

## **Stakeholder comments on Draft Import Risk Analysis Report for Horses from Approved Countries**

Biosecurity Australia received twelve submissions from stakeholders on the draft import risk analysis (IRA) report issued on 30 November 2009. These submissions were considered by the Horse IRA Expert Panel and Biosecurity Australia in finalising the IRA report.

Biosecurity Australia and the Expert Panel would like to thank all those who provided submissions. These were found to be very useful and assisted the Expert Panel and Biosecurity Australia in finalising the IRA report.

Each submission is provided in full on Biosecurity Australia's website and the issues identified have been included in the following table together with a response on how the issue was considered in the final IRA report. The table identifies in parentheses, where required, the location of the issue in the original stakeholder submission.

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# Agriculture, Fisheries and Conservation Department(AFCD), Hong Kong

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## Issues 1

Request that the technical information in the IRA report includes that:

Hong Kong has never reported CEM (point 1)

Hong Kong ... is free of EIA (point 2)

Hong Kong ... is free of EI (point 4)

equine piroplasmiasis has never been reported in Hong Kong(point 6)

EVA has never been reported in Hong Kong (point 7).

## Response

Biosecurity Australia (BA) notes the equine health status of Hong Kong. The Import Risk Analysis Report for Horses from Approved Countries (IRA report) is a generic report, covering approved countries that currently export horses to Australia. Technical information on each disease in the IRA lists the countries where specified equine diseases occur. It does not list those countries that are free of these diseases. When developing specific quarantine measures for individual countries or areas, Australia will take into account the equine health status of the particular country or area. Countries will need to provide detailed submissions on the basis of their claims for disease freedom for consideration by Australia.

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## Issues 2

Certification before export should be updated to include an option to declare country freedom [from EIA and EVA] (points 3, 8).

## Response

The IRA report includes the World Organisation for Animal Health (OIE) Terrestrial Animal Health Code 2009 (the Code) recommendations for equine infectious anaemia (EIA) and equine viral arteritis (EVA); therefore, the current wording and Code recommendations remain in the IRA report. However, BA will consider submissions to demonstrate freedom from these diseases, as is the case with New Zealand.

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## Issue 3

The assessment made regarding EI is not applicable to Hong Kong as this section deals specifically with EI endemic countries and countries where there is a “substantial equine population” and the risk assessment made in section 5.14.2 is not applicable.

In light of this we request that the pre-export quarantine is re-evaluated to reflect the significant reduction in risk of introduction of EI (point 9).

## Response

Australia will consider submissions to demonstrate freedom from equine influenza (EI). Submissions need to include such information as data demonstrating how horses vaccinated against EI are differentiated from naturally infected ones, details of targeted surveillance, and data on other monitoring and surveillance activities undertaken.

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**Issue 4**

AFCD ... have problems with running a PCR test [for influenza A] within 4 days of export due to the logistics required with sampling, transportation of the samples to the laboratory, operational hours of the laboratory (no tests run over the weekend) and arrangement of flights. AFCD would kindly request that the 4 days are extended to 6 days, or possibly the 4 days be interpreted as 4 working days (point 10).

**Response**

Four days is considered an adequate period to complete sampling and testing using a polymerase chain reaction (PCR) for influenza A virus. However, BA notes that the Code recommends testing for EI at 21 days and three days before shipment. The timing of testing most likely to detect EI virus was considered in the risk assessment of the IRA report. BA recognises there may be logistical difficulties in managing samples and has reworded the conditions to require sampling during the four days before horses leave the pre-export quarantine (PEQ) facility. In instances where testing requirements may be affected by public holidays, Hong Kong may be able to request a dispensation from the Australian Quarantine and Inspection Service (AQIS).

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**Issue 5**

AFCD would kindly request that current technology for rapid influenza antigen detection tests is also added as an alternative to the PCR test (point 11).

**Response**

Further information, including sensitivity data, about rapid antigen detection kits, such as Directigen™ and Espline®, has been added in section 5.14.1 of the IRA report. It is desirable to use the most sensitive diagnostic test available during PEQ and post-arrival quarantine (PAQ). The PCR is more sensitive than other diagnostic methods including rapid influenza antigen detection tests, and therefore the PCR remains the recommended test.

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**Issue 6**

The conclusions of Biosecurity Australia regarding Butler et al. (2008) [relating to testing for equine piroplasmiasis] are not correct, Butler et al. only looked at the PCR tests post treatment with imidocarb. At no stage did he look at the IFAT or CFT results. Thus the assumptions that a horse will be IFAT and CFT (i.e. antibody) negative post treatment are unsubstantiated. AFCD believes that the conclusions reached on page 317 should be amended to reflect the current scientific literature available, treatment with imidocarb or other anti-babesial agents should not influence the serological status of an animal as a temporary decline in PCR detectible antigen should not have a significant effect on a positive serological titre ... (point 12).

**Response**

BA notes the comment referring to the work of Butler et al. (2008) and acknowledges the citation was placed incorrectly. This has been corrected. It should be noted that Butler et al. did refer to the indirect fluorescent antibody test (IFAT) remaining positive despite treatment and 'that the CFT is not a suitable test for pre-import testing and that even high dose treatment with imidocarb may not be capable of eliminating *B. caballi* and *T. equi* infections from healthy carriers'. Other studies have reported similar results and treatment of equine piroplasmiasis (both parasites) with imidocarb has shown varying results over a long period of time. References to these have been added in section 5.16.1 of the IRA report for further clarification.

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**Issue 7**

AFCDC considers the need for an official veterinarian to be present at the loading of horses from the PEQ facility excessive for Hong Kong, as well as the sealing of vehicles ... We would kindly request that BA considers the unique situation in Hong Kong and makes allowance that this requirement can be removed if BA recognises that equivalent measures are in place (point 13).

**Response**

A request for equivalence can be considered when specific quarantine measures for Hong Kong are developed.

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**Issue 8**

AFCDC appreciates that BA has set realistic time frames for disease freedom, to realistically certify disease freedom for a disease that is not notifiable greater than 90 days ago is sometimes very difficult. (point 14).

**Response**

As stated in section 6.1 of the IRA report, the intent is to ensure a horse is not sourced from premises where a disease is known to occur. Certification for diseases that are not notifiable would need to be based on a declaration from a private veterinarian or from the vendor.

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**Issue 9**

AFCDC request that the sentence “The Official Veterinarian must certify” is amended to “The Official Veterinarian must certify after due enquiry” as the certifying veterinarian will most likely not have first-hand knowledge to enable him/her to certify ... The certifying veterinarian will have to rely on information provided by the owner/agent of the horse or the certification from the previous country. (point 15).

**Response**

Australia does not require Hong Kong to certify on behalf of a third country and therefore does not consider that the wording needs to change. In instances where horses have resided in more than one country for the 60 days before export, AQIS will need to be provided with certification from each country. All multiple-country residencies must be specifically authorised by AQIS.

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**Issue 10**

A paragraph in point (b) from Page 358, Section 8.1.3 Equine infectious anaemia is missing in Page 380 ... Is this difference intentional (point 16)?

**Response**

Yes, there is a difference. Foals are not imported under quarantine measures for temporary importation; hence, testing requirements for EIA in the quarantine measures for temporary importation do not include foals.

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## Australian Horse Industry Council

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### Issue

The assessment of the risk levels for the listed diseases should be met with the improved standards of quarantine PEQ, Border and PAQ that have been implemented as a result of the various enquiries into the 2007 EI outbreak.

There must be no relaxation of the improved situation as time goes by and no problems arise. Complacency must be avoided at all costs. Also the potential changes to the quarantine station situation that will take place in the near future must not allow any lowering of the current standards.

AHIC has consulted with the members of its Industry Advisory Committee and have had no direct response but it is possible that some of these large organisations may comment independently.

### Response

Noted

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## Crispin Bennett International Horse Transport

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### Issue 1

Our main concern in general terms is that it has already, in the wake of the EI outbreak, become incredibly difficult and expensive to import horses into Australia ...

### Response

This issue is outside the scope of the IRA report. The IRA can only consider economic and commercial costs of a pest or disease incursion.

