Australian Government

Biosecurity Australia

STAKEHOLDER COMMENTS IN RESPONSE TO THE DRAFT POLICY REVIEW FOR THE IMPORTATION OF PRESERVED DUCK EGGS FROM TAIWAN (BAPM 2007/11) AND BIOSECURITY AUSTRALIA'S RESPONSES

Comments were received from:

- New South Wales Department of Primary Industries
- Australian Poultry Veterinary Alliance
- Bureau of Animal and Plant Health Inspection and Quarantine, Taiwan
- Biosecurity Queensland, Queensland Government

New South Wales Department of Primary Industry's submission

Issue	Biosecurity Australia's response
Transmission via egg shell	
Microbial forms such as NDV and Mycoplasma with no means of locomotion were proven to be capable of penetration through the intact shell egg (Williams et al., Avian Diseases, vol 12, 1968; Arzey, G. 1989, Mechanisms of spread of ND. Tech. Bulletin Number 42, NSW Agriculture and Fisheries ISBN 0 7305 66412). Therefore, while the concept is helpful, it is important to consider that many organisms even with no inherent motility can be capable of penetration of the egg and establishing internal presence or infection regardless of the ability for vertical transmission.	Two examples were quoted: . NDV will be addressed by the proposed risk management measures. . *Mycoplasma* spp. are not considered a hazard. They are either not present in duck eggs, or are present in Australia. *Mycoplasma* spp. are fastidious organisms, which are not likely to survive the processing.
While the difference in structure between duck egg inner shell membrane and chicken egg membrane may not be significant, a transparent risk assessment should elaborate on the differences and the possible risks associated with the differences. Extrapolations from one species to another should be approached with caution and even if the differences are insignificant, it is import for a risk assessment to explore the risk.	Not accepted. The policy review is based on a conservative approach to assessing risk that is also reflected in situations where there is not full or comprehensive scientific information. Biosecurity Australia's view is that accepting there may be differences in structure between chicken and duck eggs, this would not materially affect the conclusions of the review.
Chlamydophila psittaci	
NSW DPI made a number of points for the inclusion of *Chlamydophila psittaci* in the list of diseases of quarantine concern. 1. The agent meets the international guidelines for the agent to either not be present or be associated with a notifiable status. In Australia, avian chlamydiosis is notifiable in most states and therefore meets the criteria 2. The strains of chlamydophila present in ducks in overseas countries have been reported not to be similar to serovars from other birds (Diseases of Poultry, 11th ed, pg 863 – 879) 3. While chlamydiosis has been detected in Australian domestic ducks, no studies have been done to demonstrate that the strain is different or identical to the overseas strains detected in ducks. 4. Chicken meat RAP response to one of the stakeholders in 2001 was that multi-antibiotic resistant strains <u>have been found in ducks</u> and since the IRA is considering importation of uncooked chicken meat, this is not considered to be relevant. This should be relevant for this IRA, which deals with importation of products from ducks.	*Chlamydophila* spp. is endemic and widespread in both domestic and wild birds in Australia, and does not meet the criteria for inclusion as a hazard. Avian chlamydiosis is not notifiable in all States or Territories, and is not on the national agreed notifiable disease list, nor under official control. 1. NSW DPI's statement is not correct. See point above. 2. *Chlamydophila psittaci* includes 8 known serovars (serotypes). In Europe, there have been a number of outbreaks, and isolates from a few of the outbreaks have all been serotype C. While accepting this statement, this does not alter the conclusions of the policy review. 3. Biosecurity Australia is not aware of scientific literature to support a claim that endemic strains of *C. psittaci* are different in virulence than overseas strains. 4. The multi-antibiotic resistant strains of *Chlamydia psittaci* are reported in 'Multi-antibiotic resistance in *Chlamydia psittaci* from ducks (1983) Johnson, FWA and Spenser WH, Veterinary Record, 112(9): 208'. This paper reported two strains of *Chlamydia psittaci* in the United Kingdom (not in Taiwan) that were resistant to a number of antibiotics. Since publication of the paper, Biosecurity Australia is not aware of any other studies that have reported multi-antibiotic resistant strains of *Chlamydia psittaci* anywhere else in the world.

