Import Risk Analysis: Cooked Duck Meat from Australia

Review of Submissions

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Biosecurity New Zealand
Ministry of Agriculture and Forestry
Wellington
New Zealand

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Approved for general release

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1 Executive Summary

The risk analysis examined the likelihood of infectious diseases being introduced by the importation of cooked duck meat from a particular farm under specified conditions. The cooking regime specified that the meat should be vacuum packed and cooked to a minimum temperature of 60°C for 30 minutes and 80 °C for 10 minutes. Organisms that are present in New Zealand, or are not present in Australia, or are heat sensitive to the conditions for cooking the meat were considered to not constitute a risk. Only one organism – infectious bursal disease (IBD) virus – was considered to be a hazard in the commodities. The risk analysis recommended measures to reduce the risk of IBD virus to a negligible level. It was proposed that importation of product should only be allowed from a designated farm that would be isolated from other poultry, would operate an all-in all-out system and would adhere to strictly controlled production methods. In addition, it was recommended that at the time of slaughter, a sample of birds should be tested to ensure freedom from IBD.

The risk analysis was released for public consultation in September 2006. Five submissions were received, with the most extensive comments coming from the Poultry Industry Association of New Zealand (PIANZ) and from an external consultant on avian diseases. Copies of all submissions are included in Appendix 1 of this document.

Some submissions indicate that there is some misunderstanding among stakeholders about the role of risk analysis in managing biosecurity risks in imported goods. A risk analysis examines the risks involved with a proposed imported commodity and if it is concluded that the risks posed by that commodity are unacceptable then measures are recommended to effectively manage them. The recommended measures are not the final conditions that must be followed by importers. Rather, following public consultation on the risk analysis, import health standards (IHSs) are developed and issued under section 22 of the Biosecurity Act 1993, again following a period of public consultation. The final IHS that contains the legal requirements for importation, and these reflect the recommendations of the risk analysis as well as additional relevant points that arise during consultation on both the risk analysis and any eventual IHS. Misunderstanding of the difference between a risk analysis and an IHS apparently led several submitters to suggest that the language of the risk analysis should be changed to reflect requirements rather than recommendations.

Several stakeholders expressed concern that the proposed exporter is not presently operating a management system that would ensure that their flocks are free from IBD. However, the risk analysis need not be concerned with what is presently happening on the proposed exporter's farms. Rather, the focus of the risk analysis is on an objective and science-based assessment of the risks posed by the commodity in the absence of any risk management measures, so that appropriate risk management measures may be recommended without limiting the consideration to current management practices.

Further concerns included how the farm would be audited, what procedures they would follow, who would do the auditing, and whether a system relying on such auditing could be trusted. The IHS will include further details regarding required operating procedures relating to farm management and production, including specific procedures that allow the system to be effectively audited.

There were also concerns about whether the test system for infectious bursal disease (IBD) has been sufficiently verified to provide confidence that it would be able to detect cases of

IBD in the source population of ducks. Stakeholder concerns about the validity of the test that will be used to test batches of ducks for export have been extensively addressed in this document. It is concluded that the test developed at the Australian Animal Health Laboratory will detect IBD infection if it occurs in a duck flock.

A question raised by several stakeholders was: "what constitutes a farm and whether product coming from more than one farm would be allowed to be exported?" In this document it is clarified that an export farm should be a single physical entity on which ducks are raised specifically for export of product to New Zealand. The ducks must be owned by the exporter who is also responsible for management of the farm. The farm must operate according to the specifications that will be laid down in the IHS. The present applicant has specified that they will operate only one export farm, but there is no reason why an exporter could not operate more than a single "export farm" provided these farms were fully audited and operating according to MAF's specified requirements.

Since the information in the risk analysis relating to heat sensitivity of potential hazardous organisms was limited, it has been supplemented in this review of submissions to address submitters' questions relating to heat sensitivity of specific organisms.

As a result of issues raised in submissions, it is recommended for the development of an IHS from this risk analysis, that the Bursa of Fabricius should be removed from all ducks to be processed into product for export to New Zealand, and that there should be specified procedures for keeping all finished product for New Zealand separate from product for other markets.

2 Introduction

Risk Analyses are conducted in accordance with MAF's policy on *Conducting Import Risk Analyses and Applying them in the Development of IHSs*, which can be found on the MAF website at http://www.biosecurity.govt.nz/pests-diseases/risk-policy.htm

Risk analyses are carried out by MAF / Biosecurity New Zealand under section 22 of the Biosecurity Act 1993, which lays out the requirements in regard to issuing Import Health Standards (IHSs) to effectively manage the risks associated with the importation of risk goods.

Draft risk analyses are written by the Risk Analysis Group and submitted to internal and external technical review before the final risk analysis document is released for public consultation. The Risk Analysis Group of MAF / Biosecurity New Zealand then reviews the submissions made by interested parties and produces a review of submissions document. The final risk analysis and the review of submissions together inform the development of any resulting IHS by the Biosecurity Standards Group of MAF / Biosecurity New Zealand for issuing under section 22 of the Biosecurity Act by the Director General of MAF on the recommendation of the relevant Chief Technical Officer (CTO).

Section 22(5) of the Biosecurity Act 1993 requires CTOs to have regard to the likelihood that organisms might be in the goods and the effects that these organisms are likely to have in New Zealand. Another requirement under section 22 is New Zealand's international obligations and of particular significance in this regard is the *Agreement on Sanitary & Phytosanitary Measures* (the "SPS Agreement") of the World Trade Organisation. MAF's Policy Statement on the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures is available on the MAF website: http://www.biosecurity.govt.nz/sps/resources/policies/raspspol.htm

A key obligation under the SPS agreement is that sanitary and phytosanitary measures must be based on scientific principles and maintained only while there is sufficient scientific evidence for their application. In practice, this means that unless MAF is using internationally agreed standards, all sanitary measures must be justified by a scientific analysis of the risks posed by the imported commodity. Therefore, risk analyses are by nature scientific documents, and they conform to an internationally recognised process that has been developed to ensure scientific objectivity and consistency.

MAF / Biosecurity New Zealand released the document *Import Risk Analysis: Cooked duck meat from Australia* for public consultation on 15 September 2006. Every step was taken to ensure transparency of the risk analysis to ensure that it provided a reasoned and logical discussion, supported by references to scientific literature. The draft risk analysis was peer reviewed internally and externally and then sent for interdepartmental consultation to the Ministry of Health, the Department of Conservation and the New Zealand Food Safety Authority. Relevant comments were incorporated at each stage of this review process. The closing date for public submissions on the risk analysis was 30 November 2006.

Five submissions were received. Table 1 lists the submitters and the organisations they represent.

This document is MAF / Biosecurity New Zealand's review of the submissions that were made by interested parties following the release of the final risk analysis for public consultation. Public consultation on risk analyses is primarily on matters of scientific fact that affect the assessment of risk or the likely efficacy of the recommended measures. For this reason, the review of submissions will answer issues of science surrounding likelihood[1], not possibility[2], of events occurring. Speculative comments and economic factors other than the effects directly related to a potential hazard are beyond the scope of the risk analysis and these will not be addressed in this review of submissions.

Table 1. Submitters and Organisations Represented

Date	Submitter	Organisation Represented/Location
15/11/06	Mark Schipp	Australian Quarantine and Inspection Service (AQIS)
27/10/06	Michael Brooks	Poultry Industry Association of New Zealand (PIANZ)
11/10/06	Neil Christensen	AVIVET, Poultry and bird disease consultant
4/10/06	Robert Sowman	Fish and Game , New Zealand
26/10/06	Don Matheson	Ministry of Health

[1] Likelihood**:** The quality or fact of being likely or probable; probability; an instance of this.
[2] Possible: Logically conceivable; that which, whether or not it actually exists, is not excluded from existence by being logically contradictory or against reason.

3 Review of Submissions: Duck Meat

3.1 AUSTRALIAN QUARANTINE AND INSPECTION SERVICE (AQIS)

The AQIS submission is included in Appendix 1. The discussion below summarises the main points raised and gives MAF's responses to them.

3.1.1 AQIS asked for a definition of a farm and in particular enquired whether a farm means the individual grow-out operation. AQIS believes that more than one farm could operate the same management system.

***MAF response*:** The initial draft of this risk analysis was written by a consultant on behalf of the proponent and Appendix 1 describes the management system proposed. Section 4.3.3 of the risk analysis contains the summarised recommendations. It is recommended that all batches of ducks for export to New Zealand comprise single batches from an all-in all-out system and be tested as described in Section 4.3.3.

A farm is considered to be a single unit that operates on a clearly demarcated single property that is physically separated from other properties. For the purposes of this risk analysis there are further recommendations about how the farm should operate to meet MAF's requirements. Since these requirements are quite demanding and would need to be audited by AQIS or their nominated auditors, the exporting company has opted to operate a single farm to these standards. This would be the only farm from which ducks will be sourced for the New Zealand market. The company would continue to operate a number of other farms that are not maintained or audited to the standard required by New Zealand. These farms will not be permitted to supply product for the New Zealand market but they could supply other markets such as the Australian internal market.

It is likely that the recommended requirements for the farm used to supply the New Zealand market as specified in Section 4.3.3 of the risk analysis be the basis for an IHS for the importation of duck meat. In line with normal QA system operation and auditing practices, the IHS will be the standard to which the farm must be operated. It will specify outcomes that must be achieved not procedures. The exporting company would have to produce a procedures manual that clearly defines procedures that would be operated to achieve the desired outcomes. A first step in the auditing procedure would be the auditing of the procedures manual to satisfy both the auditor and MAF that the operating procedures would result in the specified outcomes being achieved. Subsequent auditing would be done to ensure that the farm is being managed in conformity with the procedures manual.

It is likely that an IHS for duck meat from Australia would require that the farm management system be audited by AQIS, the slaughtering and processing operation be audited by PrimeSafe (Victorian Meat Authority), and the required testing be done by an AQIS approved laboratory. The final certification of product batches would be by an AQIS veterinarian who would be responsible for co-ordinating the operation; preferably this person should be the AQIS auditor. As long as the standards are maintained and regularly audited as required by MAF, there would be no reason for

MAF to object to a supplier operating multiple approved farms. Each case would be considered individually. At this point the exporting company has indicated that it would operate only one export farm.

Appendix 1 of the risk analysis describes the exporting company's present operation. Before exporting product to New Zealand they would have to nominate one of their farms to upgrade and maintain to MAF's requirements. MAF would not accept product unless the farm and farm management systems have been audited to the required standard.

3.1.2 AQIS considers that since the product is "designed for restaurant and elite hotel trade" the likelihood of the product being disposed of and becoming available to backyard poultry is negligible. It also considers that waste disposed in landfills would be sufficiently diluted by other waste to decrease the likelihood of exposure to susceptible birds.

MAF response: MAF would not have control over the use of the product once imported and given a biosecurity clearance. It cannot be assumed that it will be used only by restaurants and hotels or that waste could not become available to backyard poultry.

3.1.3 AQIS requests clarification of the requirements for auditing the farm management system.

MAF response: MAF requires only the audit of the farm that supplies product for export to New Zealand. The recommended requirements for auditing have been described in Section 3.1.1 of this document. The standard for the audit should be that the farm meets the requirements specified in the IHS which it is anticipated will mirror the recommendations of the risk analysis as specified in Section 4.3.3i. The audit of farm procedures should be done by AQIS since they are experts in farm management systems and the standard for the audit must be MAF's requirements not the requirements of an ISO system. In contrast, the auditing of the slaughtering and processing should be done to ensure that the operating systems meet the requirements of ISO 9000, AS 4465:2001 and AS 4709.2001 and that the producer is operating in conformance with their own specified manufacturing procedures.

3.1.4 AQIS notes that the Victorian Meat Authority has now been renamed as PrimeSafe.

MAF response: Noted.

3.1.5 AQIS requires some clarification of how false positive tests might be interpreted and dealt with.

MAF response: MAF would assume that any positive is a true positive unless a convincing case can be made to the contrary.

3.1.6 AQIS has requested information on what type of certification would be required for this product.

MAF response: The certification requirements will be specified exactly when the IHS for the product is written. However, the IHS will be based substantially on the risk analysis and the responses to the submission made on the risk analysis. Therefore it can be anticipated that the requirements will include certification that the farm management, processing plant and processing methods have been audited and are in compliance with the relevant standards and the required testing has been done with negative results.

3.2 POULTRY INDUSTRY ASSOCIATION OF NEW ZEALAND

The PIANZ submission is included in Appendix 1. The discussion below summarises the points of concern and gives MAF's responses to them.

3.2.1 PIANZ wish to know: Whether the the farm supplying the ducks will be owned by Luv-A-Duck or contracted to Luv-A-Duck?

Whether product to be exported will have been grown on the same farm from day old to slaughter?

Whether the export farm is a single farm or any farm that meets MAF's requirements? PIANZ stressed that the designated farm should be clearly designated and number of sheds number of birds etc clearly identified.

***MAF response*:** Final details of the requirements will be specified in the IHS. It is anticipated that they will be approximately as follows:

Whether the farm is owned by Luv-A-Duck or leased by them would not be of concern to MAF. However, MAF expects the company to be fully responsible for the management of the farm and to be the owner of the ducks on the farm. Management should not be sub-contracted to another operator.

The farm must operate an all-in all-out system. MAF will require that single batches of birds will be brought in as day olds or hatched on the farm. They will be slaughtered and processed as a single batch.

In this case Luv-A-Duck have specified that a single farm would be maintained to the standards required for export to New Zealand and only birds from this farm would be exported. Since the costs of audits and management are likely to be significant it is not envisaged that anyone wishing to export duck meat to New Zealand would wish to maintain multiple farms to the required standard. However, if Luv-A-Duck does in future wish to operate more than one export farm to the required standard it is likely that this would be acceptable to MAF.

The system will be audited by AQIS. As in any audited system the auditee will be expected to have a procedures manual that specifies full details of the management system. The manual will have procedures that are designed to ensure that every

requirement in the standard is met, and to have verifiable records that confirm that they are operating in compliance with those procedures. The procedures should include the keeping of records identifying the numbers of birds, sheds, mortalities and other relevant data. It is expected that MAF will have access to and approve the procedures manual. These are all normal requirements of a quality system.

3.2.2 PIANZ suggests that low pathogenicity avian influenza virus strains that occur in Australia have not been shown to be similar to those that occur in New Zealand, and may therefore represent a threat if introduced. Details of the PIANZ submission are given in full as Appendix 2.

MAF response: PIANZ has misinterpreted the meaning of "under regulatory control", which is synonymous with "under official control". Under official control is defined in the risk analysis as "under control by national or regional pest management strategies or by a small scale programme". Pest management strategies are defined in the Biosecurity Act. No avian diseases are presently under control in recognised pest management strategy programmes. The PIANZ assumption that the listing of diseases as unwanted or notifiable diseases as defined in the Biosecurity Act implies under official control is incorrect. Therefore all references in the PIANZ submission to diseases that are under official control are based on an incorrect assumption.

MAF acknowledges the typographical error in Table 1. MPAI should be LPAI (Low pathogenicity avian influenza).

There are an undetermined but very large number of different types of avian influenza virus. Given the propensity of influenza viruses to mutate and recombine the number changes continuously. As pointed out by PIANZ these viruses occur commonly in wild birds, particularly waterfowl. Most of these are of low pathogenicity and to restrict trade with Australia on the grounds that there may be LPAI strains in Australia that differ from the LPAI viruses that have been found in New Zealand is unacceptable under the international trade agreements and could justifiably be challenged by Australia.

In both New Zealand and Australia LPAI strains occur in wild birds and therefore both countries cannot claim to be free from avian influenza virus. New Zealand has never had an outbreak of avian influenza caused by HPAI virus. The last outbreak of avian influenza caused by a HPAI virus to occur in Australia was in 1997. Since Australia has not had an outbreak of avian influenza caused by HPAI virus for 9 years and therefore they are entitled to claim freedom from HPAI (but not LPAI) under the Article 2.7.12.3 of the OIE Code.

However, avian influenza viruses in general cannot be considered to be a hazard in cooked duck meat because they are heat sensitive and would be easily destroyed by the cooking process used for the preparation of the product. Numerous references are available indicating the heat sensitivity of the avian influenza virus e.g.

- Swayne DE, Halvorsen DA (2003) Influenza In Saif (ed) Diseases of Poultry, Ed 11. Pp135-60. Iowa State Press, Ames Iowa.
- MAF NZ (1999) Import risk analysis: chicken meat and chicken meat products: Bernard Mathews Foods Ltd turkey meat preparations from the United Kingdom, Ministry of Agriculture and Forestry, Wellington.
- Agriculture, Fisheries and Forestry – Australia (2000) The importation of non-viable eggs and products containing egg. Technical Issues paper

- OIE Technical Disease Cards: Highly pathogenic avian influenza (updated 2002) http://www.oie.int/eng/maladies/fiches/a_A150
- MacDiarmid recommended that cooked poultry meat products should be heated to 60°C or higher for 30 minutes to inactivate influenza virus (MacDiarmid SC (1991) The importation into New Zealand of meat and meat products: A review of the risks to animal Health. MAF Regulatory Authority).
- OIE also suggests that 60°C for 30 minutes will inactivate the virus.

Since the procedures for production of the product demand a core temperature in excess of 60 °C for 30 minutes and 80 °C for at least 10 minutes, it is clear that avian influenza virus will not be introduced with the product.

3.2.3 PIANZ suggests that the reference provided for classifying egg drop syndrome virus as occurring in New Zealand is not a suitable reference.

MAF response: Several other references are available to support the classification of EDS as being present in this country. For example, evidence for the presence of EDS in New Zealand has been summarized by Christensen in an article in which he describes the use of vaccine to control the disease in New Zealand (Christensen NH (1998). Trial of an inactivated vaccine against egg drop syndrome 76 in New Zealand. New Zealand Veterinary Journal 46, 237-8). In addition the poultry industry has itself reported the occurrence of antibodies to EDS in poultry e.g. in Surveillance (2000) 27(1), 26 and Surveillance (2002) 29(2), 27, and has reported clinical disease to MAF (Surveillance (2000) 27(1), 26.).

MAF believes that Egg Drop Syndrome is correctly classified as a disease that occurs in New Zealand.

3.2.4 PIANZ suggests that duck hepatitis B is under official control and should not be included in Table 1 as it has not been shown to be present in New Zealand and cannot be included in Table 2 because as it has been shown to be present in Australia.

MAF response: Duck hepatitis virus B is not under official control in New Zealand. Although it has not been described in New Zealand, it is not known to cause any disease in any bird species (Woolcock PR (2003) Duck hepatitis In Saif (ed) Diseases of Poultry, Ed 11. Pp 343-54. Iowa State Press, Ames, Iowa.), and is therefore not of concern.

3.2.5 PIANZ suggests that avirulent Newcastle disease should not be listed in Table 1 as an organism present in New Zealand, not under official control and for which there is no evidence of more pathogenic strains occurring in Australia. The details of the objections raised by PIANZ have been reproduced in full in Appendix 2.

MAF response: MAF believes Newcastle disease –avirulent is correctly placed in Table 1. Avian paramyxovirus type 1 in New Zealand and has been isolated. In addition antibodies to the virus are periodically reported by the poultry industry to

MAF e.g. Surveillance 27(1), 26. Clinical signs associated with the positive titres have not been reported. Similarly avirulent strains of the virus also occur in Australia. While PIANZ may be correct in asserting that the Australian strains of lentogenic Newcastle disease virus have not been proven to be the same as the New Zealand strains and that lentogenic strains may mutate to become virulent, this theoretical possibility is not relevant in the case of this commodity as it is clear that the cooking regime employed to process the product would inactivate all paramyxoviruses including all strains of Newcastle disease virus. OIE suggests that 60^{o}C for 30 minute is sufficient to inactivate virus (OIE (2002) http://www.oie.int/eng/maladies/fiches/a_A160.htm. This time/temperature treatment is below the temperatures that the product would be subjected to during processing before export to New Zealand. Therefore the likelihood of paramyxoviruses being present in cooked duck meat is negligible. This point is further discussed in section 3.2.7 of this document.

3.2.6 PIANZ suggests that the reference quoted as OIE (2003) World Animal Health in 2003, does not provide evidence that the strains of *Chlamydia psittaci*, *Mycoplasma gallisepticum*, *Mycobacterium avium* and *Pasteurella multocida* that occur in New Zealand have the same heat sensitivity or virulence as the strains present in Australia.

MAF response: There are no reports of higher virulence of these organisms in Australia, but moreover, as is discussed more fully in the next point, the scientific literature does not suggest that any of these organisms would survive the time/temperature treatments applied to this commodity.

3.2.7 PIANZ is concerned that MAF has not provided evidence of heat sensitivity for several organisms, in particular the following organisms included in Table 3 of the risk analysis as being sensitive to the heat treatments applied to these commodities: *Cryptosporidium bayleyi*, *Mycoplasma* spp., *Salmonella pullorum* and *Riemerella anatipestifer*.

