Import policy 'health-check' framework and tools

Final Report for CEBRA Project 21G

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Table of Definitions

Term or abbreviation	Definition					
Agent (of hazard)	A fomite (inanimate) or vector (animate) that transfers or is instrumental in the transfer of a hazard.					
Appropriate level of protection (ALOP) for Australia	The <i>Biosecurity Act 2015</i> defines the appropriate level of protection (or ALOP) for Australia as a high level of sanitary and phytosanitary protection aimed at reducing biosecurity risks to very low, but not to zero.					
Approved arrangements	An approved arrangement is an arrangement for which an approval is in force under the <i>Biosecurity Act 2015</i> .					
Australian territory	Australian territory as referenced in the <i>Biosecurity Act 2015</i> refers to Australia, Christmas Island and Cocos (Keeling) Islands.					
BA	Biosecurity advice.					
BICON	Australia's Biosecurity Import Condition System.					
Biosecurity	The prevention of the entry, establishment or spread of unwanted pests and infectious disease agents to protect human, animal or plant health or life, and the environment.					
Biosecurity import risk analysis (BIRA)	The <i>Biosecurity Act 2015</i> defines a BIRA as an evaluation of the level of biosecurity risk associated with particular goods, or a particular class of goods, that may be imported, or proposed to be imported, into Australian territory, including, if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or the class of goods, to a level that achieves the ALOP for Australia. The risk analysis process is regulated under legislation.					
Biosecurity measures	The <i>Biosecurity Act 2015</i> defines biosecurity measures as measures to manage any of the following: biosecurity risk, the risk of contagion of a listed human disease, the risk of listed human diseases entering, emerging, establishing themselves or spreading in Australian territory, and biosecurity emergencies and human biosecurity emergencies.					
Biosecurity risk	The <i>Biosecurity Act 2015</i> refers to biosecurity risk as the likelihood of a disease or pest entering, establishing or spreading in Australian territory, and the potential for the disease or pest causing harm to human, animal or plant health, the environment, economic or community activities.					
Commodity	see Goods.					
Dominant risk or hazard	A hazard or risk that has a higher risk level than other risks (for a commodity).					
Endemic	Belonging to, native to, or prevalent in a particular geography, area or environment.					
Factor	see risk factor.					
FAO	Food and Agriculture Organization of the United Nations.					

Term or abbreviation	Definition						
Fomite	Any inanimate object that, when contaminated with or exposed to infectious agents, can transfer disease to a new host.						
Goods	The <i>Biosecurity Act 2015</i> defines goods as an animal, a plant (whether moveable or not), a sample or specimen of a disease agent, a pest, mail or any other article, substance or thing (including, but not limited to, any kind of moveable property).						
Harm	An adverse event or effect on human, animal or environmental health.						
Hazard	A biological, chemical or physical agent in, or condition of, an animal or animal product with the potential to cause an adverse health effect.						
Host	An organism that harbours a parasite, mutual partner, or commensal partner, typically providing nourishment and shelter.						
IRA	Import risk analysis.						
Key risk	A risk that has an overall risk level near ALOP.						
Key risk factor	A factor of a key risk; factors most likely to cause the risk level, identified in a risk assessment, to cross the ALOP threshold when a change to that factor occurs (see <i>risk factor</i> and <i>key risk</i>).						
Non-regulated risk analysis	Refers to the process for conducting a risk analysis that is not regulated under legislation (<i>Biosecurity import risk analysis guidelines 2016</i>).						
Pathogen	A biological agent that can cause disease to its host.						
PCR	polymerase chain reaction.						
Quarantine	Official confinement of regulated articles for observation and research or for further inspection, testing or treatment.						
Restricted risk	Risk estimate with biosecurity measure(s) applied.						
Risk	In the context of this document, some undesirable impact that has some likelihood of occurring. See also <i>key risk</i> .						
Risk analysis	Refers to the technical or scientific process for assessing the level of biosecurity risk associated with the goods, or the class of goods, and if necessary, the identification of conditions that must be met to manage the level of biosecurity risk associated with the goods, or class of goods to a level that achieves the ALOP for Australia.						
Risk assessment	The scientific evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard.						
Risk management	The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.						
Risk factor	Some part or cause of a risk. For example, the presence of a disease in the origin locality is a factor of the risk of a import commodity. Similarly, the availability of mitigations such as heat treating a commodity are risk (reduction) factors.						
Sensitivity	In this document, the significance of an effect of a change in the environment, technology, policy or operational process, on a						

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Term or abbreviation	Definition
	particular risk factor and its associated risk. For example, if a risk of a particular disease is close to ALOP, and its largely mitigated through heat treatment at a particular temperature, then that heat treatment is a sensitive risk factor.
Stakeholders	Government agencies, individuals, community or industry groups or organisations, in Australia or overseas, including the proponent/applicant for a specific proposal, that have an interest in the policy issues.
Surveillance	An official process that collects and analyses information related to animal health.
Unrestricted risk	Risk estimate without application of biosecurity measures.
Vector	An organism that does not cause disease itself, but which causes infection by conveying pathogens from one host to another.
WOAH	World Organisation for Animal Health.
WOAH Code	WOAH Terrestrial Animal Health Code.
WOAH Manual	WOAH Manual of Diagnostic Tests and Vaccines for Terrestrial Animals.
WTO	World Trade Organization.

1 Executive Summary

Many Australian import policies are based on risk analyses that were conducted some period prior to the current time. In some cases, those analyses date back decades. Any such analysis may become out of date. This represents a strategic risk to the department. To achieve the consistent level of assurance required by the department, and to demonstrate confidence to stakeholders that risk analyses remain contemporary, the department needs to strengthen its processes for periodic review of risk analyses. This research project tackled the challenge of designing a strengthened process to achieve this outcome.

1.1 Project outputs and outcomes

This project developed a framework containing various procedural steps that could be incorporated into the department's current risk analysis and monitoring processes. Importantly, the framework builds upon the current risk analysis processes and the expertise of subject matter experts (SME), adding a more structured and formal process to minimising errors and thus consequences that stem from missed information. As a result of this process, additional recommendations for improving current risk analysis practices have been suggested.

1.2 Recommendations

A detailed discussion of the recommendations is contained in Chapter 6. In summary, recommendations are:

1. That the framework developed in this project be embedded in departmental processes and its use monitored.

The framework developed in this project should become part of departmental 'business as usual' processes if it is to achieve intended outcomes of facilitating a more transparent, repeatable and robust assessment of changes in biosecurity risk. Use of the framework will achieve this by more clearly articulating the reasoning used to reach conclusions when new information relating to key risk factors becomes available. The department should monitor the use of the framework.

