

Import Risk Analysis: Egg powders from all countries

REVIEW OF SUBMISSIONS

October 2008

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Policy and Risk
MAF Biosecurity New Zealand



Draft Import Risk Analysis: Egg powders from all countries

Review of Submissions

October 2008

Approved for review/public consultation/general release

A handwritten signature in black ink that reads 'Christine Reed'. The signature is written in a cursive, flowing style.

Christine Reed
Manager, Risk Analysis
MAF Biosecurity New Zealand

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1. Executive Summary

The biosecurity risks associated with the import of shelf-stable spray-dried egg powders from all countries were examined in a draft import risk analysis released for public consultation on 21 May 2008.

The draft risk analysis considered that for imported whole egg, egg yolk, and egg albumen powders, heat-resistant variants of exotic group 1 avian adenoviruses associated with hydropericardium syndrome (FAdV-4) were hazards. Options presented for FAdV-4 risk management included:

- Assurance that eggs used have been derived from flocks in countries or geographic regions where HPS has not been recognised.
- Testing to ensure source flock freedom from FAdV-4.
- Further heat treatment of manufactured powders to destroy any FAdV-4 present.

The draft risk analysis considered exotic avian influenza (AI) viruses to be a hazard in imported egg albumen powders. AI viruses were not considered to be a hazard in whole egg and egg yolk powders. Options presented for AI virus risk management included:

- Further heat treatment of manufactured egg albumen powders that have not already been subject to heat treatment proven to destroy AI viruses.
- Testing source flocks to ensure freedom from AI viruses.
- Certification that eggs used to manufacture egg albumen powders have originated from flocks in countries, zones, or compartments which are free of notifiable AI as described in Article 2.7.12.3 of the OIE *Code*.

Four submissions were received; from the Egg Producers Federation of New Zealand (Inc), Avivet Ltd., Mainland Poultry Limited, and Scitex New Zealand Limited.

The Egg Producers Federation of New Zealand (Inc) and Mainland Poultry Limited both raised concerns regarding the certification of imported egg powders and the risks associated with the packaging, storage, and transport of imported products. These points have been noted and will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any import health standard developed from this import risk analysis.

Avivet Ltd questioned the aetiology of hydropericardium syndrome and whether FAdV-4 should be considered exotic to New Zealand. These issues have been explored in this review.

Scitex New Zealand Limited raised no technical challenges to the draft import risk analysis. This submission described a spray-dried egg powder from Japan that is used in a drench for neonatal calves in New Zealand, but did not raise concerns about the analysis or the risk management options presented.

None of the issues raised in these submissions affect the conclusions of the draft import risk analysis for egg powders from all countries. Therefore, the conclusions of the draft import risk analysis are considered to be valid for the development of import health standards for these commodities.

2. Introduction

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, interdepartmental, and external technical review before the draft 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 review of submissions identifies any matters in the draft risk analysis that need amending in the final risk analysis although the decision to implement these changes lies with an internal committee of MAF Biosecurity New Zealand. The final risk analysis and the review of submissions together inform the development of any resulting IHS by the Border 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.

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: Egg powders from all countries* for public consultation on 21 May 2008. Every step was taken to ensure that the risk analysis 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 2 July 2008.

Four 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 draft 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 any risk management options presented. For this

reason, the review of submissions will answer issues of science surrounding likelihood¹, not possibility², 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

Submitter	Organisation Represented/Location
Michael Brooks	Egg Producers Federation of New Zealand (Inc)
N.H.Christensen	Avivet Ltd.
Lorna Craig	Mainland Poultry Limited
Lindsay G Chitty	Scitex New Zealand Limited

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: Egg powders from all countries

3.1. MICHAEL BROOKS, EGG PRODUCERS FEDERATION

- 3.1.1. Industry notes that it is possible for microbiological failure to occur during processing if the micro loading of the raw product is high or if there are inadequate CIP (*clean in place*) procedures. This may also include cross contamination of powders following the drying process if hygiene is poor, resulting in *Salmonella* species in the final product. Industry therefore requests that the IHS include some form of assurance that exporters can verify the effectiveness of processing standards and plant hygiene.

MAFBNZ response: This comment is noted and will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any import health standard developed from this import risk analysis. Please also see the response to 3.3.3 below regarding the role of NZFSA in monitoring the safety of imported food for human consumption.

- 3.1.2. The Industry notes the statement on page 3 that “Most of these commodities are used in the food industry, ...”. Industry acknowledges that in the main this is accurate. However Industry also notes that in some cases product which has expired or some other reason is no longer fit for human consumption may be disposed of in animal feeds. It is unclear from the current document whether this pathway has been considered by Biosecurity New Zealand or not, but the Industry believes that this potential pathway should be recognised as such and due consideration to the pathway given.

MAFBNZ response: Section 6.4 of the draft import risk analysis concluded that the only hazards identified as likely to be present in imported egg powders that conform to the commodity definition were exotic group 1 avian adenoviruses and avian influenza viruses. Although feeding of imported egg powders directly to domestic livestock has not been considered specifically in the exposure assessments for either of these hazards, the possible accidental exposure of wild avian species is recognised. Regardless of this, the risk management options described with respect to both of these hazards are considered to effectively manage any risk associated with feeding imported egg powders directly to domestic livestock.

