



**Australian Government**

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**Department of Health**

**Office of Health Protection**

**Security Sensitive Biological Agents  
Regulatory Scheme**

**Regulator Performance Framework  
External Review Report**

**August 2018**

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# Executive Summary

- The Department of Health has responsibility for administration of the Security Sensitive Biological Agents Regulatory Scheme (SSBA Regulatory Scheme). This is undertaken within the Health Emergency Management Branch in the Office of Health Protection, the Regulator.
- External reviews of regulator performance against the Regulator Performance Framework (RPF) are conducted to confirm the validity of, and provide external accountability to, regulator self-assessments of their performance against the Key Performance Indicators (KPI) under the RPF. In accordance with RPF guidelines, this review was conducted by a review panel consisting of government and industry representatives.
- The Panel found that evidence provided by the Regulator of the removal of *Salmonella* Typhi and *Vibrio cholerae* in March 2016 from the List of Security Sensitive Biological Agents (SSBAs), significantly contributed to the Regulator meeting KPIs 1, 2, 3, 5 and 6 under the RPF. The Panel found that the removal of these two agents from the List of SSBAs:
  - reduced the reporting requirements for regulated entities (KPI 1)
  - demonstrated that the Regulator’s ‘communications with its regulated entities was clear, targeted and effective’ (KPI 2)
  - was an example of the Regulator reassessing risk and adjusting their regulatory settings in proportion to the risk being regulated (KPI 3)
  - showed that the Regulator was open and transparent in their dealings with regulated entities (KPI 5); and,
  - contributed to the continuous improvement of the SSBA Regulatory Scheme (KPI 6).
- The Panel found that evidence provided by the Regulator of its compliance inspection agreement with the Office of the Gene Technology Regulator (OGTR) significantly contributed to the Regulator meeting KPIs 1 and 4. The Panel found that by coordinating compliance inspections with the OGTR, the Regulator directly reduced the regulatory burden on regulated entities (KPI 1) by reducing the duration of compliance inspections. The Panel also found that by regularly reviewing and adjusting its compliance schedule to better align with that of the OGTR (KPI 4), the Regulator’s compliance and monitoring approach continued to be streamlined and coordinated.
- The Panel agreed with the Regulator’s self-assessment for each of the KPIs and its overall self-assessment of ‘Very Good’ for its regulatory performance during the reporting period (2015-16).

## Recommendations

Whilst agreeing with the Regulator's overall self-assessment of 'Very Good', the Panel believes there are opportunities for further improvements and recommends the following:

1. The Regulator considers additional mechanisms, such as regular surveys of their regulated entities, to provide further evidence of their performance and the felt effect of their regulatory processes on their regulated entities.
2. The Regulator reviews their evidence metrics and amends them where necessary to better measure their performance against the RPF KPIs.
3. The Regulator considers opportunities to coordinate their inspections with those undertaken by regulators in other Commonwealth Departments.

# 1 Introduction

## 1.1 Security Sensitive Biological Agents Regulatory Scheme

The Department of Health has responsibility for administration of the SSBA Regulatory Scheme. This is undertaken within the Health Emergency Management Branch (HEMB) in the Office of Health Protection, the Regulator. The aim of the SSBA Regulatory Scheme is to limit opportunities for acts of bioterrorism or bio-crime to occur using harmful biological agents and to provide a legislative framework for managing the security of Security Sensitive Biological Agents (SSBAs). Part 3 of the *National Health Security Act 2007* (NHS Act) established the SSBA Regulatory Scheme for entities and facilities that handle suspected or known SSBAs. The *National Health Security Regulations 2008* support the NHS Act by providing operational detail about the SSBA Regulatory Scheme.

The SSBA Regulatory Scheme was developed using risk management principles to achieve a balance between counter-terrorism concerns and the interests of the regulated community, and, aims to maintain appropriate access to SSBAs for those with a legitimate need. The SSBA Regulatory Scheme also gives effect to Australia's obligations under the Biological and Toxin Weapons Convention and UN Security Council Resolution 1540.

## 1.2 Regulator Performance Framework

The Australian Government implemented the RPF on 1 July 2015 to assess the regulatory performance of regulators. The RPF comprises the following six outcomes-based KPIs to articulate the Government's overarching expectations of regulator performance:

1. Regulators do not unnecessarily impede the efficient operation of regulated entities
2. Communication with regulated entities is clear, targeted and effective
3. Actions undertaken by regulators are proportionate to the regulatory risk being managed
4. Compliance and monitoring approaches are streamlined and coordinated
5. Regulators are open and transparent in their dealings with regulated entities
6. Regulators actively contribute to the continuous improvement of regulatory frameworks.

These KPIs outline the principles that all regulators should be using to guide their regulatory performance. Tailored measures of good regulatory performance, based on these high-level principles, would be adopted to enable comprehensive review of individual regulators and their specific tasks and role. The KPIs are supported by 'measures of good regulatory performance' to assist regulators in assessing their achievement of the KPIs.

The RPF aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives and to effect positive, ongoing and lasting cultural change within their organisation. The RPF allows regulators to report objectively on the outcomes of their efforts to administer regulation fairly, effectively and efficiently.

The Department of Jobs and Small Business has overall policy responsibility for the Government's Deregulation Agenda. Further information about the RPF is available on the Department of Jobs and Small Business [Deregulation Agenda](#) web page.

## 1.3 External review

The assessment of regulators under the RPF involves annual self-assessments and periodic external reviews. External reviews of regulator performance against the RPF are conducted to confirm the validity of, and provide external accountability to, regulator self-assessments.