Issue	Biosecurity Australia's response
Antibiotic resistant *Campylobacter jejuni*	
NSW DPI queried whether *Campylobacter jejuni* should be included in the list of diseases of quarantine concern. Chicken meat IRA stated that quinolone-resistant strains of *Campylobacter jejuni* have been isolated from a small number of locally acquired cases (Sharma *et al* 2003). However, in the paper by Unicomb *et al* in Emerging Infec. Dis vol 9 (11), 2003 – "No resistance to fluoroquinolones was found (nalidixic acid is not a fluoroquinolone) in isolates known to be locally acquired". Therefore, the occurrence of fluoroquinolone resistant isolates in Australia is questioned by NSW DPI and aspects in 'Table 6, Hazard refinement' in the current duck eggs IRA concluding that antibiotic resistant *Campylobacter jejuni* are present in Australia and therefore should not be on the list of diseases of quarantine concern is again questioned by NSW DPI.	*C. jejuni* was included in the initial hazard list but was ruled out as a disease agent requiring further assessment. To be considered a hazard, an organism should: . be appropriate to the animal species to be imported, or from which the commodity is derived; . be present in the exporting country; and . not be present in the importing country, or, if present, the pathogenic agent should be associated with a notifiable disease, or is subject to an official control or eradication program. *C. jejuni* is a ubiquitous organism, present in commercial chickens world-wide, including Australia. *C. jejuni*, while acknowledged as a human pathogen, is not an agent that readily causes disease in poultry flocks. If the organism were introduced into poultry flocks via imported preserved duck eggs, it is unlikely that any effect on bird health or production would be detected. Campylobacteriosis is not an OIE-listed disease and is not subject to controls within Australia. Products intended for human consumption may undergo a separate assessment conducted by FSANZ to determine the public health risks.
Avian reovirus	
NSW DPI questioned whether avian reovirus should be included in the list of diseases of quarantine concern. 1. Duck reovirus has been reported to be different from chicken reovirus. The nucleotide and amino acid sequence identified in the amplified δA-encoding gene were 74.2–78.4 % and 86.9–92.0 %, respectively between duck/goose and chicken species (Archives of Virology vol 151 August 2006). This work reported findings in mainland China and is likely to be relevant to Taiwan. 2. Other reoviruses have been described in various duck species like Muscovy ducks (Arzey, G. Diseases of ducks, Post Graduate Foundation Proc 92, Poultry Health May, 1986). Although the chicken meat IRAP excluded reovirus, it stated that 'Australian strains appear to be of low virulence in comparison to North American and European strains' (chicken meat IRA, page304). However, on page 308, the chicken meat IRA states that 'there is difficulty in determining that exotic strains are more virulent than Australian strains making it difficult to accurately target risk management. Therefore, the IRA concludes that no further risk assessment is necessary (page 308). This IRA added another facet to the debate by stating in Table 6 'that some strains of reovirus are endemic in Australian poultry'. It appears that combining the comments in the duck eggs IRA and the chicken meat IRA would suggest that the Australian reovirus strains appear to be of lower virulence than overseas strains and some reovirus strains are not present in Australia. Therefore, on the balance of evidence, the justification to remove reovirus from the list of diseases of	Avian reovirus was included in the initial hazared list but was ruled out as a disease agent requiring further assessment. Some strains of avian reovirus are endemic in Australian poultry; it is not notifiable in all States or Territories nor on the national agreed notifiable disease list. Defining specific exotic strains and demonstrating that these are more virulent than Australian strains have not been done. 1. There is a temptation to implicate reovirus as a cause for a number of conditions as it is relatively easy to cultivate, and when looked for, serum antibodies are often found (Jones 2003). Apart from tenosynovitis in chickens, where a clear relationship occurs between reovirus infection and the clinical disease, the role of reoviruses in avian disease is frequently unclear. There appears to be a wide range of pathogenicity among isolates, but most are thought to be harmless. 2. As stated in the chicken meat IRA, Australian strains appear to be of low virulence in comparison to North American and European strains but there is difficulty in defining specific exotic strains that are demonstrating more virulence than Australian strains. Avian reovirus is not notifiable in all States or Territories, and is not on the national agreed notifiable disease list, nor in the emergency animal disease response agreement (EADRA).

quarantine concern is questioned.	

Issue	Biosecurity Australia's response
Non notifiable avian influenza virus	
NSW DPI considers the same principles for release and consequence assessment for notifiable avian influenza (AI) should apply to non-notifiable AI. 1. All avian influenza viruses in Australia are notifiable and therefore meet the international guidelines under the heading; not present in the importing country or is of notifiable status. Among the subtypes reported to establish stable lineage in domestic poultry in other countries are: H9N2, H9N3, H6N1, H6N2, H3N2, H3N6, H4 (Liu et al., Avian Dis 2003, vol 47, Sun Yingjie 4th International symposium on avian influenza 1997)	Not agreed. It is not possible to confirm that all Australian poultry is free of all AI viruses and hence strains of AI other than LPNAI and HPAI viruses are not included in the risk assessments. Current surveillance demonstrates that Australia is free of HPAI in poultry and no cases of LPNAI infection of poultry have been reported by State and Territory animal health authorities. Strains of AI viruses, which are not highly pathogenic and are not of the H5 and H7 subtypes, are not notifiable to the OIE. Ausvetplan does not consider occurrence of these viruses (non H5/H7) as an emergency disease outbreak. Wild birds are the usual hosts of these strains and infection does not usually result in disease. AI testing is complex and expensive. Demonstrating that Australian poultry is free of all strains of AI has not been done.
NSW DPI questions the conclusion on page 56 that overall, the likelihood of backyard and wild birds would be exposed to an infectious dose of LPNAI virus is assessed as low. Unless the infective dose is known and stated for each of these categories and allowances are made for different infective doses in different species of birds, it is not sustainable scientifically to accept this conclusion.	Not accepted. The policy review establishes that the likelihood is dependent on several factors, one of which is the infective dose. A number of factors, including susceptibility to infection and inactivation by acid pH, and environmental exposure, etc, were taken into account when assessing and concluding the low likelihood that backyard and wild birds would be infected with LPNAI virus, after ingestion of potentially contaminated preserved duck eggs.
Newcastle disease (ND) virus	
NSW DPI questions the conclusion on page 67 that overall, the likelihood of backyard and wild birds would be exposed to an infectious dose of ND virus is assessed as low. Unless the infective dose is known and stated for each of these categories and allowances are made for different infective dose in different species of birds, it is not sustainable scientifically to accept this conclusion.	Not accepted. The policy review establishes that the likelihood is dependent on several factors, one of which is the infective dose. A number of factors, including susceptibility to infection and inactivation by acid pH, and environmental exposure, etc, were taken into account when assessing and concluding the low likelihood that backyard and wild birds would be infected with ND virus, after ingestion of potentially contaminated preserved duck eggs.
Salmonella	
NSW DPI questions the conclusion on page 73 that overall, the likelihood of backyard and wild birds would be exposed to an infectious dose of *Salmonella* Pullorum or *Salmonella* Gallinarum is assessed as low. Unless the infective dose is known and stated for each of these categories and allowances are made for different infective dose in different species of birds, it is not sustainable scientifically to accept this conclusion.	Not accepted. The policy review establishes that the likelihood is dependent on several factors, one of which is the infective dose. A number of factors, including susceptibility to infection and inactivation by acid pH, and environmental exposure, etc, were taken into account when assessing and concluding the low likelihood that backyard and wild birds would be infected with *Salmonella*, after ingestion of potentially contaminated preserved duck eggs.