- 3.1.3. The New Zealand Poultry Industry acknowledges that the import risk analysis is not intended to address risks associated with the packaging, storage and transport of imported products and this should be covered under the import health standard. However, the industry would like to take this opportunity to highlight concerns around the potential for packaging of the egg products to be involved in the transmission of disease and requests that Biosecurity New Zealand take this into account when developing the import health standard.

MAFBNZ response: The risk associated with packaging, storage, and transport of these commodities is no different to that posed by all other imported packaged goods, including food, clothing, books, consumer electronics etc. Requirements in relation to the primary packaging of imported products will be addressed during the development of any import health standards. The import health standard for sea containers from all countries (see: www.biosecurity.govt.nz/files/ihs/bmg-std-seaco.pdf) specifies the requirements to be met for the effective management of biosecurity risks associated with the importation of sea containers and associated packaging of containerised cargo into New Zealand.

- 3.1.4. Similarly, the industry requests that the import health standard also include requirements to ensure that manufacturers can verify the processing temperatures claimed, that the product is stored and handled appropriately and there is no opportunity for cross contamination following processing.

MAFBNZ response: Certification issues will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any import health standards based on the findings of this risk analysis.

- 3.1.5. Industry notes the comments with regards to the standards set out in EEC Directive 89/437, and requests that a minimum standard to comply with a standard similar to this one is included in the Import Health Standard. Similarly, Industry requests that the IHS include a requirement that the time-temperature standards laid out in the Import Risk Analysis as a minimum are met.

MAFBNZ response: The draft import risk analysis has examined the biosecurity risks associated with imported egg powders that comply with the commodity definition as described in Section 4.4. Without further analysis, the findings of this risk analysis would not be considered valid for any commodity that does not comply with this definition.

3.2. N.H. CHRISTENSEN, AVIVET LTD

3.2.1. Whilst most of the imports will be of egg powders for human consumption, as a replacement for eggs or liquid egg in catering, it should be noted that some egg powders are used for nutraceutical purposes, in which egg powders from hens hyperimmunised against *Cryptosporium*, *E. coli* O157 and salmonella are used in products sold as gut health enhancers and even to supplement colostrum in calf rearing (Rotagen Combo). The hens used for the production of these products, whilst not SPF, are held in highly controlled conditions.

MAFBNZ response: The submission from Scitex New Zealand Limited (see Section 4.4 of this document) gives further details of the product described above.

3.2.2. Table 2 refers to the processing of liquid eggs (pasteurization). The temperatures used in spray drying (up to 180°C) are noted in the analysis, but this does not appear to be have given any "credit" in disease agent inactivation. A check should be made, but I believe that NZ egg pasteurization regs require 64°C for 2.5 minutes. The RMPs (*risk management programmes*) that I have evaluated use this time-temperature couplet.

MAFBNZ response: Table 2 describes the processing conditions considered by the OIE to be sufficient to inactivate any highly pathogenic notifiable avian influenza virus present in eggs and egg products and is consistent with Article 3.6.5.1 of the current (2007) *Terrestrial Animal Health Code*.

Sections 4.2 and 6.3 of the draft import risk analysis both note that manufactured egg powders are subject to spray drying using an inlet temperature of 155°C to 175°C and outlet temperature of 70°C to 80°C. Section 6.3 of the draft import risk analysis does consider the effect of these conditions on heat-sensitive pathogens. For example, Section 6.3.1 states "Given the pasteurisation temperature defined here, *and the further heating associated with the spray-drying process*, exotic *Salmonella* spp. are not considered to be a potential hazard in this commodity".

3.2.3. Vertical transmission is described as. transmission within or on the egg. I believe the two should be differentiated in any risk analysis. "On" the egg can be dealt with by sanitation of the eggs prior to breaking, but 'in' the egg cannot. You apparently do this on page 11 for Marek's disease by stating that it is not transmitted within the egg. Any disease agent can be transmitted "on" the egg shell if it is not properly sanitized.

MAFBNZ response: The preliminary hazard list (Table 3) clearly distinguishes vertical transmission in eggs from transmission on eggs or in the shell.

3.2.4. The presence of APMV2 and 3 on the list shows the subjective standards inherent in the risk analysis process as carried out by MAF. APMV2, 3. In a survey of a variety of species carried out by the (now) IDC, and published in 2001 (Stanislawek et al NZVJ 49(1) 18-23, 2001), antibodies to APMV 2 and 3 were detected in 1.7 and 2.6 percent of samples tested. Although the authors concluded that the titres were cross reactions with APMV1, they stated that APMV2 could not be excluded. Under different circumstances, I have seen these titres interpreted in other ways. In the context of this

RA, this does not matter as the processing temperatures involved will inactivate the viruses anyway.

MAFBNZ response: The paper cited above concludes, “There is no conclusive evidence of the presence of APMV-2 and APMV-3 in poultry or APMV-3 in wild birds. The results do not provide conclusive evidence for the presence of APMV-2 in wild birds in New Zealand”. MAFBNZ considers the treatment of avian paramyxoviruses 2 and 3 in the draft import risk analysis is consistent with the conclusions of this paper.

3.2.5. The analysis and proposals for Avian influenza should be uncontroversial in the current international climate, and largely follow OIE guidelines.

