



**Australian Government**

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**Department of Health**

**Office of Health Protection**

**SSBA Regulatory Scheme**

**Regulator Performance Framework**

**Self-Assessment Report 2017-18**

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# Glossary

Acronyms	Description
<b>ABLN</b>	Australian (counter) Bioterrorism Laboratory Network
<b>AIC</b>	Australian Intelligence Community
<b>DAWR</b>	Department of Agriculture and Water Resources
<b>HEMB</b>	Health Emergency Management Branch
<b>OGTR</b>	Office of the Gene Technology Regulator
<b>PHLN</b>	Public Health Laboratory Network
<b>RPF</b>	Regulator Performance Framework
<b>SSBA</b>	Security Sensitive Biological Agents
<b>UN</b>	United Nations

# Introduction

The Australian Government Department of Health (Health) has responsibility for administration of the Security Sensitive Biological Agents (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 SSBA.

Part 3 of the *National Health Security Act 2007* (NHS Act) establishes the regulatory scheme for entities and facilities that handle suspected or known SSBA. The *National Health Security Regulations 2018* (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 SSBA 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.

The Australian Government is committed to reducing the cost of unnecessary or inefficient regulation imposed on business, community organisations and individuals. The Regulator Performance Framework (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. Health is also committed to providing a comprehensive external review of each regulator in scope under the RPF once in a three-yearly cycle.

The 2015-16 self-assessment report for the SSBA Regulatory Scheme included a table under each KPI to describe each of the approved evidence metrics, approved potential sources of evidence as well as comments to demonstrate that these were addressed over 2015-16, the first year for which the SSBA Regulatory Scheme undertook an externally validated and reported self-assessment. A shortened self-assessment report was developed for use in 2016-17 and a similar format is used to develop this 2017-18 report.

In 2016-17 the SSBA Regulatory Scheme was the first Health portfolio regulator to undergo an external review under the RPF and therefore was not required to have the 2016-17 self-assessment report externally validated, however this is a requirement for 2017-18.

A self-assessed rating is provided against each of the Measures / Metrics in this report. The rating is derived from the scale provided below.

### Rating scale

Met	Substantially met	Not met
Strong performance against <i>all</i> of the measures under the KPI	Strong performance against <i>most</i> of the measures under the KPI	Poor performance against <i>all</i> of the measures under the KPI

### Overall Assessment

Using the above performance ratings, targets have been met for all measures under the six KPIs.

# 2017-18 Performance Reporting

<b>KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities</b>	
<b>Measures/Metrics</b>	<b>Evidence (Performance in 2017-18)</b>
<p><b>MEASURE 1 - REPORTING</b></p> <ul style="list-style-type: none"> <li>○ Reporting burden kept to a minimum;</li> <li>○ Reporting requirements appropriately reflect level of risk.</li> </ul> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>● Annual review of reporting requirements;</li> <li>● Availability of online data collection system; and</li> <li>● 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 about the appropriate levels of risk management).</li> </ul>	<ul style="list-style-type: none"> <li>● Informal review of reporting requirements was undertaken and the requirements remain fit for purpose;</li> <li>● Website was available 24/7. No outages were reported; and</li> <li>● A face to face meeting with PHLN and ABLN was held where relevant agenda items were discussed.</li> </ul>
<p><b>MEASURE 2 - INSPECTIONS</b></p> <ul style="list-style-type: none"> <li>○ Burden of inspections kept to a minimum;</li> <li>○ Unintended impacts on the regulated community avoided.</li> </ul> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>● Annual review of inspection requirements;</li> <li>● Review inspection schedule at every compliance committee meeting;</li> <li>● Four discussions per year with Office of the Gene Technology Regulator (OGTR) and/or Department of Agriculture and Water Resources (DAWR) to monitor for unintended impacts on the regulated community;</li> <li>● Review of feedback received from entities following inspection;</li> <li>● No charges associated with compliance inspections.</li> </ul>	<ul style="list-style-type: none"> <li>● 2017-18 annual inspection plan was developed and reviewed at each SSBA compliance meeting to ensure alignment with the OGTR schedule;</li> <li>● Informal review of inspection requirements was conducted;</li> <li>● Five Compliance Committee meetings were held over 2017-18;</li> <li>● A list of action items from each SSBA Compliance Committee meeting was maintained and actioned;</li> <li>● Feedback received from entities through inspection process was promptly responded to; and</li> <li>● Inspections continued to be undertaken at no cost to the regulated community.</li> </ul>
<p><b>MEASURE 3 – ADMINISTRATION</b></p> <ul style="list-style-type: none"> <li>○ Burden of administrative processes kept to a minimum;</li> <li>○ Administrative processing completed in a timely manner.</li> </ul> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>● Availability of online data collection system; and</li> </ul>	<ul style="list-style-type: none"> <li>● The online data collection system was available 24/7; and</li> <li>● All administrative requests were actioned within two business days of receipt where possible.</li> </ul>

