99 of the draft IRA.

38 Western Australian issues

38.1 Biosecurity have failed to make any comment on the unique position of Western Australia which is free from Apple Scab or Codling Moth.

The RAP considers that stakeholders have raised important issues in relation to the exclusion of WA specific issues in the draft IRA and these issues will be included in its analysis.

However, the RAP notes the following excerpt from page 20 of the draft IRA:

> *"Western Australia currently prohibits import of apples from the rest of Australia due to historical concerns over several pests that occur in other parts of Australia, but not in that State. Several of the pests of concern also occur in New Zealand. This IRA deals with these pests but does not propose conditions for the import of New Zealand apples into Western Australia. Biosecurity Australia will conduct a separate assessment on the issues specific to Western Australia in the future. The principal reason for this exception is that systems for quarantine management of a significant pest not present in Western Australia (apple scab,* Venturia inaequalis*) are not available at this point in time.*"

Also, although page 156 of the draft IRA classifies Codling moth as not a quarantine pest for Australia, it notes the exception of WA.

The RAP will consider the WA situation in its analysis.

38.2 Decision to import apples into mainland Australian States will impact upon a later decision about whether to import into WA.

The RAP considers that stakeholders have raised important issues in relation to the exclusion of WA specific issues in the draft IRA and these issues will be included in its analysis.

38.3 When will the assessment of NZ apples to WA be conducted?

The RAP considers that stakeholders have raised important issues in relation to the exclusion of WA specific issues in the draft IRA and these issues will be included in its analysis.

38.4 The IRA does not include all pests under official control or identify them on Table 15.

The RAP considers that stakeholders have raised important issues in relation to the exclusion of WA specific issues in the draft IRA and these issues will be included in its analysis.

Part 2 - IRA process

39 AAPGA's statistical advice

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

Biosecurity Australia has no written record of such an offer being made.

40 Authors of draft IRA

40.1 The authors name and qualification were not provided, this is totally unsatisfactory and suggests an attempt to hide a deficient document behind anonymity.

The draft IRA is a draft government policy document produced by BA with input from various AFFA staff members. The quality of the risk analysis is therefore AFFA's responsibility.

Prior to the release of this draft IRA, Plant Biosecurity moved away from a practice of including authors' names in IRA documents. This was in response to direct and unwarranted attacks on the integrity of several Plant Biosecurity staff in relation to another IRA.

The revised IRA process provides for release of certain information about the IRA team.

40.2 Do personnel in Biosecurity Australia have the qualifications or experience to make judgement?

Yes. Plant Biosecurity has a pool of plant pathologists, entomologists, risk analysts, botanists, weed scientists, disinfestation specialists and quarantine operations specialists. BA can also draw on a wide range of expertise in AFFA (eg statisticians) and in other government agencies (eg trade lawyers). All of the in-house specialists have been involved in a range of quarantine issues, including IRAs.

40.3 Were Australian scientists given the opportunity to contribute to the draft IRA?

Yes. In addition to the Australian scientists in-house, BA sought assistance from a range of Australian scientists, including three of the most experienced (with respect to *Erwinia amylovora*) plant pathologists in Australia.

41 BA's lack of co-operation

41.1 There was an initial lack of openness and timely provision of information.

BA makes every effort to fulfil all reasonable requests for information that is already in the public domain. In this instance, efforts also extended to seeking permission

from the original sources to release information that was not in the public domain. Unfortunately, delays did occur.

The revised IRA process provides for greater involvement of stakeholders, which will help to avoid unnecessary delays in the provision of information.

41.2 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.

See 41.1

42 Conclusion of IRA

42.1 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.

The RAP considers that this issue is outside the scope of this analysis. The RAP notes that changes to the existing arrangements are the responsibility of the parliament.

43 Conflicts of interest

43.1 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.

The role of government departments is to provide policy advice to government. In the context of quarantine decisions, government policy (as reflected in Section 9AA of the *Quarantine Act 1908*) vests decision making powers to the Secretary of the Department of Agriculture, Fisheries and Forestry – Australia (AFFA).

44 Consultation

44.1 Stakeholders were not consulted during the preparation of the draft IRA, therefore our input into the draft IRA was zero.

Stakeholders were informed, at the various stages (including those designated in The AQIS Import Risk Analysis Process Handbook) regarding progress during the preparation of the draft IRA. The formation of a risk analysis panel and the revisions to the IRA process will increase opportunities for stakeholders to have input into this and other IRAs.

44.2 Various elements in the protocol indicate close collaboration with MAFNZ.

Close collaboration with the government in the exporting country is the most efficient way to use government resources to obtain detailed information relevant to the risk analysis.

44.3 This draft IRA document should be published in an appropriate scientific journal and discussed at open forums of interested parties.

BA followed the process set out in The AQIS Import Risk Analysis Process Handbook. Stakeholders have had opportunities to input into the review of the process that will be used by BA for this and all future IRAs. Scientific journals would not accept government policy documents for publication. BA publishes draft IRAs. BA makes every attempt to ensure widest distribution and maximum opportunity for consultation.

44.4 The process should include a meaningful consultation with the industry. The next round of consultation should be genuine and open.

The formation of a RAP, which is determined to increase consultation, and the revisions to the IRA process will increase opportunities for stakeholders to have input into this IRA.

44.5 BA should have a decision making process that automatically takes taxpayers' concerns into account rather than ignoring them.

The RAP considers that this issue is outside the scope of this analysis.

44.6 As Australian growers why don't we have opportunity to provide input to the consequence of fire blight?

The major opportunity provided in The AQIS Import Risk Analysis Process Handbook for stakeholder input is in response to a draft IRA. Stakeholders made a significant number of comments, and the RAP will consider these in its analysis. As the RAP has also decided to conduct workshops and issue a revised draft IRA, there will be further opportunities to provide input regarding the likely consequence of fire blight entering, establishing or spreading in Australia.

45 Cost of process

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

The RAP considers that this issue is outside the scope of this analysis.

45.2 Each period of uncertainty creates delays, which place heavy burdens on the future success of the industry.

Unfortunately, it is inevitable that a thorough analysis of detailed scientific issues combined with extensive consultation will take a significant time. Biosecurity Australia is devoting a significant level of resources to this issue to ensure that the IRA process progresses in a timely manner.

45.3 Industry was denied dollar for dollar funding to provide a response to this draft IRA.

This matter was considered by the former Horticultural Research and Development Corporation (HRDC) and is outside the scope of the IRA process.

46 Delays in the IRA process

46.1 Period of uncertainty causes delays in investment decisions.

See 45.2

46.2 The time for Australia to make decision on import application has been taken too long, this has been criticised by other countries.

See 45.2

47 Failure to consider evidence

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

Evidence that has not been considered will be assessed on a case-by-case basis. Scientific evidence brought to the attention of RAP will be considered in the revised IRA. The RAP requests all stakeholders to provide any new technical information they have or any that they feel has not been considered previously to the RAP. Where appropriate, the RAP has asked BA to contact stakeholders concerned to identify the evidence they claim was not considered.

48 Industry reference group

48.1 BA refused to develop issues with the industry reference group.

BA established this group to assist it plan its communication with industry stakeholders. This approach had not been used in the past. Unfortunately, it became evident that it was not possible for BA to discuss issues with the group to the level necessary for this approach to have been worthwhile. With the appointment of a RAP new arrangements are in place to ensure effective communication.

49 Initiation of this IRA

49.1 The IRA process should not have commenced because MAFNZ has not provided sufficient information for a risk analysis process to be initiated.

Information for risk analysis comes from a diverse range of sources including the country of export. A significant body of information was available from earlier submissions for access for of New Zealand apples. Much of this information was provided by New Zealand. BA judged there was sufficient information to allow the IRA to proceed.

49.2 What makes the request from NZ any different to the 120 others also in front of AQIS?

New Zealand authorities consistently indicated that their highest priority technical market access request to Australia concerns apples. Other interested parties, such as Australian importers, proposed no other New Zealand product as a higher priority for

market access. Accordingly, AQIS (now BA) was obliged to consider the new request by New Zealand as a high priority.

50 IRA handbook

50.1 BA failed to adhere to the AQIS IRA handbook. Why does AQIS/Biosecurity Australia change the rules without consulting with stakeholders?

The process has followed the requirements set out in *The AQIS Import Risk Analysis Process Handbook*. However, there have been additional steps taken. AQIS/Biosecurity Australia did do this without consulting with stakeholders, because the changes added opportunities for involvement, and were therefore not seen to detract from stakeholders' rights to procedural fairness and/or natural justice.

50.2 BA has produced a range of draft documents, as part of the process, which have not been previously presented to the stakeholders for consideration.

The process of producing a draft IRA necessitates the development of various working documents. As these documents do not represent an official position they do not provide a basis on which to consult with stakeholders.

50.3 Our previous input regarding the IRA process has been ignored.

With the formation of the RAP and the changes to the IRA process, concerns regarding the pathway used to consider this application have been addressed.

50.4 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?

This comment has been superseded by the approval of ISPM 11 *Pest risk analysis for quarantine pests* by the third session of the Interim Commission on Phytosanitary Measures (ICPM) in 2001 and of the ISPM 14 entitled *The use of Integrated measures in a systems approach for pest risk management* at the fourth session in March 2002.

51 Public comment period

51.1 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.

Over 3000 comments or issues were identified by stakeholders in the consultation on the draft IRA. Comments are welcome at all times – stakeholders do not have to wait for formal comment periods. However, BA does need to set some limits on IRA processes to ensure that quarantine decisions are made in as timely a way as possible.

The appointment of a RAP and the further consultation planned will provide additional opportunities for stakeholder input.