MAF response: In order to minimise the size of the risk analysis it was decided to eliminate most organisms at the stage of the hazard identification stage of the risk analysis on the grounds that they already occur in New Zealand or do not occur in Australia. Organisms might equally have been eliminated as not being potential hazards since they are heat sensitive and would be destroyed by the cooking process, as the following account explains.

Experiments to determine heat sensitivity are subject to many variables, such as:

- What media was the organism suspended in when subjected to heating?
- Were large solid particles of organic material containing virus present in the medium subjected to heat treatment?
- Was the temperature quoted the temperature of the material being tested or the temperature of a waterbath in which a container of the test material was suspended?
- Did the time quoted include a lag time while the material was being heated but had not yet reached the quoted temperature?

The temperatures measured during manufacture of the duck meat products covered by this risk analysis are core temperatures measured in the meat, and the times quoted are the times after their core temperature has been reached. The temperature measurements are therefore entirely relevant and represent the strictest available method of measuring the temperature to which organisms would be exposed. The standards quoted by the manufacturer are a core temperature in excess of 60°C for 30 minutes and 80°C for at least 10 minutes. This temperature can be expected to inactive all but the most resistant spores and organisms, as can be seen from the data in Table 2.

Table 2. Heat sensitivity and other characteristics of organisms of interest.

Common name of disease	Disease agent	Heat sensitivity
Newcastle disease – virulent	Avian paramyxovirus 1	Y[1]
Newcastle disease – avirulent	Avian paramyxovirus 1	Y[1]
Avian influenza – HPAI	Avian influenza virus A	Y[1]
Avian influenza – LPAI	Avian influenza virus A	Y[1]
Infectious bursal disease (IBD)	Birnavirus	N[1,2]
Avian chlamydiosis	*Chlamydophila psittaci*	Y[1]
Avian mycoplasmosis	*Mycoplasma gallisepticum*	Y[3]
Avian tuberculosis	*Mycobacterium avium*	Y[4,5]
Fowl cholera	*Pasteurella multocida*	Y[6]
Duck virus enteritis	Anatid herpesvirus 1	Y[4]
Duck virus hepatitis type 1	Picornavirus	Y[4]
Duck septicaemia	*Riemerella anatipestifer*	Y[7]
Coliform septicaemia of ducks	*Escherischia coli*	Y[8]
Fowl typhoid	*Salmonella* Gallinarum	Y[9]
Pullorum disease	*Salmonella* Pullorum	Y[9]
Salmonellosis (paratyphoid)	*S. Typhimurium* and others	Y[10]
S. Enteritidis infection	*Salmonella* Enteritidis	Y[10]
Arizonosis	*Salmonella* Arizonae	Y[10]
Campylobacteriosis	*Campylobacter jejuni*	Y[11]
Paramyxoviruses infections	Avian paramyxoviruses 2-9	Y[1]
Bursal disease of ducks	Probably herpesvirus	?*[1]
Reovirus infection	Reoviruses	Y[12]
Ornithobacteriosis	*Ornithobacterium rhinotracheale*	Y♦
Pseudotuberculosis	*Yersinia pseudotuberculosis*	Y[13]
Rhinosporidiosis	*Rhinosporidium* spp	Y♠[14]
Intracellular yeast like infection	Intracellular yeast like organisms	Y♥
Aspergillosis	*Aspergillus fumigatus*	Y♥
Mucor pusillus infection	*Mucor pusillus*	Y♥
Erysipelas	*Erysipelothrix rhusiopathiae*	Y♥
Mannheimia haemolytica infection	*Mannheimia haemolytica*	Y♥
Pseudotuberculosis	*Yersinia pseudotuberculosis*	Y♥
Derszy's disease	Goose parvovirus	N[15]
Eastern equine encephalitis	Eastern equine encephalitis virus	Y[16]
Duck hepatitis B virus	Hepadnavirus	?†
Duck hepatitis type 2	Astrovirus	Y[17]
Duck hepatitis type 3	Picornavirus	Y[17]
Faecal Streptococcal infection	*Streptococcus faecium*	Y♥
Reticuloendotheliosis	Reticuloendotheliosis virus	Y[18]
Actinobacillosis	*Actinobacillus* spp	Y♥
Thrush	*Candida albicans*	Y♥
Fowl tick fever	*Borrelia anserine*	Y[19]
Intestinal spirochaetosis	*Angullina coli*	Y[19]
Cryptosporidiosis	*Cryptosporidium bayleyi*	Y[20]
Avian pneumovirus infection	Pneumovirus	Y[21]
Egg drop syndrome	Adenovirus subgroup III	Y[22]
External and internal parasites	Various	?♣

Notes to Table 2

* Unknown aetiology, rare trivial disease, possibly caused by a herpes virus, which is likely to be heat sensitive[1].

♦ *O. rhinotracheale* is closely related to *Pasteurella* spp. which are heat sensitive.

♠ *Rhinosporidia* is a member of the DRIP clade - so named as it contains *Dermocystidium*, Rosette-agent (*Sphaerothecum* sp.), *Ichthyophonus hoferi* and *Psorospermium* spp. This clade is more properly called the Class Mesomycetozoea, which contains two orders - Dermocystida (*Dermocystidium*, Rosette agent, *Rhinosporidium*) and Ichthyphonida (*Ichthyophonus* and *Psorospermium*). Whilst *Rhinosporidium* is more closely related to *Dermocystidium*, most work has been done on *Ichthyophonus hoferi*, the resting spores of which are very similar to those of *Rhinosporidium*. Nevertheless, both orders would be expected to behave similarly in regard to heat sensitivity. The likelihood of there being viable *Rhinosporidium* organisms after time temperature treatments as applied to this commodity would be negligible, given that *Ichthyophonus* is inactivated after 3 minutes at 40°C (Spanggaard & Huss, 1996).

♥ Non-spore forming bacterial organisms, which are likely to be inactivated at the cooking temperatures used in processing.

† Although Hepadnaviruses probably will not be completely inactivated by the time/temperature treatments applied in the production of this commodity, duck hepatitis B virus does not cause clinical disease in avian species, unlike the mammalian hepatitis B viruses[17].

♣ Internal and external parasites are complex multicellular organisms that would be unlikely to survive the time/temperature treatments applied to these commodities, but in any case they are not transmitted in meat.

1 MAF NZ (1999). Import risk analysis: chicken meat and chicken meat products; Bernard Mathews Foods Ltd turkey meat preparations form the United Kingdom, Ministry of Agriculture and Forestry, Wellington.

2 Quality-Control-Unit (1997). Study Report: heat inactivation of infectious bursal disease virus strain CS88. Study number CVLS/07/97, Central Veterinary Laboratory, Alderstone, UK.

3 Ley DH (2003). Mycoplasma gallisepticum infection. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 722-744. Iowa State Press, Ames, Iowa.

4 MacDiarmid SC (1991). The importation into New Zealand of meat and meat products: A review of the risks to animal health, Ministry of Agriculture and Forestry, Wellington

5 Sung N, Collins MT (1998). Thermal tolerance of *Mycobacterium paratuberculosis*. Applied and Environmental Microbiology, 64, 999-1005. (Closely related organism)

6 Glisson, JR, Hofacre CL, Christensen JP (2003). Fowl cholera. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 658-676. Iowa State Press, Ames, Iowa

7 Sandhu TS (2003). *Riemerella anatipestifer* infection. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 676-82. Iowa State Press, Ames, Iowa.

8 Barnes, JH, Vaillncourt J-P, Gross WB (2003). Colibacillosis In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 631-52. Iowa State Press, Ames, Iowa.

9 Shivaprasad, HL (2003). Pullorum disease and fowl typhoid. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 568-82. Iowa State Press, Ames, Iowa.

10 Gast RK (2003). Paratyphoid infections. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 583-613. Iowa State Press, Ames, Iowa.

11 Merchant IA, Packer RA (1967). *Bacteriology and Virology (7th Ed), pp268*. Iowa State Press, Iowa.

12 McNulty MS (2003). Rotavirus infections. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 308-317. Iowa State Press, Ames, Iowa (Data given for rotavirus which is closely related to reovirus).

13 Rimmler RB, Glisson JR (1997). Pseudotuberculosis. In: Calnek BW (ed). *Diseases of Poultry, Ed 10.* Pp.314-8 Iowa State University Press, Iowa.

14 Spanggaard & Huss (1996). Growth of the fish parasite *Ichthyophonus hoferi* under relevant food conditions, *International Journal of Food Science and Technology* 31, 427-432

15 Gough RE (2003). Goose parvovirus infection. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 367-374. Iowa State Press, Ames, Iowa.

16 Weaver SC et al (2000). Togaviridae in Van Regenmortel MHV et al (eds) Virus taxononmy. Classification and nomenclature of viruses. Pp. 879. Academic Press, San Diego, San Francisco, New York, Boston, London, Sydney, Tokyo.

17 Woolcock PR (2003). Duck hepatitis. In: Saif YM. *Diseases of Poultry, Ed 11*. Pp. 343-54. Iowa State Press, Ames, Iowa.

18 Hunter E, Casey J, Hahn B, Hayami M, Korber B, Kurth R, Neil J, Rethwilm A, Sonigo P, Stoye J (2000). Family Retroviridae. in Van Regenmortel MHV et al (eds) Virus taxononmy. Classification and nomenclature of viruses. Pp. 369. Academic Press, San Diego, San Francisco, New York, Boston, London, Sydney, Tokyo

19 Chia SP, Taylor TD (1978). Factors affecting the survival of *Treponema hyodysenteriae* in pig faeces. *Veterinary Record*, 103, 68-70. (information for closely related spirochaetes)

20 McDougald LR (2003). Cryptosporidiosis. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 991-96-991. Iowa State Press, Ames, Iowa.

21 Gough RE (2003). Avian pneumovirus. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 92-9. Iowa State Press, Ames, Iowa.

22 McFerran JB, Adair BM (2003). Egg drop Syndrome. In: Saif YM (ed). *Diseases of Poultry, Ed 11*. Pp. 227-237. Iowa State Press, Ames, Iowa

It can be seen from Table 1 that the only relevant heat-resistant organisms are goose parvovirus, which does not occur in Australia, and infectious bursal disease (IBD) virus, which is subjected to a full risk assessment in the risk analysis.

With regard to the organisms specifically mentioned by PIANZ:

Cryptosporidia bayleyi: The reference quoted in Table 2 indicates that the organism is inactivated at 65^{o}C. It does not specify that this only applies to cleaning of cages as suggested by PIANZ. A core temperature of 80^{o}C as specified in the production process of the duck meat is clearly well in excess what is required to inactivate the organism.

Mycoplasma spp.: *Mycoplasma* spp are organisms that do not have a cell wall and are therefore known to be particularly fragile to external environmental conditions. The reference quoted in Table 2 indicates that the organism is unstable even at 37^{o}C in PBS. It is clearly a highly heat sensitive organism.

Salmonella Pullorum: The reference quoted in Table 2 indicates that the sensitivity of *S Pullorum* and *S Gallinarum* are similar and *S Gallinarum* is inactivated at 60^{o}C for 10 minutes.

Riemerella anatipestifer: The reference quoted in Table 2 indicates that the organism does not survive after 12-16 hours at 55^{o}C. However, there is a great deal of difference between 55^{o}C and 80^{o}C. Dr Davies from VLA Weybridge was asked to comment and he considered it unlikely that the organism would remain viable after processing. In addition, this organism is closely related to the *Pasteurella* spp. and was until recently classified as a *Pasteurella.* It is reasonable to assume that its heat sensitivity is similar to other *Pasteurella* spp. On this basis it can be concluded that a core temperature of greater than 60^{o}C for 30 minutes and 80^{o}C for 10 minutes will inactivate the organism.

There is no reason to believe that duck meat is significantly different in this respect than other animal tissues. In large pieces of tissue which are poor conductors of heat, organisms can be protected from the rising temperature and therefore they may not reach the same temperature as the liquid part of the medium in which the experiment is being conducted. However, for these commodities the processing conditions specify the core temperature which is therefore the temperature that will actually be

encountered by any organisms in the meat. A temperature of 80°C is well in excess of the 60°C required to inactivate most non-sporulating organisms.

The suggestion by PIANZ that only data obtained from trials done in duck tissues is acceptable is considered to be unreasonable as there is very little experimental data carried out on these agents in duck meat but there is no reason to suspect that the agents in question would survive longer in duck meat than in other media and tissues.

3.2.8 PIANZ suggests that risk assessments should be done for anthrax and Japanese encephalitis.

MAF response:

Anthrax: The only reference quoted by PIANZ to indicate that anthrax is a disease of ducks is from the text book "Diseases of Poultry". The reference refers to a reference attributed to Snoeyenbos in the 5th edition of this book from 1965. The same reference (to Snoeyenbos) has been re-quoted in subsequent editions of "Diseases of poultry" by subsequent authors of the chapter, the latest being the 11th edition in 2003. No new references have been added in the intervening 41 years. The original source to which Snoeyenbos referred has not been located. MAF has searched two extensive electronic databases and found no reference to anthrax in ducks or poultry, only in ostriches. Anthrax is a rare disease in Australian ruminants and has not been described in Australian ducks or poultry. Poultry meat is not considered in the OIE chapter on anthrax, nor is it even considered for ruminant meat. The only OIE requirement for anthrax is that the property of origin is not under quarantine for anthrax and that it has not occurred on the property during the 3 weeks prior to export. The likelihood of importing duck meat infected with anthrax is regarded as negligible and therefore MAF has not conducted a further analysis on this disease.

Japanese encephalitis: Japanese encephalitis is exclusively an insect borne disease (*http://www.cdc.gov/ncidod/dvbid/jencephalitis/facts.htm*). Therefore, the likelihood that it will be transmitted in meat is negligible. In addition it has not been described as occurring in Southern Australia. It occurs very rarely in the far north, most probably due to wind-borne mosquitoes under specific weather conditions (*http://www.cdc.gov/ncidod/eid/vol7no5/ritchie.htm*). There is no justification for carrying out an additional risk analysis on this disease.

3.2.9 PIANZ suggests that there is not sufficient evidence to show that the source farm is free from IBD.

MAF response: MAF acknowledges that there is currently insufficient evidence to claim flock freedom of the entire source farm. However, small samples of birds have been tested with a test system that has been verified for use in chickens. Although this test system has not been validated in ducks it is probable that the system would work in ducks even if not to the same level of sensitivity as in chickens. In addition sera of 500 birds from Luv-A-Duck were used as negative controls in the validation of the serological test developed by the Australian Animal Health Laboratory (Appendix 3). These sera were clearly negative in comparison to the sera from infected birds.

Freedom from the infection in all parts of Luv-A-Duck's operation is not claimed although it appears that it is more likely to be free from the infection than infected. Freedom of all birds owned by Luv-A-Duck is not necessary to guarantee that product exported to New Zealand will be free from infection. Most importantly it is a requirement that the birds for export to New Zealand will be raised on a single farm using an all-in all-out system. The disease is not transmitted through the egg (Lukert PD, Saif YM (2003) Infectious bursal disease. In: Saif YM. *Diseases of Poultry, Ed 11*. Pp. 161-79. Iowa State Press, Ames, Iowa.).

The OIE Terrestrial Animal Health Code suggests that trade in hatching eggs is acceptable without making any recommendations for testing of the donor flock or the eggs for freedom from IBD. Since IBD is not transmitted by eggs, the birds that will be introduced onto the single farm as day-olds or hatched on the farm will be free from IBD infection.

3.2.10 PIANZ suggests that in paragraph 3 of Section 4.2.1 the words "disease by this organism" should be replaced by clinical disease by this organism.

MAF response: MAF has no objection to the change in wording and agrees that it could be used if it is relevant when writing the IHS.

3.2.11 PIANZ supports MAF's conclusion that the likelihood of exposure to susceptible species in New Zealand is considered to be non-negligible. However PIANZ suggests that more attention should be given to potential disposal of product which has passed its use-by date.

MAF response: The assessment that risk is non-negligible includes all methods of disposal and use of the product. MAF does not consider it wise to define some possible routes of infection, while possibly ignoring others. MAF will not be able to control the use, distribution and disposal of product once it has entered New Zealand. Instead the risk analysis is aimed at recommending methods that will prevent the importation of infected product. If only non-infected product is imported there is no possibility of exposure by any route.

3.2.12 PIANZ Believes that RA has minimized the consequences that the introduction of the virus could have on ostriches and native birds.

MAF response: MAF concedes that the effect that introduction of IBD virus may have on native birds is speculative. Despite attempts to infect a variety of different bird species including ducks, clinical disease has only been seen in chickens. Other species including ostriches may have antibody to the disease but clinical disease has not been described. Despite the fact that it seems unlikely that the virus would cause disease in ratites the risk analysis concluded that the possible consequences of introducing the virus are non-negligible. For this reason the rest of the risk analysis is focused on recommending methods that will ensure that the virus is not introduced. Successfully excluding the introduction of the virus will ensure that there is there is no possibility of infecting ostriches or native birds.

3.2.13 PIANZ suggests that in the risk management objective (Section 4.3.2.1) the word "must" should replace the words "need to".

MAF response: The correct usage of words has to be observed when writing risk analyses. Command words such as "must" and "shall" are not used because risk analyses only make recommendations and do not lay down instructions. Later when IHSs are written based on the risk analysis recommendations, imperative case words such as "must" and "shall" replace "could" , "should" , "need to" and similar wording that implies a recommendation.

3.2.14 PIANZ believes that the concept of compartmentalization should not be applied until it has been more widely agreed at international forums how the concept should be implemented.

MAF response: It is MAF's view that in this case the objection to the use of the word compartmentalization is one of word definition rather than fact. The compartment in this case is a single farm on which freedom from infection will be clearly demonstrated. IHSs used by MAF and all our trading partners contain many examples of cases where importation of animals or animal products is allowed from farms, herds or flocks that are "free from a particular disease', "accredited herds or flocks", "herds in which no cases of a particular disease have occurred during the last X years" etc. New Zealand has been operating these systems for many years and the introduction of a new word does not mean that we should cease trade in many different products while the concept of compartmentalisation is debated internationally. The concept of recognizing individual farms managed to a particular standard as disease–free or accredited is a well established principle that is clearly applicable to this case. Whether the term compartmentalisation will in future be applied to single farms is not of importance to this case.

3.2.15 PIANZ does not believe that "the potential benefits to New Zealand Inc. which may arise as a result of the importation of cooked duck meat outweigh the negative effects of an outbreak of any exotic disease".

***MAF response*:** MAF agrees that it is of primary importance that exotic diseases are not introduced. It is MAF's assessment that there is negligible risk of introducing IBD using the systems recommended in this risk analysis. PIANZ also suggest that according to article 1.3.5.3 the exporting country "should conduct an assessment of the resources needed to establish or maintain a compartment." Clearly this is not intended to apply to a single farm which will be certified by the proposed QA audits. If AQIS decides that they do not have the resources to carry out the audits (which will be paid for by the exporter) the conditions of the IHS will not be met and export will not proceed unless alternative auditors that are acceptable to MAF could be found.

3.2.16 PIANZ states that "in the absence of a "detailed biosecurity manual" it will be virtually impossible to implement, let alone audit, the increased levels of hygiene described below".

***MAF response*:** The risk analysis is not proposing a trivial system. When considering these matters it is necessary to keep in mind the basic principles of Quality Assurance (QA) auditing. The first step in a QA audit is for the auditee to a produce a procedures

manual which will describe in detail all the procedures used to operate the farm. The procedures must include the record keeping and checkpoints by which the auditor can ascertain that the procedures are being faithfully adhered to. The procedures manual is always written so that compliance with a particular standard can be demonstrated. In this case the standard will be the IHS. The standard specifies desired outcomes and the procedures manual specifies in detail how these outcomes will be achieved. If the manual is not acceptable to MAF and AQIS, subsequent auditing cannot proceed. The auditee must also have a nominated Quality Manager who conducts internal audits, maintains the manual in an up-to-date state and oversees the quality control measures and verifies that the procedures are being implemented. Only when this has been accomplished will audits be carried out by AQIS.

It is ultimately the prerogative of the Chief Technical Officer to decide whether the system of testing and management that is required to certify product for importation into New Zealand is adequate to ensure freedom from IBD. The suggestion by PIANZ that it should be similar to their system for maintaining New Zealand flocks free from IBD is untenable since the circumstances are not comparable. It is more appropriate to consider whether the proposed system is adequate for the particular case.

3.2.17 PIANZ believes that many of the recommended sanitary measures being suggested in the risk analysis do not appear to be currently operating on any farm operated by the exporting company. PIANZ is also concerned at the use of the word should and would as these words allow latitude to the exporter to ignore suggested systems. PIANZ also states that it is unclear whether or not a single farm will be designated the export farm.

MAF response: MAF acknowledges that the systems described are not presently in place on the exporter's farms. However, the risk analysis is not concerned with the present situation but with what must be put in place and verified as operating before exports can proceed.

The use of the word "should" has been explained previously in this review of submissions (see Section 3.2.13).

Exports will be from a single farm. In paragraph 3 of Section 4.3.2.2f it clearly states that "By defining a single farm as a compartment ……". Paragraph 4 of the same Section states that "It is only necessary to apply surveillance and monitoring to the designated farm". The final paragraph of the section states that "In this case, a compartment could be a single production unit designated as the export farm".

