



## Security Sensitive Biological Agents Regulatory Scheme

# SSBA – Guideline 6 – SSBA toxins

July 2014

## Introduction

This guideline provides information to entities and facilities about handling toxins on the List of SSBA, the reportable quantities for toxins on the List of SSBA. It also provides information on if an entity will need to register to handle a Tier 1 or Tier 2 SSBA if handling *Clostridium botulinum*.

## Toxins on the List of SSBA

The *National Health Security Act 2007* (NHS Act) provides for the Minister for Health to establish a List of Security Sensitive Biological Agents (SSBA). The NHS Act also states that if the Minister includes a toxin in the List of SSBA, the Minister may also specify the reportable quantity of that toxin.

There are three toxins on the List of SSBA: botulinum toxin, ricin and abrin. All three toxins are considered to be Tier 1 SSBA and are subject to the highest security requirements.

## Reportable quantities

The following reportable quantities have been established:

Toxin	Reportable quantity
Botulinum toxin (therapeutic <sup>1</sup> )	exempt
Botulinum toxin (non-therapeutic)	0.5 mg
Abrin	5.0 mg
Ricin	5.0 mg

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<sup>1</sup> A form approved for therapeutic use under the *Therapeutic Goods Act 1989*. For example, the forms of *Botulinum* toxin approved for therapeutic use and known under their commercial names Botox™ or Dysport™

Reportable quantities refer to the toxins in their purified form, not the quantities of crude extracts or source material. If a facility handles any of these toxins in amounts equal to or above the stated reportable quantities, the facility must register with the Department of Health (Health) as handling a Tier 1 SSBA. If the facility is unable to verify by accurate analysis that the amount of toxin it is handling is below the reportable quantity, then it should take appropriate action, e.g. register to handle or dispose of the toxin within two business days and report to Health. Handling of source material such as castor beans or extracts should also be reported if it is for the purpose of producing or extracting toxin and the amount of toxin cannot be shown to be below the reportable quantity.

## ***Clostridium botulinum***

Botulinum toxin is a Tier 1 SSBA and *C. botulinum* is a Tier 2 SSBA. Tier 1 SSBAs have higher security requirements than Tier 2 SSBAs under the *National Health Security Regulations 2008* and SSBA Standards.

Under certain conditions, *C. botulinum* produces botulinum toxin. When storing and handling *C. botulinum* in a form that is **not** producing botulinum toxin, facilities need only comply with the Tier 2 requirements of the SSBA Regulatory Scheme.

If a facility handles *C. botulinum* in a form that produces botulinum toxin, and the amount of botulinum toxin produced is over the reportable quantity stated above, the facility must register to handle *C. botulinum* (Tier 2) **and** botulinum toxin (Tier 1). When handling *C. botulinum* broth cultures, it should be assumed that the culture produces reportable levels of botulinum toxin, unless it can be established otherwise.

Further information can be found in the guideline prepared by the Australian Federal Police – *Toxin Levels in Environmental and Clinical Samples*. To obtain a copy of this document please email [SSBA](mailto:SSBA@afp.gov.au).