2. That the framework be used to improve the efficiency of the risk analysis review process.

The framework may be used to identify when a detailed review of a risk analysis is needed, and when it is not. While it does not indicate a priority order for risk analyses requiring review, its application should result in more efficient allocation of staff resources to risk analyses identified as requiring review.

3. That consideration be given to communicating the existence and use of this framework to stakeholders.

An important motivation for this project was the need for stakeholders to be confident that Australia's import policies remain contemporary and scientifically sound. Consideration should therefore be given to how the use of this framework and its outputs are communicated to stakeholders by the department.

4. That broader sources of expertise may be helpful in determining key risk factors.

While it is clear that the leading risk analysts in Biosecurity Animal Division were the greatest source of expertise on animal-health science within the department, broader sources of expertise may be helpful in determining key risk factors related to operational and compliance areas.

5. That attention be given to the risks created by strategic behaviour.

Non-compliance linked to strategic behaviour by stakeholders poses a biosecurity risk and should be considered when reviewing new information about a commodity pathway. This includes strategic behaviour of importers, Competent Authorities and third-party certifiers. Reliance on outside entities to undertake biosecurity activities on behalf of the department creates risks because it involves shifting decisions away from those with the strongest incentives to act in the interests of Australia's biosecurity system as a whole (the department), to individuals and groups who may face much weaker incentives to do so.

2 Introduction

The Department of Agriculture, Fisheries and Forestry (the department) establishes and maintains science- and risk-based biosecurity policies for the safe importation of animal and plant commodities. However, many Australian import policies are based on risk analyses that were conducted some period prior to the current time. In some cases, those analyses date back decades. Thus, for any policy, there is the possibility that the risk analysis on which it is based has become outdated. This represents a strategic risk to the department, and it is raised by stakeholders, including trading partners and domestic industries, as a factor reducing their confidence that import policies remain contemporary and scientifically sound.

The department does manage this strategic risk, in part, through discrete policy advice and through larger, but still discrete, risk reviews, bilateral negotiations, and market access requests. The Biosecurity Animal Division of the department has also established guidance material, and more recently drafted a decision-making matrix to identify 'trigger' events, which warrant assurance and verification activity (e.g. policy reviews, Competent Authority evaluations) to inform decision making and allocation of technical resources. However, the practice of assessing new information and amending import conditions to manage these new and emerging biosecurity risks that occurs in response, can lead to a potential disconnect and inconsistency between the published 'parent' risk analysis and the ongoing assessments and policy advices the department undertakes to manage biosecurity risks described therein.

For instance, risks may not be assessed against the first principles that were established in the original risk analysis, and are instead based on the previous advice, which may provide consistency, but through this practice, reasoning can become circular and/or lost. Similarly, the high frequency and volume of 'new' information the department must assess for new and emerging biosecurity risks can lead to poor transparency — especially from a stakeholder perspective — if there is no established framework that provides clear principles and procedures for this work. This means that critical pieces of new information may not be identified and directed for further assessment, and that the department's stakeholders are unaware of the large body of work the department currently does, instead believing that their interests aren't being appropriately protected or accommodated.

To achieve the consistent level of assurance required by the department, and to demonstrate confidence to stakeholders that risk analyses are 'current', further work is required to implement a formal process of continual review of risk analyses. The framework produced by the project comprises such a process.

2.1 Objectives

The overarching objective of this project was to develop a framework for improving the department's confidence in its approach to the identification of risk analyses that require review. **Ideally the framework would facilitate a more transparent, repeatable and robust assessment of a change in biosecurity risk**. The department's more detailed objectives for the framework are:

- To identify the critical information (e.g. 'assumptions') that decisions are primarily based on and that are made to manage biosecurity risk.
- To determine if that information (assumption or fact) should be shared with stakeholders.

- To analyse the sensitivity of the conclusions made in response to changes in information, including when such changes may require a different decision to be made.
- To package the outcomes above and integrate into the department's business process to review and monitor assessments of biosecurity risk. That is, the risk analysis process.

More immediately, the framework would identify key factors in the risk analysis that are most sensitive to any changes in the environment and processes contributing to the risk. These key factors may then form the basis for a continual risk monitoring process that helps determine whether a detailed risk review is necessary.

2.2 Methodology

The initial phase of the project involved a desktop review of several existing risk analyses and their associated import policies to determine the extent to which data inputs, assumptions, etc have been articulated / described historically. This allowed the project team to uncover potential risk analyses for use in case studies.

The second phase of the project involved the development and testing of a qualitative method for identifying, documenting and estimating the relative 'sensitivity' of data inputs, assumptions, etc. used in the estimation of overall biosecurity risk.

Through preliminary discussions, it also became clear that the solution was expected to be qualitative (as opposed to formal or quantitative methods) and should be constrained so that it did not add a lot of extra work to already limited risk analysis resources. However, the exact nature of what methods would satisfy these objectives and constraints was highly uncertain, and somewhat ambiguous in its success criteria (e.g. how will we know that a method will identify the right "assumptions and data inputs"? and, what is the scope for a "decision architecture"?).

After some initial consultations with the departmental project leadership, the approach for the project was one of consultative research, with rapid iterations of framework drafts. In particular, the steps followed were:

- 1. *Rapid iteration of framework drafts and reviews*. Given the somewhat uncertain criteria, the approach of rapid "idea generation" and review with stakeholders was deemed the best way to quickly discover whether the ideas in the framework were likely to work.
- 2. Initial group consultation to (re-)validate project objectives and expected deliverables. An initial group meeting was held with the departmental leadership of the project, as well as key stakeholders within the department (i.e. risk analysis leadership) to further clarify project expectations.
- 3. *Review of risk analysis method and templates*. A review of the current risk analysis method used by the Biosecurity Animal Division was conducted. The focus of this review was to identify whether the structure of a risk analysis could assist in identifying factors that would be influential in causing a need for detailed risk review.
- 4. *Consultation with leaders of contemporary departmental risk analyses.* Interviews were held with each of the leaders of four risk analyses (sausage casings, prawns, dairy, in vitro/in vivo). The focus of the consultation was to obtain expert opinion on

the current factors that result in review of risk analyses, and the expectations around a systematic process for monitoring for such factors.