3.2.18 PIANZ is concerned that the suppliers may not be able to meet the condition of being located at least 5 km from other poultry farms. PIANZ has also requested clarification about how several other points relating to the management system will be met e.g how clean up will be carried out, how sheds will be bird proofed etc.

***MAF response*:** This is not for PIANZ or MAF to speculate about. It is recommended that it will be a specified requirement and if this condition is written into the IHS it will be up to the exporting company to demonstrate to the auditor that the condition has been met. Questions relating to the details of how the requirements recommended by MAF will be met will be available only when the exporting operation has written a

manual and it has been approved for use. PIANZ should primarily be concerned about whether recommended outcomes are suitable, not about how any particular exporting operation will implement them.

3.2.19 PIANZ queries the use of the word "should" in the section on slaughtering and processing. They doubt that certification of a plant as fit to produce product for human consumption will be adequate for preventing cross contamination of carcasses in the processing plant with IBD virus. They also wish to know what the consequences would be for Luv-A-Duck if cooking and production procedures are not in compliance with the documented procedures.

MAF response: The wording of risk analyses and IHSs has been discussed in Section 3.2.13 of this document.

MAF has confidence in the ability of the Victorian Meat Authority, now known as PrimeSafe, to manage the cleaning and disinfection of plants and to audit the production methods according to the methods defined by Luv-A-Duck in Appendix 2 of this risk analysis. MAF believes that cleaning and disinfection of a modern plant to levels required to meet human health standards will reduce the likelihood of contamination with IBD within the plant to a negligible level. It should be noted that birds slaughtered for export to New Zealand will be the first batch slaughtered in the plant after it has been comprehensively cleaned and disinfected at the end of a weeks operations.

MAF notes that in Section 4.3.3.ii of the risk analysis there is a typographical error and Appendix 3 should be Appendix 2 and that 600C should be 60^{o}C and that 800C should be 80^{o}C. These errors will be noted when writing the IHS.

The consequence for an exporting company of failing to meet any of the audit requirements is that they will not be allowed to export product to New Zealand.

MAF suggests that the following statement or an equivalent statement should be included in the IHS: Before export to New Zealand all product that has been certified as suitable for export must be clearly identified and stored separately from product that has not been certified as suitable for export to New Zealand. It should also specify that all processing equipment must be cleaned and sterilised before processing product destined for New Zealand. According to recognised auditing practices details of exact procedures will be given in the procedures manuals of the auditee.

It is not acceptable to refuse entry of a product on the grounds that it may not have been processed as the veterinary authorities of the exporting country have certified. There would have to be evidence not suspicion that the audits were not efficiently carried out before refusing to allow importation. If there was general distrust of the certifying authorities of exporting countries no product could ever enter New Zealand and conversely no country would accept our certification and no product would be exported from New Zealand. International trade in animals and animal products cannot operate unless the veterinary authorities of our trading partners are trusted.

3.2.20 PIANZ is concerned that testing procedures could be negative if birds have been infected in the last 10-14 days before export, and that the sample size that will be

tested is too small. They also wish to be assured that samples collected for PCR testing will not be pooled samples. PIANZ also wishes to know what measures will be taken on the export farm if an infected bird is identified on it.

MAF response: Provided the management procedures have been followed an all-in all-out system will be used. MAF believes that under this system the likelihood of introduction of infection during the last 10 days that the birds are on the farm is negligible. Introduction of new birds at any stage is prohibited and would result in an audit failure and prohibition of exporting to New Zealand. In addition PCR antigen testing will also be carried out and birds infected with IBD virus would be expected to be positive to these tests before they have developed antibody. The possibility that an animal may be in the incubation period of a disease immediately before shipment is a risk with any importation of live animals. The way in which this danger is generally mitigated is by keeping the animals in quarantine during the critical period. In this case keeping the ducks on an isolated farm on which no other birds are kept is equivalent to keeping them in quarantine for their entire lives. Therefore the duck meat will be derived from ducks which have been effectively quarantined throughout their lives.

The risk analysis recommends that the sample size will be calculated at the time of testing according to flock size in order to detect IBD with 99% confidence at a prevalence of at least 10% (for ELISA) or at least 20% (with PCR). MAF considers that these assumed prevalences are reasonable for IBD virus, which is a highly contagious disease and is consequentially normally present at high prevalences when present in poultry flocks. The 5% prevalence cited by the PIANZ is used in IHSs for specific situations, such as for myxoviruses in hatching eggs where the prevalence can be expected to be considerably lower due to the lower likelihood of vertical transmission of those viruses compared to the higher likelihood of horizontal transmission by the faecal-oral route in the case of IBD virus.

It is not intended that samples for PCR testing will be pooled.

If a farm is shown to have positive reactors to the test the birds will not be eligible for export. The exporting company will be responsible for cleaning and sterilisation and leaving the farm vacant for a suitable interval. A new batch of birds that is re-introduced will again be tested according to the specified procedures and if they are infected they will be prohibited from being exported.

3.2.21 PIANZ has made several comments on Appendix 3 of the risk analysis. They wish to know : why it is headed a preliminary enquiry; the meaning of several acronyms in the report; further information about the origin of the experimental ducks; variations in PI values; use of normalisation procedures; source of negative control ducks.

MAF response: The meaning of acronyms that were used, for which PIANZ requires an explanation, are as follows:

SPAFAS is the company that supplied specific pathogen free chickens to AAHL It is a subsidiary of Charles River Laboratories in the USA and the only Australian supplier of SPF eggs.

PI means percentage of inhibition.

ECACC is the acronym used by the European Collection of Cell Cultures from which the African Green Monkey cell line used in the investigation was obtained.

The principles of test validation have been enunciated in the OIE Manual for Diagnostic Tests and Vaccines, Chapter 1.1.3. Stage 5 of this process is the maintenance and enhancement of validation criteria. This is an ongoing process for any test. No test is therefore irrevocably validated and the validation process is always and ongoing. For this reason the title of the AAHL investigation –"Preliminary validation of a competitive ELISA ……." is an acceptable title.

Validation of a diagnostic test is an ill-defined process which is seldom formally completed for any test. Most tests are informally accepted as validated when they have been widely used and have gained acceptance as being reliable e.g. the complement fixation test for *Brucella abortus* was never formally validated but was used as the principle diagnostic test for the eradication of brucellosis from several countries including New Zealand. The OIE produces a list of prescribed and alternative tests for use in international trade. The listing of a test by OIE could be regarded as recognition by OIE that the tests are validated. For IBD no prescribed tests are listed but AGID and ELISA are listed as alternative tests. However, OIE also states that the virus neutralisation test is more sensitive then the AGID and that VN and AGID titres correlate well. Therefore ELISA, AGID and VN can be regarded as validated tests in chickens, but OIE makes no statement about their use in ducks. It is noted that the ELISA has been previously used to test duck sera for antibody to IBD (Zhou-Jin Ping, Sun-Yuan Yun, Liu-Pei Hong, Yang-Wen, Shen-Yue, Ju-Gong Na, Lu-Jun, Xue Xia. (2005) A serological survey of viral diseases of ducks in the Shanghai area. China Poultry 27(3), 9-11.)

The evaluation of the c-ELISA test developed by AAHL for the diagnosis of IBD included the following features specified by OIE.

Stage 1. Feasibility studies

Control samples. Positive and negative control sera from ducks were not available therefore AAHL developed positive sera by the experimental infection of ducks and used putatively negative sera as negative controls This is an acceptable procedure since insistence on the use of established positive and negative controls would mean that no new test could ever be developed and would be self defeating. Positive sera were samples obtained from 30 ducks that were exposed to birds that had been experimentally infected with IBD virus. The 30 ducks used in this phase of the investigation were derived from an elite great-grandparent and grandparent flock established 9 years ago and located in isolation from commercial breeders. There is an unavoidable circularity of argument regarding validation of a test and the identification of negative sera. It is illogical to suggest that if the test is not validated it cannot be used to show that sera are suitable controls and if we do not have negative control sera we cannot validate the test. A procedure in which one starts with ducks which are presumed to be uninfected and then infects the ducks with the virus and uses the sera of the birds from before and after exposure for test validation is acceptable. If the test is suitable for use the sera of the birds have low PI levels before exposure to virus and high PI levels after exposure. The meaning of such a result is fundamental

and obvious and clearly represents a useful step in validation. However, it is unlikely that any other source of duck sera could have been found which had been verified as free from IBD. The use of the sera was in MAF's view justified because the sera from 30 ducks were negative before the birds were challenged and positive after the birds had been challenged to both the c-ELISA developed by AAHL and two alternative tests (to versions of the VN test). The VN test has been used previously to detect antibody to IBD in ducks (Eddy RK. (1990) Antibody response to IBD virus serotypes 1 and 2 in ducks. Veterinary Record 127, 382.; Yamada S, Matsuo K, Urchinuno Y. (1982) Susceptibility of ducks and duck-origin cell culture to IBD virus. Avian Diseases 26(3) 596-601; Christopher KJ (1982) Veterinarski Arhiv 52, 189 (as reported by Eddy RK)). In addition the VN test is a suitable reference test, because the indicator system for the test is the growth, or inhibition of growth, of the virus. The test therefore indicates the fundamental ability of antibody in a serum to inhibit viral growth. Therefore the comparison of the results of the c-ELISA and the VN provides valuable evidence of the suitability of the c-ELISA for detecting antibody in ducks.

Tests on a further 515 sera from the Luv-A-Duck farm has been criticised. However, tests on these sera resulted in a normal distribution of PI values centred around a mean PI of approximately 20 (See Fig 2a of Appendix 3 of the risk analysis). The mean PI was at least 2 standard deviations below that of the approximately 30 positive sera test which indicates that the test is working well. Showing that a test is working as is required, for the use for which is intended, is validation.

Normalisation of results. Variations between PI levels ELISAs run in different batches of sera are not uncommon and as suggested by PIANZ can be compensated for by comparison with results obtained on control sera with those obtained with the sera under test. This is known as normalisation of results. MAF is confident that any laboratory approved by AQIS to undertake export testing, will have excellent understanding of the principles involved in the Quality Control of serological testing, including normalisation of results and can be relied upon to test to an exacting standard. AAHL will now have suitable control sera for the test.

Stage 2. Assay development and standardisation

AAHL carried out the following steps recommended by OIE:

- The selection and optimal reagent concentrations and protocol parameters were established.
- Estimates of repeatability were made.
- Analytical sensitivity and specificity were determined.

Stage 3 . Determining assay performance characteristics

Diagnostic specificity and sensitivity were established at various cut-off levels at various times after challenge. By 21 days diagnostic sensitivity was 100% and diagnostic specificity was above 99% at a cut off level of PI >or = 40. Cut-off points using mean plus 2 or 3 standard deviations of negative duck sera were estimated at 38.71 and 52. Although the data is based on relatively few positive sera MAF believes that it clearly indicated that the test readily distinguished between infected and non-infected populations of ducks, the purpose for which it will be used.

Standards of comparison for a new assay. The c-ELISA and the VN test gave comparable results.

Precision, repeatability, reproducibility and accuracy: Repeatability and reproducibility are measures of precision which in itself is a measure of dispersion of results. Repeatability of the test based on internal quality controls of 5 ELISA plates was determined (Table 3a of Appendix 3 of the risk analysis). Reproducibility studies have not been undertaken since only one lab was involved in the development of the test. If testing is to be undertaken by a laboratory other than AAHL, reproducibility testing between the two laboratories would be a normal Quality Control measure which MAF is confident that AQIS approved laboratories would undertake. The selection of cut-off points is discussed in the paper See Fig 4a, Table 4a and Table 4b of Appendix 3 in the risk analysis.

The use of the test for export purposes will require that the testing is done in the AAHL laboratory where it has been developed or in another laboratory approved by AQIS that has undertaken interlaboratory comparative testing studies with AAHL and has been shown to be competent in the use of the test. Since the test is not a test that is routinely available in laboratories, it will be the responsibility of Luv-A-Duck to ensure that an AQIS approved laboratory is available to undertake the required testing (this also applies to PCR testing). If testing cannot be carried out export of product would not be allowed. However, MAF could consider the use of an alternative test such as AGID, VN or even an ELISA that is commercially available for testing chickens. Suitable data would have to be provided to MAF if the use of an alternative test is to be considered. Since a bank of sera is now apparently available at AAHL verification of alternative tests would be a comparatively simple matter.

Stage 4: Monitoring validity and assay performance

Monitoring predictive values of positive and negative tests is not possible when the prevalence of the disease in a population is not known. Since this is unknown for ducks in Australia or indeed probably anywhere in the world, it is unreasonable to expect AAHL, Luv-A-Duck or any other user to provide this information. This information is never provided with respect to other diseases and it would be unreasonable to require that it should be provided in this case. In any case precision of a test is a function of diagnostic sensitivity and diagnostic specificity. Diagnostic sensitivity and specificity should be monitored continuously from available data but MAF does not consider that it would be justified to prevent the use of a clearly useful test on the basis that more data should be provided at this stage. The basis for the usefulness of the test should be whether it can be reasonably expected that it would be useful for the diagnosis of the state of infection of a flock of ducks.

MAF acknowledges that the use of 30 ducks as positive controls is a small number. However, in this case what was demonstrated was a 100% conversion to positive titres by ducks which were in contact with infected chickens. This indicates that the virus spread very rapidly amongst a population of ducks and that sero-conversion occurred. Therefore the prevalence of infected ducks kept in close contact with each other in a shed can be expected to be high. Sero-conversion can confidently be expected to be detected by the c-ELISA. Since ducks will only be held for a short growing period it can be predicted that if they have become infected at any stage, the antibody levels of the majority of ducks will not have declined to negative levels by the time they are slaughtered.

The sourcing of the negative reference population from the proposed exporter's farms would only have been of concern if the population tested was infected. In fact this testing produced clear evidence that they were not and the sera can therefore be seen as an appropriate population of ducks to represent the base level of negative sera from the farm in question. In fact the results of the tests on the 515 birds tested represents a base level of negative tests on the Luv-A Duck farm from which they were derived. The PIANZ statement that no attempt was made to verify the negative status of the animals concerned is at odds with the fact that the 500 sera were tested and found to be typical of a negative population. Since there are no duck flocks that are certified as free from IBD virus it would not have been possible to start with a population from a certified IBD-free source. Had the testing of the 515 sera indicated that infection was present it could not have been used as representing a negative population.

MAF believes that the test will efficiently measure the difference between an infected population and a negative population of ducks. It is reiterated that in this case the term compartment applies to only a single farm managed and audited to standards recommended by MAF and that MAF is recommending that every batch of birds for export will be tested by two test methods and processed to strict manufacturing standards.

The risk analysis has been reviewed by a large number of internal and two external reviewers including experts on risk analysis methods, poultry diseases and serological testing (see the listed contributors to this risk analysis). Questions raised by these reviewers have been incorporated in the risk analysis as appropriate. Since one of the reviewers has chosen to make additional submissions to the public review his submissions will be considered in this review of submissions. MAF does not believe that seeking further opinions in the risk analysis will serve any purpose except to delay the procedure.

3.2.22 PIANZ considers that formal comment should be obtained from the Ministry of Health and the New Zealand Food Safety Authority.

MAF response: Both the Ministry of Health and the NZFSA were consulted with during the development of the document and the input from MoH was included in the document. In particular MoH wanted the executive summary to contain a statement that there are no potential effects on human health and this has been included. The NZFSA did not raise any concerns about food safety. MoH has also commented in response to the submission for public consultation (See Section 3.5 and Appendix 5). They have not raised any concerns about food safety.

3.2.23 PIANZ believes that consideration should be given to the relative welfare standards in both the importing and exporting country prior to the importation of any animal product.

MAF response: MAF is not in a position to dictate codes of animal welfare practice to our trading partners. It would be impossible for MAF to enforce any codes of practice in foreign countries. However, in general MAF believes that the codes of practice operating in Australia are of an equivalent standard to those operating in New Zealand and that the issue is therefore not of concern.

3.2.24 PIANZ has reported a number of typographical errors in the text.

MAF response: Although none of these typographical or editing mistakes have a significant influence on the meaning or intent of the risk analysis, MAF acknowledges that:

- In Section 3.1, sentence 3 paragraph 1 "are not be…" should be "are not…"
- In Section 4.1.6 Sentence 2 of paragraph 1, Luckert should be Lukert.
- In Section 4.2.1, Sentence 5 paragraph 7 "expected coagulate" should be "expected to coagulate".
- In Section 4.3.3 paragraph 4, "800C" should read "80^{o}C".
- The use of "Anon" and "Anonymous" has not been consistent and that one convention would have been preferable. Similarly in appendix 3 of the risk analysis "cELISA" and "c-ELISA" has not been consistently used by the writers of the AAHL report. However, MAF did not alter anything in reports written by third parties that were included in Appendices to the risk analysis
- A reference is given in the list of references that is not given in the body of the text.

PIANZ states that table numbering is inconsistent and that Table 1 appears more than once. This is incorrect. Tables given in Appendices have the numbering systems and sequences used by the authors of the Appendices. MAF does not alter documents written by third parties when they include them in Appendices. Therefore page numbering in the body of the risk analysis and in Appendices are independent of each other.

3.2.25 PIANZ Conclusion. In the conclusion to their submission PIANZ stressed a number of matters. However, no new issues were raised and all have been addressed in the preceding sections of this review of submissions.

3.3 N. H. CHRISTENSEN (AVIVET)

The Avivet submission is included in Appendix 1. The discussion below summarises the points of concern and gives MAF's response to them.

Dr Christensen reviewed a previous draft of the risk analysis. Some of his suggestions resulted in alterations being made to the risk analysis. His submission on the final document asks for the justification for some of his earlier suggestions not being incorporated in the final risk analysis released for public consultation. The following response mainly addresses the issues that Dr Christensen considers to have been ignored. MAF supplied Dr Christensen's external review to PIANZ (at their request) with the result that submissions on several aspects made by Dr Christensen and PIANZ are similar or identical. Therefore, MAF's response to several of the issues raised by Dr Christensen is to refer to the responses made to PIANZ on the same issue.

3.3.1 Dr Christensen indicates that the diseases anthrax and Japanese encephalitis have not been addressed in the final version of the risk analysis, despite his suggestion that they should be included.

MAF response: The reasons why MAF has not included these diseases is given in the response to the PIANZ submission (Section 3.2.8).

3.3.2 Dr Christensen suggests that the MAF should take steps to prevent the importation of *Salmonella* serotypes that do not occur in New Zealand and suggests that the processing temperature specified for this product are marginal for inactivation of *Salmonella*.

MAF response: Reference to Mitscherlich E, Marth, EH, (1984) Microbial survival in the environment. Springer-Verlag, Berlin, Heidelberg, New York, Tokyo, Tables 58a - 63 indicates that a large number of different *Salmonella* serotypes are inactivated in minutes at temperatures from 58-65 ^{o}C. MAF is confident that heating to reach a core temperature of 60 for 30 minutes and 80 for 10 minutes will easily inactivate *Salmonella* spp.

3.3.3 Dr Christensen's opinion supports the view that both avian influenza virus and Newcastle disease virus would be inactivated by the temperatures specified for cooking. However, since a reference suggests that *Riemerella anatipestifer* may survive for 12-16 hours at 55 ^{o}C, he suggests that it may not be as heat sensitive as believed.

***MAF's response*:** MAF's response to this question is given in Section 3.2.13.

3.3.4 Dr Christensen suggests that the FlockCheck IBD –Gumboro Disease Antibody Test Kit that was used to test ducks is not validated for use in ducks.

***MAF's response*:** MAF acknowledges that the producers of the kit do not claim that it is verified for use in ducks. However, neither MAF nor the primary author of the risk analysis claim that the Luv-A-Duck flocks have been proved to be free from the disease. No test validated for use in ducks was available at the time. The use of the test only gives some evidence that the disease was probably not present in the samples tested. MAF has not suggested that this test could be used for certification for export to New Zealand.

3.3.5 Dr Christensen questions the use of the word *should* and suggests that it indicates "we'll do our best to comply".

MAF response: MAF's response concerning the use of the correct wording is given in Section 3.2.13 of this document.

3.3.6 Dr Christensen is concerned that requirements relating to the sourcing of ducks for export is something that is intended to be implemented at some future point rather than a system which is already operational. He lists the other conditions recommended for the management of the farm from which product will be exported that he believes are not presently in operation.

MAF response: Dr Christensen is correct in this assumption. The farm management systems proposed for the farm from which product will be exported are not presently

in operation. However, they will have to be in operation and fully audited before product can be exported to New Zealand. Exporting companies will have to produce a detailed procedures manual specifying how they will meet MAF's conditions. After the manual has been approved by MAF and the auditor the operation will be audited to show that all the systems are in operation. Failure to pass audits will result in AQIS being unable to certify that the product is suitable for export and therefore the product will not be exported to New Zealand. Descriptions of how Luv-A-Duck presently operates are irrelevant to what will happen before export of product to New Zealand is permitted.

