

The Proposed Importation of Fresh Apple Fruit from New Zealand

Government Response to the Recommendations of the Senate Rural and Regional Affairs and Transport Legislative Committee's interim report

March 2003

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The Proposed Importation of Fresh Apple Fruit from New Zealand -Government Response to the Recommendations of the Senate Rural and Regional Affairs and Transport Legislative Committee's interim report - March 2003 Government response to the interim report of the Senate Rural and Regional Affairs and Transport Legislative Committee's inquiry into the Proposed Importation of Fresh Apple Fruit from New Zealand

Recommendation 1

The Committee recommends that Biosecurity Australia, as part of its current review into the future conduct of the IRA process, develop procedures to allow a decision to adopt a routine IRA to be appealed to the Administrative Appeals Tribunal.

The revision of the import risk analysis (IRA) process has overtaken this recommendation. The revised process proposes to make no distinction between routine and non-routine, but to follow a single approach, with all IRAs using an IRA team. The Executive Manager of Biosecurity Australia will determine IRA team membership after consulting stakeholders. Membership will be expertise based, and may be appealed. It will also be governed by whether Biosecurity Australia has the required technical expertise and the extent outside expertise may be required. A deputy secretary within the Department of Agriculture, Fisheries and Forestry – Australia (AFFA) will consider appeals relating to panel membership. The Government's legal advice on the recommendation that such matters be appealable to the Administrative Appeals Tribunal (AAT), indicates that for decisions to be appealable to the AAT they must have a statutory base. The conduct of IRAs is not at present part of a statutory process, and the Government considers that a change to make it so is not warranted.

Recommendation 2

The Committee recommends that Biosecurity Australia, as part of its current review into the future conduct of the IRA process, develop procedures to allow for consideration of the likely consequences of the incursion of a particular pest when deciding whether to use a routine or non-routine IRA.

The revision of the IRA process has also overtaken this recommendation. It proposes that Biosecurity Australia will determine when deciding whether an IRA is necessary whether the likely consequences differ significantly from those previously assessed. Biosecurity Australia advised stakeholders in late 2001 that a working draft of the Guidelines for Import Risk Analysis had been completed. These guidelines together AFFA's draw corporate experience in conducting IRAs, and input from risk analysts in State agriculture departments, the private government sector and overseas agencies. The guidelines describe a structured approach to the methodology used in IRAs, for use by an IRA team and contain a detailed description of consequence assessment. This is to ensure that the IRA addresses the likely consequences of incursions appropriately.

The guidelines are 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 provide terms and methods 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 document will be of interest and value to stakeholders reviewing new Biosecurity Australia IRAs, and has been placed on the AFFA internet site. Copies are also available (in paper or electronic form) at bde@affa.gov.au, from AFFA telephone 02 6272 4914 and fax 02 6272 4568.

Recommendation 3

The Committee recommends that Biosecurity Australia, as part of its current review into the future conduct of the IRA process, develop and publish widely guidelines on the purpose and the method of consultation in the IRA process.

The Biosecurity Australia Import Risk Analysis Handbook is due to be finalised in early 2003, following the review of the IRA process. It will include details relating to the purpose and method of consultation for IRAs.

Recommendation 4

The Committee recommends that Biosecurity Australia, as part of its current review into the future conduct of the IRA process, establish a Risk Assessment Committee to allow for the direct involvement of domestic stakeholders during the conduct of IRAs.

The Government recognises the need for an enhanced consultation process to improve stakeholders' ability to raise relevant concerns. While this recommendation is not specifically accepted, the Government intends to strengthen public involvement and consultative procedures in the IRA process, and this will be reflected in the Import Risk Analysis Handbook. Stronger public involvement does not need to impose further bureaucratic layers in the IRA process. An additional committee for each IRA would make the consulting and reporting mechanisms more complex and the process even longer. Some may also see it as compromising the independence of the analysis.