52 Public file

52.1 All submissions must be made public.

BA policy is that contents of submissions are not treated as confidential unless they are marked 'confidential' and they are capable of being classified as such in accordance with the *Freedom of Information Act 1982*. All except two submissions made in response to the draft IRA on New Zealand apples are kept on a public file.

52.2 All scientific responses should be on the public record.

Subject to the requirements of the *Privacy Act 1988*, all scientific responses are on the public file.

52.3 The public file does not include a draft document dated 19 July 2000 for technical consultation with State and Territory Governments.

The RAP considers that this issue is outside the scope of this analysis. This document was not released to stakeholders as it was part of a consultation process with technical experts from State and Territory Governments which, in accordance with practices at that time, was confidential.

53 Public meetings

53.1 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.

The purpose of the public meetings was to familiarise stakeholders with the draft IRA in order to assist them in making written comments.

53.2 There was a lack of time to answer all questions asked at the industry meetings, which were often confined to less than one hour.

In order to facilitate attendance by growers, local arrangements for these meetings were made with the assistance from relevant grower organisations. BA anticipated the difficulty of covering a range of technical issues in detail. Accordingly, in each location BA made the general offer of a meeting with local industry leaders and technical experts, followed by another meeting with a more general audience. Where this occurred, afternoon meetings were held with local industry leaders and technical experts, followed by an evening meeting with a more general audience. All of the general meetings lasted for several hours. The duration of each meeting was at the discretion of the stakeholders.

54 Purpose of an IRA

54.1 Australia does not need to import apples in any form.

Australia has a responsibility to consider all import requests and make decisions based on our ALOP consistent with our international obligations.

54.2 BA and their Minister are compelled to defend the draft IRA, rather than heed industry concerns.

The purpose of a draft IRA is to set out a preliminary view and facilitate consultation.

54.3 The draft IRA indicated the lack of knowledge on fire blight and the risk of fire blight entry with mature apple fruit.

The RAP considers that stakeholders have raised important issues in relation to the information on which the IRA is based and will address these comments in its analysis. The RAP has a responsibility to consider all relevant information in reaching its recommendations.

55 Role of environment portfolio

55.1 Draft IRA raises significant environmental issues and that the proposal should be formally referred to the Environment Minister under the terms of the Act.

The RAP considers this issue is outside the scope of the IRA. AFFA and Environment Australia (EA) are developing a memorandum of understanding on how they will work together to develop and review biosecurity policy. Biosecurity Australia is also developing guidelines in consultation with EA that will help AFFA officers with environmental aspects of IRAs.

55.2 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.

The RAP considers that environmental issues are important and will address these comments in its analysis.

56 Role of state departments of agriculture

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

There were no confidentiality agreements as such. AQIS (now BA) held confidential meetings with representatives of the State Departments to obtain specific technical information. See 52.3 also.

57 Senate inquiry into apples

57.1 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.

The Rural and Regional Affairs and Transport Legislative Committee tabled an interim report in July 2001. The Government is still considering this report. However, changes being made to the IRA process address many of the recommendations made in the report.

58 Significant variation to process

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

IRAs are conducted under an administrative process and, if circumstances change, there is flexibility to alter the process followed. Where significant variations have been made, Biosecurity Australia has advised stakeholders.

59 Stakeholder issues

59.1 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.

Biosecurity Australia maintains a register of IRA stakeholders and periodically advertises this fact in the national press and invites interested parties to register for specific IRAs or interest categories. General correspondence in relation to IRAs also invites recipients to nominate additional stakeholders. In order to comply with privacy legislation, Biosecurity Australia does not add people to this database without their prior permission.

59.2 The Honey bee industry has not been involved with the consultation process at the early stage of this IRA.

Representatives of this industry were listed on the stakeholder register and were sent all relevant documents.

60 Transparency

60.1 The risk analysis process has not been transparent.

The issues in relation to transparency have been addressed by the new IRA process and formation of the RAP.

60.2 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.

The RAP considers that stakeholders have raised important issues in relation to transparency. However, the RAP notes that BA considered this issue in the review of the IRA process.

BA considers that it is very difficult to have consultation with all stakeholders without unrestricted release of relevant documents.

61 Use of routine process

61.1 BA has failed to adequately consider stakeholders' comments regarding the pathway used to consider this application.

With the formation of the RAP and the changes to the IRA process, this issue has been addressed.

61.2 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.

With the formation of the RAP and changes to the IRA process, this issue has been addressed.

61.3 The draft IRA hardly fits into the category of 'technically less complex'.

With the formation of the RAP and changes to the IRA process, this issue has been addressed.

61.4 The routine approach of the risk analysis excluded major industry input into the research and minimised consultation with the industry.

With the formation of the RAP and changes to the IRA process, this issue has been addressed.

61.5 BA is required to withdraw the current draft IRA and institute a new IRA utilising the non- routine pathway.

With the formation of the RAP and changes to the IRA process, this issue has been addressed.

Part 3 - Methodology

62 ALOP

62.1 Australia should not have to reduce quarantine standards by being a member of WTO. Do you think any other country would accept the risks to their land should the situation be reversed?

Every WTO member has the right to set its own Appropriate Level of Protection (ALOP). In practice it is impossible to implement a nil-risk policy as this would require all trade and international movement of passengers to be stopped and a mechanism found to prevent natural pathways of entry (for example, windborne spores or flighted insects). The Government has consistently and explicitly set Australia's ALOP at a high or very conservative level aimed at reducing risk to very low levels.

62.2 AQIS/BA cannot define Australia's ALOP.

This is correct. ALOP is determined by broad community preferences as expressed in Government policy.

62.3 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.

In the draft IRA Biosecurity Australia provided a qualitative description of 'very low' and equates this with Australia's ALOP. Australia has been looking at other ways of expressing its ALOP but as with all other WTO Members, recognises that the difficulty of providing a more precise definition that can be applied to all cases. Like other WTO Members, Australia relies for an indication of its ALOP on community preferences as expressed in Government policy. Quarantine decision makers obtain more specific guidance from current quarantine policies and practices. Because the ALOP is a central tenet of the SPS Agreement, it is important to ensure that any statement is robust and can encompass all situations. This issue was considered in May 2002, at the meeting of all State and the Commonwealth agriculture ministers (Primary Industries Ministerial Council), in light of the work done to date on the policy framework surrounding ALOP. This work includes the draft *Guidelines for Risk Analysis*, which illustrates the concept by way of a risk estimation matrix. It was agreed that the current level of definition of ALOP adequately meets Australia's present needs, and that further work on ALOP definition should not be a priority.

62.4 ALOP set in the draft IRA was not high enough for such an extreme economic consequence disease such as fire blight.

It is important to note that the government is obliged to set quarantine policy on the basis of a relevant international standard or a risk assessment. This requires an assessment of the likelihood of entry, establishment and spread of a pest and the likely

consequences that would accrue if these events occurred. The draft IRA also sets out an initial view on measures that BA believed at that time would meet the government's ALOP. The concept of the ALOP and the way it is to be applied has been further elaborated in the draft *Administrative Handbook for Import Risk Analysis*

62.5 Australia's ALOP appears to have been defined quite arbitrarily and unrealistically, and it conveniently supports the conclusion that apple should be permitted.

Australia's ALOP is set by the Government. Since the draft IRA was published in October 2000, further work has been done on the description of ALOP and the RAP will utilise these developments.

62.6 The view that the quarantine risk can be managed, is an acknowledgment that the risk does exist.

This is correct. The draft IRA also set out an initial view on measures that would meet the government's ALOP.
See 62.1

62.7 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.

ALOP is a constant. The measures required to achieve the ALOP may vary in different areas within a member's territory.

62.8 The issue of resources should not be a limit to achieving as close to zero risk as possible.

One of BA's primary roles in developing quarantine policies is meeting Australia's ALOP. However, it is also a requirement to apply the least trade restrictive measure reasonably available - taking into account technical or economic feasibility - that would achieve this primary goal. There is also an obligation on importing countries to accept equivalent measures proposed by an exporting country if it can be scientifically demonstrated that they provide an equivalent level of protection. [This comment is equivalent to 5.2]

62.9 As Australia is still free from many serious plant diseases, we should have the right and responsibility to maintain strict quarantine conditions.

Australia does have this right, provided certain obligations are fulfilled, including basing measures (which includes a ban) on a science-based risk analysis or a relevant international standard. See 62.1

62.10 Australia's ALOP should be introduced at the risk management stage of the draft IRA, and not during the risk assessment stage.

The Government has consistently and explicitly set Australia's ALOP at a high or very conservative level aimed at reducing risk to very low levels, while not based on a

zero-risk approach. This is not the same as ascribing cautious risk estimates to certain events as a method of addressing uncertainty.

62.11 There should be a zero risk policy and no import of NZ apples under the present protocol.

Every WTO member has the right to set its own Appropriate Level of Protection (ALOP). In practice it is impossible to implement a nil-risk policy as this would require all trade and international movement of passengers to be stopped and a mechanism found to prevent natural pathways of entry (for example, windborne spores or flighted insects). The Government has consistently and explicitly set Australia's ALOP at a high or very conservative level aimed at reducing risk to very low levels.

One of BA's primary roles in developing quarantine policies is meeting Australia's ALOP. However, it is also a requirement to apply the least trade restrictive measure reasonably available - taking into account technical or economic feasibility - that would achieve this primary goal. There is also an obligation on importing countries to accept equivalent measures proposed by an exporting country if it can be scientifically demonstrated that they provide an equivalent level of protection.

63 Association with apples

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

The RAP considers that stakeholders have raised important issues in relation to the scope of the analysis and will address these comments in its analysis.

