

**Office of Health Protection (OHP)  
Security Sensitive Biological Agents (SSBA) Regulatory Scheme**

**Regulator Performance Framework Evidence Metrics**

The deliberate release of harmful biological agents such as viruses, bacteria, fungi and toxins has the potential to cause significant damage to human and animal health, the environment and the Australian economy. The Council of Australian Governments Review of biological agents of security concern in 2002 identified a need to regulate the secure storage, possession, use and transport of biological agents to minimise the risk of use for terrorism or criminal purposes. The SSBA Regulatory Scheme was created to address this need.

**Key Performance Indicator (KPI) 1: Regulators do not unnecessarily impede the efficient operation of regulated entities**

This scheme was designed to address an identified risk to national security. Some impost on the regulated community is therefore unavoidable. The scheme has consciously tried from inception to ensure that this impost is kept as small as possible.

<b>Measures (incorporate the following but are not limited to:)</b>	<b>Metric</b>	<b>Source of evidence</b>
<p>Reporting</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>	<ul style="list-style-type: none"> <li>• Annual review of reporting requirements</li> <li>• Availability of online data collection system</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</li> <li>• Website availability</li> <li>• 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 (Minutes of teleconferences, face to face meetings with PHLN/ABLN are taken but are likely to be classified and will not be published.)</li> <li>• Regulated community feedback</li> </ul>
<p>Inspections</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>	<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 Dept. of Agriculture to monitor for unintended impacts on the regulated community</li> <li>• Review of feedback received from Entities</li> </ul>	<ul style="list-style-type: none"> <li>• Annual inspection plan developed (due consideration given to concurrent OGTR schedule).</li> <li>• Informal review of inspection requirements</li> <li>• Number of Compliance Committee meetings</li> <li>• An issues register</li> </ul>

Measures (incorporate the following but are not limited to:)	Metric	Source of evidence
	following inspection. <ul style="list-style-type: none"> <li>• No charges associated with compliance inspections</li> </ul>	
Administration <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>	<ul style="list-style-type: none"> <li>• Availability of online data collection system</li> <li>• Routine administrative requests processed within two business days.</li> </ul>	<ul style="list-style-type: none"> <li>• Website availability</li> <li>• Fact Sheets</li> <li>• Standards</li> <li>• Record of admin requests that take longer than two business days to respond to.</li> </ul>
Feedback <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</li> <li>• Best practice supported</li> </ul>	<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>• Number of Compliance Committee meetings</li> <li>• Feedback received on website, forms, email inbox and telephone line</li> </ul>

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

Communications are focused on supporting cooperative compliance. This is an established, mature scheme so it is not often necessary to communicate with stakeholders about changes.

Measures (incorporate the following but are not limited to:)	Metric	Source of evidence
Materials available which clearly set out requirements of scheme	<ul style="list-style-type: none"> <li>• Number of communications materials available outlining scheme requirements and giving guidance on implementation</li> <li>• Online training tools available</li> <li>• Documentation meets accessibility requirements of Australian Government</li> </ul>	<ul style="list-style-type: none"> <li>• Standards</li> <li>• Factsheets</li> <li>• Guidelines</li> <li>• Website</li> <li>• Newsletter</li> <li>• Online training tools</li> </ul>
Communication materials to comprehensively support implementation of requirements are available	<ul style="list-style-type: none"> <li>• Number of options available providing information including:               <ul style="list-style-type: none"> <li>○ e.g. fact sheets, website, guidelines, newsletter, telephone line...</li> </ul> </li> <li>• Engagement with key representative groups such as PHLN/ABLN</li> </ul>	<ul style="list-style-type: none"> <li>• Standards</li> <li>• Factsheets</li> <li>• Guidelines</li> <li>• Website</li> <li>• Number/dates of meetings with PHLN/ABLN where issues are raised</li> </ul>
Training is available to support compliance	Training provided: <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</li> <li>• advice provided during inspections</li> </ul>	<ul style="list-style-type: none"> <li>• website</li> <li>• online training facility</li> <li>• copies of presentations</li> <li>• (records are kept of advice given during inspections, but these are classified secret)</li> </ul>
Notification of changes, issues and new developments is timely and easily accessible	Notification of changes: <ul style="list-style-type: none"> <li>• Number of newsletters produced</li> <li>• Number of newsletter articles framed to clarify issues identified</li> <li>• emails regarding changes sent to regulated community</li> </ul>	<ul style="list-style-type: none"> <li>• newsletters</li> <li>• articles</li> <li>• email correspondence</li> </ul>
A range of options are available for providing information to stakeholders and for receiving feedback.	Number of options available for providing feedback to stakeholders and receiving feedback on the scheme	<ul style="list-style-type: none"> <li>• List of options</li> <li>• All correspondence encourages feedback</li> </ul>

<b>Measures (incorporate the following but are not limited to:)</b>	<b>Metric</b>	<b>Source of evidence</b>
	<ul style="list-style-type: none"><li>• e.g. 2 way feedback provided during inspection process</li><li>• website</li><li>• dedicated telephone assistance line</li><li>• email inbox</li></ul>	

### KPI 3: Actions undertaken by regulators are proportionate to the regulatory risk being managed

This scheme has been based on risk management principles from the outset, with strong consideration of striking a balance between appropriately managing risks and achieving a reasonable impost on the regulated community. The purpose of this scheme is to address a potential threat to national security. This threat is considered high enough to warrant some impost on industry. The current environment seems to indicate it will only become more important to adequately monitor and mitigate against potential misuse of security sensitive biological agents.