<b>KPI 1 - Regulators do not unnecessarily impede the efficient operation of regulated entities</b>	
<b>Measures/Metrics</b>	<b>Evidence (Performance in 2017-18)</b>
<ul style="list-style-type: none"> <li>• Routine administrative requests processed within two business days.</li> </ul>	
<p><b>MEASURE 4 - FEEDBACK</b></p> <ul style="list-style-type: none"> <li>○ Stakeholder issues addressed in a timely manner;</li> <li>○ Advice to stakeholders of compliance issues is timely and specific; and</li> <li>○ Best practice supported.</li> </ul> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Number and types of opportunities/vehicles available to discuss and address emerging issues;</li> <li>• Feedback sought from stakeholders at each inspection on burden of regulatory requirements;</li> <li>• Opportunity for stakeholders to provide feedback on website;</li> <li>• Comment encouraging feedback on all forms;</li> <li>• At each inspection inspectors will give advice on best practice if an opportunity is noted.</li> </ul>	<ul style="list-style-type: none"> <li>• Five Compliance Committee meetings were held over 2017-18.</li> <li>• Feedback received on website, forms, email inbox and telephone were responded to within two business days of receipt where possible.</li> <li>• Advice to stakeholders with regard to compliance issues was provided at the time of inspection and by letter 'post' inspection.</li> <li>• All letters sent to the regulated community encourage and provide contact points for feedback.</li> </ul>
<b>Self-assessed rating:</b>	<b>Met</b>

## KPI 2 - Communication with regulated entities is clear, targeted and effective

Measures/Metrics	Evidence (Performance in 2017-18)
<p><b>MEASURE 1 – MATERIALS AVAILABLE WHICH CLEARLY SET OUT REQUIREMENTS OF SCHEME</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Number of communication materials available outlining scheme requirements and giving guidance on implementation;</li> <li>• Online training tools available; and</li> <li>• Documentation meets accessibility requirements of Australian Government.</li> </ul>	<ul style="list-style-type: none"> <li>• Within the reporting period the availability of the SSBA Standards, Fact Sheets and Guidelines was maintained 24/7.</li> <li>• The availability of the online training facility was maintained 24/7.</li> <li>• One newsletter was circulated during the reporting period.</li> <li>• The majority of documentation published on the SSBA website meets accessibility requirements. Lengthy documents such as the SSBA Standards, will be assessed to ensure compliance with accessibility requirements at the time of their next review.</li> </ul>
<p><b>MEASURE 2 – COMMUNICATION MATERIALS TO COMPREHENSIVELY SUPPORT IMPLEMENTATION OF REQUIREMENTS ARE AVAILABLE</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Number of options available providing information including fact sheets, website, guidelines, newsletter, telephone line; and</li> <li>• Engagement with key representative groups such as PHLN/ABLN.</li> </ul>	<ul style="list-style-type: none"> <li>• 11 SSBA Guidelines and 17 Fact Sheets were maintained and available on the SSBA website; and</li> <li>• A dedicated mailbox (ssba@health.gov.au) and phone line (02) 6289 7477 were also available over the reporting period and were attended to during business hours.</li> </ul>
<p><b>MEASURE 3 – TRAINING IS AVAILABLE TO SUPPORT COMPLIANCE</b></p> <p><b>Metrics</b></p> <p>Training provided:</p> <ul style="list-style-type: none"> <li>• Number of online training modules available;</li> <li>• Number of guidelines available;</li> <li>• Number of factsheets available;</li> <li>• Number of presentations to stakeholder fora; and</li> <li>• Advice provided during inspections.</li> </ul>	<ul style="list-style-type: none"> <li>• Within the reporting period the Online Training Facility for the regulated community was maintained 24/7;</li> <li>• 11 SSBA Guidelines and 17 Fact Sheets were maintained and available on the SSBA website;</li> <li>• A presentation on the SSBA Regulatory Scheme was delivered to Biosecurity students at the Australian National University;</li> <li>• Inspectors continued to provide regulatory advice at the time of inspections.</li> </ul>
<p><b>MEASURE 4 – NOTIFICATION OF CHANGES, ISSUES AND NEW DEVELOPMENTS IS TIMELY AND EASILY ACCESSIBLE</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Number of newsletters produced;</li> <li>• Number of newsletter articles framed to clarify issues identified; and</li> <li>• Emails regarding changes sent to regulated community</li> </ul>	<ul style="list-style-type: none"> <li>• One newsletter was produced in the reporting period;</li> <li>• No changes occurred to the SSBA Regulatory Scheme during the reporting period and hence no emails were required to be sent.</li> </ul>



