



Australian Government
**Department of Agriculture
and Water Resources**

Rural and Regional Affairs and Transport References Committee

Inquiry into biosecurity risks associated with the importation of seafood and seafood products (including uncooked prawns and uncooked prawn meat) into Australia

Submission from the Department of Agriculture and Water Resources

24 August 2017

The Department of Agriculture and Water Resources is pleased to provide this submission to the Rural and Regional Affairs and Transport References Committee to inform the committee of measures that have been implemented since the release of the interim report on the biosecurity risks associated with the importation of seafood and seafood products (including uncooked prawns and uncooked prawn meat) into Australia.

Actions to improve consistency in WSSV testing in approved Australian laboratories

Prior to the suspension of imports of raw prawns announced on 6 January 2017, all batches of raw prawns imported into Australia were required to be tested for the presence of white spot syndrome virus (WSSV) and yellow head virus (YHV) by a laboratory approved by the department for this purpose.

Three laboratories (Agrigen, Advanced Analytics Australia and the Elizabeth Macarthur Agricultural Institute) were approved by the department to conduct testing for the presence of WSSV and YHV in imported prawns. All three laboratories were accredited by the National Association of Testing Authorities (NATA) and all used a testing procedure based on the World Organisation for Animal Health (OIE) recommended method for WSSV testing.

It became apparent in late 2016 that significant quantities of imported prawns infected with WSSV were present in Australian retail outlets despite the requirement for inspection, sample collection and virus testing. In response, the department instituted an enhanced inspection and testing regime. Under this regime, consignments of prawns were inspected under seals intact conditions and samples taken randomly by biosecurity officers. If the prawn samples tested positive at the screening laboratories, the consignments were not permitted entry and were required to be re-exported, cooked or destroyed. Prawn samples that tested negative for the presence of WSSV at screening laboratories were subject to confirmatory testing at the Australian Animal Health Laboratory (AAHL).

The objectives of having AAHL conduct confirmatory testing of prawns that had tested negative for WSSV at screening laboratories were to:

- (a) ascertain whether the large quantities of WSSV infected prawns found in retail outlets was related to failures or inadequacies in WSSV testing by the screening laboratories
- (b) provide a higher level of confidence that imported prawns were free of WSSV before they were released from biosecurity control.

The AAHL confirmatory testing did not show that screening laboratory testing was a primary reason for the large quantities of WSSV infected prawns in retail outlets, but it did help identify that there were some inconsistencies in testing results across laboratories. Some prawns were tested negative at screening laboratories, then tested positive for WSSV at AAHL under the enhanced testing regime. This was mainly because each laboratory had been using slightly different testing procedures even though they were all based on the OIE recommended method. In particular, laboratories were using different cut-off values to determine negative results.

The WSSV testing method recommended by the OIE is brief and the approved laboratories implemented the method with variations. It is not unusual for different laboratories to modify the OIE recommended method and implement it with minor variations, based on their experiences and the purposes of the testing (i.e. research or disease exclusion). Although the number of cycles for the reaction is mentioned in the OIE manual, the cut-off value for a negative result is not specified. The department identified that a more prescriptive and standardised procedure is required for biosecurity risk management purposes. Details for

critical steps should be specified in this standard procedure to minimise the possibility of variation in results between laboratories performing a biosecurity regulatory function.

The prawns which were tested and reported as negative by the screening laboratories, and later tested positive at AAHL under the enhanced testing regime, all had very low levels of WSSV infection. This was indicated by the high number of cycles required to reach a threshold (cycle threshold, or Ct value) to indicate that WSSV material was present in the test sample. Inconsistency in testing procedures applied at screening laboratories may have contributed to approximately 20% of imported prawns detected with very low levels of WSSV infection found in the retail outlets. However, the inconsistency between screening laboratories can't explain why 60% of imported prawns sampled from retail outlets were found to have high levels of WSSV.

The department has now reviewed the laboratory testing program and developed a plan to further strengthen and improve the quality of this program. This plan includes the following four aspects:

1. Develop a more standardised testing procedure for WSSV

The department has been working with all the laboratories and NATA to develop a more standardised testing procedure for WSSV. The aim is to minimise between-laboratory inconsistencies and ensure a more robust testing procedure is used by all the laboratories.

The first step in developing this procedure was the department and NATA co-hosting a workshop on 17 May 2017 with the three approved screening laboratories and AAHL. At the workshop, it was agreed a more standardised testing protocol should be developed and adopted by all laboratories, including the use of a consistent cut-off value for determining positive or negative results across all laboratories. The department agreed to lead the development of a standardised testing procedure for WSSV and requested all screening laboratories and AAHL implement the main outcomes of the workshop that related to the testing procedure, while the standardised testing procedure was being finalised.