- 5. Development of draft framework. Based on the information obtained in the review and consultation, the initial ideas of the framework were drafted (and reviewed with the project leadership). The focus of the framework was on the identification of "key risk factors" that is, variables in the risk environment where a change would most likely mean that more detailed review of the risk was necessary. The framework provides a method for identifying and monitoring such factors and indicates where a detailed review might be needed. This advice is intended to feed into the department's main prioritisation process for further planning.
- 6. *Final group review of the framework, especially the categories of potential key risk factors.* A final review workshop was held for the framework, which focused especially on obtaining expert input to refine a set of categories of potential key risk factor categories. The categories enable a systematic assessment of potential sources of key risk factors, as part of a risk analysis (or risk review).

Lastly, the framework was refined and finalised, and this report was written to capture various observations from the project.

2.3 Framework Summary

The framework is designed to enable the Biosecurity Animal Division to provide assurance that the risk factors underlying contemporary import policies and risk assessments remain valid, and to assist with the prioritisation of future policy reviews.

The framework includes:

- 1. A method for identifying, documenting and estimating the assumptions and data inputs to which biosecurity risk assessments are most sensitive, which we call the *key risk factors*.
- 2. A method for assessing potential changes to risk assessments.
- 3. A process for monitoring changes to risk assessments.
- 4. Recommended inclusions to risk analysis templates for identifying and estimating the *sensitivity* of *risk factors*.

Note: this document uses some specific terminology, such as "key risk factors". These terms are italicized on first use. Please refer to the Table of Definitions for explanations of such terms.

3 Current departmental decision-making processes for risk analysis

As necessary, the department assesses information on new and emerging biosecurity risks. It does this via five main types of internal processes — policy advice, risk reviews, Biosecurity Import Risk Analysis, bilateral negotiations and new market access requests — although these are not all necessarily published, linked or stored on any internal database. In addition, the assessment of new information does not necessarily lead to updated risk analysis.

Australia bases its risk analysis methodologies and import risk management measures on the standards, guidelines and recommendations set by the IPPC and WOAH. However, when such standards do not achieve Australia's Appropriate Level of Protection (ALOP), or relevant standards do not exist, Australia exercises its right under the SPS Agreement to apply appropriate measures, justified on scientific grounds and supported by risk analysis. These are simple and readily understood where likelihoods and costs may not be available and provides a general indication of significant areas of risk to be addressed. However, these assessments and results are subjective. Independent objective metrics are not always used, and the perception of value may not realistically reflect actual value of risk. There may also be no objective basis provided to assess the efficacy of risk mitigation measures and, as such, it is difficult to track risk management performance objectively.

The current departmental risk assessment structure (Figure 1) was used in developing the framework.



Figure 1. Conceptual model of the risk assessment process

This structure of the risks assessment process for imported goods (commodities) can be represented as follows — based on, for example, Sections 3 & 4 of the Import Risk Review template (DAFF, 2021):

1. Any number of relevant hazards for the commodity are identified, and some of these are selected for further assessment (if they are not present or need to be notified as present in Australia and are present in the country of export). The *dominant* form of hazards in the current context are animal diseases. For simplicity, we will consider non-infectious toxic hazards as "diseases" with negligible likelihood of spread. We

will exclude from this framework non-incursion environmental harm, such as illegal trade in protected species.

- 2. Each retained hazard is assessed for likelihood of entry, likelihood of exposure (to Australian population and environment), likelihood of establishment and/or spread, and likely effect of the establishment and spread (the impact score of the outbreak scenario). In a *restricted* risk analysis, the likelihoods are the residual likelihoods after consideration of stipulated hazard mitigations.
- 3. The likelihood estimates for entry and exposure are combined, and this value is combined with an estimate of the consequence to provide an overall risk for each hazard. Consequence is a product of combining the likelihood of establishment and spread with overall effect of the establishment and spread. The effect is the impact score of the likely outbreak scenario, that is, the likely outcome of the establishment and spread.
- 4. The overall risk level for the commodity (i.e. as stated in the summary of the risk analysis) is determined from consideration of the individual risk level of each hazard. Each individual hazard can be understood in terms of ALOP for Australia ALOP is "very low", but not zero. Measures are subsequently applied to mitigate risks and ensure that Australia's ALOP is met.

Likelihoods, determined at step 3, are combined based on Table 1 (Burgman et al. 2010).

Table 1. Matrix of rules for combining qualitative likelihoods. Column and row headings are
qualitative descriptions of the severity levels of likelihood.

	High	Moderate	Low	Very Low	Extremely Low	Negligible
High	High	Moderate	Low	Very Low	Extremely Low	Negligible
Moderate	Moderate Low		Low	Very Low	Extremely Low	Negligible
Low			Very Low	Very Low	Extremely Low	Negligible
Very Low				Extremely Low	Extremely Low	Negligible
Extremely Low					Negligible	Negligible
Negligible						Negligible

The combined likelihood of entry and exposure, and combined likelihood of establishment and spread and impact score (there is a table of rules), are combined to provide an overall risk based on Biosecurity Import Risk Analysis Guidelines (DAFF, 2016). The resulting risk estimation matrix is illustrated in Table 2.

	High	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
lihood of entry and exposure	Moderate	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
	Low	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
	Very low	Negligible risk	Negligible risk	Negligible risk	Negligible risk Very low risk		Moderate risk
	Extremely low Negligible risk Neglig		Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
Lik	Negligible Negligible risk Negligible		Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk
		Negligible	Very low	Low	Moderate	High	Extreme

Table 2. Risk estimation matrix



The department's import risk analysis for a commodity applies ALOP to risk associated with a hazard. However, more than one hazard can be associated with a commodity, but the interaction of these risks is not explicitly described for the commodity. For instance, there are no explicit rules (matrix or otherwise) that govern whether a commodity with many hazards has more overall risk than a commodity with few hazards. However, we can distinguish some useful patterns of the commodity risk:

- *One dominant risk factor*. In this case, the commodity risk is largely attributable to one hazard, and the analysis of change to overall risk for that hazard may be able to simply focus on the change to the dominant factor.
- *Factors with the same categorical consequence*. Factors may mostly have the same consequence. For example, the presence of any of a number of relevant diseases may change Australia's health status. In this case, the aggregation is determined by the sum of likelihoods (in probabilistic terms, the inverse of the likelihood that no factor occurs, allowing for possible correlations).
- *Factors with highly correlated likelihoods*. Where factors are highly correlated, the likelihoods change together. For example, if all diseases are mitigated by the same mechanism (i.e. heat treatment), then a failure in that mechanism (i.e. Recent research finds that heat treatment is no longer effective for all diseases) would change the risk of all diseases. In such cases, it may be possible to treat the collective risks as one single risk, with respect to the change.