The RAP will consider all pests that could be associated with import of apple.

64 Australian standard for risk assessment

64.1 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.

The RAP considers that stakeholders have raised important issues in relation to the approach taken to the risk analysis and will consider the available range when deciding how to proceed.

The RAP notes that section 4.3.4 of AS/NZS 4360:1999 indicates that the informative guidelines "… need to be tailored to meet the needs of the individual organisation or the particular subject of the risk assessment." Australia uses international standards, in particular, ISPM No 11: *Pest risk analysis for quarantine pests* in assessing the importation of plant products

64.2 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.

The RAP notes that improving communication with stakeholders is one of its key duties while undertaking this analysis. The RAP will consider AS/NZ standard but it will be guided by the ISPM 11 *Pest risk analysis for quarantine pests* and the draft *Guidelines for Import Risk Analysis* which address criteria for characterising risk.

65 Definition of 'endangered area'

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

The 'endangered area' was defined in the IRA as any area within Australia, where susceptible hosts are present, and in which ecological factors favour the establishment of a pest that might be introduced in or on apple fruit from New Zealand.

Specific geographic locations were not identified, as most regions within Australia are likely to support the establishment and spread of the pests and diseases of concern. Therefore, it was not necessary to limit the analysis in a geographical sense and providing additional information on this issue was judged to be unnecessary.

66 Definition of a quarantine pest

66.1 The draft IRA infers that pests need to be under official control to meet the definition of a quarantine pest.

The IPPC definition of a quarantine pest is *"A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled."* The RAP notes that in the situation where a pest is not widely distributed, a pest risk analysis can determine if it should be placed under official control. However, it is not the purpose of an IRA on NZ apples to determine whether or not pests that occur in some part of Australia should or should not be placed under official control.

66.2 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 apples from NZ, therefore, they proposed a stringent protocol.

Australia's international obligations require us to do scientifically sound risk analysis and set appropriate risk management measures to meet our ALOP.

67 Description of likelihoods

67.1 Where do the classifications and associated descriptions come from? Are they internationally recognised?

The RAP notes that classifications were outlined in the draft and are further discussed in Biosecurity Australia's draft *Guidelines for Import Risk Analysis*.

67.2 Risk assessments are expressed in purely qualitative terms and distinctions between categories cannot be assessed as to acceptability.

The RAP has agreed to follow a semi-quantitative or quantitative approach where appropriate and practical.

67.3 If the probabilities are 'normally distributed' there should be three quantitative categories below the 'moderate' and three above.

The RAP considers that stakeholders have raised important issues in relation to the description of likelihoods and will address these comments in its analysis. However, the RAP notes that categories were chosen so as to provide for more precise classification for likelihoods closer to zero and it will use the categories as given in the draft *Guidelines for Import Risk Analysis*.

67.4 The median values and ranges which lie behind qualitative likelihoods become critically important when a risk matrix is to be developed.

The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis*.

67.5 67.5 Why use the terms primary and secondary plant species at risk, if 'primary' and 'secondary' do not indicate the magnitude of possible loss.

The RAP considers that stakeholders have raised important issues in relation to the terminology used to describe the risk assessment and will address these comments in its analysis.

68 Environmental assessment

68.1 Serious deficiencies in risk assessment methodology have led to an underestimation of the risk to the environment from pests.

The RAP considers that stakeholders have raised important issues in relation to risk assessment for environmental pests and will address these comments in its analysis.

68.2 Poor consideration was given to Australia's environment including our flora.

See 68.1

69 Estimation of consequences

69.1 There is no attempt made to quantify economic consequences and no consideration of environmental or social consequences in the risk estimation methodology.

The RAP considers that stakeholders have raised important issues in relation to assessment of consequences and will address these comments in its analysis. However, the RAP agrees that the consequence assessment followed the guidelines set out in the methodology section of the draft import risk analysis. Further, the RAP notes that both environmental and social effects are stated explicitly in the guidelines and in the case of fire blight, the consequences were in the highest category. The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis*.

69.2 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.

The RAP considers that stakeholders have raised important issues in relation to the classification of economic consequences and will address these comments in its analysis. However, the RAP agrees that the consequence assessment followed the guidelines set out in the methodology section of the draft import risk analysis. The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis*.

69.3 An arbitrary scale has been used for economic consequences in the risk estimation matrix.

The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis*.

69.4 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.

The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis*.

69.5 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'). AFFA should provide a clear explanation.

The RAP considers that stakeholders have raised important issues in relation to the terms used in this aspect of the assessment and will address these comments in its analysis. In this regard, the RAP notes that the draft *Guidelines for Import Risk Analysis* include a revised method of assessing economic impact.

70 General

70.1 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 methodology should be undertaken.

The RAP considers that stakeholders have raised important issues in relation to external review of the methodology used by BA and will address these comments in its analysis. The RAP notes that in revising the IRA process BA has consulted widely on methodology.

70.2 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.

The RAP considers that stakeholders have raised important issues in relation to the combination of likelihoods and the assessment of risk and will address these comments in its analysis.

70.3 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 RAP considers that stakeholders have raised important issues in relation to combination of likelihoods and will address these comments in its analysis.

70.4 The matrix contained in the draft IRA overestimates risk unless it is used for combining only two probabilities.

The RAP considers that stakeholders have raised important issues in relation to combination of likelihoods and will address these comments in its analysis. However, the RAP notes that the matrix was designed to be conservative - a philosophy adhered to throughout Biosecurity Australia assessments in which knowledge is imperfect and the outcome of measured events significant.

70.5 AFFA has not assessed separately the four key risks that they seek to manage (i.e. bacterial infection of mature fruit in orchard or after harvest; infestation of the calyx-end of the fruit; epiphytic contamination of fruit surfaces; and the presence of trash with imported fruit.) A separate assessment of these risks will, stakeholder believes, demonstrate that the measures proposed by AFFA are not justified.

The RAP considers that stakeholders have raised important issues in relation to the pathway used to represent relevant steps in the importation of apples and will address these comments in its analysis.

70.6 AFFA should explain the way in which each measure reduces risk (i.e. the scientific basis of the measure), and also the extent to which the measure is believed to reduce risk.

The RAP considers that stakeholders have raised important issues in relation to the scientific basis of the measure and will address these comments in its analysis. The RAP notes that the intended effect of each measure was stated explicitly following its description.

70.7 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.

The RAP considers that stakeholders have raised important issues in relation to the combination of likelihoods and the assessment of risk and will address these comments in its analysis.

70.8 Draft IRA draws on four differing methodologies for determining the probability of entry, establishment and spread.

The RAP considers that stakeholders have raised important issues in relation to the context in which IRA are undertaken and will address these comments in its analysis.

70.9 The assessment does not clearly focus on the risk as being in the trade in apple fruit.

The RAP considers that stakeholders have raised important issues in relation to the pathways established in the draft IRA and will address these comments in its analysis.

70.10 The approach to risk estimation is severely flawed and it is not appropriate to attempt to rework the economic consequences or unrestricted risk.

The RAP will follow the approach outlined in the draft *Guidelines for Import Risk Analysis*.

70.11 [Application of] the risk analysis methodology has not been transparent or consistent.

The RAP considers that stakeholders have raised important issues in relation to transparency and consistency and will address these comments in its analysis.

70.12 BA methodology of subjective assessment of each probability event is sufficiently robust and consistent with the approach used by WTO members.

The RAP considers that stakeholders have raised important issues in relation to the robustness of the methodology used in the draft IRA and will address these comments in its analysis.

71 Independence of events

71.1 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.

The RAP considers that stakeholders have raised important issues in relation to the structure of the risk assessment and will address these comments in its analysis.

71.2 Assumptions are made about the independence of various steps in the 'importation scenario' that has led to a questionable methodology for combining likelihoods.

The RAP considers that stakeholders have raised important issues in relation to the combination of likelihoods and will address these comments in its analysis.

71.3 Arbitrary distinctions have been made between entry, establishment, spread and consequences that resulted in double counting of establishment and spread and artificially reduced the assessed risk.

The RAP considers that stakeholders have raised important issues in relation to pathway used in the assessment and will address these comments in its analysis.

71.4 The rationale behind the method of combining risks is not transparent.

The RAP considers that stakeholders have raised important issues in relation to combination of likelihoods and will address these comments in its analysis.

71.5 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.

The RAP considers that stakeholders have raised important issues in relation to pathway used in the assessment and will address these comments in its analysis.

71.6 For fire blight 'entry' has been broken down to two components -'importation' and 'distribution' but for all other pests 'entry' is treated a single issue.

The RAP considers that stakeholders have raised important issues in relation to pathway used in the assessment and will address these comments in its analysis.

72 International standards

72.1 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.

The RAP considers that stakeholders have raised important issues in relation to the use of international standards and will address these comments in its analysis.

72.2 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.

The RAP considers that stakeholders have raised important issues in relation to interpretation of international standards and will address these comments in its analysis.

72.3 Before pest free production site status be granted, the growers must demonstrate a 'pest free' status, not just a symptomless status.

The RAP considers that stakeholders have raised important issues in relation to interpretation of international standards and will address these comments in its analysis.

72.4 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.

The RAP considers that stakeholders have raised important issues in relation to ISPM 'The principles of plant quarantine as related to international trade' and will address these comments in its analysis.

72.5 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 RAP considers that stakeholders have raised important issues in relation to consistency with existing quarantine policies and will address these comments in its analysis. However, the RAP notes that fire blight does not occur in these countries and that where similar diseases do occur their distribution is limited and they are under official control.

72.6 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 cannot be justified.

The RAP considers that stakeholders have raised important issues in relation to interpretation of international standards and will address these comments in its analysis.

