



Australian Government

Department of Health

**Department of Health
Office of Health Protection
SSBA Regulatory Scheme**

**Regulator Performance Framework
Self-Assessment Report
2015-16**

Executive Summary.....	3
1. Introduction	4
1.1 The Agency/Office.....	4
1.2 The Report.....	4
1.3 Methodology.....	4
2 Performance Assessment	5
2.1 KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities	5
2.1.1 Measures.....	5
2.1.2 Approved evidence metrics for KPI 1.....	5
2.1.3 Other evidence to indicate compliance with KPI 1.....	7
2.1.4 Analysis of evidence presented	7
2.1.5 Self-assessed rating of performance against KPI 1 – 2015-16.....	7
2.1.6 Actions for improving performance against KPI 1	8
2.2 KPI 2 – Communication with regulated entities is clear, targeted and effective 9	
2.2.1 Measures.....	9
2.2.2 Approved evidence metrics for KPI 2.....	9
2.2.3 Other evidence to indicate compliance with KPI 2.....	11
2.2.4 Analysis of evidence presented	11
2.2.5 Self-assessed rating of performance against KPI 2 – 2015-16.....	12
2.2.6 Actions for improving performance against KPI 2	12
2.3 KPI 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed.....	13
2.3.1 Measures.....	13
2.3.2 Approved evidence metrics for KPI 3.....	13
2.3.3 Other evidence to indicate compliance with KPI 3.....	16
2.3.4 Analysis of evidence presented	16
2.3.5 Self-assessed rating of performance against KPI 3 – 2015-16.....	16
2.3.6 Actions for improving performance against KPI 3	16
2.4 KPI 4 – Compliance and monitoring approaches are streamlined and co-ordinated 17	
2.4.1 Measures.....	17
2.4.2 Approved evidence metrics for KPI 4.....	17
2.4.3 Other evidence to indicate compliance with KPI 4.....	18
2.4.4 Analysis of evidence presented	18
2.4.5 Self-assessed rating of performance against KPI 4 – 2015-16.....	19
2.4.6 Actions for improving performance against KPI 4	19
2.5 KPI 5 – Regulators are open and transparent in their dealings with regulated entities	20

2.5.1	Measures.....	20
2.5.2	Approved evidence metrics for KPI 5.....	20
2.5.3	Other evidence to indicate compliance with KPI 5.....	22
2.5.4	Analysis of evidence presented	22
2.5.5	Self-assessed rating of performance against KPI 5 – 2015-16.....	22
2.5.6	Actions for improving performance against KPI 5	22
2.6	KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks	23
2.6.1	Measures.....	23
2.6.2	Approved evidence metrics for KPI 6.....	23
2.6.3	Other evidence to indicate compliance with KPI 6.....	24
2.6.4	Analysis of evidence presented	24
2.6.5	Self-assessed rating of performance against KPI 6 – 2015-16.....	25
2.6.6	Actions for improving performance against KPI 6	25
3	Overall Assessment	26
3.1	Analysis of evidence	26
3.2	Self-assessed rating of performance against all KPIs – 2015-16	26
4	Concluding remarks	26

Executive Summary

Under the Australian Government Regulator Performance Framework (RPF) the Department of Health is responsible for ensuring that regulators within its portfolio, who meet defined criteria, complete an annual externally validated self-assessment report. The report presented here considers the self-assessment of the Security Sensitive Biological Agents (SSBA) Regulatory Scheme, which is administered by the Office of Health Protection within the Department of Health. This report provides some background on the SSBA Regulatory Scheme, describes the intention of the annual self-assessment process, and presents the results for 2015-16. Six Key Performance Indicators (KPIs) are described under the RPF, that affected regulators across Government must address:

- 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 regulatory risk being managed;
- KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated;
- KPI 5 - Regulators are open and transparent in their dealings with regulated entities; and
- KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks.

A number of measures and evidence metrics were formulated, pre-agreed and published on the Health website in July 2015 to describe how the SSBA Regulatory Scheme would meet each of the six KPIs. The methodology used for evidence collection is described and comments against each of these metrics are provided to demonstrate how the SSBA Regulatory Scheme worked to achieve a high level of regulator performance. Further discussion is also provided to indicate:

- any other evidence of compliance with each KPI;
- an analysis of the evidence presented;
- a description of any suggested actions for improving performance against each KPI; and
- a self-assessed performance rating against each KPI.

Overall, the SSBA Regulatory Scheme considered that a high level of performance was achieved and an overall rating of 'very good' was determined. This rating was strongly supported by the Public Health Laboratory Network (PHLN) Executive Group that was appointed as the external stakeholder validation mechanism by the Minister for Health.

