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Australian import conditions for whole egg, egg yolk, and egg white powder

Final report

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Department of Agriculture, Fisheries and Forestry
GPO Box 858 Canberra ACT 2601
Telephone 1800 900 090
Web agriculture.gov.au

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Acknowledgement of Country

We acknowledge the Traditional Custodians of Australia and their continuing connection to land and sea, waters, environment and community. We pay our respects to the Traditional Custodians of the lands we live and work on, their culture, and their Elders past and present.

Executive Summary

The importation of egg white, whole egg and egg yolk powders into Australia is permitted subject to biosecurity conditions created to manage the associated biosecurity risks. Conditions include a restriction of eligible countries for sourcing of eggs and/or manufacturing, based on prior assessment of their health and production systems. As with other commodities, countries can apply to become approved source countries subject to an assessment by the Department of Agriculture, Fisheries and Forestry.

The department conducted a technical review of the import conditions for egg powders (whole egg, egg yolk and egg white) into Australia. The objective of the review was to determine whether changes to the import conditions, in line with standard industry practices, to ensure they were least restrictive would continue to manage biosecurity risks consistent with Australia's appropriate level of protection (ALOP).

The review focused on the two primary biosecurity hazards associated with this commodity, avian orthoavulavirus 1 (AOAV-1) and avian influenza virus (AIV), and the thermal treatments required to inactivate them. Appendix 1 provides the risk matrix and a brief explanation of the department's process for assessing overall biosecurity risk.

These two viruses represent the most heat resistant and geographically widespread hazards of concern for these commodities. Other hazards of concern, such as exotic salmonellas, are managed by thermal processes sufficient to inactivate AOAV-1. More thermally resistant hazards such as infectious bursal disease virus are not transmitted inside eggs and so do not require risk management in egg powders.

As part of this review, the department contracted CSIRO to produce a report (Scott, 2021) on the current scientific literature regarding the likely presence of the hazards (AOAV-1 and AIV) in eggs that are manufactured into egg powders, and the current scientific knowledge on the effectiveness of thermal processes applied to egg powders to inactivate the hazards should they be present.

The review found that the likelihood of viable virus being present in egg powders is lower than previously assessed, and that thermal treatment requirements for egg powders could be reduced while still providing sufficient biosecurity risk management to meet Australia's ALOP. Factors assessed include the likelihood of viable virus being present in the commodity, additional standard thermal treatments applied to the product by industry, and the data available to validate the effectiveness of various thermal treatments to inactivate the hazards of biosecurity concern. For this commodity, management of potential thermostable AOAV-1 strains are the determining factor in the recommendations for risk management.

This review recommends the existing import conditions continue to be accepted and the following new heat treatment requirements be added as alternative options:

Whole egg and egg yolk powder conditions:

- Require heat treatment of the product by
    - Pasteurisation of liquid whole egg and egg yolk for a minimum of 65°C for 6 minutes.

Egg white powder conditions:

- Require heat treatment of the product after spray-drying by ‘hot-boxing’ for a minimum of 65°C for 5 days.

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Detailed Assessment

1.1 Egg powder production

- It is unlikely that eggs will be sourced from flocks infected with either AOAV-1 or AIV (in approved countries).
    - Flocks infected with either AOAV-1 or AIV will have their reproduction affected (decreased egg production and egg defects), thereby producing clinical signs to alert producers of disease presence.
    - Biosecurity controls are typically applied by the veterinary services of approved countries as soon as clinical signs of such diseases are identified (e.g. destruction or vaccination, contact tracing and prevention of using those eggs in the food supply chain).

- Virus replication in eggs selected for the production of egg powders is unlikely.
    - Eggs used in the production of egg powders (and eggs for human consumption in general) are typically unfertilised (because of industry structure, including very high sexing accuracy rates).
    - The likelihood of fertilised eggs being in these supply chains is quite low and therefore miniscule in volume.
    - Viruses require living cells to propagate. Actively dividing cells are not present in unfertilised eggs, so there is unlikely to be an increase in virus concentrations in these source eggs.

