Draft generic import risk analysis (IRA) for honeybee semen

Technical Issues Paper

August 2002

AGRICULTURE, FISHERIES AND FORESTRY - AUSTRALIA

Foreword

Contents

GLOSSARY OF TERMS AND ABBREVIATIONS

ABPM	Animal Biosecurity Policy Memorandum
AFFA	Commonwealth Department of Agriculture, Fisheries and Forestry - Australia
ALOP	Appropriate level of protection
AQIS	Australian Quarantine and Inspection Service
Codex	Codex Alimentarius Commission
ICON	AQIS Import Conditions database
IPPC	International Plant Protection Convention
IRA	Import risk analysis
OIE	Office International des Epizooties
SPS	Sanitary and Phytosanitary
SPS Agreement	WTO Agreement on the Application of Sanitary and Phytosanitary Measures
WTO	World Trade Organization

EXECUTIVE SUMMARY

Biosecurity Australia is conducting an import risk analysis (IRA) on honeybee semen. This Technical Issues Paper is the first major technical consultation for the IRA. It contains the following sections:

- an introductory description of Biosecurity Australia's framework for quarantine policy and for IRAs;
- the background to this IRA, including administration issues, and Australia's current policy for bees,
- an outline of the methods for, and results of, hazard identification
- a list of pathogens for which risk assessments will be undertaken.

Biosecurity Australia advised stakeholders of the commencement of the import risk analysis (IRA) of honeybee semen on 6 June 2002. It was proposed that a team from within Biosecurity Australia should conduct the IRA.

The Technical Issues Paper has considered 17 pest and disease agents, including parasites. Of these, we propose 7 be retained for risk assessment. A list of these retained hazards can be found below.

Following consideration of stakeholder comments on the Technical Issues Paper, Biosecurity Australia will release a Draft IRA Report and subsequently a Final IRA Report. The Draft IRA Report will contain the methods for, and results of, risk assessment and risk management, and will provide a preliminary position on the importation of honeybee semen. The Final IRA Report will include the same elements with any necessary revisions following consideration of stakeholder comments, and also a description of quarantine conditions for honeybee semen.

The following agents were selected for further examination in the IRA:

- American foulbrood
- European foulbrood
- Acute paralysis virus
- Deformed wing virus
- Filamentous virus
- Apis mellifera capensis
- Apis mellifera scutellata

AUSTRALIA'S BIOSECURITY POLICY

Legislative framework

The Department of Agriculture Fisheries and Forestry - Australia's (AFFA) objective is to adopt biosecurity policies that provide the health safeguards required by government policy in the least trade-restrictive way and that are, where appropriate, based on international standards. In developing and reviewing quarantine (or biosecurity) policies, disease risks associated with importations may be analysed using an IRA — a structured, transparent and science-based process.

The *Quarantine Act (1908)* and its subordinate legislation, including the *Quarantine Proclamation (1998)*, are the legislative basis of human, animal and plant biosecurity in Australia. The *Quarantine Amendment Act (1999)*, which commenced in June/July 2000, incorporates major changes to the *Quarantine Act* as recommended in the report of the Australian Quarantine Review Committee (AQRC).

Section 4 of the *Quarantine Act* defines the scope of quarantine as follows.

In this Act, quarantine includes, but is not limited to, measures:

- *for, or in relation to, the examination, exclusion, detention, observation, segregation, isolation, protection, treatment and regulation of vessels, installations, human beings, animals, plants or other goods or things*
- *having as their object the prevention or control of the introduction, establishment or spread of diseases or pests that will or could cause significant damage to human beings, animals, plants, other aspects of the environment or economic activities*.

Quarantine Risk

The concept of level of quarantine (or biosecurity) risk has been introduced as the basis of quarantine decision-making. When making decisions under the *Quarantine Act*, decision-makers must consider the level of quarantine risk and must take prescribed actions to manage the risk if it is unacceptably high. For example, Section 44C of the *Quarantine Act* concerns the examination of goods on importation and requires quarantine officers to order goods into quarantine if they decide the level of quarantine risk is unacceptably high. Section 46A concerns approvals for goods ordered into quarantine, and requires consideration of the level of quarantine risk with regard to matters such as the proposed procedures and the construction and management of biosecurity premises. Section 5D includes harm to the environment as a component of the level of quarantine risk.

Section 5D: level of quarantine risk

A reference in this Act to a level of quarantine risk is a reference to:

(a) the probability of:

(i) a disease or pest being introduced, established or spread in Australia or the Cocos Islands; and

(ii) the disease or pest causing harm to human beings, animals, plants, other aspects of the environment, or economic activities; and

(b) the probable extent of the harm.

Quarantine Proclamation

Subsection 13(1) of the *Quarantine Act* provides that the Governor-General in Executive Council may, by proclamation, prohibit the importation into Australia of any articles or things likely to introduce, establish or spread any disease or pest affecting people, animals or plants. The Governor-General may apply this power of prohibition generally or subject to any specified conditions or restrictions.

