



Senator the Hon. Joe Ludwig

Minister for Agriculture, Fisheries and Forestry
Senator for Queensland

COPY

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The Hon. David O'Byrne MP
Minister for Infrastructure, Police and Emergency
Management, Economic Development, Workplace
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Dear Minister

Thank you for our meeting of 13 March 2013 in which you canvassed a series of issues related to the biosecurity legislation before the Australian Parliament.

Australia has a world-class biosecurity system. Our reputation as an exporter of quality food and agricultural products hinges on our enviable animal and plant health status. In order for the system to remain responsive and targeted in a changing global environment, a comprehensive modernisation of Australia's biosecurity regulatory framework is required.

The biosecurity legislation introduced into Parliament on 28 November 2012 is the first step in the development of this framework. At our meeting on 13 March 2013, you raised a number of issues in relation to the proposed Biosecurity Import Risk Analysis (BIRA) process and how it will operate under the biosecurity legislation. I would like to provide you with some additional information and clarification on this matter.

Biosecurity Bill

The Biosecurity Bill contains provisions relating to the Biosecurity Import Risk Analysis (BIRA) process, which will replace the current Import Risk Analysis (IRA) process in the *Quarantine Regulations 2000*. The BIRA process will play an important role in managing the risk of pests and diseases entering Australia and the impact they may have on our economy, local industry, environment and community. A high level comparative analysis of the current IRA regulatory framework and the proposed BIRA regulatory framework can be found at [Attachment A](#).

The Bill will allow the Director of Biosecurity to conduct a BIRA in order to evaluate the potential pest and disease risks associated with a proposed import of goods, animals or plants into Australia. Where the risk posed is greater than Australia's appropriate level of protection (ALOP), sanitary or phytosanitary measures may be identified to reduce the risk to a level that achieves Australia's ALOP. If no risk management measures are available to do this, the proposed import will not be allowed.

The Bill provides that:

- the Agriculture Minister may direct the Director of Biosecurity to commence a BIRA, but the Director of Biosecurity is not subject to direction by the government in relation to the conduct, findings or outcomes of a BIRA
- the Director of Biosecurity may request the Director of Human Biosecurity to prepare a statement of the human biosecurity risks associated with the import
- a BIRA must be conducted in accordance with the process set out in regulations
- the Director of Biosecurity may make guidelines setting out matters to be taken into account in conducting a BIRA—and, if made, are required to be published
- the Director of Biosecurity must prepare and publish certain reports as part of the process of conducting a BIRA.

These provisions have been included in the Bill to ensure that the BIRA process is open and transparent, with responsibilities and accountabilities clearly stated. It further demonstrates that the BIRA process is conducted independently from political processes. The Bill defers the remainder of the BIRA process to regulations.

Issues raised by you in our meeting

You raised a number of concerns that have been put to you by Tasmanian primary producers including:

- concerns about the 'covering the field' provisions in relation to the importation of goods
- the need to consider regional differences in national risk assessments
- independent input into, and review of the BIRA process
- appeals of final BIRA reports
- role of the Director of Biosecurity.

I provide further information on these issues below.

Covering the field

The Biosecurity Bill, if enacted, will clarify that its provisions will apply to the exclusion of any law of a state or territory government that prohibits or restricts the bringing or importation of particular goods into Australia for the purpose of managing biosecurity risks associated with the goods (clause 169). This is commonly known as 'covering the field'. This reflects Recommendation One of the Beale Review, the intent of the Intergovernmental Agreement on Biosecurity, which states that nationally set import conditions are set for goods brought in or imported into Australia, and aligns with the 1995 Memorandum of Understanding on Animal and Plant Quarantine Measures, agreed to by all state and territory governments.

Any additional measures state and territory governments place on imported goods, that are inconsistent with those imposed by the Commonwealth, may be subject to legal challenge under this provision. As is the case now, section 109 of the Constitution allows for Commonwealth law to prevail over state law if the state law is inconsistent. Anyone, including importers, can already take action through the courts to challenge validity of any state biosecurity condition and its relationship with federal conditions. For its part, I can assure you that the Commonwealth would only use this provision in exceptional circumstances and there is no plan to challenge any current state law should the legislation pass.