72.7 The 'quotes' from Standards (eg. ISPM 4) used are not complete and are misleading.

The RAP is aware of the ISPMs and will consider these in its analysis

72.8 It is inappropriate to use draft standards (eg 'quarantine pests' and 'systems approach') which are deficient in a number of areas.

This comment has been superseded by the approval of ISPM 11 *Pest risk analysis for quarantine pests* by the third session of the Interim Commission on Phytosanitary Measures (ICPM) in 2001 and of the ISPM 14 entitled *The use of Integrated measures in a systems approach for pest risk management* at the fourth session in March 2002.

72.9 Australia's standard for area freedom in other import protocols is large scale "Area Freedom" eg. Korea – 15 km, Japan –disease free islands only.

The RAP considers that stakeholders have raised important issues in relation to consistency with existing quarantine policies and will address these comments in its analysis.

72.10 What are the internationally known management systems that are to be used in maintaining pest freedom?

The RAP considers that stakeholders have raised important issues in relation to international standards and will address these comments in its analysis.

72.11 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?

The RAP notes that Australian input during the development of ISPMs is developed through a consultation mechanism with State and Territory departments responsible for agriculture.

73 Iso-risk curve

73.1 The iso-risk curve (figure 5) conveys absolutely no meaningful information.

The iso-risk curve represents the principle behind the risk estimation matrix. This matrix in turn conveys the decision rules used by Biosecurity Australia to combine the likelihood and consequence elements of biosecurity 'risk'. The concept and principles of the matrix have been used worldwide - a similar matrix appears in the Australian/New Zealand Standard for Risk Management (AS/NZS 4360:1999).

73.2 Iso-risk curve has the undesirable effect of reducing, to a smaller extent, the positive effect of an extreme consequence.

The stakeholder is arguing that an extreme consequence is not given enough weight in the risk estimation matrix. This matrix combines likelihood and consequence elements to give an estimate or 'risk', or 'expected impact'. Hence, the structure of this matrix needs to be considered together with the descriptions of the various inputs. It is important to note that Biosecurity Australia has made adjustments to this aspect of the methodology and that the draft *Guidelines for Import Risk Analysis* include a more detailed description than was provided in the draft IRA.

73.3 The iso-risk curve should be 'shifted to the left' by approximately one order of magnitude for fine-tuning judgements.

See 73.2

74 Method of estimation

74.1 Were the ratings qualitative, quantitative or personal judgements?

The ratings made in the draft IRA were qualitative and made against the classifications described in the methodology section. Individual ratings were made in the context of the available information, both qualitative and quantitative. Preference was given to information published in scientific journals. However, where information was limited other sources were relied on, including the judgement of various international experts.

74.2 Can you provide level of fire blight incidence (in percentage of infection) that were called severe or negligible level in NZ?

Plant diseases can be measured in three ways. (1) the incidence of the disease i.e. the number or proportion of plant units infected (2) the severity of the disease i.e. the proportion of the area or units of plant tissue that is infected (3) the yield loss caused by the disease i.e. the amount of crop loss as a result of the disease.

There is no standard for reporting the level of fire blight infection in New Zealand. Comprehensive and detailed information on the incidence of fire blight is not available. Occasionally, estimated crop losses are reported for some apple production areas. In one instance, Clark *et al*., (1993) recorded the level of fire blight infection in terms of strikes per tree, which indicates the severity of the disease. They categorised orchards into those with severe infection (75 strikes per tree), medium infection (1-2 strikes per tree) and low infection (<1 strike per tree).

74.3 How did you arrive at the probability of entry for fire blight and other quarantine pests and diseases?

The procedure followed is described in the methodology section of the draft IRA.

75 Organic production

75.1 The organic products are likely to have a much higher incidence of fire blight within the orchard and on fruit.

The risk management proposed in the draft IRA would be applied equally to prospective imports of mature apple fruit from all sources, including non-commercial as well as different types of commercial production. Where the requirements could not be met, export would not be permitted.

75.2 What additional and/or new requirements will be placed on organic Registered Export Blocks to meet Australia's ALOP.

See 75.1

75.3 What protocols does Biosecurity Australia recommend for organic packing facilities?

See 75.1

75.4 Is chlorine certified as an approved chemical within an organic packing facility?

If a protocol is established and organic fruit cannot be produced in accordance with it, then the fruit could not be exported.

76 Pathways

76.1 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.

In the draft IRA, "waste" was defined as "the unconsumed part of the apple (for example, core, skin or whole fruit) discarded by the consumer, by a wholesale or retail distributor, or by a manufacturer." This definition provides for the broadest consideration of pathways, including whole apples discarded in bulk by a wholesaler.

The RAP will reconsider all relevant pathways in its analysis.

76.2 Seed is part of the infested fruit and should be identified at Step 2. Technically it is not a waste.

The RAP will consider all relevant pathways in its analysis.

76.3 Contaminated fruit packages are a potential pathway for entry of fire blight to Australia.

The RAP will consider all relevant pathways in its analysis.

76.4 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 RAP will consider all relevant pathways in its analysis.

76.5 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.

The RAP is aware of the potential host range of pests that may be associated with New Zealand apples and will consider this in the analysis.

76.6 Is dried bacterial ooze another pathway for fire blight to enter Australia?

The RAP will consider all relevant pathways in its analysis.

76.7 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.

The RAP will consider all relevant pathways in its analysis.

76.8 Draft IRA assumes simultaneous heavy infestation throughout all production areas, a scenario that is highly improbable.

The RAP considers that stakeholders have raised important issues in relation to the likelihood of heavy infestation in New Zealand and will address this in its analysis.

77 Probability theory

77.1 It has not been shown how probability theory can apply to the qualitative expressions in the draft IRA.

The RAP considers that stakeholders have raised important issues in relation to probability theory and will address these comments in its analysis. The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis*.

77.2 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 RAP considers that stakeholders have raised important issues in relation to probability theory and will address these comments in its analysis. The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis*.

77.3 The mechanism by which Risk (R) is obtained from PxC in Table 9 is not transparent.

The RAP considers that stakeholders have raised important issues in relation to the risk estimation matrix and will address these comments in its analysis. The RAP will use the approach outlined in the draft *Guidelines for Import Risk Analysis.*

78 Qualitative verses quantitative

78.1 The risk assessment is subjective and not quantitative. The Nairn report recommended the quantitative approach.

The RAP notes that the Australian Quarantine Review Committee report (The Nairn report) concluded (on page 108) that the semi-quantitative and qualitative approaches were the most appropriate for the vast majority of import risk analyses. The RAP intends to investigate all approaches, with a view to following a semi-quantitative or quantitative approach, if appropriate and practical.

78.2 The draft IRA uses a very subjective method of assessment, therefore producing a subjective result.

The RAP considers that stakeholders have raised important issues in relation to the approach taken to the risk analysis and will consider the available range when deciding how to proceed.

The RAP intends to follow a semi-quantitative or quantitative approach where appropriate and practical.

78.3 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.

The RAP considers that stakeholders have raised important issues in relation to the approach taken to the risk analysis and will consider the advantages and disadvantages of different approaches in deciding how to proceed.

78.4 Quantitative basis for the risk estimation matrix remains a mystery.

The use of risk estimation matrices is a common approach in risk analysis. BA has revised the matrices and these are provided in the draft *Guidelines for Import Risk Analysis*.

78.5 A quantitative approach must be developed in consultation with industry stakeholders and qualified statisticians.

The RAP considers that stakeholders have raised important issues in relation to the approach taken to the risk analysis and will consider the available range when deciding how to proceed.

79 Risk assessment matrix

79.1 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.

The use of risk estimation matrices is a common approach in risk analysis. BA has revised the matrices and these are provided in the draft *Guidelines for Import Risk Analysis*.

79.2 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 use of risk estimation matrices is a common approach in risk analysis. BA has revised the matrices and these are provided in the draft *Guidelines for Import Risk Analysis*.

79.3 The matrices combining the probabilities of independent events are methodologically and statistically flawed.

The use of risk estimation matrices is a common approach in risk analysis. BA has revised the matrices and these are provided in the draft *Guidelines for Import Risk Analysis*.

80 Terminology

80.1 BA used 'importation' and 'distribution' pathways in considering Entry Potential whereas AQIS Handbook talks of Introduction Potential.

The quote from The AQIS Import Risk Analysis Process Handbook actually comes from ISPM2 *Guidelines for Pest Risk Analysis*, which is provided in an annex to the handbook, and is not part of the handbook itself. The term introduction is defined as "the entry of a pest resulting in its establishment." In order to provide some consistency between this international standard and Australia's quarantine legislation, which requires an assessment of the entry, establishment or spread, the term

introduction was not used. So that the components of entry could be studied in more detail, this step was broken down using the terms importation and distribution. Therefore the likelihood of importation, distribution and establishment equates to introduction potential. (see figure 2, page 36 of the draft IRA)

80.2 What is the formal definition of entry?

Entry (of a pest) is defined as the "movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled." (see Glossary of Terms, page 7 of the draft IRA)

80.3 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.

The RAP considers that stakeholders have raised important issues in relation to the relationship between 'likelihood', 'consequence' and 'risk' and will address these comments in its analysis.

81 Uncertainty

81.1 Uncertainty should be explicitly addressed so that decision-makers and the public can recognise that some hazards might not be well enough understood to be simply classified as, for example, 'very low'.

The RAP considers that stakeholders have raised important issues in relation to the explanation of how uncertainty is accounted for and will address these comments in its analysis.

81.2 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 RAP considers that stakeholders have raised important issues in relation to dealing with incomplete knowledge and will address these comments in its analysis.