3.3.7 Dr Christensen states that no effort has been made to correct the present deficiencies in the Luv-A-Duck operating systems. He then lists several aspects of their management system which are not in line with what is required in the risk analysis.

MAF response: Luv-A-Duck is presently operating to supply the Australian market, how they do this is not of importance to New Zealand. As explained above, before they will be allowed to export product to New Zealand they will have to meet the conditions specified in the appropriate IHS and be audited to verify that they are operating as required.

3.3.8 Dr Christensen wishes to know how audits will be carried out and suspects that documentation relating to the details of the system does not presently exist.

MAF response: Audits will be carried out in the standard manner in which audits are done by trained auditors. This implies that the procedures of the auditees will be inspected and found to be adequate to cover all the points of concern to MAF. Audits will involve physical inspection of facilities, interviews with staff, inspection of records, inspections of verification records of all operating equipment. Staff at all levels will be expected to be familiar with those parts of the standard and operating procedures for which they have responsibility. For each point in the manuals there will have to be a method of verifying that the auditees are operating in compliance with the standard and the procedures, there will have to be signed and dated records wherever these are required etc. The auditing will follow standard auditing practices. More detailed information on the principles of auditing to ISO standards can be found in the ISO standard ISO/IEC 17021:2006.

3.3.9 Dr Christensen is concerned about who will be responsible for collecting samples for testing.

MAF response: Responsibility for collecting samples and having them tested will be the responsibility of the AQIS veterinarian that signs the export certificate verifying that the conditions of export have been met. This does not imply that the veterinarian will himself collect the samples, he may do this or it may be done by someone to whom he has delegated the task. As with all export testing the samples will be properly identified and tested by a testing laboratory accredited by AQIS to carry out the testing.

3.3.10 Dr Christensen asks the same questions asked by PIANZ that relate to testing procedures, likelihood of missing recently infected birds using the testing proposed, sampling procedures etc.

MAF response: MAF's response to the questions regarding testing have been given in Sections 3.2.20.

3.3.11 Dr Christensen wishes to know whether bursa samples collected for PCR testing will be pooled and suggests that they should be collected from the same ducks as the blood samples.

MAF response: Samples for PCR testing will not be pooled. If collected from the same birds as the blood samples this will provide additional evidence should the question of false positive or false negative blood test arise. However, if collected from different birds it will increase the number of birds from which samples have been collected and thereby increase overall sensitivity.

3.3.12 Dr Christensen is concerned that site 8 will be used to house the birds at some stage before slaughter and that site 8 does not conform to the specifications recommended by the risk analysis.

MAF response: Site 8 is not a site that has been designated for use. Before Luv-A-Duck proceeds with exporting duck meat to New Zealand they will have to nominate a site and bring it up to the standards required by MAF and implement the management practices that are required. Only when this has been done and they have been audited and found to be in compliance will exports be allowed to proceed.

3.3.13 Dr Christensen suggests that the reference to the 11th edition of Diseases of Poultry should give the publisher as Iowa State Press not Iowa State University Press.

MAF response: MAF acknowledges this error. The publisher's name was altered in the 11th edition of the book.

3.3.14 Dr Christensen notes that there is a variation in the terminology used to describe the ELISA developed by AAHL it is variously described a C ELISA, C- invalidate the testing since birds will not have had time to seroconvert after being introduced onto the site.

MAF response: MAF's response to this question is given in Section 3.2.24 of this document.

3.3.15 Dr Christensen believes that the use of the word challenge in referring to days post exposure is incorrect and it should be post exposure.

MAF response: MAF believes that the use of the word challenge is acceptable. MAF does not believe that the use of challenge instead of exposure alters the meaning of the report. In any case it is not MAF's policy to edit or change the wording of a third party report that MAF uses as an Appendix.

3.3.16 Dr Christensen asks for definition of some Acronyms and abbreviations used in the AAHL report. .

MAF response: Abbreviations/acronyms for which the meanings are requested are:
Mab = monoclonal antibody
PI = percentage inhibition
PE = post exposure
ROC = "receiver operator characteristic" A ROC analysis curve is essentially a plot of diagnostic sensitivity and diagnostic specificity at various diagnostic cut-off points that allows the selection of the optimal cut-off point for a particular case. In Appendix 3 Fig 4a there is a ROC plot and selected data, from the data used to make the plot, is given in Table 4a.

3.3.17 Dr Christensen is concerned with a number of details concerning the manufacturing process. He lists a number of points that are of concern to him since he believes they are not presently in operation.

MAF response: The systems that are of concern may or may not be available or in operation at present. This is of no concern to MAF as long as Luv-A-Duck is only supplying the Australian domestic market. However, all systems will have to be in operation and fully audited before product is exported to New Zealand. It is not appropriate to specify procedural details in a risk analysis. Instead MAF specifies required outcomes that must be met in an IHS and the auditee must produce procedures and operate in compliance with those procedures to satisfy the auditors that the procedures are being followed and that the required outcomes have been achieved.

3.3.18 Dr Christensen is concerned that the risk analysis does not specify whether the Bursa of Fabricius should be removed from half-carcases that will be processed for export.

MAF response: MAF notes Dr Christensen's concern and recommends that in the writing of the IHS it should be specified that the bursa of Fabricius must be removed from all ducks before processing.

3.3.19 Dr Christensen is concerned that the numbering of tables in the body of the risk analysis and in the appendices is not consecutive.

*MAF response***: MAF's response is given in Section 3.2.24.**

3.3.20 Dr Christensen indicates that the AAHL report (Appendix 3) states that "chickens were euthanased on day 6 after infection" and that samples were collected from directly infected birds on days 3 and 4 post infection, and from all

birds on days 5, 6 and 7 post infection.". Dr Christensen asks whether all birds means ducks?

MAF response: In the experimental procedure AAHL infected three 3-week SPF chickens and three 3-week old ducks, and after 48 hours placed them in contact with 30 3-week old ducks and five 3-week old SPF chickens. The AAHL report states that directly infected birds were sampled on days 3 and 4 and chickens were euthanased on day 6 and that all birds were sampled on days 5, 6 and 7. This is somewhat difficult to interpret. MAF assumed that the three chickens and three ducks that acted as a source of infection for the 30 ducks and 5 SPF chickens are those referred to as directly infected. They were euthanased on day 6 and that the rest of the in contact birds (30 ducks and 5 SPF chickens) were sampled on days 5, 6 and 7. MAF did not seek further clarification from the authors on this point since it has no bearing on the subsequent results. The authors state that pooled cloacal swabs from all in contact ducks were each positive for the presence of IBD virus, confirming that viral replication occurred in the in contact birds. Sera from them were available at later stages and the results of tests done on them are given in the report.

3.3.21 Dr Christensen asks for clarification about which strain of IBD virus is prevalent in Luv-A-Duck birds.

MAF response: There is no evidence that any IBD strain has been or is present in Luv-A-Duck birds. Although MAF and the writer of the risk analysis do not claim that the Luv-A-Duck flocks could be certified as being free from infection without further investigation, the available evidence provides no evidence of infection. The steps recommended in the risk analysis are intended to ensure that product exported to New Zealand will not contain virus.

3.3.22 Dr Christensen takes issue with the use of the term natural infection used by the AAHL report writer since he regards it as "in contact infection with experimentally-infected chickens and ducks". He also wishes to know the significance of the difference between the two VN tests used.

MAF response: The method of infection of the ducks is clearly given in the report. MAF believes that the authors of the report regard contact with infected ducks as a more natural method of infecting the birds than ocular, nasal or oral instillation. MAF detects no attempt to mislead readers about what was done. Since both VN tests clearly demonstrated conversion from negative to positive in 100% of ducks MAF does not regard them as having given significantly different results, no statistical tests were done to test significance. The authors of the paper did not provide details of the test procedures but this is of little significance, the results are what matters. There are many commercial test used for certification and somehow the use of a commercially acceptable test seems to inspire confidence, however these tests seldom if ever give details of how the test reagents were prepared and other technical details they regard as commercially sensitive. AAHL has an equal right to not divulge the details of how their test was developed since it has no bearing on the fundamental results reported.

3.3.23 Dr Christensen wants to know the meaning of the numbers (0004-13-0050 and 0309-11-1501) in the section on virus titration in the risk analysis

***MAF response*:** MAF's interpretation is that these are simply strain numbers of the viruses used. The infectivity titres indicate that the cell lines used were susceptible to and supported growth of IBD virus. It is not stated in the report whether it was these strains that were used to produce antigen for the VN and c-ELISA tests. However, this is irrelevant as it is the test results that are important and AAHL is not under any obligation to describe how the antigen was produced.

3.3.24 Dr Christensen states that no tests were conducted to verify the negative status of the 515 putatively negative ducks.

MAF response: The statement ignores the fact that 515 sera were tested and gave results typical of a negative population. This is a good indication that the sera came from a negative population.

Since the mean was 10.93 and the standard deviation is 13.89 a PI of 20 is unsuitable for a cut-ff point as it is less than one standard deviation above the mean. It is not surprising that about 25% of negative sera fell above this range. Diagnostic sensitivity and sensitivity when two or three standard deviations above the mean are used as a cut-off point are very high. However the figure for sensitivity cannot be relied upon as the sample of positive animals is small but the specificity should be representative of the population of ducks on Luv-A-Duck farms since the data represents a large sample of ducks from Luv-A-Duck farms. Ideally the cut-off point may be varied according to the circumstances for which the test is being used and other information about the status of the flock etc. For a discussion of this point readers should refer to the Chapter on Validation of Diagnostic Assays for Infectious Diseases, in the "OIE Manual for Diagnostic Tests and vaccines". This article suggests that "rather than a single cut-off, two cut-offs can be selected that define a high DSe (e.g. inclusion of 99% of the values from infected animals), and a high DSp (e.g. 99% of the values of uninfected animals). The values that fall between these percentiles would then be classifies as suspicious or equivocal". Interpretation of the results of tests will be the responsibility of the testing laboratory but it is clear that since they are testing on behalf of the importing country they should use strict cut-of criteria that are biased toward having a high sensitivity rather than a high specificity. A cut-off of the mean plus two standard deviations would be suitable. However, since the test will be used for flock testing, not for individual animals, and the virus is one that spreads rapidly through a flock, the sensitivity of the test for this purpose will be very high. In practice, within reason, the cut-off level is likely to have only a small effect on the ability of the test to detect an infected flock.

MAF is confident that the test is suitable for the purpose for which it will be used.

3.3.25 Dr Christensen states that on the final page of the AAHL report (Appendix 3 page 41 of the risk analysis) it is suggested that the prevalence of IBD is likely to be very low (<1% or even 0.1%). However, Dr Christensen says when natural infection occurs prevalence is likely to be much higher than this and that predictive values should be calculated for a prevalence of 10 or 20%. He is also concerned that there is no reference for the data given in Table 6a.

MAF response: The predictive values of a test at various prevalence levels vary according to the diagnostic specificity and diagnostic sensitivity of the test being used. Predictive values of a positive test can be calculated as follows:

$$PV+ = (pr \times DSe)/ (pr \times DSe) + (1-pr)(1-DSp)$$

Where PV+ is the predictive value of a positive test, pr = prevalence, DSe = diagnostic sensitivity and DSp = diagnostic specificity.

PV+ values can be calculated for any given parameters. Some examples of PV+ values are given in the table below

Comparison of PV+ values at different levels of prevalence for tests with different D-SN and D-SP values.

Prevalence	DSn = 0.95 D-Sp = 0.99	DSn = 0.90 DSp = 0.95	DSn = 0.80 DSp = 0.80
	PV+	PV+	PV+
0.90	0.9988	0.9937	0.9863
0.80	0.9970	0.9860	0.9697
0.70	0.9955	0.9763	0.9492
0.60	0.9930	0.9636	0.9231
0.50	0.9896	0.9434	0.8889
0.40	0.9844	0.9216	0.8421
0.30	0.9760	0.8832	0.7742
0.20	0.9596	0.8152	0.6667
0.10	0.9135	0.6623	0.4706
0.05	0.8333	0.4815	0.2963
0.01	0.4897	0.1513	0.0748
0.001	0.0868	0.0174	0.0079

3.4 FISH AND GAME NEW ZEALAND

3.4.1 Robert Sowdon is concerned that if duck meat is allowed to be imported from Australia mallard from Australia could be sold in restaurants in New Zealand. If this happens there would be a temptation for restaurants to substitute the

imported meat with New Zealand wild mallard. Since the sale of wild mallard is prohibited in New Zealand this could result in an illegal trade of wild mallard.

MAF response: The risk analysis only deals with the importation of vacuum packed duck meat produced by a particular supplier and processed by cooking to demanding specifications. The recommendation is that ducks for export should be raised on an isolated farm in an all-in all-out management system and subjected to testing for IBD when slaughtered. Wild mallard will not be able to meet the specifications and will not be eligible for importing into New Zealand.

3.5 MINISTRY OF HEALTH

The only comment in this submission was that the Ministry of Health was pleased to see in the executive summary that there are no potential effects on humans or the environment.

4 APPENDIX 1: COPIES OF SUBMISSIONS

4.1 AQIS

Australian Government
Australian Quarantine and Inspection Service

Martin Van Ginkel
Biosecurity New Zealand
Ministry of Agriculture and Forestry
Wellington
New Zealand
Martin.van_Ginkel@maf.govt.nz

Dear Dr Van Ginkel

Comments on the Import Risk Analysis for Cooked Duck Meat

Thank you for advising Australia of the release of an import risk analysis for cooked duck meat from Australia, in September 2006, for public submissions.

The Government of Australia is pleased with New Zealand's intent to facilitate trade in cooked duck meat and supports the objective of laying down animal and public health rules for cooked duck meat to prevent this product from presenting a risk to the New Zealand's animal or public health, provided these measures:

- are based on sound risk assessments that address real risks;
- are not more trade restrictive than necessary to meet its objective/s;
- focus on outcomes rather than prescribing specific measures to achieve them; and
- allow for the recognition of alternative systems in achieving its objective/s.

Australia welcomes the opportunity to comment on the Biosecurity New Zealand Import Risk Analysis for Cooked Duck Meat from Australia and accordingly I offer the following comments:

Page 3, Heading 2.2 Source of Products
This paragraph refers to the "source farm" described in detail in Appendix 1, and goes on to state that "all products for export to New Zealand will be derived from a single farm", and "All batches of ducks for export to New Zealand will comprise single batches from an all-in, all-out system". I would be grateful for your clarification of these statements, as Appendix 1 describes the entire Luv-A-Duck operation, which consists of a number of sites, which are all owned by or grow out ducks under contract to Luv-A-Duck. At least one of the sites described in Appendix 1 clearly does not currently meet this requirement (see the final paragraph, Appendix 1 page 22). This site is not "all-in, all-out", and in addition is not fully bird-proofed (contrary to the foot note at the bottom of Table 1, Appendix 1 page 23).

I would be grateful if you could clarify the definition of "farm" to ensure there is no misunderstanding what is intended here. If the "farm" means the individual grow-out operation, which appears to be the intent, it should be clarified. Also, why is an individual grow-out operation restricted to only one farm? We believe that more than one farm could operate the same

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DEPARTMENT OF AGRICULTURE, FISHERIES AND FORESTRY

management system. If "farm" does apply to only individual grow-out sites, is the management of the hatcheries considered in the management system, or just the grow-out sites?

Page 11, Heading 4.2.2 Exposure Assessment
I have some concerns with the argument that home disposal is a "non-negligible" source of exposure to backyard poultry. The products being considered are "ready to cook", and "are designed for the restaurant and elite hotel trade". As the document states, this means that it will be "highly unlikely that any trimming would be carried out". It is also highly unlikely that this material would be consumed at home, so the overall likelihood of trimmings being discarded and becoming available to backyard poultry is negligible.

It is of course still likely that commercial wastes from restaurants and hotels will be discarded on commercial waste tips, but the wastes will be diluted with much larger quantities of domestically sourced NZ waste, and this must decrease the likelihood of exposure to susceptible NZ birds significantly.

Page 14, Heading 4.3.3 Recommended sanitary measures. Farm Management system
The proposed farm management system seems to reflect good biosecurity practice, and unlike previous versions does not refer to ISO 9000 or external auditing. The document states that "The farm management system should be audited at least once each export cycle by AQIS or an independent authority approved by AQIS." Subject to previous comments about the definition of the "farm" and therefore how widely the auditing process needs to be applied, this should be manageable.

Page 15, Heading 4.3.3 Recommended sanitary measures, ii) Slaughtering and processing.
This refers to quality assurance systems "based on" ISO 9000 and the relevant Australian standards, and audited by the Victorian Meat Authority. The Victorian Meat Authority is now known as PrimeSafe.

Page 15, Heading 4.3.3 Recommended sanitary measures, iii) Testing for IBDV.
The final paragraph in this section (page 16) states "Any positive test results would be interpreted as indicating that the compartment was not free from IBD, and this would make the product non-compliant with New Zealand's certification requirements."

It would be valuable to clarify, prior to commencement of trade, what procedures might be used in the event of false positive tests – backup/confirmatory tests etc. No test is perfect, and none have perfect sensitivity and specificity, so at some point a false positive test might be expected. A strategy for dealing with positive findings that does not automatically disqualify the trade completely should be at least discussed in advance, with only product from the affected compartment being prevented entry.

In addition, if a compartment is deemed to be non-compliant, I would appreciate clarification as to what measures would be required in order for the compartment to become compliant again.

Certification
I would appreciate your advice on what kind of certification, if any, would be required for this product.

Thank you for your assistance and cooperation in resolving these matters. I look forward to receiving your advice.

Yours sincerely

Mark Schipp
General Manager
Technical Standards Branch
Export and Animal Programs Division

15 November 2006

4.2 PIANZ

Poultry Industry Association of New Zealand (Inc)

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Martin van Ginkel
Pre-Clearance
Biosecurity New Zealand
P. O. Box 2526
Wellington

27 October 2006

Dear Martin

Import Risk Analysis: Cooked Duck Meat from Australia

The Poultry Industry Association of New Zealand (PIANZ), contactable at the above address, represents almost all of the poultry breeding and processing companies in New Zealand. Similarly, the Egg Producers Federation of New Zealand (EPF) represents all commercial egg producers in New Zealand. The PIANZ and EPF Veterinary Technical Committee has reviewed the Import Risk Analysis for the Importation of Cooked Duck Meat from Australia into New Zealand (subsequently referred to as the IRA). The New Zealand Poultry Industry (including PIANZ and the EPF) subsequently notes the following points in this regard.

1. Source of Products

The IRA states that all products for export to New Zealand will be derived from a single farm, with the source farm described in detail in Appendix 1. Having reviewed Appendix 1, the New Zealand Poultry Industry believes a number of fundamental questions have not been answered by the IRA and these are detailed below. The New Zealand Poultry Industry requests that Biosecurity New Zealand provide detailed answers to these questions and subsequently allow further comment on the IRA, if necessary, as the answers to these questions will impact on how the IRA is interpreted.

• Is the source farm owned by Luv-a-Duck or is the source farm contracted to Luv-a-Duck?

• Are the ducks grown on the same farm from day old till slaughter? If not, how long do the ducks remain on any of the farms / properties on which they are reared?

• It is unclear, as a result of the wording of the IRA, whether or not the designated "export farm" is a single farm or whether the IRA and subsequent Import Health Standard (IHS) would allow for the designation of any farm which meets the "criteria" laid out in section 4.3.3 as an "export farm".

However, it is fundamental to the transparency, as well as the underlying principals of the IRA and any subsequent IHS, that this is clearly laid out in the Introduction to the IRA. Should a single farm be designated as the "export

farm", the farm must be clearly identified, the number of birds and sheds on the farm must be detailed and the age at which birds are placed on the farm and subsequently sent for slaughter must be stated.

2. Hazard Identification
Organisms present in New Zealand, not under official control and for which there is no evidence of more pathogenic strains existing in Australia are detailed in Table 1 of the Hazard identification.

Table 1 includes Avian Influenza - MPAI. It is unclear from the table what MPAI refers to. Similarly, the New Zealand Poultry Industry is unaware of any definition of MPAI under the current definitions of avian influenza accepted by the OIE (2005). The New Zealand Poultry Industry therefore does not support the use of the term MPAI in the IRA.

The New Zealand Poultry Industry believes it is fundamental that the IRA separately consider highly pathogenic notifiable avian influenza (HPNAI), Low pathogenicity notifiable avian influenza (LPNAI) and low pathogenicity avian influenza (LPAI) as defined by the OIE (2005). Consideration must also be given to the current status of all types of avian influenza in New Zealand as defined under the Biosecurity New Zealand Technical Response Policies for Avian Influenza Viruses of Regulatory Concern (subsequently referred to as the Technical Response Policies) (Biosecurity New Zealand, 2006). Under these policies, any cases of either HPNAI or LPNAI identified in New Zealand require some level of investigation and / or response. It cannot therefore be argued that HPNAI viruses or LPNAI viruses are not under regulatory control in New Zealand. Similarly as the Technical Response policies apply to all viruses of regulatory concern to New Zealand, including LPAI strains that have not previously been identified in New Zealand, it cannot be argued that these viruses are not under regulatory control.