Issue	Biosecurity Australia's response
NSW DPI also believes that the cost associated with outbreak scenarios should include the overall cost associated with eradication of *S.* Pullorum from commercial flocks in Australia in the past and the current cost of monitoring.	It is not appropriate to consider the costs of historical disease freedom or disease monitoring. The benefits arising from Australia's favourable health status and disease freedom accrues to industry. The review, as per the SPS agreement, considers the costs associated with a disease incursion in terms of eradication, control, surveillance, compensation, and trade and industry impacts.
Based on effective control and eradication the impact of *S.* Pullorum should be consistent with the impact of *S.* Enteritidis (moderate for *S.* Enteritidis and low for *S.* Pullorum)	The impact of *S.* Enteritidis is higher than that of *S.* Pullorum: *S.* Pullorum is a pathogen of poultry whereas *S.* Enteritidis is a pathogen of many species including humans. An outbreak of *S.* Enteritidis in ducks and other poultry (chickens) would be likely to lead to disease in humans, with associated loss of domestic markets and other flow on effects.
DEV	
NSW DPI questions the conclusion on page 86 that overall, the likelihood of backyard and wild birds would be exposed to an infectious dose of duck viral enteritis virus is assessed as extremely low. Unless the infective dose is known and stated for each of these categories and allowances are made for different infective dose in different species of birds, it is not sustainable scientifically to accept this conclusion and the negligible risk estimation.	Not accepted. The likelihood is dependent on several factors, one being the infective dose. A number of factors, including susceptibility to infection and inactivation by acid pH, and environmental exposure, etc, were taken into account when assessing and concluding the low likelihood that backyard and wild birds would be infected with DEV, after ingestion of potentially contaminated preserved duck eggs.
It is also difficult to understand how the impact from DEV, a disease that can affect only ducks is low and that from *Salmonella* Pullorum and *S.* Gallinarum that can affect a variety of avian species is also classified as low. The impact of a disease may be diluted if it is estimated on the entire industry rather than a small fraction of the industry. The duck industry is significantly smaller than the chicken industry and the impact of a disease outbreak may affect a higher percentage of duck producers than for example Newcastle disease in chickens. It is not clear to what degree this potential has been assessed.	The review considers a number of factors in reaching its conclusions on DEV. While *S.* Pullorum and *S.* Gallinarum can affect a variety of avian species, the impact of these diseases spreading to commercial poultry in Australia will be due mainly to costs associated with disease control and eradication. Whereas, DEV is a serious disease of ducks only, and economic losses in flocks of ducks are similar to those caused by Newcastle disease (ND) in chickens. The impact of ND virus spreading and becoming endemic in Australia is assessed as moderate. Given that the duck industry is much less widespread than the poultry industry generally, it is considered the impact of DEV in Australia is less and is assessed as low
Japanese encephalitis (JE) virus	
No occurrence has been reported in poultry in Australia and the reported serological evidence in sentinel pigs in Cape York should not be accepted or used in any manner to extrapolate/insinuate the status of this disease in Australia in commercial poultry.	Biosecurity Australia accepts that JE virus has not been reported in poultry in Australia. The policy review has taken into account that there has been a report of one human case of JE acquired on the Australian mainland and serological evidence of infection in sentinel pigs on Cape York Peninsula.
Table 6 does not state the effect of pH or salting/heat inactivation and while NSW DPI agrees that it is unlikely to be present inside the egg contents it is not entirely clear that the organism may not be present on the egg shell.	Transmission of JE via egg has not been reported. The virus has not been reported to be present on or in egg shell or within the egg content of duck eggs. As such, there was no need to consider the effects of alkaline or heat treatment. Nonetheless, JE virus belongs to the genus *Flavivirus* that are stable at slight alkaline pH 8.0 but are readily inactivated at acidic pH and temperatures above 40 ºC. JE virus is an arbovirus, and is unlikely to become

	established from the import of preserved eggs.

Issue	Biosecurity Australia's response
West Nile virus	
Outbreaks of West Nile virus involving ducks have been reported from Israel and Romania. Arboviruses have been isolated from fertile eggs of quails. A full risk assessment would benefit the policy review rather than exclusion based on a summary table that is not entirely accurate.	West Nile virus has not been reported to be present on or in egg shell or within the egg content of duck eggs. As such, there was no need to consider the effects of alkaline or heat treatment. Nonetheless, West Nile virus belongs to the genus *Flavivirus* that are stable at slight alkaline pH 8.0 but are readily inactivated at acidic pH and temperatures above 40ºC. West Nile virus is an arbovirus, and is unlikely to become established from the import of preserved eggs.
Eastern equine encephalitis	
Eastern equine encephalitis (EEE) is not listed in this policy review. EEE was described in ducks as early as 1912 and sporadic outbreaks have been reported. The host range of EEE includes many mammals as well as at least 30 wild bird species as well as ducks, quails, chicken (note that EEE was also omitted from the chicken meat IRA), turkey, pheasants and guineafowl (Avian Dis 1960, vol 4 page 247). The isolation of the virus from fertile eggs of quails was reported and the possibility of transfer in duck fertile eggs was not investigated.	Chickens and quails are very susceptible to experimental infection but clinical disease due to natural infection has not been reported in chickens and quails. An outbreak of EEE has been reported in ducks (Dougherty and Price 1960). However, vertical transmission in ducks has not been reported. If transmission of flaviviruses were a possibility through ingestion of duck eggs, it would be likely to be reported in the literature as a risk for fresh duck eggs. The heating or alkaline treatment makes it less likely for the virus to survive in processed eggs than for fresh eggs. According to the OIE, EEE has never been reported in Taiwan.
There is also evidence that direct transmission through ingestion of infective material may play a role. More weight should be given to this route of infection in the assessment of the pathways of exposure.	Direct transmission of EEE has been reported to occur in pheasants as a result of feather picking and cannibalism (Holden 1955). However, there is no evidence of EEE virus being present either in or on duck eggs. If transmission of flaviviruses were possible through ingestion of duck eggs, it would be likely to be reported in the literature. The heating or alkaline treatment makes it less likely for the virus to survive in processed eggs than for fresh eggs.
General	
NSW does not support the rationale outlined on page 25 of the policy review that 'if the adverse effects of a pathogenic agent entering, establishing and spreading had already been determined by another related risk analysis (chicken meat IRA), and were evaluated to be very low or negligible, no further risk assessment was necessary. The statement presumes that the determination of the risk in the draft chicken meat IRA was accepted by all stakeholders and therefore it is not appropriate to use the outcomes of a draft document under review to provide final determination of the risk for a new IRA such as the current duck eggs importation.	The chicken meat IRA is well advanced and information in this report has been taken into account in this policy review.