The new process will give all stakeholders more scope to contribute to the technical aspects of each IRA, either directly or through scientific experts. Areas of particular relevance in this context are those which may disease influence spread, likelv consequences and subsequent risk This would include management. providing and examining information on industry structure, distribution networks and common industry practices.

Recommendation 5

The Committee recommends that Biosecurity Australia, as part of its current review into the future conduct of the IRA process, clarify with Environment Australia the definition of pathogens which pose a significant risk harm to the natural of environment. Such pathogens must be referred to the Minister for the Environment for advice under the terms of the Quarantine Amendment Act 1999.

AFFA's Biosecurity Australia and Environment Australia (EA) concluded a memorandum of understanding (MOU) on import risk analyses on 11 October 2002. Biosecurity Australia is also developing guidelines in consultation with EA that will help AFFA officers with environmental aspects of import risk analyses.

The concept of 'referring a pathogen' is problematic and is not required under Under current legislation. the Quarantine Act 1908, decisions which may result in a significant risk of harm to the environment must be referred. In addition, 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 will be formalised through revised arrangements established under the MOU and draft guidelines mentioned above.

Recommendation 6

The Committee recommends that Biosecurity Australia incorporate a full quantitative risk evaluation in the final IRA on the possible importation of New Zealand apples, in preference to the current unsatisfactory qualitative risk evaluation used in the draft IRA.

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. This methodology was developed by the same process as the IRA guidelines (see recommendation 2).

This approach was also in line with that described in the Australian/New Zealand Standard for Risk Management (AS/NZS 4360:1999), for qualitative analyses. Australia is a leader in risk analysis, and AS/NZS 4360 is the first national standard of its type in the world. AS/NZS 4360 also provides for a semi-quantitative method of risk analysis. This approach uses the rigour of the fully quantitative method where feasible, but deals with data deficits by accepting semiquantitative assessments as inputs.

The Government acknowledges that an accurate and robust model is essential to produce an accurate risk analysis. The risk analysis panel (RAP) will need to consider how best to deal with this issue in light of the guidance provided in the IRA guidelines, which encompass qualitative, semiquantitative and quantitative methods. The RAP will also consult AS/NZS 4360.

The Government recognises that the discipline of applying quantitative risk assessment to quarantine is evolving and notes that international risk analysts understand these methodologies better than they did several years ago. However, the use of quantitative risk assessment in certain situations does not necessarily have a significant advantage over qualitative semi-quantitative or techniques. Quantitative risk assessment requires more resources and is problematic when the data are of poor quality. Therefore, judgements on the efficient and effective use of resources, and the applicability of the various methodologies, need to be made case by case.

In all analyses, the outcomes, whether expressed in words or numbers, guide decision-making in the broader context importing set by the country's appropriate level of protection (ALOP). It is important to note that in all known cases, WTO members express ALOP in general, qualitative terms.

Biosecurity Australia will continue to use quantitative risk assessment methodology when feasible and appropriate. The RAP is investigating options for doing a more quantitative analysis of *Erwinia amylovora* than for the original draft IRA.

Recommendation 7

The Committee recommends that Biosecurity Australia revise the combined events in the entrv. establishment and spread pathways in final IRA on the possible the importation of New Zealand apples. This is to measure more accurately and transparently the unrestricted risk associated with Erwinia amylovora and other pests.

It is vital in developing a thorough risk analysis to identify and fully assess the various combinations of independent events in all pathways through which a potential quarantine pest could enter Australia. The RAP is considering this area in detail.

Recommendation 8

The Committee recommends that Biosecurity Australia develop a quantitative measure of what constitutes a 'very low' risk in the final IRA on the possible importation of New Zealand apples, based on a full quantitative risk assessment.

In the draft IRA, Biosecurity Australia provided a qualitative description of 'very low' and equates this with Australia's ALOP.