1. Introduction

1.1 The Agency/Office

The Australian Government Department of Health has responsibility for administration of the SSBA Regulatory Scheme. This is undertaken within the Health Emergency Management Branch (HEMB) of the Office of Health Protection. The aim of the scheme is to limit opportunities for acts of bioterrorism or biocrime to occur using harmful biological agents and to provide a legislative framework for managing the security of SSBAs. Part 3 of the *National Health Security Act 2007* (NHS Act) establishes the regulatory scheme for entities and facilities that handle suspected or known SSBAs. The *National Health Security Regulations 2008* (NHS Regulations) support the NHS Act by providing operational detail about the SSBA Regulatory Scheme. Compliance obligations are described within the SSBA Standards and a monitoring and compliance program is run in cooperation with inspectors from the Office of the Gene Technology Regulator (OGTR).

The 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 full access to SSBAs for those with a legitimate need. The SSBA Regulatory Scheme also builds on Australia's obligations under the Biological and Toxins Weapons Convention and UN Security Council Resolution 1540.

1.2 The Report

The Australian Government is committed to reducing the cost of unnecessary or inefficient regulation imposed on business, community organisations and individuals. The RPF commenced on 1 July 2015 to establish a common set of performance measures that allows for the comprehensive assessment of regulator performance and their engagement with stakeholders. The way regulators administer regulations can have a major effect on the burden imposed, and therefore the framework aims to encourage regulators to undertake their functions with the minimum impact necessary to achieve regulatory objectives. Under the RPF, regulators are required to undertake an annual, externally validated self-assessment against a common set of performance measures and pre-agreed evidence metrics. This report includes a table under each KPI to describe each of the approved evidence metrics, approved potential sources of evidence as well as comments to demonstrate these were addressed over 2015-16, the first year for which the SSBA Regulatory Scheme must undertake a self-assessment which is externally validated and reported.

1.3 Methodology

To inform this self-assessment report the SSBA Regulatory Scheme policy team gathered information from all supporting platforms of the scheme, including the National Register of SSBAs (security classified), dedicated communication mechanisms, such as email inbox, annual inspection plan, relevant meeting outcomes and knowledge from within the administration team. This information was reviewed and included in the report where appropriate, to provide the evidence upon which the pre-agreed metrics were met. The OGTR and internal OHP Executive were also consulted on the information provided in this report. Following review the report was then submitted to the PHLN Executive Group for external validation.

2 Performance Assessment

2.1 KPI 1 – Regulators do not unnecessarily impede the efficient operation of regulated entities

Over 2015-16, the SSBA Regulatory Scheme continued to provide mechanisms to assist the regulated community to meet their legislative requirements efficiently, for example, through maintaining an online training facility, an online data collection system and through the alignment of monitoring inspections with that of the OGTR. The SSBA Regulatory Scheme also continued to engage with, and provide timely and consistent advice to affected stakeholders to ensure the efficient operation of their facilities through a variety of mechanisms.

2.1.1 Measures

1. Reporting
 - Reporting burden kept to a minimum; and
 - Reporting requirements appropriately reflect level of risk.
2. Inspections
 - Burden of inspections kept to a minimum; and
 - Unintended impacts on the regulated community avoided.
3. Administration
 - Burden of administrative processes kept to a minimum; and
 - Administrative processing completed in a timely manner.
4. Feedback
 - Stakeholder issues addressed in a timely manner;
 - Advice to stakeholders of compliance issues is timely and specific; and
 - Best practice supported.

2.1.2 Approved evidence metrics for KPI 1

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
1. Reporting <ul style="list-style-type: none"> - Annual review of reporting requirements; - Availability of online data collection system; and - Annual discussion with Public Health Laboratory Network (PHLN)/Australian (counter) Bioterrorism Laboratory Network (ABLN) to maintain awareness of the regulated community operational environment (to inform judgements) 	<ul style="list-style-type: none"> - Informal review of reporting requirements was undertaken; - Website was available 24/7. No outages were reported; - Number of meetings held with PHLN/ABLN where relevant agenda items are discussed (minutes of teleconferences, face to face meetings with PHLN/ABLN are taken but are likely to be classified and will not be 	Within the reporting period: <ul style="list-style-type: none"> - Reporting requirements were considered and adjusted where necessary i.e. following amendment to the List of SSBA's; - The online data collection system (for the electronic submission of reports) was available 24/7 and no outages were reported; and - Reporting requirements