81.3 The uncertainties involved in probability estimates, when combined to yield cumulative probabilities, gives rise to a cumulative multiplication of those uncertainties.

The RAP considers that stakeholders have raised important issues in relation to cumulative uncertainties and will address these comments in its analysis.

82 Use of case studies

82.1 There are deficiencies trying to develop risk analyses and phytosanitary measures on the basis of published literature alone.

The RAP will take into account all relevant information in reaching its recommendations.

82.2 The draft IRA cannot be completed without such case studies of other areas where the pest in question occurs.

The RAP considers that stakeholders have raised important issues in relation to case studies and will address these comments in its analysis. However, the RAP notes that the impact of each pest in NZ and elsewhere was considered and discussed explicitly in the draft import risk analysis.

83 Use of caution

83.1 In the absence of relevant information a precautionary approach should be applied to decision-making.

The RAP notes that Australia's quarantine policy is highly conservative.

83.2 . 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 RAP considers that stakeholders have raised important issues in relation to the level of uncertainty in relation to environment impacts and will consider these comments in its analysis. The RAP will seek expert advice on the potential environmental effects of pests that may be associated with New Zealand apples.

83.3 The draft IRA relies on 'suggestions' and what may be considered 'plausible' rather than what has been proven through research.

The RAP considers that stakeholders have raised important issues in relation to evidence used in the risk assessment and will address these comments in its analysis. However, the RAP notes that Biosecurity Australia used both published information and expert opinion when assessing either the likelihood of an event or the impact of a pest in the draft IRA.

83.4 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.

The RAP considers that stakeholders have raised important issues in relation to the application of a precautionary approach and will address these comments in its analysis. The RAP notes that Australia's quarantine policy is highly conservative.

83.5 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.

The RAP considers that stakeholders have raised important issues in relation to addressing information gaps and will address these comments in its analysis. The RAP is considering the potential usefulness and practicality of additional research.

84 Volume and time factors

84.1 Volume of trade and length of time over which trade may occur have not been taken into account in the draft IRA.

The RAP considers that stakeholders have raised important issues in relation to addressing volume and time factors and will address these comments in its analysis the RAP is aware that volume and time factors are explicitly covered in the draft *Guidelines for Import Risk Analysis*. The RAP will use the approach outlined in the guidelines.

84.2 The worse case scenario indicated that between 276-570 million infested apple fruits would enter Australia each year.

The RAP considers that stakeholders have raised important issues in relation to the effect that volume of fruit has on various likelihoods and will address these comments in its analysis. The RAP is seeking expert advice on the potential volume of fruit that may be imported.

84.3 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.

The RAP considers that stakeholders have raised important issues in relation to the effect of time factors on the assessment of consequences and will address these comments in its analysis.

84.4 End use patterns and product distribution patterns have not been addressed in the assessment of risk.

The RAP is aware of different patterns of end use and distribution pathways. These will be considered in its analysis.

Part 4 - Risk assessment [9]

85 Fire blight; Consequences

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

86 Fire blight; Risk level

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

87 Fire blight; Probability of entry

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

88 Fire blight; Models

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

89 Fire blight; Establishment

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

90 Fire blight; Monte Carlo simulation

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

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

[9] In many cases every individual issue under a particular subject heading will be addressed in the revised draft IRA. In such cases the issues, as set out in the final inventory, have not been reproduced in this paper. This does not affect the status of the issues in any way and has been done solely to improve ease of reading and to save space.

91 Fire blight; Quantitative risk assessment

91.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

92 Fire blight; Consequences to honey-bee industry

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

93 Fire blight; Spread

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

94 Fire blight; A 'second line of defence'

94.1 There are no protocols or activities that reduce risk of establishment and/or spread to create a 'second line of defence'.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

95 Fire blight; Streptomycin registration

95.1 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.

The RAP is aware of possible difficulties in the registration and use of control agents for fire blight such as streptomycin. These issues will be considered by the RAP in assessing the potential impact and spread of fire blight should it establish in Australia.

96 Fire blight; Incidence in New Zealand

96.1 Can you provide level of fire blight incidence (in percentage of infection) that were called severe or negligible levels in NZ?

Plant diseases can be measured in three ways. (1) the incidence of the disease i.e. the number or proportion of plant units infected (2) the severity of the disease i.e. the proportion of the area or units of plant tissue that is infected (3) the yield loss caused by the disease i.e. the amount of crop loss as a result of the disease.

There is no standard for reporting the level of fire blight infection in New Zealand. Comprehensive and detailed information on the incidence of fire blight is not available. Occasionally, estimated crop losses are reported for some apple production areas. In one instance, Clark *et al.*, (1993) recorded the level of fire blight infection in terms of strikes per tree, which indicates the severity of the disease. They categorised orchards into those with severe infection (75 strikes per tree), medium infection (1-2 strikes per tree) and low infection (<1 strike per tree).

97 Fire blight; Biofilms and dried bacterial ooze

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

98 Fire blight; Latent infection

98.1 Fire blight bacteria can survive in a tree in a latent form for an indeterminate time.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

99 Fire blight; Competent epiphyte

99.1 Steiner (1998) has observed that Erwinia amylovora is a competent epiphyte capable of colonising and multiplying on the surfaces of plants. Furthermore, it makes little difference whether the plants colonised are susceptible or resistant to fire blight. It has also been shown that Erwinia amylovora remained viable for periods of up to 10 months on wood (Nachtigall et al. (1985) and 4 months on plastic (Keck et al. (1996). Full consideration of the characteristics of Erwinia amylovora and its ability to survive in a range of environments is required.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

100 Fire blight; Dormancy

100.1 There is insufficient scientific evidence on dormancy and disease outbreaks.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

101 Fire blight; Cross contamination

101.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

102 Fire blight; Infestation of immature fruit

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

103 Fire blight; Fruit infestation

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

104 Fire blight; Fruit infection

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

105 Fire blight; Infected trash

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

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

106 Fire blight; Infective dose

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

107 Fire blight; Infection and infestation

107.1 There is a failure to differentiate between the risk presented by infection and infestation.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

108 Fire blight; Orchard freedom

108.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

109 Fire blight; Other hosts

109.1 There are claims that plums, strawberries, blackberries, raspberries and cherries are infected by fire blight.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

110 Fire blight; Spread by seed

110.1 The analysis has ignored the possibility of apple seed being part of the pathway for fire blight.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

111 Fire blight; Apple varieties

111.1 Van der Zwet studied Delicious apples only. The apple fruits from NZ are unlikely to be varieties of Delicious apples.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

112 Fire blight; Vectors of

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

113 Fire blight; UV radiation

113.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

114 Fire blight; Viable but non-culturable

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

115 Fire blight; Laboratory testing

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

116 Fire blight; Experts opinions

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

117 Fire blight; Misquotes

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

118 Fire blight; Equivalence

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

This comment is actually referring to the New Zealand Flower thrips *Thrips obscuratus* and not to fireblight. Please refer to 173.3.

119 Pathogens; European canker

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

120 Pathogens; Data sheets

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

121 Arthropods; Leaf rollers

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

122 Arthropods; Apple blister mite

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

123 Arthropods; Apple leaf-curling midge, consequences

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

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

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

125 Arthropods; Mealybugs

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

126 Arthropods; NZ flower thrips

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

127 Arthropods; Carpophilus species

127.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

128 Arthropods; Noctuid moth

128.1 The economic consequences of Graphania mutans to the wheat industry should be thoroughly assessed.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

129 Arthropods; Black lyre moth

129.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

130 Arthropods; Oecophorid moth

130.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

131 General issues; Requirements for a valid risk assessment

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

132 General issues; Assessing data

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

133 General issues; Insufficient science

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

134 General issues; Additional pests

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

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

135 General issues; Pests, general consequences

135.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

136 General issues; Taxonomic resolution

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

137 General issues; Pests, general risk

137.1 The unrestricted risks for all pests are much higher than the BA's assessments.

137.2 The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

138 General issues; Supplementary information

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

139 General issues; Assessment of managed risks

139.1 Draft IRA lacks a risk analysis of managed risks.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

140 General issues; Consequences; General

140.1 Australian apple growers are working hard to develop a sustainable orchard and would be devastated to see new pests and diseases invade our country.

Quarantine activities are designed to meet quarantine goals through the implementation of effective control on the entry of people, animals, plants and goods that may introduce unwanted pests and diseases into Australia. BA is conducting an IRA in order to determine if the risks associated with the introduction of exotic pests via trade in apples can be managed to an acceptably low level. This IRA is consistent with both government policy and Australia's international obligations. This approach ensures that if imports are approved they will present a very low risk of introduction of new pests, which in turn would continue to safeguard the competitiveness, profitability and sustainability of Australian industry.

140.2 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.

See 140.1

141 General issues; Australian exports

141.1 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.

The RAP considers that this issue is outside the scope of this analysis.

141.2 It is inappropriate for the inspection to be 600 pieces of fruit when inspection of Australian product leaving the country is far greater.

Australia inspects exports according to import country requirements. Where there are no specific importing country requirements relating to inspection sample size, as is generally the case for fresh fruit and vegetables, AQIS applies a default. This is 600 units for consignments greater than 1000 units (and 450 for consignments less than 1000), for fresh fruit and vegetables. The objective of this sample is to enable detection of an infection/infestation rate of 0.5% with 95% confidence. Inspection for fruit flies in products going to Japan (5% of the consignment for mangoes and apples and 2% of the consignment for oranges) is an example of a specific importing country requirement. The inspection rate under the US Animal and Plant Health Inspection Service (APHIS) preclearance program for pome fruit is approximately 300 cartons. The objective of this sample is to enable detection of 1% of infested cartons (due to the likelihood of Light Brown Apple Moth (LBAM) infesting cartons), with 95% confidence. The justification for both these measures has long been under question, and at the behest of Australian exporters, BA is seeking to have them changed.