MAFBNZ response: Noted

3.2.6. The adenovirus section does not reference the only comprehensive study of adenoviral disease in poultry carried out in New Zealand. See Md Saifuddin : the aetiology and pathogenesis of Avian Inclusion Body hepatitis PHD thesis Massey university 1990, and the published papers derived from it.

MAFBNZ response: The thesis referenced above details a study into the aetiology of inclusion body hepatitis in New Zealand poultry and identifies Fowl adenovirus 8 (FAdV-8) as the predominant FAdV serotype associated with this disease. This study also identifies evidence for New Zealand poultry exposure to FAdV-1 and FAdV-12 although no other serotypes are described. Subsequent papers from the author of this thesis have published these findings in peer-reviewed journals although none of these papers present evidence for other genotypes of FAdV being present in New Zealand poultry.

The findings of this thesis and subsequent publications therefore do not alter the conclusions of the draft import risk analysis.

3.2.7. The adenovirus section is open to criticism, and is likely to result in a degree of international skepticism about the risk analysis process in New Zealand, as Angara disease or Hydropericardium syndrome is the description of a clinical or post mortem entity rather than an agent. The people who worked on the condition in Pakistan in the early 1990s were unable to reliably fulfill Koch's postulates, and a number of adenovirus serotypes were isolated from cases of the syndrome.

MAFBNZ response: As is frequently the case when an emerging disease is first recognised, the aetiology of hydropericardium syndrome (HPS) was poorly understood and the draft import risk analysis comments that initial studies hypothesized that the disease was associated with a nutritional disorder (see Section 7.1.4). However, later studies have provided sufficient evidence to conclude that HPS is associated with infection by a virulent strain of FAdV-4.

Abe et al (1998)³ isolated fowl adenovirus from the livers of affected birds with HPS in Japan and these were serotyped as FAdV-4 using virus neutralisation tests. Nakamura et al (1999)⁴

³ Abe T, Nakamura K, Tojo H, Mase M, Shibahra T, Yamaguchi S and Yuasa N (1998) Histology, immunohistochemistry, and ultrastructure of hydropericardium syndrome in adult broiler breeders and broiler chicks. *Avian Diseases* 42, 606-612.

then experimentally infected specific pathogen free (SPF) chickens with Japanese FAdV-4 isolates to reproduce HPS lesions and mortality in both chicks and adults. These authors also went on to comment that “the present experiments indicate that adenovirus isolated from adult breeder chickens suffering from HPS can reproduce HPS lesions and mortality in adult SPF chickens. Few avian viruses by themselves, if there is no concurrent infection, can cause mortality in adult chickens. Thus, HPS adenovirus is a highly pathogenic strain in comparison with previously studied adenovirus strains isolated from cases of inclusion body hepatitis.”

Similarly, Mazaheri et al (1998)⁵ isolated adenoviruses from severe cases of HPS in Ecuador and Pakistan, which were identified as FAdV-4 and shown to produce high mortality when inoculated in SPF chicks

Hess et al (1999)⁶ examined 12 fowl adenoviruses isolated from field outbreaks of infectious HPS in seven countries in Asia and America. All isolates were identified by serum neutralisation tests as FAdV-4.

Toro et al (1999)⁷ characterised three adenoviruses recovered from field outbreaks of HPS in Chile using virus neutralisation tests and restriction enzyme analysis. All three isolates were identified as FAdV-4 and when SPF chickens were experimentally infected there was 9 percent mortality accompanied by characteristic gross and histopathological lesions.

Ganesh et al (2001)⁸ collected 73 liver samples from five diagnostic laboratories in Bangalore that had investigated outbreaks of HPS reporting 60-75 percent mortality. FAdV-4 was isolated from liver homogenates and experimental infection of birds with this purified virus produced 80 percent mortality. These authors concluded that “the experimental reproduction of the disease in susceptible chicks, accompanied by appropriate serological and electron-microscopic evidence, suggests that the fowl adenovirus serotype 4 from the material studied was solely responsible for causing HPS.”

Balamurugan and Kataria (2004)⁹ described the early problems with identifying the aetiological agent of HPS but went on to state that “HPS was reproduced in SPF chicks using isolated and purified virus from field cases of HPS (Mazaheri et al 1998) thus proving the

⁴ Nakamura K, Mase M, Yamaguchi S, Shibahara T and Yuasa N (1999) Pathologic study of specific-pathogen-free chicks and hens inoculated with adenovirus isolated from hydropericardium syndrome. *Avian Diseases* 43, 414-423.

⁵ Mazaheri A, Prusas C, VoB M and Hess M (1998) Some strains of serotype 4 fowl adenoviruses cause inclusion body hepatitis and hydropericardium syndrome in chickens. *Avian Pathology* 27, 269-276

⁶ Hess M, Raue R, Prusas C (1999) Epidemiological studies on fowl adenovirus isolated from cases of infectious hydropericardium. *Avian Pathology* 28, 433-439.

⁷ Toro H, Prusas C, Raue R, Cerda L, Geisse C, Gonzalez C and Hess M (1999) Characterisation of fowl adenoviruses from outbreaks of inclusion body hepatitis / hydropericardium syndrome in Chile. *Avian Diseases* 43, 262-270.