The self-assessment of the Regulator's performance that is the subject of the external review covered the period of the 2015-16 financial year (the reporting period) and was finalised and [published](#) in December 2016. The Regulator's 2015-16 self-assessment report (the Report) was used for the purposes of the external review because that process commenced before the results of the 2016-17 self-assessment became available.

### 1.3.1 The Panel

In accordance with RPF guidelines, the review was conducted by a review panel consisting of government and industry representatives. The Panel included: a representative from the Department of Health; a representative from a comparable regulator and a representative of the Regulator's regulated community. The Panel members appointed to undertake the review in late 2017 were:

- Gillian Shaw, Assistant Secretary, Health Systems Policy Division, Department of Health;
- Neil Ellis, Acting Assistant Secretary, Office of the Gene Technology Regulator; and
- Public Health Laboratory Manager and member of the regulated community.

### 1.3.2 External review rating scale of performance against KPIs

For consistency, the Panel has used the same rating scale below that the Regulator used in its self-assessment Report, as follows:

<b>Excellent</b>	<b>Very Good</b>	<b>Good</b>	<b>Fair</b>	<b>Poor</b>
Strong performance against all the measures under the KPI	Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure	Average performance against the measures under the KPI	Poor performance against some measures under the KPI	Poor performance against most of the measures under the KPI

## **2 Results**

### **2.1 KPI 1: Regulators do not unnecessarily impede the efficient operation of regulated entities**

#### **2.1.1 Overall assessment**

The Regulator provided evidence that it had reduced the amount of regulation that its regulated entities were required to comply with and that it did not unnecessarily impede the efficient operation of its regulated entities during the reporting period. The Panel was satisfied that evidence provided by the Regulator supported their self-assessed rating of ‘Very Good’ for KPI 1.

#### **2.1.2 Performance overview**

##### ***2.1.2.1 Removal of biological agents from the List of SSBA***

Evidence provided to the Panel of the removal of *Salmonella Typhi* and *Vibrio cholerae* in March 2016 from the List of SSBA significantly contributed to the Regulator meeting KPI 1. This measure resulted in reduced reporting for regulated entities holding these agents. Additionally, entities that were only holding one or both of these agents were no longer required to comply with the requirements of the SSBA Regulatory Scheme as a whole. The Panel found that the removal of these two agents from the List of SSBA reduced the reporting requirements for regulated entities, and for some regulated entities, the need to undergo on-going inspections and thereby contributed to the efficiency of their operations.

##### ***2.1.2.2 Reporting***

The Panel received evidence of the availability of regulated entities to provide reports to the Regulator on-line which supported the Regulator meeting KPI 1. Although the on-line reporting facility was available prior to the beginning of the reporting period, it was maintained fault-free and was available 24/7 throughout the reporting period. The Panel found that on-line reporting provided a more efficient means of entry and transmission of data for regulated entities.

##### ***2.1.2.3 Compliance inspections***

The Regulator provided evidence of the coordination of compliance inspections with the OGTR which contributed to the Regulator meeting KPI 1. Although the evidence presented concerning compliance inspections under KPI 1 outlined facilitation work undertaken by the Regulator, the Panel heard that the streamlining of the Regulator’s compliance inspections by combining them with those of the OGTR was well received by regulated entities. With compliance inspections taking up to several days to complete, the Panel found that coordinating compliance inspections with the OGTR directly reduced the regulatory burden on regulated entities.

##### ***2.1.2.4 Correspondence***

The Panel heard evidence of the diverse methods of correspondence made available for regulated entities to provide feedback to the Regulator, which supported the Regulator meeting KPI 1. The Panel found that the diversity of contact methods available provided flexibility for regulated entities in the way they were able to communicate with the Regulator and thereby contributed to the efficiency of their operations. The Regulator received no formal complaints regarding the SSBA Regulatory Scheme during the reporting period.

## **2.2 KPI 2: Communications with regulated entities is clear, targeted and effective**

### **2.2.1 Overall assessment**

Evidence provided by the Regulator concerning information and the channels for information exchange available to their regulated entities demonstrated that the Regulator's 'communications with its regulated entities was clear, targeted and effective' and supported their self-assessed rating of 'Very Good' for KPI 2.

### **2.2.2 Performance overview**

#### **2.2.2.1 SSBA webpage**

The Panel found that the provision of information on the SSBA webpage was a primary source of evidence that supported the Regulator meeting KPI 2. This included two SSBA Newsletters during the reporting period (December 2015 and June 2016), which provided regulated entities with information about the removal of *Salmonella* Typhi and *Vibrio cholerae* from the List of SSBAs. Additionally, the Panel found that the availability of the SSBA Standards, Fact Sheets and Guidelines on the webpage allowed regulated entities to quickly and easily access the information they required to comply with the SSBA Regulatory Scheme.

#### **2.2.2.2 Regulator presentations**

The Regulator provided evidence that during the reporting period it delivered three formal presentations on the SSBA Regulatory Scheme. These included presentations at the Australian National University (ANU) (Biosecurity Course), ANU (National Security College) and Association of Biosafety for Australia & New Zealand (ABSANZ) conference. The Panel found that these presentations allowed the Regulator to tailor its information to targeted audiences and provide responsive feedback on issues raised, which in turn supported the Regulator meeting KPI 2.

#### **2.2.2.3 On-line training**

The Regulator provided evidence that it maintained an on-line training facility for its regulated entities, which was found by the Panel to contribute to the Regulator meeting KPI 2. This online training facility, while not mandatory, was provided to assist regulated entities to explain the supporting legislation and to deliver training in accordance with the SSBA Standards.

#### **2.2.2.4 Correspondence**

Evidence of the range of correspondence methods offered by the Regulator to enable regulated entities to provide feedback supported the Regulator meeting KPI 2. As with KPI 1, the Panel found that the diversity of contact methods available provided flexibility for regulated entities in the way they were able to communicate with the Regulator.