3.1 Risk Principles

The risk analysis method that is used in the department largely reflects probabilistic thinking in terms of qualitative likelihood and a score-based impact. There is a long-running history and discourse within the department on the reasons for using this qualitative approach, which falls outside the scope of this project. However, even though the current methods are qualitative, their underlying principles remain generally consistent with principles of probability. This makes sense, because probability principles remain globally the most accepted paradigm for valid analysis of uncertainties.

We set the approach into an informal probability framework. Assuming underlying principles of probability enabled us to identify a structural element of key risk factors. Namely, that the resulting risk level is the qualitative equivalent of a combination of likelihood and consequences. The combinatorial tables of entry, exposure and establishment/spread are essentially the qualitative equivalent of probability multiplication, including the final multiplication of likelihood and some quantification of impact. The risk level can be estimated without mitigations in place (i.e. the "unrestricted" risk), or inclusive of such mitigations (i.e. the "restricted" risk). Where possible, a risk analysis will include sufficient mitigations to bring the overall risk down to meet ALOP.

The underlying principles of probability are useful, because they enable us to infer that the final risk level of a particular commodity (or, more granularly, particular hazard) can be further, or closer, to ALOP than some other commodity. Similarly, a particular mitigation can bring a risk level further from ALOP than another mitigation. In other words, factors associated with particular commodities or mitigations can be more (or less) critical in affecting whether a risk level crosses the ALOP boundary. For example, a change in cooking temperature for certain products may be more "key" than, say, the packaging material for that product, because it has a bigger effect on the likelihood of mitigating certain diseases. We use this logic as a starting point in the framework, noting that some factors that are further from ALOP could change significantly enough to cross the ALOP boundary. This is particularly likely to be the case for new diseases or recently constructed risk analyses where risk factors may not be close to ALOP because they are yet to be identified.

4 Assurance Framework

The assurance framework proposed here defines a process for continual review of import risk assessments, to provide assurance that the underlying assumptions remain valid, and to assist with the Division's prioritisation of future policy reviews. Important parts of the framework are:

- 1. A method for identifying key risk factors (i.e. assumptions and data inputs), i.e. the factors to which the overall risk analysis is most sensitive.
- 2. A method for assessing potential changes to risk assessments.
- 3. A process for ongoing monitoring of changes to risk assessments.

Additionally, the framework provides template(s) for identifying and evaluating the key risk factors.

4.1 A method for identifying key risk factors

Key risk factors are those factors most likely to cause the risk level, identified in a risk assessment, to cross the ALOP threshold when a change to that factor occurs (e.g. information about a new disease, a new mitigation, changes in the environment, etc.). Key factors are "key", because the risks that they contribute to are close to ALOP (and therefore those risks are most sensitive to changes in their contributing factors)¹. These factors can be combined in a checklist, used to assess the material consequences of a change, and determine if the change indicates that a full (detailed) review of the current risk and policy is needed. The checklist is analogous to a checklist of "vital signs" in a triage process. In practice, most changes will come to notice through some form of information obtained by the department.

The 'key risk factors checklist' can be developed as part of a new risk analysis (or review), or, for pre-existing risks and policies, in a separate process.

Development of the checklist has the following steps:

1. For new risk analyses, a draft list of key risk factors can be identified as part of the analysis process, or as part of summarising the individual risk assessments. The most likely timing is to develop the draft checklist in the last quarter of the risk analysis process, when most of the risk information is known.

If the risk analysis is already pre-existing, a draft list of key risk factors can be identified by summarising the individual risk assessments, in terms of hazards, mitigations, and changes to risk level as a result of mitigations or changes in other circumstances. The process of identifying this draft list of factors is not that different from identifying the draft factors during a new risk analysis, except that a new analysis offers opportunity for interactive analysis of risks and key factors (i.e. one process can inform the other). It would be logical for the identification of key risk factors from existing risk analyses to be undertaken by the subject matter expert (SME) or risk analyst familiar with the risk analysis. An initial analysis of the potential impact of changes in these key risk factors should also be undertaken (see 4.2 below and 4.2.1).

¹ Risk that are closer to ALOP are more likely to cross the ALOP threshold if there are changes in the risk environment. Therefore, factors that contribute to that risk are more likely to be "key". That doesn't mean other factors cannot cause a risk to cross ALOP, but it just means that all else being equal, they are less likely to do so.

- 2. Next, convene a workshop to critically review and elaborate on the draft key risk factors, and provide an assessment of how changes in hazards, governance or environment of the risk factors might affect the risk level. The aim of the workshop is to efficiently apply the available range of expertise to select and refine the key risk factors and test them against hypothetical changes. The workshop might, by default, be a relatively informal exercise involving only the most directly relevant expert(s). However, there are good reasons to think that better results can often be obtained by having input from a wider group, and using a facilitated structured elicitation process (Burgman, 2016). Hence, where time and resources allow, the workshop should have the following features:
 - a. **Participation:** for best results, the participant group should have a broad range of experience and expertise in import policy and risk management. For example, expertise may be drawn from across various departments involved in the end-to-end import process and policy development. However, workshop participants need to be selected taking into account the context and particular needs of the risk assessment. The timing of the workshop for new risk assessments would most likely be in the last quarter of the assessment process, when relevant knowledge has already been distilled and made available for assessment as key risk factors.
 - b. **Materials:** the preparation and materials for the workshop would include the list of draft key risk factors that were previously identified, and relevant reference material (such as prior risk assessments). Materials that are typical for idea or knowledge elicitation (i.e. whiteboards, "sticky notes", etc.) are also required. Alternatively, a "virtual" workshop may make use of equivalent online tools. In addition to the materials identified above, the template contained in Appendix A.1 and the risk factor categories in Appendix A.2 may be used to systematically prompt participants to identify key risk factors. The form considers — at a broad level — the department's risk analysis structure and the import process.
 - c. **Format**: Participants will be sent an overview of the workshop, including a summary of the commodity information and previously prepared high-level factors, at least a week prior to the workshop. The workshop is envisaged as a half-day or full-day activity, depending on the scope of the assessment. Generally, the most effective structure for this kind of knowledge elicitation is to elicit individual contributions first, and then arrive at a consolidated list through rounds of rating, discussion, and refinement (Burgman 2016; van Gelder, De Rozario, and Sinnott 2018). Part of the process will be to test the factors with elicited hypothetical changes, such as new diseases, breakdowns in mitigation and passage of time.
 - d. **Facilitation**. For best results the workshop should be led by an independent facilitator with experience in eliciting complex analytical knowledge.
 - e. **Deliverables**: The main deliverable of the workshop will be a list of key risk factors, including descriptions and annotations that could help to identify if a change may impact the factors, or that could help in the use of the list. Depending on the format of the workshop (i.e. the facilitation tools used), a secondary output may be the selected documentation of the workshop proceedings, such as captured fragments of supporting analysis of the factors.