Issue	Biosecurity Australia's response
The avian health status portrayed by the Taiwanese regarding *Salmonella* species as apparently found in survey of retail markets in 2003 and 2004 is intriguing. It is difficult to believe *Salmonella*, a ubiquitous organism found in the environment and with extremely high prevalence in commercial poultry flocks across the world, has not been detected in processed ducks in Taiwan.	Taiwan conducted monitoring for *Salmonella* spp. in preserved duck eggs (salted/heated and alkalised), not processed ducks, from retail market in 2003 and 2004, with negative results. The relevant text in the policy review (page 12) has been amended to clearly state that the survey was conducted on the presence of *Salmonella* spp. in preserved duck eggs. Biosecurity Australia has considered the information provided by Taiwan in relation to *Salmonella* spp. in processed duck eggs in retail market, and is proposing that the heat treatment applied to the salted duck eggs address the quarantine concerns for *S*. Pullorum, *S*. Gallinarum, *S*. Enteritidis and *S*. Typhimurium. On the other hand, for the alkalised duck eggs, Biosecurity Australia is proposing that risk management is required for *S*. Enteritidis and *S*. Typhimurium.

Reference List

1. Dougherty, E Jr, and JI Price. 1960. Eastern encephalitis in White Pekin ducklings on Long Island. *Avian Diseases* 4: 247-58.

2. Holden, P. 1955. Transmision of Eastern Equine Encephalomyelitis in ring-necked pheasants. *Proceedings of the Society for Experimental Biology and Medicine* 88: 607-10.

3. Jones, R. C. 2003. Other reovirus infections. In *Diseases of poultry.* 11th ed. Editors Y. M. Saif, H. J. Barnes, J. R. Glisson, A. M. Fadly, L. R. McDougald, and D. E. Swayne, 293-98. Iowa, USA: Iowa State Press.

Australian Poultry Veterinary Alliance's submission

Issue	Biosecurity Australia's response
Transmission via egg shell	
Microbial forms such as NDV and *Mycoplasma* with no means of locomotion were proved to be capable of penetration through the intact shell egg. Therefore, while the concept is helpful, it is important to consider that many organisms even with no inherent motility can be capable of penetration of the egg and establishing internal presence or infection regardless of the ability for vertical transmission.	Two examples were quoted: . NDV will be addressed by the proposed risk management measures. . *Mycoplasma* spp. are not considered a hazard. They are either not present in duck eggs, or are present in Australia. *Mycoplasma* spp. are fastidious organisms, which are not likely to survive the processing.
While the difference in structure between duck egg inner shell membrane and chicken egg membrane may not be large, a transparent risk assessment should elaborate on the differences and the possible risks associated with the differences. Extrapolations from one species to another should be approached with caution and even if the differences are minor, it is important for a risk assessment to explore the risk.	The policy review is based on a conservative approach to assessing risk that is also reflected in situations where there is not full or comprehensive scientific information. Biosecurity Australia's view is that accepting there may be differences in structure between chicken and duck eggs, this would not materially affect the conclusions of the review.
Chlamydophila psittaci	
APVA made a number of points for the inclusion of *Chlamydophila psittaci* in the list of diseases of quarantine concern: 1. In Australia, avian chlamydiosis is notifiable in most states and therefore meets the criteria. 2. The strains of chlamydophila present in ducks in overseas countries have been reported not to be similar to serovars from other birds (Diseases of Poultry, 11th ed, pg 863 – 879) 3. While chlamydiosis has been detected in Australian domestic ducks, no studies have been done to demonstrate that the strain is different or identical to the overseas strains detected in ducks. 4. Chicken meat RAP response to one of the stakeholders in 2001 was that multi-antibiotic resistant strains have been found in ducks and since the IRA is considering importation of uncooked chicken meat, this is not considered to be relevant. This should be relevant for this IRA, which deals with importation of products from ducks.	*Chlamydophila* spp. is endemic and widespread in both domestic and wild birds in Australia, and does not meet the criteria for inclusion as a hazard. Avian chlamydiosis is not notifiable in all States or Territories, and is not on the national agreed notifiable disease list, nor under official control. 1. APVA's statement is not correct. See point above. 2. *Chlamydophila psittaci* includes 8 known serovars (serotypes). In Europe, there have been a number of outbreaks, and isolates from a few of the outbreaks have all been serotype C. While accepting this statement, this does not alter the conclusions of the policy review. 3. Biosecurity Australia is not aware of scientific literature to support a claim that endemic strains of *C. psittaci* are different in virulence than overseas strains. 4. The multi-antibiotic resistant strains of *Chlamydia psittaci* are reported in 'Multi-antibiotic resistance in *Chlamydia psittaci* from ducks (1983) Johnson, FWA and Spenser WH, Veterinary Record, 112(9): 208'. This paper reported two strains of *Chlamydia psittaci* in the United Kingdom (not in Taiwan) that were resistant to a number of antibiotics. Since publication of the paper, Biosecurity Australia is not aware of any other studies that have reported multi-antibiotic resistant strains of *Chlamydia psittaci* anywhere else in the world.