## **2.3 KPI 3: Actions taken by regulators are proportionate to the regulatory risk being managed**

### **2.3.1 Overall assessment**

Evidence provided by the Regulator of the process undertaken for the removal of *Salmonella* Typhi and *Vibrio cholerae* from the List of SSBA and of the risk-based settings for their compliance program, supported their self-assessed rating of 'Excellent' for KPI 3.

### **2.3.2 Performance overview**

#### ***2.3.2.1 Removal of biological agents from the List of SSBA***

As with KPI 1, the Panel found that the removal of *Salmonella* Typhi and *Vibrio cholerae* in March 2016 from the List of SSBA significantly contributed to the Regulator meeting KPI 3. The removal of these two agents followed a review by the Regulator which is undertaken at five year intervals. The re-classification of *Salmonella* Typhi and *Vibrio cholerae* as not being SSBA was an example of the Regulator reassessing risk and adjusting their regulatory settings in proportion to the risk being regulated.

#### ***2.3.2.2 Compliance inspections***

The Regulator provided evidence that it undertook compliance inspections proportionate to the risk being managed. For example, the Regulator inspected all facilities within the first 12 months of registration. Thereafter, registered facilities handling Tier 1 SSBA were inspected every 18 months and registered facilities handling Tier 2 SSBA were inspected every two years. Non-registered facilities were inspected on an as-needed basis. Spot checks of registered and non-registered facilities occurred on a random basis. The Regulator also employed compliance inspection plans for registered and non-registered entities based on the risks posed. The Panel found that these compliance practices contributed to the Regulator meeting KPI 3.

#### ***2.3.2.3 Consultations***

The Regulator provided evidence that the requirements of the SSBA Regulatory Scheme, particularly in relation to the review of the List of SSBA, was discussed with the Public Health Laboratory Network (PHLN) at two meetings and with the Australian (counter) Bioterrorism Laboratory Network (ABLN) at one meeting. The purpose of these meetings, as stated in the Regulator's RPF Evidence Metrics, was to discuss and seek feedback from PHLN and ABLN on the appropriateness of the SSBA Regulatory Scheme requirements against the risk being managed. Both the PHLN and the ABLN were also approached during the formal consultation period for the review of the List of SSBA as scientific and technical experts, as required by s 33(1)(a)(ii) of the NHS Act. The Panel found that these consultation activities supported the Regulator meeting KPI 3.

## **2.4 KPI 4: Compliance and monitoring approaches are streamlined and coordinated**

### **2.4.1 Overall assessment**

Evidence provided by the Regulator of its compliance inspection agreement with the OGTR to coordinate and streamline its compliance inspections supported their self-assessed rating of ‘Very Good’ for KPI 4.

### **2.4.2 Performance overview**

#### ***2.4.2.1 Compliance inspections***

The Panel found that evidence provided by the Regulator that it continued to coordinate compliance inspections of its regulated entities’ facilities with the OGTR significantly contributed to the Regulator meeting KPI 4. The Regulator reviewed its inspection schedule, for example, at each SSBA Compliance Committee meeting and adjusted its schedule to better align with that of the OGTR and the Regulator’s priorities, as necessary. By coordinating and streamlining its compliance inspections with those of the OGTR, the Panel found that the Regulator reduced the impost it posed on regulated entities while continuing to carry out its compliance inspection plan.

## **2.5 KPI 5: Regulators are open and transparent in their dealings with regulated entities**

### **2.5.1 Overall assessment**

The Panel found that there are sufficient similarities between KPI 2 and KPI 5 that they could be assessed using the same evidence. The RPF describes better practice for both KPI 2 and KPI 5 as ‘regulators clearly communicating the compliance requirements of a regulatory scheme and clearly communicating why and how the requirements contribute to its achievement’. Evidence provided by the Regulator under KPI 2 was assessed as sufficient to show that the Regulator met KPI 5 and is commensurate with their self-assessed rating of ‘Very Good’ for this KPI.

### **2.5.2 Performance overview**

In addition to evidence provided under KPI 2, the Regulator also provided evidence to support it meeting KPI 5. This included:

- the availability of on-line information
- consultation meetings regarding changes to the List of SSBA's
- the diverse options for regulated entities to communicate with the Regulator; and
- the efficient and effective manner in which the Regulator responded to correspondence from regulated entities.

The Panel found that these measures accord with the Regulator being open and transparent in their dealings with regulated entities and communicating in a clear, targeted and effective manner.

## **2.6 KPI 6: Regulators actively contribute to the continuous improvement of regulatory frameworks**

### **2.6.1 Overall assessment**

Evidence provided by the Regulator concerning the review of the List of SSBA and consideration of issues raised by their stakeholders, contributed to the continuous improvement of the SSBA Regulatory Scheme and supported the Regulator's self-assessed rating of 'Very Good' for KPI 6.

### **2.6.2 Performance overview**

#### ***2.6.2.1 Regular review of SSBA***

The Panel found that the removal of *Salmonella* Typhi and *Vibrio cholerae* from the List of SSBA contributed to the Regulator meeting KPI 6 as this action reduced the regulatory burden on SSBA regulated entities, and thereby contributed to the efficiency of their operations as described under KPI 1 at 2.1.2.1. The Report lists amendments to SSBA Guidelines and Fact Sheets to reflect the change in the List of SSBA in support of the Regulator meeting KPI 6. The Panel found that the review of the List of SSBA and the subsequent removal of the two agents was an example of the Regulator actively contributing to the continuous improvement of the SSBA Regulatory Scheme.