The New Zealand Poultry Industry does not believe that sufficient consideration has been given to all strains of avian influenza, in particular to those strains of avian influenza considered LPNAI by the OIE (2005) and under the current Technical Response Policies (Biosecurity New Zealand, 2006).

The New Zealand Poultry Industry does not believe that it is possible to consider any avian influenza viruses, other than LPAI viruses previously identified in New Zealand, as "not under official control", and subsequently include them in Table 2. This is supported by the fact that all H5 and H7 strains of avian influenza and all exotic strains of avian influenza are listed by Biosecurity New Zealand on the Unwanted Organisms Register (which can be found at http://mafuwsp6.maf.govt.nz/uor/searchframe.htm).

The Industry believes that the references listed in the IRA in support of the classification of Avian Influenza - MPAI are inadequate and irrelevant for the reasons listed below:

• Both references cited in the IRA provide some evidence in regards to the New Zealand situation. They do not provide any evidence that the strains of avian influenza virus present in Australia are the same as those present in New Zealand.

• The reference Stanislawek (1990) included in the IRA only reports the presence of two Type A Avian Influenza viruses, the subtypes of which were not identified in the article. The second report (Stanislwek, 1992) states that

these isolates were identified as single H4N6 isolate and a single H6N4 isolate. Both these isolates are considered LPAI. No further viruses were isolated in the later study.

Further detail must be provided on any LPNAI or LPAI viruses present in Australia, and these must be considered in conjunction with the current status of all strains of avian influenza virus in New Zealand. The New Zealand Poultry Industry believes that it is pertinent to note the following points and extracts from the PIANZ submission to MAF Biosecurity Authority in regards to the "Preliminary Hazard Identification Cooked Duck Meat from Australia" (hereafter referred to as the Preliminary Hazard Identification) on which MAF Biosecurity Authority sought comment in December of 2003.

• Stallknecht (1998, cited by Swayne and Halvorson, 2003) suggested that birds of the orders Anseriformes (ducks and geese) and Charadriiformes are the genetic reservoirs of all avian influenza viruses. However, infections of these birds with avian influenza viruses do not usually cause disease (Swayne and Halvorson, 2003). The New Zealand Poultry Industry firmly believes that there is inadequate evidence that Australian commercial duck flocks are not latently infected with avian influenza viruses which would be under regulatory control in New Zealand.

• There have been five outbreaks of highly pathogenic avian influenza in Australia between 1976 and 1997 (Westbury, 1997). Three of these occurred in Victoria, the state in which Luv-a-Duck is located.

• H5 and H7 subtypes have been isolated from ducks in Victoria (Westbury *et al.*, 1979; Selleck *et al.*, 1994) as well as wild birds including ducks in other areas of Australia (Mackenzie *et al.*, 1985; Mackenzie *et al.*, 1984; Downie *et al.*, 1977; Downie and Laver 1973; Downie *et al.*, 1973).

The New Zealand Poultry Industry is aware that Avian Influenza H4N8 has been isolated from ducks owned by Luv-a-Duck (Williamson, 2002a). H4N8 avian influenza viruses have not been reported in New Zealand (Geale, 2006).

Industry therefore requests that the IRA is amended to take account of the comments detailed above and that the relevant risk assessment is carried out for avian influenza viruses as defined by the OIE (2005).

Table 1 lists Egg Drop Syndrome as an organism present in New Zealand which is not under official control and for which there is no evidence of more pathogenic strains existing in Australia. While the New Zealand Poultry Industry does not dispute the conclusion, the reference cited in the IRA (Howell, 1992) is not suitable to demonstrate the disease organism is present in New Zealand for the following reasons:

• There are numerous more recent references in regards to the status of both the commercial poultry flocks and wild birds in New Zealand in regards to Egg Drop Syndrome.

• The reference states "No vaccine was introduced to control the disease and apart from a very occasional low titre reaction, believed to be non-specific, in serological tests, there is no evidence that the virus is now present in commercial poultry flocks". This would suggest that the virus is not present in

New Zealand and therefore is contradictory to the inclusion of the organism in Table 1.

Duck hepatitis B virus is listed in table 1 as an organism present in New Zealand, not under official control. The New Zealand Poultry Industry believes that this organism has been incorrectly classified and must be reclassified.

• The reference given in the IRA does not provide any evidence that Duck hepatitis B virus is present in New Zealand. It cannot therefore support the conclusion that either
a) Duck hepatitis B virus is present in New Zealand or
b) New Zealand strains (the existence of which has not been demonstrated) are no less pathogenic than those existing in Australia.

• Duck hepatitis B virus cannot be listed as "not under official control" as this organism is listed on the Biosecurity New Zealand Unwanted Organisms Register (http://mafuwsp6.maf.govt.nz/uor/searchframe.htm). The organism is categorised as a *Notifiable organism* with an *unwanted* status.

• There is evidence of the natural occurrence of this organism in Australia (Jilbert *et al.*, 1998; Freiman and Cossart, 1986), therefore the virus cannot be included in Table 2.

The New Zealand Poultry Industry requests that Biosecurity New Zealand review the classification of this organism in accordance with the Unwanted Organism Register and subsequently conduct a risk assessment to ensure that the hazard and associated risks are adequately addressed prior to the completion of any subsequent steps in the development of an Import Health Standard.

The New Zealand Poultry Industry notes with concern that "Newcastle disease - avirulent" is listed in Table 1 and does not support this classification for the reasons listed below:
• Having reviewed the paper by Howell (1992) the Poultry Industry does not believe that this single paper provides sufficient evidence to demonstrate that the strains of avirulent strains of Newcastle disease present in Australia are no more pathogenic than those present in New Zealand. It therefore does not support the inclusion of "Newcastle disease - avirulent" in Table 1.

• The New Zealand Poultry Industry is unaware of any molecular characterisation of the Australian strains which show that these strains are similar to those observed in New Zealand.
Pharo *et al.* (2000) reported that the 17 APVM-1 viruses isolated in New Zealand have been characterised using biological and molecular approaches. The highest ICPI identified was 0.16, whilst only two amino acid sequences were identified, both of which are typical for viruses of low virulence. In contrast, Animal Health Australia (2004) reported that Newcastle Disease "virus isolates need to be pathotyped to define their virulence".

• Biosecurity New Zealand will be aware of the submission made by PIANZ in regards to the Preliminary Hazard Identification. This submission stated "It has been hypothesized, based on molecular evidence that the virulent Newcastle

disease viruses causing outbreaks of clinical Newcastle disease in NSW have evolved from Australian precursor viruses (Westbury, 2002; Gould *et al*., 2001; Westbury 2001). The Victorian outbreak was caused by a Newcastle disease virus molecular type that had not previously been found in Victoria and was identical to the Newcastle disease virus causing disease in NSW (Wilks, 2002).
Similarly, Pharo (2001) stated "there is now good evidence that APMV-1 viruses may become virulent by mutation after introduction into chickens". It was further suggested that "this may be how some virulent viruses emerge, perhaps requiring as few as two point mutations (Alexander, 2001, cited by Pharo, 2001).

Therefore, it is essential that prior to the inclusion of "Newcastle disease – avirulent" in Table 1, detailed assessment of the viruses present in Australia is undertaken and a detailed risk assessment for these viruses developed.

• Beard and Hanson (1984, cited by Animal Health Australia, 2004) reported that ducks and geese can be reservoirs of virus and Newcastle disease outbreaks have occurred where a virulent virus, which did not cause clinical signs in infected geese and ducks, was transmitted to domestic poultry. Natural infections of ducks with apathogenic Newcastle disease viruses have been reported in Victoria (Peroulis-Kourtis *et al.*, 2002; Hodder *et al.*, 1994; Selleck *et al.*, 1994) and Western Australia (Alexander *et al.*, 1986; Mackenzie *et al.*, 1985). In addition, antibodies to Newcastle disease have been detected in wild ducks in Victoria (Hore *et al*., 1973).

• The New Zealand Poultry Industry acknowledges that Australia has an active stamping out policy for virulent Newcastle disease. However, the New Zealand Poultry Industry is also aware that Australia has in place a policy of mandatory vaccination for all chicken (but not duck) flocks in an ongoing effort to "reduce the risk of circulating precursor Newcastle disease viruses mutating into virulent forms resulting in clinical disease" (OIE, 2006a). Similarly, Animal Health Australia (2004) notes that "Australian-origin Newcastle disease can only be eradicated if the precursor lentogenic viruses are also eradicated and this is likely only if a long-term vaccination strategy is in place".

The New Zealand Poultry Industry strongly believes that IRA must address all strains of APVM-1 and not only those which fit the OIE (2004a) definition of Newcastle disease virus. Pharo (2001) stated that "regardless of pathogenicity any introduction of exotic virus would adversely impact on the small but expanding export trade in poultry products and genetic material". The Poultry Industry strongly supports this statement and believes it applies equally to the importation of hatching eggs and duck meat, and indeed to any poultry product to be imported into New Zealand. It should also be noted that there has been a 107% increase in the value of poultry exports between 2001 and 2005, which equates to an average annual increase of nearly 20 %. At the same time the annual tonnage of poultry produced in New Zealand has increased by almost 35 %. The negative consequences of any introduction of an exotic disease to the New Zealand industry would therefore be considerably increased compared to any estimate made in 2001.

Similarly, the statement "it is difficult to predict how APVM-1 virus would affect other

avian species in this country but aviary or native birds could be adversely affected" remains as valid today as it was when the Import risk analysis: avian paramyxovirus type 1 in hens' hatching eggs (Pharo, 2001) was completed.

The proposed IRA for Cooked Duck Meat from Australia must therefore consider all strains of Newcastle disease virus and subsequently conduct a suitable risk assessment for these viruses. In reviewing the list of references in support of the inclusion of organisms in Table 1, we have been unable to find suitable evidence in the reference "**OIE (2003)**. *World Animal Health In 2003*. OIE, Paris." cited in the IRA which supports the inclusion of Avian chlamydiosis, Avian mycoplasmosis, Avian tuberculosis or Fowl cholera in Table 1. Industry does not dispute that these diseases are not listed on the Biosecurity Unwanted Organisms register, or that they do occur in New Zealand. However, we do not believe that the reference cited provides sufficient evidence that there is no difference in virulence or heat stability between strains isolated in New Zealand and Australia.

As stated earlier, PIANZ has commented previously on the Preliminary Hazard Identification. In their earlier submission, PIANZ requested that the "hazard analysis to determine heat susceptibility" as stated under **sections 1.1.6** (Conclusions: Avian chlamydiosis), **2.1.6** (Conclusions: Avian mycoplasmosis) and **4.16** (Conclusions: Fowl Cholera) in the original Preliminary Hazard Identification was completed prior to Industry evaluating this portion of the Hazard identification. The New Zealand Poultry Industry is extremely concerned that no effort appears to have been made by the authors of the IRA to conduct a hazard analysis to determine heat susceptibility even though this was identified by in the Preliminary Hazard Identification as a risk. The Industry is even more concerned at what appears to be an attempt to demonstrate the absence of strain differences and thereby circumvent the necessity to conduct a hazard analysis to determine heat susceptibility. Whilst this action in itself is not unjustified, the New Zealand Poultry Industry is surprised that no effort has been made to provide adequate scientific justification which supports the inclusion of these organisms in Table 1. The lack of appropriate references in this and other instances in the IRA casts doubt on the validity of the conclusions drawn in the document as a whole.

Other references listed in Table 1 which we do not believe support the inclusion of the organism in this table are:

• Kunkle, 2003 in respect to Aspergillosis.
This reference does not specifically discuss either the New Zealand or Australian situation. Therefore it is not possible to conclude based on the evidence provided in the reference that there is "no evidence of more pathogenic strains existing in Australia".

• Howell, 1992 in respect to *M. haemolytica* infection.
In fact the reference is entitled "Viral diseases and the New Zealand Poultry Industry" whilst *M. haemolytica* is in fact a coccobacillus.

• Howell, 1992 in respect to Reovirus infection
This reference notes that reoviruses have been isolated from chickens on several occasions in New Zealand. However, it states "One of the latter isolates was used under experimental conditions to orally challenge day-old commercial broilers but produced no obvious pathogenic effects". The reference does not provide any information on the strains of virus present in Australia. The reference therefore cannot be used to support the conclusion that there is "no evidence of more pathogenic strains existing in Australia".

• Howell, 1992 in respect to Reticuloendotheliosis
Although the reference states that antibodies to this virus have been identified in New Zealand, the reference does not provide any information on the Australian situation, nor does it provide any details on the strains of reticuloendotheliosis viruses present in either New Zealand or Australia. The reference therefore cannot be used to support the conclusion that there is "no evidence of more pathogenic strains existing in Australia"

Organisms known to be exotic to Australia are listed in Table 2.

Although *Salmonella arizonae* is included in the list of organisms known to be exotic to Australia, Biosecurity Australia (2006a) reported that *S. arizonae* occurs in Australia although *S. arizonae* serovar 18:Z4, Z32 is considered to be exotic. A review of *Salmonella* isolates from poultry in New Zealand between 1997 and 2005 does not indicate the presence of this organism in New Zealand poultry (Poland, 2006; Poland, 2005; Poland, 2004; Poland, 2003; Poland, 2002; Anon, 2001; Anon, 2000; Anon, 1999; Anon, 1998). Similarly *S. arizonae* was not isolated from humans between October 2000 and August 2006 (ESR, 2006). The organism is listed by Biosecurity New Zealand on the Unwanted Organism register (http://mafuwsp6.maf.govt.nz/uor/searchframe.htm).

The New Zealand Poultry Industry therefore requests that the categorisation of this organism be reconsidered and the relevant risk assessment developed.

Table 3 lists those organisms inactivated at the time / temperature combinations used in the manufacture of the commodities.

The poultry industry notes that *Cryptosporidium bayleyi* is included in this list with the supportive reference listed as McDougald (2003). We do not believe that this reference provides sufficient evidence for the destruction of *C. bayleyi* at the time / temperature combinations used in the manufacture of these commodities. This is because

• the reference refers principally to the destruction of the organism whilst cleaning laboratory cages. It does not provide evidence for the destruction of the organism during cooking when the organism may be surrounded by potentially protective organic media such as carcass tissue.

• there is no primary reference or indeed evidence included in the text by McDougald (2003) to support the conclusion that the organism is killed at temperatures greater than 65 ^{o}C.

Mycoplasmosis caused by exotic *Mycoplasma* spp. (e.g. *Mycoplasma anatis*) is listed in Table 3. Having reviewed the reference "**Bradbury JM (2002).** Avian Mycoplasmas. In Jordan, F et al (eds). *Poultry Diseases*. *Ed 5*. pp178 - 93. WB Saunders, London." cited in the IRA, the New Zealand Poultry Industry does not believe that this article provides sufficient evidence that exotic *Mycoplasma* spp. are inactivated at the time / temperature combinations used in the manufacture of the commodities.

Pullorum disease requires further consideration in the IRA. Although the reference provided in the IRA ("**Shivaprasad HL (2003).** Pullorum disease and fowl typhoid. In: Saif YM (ed.). *Diseases*

of Poultry. Ed. 11. Pp 568-82. Iowa State University Press, Iowa") suggests that *S. pullorum* and *S. gallinarum* are less resistant to heat than paratyphoid salmonellae, the reference does not provide sufficient evidence that the *S. pullorum* is inactivated at the time temperature combinations stated in the IRA.

The risk analysis lists four organisms of potential concern in Table 4. Duck septicaemia (*Riemerella anatipestifer*) is included in this table, however it is not considered by the authors of the IRA to be a potential hazard. The New Zealand Poultry Industry does not support this conclusion.

• Although the IRA concludes that "it is considered unlikely that *R. anatipestifer* would remain viable after processing. The New Zealand Poultry Industry does not believe that there is sufficient evidence on which to base this conclusion. This is supported by an earlier sentence in the IRA which states "The thermal stability of *R. anatipestifer* has not been extensively researched".

• The IRA does not provide sufficient evidence in the text to support the conclusions drawn in the IRA. The study reported by Bangun *et al.* (1980, cited in the IRA) investigates the heat stability of the virus on agar plates, while that reported by Harry and Deb (1979, cited in the IRA) investigated the heat stability of the organism in a suspension. Neither of these studies investigated the heat stability of the organism in meat or duck tissue. Until such time as evidence to demonstrate that the organism is inactivated in poultry tissues subjected to the time / temperatures combination at which the product is processed, it cannot be concluded that duck septicaemia (*R. anatipestifer*) is not a potential hazard in the commodity.

The New Zealand Poultry Industry requests that Biosecurity New Zealand revise the classification of this organism and conduct a suitable risk assessment before any further steps in the development of any subsequent import health standard are considered. The New Zealand Poultry Industry believes that two additional organisms of potential concern, *Bacillus anthracis* and Japanese Encephalitis virus must also be included in this list and the appropriate risk assessment and / or mitigation steps subsequently laid out.

B. anthracis must be included as

• this organism has been known to affect ducks (Barnes, 2003)

• New Zealand livestock has been free of anthrax since 1954 (OIE, 2006b) whilst the disease is known to be and has been reported present in the zones of Australia on an annual basis (OIE, 2006c). Outbreaks between 1997 and 2005 have occurred principally in New South Wales and Victoria in what is referred to as the "anthrax belt".

• Meat meal, blood meal or bone meal intended for stock feed were identified by MacDiarmid (1991) as a vehicle for introducing anthrax into a population and hence it was recommended that the importation of meat, blood or bone meal for feeding to livestock was prohibited.

• There is no evidence in the IRA to demonstrate that the feed used in the

production of commercial ducks is free from meat and bone meal and produced in a mill that does not use meat and bone meal. This information must be provided in the IRA. Alternatively, if meat and bone meal is used in the duck feed or is used in the mill producing the duck feed, sufficient evidence that meat and bone meal used is sourced from areas free of *B. anthracis* or treated sufficiently to inactivate the organism must be provided in the IRA.

• The effect of the entry of this organism into the country would have a significant impact not only on the poultry industry but also on the wider pastoral agricultural industry.

Similarly, Japanese Encephalitis virus should be considered in the IRA as
• Tsai *et al*. (1999, cited by Woolcock, 2003) reported that 77.3 % of 611 ducks surveyed in Taiwan were positive for antibodies to Japanese Encephalitis virus.

• This disease has been reported in Australia (OIE, 2006d) but not in New Zealand (OIE, 2006d).

• The organism is listed on the Biosecurity New Zealand Unwanted Organism Register (http://mafuwsp6.maf.govt.nz/uor/searchframe.htm) as a *Notifiable organism* with an *unwanted* status.
Although the Generic Import Risk Analysis for Pig Meat released by Biosecurity Australia (2004) suggests that risk management would not be required for Japanese Encephalitis virus, this risk assessment applies to pig meat and cannot be directly applied to duck meat. A similar risk assessment should be provided for the transmission of Japanese Encephalitis in duck meat.

3. Infectious Bursal Disease: Hazard Identification

3.1 Source farm status

The New Zealand Poultry Industry does not support the inference in the IRA that the source farm status is negative for Infectious bursal disease (IBD) for those reasons detailed below.

• The commercially available test kit used to test for the presence of IBD antibodies on the source farm is not designed for use in ducks and to our knowledge, the test has not been validated for the detection of IBD antibodies in ducks. In order for any conclusions to be drawn in regards to the status of the source farm, more robust testing methods, validated for use in ducks, must be applied.

• The IRA states "A small sample (30 birds) has been tested on two occassions by the commercially available ELISA test for IBDV antibody (IDEXX test kit) with negative results (Williamson, 2002a). This suggests that ducks on the source farm have been tested for the presence of IBD antibodies on two occassions. However, the reference cited in the IRA "**Williamson, M., 2002a.** Laboratory report 02-005382-MW, Attwood, Victoria, Australia", only reports a single set of tests.

• In addition, the New Zealand Poultry Industry believes that the test method used was inappropriate to demonstrate freedom from IBD. Similarly, the

results of tests carried in 2002 do not provide any evidence of the current IBD status of the source farm. Nor does industry believe that this provides sufficient information of the status of the farm from the time the previous tests were completed till now.

• No details are provided on the age of the birds tested either in the laboratory report (Williamson, 2002b) or in the body of the IRA. It is therefore impossible to determine whether or not the birds were sufficiently old enough for any seroconversion to have occurred.

• The IRA does not specify whether or not the birds sampled were all housed in a single shed. Similarly it is unclear whether or not there is (or was) more than a single shed on the property. In addition, the total number of birds housed on the source farm at the time of the testing is not provided. It is therefore not possible for readers of the IRA to determine whether or not the sample size was sufficiently large enough to provide the required certainty that IBD virus was not present.

• It is clear from a review of the laboratory reports (Williamson, 2002a; Williamson, 2002b) that the primary objective of the serological testing of ducks for IBD was not to determine the IBD status of the farm but rather to provide additional information on a potential precursor for *R. anatipestifer* infection in the population under consideration. The results of this testing (using, in our opinion, inappropriate test methods) cannot therefore be used to support the conclusion that the source farm is free of IBD.