Quarantine Proclamation 1998 is the principal legal instrument used to control the importation into Australia of goods of quarantine (or biosecurity) interest. A wide range of goods is specified in Quarantine Proclamation *1998* including animals, plants, animal and plant products, micro-organisms, and certain other goods which carry a high risk if uncontrolled importation is allowed — e.g. soil, water, vaccines, feeds.

For articles or things prohibited by proclamation, the Director of Animal and Plant Quarantine may permit entry of products on an unrestricted basis or subject to compliance with conditions, which are normally specified on a permit. An import risk analysis provides the scientific and technical basis for biosecurity policies that determine whether an import may be permitted and, if so, the conditions to be applied.

The matters to be considered when deciding whether to issue a permit are set out in Section 70 of *Quarantine Proclamation 1998* as follows:

70 Things a Director of Quarantine must take into account when deciding whether to grant a permit for importation into Australia

(1) In deciding whether to grant a permit to import a thing into Australia or the Cocos Islands, or for the removal of a thing from the Protected Zone or the Torres Strait Special Quarantine Zone to the rest of Australia, a Director of Quarantine:

(a) must consider the level of quarantine risk if the permit were granted; and

(b) must consider whether, if the permit were granted, the imposition of conditions on it would be necessary to limit the level of quarantine risk to one that is acceptably low; and

(c) may take into account anything else that he or she knows that is relevant.

The matters include the level of quarantine risk (see above), whether the imposition of conditions would be necessary to limit the quarantine risk to a level that would be acceptably low, and anything else known to the decision maker to be relevant.

Environment

While protection of the natural and built environment has always been an objective of Australian quarantine policy and practice, recent amendments to the *Quarantine Act 1908* make explicit the

responsibility of quarantine officers to consider impact on the environment when making decisions. In particular, the scope of quarantine (as described in Section 4 of the *Quarantine Act*), and the level of quarantine risk (as described in Section 5D of the *Quarantine Act*), include explicit reference to the environment.

Environment is defined in Section 5 of the *Quarantine Act* as:

> *... all aspects of the surroundings of human beings, whether natural surroundings or surroundings created by human beings themselves, and whether affecting them as individuals or in social groupings.*

When undertaking an IRA, Biosecurity Australia fully takes into account the risk of harm to the environment to ensure that the biosecurity policies developed reflect the Australian Government's approach to risk management. This is achieved through the involvement of Environment Australia in decisions on the import risk analysis work program and, for particular import risk analyses, discussions on the scope, the likely risks, and the expertise which may be required to address those risks. Environment Australia may identify additional technical issues that it believes should be considered during an IRA, and may nominate officers with relevant expertise who would be available to participate in the IRA — as a member of the IRA or on a technical working group.

Policy framework

The primary purpose of biosecurity is to protect Australia from the entry, establishment or spread of unwanted pests and diseases that may cause social, economic or environmental damage, while minimising the restrictions on the entry of commodities.

Due to Australia's unique and diverse flora and fauna and the value of its agricultural industries, successive Australian Governments have maintained a highly conservative but not a zero-risk approach to the management of biosecurity risks. This approach is evident in the strictness of all biosecurity-related activities, including policies on imported commodities, procedures at the border and operations against incursions of pests and diseases.

Recent inquiries into Australia's biosecurity regime have recognised that it is impossible in practice to operate a zero-risk biosecurity regime. In 1979, the Senate Standing Committee on Natural Resources stressed that there is no such thing as a zero-risk quarantine policy, and it believed that Australia's approach should be better described as '*scientific evaluation of acceptable risk*'. In 1988, the Lindsay review of Australian quarantine concluded that '*a no risk policy is untenable and undesirable and should be formally rejected*'. In 1996, the Senate Rural and Regional Affairs and Transport Committee was of the view that a zero-risk approach was unrealistic and untenable, and that its currency only demonstrated that the concepts of risk assessment and risk management were widely misunderstood. These themes were repeated in the AQRC report. In its 1997 response to that report, the Government confirmed a managed risk approach.

IRAs provide the basis for considering import applications for the importation of animals and animal-derived products, and plants and plant-derived products. In keeping with the scope of the *Quarantine Act* and Australia's international obligations, only factors relevant to the evaluation of quarantine risk (i.e. the risk associated with the entry, establishment and spread of unwanted pests and diseases) are considered in the IRA. The potential competitive economic impact of prospective imports is not within the scope of the IRA process, and any discussion on industry support mechanisms would need to remain quite separate from the analysis.

WTO AND IMPORT RISK ANALYSIS

One of the principal objectives in developing the administrative framework for import risk analysis was to ensure that it complied with Australia's international rights and obligations.