4.2 A method for assessing potential changes to risk assessments

The method described here assesses how sensitive a risk analysis is to changes in key risk factors (i.e. assumptions and data inputs) identified in 4.1. Based on that assessment, it also aims to assess which factors are most important in determining the level of risk. For example, if the risk of a commodity is predominantly due to a single disease, which in turn is mitigated by a specific treatment, then that treatment is a key risk factor.

The risk of a hazard/disease may change due to new or expired factors that underpin the assessment. For example, the relevant animal population in Australia may have changed since the last assessment, rendering the factor of population size in the consequence estimates obsolete (expired). An example of a new factor might be a new disease now associated with a pathway, or changes to a mitigation method.

The method for determining the sensitivity of the risk assessment to change consists essentially of systematically assessing the sensitivity to factors within the risk assessment. Ideally, the method will enable us to identify, within the full set of key risk factors, a smaller number of factors against which changes can be assessed.

We first look at a method for estimating the potential impact of changes. A diagram of the method is shown in Figure 2.

The method:

1. Define the change to be assessed. The change may be due to new information, or an awareness (alert) that some factor(s) of a current risk assessment are expiring, or where the risk is highly uncertain or ambiguous.

2. Next, for changes that mainly affect the impact estimates, determine the following:

- For a risk assessment that has a (mainly) common consequence (e.g. introduction of an exotic disease), or an assessment with a dominant risk factor (e.g. a heat treatment to mitigate one or more diseases), estimate whether the change in consequence will move the risk across the ALOP threshold (above 'very low').
- For non-dominant or non-common consequences, go to likelihood-based assessment, below.



Figure 2. A schematic representation of assessing how a risk assessment might be affected by change in key risk factors

Or, for changes that mainly affect likelihood (estimate for either entry, exposure or establishment and spread), or where there is no common or dominant consequence, determine the following:

- Where there are multiple changes, or where the change might affect multiple risks, start with risks closest to the ALOP threshold. For these risk(s), estimate if the change (combined entry, exposure and establishment and spread) or the likely consequence will move the individual risk or the perceived overall risk across the ALOP threshold.
- For individual risks that are not near the ALOP threshold (e.g. negligible), but where there are interactions between the hazards, estimate if the change will affect ALOP on any individual risk (or, less likely, collectively).
- Other changes are unlikely to move the overall risk assessment across the ALOP threshold. No further action is required in this case

3. Finally, if the estimates show that a change will move risk across the ALOP threshold, a detailed review of the risk analysis or assessment is needed.

Identifying key risk factors:

As detailed in Step 2 above, key risk factors will be:

- Risk factors on, or just above, the ALOP threshold (or classified as "unknowns") and/or
- Where large changes (in total) of highly correlated risks occur.

Additionally, we can identify key risk factors by considering hypothetical change scenarios based on general characteristics of the commodities, import processes, and supply chains.

Beyond these general characteristics, domain expertise will be needed to identify the specific factors for the commodity under consideration (see Section 4.1).

4.2.1 Example of method for assessing factors sensitive to change

To illustrate the method described in step 1 in Section 4.1, we will review the draft report on "Importation of cooked turkey meat from the United States" (DAFF, 2016). Note that this example only reflects step 1 and would provide input into the subsequent elicitation activity of step 2.

Firstly, the risk assessment(s) (collected from each relevant section of the risk review document) is summarised by hazard, mitigation strategy, and sorted by overall risk level (shown in Table 3). Mitigation strategies (*Mitigation Strategy 1, 2, 3*) are those that have been applied to reduce the risks. The risk of entry (*entRisk*), risk of exposure (*expRisk*), risk of establishment and spread (*estRisk*), the effect (*Effect*) and consequence (*Conseq*) all combine into an 'overall' risk for each disease. This *Overall* column is sorted by how close the risk is to ALOP (i.e. how close to "very low"), or if it is "unknown". This sorting gives an order of priority to how affected the risk is to changes in the key risk factor.

As can be seen from Table 3, three hazards are at a risk level near ALOP or unknown: MES; IBD; and aReo. For two of the hazards (IBD and aReo), cooking is a common mitigation measure, and therefore a sensitive factor. For other risks that do not have levels near ALOP, removal (of the hazard) is also a common factor (albeit with slight technical differences) – but since these risks are not near ALOP, they won't be considered further in identifying key risk factors.

Table 3. A summary of the risk assessments in the draft risk analysis for the 'Importation of cooked turkey meat from the United States', sorted by level of overall risk, for those diseases that have been assessed[#]. Diseases are prioritised based on distance from ALOP

Mitigation Strategy			-								
Abbrev	Name	1	2	3	entRisk	expRisk	EstRisk	Effect	Conseq.	Overall	Notes
MES	Multicausal Enteric Syndromes		cooking								Too many unknowns
IBD	Infectious Bursal Disease	Removal	cooking		2-low	3-mod	2-low	3-mod	2-low	1-vlow	Cloacal swabs- based removal, >80C 12min
aReo	Avian reovirus	Vaccination	cooking	canning	2-low	1-vlow	2-low	2-low	1-vlow	0-neg	>80C

aMPV, CD, Miowae, TCV, TVH have not been included because they were found to have met ALOP and so no further assessment was required.

An initial checklist of sensitive factors (to be explored further with expert elicitation via a collaborative workshop) to check any changes against, might be as follows:

- □ Factors related to Multicausal Enteric Syndromes
- □ Factors related to cooking >76.6C for 30min
- □ Factors related to selection of birds and removal of bird sections

The above checklist would be a starting point for further analysis to consider alternatives, or to gather more detail. This analysis would also consider non-disease factors, such as perhaps inspection processes, or supply-chain factors.

4.3 Process for ongoing monitoring changes to risk assessments

The process for monitoring ongoing changes to risk assessments (and the import policy that is based on the assessments), comprises two main parts:

- 1. Developing the sensitive risk factor checklist (see 4.1) and
- 2. Monitoring change

4.3.1 Process for Monitoring Change

The process for monitoring change can occur at two different levels:

- 1. Monitoring that is embedded in operations and intelligence activities; and/or
- 2. Periodic review of accumulated information related to trigger factors.

Operational Monitoring for Changes in the Risk Environment

The aim of operational monitoring for changes to risk is to ensure that any changes in key risk factors are efficiently and systematically assessed for criticality. The general concept is that the monitoring be embedded in existing operations and intelligence activities, where staff would flag and escalate information that may imply a risk change; the information subsequently flows to the risk analyst(s) of the relevant areas, who then use the key risk factors to assess whether the established risk assessments or policies will need detailed review.

