11 AUGUST 2021

AMENDMENTS TO U.S. CONFIDENCE BUILDING MEASURE RETURNS

The United States is committed to making its annual Biological Weapons Convention (BWC) Confidence Building Measure (CBM) returns as complete, accurate, and transparent as possible. Pursuant to this goal, the U.S. Government continually works to improve the process by which information is assembled and reviewed for the annual U.S. CBM submission. When an issue is discovered during this process, the U.S. Government will amend the relevant CBM return(s).

ERRATUM:

In the United States CBM return covering 2019, submitted in April 2020, information has been identified that should have been included in the entry for the U.S. Department of Agriculture on Form A, Part 2 (iii) for the Agricultural Research Service Floral and Nursery Plants Research Unit, Beltsville Agricultural Research Center (BARC). The corrected form, which should have appeared in Form A, Part 2 (iii) in the CBM return, is below and corrected in the corresponding Supplemental Information to the U.S. CBM Return covering 2019. This text is colored red to denote a change in the Form.

Additionally, this facility entry should have been included in previous CBM returns as follows:

- The Floral and Nursery Plants Research Unit, Beltsville Agricultural Research Center (BARC) should have been included in previous CBM returns. The nature of the work over the years 2011-2018, including laboratory space, personnel, and funding levels as well as the microorganisms studied, was similar to the corrected CBM return covering the year 2019.

Corrections to "Floral and Nursery Plants Research Unit, Beltsville Agricultural Research Center (BARC)" entry to Form A, Part 2 (iii),
National biological defence research and development programmes - Facilities:

1. What is the name of the facility?
Floral and Nursery Plants Research Unit, Beltsville Agricultural Research Center

2. Where is it located (include both address and geographical location)?
10300 Baltimore Avenue, Beltsville, MD 20705

3. Floor area of laboratory areas by containment level (m^2):

BSL-2	98.8 m^2
BSL-3	0 m^2
BSL-4	0 m^2
Total laboratory floor area	98.8 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 3

(ii) Division of personnel:

Military	0
Civilian	3

(iii) Division of personnel by category:

Scientists	2
Engineers	0
Technicians	1
Administrative and support staff	0

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Bacteriology, Bioinformatics, Genomics, Horticulture, Molecular Diagnostics, Plant Pathology

(v) Are contractor staff working in the facility? If so, provide an approximate number.
No Number: Not Applicable

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
U.S. Department of Agriculture (USDA)

(vii) What are the funding levels for the following programme areas:

Research	$ 456,019
Development	$ 0
Test and evaluation	$ 0
Total	$ 456,019

(viii) Briefly describe the publication policy of the facility:
All scientific research data is available for publication in peer-reviewed publications. All scientists are required to have a minimum of two peer-reviewed publications per year (not all publications by these scientists are relevant to this report). They are encouraged to present research at scientific conferences and to publish in books and proceedings. The USDA

Agricultural Research Service (ARS) maintains a searchable online database of publications by scientists at this location (available at https://www.ars.usda.gov/research/publications/publications-at-this-location/?modeCode=80-20-05-05&

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.):

1. Addy, HS., Ebrahim, A, Huang, Q. Molecular and biological characterization of Ralstonia phage RsoM1USA, a new species of P2Virus, isolated in the USA. Frontiers in Microbiology. 2019; 10:267. https://doi.org/10.3389/fmicb.2019.00267.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[1] and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: The specific research objectives in this project include studies on detection, host range, epidemiology, and control of bacterial wilt and are included in the ARS Research Project entitled "Detection, Identification, and Characterization of New and Emerging Viral and Bacterial Diseases of Ornamental Plants". Specifically, the overall approach is to develop knowledge and tools that will aid U.S. regulatory agencies to establish effective pathogen testing protocols, and U.S. floriculture companies to improve clean stock production for new vegetatively propagated annuals and perennials. The goals of the current research project include: 1) identification and characterization of genes and/or regulatory elements, in order to facilitate the accurate definition, detection, and control; and 2) isolation and biological and molecular characterization of bacteriophages to better understand their involvement in competitive fitness and virulence. Additional information about this research project is available at https://www.ars.usda.gov/research/project/?accnNo=432744; https://www.ars.usda.gov/research/project/?accnNo=431988; and, https://www.ars.usda.gov/research/project/?accnNo=430955.