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
<p>about the appropriate levels of risk management).</p>	<p>published); and</p> <ul style="list-style-type: none"> - Regulated community feedback. 	<p>in relation to the review of the List of SSBAs were discussed twice with PHLN and once with ABLN.</p>
<p>2. Inspections</p> <ul style="list-style-type: none"> - Annual review of inspection requirements; - Review inspection schedule at every compliance committee meeting; - Four discussions per year with Office of the Gene Technology Regulator (OGTR) and/or Dept. of Agriculture to monitor for unintended impacts on the regulated community; - Review of feedback received from Entities following inspection; and - No charges associated with compliance inspections. 	<ul style="list-style-type: none"> - Annual inspection plan developed (due consideration given to concurrent OGTR schedule); - Informal review of inspection requirements; - Number of Compliance Committee meetings; and - An issues register. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - A 2015-16 inspection schedule was developed to align with the inspection priorities of OGTR; - The 2015-16 inspection plan was reviewed at each of the 11 SSBA Compliance Committee meetings; - Inspections continued to be undertaken free of charge; and - A list of action items following each SSBA Compliance Committee meeting was maintained.
<p>3. Administration</p> <ul style="list-style-type: none"> - Availability of online data collection system; and - Routine administrative requests processed within two business days. 	<ul style="list-style-type: none"> - Website availability; - Fact Sheets; - Standards; and - Record of admin requests that take longer than two business days to respond to. 	<ul style="list-style-type: none"> - Within the reporting period: - The online data collection system was available 24/7; and - All admin requests were actioned within two business days of receipt.
<p>4. Feedback</p> <ul style="list-style-type: none"> - Number and types of opportunities/vehicles available to discuss and address emerging issues; - Feedback sought from stakeholders at each inspection on burden of regulatory requirements; - Opportunity for stakeholders to provide feedback on website; - Comment encouraging 	<ul style="list-style-type: none"> - Number of Compliance Committee meetings; and - Feedback received on website, forms, email inbox and telephone line. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - 11 SSBA Compliance Committee meetings were held; - Feedback received via the email inbox, telephone or via paper-based correspondence was responded to within two business days; and - Advice to stakeholders with regard to compliance issues

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
feedback on all forms; and - At each inspection inspectors will give advice on best practice if an opportunity is noted.		was provided at the time of inspection and by letter post-inspection. On occasion letters were sent more than two months post-inspection, due to resourcing constraints.

2.1.3 Other evidence to indicate compliance with KPI 1

Informal feedback is often received from the regulated community to indicate an appreciation of the non-prescriptive nature of the scheme allowing facilities a level of flexibility within the requirements set. No costs are associated with facility registration or the monitoring program and scheduling inspections to align with those for the OGTR (where applicable) assists to ensure that the operation of regulated entities is not unnecessarily impeded. No formal complaints with regard to the SSBA Regulatory Scheme were received in the reporting period. Feedback from the regulated community was also sought during formal presentations given about the scheme e.g. at ABSANZ conference in November 2015 and at the Australian National University (ANU) in July 2015.

2.1.4 Analysis of evidence presented

Based on the evidence provided above, the SSBA Regulatory Scheme considers that the measures and indicators described under KPI 1 have been successfully addressed. Reporting requirements were reviewed, online systems were maintained, feedback was efficiently responded to and regular meetings of related committees were held. The SSBA Regulatory Scheme continues to explore new ways to streamline administration of the scheme so as not to unnecessarily impede the efficient operation of affected facilities.

2.1.5 Self-assessed rating of performance against KPI 1 – 2015-16

Excellent	Very Good	Good	Fair	Poor
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

2.1.6 Actions for improving performance against KPI 1

The SSBA Regulatory Scheme considers that reporting requirements continue to appropriately reflect the level of risk posed to the Australian community and that administrative processes are minimal and enhanced through the provision of an online reporting system. The SSBA Regulatory Scheme recognises however, that the timeliness of responses to facilities post-inspection could be further improved and will strive to ensure these are provided within two months of inspection over 2016-17.

2.2 KPI 2 – Communication with regulated entities is clear, targeted and effective

Over 2015-16 the SSBA Regulatory Scheme undertook to communicate consistently with the regulated community in a targeted and effective manner. Online platforms, such as the SSBA website and Data Collection System (DCS) were maintained with up-to-date information and were available without interruption. Guidance material, including Fact Sheets, Guidelines and a bi-annual newsletter were updated and made available freely to the community via the SSBA website. Feedback opportunities for the regulated community were provided through a number of mechanisms and feedback received was considered appropriately.

2.2.1 Measures

1. Materials available which clearly set out requirements of scheme.
2. Communication materials to comprehensively support implementation of requirements are available.
3. Training is available to support compliance.
4. Notification of changes, issues and new developments is timely and easily accessible.
5. A range of options are available for providing information to stakeholders and for receiving feedback.

2.2.2 Approved evidence metrics for KPI 2

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
1. Materials available <ul style="list-style-type: none"> - Number of communication materials available outlining scheme requirements and giving guidance on implementation; - Online training tools available; and - Documentation meets accessibility requirements of Australian Government. 	<ul style="list-style-type: none"> - Standards; - Factsheets; - Guidelines; - Website; - Newsletter; and - Online training tools. 	Within the reporting period: <ul style="list-style-type: none"> - The availability of the SSBA Standards, Fact Sheets and Guidelines was maintained; - A bi-annual newsletter was circulated (December 2015 and June 2016); and - All communication material was available on the SSBA website and all except the SSBA Standards were available in a form that meets the accessibility requirements of the Australian Government. The SSBA Standards will be reviewed over 2016-17 and will be updated to ensure these requirements are met.
2. Communication materials <ul style="list-style-type: none"> - Number of options available providing information 	<ul style="list-style-type: none"> - Standards; - Factsheets; - Guidelines; 	Within the reporting period: <ul style="list-style-type: none"> - 11 SSBA Guidelines and 17 Fact Sheets were maintained