The current operations and intelligence activities where this monitoring will occur include:

- Compliance Division
- Biosecurity Operations Division
- Biosecurity Animal Division

The monitoring generally takes the form of:

- Some form of query-based facility, where key phrases (e.g. commodity labels, situational descriptions, origin countries, etc.) can be entered, and relevant guidance and criteria (or even key risk factors) are provided to assess and process the change information
- A facility for escalating a change information evaluation request.
- A database for storing, reporting and managing the history of change assessment. This will most likely be Animal Technical Advice Platform (ATAP). ATAP would be used to transfer intelligence briefs to the analyst and also to communicate the request and provision of advice between Animal and Biological Imports Branch (ABIB) and Animal Biosecurity Branch (ABB) to facilitate the assessment of import permit applications.

Periodic review of Accumulated Change information

The periodic review of changes relevant to animal import policy (as obtained through operations and intelligence activities) aims to take stock of accumulated change information and assessments and assess whether the information as a whole escalates the priority for a detailed review of the established risk assessments or policy. Aside from summarising the current risk environment for a commodity, this periodic review also examines whether the accumulated changes show a trend or systemic risk. In short, this process provides a systematic method for dealing with changes that might affect risk, thereby filling a gap in the end-to-end management of import risk.

The periodic review includes the following components:

- **Staffing**: the review is intended to be performed by the risk analyst(s) for the relevant commodities or risk areas.
- **Resources**: the primary resource will comprise reporting from the operational risk monitoring database, to obtain the accumulated change reporting and assessments from the last period. The database may also provide the facility to document and manage the periodic assessment itself.
- **Process**: The risk analyst(s) will assess this information against the key risk factors, both for any updates or changes to individual cases, as well as in total with regards to potential trends and systemic issues. Based on these case reviews, an overall assessment is entered to determine the priority for a detailed risk review. Note that the process given here only identifies where a detailed review might be needed. This advice is intended to feed into the department's main prioritisation process for further planning.

4.4 Recommended Risk Assessment template changes

The checklist of key risk factors will be developed during or after a risk assessment, using the process outlined in this framework. As such, a table like Table 3 (in Section 4.2.1), which summarises and orders the key risk factors, can be included in the risk assessment template (probably with a short explanation of the table and its intent). In addition, a list of elicitation prompting questions, based on Appendix A, can be included in the Risk Review template, to assist in identifying the key risk factors.

A more elaborate list of key risk factors can be included in the systems used for monitoring the risks (e.g. ATAP). The key elaboration of the list in this setting is the inclusion of additional guidance for monitoring each factor and the possible information that may be salient to changes in risk. A suggested format for a Risk Monitoring template is shown in Table 4.

Note that additional columns and tags may be inserted in alignment with systems used for monitoring key risk factors, and in alignment with data integration strategies.

Table 4. Suggested template, including a hypothetical example, for monitoring key risk factors that are being managed in order to meet ALOP. Diseases should be prioritised based on their distance from ALOP.

Abbrev	Туре	Name	Priority	Guidance				
Varroa	Pest	Varroosis	high	Specific guidance for monitoring Varroosis factor				

5 Case Study: Importation of Queen Honey Bees

To further illustrate the framework outlined in Section 4, we detail here an example of applying the framework to the case of importation of Queen Honey Bees. At the time of writing, the last risk review for importation of queen honey bees was performed in 2012 (DAFF, 2012).

Step 1. A desktop review of the key risks shows the following priorities (by overall risk):

From the (unrestricted) overall risk, the following risks were identified as closest to ALOP and therefore any factors related to those risks (and the hazards they stem from) are deemed most sensitive to changes (Table 5):

- Varroa mites
- Tracheal mites
- Africanised Honey Bees hybrids
- Tropilaelaps
- Deformed wing virus

A single interview (not full workshop) was conducted with the SME to further examine the potential key risk factors. A summary of the process is described in Section 5.1.

5.1 Key risk factors Workshop

Given the exploratory nature of the elicitation workshop, the interview was a "light" version of the elicitation workshop described in step 2 of the method described in Section 4.1, in the sense that only one SME was involved in the elicitation. A full workshop would probably have added more in-depth challenges of assumptions and possibly insight into import controls such as inspection protocols. Suggested experts for such a workshop would include staff involved in border inspections (incl. entomologists), and monitoring/intelligence staff. Staff with expertise related to crops or plants most affected by honey bees in Australia would potentially be useful as well.

The questions posed around possible trigger factors followed the prompting structure given in step 2b of 4.1, but not all prompts were used (e.g. if prior questions or context indicate the information is already captured, or not applicable).

The questions followed the format of:

- How would risk assessment or import conditions change if... [followed by prompting categories from the list in Appendix A.2]
- (and do any answers suggest factors to monitor and assess as risk review trigger)

The workshop largely confirmed the key risk factors given in Table 5.

Table 5. A summary of the risk assessments in the risk analysis for the 'Importation of queen honey bees', sorted by level of overall risk for those diseases that have been assessed.[#] Diseases are prioritised based on distance from ALOP.

Mitigation Strategy											
Abbrev Type Name 1				2	entRisk	expRisk	EstRisk	Effect	Conseq	Overall	Notes
Varroa	Pest	Varroosis	Lab detection		5-high	5-high	5-high	5-high	5-high	5-high	unrestricted risk estimate
Trach	Pest	Acarapisosis (tracheal mite)	Lab detection		5-high	4-mod	5-high	4-mod	4-mod	4-mod	unrestricted risk estimate
African	Other	Africanised honey bee (A. m. <i>scutellata</i> and its hybrids)	Lab detection	inspection	4-mod	4-mod	5-high	5-high	4-mod	4-mod	unrestricted risk estimate
Tropi	Pest	Tropilaelaps	Lab detection		3-low	4-mod	5-high	4-mod	3-low	3-low	unrestricted risk estimate
Wing	Virus	Deformed wing virus	Lab detection		5-high	4-mod	4-mod	2-vlow	2-vlow	2-vlow	
Braula	Pest	Braula fly	inspection		2-vlow	5-high	3-low	0-neg	0-neg	0-neg	
Phorid	Pest	Phorid fly (Apocephalus borealis)	inspection		0-neg	3-low	2-vlow	2-vlow	0-neg	0-neg	
Acute	Virus	Acute paralysis virus	Lab detection		4-mod	4-mod	4-mod	2-vlow	0-neg	0-neg	
Slow	Virus	Slow paralysis virus	Lab detection		2-vlow	2-vlow	3-mod	2-vlow	0-neg	0-neg	

American Foulbrood, European Foulbrood, Small Hive Beetle, Cape Honey, Colony Collapse Disorder have not been included because they were found to have met ALOP and so no further assessment was required.