- For whole egg and egg yolk powders, standard industry practices will provide some reduction of the amount of viable AIV and AOAV-1 present.
    - It is standard industry practice to pasteurise liquid whole egg and egg yolk prior to spray drying. Canada, and the United States use a minimum of 60°C for 3.5 minutes for egg yolk, and 64°C for 2.5 minutes for whole egg pulp. In the European Union, standard temperatures are higher, typically 65°C for 5 minutes or more (Belyavin, 2016; EFSA, 2014; Lechevalier et al, 2013).
        - Pasteurisation is applied to liquid product which is generally homogenised. This ensures any pathogens in the product are subjected to moist heat. Moist heat is more effective at pathogen inactivation than dry heat.
    - Spray drying also occurs which, whilst not being a reliable means of thermal inactivation of pathogens on its own, does significantly reduce the water content of the product. Desiccation reduces virus viability, so spray drying contributes to overall biosecurity risk reduction.

- For egg white powders, standard industry practices will provide at least 5 to 6-log reduction of infectivity of any AIV present. For AOAV-1, industry standards will provide at least 2 to 3-log reduction at the lower end of the standard ranges (55°C for 3 days) (Scott, A 2021).
    - Egg white powders are 'hot-boxed' after spray drying, so the heat treatment is applied to dry product.
        - Pasteurisation of liquid egg white may be performed prior to spray drying, at a milder time/temperature combination than whole egg and egg yolk (e.g. 55-57°C for 2-5 minutes in the European Union, at least 3.5 minutes in the United States). However, this scenario is not common in the production of egg white powders and is not considered in this assessment, the assumptions (and subsequent requirements) are based on common industry practises.

  - Hot-boxing temperatures and times vary depending on the desired properties of the egg white powder. Temperatures of 55-65°C for 3-5 days is the common range, though 80°C for 5-10 days may be preferred by some manufacturers to achieve preferred final product properties (EFSA, 2014; Lechevalier et al, 2017).

1.2 AIV inactivation

- AIV is somewhat unlikely to be present in significant quantity in or on the eggs used for production of egg powders.
  - While it is possible for an egg laid by a bird infected with AIV to contain AIV in both the yolk and albumin, viral replication requires actively dividing cells to be present. As described above, the eggs used for production of egg powders are unfertilised and are not incubated; they do not contain actively dividing cells. Therefore, high viral titres cannot be present in the eggs used to produce egg powders.
  - Similarly, while a bird infected with AIV can shed virus in faeces and it is possible for these faeces to contaminate the shell of an egg that bird lays, it is standard industry practice to reject dirty eggs or to clean any contamination off the shell before they are used to produce egg powders.
  - Finally, birds infected with AIV typically show clinical disease. In the case of highly pathogenic AIV, signs are typically severe and include a large drop in egg production and high numbers of deaths in the flock. Thus, the inherent nature of the disease itself limits the likelihood for the virus to be present in the egg powder supply chain.

- Any AIV that is present in or on the eggs is likely to be inactivated by standard industry practices used in the manufacture of egg powders. These standard practices, described above, are likely to provide a 6 to 7-log reduction in infectivity of virus in liquid yolk and whole egg. For egg white powder, the higher ends of industry standard practices are likely to provide a 6-log reduction in infectivity of virus.
  - The World Organisation for Animal Health Terrestrial Animal Health Code (WOAH Code) recommends liquid whole egg be treated at 60°C for 3.1 minutes to achieve a 7-log virus reduction, and that dried egg white is treated at 54.4°C for 50.4 hours to achieve a 7-log virus reduction (WOAH 2022a).
  - Some earlier studies suggest longer times at 55-60°C are required for AIV inactivation. For example, Lu et al (2003) found that 60°C for 10 minutes was required to inactivate AIV in allantoic fluid; Lang et al (1968) found 56°C for 30 minutes worked for one strain but 60 minutes was required for another (in allantoic fluid). However, these studies are referring to *total infectivity* in chicken embryos in a laboratory setting. The titre reduction sufficient to preclude infection in a real-world, commodity-fed, live animal scenario is much more readily achieved.
  - Scott (2021) identified studies showing that common industry pasteurisation of egg white powders can be expected to provide 6 to 7-log reductions in AIVs present (Swayne & Beck, 2004; Thomas & Swayne, 2009). A 7-log reduction in HPAI virus in dried egg white was found after 2.6 days (62.4 hours) at 54.4°C by Thomas & Swayne (2009).