4. Infectious Bursal Disease: Risk Assessment

4.1 Release assessment

Paragraph 3 of **Section 4.2.1** (Release assessment) states "Infection of ducks with IBDV is not well studied, but disease by this organism has not been reported in ducks (Gilchrest, 2005)". The New Zealand Poultry Industry believes that this sentence must be reworded to read "Infection of ducks with IBDV is not well studied, but clinical disease by this organism has not been reported in ducks".

The New Zealand Poultry Industry strongly supports the conclusion of the release assessment that the likelihood that IBD virus is present in cooked duck meat imported from Australia is non-negligible.

4.2 Exposure assessment

The exposure assessment concludes that the "likelihood of exposure to susceptible species in New Zealand is considered to be non-negligible". The New Zealand Poultry Industry strongly supports this conclusion.

However, the New Zealand Poultry Industry does not believe that sufficient attention has been given to the potential disposal of product which is expired (or past it's use by date) or which is not consumed e.g. as leftovers which are subsequently disposed of.

Similarly, the IRA states in **section 4.2.2** (Exposure assessment) "the "ready to cook" nature of the commodities considered in this risk analysis make it highly unlikely that any trimming would be carried out". However, **section 6.2** (Appendix 2: Products to be imported) which lists the product details for each of the six products to be imported, states that four of these products contain bone, which is unlikely to be consumed and will be disposed of.

These potential pathways for the infection of susceptible bird populations in New Zealand must be considered in the IRA.

Although the duck meat which is to be imported into New Zealand is the primary product (or potential disease conveyor) of concern, other associated goods, such as the packaging in which the product is contained may also act as conveyors, particularly where the product is contained in a sauce or a jelly. These associated goods must also be considered in the IRA.

4.3 Consequence assessment

The IRA states "Since disease caused by IBDV only occurs in poultry, there would be no consequences to either humans or native animal species in New Zealand". Although the Industry agrees that there would be no consequences for human health, we strongly disagree with the statement that there would no consequences resulting from the introduction of IBD virus on native New Zealand fauna.

Woolcock *et al.* (personal communication cited by Lukert and Saif, 2003) reported the isolation of serotype 1 IBD virus from two 8-week old ostrich chicks that had lymphocyte depletion in the bursa of Fabricus, spleen and / or thymus. Although there appear to be few other reports of the isolation of IBD virus from ratite species, the impact of this virus on native New Zealand species such as the kiwi must not be overlooked in the IRA. Similarly, consideration should be given to other native New Zealand avian species, particularly those which are endangered.

5. Infectious Bursal Disease: Risk Management

5.1 Risk management objective

The IRA states "To effectively manage the risk of IBDV, sanitary measures need to ensure that the likelihood of this virus being introduced in the commodity is negligible". This sentence should be reworded to read "To effectively manage the risk of IBDV, sanitary measures must ensure that the likelihood of this virus being introduced in the commodity is negligible". The use of the phrase "need to" does not adequately reflect the significance of ensuring that New Zealand remains free of IBD.

5.2 Compartmental freedom

The New Zealand Poultry Industry recognises the recent inclusion of the concept of compartmentalisation as defined in the Terrestrial Animal Health Code (OIE, 2006e).

However, compartmentalisation remains a concept, the practicalities of the implementation of which have yet to be resolved. PIANZ are aware of an upcoming meeting of the QUADS scheduled for February 2006 the objective of which is "to articulate recommendations for QUAD countries on how approaches to compartmentalization and zoning can be effectively implemented". The Poultry Industry does not believe that the practical implementation of compartmentalisation, as proposed in the IRA, can even be considered until such time as consensus on the approaches has been reached at an industry, national and international level. Similarly, we are unaware of any case where the concept of compartmentalisation has, as yet, been successfully applied. The New Zealand Poultry Industry does not believe that the potential benefits to New Zealand Inc. which may arise as a result of the importation of cooked duck meat into New Zealand, are sufficient to outweigh the potential negative effects of an outbreak of any exotic disease. We therefore do not believe that there is sufficient reason for the, as yet untried, concept of compartmentalisation to be applied in this IRA.

In respect to prerequisite considerations in defining a zone or compartment, the OIE (2006e) states in Article 1.3.5.3, "The exporting country should conduct an assessment of the resources needed and available to establish and maintain a zone or compartment for international trade purposes. These include the human and financial resources and the technical capability of the Veterinary Services (and of the relevant industry, in the case of a compartment)". Similarly, Article 1.3.5.4 states "the requirements regarding a compartment should be established by the Veterinary Administration on the basis of relevant criteria such as biosecurity management and husbandry practices, and made public through official channels". The New Zealand Poultry Industry is unaware of either of these criteria having been met.

The OIE (2006e) further details the steps required for the establishment of a compartment in an exporting country under point 2 of Article 1.3.5.5. Point b. states
"The exporting country examines the "biosecurity management manual" produced by the enterprise / industry for such establishment(s) and confirms through an audit that
i) such establishment(s) is(are) epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its "biosecurity management manual"; and
ii) the surveillance and monitoring programme in place is appropriate to verify the free status of such establishment(s) with respect to such diseases(s)."
The New Zealand Poultry Industry is not aware of any "biosecurity management manual" produced by and relating to the exporting company, nor is it aware of any audit of such a manual conducted by the Veterinary Administration of the exporting country. The New Zealand Poultry Industry therefore does not believe that sufficient evidence has beenprovided to demonstrate that the establishment(s) for which compartmentalisation has been proposed are epidemiologically closed throughout routine operating procedures.

The recently released Draft Generic Import Risk Analysis Report for Chicken Meat (Biosecurity Australia, 2006b) states that "a rigorous assessment of any application for approval of compartmentalisation or flock accreditation schemes will be undertaken to ensure that biosecurity measures are implemented and maintained throughout the complete chain from farm to slaughter to export". The New Zealand Poultry Industry would support the comprehensive and detailed approach proposed by Biosecurity Australia in approving any application for compartmentalisation. In particular, the New Zealand Poultry Industry believes that it is essential that any biosecurity measures (and the auditing of these procedures) required for the establishment of a compartment are implemented across the whole production chain.

In addition to the factors detailed above, the New Zealand Poultry Industry is strongly

opposed to the implementation of compartmentalisation as described in the IRA on the basis of the points noted below:

• The IRA states "By defining a single farm as a compartment, and designing the compartmentalisation case accordingly, it is possible to achieve a negligible likelihood of entry of IBDV". It further states "Hygiene discipline is thus more likely to be observed and is more easily monitored. It is also only necessary to apply surveillance and monitoring to the designated farm".

The New Zealand Poultry Industry believes that in the absence of a detailed "biosecurity management manual" it will be virtually impossible to implement, let alone audit, the increase levels of hygiene described above.

In addition, the New Zealand Poultry Industry believes that it is practically impossible to implement the concept of compartmentalisation for a single farm particularly where that farm is inextricably linked to other farms owned by or contracted to the exporting company. This applies particularly at the processing plant level. The application of compartmentalisation to processing plants, in particular those processing animal products from compartments with different animal health statuses, has not been considered in detail by the OIE (2006e).

• The New Zealand Poultry Industry does not support the opinion stated under point f, **section 4.3.2.2** (Options, Compartmental freedom) that the option of compartmentalisation could "rely on the following components being applied for the cycle preceding the batch intended for export and each export batch of birds".

Biosecurity New Zealand will be aware that the New Zealand Poultry Industry currently has in place a Quality Plan for Country Freedom from IBD virus, which includes a surveillance programme, with extensive routine surveillance of farms throughout New Zealand for the presence of IBD virus. Under this programme, farms in New Zealand can only be accredited free of IBD following the completion of three consecutive negative tests within one year i.e. one every six months. The New Zealand Poultry Industry does not support the implementation of an accreditation regime which is less rigorous than that currently in place in New Zealand.

As IBD virus is present in Australia, the New Zealand Poultry Industry believes that at a minimum the three batches of ducks raised on the "export farm" must be reared under the same conditions as those prescribed for any export batches. Similarly, these three preceding batches must all be tested for IBD virus using an accepted and validated method before the "export farm" can be considered free of IBD.

• The concept of compartmentalisation has only recently been introduced by the OIE (2006e) and the New Zealand Poultry Industry is, to date, unaware of any successful implementation of this concept.

In contrast, the concept of zoning is and has been applied widely in the control

of exotic disease outbreaks, as a tool in the eradication of disease and to allow for trade in certain commodities from disease free zones. However, although the principles of zoning are consistent across different circumstances, the application of zoning with respect to time can vary depending on the reasons why zoning is being applied.

Thus, where zones are applied in the control of exotic disease outbreaks, as would be the case during a foot and mouth disease outbreak in New Zealand, zones can and will be lifted once the disease outbreak has been controlled and surveillance has demonstrated the zone to be free of the exotic disease under consideration. In contrast, where diseases are endemic to certain areas or populations within a country, for example foot and mouth disease in the South African Buffalo population, designated zones and associated surveillance and control measures must remain in place continuously and not only during periods where animal products are exported.

Therefore, the New Zealand Poultry Industry does not believe the concept of compartmentalisation, as defined by the OIE (2006e), would support the *ad hoc* use of compartmentalisation as a measure to ensure continued freedom from an endemic disease. The New Zealand Poultry Industry therefore believes that the proposals for the application of *ad hoc* compartmentalisation as and when exports to New Zealand are scheduled, as alluded to in the IRA, are neither appropriate nor justified.

5.3 Recommended sanitary measures

The IRA lays out a number of recommended sanitary measures which should be implemented either on farm or at the processing plant. However, the New Zealand Poultry Industry is extremely concerned that the measures laid out are not minimum required standards but appear to be suggested potential control measures many of which do not appear to be currently operating on either the source farm or any other farm owned by the exporting company.

Specific concerns are detailed below.

5.3.1 Farm management system

The IRA states “All ducks from which product for export to New Zealand is derived should be sourced from a single farm (specified in appendix 1), which should operate a management system based on:”. The New Zealand Poultry Industry is particularly concerned about the continued use of the word “should” in the IRA. We believe that this allows considerable latitude when implementing any form of compartmentalisation and the associated auditing procedures. We do not believe that this IRA lays out the necessary minimum practices essential to maintain the appropriate level of protection, required toensure that either IBD virus or any other exotic disease does not enter New Zealand.

As stated previously, it is unclear to the New Zealand Poultry Industry whether or not a single farm will be designated as the export farm. This must be clarified.

The IRA lists the following farm elements which should be included in the management system. New Zealand Poultry Industry comments are detailed below each point.

IRA Point: A farm located at least 5 km from other poultry farms.
Industry Comment: It is unclear to the New Zealand Poultry Industry how this could be maintained. To maintain a 5 km radius from a single unit would require at least an area of 7853 hectares around the property to be free of poultry. Unless this area is owned by the supplier, it is unclear how this requirement could be met.

IRA Point: Single age, all-in, all-out operation (including single pick-up).
Industry Comment: It is unclear whether an all-in, all-out operation refers to all-in, allout by shed or by farm.
As stated earlier it is unclear from the description of Luv-a-Duck provided in the IRA if a single farm will be designated as the export farm and if so which. However, the final paragraph of **section 6.1** (Appendix 1: Source of supply) states "Housing on this property is in open sided shed without bird proofing" and "sheds are separated from one another by a laneway about 10 m wide". If this farm is to be the designated export farm (or if the designated farm is similarly constructed) there is potential for mechanical transmission of IBD virus by wild birds between sheds and this is not accounted for in the IRA.

IRA Point: Locked and effectively bird-proofed sheds.
Industry Comment: Little detail is provided on how bird proofing of sheds may be achieved. However, the final paragraph of **section 6.1** (Appendix 1: Source of supply) states "Housing on this property is in open sided sheds without bird proofing". The IRA must state which property or properties are to be designated as the "export farm(s)" and provide detailed information on the facilities available on these sites.

IRA Point: Extensive hygiene clean-out between batches.
Industry Comment: It is unclear what is meant by "extensive". IBD virus is an extremely hardy virus and is difficult to eradicate. Further details of the minimum requirements at clean out and the subsequent stand down time must be provided.

IRA Point: Equipment dedicated to the export farm.
Industry Comment: In order to consider the application of compartmentalisation all equipment used in the compartment must be dedicated to that compartment. All catching equipment must be included in the list of equipment dedicated to the farm.
IRA Point: Log book for recording of people and equipment movements.
Industry Comment: The previous point suggests that all equipment is dedicated to the export farm. It is therefore unclear what equipment movements would occur other than inter-shed. Further clarification is sought on this point.

IRA Point: Records kept of production data, mortalities and relevant events.
Industry Comment: The New Zealand Poultry Industry would expect that these records were kept as standard practice for any operation intending to export

poultry and would expect that these records are kept as standard Good Agricultural Practice. The New Zealand Poultry Industry seeks further details on the records currently maintained on grower farms owned by or contracted to the exporting company.
It is unclear to the New Zealand Poultry Industry what would constitute a "relevant" event and what subsequent action if any would be taken should such an event occur.
The benefits of these records in the establishment of an IBD free compartment are unclear to the New Zealand Poultry Industry as IBD is usually asymptomatic in ducks.

IRA Point: Shower-in and change of clothes.
Industry Comment: Although the IRA suggests that this would be a requirement for compartmentalisation, there is no evidence in the IRA that any of the sites on which commercial meal ducks or fattening meat ducks (Table 1, Appendix 1, **section 6.1**) are equipped with facilities which would allow for staff or visitors to shower in and change their clothes. In fact, site 8 does not even appear to have dedicated staff.

IRA Point: Separate feed delivery (first of the week) by washed truck or delivery tube sited outside perimeter fence.
Industry Comment: The New Zealand poultry industry is particularly concerned about the potential for the introduction of IBD into any compartment as a result of feed delivery for the following reasons:

• Insufficient detail on the source of the commercial duck feed is provided in the IRA. As the feed mill is a separate commercial supplier (Table 1, Appendix 1, **section 6.1**), it is unlikely that Luv-a-Duck is the sole poultry producing customer. There is therefore considerable potential for the transmission of IBD virus in or on fomites.

• It is unclear from the IRA which method of feed delivery will be used i.e. either by washed truck or by delivery tube. The New Zealand Poultry Industry is concerned that as there is no specifically stated mechanism of feed delivery, either
a) it is intended that more than one farm will be designated the export farm or,
b) there are no facilities currently in place to allow for washing of truck or delivery by tube or
c) both of the above.

Further clarification on this issue is sought.

• The IRA suggests that the feed should be delivered by washed truck. Further detail must be provided on how the trucks will be washed and what verification will be undertaken. Similarly, as the feed mill is not owned by Luva-Duck, it is uncertain to what extent they will be able to

control the delivery of feed.
The IRA lists the following staff elements which should be included in management system. New Zealand Poultry Industry comments are detailed below each point.

IRA Point: Staff dedicated to export farm.
Industry Comment: The New Zealand Poultry Industry notes that this does not currently appear to be the case for site 8 (Table 1, Appendix 1, **section 6.1**).

IRA Point: A condition of employment is for staff to have no access to other poultry farms, backyard poultry or to pet birds.
Industry Comment: The New Zealand Poultry Industry fails to see how the exporter could control the access of staff to other backyard poultry or pet birds, which may belong to neighbours, family, friends or acquaintances of the staff.

IRA Point: Educational program for staff.
Industry Comment: What will be taught in this program?

5.3.2 Slaughtering and processing

The IRA states "Slaughter of birds should be done at the plant that is operated by the supplier of the birds". This sentence should be reworded "Slaughter of birds must be done at the plant operated by Luv-a-Duck". Similarly, the statement "The Victorian Meat Authority should be responsible for supervision of the plant and for auditing these procedures" must be reworded "The Victorian Meat Authority must be responsible for supervision of the plant and for auditing these procedures.". The IRA does not detail what the consequences would be should the processing plant not meet the requirements. This must be detailed in the IRA.

While the New Zealand Poultry Industry acknowledges the benefits of ISO 9000, and the Australian Standards in the production of food fit for human consumption, the New Zealand Poultry Industry does not believe that these processing standards take into account the necessary steps and procedures required to prevent cross contamination of carcasses in the processing plant with IBD virus.

The IRA states that "the Victorian Meat Authority should also be responsible for auditing the manufacturers cooking and production procedures. However, no details are provided on what the consequences for Luv-a-Duck would be if the cooking and production procedures do not meet the necessary specifications.

The New Zealand Poultry Industry acknowledges that this would have no material impact on the risk of the introduction of IBD virus into New Zealand, as the IRA proposes that this be managed through the implementation of compartmentalisation. However, there are at least six diseases listed in Table 3 (**section 3.1** Organisms of potential concern) which may be introduced into New Zealand should the minimum time and temperature combinations stated for the manufacture of the product not be met. It is therefore fundamental to the validity of the IRA that the implementation and auditing of the manufacturers procedures be given significant attention in the IRA and any subsequent IHS.

Similarly, as IBD virus is not destroyed during the cooking process, export batches must be cooked separately from non-export batched. In addition, sufficient cleaning or heating of facilities and utensils to destroy the IBD virus will be required prior to further processing of any export batch. Auditing of these procedures by the Victorian Meat Authority will be required to ensure compliance.

The IRA provides insufficient detail on how the manufacturing process would be audited. This is of particular concern as both Diagram 1 and Diagram 2 (**section 6.2**, Appendix 2: Products to be imported) suggest that the processing of all products takes place over a number of days.

Similarly, although the IRA suggests that the "birds for export to New Zealand should be the first batch of birds slaughtered at the plant after approved end of the week cleaning, disinfection and drying", the IRA does not detail any measures to prevent crosscontamination following slaughter. For example, if further processing does not take place on the same day, export consignments must be clearly identified and separated from non-export consignments. The IRA must detail how this will be achieved.

5.3.3 Testing for IBDV

The New Zealand Poultry Industry is particularly concerned about the validity of the proposed testing regime for the reasons detailed below.

• Collection of serological and bursal samples at slaughter is proposed in the IRA. However, the New Zealand Poultry Industry notes that
a) serological testing could return a negative result if the birds have been infected in the last 10 - 14 days
b) if the birds are transferred between farms at five weeks of age (as is suggested in Table 1, Appendix 1, **section 6.1**) birds are unlikely to seroconvert and therefore serological testing is invalid.

• The IRA states "A randomly collected sample of birds should be tested with negative results, by the AAHL ELISA (Appendix 3). Comments on Appendix 3 are provided later in this submission (see point 6)

• The IRA further states that "The sample size should be sufficient to detect a prevalence of 10 % of birds with IBD titres, with a confidence of 99 %. The New Zealand Poultry Industry notes that the Import Health Standards for chicken hatching eggs from various countries (Birpheic.aus, 2005; Birpheic.gbr, 2005; Birpheic.usc, 2005) and turkey hatching eggs from various countries (Birtheic.spe, 2005; Birtheic.uk, 2005) require testing of both source flocks and chicks hatched from imported eggs at a level sufficient to detect a prevalence of 5 % with at least 99 % confidence.

Whilst the New Zealand Poultry Industry acknowledges that this level of testing is required for APVM-1 virus and all avian influenza viruses, the New Zealand Poultry Industry does not support the implementation of a less stringent testing regime for an exotic disease which could have as great, if not greater, impact on the New Zealand Poultry Industry and our native (and in some cases endangered) fauna. The sample size must be sufficient to detect a prevalence of 5 % with at least a 99 % confidence.

• Bullet point 2, part iii (Testing for IBDV), **section 4.3.3** (Recommended sanitary measures) states "A randomly sample of bursa from the birds should be collected and tested for the presence of IBD RNA by a PCR test that has been approved by AAHL, with negative results". This sentence should read "A random sample of bursa ….".
• Bullet point 2 further states "The sample should be of sufficient size to detect a prevalence of 20 % with 99 % confidence". As stated previously the New Zealand Poultry Industry does not support the implementation of a testing regime which does not enable the detection of the agent under consideration at a prevalence of 5 % with a 99 % confidence.

• The IRA does not detail whether the PCR samples collected under bullet point 2 will be pooled or not. If pooling is not intended, this must be stated in the IRA. However, if the intention is to pool samples, the IRA must detail what pooling will occur and must further discuss the effect of this pooling on the number of samples required to provide the same level of detection and confidence.

• The final paragraph of the IRA states "Any positive test result would be interpreted as indicating that the compartment was not free from IBD, and this would make the product non-compliant with New Zealand's certification requirements.".

The IRA suggests that product for export could be frozen pending the receipt of test results (**section 4.3.2.2**, point f). The New Zealand Poultry Industry therefore believes it is essential that the IRA state specific steps which must be taken to ensure that any frozen product pending export is not exported and is identified as "Not fit for Export to New Zealand".

Similarly, the IRA must clearly state what steps will be taken on farm following even a single positive result in a batch of birds. This is of particular concern to the Industry as it would suggest that it is impossible to effectively compartmentalise any part of the Luv-a-Duck operation.