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
including fact sheets, website, guidelines, newsletter, telephone line; and - Engagement with key representative groups such as PHLN/ABLN.	- Website; and - Number/dates of meetings with PHLN/ABLN where issues are raised.	and available on the SSBA website. These are regularly updated in accordance with any changes to the administration of the SSBA Regulatory Scheme; - The SSBA website front page was accessed 446 times, the Fact Sheets page 313 times and the Guidelines page 519 times; and - A dedicated mailbox (ssba@health.gov.au) and phone line (02) 6289 7477 were also available over the reporting period.
3. Training provided: - Number of online training modules available; - Number of guidelines available; - Number of factsheets available; - Number of presentations to stakeholder fora; and - Advice provided during inspections.	- Website; - Online training facility; - Copies of presentations; and - (Records are kept of advice given during inspections, but these are classified secret).	Within the reporting period: - The Online Training Facility for the regulated community was maintained; - 11 Guidelines and 17 Fact Sheets were maintained and available on the SSBA website; and - Three formal presentations on the SSBA Regulatory Scheme were delivered, at the ANU (Biosecurity Students), ANU (National Security College) and ABSANZ conference.
4. Notification of changes - Number of newsletters produced; - Number of newsletter articles framed to clarify issues identified; and - Emails regarding changes sent to regulated community;	- Newsletters; - Articles; and - Email correspondence.	Within the reporting period: - Two newsletters were developed and circulated (December 2015 and June 2016). These contained a number of articles which clarified either identified issues or specific changes to administration of the scheme; and - Emails were sent to the regulated community, when necessary to advise of changes

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
		made to the scheme i.e. changes to the List of SSBAs.
5. Feedback options <ul style="list-style-type: none"> - Two way feedback provided during inspection process; - Website; - Dedicated telephone assistance line; and - Email inbox. 	<ul style="list-style-type: none"> - List of options for providing feedback; and - All correspondence encourages feedback. 	Within the reporting period: <ul style="list-style-type: none"> - All correspondence templates were updated to include provision for feedback; - Inspectors continued to encourage that feedback be provided by regulated entities during monitoring inspections; and - The SSBA phone line and email inbox continued to be monitored and any feedback received was responded to appropriately.

2.2.3 Other evidence to indicate compliance with KPI 2

The SSBA Regulatory Scheme considers that sufficient mechanisms are provided to ensure that communication with regulated entities is clear, targeted and effective, however welcomes feedback from affected stakeholders if there are other communication platforms that would be beneficial and could be considered. Formal consultation with the regulated community was undertaken prior to amendment of the List of SSBAs, during which the provision of feedback was strongly encouraged.

2.2.4 Analysis of evidence presented

Based on the evidence provided above, the SSBA Regulatory Scheme considers that the measures and indicators described under KPI 2 have been successfully addressed. Communication materials were maintained and were available online for the duration of the reporting period. Guidance and training material were consistently available and formal presentations were provided on a number of occasions. The SSBA Regulatory Scheme continued to strengthen relationships with affected stakeholders through regular engagement and provision of a number of communication mechanisms to assist to achieve cooperative compliance and provide opportunities for feedback.

2.2.5 Self-assessed rating of performance against KPI 2 – 2015-16

Excellent	Very Good	Good	Fair	Poor
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

2.2.6 Actions for improving performance against KPI 2

The recent removal of Salmonella Typhi and Vibrio cholerae from the List of SSBA (see 2.3.iii for further information) has meant that some registered and many non-registered facilities are no longer required to report to the Department of Health or be engaged with the scheme. While this has resulted in a positive reduction in regulatory burden, the SSBA Regulatory Scheme needs to take steps to ensure that such facilities maintain an awareness of the scheme so that they are informed of any changes to requirements, should there be a need for them to handle any suspected or confirmed SSBA in future. This could be achieved through ensuring that contacts at such facilities continue to receive a copy of the bi-annual SSBA newsletter.

2.3 KPI 3 – Actions undertaken by regulators are proportionate to the regulatory risk being managed

During establishment of the scheme a risk-based approach was taken to determine associated regulatory requirements. Over 2015-16, the SSBA Regulatory Scheme continued to consider that all activities conducted and requirements applied under the scheme were proportionate to the regulatory risk being managed. This is demonstrated through the clear differential treatment of risk between those that handle SSBA on an ongoing basis (registered facility) and those that handle SSBA on a temporary basis (non-registered facility). This is also demonstrated by the differential requirements for handling a Tier 1 (highest security concern) versus a Tier 2 (high security concern) agent.

2.3.1 Measures

1. Risks comprehensively assessed.
2. Risk assessment remains up to date.
3. Requirements of scheme are commensurate with risk.
4. Scheme supports differential treatment of risk.
5. Feedback on appropriateness of risk management measures sought periodically from stakeholders.

