

Security Sensitive Biological Agents Regulatory Scheme

Removal of Salmonella Typhi and Vibrio cholerae

Release Date: July 2019

Introduction

From **14 March 2016** Salmonella Typhi and Vibrio cholerae will no longer be classed as security sensitive biological agents (SSBAs). The removal of these agents from the List of Security Sensitive Biological Agents (List of SSBAs) means that any facility handling *S.* Typhi or *V. cholerae* is no longer required to comply with the SSBA Regulatory Scheme requirements in relation to these agents.

If a facility is handling any other biological agents designated as SSBAs (as determined on the List of SSBAs dated 14 March 2016), it must continue to comply with the requirements of the SSBA Regulatory Scheme in relation to those agents.

Removal of S. Typhi and V. cholerae from a facility registration

The listing of *S*. Typhi and *V. cholerae* will be automatically removed from a facility's registration by Health from 14 March 2016. Facilities are <u>not</u> required to dispose of these agents.

De-Registration

Following the automatic removal of *S*. Typhi and *V. cholerae* from the List of SSBAs, facilities may apply to de-register with the SSBA Regulatory Scheme as long as no SSBAs (as determined on the List of SSBAs dated 14 March 2016) are held.

If SSBAs are held and the facility is to de-register, then the **entire** holdings of SSBAs must be disposed of, via complete transfer or destruction, before de-registration can occur.

<u>Note</u>: as S. Typhi and V. cholerae are no longer considered SSBAs, the facility may retain all holdings of these agents and still apply for de-registration.

Providing information to the Department of Health

The information you provide to Health is mandated by the *National Health Security Act 2007* and will be included on the National Register of SSBAs.

It is important to answer all questions and to provide accurate information. If the information you provide is incorrect or incomplete, Health may require you to provide additional information. This may cause delays.

Privacy

Personal information provided to Health will comply with the requirements of the *Privacy Act 1988*.

Application Authorisation

Please ensure that the person completing this form holds the appropriate authority to submit this application on behalf of the entity or facility.

Instructions on preparing this notification

This document allows electronic entry of information into the required fields. It is recommended that, where possible, this form should be completed on a computer and a copy printed, signed and sent to Health.

All questions are mandatory and must be completed unless otherwise stated in this form. If the space provided in each field is not sufficient to complete your answer, please include any additional information in an attachment with the information clearly marked as to which question it relates to.

Please ensure you retain a copy of this completed form as Health is unable to provide copies of submitted documents.

Lodgement

To lodge this form via post you will need to use an opaque envelope and post using Australia Post's Registered Mail service. You are considered to have submitted the report at the date and time shown on the registered post receipt.

Please do not email or fax forms to Health as these cannot be accepted.

Please submit all postal applications to:

The Director
Health Emergency Planning, Security and Laboratories Section
Department of Health
MDP 140, GPO Box 9848
Canberra ACT 2601

Once Health has received the form, you will be provided with a confirmation of receipt by email to the contact officer listed for the facility.

Further Information

Please use your facility reference number to refer to any matters relating to your facility.

If you have any queries about this form please contact the SSBA Regulatory Scheme:

Telephone: (02) 6289 7477 Email: ssba@health.gov.au

PART 1: FACILITY DETAILS

Please complete the details for the entity and facility.		
Facility registration number		
Entity name		
Facility name		

PART 2: DE-REGISTRATION

SSBA Details				
Do you intend to De-Register this facility?	Yes		please be aware that if you receive SSBAs in the future you will need to complete a new <i>Initial Registration</i> application form. Please move to next question.	
	No		you must continue to report Administrative Reportable Events ¹ and must inform Health when you receive SSBAs in the future. Move to Part 4	
Do you handle any SSBAs* in this facility? * as designated on the List of SSBAs dated 14 March 2016.	Yes		you must dispose of all SSBAs handled in the facility before you can de-register. Move to Part 3.	
	No		move to Part 4	

PART 3: DISPOSAL OF SSBAS

Please complete this section if you are disposing of your entire holding of an SSBA.