⁸ Ganesh K, Raghavan R, Gowda RND, Satyanarayana ML and Suryanarayana VVA (2001) Purification and characterisation of the aetiological agent of hydropericardium hepatitis syndrome from infected liver tissues of broiler chickens. *Tropical animal health and production*, 34, 7-17.

⁹ Balamurugan V and Kataria JM (2004) The hydropericardium syndrome in poultry – a current scenario. *Veterinary research communication* 28 (2), 127 – 148

association of FAdV-4 with HPS as the sole agent responsible for causing the disease. The experimental reproduction of the disease in susceptible chicks, accompanied by the serological and electron-microscopic evidence also indicated that FAdV-4 is solely responsible for causing HPS (Ganesh et al 2001).”

This position is consistent with the statement by Rahul et al (2003)¹⁰ that “Inclusion body hepatitis-hydropericardium syndrome (IBH-HPS), also known as “litchi disease” is a common disease of broiler chicken caused by fowl adenoviruses of serotype 4.”

3.2.8. Surveys of poultry from around the world show a high level of adenovirus presence. Why single out Adenovirus 4 – there is no evidence either way that our native birds would not be susceptible to some other type of adenovirus.

MAFBNZ response: As indicated in Section 7.1.1 of the draft import risk analysis, the role of most group 1 avian adenoviruses as pathogens is not well defined with the exception of those associated with quail bronchitis and HPS. Furthermore (Section 7.1.3), group 1 avian adenoviruses are considered commonplace in New Zealand, and the majority of them have a limited role, if any, as primary pathogens.

However, Nakamura et al (1999)¹¹ commented that “Few avian viruses by themselves, if there is no concurrent infection, can cause mortality in adult chickens. Thus, hydropericardium syndrome adenovirus is a highly pathogenic strain in comparison with previously studied adenovirus strains isolated from cases of IBH”. More recently, Balamurugan and Kataria (2004)¹² commented that “From the economic and welfare standpoints, (FAdV-4) is a threat to the poultry industry, particularly the broiler industry, causing heavy mortality. As the HPS agent is highly pathogenic, it rapidly spreads horizontally among broilers, either by the oral-faecal route or by mechanical means, which leads to potential spread to other geographical areas, as when the disease emerged in India by spreading from neighbouring Pakistan through Jammu and Kashmir in 1993.”

The draft import risk analysis accepts that most avian adenoviruses are considered to have a limited role as primary pathogens. However, there is sufficient published evidence to conclude that exotic strains of FAdV-4 may act as a primary pathogen with potentially significant consequences for New Zealand’s poultry industry.

¹⁰ Rahul S, Kataria JM, Senthil Kumar N, Dhama K, Dash BB, Uma R and Praveen BN (2003) Application of polymerase chain reaction and fluorescent antibody technique for the diagnosis of inclusion body hepatitis-hydropericardium syndrome (IBH-HPS) caused by fowl adenovirus serotype-4. *Indian J Comp Microbiol. Immunol. Infect. Dis.* 24 (2) 137-142.

¹¹ Nakamura K, Mase M, Yamaguchi S, Shibahara T and Yuasa N (1999) Pathologic study of specific-pathogen-free chicks and hens inoculated with adenovirus isolated from hydropericardium syndrome. *Avian Diseases* 43, 414-423.

¹² Balamurugan V and Kataria JM (2004) The hydropericardium syndrome in poultry – a current scenario. *Veterinary research communication* 28 (2), 127 – 148

- 3.2.9. Countries are able to declare themselves free of HPAI or NDV six months after the last isolation of the agent, and New Zealand accepts this, but is apparently prepared to impose restrictions on trade based on the occurrence of a non-notifiable disease, the last reports of which may have been published 10 years ago.

MAFBNZ response: The details of certification requirements for imported egg powders will be determined when an Import Health Standard (IHS) for this commodity is developed.

Based on the options suggested in the draft import risk analysis and comments by reviewers of the risk analysis, the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ will produce an IHS for egg powders from all countries. The IHS will specify precisely what measures must be followed when importing this commodity. The final measures recommended will be based on science and the appropriate level of protection and stakeholders will be given the opportunity to comment on a draft IHS before it is finalised.

- 3.2.10. Saifuddin Md, Wilks CR and Murray A (1992) Characterisation of avian adenoviruses associated with inclusion body hepatitis NZVJ 40: 52-55, shows that the full range of avian adenoviruses were imported into New Zealand at the time to carry out the research, which was not done in a secure facility. A reading of this paper will therefore show that we are on insecure ground in claiming that Fadv 4 is not present here.

MAFBNZ response: The above paper cited by this stakeholder does indicate that a prototype strain of FAdV-4 (identified as virus KR5) was imported into New Zealand for research purposes. Given that there are no records of exposure of New Zealand birds to FAdV-4, MAFBNZ believes there to be no evidence of spread of this virus from the research facility to support such conjecture.

It should be noted that Mazaheri et al (1998)¹³ isolated and characterised FAdV-4 isolates from field cases of HPS in Ecuador and Pakistan and compared the pathogenicity of these viruses with the KR5 reference strain. Inoculation of 1-day-old chicks with the field isolates of FAdV-4 resulted in 100 percent mortality up to 10 days after inoculation whereas no mortality was seen after 15 days in chicks given an equivalent dose of the KR5 virus.