### Issue 2

...I have concerns that in the thrust to balance risk management of disease, cover the public's concerns and consider the recommendations made in the Callinan report, testing requirements for EI are still overly cautious. In part, the Callinan report mentioned that retrospective testing of horses quarantined at Spotswood Quarantine Station (SQS), Victoria, showed them to have been infected with EI. If this were so it proves that quarantine works, as EI did not occur in Victoria.

### Response

BA and the Expert Panel considered that the quarantine measures recommended for EI during PEQ and PAQ address the risk of EI with imported horses.

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**Issue 3**

The horses have also travelled from a different climate and the change from a northern winter to an Australian summer can also cause an increase in rectal temperature particularly should a horse have a woolly coat, the weather temperature be high and conditions humid. Weanlings have been shown to have a naturally higher temperature than older horses which make them more prone to readings above 38.5C in the conditions as above.

**Response**

It is acknowledged that rectal temperature may be affected by such things as coat, body condition score, ambient temperature and diurnal variation. Importers can help manage some of these by attention to the horse's welfare before and during transit.

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**Issue 4**

The Expert Panel has made recommendations for arrival of horses in Australia but has not indicated the minimum number of AQIS staff required to fulfil the recommendations.

**Response**

This issue is beyond the scope of the IRA report.

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## Dr Michelle Dawson, University of Wollongong

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**Issue**

Horses are not the only susceptible species to proliferative enteropathy and gullet worm.

**Response**

The list of species that are susceptible to proliferative enteropathy and gullet worm has been modified in Table 4.1 of the IRA report.

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## Department of Agriculture, Fisheries and Food, Ireland

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**Issue**

In general we do not have problems with the document but seek clarification on a few items ...

**Response**

BA will write to Ireland to provide further details on changes to Australia's quarantine measures and implementation.

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## Department of Energy, Water, Heritage and the Arts

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**Issue**

The Department of the Environment, Water, Heritage and the Arts is supportive of these measures and has no objections to the draft IRA for horses from approved countries

**Response**

Noted

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## Dr Kevin Doyle, Australian Veterinary Association

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| <b>Issue</b>  | <b>Response</b>   |
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| In the Summary and the background there is reference to 'Importation by air began in the 1970s and became routine from the mid-1990s'. This is incorrect. It was routine from the mid 70s. At that time horses came only from UK, Ireland and NZ. It's not really relevant but Canada and USA and European countries were added in the 80s and UAE Singapore etc were added in the 90s. | Restricted transport routes and conditions before 1992 limited horse imports to chartered loads. During the 1990s risk analysis and improved knowledge about the epidemiology of insect-borne diseases allowed access to routinely scheduled services of major airlines including those operating by eastern routes through newly approved ports in the Middle East and Europe. The resulting increase in horse imports is the basis of the referred statement. |

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## Harness Racing Australia

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| <b>Issue</b>   | <b>Response</b> |
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| HRA both acknowledges and fully supports the rigorous border protection and risk management measures detailed in the report, as a key plank in Australia's quarantine program. | Noted           |

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# International Racehorse Transport

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## Issue 1

### Residency requirements

The draft protocol differs significantly from the existing protocol in as much as it requires certification that the horse has been resident for up to 6 months, prior [to] export, on properties that have been free of certain diseases (i.e. for a period well in excess of the 60 days - the present requirement). For instance EEE/WEE 90 days, Glanders 6 months, Horse Pox 90 days, Rabies 6 months. Would reverting to the existing approach of providing residency certification for 60 days be considered?

## Response

BA notes the potential difficulties in certification of lengthy and differing residency periods. This issue is addressed in section 8.1 of the IRA report and reflected in the quarantine measures for a hypothetical country in section 8.3.

Horses must be continuously resident in an approved country for not less than 60 days immediately before export to Australia. This is described in section 6.1 of the IRA report.

For premises residency, the periods recommended in sections 8.1 and 8.2 of the IRA report, for the diseases listed, are based on Code recommendations. As described in the introduction to chapter 8 of the IRA report, the recommended premises residency periods range from less than 30 days to 90 days and in most cases are 60 days. The Expert Panel and BA have reviewed these diseases and relevant recommendations in the Code, and have concluded, for consistency and clarity of certification, that a 60 day requirement for premises residency is reasonable and appropriate in most cases. For each disease listed, the country or premises residency period in section 8.3 of the IRA report is 60 days with the exception of glanders, which is 180 days, due to a lengthy and variable incubation period, and the Code recommendation remains appropriate.

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## Issue 2

### PEQ within 250kms of departure airport

Several of the existing AQIS/BA approved PEQs in Kentucky are over 250 kms from the port of departure. For instance Lexington to Chicago is c 350 miles and Lexington to JFK is c 750 miles. An increase in the distance is requested.

## Response

The Expert Panel and BA are aware that in some instances PEQ facilities may be considerable distances from the port of export and recognises the increased risk in both biosecurity and welfare associated with long transit distances. These issues are addressed in section 7.1 of the IRA report, which has been amended for clarification to include that approval to stop and rest the horses during transport must be obtained from AQIS as part of the approval of the PEQ facility. Nonetheless, to minimise the risk, PEQ facilities should be located within 250 kilometres of the port of export.

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## Issue 3

### All feed and bedding in before PEQ starts

There needs to be a process for replenishment of feed in the event of a flight delay or spoilage.

## Response

Quarantine measures in chapter 8 of the IRA report state that, 'any variation from the pre-export quarantine requirements must be specifically authorised by AQIS'. A flight delay or feed spoilage should be part of contingency planning. In exceptional circumstances, there may be grounds for consideration of alternative arrangements by AQIS.



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**Issue 4**

... we would ask that AQIS allow use of National Laboratory results in the export certification process from the country of origin's National Laboratory as well as those from the country of export.

**Response**

The intent was that laboratory testing can be conducted in another country at a laboratory recognised by the Veterinary Authority of the country of export. This requirement has been reworded for clarification.

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**Issue 5**

Tamper Evident seals

Vet needs to oversee loading at PEQ to put on seals. No mention what the process is for breaking seals.

**Response**

This has been clarified and amended in chapter 7 and chapter 8 of the IRA report to include the checking of seals on arrival at the airport.

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**Issue 6**

Borna - 60 Day Country freedom

.... we request this wording be changed to allow the 60 days prior to export to be spent in a region of a country free of Borna.

**Response**

The risk assessment conclusion for Borna disease has been clarified and the wording amended. Certification for Borna disease has been amended to require premises freedom, on the basis that Borna disease is an emerging disease of quarantine concern.

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**Issue 7**

CEM samples collected in the 30 days immediately before commencement of PEQ

Completing the swabs prior to PEQ is an advantage however there are certain difficulties with this. 1) In the case of exports from UK originating from the continent DEFRA cannot use CEM testing other than that conducted at VLA in complying with the Australia import regulations. Furthermore, logistically collecting swabs from the continent for testing at CVL is problematic in that often the swabs won't arrive on time (i.e. within 48hrs) plus many vets who usually service training/racing establishments will not be familiar with collection & the form of media required for transport. ... A possible solution would be marshalling the horses at or near PEQ prior to the start of PEQ and testing them on days 1, 4 & 7. This would allow testing to be completed by a 'breeding vet' experienced in the collection of CEM swabs providing timely, uniform & effective quality control not possible when testing in many far flung locations. From consulting with research vets familiar with CEM testing there appears no scientific data supporting the 7 day gap between tests ...

**Response**

The Expert Panel and BA recognise the logistical difficulties described but do not support the change from what is recognised as best practice by the OIE with respect to the interval between collecting samples. The requirement is reworded to allow testing to be carried out before or in PEQ, which may reduce the required period for assembly of horses for contagious equine metritis (CEM) testing before export.

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**Issue 8**

Endometrial or deep cervix swabs

Collection of endometrial or deep cervix swabs is not encouraged by practicing vets. Taking one swab in during oestrus is difficult enough, especially in winter months.

**Response**

The Expert Panel and BA support best practice for collecting swabs for testing for CEM. The OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals (OIE Manual) refers to the Horserace Betting Levy Board (HBLB) in its recommendations for swabbing mares and these guidelines are the basis of Australia's sampling requirements for CEM. This includes the collection of a sample from the endometrium or deep cervix during oestrus.