These derive principally from the Agreement on the Application of Sanitary and Phytosanitary Measures, or *SPS Agreement*, although other WTO Agreements (including the *Agreement on Technical Barriers to Trade*) may be relevant in certain circumstances. Specific international guidelines on risk analysis developed under the International Plant Protection Convention (IPPC) and by the Office International des Epizooties (OIE) are also relevant.

The *SPS Agreement* applies to measures designed to protect human, animal and plant life and health from pests and diseases, or a country from pests, and which may directly or indirectly affect international trade. It also recognises the right of WTO Member countries to determine the level of protection they deem appropriate and to take the necessary measures to achieve that protection. Sanitary (human and animal health) and phytosanitary (plant health) measures apply to trade in or movement of animal and plant based products within or between countries.

In the *SPS Agreement*, SPS measures are defined as any measures applied:

- *to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms*
- *to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs*
- *to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests*
- *to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.*

The key provisions of the *SPS Agreement* are as follows:

- An importing country has the sovereign right to adopt measures to achieve the level of protection it deems appropriate (its appropriate level of protection, or ALOP) to protect human or animal life or health within its territory, but such a level of protection must be consistently applied in different situations.
- An SPS measure must be based on scientific principles and not be maintained without sufficient evidence.
- In applying SPS measures, an importing country must avoid arbitrary or unjustifiable distinctions in levels of protection, if such distinctions result in discrimination or a disguised restriction on international trade.
- An SPS measure must not be more trade restrictive than necessary to achieve an importing country's ALOP, taking into account technical and economic feasibility.
- An SPS measure should be based on an international standard, guideline or recommendation, where these exist, except to the extent that there is scientific justification for a more stringent measure which is necessary to achieve an importing country's ALOP.
- An SPS measure conforming to an international standard, guideline or recommendation is presumed to be necessary to protect human, animal or plant life or health, and to be consistent with the *SPS Agreement*.

- Where an international standard, guideline or recommendation does not exist or where, in order to meet an importing country's ALOP, a measure needs to provide a higher level of protection than accorded by the relevant international standard, such a measure must be based on a risk assessment; the risk assessment must take into account available scientific evidence and relevant economic factors.
- When there is insufficient scientific evidence to complete a risk assessment, an importing country may adopt a provisional measure(s) by taking into account available pertinent information; additional information must be sought to allow a more objective assessment and the measure(s) reviewed within a reasonable period.
- An importing country must recognise the measures of other countries as equivalent, if it is objectively demonstrated that the measures meet the importing country's ALOP.

The rights and obligations in the *SPS Agreement* must be read as a whole. The articles must be interpreted in relation to each other. That is, the articles do not stand alone.

In many instances, the biosecurity policies that Biosecurity Australia develops are based on the relevant international standards, guidelines and recommendations. In certain instances and in conformity with rights under the *SPS Agreement*, Australia has not adopted such international norms because to do so would result in an unacceptably high level of risk of disease or pest entry and establishment. Instead, the policies are based on a risk analysis.

The text of the *SPS Agreement* can be found at the WTO Internet site.[1]

The following issues are discussed in greater detail:

- notification obligations
- use of international standards
- equivalence
- risk assessment
- ALOP
- consistency in risk management.

Notification obligations

The WTO SPS Committee has been established to oversee the implementation of the *SPS Agreement*, and to provide a forum for the discussion of any trade issues related to biosecurity policies. Like other WTO committees, all WTO Members have the right to participate in the work and decision making of the SPS Committee; decisions are taken by consensus. The SPS Committee has accepted, as observers, the Codex Alimentarius Commission (Codex), OIE and IPPC, as well as other international and regional intergovernmental organisations with activities in food safety, animal health and plant protection to maximise knowledge of and participation in its work.

The SPS Committee normally meets three times a year at the WTO headquarters in Geneva, Switzerland.

In addition to considering any specific trade concerns raised by governments, the *SPS Agreement* has set specific tasks for the Committee. One of these is to monitor the extent to which governments are using internationally developed standards as the basis for their requirements for imported products. Countries identify cases where the non-use, or non-existence, of an appropriate

[1] Available at http://www.wto.org/english/docs_e/docs_e.htm

international standard is causing difficulties for international trade. After consideration by the SPS Committee, these concerns may be brought to the attention of the relevant standard-setting organisations.

Under the *SPS Agreement*, Members are required to notify WTO of new sanitary or phytosanitary regulations or modifications to existing regulations that are not substantially the same as the content of an international standard and that may have a significant effect on international trade. Australia notifies new measures and comments on draft policies proposed by other countries through the SPS Notification Point in AFFA.

Use of international standards

The *SPS Agreement* has conferred new responsibilities on three international organisations by requiring WTO Members to harmonise their sanitary and phytosanitary measures on the standards, guidelines and recommendations produced by those organisations unless there is scientific justification for a more stringent measure.