From 7 July 2017, approved laboratories have been required to implement the following actions for WSSV testing of imported prawns:

- The real-time PCR must run for 45 cycles.
- A *negative result* is where there is no amplification of WSSV DNA within 45 cycles (Ct) in all 13 samples.
- A *positive result* is where there is detectable amplification of WSSV DNA before 40 cycles (Ct<40) in any one of the 13 samples.
- A *suspected positive result* is where there is detectable amplification between 40 and 45 cycles in any one of the 13 samples
- When a laboratory determines one or more suspected positive results in a batch, the laboratory should advise the importer to request confirmatory testing from AAHL.
 - Note, only those samples testing suspected positive would be subject to confirmatory testing, not samples that tested negative at the approved laboratories.
- If the importer chooses not to request confirmatory testing for suspected positive samples, a batch of prawns containing one or more suspected positive samples will be reported as positive for WSSV.
- In cases where there are positive and suspected positive samples in the batch, the importer also has the option to request confirmatory testing for those samples at AAHL.

- For confirmatory testing at AAHL, any sample that produces a typical amplification curve before 45 cycles is reported as positive.

Since the workshop, the department has been working on the standardised testing procedure in consultation with all laboratories and NATA. This procedure includes the aspects listed above that have been implemented by labs from 7 July 2017.

The testing procedure is expected to be approved by the department before the end of August 2017. Once approved, the testing procedure will be adopted by all approved laboratories testing imported prawns. NATA will assess the implementation of the procedure in each laboratory. The department will also provide the testing procedure to relevant trading partners and it will be made available upon request to other Australian laboratories that may be considering providing testing services for imported prawn products. The department has also provided comments to the OIE, recommending the WSSV section in the OIE manual of diagnostic tests be updated.

2. Develop a laboratory testing quality assurance program for WSSV

In addition to the Australian National Quality Assurance Program (ANQAP) for various aquatic animal diseases, the department is developing an additional quality assurance program for WSSV to monitor the performance of approved screening laboratories. In essence, this program will be a WSSV-specific proficiency testing program that is undertaken more frequently than the current program under ANQAP. The department will consult with screening laboratories, AAHL and NATA to develop the program plan.

3. Update the policy for laboratory approval

The department is also reviewing and updating the *Policy for the suitability of laboratory facilities for testing imported aquatic animals and/or their products for biosecurity purposes*.

4. Consolidated policy for testing of imported prawns

The department is also developing a consolidated policy document covering major steps in risk management of the sampling and testing of imported prawns. This document will describe and provide rationale about the main steps such as sampling, nomination of an approved laboratory for testing, transport of samples, testing of samples, reporting of results, and the confirmatory testing procedure. This document will be used as the basis for communication with stakeholders.

The department anticipates these four activities will be completed by mid-October 2017 with implementation already commenced.

Communication with trading partners

Australia's enhanced import conditions for uncooked prawns require the government competent authority of prawn exporting countries to certify that each batch of uncooked peeled prawns has been found, post-processing, to be negative for WSSV and YHV. This is based on a sampling and testing method recognised by the OIE for demonstrating absence of disease.

The department has communicated this information to trading partners and industry participants through direct correspondence with the competent authorities, WTO SPS notifications (which provides a link to the model health certificate), the department's agriculture counsellors, Biosecurity Advice notices placed on the department's website and through the weekly updates circulated by the department's Prawn Liaison Officer.

Once finalised, the department will be providing trading partners with the final standardised testing procedure developed for on-arrival WSSV testing. Trading partners will be advised

that implementation of this standardised testing procedure in exporting countries is recommended to harmonise WSSV testing conducted pre-export and on-arrival in Australia.

The department is also planning visits to major prawn exporting countries to discuss aquatic animal health controls and systems in place to manage the biosecurity risk of prawns and prawn products exported to Australia. These visits will provide an opportunity for the department to clarify Australia's enhanced import conditions and to discuss technical details on pre-export or on-arrival testing for WSSV. Representatives of the department visited Thailand in late June 2017 and are planning a visit to Malaysia in early September 2017. Visits to all other major trading partners will occur over the next 6 to 12 months.

In collaboration with AAHL, the department is also developing a short technical training program in real-time PCR techniques. This technical training will be offered to laboratory technicians responsible for WSSV testing in major prawn exporting countries. The proposed training will have a focus on the standardised testing procedure for WSSV to further increase the consistency in WSSV testing procedures applied by exporting countries pre-export and by Australia's approved screening laboratories.