6. Appendix 3

The New Zealand Poultry Industry notes that the report included in Appendix 3 is entitled "Preliminary validation of a competitive ELISA, and two Serum Neutralisation Tests (1 and 2) for serological diagnosis of IBDV in ducks". It is unclear to the New Zealand Poultry Industry why this study is a preliminary study. If further information is required prior to the report being finalised, this should be obtained and / or included in the IRA, prior to any further steps in the development of an IHS for the importation of cooked duck meat into New Zealand.

Section 6.3 (Appendix 3: Validation of ELISA test) contains a number of abbreviations which are not included in the glossary and which must be defined. These include
• SPAFAS
• ECACC
• PI

The IRA states, in the section entitled Materials and methods, "a panel of duck sera

(collected at slaughter of meat birds reared in isolation from poultry) were obtained from Luv-a-Duck". Although the IRA states that the birds were reared in isolation from poultry, it is not clear from the report what level of isolation the birds were reared under. For example, it is unclear whether the birds were reared in bird proof sheds or if staff working with the birds were required to shower and change their clothes before entering the sheds. This is particularly important as contaminated personnel have been implicated in the spread of IBD virus (van den Berg et al, 2000; MAF, 1999). The age of the birds at slaughter must also be stated.

The IRA states, in the section titled Positive Reference Population, that positive reference sera were available from between 26 and 29 ducks infected naturally. The report does not state why sera were not available from all 30 3-week old ducks placed in contact with the experimentally infected birds.

The New Zealand Poultry Industry is aware that extensive comments were made on this section of the IRA by both External Reviewers. Industry acknowledges that following completion of the experimental or analytical aspects report it is not always possible to make significant amendments to these aspects of test development. However, the New Zealand Poultry Industry is extremely concerned that many of the points noted by the external reviewers have not been included, either as amendments or shortcomings noted in the general or specific considerations sections of the report and that these issues have not been highlighted in the IRA released for comment by Biosecurity New Zealand.

The New Zealand Poultry Industry therefore reiterates the following points in regards to **section 6.3** (Appendix 3: Validation of ELISA test).

• A maximum of 29 positive control sera are used in the analysis of the cut-off point. The New Zealand Poultry Industry notes that this is a very small sample size on which to base this analysis.

• All sera used in the positive control panel were derived from birds infected between 10 and 21 days before bleeding. This panel therefore only represents a segment of the natural population. Some ducks sampled under natural conditions may have been infected some time before sampling and therefore may have decreasing titres.

• Under natural conditions, ducks may become infected at any stage between day-old and slaughter. The production of antibodies is likely to vary depending on the age of the duck at infection. As the sera used for the positive control panel was derived from 3-week old ducks, ducks infected at a younger age may not be adequately represented in the positive control population.

• The cELISA PI values described for the negative reference population range from - 39.00 to 55.00, with an average of 10.93. This is in contrast to that of the positive reference population prior to infection which ranged from 12.00 to 35.00 with an average of 21.14. Although this may be a result of the small sample size for the positive reference population, this makes the determination of an appropriate cut-off for the cELISA difficult. Every batch of samples should be related to known positive and negative controls tested on each plate (referred to as normalisation by the OIE (2004b)).

• The New Zealand Poultry Industry is concerned that the negative reference population was sourced from the same source as the proposed export. Industry is particularly concerned that no attempt was made to verify the negative status of these animals. It is not, in our opinion, good laboratory or experimental practice to define the negative reference population, for the test that is being validated, as the same population that the test under consideration is designed to show is negative. Sentence 2, paragraph 2 of the section entitled General considerations states "and at a 0.1 prevalence 11 out of 10 positive test results will be false positives". This is clearly an error and should be corrected.

The New Zealand Poultry Industry is extremely concerned about the validity of the cELISA reported in **section 6.3** and notes that although the IRA has been reviewed by external reviewers and significant concerns raised in regards to the validity of the cELISA, little notice has been taken of these comments in the IRA. The New Zealand Poultry Industry is particularly concerned about this as the IRA is fundamentally based on the concept of maintaining a compartment free from IBD. The New Zealand Poultry Industry does not believe that the proposed testing regime is sufficiently robust or proven to meets the requirement for compartmentalisation laid out by the OIE (2006) namely that "the surveillance and monitoring programme in place is appropriate to verify the free status of such establishment(s) with respect to such disease(s)".

The New Zealand Poultry Industry requests that Biosecurity New Zealand seek further comment on the report included in **section 6.3** to ensure that the most appropriate and adequate testing methods are used and that New Zealand's right to determine its own appropriate level of protection is not compromised as a result of insufficient validation of laboratory tests. The New Zealand Poultry Industry requests that Biosecurity New Zealand seek comment from New Zealand based experts at the Investigation and Diagnostics Centre, Wallaceville and from both the reference laboratories nominated by the OIE for IBD testing. The contact details for these reference laboratories are detailed below.

• **Dr Y.M. Saif**
Food Animal Health Research Program,
Ohio Agricultural Research and Development Centre, Ohio State University
1680 Madison Avenue, Wooster, OH 44691-4096
United States of America
Tel: + 1 330 263 37 43 Fax: + 1 330 263 36 77
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• **Dr N. Eterradossi**
AFSSA Ploufragan,
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Similarly, the New Zealand Poultry Industry request that Biosecurity New Zealand seek sign-off from Biosecurity Australia on the appropriateness of the proposed testing method to demonstrate and confirm the absence of IBD virus in ducks.

7. Additional considerations not included in the current IRA

7.1 Human health

The current IRA does not give any consideration to human health concerns associated with the importation of cooked duck meat into New Zealand. The New Zealand Poultry Industry requests that Biosecurity New Zealand seek formal comment on the IRA from the Ministry of Health and the New Zealand Food Safety Authority.

7.2 Animal welfare

The New Zealand Poultry Industry acknowledges that there is little scope in the traditional Import Risk Analysis to consider animal welfare. However, the issue of production animal welfare continues to receive increasing public attention and the OIE Terrestrial Animal Health Code (2006) includes detailed guidelines for the transport of animals, the slaughter of animals for human consumption and the slaughter of animals for disease control purposes. Similarly, New Zealand currently has in place a number of Codes of Welfare, Codes of Recommended practice and Minimum Standards. In addition, a number of Welfare Codes are currently under development. One such code is the Animal Welfare (Commercial Slaughter) Code of Welfare 2002, which will apply to New Zealand duck producers.

The New Zealand Poultry Industry believes that, the increased focus of the OIE on animal welfare and the inclusion of guidelines as detailed above in the Terrestrial Animal Health Code, suggests that this issue should be considered when importing any animal product.

It is accepted that the basic tenet of the WTO SPS agreement is to prevent the establishment of unjustified trade barriers (thereby prejudicing potential exporting countries) whilst still allowing (importing) member countries to determine the level of sanitary and phytosanitary protection they deem appropriate for protection of their human, animal or plant life. The New Zealand Poultry Industry supports this approach. Similarly, we believe that consideration should be given to the relative welfare standards in both the importing and exporting country prior to the importation of any animal product.

8. General comments

Sentence 3, paragraph 1, **section 3.1** (Organisms of potential concern) reads “Many of the organisms considered as a result are not be pathogenic to ducks ….”, it should read “Many of the organisms considered as a result are not pathogenic to ducks ….”

Tables 1 and 2 include a reference to “Anon 2000”. Sentence 6, paragraph 7, **section 4.2.1** (Release Assessment) includes a reference to “Anonymous, 1997. A single convention (i.e. Anon or Anonymous) should be adopted and used throughout the document.

Sentence 2, paragraph 1, **section 4.1.6** (Epidemiology) includes a reference to “Luckert and Saif, 2003”. The reference should be “Lukert and Saif, 2003”. This error is repeated on numerous occasions in the IRA and is also included in the reference list.

Sentence 5, paragraph 7, **section 4.2.1** (Release Assessment) reads “Protein and skin in poultry meat are normally expected coagulate with rising temperature ….”. This should read “Protein and skin in poultry meat are normally expected to coagulate with rising temperature ….”.

Paragraph 4, **section 4.3.3** (Recommended sanitary measures), part ii (Slaughtering and

processing) states "including certification that all products are heated to a minimum core temperature of 600C for 30 minutes and 800C for 10 minutes". This should read "including certification that all products are heated to a minimum core temperature of 60$_o$C for 30 minutes and 80$_o$C for 10 minutes".

The second paragraph of **section 6.3** (Appendix 3: Validation of ELISA test) states the objectives of the study. The competitive ELISA is abbreviated to cELISA in this paragraph. However, it is subsequently referred to as cELISA and c-ELISA. A single convention should be adopted and maintained throughout.

Tables and diagrams are not number consistently or consecutively throughout the IRA including the various appendices. For example, both **section 3.1** and **section 6.1** contain Table 1, while figures are referred to as diagrams (**section 6.2**) or figures (**section 6.3**). Although the reference list contains a reference "**Williamson M (2002b).** Laboratory report 02-005383-MW, Attwood, Victoria, Australia", there is no citation of this reference in the body of the IRA.

9. Conclusions

The New Zealand Poultry Industry is concerned that the IRA, in its current state does not adequately identify or address a number of potential hazards associated with the importation of cooked duck meat into New Zealand. Industry is particularly concerned at the lack of clarity and transparency in the IRA, primarily in relation to the source farm (or farms). Similarly, Industry is concerned that insufficient evidence has been provided in the IRA to support the claim that compartmentalisation is an appropriate mechanism by which the risk of importation of IBD virus into New Zealand can be managed. Equally, the New Zealand Poultry Industry is concerned about the use of the concept of compartmentalisation when the practical application has not been extensively considered or agreed at industry, national or international level. Moreover, the New Zealand Poultry Industry does not believe the test methods detailed in **section 6.3** (Appendix 3) are suitably robust, validated or tried and tested in a practical situation to ensure that New Zealand can maintain the appropriate level of protection for our local poultry industry or our native fauna.

In addition, the New Zealand Poultry Industry considers that insufficient consideration has been given to a number of diseases which must, in our view, be considered as potential hazards in the IRA and appropriate risk assessments developed. These include

1. Low pathogenicity notifiable avian influenza (LPNAI)
2. Low pathogenicity avian influenza (LPAI) which have not been identified in New Zealand
3. Duck hepatitis B virus
4. All strains of Newcastle disease
5. Avian chlamydiosis, Avian mycoplasmosis, Avian tuberculosis and Fowl cholera
6. *S. arizonae*
7. *Cryptosporidium bayleyi*
8. Exotic *Mycoplasma* spp.
9. Duck septicaemia
10. *Bacillus anthracis*
11. Japanese Encephalitis virus

The New Zealand Poultry Industry vehemently believes that any Import Risk Analysis should be based on sound (and if possible peer reviewed and published) science. Where

sufficient scientific evidence is unavailable, a precautionary approach to the risk analysis must be adopted and this is particularly true for New Zealand. The New Zealand Poultry Industry is therefore dismayed at the use of inappropriate references and personal communication in the hazard refinement steps of the IRA. As stated previously, the lack of appropriate references casts doubt on the validity of the conclusions drawn in the document as a whole.

Following the amendment of the IRA to appropriately address the potential hazards detailed in this submission, it is our belief that the IRA should be re-released for consultation and comment. Any comments made in this submission on the remainder of the document do not indicate a willingness on the behalf of the wider New Zealand Poultry Industry to accept the categorisation of those organisms of concern which Industry believe warrant (significant) further consideration.

Similarly, the New Zealand Poultry Industry believes that further consultation must be undertaken once comment on the validity of the cELISA proposed in **section 6.3** (Appendix 3) have been received from both international and local experts.

In addition, the New Zealand Poultry Industry does not support the application of compartmentalisation to a single farm or on an *ad hoc* basis as is proposed in the IRA. The New Zealand Poultry Industry believes that this is practically impossible in the current instance, especially when the resultant product is effectively being processed alongside product, the status of which is unknown. Equally, the New Zealand Poultry Industry does not believe that the exporter has demonstrated sufficient willingness to adopt the concept of compartmentalisation in the spirit intended by the OIE (2006e). This is demonstrated equally effectively by the absence of

• an assessment of the resources needed and available to establish and maintain a zone or compartment for international trade purposes

• the establishment of requirements for a compartment and the publication of these via official channels by the Veterinary Administration of the exporting country.

• a biosecurity management manual produced by the exporting company

• confirmation by means of an audit by the Veterinary Administration of the exporting country that the establishment is epidemiologically closed and that appropriate surveillance and monitoring programmes are in place.

Finally, the New Zealand Poultry Industry does not believe that there is likely to be sufficient public good in the importation of cooked duck meat from Australia to outweigh the potential negative effects of an exotic disease outbreak in either the New Zealand Poultry Industry or our native bird population. It is our opinion that the IRA has not adequately identified or addressed the potential risks to New Zealand (both on a commercial and ecological level) and that the acceptance of the IRA in it's current state would not be in alignment with New Zealand's traditional and warranted conservative approach to Biosecurity and would infringe upon the rights of New Zealanders under the WTO SPS Agreement to establish our own appropriate level of protection.

Please do not hesitate to contact our offices should you have any queries.
Kind regards
Michael Brooks

Executive Director

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Response to final *Import risk analysis:* Cooked duck (A*nas platyrhynchos*) meat from Australia. This response is provided in the form of comments on my Review of a draft risk analysis (AR –60- 65 Cooked duck (*Anas platyrhynchos*) meat from Australia, on behalf of Luv-A-Duck Pty Ltd Nhill Victoria Australia sent to me in January of this year. Very little notice has been taken of the points raised in that review, and they are repeated here as part of this submission, with further comment attached. The further comments are in bold, highlighted in yellow, but the entire document constitutes my submission on the final Risk Analysis.

4.3.1.1

The document is a qualitative analysis of the risks posed by the importation into New Zealand of six cooked duck meat products produced by the Australian company Luv-A-Duck Pty Ltd. The risk analysis framework is based on that recommended by OIE in the *Terrestrial Animal Health Code* and follows MAF's publication *Import Risk Analysis – Animals and Animal Products* (1) Murray 2002). The analyst relies heavily on the MAF analysis of the risks associated with importation of chicken meat to justify the exclusion of most agents from the imported product via the cooking process. The Analysis framework is sound, but the way in which the document is assembled makes it difficult to follow at times. This together with the description of parts of the process makes it hard to rely on the risk mitigation measures proposed without further clarification and assurances, and possibly, work. The problems are discussed below.

1 In the Hazard Identification step, agents known to infect ducks are listed on pages 8,9 and 10. These lists are split into organisms known to commonly infect ducks, and organisms known to occasionally infect ducks. I would debate some of the details (e.g. I submit that aspergillosis commonly infects ducks), but such debate would not have any meaningful effect on the Risk Analysis.

This has been substantially corrected in the final RA

2 Pages 8-10. The citing of the references used in these tables on the adjacent pages is very basic. Also it is not stated that the numeric references in the tables correspond via the authors' names with the main reference lists on pages 21-24. It would be preferable if a uniform reference citation system were used throughout the document.

This has been corrected in the final RA

3 Pages 8-10. I could not find any diseases missing from the lists, except *Bacillus anthracis* (3*)* and Japanese encephalitis virus (4), both of which are listed in Diseases of Poultry as occasionally infecting ducks.

These diseases are still not addressed

4 Page 8-10. New Zealand livestock has been free of anthrax for about 40 years, but Australia experiences between 5 and 10 outbreaks a year in various livestock sectors (5), mainly in the NSW-Victoria "anthrax belt". I doubt if ducks on a farm feeding compounded poultry feed would be exposed, but it is possible if feed contained spores from a contaminated batch of meat and bone meal. The cooking regime proposed would not inactivate *B anthracis* spores. Research indicates that temperatures in excess of 90°C are required to achieve meaningful reduction in spore survival. (6). Whether the risks associated with *B anthracis* spores is negligible depends on your definition of negligible.

The Anthrax situation is still not addressed. I would have expected that a clarification as to whether the source farm was within the Victoria anthrax belt or not as a minimum response.

5 There are some diseases on the list where the assessment of New Zealand's status as infected is open to dispute. Chief among these is the assessment of New Zealand as infected with paratyphoid salmonellae (*S typhimurium* and others), as if all serotypes of salmonellae carried the same public health significance. The analyst quotes various ESR reports from 2003 and 2004 as references. New Zealand should ensure that exotic strains of salmonella that occur in Australia are not imported to New Zealand. The time-temperature cooking requirements for destruction of salmonellae contaminating poultry meat are not addressed in the risk analysis. Examination of the 1999 MAF document Import Risk Analysis for the importation of chicken meat and chicken meat products (2) page 32 produces figures that suggest that the current cooking proposals are adequate, but marginal for salmonella removal. The biosecurity measures proposed in the IRA should be sufficient to ensure that the flocks are free of paratyphoid salmonellae, but a test on each export batch a week before slaughter would be a sensible precaution.

This is not addressed, but has minimal effect on RA.

6 Page 8 Even though Australia, including Victoria where it is proposed the ducks be imported from, has suffered outbreaks of both Newcastle disease and Avian influenza in the relatively recent past, the IRA does not include Newcastle disease (NDV) and Avian influenza (AIV) viruses as potential hazards in the commodity. These should be included, although the cooking proposals contained in the document are adequate for the elimination of NDV, as established by the 1999 MAF document (2). (9 minutes at 80°C). Evidence quoted in the 1999 document (2) suggests that Avian Influenza virus is more susceptible to inactivation by heating than NDV. (60°C for 30 minutes is adequate).

7 Page 8. Of the organisms listed in Table 1, the occurrence of *Riemerella anatipestifer* in New Zealand is open to question. This organism has been reported twice in New Zealand, one report from 1970s (7), and the second from 1990 (8). The1990 reference indicates that the organism was not grown; *Pasteurella multocida* also causes meningoencephalitis in ducks. The lesions described in 1974 (the only reference cited in the current IRA) are much more characteristic of *R anatipestifer,* and a credible bacteriological isolate was obtained. Australian producers have regular problems with anatipestifer (Paul Gilchrist – email correspondence with NC, 2004). The NZ duck industry would be unimpressed with a single isolate from the 1970s being regarded as proof that anatipestifer was present in New Zealand ducks. Given the susceptibility of Pasteurella-like organisms to heat inactivation [(15 minutes at 56°C for P multocida (9)], the cooking proposals for this commodity should ensure that the organism does not present a hazard to the New Zealand duck industry. The same publication (10) gives a figure of 12-16 HOURS at 55°C for *Riemerella anatipestifer*, so it may not be as heat-susceptible as believed. The Australian Chicken Meat IRA (11) makes it clear how serious the disease is for the duck industry, so

issues regarding post-cooking recontamination of duck products should be addressed in more detail than at present.

8 Page 12 The IRA concludes that the only potential hazard is Infectious bursal disease virus (IBDV), which is present in Australia, can infect ducks and is not inactivated by the cooking processes used in the preparation of the commodities under consideration. The IRA proposes that flock freedom from IBD be demonstrated for each import of duck products. In addition, various farm management measures to prevent infection are recommended. The proposals raise a number of questions, which are set out in italics following the descriptions of the proposed management system in the IRA, which are copied from the summary and discussed below. **No attempt has been made in the final RA to clarify the issues raised in my review.**

9 On page 13 of the IRA it is stated that the source flock was tested twice with an Idexx ELISA test. The reference is an Attwood Laboratory report from 2002.
This test is an indirect not a competitive ELISA, and has not been validated for duck sera.

IBD

FlockChek* Infectious Bursal Disease—Gumboro Disease Antibody Test Kits

Infectious bursal disease (IBD), or Gumboro disease, is a viral disease affecting chickens in a subclinical form (early bursa atrophy) that may lead to a temporary or permanent immunosuppression. The clinical form in chickens may appear at 3–6 weeks of age. The bursa becomes swollen and then quickly regresses to a small size, leading to suppression of the immune system. Symptoms include anorexia, incoordination and depression. Affected birds are more susceptible to a variety of infectious agents, including *Staphylococcus*, *Clostridium*, *E. coli* and the respiratory viruses. Coinfection with CAV can enhance the immunosuppression condition. Losses may approach 20% in an infected flock, and subsequent flocks may become infected from a contaminated living environment. An assessment of immune status, as well as serologic identification of IBD, requires a measurement of antibody to IBD in serum. Enzyme immunoassay systems are efficacious in the quantification of antibody levels to IBD, facilitate the monitoring of immune status in large flocks, and aid in determining the appropriate time for vaccination.

- **IBD ELISA:** 5 plates, serum samples, indirect format
- **IBD-XR ELISA (extended range):** 5 plates, serum samples, indirect format, extended titer range, enhanced detection of variant strains

Email received by N.H. Christensen 15/12/2005

Dear Sir/Madam

The test was not designed for ducks, sorry
No experience with that
IBD is more economical important for Chickens

There are some studies in trying to correlate the importance of IBD, serotype two in Turkeys, but still not clear

kind regards

Dr.Ricardo Munoz

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The final RA carries the reference to the non-validated test as section 4.15 on page 9. One wonders what standards BNZ applies to the final process if it can include reference to a test that the manufacturer cannot support. The purpose of this test in whole RA development is unexplained. If its non-validity had been raised by the analyst as a reason for developing the AAHL test, then it has a place in the RA, but the non-validity should be flagged.

