



Australian Government

**Department of Agriculture,
Fisheries and Forestry**

INTERIM INSPECTOR GENERAL OF BIOSECURITY

**An examination of what caused a consignment of imported
raw peeled prawns that tested positive for White Spot
Syndrome Virus (WSSV) to be mistakenly released into
Australia by the Biosecurity Services Group (BSG)**

**INTERIM INSPECTOR GENERAL OF BIOSECURITY
INCIDENT REVIEW
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BACKGROUND

On 28 September 2010, the Deputy Secretary, BSG and Executive Director, Australian Quarantine and Inspection Service (AQIS) requested independent advice (an Incident Review or the review) from the Interim Inspector General of Biosecurity (Interim IGB). The request was in relation to an incident involving the mistaken release into Australia by a BSG officer of a consignment of raw peeled prawns intended for human consumption that had tested positive for WSSV.

The Incident Review was conducted in two parts. This paper outlines the outcomes of part one of the review. A separate paper will be prepared in relation to part two.

OBJECTIVES

To determine:

- what caused a consignment of imported raw peeled prawns that tested positive for WSSV to be mistakenly released into Australia by BSG
- whether any improvements are required to BSG's current work practices to further mitigate the risk of this event occurring again in the future.

SCOPE

Part one of the review was limited to an examination of the inspection, testing and release from quarantine processes which resulted in the release of the consignment of raw peeled prawns in question.

METHODOLOGY

The methodology for part one of the Incident Review included:

- conducting an entry meeting to establish background information regarding the release of the consignment
- interviewing relevant BSG staff to understand the work undertaken to date in reviewing the circumstances which lead to the release of the infected consignment of raw peeled prawns
- obtaining copies of the import conditions relating to raw peeled prawns and the work instructions in relation to the inspection, testing and release of consignments of raw peeled prawns
- conducting discussions with relevant BSG staff of the processes regarding the inspection, testing and release of consignments
- obtaining copies of documentation relating to the inspection, testing and release of the consignment of raw peeled prawns in question
- through a combination of an examination of documentation regarding the consignment and an interview of staff involved in the inspection, testing and release of the consignment, evaluating the extent to which established procedures were followed and determine the circumstances which lead to the consignment being mistakenly released
- selecting a sample of 21 further prawn consignments released during the period 1 August 2010 to 30 September 2010 and examining laboratory reports and AQIS

Import Management System (AIMS) release records to determine whether any consignments with positive test results for WSSV had been incorrectly released

- conducting an exit meeting with relevant staff within the Central East Region Office
- conducting a preliminary briefing with the General Manager, BSG Quarantine Operations
- conducting a briefing with BSG stakeholders.

This review was undertaken on behalf of the Interim IGB by an external provider in conjunction with the Biosecurity Secretariat.

FINDINGS

Overview of release processes

Release processes for raw peeled prawns involve an administrative officer printing a copy of laboratory testing results that have been received by BSG directly from the testing laboratory via the post-inspections email in-box and passing these reports to BSG post-inspections officers for processing in AIMS. Processing involves either releasing the consignment if test results are negative, or, holding the consignment pending advice regarding re-export, destruction or cooking in a Quarantine Approved prawn processing facility if the test results are positive.

Laboratory test result emails are also copied to the post-inspection team supervisor as a back-up if issues are experienced in accessing the generic email in-box. These are, however, not consistently checked.

The importer nominates the BSG-accredited testing laboratory that will undertake the testing of the prawns when the 'Raw Prawn Sampling Declaration' is completed. The importer is also responsible for meeting the costs associated with the laboratory testing and is provided with a copy of the report directly by the laboratory.

Appendix A provides an overview of the inspection, testing and release processes relating to consignments of prawns. *Appendix A* also lists the chronology of events in relation to the consignment in question, as provided by BSG.

As the majority of processes relating to the release of prawns are manual, there is an increased risk that human error may periodically occur and this appears to be the primary cause for the mistaken release of the consignment of prawns in question. This is further discussed in the findings provided below.