Lapsing of suspension of imports of uncooked prawns

The *Biosecurity (Suspended Goods – Uncooked Prawns) Determination 2017* (Determination), made on 6 January 2017, suspended imports of some uncooked prawns and prawn products for human consumption for a period of six months. The suspension allowed the department to conduct a review of risk management measures for uncooked prawns and implement new measures where necessary. The suspension of imports under the Determination lapsed on 6 July 2017.

In the period between 6 January 2017 and 6 July 2017, the Determination was varied a number of times to allow trade in prawns and prawn products which had been assessed and found to have an acceptably low level of biosecurity risk to meet Australia's appropriate level of protection (ALOP).

This approach enabled the resumption of safe trade in all prawn products during the suspension, except for raw prawns (that is those that are uncooked, frozen and have had the head and shell removed (the last shell segment and tail fans permitted)) which were the last remaining commodity within the scope of the Determination to be assessed.

Enhanced import conditions

When suspension of trade for raw prawns lapsed on 6 July 2017, the department implemented enhanced import conditions for all types of raw prawn products to ensure that imported prawns would meet Australia's ALOP.

Since 7 July 2017, uncooked prawns, marinated prawns, and Australian prawns processed overseas in a non-Australian government audited supply chain, have been consolidated into one product class.

- Prawns within this class must be uncooked, frozen and have had the head and shell removed (the last shell segment and tail fans permitted).
- Exporting countries are required to certify that these prawns have been found to be free of WSSV and YHV based on sampling and testing methods recognised by the World Organisation for Animal Health (OIE). Pre-export sampling and testing is to be conducted post-processing.

- The prawns are also subject to 100 per cent secure seals intact inspection on-arrival in Australia and testing for WSSV and YHV at an Australian screening laboratory. Only those prawns which pass testing for both WSSV and YHV will be released from biosecurity control.

Australian prawns processed overseas through an Australian Government approved supply chain (as exists for Thailand) will not be subject to pre-export testing. However, this product will continue to be tested on-arrival for WSSV and YHV and must pass testing before being released from biosecurity control.

Breaded, battered and crumbed prawns will not be subject to pre-export or on-arrival testing. However, this product will continue to be subject to 100 per cent secure seals intact inspection on-arrival to ensure minimum coating requirements are met.

Whole (head-on) prawns may only be imported from countries, zones or compartments confirmed to be free of all pathogens of biosecurity concern. These pathogens currently include WSSV, YHV and Taura syndrome virus, and if the product is not frozen, necrotising hepatopancreatitis bacterium (NHPB). Currently, only New Caledonia is approved to export whole head on prawns to Australia.

Changes to import permits for prawns

In preparation for the suspension lapsing on 6 July, 2017, the department wrote to all holders of import permits for prawns and prawn products to advise of its intentions to vary, suspend or revoke permits that had been affected by the suspension. By 7 July 2017 a total of 213 permits had been varied to reflect the enhanced conditions. Of the varied permits, 205 cover product from countries that have provided written confirmation to the department that they can meet the enhanced import conditions. The other 8 permits relate to countries that have not yet provided confirmation that they can meet Australia's enhanced import conditions. Prawns are not able to be imported until the exporting countries have confirmed that they can meet the enhanced import conditions. Work continues with trading partners to seek assurances and to finalise agreed health certificates that will support the trade.

Imports since the lapsing of the trade suspension

As at 22 August 2017, 10 consignments have been imported under the enhanced import conditions. Seven consignments have tested negative for white spot syndrome virus (WSSV) and yellow head virus (YHV) and have been released from biosecurity control. Three consignments are currently held under biosecurity control pending WSSV and YHV test results.

Inspection and Training

Updated instructional material has been implemented which addresses the inspection processes for the following commodities under the arrangements which came into effect on 10 July 2017:

- inspecting uncooked, unprocessed prawn and prawn products (including marinara mix)
- uncooked marinated prawns and prawn products (both wet and dry)
- Australia –origin uncooked prawns processed in an overseas facility and re-imported into Australia

All relevant staff have been formally trained on these arrangements and there is an ongoing verification process underway to ensure that these are being consistently applied at a national level.

To ensure a consistent approach to random sampling, a new approach is currently being trialled which seeks to reduce the risks associated with deliberate circumvention of controls.

Given the significant additional workload associated with the enhanced inspection arrangements for prawns, the department sought and gained approval for 105 additional staff. Of these 74 staff are associated with frontline inspection and assessment activities and the remainder are associated with compliance, enforcement, policy and supporting roles.