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**Issue 9**

No use of antibiotics

There would be more certainty this condition had been met if all CEM swabbing took place at a centralised location under the control of the certifying vets as suggested above.

**Response**

Alterations made to the period during which CEM swabbing can occur should allow certification that horses have not been treated with antibiotics before testing.

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**Issue 10**

Equine Influenza - vaccination

The position re EI vaccination of foals less than 6 months is contradictory in the draft. The modification of the EI conditions allowing a primary within 21-90 days of the start of PEQ is welcomed. However, as very few vaccines include the strains prescribed most (all) horses will require total revaccination if a booster, to a previously certified course using unprescribed vaccines, is not permissible. Furthermore, because of the varying vaccine manufacturer's recommendations (MRs) the racing authorities & FEI in Europe have adopted policies to embrace all the MR's which result in many histories meeting the racing authority conditions to perform but not the specific MRs. A similar policy adopted by AQIS/BA would avoid the constant need for a CofEs.

**Response**

Vaccination of foals less than six months of age is not required. Part b. under the risk management requirements for EI in section 8.1.3 of the IRA report exempts foals less than six months of age from vaccination. The IRA report does not recommend historical compliance with vaccination conditions but does recommend that a compliant vaccine (where available in the country of export) is given during the period specified before export. Management in situations where a compliant vaccine is not commercially available in the country of export will be determined when developing specific quarantine measures for individual countries or areas.

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**Issue 11**

EI Swab - within 4 days of departure

... EI swabs cannot be completed with any certainty within 4 days of export in USA.

**Response**

Four days is considered an adequate period to complete sampling and testing using a PCR for influenza A virus. BA notes that the Code recommends testing for EI at 21 days and three days before shipment. The timing of testing most likely to detect EI virus was considered in the risk assessment. BA recognises there may be logistical difficulties in managing samples and has reworded the conditions to require sampling during the four days before horses leave the PEQ facility.

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**Issue 12**

Dacron swabs

Dacron is not the preferred fabric for collecting nasopharyngeal samples in UK. The swabs provided to NEH (Official Vets) by AHT (Richard Newton) are cotton wool & gauze. The availability of Dacron swabs in UK & USA is being determined.

**Response**

Wording in the IRA report has been amended and the requirement to use a particular material for the swab removed.

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**Issue 13**

Temps twice daily - 8 hours apart

Temperature taking twice daily is a continual hazard to the attendants collecting the recordings & to the horses themselves. Daily collection should be adequate except where a horse is sick or circumstances require more regular monitoring. If twice daily temperatures are to continue we need to find a better way that does [not] impinge so heavily on OH&S issues.

**Response**

Difficulties in obtaining rectal temperatures are acknowledged. Management alternatives involving clinical examination by a registered veterinarian are addressed in section 8.1.3 of the IRA report.

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**Issue 14**

Piroplasmosis Bloodtesting - 7 days into PEQ

Based on the 14 days PEQ included in the draft conditions this allows only 7 days for piroplasmosis testing. Considering IFAT testing is so close to departure to if flight cancellations are bound to occur. Furthermore to accommodate for those instances when a reliable IFA result cannot be achieved should a different test being provided - ELISA?

**Response**

Difficulties with the time allowed for piroplasmosis testing is acknowledged. Timing of diagnostic tests has been re-evaluated, and aligned where possible and where the risk can be managed, to improve management of test results before export and rationalise veterinary attendance. Timing of testing, where possible, has been amended to require testing four to six days after commencement of PEQ. This re-consideration will also apply to sampling for EIA, EVA and vesicular stomatitis, and taking reference sera. The introduction to chapter 8 and the example quarantine measures in section 8.3 have been amended in the IRA report to reflect this.

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**Issue 15**

EVA Bloodtesting - 7 days into PEQ

Based on the 14 days PEQ included in the draft conditions this allows only 7 days for EVA testing. Considering EVA testing is so close to departure last minute flight cancellations are bound to occur. Furthermore, to prevent a positive in PEQ delaying shipment, it appears to us each horse will need to be tested prior to the start of PEQ so that adequate time is available to demonstrate a stable titre is present on blood collected 14 days apart.

**Response**

See response to IRT issue 14.

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**Issue 16**

## EVA vaccination

Option 1 (vaccination between 6/9 months) seldom occurs. Option 2 does not reflect the process adopted by the thoroughbred industries in Europe & USA where they test negative & then vaccinate. The process put forward by AQIS/BA recently with a negative blood test & vaccination on the same day plus boosters as necessary seems to better reflect the procedure adopted by industry. Where an EVA vaccinated stallion fails to receive adequate boosters then a process of VI testing followed by revaccination should be articulated in the conditions. Further we believe EVA VI testing should be within 60 days as that gives adequate time to collect & get a result before the horses enters PEQ. 28 days as in the draft is impractical & results in horses entering PEQ before a result is available.

**Response**

Code recommendations for EVA have been included in the IRA report. Vaccination after negative virus isolation on semen is not addressed in the Code. Seropositive, virus isolation tested negative horses will be considered on a case-by-case basis. The Code recommends virus isolation testing within 28 days before shipment. Should changes to the Code occur, Australia will update these requirements accordingly.

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**Issue 17**

## West Nile Fever - Vaccination

With vaccine unavailable in Australia the vaccination requirement restricts the ability for Australian based horses to travel to the Northern Hemisphere to compete and return in a timely manner. Horses have to wait an additional 28 days to receive a primary course of West Nile post competition. As horses are a dead end host is vaccination necessary?

**Response**

Requirements for West Nile fever have been amended to only require vaccination of horses against West Nile virus from countries where clinical disease is known to occur, recognising best practice with respect to animal health and welfare.

Currently, quarantine conditions for the return of Australian horses after racing exist for Hong Kong, Macau, Singapore and the United Arab Emirates. Clinical West Nile fever is not known to occur in these countries so vaccination would not be required. Australian horses returning from other countries would be imported under Australia's permanent (or temporary) conditions and the 60 days residency requirement would apply. If clinical West Nile fever occurs in those countries the horse should be vaccinated during the 60-day residency period.

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**Issue 18**

## Insect nets on all flights - HKG/SIN to Aust

On direct flights Asia to Australia or USA via Honolulu to Australia, nets would appear superfluous.

**Response**

The requirement is made as a contingency for unscheduled redirection of aircraft. It is not necessary that nets be used, simply carried, in the event that an aircraft is forced to land in an area where vectors of quarantine concern may be present.

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**Issue 19**

## AQIS - Check horse docs at airport - Why?

**Response**

Accepted. This requirement has been removed.

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**Issue 20**

CEM - importing pregnant mares

No CEM surveillance conditions have been included in the IRA. If the foal at foot is CEM tested why should it not be released from quarantine surveillance?

**Response**

The OIE Manual recognises the possibility of infection in newborn foals at parturition and the potential to become carriers of infection. Foals at foot present limited risk of spreading infection if their dam is cleared by sampling at her next oestrus. Importer commitment and foal traceability are essential if this situation is to be managed effectively. Neither the Code nor the HBLB have recommendations for testing foals for CEM. Accordingly it is recommended that the foal not be released until the dam has tested negative for CEM.

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**Issue 21**

Equine Influenza - 21 Day PAQ [for consignments from multiple PEQ facilities]

Based on the additional vaccination requirements, PCR tests and temperature taking, is the additional 7 necessary? Even with the case in Australia the Flu was found within the 14 day PAQ. The extra 7 days has a large impact on the cost and rotation of shipments through the quarantine station. Especially for breeding stallions.

**Response**

The proposed PAQ period has not been increased over that currently required in the interim quarantine measures. Under these measures, 21 days PAQ is required for horses originating from multiple PEQ facilities and 14 days PAQ for horses originating from a single PEQ facility.

In the Expert Panel's opinion, commingled consignments increase the risk of infection with EI virus (EIV) to justify a further seven days PAQ. After further consideration of risks of commingling and effects of prior exposure and heterogeneous strains of EI virus, the Expert Panel and BA considered that the risks could be managed with a 14-day PAQ for commingled consignments originating from the same region.

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**Issue 22**

During PAQ, the facility must be occupied only by horses of the import consignment.