2.3.2 Approved evidence metrics for KPI 3

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
<p>1. Risks Assessed</p> <ul style="list-style-type: none"> - Experts engaged to assess target agents for scheme; - Risk level (ie. biological threat level) reviewed by experts through liaison with Australian Intelligence Community; - Experts engaged to consider high risk areas of work e.g. the Australian Federal Police comments on research applications; - Staff administering scheme trained in risk assessment and familiar with operational environment; and - Regulated entities provided with guidance materials to assist in risk assessment for biological 	<p>List of areas assessed on risk basis:</p> <ul style="list-style-type: none"> - SSBA List i.e. Tier 1 vs. Tier 2; - SSBA Standards differential requirements; - Inspections Tier 1 = eighteen months; - Inspections Tier 2 = twenty-four months; and - Inspections Non-Registered = as needed. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - The SSBA Regulatory Scheme completed a review of the List of SSBA which resulted in the removal of two agents considered to no longer be of security concern; - The differential requirements within the SSBA Standards continued to be applied as necessary; - Inspections continued to be carried out on the basis of risk i.e. Tier 1 agents every 18 months and Tier 2 agents every two years; - Post-inspection

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
<p>security.</p>		<p>compliance outcomes were also considered from risk-based perspective.</p> <ul style="list-style-type: none"> - Staff administering the scheme have been trained in risk assessment and continue to be familiar with the operational environment; and - Security Risk Template was maintained and available to assist regulated entities to maintain their required risk assessment and risk management plans.
<p>2. Risk assessment up to date</p> <ul style="list-style-type: none"> - Six monthly security briefing provided by the Australian Intelligence Community (AIC); - Australia’s risk setting routinely monitored through regular analysis of intelligence community briefing material; and - List of Security Sensitive Biological Agents reviewed every 5 years. 	<ul style="list-style-type: none"> - Scheduling of briefing meetings (no minutes are taken due to the coverage of classified material); - (Intelligence community briefings are classified); and - List review. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - A scheduled security briefing was provided to HEMB by the AIC (November 2015); and - The review of the List of SSBA was completed.
<p>3. Scheme requirements commensurate with risk</p> <ul style="list-style-type: none"> - Similar schemes overseas investigated annually to compare risk management approach; - Scheme processes reviewed annually; - Document template available to support security risk assessment by participating entities 5 year compliance audit of 	<ul style="list-style-type: none"> - Risk assessment template; - Compliance audit; and - Information regarding similar schemes. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - A watching brief of international schemes was continued; - Scheme processes continued to be both formally and informally reviewed; and - Security Risk Template was maintained and available to assist regulated entities to

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
<p>research status; and</p> <ul style="list-style-type: none"> - Regulated entities provided with guidance materials to assist in risk assessment including a Risk Assessment Template to meet Part 2 of the Standards. 		<p>maintain their required risk assessment and risk management plans.</p>
<p>4. Scheme supports differential treatment of risk</p> <ul style="list-style-type: none"> - Stratified scheme maintained with two tiers of agents, each having requirements commensurate to risk; - Specified strategies available for entities with identified compliance issues e.g. repeat inspections or spot checks; and - Different requirements for different/higher risk purposes (known vs suspected SSBA handling, handling agents for the purpose of research). 	<ul style="list-style-type: none"> - List of two tiers of agents; - SSBA Standards; and - Transport, personnel and physical security requirements commensurate with risk. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - A review of the List of SSBAs was completed and two Tier 2 agents were removed from the list; and - The requirements within the SSBA Standards continued to be applied commensurate with the level of risk posed.
<p>5. Feedback on risk management sought from stakeholders</p> <ul style="list-style-type: none"> - Feedback sought from PHLN/ABLN on appropriateness of scheme requirements. 	<ul style="list-style-type: none"> - Number/dates of meetings with PHLN /ABLN at which this is discussed. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - The requirements of the SSBA Regulatory Scheme particularly in relation to the review of the List of SSBAs was discussed with PHLN at two meetings and with ABLN at one meeting. Both committees were also approached during the formal consultation period as scientific and technical experts.

2.3.3 Other evidence to indicate compliance with KPI 3

During 2015-16, a review of the List of SSBAs was completed. This review examined SSBAs currently on the List, as well as any others that had the potential to be used as biological weapons. The health impact, feasibility of use and level of interest was considered in this context. A final determination was made by the Minister for Health to remove two agents from the Tier 2 List of SSBAs on the basis that they no longer posed a security risk within the Australian context. This took effect as of 14 March 2016.

2.3.4 Analysis of evidence presented

Based on the evidence provided above, the SSBA Regulatory Scheme considers that the measures and indicators described under KPI 3 have been successfully addressed. The SSBA Regulatory Scheme continued to apply a risk-based approach to all regulatory activities. A review of the List of SSBAs was completed and the regulatory requirements as described by the SSBA Standards continued to be applied proportionate to the regulatory risk being managed i.e. more complex regulatory requirements applied to facilities that are registered to handle Tier 1 SSBAs as opposed to Tier 2 SSBAs.

2.3.5 Self-assessed rating of performance against KPI 3 – 2015-16

Excellent	Very Good	Good	Fair	Poor
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

2.3.6 Actions for improving performance against KPI 3

The current SSBA regulatory requirements remain appropriate to the level of risk posed i.e. interest in and feasibility of use of biological agents of security concern. These requirements will continue to be evaluated as needed to ensure they continue to remain appropriate in the Australian national security context.

