DAFF Biosecurity Quarantine Operations Risk-Based Approach ACERA 1001 Study H

Overview of Case Studies

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Contents

1

Executive summary

1.1 Overview

This report summarizes the results of a suite of six ACERA case studies undertaken from 2008 to 2010. It provides an overview of those studies, a discussion of their common elements, and a structure for further reading.

The six case studies were part of ACERA project 1001 and focused on the six following pathways: aircans (Unit Load Devices, ULDs, also called aircans), reportable documents (RD), external container inspection regime (ECIR), rurally-destined containers (RDI), international vessels arriving at seaports, and the plant product commodity white rice. Four of these pathways were deemed suitable for a risk-based approach: aircans, RDs, ECIR, and routine first-port inspection for seaports.

1.2 Recommendations

This report makes the following recommendations.

1. Concerns about poor data quality should not impede the best possible use of available data resources.
2. Each pathway that is moved to a risk-based management scheme should be subjected to a post-implementation review, for example after one year.
3. Savings that arise from the implementation of risk-based management schemes should be invested in ways that will improve biosecurity outcomes.
4. The identification of further pathways as candidates for risk-based management schemes should be automated and streamlined.
5. Quantitative and technical support for pathway managers should be centralized into a specialist analytics team.

2

Background

2.1 Introduction

The purpose of this report is to provide some structure for the reporting of six case studies undertaken under ACERA project 1001 from 2008 to 2010. We summarize each study, identify the common factors and unique elements, and draw some general conclusions about the deployment of risk-based principles in quarantine inspection operations. That way, the interested reader can start with this document and continue as their needs dictate. Full details for each case study can be found in the relevant reports.

The overarching purpose of project 1001 was to identify the challenges and opportunities for implementing a risk-based approach for various border activities. The approach was to implement earlier ACERA work (e.g., tools that were developed in ACERA reports **AR0804** and **AR0804a**) and provide some post-implementation review.

ACERA project 1001 was designed as a collection of case studies that focused on different challenges within the border biosecurity environment. Each study presented a challenge: the sea cargo case studies were connected to one another because the inspection of rurally-destined containers could be thought of as a re-inspection from ECIR, the seaports case study required the merging of various sources of data, and the air cargo case studies involved the analysis of sub-pathway (i.e., flight) inspection data.

For brevity we shall refer to the ACERA reports by number, so for example **AR1001e1** refers to ACERA project 1001 case study E, Report 1. The full citation list can be found on page 25.

2.2 History

We begin with a brief history that provides the context for the ACERA projects. In the 1990s, only some pathways were monitored regularly. We were unable to locate any official records or public documents that may be readily accessed to provide information about inspection regimes that predate the Increased Quarantine Intervention (IQI), introduced in 2001. However, several DAFF Biosecurity officers who worked at various regional offices in the 1990s provided us the following recollections of contemporary inspection procedures for the case studies covered in this report.

1. *Sea containers* were externally inspected on a 5% basis, and also when officers were required to perform wharf inspections. The purpose of wharf inspections was to monitor break-bulk cargo, which is transported in ship holds rather than in containers. Containers were typically stacked up in the wharf, so often only two sides were visible, and inspections were less rigorous than they would be under the External Container Inspection Regime (ECIR), which was introduced as part of IQI.

2. All *rurally-destined sea containers* were inspected externally and partially internally at appropriate Quarantine Approved Premises (QAPs). The internal inspection involved opening the tailgate of the container and examining the contents that were visible from the gate. Most of the contamination that was detected was untreated timber in the container.

3. The external inspection of *Unit Load Devices* (ULDs, aircans) was even less formal than the external inspection of sea containers. The aircans were located at airfreight bond stores and Cargo Terminal Operators (CTOs), and if an officer happened to be visiting a bond or CTO then there was an option that available aircans could be inspected externally. If contaminants were found, they were generally cleaned on the spot. This activity was only conducted as an adjunct to other inspection activities and even then only if time permitted. As a result, only a tiny fraction (substantially less than 1%) of air cans were subject to any kind of inspection before IQI.

4. Until the late 1990s, *reportable documents* (RD, then referred to as *high-volume, low-value*, HVLV) were screened by Customs on behalf of DAFF Biosecurity, like all cargo. Biosecurity risk material (BRM) would be referred to DAFF Biosecurity officers for further action. No data are available on the historical inspection or interception rates.

5. Consignments of white rice have always been subjected to quarantine inspection at 100%.

In 2001, IQI funding was provided by the Commonwealth in response to the devastating foot-and-mouth disease outbreak in the United Kingdom. The IQI set an intervention rate to 100% for a number of activities. As mentioned above, some of these activities, such as the external surfaces of containers, had not previously been systematically inspected. Other activities funded under IQI included the inspection of RD, and the first-port arrival inspection of international ocean vessels.

In 2006, operational programs within DAFF Biosecurity asked ACERA to assist in a risk-measurement exercise to develop and refine simple software tools that would enable a statistical analysis of DAFF Biosecurity inspection data. The ultimate goal of these tools was to assist in identifying areas of DAFF Biosecurity operation that were subject to greater or lesser degrees of quarantine contamination. The studies described in this report began and built upon the delivery of these tools.

The Beale review (**Beale-2008**) was published while the projects were still underway, and its recommendations anticipated a number of the developments that we report.

3

Common Elements

This chapter provides an overview of the common elements in the following case studies.

3.1 Design

Here, *design* refers to the definition of the pathway and the inspection units, determination of the number of units to be inspected, and the establishment of rules that guide the choice of units to be inspected.

3.1.1 What is an Inspection Unit?

An *inspection unit* will be the entity that is singled out by the pathway manager for possible inspection. Examples include an air passenger, a maritime vessel, and a sea container. The definition of the inspection unit is subjective, and usually based on operational convenience; here there is no wrong definition, only definitions that are more or less useful. The definition of an inspection unit is stable within a pathway, that is, despite it being subjective, it should not change arbitrarily.