Does this mean it would not be possible for International Runners or Return Australian horses to have local horses as a companion horses in PAQ?

**Response**

Quarantine measures in chapter 8 of the IRA report state that, 'any variation from the post-arrival quarantine requirements must be specifically authorised by AQIS'. Approval for horses other than those of the import consignment to enter PAQ may be given on a case-by-case basis. A local horse (as a companion horse) could be permitted entry to the PAQ facility. The local horse would have the same status as imported horses and be subject to the same PAQ requirements.

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**Issue 23**

Horses must not leave the facility during PAQ:

We assume BA considers the track part of the PAQ?

**Response**

Training tracks may be considered part of the PAQ facility under certain requirements to minimise disease risk.

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**Issue 24**

For the duration of PEQ the horse has not been held, housed or exercised within 100 metres of other equids not of equivalent health status.

What's the basis of this ruling? Why 100m ? Should the same distance apply for all countries?

**Response**

Spread of EIV is discussed in section 5.14.1 of the IRA report. In section 6.2.1, it is acknowledged that a range of views exist, and the Expert Panel concluded that aerosol and windborne spread is unlikely to occur over a distance greater than 100 metres, particularly from contiguous vaccinated populations of horses in the exporting country. An example of equivalent biosecurity measures that may be authorised by AQIS (i.e. impervious barriers between horses in PEQ and other equids) has been included in the IRA report (section 6.2.1). When developing specific quarantine measures for individual countries or areas, Australia will take into account country-specific factors including approved PEQ facilities.

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**Issue 25**

Exporters or their agents must have detailed SOPs consistent with a risk-based approach and approved by AQIS, to cover procedures including contingency plans, for transporting the horse from PEQ until arrival in Australia

There are so many variables that it is impossible to have a detailed contingency. There are thousands of alternate airports that an aircraft could land at between the Northern Hemisphere and Australia. Also the actions of the airline are outside the control of the shipping agent. The most practical solution would be a simple action plan that should be implemented including Key Contact personnel in the event of an aircraft diversion, as is the case now.

**Response**

Contingencies are not required to identify actual events but to take into account how to address changes to arrangements and procedures. They need to consider, but not be limited to, welfare, biosecurity measures and prompt communication with AQIS. This could include a simple action plan.

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# Racing Victoria Limited (on behalf of the Australian Racing Board)

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## Issue 1

.... the racing industry is concerned that the information presented does not support the introduction of policies that both prevent disease introduction and maximise the economic opportunities associated with international horse movement (page 4 paragraph 3)

## Response

The IRA report is science-based, and consistent with other IRA reports produced by Biosecurity Australia. The IRA has been conducted according to the *IRA Handbook 2007*. As stated in the Handbook, the IRA process complies with Australia's *Quarantine Act 1908* and international obligations. Australia's process adopts approaches to risk assessments as set out in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Code. Risk management measures recommended are the least trade restrictive which would achieve Australia's appropriate level of protection (ALOP).

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## Issue 2

In particular, the increase in PAQ for mixed PEQ consignments is not supported. (page 6 paragraph 3)

## Response

The proposed PAQ period has not been increased over that currently required in the interim quarantine measures. Under these measures, 21 days PAQ is required for horses originating from multiple PEQ premises and 14 days PAQ for horses originating from a single PEQ premises.

In the Expert Panel's opinion commingled consignments increase the risk of infection with EIV to justify a further seven days PAQ. After further consideration of risks of commingling and effects of prior exposure and heterogeneous strains of EI virus, the Expert Panel and BA considered that the risks could be managed with a 14-day PAQ for commingled consignments originating from the same region.

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## Issue 3

As a comment on the tenor of the IRA, the racing industry is concerned that risk assessment and risk management in the IRA have too often been approached with an excessive focus on keeping exotic disease out of Australia, as opposed to focussing on how to import horses to Australia without importing exotic disease. (page 8 paragraph 5)

## Response

The IRA has been conducted according to established processes that are consistent with Australia's domestic and international obligations. Least trade restrictive risk management measures, which achieve Australia's ALOP, have been recommended.

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**Issue 4**

The IRA process only includes one consultation step. As such, interested parties are not given the opportunity to consider general comments from other parties or the opportunity to consider comments relating to scientific, technical, or other gaps in the data, misinterpretations and errors. (page 9 paragraph 2)

**Response**

The IRA is being conducted as a non-regulated IRA which includes consultation on the draft IRA report. This is also consistent with the regulated IRA process. Stakeholder comments and responses are included as part of the final IRA report.

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**Issue 5**

The racing industry believes that there should be an ongoing review of quarantine procedures. (page 9 paragraph 3)

**Response**

The Australian Government has accepted the Callinan Inquiry recommendation relating to a two yearly review of the IRA report to take into account any relevant developments in scientific knowledge or quarantine measures. BA monitors and continues to review existing import policies in light of new scientific information.

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**Issue 6**

A criticism of the application of the method is that it is formulaic and does not provide insight into the decision making process. The racing industry believes an approach using a combination of empirical analysis, risk matrices and quantitative analysis would have improved objectivity and transparency and thereby improved the analysis. (page 9 paragraph 4)

**Response**

The IRA has been conducted according to established processes that are consistent with Australia's domestic and international obligations. Both qualitative risk assessment and quantitative risk assessment methods are valid according to the Code. Due to insufficient relevant quantitative data, the IRA report took a qualitative approach.

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**Issue 7**

... there is limited explanation of what is meant by the terms used to describe likelihood ... So for example, it is unclear what is meant by low, very low or extremely low. (page 9 paragraph 6)

**Response**

Descriptions for these qualitative likelihoods are provided in Table 3.1 in chapter 3 of the IRA report.

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**Issue 8**

In many disease situations qualitative descriptions may be the only available. This is not always the case and in some situations quantitative descriptions are indicated. Instances where quantitative methods may be indicated include assessment of the effectiveness diagnostic tests and estimates of disease incidence in the populations from which horses are imported. For example, utilising information on the sensitivity of clitoral and cervical CEM swabs may be used to estimate the likelihood of detecting an infected animal. (page 9 paragraph 7)

**Response**

The information quoted section 5.6.1 refers to detection by culture of swabs from mares where disease histories were known. The Expert Panel does not consider it possible to extrapolate this information to sensitivity of culture for the general horse population.



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**Issue 9**

It is also surprising that there is limited review of the history of EI quarantine failures over the last 40 years and of the Commission of Inquiry into the Australian 2007 EI outbreak. (page 10 paragraph 6)

**Response**

The history of EI quarantine failures and the findings of the Commission of Inquiry have been considered throughout the report and are referred to where relevant.

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**Issue 10**

One key learning from the Australian EI Inquiry was that human behaviour was probably the cause of quarantine failure. While it may be that AQIS, and not Biosecurity Australia, are responsible for implementation of quarantine procedures, and therefore operational risks, it is difficult to understand why the IRA did not consider operational risks more extensively. Indeed a stepwise analysis that reviewed critical points in the import process, using principles similar to those of HACCP programs, would have provided very valuable information. Analysis of human behaviour and attitude to risk could have also provided additional useful insight into why quarantine fails. (page 10 paragraph 7)

**Response**

Operational issues are addressed in inspection and certification requirements. Standard operating procedures (SOPs) for PEQ and PAQ facilities must be developed using a risk-based approach and, in the case of PEQ facilities, assessed by AQIS. PAQ procedures have been reviewed according to the Government's response to the Commission of Inquiry.

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**Issue 11**

While EI is not a notifiable disease in many approved countries, disease incidence information from countries where EI is endemic is available. (page 11 paragraph 2)

**Response**

Information has been added in section 5.14.1 of the IRA report. It notes that there is little information available on prevalence and incidence of disease in endemic populations, or on vaccine usage in horse populations outside regular competition.

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**Issue 12**

In recent personal communications with Dr Richard Newton from the Animal Health Trust in Newmarket ... Dr Newton stated that in a longitudinal study of EI in racehorses in the UK, only one incursion of EI was seen in a three year period. (page 11 paragraph 2)

**Response**

It is not clear if the longitudinal study referred to was based on clinical detection alone, viral detection or serological testing. Information has been added in section 5.14.1 of the IRA report. It notes that there is little information available on prevalence and incidence of disease in endemic populations, or on vaccine usage in horse populations outside regular competition. Also, the IRA is based on the importation of horses from approved countries, and is not limited to those in competition or from a particular country.