2.4 KPI 4 – Compliance and monitoring approaches are streamlined and co-ordinated

In 2015-16 the SSBA Regulatory Scheme continued its engagement with OGTR for the provision of inspectors to support the SSBA monitoring and compliance program. Inspections continue to be aligned where possible with that of the OGTR and are undertaken on a schedule commensurate with the risk associated with the Tier level of agents being handled. When more than one facility is registered under the same entity and are located in close proximity, these are inspected at the same time.

2.4.1 Measures

1. Inspections coordinated with other regulatory agencies.
2. Compliance and monitoring processes are streamlined.
3. Feedback sought on opportunities for further streamlining.

2.4.2 Approved evidence metrics for KPI 4

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
<p>1. Inspections coordinated</p> <ul style="list-style-type: none"> - Inspections carried out by OGTR staff trained in laboratory assessments; - SSBA scheme keeps pace with OGTR and Dept. of Agriculture work on closer alignment; - OGTR consulted regarding any changes of legislation; and - Number of inspections scheduled to coordinate with inspections by other regulatory agencies. 	<ul style="list-style-type: none"> - SSBA inspection schedule considered in cooperation with OGTR schedule; - Number of monthly compliance meetings with OGTR; - Legislative consultation program; and - Emails/letters regarding changes of legislation. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - The SSBA inspection schedule was considered at each SSBA Compliance Committee meeting and adjustments made to align with OGTR and Health priorities as necessary; - 11 SSBA Compliance Committee meetings were held; and - OGTR was consulted on the changes to the List of SSBAs.
<p>2. Compliance and Monitoring streamlined</p> <ul style="list-style-type: none"> - Review of inspection frequency and duration; - Inspection 	<ul style="list-style-type: none"> - Inspection requirements / process reviewed annually. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - Inspection frequency and duration was considered to remain appropriate;

Indicator (Approved evidence metrics)	Evidence (Approved potential evidence source)	Comment (2015-16 evidence)
<p>frequency is risk based;</p> <ul style="list-style-type: none"> - All facilities at the same location within the one entity are inspected at the same time; - SSBA Standards align with other regulatory scheme requirements as much as possible (for example, record keeping for disposal records etc). 		<ul style="list-style-type: none"> - Where an entity has more than one registered facility within close proximity, inspections continued to be undertaken at the same time; and - The SSBA Standards continue to align with other Australian regulatory scheme requirements. A review of the SSBA Standards is planned for 2016-17.
<p>3. Feedback sought</p> <ul style="list-style-type: none"> - Streamlining and coordination discussed with OGTR / Agriculture. 	<ul style="list-style-type: none"> - Number/dates of meetings at which this is discussed. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - Streamlining of inspections with the OGTR continued and was discussed at 11 SSBA Compliance Committee meetings.

2.4.3 Other evidence to indicate compliance with KPI 4

In June 2016, a new Service Level Agreement between the Office of Health Protection and the OGTR was signed for the purpose of provision of inspectors for the period 2016-19. The responsibilities of each party in relation to this arrangement were reviewed and agreed. The SSBA Regulatory Scheme continues to maintain a strong relationship with the Monitoring and Compliance Section within the OGTR to administer this essential element of the scheme.

2.4.4 Analysis of evidence presented

Based on the evidence provided above, the SSBA Regulatory Scheme considers that the measures and indicators described under KPI 4 have been successfully addressed. The annual inspection plan was regularly reviewed and SSBA Compliance Committee meetings were held on 11 occasions during the reporting period and were well attended. Careful consideration continued to be given when scheduling inspections to ensure, where possible, that SSBA inspections coincide with those of the OGTR. Consideration was also given to arranging inspections for entities that are responsible for more than one facility at the same time. Overall, the SSBA Regulatory Scheme continued to review compliance and monitoring approaches to ensure that they remain streamlined and coordinated.

2.4.5 Self-assessed rating of performance against KPI 4 – 2015-16

Excellent	Very Good	Good	Fair	Poor
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

2.4.6 Actions for improving performance against KPI 4

The SSBA Regulatory Scheme should continue to engage with other related regulatory bodies i.e. OGTR and Department of Agriculture and Water Resources to ensure that regulatory requirements do not over lap and create unnecessary burden on affected Entities. Monitoring and compliance programs should continue to be aligned where practical.

2.5 KPI 5 – Regulators are open and transparent in their dealings with regulated entities

Over 2015-16, the SSBA Regulatory Scheme continued to be open and transparent in their dealings with regulated entities. Up to date guidance material was consistently available and a bi-annual newsletter was circulated. Consultation with the regulated community was undertaken regarding proposed changes to the List of SSBAs and following its amendment in March 2016 to remove two agents from the Tier 2 list, communication with affected stakeholders was undertaken to describe how this impacted upon reporting and registration requirements.

2.5.1 Measures

1. Purpose of scheme, processes and use of data is clearly stated.
2. Consultation undertaken on changes to Scheme.
3. Opportunities are regularly available for the regulated community to ask questions and to provide feedback about the scheme.

