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Committee on Sanitary and Phytosanitary Measures

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**RESPONSES TO COMMENTS RECEIVED FOLLOWING RELEASE OF THE DRAFT
BIOSECURITY BILL AND INSPECTOR-GENERAL OF BIOSECURITY BILL**

COMMUNICATION FROM AUSTRALIA

The following communication, received on 16 January 2013, is being circulated at the request of the delegation of Australia.

As outlined in G/SPS/N/AUS/298, the Australian Government is developing new biosecurity legislation to replace the century-old Quarantine Act 1908. The legislation package comprises the Biosecurity Bill 2012 and the Inspector-General of Biosecurity Bill 2012. The new biosecurity legislation is expected to enable the Australian Government to continue to manage the risks that could arise from the entry, establishment or spread of pests and diseases into Australia, provide transparency and accountability and promote good governance and procedural fairness.

The Biosecurity Bill 2012 and the Inspector-General of Biosecurity Bill 2012 were introduced into Parliament on 28 November 2012. The progress of both Bills can be tracked through the Australian Parliament House website (<http://www.aph.gov.au>). Subordinate legislation and supporting policy documents are currently being developed and are expected to be released in the coming months. The draft subordinate legislation will be notified to the SPS Committee for comment.

Following the initial consultation period submissions were received from a number of trading partners. The comments, questions and issues raised are provided below, along with Australia's responses.

1 APPROPRIATE LEVEL OF PROTECTION (ALOP)

1.1. Which measures will be taken to achieve the appropriate level of protection in the future?

The Biosecurity Bill and subordinate legislation will provide for a number of measures to achieve Australia's appropriate level of protection. These include biosecurity import risk analysis, import permits and appropriate powers for Biosecurity Officers to proportionately and appropriately deal with risk when that risk is considered unacceptable.

1.2. While it is Australia's right under the WTO SPS Agreement to set its own ALOP, does the current ALOP meet the requirement of Art. 5.4, namely 'Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimising negative trade effects'?

Australia's ALOP will not change as a result of this legislation. Australia's biosecurity system will continue to require that biosecurity risks associated with the arrival of goods, cargo, passengers, vessels and other imports are reduced to a very low level, but not to zero (as mentioned in clause 5 of the Biosecurity Bill). Sanitary and phytosanitary measures will

continue to be imposed where they are required to manage the biosecurity risk to achieve this level.

The legislation is designed to further embed existing processes to promote consistency, transparency and certainty in biosecurity risk decision-making. Under the new legislation, biosecurity risk assessments will continue to be scientific and evidence-based and provide appropriate separation from political processes. For example, see subclause 165(5) of the Biosecurity Bill.

1.3. Which appropriate regulatory intervention measures will be taken so that importers can meet the new requirements of the legislation?

Importers will experience more appropriate regulatory intervention according to the level of risk. For example, compliant importers may be subject to fewer inspections while higher risk activities and behaviours may attract increased interventions.

2 BIOSECURITY IMPORT RISK ASSESSMENT (BIRA)

2.1. Will products that currently have access to Australia or have previously completed an IRA be required to complete a BIRA following the Biosecurity Bills implementation?

The future repeal of the Quarantine Act (and associated Regulations) will not affect the validity of existing IRAs and a BIRA will not be required to be completed in relation to goods where an IRA already exists. An existing IRA will be considered, where relevant, when deciding to issue an import permit in relation to particular goods. Import permits issued under the Quarantine Act will remain in effect following the commencement of the new legislation.

2.2. When will a BIRA be undertaken and when will a non-regulated risk analysis be undertaken?

As is currently the case for an IRA, a BIRA will be undertaken when:

relevant risk management measures have not been established; or

relevant risk management measures for a similar good and pest/disease combination do exist, but the likelihood and/or consequences of entry, establishment or spread of pests or diseases could differ significantly from those previously assessed.

Additionally, under the new legislation a BIRA will be undertaken when the Agriculture Minister directs the Director of Biosecurity to commence a BIRA, as per clause 165 of the Biosecurity Bill.

A risk analysis which does not meet these criteria will be undertaken as a non-regulated analysis of existing policy.

2.3. What information does a proposer need to provide to the Director of Biosecurity?

The information required will vary and is dependent on the good.

2.4. What reasons might the Agriculture Minister direct the Director of Biosecurity to commence BIRA?

The Agriculture Minister may direct the Director of Biosecurity to commence a BIRA when there is a risk of national significance. The Minister cannot give direction on how the functions relating to the BIRA should be performed. This ensures that BIRAs are conducted in accordance with Australia's international trade obligations and that the decision-making is independent and science-based.

2.5. What specific factors will be considered during the BIRA process, including any sanitary and phytosanitary (SPS) concerns that differ from the current IRA process?

The Director of Biosecurity can make guidelines setting out matters to be taken into account when conducting a BIRA, as per clause 166 of the Biosecurity Bill. As per the explanatory memorandum, this may include factors to be considered when deciding whether to commence a BIRA process. It is the intention of DAFF to consult with stakeholders in the development of these guidelines. Guidelines will be made publicly available on the Department of Agriculture, Fisheries and Forestry (DAFF) website as stated in clause 166 of the Biosecurity Bill.