3.1.2 What is a Pathway?

As with the identification of an inspection unit, the identification of what is a pathway is subjective, and guided both by operational convenience and similarity of risk both in terms of likelihood of contamination and consequences of contamination. Broadly speaking, a pathway is defined as a collection of activities that culminate in the arrival to Australia of a set of alike inspection units. Examples are: the arrival of sea containers, or the arrival of sea containers from a particular vessel, or the arrival of sea containers from a particular port. Pathways can be subdivided to reflect management constraints or to focus inspection resources on sub-pathways that are thought to be riskier.

3.1.3 Inspection Effectiveness

This report uses the noun *effectiveness* in a very specific way that reflects the term's history within DAFF Biosecurity. Effectiveness is taken to mean the quality of intervention, usually the quality of inspection, and is commonly defined as the probability that existing contamination will be detected. That is, if a unit is contaminated, the effectiveness of inspection is the probability that the contamination will be detected if the unit is inspected. Mostly effectiveness is measured using instruments called 'leakage surveys' (see Section 3.2.1).

Hence, when we write 'estimate the effectiveness of inspection' we are referring to a specific process in which the quality of the intervention is quantitatively assessed. The *pathway leakage* *rate* will be the estimated rate at which the items that are released after processing (which may involve inspection) are contaminated.

3.1.4 Inspection Sample Size

Briefly, the approach to setting an inspection sample size that was advocated in the case studies is as follows.

- Set a minimum performance target (a 'risk cutoff') in terms of percentage of inspection units free of contamination after intervention.
- Each quarter, say, use the preceding year's data for the percentage and number of units inspected and the number of units found to be contaminated for both intervention and leakage surveys. Estimate the effectiveness of inspection and approach rate of contaminated units.
- Estimate upper confidence limits for the approach rate and use it, the leakage and the target to work out a sampling rate for the quarter. Be pragmatic if it is close to what is being done, don't change the rate, ie. if it should be 23.47% leave it at 20% or maybe increase it to 25%.
- Determine whether the risk profile of the pathway is sufficiently heterogeneous to justify splitting the pathway into sub-pathways and developing distinct inspection programs for each sub-pathway.

This algorithm is captured in the IRIS spreadsheet tool, which was provided for a number of the case studies.

Each of the case studies has involved the inspection of pathways with high volume, with the exception of the white-rice pathway (Section 4.5). In each of these cases, use of the IRIS tool to establish a national pathway-level inspection rate is reasonable. Although the IRIS tool was designed to enable pathway managers to fine-tune the inspection commitment, on the whole, managers preferred to use it in a confirmatory context: e.g., IRIS might prescribe a 0.5% sampling rate to achieve the nominated cutoff, and the manager might opt for a 20% sampling rate, that being easier to operationalize while maintaining credibility and confidence that the risk cutoff will be easily met, based on the IRIS output.

3.1.5 Inspection Sample Selection

The selection of units to inspect has mostly been driven by operational convenience, with compromises to try to make the resulting data reasonably representative. There are three goals for inspection:

1. intercept contamination,
2. estimate contamination rate, and
3. deter maleficent agents.

Goals (1) and (2) are often at cross-purposes. Targeting inspection resources is good for goal (1) and can be bad for goal (2) unless augmented with random samples. Furthermore, leakage surveys are vital for goal (2) and, by monitoring the effectiveness of intervention, benefit goal (1).

Intercepting contamination is the highest priority. If we knew which units were more likely to be contaminated, then we would target those units using methods covered in Section 5.2. Here we consider the case in which the pathway contamination seems uniform, that is, we have no particular intelligence about it. Consequently the interception rate would be proportional to the intervention rate, and estimating the contamination rate and deterring maleficent agents become more significant goals.

3.2 Data Collection

Collection of data that can be used to inform the inspectorate about the environment in which it is intervening is essential to risk-based pathway management. It is essential that the following quantities be collected and available to agreed standards. Where the measurement of the quantities is impractical, eg. in the case of the number of RDs that are inspected in a bag, an estimate must be made, ideally using statistical tools and other measured data.

1. Volume — the number of consignments arriving in the pathway,
2. Inspection count — the number of consignments actually inspected,
3. Interception count — the number of consignments determined to require remediation,
4. Leakage survey effort — the number of consignments re-inspected during the leakage survey, and
5. Leakage survey interception count — the number of consignments detected as requiring remediation in the leakage survey.

The point about the data being available to an agreed standard means that the definition of contamination should be consistently applied, within reason, across different inspectors. Also, the intervention should be identified as rectifying (contamination is cleaned and unit returns to the pathway) or non-rectifying (unit is returned to supplier or destroyed), or in the case of either, the proportion of each. Finally, the timing of the return of the rectified items to the pathway — before or after the leakage survey is performed — also affects the analysis of the leakage survey data.

3.2.1 Leakage Survey

An estimate of leakage from the standard intervention is essential for computing measures of inspectorate performance. A regular and on-going leakage survey is therefore a vital component of the pathway manager's information. While meaningful statistics on contamination rate will be obtained quite quickly, meaningful results about effectiveness require the results from the leakage survey over a longer time period so that variability from the leakage survey does not swamp the performance estimate.

3.3 Analysis

Statistical analysis of the pathway inspection data is critical for risk-based management. Three questions are of interest, and will need to be addressed on different timescales.

The primary purpose of analysis is to determine whether DAFF Biosecurity's performance for the pathway is satisfactory, that is, an assessment of the overall outcome of the inspection process. The effectiveness of inspection, ie. the probability that existing contamination will be found, is an important component of this performance, but only a component.