Examination of processes and circumstances surrounding the release in question

During the examination, consideration was given to whether there may have been any factors which might have contributed to an increased risk of procedural oversight or human error. The procedures highlighted that:

- the processing of the laboratory report and the updating of AIMS occurred early in the morning (just after 7.00 am) on 3 September 2010. This may suggest that the time of day that the processing occurred could limit the potential for distractions or fatigue being contributing factors to the error, although these factors cannot be completely discounted
- there were no other consignments of prawns processed on 3 September 2010. The potential for errors due to repetition of the same tasks or by miss-matching laboratory

reports from one consignment and AIMS entries for another does not, therefore, appear to be a contributing factor

- process complexity also does not appear to be a distinct contributing factor, as the underlying processes appear straightforward with laboratory results being easy to interpret. It should also be noted that the officer responsible for processing the release in AIMS is experienced and demonstrated a high degree of knowledge and understanding of prawn inspection, sampling and release processes during discussions with him
- the covering emails for laboratory reports are usually printed out with the laboratory reports. The covering emails from the laboratory that undertakes the testing highlight whether test results are positive or negative. In this instance, the covering email was not printed out. The officer that released the consignment suggested that this was not a contributing factor to the error as the laboratory report is always referred to, however it may have provided an additional prompt if it had been printed. It should be noted that one other laboratory report examined did not include this detail on their covering email or the covering letter accompanying the report
- the results of the tests for each of the 13 samples are listed individually line by line on the laboratory reports (13 separate samples of five prawns are required to be tested for each batch within each consignment). While the results are not difficult to interpret, positive results do not necessarily have any specific formatting to clearly identify them from negative results. This may increase the risk of oversight occurring as it is more likely that positive results could be accidentally overlooked.

Discussions with BSG post-inspection officers

A number of experienced BSG post-inspection officers were interviewed during the fieldwork to ascertain whether there were any additional factors which may have contributed to the error.

All officers indicated that they did not believe there were any additional factors which may have led to the error and felt that oversight was the primary reason. Officers interviewed did provide suggestions for improving processes, which have been incorporated into the recommendations provided in this briefing.

Examination of further consignments released

To further understand the release procedures and to assist in assessing the potential for human error occurring more frequently, further examination of a sample of laboratory reports recorded in the August 2010 and September 2010 post-inspections email in-boxes was performed by the Interim IGB. A total of 21 further consignments were examined which had been tested by two separate laboratories. This examination identified an additional consignment which had been incorrectly released by BSG.

The Interim IGB did not undertake a detailed review of the circumstances which led to this error as it was not within the scope of this review. However certain advice was requested from BSG post-inspection officers and an examination of a small number of documents identified that:

- the consignment was for frozen raw peeled deveined shrimp tail on (3,500 kg) and off (5,000 kg) and it was treated as two separate batches
- the consignment was released on 28 July 2010 at 3.35 pm

- the laboratory report had been received on 29 July 2010 at 1.31pm
- one of these two batches of prawns returned no positive test results and was appropriately released
- the second of these batches contained one sample with a positive test result for WSSV
- the consignment was for a different importer to the consignment being examined by the review
- this release was processed by a different officer from that who had processed the release being examined by this review
- the testing of this consignment had been completed by a different laboratory from that which tested the consignment being examined by this review.

Therefore the consignment had been released before the laboratory result had been received. This may have been due to the officer incorrectly matching the laboratory report and AIMS entry.

BSG post-inspection officers advised that they had immediately (the afternoon that the second error was identified) initiated a check of all consignments of prawns released over the previous seven months (between the period 1 April 2010 and 31 October 2010). The Executive Manager of BSG Quarantine Operations subsequently advised that this check had also been extended to all Region Offices and that no further errors were found.

The outcomes of the sample examination indicates that there is an increased level of risk that errors in releasing consignments of prawns may be occurring on a more frequent basis and that this should be taken into account when considering the recommendations for control enhancements provided below.

Determining batch numbers

The 'Prawn Sampling for Disease Testing (updated)' Work Instruction defines a batch as:

'A processing run of a particular product. Different batches are identified by different production dates, lot numbers, processing plants or pond numbers. For further details see the ICON case PQA0455.'