**KPI 2 - Communication with regulated entities is clear, targeted and effective**

<b>Measures/Metrics</b>	<b>Evidence (Performance in 2017-18)</b>
<p><b>MEASURE 5 – A RANGE OF OPTIONS ARE AVAILABLE FOR PROVIDING INFORMATION TO STAKEHOLDERS AND FOR RECEIVING FEEDBACK</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"><li>• Two way feedback provided during inspection process;</li><li>• Website;</li><li>• Dedicated telephone assistance line; and</li><li>• Email inbox</li></ul>	<ul style="list-style-type: none"><li>• Inspectors continued to encourage that feedback be provided by regulated entities during monitoring inspections; and</li><li>• The SSBA phone line and email inbox continued to be monitored and any feedback received was responded to appropriately.</li></ul>
<b>Self-assessed rating:</b>	<b>Met</b>

**KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed**

Measures/Metrics	Evidence (Performance in 2017-18)
<p><b>MEASURE 1 – RISKS COMPREHENSIVELY ASSESSED</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Experts engaged to assess target agents for scheme;</li> <li>• Risk level (i.e. biological threat level) reviewed by experts through liaison with Australian Intelligence Community;</li> <li>• Experts engaged to consider high risk areas of work e.g. the Australian Federal Police comments on research applications;</li> <li>• Staff administering scheme trained in risk assessment and familiar with operational environment; and</li> <li>• Regulated entities provided with guidance materials to assist in risk assessment for biological security.</li> </ul>	<ul style="list-style-type: none"> <li>• The differential requirements within the SSBA Standards continued to be applied as necessary;</li> <li>• Health continued to liaise with the Australian Intelligence Community to monitor biological agent threat levels.</li> <li>• Health continued to consult the Australian Federal Police on any research applications related to the handling of SSBA's.</li> <li>• Staff administering the scheme have been trained in risk assessment and continue to be familiar with the operational environment.</li> <li>• Security Risk Template was maintained and available to assist regulated entities to maintain their required risk assessment and risk management plans.</li> </ul>
<p><b>MEASURE 2 – RISK ASSESSMENT</b></p> <p>REMAINS UP TO DATE</p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Six monthly security briefing provided by the Australian Intelligence Community (AIC);</li> <li>• Australia's risk setting routinely monitored through regular analysis of intelligence community briefing material; and</li> <li>• List of Security Sensitive Biological Agents reviewed every 5 years.</li> </ul>	<ul style="list-style-type: none"> <li>• An annual security briefing was provided by the Australian Intelligence Community;</li> <li>• Health continues to routinely monitor Australia's risk setting for the handling of biological agents of security concern, through analysing intelligence community briefing material;</li> <li>• The List of SSBA's was reviewed and amended in 2016. A review of the listing of Highly Pathogenic Influenza is currently being undertaken and is to be finalised in 2019.</li> </ul>
<p><b>MEASURE 3 – REQUIREMENTS OF SCHEME ARE COMMENSURATE WITH RISK</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Similar schemes overseas investigated annually to compare risk management approach;</li> <li>• Scheme processes reviewed annually;</li> <li>• Document template available to support security risk assessment by participating entities</li> <li>• 5 year compliance audit of research status; and</li> <li>• Regulated entities provided with guidance materials to assist in risk assessment including a Risk Assessment Template to meet Part 2 of the Standards.</li> </ul>	<ul style="list-style-type: none"> <li>• Health continued to maintain a watching brief of international schemes;</li> <li>• Scheme processes continued to be both formally and informally reviewed; and</li> <li>• Security Risk Template was maintained and available to assist regulated entities to maintain their required risk assessment and risk management plans.</li> </ul>