142 General issues; Consistency

142.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

143 General issues; Detail of analysis

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

Part 5 – Risk management[10]

144 Fire blight; Area freedom

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

145 Fire blight; Block freedom

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

146 Fire blight; Bee hive management

146.1 REBs should be in quarantined bee-free areas.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

147 Fire blight; Detection zone

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

148 Fire blight; Orchard surveys

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

149 Fire blight; REB management

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

[10] In many cases every individual issue under a particular subject heading will be addressed in the revised draft IRA. In such cases the issues, as set out in the final inventory, have not been reproduced in this paper. This does not affect the status of the issues in any way and has been done solely to improve ease of reading and to save space.

150 Fire blight; Harvest management

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

151 Fire blight; Harvest bins

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

152 Fire blight; Packing line requirements

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

153 Fire blight; Fruit inspection

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

154 Fire blight; Calyx infestation

154.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

155 Fire blight; Chlorine dip

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

156 Fire blight; Disinfestation alternatives – Water

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

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

157 Fire blight; Disinfestation alternatives – Cold

157.1 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.

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

158 Fire blight; Disinfestation alternatives - Irradiation

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

159 Fire blight; Fruit injury

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

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

160 Fire blight; Trash

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

161 Fire blight; On-arrival inspection

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

162 Fire blight; Cross contamination or substitution

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

163 Fire blight; General management issues

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

164 Fire blight; Prohibition

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

165 European canker; General

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

166 European canker; Orchard inspection

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

167 European canker; Latent infection

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

168 European canker; Incidence

168.1 If the incidence of the pathogen increases will Biosecurity Australia review the measures for Nectria galligena?

The RAP considers that stakeholders have made important comments in relation to this issue and will address these comments in its analysis.

169 Arthropods; Apple blister mite

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

170 Arthropods; Apple leaf-curling midge

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

171 Arthropods; Leafrollers

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

172 Arthropods; Mealybugs

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

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

173 Arthropods; New Zealand flower thrips

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

174 Arthropods; Hitchhikers

174.1 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?

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

175 Pests; General

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

176 Pests; Orchard inspections

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

177 Pests; Fumigation

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

178 Pests; Fruit inspection

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

179 Pests; On-arrival inspection

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

180 Post harvest requirements; Packaging requirements

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

181 Post harvest requirements; Storage requirements

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

182 Post harvest requirements; Definition of a pallet

182.1 What do you define as a pallet?

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

183 Post harvest requirements; Sampling

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

184 Post harvest requirements; Fruit security; Post packing

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

185 Post harvest requirements; Pre-clearance

185.1 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.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

186 Standard AQIS inspection

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

This oversight will be corrected in the revised draft IRA. AQIS's standard on-arrival inspection for fresh fruit and vegetables involves visual inspection of a randomly drawn sample (see 141.2). AQIS inspectors are trained in inspection techniques that are aimed at maximising the detection of pests and diseases. Any suspect fruit are further investigated using 10x magnification and destructive investigation if

necessary. Inspections are carried out with fruit surface temperature above 12^{o}C, on a white background and under good lighting.

187 Fruit labelling

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

See 1.6 and 188.1

188 Marketing

188.1 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.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis. However, the RAP notes that any phytosanitary measures proposed have to be assessed in relation to their effect on an identified and unacceptably high risk and in relation to other measures that could achieve the same outcome.

189 Traceback

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

190 Non-compliance

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

191 Audit provisions

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

192 Systems approach

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

193 Integrated fruit production

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

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

194 Arrangement document

194.1 What is an arrangement document? Where is this document? Why isn't it part of the Draft IRA? When will it be prepared?

The RAP considers this issue is outside the scope of the IRA. An arrangement document would be prepared only after the Director of Animal and Plant Quarantine has approved the final IRA. It is prepared by BA and specifies the required phytosanitary requirements for the importation. It is not a legal document and becomes operational only after the appropriate authorities of the importing and exporting countries sign it. There is provision for it to be reviewed at the end of first year's trade.

194.2 A grower representative (eg. from AAPGA) should be involved in the development of the arrangement document.

The RAP considers this issue is outside the scope of the IRA. Biosecurity Australia will consult with relevant industry experts during the development of the arrangement document.

194.3 'The appropriate laboratory test' should be described.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

194.4 The entire sections of the protocol on packing line and pack house hygiene and sanitation are vague and undefined.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

194.5 Details of handling rejected consignments would be required to be specified in detailed work plans.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

194.6 No guidelines are proposed about how cross-contamination or substitution is to be overcome.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

194.7 There is no methodology proposed for identifying or confirming the presence of Erwinia amylovora infection.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

194.8 What are 'specific operational procedures'?

Specific operational procedures are the field and packinghouse operations that New Zealand would be required to comply with to meet the import requirements specified by Australia. Operational procedures also spell out the roles and responsibilities of each party involved in the importing and exporting countries and these are incorporated into an in-house document referred to as the 'Work Plan', prepared by AQIS.

195 Respective roles of AQIS and MAFNZ

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

196 Risk management; Organic production

196.1 What controls are in place to deal with organic and conventional orchards?

The risk management proposed in the draft IRA would be applied equally to prospective imports of mature apple fruit from all sources, including non-commercial as well as different types of commercial production. Where the requirements could not be met, export would not be permitted.

196.2 The draft IRA did not offer the appropriate level of protection required by the organic industry.

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis. However, the RAP notes that the Director of Quarantine cannot apply a different ALOP for the organic industry. Australia's ALOP is set by the Government at a high or very conservative level aimed at reducing risk to very low levels, while not based on a zero-risk approach.

197 Risk management; Expert opinions

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

The RAP considers that stakeholders have raised an important issue in relation to this issue and will address these comments in its analysis.

198 Risk management; General

The RAP considers that stakeholders have made important comments in relation to every issue under this heading and will address these comments in its analysis.

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[i] Sources: WinSpirs 4.01 [AGRICOLA 1970-2002/03; CAB Abstracts 1972-2002/04; Zoo record 1978-2001/09; EconLit 1969-2002/04; AGNR:ABOA (Agriculture); AGNR:CARRP (Rural Research); AGNR:STREAMLINE (Natural Resources) databases], Review of Plant Pathology October 2000-June 2002 and Proceedings of the Australasian Plant Pathology Conference.

9TH INTERNATIONAL WORKSHOP ON FIRE BLIGHT PROGRAMME

SUNDAY 7 OCTOBER

1900 Workshop Registration and Welcome Reception – Hawke's Bay Club, Napier

MONDAY 8 OCTOBER

0800-0900 Registration

0900-1000 Opening

Coffee

SESSION 1 SPREAD AND ECONOMICS

Chairperson: Jean-Pierre Paulin

1015-1030 **O-1**: Present worldwide distribution of fire blight
T. van der Zwet

1030-1045 **O-2:** Chronicle of a disease foretold (that advances slowly): The 2001 Spanish situation

M.M.López, P.Llop, V.Donat, J.Peñalver, A.Rico, A.Ortiz, J.Murillo, I.Llorente, E.Badosa and E.Montesinos.*

1045-1100 **O-3:** National surveys did not detect *Erwinia amylovora* on host plants in Australia

B.Rodoni, P.Merriman, M.Kinsella, R.Gardner, R.Giles, S.Wimalajeewa, W.Zeller and T.van der Zwet*

1100-1115 **O-4:** Evaluation of buffer zone size and inspection number reduction on phytosanitary risk associated with fire blight and export of mature apple fruit.

1 R.G.Roberts*

1115-1130 **O-5:** The role of honeybees/*Apis mellifera* L. in spreading *Erwinia amylovora*

2 M.Alexandrova*, B.Cimini, E.Carpana, S.Massi, A.G.Sabatini and C. Bazzi

Posters

P-1: **A re-examination of fire blight epidemiology in England**

3 E.Billing

P-2: Standardisation of diagnostic protocols for *Erwinia amylovora* in the European Union (EU)

4 M.M.López*, M.T.Gorris, P.Llop, J.Peñalver, V.Donat and M.Cambra

P-3: Evaluations of pear fruit for presence and survival of *Erwinia amylovora* to assess risk to import into countries without fire blight

P.L.Pusey and R.G.Roberts*

P-4: Fire blight situation in Switzerland

5 T.Hasler*, H.Schärer, J.Vogelsanger, B.Schoch and A.Vignutelli

P-5: Prevalence and intensity of fire blight of pears in Israel: results of a survey conducted in 1996 to 2000

D.Oppenheim, D.Shtienberg, M.Peres, Z.Herzog, M.Zillberstaine and G. Kritzman*

P-6: Ornamental hosts of *Erwinia amylovora* and the effect of the fire blight control policy in the Netherlands

6 R. van Teylingen*

P-7: Isolation of *Erwinia amylovora*-like organisms from blighted plums (*Prunus domestica)* and potato roses (*Rosa rugosa)*

*J.Vanneste, S.Lex, M.Vermeulen and F.Berger**

P-8: Fire Blight in the Republic of Moldova: Present status of its occurrence and characteristics of its pathogen *Erwinia amylovora*

7 A.N.Nicolaev and P.Laux*

P-9: The status of fire blight disease on pome fruits in Iran

K.Rahnama and M.Mazarei*

1200-1300 Lunch

SESSION 2 EPIDEMIOLOGY AND PREDICTION

Chairperson: Gary Lightner

1300 1315 **O-6:** Tribute to the late Paul Steiner

8 G.Lightner*

1315-1330 **O-7:** A report on the three-year evolution of a fire blight outbreak in nurseries using a contaminated apple budwood source.