The three international organisations are referenced in Annex A of the *SPS Agreement* as follows:

- *for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice*
- *for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics*
- *for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention*

Office International des Epizooties

The OIE, the world organisation for animal health, is an inter-governmental organisation created by the International Agreement of 25 January 1924, signed by 28 countries.

The objectives of OIE, laid out in 1924, continue to be valid:

- to keep member countries informed of the occurrence and course of significant animal diseases throughout the world, and of means of controlling these diseases
- to coordinate, at the international level, studies devoted to the surveillance and control of significant animal diseases
- to harmonise health standards covering trade in animals and animal products.

The OIE currently comprises over 160 member countries and operates under the authority of an International Committee formed by permanent delegates designated by the governments of all member countries.

The standards referenced in the *SPS Agreement* include the following OIE Codes and Manuals:

- the *OIE International Animal Health Code*, prepared by the International Animal Health Code Commission, contains standards, guidelines and recommendations designed to prevent the introduction of pests and diseases into the importing country during trade in animals, animal genetic material and animal products

- the *Manual of Standards for Diagnostic Tests and Vaccines*, prepared by the Standards Commission, lists laboratory diagnostic techniques and requirements for production and control of biological products (mainly vaccines)
- an *Aquatic Animal Health Code* and a *Diagnostic Manual for Aquatic Animal Diseases*, prepared by the Fish Diseases Commission. These are sister publications to the OIE Code and Manual above.

The OIE has developed guidelines for risk analysis which recognise that the importation of animals and animal products may involve a degree of risk to the importing country. The OIE supports risk analysis because it provides importing countries with an objective method of assessing risks associated with importation and of determining how those risks may be managed. It notes that analysis should be transparent so that the exporting country is provided with a clear and documented decision on the measures imposed on imports or the reasons for refusing to allow importation.

Equivalence

Article 4 of the *SPS Agreement* states that:

> *Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.*

Members must accept the SPS measures of other Members as equivalent to their own if the latter can demonstrate objectively that their measures provide the level of protection required by the importing country. Often there are several alternative measures that may either singly or in combination achieve ALOP (e.g. treatment, quarantine or increased inspection). In choosing among such alternatives, a Member should put in place measures that are no more trade-restrictive than required to achieve its health protection objectives, provided those measures are technically and economically feasible. In doing so, the importing country must remain open to approaches from exporting countries with regard to alternative measures that may meet its ALOP.

Risk assessment

Articles 5.1 to 5.3 of the *SPS Agreement* outline the requirements that Members should follow when carrying out an import risk assessment.

Article 5.1 provides a basic statement of the obligation:

> *Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organisations.*

Annex A of the *SPS Agreement* contains two definitions of risk assessment; the following is the definition applicable to biosecurity assessments:

> *The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences.*

On the basis of this definition, the Appellate Body examining Australia's appeal against the dispute settlement panel's finding on Australia's prohibition of imports of Canadian salmon considered that a risk assessment within the meaning of Article 5.1 must:

- identify the hazards whose entry, establishment or spread within its territory a Member wants to prevent, as well as the associated potential biological and economic consequences
- evaluate the likelihood of entry, establishment or spread of these hazards, as well as the associated potential biological and economic consequences
- evaluate the likelihood of entry, establishment or spread of these hazards according to the SPS measures that might be applied; measures which might be applied are those which reduce the risks to the appropriate level, with the aim of being least trade restrictive.

The Appellate Body believed that, for a risk assessment to fall within the meaning of Article 5.1 and the first definition in paragraph 4 of Annex A of the Agreement, it is not sufficient that it conclude that there is a 'possibility' of entry, establishment or spread of diseases and their associated biological and economic consequences. That is, an assessment must evaluate the 'likelihood' (the 'probability') of entry, establishment or spread of diseases and their associated biological and economic consequences. Furthermore, likelihood should be evaluated without and then with any SPS measures that might be required.

Article 5.2 outlines factors that should be considered when assessing the risks associated with a proposed importation. Specifically, it states that:

> *In the assessment of risks Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological or environmental conditions; and quarantine or other treatment.*

This paragraph emphasises the need to consider a wide range of factors in both the importing and exporting country.

Article 5.3 describes the need to include a consequence assessment in a risk assessment, and lists dimensions that should be considered when assessing 'potential damage' arising from a disease or pest incursion. Specifically, it states that:

> *Members shall take into account as relevant economic factors; the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the cost of control or eradication in the territory of the importing Member.*

This list of 'relevant economic factors' may be viewed as the bare minimum that must be considered if an analysis is to comply with the terms of the *SPS Agreement*. In addition, both the *OIE Code* and IPPC standards for risk analysis have outlined factors that should be considered when assessing consequences. These two standards also stress the need to consider the 'likely magnitude' of consequences — that is, to base an assessment of consequences on the likelihood of various levels of damage in the importing country. Finally, Article 5.3 states that Members should consider '*... the relative cost-effectiveness of alternative approaches to limiting risks ...*'. This is an issue that should be explored during risk management. Among factors that may not be taken into account are those relating to import competition.