Further work about performance indicators has been done since the reports summarised herein were written. **AR1001i1** recommends that post-intervention compliance (PIC) be the principal performance indicator. PIC measures the proportion of the pathway that is compliant after intervention. The specific details for calculating this indicator will depend on the characteristics of the pathway. The PIC depends on several statistics about the pathway that are useful in their own right:

- the number of goods on the pathway, which indicates the substance of the management task for DAFF Biosecurity,
- the number of items inspected, which indicates the amount of effort undertaken by DAFF Biosecurity with regard to this pathway,

- the approach rate of contamination on the pathway, which is one component of the biosecurity risk represented by the pathway,
- the effectiveness of inspections, which is useful to know for the purposes of training and inspection resources deployment, and
- the pathway leakage, which is an estimate of the number of units on the pathway that still have biosecurity contamination after intervention.

These five statistics can be derived from the five pieces of data mentioned in Section 3.2.

It is worth noting that this formulation of the PIC assumes that the effectiveness of the leakage survey is 100%.

In the first instance, we recommend that this analysis of pathway data be undertaken at least every three months. The advantage of a short period is that quick feedback will be available in terms of pathway compliance and diversity, and the performance of intervention tasks, including representativeness of the sampling. We also recommend monthly or even weekly monitoring for some statistics, for example, interception rates. Early detection of an upward or downward spike in interception rates could be valuable for the pathway manager.

Second, analysis should determine if any of the existing sub-pathways need to be handled differently — for example, whether sub-pathways that are under heightened surveillance could be moved to a sampling regime, or whether sampled pathways have proven to be sufficiently high-risk that surveillance should be increased. This analysis should occur regularly, typically quarterly, perhaps using a rolling 12-month data set. If the volume of data will support it, a monthly analysis, which may be less detailed, might provide advance warning of unpleasant surprises and allow for earlier rectification of any problems detected.

Another element of this analysis is to determine whether each of the sub-pathways are being sampled sufficiently. It may be that, for example, operational decisions lead to some sub-pathways being under-represented in the inspection data.

Finally, the analyst may ask whether the existing stratification of the pathway, if there is one, is the most efficient for the purposes of pathway management. The analyst may perform data mining and statistical testing of alternative stratification variables. The goal would be to determine whether it would be worthwhile splitting the pathway into different sets of sub-pathways to better target intervention effort. For example, it may be more efficient to target a pathway by importer than by country. This analysis could be performed annually.

Further analyses might be possible: for example, the pathway manager may wish to compare the compliance of several pathways to assess the utility of profiling exercises, and the efficiency of pathway inspection may be scrutinized. Also, when sufficient data are available, industrial quality control statistical tools such as control charts may become useful (see, e.g. **AR0605**).

We further recommend that a substantial post-implementation review of changes to intervention procedures be undertaken after about a year. At this point it should be possible to determine how often each analysis needs to be performed.

3.4 Reporting

The various pathway characteristics listed above may be of interest to several different parties. DAFF Biosecurity will need to determine how much information they wish to make available and in what form, recognizing that given enough information it may be possible for third parties to construct estimates that DAFF Biosecurity would prefer not to reveal.

For example, if DAFF Biosecurity reports the number of units on the pathway v, the number of units inspected i, the estimated approach rate a, and the estimated PIC, then it would be possible to compute the inspection effectiveness, which DAFF Biosecurity may prefer not to reveal. In that case, one of the four items mentioned above should be omitted from public reports.

4

Case Studies

4.1 Introduction

We start with a definition of some of the key concepts. When we refer to a *pathway*, we refer in the most general possible way to a sequence of actions that culminates in the entry of persons, animals, plants, or goods into Australia. For example, the entry of goods by air cargo is a pathway.

Pathways may also be split into smaller coherent sub-pathways. For example, we might consider the load port, the importer, or the destination port in the definition of the pathway. In some cases there is considerable differentiation in the risk of the sub-pathways. For example, some suppliers might have particularly high-quality operations that very rarely or never result in contaminated consignments. Such information can be used to target resources to reduce risk as much as possible; this is the essential feature of risk-based inspection systems. Of course, the statistical information about the pathway is also partitioned, so the quality of knowledge at the sub-pathway level is less than at the pathway level. It is important to account for this difference when planning inspection regimes. This issue will be revisited below.

Each of the following case studies were developed for a specific pathway which had been nominated by DAFF Biosecurity.

4.2 Air Cargo

ACERA undertook two case studies for the Air Cargo Program: Unit Load Devices (Aircans), and Reportable Documents.

4.2.1 Aircans

This case study focused on the external inspection of aircans (Unit Load Devices, ULDs), which are containers used to consolidate air freight. The study produced three reports (**AR1001e1**; **AR1001e2**; **AR1001e3**). Briefly, the aircan case study involves the migration from a 100% inspection regime to a low-level monitoring inspection regime. As we shall see below, appropriate statistical analyses of historical inspection data demonstrated that the aircan pathway represented low biosecurity risk. An integral part of the monitoring regime is the on-going collection and analysis of appropriate inspection data to be sure that the pathway maintains its low-risk status.

The following comments have been extracted from **AR1001e1** and **AR1001e2**. Other ACERA reports that touch upon the aircan pathway are **AR0804**, **AR0804a**, and **AR1001e3**.

External inspection was mandated for all aircans in 2001 under IQI. Based in part on the results of **AR0804** and **AR0804a**, the Air Cargo Program decided to implement a two-phase deployment of risk-based principles for external inspection of aircans.

Phase 1 involved the releasing, without inspection, of aircans that arrive during the night shift or on weekends, for each of the three most active regional facilities: Sydney, Melbourne, and Brisbane. For these purposes, the night shift is defined as comprising all flights that arrive after 6 pm and before 6 am.

Phase 2 involved the releasing without inspection, for all regions, of

- 80% of aircans that arrive during the weekday day shifts, and
- all aircans that arrive during all but some randomly chosen night shift and weekend shifts.

AR1001e1 used historical inspection data to determine that the likely impact of the implementation of Phase 1 on the pathway-level risk was very low.