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Antibiotic resistant *Campylobacter jejuni*	
APVA queried whether *Campylobacter jejuni* should be included in the list of diseases of quarantine concern. Chicken meat IRA stated that quinolone-resistant strains of *Campylobacter jejuni* have been isolated from a small number of locally acquired cases (Sharma *et al* 2003). However, in the paper by Unicomb *et al* in Emerging Infec. Dis vol 9 (11), 2003 – "No resistance to fluoroquinolones was found (nalidixic acid is not a fluoroquinolone) in isolates known to be locally acquired". Therefore, the occurrence of fluoroquinolone resistant isolates in Australia is questioned by the APVA and aspects in 'Table 6, Hazard refinement' concluding that antibiotic resistant *Campylobacter jejuni* strains are present in Australia and therefore should not be on the list of diseases of quarantine concern is question by the APVA.	*C. jejuni* was included in the initial hazard list but was ruled out as a disease agent requiring further assessment. To be considered a hazard, an organism should: . be appropriate to the animal species to be imported, or from which the commodity is derived; . be present in the exporting country; and . not be present in the importing country, or, if present, the pathogenic agent should be associated with a notifiable disease, or is subject to an official control or eradication program. *C. jejuni* is a ubiquitous organism, present in commercial chickens world-wide, including Australia. *C. jejuni*, while acknowledged as a human pathogen, is not an agent that readily causes disease in poultry flocks. If the organism were introduced into poultry flocks via imported preserved duck eggs, it is unlikely that any effect on bird health or production would be detected. Campylobacteriosis is not an OIE-listed disease and is not subject to controls within Australia. Products intended for human consumption may undergo a separate assessment conducted by FSANZ to determine the public health risks.
Avian reovirus	
APVA questioned whether avian reovirus should be included in the list of diseases of quarantine concern. 1. Duck reovirus has been reported to be different from chicken reovirus. The nucleotide and amino acid sequence identified in the amplified δA-encoding gene were 74.2–78.4 % and 86.9–92.0 %, respectively between duck/goose and chicken species (Archives of Virology vol 151 August 2006). This work reported findings in mainland China and is likely to be relevant to Taiwan. 2. Other reoviruses have been described in various duck species like Muscovy ducks (Arzey, G. Diseases of ducks, Post Graduate Foundation Proc 92, Poultry Health May, 1986). Although the chicken meat IRAP excluded reovirus, it stated that 'Australian strains appear to be of low virulence in comparison to North American and European strains' (chicken meat IRA, p304). However, on page 308, the chicken meat IRA states that 'there is difficulty in determining that exotic strains are more virulent than Australian strains making it difficult to accurately target risk management. Therefore, the IRA concludes that no further risk assessment is necessary (p 308). The policy review added another facet to the debate by stating in table 6 'that some strains of reovirus are endemic in Australian poultry'. It appears that combining the comments in the policy review and the chicken meat IRA would suggest that the Australian strains appear to be of lower virulence than overseas strains and some reovirus strains are not present in Australia.	Avian reovirus was included in the initial hazard lit but was ruled out as a disease agent requiring further assessment. Some strains of avian reovirus are endemic in Australian poultry; it is not notifiable in all States or Territories nor on the national agreed notifiable disease list. Defining specific exotic strains and demonstrating that these are more virulent than Australian strains have not been done. 1. There is a temptation to implicate reovirus as a cause for a number of conditions as it is relatively easy to cultivate, and when looked for, serum antibodies are often found (Jones 2003). Apart from tenosynovitis in chickens, where a clear relationship occurs between reovirus infection and the clinical disease, the role of reoviruses in avian disease is frequently unclear. There appears to be a wide range of pathogenicity among isolates, but most are thought to be harmless. 2. As stated in the chicken meat IRA, Australian strains appear to be of low virulence in comparison to North American and European strains but there is difficulty in defining specific exotic strains that are demonstrating more virulence than Australian strains. Avian reovirus is not notifiable in all States or Territories, and is not on the national agreed notifiable disease list, nor in the emergency animal disease response agreement (EADRA).