6 Conclusions and Recommendations

This project aims to enable the Biosecurity Animal Division to provide assurance that the assumptions underlying contemporary import policies and risk assessments remain valid, and to assist with the prioritisation of future policy reviews. It achieves this through a framework that comprises a structured process of identifying key risk factors for each risk analysis. Those key risk factors are monitored through ongoing operations and a periodic review process, in order to determine whether (and when) a risk analysis may need in-depth review.

The main deliverable (the framework) provides various procedural steps to be incorporated into Biosecurity Animal Division's current risk analysis and monitoring processes. In addition, some peripheral recommendations have been suggested that may improve current practices.

6.1 Embedding the framework in departmental processes

The framework developed in this project should become part of the departmental 'business as usual' processes to achieve intended outcomes of facilitating a more transparent, repeatable and robust assessment of biosecurity risk. Use of the framework will achieve this by more clearly articulating the reasoning used to reach conclusions from underpinning assumptions and data sources. Its use should be monitored.

6.2 Improving the efficiency of the risk analysis review process

The framework may be used to identify when a detailed review of a risk analysis is needed, based on whether new information affects the key risk factors identified. For example, new information about a heat treatment no longer mitigating one or more diseases, or information about disease presence in a trading partner country, might mean a risk analysis should be reviewed. Diseases and other key risk factors are prioritised within the framework based on their 'closeness' to ALOP (see 4.2.1). Importantly, however, the framework is unable to advise on a priority order for risk analyses that are identified for review. Rather, the advice on which risk analyses have been identified for review is intended to feed into the department's main prioritisation process for further planning. This prioritisation of reviews should include consideration where the value of risk-reduction (from making risk analyses contemporary) is greatest (Kompas et al. 2019).

By default, this framework also indicates where a risk analysis remains contemporary and therefore where no review is required — i.e. where no key risk factors have been identified as changing materially or in such a way as to impact ALOP. This is useful because these particular risk analyses would be removed from the list of those potentially requiring review, allowing staff time to be allocated more efficiently, i.e. to those risk analyses that do require review.

6.3 Communicating the existence and use of this framework to stakeholders.

Consideration should also be given to how the use of this framework and its outputs are communicated to stakeholders, including the pros and cons of doing so. This is in response to an important motivation of the project – namely, that stakeholders may have concerns that risk analyses on which policies are based are outdated, thus reducing stakeholders' confidence that import policies remain contemporary and scientifically sound.

6.4 Sources of expertise

Throughout the interviews and discussions, it became clear that the leading risk analysts were also the greatest source of expertise on the science of their respective commodities. This raises the question: "why not simply ask them to list the key assumptions and data inputs (i.e. the key risk factors) that are most sensitive to change and monitor those factors?".

There are at least three reasons why it will generally be beneficial to involve others with different expertise.

First, there are the inherent limitations on expertise in any complex domain, particularly when operating under time pressure. Even the best experts are never 100 per cent correct (Burgman, 2016). We expect that the risk analysts operating alone would perform well in correctly identifying key risk factors, but outside perspectives will generally result in incremental improvement.

Second, a framework was needed to ensure a systematic, transparent process of identifying and monitoring the factors. Currently, risk analysts do monitor changes in the risk environment, but the process is not very transparent, and as such consistency cannot be assured. For example, if there is a change in risk analyst staff, there is no guarantee that the same level of monitoring will occur. To be fair, there is a trade-off that needs to be managed in the framework between the formality of the process and the workload, because resources are finite and already committed to the current processes of risk analysis. Therefore, the framework aims to augment this process by allowing demonstration of consistency, but which can be accommodated by slight changes to the current work practices. To achieve this, the framework relies largely on the existing expertise of risk analysts.

The third reason is the potential sources of risk. Namely, in a number of discussions, challenges to the perceived risk levels arose out of more operational and compliance areas, rather than the scientific basis of risk — the latter being the risk analysts' speciality. For example, there might be issues of third-country routing in trade paths, or questions about verification practices, or even assessments of industry impacts. In these cases, broader sources of expertise may be helpful in determining key risk factors. In order to address this issue, the framework recommends that workshops for identifying or reviewing key risk factors have as broad a participation (i.e. from different department areas such as operations) as practical. However, the practicalities of participation depend on the specific risk analysis (and commodity, policy, etc.) — so the specific decision for each analysis is left with the relevant business owner.

6.5 Non-compliance linked to strategic behaviour creates biosecurity risks

The department routinely relies upon many biosecurity management tasks being conducted by outside entities (e.g exporters/importers, vessel owners, Competent Authorities, third-party certifiers). The process of relying on outside entities create risks because it involves shifting decisions away from those with the strongest incentives to act in the interests of Australia's biosecurity system as a whole (the department), to individuals and groups who face much weaker incentives to do so (Campbell et al. 2021). For those outside entities who are trying to maximise profit, additional biosecurity effort costs money, and so will reduce profit if undertaken. In the case of Competent Authorities, one of the challenges Australia faces is that it has far less control of the systems, monitoring and processes that apply to a Competent Authority's staff than it does for its own staff.

Outside entities make choices strategically to meet their own objectives, and those choices might not necessarily align with Australia's national biosecurity objectives. The level of alignment will depend on the incentive properties of the regulations under which the outside entities operate — regulation by itself is not enough to align the actions of importers/vessel operators etc., with national biosecurity objectives. Explicit consideration of incentives in the design of regulations is required if regulations are to create the stakeholder behaviour required by biosecurity agencies. Where regulations have not been designed to be 'incentive-compatible', there is scope for strategic avoidance of biosecurity conditions. Non-compliance linked to strategic behaviour poses a biosecurity risk and should be considered when reviewing new information about a commodity pathway. These risks were discussed at a project workshop and have been included in the template for key risk factor identification (Appendix A.1). Evidence that suggests strategic behaviour is occurring includes:

- Deliberate non-compliance in the import supply chain
- Illegal imports
- Coordinated behaviour
- Goods declared as something they are not
- Incorrect permits used
- Lack of credibility in policy

Economic theory provides a number of insights into how to design incentives to ensure an individual or organisation with a certain objective will act in a particular way — if one has a measure of the output or type of activity that one wants to facilitate, **and** can influence directly or indirectly something that the individual or organisation cares about, then one can affect behaviour in a beneficial (economically efficient) manner through rewards and punishments. This occurs by creating 'incentive-compatible' biosecurity regulations so that strategic behaviour is avoided or minimised.²

 $^{^2}$ See Campbell et al. (2021) for more details. CEBRA 21C is developing a framework for designing incentivecompatible biosecurity regulations that could be embedded into a biosecurity system

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Appendix A. Elicitation

A.1. Template for Key Risk Factor Identification

Use this template as an aid in systematically identifying key risk factors associated with a risk analysis. The template incorporates a "master list" of high-level categories of potential key risk factors.