AR1001e2, which superseded **AR1001e1**, used historical inspection data and data arising from Phase 1 to determine that the likely impact of the implementation of Phase 2 on the pathway-level risk was very low. Using inspection data supplied by the Sydney and Melbourne regional offices, **AR1001e2** estimated that the expected pathway leakage rate would be

- NSW: 0.004%, with upper limit 0.008% and lower limit 0.001%.
- VIC: 0.013%, with upper limit 0.023% and lower limit 0.003%.

Statistics for the other regions were unavailable. However, those regions that were analyzed represent a substantial proportion of the total aircan pathway activity, so the analysis was considered indicative.

Finally, **AR1001e3** presented a recommended workflow for pathway risk management, including region-specific inspection regime recommendations and algorithms for the analysis of inspection data.

An important issue that remains unresolved in this case study is the implementation of leakage surveys (see Section 3.2.1). Under the IQI-mandated inspection scheme, the leakage survey was straightforward because the inspectors could assume that all aircans had been inspected. However, the risk-based inspection regime has only a fraction of the aircans being inspected, so a contaminated aircan that is detected in the leakage survey may not have been inspected. This uncertainty makes the effectiveness of inspection more difficult to determine accurately. An example of the calculation can be found in Appendix B.

Potential strategies for improving this estimate of effectiveness include: use of a temporary mark on the inspected aircan; performing leakage inspection on aircans from certain flights only; and using a periodic intensive inspection approach which may be assumed to have no leakage. Each of these strategies would then require a slightly different but still straightforward leakage calculation.

This pathway has been managed on a risk-based approach since about October 2009. A post-implementation review has shown that the pathway has continued to be low risk, meaning that there is low probability of contamination, and no detected contamination has been of particularly high risk. However, two related elements have risen for further consideration: first, how to deal with regions that have small numbers of aircans, and second, how to handle risky flights. We address these issues in Sections 5.1 and 5.2 respectively.

4.2.2 Reportable Documents

This case study focused on the inspection of Reportable Documents (RD), which are a document class of air freight that is transported by courier companies. The case study produced three reports (**AR1001f1**; **AR1001f2**; **AR1001f3**). As for aircans, the RD case study involves the migration from a 100% inspection regime to a low-level monitoring inspection regime. As with aircans, the RD pathway was shown to be low biosecurity risk by using appropriate statistical analyses of historical inspection data. An integral part of the monitoring regime is the on-going collection and analysis of appropriate inspection data to be sure that the pathway maintains its low-risk status.

The following comments have been extracted from both **AR1001f1** and **AR1001f2**. Other ACERA reports that touch upon the RD pathway are **AR0804**, **AR0804a**, and **AR1001f3**.

Inspection was mandated for all RDs as of 2001, under IQI. Based in part on the results of **AR0804** and **AR0804a** the Air Cargo Program decided to implement a two-phase deployment of risk-based principles for RD inspection.

Phase 1 involved the releasing, without inspection, of RDs that arrive during the night shift or on weekends, for each of the three most active regional facilities: Sydney, Melbourne, and Brisbane. For these purposes, the night shift is defined as comprising all flights that arrive after 6 pm and before 6 am.

Phase 2 involved the releasing without inspection, for all regions, of

- 80% of RDs that arrive during the weekday day shifts, and
- all RDs that arrive during all but some randomly chosen night shift and weekend shifts.

AR1001f1 used historical inspection data to determine that the likely impact of the implementation of Phase 1 on the pathway-level risk was very low. The methodology and estimates from that report were superseded by **AR1001f2**.

AR1001f2 used historical inspection data and data arising from Phase 1 to determine that the likely impact of the implementation of Phase 2 on the pathway-level risk was low. Using inspection data supplied by the Brisbane, Sydney and Melbourne regional offices, **AR1001f2** estimated that the expected pathway leakage rate would be

- NSW: 0.99%, with upper limit 1.23% and lower limit 0.77%.
- QLD: 0.47%, with upper limit 0.76% and lower limit 0.19%.
- VIC: 0.26%, with upper limit 0.44% and lower limit 0.09%.

Statistics for the other regions were unavailable. However, those regions that were analyzed represent a substantial proportion of the total RD pathway activity, so the results were considered indicative.

Finally, **AR1001f3** presented a recommended workflow for pathway risk management, including region-specific inspection regime recommendations and algorithms for the analysis of inspection data.

Unlike the aircan pathway, the inspection status of RD consignments would be known at the time of implementing a leakage survey. Consequently, the leakage survey strategy that was used during the IQI-mandated 100% inspection can be continued. Estimation of effectiveness would use existing calculations based on the leakage surveys of inspected RD. Leakage surveys done during the night / weekend day shifts would directly estimate the approach rates for those flights in order to confirm that the approach rate has not changed.

This pathway has now been managed on a risk-based approach since about October 2009. A post-implementation review has shown that the pathway has continued to be low risk, in terms of low probability of contamination, and no detected contamination has been of particularly high risk.

4.2.3 Generalities

The following general principles held for the two case studies of pathways managed by Air Cargo. Because of operational constraints, the selection of units for inspection is performed on a flight-by-flight basis, rather than a unit-by-unit basis. That is, all the units on a chosen flight are inspected. In statistical practice this design is called *cluster* sampling.

The flights are divided into two sub-pathways, or strata: those that arrive between 6 am and 6 pm on weekdays, and other flights. For the purposes of discussion we will call these the business hours (BH) stratum and the after hours (AH) stratum respectively. The sub-pathways were created for operational convenience. The consequences of a two-level approach are discussed in Section 5.3.

The intention of the design is to obtain a representative 20% sample of units for BH, and a representation 3% sample of AH units (that is, one shift per month). Ideally the selection of flights for inspection is on a rotating basis, so that over time, each flight number would be inspected in the minimum amount of time. Negotiated deviations from this design have been implemented in specific regions (**AR1001e3**; **AR1001f3**).