2.5.2 Approved evidence metrics for KPI 5

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
<p>1. Purpose, processes clearly stated</p> <ul style="list-style-type: none"> - Communication materials available i.e. Factsheets, guidelines, website. 	<ul style="list-style-type: none"> - Factsheets; - Guidelines; - Website; and - Emails. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - Communication material remained available and up to date.
<p>2. Consultation on changes undertaken</p> <ul style="list-style-type: none"> - Consultation with OGTR, PHLN, ABLN, Australia New Zealand Counter Terrorism Committee Chemical Biological Radiological Nuclear Security Subcommittee, State and Territory counterparts, Australian Intelligence Community; - Newsletters; - Consultation with government agencies (Dept of Ag etc); and - Consultation on changes with regulated community and other interested stakeholders. 	<ul style="list-style-type: none"> - Number of Compliance Committee meetings; and - Number of relevant PHLN, ABLN teleconferences and/or face to face meetings. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - 11 SSBA Compliance Committee meetings were held; and - Consultation regarding proposed changes to the List of SSBAs was undertaken with OGTR, PHLN, ABLN, Australia

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
		<p>New Zealand Counter Terrorism Committee, relevant intelligence related committees, the regulated community and other relevant Government agencies.</p>
<p>3. Opportunities for feedback</p> <ul style="list-style-type: none"> - Options for seeking information and providing feedback: <ul style="list-style-type: none"> o Correspondence associated with reports and inspections; o Email inbox; o Dedicated phone line; and o Inspections. 	<ul style="list-style-type: none"> - (Correspondence associated with reports and inspections is classified); - Availability of email inbox and dedicated phone line 9:00am – 5:00pm on business days; and - National Incident Room phone line available 24/7 in case of an emergency or high risk situation. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - All correspondence templates were reviewed to ensure that mechanisms for the provision of feedback were described; - The SSBA email inbox and phone line were monitored from 9:00am – 5:00pm on business days; - The National Incident Room phone line was available 24/7 for emergency use; - SSBA inspections provided another mechanism by which facilities could provide feedback. <p>Questions raised were responded to by inspectors or the SSBA policy</p>

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
		team efficiently and effectively.

2.5.3 Other evidence to indicate compliance with KPI 5

Over the 2015-16 reporting period, the SSBA Regulatory Scheme continued to monitor existing communication mechanisms and platforms to ensure that they remained appropriate for the delivery of information to affected stakeholders. Members of both the SSBA Regulatory Scheme policy team and the SSBA inspection team remained available on all business days to respond to stakeholder questions and concerns, of which there were relatively few. A high level of compliance among the regulated community continued through 2015-16 which demonstrates that the open and transparent communication strategies employed remain effective and continue to meet the needs of affected stakeholders.

2.5.4 Analysis of evidence presented

Based on the evidence provided above, the SSBA Regulatory Scheme considers that the measures and indicators described under KPI 5 have been successfully addressed. The purpose and related processes of the SSBA Regulatory Scheme remained clearly stated, consultation with regard to changes made were undertaken widely, and responses received were considered efficiently and opportunities for the provision feedback were expanded. Both formal and informal feedback was considered and responded to appropriately and efficiently.

2.5.5 Self-assessed rating of performance against KPI 5 – 2015-16

Excellent	Very Good	Good	Fair	Poor
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

2.5.6 Actions for improving performance against KPI 5

The SSBA Regulatory Scheme considers that it is as open and transparent in its dealings with entities as possible within the current National security environment. Regulated entities are encouraged to provide feedback to the SSBA Regulatory Scheme if any concerns with regard to the transparency of the scheme are raised so that they can be addressed as efficiently as possible.

2.6 KPI 6 – Regulators actively contribute to the continuous improvement of regulatory frameworks

Over 2015-16 no changes were required to be made to the *National Health Security Act 2007* (NHS Act), the *National Health Security Regulations 2008* or the SSBA Standards. A review of the List of SSBAs was undertaken and it was subsequently amended. The SSBA Regulatory Scheme maintained a continual watch of regulatory schemes being implemented in comparable countries. Stakeholder feedback was monitored where it pertained to potential amendment to the NHS Act or subordinate legislation and guidance documents.

2.6.1 Measures

1. Regular review of legislation, regulations and standards.
2. Feedback sought to enable continuous improvement.

2.6.2 Approved evidence metrics for KPI 6

Indicator (Approved evidence metrics)	Evidence (Approved potential evidence source)	Comment (2015-16 evidence)
<p>1. Regular review of legislation, regulations and standards</p> <ul style="list-style-type: none"> - Review of legislation, regulations and Standards; - Non-compliance trends analysed and considered; - Stakeholder feedback collected; - Broad assessment of lessons observed in the regulatory schemes of comparable countries; - Mention of the scheme internationally as a model or to demonstrate good practice; and - Support the development of other legislative schemes. 	<ul style="list-style-type: none"> - Copies of amendments to legislation, regulations or standards; - Articles on comparable schemes; - International articles, documents referring positively to the scheme; - Copies of stakeholder feedback (if not classified); and - Comments/input provided into the development of other schemes. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - Apart from amendment to the List of SSBAs, no changes to SSBA legislation were required; - Non-compliance trends continued to be reviewed and general advice /education with regard to this was provided through the bi-annual newsletter; - Feedback from stakeholders was considered and added to a matrix of issues, if deemed necessary; - Relevant Fact Sheets and Guidelines were amended where necessary to capture changes to the List of SSBAs; - A watching brief over international legislation was continued; and