#### ***2.6.2.2 Consultation***

The Regulator provided evidence that feedback from its regulated entities was encouraged through the SSBA email inbox, phone line and correspondence with stakeholders, including during compliance inspections. When appropriate, issues raised by regulated entities were added to a matrix of issues indicating the Regulator's willingness to consider feedback that may contribute to the continuous improvement of the SSBA Regulatory Scheme. The Panel found that the Regulator's consultations with stakeholders contributed to the review of SSBA and the subsequent removal of *Salmonella* Typhi and *Vibrio cholerae* from the List.

## **3 General observations**

### **3.1 Overall assessment of the Regulator's performance**

Overall, the Panel found that evidence provided by the Regulator to support its Report was sufficient to assess the Regulator as having met the requirements of the six RPF KPIs. The Panel agrees with the Regulator that an overall performance rating of 'Very Good' was appropriate for the reporting period and acknowledged this was strongly supported through the external stakeholder validation process.

The Regulator indicated to the Panel that the felt effect of their regulatory performance on their regulated entities was primarily received through monitoring inspections rather than via correspondence or formal surveys. The Panel sought contact details for the Regulator's regulated entities from the Regulator in order to further assess the felt effect of the Regulator's regulatory performance. However, the Regulator was unable to provide these details to the Panel due to National Security considerations.

The Panel found the SSBA Regulatory Scheme to be a mature regulatory scheme and as indicated by the peak association representing its regulated community, that it was widely supported. The Regulator and its regulated entities have a shared and common interest in the success of the SSBA Regulatory Scheme and as such, there is a high level of compliance with the SSBA regulations and cooperation between the Regulator and its regulated entities.

### **3.2 Observations of the Regulator Performance Framework**

The Panel notes that:

- There is a significant amount of overlap/cross-over between the RPF KPIs, particularly between KPI 2 and KPI 5. Accordingly, an opportunity exists for the Department of Jobs and Small Business, which has responsibility for the RPF for the Commonwealth, to rationalise and refine the RPF to make it more efficient and effective.
- The development of better guidance for panel members on their assessment responsibilities, and on the overall external review process by the Department of Jobs and Small Business, would help to ensure consistent processes and comparable outcomes.
- There is a risk of stakeholder consultation fatigue given the frequency of RPF reviews, particularly the annual self-assessments that must be externally validated. Therefore, more value might be extracted from the RPF if reviews were less frequent, and agencies were given time to act on previously identified opportunities for improvement.
- The SSBA Regulatory Scheme is a small, well-established and mature regulatory scheme with a small cohort of supportive and compliant stakeholders and therefore, consideration should be given by the Department of Jobs and Small Business to exempt such small regulators from the requirements of the RPF due to its disproportionate impact.

## 4 Recommendations

Whilst agreeing with the Regulator's overall self-assessment of 'Very Good', the Panel believes there are opportunities for further improvements and recommends the following:

1. The Regulator considers additional mechanisms, such as regular surveys of their regulated entities, to provide further evidence of their performance and the felt effect of their regulatory processes on their regulated entities.
2. The Regulator reviews their evidence metrics and amends them where necessary to better measure their performance against the RPF KPIs.
3. The Regulator considers opportunities to coordinate their inspections with those undertaken by regulators in other Commonwealth Departments.

## 5 Terms of reference

### External Review of the regulatory performance of the Security Sensitive Biological Agents, Office of Health Protection

#### Terms of Reference

##### Context

##### *The Regulator Performance Framework*

The Regulator Performance Framework (RPF), which came into operation on 1 July 2015, aims to increase transparency and accountability in the way regulators perform their role. The RPF sets out six broad outcome-based Key Performance Indicators (KPIs) to measure and assess the performance of regulators.

The RPF includes a tiered process of reviews of the regulatory performance of regulators including annual self-assessments and periodic external reviews. Health's programme of external reviews of its regulators over 2015-18 was agreed with the Prime Minister in October 2016.

All Australian Government regulators subject to the RPF are required to develop, and publish, a set of evidence metrics (output/activity based indicators) to assess their performance against the RPF KPIs through the annual self-assessments and periodic external reviews.

##### *The Security Sensitive Biological Agents Regulatory Scheme (SSBA), Office of Health Protection*

The SSBA is one of the Health regulators subject to the requirements of the RPF.

The SSBA published its evidence metrics in July 2015 on Health's website and conducted its first annual self-assessment of its regulatory performance in 2015-16. This self-assessment report was validated by the Public Health Laboratory Network Executive Group (PEG), and published on Health's website on 23 December 2016.

The SSBA Regulatory Scheme was nominated for an external review of its regulatory performance during 2015-18 and is the first regulator in the Health Portfolio to participate.

##### Purpose and Scope

The purpose of this external review of regulatory performance under the RPF is to confirm the validity of, and provide external accountability for, the SSBA Regulatory Scheme's 2015-16 self-assessment and highlight areas for improvement of their regulatory performance.

The RPF requires that the review panel (the Panel) limit the focus of the review to the regulator's performance in applying legislation efficiently and with as minimum impact on stakeholders as possible rather than on the appropriateness or fairness of the legislation itself.

With reference to the purpose, the Panel will:

- review evidence to assess the SSBA Regulatory Scheme's performance against the RPF KPIs, listed at [Attachment A](#)
- focus on the SSBA Regulatory Scheme's communication methods and channels with its regulated community
- assess the extent to which the SSBA Regulatory Scheme's evidence metrics align with, and contribute to, the Scheme meeting the RPF KPIs
- assess the extent to which the SSBA Regulatory Scheme's 2015-16 self-assessment report clearly explains the Scheme's performance against RPF KPIs
- identify areas in need of improvement and suggest actions for improving performance; and
- highlight areas of best practice performance observed during the review.

