EXPLANATORY STATEMENT

Select Legislative Instrument 2007 No. 28

Issued by the authority of the Minister for Agriculture, Fisheries and Forestry

Quarantine Act 1908

Quarantine Amendment Regulations 2007 (No. 1)

Subsection 87 (1) of the Quarantine Act 1908 (the Act) provides that the Governor-General may make Regulations prescribing matters required or permitted by the Act to be prescribed or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The Act provides for certain decisions to take account of quarantine risks; the expression ‘level of quarantine risk’ is defined in section 5D of the Act. To give effect to the requirements of the Act, risk analyses are conducted to assess the level of quarantine risk arising from the importation of animals, plants or other goods into Australia, the Cocos Islands or Christmas Island. Risk analyses are conducted across a spectrum of scientific complexity and available scientific information. An import risk analysis (IRA) is a type of risk analysis for assessing new risks or where aspects of the risk may differ significantly from those previously assessed. The process for undertaking IRAs is characterised by formal periods of consultation and review.

The Quarantine Amendment Regulations 2007 (No. 1) amend the Quarantine Regulations 2000 (the Principal Regulations) to regulate timeframes for certain steps in the process for conducting an IRA.

The purpose of the Quarantine Amendment Regulations 2007 (No. 1) is to:

− identify two types of IRA, a standard IRA and an expanded IRA;
− identify certain steps which must be included in each type of IRA;
− specify time limits for certain steps and overall timeframes for the completion of IRAs;
− specify publication requirements;
− make provision for termination of an IRA; and
− allow for a part-completed risk analysis to be completed as an IRA under the Regulations.

The Regulations also provide that:

− failure to comply with the steps which must be included in an IRA or with the time limits does not affect the validity of a report published by Biosecurity Australia in respect of an IRA; and
− the preparation and publication of a report under the Regulations is not required before a decision can be made as to whether an import permit may be granted under the Act.

For the purposes of the Regulations, an IRA ends when a provisional final IRA report is released. The report is ‘provisional’ because stakeholders can request a review of the
provisional report by an appeals panel. This review process is not included in the Regulations.

Background on the IRA system is included in Attachment A and details of the Regulations are set out in Attachment B.

The Department of Agriculture, Fisheries and Forestry (DAFF) consulted with a range of stakeholders during the development of options for reform and following the Government’s announcement of the reforms to the IRA process. DAFF canvassed industry views on the IRA process at an industry–government forum on biosecurity during the development of options for reform. There has been extensive consultation with other Government departments and Australia’s peak national farmer body on the reforms to the IRA process. DAFF has also briefed state and territory governments and industry groups and has published information for all stakeholders, including overseas trading partners, on the key elements of the reforms to the IRA process.

The regulations 1 to 3 commence on the day after the Regulations are registered. Schedule 1 to the Regulations would commence on a day fixed by legislative instrument made by the Minister. This provision provides necessary flexibility to allow the Regulations to commence as soon as the supporting materials become available and transitional arrangements have been made for risk analyses already underway. The Regulations would commence in 6 months if an instrument is not made.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*. However, the Regulations also provide that the legislative instrument made by the Minister is not to be subject to the standard disallowance or sunsetting provisions contained in the *Legislative Instruments Act 2003*. This is because it is an instrument solely for the commencement of the regulations and is essentially spent once they come into effect. Since the *Legislative Instruments Act 2003* does not provide an exemption from disallowance or sunsetting specifically for instruments commencing regulations, the exemption must be specified. Therefore, the instrument would be prescribed for the purposes of the tables in subsections 44(2) and 54(2) of the *Legislative Instruments Act 2003* with the effect that it is not subject to the disallowance and sunset provisions of that Act.
Import Risk Analysis - Background

The occasion for an IRA usually arises as a result of an import proposal, that is, a request from another country or an importer to import goods into Australia. An IRA may also be instigated by the Department of Agriculture, Fisheries and Forestry, for example, when there has been a change in the level of quarantine risk associated with an import.

A risk analysis, including an IRA, may be taken into account by a decision maker under the *Quarantine Act 1908* (the Act) when there is a requirement to consider the level of quarantine risk. For example, a risk analysis may be taken into account by the Director of Quarantine when deciding whether to grant a permit under one or other of the Quarantine Proclamation 1998, the Quarantine (Cocos Islands) Proclamation 2004 or the Quarantine (Christmas Island) Proclamation 2004.