Hess et al (1999)¹⁴ used the restriction endonuclease *Pst*I to demonstrate five genotypes of FAdV-4 isolates. The KR5 reference strain was found to be the sole member of genotype I whereas FAdV-4 isolates recovered from clinical cases of HPS were found to belong to either genotype II (Mexico), III (Ecuador, Peru, and Chile), IV (Kuwait), or V (Pakistan and India).

The above studies clearly show that the FAdV-4 strain imported for research purposes should be considered distinct from the highly pathogenic strains associated with hydropericardium syndrome.

¹³ Mazaheri A, Prusas C, VoB M and Hess M (1998) Some strains of serotype 4 fowl adenoviruses cause inclusion body hepatitis and hydropericardium syndrome in chickens. *Avian Pathology* 27, 269-276

¹⁴ Hess M, Raue R, Prusas C (1999) Epidemiological studies on fowl adenovirus isolated from cases of infectious hydropericardium. *Avian Pathology* 28, 433-439.

3.2.11. The control measures proposed

Assurance that the eggs come from flocks in countries or geographic regions where Angara disease has not been recognized. *If it is not notifiable, and there is an unclear association between disease and an agent this offers little security.*

Source flock freedom from Fadv4 These PCRs are research tools, and are unlikely to be commercially available, as commercial interest Fadv4, or other adenovirus infections in likely source countries is lacking.

Heating – this is the obvious way to ensure that powders do not contain viable adenovirus of any type.

MAFBNZ response: Comments on the suitability of the options presented for risk management will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ when drafting any import health standards developed from this import risk analysis.

3.3. LORNA CRAIG, MAINLAND POULTRY LIMITED

- 3.3.1. Section 4.2 Processing: This reads that MAF assumes all countries will operate to the strict standards set out in EEC Directive 89/437 EEC and that there are controls to limit the quantity of eggshell in the final product.

MAFBNZ response: The egg powders considered in this risk analysis are only those prepared from clean eggs and contain less than 100mg/kg of eggshell remains, egg membrane and other particles. Egg powders which are not prepared from clean eggs or contain greater than 100mg/kg of eggshell remains, egg membrane and other particles would not be considered to comply with the commodity as defined in the draft import risk analysis.

- 3.3.2. What physical verification has MAF undertaken of processing standards in countries outside of the EU, Canada and the States i.e. 3rd World countries?

Is MAF confident that verification procedures by competent veterinary authorities outside of the EU will deliver well controlled processing regimes re time/ temperature, microbiological testing, testing of raw materials for veterinary drug residues and chemical residue (i.e. pesticides, dioxins) which may influence product safety?

... What physical verification / evaluation has MAF undertaken to deliver confidence and that any assurances are not just purely based from a desk top exercise. For example, are unannounced audits, independent verification and testing carried out for 3rd World egg processors?

MAFBNZ response: Certification issues such as these will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ responsible for drafting any import health standards based on the findings of this risk analysis.

- 3.3.3. Salmonellae species can also occur in the egg powders post processing through cross contamination if poor plant hygiene exists.

MAFBNZ response: NZFSA reviewed the draft risk analysis and commented that NZFSA is supportive of the Risk Analysis as any food safety concerns related to the importation of this product are addressed by the recommended sanitary measures.

Please also see Section 4.8 of MAF's review of submissions on the import risk analysis for Belovo egg powders (www.biosecurity.govt.nz/files/regs/imports/risk/belovo-egg-powder-rev-subs.pdf), which indicates that NZFSA reserves the right to intercept and test any food commodity for evidence of residues or human pathogens, and should violative residues or pathogens be detected, the NZFSA would place that product into an alert system and all imports would be tested until the problem no longer existed.

Further details of how the NZFSA sets policies, criteria and procedures to monitor the safety of imported food for human consumption can be found at www.nzfsa.govt.nz/imported-food/index.htm.

- 3.3.4. Whilst the EU has set standards for clean eggs for processing the growth of the industry has relied on using second grade eggs not fit for shell egg consumption which includes eggs with shell contamination.

MAFBNZ response: As indicated in Section 4.4 of the draft import risk analysis, the commodity assessed in the risk analysis was defined as imported egg powders are prepared from clean eggs (defined as visibly free from dirt or other foreign matter), or eggs which have been washed and dried to a standard equivalent to that described in for EEC directive 89/437/EEC Chapter V.

- 3.3.5. We have concerns that MAF assumes all countries will be following equivalent standards to EEC Directive 89/437 which forms the basis for many aspects of this risk analysis.

MAFBNZ response: Certification that imported egg powders comply with the commodity definition for this risk analysis will be considered by the Animal Imports and Exports Section of the Border Standards Directorate of MAFBNZ in drafting any import health standards based on the findings of this risk analysis.

- 3.3.6. Whilst not within the scope of this risk analysis what assurances can MAF provide that the animal welfare standards adopted in all countries meet the same high standards which exist here in New Zealand and in the EU?

MAFBNZ response: As noted, Animal Welfare Standards are outside the scope of this risk analysis. For reader's information, the World Organisation for Animal Health (OIE) Member Countries and Territories mandated the organisation to take the lead internationally on animal welfare and, as the international reference organisation for animal health, to elaborate recommendations and guidelines covering animal welfare practices, reaffirming that animal health is a key component of animal welfare. The Permanent Animal Welfare Working Group was inaugurated at the 70th General Session of the OIE in May 2002. New Zealand continues to play an active role in OIE Animal Welfare activities including chairing the Permanent Animal Welfare Working Group since its inception.