## **Governance**

### ***The Review Panel***

The review will be conducted by a review panel.

The membership of the Panel, which was developed in accordance with RPF guidelines, is:

- Assistant Secretary, Best Practice Regulation Branch (BPRB), as a Departmental representative
- an officer from the Office of the Gene Technology Regulator, as a comparable regulator representative; and
- a member of the Public Health Laboratory Network, as a key stakeholder group for the SSBA Regulatory Scheme.

The Assistant Secretary, BPRB will chair the Panel.

The Panel will be expected to meet 1-2 times during November-December 2017. The meetings may be attended in person or via teleconference.

The Panel will cease to exist with the finalisation of the review report.

### ***The review secretariat***

Regulatory Reform Section, BPRB will provide secretariat support to the Panel.

The secretariat will be available to undertake, at the Panel's discretion, supporting activities, including:

- developing a draft design of the review including methodology
- gathering and analysing evidence for the review; and
- preparing a draft report, for the Panel's consideration and approval.

## **Review Approach**

The RPF encourages review panels to complement the reporting of quantitative data with qualitative information and recommends judgments on performance be made by drawing on a range of evidence from different sources to allow a comprehensive assessment of performance.

The Panel also needs to balance the benefits of transparency against the costs (time and money) associated with collecting the evidence necessary to make an assessment of the SSBA Regulatory Scheme's performance.

## **Deliverable**

The results of the review are expected to be reported to the Minister and published on the Department of Health's website.

## **Review Methodology**

The external review will examine the SSBA Regulatory Scheme's performance against the RPF focussing on its communication methods and channels with its regulated community. In doing so, it will confirm the validity of and provide external accountability for the SSBA Regulatory Scheme's 2015-16 self-assessment report.

The external review will be a desktop exercise examining performance against the six RPF KPIs.

During the review the Panel will:

- have access to an SSBA subject matter expert (SSBA expert); and
- have the opportunity to request further information/evidence.

The SSBA expert will attend the first Panel meeting and provide an overview of the SSBA Regulatory Scheme's regulatory functions and regulatory performance relating to the RPF. The SSBA expert will also answer questions from the Panel and respond to requests for further evidence to support their performance.

Appendices 1–6 provide an assessment framework for each KPI, drawing on the Department of Prime Minister and Cabinet's (PM&C) examples of:

- better practice
- measures of good regulatory performance; and
- output/activity based evidence.

The proposal is for the Panel to use the assessment framework to guide its examinations.

At the conclusion of the Panel's review, the secretariat will use the Panel's completed assessment to form the basis of the draft report, which will be provided to the Panel for review and agreement.

**The Regulator Performance Framework (RPF) Key Performance Indicators (KPIs)**

The RPF comprises the following six outcomes-based KPIs against which the regulatory performance of regulators is measured. These are:

- KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities.
- KPI 2 – Communication with regulated entities is clear, targeted and effective.
- KPI 3 – Actions undertaken by regulators are proportionate to the risk being managed.
- KPI 4 – Compliance and monitoring approaches are streamlined and coordinated.
- KPI 5 – Regulators are open and transparent in their dealings with regulated entities.
- KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks.



**PANELLIST:**

**BETTER PRACTICE**

The way regulation is implemented and enforced can have as significant an impact on productivity and economic growth, and cause as much overhead for individuals, as the content of the regulation itself.

Effective regulatory administration allows, and through regulatory actions encourages, efficient operations of regulated entities. Better practice regulators aim to achieve the intended outcomes of their regulations without unnecessarily restricting or imposing unnecessary burden on regulated entities. Enforcement activities only occur when there is a clear case for doing so.

These regulators also, where appropriate, recognise that they may need to adapt approaches to particular stakeholders. For example, regulators may need to consider different approaches for small business to demonstrate compliance with regulatory standards, particularly where approaches applied to larger business could create disproportionate burdens for small business.

Within the context of its statutory obligations and priorities as defined by the Government, the activities of a better practice regulator do not unnecessarily impede the efficient operations of regulated entities. When designing and reviewing policies and operational procedures and practices, these regulators consider how they might avoid imposing unnecessary costs while fulfilling their statutory role. They seek to achieve a balance between the responsibility to deliver protection to the community and the burden imposed by external intervention.

Regulators have regard to their legislative and authorising environment at all times and take steps to minimise duplication and optimise harmonisation with other relevant regulators.

**QUESTIONS – measures of good regulatory performance**

1. How does SSBA gain and demonstrate an understanding of the operating environment of the industry or organisation, or the circumstances of individuals and the current and emerging issues that affect the sector?

2. What actions does SSBA take to minimise the potential for unintended negative impacts of regulatory activities on regulated entities, affected supplier industries and supply chains?

3. What continuous improvement strategies does SSBA have to reduce the costs of compliance for those they regulate?

**EVIDENCE – outputs and activities**

- Examples from the RPF:
- Regular, ongoing consultations or engagement with stakeholders on policies and procedures, including independent experts and industry associations.
  - Documented responsiveness to feedback from regulated entities, including feedback from existing complaint mechanisms and surveys of regulated entities.
  - Environment scanning is undertaken regularly and at a minimum, on an annual basis.
  - Demonstrated engagement with relevant international organisations to learn from peer experiences and share better practices.