Issue	Biosecurity Australia's response
Non notifiable avian influenza virus	
APVA considers the same principles for release and consequence assessments for notifiable avian influenza (AI) should apply to non-notifiable AI. 1. All avian influenza viruses in Australia are notifiable and therefore meet the international guidelines under the heading; not present in the importing country or is of notifiable status. Among the subtypes reported to establish stable lineage in domestic poultry in other countries are: H9N2, H9N3, H6N1, H6N2, H3N2, H3N6, H4 (Liu et al., Avian Dis 2003, vol 47, Sun Yingjie 4th International symposium on avian influenza 1997)	Not agreed. It is not possible to confirm that all Australian poultry is free of all AI viruses and hence strains of AI other than LPNAI and HPAI viruses are not included in the risk assessments. Current surveillance demonstrates that Australia is free of HPAI in poultry and no cases of LPNAI infection of poultry have been reported by State and Territory animal health authorities. Strains of AI viruses, which are not highly pathogenic and are not of the H5 and H7 subtypes, are not notifiable to the OIE. Ausvetplan does not consider occurrence of these viruses (non H5/H7) as an emergency disease outbreak. Wild birds are the usual hosts of these strains and infection does not usually result in disease. AI testing is complex and expensive. Demonstrating that Australian poultry is free of all strains of AI has not been done.
The APVA questions the conclusion that overall, the likelihood of backyard and wild birds would be exposed to an infectious dose of LPNAI virus is assessed as low. Unless the infective dose is known and stated for each of these categories and allowances are made for different infective doses in different species of birds, it is not sustainable scientifically to accept this conclusion.	Not accepted. The policy review establishes that the likelihood is dependent on several factors, one of which is the infective dose. A number of factors, including susceptibility to infection and inactivation by acid pH, and environmental exposure, etc, were taken into account when assessing and concluding the low likelihood that backyard and wild birds would be infected with LPNAI virus, after ingestion of potentially contaminated preserved duck eggs.
Newcastle disease (ND) virus	
The APVA questions the conclusion that overall, the likelihood of backyard and wild birds would be exposed to an infectious dose of ND virus is assessed as low. Unless the infective dose is known and stated for each of these categories and allowances are made for different infective dose in different species of birds, it is not sustainable scientifically to accept this conclusion.	Not accepted. The policy review establishes that the likelihood is dependent on several factors, one of which is the infective dose. A number of factors, including susceptibility to infection and inactivation by acid pH, and environmental exposure, etc, were taken into account when assessing and concluding the low likelihood that backyard and wild birds would be infected with ND virus, after ingestion of potentially contaminated preserved duck eggs.
Salmonella	
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The APVA also believes that the cost associated with outbreak scenarios should include the overall cost associated with eradication of *S.* Pullorum from commercial flocks in Australia in the past and the current cost of monitoring.	It is not appropriate to consider the costs of historical disease freedom or disease monitoring. The benefits arising from Australia's favourable health status and disease freedom accrues to industry. The review, as per the SPS agreement, considers the costs associated with a disease incursion in terms of eradication, control, surveillance, compensation, and trade and industry impacts.
Based on effective control and eradication the impact of *S*. Pullorum should be consistent with the impact of *S*. Enteritidis (moderate for *S.* Enteritidis and low for *S*. Pullorum)	The impact of *S*. Enteritidis is higher than that of *S*. Pullorum: *S*. Pullorum is a pathogen of poultry whereas *S*. Enteritidis is a pathogen of many species including humans. An outbreak of *S*. Enteritidis in ducks and other poultry (chickens) would be likely to lead to disease in humans, with associated loss of domestic markets and other flow on effects.
DEV	
The APVA questions the conclusion that overall, the likelihood of backyard and wild birds would be exposed to an infectious dose of duck viral enteritis virus is assessed as extremely low. Unless the infective dose is known and stated for each of these categories and allowances are made for different infective dose in different species of birds, it is not sustainable scientifically to accept this conclusion and the negligible risk estimation.	Not accepted. The likelihood is dependent on several factors, one being the infective dose. A number of factors, including susceptibility to infection and inactivation by acid pH, and environmental exposure, etc, were taken into account when assessing and concluding the low likelihood that backyard and wild birds would be infected with DEV, after ingestion of potentially contaminated preserved duck eggs.
It is also difficult to understand how the impact from DEV, a disease that can affect only ducks is low and that from *Salmonella* Pullorum and *S*. Gallinarum that can affect a variety of avian species is also classified as low. The impact of a disease may be diluted if it is estimated on the entire industry rather than a small fraction of the industry. The duck industry is significantly smaller than the chicken industry and the impact of a disease outbreak may affect a higher percentage of duck producers than for example Newcastle disease in chickens. It is not clear to what degree this potential has been assessed.	The review considers a number of factors in reaching its conclusions on DEV. While *S*. Pullorum and *S*. Gallinarum can affect a variety of avian species, the impact of these diseases spreading to commercial poultry in Australia will be due mainly to costs associated with disease control and eradication. Whereas, DEV is a serious disease of ducks only, and economic losses in flocks of ducks are similar to those caused by Newcastle disease (ND) in chickens. The impact of ND virus spreading and becoming endemic in Australia is assessed as moderate. Given that the duck industry is much less widespread than the poultry industry generally, it is considered the impact of DEV in Australia is less and is assessed as low.
Japanese encephalitis (JE) virus	
No occurrence has been reported in poultry in Australia and the reported serological evidence in sentinel pigs in Cape York should not be accepted or used in any manner to extrapolate/insinuate the status of this disease in Australia in commercial poultry.	Biosecurity Australia accepts that JE virus has not been reported in poultry in Australia. The policy review has taken into account that there has been a report of one human case of JE acquired on the Australian mainland and serological evidence of infection in sentinel pigs on Cape York Peninsula.
Table 6 does not state the effect of pH or salting/heat inactivation and while the APVA agrees that it is unlikely to be present inside the egg contents it is not entirely clear that the organism may not be present on the egg shell.	Transmission of JE via egg has not been reported. The virus has not been reported to be present on or in egg shell or within the egg content of duck eggs. As such, there was no need to consider the effects of alkaline or heat treatment. Nonetheless, JE virus belongs to the genus *Flavivirus* that are stable at slight alkaline pH 8.0 but are readily inactivated at acidic pH and temperatures above 40 ºC. JE virus is an arbovirus, and is unlikely to become

	established from the import of preserved eggs.

West Nile virus	
Outbreaks of West Nile virus involving ducks have been reported from Israel and Romania. Arboviruses have been isolated from fertile eggs of quails. A full risk assessment would benefit the policy review rather than exclusion based on a summary table that is not entirely accurate.	West Nile virus has not been reported to be present on or in egg shell or within the egg content of duck eggs. As such, there was no need to consider the effects of alkaline or heat treatment. Nonetheless, West Nile virus belongs to the genus *Flavivirus* that are stable at slight alkaline pH 8.0 but are readily inactivated at acidic pH and temperatures above 40ºC. West Nile virus is an arbovirus, and is unlikely to become established from the import of preserved eggs.
Eastern equine encephalitis	
Eastern equine encephalitis (EEE) is not listed in this policy review. EEE was described in ducks as early as 1912 and sporadic outbreaks have been reported. The host range of EEE includes many mammals as well as at least 30 wild bird species as well as ducks, quails, chicken (note that EEE was also omitted from the chicken meat IRA), turkey, pheasants and guineafowl (Avian Dis 1960, vol 4 page 247). The isolation of the virus from fertile eggs of quails was reported and the possibility of transfer in duck fertile eggs was not investigated.	Chickens and quails are very susceptible to experimental infection but clinical disease due to natural infection has not been reported in chickens and quails. An outbreak of EEE has been reported in ducks (Dougherty and Price 1960). However, vertical transmission in ducks has not been reported. If transmission of flaviviruses were a possibility through ingestion of duck eggs, it would be likely to be reported in the literature as a risk for fresh duck eggs. The heating or alkaline treatment makes it less likely for the virus to survive in processed eggs than for fresh eggs. According to the OIE, EEE has never been reported in Taiwan.
There is also evidence that direct transmission through ingestion of infective material may play a role. The APVA is of the opinion that not enough weight is given to this route of infection in the assessment of the pathways of exposure.	Direct transmission of EEE has been reported to occur in pheasants as a result of feather picking and cannibalism (Holden 1955). However, there is no evidence of EEE virus being present either in or on duck eggs. If transmission of flaviviruses were possible through ingestion of duck eggs, it would be likely to be reported in the literature. The heating or alkaline treatment makes it less likely for the virus to survive in processed eggs than for fresh eggs.