The Commonwealth does not intend to redo existing risk assessments, including IRAs, as part of the legislation implementation process.

Regional differences

With the Commonwealth covering the field, it is therefore even more important that the Commonwealth considers regional differences.

In setting national import conditions, the Australian Government Department of Agriculture, Fisheries and Forestry (the department) has always considered regional differences which are recognised in international instruments to which Australia is a party, like the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

The Biosecurity Bill enables consideration of regional differences through the definition of *biosecurity risk* in section 9, which includes reference to the likelihood of a pest or disease entering Australian territory or a part of Australian territory. The reference to a part of Australian territory allows for biosecurity risk to be assessed for a specific area or region, as well as for Australia as a whole.

The term *biosecurity risk* is used more than 280¹ times in the Biosecurity Bill as the basis of decision-making and the use of regulatory powers, embedding the concept of regional differentiation throughout the legislation (the phrase *biosecurity risk* also occurs more than 500 times in the Explanatory Memorandum). There are also a number of explicit references to regional differences (including the Commonwealth's commitment to consult with states and territories in considering regional differences) in the Explanatory Memorandum.

With a definition of biosecurity risk that provides for consideration of regional differences and up to 1000 references in the bill and supporting materials, I believe this issue is appropriately recognised in the Bill.

Independent expert input and review

The Biosecurity Bill does not explicitly refer to independent scientific review (although the Explanatory Memorandum does), or the Eminent Scientists Group (ESG), as part of the BIRA process. I was convinced by your arguments about the merits of including the ESG in the BIRA process. In this respect I have asked the department to include appropriate provision for independent expert input and review of BIRAs in the regulations. Draft regulations, which I expect to be released shortly, will also include specific reference to the ESG.

In fact, the BIRA Regulations will have multiple provisions for the Director of Biosecurity to request independent expert input and advice *at any time* throughout the BIRA process, as indicated on page 13 of the Biosecurity Bill's Explanatory Memorandum. This approach will provide a more flexible option than is currently available. The Director of Biosecurity will be able draw on a broader range of expertise to best suit the needs of an individual BIRA. It will also allow independent input and review at any stage throughout the BIRA process; unlike the current process where the ESG only reviews provisional draft IRAs in an expanded IRA process.

¹ Excluding table of contents and headers and footers

Appeals of BIRAs

The biosecurity bills provide for further independent oversight of the BIRA process to be undertaken by the Inspector-General of Biosecurity (IGB), an independent statutory office appointed by the Minister. The IGB Bill, if enacted, will establish the IGB and subsume the role of the current Import Risk Analysis Appeals Panel. The IGB will not undertake the function of the current or future ESG.

The review of a BIRA process would be triggered if an appeal is made to the IGB during the public consultation period on a provisional BIRA report. An appeal can be made to the IGB if a person believes that they have had their interests affected by a significant deviation from the BIRA process. The IGB will be able to review the process that was used to conduct the BIRA and make any findings publicly available.

On a point of clarification about appeals - as per the current IRA process, a final BIRA report, agreed to by the Director of Biosecurity represents a policy commitment rather than a statutory decision to allow imports into Australia.

Rather, a final BIRA report will provide information and advice to the Director of Biosecurity to take into consideration in assessing an import permit application. This distinction was explained in *Director of Animal and Plant Quarantine v Australian Pork Limited [2005] FCAFC 206* at 85²:

'The [Final IRA Report Policy] Determination did not 'authorise' anything. It did not affect anyone's rights or impose obligations. On its face, as already mentioned, it did no more than put forward matters to be taken into account by the Director in granting permits. There was no jurisdictional error because no statute conferred jurisdiction to make the Determination; it was a purely internal administrative exercise.'