**OVERALL ASSESSMENT**

<b>Excellent</b>	Strong performance against all the measures under the KPI
<b>Very Good</b>	Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure
<b>Good</b>	Average performance against the measures under the KPI
<b>Fair</b>	Poor performance against some measures under the KPI
<b>Poor</b>	Poor performance against most of the measures under the KPI

**COMPARISON – SSBA 2015-16 self-assessment result for KPI 1:**

**Very Good**

Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure

**Comments:**

APPENDIX 2: REGULATOR PERFORMANCE FRAMEWORK (RPF) EXTERNAL REVIEW  
SECURITY SENSITIVE BIOLOGICAL AGENTS REGULATORY SCHEME (SSBA), OFFICE OF HEALTH PROTECTION



KPI 2 – COMMUNICATIONS WITH REGULATED ENTITIES IS CLEAR, TARGETED AND EFFECTIVE

PANELLIST:

**BETTER PRACTICE**  
Effective communication is vital for the efficient delivery of regulatory services and the achievement of positive regulatory outcomes. Clear advice and guidance can reduce the compliance burden on regulated entities and reduce non-compliant activity. Better practice regulators communicate in such a way that regulated entities clearly understand what they need to do in order to comply with regulation. Regulated entities are able to find out quickly which regulations apply to them, what the requirements are, and how they can comply and/or improve compliance over time. Once regulated entities understand both what they need to do to comply and how this contributes to regulatory objectives, regulated entities are more likely and more willing to comply. Effective regulators explain how specific requirements and processes fit into the overarching regulatory frameworks. The reasons for regulatory decisions are clearly communicated. Communication with regulated entities is consistent to assist regulated entities to quickly understand the compliance requirements. This also increases confidence in the regulation.

**QUESTIONS – measures of good regulatory performance**

1. How does SSBA ensure that their guidance and information is up to date, clear, accessible and concise, and provided to the target audience through appropriate media?
2. How does SSBA consider the impact on regulated entities and engage with industry groups and representatives of the affected stakeholders before changing policies, practices or service standards?
3. Does SSBA communicate its decisions and advice in a timely manner, clearly articulating expectations and the underlying reasons for decisions?
4. Is the advice SSBA provides consistent, and support predictable outcomes?

**EVIDENCE – outputs and activities**

Examples from the RPF:

- Percentage of guidance materials that complies with government accessibility guidelines. Minimum, maximum and average time for decision.
- Published timeliness for decision making.
- Percentage of decisions accompanied by statement of reasons and advice about relevant review or appeal mechanisms, where appropriate.
- Number of policy/standards changes which are preceded by comprehensive engagement with stakeholders.
- Approved procedures for communications (including issue-specific scripts if relevant) are available for staff use when interacting with regulated entities.
- Advice provided to regulated entities is consistent with communication policies.
- Demonstrated feedback is sought from stakeholders on guidance and advice provided by the regulator via a wide range of mechanisms, including stakeholder surveys.
- Demonstrated mechanisms for responding to stakeholder engagement/complaint.

**OVERALL ASSESSMENT**

<b>Excellent</b>	Strong performance against all the measures under the KPI
<b>Very Good</b>	Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure
<b>Good</b>	Average performance the measures under the KPI
<b>Fair</b>	Poor performance against some measures under the KPI
<b>Poor</b>	Poor performance against most of the measures under the KPI

**COMPARISON – SSBA 2015-16 self-assessment result for KPI 2:**

**Very Good**

Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure

**Comments:**



**KPI 3 – ACTIONS UNDERTAKEN BY REGULATORS ARE PROPORTIONATE TO THE REGULATORY RISK BEING MANAGED**

**PANELLIST:**

**BETTER PRACTICE**

Comprehensive risk assessment processes are essential to ensuring that resources are targeted to the areas requiring the most attention. A risk-based approach promotes the most efficient use of resources and improves the effectiveness of the regulatory framework through minimising burden on those who are voluntarily compliant and ensuring that enforcement action is proportionate and undertaken only when necessary.

Efficient regulatory risk assessment takes account of the regulated activity, the nature of the regulated cohort, including its compliance history, and other external factors affecting risk. Risk assessments are balanced and implemented firmly and impartially, while also being dynamic and open to scrutiny. They're based on the recognition that not all risk can be eliminated and not all risk can be effectively mitigated by government.

Where the risk of non-compliance is high or the consequence of non-compliance significant, there is a higher degree of monitoring. Where the risk of non-compliance is low or the consequences of non-compliance minor, regulators take lighter touch approaches. For example, regulators consider light touch responses for stakeholders that may be disproportionately affected by regulatory burden, such as small business, individuals and community organisations that may have more difficulty in finding the resources or skills to respond to compliance requirements.

A full suite of regulatory tools is appropriately utilised to ensure compliance. Where possible, regulators consider the use of positive incentives, cooperation from industry groups, and other means to encourage compliance. Any enforcement action undertaken is within the constraints of the authorising legislation and penalties are proportionate to both the seriousness of the breach and the risk being managed.

**QUESTIONS – measures of good regulatory performance**

1. Does SSBA apply a risk-based, proportionate approach to compliance obligations, engagement and regulatory enforcement actions?
2. How regulatory is SSBA's approach to regulatory risk reassessed?
3. Are SSBA's strategies, activities and enforcement actions amended to reflect changing priorities that result from new and evolving regulatory threats, without diminishing regulatory certainty or impact?
4. How does SSBA acknowledge the compliance record of regulated entities, including using earned autonomy where appropriate?
5. Is all available and relevant data on compliance, including results of relevant external verification, considered?

**EVIDENCE – outputs and activities**

Examples from the RPF:

- Percentage of guidance materials that complies with government accessibility
- Risk management policies and procedures are available to regulator staff and the public.
- Compliance and enforcement strategies, consistent with agreed risk management policies are published.
- Documented approaches in place to review risk, approaches regularly.
- Statements of expectations and intent are published.
- Agreed quality assurance processes are in place for staff use.
- Relevant staff trained in risk management policies, processes and procedures.
- Documented enforcement strategy, which allows for the compliance records of regulated entities to be considered in determining regulatory actions.
- Documented enforcement strategy includes options for graduated compliance actions consistent with regulators' powers.
- Demonstrated engagement with regulated entities to inform them of the regulators' expectations
- Demonstrated avenues for stakeholders to provide feedback, and processes or policies to incorporate/consider this when tailoring approaches to risk.