Microorganisms and/or Toxins Studied: Plant Protection and Quarantine (PPQ) Select Agent

Outdoor studies: No outdoor studies performed

[1] Including viruses and prions.

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AMENDMENTS TO U.S. CONFIDENCE BUILDING MEASURE RETURNS

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ERRATUM:

In the United States CBM return covering 2019, submitted in April 2020, information has been identified that should have been included in the entries for the U.S. Department of Health and Human Services on Form A, Part 2 (iii) for the Food and Drug Administration White Oak Campus, the College Park Campus, and the Moffett Campus. The corrected or additional forms, which should have appeared in Form A, Part 2 (iii) in the CBM return, are below or are corrected in the corresponding Supplemental Information to the U.S. CBM Return covering 2019. This text is colored red to denote a change in the Form.

Additionally, these three facility entries should have been included in previous CBM returns as follows:

- The Food and Drug Administration White Oak Campus entry should include information on the Center for Drug Evaluation and Research (CDER) in addition to the information provided for the Center for Biologics Evaluation and Research (CBER). The nature of the work over the years 2015-2018, including laboratory space, personnel, and funding levels as well as the microorganisms and toxins studied, was similar to the corrected CBM return covering the year 2019.
- The Food and Drug Administration College Park Campus should have been included in previous CBM returns. The nature of the work over the years 2015-2018, including laboratory space, personnel, and funding levels as well as the microorganisms and toxins studied, was similar to the corrected CBM return covering the year 2019.
- The Food and Drug Administration Moffett Campus should have been included in previous CBM returns. The nature of the work over the years 2015-2018, including laboratory space, personnel, and funding levels as well as the microorganisms and toxins studied, was similar to the corrected CBM return covering the year 2019.

Corrections to "Food and Drug Administration White Oak Campus" entry to Form A, Part 2 (iii), National biological defence research and development programmes - Facilities:

3. Floor area of laboratory areas by containment level (m^2):

BSL-2	654 m^2
BSL-3	184 m^2
BSL-4	0 m^2
Total laboratory floor area	838 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 82

(ii) Division of personnel:

Military	0
Civilian	82

(iii) Division of personnel by category:

Scientists	62
Engineers	0
Technicians	0
Administrative and support staff	20

(v) Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 10

(vii) What are the funding levels for the following programme areas:

Research	$ 1,843,315
Development	$ 0
Test and evaluation	$ 0
Total	$ 1,843,315

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.):

2. Adams SE, Lee N, Lugovtsev VY, Kan A, Donnelly RP, Ilyushina NA. Effect of influenza H1N1 neuraminidase V116A and I117V mutations on NA activity and sensitivity to NA inhibitors. Antiviral Res. 2019; 169:104539. doi: 10.1016/j.antiviral.2019.104539. https://www.ncbi.nlm.nih.gov/pubmed/31228489
3. Ilyushina NA, Dickensheets H, Donnelly RP. A comparison of interferon gene expression induced by influenza A virus infection of human airway epithelial cells from two different donors. Virus Research. 2019; 264:1-7. doi: 10.1016/j.virusres.2019.02.002. https://www.ncbi.nlm.nih.gov/pubmed/30779949/
4. Ilyushina NA, Komatsu TE, Ince WL,Donaldson EF, Lee N, O'Rear JJ et al. Influenza A virus hemagglutinin mutations associated with use of neuraminidase inhibitors correlate with decreased inhibition by anti-influenza antibodies. Virol J. 2019; 16(1):149. doi: 10.1186/s12985-019-1258-x. https://www.ncbi.nlm.nih.gov/pubmed/31783761
5. McWilliams IL, Kielczewski JL, Ireland DDC, Sykes JS, Lewkowicz AP, Konduru K et al. Pseudovirus rVSVΔG-ZEBOV-GP Infects Neurons in Retina and CNS, Causing Apoptosis and Neurodegeneration in Neonatal Mice. Cell Rep. 2019; 26(7):1718-26.e4. doi: 10.1016/j.celrep.2019.01.069. https://www.ncbi.nlm.nih.gov/pubmed/30759384