Issue	Biosecurity Australia's response
General	
APVA questions the avian health status portrayed by the Taiwanese regarding *Salmonella* species as apparently found in survey of retail markets in 2003 and 2004. It is difficult to believe *Salmonella*, a ubiquitous organism found in the environment and with extremely high prevalence in commercial poultry flocks across the world, has not been detected in processed ducks in Taiwan? This is particularly of concern since the standards of the veterinary services in Taiwan are deemed satisfactory by the Australian authorities.	Taiwan conducted monitoring for *Salmonella* spp. in preserved duck eggs (salted/heated and alkalised), not processed ducks, from retail market in 2003 and 2004, with negative results. The relevant text in the policy review (page 12) has been amended to clearly state that the survey was conducted on the presence of *Salmonella* spp. in preserved duck eggs. Biosecurity Australia has considered the information provided by Taiwan in relation to *Salmonella* spp. in processed duck eggs in retail market, and is proposing that the heat treatment applied to the salted duck eggs address the quarantine concerns for *S*. Pullorum, *S*. Gallinarum, *S*. Enteritidis and *S*. Typhimurium. On the other hand, for the alkalised duck eggs, Biosecurity Australia is proposing that risk management is required for *S*. Enteritidis and *S*. Typhimurium.
The APVA does not support the rationale outlined on page 25 of the policy review that 'if the adverse effects of a pathogenic agent entering, establishing and spreading had already been determined by another related risk analysis (chicken meat IRA), and were evaluated to be very low or negligible, no further risk assessment was necessary. The statement presumes that the determination of the risk in the draft chicken meat IRA was accepted by all stakeholders. The APVA has not seen a final document on the chicken meat IRA and therefore believes it is not appropriate to use the outcomes of a draft document under review to provide final determination of the risk for a new risk assessment such as the policy review for the importation of preserved duck eggs from Taiwan.	The chicken meat IRA is well advanced and information in this report has been taken into account in this policy review.

Reference List

1. Dougherty, E Jr, and JI Price. 1960. Eastern encephalitis in White Pekin ducklings on Long Island. *Avian Diseases* 4: 247-58.

2. Holden, P. 1955. Transmision of Eastern Equine Encephalomyelitis in ring-necked pheasants. *Proceedings of the Society for Experimental Biology and Medicine* 88: 607-10.

3. Jones, R. C. 2003. Other reovirus infections. In *Diseases of poultry.* 11th ed. Editors Y. M. Saif, H. J. Barnes, J. R. Glisson, A. M. Fadly, L. R. McDougald, and D. E. Swayne, 293-98. Iowa, USA: Iowa State Press.

Taiwan's Bureau of Animal and Plant Health Inspection and Quarantine's submission

Issue	Biosecurity Australia's response
1. Request for amendments in Section 2.6.1:	
Paragraph 4, which states that 'The Taiwan Bureau of Health of Local Government (sic)….' should be amended to read: 'Provincial Municipalities and Counties – Public Health Bureau and Municipalities – Department of Health'	Amended in light of comment.
Paragraph 1 states that 'Taiwan does not import ducks or their genetic material' should be amended to read 'Taiwan imports of day-old ducks from Britain (in 2003 and 2006) and France (in 2005), amounted to 7,459 and 5,382, respectively'.	Amended in light of comment.
2. Comments on risk assessment for alkalised eggs:	
(1) Identical products should be treated equally (relates to Taiwan's concerns that Chinese alkalised eggs are sold in Australia).	This issue is outside the scope of the review. The Australian Quarantine and Inspection Service (AQIS) is responsible for ensuring imported products meet Australia's quarantine requirements, including alkalised eggs from China. Taiwan has regularly raised its concerns and AQIS has written to BAPHIQ on the matter.
(2) The trade volume for alkalised eggs from Taiwan is over-estimated	
In Section 3.2 (page 17), Australia has calculated the figure for imports of alkalised eggs from Taiwan to be equivalent to the current volume imported to Australia from China. This is based on the assumptions that: 1) The consumption of alkalised eggs in Australia will increase with the opening of the domestic market to alkalised eggs imports from Taiwan; and 2) Alkalised eggs from Taiwan will displace some of the alkalised eggs from China. Taiwan agrees with the above assumptions, however, alkalised eggs are not considered as a staple food that would be consumed daily, and the market is a specialized one (specialty food consumers mainly of Asian extraction). Therefore although the number of alkalised eggs sold and consumed in Australia will increase following the opening of the market to alkalized eggs from Taiwan, this will only be by a small amount.	Amended. The policy review (on page 17) may be unclear; it states that 'given the nature of the product, it is considered that there may be a small increase in the total market following the import of preserved eggs from Taiwan'. The relevant sections of the review have been amended to clarify the issue: 'The policy review estimated that the annual volume of trade in salted/heat-treated eggs and alkalised eggs from Taiwan to be approximately 380,000 and 120,000 eggs, respectively'. The amended text does not alter the assessments and conclusions in the review.
(**3) Risk ratings should be adjusted to "negligible" or "very low"**	
In section 3.2.2, Figure 3 shows the exposure pathways for imported alkalised eggs from Taiwan. Since alkalised eggs are only for human consumption, it would not cause a direct risk of harm to poultry. The probability of risk of harm through waste to domestic or wild poultry by humans is minimal. In addition, Australia prohibits the feeding of kitchen scraps to poultry, so the risk associated with the pathways in Figure 3 are extremely limited. Given the above, the overall impact of the outbreak should be amended from "low" to "negligible" or "very low".	Not accepted. While agreeing that preserved ducks eggs are manufactured and marketed for human consumption, wild birds and low biosecurity backyard poultry are at risk of direct exposure through scavenging waste at dumps and through the feeding of kitchen scraps, respectively. Taiwan's statement that Australia prohibits feeding of kitchen scraps to low biosecurity backyard poultry is incorrect. There are no controls on feeding of kitchen scraps to low biosecurity backyard poultry and any controls would be difficult to enforce. In these circumstances, there is no justification for changing the risk ratings.