While a final BIRA report would not be reviewable under administrative law, the department nonetheless has an obligation to consider any new information that may shed light on the need for tougher biosecurity import conditions at any time.

Decisions on prohibiting goods or conditionally non-prohibiting goods under the Bill are, however, reviewable under the *Administrative Decisions (Judicial Review) Act 1977*.

Role of the Director of Biosecurity

The Beale Review recommended a separation of powers between a National Biosecurity Commission and a National Biosecurity Authority. Following the government's decision in May 2011 not to implement this recommendation, these powers have been consolidated under the Director of Biosecurity.

The government considered that the creation of new statutory bodies and administrative arrangements would be a distraction from ongoing efforts to implement much needed administrative reform to Australia's biosecurity system by diverting resources away from implementing an evidence-led and science-based risk return operating model.

² Full court decision of the Federal Court of Australia can be found at:
<http://www.austlii.edu.au/au/cases/cth/FCAFC/2005/206.html>

The government has taken the view that decision-making could be managed through strong and explicit statutory requirements, such as those set down in the Biosecurity Bill. This approach is consistent with other structural arrangements in the Commonwealth related to regulatory risk assessment and decision making; for example the Therapeutic Goods Administration within the Health and Ageing portfolio.

Some in the community believe that there may be a conflict of interest for the Secretary in administering his role as Director of Biosecurity against his priorities as the Secretary of the department.

The Secretary's responsibilities as Director of Biosecurity, which are broadly consistent with current responsibilities as Director of Animal and Plant Quarantine, will be statutory and must be carried out in accordance with the legislation. As discussed at our meeting, if the Director of Biosecurity made a decision beyond the legal authority of the legislation (including taking into account considerations outside of the law), such a decision would be *ultra vires* (beyond power) and invalid.

Nonetheless, in response to stakeholders who expressed concern about this issue, I amended the Bill to explicitly state that '*in performing functions or exercising powers under this Act, the Director of Biosecurity must have regard to the objects of the Act...*' (subclause 579(4)).

Those concerned about the Secretary's role in administering the Act should be aware that the Secretary has no statutory obligations with respect to trade. The Secretary has no trade responsibilities under the Commonwealth's Administrative Arrangements Order. Every bilateral and multilateral international agreement to which Australia is a party recognises the right of parties to put in place their own biosecurity / quarantine arrangements.

For these reasons I do not believe there is any conflict of interest.

The regulatory framework

The biosecurity legislation is before a Senate Committee inquiry. Senate Standing Orders prevent any debate or vote on legislation before an inquiry is finalised. The Committee will not report before 24 June 2013. Even in the event the Committee unanimously recommends the bills pass in their current form, the prospect of getting the legislation through two chambers in the remaining three sitting days of the 43rd Parliament is remote.

Notwithstanding, I am aware of the significant public interest in proposed regulations. The department will shortly publish draft Regulations associated with BIRAs and the Inspector General of Biosecurity, with draft Regulations relating to ballast water to follow.

The department will make contact with Tasmanian officials and industry representative groups, at the time of publication.

Next steps

The department will work with stakeholders—including state and territory governments—in progressing development of the biosecurity regulatory framework. I thank you for the Tasmanian Government's input to date.

I have sent a copy of this letter to the Hon. Bryan Green MP, Tasmanian Minister for Primary Industries and Water, Energy and Resources, Local Government, Planning and Racing.

I have provided a copy of this correspondence to the Tasmanian Deputy Premier and Minister for Primary Industries and Water, the Hon. Bryan Green MP and to the Senate Standing Committee on Rural Affairs and Transport (Legislation Committee).

Yours sincerely

Joe Ludwig

Minister for Agriculture, Fisheries and Forestry
Senator for Queensland

/s/ April 2013

cc The Hon. Bryan Green MP, Tasmanian Minister for Primary Industries and Water, Energy and Resources, Local Government, Planning and Racing
Senator Glenn Sterle, Chair (Legislation Committee), Senate Rural and Regional Affairs Committee