

**United States Department of Agriculture's (USDA) Comments on
Australia's Quarantine and Biosecurity Review Issues Paper**

BEGIN COMMENTS

The United States appreciates the opportunity to comment on Australia's proposed Quarantine and Biosecurity Review. We fully understand the need for our trading partners to assess periodically their safeguarding measures, as well as the efficacy of their system for implementing and maintaining those safeguards. Our comments on the "Quarantine and Biosecurity Review Issues Paper" are as follows.

Part B –Context and Boundaries

B1. Quarantine and biosecurity

In the *Scope of Review* section, point 18, it states that the review will not consider the level at which Australia has set its appropriate level of protection (ALOP) – very low, but not zero; or its rights and obligations as a signatory to the World Trade Organization (WTO) *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement).

The United States believes that Australia's obligations as a signatory to the WTO *SPS Agreement* should be considered in this review. For example, Australia has had legislation in place since 1965 that prohibits the importation of any animal-origin materials intended for use in livestock or poultry feeds from any country with the exception of New Zealand. The broad scope of this law does not appear to be based on science nor is the United States aware of an appropriately conducted risk assessment to justify it. The law, which seems to be used to justify a negative response to requests for new market access, essentially establishes an ALOP of "zero risk".

In Box 1: Description of terms, the white paper defines exotic pests and diseases as those pests and diseases which are not yet present in Australia, or which have yet to become established.

We assume that this definition is applicable only to those pests and diseases of plants and animals, not human diseases.

In Point 15, the panel states that the risks posed to human health, agriculture, forestry, fisheries and the environment by exotic pests and diseases are all included.

Will the review also consider other invasive species that are not pests of plants?

B2. Australia's system

In Point 24, the Panel states that it wishes to explore the question of whether Australian policy makers, administrators and the broader community have a clear or common interpretation of the qualitative concept of Australia's appropriate level of protection – a high level of sanitary and phytosanitary protection, aimed at reducing risk to a very low level but not to zero.

The United States perceives that some Australian stakeholders may see any risk as unacceptable, thereby interpreting the ALOP as “zero risk”. The United States is also concerned that Australian domestic industries facing competition from international suppliers may demand “zero risk” as a means to restrict trade.

Zero risk is not attainable and is actually a counterproductive goal. Prohibition or severe restriction of trade in the face of internal demand may lead to illegal trade or movement of commodities. Such unregulated trade is likely to result in a much higher risk than would be experienced if trade is allowed to occur with reasonable risk mitigation measures.

In Point 28, the Panel acknowledges that Australia exports approximately two-thirds of its agricultural production. Compliance with the SPS rules and obligations allows Australia to expect similar compliance from trading partners

The United States strongly supports this statement and encourages the Panel to emphasize this point in its review.

B4. Parallel reviews and previous reviews

In the *Parallel reviews* section, points, 45 and 47, it is noted that two other reviews relevant to Australia's quarantine and biosecurity system are being conducted: the *Equine Influenza Inquiry*, an independent inquiry into the outbreak of equine influenza in Australia in August 2007; and the *Homeland and Border Security Review*, which will consider the roles, responsibilities and functions of departments and agencies involved in homeland and border security.

How will the findings of these two other independent reviews be considered, utilized and/or integrated with this review?

Part C – Issues for Consideration

C1. Risk across the quarantine and biosecurity continuum

Under point 54, a number of questions are raised by the Panel, including the following:

Is ALOP understood and applied in a consistent way? Is it achieved in a way that is not more trade restrictive than required?

The United States' perspective is that Australia has occasionally adopted measures that are significantly more trade-restrictive than required to achieve the ALOP. In many cases, mitigations defined for specific commodities have included prohibition, either into the country as a whole or into certain States, or have resulted in access for products with mitigations that are overly stringent and often inconsistent with other measures to address similar risk.

Is it well understood in the Australian community that quarantine measures can only be applied to the extent that they are necessary to protect human, animal or plant life or health; that they are not more trade restrictive than required; and that they may not be used as an industry protection mechanism?