6. Adams SE, Lee N, Lugovtsev VY, Kan A, Donnelly RP, Ilyushina NA. (2019) Effect of influenza H1N1 neuraminidase V116A and I117V mutations on NA activity and sensitivity to NA inhibitors. Antiviral Research 169:104539. doi: 10.1016/j.antiviral.2019.104539"
7. "Ilyushina NA, Dickensheets H, Donnelly RP. (2019) A comparison of interferon gene expression induced by influenza A virus infection of human airway epithelial cells from two different donors. Virus Research 264:1-7. doi: 10.1016/j.virusres.2019.02.002"
8. Stantchev TS, Zack-Taylor A, Mattson N, Strebel K, Broder CC and KA Clouse 2019, "Cytokine Effects on the Entry of Filovirus Envelope Pseudotyped Virus-Like Particles into Primary Human Macrophages". Viruses 11(10): 889 (published September 23, 2019)
9. ~~Ouyang W, Guo P, Takeda K, Fu Q, Fang H, Frucht DM. Erk1/2 inactivation promotes a rapid redistribution of COP1 and degradation of COP1 substrates. Proc Natl Acad Sci USA. 2020. doi: 10.1073/pnas.1913698117. https://www.ncbi.nlm.nih.gov/pubmed/32041890~~

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[2] and/or toxins studied, as well as outdoor studies of biological aerosols.

(A correction was made in the Supplemental Information to the 2020 U.S. CBM Return)

[2] Including viruses and prions.

Correction to “Food and Drug Administration College Park Campus” entry to Form A, Part 2 (iii), National biological defence research and development programmes - Facilities:

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[3] and/or toxins studied, as well as outdoor studies of biological aerosols.

(A correction was made in the Supplemental Information to the 2020 U.S. CBM Return)

[3] Including viruses and prions.

Addition of "Food and Drug Administration Moffett Campus" entry to Form A, Part 2 (iii), National biological defence research and development programmes - Facilities:

1. What is the name of the facility?
Food and Drug Administration Moffett Campus

Note: This facility is a new addition to the 2019 CBM report.

2. Where is it located (include both address and geographical location)?
6502 South Archer Road, Bedford Park, IL 60501-1957

3. Floor area of laboratory areas by containment level (m^2):

BSL-2	167 m^2
BSL-3	0 m^2
BSL-4	0 m^2
Total laboratory floor area	167 m^2

4. The organizational structure of each facility:

(i) Total number of personnel: 4

(ii) Division of personnel:

Military	0
Civilian	4

(iii) Division of personnel by category:

Scientists	3
Engineers	0
Technicians	0
Administrative and support staff	1

(iv) List the scientific disciplines represented in the scientific/engineering staff.
Chemistry, Biochemistry, Biological Science, Microbiology, Genomics

(v) Are contractor staff working in the facility? If so, provide an approximate number.
No Number: Not applicable

(vi) What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?
Department of Health and Human Services (HHS)

(vii) What are the funding levels for the following programme areas:

Research	$ 50,000
Development	$ 0
Test and evaluation	$ 0
Total	$ 50,000

(viii) Briefly describe the publication policy of the facility:
FDA staff are encouraged to publish their research results in peer-reviewed scientific journals. The FDA review and clearance policy ensures publications are of high quality and vetted by subject matter experts

as well as leadership. In addition, compliance with the public access to federally-funded scientific research (including digital data and publications) is assured by following FDA's data management plan. The policy states that publications must be uploaded to PubMed Central one year after the publication date.

- FDA review and clearance policy: https://www.fda.gov/media/80061/download
- FDA Data Management Plan: (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/StaffManualGuides/UCM479268.pdf)

(ix) Provide a list of publicly-available papers and reports resulting from the work published during the previous 12 months. (To include authors, titles and full references.):

There were no publicly available papers or reports resulting from the work published during the previous 12 months.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of micro-organisms[4] and/or toxins studied, as well as outdoor studies of biological aerosols.

Objectives: This facility includes work undertaken by the FDA's Center for Food Safety and Applied Nutrition (CFSAN), a national leader in protecting and promoting public health. Biodefense work at CFSAN is aimed at developing diagnostic assays for public health and food safety. The microbial genomics and analytical chemical and food technology processing techniques developed at CFSAN are available to other Federal agencies charged with forensic investigations

Microorganisms and/or Toxins Studied: HHS Select Agent and Toxin, NIAID Category A

Outdoor studies: No outdoor studies performed.

[4] Including viruses and prions.