Indicator <i>(Approved evidence metrics)</i>	Evidence <i>(Approved potential evidence source)</i>	Comment <i>(2015-16 evidence)</i>
		<ul style="list-style-type: none"> - The SSBA Regulatory Scheme remained open to the provision of advice relating to the development of other schemes.
<p>2. Feedback opportunities</p> <ul style="list-style-type: none"> - Email inbox / phone line / website /correspondence comments monitored for issues, potential for improvement; and - Inspectors explore reasons for non-compliance (with a view to addressing the cause). 	<ul style="list-style-type: none"> - Email inbox, dedicated telephone line available; and - Comment on website/forms encouraging feedback. 	<p>Within the reporting period:</p> <ul style="list-style-type: none"> - Feedback from the regulated community was encouraged through the SSBA inbox, phone line and all correspondence with stakeholders.

2.6.3 Other evidence to indicate compliance with KPI 6

During 2015-16, the SSBA Regulatory Scheme maintained a strong relationship with the OGTR for provision of the SSBA monitoring and compliance program. Regular engagement between these two groups continued to occur, with 11 formal compliance committee meetings held. This regular forum encourages discussion around continuous improvement of the SSBA regulatory framework and of alignment between the operational aspects of the two inspection programs.

2.6.4 Analysis of evidence presented

Based on the evidence provided above, the SSBA Regulatory Scheme considers that the measures and indicators described under KPI 6 have been successfully addressed. Non-compliance trends continued to be reviewed and consideration was given as to whether supporting materials / platforms required subsequent amendment. A number of articles were provided in the bi-annual newsletter to provide general guidance on compliance issues. While no legislative changes were necessary, amendments to relevant SSBA Fact Sheets and Guidelines were undertaken following changes to the List of SSBAs. A watching brief over related international schemes continued and the SSBA Regulatory Scheme remained available to provide advice if sought from other countries that are developing similar schemes.

2.6.5 Self-assessed rating of performance against KPI 6 – 2015-16

Excellent	Very Good	Good	Fair	Poor
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

2.6.6 Actions for improving performance against KPI 6

The SSBA Regulatory Scheme considers that where possible, it actively contributes to the continuous improvement of the regulatory framework within which it operates and by which it is governed, as well as to related regulatory frameworks. Feedback is encouraged from affected stakeholders, whose perspective is critical to understanding the impacts of regulatory burden including that which may be unintended.

3 Overall Assessment

3.1 Analysis of evidence

Overall, the SSBA Regulatory Scheme was able to demonstrate meaningful evidence, both quantitative and qualitative, against each of the pre-agreed metrics and continues to explore new ways to reduce regulatory burden among the affected stakeholder community.

The SSBA Regulatory Scheme has identified a number of areas where performance may be strengthened or more closely monitored, these include:

1. ensuring the timeliness of responses to facilities post-inspection;
2. continuing to engage with laboratories that are no longer regulated under the scheme following amendment to the List of SSBAs in March 2016;
3. continuing to evaluate the Australian national security risk context;
4. continuing to engage with related regulatory bodies to ensure that unnecessary or duplicate regulation is minimised; and
5. continuing to encourage the provision of feedback from affected stakeholders with regard to all aspects of the scheme.

3.2 Self-assessed rating of performance against all KPIs – 2015-16

Excellent	Very Good	Good	Fair	Poor
Strong performance against all the KPIs	Strong performance against majority of the KPIs and no evidence of negative/poor performance against any KPI	Average performance against the KPIs	Poor performance against some KPIs	Poor performance against most of the KPIs

4 Concluding remarks

Overall the SSBA Regulatory Scheme considers that the evidence provided for 2015-16 demonstrates a high level of performance against each of the approved KPIs, measures and evidence metrics and collectively aligns with the requirements of the Framework. An overall rating of 'Very Good' is considered appropriate for the SSBA Regulatory Scheme over 2015-16 and this was strongly supported through the external stakeholder validation process. The self-assessment process promoted awareness of, and highlighted opportunities for, reducing regulatory burden among a community which is both highly specialised and regulated. A number of areas were identified where performance and engagement may be strengthened and these will be monitored closely over future years.

As 2015-16 was the first year for which regulators were required to undertake a self-assessment, the SSBA Regulatory Scheme may make slight amendments to the evidence metrics reviewed to ensure that they continue to be as highly relevant and measurable as possible. The SSBA Regulatory Scheme maintains a commitment to supporting quality improvement and will continue to work towards achieving best practice regulation within Australia.