1.3 AOAV-1 inactivation

- AOAV-1 is somewhat unlikely to be present in significant quantity in or on the eggs used for production of egg powders.

  - Like AIV, while it is theoretically possible for an egg laid by a bird infected with AOAV-1 to contain AOAV-1 in both the yolk and albumin, viral replication requires actively dividing cells to be present. The eggs used for production of egg powders are unfertilised and are not incubated; they do not contain actively dividing cells. Therefore, high viral titres cannot be present in the eggs used to produce egg powders.
  - While a bird infected with AOAV-1 can shed virus in faeces and it is possible for these faeces to contaminate the shell of an egg that bird lays, it is standard industry practice to reject dirty eggs or to clean any contamination off the shell before they are used to produce egg powders.
  - Additionally, vaccination of poultry for AOAV-1 is common practice and decreases contamination of eggshells (Scott, 2021).
  - Finally, infection with AOAV-1 typically leads to a dramatic decrease in egg production and an increase in egg defects (Scott, 2021). This is in addition to increased sudden deaths in a flock. Thus, the inherent nature of the disease itself limits the likelihood for the virus to be present in the egg powder supply chain.

- Any AOAV-1 that is present in or on the eggs is likely to be inactivated by standard industry practices used in the manufacture of egg powders. However, the higher end temperatures of common commercial thermal processing for egg powders are likely required to reliably provide a 5 to 6-log reduction in infectivity of thermostable AOAV-1 strains.
  - Standard industry practices are likely to provide a 5 to 6-log reduction in infectivity for thermolabile strains of AOAV-1 virus in liquid yolk and whole egg (Scott, 2021).
    - There is also good evidence of a 5.6-log reduction after 3 minutes at 65°C and complete inactivation at 6 minutes (Alexander & Manvell, 2004).
  - The higher end of standard practices are likely required to assure a 5 to 6-log reduction is achieved for thermostable AOAV-1 strains.
    - Standard practices in the production of egg white powder are expected to produce a few logs reduction in AOAV-1 infectivity for any virus present. Scott (2021) reports that 55°C for 48 hours on spray dried egg white powder is likely to provide a 6-log reduction, although there is no definitive data available to confirm this.
    - This finding is extrapolated from a study showing the time for a single log reduction. This study was not conducted on a thermostable strain and some AOAV-1 strains may have biphasic inactivation curves or require higher thermal treatments to produce sufficient inactivation (Alexander & Manvell, 2004; Thomas et al, 2008). Despite these potential complicating factors, these limitations were not considered significant enough to offset the risk management provided by the standard industry processes and the likely very low to negligible viral pre-load in the eggs used to manufacture egg powders.
    - There is minimal literature directly addressing the inactivation of thermostable strains but Scott (2021, reviewing Lomniozi, 1975, and Wambura et al, 2006) reports on a 2 to 3-log infectivity reduction at 50-55°C for 10 minutes.
    - The WOAH Code recommends dried egg white be heat treated at 57°C for 50.4 hours to achieve a 7-log reduction, however the underlying data for this recommendation was not located to compare with the above findings (WOAH 2022b).

1.4 Risk assessment

- The likelihood of AIV or AOAV-1 entering Australia in egg powder that has been produced in accordance with the upper limits of standard industry practices described above, and then an infective dose being exposed to susceptible species, is considered to be **extremely low**.
    - (Using average or lower ends of industry standards, the likelihood would instead be considered as *very low*. In the absence of these well-established processing standards the likelihoods would be higher*).*
- The likely consequences if AIV or AOAV-1 were to establish and spread and cause an outbreak in Australia are considered to be **moderate** to **high**.
    - This consequence rating range is based on other departmental work including the Generic import risk analysis report for chicken meat: final report (Biosecurity Australia 2008), the Import risk review for psittacine birds from all countries – draft review (DAWE 2020), and internal bespoke commodity risk assessments. Whilst the more likely outbreak scenario will differ per commodity, the overall likely consequence is estimated to be in this range given the known effects from historical disease responses and export market access losses. An estimate of **high** will be used in order to be conservative.
- Taking these ratings and using the risk estimation matrix provided in Appendix 1, to combine the **extremely low** likelihood of entry and exposure with the **high** likely consequences of establishment and/or spread, the overall risk is estimated to be **very low**. This achieves Australia's appropriate level of protection (ALOP).