<b>KPI 3 - Actions undertaken by regulators are proportionate to the regulatory risk being managed</b>	
<b>Measures/Metrics</b>	<b>Evidence (Performance in 2017-18)</b>
<p><b>MEASURE 4 - SCHEME SUPPORTS DIFFERENTIAL TREATMENT OF RISK</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Stratified scheme maintained with two tiers of agents, each having requirements commensurate to risk;</li> <li>• Specified strategies available for entities with identified compliance issues e.g. repeat inspections or spot checks; and</li> <li>• Different requirements for different/higher risk purposes (known vs suspected SSBA handling, handling agents for the purpose of research).</li> </ul>	<ul style="list-style-type: none"> <li>• The two tiered List of SSBA's (containing 20 agents) was maintained over the reporting period; and</li> <li>• A range of inspection options continued to be maintained over the reporting period i.e. comprehensive, mid-cycle, spot checks, special inspections and desktop reviews;</li> <li>• The requirements within the SSBA Standards continued to be applied commensurate with the level of risk posed.</li> </ul>
<p><b>MEASURE 5 – FEEDBACK ON APPROPRIATENESS OF RISK MANAGEMENT MEASURES SOUGHT PERIODICALLY FROM STAKEHOLDERS</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Feedback sought from PHLN/ABLN on appropriateness of scheme requirements.</li> </ul>	<ul style="list-style-type: none"> <li>• The requirements of the SSBA Regulatory Scheme are regularly informally discussed with PHLN and ABLN committee members. No formal consultation with these two committees was required during the reporting period.</li> </ul>
<b>Self-assessed rating:</b>	<b>Met</b>

## KPI 4 - Compliance and monitoring approaches are streamlined and co-ordinated

Measures/Metrics	Evidence (Performance in 2017-18)
<p><b>MEASURE 1 – INSPECTIONS COORDINATED WITH OTHER REGULATORY AGENCIES</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Inspections carried out by OGTR staff trained in laboratory assessments;</li> <li>• SSBA scheme continually monitors the work of OGTR and DAWR to ensure alignment;</li> <li>• OGTR consulted regarding any changes of legislation; and</li> <li>• Number of inspections scheduled to coordinate with inspections by other regulatory agencies.</li> </ul>	<ul style="list-style-type: none"> <li>• Inspections continued to be carried out by inspectors who are comprehensively trained in laboratory quality management systems, risk management and statutory compliance;</li> <li>• The 2017-18 SSBA inspection schedule was considered in cooperation with the OGTR at the commencement of the calendar year and at each Compliance Committee meeting. Adjustments were made to align with OGTR and Health priorities as necessary;</li> <li>• Five Compliance Committee meetings were held with OGTR over the reporting period;</li> </ul>
<p><b>MEASURE 2 – COMPLIANCE AND MONITORING PROCESSES ARE STREAMLINED</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Review of inspection frequency and duration;</li> <li>• Inspection frequency is risk based;</li> <li>• All facilities at the same location within the one entity are inspected at the same time;</li> <li>• SSBA Standards align with other regulatory scheme requirements as much as possible (for example, record keeping for disposal records etc.).</li> </ul>	<ul style="list-style-type: none"> <li>• Within the reporting period the inspection frequency and duration was considered to remain appropriate</li> <li>• 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;</li> <li>• Post-inspection compliance outcomes were also considered from a risk-based perspective and relayed to facility representatives once approved by the appropriate departmental delegate. Opportunities to improve the timeliness of this process will continue to be explored; and</li> <li>• Where possible facilities registered under the one entity were inspected at the same time.</li> </ul>
<p><b>MEASURE 3 – FEEDBACK SOUGHT ON OPPORTUNITIES FOR FURTHER STREAMLINING</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Streamlining and coordination discussed with OGTR / DAWR.</li> </ul>	<ul style="list-style-type: none"> <li>• Streamlining of inspections with the OGTR continued and was discussed at the five SSBA Compliance Committee meetings. Opportunities to improve alignment of inspections with the OGTR will continue to be explored.</li> </ul>
<b>Self-assessed rating:</b>	<b>Met</b>