For the first 12 months, the Cargo Risk Program[1] will analyse inspection data provided by the pathway managers no less frequently than quarterly, using the algorithms and spreadsheet tools detailed in **AR1001e3** and **AR1001f3**. After the first year the analysis frequency should reflect management needs.

As outlined above, the sample design is a stratified, systematic, cluster sample of inspection units. Rigorous analysis of data from such designs is complicated, and beyond the scope of readily-available standard software. In order to simplify the implementation and maintenance of the ACERA software tools, we have used estimators from a simpler design: a simple random sample. Although this simplification will underestimate the pathway risk, we expect the error to be small. Further analysis could be undertaken to check this supposition.

The purpose of the quarterly analysis of inspection data by the Cargo Risk Program is to produce statistical information that can be used to assist the pathway managers in managing the biosecurity risk of the pathway. Pathway managers will use the statistical information as one component of the pathway risk management decision-making process.

In order for such a reduction in inspection rates to be aligned with the principles of risk-based management (**Beale-2008**), a concomitant increase in inspection effort should be undertaken in pathways that are identified as being of higher risk, for example, the Cargo Assurance Air pathway (CAA, also called the *freeline*).

4.3 Sea Cargo

ACERA undertook two case studies for the Sea Cargo Program, both focusing on the inspection of sea containers: the External Container Inspection Regime (ECIR) case study focused on the external inspection of sea containers at the port gate, and the rurally-destined container inspection (RDI) case study focused upon the tail-gate inspection of all containers for which the destination was rural (defined by destination postcode). Note that some containers may be inspected externally twice: the first time at the gate (as part of ECIR), and the second as part of an RDI at a suitably-licensed location, a fact that was used as an economic way to do a leakage survey for ECIR.

4.3.1 External Container Inspection Regime (ECIR)

This case study focused on the external inspection of sea containers (**AR1001a1**; **AR1001a2**; **AR1001a3**). The ECIR case study involves the migration from a 100% inspection regime to a low-level monitoring inspection regime. The pathway was demonstrated to be low biosecurity risk by using appropriate statistical analyses of historical inspection data. An integral part of the monitoring regime is the on-going collection and analysis of appropriate inspection data to be sure that the pathway maintains its low-risk status.

The following comments have been extracted from both **AR1001a1** and **AR1001a2**. Other ACERA reports that touch upon the ECIR pathway are **AR0804a**, and **AR1001a3**.

[1] Since the drafting of this report, the Cargo Risk Program organizational unit has been restructured and relabeled at least once. Here and elsewhere we retain the unit identity from the original reports.

External inspection was mandated for all sea containers from 2001, under IQI. Based in part on the results of **AR0804a**, the Sea Cargo Program decided to deploy risk-based principles for external inspection.

AR1001a1 used historical inspection data to determine that the likely impact of the implementation of a reduction in inspection load upon pathway-level risk was very low. The methodology and estimates from that report were superseded by **AR1001a2**.

The management prescription that was tested for ECIR was a 30% inspection rate for all containers. **AR1001a2** reported that the expected pathway leakage rate for ECIR containers, using 2008 inspection results and assuming a 30% inspection rate with 95% effectiveness, is 0.72%. Reasonable upper and lower limits for this figure are (0.70%, 0.75%). Further, the expected contamination approach rate for ECIR containers, using 2008 inspection results, was 0.99%. Reasonable upper and lower limits for this figure were (0.97%, 1.01%). Here, contamination refers to high-level contamination, for which the containers must be sent for washing before being released.

Finally, **AR1001a3** presented a recommended workflow for pathway risk management, including region-specific inspection regime recommendations and algorithms for the analysis of inspection data.

The external container inspection uses RDI tailgate surveys as a source of leakage survey data (see Section 4.3.2).

4.3.2 Rural-Destination Inspection (RDI)

This case study focused on the external re-inspection and tailgate internal inspection of sea containers whose destination was rural according to postcode (**AR1001b1**; **AR1001b2**). The outcome of the case study is maintenance of a 100% inspection regime. The pathway was not demonstrated to be of a sufficiently low biosecurity risk to reduce the inspection rate.

The following comments have been extracted from **AR1001b1** and **AR1001b2**; the latter is the main source.

Tailgate inspection was mandated for all rurally-destined sea containers as of 2001, under IQI, although the activity predates IQI. Based in part on the results of **AR0804a**, the Sea Cargo Program decided to examine the utility of 100% inspecting this pathway using risk-based principles.

AR1001b1 used historical inspection data to determine that the likely impact of the implementation of a reduction in inspection load upon pathway-level risk was too high. The methodology and estimates from that report were improved on by **AR1001b2**.

AR1001b2 reported that the expected pathway leakage rate for 100% inspection of RDI containers, using 2008 inspection results and assuming a 30% ECIR inspection rate with 95% effectiveness for (see Section 4.3.1), is 0.073%. Reasonable upper and lower limits for this figure are (0.03%, 0.13%). Here, contamination refers to high-level contamination, for which the containers must be sent for washing before being released.

The difference between the inspection regimes for urban- and rural-destined sea-containers results from the different consequences of contamination. Because there is a greater chance for any pests or diseases to come into contact with a host, have the opportunity to establish, and spread undetected, if the container goes to a rural destination, extra inspection was deemed necessary for such containers.

4.3.3 Generalities

The following general principles held for the two case studies of pathways managed by Sea Cargo. For the first 12 months, the Cargo Risk Program should analyze inspection data provided by the pathway managers no less frequently than quarterly, using the algorithms and spreadsheet tools detailed in **AR1001a3**. After that the analysis period should reflect the management cycle.

The purpose of the quarterly analysis of inspection data by the Cargo Risk Program is to produce statistical information that can be used to assist the pathway managers in managing the biosecurity risk of the pathway. Pathway managers will use the statistical information as one component of the pathway risk management decision-making process.

In order for such a reduction in inspection rates to be aligned with the principles of risk return (**Beale-2008**), a concomitant increase in inspection effort should be undertaken in pathways that are identified as being of higher risk, for example, containers that arrive from countries that are on the Country Action List (CAL).