1.5 Conclusions

- Egg powders produced using the upper limits of standard industry practices described above meet Australia's ALOP. This means that revising Australia's current import conditions to be consistent with these standard industry practices will manage the biosecurity risks associated with the importation of egg powders.
- This revision of the egg powder import conditions will be less restrictive and support trade while continuing to meet Australia's ALOP.
    - Alternative conditions that can provide equivalent biosecurity risk protection, supported by evidence, will continue to be considered by the department (e.g. countries claiming freedom from AOAV-1 of biosecurity concern).
- The following key points were taken into account:
    - Viable AOAV-1 and/or AIV are unlikely to be present in significant quantities in fully finished egg powders.
    - Standard industry processes provide some risk mitigation against any virus present.
    - The standard industry processes used in the assessment are those from the European Union, Canada, the United States, New Zealand, and Australia.
        - Whilst this risk assessment does not specifically address individual country eligibility, the inherent risk mitigation of this commodity does allow for countries with similar standard industry processes to be assessed for access in a more streamlined manner.
        - Countries outside the above group are not precluded from eligibility to export egg powders to Australia, however, approval would involve a more rigorous assessment to ensure the assumptions of this risk assessment are applicable. This assessment would include examination of a prospective exporting country's standard egg powder production processes, industry

systems and structure, and the level of oversight provided by the government veterinary authority.

- To sufficiently inactivate thermostable AOAV-1 strains, it is prudent that thermal treatments that are at the upper end of the assessed industry standard practices are employed to mitigate this risk.

1.6 Current Australian requirements and proposed changes

Whole egg and egg yolk powder conditions:

Current thermal requirements (will remain):

- A statement that the spray dried egg powder has been heated with a dry heat to a minimum core temperature of not less than 70°C for at least 120 minutes.

Proposed thermal requirements (to be added as an alternative option):

- A statement that the liquid whole egg or egg yolk was pasteurised for a minimum of 65°C for 6 minutes prior to spray drying.

Egg white powder conditions:

Current thermal requirements (will remain):

- The spray dried egg white has been 'hot boxed' in its final packaging for a minimum of:
    - 70°C for at least 7 days, or
    - 62°C for at least 10 days.

Proposed thermal requirements (to be added as an alternative option):

- The spray dried egg white has been 'hot boxed' in its final packaging for a minimum of 65°C for 5 days.

Appendix 1

Australia maintains a conservative approach to managing biosecurity risks. This is reflected in Australia's appropriate level of protection (ALOP) which is described in section 5 of the *Biosecurity Act 2015* as providing a high level of protection aimed at reducing biosecurity risks to a very low level, but not to zero.

This review examined the current production pathways and common industry heat treatment processes for manufacturing egg powders in order to determine the overall biosecurity risk associated with their import. This involved the assessment of likelihood of entry and exposure of diseases of biosecurity concern associated with the importation of egg powders. The estimate of likely consequences of establishment and/or spread of these diseases, once exposure of susceptible species occurred, was then combined with the likelihood of entry and exposure using the risk estimation matrix in Figure 1. This resulted in the estimate of the overall risk.

Following risk assessment, if the overall risk was 'negligible' or 'very low', then the processes applied achieved Australia's ALOP. If the overall risk exceeded 'very low' and was 'low', 'moderate', 'high' o~~f~~r 'extreme' then additional risk management measures would need to be applied to meet Australia's ALOP.

Figure 1 Risk Estimation Matrix

Likelihood of entry and exposure						
High	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Low	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
Very low	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
Extremely low	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
Negligible	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk
	Negligible	*Very Low*	*Low*	*Moderate*	*High*	*Extreme*

Likely consequences

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