**OVERALL ASSESSMENT**

<b>Excellent</b>	Strong performance against all the measures under the KPI
<b>Very Good</b>	Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure
<b>Good</b>	Average performance against the measures under the KPI
<b>Fair</b>	Poor performance against some measures under the KPI
<b>Poor</b>	Poor performance against most of the measures under the KPI

**COMPARISON – SSBA 2015-16 self-assessment result for KPI 3:**

**Excellent**  
Strong performance against all the measures under the KPI

**Comments:**



**KPI 4 – COMPLIANCE AND MONITORING APPROACHES ARE STREAMLINED AND COORDINATED**

**PANELLIST:**

**BETTER PRACTICE**

Compliance and monitoring are an essential part of regulatory frameworks. These processes allow regulators to determine the level of compliance with regulation.

The collection of information and/or data, while necessary to determine compliance with regulations, imposes costs on regulated entities. These costs are considered by better practice regulators in the design and implementation of a compliance regime. These regulators seek to minimise the compliance costs imposed on entities by inspection and monitoring approaches. Compliance costs can be minimised in a number of ways, including through implementing risk-based approaches and streamlining inspection and monitoring processes as far as possible.

Effective regulators do not seek information from regulated entities unless the information is required to achieve the regulatory outcome sought. Regulators minimise duplicative information requests, including between regulators where possible, and consider whether the information sought is a valuable from alternative means.

Inspections focus on identifying and addressing persistent breaches of regulation and aim to improve compliance. They are justified and targeted on the basis of an assessment of the compliance risk. The possibility of joint or coordinated inspections is considered to assist in reducing the burden on business.

**QUESTIONS – measures of good regulatory performance**

1. Are SSBA's information requests tailored, and only made when necessary to secure regulatory objectives, and only then in a way that minimises impact?
2. Does SSBA try to minimise the frequency of information collection, and do they coordinate with similar processes - including those of other regulators - so that as far as possible information is only requested once?
3. Does SSBA utilise existing information to limit the reliance on requests from regulated entities, and do they share the information among other regulators where possible?
4. Are SSBA's monitoring and inspection approaches based on risk and, where possible, do they take into account the circumstance and operational needs of the regulated entity?

**EVIDENCE – outputs and activities**

*Examples from the RPF:*

- Number of repeat information requests made to regulated entities annually
- Percentage of inspection visits coordinated with similar regulators
- Percentage of information shared and received among regulators
- Proportion of information obtained from other sources, with input not required from regulated entities.
- Evidence of collected information being acted upon, stored and re-used.
- Demonstrated transparency of inspection and monitoring arrangements.
- Feedback mechanisms to seek stakeholder views on inspection and monitoring regime.
- Monitoring and enforcement strategies that allow for a range of regulatory responses.
- Regular review and assessment of agreed monitoring and compliance strategies, including use of earned autonomy approaches.
- Demonstrated avenues for stakeholder to provide feedback and processes or policies to incorporate/consider this when tailoring approaches to risk.

**OVERALL ASSESSMENT**

<b>Excellent</b>	Strong performance against all the measures under the KPI
<b>Very Good</b>	Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure
<b>Good</b>	Average performance the measures under the KPI
<b>Fair</b>	Poor performance against some measures under the KPI
<b>Poor</b>	Poor performance against most of the measures under the KPI

**COMPARISON – SSBA 2015-16 self-assessment result for KPI 4:**

**Very Good**

Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure

**Comments:**



**PANELLIST:**

**BETTER PRACTICE**

It is important that regulators are open and transparent in the way they regulate to ensure the confidence of those being regulated and the wider community. If regulated entities understand how and why they are being regulated, compliance may increase and regulatory outcomes are more likely to be achieved. Transparency also contributes to a greater understanding of the regulators role by both the regulated cohort and the broader community.

Open and transparent dealings with regulated entities increases the accountability of both regulators and government. Increased accountability, to both regulated entities and the wider community, improves the overall performance of regulators. Ensuring regulators are accountable for their decisions also improves community confidence in the regulator. Increased transparency and accountability provides regulated entities with a greater understanding of how the regulator seeks regulatory outcomes and addresses misgued perceptions of regulator performance.

Where possible, better practice regulators clearly communicate the evidence base and approach used in the regulatory decision making process to regulated entities. Regulatory objectives and risk-based frameworks are made publicly available whenever possible. While the risk of gaming from regulated entities is considered, risk-based frameworks are made public unless it can be clearly demonstrated this would lead to a failure of the regulatory system. Publishing risk-based frameworks helps to ensure the regulated entity understands what is required and provides a clear statement of what the regulator is trying to achieve. Results from performance measurement against this framework are also made public in a timely way to ensure an open and transparent relationship with regulated entities.

**QUESTIONS – measures of good regulatory performance**

1. Are SSBA's risk-based frameworks publicly available in a format which is clear, understandable and accessible?
2. Is SSBA open and responsive to requests from regulated entities regarding the operation of the regulatory framework, and the approaches implemented?
3. Does SSBA publish its performance measurement results in a timely manner to ensure accountability to the public?

**EVIDENCE – outputs and activities**

- Examples from the RPF:*
- Enforcement strategy and risk approach are published.
  - Performance measurement results are published.
  - Percentage of regulated entities that receive requests for information with the reasons for these requests communicated clearly and consistently.
  - Percentage of performance information publicly available.
  - Number of responses to requests from regulated entities provided within specified timeframes.
  - Advice and guidance is widely available to stakeholders, with feedback mechanisms in place to support and inform continuous improvement.