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**Issue 13**

If the moderate likelihood is correct, on average at anyone time in countries where EI is endemic, approximately one out of 500 horses would be subclinically infected with EI. Available information suggests that this is probably not so in countries where EI is known to circulate. It [likelihood of release] is certainly not realistic in countries such as Hong Kong, where EI has not been recorded since 1992, despite continued and extensive surveillance programs. (page 11 paragraph 3)

**Response**

Information has been added in section 5.14.1 of the IRA report. It is noted that there is little information available on prevalence and incidence of disease in endemic populations, or on vaccine usage in populations outside regular competition.

When developing specific quarantine measures for individual countries or areas, Australia will take into account the equine health status of the particular country or area. Countries may need to provide detailed submissions on the basis of their claims for consideration by Australia.

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**Issue 14**

The major concern with the statements is that they could be viewed by many interested parties as justification for extending PAQ periods. [reference to the paper of Powell et al.] (page 12 paragraph 2)

**Response**

The reference to Powell et al. (1992) in the IRA report has been reworded for clarification. This paper was cited in the IRA report to demonstrate the difficulty of detecting clinical infection with EI in vaccinated populations.

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**Issue 15**

The Directigen test has been shown to be very useful in outbreaks of EI (Powell et al 1992). More recently the Japanese Espline test has been adopted for use in Hong Kong. (page 13 paragraph 2)

**Response**

Further information, including sensitivity data, about rapid antigen detection kits, such as Directigen™ and Espline®, has been added in section 5.14.1 of the IRA report.

This test was shown to be very useful in Japan in 2007 and is easier to use than Directigen. (page 13 paragraph 2)

It is desirable to use the most sensitive diagnostic test available for PEQ and PAQ. The PCR is more sensitive than other diagnostic methods and is discussed in more detail in section 5.14.1 of the IRA report.

Even if the sensitivity of Directigen is not high, this evidence suggests that the incidence of EI in horses being shipped internationally is very to extremely low. (page 13 paragraph 3)

Any new scientific information presented on the efficacy of different tests will be considered.

Investigation of the use of Directigen testing in Australian quarantine operations was suggested by Racing Victoria in a 2000 submission to Biosecurity Australia and AQIS... (page 13 paragraph 4)

In the past, before the EI outbreak (and development of PCR tests), horses showing clinical signs of EI in Australian quarantine stations were tested using Directigen™.

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**Issue 16**

Repeat testing during PEQ and/or PAQ will have a much greater chance of detecting infected animals. (page 14 paragraph 2)

**Response**

Agreed. Testing for EI is required on at least two occasions during PEQ and at least two occasions during PAQ (if a single consignment).

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| <p><b>Issue 17</b></p> <p>ELISA tests and RT-PCR tests are more sensitive than Directigen and probably also more sensitive than the Espline test. (page 14 paragraph 3)</p>   | <p><b>Response</b></p> <p>Agreed. Testing for EI must be by PCR for influenza A.</p>   |
| <p><b>Issue 18</b></p> <p>The infected horses, showing clinical signs of EI, were stabled in a separate stable block approximately four metres from the horses that were due to complete quarantine. The latter contracted EI and then moved into the local horse population ... (page 14 paragraph 7)</p>  | <p><b>Response</b></p> <p>This supports the need for all-in all-out quarantine processes and adequate biosecurity procedures at PEQ and PAQ facilities.</p>  |
| <p><b>Issue 19</b></p> <p>In Japan, the exact source of infection was not apparent but was associated with mixing of horses during quarantine. (page 15 paragraph 3)</p>  | <p><b>Response</b></p> <p>Noted.</p>   |
| <p><b>Issue 20</b></p> <p>So while it is known that EI often presents mildly or sub-clinically, evidence from the above well documented outbreaks reveals that when quarantine failure has occurred there have always been some horses in PAQ with clinical signs of EI. (page 16 paragraph 2)</p> <p>In the Dubai 1995 outbreak, two horses that tested negative on Directigen were released after 3 days of quarantine and spread EI to local horses. (page 16 paragraph 3)</p> | <p><b>Response</b></p> <p>It is recognised that clinical signs may be present, albeit mild, and thus the IRA report includes monitoring of horses for clinical signs of respiratory disease and temperatures during quarantine.</p>  |
| <p><b>Issue 21</b></p> <p>Another informative fact is that there does not appear to be an instance where horses have completed 14 days PEQ and 14 days PAQ and then been released and spread disease to local horses. This is despite the poor quarantine operations in many parts of the world. (page 16 paragraph 4)</p>  | <p><b>Response</b></p> <p>The IRA report reflects the Expert Panel's consideration of appropriate PEQ (14 days) and PAQ (14 days) periods, including that commingled consignments increase the risk of infection with EIV enough to justify a further seven days PAQ (21 days).</p> <p>After further consideration of risks of commingling and effects of prior exposure and heterogeneous strains of EI virus, the Expert Panel and BA considered that the risks could be managed with a 14-day PAQ for commingled consignments originating from the same region.</p> |

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| <p><b>Issue 22</b></p> <p>... the majority of the risk management measures suggested in the draft IRA are supported by the racing industry, there are significant concerns. (page 16 paragraph 6)</p>  | <p><b>Response</b></p> <p>Noted.</p>   |
| <p><b>Issue 23</b></p> <p>The racing industry believes that there should be different levels of approval between approved countries ... It would be reasonable to view Hong Kong and Singapore in a different light to regions such as the EU and USA where many significant equine diseases are endemic. (page 16 paragraph 7)</p>  | <p><b>Response</b></p> <p>The IRA is a generic report, covering approved countries that currently export horses to Australia. When developing specific quarantine measures for individual countries or areas, Australia will take into account the equine health status of the particular country or area. Countries may need to provide detailed submissions on the basis of their claims for consideration by Australia.</p> |
| <p><b>Issue 24</b></p> <p>Country or area Freedom</p> <p>It is not restrictive if AQIS specifically approves that the 60 days residency may be achieved in multiple countries and this approval is generally forthcoming. However, the racing industry would like to know on what basis is this approval given and if there are times when it will not be given. (page 17 paragraph 1)</p> | <p><b>Response</b></p> <p>In instances where horses have resided in more than one approved country for the 60 days before export, AQIS will need to be provided with certification from each country. All multiple-country residencies must be specifically authorised by AQIS.</p>  |
| <p><b>Issue 25</b></p> <p>In the technical assessment the sensitivity of CEM testing is stated. (page 17 paragraph 2)</p>  | <p><b>Response</b></p> <p>The data cited in section 5.6.1 of the IRA report do not state test sensitivity.</p>   |
| <p><b>Issue 26</b></p> <p>Similar statements are not made in relation to EI other than to say PCR testing is more sensitive than rapid antigen detection kits. (page 17 paragraph 2)</p>   | <p><b>Response</b></p> <p>Further information on the sensitivity of diagnostic tests for EI has been added in section 5.14.1 of the IRA report.</p>  |

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**Issue 27**

It is stated that it is difficult for a country to demonstrate disease freedom if there has been prior exposure to endemic disease and/or vaccination. This may be true, however in the case of Hong Kong a rigorous surveillance system makes it extremely unlikely that EI is circulating in the population. (page 17 paragraph 3)

**Response**

The IRA is a generic report, covering approved countries that currently export horses to Australia. When developing specific quarantine measures for individual countries or areas, Australia will take into account country-specific factors. Countries may need to provide detailed submissions on the basis of their claims for consideration by Australia.

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**Issue 28**

To better understand the true incidence of disease [EI] in these countries the racing industry would encourage sentinel population to be developed in approved countries .... The racing industry encourages investigation of such a system that could be managed with some financial support from Australia, as a part of risk reduction for importing horses to Australia. (page 17 paragraph 4)

**Response**

BA is not aware of any proposal to establish a sentinel system in countries in which EI occurs. The use of sentinels for surveillance, such as for bluetongue virus, requires detailed planning and ongoing monitoring to provide useful information. For some other diseases, exporting countries, often in cooperation with industry, have developed sentinel herds for surveillance.