- 3.3.7. In addition, what assurances can MAF provide regards the risks associated with the packaging, storage and transport of imported products? These areas can act as potential pathways for disease transmission and should be included within the scope of the risk analysis.

MAFBNZ response: Requirements in relation to the primary packaging of imported products will be addressed during the development of any import health standards based on the findings of this risk analysis. The import health standard for sea containers from all countries (see: www.biosecurity.govt.nz/files/ihs/bmg-std-seaco.pdf) specifies the requirements to be met for the effective management of biosecurity risks associated with the importation of sea containers and associated packaging of containerised cargo into New Zealand.

3.4. LINDSAY G CHITTY, SCITEX NEW ZEALAND LIMITED

This submission describes a spray dried egg powder from Japan (Globigen), imported by the submitter for use as a key ingredient in a drench for neo-natal calves. No technical challenges to the draft import risk analysis are contained in this submission.

4. Appendix 1: Copies of Submissions

4.1. MICHAEL BROOKS, EGG PRODUCERS FEDERATION

The Egg Producers Federation of New Zealand (EPF), contactable at the above address, represents all commercial egg producers in New Zealand. Similarly, the Poultry Industry Association of New Zealand (PIANZ) represents almost all of the poultry breeding and processing companies in New Zealand. The PIANZ and EPF Veterinary Technical Committee has reviewed the Import Risk Analysis for the importation of egg powders from all countries into New Zealand (subsequently referred to as the IRA).

In addition, the New Zealand Feed Manufacturers Association (NZFMA), contactable at the above address, has also reviewed the draft IRA. The NZFMA represents almost all of the animal feed manufacturing companies in New Zealand, with NZFMA members producing in excess of 80 percent of animal feed produced in New Zealand.

The New Zealand Poultry Industry (including the EPF and PIANZ) and the NZFMA subsequently note the following points in this regard.

Chapter 4.2 Processing

Industry notes that it is possible for microbiological failure to occur during processing if the micro loading of the raw product is high or if there are inadequate CIP procedures. This may also include cross contamination of powders following the drying process if hygiene is poor, resulting in *Salmonella* species in the final product. Industry therefore requests that the IHS include some form of assurance that exporters can verify the effectiveness of processing standards and plant hygiene.

Chapter 4.3 Use of Imported commodities

The Industry notes the statement on page 3 that “Most of these commodities are used in the food industry, ...”. Industry acknowledges that in the main this is accurate. However Industry also notes that in some cases product which has expired or some other reason is no longer fit for human consumption may be disposed of in animal feeds. It is unclear from the current document whether this pathway has been considered by Biosecurity New Zealand or not, but the Industry believes that this potential pathway should be recognised as such and due consideration to the pathway given.

Additional issues

The New Zealand Poultry Industry acknowledges that the import risk analysis is not intended to address risks associated with the packaging, storage and transport of imported products and this should be covered under the import health standard. However, the industry would like to take this opportunity to highlight concerns around the potential for packaging of the egg products to be involved in the transmission of disease and requests that Biosecurity New Zealand take this into account when developing the import health standard. Similarly, the industry requests that the import health standard also include requirements to ensure that manufacturers can verify the processing temperatures claimed, that the product is stored and handled appropriately and there is no opportunity for cross contamination following processing.

Industry notes the comments with regards to the standards set out in EEC Directive 89/437, and requests that a minimum standard to comply with a standard similar to this one is included in the Import Health Standard. Similarly, Industry requests that the IHS include a requirement that the time-temperature standards laid out in the Import Risk Analysis as a minimum are met.

The New Zealand Poultry and Feed Industries appreciate the opportunity to comment on the draft IRA. We look forward to continued work with Biosecurity New Zealand on this topic to ensure the establishment of a robust and appropriate IHS.

Please do not hesitate to contact our offices should you have any queries.

Kind regards,
Michael Brooks
Executive Director

4.2. N. H. CHRISTENSEN, AVIVET LTD.

Submission on: Import Risk Analysis - Egg powders from all countries

Neil Christensen Avivet Ltd Registered specialist in avian medicine

4.3 Use of imported commodities

Whilst most of the imports will be of egg powders for human consumption, as a replacement for eggs or liquid egg in catering, it should be noted that some egg powders are used for nutraceutical purposes, in which egg powders from hens hyperimmunised against Cryptosporium, E coli O157 and salmonella are used in products sold as gut health enhancers and even to supplement colostrum in calf rearing (Rotagen Combo). The hens used for the production of these products, whilst not SPF, are held in highly controlled conditions

4.2 Processing

Table 2 refers to the processing of liquid eggs (pasteurization). The temperatures used in spray drying (up to 180°C) are noted in the analysis, but this does not appear to have given any “credit” in disease agent inactivation. A check should be made, but I believe that NZ egg pasteurization regs require 64°C for 2.5 minutes. The RMPs that I have evaluated use this time-temperature couplet.

6 Preliminary hazard list

Vertical transmission is described as transmission within or on the egg. I believe the two should be differentiated in any risk analysis. “On” the egg can be dealt with by sanitation of the eggs prior to breaking, but “in” the egg cannot. You apparently do this on page 11 for Marek's disease by stating that it is not transmitted within the egg. Any disease agent can be transmitted “on” the egg shell if it is not properly sanitized.