In all analyses, the outcomes, whether expressed in words or numbers, need to be applied in the context of the importing country's ALOP. For the NZ apple IRA, a 'very low' risk has been described as a band of cells running through the risk assessment matrix^a. This concept is included in the for IRA Guidelines and the Australian/New Zealand Standard for Risk Management (AS/NZS 4360:1999). Six separate definitions for a 'very low risk' context can be derived from this matrix and the associated definitions of likelihood^b and consequence^c.

Australia has looked 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 in Government policy. expressed Quarantine decision makers obtain additional guidance from current quarantine policies and practices. Because the ALOP is a central tenet of the SPS Agreement, it is important to

^a See attachment 1 for Table 9 of the draft IRA

^b See attachment 1 for Table 6 of the draft IRA ^c See attachment 1 for and excerpt from page

⁴⁶ of the draft IRA

ensure that any statement is robust and can encompass all situations.

Recommendation 9

The Committee recommends that Biosecurity Australia immediately commission research by the CSIRO, the NZ Horticulture and Food Research Institute or independent authorities into whether export-ready apples from New Zealand can carry viable colonies of Erwinia amylovora in their core, calyx or flesh.

There is evidence that mature apple fruit, even from apparently healthy orchards, can carry viable bacteria. However, there is conjecture about the presence of bacteria on the skin, or in the core, calyx or flesh. The RAP is considering the feasibility of additional research and which, if any, areas of uncertainty can and should be further clarified using the research techniques available.

Recommendation 10

The Committee recommends that Biosecurity Australia incorporate in the final IRA further research into the role of other pests in the possible broadcast of Erwinia amylovora in Australia, notably the apple leaf-curling midge.

The RAP will consider research needs regarding *Erwinia amylovora* vectors, and incorporate all relevant aspects into the revised draft IRA. Reports in the literature indicate that such research is continuing on apple leaf-curling midge.

Recommendation 11

The Committee recommends that Biosecurity Australia adopt as a better alternative to the protocols outlined in the draft IRA the following measures:

- i) the use of random drop sampling at certified New Zealand packing houses for sampling of New Zealand apple lots earmarked for possible export to Australia
- *ii)* the DNA testing of apples taken during random drop sampling for the presence of Erwinia amylovora
- iii) the acceptance or rejection of apple lots from New Zealand earmarked for export to the Australian market based on the results of the above DNA testing and other relevant testing.

The RAP will consider these measures, when examining risk mitigation options in the context of the revised draft IRA.

Recommendation 12

The Committee recommends that Biosecurity Australia themselves conduct tests with at least two major New Zealand export packing houses on the appropriate apple processing speed and staffing levels required to guarantee that apples destined for possible export to Australia would be completely trash free.

The RAP will consider trash-related issues in more detail.

Recommendation 13

The Committee recommends that Biosecurity Australia incorporate in the final IRA advice from the NRA as to the circumstances under which the NRA would permit the spraying of streptomycin or terramycin in Australia in response to an outbreak of Erwinia amylovora. This advice should be based on research by Biosecurity Australia the number on of applications of streptomvcin or terramvcin which would be required each season to contain an outbreak of Erwinia amylovora in the various apple growing regions of Australia.

The Government recognises the increasing public concern about the health threat of antibiotic-resistant bacteria as a consequence of the selective effect of agricultural use and medical over-use of antibiotics. The Joint Expert Technical Advisory Committee on Antibiotic Resistance (JETACAR)^d was established in these concerns. response to The Government is systematically its recommendations implementing through the Commonwealth Interdepartmental JETACAR Implementation Group. The Government also recognises the potential impact on the profitability of the pome fruit industry from the direct and indirect costs of using antibiotic sprays. In addition, the use of chemical treatments to control an incursion of Erwinia amylovora into Australia could present risks to the environment. The RAP will consider relevant ecological and environmental impacts of control measures when assessing the likely consequences of any incursion.