ICON case PQA0455 notes that:

- if the number of batches cannot be determined from documentation, a full unpack and inspect may be required in order to determine the number of batches
- a batch is defined as a processing run of a single lot of raw materials
- in an aquaculture establishment, prawns raised in separate ponds would generally form a different population. When sampled, each population is called a batch
- when there is difficulty in identifying batches the following batch indicators will be used:
 - different species = different batches (populations)
 - different country of origin = different batches (populations)
 - farmed and wild caught = different batches (populations)
 - different processing runs = different batches (populations).

The Work Instruction and associated ICON case is somewhat contradictory in its current form as it appears to offer a number of options for defining a batch (e.g. processing runs and prawns raised in separate ponds) and is therefore open to varying interpretations, although we acknowledge that the key determinant appears to be the production date of the prawns.

The consignment of prawns in question was treated as a single batch as requested by the importer. It contained different types of prawns (ocean caught and farmed) that were classified into four different lots based on presentation (cutlets or meat). There were two lots of ocean caught prawns and two lots of farmed prawns. Some BSG post-inspection staff interviewed believed that this treatment was correct as the overriding requirement, as indicated in the Work Instruction, is to define batches according to the production date. However one officer indicated that it was believed that the consignment should have been classified as two batches due to the presence of two different types of prawns.

Summary

Overall, the circumstances surrounding the release of the consignment of prawns examined as part of this review would suggest that the primary cause of the mistaken release was human error or accidental oversight by the officer involved.

However, further work undertaken during the examination indicates that this error may not be isolated, and similar mistaken releases may have occurred in the past and may continue to occur in the future if improvements to the controls are not implemented.

RECOMMENDATIONS

Several initial recommendations have been identified which should be considered by BSG to improve processes and reduce the risk of similar errors occurring again in the future.

These improvements range from controls which can be implemented immediately with relatively little investment to those which will require cost/benefit analyses to be undertaken to determine whether the level of risk within the current release processes warrants the required level of investment to further mitigate the risk.

BSG should also consider a staged approach where additional manual controls are implemented in the interim while more sophisticated and automated controls are evaluated and, if appropriate, developed and implemented.

The need for, and the extent of the implementation of, the recommendations provided below will also be influenced by the outcomes of the additional examination of consignments processed over the last four months which is currently being completed by the Region Offices. Should this examination identify additional errors in the release of prawn consignments, there would potentially be an increased need for automated controls to be implemented in the medium term and additional manual controls to be implemented in the short term.

The following recommendations should be considered by BSG:

1. Placing a requirement on the importer for scrutinising laboratory results and explicitly stating to BSG whether the outcomes are positive or negative. This would require the importer to provide a positive statement regarding the test results which would provide an extra preventative measure to ensure that laboratory results are treated correctly. This should be reinforced with appropriate sanctions for false declarations and by BSG assurance measures. However the requirement for BSG to verify the outcomes of the testing, based on the copy of the report provided directly to them by

the laboratory, and then process the release of consignments in AIMS would remain and therefore the risk of mistaken release would ultimately remain.

2. The development of a system interface between the laboratory and AIMS to allow for testing results to be directly input into AIMS, which would reduce the risk of human error. We understand that a similar automated update process has been implemented for consignments sent for testing under the *Imported Food Control Act 1992* and BSG should evaluate whether this automated process can be extended to prawn releases.
3. The consistency of release processes throughout the Region Offices should be reviewed by the Central Office (Operations Division) to assess whether there are other opportunities for improving release processes. This assessment should also consider whether reporting and release functions could be centralised (as suggested by BSG) to the BSG Entry Management National Coordination Centre in Adelaide to provide more dedicated attention to these specific processes.
4. Implement an additional control which requires that all emailed laboratory test results be reviewed by the supervisor each day and verification that positive test results have been treated correctly in AIMS be performed. This additional control is not considered to result in significant additional workload on the supervisor as, on average, there are only a few laboratory test results released each day.
5. The accredited laboratories should change the format of reports to make positive test results stand out more clearly from negative test results. The format of the laboratory reports should also be amended to ensure that these contain a definitive statement regarding whether testing has resulted in positive or negative results. This will provide staff with a single point of reference to inform the release of consignments.
6. Post-inspection officers should ensure that the quarantine entry number and the results of the testing of each of the 13 individual samples of five prawns are acknowledged on the laboratory reports in order to verify that the correct laboratory report is being referred to, and the outcomes of the testing of each sample have been individually reviewed.
7. The 'Prawn Sampling for Disease Testing (updated)' Work Instruction should be amended to more clearly define what exactly constitutes a batch by, for example, providing a single definitive identifier such as the processing run and clarifying all additional defining attributes that should then be evaluated and in order of importance.