The Full Federal Court in *Director of Animal and Plant Quarantine v Australian Pork Limited* [2005] FCAFC 206 considered the IRA process, finding that it did not authorise anything or affect anyone’s rights or impose obligations, and was therefore not subject to review under the *Administrative Decisions (Judicial Review) Act* 1977. The Regulations are not intended to alter the essential nature of the IRA process as described by the Federal Court. The Regulations are not intended to allow the IRA process itself to be the subject of judicial review, since this would be inconsistent with the aim of providing for improved timeliness and certainty. It is considered that stakeholders’ rights and interests are sufficiently protected by the right to seek judicial review of an import permit decision under the Act. The Regulations do not confer on any person a power or duty to decide whether there should be an IRA, and if so what type of IRA. In practice, the Chief Executive will make these decisions purely as a matter of administration, and not pursuant to any statutory power.

On 18 October 2006, the Australian Government announced that Australia’s IRA process would be strengthened by increasing the level of scientific scrutiny, improving consultation with stakeholders and regulating timeframes to improve timeliness and certainty in the process. The reforms aim to increase confidence in the IRA process.
Details of the *Quarantine Amendment Regulations 2007 (No. 1)*

Regulation 1 provides that the name of the Regulations is the *Quarantine Amendment Regulations 2007 (No. 1)*.

Regulation 2 provides that Regulations 1 to 3 commence on registration. Schedule 1, which sets out the requirements for the IRA process, will commence 6 months after registration or on an earlier day fixed by a legislative instrument made by the Minister. The instrument setting the commencement date for Schedule 1 is prescribed for the purposes of the tables in subsections 44 (2) and 54 (2) of the *Legislative Instruments Act 2003* to ensure that it is not subject to the disallowance and sunset provisions of that Act.

Regulation 3 provides that Schedule 1 amends the *Quarantine Regulations 2000* (the Principal Regulations).

Schedule 1 - Amendments

Items 1 – 3 update the Readers Guide. Item 1 replaces a specific date relating to an offence provision of the Principal Regulations with ‘Currently’ to ensure the Guide remains up to date. Item 2 inserts a new Part 6A for import risk analysis. Item 3 sets out what is contained in the new Part and renumbers the subsequent Part.

Item 4 provides for a new Part 6A to be inserted into the Principal Regulations. The Regulations in Part 6A set out key steps and timeframes to make the IRA process more timely and predictable. A detailed description of the IRA process is set out in the IRA Handbook which will be available on the Department of Agriculture, Fisheries and Forestry website at the commencement of the Regulations.

Regulation 69A states that the new Part 6A deals with import risk analysis. Two notes accompany this item. The first informs the reader that the Chief Executive of Biosecurity Australia may make an administrative, non-statutory, decision to conduct an IRA under the Regulations. Criteria for decisions are publicly available and will be included in amendments to the IRA Handbook available at the commencement of the Regulations. The second note informs the reader that a decision to issue an import permit is not dependent on an IRA having been conducted.

Regulation 69B specifies definitions that apply to the Regulations, including the following two terms of note.

The term ‘import risk analysis’ means a risk analysis conducted under these Regulations.

The term ‘proposer’ means the person who proposes the relevant import. It applies to individuals, organisations, companies and governments of other countries who make a proposal to import animals, plants or other goods.

Regulation 69C specifies the steps that must be undertaken in a standard IRA and an expanded IRA. An expanded IRA will be conducted where there are significant differences in scientific opinion, or where significant harm to humans, animals and
plants, or the environment may result from an importation. An expanded IRA is subject to scientific review by the Eminent Scientists Group. Other IRAs will be conducted as standard IRAs. The note lets the reader know that the decision to conduct an IRA and whether that IRA is to be conducted as a standard or expanded IRA is a non-statutory, administrative decision at the discretion of the Chief Executive. Criteria to guide the Chief Executive’s choice of a standard or expanded IRA should be used and will be included in the IRA Handbook available at the commencement of the Regulations.

The Regulation also specifies the reports that Biosecurity Australia must produce during a standard or expanded IRA and stipulates that public submissions are to be invited at certain stages.