2.6. How will Australia's ALOP define the biosecurity risks identified during the BIRA process?

BIRAs are conducted to analyse or consider potential biosecurity risks and the Director of Biosecurity must apply Australia's ALOP in conducting a BIRA as mentioned in clause 164 of the Biosecurity Bill. The BIRA process plays an important role in managing the risk of pests and diseases entering Australia and impacting upon the economy, environment and community. In the BIRA process, the biosecurity risks associated with the importation of a specific good are assessed. Where risks do not achieve Australia's 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 import will not be allowed.

2.7. Is it DAFF's intention to maintain the current procedures for conducting Import Risk Analyses (IRA) for those commodities for which an IRA is required - the draft IRA, provisional final IRA, and the final IRA and policy (published once the appeal process is completed)?

Clause 167 of the Biosecurity Bill provides that the regulations must require the Director of Biosecurity to prepare draft, provisional and final BIRA reports.

Each of the reports must be published and contain the information prescribed by the regulations. It is intended that stakeholders will be able to comment on the draft BIRA report. The provisional BIRA report will build on the draft BIRA report, taking into account stakeholder comments. After the provisional BIRA report is published, there will be an appeal period. After the conclusion of the review period, the final BIRA report will be issued.

2.8. How will scientific and independent analysis occur given the Eminent Scientists Group has been removed from the process?

As contained within the Biosecurity Bill explanatory memorandum (page 13), the BIRA process will be subject to independent scientific review, similar to the Eminent Scientists Group process outlined in the Quarantine Regulations, to ensure that the outcomes in the final BIRA have a solid scientific basis and independent analysis. It was not intended to exclude scientific and independent analysis from the BIRA process and the subordinate legislation will include an independent expert input and review mechanism.

2.9. How will prioritisations of BIRAs occur?

The Director of Biosecurity may determine the order in which BIRAs are to be conducted and a range of factors will be taken into account in determining the priority order for BIRAs. These factors will not be specified in the legislation. However, Australia is aware of and will continue to meet its obligations under the WTO SPS Agreement.

2.10. What are the timeframes for each step of market access application?

The subordinate legislation will outline the maximum timeframes that a BIRA must be completed within (subject to any 'stop the clock' mechanisms to either seek more information or because of a serious and urgent emergency). This maximum timeframe is proposed to be the same as the current maximum timeframe to complete an expanded

imported risk analysis. To simplify and add transparency to the process there will no longer be two types of regulated Import Risk Analysis (standard and expanded) - instead, there will be one process with a maximum 30 month regulated timeframe. There will also be regulated timeframes for significant stages of a BIRA in the regulations.

2.11. Will Australia be consistent with the requirements of the ISPM standard in timelines to make scientific based decisions (especially risk assessments)?

Yes. Australia is a party to the International Plant Protection Convention and has contributed to the consensus for all adopted International Standards for Phytosanitary Measures (ISPMs). It is an active participant in the development of proposed standards and has implemented adopted standards. Australia is aware of and meets its obligations under the IPPC and the WTO SPS Agreement.

3 MANAGING BIOSECURITY RISKS - GOODS

3.1. The Biosecurity Bill will override Australian state and territory laws that relate to bringing in or importing goods to the extent they are inconsistent with the Commonwealth. If, under the new legislation, Australian states and territories will not be able to impose measures that are more restrictive than those imposed by the Commonwealth, what is the relevant clause?

Under clause 8 of the proposed legislation, Australian States and Territories will not be able to impose measures that are more trade restrictive than those imposed by the Commonwealth. Clause 169 indicates that the Biosecurity Bill should operate to exclude any state or territory law that purports to prohibit or restrict the bringing in or importing of goods on biosecurity grounds. An example of where the Biosecurity Bill may operate to the exclusion of a state law would be if a state law purports to prohibit the importation of a good on biosecurity grounds and the Biosecurity Bill permits the importation, then the Biosecurity Bill would prevail and the goods would be able to be imported. Conditions on importation of goods into Australia imposed by the Commonwealth will be based on the outcomes of a risk assessment process, which will take into account regional differences within Australia.

4 GOVERNANCE AND OFFICIALS

4.1. Will there be more refined terms to bind and regulate the powers of biosecurity officials? The new legislation appears to provide biosecurity officials with a greater level of discretion and power compared with the Quarantine Act for prohibiting the entry of goods that might cause introduction, establishment and spread of disease or pests.

One of the aims of the proposed biosecurity legislation is to provide transparency, accountability and promote good governance and procedural fairness. Chapter 12 of the Biosecurity Bill, Governance and Officials, provides refined terms to specify the powers of various biosecurity officials, including any powers that may be delegated to them. While performing any functions under the biosecurity legislation, biosecurity officials are required to follow the directions of the Director of Biosecurity, and satisfy particular training and qualification requirements as set by the Director of Biosecurity. Further information on roles and responsibilities of biosecurity officials will be included in relevant subordinate legislation, supporting policies and procedures.