The environmental and ecological consequences of pest or disease introduction are legitimate considerations in a risk assessment. The *SPS Agreement* provides a basic right to take measures to

protect animal or plant life or health (Article 2). In Annex A, 'animal' is defined to include fish and wild fauna; and 'plant' to include forests and wild flora.

Additional to the economic factors identified in Article 5.3, the definition of risk assessment in Annex A, paragraph 4 (' ... *evaluation of the likelihood of entry, establishment or spread of a pest or disease … and of the associated potential biological and economic consequences ...*') provides for general consideration of the biological consequences, including those for the environment. The environment is included in paragraph 1(d), which states that an SPS measure is one that is applied to ' ... *prevent or limit other damage to a country from the entry, establishment or spread of pests* ...'.

Article 5.7 provides for the use of precaution when information is insufficient. This paragraph states that:

> *In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.*

Members, in adopting provisional measures, must demonstrate that there is insufficient information for an objective assessment of the risk. The provisional measures must be based on available information including international standards and the approaches of other countries. Countries adopting provisional measures are obliged to identify the additional information required for a more objective assessment and to seek that information in a timely manner. The provisional measure must be reviewed within a reasonable period because such measures are assumed to be trade limiting and contrary to the interests of WTO agreements.

Appropriate level of protection

The *SPS Agreement* defines '*appropriate level of sanitary or phytosanitary protection*' as the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. The *SPS Agreement* notes that many Members also refer to this concept as the '*acceptable level of risk*'. In setting their ALOP, Members are to take into account the objective of minimising negative trade effects (Article 5.4).

Determination of Australia's ALOP is an issue for government in consultation with the community — it is not a prerogative of WTO. ALOP reflects government policy that reflects community expectations; it is a societal value judgement to which AFFA contributes by providing technical information and advice. It is important to note that the *SPS Agreement* does not require a Member to have a scientific basis for its ALOP determination.

The ALOP can be illustrated using a *risk estimation matrix* (Table 1). The cells of this matrix describe the product of likelihood and consequences — termed 'risk'.

When interpreting the risk estimation matrix it should be remembered that although the descriptors for each axis are similar ('low', 'moderate', 'high', etc.), the vertical axis refers to *likelihood* and the horizontal axis refers to *consequences*.

One implication of this is that a 'negligible' probability combined with 'extreme' consequences, is not the same as an 'extreme' probability combined with 'negligible' consequences — that is, that the matrix is *not symmetrical*. Another implication is that 'risk' is expressed in the same units as are used to estimate consequences — that is, risk is *not* a likelihood.

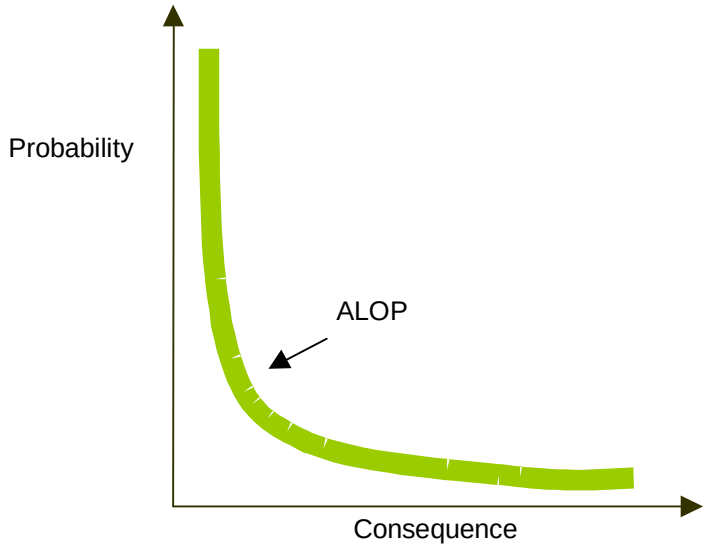
Table 1 Risk estimation matrix

Likelihood of entry and exposure	Negligible impact	Very low	Low	Moderate	High	Extreme impact
High likelihood	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Low	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
Very low	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
Extremely low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
Negligible likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk

Consequences of entry and exposure

The band of cells in Table 1 marked 'very low risk' represents Australia's ALOP, or tolerance of loss. This band of cells represents an approximation of a continuous 'iso-risk curve' — a curve that will be asymptotic at the minimum level of consequences considered to be 'acceptable' (which, in Australia's case, is 'very low') and at a likelihood that tends toward zero. The principle of an iso-risk curve is illustrated in Figure 1.

Figure 1 Theoretical iso-risk curve



Consistency in risk management

Article 5.5 states:

> *With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.*

WTO Members are obliged to avoid arbitrary or unjustifiable distinctions in the levels of protection applied in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. This obligation reflects the objective of consistency in applying the concept of ALOP against risks to human, animal and plant life or health — that is, consistency in risk management. In other words, it is not open to a Member to arbitrarily vary its attitude to the acceptance of risk from one situation to another.