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**Issue 29**

... why is the first PAQ test [for EI] done at four to six days and not within 24 hours of arrival? (page 17 paragraph 5)

**Response**

For horses originating from a single PEQ facility, the IRA requires nasopharyngeal samples for PCR testing to be taken within 4–6 days of arrival in Australia rather than within 24 hours of arrival. This is to maximise the likelihood of detecting a horse infected at the end of PEQ or infected during transit. In addition, any horse showing an elevated temperature on two consecutive recordings or other signs of infectious respiratory disease must be tested.

For horses originating from multiple PEQ facilities, the IRA requires an additional nasopharyngeal sample for PCR testing within 24 hours of arrival. Early detection of EIV in a consignment would allow subsequent consignments to be postponed. This is intended to decrease numbers of horses and personnel affected, reduce the amount of contaminated equipment in the PAQ facility, and may assist in more rapid resolution of the incident.

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**Issue 30**

The recommendation to subject horses with temperatures above 38.5C to RT-PCR should be strengthened by adding “or other signs of infectious respiratory disease” or similar. (page 18 dot point 1)

**Response**

Agreed. This has been added to the quarantine requirements for EI.

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**Issue 31**

The maintenance of an increase in the PAQ period from 14 to 21 days for mixed PEQ consignments. There is not an historical precedent for this change and little theoretical justification is provided in the IRA. The authors suggest the increase is necessary because horses may be exposed to a different strain. What this means is not elaborated upon. (page 18 dot point 2)

**Response**

Further information about circulation of different strains of EIV has been added for clarification in section 5.14.1 of the IRA report.

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**Issue 32**

AQIS should have the right to approve other horses entering PEQ. (page 18 dot point 3)

**Response**

Quarantine measures in chapter 8 of the IRA report state that, 'any variation from the pre-export quarantine requirements must be specifically authorised by AQIS'. Approval for horses other than those of the import consignment to enter PEQ may be given on a case-by-case basis. Local horses would be subject to PEQ requirements as for horses in the consignment.

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**Issue 33**

Removal of the condition that allows AQIS the right to approve horses, other than horses of the import consignment, to enter PAQ: This will prevent international race horses having a local companion horse or galloping partner in quarantine station. (page 18 dot point 4)

**Response**

Quarantine measures in chapter 8 of the IRA report state that, 'any variation from the post-arrival quarantine requirements must be specifically authorised by AQIS'. Approval for horses other than those of the import consignment to enter PAQ may be given on a case-by-case basis. A local horse (as a companion horse) could be permitted entry to the PAQ facility. The local horse would have the same status as imported horses and be subject to the same PAQ requirements.

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**Issue 34**

Lack of analysis of the effect of reducing the distance of PEQ stables from other horses to less than 100m. (page 18 dot point 5)

**Response**

Spread of EIV is discussed in section 5.14.1 of the IRA report. In section 6.2.1, it is acknowledged that a range of views exist, and the Expert Panel concluded that aerosol and windborne spread is unlikely to occur over a distance greater than 100 metres, particularly from contiguous vaccinated populations of horses in the exporting country. An example of equivalent biosecurity measures that may be authorised by AQIS (i.e. impervious barriers between horses in PEQ and other equids) has been included in the IRA report (section 6.2.1). When developing specific quarantine measures for individual countries or areas, Australia will take into account country-specific factors including approved PEQ facilities.

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**Issue 35**

... Use of serology could be an adjunct to assessing the immune status of individual horses. Horses with low antibody titres are the horses that are likely to be amplifiers of virus and so may warrant extra scrutiny... (page 18 dot point 6)

**Response**

In a quarantine setting, all animals need to be managed as potentially infected for the duration of the quarantine period. In some circumstances, serology has been used for disease investigations.

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**Issue 36**

The 2007 paper of Evaluation of Antigen Detection Kits for Diagnosis of Equine Influenza by Yamanaka et al provides useful information on the Espline test. (page 18 dot point 7)

**Response**

Further information about Espline® has been added in section 5.14.1 of the IRA report.

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**Issue 37**

Since 1992 no positive [rapid antigen] tests [for EI] have been recorded [in Hong Kong]. (page 21 dot point 1)

**Response**

The IRA is a generic report, covering approved countries that currently export horses to Australia. When developing specific quarantine measures for individual countries or areas, Australia will take into account the equine health status of the particular country or area. Countries may need to provide detailed submissions on the basis of their claims for consideration by Australia.

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**Issue 38**

... An infected horse must enter quarantine or EI must enter on a fomite during PEQ or transportation... There must be enough horses in the shipment to sustain EI during the entire PEQ or from the time of entry on a fomite till arrival in PAQ. (page 22 paragraph 2 numbers 1,2)

**Response**

Noted. The risk management measures for EI, including the length of PEQ, PAQ, monitoring and testing, take these scenarios into account.

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**Issue 39**

The probability of an [EI] infected horse entering PEQ is low. ...If this assessment is based on approximately 500 horses imported per year, and a four day incubation period and four day infectious period applied, the annual incidence of disease in the imported population would have to be at least 10%. (page 22 paragraph 3)

**Response**

Information has been added in section 5.14.1 of the IRA report, noting there is little information available on prevalence and incidence of EI in endemic populations, or on vaccine usage in populations outside regular competition.

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**Issue 40**

If the incidence of EI is very much lower than 10% then according to the draft IRA method, Australia's ALOP has probably been achieved. If the horse has been subject to PEQ then the Australia's ALOP will almost certainly have been achieved. It is not suggested that this should lead to an abandonment of PEQ and PAQ ... (page 22 paragraph 4)

**Response**

The Expert Panel and BA did not consider that the risk of disease introduction was adequately addressed by PEQ alone. Additional measures were required to meet Australia's ALOP.

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**Issue 41**

While the OIE code suggests a 21 day infectious period, numerous references indicate that the period of viral shedding is only up to 7 days in non-vaccinated horses and up to 4 days in vaccinated horses. Incubation periods are also short and references quote 1 to 4 days. In all horses, viral shedding will be maximal in the first few days after becoming infectious. (page 22 paragraph 5)

**Response**

The Expert Panel and BA recognise that the infectious period for EI may be shorter than the time period specified in the Code. Incubation periods and duration of viral shedding for horses infected with EIV is discussed in section 5.14.1 of the IRA report.

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**Issue 42**

... in a recent trial in Newmarket, virus was detected with RT-PCR in all vaccinated horses infected with the Australian EI strain (James Watson personal communication). (page 22 paragraph 5)

**Response**

Noted.

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**Issue 43**

The disease transmission principles outlined above can be applied to multiple PEQ shipments. If it is assumed that a minimum of four horses, and more realistically at least six or seven horses, are required to sustain EI for 28 days and the total number of horses is less than this, whether or not the horses come from different PEQ sites is largely irrelevant. (page 26 paragraph 1, Figures 6-8)

**Response**

The Expert Panel considered at length the disease transmission possibilities involved in commingled consignments. These considerations are outlined at the response to Issue 46 below. It is noted that the Figures provided represent only a single transmission scenario, and do not consider fomites or variable transmission times.

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**Issue 44**

... the number of horses required to sustain EI is likely to be greater than 6 horses. (page 27 paragraph 1)

**Response**

The minimum number of horses required to sustain EI would depend on many factors, including immune status of horses with respect to the strain of EIV encountered, the stochastic nature of influenza transmission, relative biosecurity within and between consignments, and conditions for persistence of EIV on fomites.



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**Issue 45**

In personal communication with Richard Newton, he has stated that depending on the time of testing the NP Elisa test utilized in the UK properly applied probably has sensitivity greater than 95% and that PCR tests have a higher sensitivity. (page 29 paragraph 1)

**Response**

Further information about the sensitivity of diagnostic tests has been added in section 5.14.1 of the IRA report.