A 12–month post-implementation review of pathway risk management should be undertaken, including the utility and appropriateness of the IRIS tool and the analytical strategies that were recommended for the pathway.

4.4 Seaports

This case study focused on the routine first-port inspection of international ocean vessels, and is documented in reports **AR1001d1**, **AR1001d2**, and **AR1001d3**. The first-port inspection is for quarantine cleanliness and biosecurity.

The Seaports case study involves the migration from a 100% inspection regime to a low-level monitoring inspection regime. The monitoring involves the use of documentation and vessel inspection history to determine whether or not the vessel is eligible for Pratique Documentary Clearance (PDC). Vessels that are eligible for PDC are inspected 2 times each 5 visits, and are cleared on documentation otherwise. Vessels that are not eligible for PDC are inspected every visit.

The pathway was demonstrated to be low biosecurity risk using appropriate statistical analyses of historical inspection data. An integral part of the monitoring regime is the on-going collection and analysis of appropriate inspection data to be sure that the pathway maintains its low-risk status.

Routine first-port inspection was mandated for all vessels in 2001, under IQI. Based in part on the results of **AR1001d1**, the Seaports Program decided to implement a two-phase deployment of risk-based principles for this inspection.

Phase 1 of PDC (2009–10) involved the releasing, without inspection, upon presentation of appropriate documentation, of 60% of certain vessel and location combinations. The combinations can be broadly summarized as being bulk carriers and tankers that were regular visitors (more than two visits in preceding twelve months), arriving at certain ports in northern Australia. There were 2257 eligible vessel visits out of a total of 13975 visits during Phase 1. Of these 2257 vessel visits, 1036 resulted in inspection and 1221 resulted in release upon presentation of suitable documentation.

The sample design of Phase 1 is as follows. The vessels that are eligible for PDC are inspected systematically, on the second and fifth visit out of every five. If an inspection results in quarantine failure then the vessel will be inspected at 100% until it has returned one first-port inspection pass (**AR1001d3**).[2]

AR1001d1 used historical inspection data to determine that the likely impact of the implementation of Phase 1 on the pathway-level risk was very low. The methodology and estimates from that report were superseded by **AR1001d2**, which also reported on the Phase 1 trial.

Phase 2 (from 2 July 2011) involved the releasing without inspection, upon presentation of appropriate documentation, of 60% of almost all vessel and location combinations. **AR1001d2** used historical inspection data and data arising from Phase 1 to determine that the likely impact of the implementation of Phase 2 on the pathway-level risk was low. Using Vessel Monitoring System (VMS) data, **AR1001d3** estimated that the expected pathway leakage rate would be 0.47%, with upper limit 0.61%.

[2] This inspection design is called a *CSP-1* design, with sampling fraction 0.4 and clearance number 1.

Several elements of this case study remain unresolved. First, the effects of adoption of PDC upon the (i) frequency, and (ii) hit rate of second-port inspection remain to be examined. Furthermore, the principles of risk return suggest that the reduction in first-port inspections should be offset by a concomitant increase of effort elsewhere. For example, the potential exists for further scrutiny of ballast water and biofouling. Finally, VMS represents a substantial data resource with considerable potential for data mining operations to see if the pathway can be sensibly sub-divided into areas of higher and lower frequency of actionable biosecurity contamination. An example of such a subdivision would be the owning company of the vessels.

For the first 12 months, the Cargo Risk Program should analyze inspection data provided by the pathway managers no less frequently than quarterly, using the algorithms and spreadsheet tools detailed in **AR1001d3**. After that the analysis period should reflect the management cycle.

4.5 White Rice

The white rice case study focused on the inspection of consignments of polished white rice (**AR0804**). This case study evaluated the risk-based maintenance of a 100% inspection regime. The pathway was not demonstrated to be of a sufficiently low biosecurity risk to reduce the inspection rate.

The following comments have been extracted from **AR0804**. Polished white rice is inspected at 100%. The managing program decided to examine the utility of 100% inspecting this pathway using risk-based principles. **AR0804** used historical inspection data to determine that the likely impact of the implementation of a reduction in inspection load upon pathway-level risk was too high.

The predicted risk was the measure recommended by **AR0804** for deciding upon inspection regimes. It is defined as an estimated upper confidence interval for the average rate, so it takes account of the number of inspections. Predicted risk can be interpreted as an approximate upper limit on the potential contamination assuming that the true rate does not increase.

Although there were no failures for white rice inspection in 2007, the predicted risk for white rice inspection for 2007 was 1.5%; this number is an upper limit on the potential contamination assuming that the rate does not increase. This number is above the nominal cutoff of 1%, and reflects the small number of polished white rice consignments that were available for inspection in 2007. In short, although no contamination was found, too few consignments were inspected for the zero detection rate to mean very much. The pathway does have a history of failures; the total number of failures detected nationally from July 2003 until December 2007 was 3, from a total of 569 inspections, an average rate of 0.527%.

5

Discussion

5.1 Resolving Pathways and Sub-Pathways

A risk cutoff that is established for a pathway may not be achievable in sub-pathways that have much smaller volumes. For example, if national inspection data are used to formulate a risk cutoff, then individual regions that have much lower volumes may well have higher predicted risk values even though they may have negligible or zero contamination.

Briefly, because risk management relies on a measure of statistical uncertainty, which in turn depends on the number of items inspected, the decision about management at the national level may not be the same as decisions about management at the regional levels based on that region's data alone. This difference leads to the possibility that an inspection prescription that has been established at the national level — say only 20% of items to be inspected — may lead to a higher predicted risk at the regional level, simply because the sample size is low.

Consequently, pathways for regions that have comparatively few units to inspect may appear to have leakage that exceeds the risk cutoff even when there is no contamination detected in the inspected units. There are several remedies, here presented in *decreasing* order of recommendation.

