Erratum: 2015 Annual Report of the Federal Select Agent Program

In the <u>2015 Annual Report of the Federal Select Agent Program</u>, first published online on June 30, 2016:

- On page 3, the first sentence should have read "In 2015, FSAP renewed the registration of 104 entities (12 AgSAS and 92 DSAT)."
- On page 3, the second sentence should have read "Two entities applied to AgSAS for new registrations (both registrations were approved), two entities applied to DSAT for new registrations (both registrations were approved), and 27 entities withdrew from the program."
- On page 12, the third sentence in the section "New Registrations" should have read "DSAT approved two
 new applications from entities requesting to register for permission to possess, use, or transfer BSAT."
- On page 12, the third sentence in the section "Renewals" should have read "In 2015, all registration renewals were approved: AgSAS approved 12 and DSAT approved 92, for a total of 104 renewals processed."
- On page 13, the dark blue call-out box should have read "51% of all FSAP-regulated entities are registered for Tier 1 BSAT."
- On page 13, the third sentence below the dark blue call-out box should have read "One hundred thirty-five
 entities are registered for Tier 1 BSAT with DSAT as their lead agency, representing 53.8% of all DSAT-led
 entities."
- On page 14, in the light blue call-out box titled "Top 10 Agents Registered by Entities," the list under "Registered with DSAT" should have read:
 - 1. Brucella melitensis
 - 2 Brucella suis
 - 3. Brucella abortus
 - 4. Bacillus anthracis (Pasteur strain)
 - 5. Francisella tularensis*
 - 6. Yersinia pestis*
 - 7. Bacillus anthracis*
 - 8. Burkholderia pseudomallei*
 - 9. Burkholderia mallei*
 - 10. Botulinum neurotoxin producing species of *Clostridium**

This erratum was issued on November 18, 2016.

In the <u>2015 Annual Report of the Federal Select Agent Program</u>, first published online on June 30, 2016:

- On page 4, the "Exclusions" section should have read: "An entity or individual may request to exclude from SAR an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. In 2015, there were four requests for permission to exclude attenuated select agent strains or less potent/toxic forms of select toxins. All four requests were approved. A detailed list of all excluded select agent strains can be found at <u>Select Agents and Toxins Exclusions</u>."
- On page 21, the sixth sentence of the first paragraph in the section "Exclusions" should have read: "In 2015,
 there were four requests for permission to exclude attenuated select agent strains or less potent/toxic forms
 of select toxins all of which were approved, which are detailed in Table 5 below."
- On page 22, Table 5 was updated to remove the four listed recombinant avian influenza strains. These
 recombinant avian influenza strains are being removed from the exclusion list because these candidate
 vaccine strains were considered low pathogenic strains of avian influenza virus, which are not regulated
 under the select agent regulations. Table 5 should be replaced with the following table:

Exclusion Requests Received in 2015

Entity Type	Select Agent	Decision Status
Academic	Brucella melitensis strain ΔnorD Δznu Brucella melitensis-lacZ	Approved
	Burkholderia mallei strain CHL001 (ΔtonB Δhcp1)	
Commercial	Anhydrotetrodotoxin	
	Recombinant Newcastle disease virus	

Table 5: Summary of requests for exclusions by entity type, select agent, and approval status

 On page 22, the second sentence in the first paragraph on the page in the section "Exclusions" should have read: "The recombinant candidate vaccine strain of Newcastle disease virus has been excluded based on results from in vitro and in vivo studies indicating that this strain does not pose a severe threat to animal health or animal products."

This erratum was issued on April 8, 2020.