The presence of APMV2 and 3 on the list shows the subjective standards inherent in the risk analysis process as carried out by MAF. APMV2, 3. In a survey of a variety of species carried out by the (now) IDC, and published in 2001 (Stanislawek et al NZVJ 49(1) 18-23, 2001), antibodies to APMV 2 and 3 were detected in 1.7 and 2.6 percent of samples tested. Although the authors concluded that the titres were cross reactions with APMV1, they stated that APMV2 could not be excluded. Under different circumstances, I have seen these titres interpreted in other ways. In the context of this RA, this does not matter as the processing temperatures involved will inactivate the viruses anyway.

The two diseases that are identified as Hazards are Avian Influenza and Avian adenoviruses.

8. AVIAN INFLUENZA

The analysis and proposals for Avian influenza should be uncontroversial in the current international climate, and largely follow OIE guidelines..

7. AVIAN ADENOVIRUS

The adenovirus section does not reference the only comprehensive study of adenoviral disease in poultry carried out in New Zealand. See Md Saifuddin : the aetiology and

pathogenesis of Avian Inclusion Body hepatitis PHD thesis Massey university 1990, and the published papers derived from it.

Saifuddin Md and Wilks CR (1990) Development of an enzyme linked immunosorbent assay to detect and quantify adenovirus in chicken tissues Avian Disease 34

Saifuddin Md, Wilks CR and Murray A (1992) Characterisation of avian adenoviruses associated with inclusion body hepatitis NZVJ 40: 52-55

Saifuddin Md and Wilks CR (1990) Reproduction of inclusion body hepatitis in conventionally raised chickens inoculated with a NZ isolate of avian adenovirus NZVJ 38: 62-65

Saifuddin Md and Wilks CR (1990) Pathogenesis of an acute viral hepatitis in chickens Arch Virology.

The adenovirus section is open to criticism, and is likely to result in a degree of international skepticism about the risk analysis process in New Zealand, as Angara disease or Hydropericardium syndrome is the description of a clinical or post mortem entity rather than an agent. The people who worked on the condition in Pakistan in the early 1990s were unable to reliably fulfill Koch's postulates, and a number of adenovirus serotypes were isolated from cases of the syndrome. The fact that it is not notifiable makes it more likely that suppliers in countries where there is a more sophisticated veterinary research capability will publish reports of the occurrence of this type of disease. However, since the disease is now rather "old hat" it is unlikely to be reported. This is borne out by the dates of the references to Angara disease/Hydropericardium syndrome in Diseases of Poultry 11th Edition. Apart from reference to research work published in 1999 on the pathogenicity of the earlier Pakistan isolates, the others are all from the period 1987 to about 1992. Co-incidentally, it was in 1987 when parts of the New Zealand broiler industry was severely affected by IBH (see Christensen and Saifuddin Av Dis 622-630,1989), although FadV 4 was not isolated (types 1,8, 12 were). Currently, the severe IBH problems (some birds have hydropericardium) being experienced by broiler growers in the Pacific with birds hatched from eggs imported from both major NZ hatcheries would also give rise to some skepticism about the Adenovirus section in this IRA. Surveys of poultry from around the world show a high level of adenovirus presence. Why single out Adenovirus 4 – there is no evidence either way that our native birds would not be susceptible to some other type of adenovirus.

The lack of differentiation in the relativity of consequences of risk between notifiable disease and non-notifiable disease is also likely to give rise to some international skepticism. Countries are able to declare themselves free of HPAI or NDV six months after the last isolation of the agent, and New Zealand accepts this, but is apparently prepared to impose restrictions on trade based on the occurrence of a non-notifiable disease, the last reports of which may have been published 10 years ago.

Saifuddin Md, Wilks CR and Murray A (1992) Characterisation of avian adenoviruses associated with inclusion body hepatitis NZVJ 40: 52-55, shows that the full range of avian adenoviruses were imported into New Zealand at the time to carry out the research, which was not done in a secure facility. A reading of this paper will therefore show that we are on insecure ground in claiming that FadV 4 is not present here.

The control measures proposed

Assurance that the eggs come from flocks in countries or geographic regions where Angara disease has not been recognized. *If it is not notifiable, and there is an unclear association between disease and an agent this offers little security.*

Source flock freedom from Fadv4 These PCRs are research tools, and are unlikely to be commercially available, as commercial interest Fadv4, or other adenovirus infections in likely source countries is lacking.

Heating – this is the obvious way to ensure that powders do not contain viable adenovirus of any type.

4.3. LORNA CRAIG, MAINLAND POULTRY LIMITED

Our comments to the above import risk analysis are outlined below:

Section 4.2 Processing

This reads that MAF assumes all countries will operate to the strict standards set out in EEC Directive 89/437 EEC and that there are controls to limit the quantity of eggshell in the final product.

What physical verification has MAF undertaken of processing standards in countries outside of the EU, Canada and the States i.e. 3rd World countries?

Is MAF confident that verification procedures by competent veterinary authorities outside of the EU will deliver well controlled processing regimes re time/ temperature, microbiological testing, testing of raw materials for veterinary drug residues and chemical residue (i.e. pesticides, dioxins) which may influence product safety?