**KPI 5 – REGULATORS ARE OPEN AND TRANSPARENT IN THEIR DEALINGS WITH REGULATED ENTITIES**

**OVERALL ASSESSMENT**

<b>Excellent</b>	Strong performance against all the measures under the KPI
<b>Very Good</b>	Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure
<b>Good</b>	Average performance the measures under the KPI
<b>Fair</b>	Poor performance against some measures under the KPI
<b>Poor</b>	Poor performance against most of the measures under the KPI

**COMPARISON – SSBA 2015-16 self-assessment result for KPI 5:**

**Very Good**

Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure

**Comments:**



PANELLIST:

KPI 6 – REGULATORS ACTIVELY CONTRIBUTE TO THE CONTINUOUS IMPROVEMENT OF REGULATORY FRAMEWORKS

**BETTER PRACTICE**

Better practice regulators actively contribute to the continuous improvement of regulatory frameworks. No service remains the same over time, and continuous improvement ensures a regulatory framework has the flexibility to adjust to changing circumstances.

Better practice regulators follow the principles identified in KPI 2, building appropriate communication channels to promote a regular feedback cycle with peers and regulated entities. Information collected as part of monitoring and compliance approaches is used by these regulators to inform improvements in the authorising legislation and achieve reductions in compliance costs. Stakeholder feedback informs the development of any proposed change to management activities, to ensure the proposed actions are appropriately targeted. These actions, taken to improve frameworks, are clearly articulated and communicated to stakeholders.

This process maintains the cycle of continuous improvement, and provides the flexibility for regulatory frameworks to adapt to changes in the external environment.

**QUESTIONS – measures of good regulatory performance**

4. How does SSBA establish cooperative and collaborative relationships with stakeholders to promote trust and improve the efficiency and effectiveness of the regulatory framework?

5. How does SSBA engage stakeholders in the development of options to reduce compliance costs? This could include industry self-regulation, changes to the overarching regulatory framework, or other strategies to streamline monitoring and compliance approaches.

6. Does SSBA regularly share feedback from stakeholders and performance information (including from inspections) with policy departments to improve the operation of the regulatory framework and administrative processes?

**EVIDENCE – outputs and activities**

Examples from the RPF:

- Documented procedures are in place to allow active and regular engagement with stakeholders.
- Feedback mechanisms are available and made known to all stakeholders.
- Number of stakeholder events held to facilitate participation in the development and/or amendment of regulatory frameworks.
- Documented procedures are in place to facilitate the flow of information between the regulator and policy departments.
- Percentage of performance data, feedback from regulated entities, and/or advice provided by the regulator to the policy departments.

**OVERALL ASSESSMENT**

<b>Excellent</b>	Strong performance against all the measures under the KPI
<b>Very Good</b>	Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure
<b>Good</b>	Average performance the measures under the KPI
<b>Fair</b>	Poor performance against some measures under the KPI
<b>Poor</b>	Poor performance against most of the measures under the KPI

**COMPARISON – SSBA 2015-16 self-assessment result for KPI 6:**

**Very Good**

Strong performance against majority of the measures under the KPI and no evidence of negative/poor performance against any measure

**Comments:**

## 5.1 List of evidence

1. [National Health Security Act 2007](#)
2. [National Health Security Regulations 2008](#)
3. [SSBA RPF 2015-16 Self-assessment report](#)
4. [SSBA RPF Evidence metrics](#)
5. [SSBA Standards](#)
6. [Review of Biological Agents of Security Concern Final Report February 2016](#)
7. [Review of Biological Agents of Security Concern Consultation Report October 2015](#)
8. [SSBA Regulatory Scheme Inspection Program](#)
9. [SSBA Internal Review Tool](#)
10. [SSBA Security Risk Template](#)
11. [SSBA website](#)
12. [SSBA Fact Sheets](#)
  - Fact Sheet 1 – Overview
  - Fact Sheet 2 – About Us
  - Fact Sheet 3 – Legislative Framework
  - Fact Sheet 4 – Exemptions
  - Fact Sheet 5 – List of Security Sensitive Biological Agents
  - Fact Sheet 6 – Top Management
  - Fact Sheet 7 – Monitoring and Compliance
  - Fact Sheet 8 – Emergency Disease Situations
  - Fact Sheet 9 – Disposal
  - Fact Sheet 10 – Information Security
  - Fact Sheet 11 – Upgrading a Facility from Tier 2 to Tier 1 SSBA
  - Fact Sheet 12 – Domestic Legislation
  - Fact Sheet 13 – International Conventions and Agreements
  - Fact Sheet 14 – Dual-Use
  - Fact Sheet 15 – National Health Security Checks
  - Fact Sheet 16 – Emergency Situations
  - Fact Sheet 17 – Changes to the National Health Security Legislation
13. [SSBA Guidelines](#)
  - Guideline 1 – Entities and Facilities
  - Guideline 2 – Registered Facility Reporting Requirements
  - Guideline 3 – Handling a Person or Animal, or Samples from a Person or Animal, Affected by an SSBA
  - Guideline 4 – Defining Loss, Theft and Accidental Release of SSBA
  - Guideline 5 – Reporting to Law Enforcement or the National Security Hotline

- Guideline 6 – SSBA Toxins
- Guideline 7 – SSBAs in the Natural Environment
- Guideline 8 – Transporting SSBAs and Suspected SSBAs
- Guideline 9 – Non-Registered Facility Reporting and Requirements
- Guideline 10 – SSBA Regulatory Scheme Monitoring Inspections
- Guideline 11 – SSBAs and Other Regulatory Schemes