Issue	Biosecurity Australia's response
(4) Section 4.3, "Insufficient information" to demonstrate certain disease agents are killed during the production process	
Alkalised eggs are a traditional Chinese delicacy, and eggs can be kept at normal room temperature for a number of years because of the special manufacturing and production process. For this reason they are known as "thousand-year eggs". Therefore, not just among the Chinese diaspora, but neither the U.S., Canada, Japan, Singapore nor other importers have requested any additional risk measures to allow importation of alkalised eggs from Taiwan, which should demonstrate that the pathogens of concern are destroyed effectively during the production process.	Not accepted. No scientific evidence has been provided to support the approach taken by the US, Canada, Japan and Singapore. The additional risk management measures imposed by Biosecurity Australia are to protect Australia's favourable animal health status. The policy review is based on the latest available scientific information. Where there was insufficient information on diseases, these were retained for further risk assessment. Taiwan has been encouraged to provide further relevant scientific information on the effectiveness of the alkalising process in inactivating diseases of animal quarantine concern, including that which may have been used by the countries listed above.
In Section 4.3 (page 33, Table 6), the grounds to retain alkalized eggs for risk assessment for OIE-listed disease agents was because there was "insufficient information" to prove that particular OIE-listed disease agents were destroyed. However, from an objective point of view, although there is "insufficient information" to prove that the production process could be effective in dealing with the pathogens of concern", on the other hand, it is impossible to deny that the production processes might be able to effectively deal with the pathogens of concern. What the Australian side is using in terms of number and variety of pathogens of concern in the laboratory situation would, of necessity, be different to the quantity of pathogens in the event of a contamination outbreak in a real life situation. The references in the draft policy review only consider pathogens of concern in a laboratory situation; therefore the references are insufficient to represent the facts of the matter in reality. Hence the conclusions drawn in Table 6 that further disease assessment is required for certain viruses in alkalised eggs should not be required, nor are they reasonable.	As above.
3 Suggested Amendments to the Draft Certification	
In section 8.1.2, the words read " *The Official Veterinarian of Taiwan must certify in English, that*:" **should be amended to read**: "*The official of Competent Authority of Taiwan must certify in English, that…*", as food processing factories in Taiwan fall under the provision of Taiwan's Department of Health, Executive Yuan, not Taiwan's Official Veterinarian agencies.	Where certification is required attesting to the animal health status of Taiwan, this will need to be provided by an official veterinarian. In relation to processing of a product, certification can be provided by the Competent Authority. The precise wording of health certificates can be negotiated as appropriate, following finalisation of the policy review.

Issue	Biosecurity Australia's response
In section 8.1.2.c states that: "*Officials of the Veterinary Authority of Taiwan supervised the operation of the plants at all times when salted and heat-treated preserved eggs were being processed for export to Australia"* **should be amended to read**: "*Officials of the Competent Authority of Taiwan supervised the operation of the plants which salted and heat-treated preserved eggs were processed for export to Australia*". The reasons being: (i) Alkalised eggs are soaked in saline solution for 30 days, therefore it is not reasonable to ask officials to supervise on the entire process. (ii) In section 5.1.2, the risk assessment on salted eggs was "very low". Taiwan will ensure that the eggs are not contaminated during the production process to achieve an acceptable level of protection (ALOP) for Australia. (iii) In section 8.1.2b, since both AQIS and Taiwan will need to approve the production establishments, the facilities and the production process should be at standard required by Australia and Taiwan. (iv) In Section 2.2.2 of Australia New Zealand Food Standards Code stipulates that egg products must be pasteurised or undergo an equivalent treatment so that the egg product meets the microbiological criteria specified in the Standard, but does not require that government officials supervise domestic egg production processes or facilities.	Amended in light of comment.
4. Other comments: "Responsibilities in case of an incident occurring after importation" should revert to Australia	
According to OIE's Aquatic Animal Health Code, one of the principles of the code is that the importing country should be responsible in the case of an incident occurring after importation of a product for human consumption. As the competent authority of the importing country is entitled to execute domestic quarantine measures and risk controls, it is reasonable that the responsibility in the case of an incident occurring after importation revert to the import country. Indeed, it would be contrary to the logic and principles of risk assessment to say that the exporting country should bear all the responsibilities in case of an incident occurring after importation, and it would be an impediment to the flow of international trade.	Biosecurity Australia could not find 'responsibilities in case of an incident occurring after importation' in the draft review report. However, should an outbreak of disease occur as a result of importation of preserved eggs under the proposed policy, responsibility for dealing with the outbreak will rest with Australian authorities. Nevertheless, it is appropriate for Australia to take the risk of a particular incident, such as the feeding of kitchen waste to backyard poultry, and its potential consequences including the costs to government and industry of any disease outbreak, into account during its risk assessment.

Issue	Biosecurity Australia's response
Australia prohibits the feeding of poultry kitchen scraps to poultry. In Section 3.2.2, illegal feeding to backyard or wild birds is identified as a pathway leading to the identified exposure groups coming into contact with each pathogenic agent of concern. Australia should increase public awareness and compliance. Further, according to international standards, pathogenic diseases caused by wild birds in the exporting country are not included as part of the importation risk assessment by the importing country. Each country should take appropriate actions to prevent the spread of pathogenic disease from domestic wild birds to poultry, but it is the responsibility of the importing country to implement effective measures, not the responsibility of the exporting country alone.	As above. Taiwan's statement Australia prohibits feeding of kitchen scraps to low biosecurity backyard poultry is incorrect. There are no controls on feeding kitchen scraps to low biosecurity backyard poultry and any controls would be difficult to enforce. The policy review's conclusion remains that low biosecurity backyard poultry are at risk of direct exposure to disease through feeding of kitchen scraps.
In conclusion, responsibilities in the case of an incident occurring after importation should revert to Australia. Taiwan would like to stress again that the risk estimation of the diseases mentioned in Chapter 6 should be adjusted from "low" to "negligible" or "very low".	On the basis of the arguments in the 2 responses above, Biosecurity Australia considers that there is no justification to change the risk estimation of disease agents in Chapter 6, they have been retained as 'low'.

Biosecurity Queensland's submission

Issue	Biosecurity Australia's response
The Policy Review comprehensively and thoroughly addresses the disease risks associated with the importation of preserved duck eggs from Taiwan.	Noted.
With regard to salt and heat treated eggs, it is considered essential that all the criteria on the import certificate are inspected and checked by Australian officials before importation is permitted. It must be confirmed that the production, processing and packaging of eggs is in accord with the expectations of the risk assessment.	Agreed. The Australian Quarantine and Inspection Service (AQIS) will have responsibility for these matters.