<b>KPI 5 - Regulators are open and transparent in their dealings with regulated entities</b>	
<b>Measures/Metrics</b>	<b>Evidence (Performance in 2017-18)</b>
<p><b>MEASURE 1 – PURPOSE OF SCHEME, PROCESSES AND USE OF DATA IS CLEARLY STATED</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Communication materials available i.e. Factsheets, guidelines, website.</li> </ul>	<ul style="list-style-type: none"> <li>• Within the reporting period communication material remained available and up to date.</li> </ul>
<p><b>MEASURE 2 – CONSULTATION UNDERTAKEN ON CHANGES TO SCHEME</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Consultation with OGTR, PHLN, ABLN, Australia New Zealand Counter Terrorism Committee Chemical Biological Radiological Nuclear Security Subcommittee, State and Territory counterparts, Australian Intelligence Community;</li> <li>• Newsletters;</li> <li>• Consultation with government agencies (DAWR etc.); and</li> <li>• Consultation on changes with regulated community and other interested stakeholders.</li> </ul>	<ul style="list-style-type: none"> <li>• Five Compliance Committee meetings were held over the reporting period; and</li> <li>• No changes were made to the SSBA Regulatory Scheme over the reporting period, and therefore no formal consultation or informal consultation was required.</li> </ul>
<p><b>MEASURE 3 – OPPORTUNITIES ARE REGULARLY AVAILABLE FOR THE REGULATED COMMUNITY TO ASK QUESTIONS AND TO PROVIDE FEEDBACK ABOUT THE SCHEME</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Options for seeking information and providing feedback: <ul style="list-style-type: none"> <li>○ Correspondence associated with reports and inspections;</li> <li>○ Email inbox;</li> <li>○ Dedicated phone line; and</li> <li>○ Inspections.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Mechanisms for the provision of feedback continued to be described in all correspondence templates;</li> <li>• The SSBA email inbox and phone line continued to be monitored during business hours;</li> <li>• The National Incident Room phone line was available 24/7 for emergency use only;</li> <li>• SSBA inspections provided another mechanism by which facilities could provide feedback. Any questions raised were responded to by inspectors or the SSBA policy team efficiently and effectively.</li> </ul>
<b>Self-assessed rating:</b>	<b>Met</b>

<b>KPI 6 - Regulators actively contribute to the continuous improvement of regulatory frameworks</b>	
<b>Measures/Metrics</b>	<b>Evidence (Performance in 2017-18)</b>
<p><b>MEASURE 1 – REGULAR REVIEW OF LEGISLATION, REGULATIONS AND STANDARDS</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Review of legislation, regulations and Standards;</li> <li>• Non-compliance trends analysed and considered;</li> <li>• Stakeholder feedback collected;</li> <li>• Broad assessment of lessons observed in the regulatory schemes of comparable countries;</li> <li>• Mention of the scheme internationally as a model or to demonstrate good practice; and</li> <li>• Support the development of other legislative schemes.</li> </ul>	<p>Within the reporting period:</p> <ul style="list-style-type: none"> <li>• No changes to SSBA legislation were required during the reporting period. Work continued to have the <i>National Health Security Regulations 2008</i> re-made (due to a sunset date of 1 October 2018);</li> <li>• Non-compliance trends continued to be reviewed and general advice /education with regard to this was provided when necessary to the regulated community;</li> <li>• Feedback from stakeholders was considered and added to a matrix of issues, if deemed necessary;</li> <li>• Amendments were made where necessary to Fact Sheets and Guidelines (minimal changes made); and</li> <li>• The SSBA Regulatory Scheme remained open to the provision of advice relating to the development of other schemes.</li> </ul>
<p><b>MEASURE 2 – FEEDBACK SOUGHT TO ENABLE CONTINUOUS IMPROVEMENT</b></p> <p><b>Metrics</b></p> <ul style="list-style-type: none"> <li>• Email inbox / phone line / website /correspondence comments monitored for issues, potential for improvement; and</li> <li>• Inspectors explore reasons for non-compliance (with a view to addressing the cause).</li> </ul>	<ul style="list-style-type: none"> <li>• Feedback from the regulated community continued to be encouraged through the SSBA inbox, phone line and all correspondence with stakeholders;</li> <li>• The inspectors continued to seek guidance from the SSBA policy team when more complex compliance issues arose. These were promptly addressed and where necessary raised for discussion at the Compliance Committee Meetings.</li> </ul>
<b>Self-assessed rating:</b>	<b>Met</b>

## Concluding remarks

Overall it is considered that the evidence provided for the SSBA Regulatory Scheme for 2017-18 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 'Met' is considered appropriate for the SSBA regulatory Scheme over 2017-2018.

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.

During this period the scheme maintained a strong relationship with the OGTR for the provision of the SSBA monitoring and compliance program. Regular engagement between these two groups continued to occur with five 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.

As noted in the report, work continued to have the *National Health Security Regulations 2008* re-made due to sunset date of 1 October 2018. Health considers that these regulations have been operating effectively and are fit for purpose. Health commenced the process to have these re-made with minor administrative amendments and consulted with the regulated community and other related stakeholders as appropriate. The outcome of this work will be reported in the 2018-19 self-assessment report.

The SSBA Regulatory Scheme maintains a commitment to supporting quality improvement and will continue to work towards achieving best practice regulation within Australia.