Consistency is achieved by using the risk estimation matrix (Table 1).

OVERVIEW OF OIE APPROACH TO IMPORT RISK ANALYSIS

Under the OIE Code, IRAs for animals and animal products are based on the following procedures:

- hazard identification
- risk assessment, incorporating:
    - release assessment
    - exposure assessment
    - consequence assessment
    - risk estimation
- risk management
- risk communication[2]

The key objective of this *Technical Issues Paper* is to document the approach to and results of hazard identification. This step is discussed in further detail.

METHOD FOR HAZARD IDENTIFICATION

Hazard identification is described in the OIE Code as a classification step, for identifying pathogenic agents (or clearly identified strains of pathogenic agents) that could be associated with the importation of a commodity. Agents thus classified are termed 'potential hazards'.

The OIE Code states that to be identified as a potential hazard, a pathogenic agent should comply with all of the following criteria:

- the pathogenic agent should be appropriate to the animal species to be imported, or from which the commodity is derived
- the pathogenic agent could produce adverse consequences in the importing country
- the pathogenic agent may be present in the exporting country[3]
- the pathogenic agent should not be present in the importing country. If present, the pathogenic agent should be associated with a notifiable disease, or should be subject to control or eradication measures.[4]

Hazard identification was initiated by generating a comprehensive list of disease agents likely to be relevant to the importation of honeybee semen. The list includes those disease agents associated with OIE List B diseases and known to affect bees, and any other agents considered relevant to

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[2] Risk communication is an iterative process carried out in accordance with AFFA's IRA process.

[3] The OIE Code states that ' ... *the evaluation of the veterinary services, surveillance and control programs and zoning and regionalisation systems are important inputs for assessing the likelihood of hazards being present in the animal population of the importing country* ...'

[4] In this context, 'control or eradication measures' are taken to mean a compulsory control or eradication program.

honeybee semen. The list was subsequently refined by applying to each disease agent, the four criteria stated above. If reasons for the inclusion/exclusion of particular pathogenic agents were not clear-cut, these agents were retained on the list and examined in the formal risk assessment.

BACKGROUND

The Australian Honey Bee Industry Council has had a longstanding request with AFFA to develop health conditions for the importation of semen of the European honeybee (*Apis mellifera*). Industry requires imported semen for genetic improvement programs in commercial honeybee breeding enterprises in Australia. Imported semen will also provide counter-seasonal trade opportunities for honeybee exports. The importation of honeybee semen is expected to provide a more cost-effective means of accessing overseas genetic material with lower associated quarantine risk than the existing policy for the importation of queen honeybees.

Animal Biosecurity Policy Memorandum (ABPM) 2002/29 of 6 June 2002 notified stakeholders of Biosecurity Australia's intention to conduct an IRA for the importation of honeybee semen. The ABPM proposed the scope, indicative timetable and that a team of Veterinary Officers from within Animal Biosecurity should conduct the IRA. No stakeholder commented on the ABPM. Subsequently, the Executive Director of Biosecurity Australia confirmed the scope, indicative timetable and the in-house team. ABPM 2002/36 of 17 July 2002 advised stakeholders of the decision and an appeal opportunity was provided until 19 August 2002. No appeals were received.

ADMINISTRATION

Timetable

As part of the proposed approach to the IRA, ABPM 2002/29 indicated to stakeholders that the process would take approximately 18 months to two years to complete.

A review of the IRA process is currently underway; this review is expected to be finalised by the end of 2002. A draft framework document was circulated in September 2001 (ABPM 2001/26). There has been general acceptance of several proposed changes including the release of a Technical Issues Paper for all IRAs. On this basis, such a document has been prepared for this analysis.

This is the first technical document of the IRA to be circulated for comment. All technical comments received during the 60-day consultation period will be considered in finalising the list of hazards. A Draft IRA Report will be subsequently circulated to stakeholders for 60 days for comment, and will include further assessment of the pest and disease risks and proposed risk management options. Comments on the draft IRA will be considered as the IRA is finalised. The Director of Quarantine will consider the final report and its recommendations and will make a determination. The determination will be subject to a 30 day appeal period. Appeals are to be based on failure of process, ie that the steps in the process were not followed or the IRA failed to consider a significant body of technical evidence. Once the appeal period closes and/or any appeals are addressed, the policy is adopted.