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**Issue 46**

In the draft IRA, details of risks created by mixed PEQ shipments are not clearly specified ... (page 29 paragraph 2)

If a breach occurs close to the end of PEQ or during transport mixed PEQ will have minimal influence. If the breach occurred at the commencement of PEQ there will be some increase in risk. (page 29 paragraph 5)

**Response**

It is not possible within the scope of the IRA report to speculate with any confidence on when or how transmission might occur, and all scenarios need to be addressed. Further information about circulation of different strains of EIV has been added for clarification in section 5.14.1 of the IRA report. After further consideration of risks of commingling and effects of prior exposure and heterogeneous strains of EIV, the Expert Panel and BA considered that the risks could be managed with a 14-day PAQ for commingled consignments originating from the same region.

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**Issue 47**

... horses in PEQ are vaccinated [against EI] and most horses in the area around PEQ are also likely to be vaccinated. (page 30 paragraph 4)

**Response**

The IRA report covers horses, including for breeding, companion, pleasure and competition, donkeys and mules. Information has been added in section 5.14.1 of the IRA report. It notes that there is little information available on prevalence and incidence of disease in endemic populations, or on vaccine usage in populations outside regular competition.

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**Issue 48**

Reasons for no longer permitting local horses into PAQ are not provided. (page 30 paragraph 6)

**Response**

Quarantine measures in chapter 8 of the IRA report state that, 'any variation from the post-arrival quarantine requirements must be specifically authorised by AQIS'. Approval for horses other than those of the import consignment to enter PAQ may be given on a case-by-case basis. A local horse (as a companion horse) could be permitted entry to PAQ. The local horse would be subject to PAQ requirements as for horses in the consignment.

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**Issue 49**

Reasons for this [no presence of local horses in PEQ] are not specified however considering the review of first principles, there does not seem to be a need for this restriction (page 30 paragraph 7)

**Response**

Quarantine measures in chapter 8 of the IRA report state that, 'any variation from the pre-export quarantine requirements must be specifically authorised by AQIS'. Approval for horses other than those of the import consignment to enter PEQ may be given on a case-by-case basis. A local horse (as a companion horse) could be permitted entry to the PEQ facility. A local horse would be subject to PEQ requirements as for horses in the consignment.

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**Issue 50**

Considering the incidence of disease [EI] and the likelihood of transmission from the ground it is recommended that risks associated with training location are review. (page 30 paragraph 8)

**Response**

This may be considered as part of the approval of the PEQ facility and facility SOPs on a case-by-case basis.

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**Issue 51**

If the probability of some of these events can be calculated, or reasonably estimated, quantitative analysis can be utilized. (page 30 paragraph 9)

**Response**

Both qualitative risk assessment and quantitative risk assessment methods are valid according to the Code. Due to insufficient relevant quantitative data, the IRA report took a qualitative approach.

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**Issue 52**

... some investigation of the impact of biosecurity breaches during PEQ and PAQ are investigated on a quantitative basis by BA and AQIS. (page 31 paragraph 1)

**Response**

Both qualitative risk assessment and quantitative risk assessment methods are valid according to the Code. Due to insufficient relevant quantitative data, the IRA report took a qualitative approach.

In relation to the effect of disease incursion information on the costs of disease outbreaks are included where available. In the case of EI, information has been provided in chapter 2 of the IRA report on the cost of the outbreak in Australia.

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**Issue 53**

The specific issue of concern is that single consignments (not commingled with other consignments from different sources) require only 2 weeks PAQ, whereas mixed consignments (from multiple sources) require an additional week of PAQ. The additional time for mixed consignments may act as a deterrent for owners considering whether to send racehorses to Australia. (page 39 paragraph 3)

**Response**

The IRA report reflected the Expert Panel's consideration that commingled consignments increase the risk of infection with EI virus enough to justify a further seven days PAQ. After further consideration of risks of commingling and effects of prior exposure and heterogeneous strains of EI virus, the Expert Panel and BA considered that the risks could be managed with a 14-day PAQ for commingled consignments originating from the same region.

The key issue identified above (additional one week of PAQ for mixed consignments) is the only matter where, in our opinion, the draft IRA has not presented a well reasoned and documented justification for the recommendation of an additional week of PAQ. Other measures imposed, including requirements for PEQ & PAQ, clinical monitoring, rectal temperature monitoring and PCR testing appear appropriate and reasonable. (page 40 paragraph 2)

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**Issue 54**

We could find no evidence in the draft report that any formal or structured assessment was performed to determine the likelihood or risk under varying conditions (non-mixed consignments vs mixed consignments, and two vs three weeks of PAQ) in order to arrive at a justified and documented conclusion that the extra week of PAQ was warranted for mixed consignments and not warranted for non-mixed consignments. (page 40 paragraph 6)

**Response**

After further consideration of risks of commingling and effects of prior exposure and heterogeneous strains of EI virus, the Expert Panel considered, based on available scientific information and its expert judgement, that the risks could be managed with a 14-day PAQ for commingled consignments originating from the same region. The IRA report includes reasoning on the various PEQ and PAQ periods.

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# Thoroughbred Breeders Australia

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## Issue 1

The selection of most diseases for risk management is clearly defined. In contrast the steps taken in arriving at specific guidelines for diseases requiring management were at times difficult to follow, particularly when the guidelines exceeded those described by the OIE. (page 1 paragraph 5)

## Response

The IRA report has been conducted according to established processes that are consistent with Australia's domestic and international obligations. For disease agents for which there are no Code recommendations further information has been provided in the IRA report.

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## Issue 2

Zebras and other non-domesticated equids should be considered along with domesticated horses and that importation requirements [for African horse sickness] be updated accordingly. (page 3 paragraph 2)

## Response

The biosecurity risks posed by non-domestic equids are different to those of domestic equids due to different management. BA will conduct a review of the quarantine requirements for zoo perissodactyls following finalisation of the horse IRA report. Australia does not import zoo perissodactyls from countries where African horse sickness occurs.

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## Issue 3

That consideration be given to reducing the disease-free period [for Borna disease] to 12 months and that defined regions are more accurately described in the report. (page 4 paragraph 3)

## Response

Certification for Borna disease has been amended to require premises freedom.

Defined areas will be specified in development of specific quarantine measures for individual countries and has been clarified in section 6.1 of the IRA report to include examples, such as states or provinces.

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## Issue 4

We recommend that a risk assessment be undertaken into CEM and that current guidelines are reassessed. (page 4 paragraph 7)

## Response

The OIE Manual refers to the HBLB in its recommendations and this is considered best practice. In light of the Code recommendations, the Expert Panel and BA did not consider that a separate assessment is required for CEM. Quarantine measures are reviewed as new information is available, such as disease reports, new technologies and new protocols for diagnosis. BA monitors and continues to review existing import policies in light of new scientific information.

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**Issue 5**

The proposed guidelines [for equid herpesviruses] appear adequate based on the difficulties in identifying carrier horses. Outbreaks attributed to the neuropathic strain of EHV-1 appear to be inevitable; therefore we strongly recommend development of an AUSVETPLAN or similar response plan. This recommendation is beyond the scope of the IRA report. (page 5 paragraph 4)

**Response**

The issue is beyond the scope of the IRA report and will be forwarded to Australia's Office of the Chief Veterinary Officer.

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**Issue 6**

Although beyond the scope of the document we believe that this disease [equine granulocytic anaplasmosis] should be notifiable in all states and territories within Australia. (page 5 paragraph 7)

**Response**

The issue is beyond the scope of the IRA report and will be forwarded to Australia's Animal Health Committee.

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**Issue 7**

Although beyond the scope of the document consideration should be given to development of a control program for EIA in Queensland. (page 6 paragraph 2)

**Response**

The issue is beyond the scope of the IRA report and will be forwarded to Biosecurity Queensland.

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**Issue 8**

Recommend that additional quantitative analysis [for EI] of the proposed guidelines be undertaken to reassure stakeholders of the magnitude of the risk reduction relative to Australia's ALOP. Assurance from AQIS and Biosecurity Australia that importation of horses would continue into Australia to unaffected quarantine stations in the advent of identification of a single EI infected horse. (page 6 paragraph 7)

**Response**

Both qualitative risk assessment and quantitative risk assessment methods are valid according to the Code. Due to insufficient relevant quantitative data, the IRA report took a qualitative approach.

Horses could be permitted to enter into another quarantine station subject to its location and consultation with the state governments.