9 T.J.Smith*

1330-1345 **O-8:** The roles of tree age and borer damage in the infection of apple rootstocks by *Erwinia amylovora*

H.S.Aldwinckle, J.L.Norelli and M.V.Bhaskara Reddy*

1345-1400 **O-9:** Fluorescence imaging as a tool to study the infection pattern of apple roostock by *Erwinia amylovora*

10 K.Heyens , M. vande Ven, T.Deckers, T.Maes and R.Valcke*

1400-1415 **O-10:** Investigating the reliability of the easy-to-use methods to predict fire blight infection risk

11 T.Bubán*, L.Dorgai, P.Sallai and A.Varga

1415-1430 **O-11:** Changes in host susceptibility as a factor in fire blight control strategies.

12 T.Deckers* and H.Schoofs

1430-1445 **O-12:** Characterisation of an E*rwinia* sp. isolated from necrotic pear blossoms in Valencia (Spain).

*M.Rosello, A.Tarín, P.Llop, M.T.Gorris, V.Donat, S.García Vidal, L.Gardan and M.M.López**

1445-1500 **O-13:** Population of *Erwinia amylovora* in pear blossoms

G.Kritzman,H.Shwartz, A.Levin, Z.Herzog, M.Zillberstaine, D.Oppenheim, A.Yogev, M.Kimcki, B.Kirshner, I.Dornai, V.Pkerski, S.Zarka and D.Shtienberg*

Posters

P-10: Effects of weather conditions in development of trauma blight of shoots.

13 D.I.Breth*, H.S Aldwinckle and R.C.Seem

P-11: Comparison of models for blossom blight prediction in Western New York

14 D.I.Breth*, H.S,Aldwinckle and R.C.Seem

P-12: The viability and persistence of *Erwinia amylovora* associated with apple discards in an orchard. Are they potential inoculum sources?

15 R.K.Taylor*, C.N.Hale and J.W.Marshall

P-13: Overwintering of *Erwinia amylovora* in naturally and artificially infected apple shoots

16 K.Kielak., P.Sobiczewski* and J.Pulawska

P-14: Detection of *Erwinia amylovora* in and on apple tissue using PCR

*J.Pulawska and P.Sobiczewski**

P-15: Developments in the quantitative detection of fire blight in apple tissue

17 S.Keenan*, R.K.Taylor, J.Armstrong, C.N.Hale and J.W.Marshall

P-16: Predicting the occurrence of fire blight in the San Joaquin Valley of California.

18 B.Holtz*, B.Teviotdale and E.Hoffman

P-17: Development of a forecasting model to optimize biological control of blossom infection by *Erwinia amylovora*.

19 K.B.Johnson*, T.L.Sawyer and V.O.Stockwell

P-18: Rapid estimation of the epiphytic population size of *Erwinia amylovora* by PCR

20 L.Dorgai* and T.Bubán

P-19: Population dynamics of *Erwinia amylovora* on different blossom elements

T.Hasler and L.Mamming*

P-20: Application of total cellular protein and fatty acid patterns for identification and monitoring of *Erwinia amylovora*

21 R.Zarnowski and T.Lewicka

P-21: Is it possible to "import" decision support systems? A case study of fire blight in pears

H.Shwartz, D.Shtienberg, D.Oppenheim, M.Zillberstaine, Z.Herzog, M. Peres and G.Kritzman*

P-22: Pruning infected tissues as a tool to cope with fire blight in pears

M.Zilberstaine, D.Shtienberg, Z.Herzog, S.Levi, H.Shwartz, D.Oppenheim and G.Kritzman*

P-23: Reduction of fire blight severity by manipulation of pear tree water status

22 M.Toselli, B.Marangoni, C.Bazzi and D.Scudellari

P-24: *Erwinia amylovora* longevity in beehive, beehive products and honeybees/*Apis melifera* L.

M.Alexandrova, E.Carpana, M.Bigliardi, A.G.Sabatini, C.Porrini and C.Bazzi*

P-25: Effect of mineral nutrition on blossom, shoot and rootstock fire blight of young, dwarf apple trees

T.Robinson, H.S.Aldwinckle and J.L.Norelli*

P-26: **Fire blight in Emilia-Romagna (Italy): Searching possible relationships between epidemic spread, climate and territory using the regional geographic database and GIS technology**

G.Benedettini, R.Bugiani, A.Calzolari, F.Finelli, M.Gherardi, P.Govoni and G.Mazzoli*

1500-1530 Coffee

1530-1700 Discussion

"Technical issues associated with export of fruit to countries without fire blight"

Facilitator: G.Lightner

Evening Free

TUESDAY 9 OCTOBER

SESSION 3 FIRE BLIGHT MANAGEMENT

Chairperson: Ken Johnson

1 Systemic acquired resistance

0900-0915 **O-14:** Management of fire blight with gibberellin inhibitors and SAR inducers

23 K.Maxson* and A.L.Jones

0915-0930 **O-15:** Biological control of fire blight by using *Rahnella aquatilis* Ra39 and *Pseudomonas* spec. R1.

P.Laux, Ö.Baysal and W.Zeller*

2 Biological control

0930-0945 **O-16:** Enhancement of biocontrol of fire blight by combining *Pseudomonas fluorescens* A506 with the iron chelate FeEDDHA.

24 V.O.Stockwell*, K.B.Johnson and J.E.Loper

0945-1000 O-17: **P10C: a new biological control agent for control of fire blight on the New Zealand market, which can be sprayed or distributed using honey bees**

25 J.L.Vanneste*, D.C.Cornish, J.Yu, M.D.Voyle and R.J.Boyd

1000-1015 Coffee

1015-1030 **O-18:** Genes for biosynthesis of antibiotics by *Pantoea agglomerans* Eh318

S.A.I.Wright and S.V.Beer.*

1030-1045 **O-19:** Newest results on the biocontrol of fire blight on pome fruits in Germany
W.Zeller*

1045-1100 **O-20:** Interrelationships of temperature, flower development, and biological control of fire blight
P.L.Pusey*

1100-1115 **O-21:** Environmental factors affecting growth and spread of *Pantoea agglomerans* on and among blossoms of pear and apple
K.B.Johnson, V.O.Stockwell, T.L.Sawyer and D.Sugar*

Chemical management

1115-1130 **O-22:** Etiology and control of fire blight in loquat in Israel

M.Zilberstaine, S.Manulis, F.Kleitman and S.Levi*

1130-1145 **O-23:** It is possible to cope with fire blight in pears! Experience from Israel

D.Shtienberg, M.Zilberstaine, D.Oppenheim, Z.Herzog, H.Shwartz, S.Manulis and G Kritzman*

Posters

Systemic acquired resistance

P-29: Trials with applying chemical agents other than bactericides to control fire blight in pear orchards

T.Buban*, P.Sallai, L.Herelendy and E.Obsut-Tuskovsky

P-30: Studies on Systemic Acquired Resistance (SAR) effect of BTH (BION®) against fire blight

*Ö.Baysal, P.Laux and W.Zeller**

P-31: Further studies on the Induced Resistance (IR) effect of the plant extract from *Hedera helix* against fire blight

*Ö.Baysal, P.Laux and W.Zeller**

P-32: Metabolites from biological control of fire blight induce an hypersensitive-like reaction on tobacco leaves

J.Yu, T.Reglinski, A.Allan and J L Vanneste*

3 Biological control

P-33: Optimizing mixtures of bacterial antagonists for fire blight suppression

V.*O.Stockwell*, K.B.Johnson, D.Sugar and J.E.Loper*

P-34: Contribution of antibiosis to biological control of fire blight in the orchard environment by *Pantoea agglomerans* 252

26 V.O.Stockwell*, K.B.Johnson, D.Sugar and J.E.Loper

P-35: The peptide antibiotic produced by Erwinia herbicola Eh252 is a microcin

J.L.Vanneste, D.C.Cornish, J.Yu and M.D.Voyle*

P-36: *Bacillus subtilis* strain BS-F3: Colonisation of pear organs and its action as a biocontrol agent

M.Alexandrova*, P.Lameri, and C.Bazzi

P-37: Characterisation of two fluorescent strains of *Pseudomonas* as biocontrol agents against fire blight

O.Galasso, C.Bazzi and J.L.Vanneste*

P-38: Current research on natural compounds for control of fire blight

R.E.Mitchell, W.T.Jones and D.Harvey*

P-39: A new experimental design for testing control agents for fire blight under nearly natural conditions

E.Moltmann and A.Fried*

P-40: Application of bacteriocin as a biological control agent against fire blight

A.Pierrard, T.Deckers, A.Cheggour, K.Vanderbroek, R.Drion H.M.Jijakli, P.Lepoirve and P.Thonart*

P-41: Inhibition of *Erwinia amylovora* and potential antagonistic bacteria by essential oils and natural compounds

27 R.J.Boyd and J.L.Vanneste*

Integrated management

P-42: Enhancing flower colonisation of the biological control agent *Pseudomonas fluorescens* strain A506, and the efficacy of Apogee and Serenade, for fire blight control in the San Joaquin Valley of California

B.Holtz, S.Lindow, B Teviotdale and E Hoffman*

P-43: Evaluation of control of fire blight infection of apple blossoms and shoots with SAR inducers, biological agents, a growth regulator, copper compounds, and other materials

H.S.Aldwinckle, M.V.Bhaskara Reddy and J.L.Norelli*

P-44: **Evaluation of some recommended compounds for control of pear and apple fire blight disease in Qazvin**

*N.Hassanzadeh**

P-45: **Efficacy of bactericides and dormancy-breaking agents on the incidence of fire blight and fruit production of pear in Egypt**

28 A.E.Tawfik*, A.I.Hanna, L.A.El-Gharib, A.A.Gomma, S.M.Mahmoud and S.A.El-Shall

1200-1300 Lunch

SESSION 4 PLANT-BASED STRATEGIES FOR CONTROL

Chairperson: Jay Norelli

1300-1310 Introducton – *Jay Norelli*

<u>Host responses to infection and their manipulation for enhanced resistance</u>

1310-1325 **O-25:** Resistance of *hrp*N-transgenic M.26 apple rootstock plants to *Erwinia amylovora*

E.Borejsza-Wysocka, J.L.Norelli, D.Bauer, S.V.Beer and H.S.Aldwinckle*

1325-1340 **O-26:** Induced resistance to *Erwinia amylovora* in apple and pear

*M-N.Brisset, M.Faize, C.Heintz, S.Cesbron, R.Chartier, M.Tharaud and J-P.Paulin**

1340-1410 Poster Summaries

Posters

P-46: Differential expression of PR genes in apple in response to SAR inducers and *Erwinia amylovora*

29 J-P.Reynoird, J.Bonasera, J.L.Norelli, S.V.Beer and H.S.Aldwinckle*

P-47: Salicylic acid as a possible component in the susceptibility of apple rootstock for fire blight infections.