1. Increase the time period upon which the risk calculation is based, e.g., from three months to six months or even more. Extending the length of the period is already done for some activities and can be simply and correctly justified as "we need longer to get sufficient data".

2. Use national figures for small-volume regions, as is presently done for the calculation of amnesty bin interception rates by the Passengers Program, or use a statistical model to provide reasonable estimates. A degree of homogeneity between regions must be assumed for this approach, and can usually be justified.

3. Change the confidence with which the risk should be below the cutoff. The confidence (by default 0.95) should be reduced so that it matches the confidence that is achieved by inspecting the prescribed proportion of units and detecting no contamination during a typical period.

4. Change the specified risk cutoff for the low-volume regions. The cutoff could be increased so that it matches the cutoff that is achieved by inspecting the prescribed proportion of units and detecting no contamination during a typical period.

5. Inspect more units in the low-volume regions, to bring the risk measure below the national cutoff. This solution seems unreasonable, because it punishes the low-volume regions for having low volume.

6. Ignore the problem.

5.2 Low-Volume Sub-Pathways

As noted above, the smaller number of inspections available in low-volume sub-pathways can make it difficult to meet risk targets at the sub-pathway level. Some sub-pathways are sufficiently low in volume that using the IRIS algorithm is inappropriate. This section details a strategy for handling such sub-pathways.

To provide an example of low volume sub-pathways we divide the single national pathway for aircan inspection into sub-pathways defined by flight numbers. Inspection of the units in the aircan case study demonstrated that there may be patterns of contamination on specific flight numbers. It is possible that these patterns are statistical anomalies, but they may represent systematic failures on some sub-pathways. Ideally, the manager could develop a unique inspection regime for that pathway using the IRIS tool. However, even by inspecting 100% of such sub-pathways, it is unlikely that sufficient data will be available to use IRIS satisfactorily. As in the case of dividing the pathway up by region, dividing the pathway by flight number creates problems owing to the much smaller sample size that results. Recall that, for example, in order to obtain 95% confidence that the fixed, true contamination rate is less than 0.5%, the inspectorate must inspect 600 units without detecting contamination. The inspectorate may be able to inspect 600 aircans from a given flight number, but it seems difficult to believe that the contamination rate will be constant across the time taken to amass that inspection count. Therefore deploying the IRIS solutions seems complicated and clumsy.

Since the original reports were prepared further work on this problem has been done which suggests that a specific sub-pathway (such as aircans on a flight level) uses a continuous sampling plan (that goes by the name of CSP–3, see **AR1001j1**) with these rules:

1. Inspect sub-pathways at the sampling rate f% (e.g., 20%, or every fifth flight of a given number)
2. Any time a non-conformity is detected, the next four flights must be inspected.
3. When a non-conformity is detected on a sub-pathway more than two times per i (e.g., 10) consecutive inspections,
   (a) Change the inspection rate for that sub-pathway to 100%.
   (b) Maintain the higher inspection rate until i consecutive flight inspections have identified no contaminated units.

It is important to strike a balance when selecting the control parameters (the sampling rate f and the clearance number i). Obviously, instances of systematic contamination demand scrutiny and impediment, but random non-conformity that is acknowledged to occur from time to time really should not be punished. If the pathway being managed is of a nature such that even one-off instances of contamination are of quarantine concern, then it should be inspected at 100%. It may be worthwhile establishing the parameters based on some statistical analysis of what kinds of patterns of contamination are consistent with "random" contamination, and tuning the parameters so that those levels pass with, for example, a courtesy alert to the relevant parties. The outcomes of this analysis would lead to different control parameters for different pathways, which seems reasonable. The control parameters can be tuned using simulation experiments that are based on historical inspection data. An example of such a project is **AR1001j1**.

Some pathways in DAFF Biosecurity already deploy a similar methodology, for example, in the Broker Accreditation Scheme (BAS), and the first-port inspection of vessels.

5.3 Two-level Pathways

A reviewer rightly asked "Could known reduction in inspection of certain sub-pathways encourage maleficent agents to target these pathways, and would review processes be sufficient to detect this?" DAFF Biosecurity has been sensitive to the possibility of maleficent agents trying to identify and select softer targets; this process is called port-shopping in the context of cargo. There is a real risk that the reduction of surveillance at regular and predictable intervals could encourage agents who want to avoid either the penalties associated with quarantine contamination or even the inconvenience associated with quarantine inspection. The best solution is to ensure that, at random times, the inspection effort for the time periods for which inspection efforts are ordinarily reduced should be sharply increased, and that the penalties for contamination are sufficient that the shift-based equivalent of port-shopping does not appear to be a good strategy. For example, inspection for one random AH shift per month could be a suitable deterrent. Also, opportunistic inspection is another way to add to the uncertainty of when goods might be inspected.

6

Recommendations

We conclude with a collection of recommendations that reflect the common experience of the case studies.

6.1 Data Quality

Concerns about data quality recurred throughout each of the case studies, and remain a common theme in discussions with DAFF Biosecurity managers and scientists. It is true that, for a variety of reasons, the data resources are uneven, that there are gaps in places where information would be valuable, and that some of the recorded information is of questionable reliability. A detailed discussion of the possible causes and remedies for this situation is beyond the scope of this report.

However, it is important to note that in many cases the data are sufficient to identify and support high-quality decisions. It would be a grave error for the organization to delay making important decisions until the data achieve some arbitrary level of quality. It is far better to make the best decision possible with the best possible use of the data that are available, than to wait an unknown time for the best possible data. Being conservative in drawing conclusions from analyses of data is sensible, but being conservative in the scope of their application is a waste of opportunity.

6.2 Post-Implementation Review

A post-implementation review of pathway risk management should be undertaken for each of the pathways. This review should include at least the following topics within its scope.

- Does the estimated pathway compliance conform to expectations?
- Does the workload experienced reflect the reduction that was intended?
- Are there ways to simplify, reduce, or clarify the implementation? For example, can data handling be streamlined?
- Have there been any unintended consequences, positive or negative, from the implementation of the strategy?
- Are the ACERA tools working as expected?