The United States perceives that some members of the Australian community may expect biosecurity and quarantine measures to be used as a means of protecting domestic industries from import competition and that the concept of least trade restrictive measures is not well understood.

Should the wider implications - for exporters, consumers, and the economy – be taken into account when developing quarantine and biosecurity arrangements and if so, how?

Attaining balance of competing interests is often a difficult task for governments, but should be assessed in the context of a country's international obligations. Beyond international obligations, the criteria for including wider implications of consequences should be transparent and consistently applied.

Do Australia's risk assessments (including import risk analyses) competently and comprehensively assess risk and risk management issues when providing advice on market access requests and import applications? Are they sufficiently timely?

One question that may be useful for the Panel to ask is: What are the criteria to ensure that a risk assessment is done properly?

In recent draft and final IRAs published by Australia, the United States has noted that some of the approaches and methods used by Australia overestimated risk and have at times appear to have deviated from relevant World Organization for Animal Health (OIE) and International Plant Protection Convention (IPPC) guidelines (see examples below). As such, we would question whether the resulting advice is appropriate.

For example, in some cases, Biosecurity Australia uses a procedure to translate risk estimates between quantitative and qualitative measurements. The procedure assigns numerical likelihood estimates to qualitative descriptors ranging from high to negligible. The qualitative descriptors are value-laden, and the numerical

likelihood estimates are arbitrarily chosen. In the chicken meat and pig meat IRAs, this procedure is used to incorporate the opinions of an expert panel into the risk assessment. Expert opinion, which is inherently subjective, is often used instead of country specific or other scientific, peer-reviewed data to bias results toward overly conservative risk estimates instead of science-based risk estimates using the best available data.

Generic Risk Assessment Approach: Biosecurity Australia conducts “generic” risk assessments and uses them to establish trade restrictions. Often risk estimations are overly conservative. For example, in Australia’s chicken meat and pig meat assessment, Australian risk assessors assume “if a disease agent is present in a country, it is present at the highest sustainable flock/herd level and within-flock/herd level prevalence.” The underlying assumption is that “prevalence would be dictated by epidemiological characteristics of the disease, and is, by nature, dynamic and thus may not remain at a level cited by a particular country at the time that an assessment is done.” Furthermore, risk estimations from countries with high known prevalence are often incorporated into the generic risk assessment.

The notion that prevalence is based solely on characteristics of the disease disregards country specific factors such as environment, husbandry, veterinary services, animal density, reservoirs of infection, and immunization status. These factors should be taken into consideration.

The SPS Agreement requires a risk assessment to consider other factors that may be country-specific, such as relevant processes and production methods; relevant inspection, sampling, and testing methods; existence of pest or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment. The Australian generic risk assessments reviewed by the United States have not taken these factors into consideration.

Risk Assessment Methodology: In reviewing Australia’s semi-quantitative chicken meat and pig meat IRAs, we find that the methodology used deviates at times from OIE guidelines. For example, volume of trade is implicitly incorporated into Release Assessment or Exposure Assessment, as recommended by OIE guidelines; however, Australian risk assessors also explicitly incorporated volume of trade into the Consequence Assessment, thereby doubling the effect. As another example, wildlife is defined as a susceptible group to a hazard and as an exposure pathway for disease transmission to domestic livestock or poultry. Biosecurity Australia assumes that the impacts of exposure will be the same for all exposure groups, no matter which exposure group has been directly exposed. By making this assumption, the risk assessment fails to establish a causal process that must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences.

The United States also questions Biosecurity Australia's (BA) rationale for the levels of risk established in some recent IRAs and the determinations of whether these established levels met Australia's ALOP. In some cases, BA assigned probabilities to hypothetical events despite scientific evidence indicating that these events would not occur in nature. When the probabilities are associated with quantitative estimates, we question how these values are estimated for hypothetical events.

We believe that the cumulative effect of these and other IRA methodologies can result in the model overestimating risk, possibly resulting in mitigations that are not warranted for the product assessed.

In our experience, the reasons for choosing to use the semi-quantitative assessment is not always well-communicated by BA. We would hope that BA will communicate its rationale for applying semi-quantitative models to risk analysis for individual commodities and/or individual pests to stakeholders.