The Regulation specifies that the IRA process ends when a provisional final IRA report is published. An accompanying note informs the reader that a provisional final IRA report may be reviewed, pursuant to a non-statutory review process, and that it becomes final at the end of such a process.

The subregulation 69C(4) makes clear that the decision to issue an import permit is not dependent on an IRA being conducted or completed.

Regulation 69D imposes time limits for periods of public consultation and consideration by the Eminent Scientists Group. A time limit for these key steps provides a level of certainty for all involved in conducting and contributing to an IRA. There is provision for one extension of the consultation period on a draft IRA report if stakeholders have not had reasonable opportunity to comment. This provision recognises that, in some cases, stakeholders may need more time to consider the draft report. For example, an extension to the comment period might be made if it falls during an annual harvest period for key stakeholders, or if the country proposing the import is dealing with a quarantine emergency.

Regulation 69E imposes overall time limits for the completion of standard and expanded IRAs subject to provisions in Regulation 69H. Biosecurity Australia must complete standard IRAs within 24 months and expanded IRAs within 30 months.

Regulation 69F allows the IRA report to remain valid even if the timeframes are not met. This prevents the work and effort taken in preparing and commenting on an IRA being set aside because of a failure to meet a timeframe. This does not mean that timeframes should not be adhered to.

Regulation 69G specifies circumstances that critically affect the completion of an IRA. These circumstances may result in certain periods of time being disregarded, as outlined in Regulation 69H. The circumstances include waiting for information requested or waiting for the outcome of research that is essential to complete the IRA.

The Chief Executive may also determine that a national or international quarantine circumstance exists, that limits Biosecurity Australia’s ability to complete an IRA within the time required. This provision is intended to cover a range of events of a quarantine emergency nature and is not more specifically defined because of the potential to omit some future event. Biosecurity Australia’s ability to complete an IRA may be limited by a significant outbreak of pests or disease overseas where:
Australia has agreed to provide technical assistance under international agreements; or

the proposer or other person is unable to provide necessary information or comment due to the spread of the pest or disease.

A significant national quarantine circumstance might include an outbreak of an exotic pest or disease in Australia, (such as highly pathogenic avian influenza or foot and mouth disease) or a major outbreak of a new or emerging pest or disease (such as virulent Newcastle disease) for which a major control or eradication response is mounted. In such situations, scientists from Biosecurity Australia may be involved in the responses and may not be available to work on IRAs.

Regulation 69H allows certain periods of time to be disregarded when calculating the time taken to complete an IRA. It is a ‘stop the clock’ mechanism. The circumstances in which time might be disregarded are outlined in Regulation 69G. To ensure the open and transparent use of this provision, time can only be disregarded after the Chief Executive publishes a notice to this effect. The notice must state why the time is to be disregarded and the period of time to be disregarded. The Chief Executive may decide that the ‘clock’ should restart on an earlier or later day than initially advised. The Chief Executive must advise by notice if this is to occur. Before altering the restart date, the Chief Executive must consider matters relating to whether the circumstances that gave rise to ‘stopping the clock’ still exist.

Regulation 69I specifies where public notices, reports and invitations are to be made available. Regulation 69I also details what must be included in notices and invitations.

Regulation 69J describes the circumstances when an IRA may be terminated by the Chief Executive prior to its completion. These include situations where the proposer advises they no longer wish the IRA to proceed, or where there is insufficient information available to complete the IRA satisfactorily. The proposer must be advised in writing beforehand of any decision to terminate an IRA prior to its completion because of lack of information. The Chief Executive may also decide to terminate, before completion, an IRA that has been generated from within DAFF and for which there is no proposer. A notice must be published advising of a decision to terminate an IRA.

Regulation 69K allows for a risk analysis that was started prior to the commencement of these Regulations to be continued as an IRA under these Regulations. In addition, where a risk analysis starts after the commencement of these Regulations, but not as an IRA, the Chief Executive may elect to continue it as an IRA under these Regulations. Steps in a risk analysis that have been completed do not need to be repeated under the Regulations. A notice must be published advising if the IRA is a standard or expanded IRA and the step at which the IRA is to commence.

Item 5 renumbers the existing Regulation 69A to accommodate the insertion of the new Part.