Note – you may both destroy and transfer the biological agent to dispose. It is not a requirement to dispose of S. Typhi or V. cholerae before de-registration.

SSBA Details				
Have you destroyed or transferred your entire holding of SSBAs	Destroyed move to Part 3.1			
	Transferred move to Part 3.2			
3.1 - Destruction of SSBAs				
What SSBA have you destroyed?	SSBA 1 -			
	SSBA 2 -			
Specific strain, serotype or toxin subunit (if applicable)	SSBA 1 -			
	SSBA 2 -			
Have you destroyed your entire holding ² of this/these SSBA at this facility?	Yes please complete the remain questions in this section			
	No please complete the rest of this section AND section 3.2 explaining what you have done with the remainder of the SSBA			
Date of destruction	SSBA 1 -			
	SSBA 2 -			

³ This includes changes to Responsible Officer details.

² If the SSBA is a toxin has the remaining quantity fallen below the reportable quantity?

Reason for destruction	SSBA 1 -			
	SSBA 2 -			
Method of destruction	SSBA 1 -			
Weiled of destruction	SSBA 2 -			
Comments				
Section 3.2: Transfer of SSBAs				
Which SSBAs have you	SSBA 1 -			
transferred?	SSBA 2 -			
Have you transferred your <u>entire</u> holding of this/these SSBAs?	Yes Please complete remaining questions in this section			
	No Please complete the remaining questions in this section AND section 3.1 explaining what you have done with the remainder of the SSBA			
Date of transfer	SSBA 1 -			
2 disc of trainerer	SSBA 2 -			
Receiving organisation name	SSBA 1 -			
0	SSBA 2 -			
Receiving organisation address	SSBA 1 -			
	SSBA 2 -			
Receiving organisation contact	SSBA 1 -			
name	SSBA 2 -			
Receiving organisation contact	SSBA 1 -			
telephone number	SSBA 2 -			
Arrival date at receiving facility (if known)	SSBA 1 -			
	SSBA 2 -			
Was the transfer successful ¹ according to the SSBA standards for all SSBAs transferred?	Yes Move to Section 4			
	No Please complete remaining question			
Lost in Transit or Unsuccessful Transfer				
Please provide a brief description of what happened				
Reporting to law enforcement may be required. Please see the guideline "Reporting to Law Enforcement or the National Security Hotline" for further information.				

¹ A successful transfer is defined under the SSBA Standards as verification that the complete shipment of the SSBA (quantity and type), as covered by the shipment documents, has been received and that there is no evidence of tampering to the shipping container.

Removal of *S. Typhi* and *V. cholerae*Page 4 of 5

PART 4: SIGNATURES

The information collected on this form may be used by Health to decide whether to vary the National Register of Security Sensitive Biological Agents (National Register). If a decision is made to vary the National Register, the information contained on this form, including personal information, will be recorded on the National Register by Health.

The information collected on this form is authorised under the *National Health Security Act 2007* and *National Health Security Regulations 2018*. Information collected on this form may be disclosed by Health to the Australian Security Intelligence Organisation, law enforcement agencies such as the Australian Federal Police and State and Territory police forces, other agencies responsible for responding to emergencies and other specified persons. Health is unlikely to disclose personal information to overseas recipients.

Health has an Australian Privacy Principles (APP) privacy policy which you can read at www.health.gov.au/internet/main/publishing.nsf/content/privacy-policy. You can obtain a copy of the APP privacy policy by contacting Health by telephone on (02) 6289 1555, freecall 1800 020 103 or by using the online enquiries form at www.health.gov.au.

The National Register is hosted and maintained by the Department of Home Affairs.

I declare that:

- I am duly authorised to sign this declaration on behalf of the entity associated with this facility;
- The information supplied on this form and any attachment is true and correct; and
- If the entity is handling SSBAs, this entity is compliant with the SSBA Standards currently in force.

Signature	
Date	
Full name (Please print)	
Position title	
Contact telephone number	
Contact e-mail address	