The Expert Advisory Group on Antimicrobial Resistance (EAGAR) has recommended that any permits issued for the use of streptomycin should be valid for no longer than three months. The National Health and Medical Research Council recently established EAGAR, in response to the JETACAR report. The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) considers EAGAR's advice when taking decisions in relation to registration of antimicrobial chemicals.

The NRA advises that it could issue an emergency use permit for streptomycin for period of 3 months in the event of an *Erwinia amylovora* incursion. The major concern is the potential for the development of resistance, which is likely to become a problem with sustained use. Any period greater than 3 months would need re-consideration EAGAR. EAGAR bv has not considered the emergency use of terramycin (oxytetracycline) against Erwinia amylovora, and would need to do so before a permit for this use could be issued. While terramvcin (oxytetracycline) is not used as a human therapeutic in Australia, many other members of the tetracycline family are. However, in comparison with streptomycin, horticultural use of terramycin (oxytetracycline) is less likely to lead to the development of resistance problems. Antibiotics to control fire blight are usually only applied to pome fruit crops during flowering, which is a high risk period for infection and long distance dispersal of Erwinia amylovora. A fire blight eradication campaign would depend on a combination of measures, including the use of copper and antibiotic sprays, control of vectors, and hygiene practices (e.g. removal of affected plants). The key role of antibiotic sprays would be as a risk

^d The JETACAR report and the Government's response to it, are available at

http://www.health.gov.au/pubhlth/publicat/doc ument/metadata/jetacar.htm

minimisation strategy at flowering. Copper-based compounds can protect against bacterial diseases but can have limited effectiveness because new growth is not protected. Although the phytotoxic effects of copper compounds on growing shoots in spring and early summer are a major production concern, they are less of a concern in an eradication campaign. Copper sprays may therefore be a feasible substitute for antibiotics in of an eradication some stages campaign.

The number of antibiotic sprays that may be required would be determined by the context of an incursion. The RAP will have additional information on this issue to include in the revised draft IRA.

Recommendation 14

The Committee recommends the independent scientific review conducted as part of the revised public consultation process announced on 6 March 2000 by the Director of Quarantine, Mr Taylor, should be similar to that used in non-routine IRAs.

AFFA responded to the committee's recommendation by announcing the establishment of a RAP on 13 August 2001. The panel brings together a range of expertise, including plant pathology, environmental science and industry practice, and is drawn from various sources, including Biosecurity Australia, CSIRO and State Governments. The RAP was finalised on 10 January 2002, and comprised the following people:

§ Dr Bill Roberts (Chairman), Australia's Chief Plant Protection Officer

- § Mr Bill Hatton, a fruit producer with expertise in growing, packing and shipping various fruits, and experience in pest and disease incursion planning for the stone fruit industry
- § Mr David Cartwright, a plant pathologist and Manager, Plant Health, Department of Primary Industries and Resources South Australia
- § Dr Kent Williams, Principal Research Scientist, CSIRO Sustainable Ecosystems
- Mr Mike Kinsella^e, a horticulturalist and consultant, and a former Chief Quarantine Officer and Director of Quarantine and Inspection Services, Victoria
- § Mr Ian Armour, owner/manager of an apple orcharding business east of Melbourne
- § Dr Brian Stynes, a plant pathologist and General Manager, Plant Biosecurity, Biosecurity Australia.

Establishing a RAP is consistent with the proposed revisions to the IRA process regarding IRA teams.

The RAP intends to consult widely with stakeholders, and has begun its work by considering the matters that were raised in the public submissions responding to the original draft IRA. The RAP has prepared a scientific review paper and has held an initial consultative workshop to address the scientific, operational and technical issues at the heart of the risk analysis.

^e On 22 January 2002, BA was informed that Mike Kinsella had passed away. As a result BA has considered the range and balance of skills among the remaining members. Following consultation with RAP members, BA has decided not to seek a replacement.