Risk Analysis	
Individual/team conducting this identification	
Date	Click or tap to enter a date.
Completed?	\Box (check to indicate Yes)
Version no:	

Categories

1. Understanding of the biology of the hazard	Adequately considered? \Box (check to indicate Yes)
Key risk factors identified:	
Explanation: this involves understanding the biological characteristics of the hazard that are material to assessing the likelihood of entry, establishment and spread, for example:	
• The hazard's taxonomy	

- Hosts, host susceptibility and host range
- Susceptible species
- Changes to diagnosis, mechanism of spread, mode of transmission

Summary Analysis:

2. Disease movements worldwide	Adequately considered? \Box	
Key risk factors identified:		

Explanation: This is the biology/distribution of the hazard as it applies/or relates to a policy For example:

- Geographical distribution
- Disease presence in Australia
- Whether the outbreaks reported are exotic, endemic or endemic seasonal events and how they relate to policy and risk assessments Changes related to transmission, pathways and trade routes

Summary Analysis:

3. Country Health Status (AUS and O/S)	Adequately considered?
Key risk factors identified:	
Explanation: This is the biology/distribution of the hazard at it applies/relates to the Competent Authority and its capacity to detect and notify. For instance, a Competent Authority may claim a status of freedom from disease, and the department may or may not accept this determination on expert judgement or an evaluation etc.	
Summary Analysis:	

4. International Standards (WOAH)	Adequately considered? \Box	
Key risk factors identified:		
Explanation: This is the biology/distribution of the hazard at it applies/relates to the international trade rules.		
For example:		
• If the baseline standards /rules for international trade change, how do claims of disease freedom change as a result?		
Summary Analysis:		

5. Trading partner and Competent Authority systems and processes	Adequately considered?
Key risk factors identified:	
Evaluation: This relates to risk management measures for maintaining animal health status	

Explanation: This relates to risk management measures for maintaining animal health status in trading-partner countries and compliance (see Campbell et al. 2021).

For example:

- Change in Competent Authority (CA) status (both by Australia and/or Exporting country)
- Communication between Australia and CA
- Capacity to comply with requirements

Summary Analysis:

6. Trading partner import conditions	Adequately considered? \Box
Key risk factors identified:	
Explanation: A trading partner's import conditions can influence the department's evaluation of country health status, and influences policies including around transhipment.	
Summary Analysis:	

7. Testing and Verification Methodology	Adequately considered? \Box
Key risk factors identified:	
Explanation: This relates to a country's capacity to meet requirements which is based on their surveillance system etc and includes Australia's import requirements, monitoring, enforcement, and risk management measures.	
Summary Analysis:	

8. Processing and/or Technology	Adequately considered? \Box
Key risk factors identified:	
Explanation: This relates to risk management measures that suppliers on commercial and non-commercial pathways use to mitigate risks in accordance with Australia's import conditions. Have these changed?	
Summary Analysis:	

9. Non-compliant behaviour	Adequately considered?
Key risk factors identified:	
Explanation:	
Non-compliance linked to strategic behaviour poses a biosecurity risk (see Campbell et al.	

Non-compliance linked to strategic behaviour poses a biosecurity risk (see Campbell et al. 2021 for more details). The nature of past non-compliances should be checked. Examples of evidence that suggests strategic behaviour is occurring include:

- Deliberate non-compliance in the import supply chain
- Illegal imports
- Coordinated behaviour
- Goods declared as something they are not
- Incorrect permits used
- Lack of credibility in policy

Summary Analysis:

10. Socio-economic Factors (incl. Impact– social, industrial, trade,environmental)	Adequately considered?
Key risk factors identified:	
Explanation: There are a range of domestic factors that could influence outcomes of a risk assessment. These might include:	
 Change in industry type or size Change in knowledge about the impact of a hazard post-border Changes in local routing or transport mode Change in official control measure 	
Summary Analysis:	

A.2. Master list of risk factor categories for elicitation topics (full list)

The following is a more extended list of risk factors (i.e. potential key risk factors) drawn from departmental materials and the workshop(s) conducted. Use this list as a supplement to the short form in Appendix A.1. This list is organised along the major categories of risk analysis used in the department.

Hazard Identification

- 1. Pests/diseases associated with commodity
- 2. Status of those pests/diseases in exporting country
- 3. Status in Australia
- 4. Adverse consequences in Australia
- 5. WTO/SPS standards and obligations

Risk Assessment

- 1. Pathway
 - a. Entry
 - i. Biological
 - 1. Species, age, breed of animals
 - 2. Agent predilection sites
 - 3. Vaccination, testing, treatment and quarantine.
 - b. Country
 - i. Incidence or prevalence
 - ii. Veterinary services, surveillance and control programs
 - c. Commodity
 - i. Quantity to be imported
 - ii. Ease of contamination
 - Effect of processing (e.g. cooking process temperature and duration, e.g. FDA requirement of cooking turkey meat for certain temperature and duration)
 - iv. Effect of storage and transport
 - d. Exposure
 - i. Biological
 - 1. Properties of the agent
 - ii. Country
 - 1. Presence of potential vectors
 - 2. Human and animal demographics
 - 3. Customs and cultural practices
 - 4. Geographic and environmental characteristics
 - iii. Commodity
 - iv. Quantity to be imported
 - v. Intended use and potential unintended uses
 - vi. Disposal practices
 - e. Establishment and Spread

- 2. Consequences
 - a. Direct impacts on:
 - i. Animal infection, disease, and production losses
 - ii. Public health
 - b. Indirect impacts on:
 - i. Control, monitoring, surveillance and eradication costs
 - ii. Compensation
 - iii. Domestic trade or industry
 - iv. International trade
 - v. Environment (inc. biodiversity)
 - vi. Communities inc. tourism, reduced economic viability

Risk Management

- 1. Risk evaluation
- 2. Option evaluation
- 3. Implementation
- 4. Compliance
 - a. Fraud
 - b. Substitution
 - c. Costs of compliance vs non-compliance
 - d. Assurance and verification
- 5. Monitoring and Review