5 CONVEYANCES

5.1. Explain on what basis a conveyance will be destroyed.

Clause 204 of the Biosecurity Bill states that a biosecurity officer may require biosecurity measures to be taken in relation to a conveyance if a biosecurity officer suspects, on reasonable grounds, that the level of biosecurity risk associated with a conveyance is unacceptable. These biosecurity measures include directions to move or not to move the conveyance, or causing the conveyance to be moved to a place outside of Australian territory, or treatment of the conveyance, or requiring destruction of the conveyance. A conveyance would only be destroyed where it poses an unacceptable biosecurity risk and

where other biosecurity measures to manage the risk such as treatment or removal from Australian territory would be unable to treat the biosecurity risk.

Clauses 209 and 210 of the Biosecurity Bill provide a number of protections and steps that must occur prior to destruction being required. These include that a biosecurity officer must obtain written approval from the Director of Biosecurity prior to requiring a conveyance to be destroyed. There are a number of principles in clause 210 of the Biosecurity Bill that the Director of Biosecurity must be satisfied with prior to providing the written approval. In addition, a decision to give approval for a conveyance to be destroyed is a reviewable decision, which means that the conveyance must not be destroyed until the review period is completed or any review and subsequent proceedings - for example an appeal - have been concluded.

6 BALLAST WATER

6.1. On what basis is an acceptable location for discharging and refilling ballast water set in the new legislation - what are the specific provisions?

Chapter 5 of the Bill provides for the management of risks associated with ballast water and sediment. The chapter will apply to all vessels in Australian seas, including coastal seas, the waters surrounding any external territory of Australia or the waters within 12 nautical miles from the Australian coast (also known as the outer limits of the territorial sea). Subclause 275(4) states that the Director of Biosecurity may, by legislative instrument, declare which area is an acceptable location for discharging and refilling ballast water. However, in line with Australia's rights and obligations under international law, Australia may choose to vary this requirement once the International Convention for the Control and Management of Ships Ballast Water and Sediments 2004 comes into force.

6.2. The associated issue of biofouling which was included in the Beale Review is not dealt with in the Biosecurity Bill.

The provisions in Chapter 4: Managing biosecurity risks: conveyances allows for the management of biosecurity risks - including biofouling - in relation to all conveyances which are subject to biosecurity control.

7 DEFINITIONS

7.1. Would the modified definition of invasive pests be used in some way to restrict imports?

The modified definition of biosecurity risk that refers to invasive pests is not going to restrict imports as it relates to measures that can be imposed within Australia to manage incursions.

7.2. Is it possible to include a definition of - reasonable grounds - listing the conditions in which a biosecurity officer may deem a shipment unacceptable when assessing biosecurity risks?

A definition of reasonable grounds has not been included because it is a subjective measure and it is not possible to have objective criteria for reasonable grounds. The reasonable grounds in relation to biosecurity risk will depend on the circumstances of the goods (for example, the condition of the goods or where the goods are from) as well as the knowledge, training and skills of the biosecurity officer.

7.3. Is it possible to provide a definition of what is considered an 'unacceptable' biosecurity risk, and further explain the measures the Director of Biosecurity is permitted to take in the event that a non-prohibited or conditionally non-prohibited good is found to be in violation of the Biosecurity Bill?

Unacceptable biosecurity risk is a level of risk which requires management, such as treatment, to reduce the level of risk to a level that achieves Australia's ALOP.

In the event a non-prohibited or conditionally non-prohibited goods are found to pose a biosecurity risk, a biosecurity officer may:

Treat the good in a specific manner to reduce the risk to an acceptable level (see clause 131);

Require goods to be exported from Australian territory (see clause 132);

Require the goods to be destroyed if the biosecurity officer suspects that on reasonable grounds that the goods cannot be effectively treated. If the goods are high-value goods - that is the value of the goods is greater than the amount prescribed in the regulations - the goods must not be destroyed without written approval from the Director of Biosecurity (see clause 133).

In addition, clause 185 creates a fault-based offence where a person brings in, or imports conditionally non-prohibited goods into Australian territory in contravention of a condition specified in the determination made under clause 171.

8 CONCLUDING COMMENTS

Following consultation, changes have been made to the primary legislation - such as strengthening the role of the Director of Biosecurity to give effect explicitly to the objects of the Biosecurity Act when making decisions under the legislation. Other suggestions and comments will be considered in the development of subordinate legislation and supporting policies. For example, specific wording on a mechanism for independent scientific review will be included in the subordinate legislation.

Further consultation opportunities with trading partners will occur following the release of subordinate legislation and trading partners will be provided with further information via the SPS notification point.

The Biosecurity Act is proposed to commence one year after Royal Assent.

Further details and full text is available (in English) at:
<http://www.daff.gov.au/bsg/biosecurity-reform/new-biosecurity-legislation>.