ACKNOWLEDGEMENT

The Interim IGB wishes to acknowledge the support and assistance provided by BSG Quarantine Operations staff and BSG post-inspections officers within the Central East Region Office.



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PROCEDURAL OVERVIEW

At the time that the consignment of prawns in question was released, the following processes were in place at the Central East Region in relation to the inspection, testing and release of prawn consignments:

- on arrival of the consignment, a quarantine entry order form is completed and the consignment is transported to a Quarantine Approved Premise, including a class 2.5 cold store, for a full unpack, inspection and sample testing
- relevant paper work is checked by BSG staff to ensure that there is:
 - an import permit which is valid at the time the goods are imported into Australia
 - a consignment specific health certificate issued by the competent authority of the country of origin
 - documentation from the exporter, supplier or competent authority verifying the number of batches in the consignment and the labelling of each batch in the consignment
- a 'Raw Prawn Sampling Declaration' form is completed by the importer which includes a nomination of the testing laboratory and the number of batches to be tested. With each consignment the importer may nominate additional batches over and above the minimum standards required by BSG, as this may limit the amount of the consignment which will need to be held for re-export, destruction or cooking if positive test results are detected
- an inspection and sampling appointment is booked by the importer or their agent with BSG
- BSG carries out the inspection and sampling in accordance with the 'Prawn Sampling for Disease Testing (updated)' Work Instruction. This requires that the number of batches identified by the importer be verified as appropriate and that 13 separate random samples (ideally from different pallets) comprising five prawns from each batch be selected for laboratory testing
- the BSG officer packs the samples in a foam esky with ice or freezer blocks and transports the samples to the Region Office
- a 'Specimen Notification Fax' is sent to the laboratory nominated by the importer to notify them that the samples are being delivered to them for testing
- a courier picks up the samples from the Region Office and transports them to the laboratory for testing
- on completion of testing, laboratory results are e-mailed to the importer, a generic post-inspections outlook in-box and to the Team Supervisor
- an BSG administrative officer prints the laboratory test results and files the email in a separate folder in outlook
- the BSG administrative officer passes the printed version of the laboratory test results to a team member who reviews the results and updates the AIMS import entry record to either release the consignment if test results are negative, or, to hold the consignment pending re-export, destruction or cooking in a Quarantine Approved prawn processing facility if the test results are positive for WSSV or YHV

- a verification line is added to AIMS to record the method of treatment for consignments that have tested positive. The majority of importers opt to re-export (generally to the country of origin) the product and a line is added in AIMS to reflect this
- BSG officers verify that the product has been packed for re-export
- positive test results are recorded on a whiteboard in the Region Office which is designed to act as a reminder to staff to follow up to ensure that appropriate action is taken where positive test results are received as re-export can take some time to occur and there is no AIMS entry which records that this has occurred
- once confirmation that re-export or destruction has occurred, the consignment detail is removed from the whiteboard and no further action is required.

CHRONOLOGY OF EVENTS

20 August	Consignment of frozen raw peeled prawns from Malaysia arrives in Sydney and is held at a Quarantine Approved Premise with entry documentation requested by BSG
23 August	Entry documentation received and processed by BSG
26 August	Prawns inspected by BSG and samples sent for testing to an accredited laboratory
2 September	Results of tests of the samples received by BSG with all 13 YHV tests being negative and four of the 13 samples testing positive for WSSV
3 September	‘Prawn testing results received consignment has now passed quarantine’ entered into AIMS
23 September	Central East Region Office staff member discovers incorrect release when reviewing related documentation. Central Office (Animal Division) notified
24 September	Recall process initiated and Central East Region Office commences consignment distribution tracing to NSW, Queensland, Victoria and South Australia
28 September	Deputy Secretary, BSG and executive Director, AQIS initiates review by Interim IGB