Our concerns are based on feedback from colleagues in the UK Egg Processing Industry, which relate to egg powders produced in India. Traders in Europe are wary of egg powders from this country because of issues relating to chemical residues arising from the fertilizers that this country uses.

What physical verification / evaluation has MAF undertaken to deliver confidence and that any assurances are not just purely based from a desk top exercise. For example, are unannounced audits, independent verification and testing carried out for 3rd World egg processors?

Whilst we accept that the EU has strict processing controls in addition to independent audits by key retailers we are less confident that processing standards and verification exist for 3rd World Countries.

In our experience microbiological failure of the processed product can occur even if the correct time and temperature regimes have been followed. This can happen if the raw product has a very high microbial loading prior to pasteurization, if the raw product is not temperature controlled and pasteurized promptly post breaking, if CIP and hygiene controls are not effective.

Microbiological failure can allow coliforms and salmonellae species to be present in final product prior to drying.

Salmonellae species can also occur in the egg powders post processing through cross contamination if poor plant hygiene exists.

Section 4.4 Commodity Definition Conclusion

Whilst the EU has set standards for clean eggs for processing the growth of the industry has relied on using second grade eggs not fit for shell egg consumption which includes eggs with shell contamination.

We have concerns that MAF assumes all countries will be following equivalent standards to EEC Directive 89/437 which forms the basis for many aspects of this risk analysis.

General Comments

Whilst not within the scope of this risk analysis what assurances can MAF provide that the animal welfare standards adopted in all countries meet the same high standards which exist here in New Zealand and in the EU?

In addition, what assurances can MAF provide regards the risks associated with the packaging, storage and transport of imported products? These areas can act as potential pathways for disease transmission and should be included within the scope of the risk analysis.

We look forward to your responses regards the comments outlined above outlining the areas of concern to allow egg powders from all countries to enter New Zealand.

Yours Sincerely,

Lorna Craig
Technical Manager

4.4. LINDSAY G CHITTY, SCITEX NEW ZEALAND LIMITED

4.3 Use of Imported Commodities

Most importers of egg powder import egg powder for human consumption with the possibility that scraps could end up in the chicken food chain. Scitex New Zealand Limited imports spray dried egg powder from Japan, called Globigen, containing specific antibodies as the key ingredient in Rotagen “Combo”, a registered animal remedy as a drench for neo-natal calves, with the ACVM group of the New Zealand Food Safety Authority. Rotagen "Combo" is registered pursuant to the ACVM Act, 1997, No A9928. See www.nzfsa.govt.nz/acvm for registration conditions.

Globigen is made by Ghen Corporation from eggs from hens that have been vaccinated against a range of specific pathogens. The egg powder that Scitex import contains antibodies against Bovine Rotavirus (G6 and G10 serotypes), Bovine Coronavirus, *Escherichia coli* K99, *Escherichia coli* K88, Salmonella typhimurium, Cryptosporidia, and others. The antigens that are used to vaccinate the hens are killed and special adjuvants are used to enhance the production of antibodies in the egg yolk.

The chickens that are used to produce these antibodies are from high health status farms, but are not of specific pathogen free status. They are free from Avian influenza virus, and to the best of their knowledge free from Angara disease.

4.2 Processing

The eggs are processed into powder by the following method. The eggs are cleaned, and broken. The content of egg shell in the dried product is less than 100mg / kilogram. The egg is pasteurized at 61°C for 30 minutes. The inlet temperature of the spray drier is 170°C ± 10°C for a few seconds, and the outlet temperature is 73°C ± 5°C for 30 minutes. Ghen Corporation are happy that with this processing methodology that the risk of microbes surviving is nil.

The imported Globigen is held in a secure Transitional Facility at Vetpak Limited, 150 Rickit Road, Te Awamutu, until it is processed.

The Globigen with the addition of kaolin, and dextrose to add bulk, and sodium bicarbonate as an antacid is manufactured into Rotagen “Combo”. Rotagen “Combo” is marketed through Veterinarians to prevent and treat neo-natal calf scours.

Last year approximately 135,000 doses of Rotagen “Combo” were sold. Sales are expected to substantially increase this year. This product is used as a drench to dose calves as a preventative and treatment against neo-natal calf scours. So it is most unlikely to be fed to chickens or other bird life. Rotagen “Combo” is a very effective product, proven by substantial trial work with Veterinarian and Farmer acceptance in New Zealand. Rotagen “Combo” has an important place in the New Zealand calf rearing industry by preventing and alleviating animal suffering. It is the only product available in New Zealand with a claim of preventing as well as treating neo-natal calf scours. It has no withholding period unlike antibiotics, so is very safe in the food chain.

Conclusion

It is important that this product remains available for veterinarians and farmers to prevent and treat neo-natal calf scours. Any loss of this product would be a severe blow to the calf rearing

industry and result in animal welfare issues. The risks of any exotic diseases arriving in New Zealand and establishing with this product are virtually non-existent because:

The origin of the eggs is from high health farms

The pasteurization and spray drying heat processes are more than adequate.

The chance of Rotagen “Combo” entering the chicken food chain in New Zealand is non-existent because this product is a drench for neo-natal calves.

I would very much like to be kept informed of any developments in regard to this risk analysis.

Lindsay G Chitty B.V.Sc