Scope

This generic IRA considers quarantine risks that may be associated with the importation to Australia of semen of the honeybee, *Apis mellifera*, L. *Apis mellifera*, L comprises numerous subspecies that evolved from European and African strains. Most honeybees in temperate climates have been derived from European races, *A. m. mellifera*, L (Germany), *A. m. ligustica*, L (Italy), *A. m. caucasica* Gorb. (Caucasus mountains, northern Europe and west central Russia) and *A. m carnica* Pollman (southern Austrian alps, northern Yugoslavia, Danube Valley). African strains of *A. mellifera* are not known to be present in Australia and are known to have undesirable genetic traits for beekeeping operations. The intent of the IRA is to develop conditions for the importation of semen of honeybees that do not contain African genotypes. Accordingly, in addition to consideration of infectious agents of quarantine concern that may be introduced via semen of *A. mellifera*, this IRA evaluates the risks associated with the importation of semen of the African strains of *A. mellifera* and their hybrids. For the same reasons, it also evaluates risks associated with the 'Cape honeybee', *Apis mellifera capensis.*

AUSTRALIA'S CURRENT QUARANTINE POLICY FOR IMPORTS OF HONEYBEE SEMEN

International quarantine policy

Australia does not currently have any policy to allow the importation of honeybee semen. Australia does have a policy that allows live queen honeybees to be imported and propagated under secure quarantine conditions with subsequent release of grafted larvae.

Domestic arrangements

The Commonwealth Government is responsible for regulating the movement of animals and their products into and out of Australia, but the State and Territory Governments have primary responsibility for animal health controls within their State or Territory. Legislation relating to resource management or animal health may be used by State and Territory government agencies to control interstate movement of honeybees and their products.

There are certain interstate movement controls for honeybees and their products. In particular, Western Australia is free of European foul brood and prohibits the importation of honey and other honeybee products unless pasteurised/treated.

THE HONEYBEE INDUSTRY

The honeybee industry in Australia

Managed honeybees are found in all Australian States and Territories. There are around 673,000 registered hives in Australia, producing not only honey and beeswax but also live bees (queens and package bees), and other products such as pollen. About 467,000 hives are operated by beekeepers with a minimum of 200 hives, and these are considered to represent the commercial industry. It is estimated that an average of at least 30,000 tonnes of honey are produced each year in Australia,

with nearly 45% of this total coming from beekeepers resident in NSW. Between 9,000 and 12,000 tonnes of honey is exported each year and about 2,000 tonnes is imported.

The apiary industry has a direct value (the gross value of production), as well as an indirect value (demand stimulated in linked sectors) and crop pollination services. The gross value of production over all sectors of the industry is estimated as being between $60 and $65 million per annum (Gibbs and Muirhead, 1998), of which $49 million comprises honey production. NSW beekeepers contribute around 44% of this total value of production, consistent with that State having the largest number of registered hives.

Major items of expenditure for the industry are labour and transport – with fuel being the largest single component of the latter. It is estimated that around 80% of income (turnover) is spent on costs of production, which means that much of the income generated by the sale of honey and other products remains in rural areas of Australia.

Some horticultural crops like almonds set very little fruit without insect pollination. Others like cucurbits and strawberries also require effective pollination by bees for fruit quality – shape and size. The benefits of crop pollination accrue to the agricultural sector and flow on to the entire Australian community. Gibbs and Muirhead 1998 estimated the total value of paid and unpaid pollination at around $1.2 billion/year. Estimates of values to individual states vary from $60 - 251 million. Income from paid pollination services (although representing a minor part of this total estimated value) is important to individual beekeepers in every State, and this sector is expected to expand (Gibbs and Muirhead, 1998).

PRELIMINARY IDENTIFICATION OF HAZARDS

The list of 'potential hazards' (see Method for Hazard Identification) outlined below was derived from OIE Lists A and B, and from a list of the causative agents for other diseases considered to be of importance in the importation of honeybee semen.

OIE List A diseases

- Nil.

OIE List B diseases

- *Acarapis woodi* - causes Acariosis
- *Paenibacillus larvae* - causes American foulbrood
- *Melissococcus pluton* - causes European foulbrood
- *Varroa destructor*[5] - causes varroasis
- *Nosema apis* - causes nosemosis

Other diseases/disease agents

Viruses of bees

- sac brood virus
- chronic paralysis virus
- Kashmir bee virus
- cloudy wing virus
- acute paralysis virus
- black queen cell virus
- deformed wing virus
- slow paralysis virus

[5] The OIE Manual of Standards for Diagnostic Tests and Vaccines, 3rd Ed., 1996, refers to *Varroa jacobsoni* (Oudemans) as the member of the genus Varroa that is parasitic on *Apis mellifera*. The taxonomy of mites in the genus Varroa has recently been revised (Anderson and Trueman, 2000). *V. jacobsoni* is now recognised to be restricted in its distribution to south-east Asia and is primarily restricted in host range to *Apis cerana javana*. The primary member of the genus Varroa that is parasitic on *A. mellifera* in North America, South America, Europe, Africa and Asia is the species known as *Varroa destructor* (Anderson and Trueman).

- bee virus X
- bee virus Y
- filamentous virus

Fungal infections

- *Ascosphaera apis*, causative agent of chalk brood

Protozoal infections

- *Malpighamoeba mellificae*, causative agent of amoeba disease

Exotic ectoparasites and insect pests

- Not considered because they are not associated with bee semen.