K.Heyens, T.Deckers and R.Valcke*

P-48: Activity of peroxidases in plant material infected with *Erwinia amylovora*

30 M.Keck*, S.Richter, B.Suarez and E.Kopper

P-49: The *hrp* gene cluster is required for activation of Pgst 1 by *Erwinia amylovora* in transgenic apple

*J-P.Reynoird, D.W.Bauer, S.V.Beer and H.S.Aldwinckle**

1410-1430 Discusion:

What is the future potential to control fire blight by manipulation of host response?

Conventional plant breeding for enhanced resistance

1430-1445 **O-27:** Natural occurrence of fire blight in the USDA Apple germplasm collection after 10 years of observation

P.L.Forsline and H.S.Aldwinckle*

1445-1500 **O-28:** Resistance of Cornell-Geneva apple rootstocks to *Erwinia amylovora* when grown as vegetative shoots and orchard trees

J.L.Norelli, H.S.Aldwinckle, H.T.Holleran, T.L.Robinson and W.C.Johnson*

1500-1530 Coffee

1530-1600 Poster Summaries and Discussion

Posters

P-50: Host-pathogen interactions of *Erwinia amylovora* on apple and pear in New Zealand

R.K.Taylor, C.Ranatunga, P Alspach and V.Bus*

P-51: Fire blight resistance of *Malus* species from Sichuan (China), Russian Caucasus, Turkey, and Germany

H.S.Aldwinckle, P.F.Forsline, H.L.Gustafson and M.V.Bhaskara Reddy*

P-52: Evaluation of apple varieties for susceptibility to *Erwinia amylovora* by artificial inoculation under field conditions

S.*K.Mohan*, E.Fallahi and V.P.Bijman*

P-53: Field evaluation of *Prunus* species for susceptibility to *Erwinia amylovora* by artificial inoculation.

31 S.K. Mohan*, V.P. Bijman and E. Fallahi

P-56: Stability of fire blight resistance in apple

32 K.Richter and C.Fischer

P-57: A genotype of *Cotoneaster* with a high level of resistance to fire blight

*V.Bellenot, R.Chartier, M-N.Brisset and J-P.Paulin**

Enhancing resistance by transgenic expression of antimicrobial gene products

1600-1615 **O-29:** Plant transformation for induction of fire blight resistance: Transgenic apples expressing viral eps-depolymerase

33 V.Hanke*, W-S.Kim, K.Geider, K.Richter, J.L.Norelli and H.S.Aldwinckle

1615-1630 **O-30:** Fruit characteristics of lytic protein transgenic Royal Gala apple lines with resistance to fire blight

34 H.S.Aldwinckle*, E.E.Borejsza-Wysocka and J.L.Norelli

1630-1645 Poster Summaries

Posters

P-58: A new approach to evaluate fire blight resistance *in vitro*

35 V.Hanke* and K.Geider

P-59: Expression of a depolymerase gene in transgenic pears increased only slightly their fire blight resistance

M.Malnoy, M-N.Brisset and E.Chevreau*

P-60: Transformation of SR1 tobacco and JTE-H apple rootstock with the EPS-depolymerase gene from an *Erwinia amylovora* phage

S.Sule, W-S.Kim, E.Kiss and K.Geider*

1645-1700 Discussion:

Advantages and disadvantages of the various approaches to enhancing plant resistance

Evening Function: Barbeque at East Pier On The Beach, Napier

WEDNESDAY 10 OCTOBER

FIELD TRIP

0800 – Buses leave

*Packhouse visit

*Orchard Visit

*HortResearch – Hawke's Bay Research Centre

Lunch

*Vineyard visits

Evening Free

THURSDAY 11 OCTOBER

SESSION 5 BIOCHEMISTRY AND MOLECULAR ADVANCES

Chairperson: Joel Vanneste

Molecular tools for differentiation of *E amylovora* strains

0900-0915 **O-31:** Genetic diversity among *Erwinia amylovora*'s ubiquitous plasmid pEA29

*G.C.McGhee, G.C.Foster and A.L.Jones**

0915-0930 **O-32:** Molecular comparison and differentiation of *Erwinia* strains causing fire blight and Asian pear blight

36 S.Jock*, W-S.Kim and K.Geider

0930-0945 **O-33:** Comparison of *groEL* sequences, 16S-rDNA spacer diversity, and pEA29-type plasmids from *Erwinia amylovora* and *E.pyrifoliae*

*E.L.Schnabel, G.C.McGhee and A.L.Jones**

0945-1000 Discussion

1000-1015 Coffee

Focus on the pathogen

1015-1030 **O-34:** Visualisation of secreted Hrp and Avr proteins along the Hrp pilus during type III secretion in *Erwinia amylovora* and *Pseudomonas syringae*

37 Q.Jin, W.Hu, I.Brown, G.C.McGhee, P.Hart, A.L.Jones and S.Y.He*

1030-1045 **O-35:** Changes in flagellin secreted by *hrp* regulatory mutants of *E.amylovora*

M.Faize, M-N.Brisset, C.Heintz, M.Tharaud, M-A.Barny and J-P.Paulin*

1045-1100 **O-36:** Using the green fluorescent protein to determine virulence and gene expression of *Erwinia amylovora*

38 J.Bogs, K.Richter and K.Geider*

1100-1115 **O-37:** Temperature dependent expression and functional analysis of a multi-drug efflux protein in *Erwinia amylovora*

A.Burse, C.Goyer and M.S.Ullrich*

1115-1130 **O-38:** Regulation and biochemistry of exopolysaccharide synthesis by *Erwinia amylovora*

K.Geider, Z.Du, M.Hildebrand, W-S.Kim and M.Schollmeyer*

1130-1200 Discussion

1200-1300 Lunch

Focus on the plant

1300-1315 **O-39:** DspE protein of *Erwinia amylovora* interacts with kinases from apple

*X.Meng, J.M.Bonasera, J.F.Kim, R.M.Nissenin, W-S.Kim and S.V.Beer**

1315-1330 **O-40:** Mechanisms underlying the disease and resistance responses in host plants of fire blight

39 J-S.Venisse and M-N.Brisset*

1330-1345 **O-41:** Gene expression in apple in response to inoculation with *Erwinia amylovora*

40 J.M.Bonasera and S.V.Beer*

1345-1400 **O-42:** Alteration of phenylpropanoid biosynthesis of fruit trees as a tool for enhancement of fire blight resistance

S.Roemmelt, W.Rademacher and E.Treutter*

Posters

P-61: Biochemical and molecular biological investigations with respect to induction of fire blight resistance in apple and pear by transiently altering the flavanoid metabolism with specific enzyme inhibitors

H.Halbwirth, T.C.Fischer, S.Roemmelt, W.Kampan, G.Forkmann and K.Stich

P-62: The use of immunobinding assay on nitrocellulose membranes and SDS-polyacrylamide gel electrophoresis to detect and differentiate *Erwinia amylovora* in pear orchards in Egypt

*M.S.Khalil, A.E.Tawfik, A.M.Ismael and S.M.Moustafa-Mahmoud**

P-63: Characterisation of transposon, genes and mutations which confer streptomycin resistance in bacterial strains isolated from New Zealand orchards

*M.D.Voyle and J.L.Vanneste**

P-64: Pathogenicity factors of *E.amylovora* and their role in the induction of defenses in susceptible hosts

J-S.Venisse, H.El-Maarouf, C.Perino, M-A.Barny, J-P.Paulin, D.Expert and M-N.Brisset*

1500-1515 Coffee

1515- ISHS Working Group on Fire Blight Business Meeting

Evening Function – Workshop Dinner at Ormlie Lodge

FRIDAY 12 OCTOBER

1000-1015 Coffee

OPEN FORUM - Research and Management 2001-2010

1015 Introductory Presentation

41 Herb Aldwinckle

Session Summaries – Research Advances and Issues

Session 1 *Jean-Pierre Paulin*

Session 2 *Gary Lightner*

Session 3 *Ken Johnson*

Session 4 *Jay Norelli*

Session 5 *Joel Vanneste*

Panel Discussion – Session Chairpersons

Facilitator: *Herb Aldwinckle*

1200-1300 Lunch

1300 - Workshop Sum Up

Action points

Collaborative projects identified by the Working Group

1500 Closing and Refreshments