Justification for Change

Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73)

(OMB Control No. 0920-0576) Expiration 10/31/2020

Non-Substantive Change Request

Centers for Disease Control and Prevention

Office of Public Health Preparedness and Response

Division of Select Agents and Toxins

Lori Bane

(404) 718-2006

(404) 718-2097 FAX

zoz1@cdc.gov

August 8, 2018

Nonmaterial/non-substantive change to an OMB approved information collection for Possession, Use, and Transfer of Select Agents and Toxins (42 CFR Part 73) (OMB Control No. 0920-0576) Expiration 10/31/2020

Justification for the Change - A nonmaterial/non-substantive can be explained in table format as shown below:

Form	Current Item	Requested Change	Justification
APHIS/CDC Form 4, Section B, Block 1	"1. Select Agent or Toxin Identified:" If "Botulinum neurotoxins" is selected from drop down box. Question is added "If Botulinum neurotoxins identified in Block #1, will you attempt to isolate Botulinum neurotoxin producing species of Clostridium? Yes (if yes, an update answering questions 1b and 1c is required within 7 days of identification) No" If yes, then, questions 2 & 8 of current form are asked.	"1. Select Agent or Toxin Identified:"	This change clarifies the meaning/intent of the question.
APHIS/CDC Form 4 Guidance, Page 6	Block B1 – Select Agent or Toxin Identified: "If Botulinum neurotoxins identified in Block #1, complete block 1a. If yes is selected for block 1a, complete blocks 1b and 1c by using instructions provided below for "Block B2 – Date Identified:" and "Block B8 – Disposition of Select Agent or Toxins."	Remove the statement "If Botulinum neurotoxins identified in Block #1, complete block 1a. If yes is selected for block 1a, complete blocks 1b and 1c by using instructions provided below for "Block B2 – Date Identified:" and "Block B8 – Disposition of Select Agent or Toxins."	This change clarifies the meaning/intent of the question.

Justification for Change

Change to Electronic Federal Select Agent Program portal (eFSAP)Electronic Import Permit Program (eIPP)

There are no changes to the forms approved by the Office of Management and Budget (OMB) for OMB Control No. 0920-0199 (Expiration date 04/30/2021). The request for nonmaterial/non-substantive changes consists of changing to a database, "Electronic Federal Select Agent Program portal (eFSAP)/Electronic Import Permit Program portal (eIPP)." There are no changes in the data that will be maintained in eIPP system. For NSAR, the regulated entities use the pdf-fillable forms found at https://www.cdc.gov/phpr/ipp/applications/index.htm. The pdf-fillable forms are completed by the respondents, saved to their local drive, and then submitted to the Centers for Disease Control and Prevention (CDC)/Import Permit Program (IPP). Once at IPP, the data found in the pdf-fillable forms are entered into NSAR by IPP staff. The respondent maintains the pdf-fillable forms so they can retain an electronic copy of their

submission, which will make it easier for the entity to amend any future submissions. For eIPP, the information is entered directly into database by the respondent. Therefore, eliminating the need for respondent to complete the pdf-fillable forms and send to IPP for the information to be entered into the database.

Form 4 Change

This is a request for nonmaterial/non-substantive change clarifies the meaning/intent of the question for the select agent or toxin identified. In the list of select agents and toxins, there is a toxin Botulinum neurotoxins that is produced by the select agent, Botulinum neurotoxin producing species of *Clostridium*. The APHIS/CDC Form 4, Report of the Identification of a Select Agent or Toxin, is used by clinical or diagnostic laboratories and other entities to notify the Federal Select Agent Program of the identification of a select agent or toxin as the result of diagnosis, verification, or proficiency testing and of the final disposition of that identified agent or toxin. In the case of Botulinum neurotoxins, the entity also reports Botulinum neurotoxin producing species of *Clostridium* for the same specimen. To reduce confusion of an entity report trying to report the toxin and select agent using the same form, we are asking the entity to submit two notifications. To ensure that there is no additional burden to the approximately 8 entities that report about 120 additional forms annually both the agent and the toxin, our IT system, eFSAP, has been modified to allow the entity to copy and paste the information from the previously submitted form. Using the data obtained from the 2016 Annual Report of the Federal Select Agent Program (https://www.selectagents.gov/resources/FSAP_Annual_Report_2016.pdf) the Division of Select Agents and Toxins received 1,030 reports in 2016. The public reporting burden of providing this information is estimated to average 30 minutes per response. Given the changes to eFSAP, we believe responders can complete Form 4 in an average of 15 minutes per response. Therefore, reducing the public burden by 227.5 hours from the approved 455 hours to 227.5 hours.