10 We have to place our reliance on the AAHL test developed for use in ducks, as presented in appendix 3

11 There is widespread use of the word "should" in the document, which indicates a degree of " we'll do our best to comply, but if it is inconvenient then standards will slide" attitude to the management system.

This issue is unaddressed, either by firming the compliance standard to must in the RA, or by changing the risk mitigation measures.

12 Page 19 The recommendations for risk management of the IBDV risks include *(reviewers reservations are in italics after each point):*

i. Farm management system

All ducks from which product for export to New Zealand is derived should be sourced from a single farm, which should operate a management system based on:
I have reservations about the documentation provided. My reading of the documentation shows that it contains a degree of "woolliness", which indicates that these provisions are something that is intended to be implemented at some future point, rather than a system that is already operational.
This issue remains unclarified as the appendices are included in the final RA unchanged

- A farm located at least 5 km from other poultry farms.
- Single age, all-in, all-out operation (including single pick-up).
  (Does "operation" mean AI-AO by shed or by farm? If by farm, how many sheds are present on the source farm? How many farms are proposed to be involved if importation is to be at less than seven-week intervals?)
- Locked farm - residences located outside dedicated area.
- Locked and effectively bird-proofed sheds.
  (Site 8 is not bird proofed)

It is still not bird proofed in the final RA, despite one of the risk mitigation measures being bird proofing

- Extensive hygiene clean-out between batches.
  (What is meant by extensive? How does this differ from an intensive clean out?)

- Equipment dedicated to the export farm. **The export farm appears to vary from cycle to cycle.**
- Log book for recording of people and equipment movements.
  Does this refer to inter-shed movement of equipment as, according to the IRA equipment is dedicated to each farm
- Records kept of production data, mortalities and relevant events.
  The significance of this is not apparent as it is generally agreed that IBDV is asymptomatic in ducks. Who would decide on what constituted a relevant event? What would happen if a relevant event took place?

  What relevant events have occurred and been documented in the past 5 years to indicate that the system works?

- Shower-in and change of clothes.
  Is this a historical management practice or a proposal?
  BNZ should make or have made enquiries about this before approving the Risk Analysis.
- Separate feed delivery (first of the week) by washed truck or delivery tube sited outside perimeter fence.
  The "or" implies that this measure is not currently in place at the farm(s). Alternately some farms could have one and other farms the other measure in place, "export farm" is always referred to in the singular.
  BNZ should make or have made enquiries about this before approving the Risk Analysis.

- Staff dedicated to the export farm.
- A condition of employment is for staff to have no access to other poultry farms, backyard poultry or to pet birds. *I cannot see the relevance of pet birds to IBDV infection*
- Educational program for staff. *What are they going to be taught?*
- Auditing of the farm management system by the appropriate Australian authority.

It is proposed that the farm management system should be audited at least once each export cycle by AQIS or an independent authority approved by AQIS. *I have little faith in this type of auditing, as it is easy to fake the results, unless the auditor knows a fair bit about poultry, and if they do it would be bringing someone who has regular contact with poultry and is a potential biosecurity hazard onto the farm.*

13 Pages 25-26. The growout procedures detailed on page 25 and summarised in table 1 on page 26: ***These are repeated verbatim in the final RA on pages 22 and 23. No effort has been made to clarify the apparent deficiencies, hence the paras below are emboldened in accordance with the format of this submission.***

"The broiler ducks are grown under two sets of conditions. The first set comprises a number of single age, all-in, all-out sheds on various contract or company-owned farms in the local area, but all located over 15 km from the processing plant." ***(These are presumably sites 6 and 7 in table 1)***

"The second is a multi-age site on the property adjacent to the processing plant. *(this is site 8?)* This section is progressively being converted to three isolated units operating on an all-in, all-out, single age basis. Housing on this property is in open sided sheds without bird proofing (*highlight in this submission)*** and with partial curtaining for protection against the prevailing wind. Sheds are separated from one another by a laneway about 10 m wide."**

Table 1 (part showing growout)

Site 6	**Contract Commercial meat ducks**	**Various sites 15 km to 200 km**	**Day-olds from commercial hatchery**	**Restricted access Separate staff**
7	**Company commercial meat ducks**	**One site 15 km from base**	**Day-olds from commercial hatchery**	**Restricted access Separate staff**
8	**Fattening meat ducks**	**500m from base**	**5 week old ducks moved from sites 6 & 7.**	**Restricted access**

The Luv a duck operation as detailed on pages 25 and 26 appears to depend on having 6 and 7 week old birds on site 8, located 500m from base i.e. the processing plant); birds are moved there at the end of the 5th week from single aged sites 6 and 7. The operation of this continuous flow pre-slaughter site seems to be at odds with what is proposed above. The use of such a growout and slaughter programme would make the IBD serological screening of the flocks unreliable, as infection of pre-slaughter ducks located adjacent to the processing plant on site 8 would not be reliably detected by serology prior to slaughter.

Even if only some birds are moved to site 8, and the remainder left at sites 6 and 7, it is not possible to do this without compromising the "no thinning" farm management aspect of the risk management proposals in the IRA.

The description of the current operation does not match the biosecurity proposals

14 page19 ii. Slaughtering and further processing

- Slaughter of birds *should* be done at the plant that is operated by the supplier of the birds. *The use of the word "should" as opposed to "must" implies that slaughter may on occasion take place elsewhere.*
- The slaughter plant should operate to Quality Standards that are approved and audited by the Victorian Meat Authority. *The should word – what happens if it does not meet requirements?*

15 Page 19 iii. Manufacturing

The Victorian Meat Authority should be responsible for auditing the manufacturer's cooking and production procedures as specified in this document and in particular for ensuring that all product is heated to achieve a minimum core temperature of 60^0C for 30 minutes and 80^0C for 10 minutes. Published work (12) shows that at 80^oC, 3 minutes was required to reduce the virus titre by $1\log_{10}$. Since the highest titre the attained by the virus in (chicken) bursal homogenate was 10^4 CID_{50}/0.1ml (12), the work shows that heating at 80^oC, will achieve a reduction to $10^{-2}CID_{50}$/ml after 10 minutes – a probability of 0.01 that $1CID_{50}$ remains in 0.1ml of homogenate. As pointed out by the analyst this work was done with bursal homogenate, which is relatively unprotected compared with virus in

meat, and a cooking time of 120 minutes at 80°C was shown to be required to remove all virus (13). However, ref 12 shows the titre to which IBD virus grows in bursas.

How is the VMA auditing to be done? If the birds are all killed and processed on one day (which must happen as no thinning is permitted?) is it proposed that a VMA presence on slaughter days be required?

Will the further processing be carried out on the same day as slaughter? Diagrams 1 (Confit) and 2 (Roasted Product) both state that product will be taken from the line and chilled to achieve a core temperature of 5°C within 3 hours, and then they are collected from the coolroom and boned. It does not state how long they will be in the coolroom, and whether other products held over the week end will be there. If the further processing does not take place on the same day, how will the export consignments be identified and separated from non-export? Although the export processing and further processing could take place on the same day as slaughter, the product will have to be stored separately until the results of the testing for IBD that is proposed in the IRA become available.

Do the quality standards of the VMA ensure that there is no contact with uncooked non-export meat before cooking? In theory, as IBD is not eliminated by the cooking, the cooking of the export batches will need to be carried out in isolation from domestic product, and the rooms cleaned and disinfected (or heated to a temperature that does kill IBDV) prior to loading with export batches. All this is likely to require a VMA/AQIS presence to ensure compliance. This would apply in particular to the roasted product (diagram 2). Which undergoes an unpacked cooling process. The Confit product is vacuum packed directly after boning.

The documentation used by the slaughter and secondary processing plants needs to be provided as an appendix to the Risk Analysis in a similar manner to the validation appendices of the ELISA tests. **This documentation is not provided in the final RA. One suspects that this is because it does not exist.**

Page 27-28 Appendix 2 describes the products. Products 5 and 6 are “whole half duck”. The disposition of the bursa of Fabricus is not described. Is the BoF sectioned and left in the half-carcases, or removed prior to splitting the carcase? The removal of the bursa would seem to be a reasonable precaution to reduce the initial load of any IBD entering the cooking and reduce the probabilities discussed above (11).

The disposition of the bursa is still not specifically addressed.

17 Page 20 iv. Testing.

At slaughter each batch of birds should be tested to ensure freedom of the flock from IBDV according to testing and sampling procedures specified in this risk analysis. The sampling procedures are not fully specified (see below).

It is not stated who will collect the samples VMA? AQIS? Exporter farm or QC staff?

18 Page 20 I have reservations about the testing proposed. *(italics)*
ii) Valid tests for monitoring the negative status of the flocks.

At slaughter, each batch of birds should be tested as follows:

- A randomly collected sample of birds should be tested, with negative results, by the AAHL ELISA (Appendix 3). The sample should be of sufficient size to detect a prevalence of 10% of birds with IBD titres, with a confidence of 99%.
- A randomly selected collection of bursa from the birds should be collected and tested for the presence of IBD RNA by a PCR test that has been approved by AAHL, with negative results. The sample should be of sufficient size to detect a flock prevalence of 20% with 99% confidence

Serological testing could return a negative test if the flock has been infected within the past 10-14 days. This problem is largely overcome by the antigen detection test (IBD RNA by PCR).

There is no reason given for the difference in detection prevalence that is proposed for the two tests.

The serological testing proposed above, given a flock size of 2200 birds would require (using table 6a on page 45) the testing of about 40 birds. The PCR testing would require about 20 birds.

19 Page 20 There is no discussion of the effects of pooling of the (PCR) samples on the statistics quoted above. If pooling is envisaged (the cost of 20 individual PCR tests would be high) then it should be clearly stated what is proposed. The current wording "a randomly selected collection of bursa from the birds" appears to be deliberately attempting to fudge the pooling issue.

The issue of pooling of PCR samples remains unclarified in the final RA

20 *Given the discussion on page 41, lines 40-43, I would prefer to see the PCR bursal samples collected from the same (identified) birds as the sera. If infected, the birds should have antibodies, or a PCR product should be detectable.*

21 The use of site 8, as indicated on page 26 of the IRA will invalidate the serological testing protocol, as birds are unlikely to have time to seroconvert.
This vital issue is unaddressed

22 Pages 21-24. The references need to be standardised through the document. Note also that the 11th edition of Diseases of Poultry is published by Iowa State Press, not Iowa State University Press.

Even this minor issue of the correctness of the reference has not been corrected in the final RA. Did anyone read my review of the earlier document?

23 Pages 33-47 Validation of the IBD ELISA

There are a number of shortcomings in this appendix that should be corrected to ensure that it could be followed by most stakeholders.

A glossary would be useful. E.g. there is no explanation of what is meant by PI and how this is related to OD (also unexplained). On page 37 the SNT test results are compared to an ELISA PE. What is the difference between a PE and a PI? PE first

appears on page 35 as post exposure, but this cannot be its meaning in table 1 on page 37.
What is mab? Monoclonal antibody?
ROC curve (page 42)

We are frequently told that RA carried out by BNZ are intended to intelligible to all stakeholders. Whilst not an expert in ELISA use and development, I am probably better equipped than most to understand this aspect of the RA; the issues surrounding the transparency of the ELISA development process are totally unaddressed in the final RA.

c-ELISA should be standardised (it is variously referred to as cELISA, c-ELISA, C-ELISA)

Specific points of discussion from appendix 3

Page 33 line 21 Why *preliminary* validation data?. This work was done some months or possible years ago. Has further data been generated? If so, it should be presented.

If the report I reviewed a year ago was based on preliminary validation data, one could reasonably expect the final RA to have final data. This is not the case. Appendix 3 (now page 30) twice refers to preliminary data. If the test validation is not final, why should stakeholders accept it?

Page 33 line 33. This refers to commercial generation ducks identical to those that are proposed to be exported. This discussed further later in this report.

Page 34 lines 6,7 refer to appendix 1 and appendix 2. In the test validation document (appendix 3) there is addendum 1 and addendum 2 on pages 46 and 47. Appendix 1 and 2 of the IRA refer to the source of supply (pages 25-26) and the products to be imported, respectively (pages 27-32).

The tables in the appendices should be numbered consecutively with those in the body of the IRA. Currently we have two table Is (on pages 26 and 37). Appendix 3 reads as though it has been copied verbatim from another report without due consideration being given to how it fits with the overall IRA. Page 42, line 10, which refers to vaccination, furthers this impression, as there is no question of ducks being vaccinated against IBD.

Page 34 lines 20-34 is not clear. It says that "chickens were euthanased on day 6 after infection", but "cloacal swabs were collected from directly infected birds on days 3 and 4 post infection, and from *all birds* on days 5, 6 and **7** post-infection". Does this mean *all ducks?*
Unaddressed in final RA

Page 34 line 27
This refers to *"6 days post challenge"*. It should refer to *6 days post infection,* as there is no attempt to test (challenge) any immunity. Figures 1a,b,c refer to *"days post inf contact"*, presumably infectious contact, which is preferable to *"challenge"*.
Unaddressed in final RA

Page 34 line 39 Virus titrations
It is not clear what the numbers (0004-13-0050 and 0309-11-1501) after IBDV represent. They have the same format as the AAHL reference for classical Australian

IBDV (0406-15-0273) that was used in the validation exercise. **Recent research (14) has shown two distinct genetic groups of IBDV in Australia, with the second or variant group being most prevalent amongst Victorian isolates. Which genetic grouping is prevalent in the Luv-a-duck birds is not discussed; neither is the performance of the c-ELISA with antibodies to the variant group discussed. Unaddressed in final RA**

Validation of testing
Positive reference population Page 35 Line 3
Since the ducks used were from conventional sources and already three weeks old, it is possible (but unlikely) that they were already IBD positive. The positive reference sera were surely derived by in contact infection with experimentally-infected chickens and ducks, rather than by natural infection as stated.

Page 36 The significance of the difference between SNT 1 and SNT 2 tests is not explained. Is one in CEF and one in BGM cells? If two SNTs were to be trialled then one should have utilised variant IBD virus.

Negative reference population Page 37

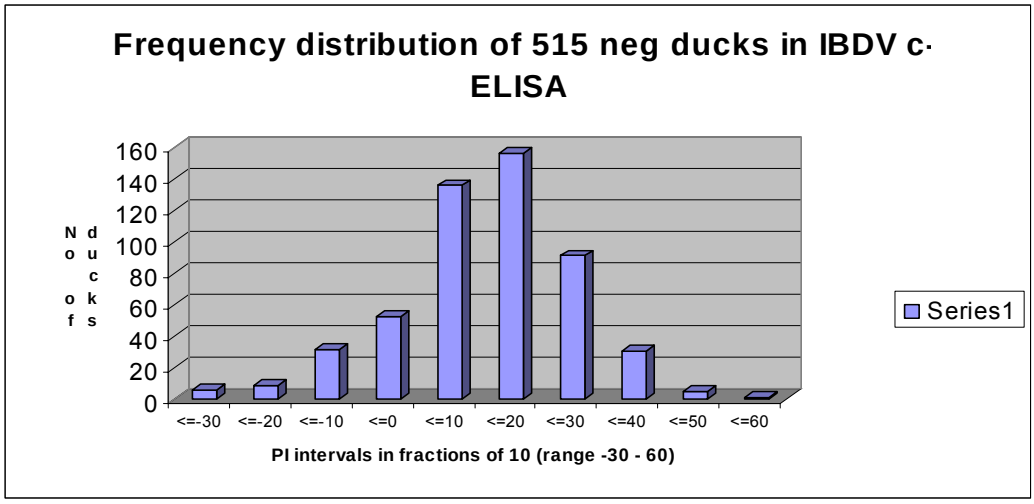
The negative reference population consisted of 515 "putatively" negative ducks. These ducks were standard commercial generation meat ducks identical to those that are being proposed as the source of imports. No tests were carried out to verify the negative status of these animals. Putting SPF chicken sentinels with the flocks, and doing serological and PCR tests on the sentinels would go some way to providing verification that the flocks were in fact negative.

Irrespective of the validity of the testing protocols, it seems unreasonable to define the negative reference frame for the test that is being validated as the same source (and status) as the birds that the test is designed to show are negative!
No comment in the final RA!!

Two solutions present themselves
1) Have some New Zealand duck sera sent to AAHL for testing. I doubt if duck sera from New Zealand have ever been tested for IBD antibodies and, although unlikely we get an unpleasant surprise! (only the Idexx ELISA kits are used commercially here, and these are not validated for ducks).
2) Carry out serial testing on GGP or GP ducks. These are raised in conditions of maximum isolation. Tests carried out on identified birds (many of these GGPs and some GPs will be identified anyway) at 3, 6, 9 weeks, housed together with a small number of SPF chickens would provide a high level of assurance that the duck sera tested were truly negative for IBDv antibodies.

Snyder and Marquardt (14 p204) recommend that 3 std deviation units above the mean of the non-infected group be used as the positive negative threshold (PNT). This has been followed in Appendix 3. This provides a PNT of 10.93 + (3 x 13.89) or 52.6. for 515 negative ducks It is worth noting that the mean ELISA PE + 3 Std Deviations of the sera day 0 group used to produce the positive group is 38.5 (21.14+ 3x5.5). These were from GGP and GP sources (page 33, line 29), and are somewhat different.

Leaving out reservations as to the selection of the negative reference frame and looking at the data (page 38)



The graph shows that (126/515) nearly 25% of putatively negative ducks had ELISA PI in excess of 20. The tables (1 page 37, 2a page 38) has PE values, the graph (fig1a page 35, fig 2a page 38) show a PI value. This needs clarification.

Page 41 General considerations

Line 10 I doubt if any ducks in New Zealand have been tested for IBD antibodies

Line 13 Apathogenic IBDV has been present in New Zealand in the past without any evidence of spread to poultry beyond chickens, let alone native birds.

Line 10 Who is the end-user of the test? Is it Luv-a-duck? AQIS? NZMAF? or the New Zealand poultry industry?. These organisations are likely to have differing views on cut-off points.

Lines 24-40. The discussion of screening and confirmatory cut of values is illuminating, but the report does not offer an opinion as to where the diagnostic cut-off should be set. A confirmatory test would have to be a different test (SNT?) to offer any further information.

Lines 40-43 discuss the use of PCR/virus isolation. The discussion cannot be faulted but these techniques are surely there to complement the antibody testing regime to pick up recently infected ducks.

Page 42 line 10 Vaccination of ducks against IBD is irrelevant.

Page 42 lines 19-21 Reservations regarding the status of the 515 “normal’ ducks used in the programme are expressed elsewhere.

Page 44 Specific considerations

Lines 1-5 state that due to epidemiological considerations, the prevalence of IBD infected birds is likely to be very low (<1% or even 0.1%). **However if a flock is exposed, the prevalence of infection within a flock is likely to be high even if**

seroconversion is not, due to there being insufficient time post exposure for this to occur. The figures given in the second paragraph on page 44 (Now page are unlikely to reflect field reality, and should be reworked using the assumptions on page 20, where a 10% or 20% prevalence of infection is used. Under these situations the likelyhood of a positive result being a false positive are very much lower than the 96% inferred on page 44 for a 1% prevalence. The origin of table 6a is unreferenced. In fact the whole of appendix 3 is unreferenced.

This issue is unaddressed

N.H. Christensen

11 October 2006

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4.4 FISH AND GAME NEW ZEALAND

4 October 2006

Martin Van Ginkel
Team Support Officer
Risk Analysis
Biosecurity New Zealand
PO Box 2526
WELLINGTON

Dear Martin

IMPORT RISK ANALYSIS: COOKED DUCK MEAT FROM AUSTRALIA

Thank you for your letter of 21 September correcting the name of a risk analysis you sent us for comment on cooked duck meat.

Fish and Game New Zealand are the statutory managers of game birds, including mallard introduced to this country in the late 1800s and now our number one game bird.

Wild mallard are referred to in the analysis. Mallard in Australia can be killed at any time by any method and are not a valued game species as in New Zealand. The sale of game birds in New Zealand is prohibited. Fish and Game New Zealand's concern would not be in the importation of the meat but the temptation by restaurants and other food outlets to substitute the imported meat with New Zealand wild mallard and claim it comes from Australia.

Yours sincerely

Robert Sowman
Policy and Planning Manager

4.5 MINISTRY OF HEALTH

MINISTRY OF HEALTH
MANATŪ HAUORA

133 Molesworth St
P.O. Box 5013
Wellington
New Zealand
Phone (04) 496 2000
Fax (04) 496 2340

Ref. No:_____

26 September 2006

Martin Van Ginkle
Pre Clearance
Biosecurity New Zealand
Ministry of Agriculture and Forestry
P O Box 2526
Wellington

Dear Martin

RE: IMPORT RISK ANALYSIS: COOKED DUCK MEAT FROM AUSTRALIA

Thank you for sending me a copy of this risk analysis. I am pleased to see in the executive summary of the document that there are no potential effects on humans or the environment. Given this assurance, I do not wish to make a submission on behalf of the Ministry of Health.

Dr Don Matheson
Deputy Director General
Public Health Directorate