Recommendation 15

The Committee recommends that Biosecurity Australia contact countries to which Australia exports apples to clarify their position should Australia allow importation of apples from New Zealand. This is to avoid Australian apples being assessed as posing a risk by other countries should Australia accept apples from New Zealand.

WTO members are required to base import measures on international standards or a valid risk assessment. As there are no standards specific to apple pests or diseases at present, import measures must be based on a risk assessment of the pests and diseases that actually occur in the country of potential export. If Australia were to allow entry for New Zealand apples, then requesting countries to which we export apples to clarify their position, is likely to be interpreted as asking if they would act contrary to the SPS agreement.

Such a request could affront some key trading partners, and therefore affect our trading interests. The Government notes that most of the major export destinations for Australian apples and pears either do not have an apple or pear industry (and are therefore not concerned about the disease) or have wide spread fire blight (and therefore justify restrictive cannot import measures^f). Australia's remaining trading partners, have so far not indicated any concerns arising from the draft IRA. Japan, as an importer of apples from Tasmania, and a country that does not have fire blight, has been monitoring this issue and has sought answers to a small number of technical

questions, unrelated to this recommendation.

^f In the phytosanitary context, 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."

Attachment 1

Selected sections from the Draft Import Risk Analysis on the Importation of Apples (Malus x domestica Borkh.) from New Zealand, October 2000

Probability of entry,	establishment and spread	<u>extreme</u>	negligible	very low	low	moderate	high	extreme
		<u>high</u>	negligible	very low	low	moderate	high	extreme
		moderate	negligible	negligible	very low	low	moderate	high
		low	negligible	negligible	negligible	very low	low	moderate
		<u>very low</u>	negligible	negligible	negligible	negligible	very low	low
		<u>negligible</u>	negligible	negligible	negligible	negligible	negligible	very low
			negligible	very low	low	moderate	<u>high</u>	extreme

Table 9 Risk estimation matrix⁹

Consequence of entry, establishment and spread

Likelihood	Description
extreme	the event would be virtually certain to occur
high	the event would be likely to occur
moderate	the event would occur with an even probability
low	the event would be unlikely to occur
very low	the event would be very unlikely to occur
negligible	the event would almost certainly not occur

^g Page 48, Draft Import Risk Analysis on the Importation of Apples (*Malus x domestica* Borkh.) from New Zealand, October 2000.

^h Page 39, Draft Import Risk Analysis on the Importation of Apples (*Malus x domestica* Borkh.) from New Zealand, October 2000.

Excerpt from page 46 of the Draft Import Risk Analysis on the Importation of Apples (*Malus x domestica* Borkh.) from New Zealand, October 2000

Estimation of consequences

The classifications outlined below were used to estimate the combined extent of direct and indirect consequences. These classifications may be interpreted in dollar terms, in terms of particular societal values or social wellbeing, or as a combination of both.

negligible:	The impact is unlikely to be recognised by directly affected parties. ⁹
very low:	The impact on a given criterion is likely to be minor to directly affected parties. The impact is unlikely to be discernible at any other level.
low:	The impact is likely to be recognised within an affected geographic region, and significant to directly affected parties. It is not likely that the impact will be recognised at the national level.
moderate:	The impact is likely to be recognised at a national level, and significant within affected geographic regions. The impact is likely to be highly significant to directly affected parties.
high:	The impact is likely to be significant at a national level, and highly significant within the affected a geographic regions. This classification implies that the impact would be of national concern. However, the serious effect on economic stability, societal values or social wellbeing would be limited to a given geographic region.
extreme :	The impact is likely to be highly significant at the national level. This classification implies that the impact would be of significant national concern. Economic stability, societal values or social wellbeing would be seriously affected in more than one geographic region.

ⁱ Page 46, Draft Import Risk Analysis on the Importation of Apples (*Malus x domestica* Borkh.) from New Zealand, October 2000.

⁹ In this IRA, a 'directly affected party' is taken to mean the individual, or group of individuals, who experience the introduced pest.