Timeliness: Timeliness has been of concern to the United States regarding both plant and animal market access issues. Key examples of our longstanding market access issues include access for U.S. stone fruit, which first was discussed in 1993, and access for U.S. apples, first discussed in 1989.

We look forward to a more timely review of access for U.S. products under the new Import Risk Assessment (IRA) procedures approved in September 2007. The new procedures have not yet been tested and have raised some questions of transparency, including the rationale for determinations that IRAs be "expanded" and for the engagement of an Eminent Scientists Group to review expanded IRAs.

Does Australian Quarantine and Inspection Service (AQIS) implement risk management in a manner consistent with the advice/recommendations provided by Biosecurity Australia and the Director of Animal and Plant Quarantine?

The United States' Animal and Plant Health Inspection Service (APHIS) has noted some instances in which AQIS implementation of BA's final IRA conditions is more conservative than implied by BA's policies. For example, AQIS interpreted Biosecurity Australia's policy for the safeguarding of table grapes more restrictively than expected.

Is the role of the Eminent Scientists Group in the import risk analysis process understood and appropriate?

In Point 34, the Panel describes the Eminent Scientists Group as a high level review group independent of Biosecurity Australia that is tasked with providing external scientific scrutiny of import risk analysis. The United States hopes that the Panel thoughtfully considers how the members of the Eminent Scientists Group are chosen and the systems in place to ensure that the members are

objective and knowledgeable reviewers of the science impacting the IRA in question.

C3. Jurisdictional and institutional arrangements

Point 64 recognizes trading partner claims of the appearance of political pressure playing a role in SPS determinations that should be science-based. Industry protection and approaches to import risk that are inconsistent with Australia's ALOP or scientific evidence are cited as possible sources of this political pressure.

The United States acknowledges that these pressures can at time be great but believes firmly that science-based regulation is both defensible and in the long-term interests of all countries seeking to benefit from agricultural trade.

C4. Culture, Efficiency and Resourcing

Under this section, the QBR report raises questions about the Australian Quarantine and Inspection Service's mandated screening level of 81 percent for passenger baggage, the consistency of the screening requirements with the risks and returns from conducting the screening, and the likelihood that this target will be difficult to achieve with rising international passenger numbers. The report also asks questions about the benefits of cargo screening and off-shore mitigations.

We suggest that the panel consider reviewing and/or suggesting performance measures for these operational issues. Programs such as APHIS' Agricultural Quarantine Inspection Results Monitoring (AQIM) program give us baseline risk data for all passenger baggage but also for specific passenger/country combinations. They help us measure the value of inspection of all conveyances and better target lower- versus higher- risk conveyances. An example of AQIM is for vessels coming from countries with Asian gypsy moth (AGM).

Developing performance measures under AQIM also helps us decide whether inspection is sufficient to lower the risks associated with material coming from other countries or if off-shore mitigations are needed to mitigate the risk.

We also suggest more cooperative efforts between APHIS Plant Protection and Quarantine (PPQ) and its counterparts in the Australian plant health system to develop performance measures for port of entry and offshore mitigations.

C5. Communication and consultation

In the box following point 82, the following question is posed:

Australia's ALOP is very low, but not zero. Is this understood in the relevant communities?

As stated in earlier comments, the United States believes there may be a tendency among many Australian stakeholders to mistake Australia's ALOP for a zero tolerance and also to view ALOP as a means to protect domestic producers from foreign competition. Australia is entitled under the WTO SPS Agreement to take necessary steps to protect human, animal, and plant life or health, provided these steps are justified by sound science and are no more trade restrictive than necessary to achieve the appropriate level of protection. The United States encourages Australia to undertake an effort to inform Australian stakeholders of the proper scope of ALOP, recognizing that misuse of the ALOP principle is damaging to the international trade system. Australia, as a country that exports two thirds of its agricultural production, should be seen as strongly supportive of quarantine measures that are consistent with international trade obligations and that are implemented in the least trade restrictive manner possible.

END COMMENTS