Measures (incorporate the following but are not limited to:)	Metric	Source of evidence
Risks comprehensively assessed	<ul style="list-style-type: none"> <li>• Experts engaged to assess target agents for scheme</li> <li>• Risk level (ie. 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</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>• List of areas assessed on risk basis               <ul style="list-style-type: none"> <li>- SSBA List i.e. Tier 1 vs. Tier 2</li> <li>- SSBA Standards differential requirements</li> <li>- Inspections Tier 1 = eighteen months</li> <li>- Inspections Tier 2 = twenty-four months</li> <li>- Inspections Non-Registered = as needed.</li> </ul> </li> </ul>
Risk assessment remains up to date	<ul style="list-style-type: none"> <li>• 6 monthly security briefing provided by Intelligence community</li> <li>• Australia's risk setting routinely monitored through regular analysis of Intelligence community briefing material</li> <li>• List of Security Sensitive Biological Agents reviewed every 5 years</li> </ul>	<ul style="list-style-type: none"> <li>• scheduling of briefing meetings (no minutes are taken due to the coverage of classified material)</li> <li>• (Intelligence community briefings are classified)</li> <li>• List review</li> </ul>
Requirements of scheme are commensurate with risk	<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> </ul>	<ul style="list-style-type: none"> <li>• Risk assessment template</li> <li>• Compliance audit</li> <li>• Information regarding similar schemes</li> </ul>

Measures (incorporate the following but are not limited to:)	Metric	Source of evidence
	<ul style="list-style-type: none"> <li>• 5 year compliance audit of research status</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>	
Scheme supports differential treatment of risk	<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.</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>• List of two tiers of agents</li> <li>• SSBA Standards</li> <li>• Transport, personnel and physical security requirements commensurate with risk</li> </ul>
Feedback on appropriateness of risk management measures sought periodically from stakeholders	<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>• Number/dates of meetings with PHLN/ABLN at which this is discussed</li> </ul>

#### KPI 4: Compliance and monitoring are streamlined and coordinated

Measures (incorporate the following but are not limited to:)	Metric	Source of evidence
Inspections coordinated with other regulatory agencies	<ul style="list-style-type: none"> <li>• Inspections carried out by OGTR staff trained in laboratory assessments</li> <li>• SSBA scheme keeps pace with OGTR and Dept. of Agriculture work on closer alignment.</li> <li>• OGTR consulted regarding any changes of legislation</li> <li>• Number of inspections scheduled to coordinate with inspections by other regulatory agencies</li> </ul>	<ul style="list-style-type: none"> <li>• SSBA inspection schedule considered in cooperation with OGTR schedule.</li> <li>• Number of monthly compliance meetings with OGTR</li> <li>• Legislative consultation program</li> <li>• Emails/letters regarding changes of legislation</li> </ul>
Compliance and monitoring processes are streamlined	<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>• Inspection requirements / process reviewed annually.</li> </ul>
Feedback sought on opportunities for further streamlining	<ul style="list-style-type: none"> <li>• Streamlining and coordination discussed with OGTR/Agriculture</li> </ul>	<ul style="list-style-type: none"> <li>• Number/dates of meetings at which this is discussed</li> </ul>

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

The location of materials and identity of entities involved in this scheme are classified, so the opportunities for transparency must be seen within certain parameters. A range of vehicles are available for stakeholders to pose questions about the scheme. Staff answer these as fully as possible within security constraints.

Measures (incorporate the following but are not limited to:)	Metric	Source of evidence
Purpose of scheme, processes and use of data is clearly stated	<ul style="list-style-type: none"> <li>• Communication materials available               <ul style="list-style-type: none"> <li>○ Factsheets, guidelines, website</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Factsheets</li> <li>• Guidelines</li> <li>• Website</li> <li>• Emails</li> </ul>
Consultation undertaken on changes to scheme	<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 (Dept of Ag etc)</li> <li>• Consultation on changes with regulated community and other interested stakeholders</li> </ul>	<ul style="list-style-type: none"> <li>• Number of Compliance Committee meetings</li> <li>• Number of relevant PHLN, ABLN teleconferences and/or face to face meetings</li> </ul>
Opportunities are regularly available for the regulated community to ask questions and to provide feedback about the scheme	<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 telephone line</li> <li>○ inspections</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• (correspondence associated with reports and inspections is classified)</li> <li>• Availability of email inbox and dedicated phone line 9:00am – 5:00pm on business days</li> <li>• National Incident Room phone line available 24/7 in case of an emergency or high risk situation</li> </ul>



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

This scheme was a world first and often provides advice and shares information with other countries setting up comparable programs. This is an established scheme which has already gone through amendments to ensure it is suited to its purpose. It is not anticipated that there will need to be frequent amendments in future.

<b>Measures (incorporate the following but are not limited to:)</b>	<b>Metric</b>	<b>Source of evidence</b>
Regular review of legislation, regulations and standards	<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</li><li>• Support the development of other legislative schemes</li></ul>	<ul style="list-style-type: none"><li>• Copies of amendments to legislation, regulations or standards</li><li>• Articles on comparable schemes</li><li>• International articles, documents referring positively to the scheme</li><li>• Copies of stakeholder feedback (if not classified)</li><li>• Comments/input provided into the development of other schemes.</li></ul>
Feedback sought to enable continuous improvement	<ul style="list-style-type: none"><li>• Email inbox/telephone line/website/correspondence comments monitored for issues, possibilities for improvement</li><li>• Inspectors explore reasons for non-compliance (with a view to addressing the cause)</li></ul>	<ul style="list-style-type: none"><li>• Email inbox, dedicated telephone line available</li><li>• Comment on website/forms encouraging feedback</li></ul>