Remaining diseases of importance

Undesirable genotypes

- *Apis mellifera scutellata* (Africanised honeybee)
- *Apis mellifera capensis* (Cape honeybee)

HAZARD REFINEMENT

To be identified as a potential hazard, a pathogenic agent should satisfy the following criteria:

- the pathogenic agent should be appropriate to the animal species to be imported, or from which the commodity is derived
- the pathogenic agent could produce adverse consequences in the importing country
- the pathogenic agent may be present in the exporting country
- the pathogenic agent should not be present in the importing country or, if present, the pathogenic agent should be associated with a notifiable disease and be subject to control or eradication measures.

These criteria were applied to each pathogenic agent in Table 2.

Table 2 Refinement of hazard list

Disease agent (disease)	Susceptible species	Adverse consequences in Australia (Yes / No)	Distribution	Potential hazard? (Yes / No)	Reasons for removal
Bacteria					
American foulbrood	Honeybee	Yes	Worldwide including Australia Notifiable disease with movement controls	Yes	
European foulbrood	Honeybee	Yes	Worldwide including Australia Notifiable disease with movement controls	Yes	
Viruses					
Acute paralysis virus	Honeybee	Yes	Worldwide. Not in Australia	Yes	
Bee virus X	Honeybee	Yes	USA, UK, Fiji and NZ and Australia. Probably worldwide	No	Present in Australia with no control measures
Bee virus Y	Honeybee	Yes	USA, UK, Fiji and NZ and Australia. Probably worldwide	No	Present in Australia with no control measures
Black queen cell virus	Honeybee	Yes	Worldwide including Australia	No	Present in Australia with no control measures
Cloudy wing virus	Honeybee	Yes	Worldwide including Australia	No	Present in Australia with no control measures
Deformed wing virus	Honeybee	Yes	Nth America and Europe Probably present in Australia	Yes	
Filamentous virus	Honeybee	Yes	USA and UK Not reported in Australia	Yes	
Kashmir bee virus	Honeybee	Yes	Worldwide including Australia	No	Present in Australia with no control measures

Disease agent (disease)	Susceptible species	Adverse consequences in Australia (Yes / No)	Distribution	Potential hazard? (Yes / No)	Reasons for removal
Sacbrood virus	Honeybee	Yes	Worldwide including Australia	No	Present in Australia with no control measures
Slow bee paralysis virus	Honeybee	No	USA and Europe Present in Australia	No	Present in Australia with no control measures
Fungi					
Ascosphaera apis	Honeybee	Yes	Worldwide including Australia	No	Present in Australia with no control measures
Protozoa					
Malpighamoeba mellificae	Honeybee	Yes	Worldwide including Australia	No	Present in Australia with no control measures
Nosema apis	Honeybee	Yes	Worldwide including Australia	No	Present in Australia with no control measures
Bee strains					
Apis mellifera capensis	Honeybee	Yes	Southern Africa Not in Australia	Yes	
Apis mellifera scutellata	Honeybee	Yes	Africa, Sth America, USA Not in Australia	Yes	

CONCLUSIONS

The following disease agents/hazards were retained for further consideration in the IRA.

- American foulbrood
- European foulbrood
- Acute paralysis virus
- Deformed wing virus
- Filamentous virus
- Apis mellifera capensis
- Apis mellifera scutellata

FURTHER STEPS IN THE IMPORT RISK ANALYSIS PROCESS

The IRA process requires that the following steps be undertaken for this IRA:

- release of the Technical Issues Paper for stakeholder comment
  - comments to be received within 60 days
- release of the Draft IRA Report for stakeholder comment
  - comments to be received within 60 days
- consideration of stakeholder comment on the Draft IRA Report
  - stakeholders consulted further as necessary
- submission of recommendations to the Director of Animal and Plant Quarantine
- consideration of recommendations by the Director of Animal and Plant Quarantine, and final determination made
- release of the Final IRA Report
- consideration of any appeals
- if no appeals, or if appeals are rejected, adoption of the quarantine policy.

Stakeholders will be advised of any significant variations to this process.

Biosecurity Australia is committed to a thorough risk analysis of the proposed importation of honeybee semen from exporting countries. This analysis requires that technical information be gathered from a wide range of sources. The timely contribution of information would be much appreciated.[6]

[6] Contact details for stakeholder contributions are provided in the accompanying Animal Biosecurity Policy Memorandum (ABPM).

REFERENCES

1 Gibbs, DMH and IF Muirhead. (1998). *The economic value and environmental impact of the Australian beekeeping industry*. A report prepared for the beekeeping industry, February 1998.

2 Anderson DL and Trueman JWH. (2000). *Varroa jacobsoni (Acari: Varroidae) is more than one species*. Experimental and Applied Acarology 24: 165-189.