6.3 Risk-Based Approach

The principles of risk-based management require that, in order to offset the increased risk that inevitably arises from a reduction in effort in one activity, investment be made in other activities that are considered to pose a greater risk. In short, what should the organization do with the resources that it saves by reducing the levels of inspections? There are several themes.

1. Identify other pathways that may carry BRM and establish rigorous inspection regimes for those pathways. Examples: cargo air assurance (CAA, the freeline) in air cargo, unaccompanied personal effects (UPE). ACERA report **AR0804** identified a number of opportunities, and consultation with regional offices will certainly uncover more.

2. Prepare for further risk-based opportunities by investing in the quality of data capture. For example, (i) augment the tariff code system by recording whether stockfeed is animal- or plant- based, and (ii) ensure that fumigation provider details are recorded in AIMS.

3. Improve the effectiveness of inspections in high-risk pathways by increasing the effort undertaken. However, overall efficiency is also an important consideration. It may be that a small increase in inspection effectiveness that results from greater scrutiny of a high-risk pathway is not as good an investment as the possibly larger increase in overall effectiveness brought about by inspecting more items on other pathways.

4. Implement detailed leakage inspections in order to permit estimation of inspection effectiveness.

6.4 Support and Maintenance

An important characteristic of the risk-based projects that only became obvious towards their conclusion is that each of the monitoring strategies requires maintenance, meaning on-going statistical and operational analysis. In some cases the maintenance is relatively minor, in others the investment will be greater. This report echoes the recommendation of ACERA report **AR0804a** that the maintenance of the risk-based management of pathways be undertaken with the support of an in-house team of quantitative analysts. This team would be ideally situated to provide support for the assessment and implementation of risk-based management on newly identified pathways, and to deploy statistical tools to identify patterns of contamination across and within pathways to enable greater efficiencies.

6.5 Further Work

The resolution of the reported case studies has provided a loose framework for how to implement a risk-based pathway management system. The pathways were identified after extensive consultation with personnel in the regional offices, a process that is documented in **AR0804**. An important next step is to automate, or at very least augment, the process of identifying candidate pathways using statistical analysis tools such as data mining. Data mining tools, coupled with a suitable data source and some clear definitions of what characteristics to try to identify, would enable the rapid and ongoing identification of pathways that may be suitable for management following the principles used in this report.

7

Conclusions

The case studies summarized in this report demonstrate that DAFF Biosecurity has the capacity and the appetite to apply risk-based management principles to pathways under its purview. They also demonstrate that some pathways are not presently suited to the approaches outlined. For these pathways, the existing management scheme provides a better match than the alternative scheme, at least until the data indicate that these pathways have changed suitably.

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Appendix A

Glossary

A.1 Acronyms

BRM	Biosecurity Risk Material
CTO	Cargo terminal operator
ECIR	External container inspection regime
HVLV	High-volume, low-value (now called RD, Reportable Documents)
IQI	Increased quarantine intervention
PDC	Pratique documentary clearance
PIC	Post-intervention compliance
QAP	Quarantine-approved premises
RD	Reportable documents
ULD	Unit load device

Appendix B

Estimating Leakage

We assume that the leakage survey is not part of the regular intervention, iėwe do not include the count of the leakage survey amongst the 'interceptions'. The following quantities must have been collected.

N is the number of units arriving
Q is the proportion that are inspected
F is the number found to be contaminated, and

We want to estimate the following unknown quantities:

D is the number of contaminated units
M is the number missed either through poor inspection or no inspection, and
E is the effectiveness of inspection.

B.1 Only Inspected Items Included in Leakage Survey

Assume that

L is the observed leakage (proportion) in the leakage survey, which is taken only of inspected aircans.

The estimated leakage count from the inspected units is $N \times Q \times L$. So, the estimated effectiveness is

$$E = \frac{F}{F + N \times Q \times L} \tag{B.1}$$

The estimated number of contaminated units is the number intercepted added to the number leaked, pro-rated to the total units arriving, which is

$$D = \frac{1}{Q}(F + N \times Q \times L) = \frac{F}{Q} + N \times L \tag{B.2}$$

Finally, the estimated number missed is calculated by subtracting the number intercepted from the previous quantity

$$M = \frac{F}{Q} + N \times L - F \tag{B.3}$$

B.2 Inspection Status Unknown at Leakage Survey

The following calculation of effectiveness assumes that the leakage surveys are done with no knowledge of whether inspection has been done or not. The context is ULDs (aircans) but could be any other pathway in which it is not possible for the person doing the leakage survey to determine whether the item has been inspected. It is best if the leakage survey only inspects items that have already been inspected, because a more accurate estimate is obtained, but for some activities that is not possible. Note also that under this approach, it is possible to get an estimated effectiveness of more than 100%.

Assume that

L is the observed leakage (proportion) in the leakage survey, which does not know whether the aircan had been inspected.

The estimated number missed is calculated by $M = N \times L$. The estimated number of contaminated aircans is $D = F + M = F + N \times L$. Since the number found is $F = D \times Q \times E$, the effectiveness is

$$E = \frac{F}{D \times Q} = \frac{F}{(F + N \times L) \times Q} \tag{B.4}$$

It must be pointed out that, to obtain comparable accuracy, the size of the leakage survey using this method (we don't know if the item surveyed had been inspected) needs to be much larger - by a factor of $1/Q$ at least - than the size of a leakage survey that only looks at inspected items. As an aside, it should be noted that, all things being equal, the observed value of L when the leakage survey is only done on inspected aircans would be considerably lower than the observed value of L when the inspection status of the aircans that form the leakage survey is not known. In the former case, $L = D \times (1 - E)/N$ since we are only looking at inspected aircans. In the latter case $L = D \times (1 - QE)/N$ because the leakage survey looks at both inspected and non-inspected aircans.