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**Issue 9**

It is assumed that should improved diagnostic tests, [for equine piroplasmosis] e.g. PCR, become commercially available that they would be adopted by Biosecurity Australia (page 7 paragraph 3)

**Response**

Quarantine measures are reviewed as new information is available, such as disease reports, new technologies and development of new vaccines. If more sensitive, validated tests become available these would be included.

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**Issue 10**

We believe that the risk assessment for this disease [Lyme disease] over-estimated its importance as a threat to the horse industry. However given that the recommendations for minimisation of release are not onerous it has little to no impact to key stakeholders. Although beyond the scope of this document we would suggest that Lyme Disease be added to the national notifiable disease list. (page 9 paragraph 2)

**Response**

The issue is beyond the scope of the IRA report and will be forwarded to Australia's Animal Health Committee.

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**Issue 11**

The emergence of this disease [Nipah virus encephalitis] in neighbouring countries should be monitored and guidelines modified as per the draft IRA recommendations. (page 9 paragraph 3)

**Response**

Quarantine measures are reviewed as new information is available, such as disease reports, new technologies and development of new vaccines. Currently Australia does not permit the importation of horses from countries where Nipah virus is present. Should Australia consider importation from these countries then consideration will be given to the risk of Nipah virus with the importation of horses.

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**Issue 12**

We suggest a change in terminology to Equine Monocytic Ehrlichiosis; the term Potomac horse Fever has been discouraged in the United States. (page 9 paragraph 5)

**Response**

The name, Potomac horse fever, is widely used and recognised in text books and scientific papers. Chapter 5.28 of the IRA report lists other disease names that are used including equine monocytic ehrlichiosis. The causal agent, formerly classified in the genus *Ehrlichia*, is now *Neorickettsia risticii*.

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**Issue 13**

Given the circumstances of the most recent reported case that consideration is given to changing the guidelines such that a clinical equine case of Surra within a country should not preclude exportation if other requirements are met. Alternatively establishment of defined areas of freedom may be considered. (page 10 paragraph 5)

**Response**

In the event of an outbreak of surra in equids in an approved country, Australia may recognise free zones or compartments based on a detailed submission from the affected country.

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# The United States

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## Issue 1

### Generic Approach

In general, the United States is concerned that Australia's generic approach to risk analysis appears to disregard many important country-specific factors that affect risk.

## Response

The IRA is a generic report, covering approved countries that currently export horses to Australia. When developing specific quarantine measures for individual countries or areas, Australia will take into account the country-specific factors, such as the equine health status of the particular country or area. Countries may need to provide detailed submissions on the basis of their claims for consideration by Australia.

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## Issue 2

### Inconsistencies in Methodology

We are also concerned about inconsistent application of Australia's own risk assessment standards throughout the document. According to the IRA methodology, disease agents with an overall risk estimation of "very low" or "negligible" were considered to achieve Australia's conservative appropriate level of protection (ALOP) and further risk management was not required (Chapter 3.2.7). As an example, the risk assessment concludes that the unrestricted risk for both Borna disease (Chapter 5.4.2) and West Nile fever (Chapter 5.38.2) is negligible. Thus, Australia's ALOP is achieved for both diseases and further risk management was not required. Despite this conclusion, the IRA recommends certification of country freedom from Borna disease and certification of country freedom or vaccination for West Nile fever. These import requirements not only contradict Australia's own methodology but also OIE Code Article 5.1.2...

## Response

The risk assessment conclusions for Borna disease and West Nile fever have been clarified and the wording amended. This is in recognition of best practice with respect to animal health and welfare and that, in the case of Borna disease, horses should not be sourced from premises where an emerging disease agent of potential quarantine concern is known to occur.

Certification for Borna disease has been amended to require that for 60 days immediately before export horses have not resided on any premises in the country of export where clinical evidence of Borna disease has occurred.

Due to the serious nature of West Nile fever, a clinical case during PAQ would raise animal welfare concerns for the affected horse, result in disease investigations that could delay the release of all horses in the PAQ facility and disrupt entry of subsequent consignments. The certification for West Nile fever has been amended to require vaccination of horses against WNV from countries where clinical disease is known to occur.

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**Issue 3**

## Flawed Assumptions

The release assessment for each disease considered a single scenario, in which horses entering Australia were sourced at random from the general horse population in an approved country. This assumption leads to an inflated estimate of risk of release. As acknowledged in Chapter 2.3.3, due to the commitment of time and money required to export a horse, animals selected for export are generally of very high economic or sentimental value. These horses could reasonably be expected to be of better health status than the general horse population. In addition, as previously mentioned, this assumption does not account for differences in disease incidence and prevalence between approved countries.

As stated in Chapter 3.2.5, the risk of release and exposure was 'the estimated likelihood that there was at least one exposure event during an average year for the expected number of horses imported from countries where the disease being assessed was endemic. The risk of one exposure event occurring is proportional to the number of horses imported, and since the number of horses arriving in Australia from each approved country is quite different, considering the volume from each approved country would provide a more appropriate estimate of risk, as well as allowing for consideration of disease prevalence in the approved country.

**Response**

The IRA is a generic report, covering approved countries that currently export horses to Australia. When developing specific quarantine measures for individual countries or areas, Australia will take into account the equine health status of the particular country or area. Countries may need to provide detailed submissions on the basis of their claims for consideration by Australia.

It should be noted that horses of high economic value have introduced disease, including the introduction of EI in Australia. In addition, consignments of horses from countries with different equine health status or disease prevalence are frequently mixed in PAQ before an imported horse is released into the Australian horse population.

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**Issue 4**

## Documentation

We request removal of the requirement to include laboratory reports with the export certificate. As the competent veterinary authority of the United States, it is the responsibility of the U.S. Department of Agriculture to officially attest to laboratory test results.

**Response**

Australia requires laboratory test results as part of the veterinary certification.

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**Issue 5**

## Contagious equine metritis

We suggest that the sampling sites for colts and stallions should include the urethral sinus which is most frequently associated with persistence of *T. equigenitalis* and *T. asinigenitalis* in the male equid.

**Response**

BA accepts this suggestion and has amended the sampling sites to include the urethral sinus.



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**Issue 6**

## Equine influenza

We request that the time period for taking the second nasopharyngeal swab for conducting the polymerase chain reaction (PCR) test for equine influenza be extended to 7 days. Four days before export is not sufficient to transport specimens to an appropriate laboratory for PCR testing, conduct the test, and report the result.

**Response**

Four days is considered an adequate period to complete sampling and testing using a PCR for influenza A virus. BA notes that the Code recommends testing for EI at 21 days and three days before shipment. The timing of testing most likely to detect EI virus was considered in the risk assessment. BA recognises there may be logistical difficulties in managing samples and has reworded the conditions to require sampling during the four days before horses leave the PEQ facility.

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**Issue 7**

## Equine piroplasmiasis

As both the indirect fluorescent antibody test (IFAT) and the competitive enzyme-linked immunosorbent assay (cELISA) are recognized by the OIE as prescribed tests [for equine piroplasmiasis] for international trade, we recommend that Australia accepts the use of either test in screening imported horses for evidence of *Babesia caballi* and *Theileria equi* infection rather than restrict the testing method to the IFAT.

**Response**

The ELISA for equine piroplasmiasis has been reported to give false negative results and is not considered as sensitive as the IFAT. This was demonstrated in reports to the OIE in 2009 from the United States of negative ELISA results on samples found to test positive to the IFAT and PCR. Accordingly the IFAT is the recommended test.

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**Issue 8**

## Equine viral arteritis

We question the scientific rationale for testing colts or stallions between six and nine months of age on two occasions with vaccination against EVA immediately after the second test. We contend that a single blood sample taken at the time of vaccination would be sufficient to determine the serological status of individual colts at time of vaccination. Since it has been shown that pre-pubertal colts are refractive to establishment of the carrier state, there would be no increased risk to the importing country by reducing the blood sampling to one taken at time of initial vaccination. This proposal was submitted to the OIE Code Commission with the endorsement of three OIE-designated EVA specialists.

**Response**

The Code recommendations for EVA have been included in the IRA report, and specify the option of testing colts and stallions between six and nine months of age. Should changes to the Code occur, Australia will update these requirements accordingly.