Biological situation regarding extremely hazardous and dangerous human and economically significant animal diseases

Statement of U.S. Department of State (29 August 2022)

U.S. DEPARTMENT of STATE

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Joint Statement on the Contribution of Cooperative Threat Reduction Partnerships to Global Health Security

MEDIA NOTE

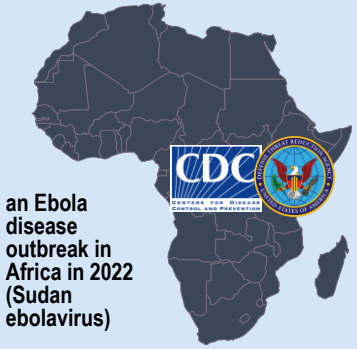
OFFICE OF THE SPOKESPERSON

AUGUST 29, 2022

The text of the following statement was released by the Governments of the United States of America, Armenia, Georgia, Iraq, Jordan, Liberia, Philippines, Sierra Leone, Uganda, and Ukraine.

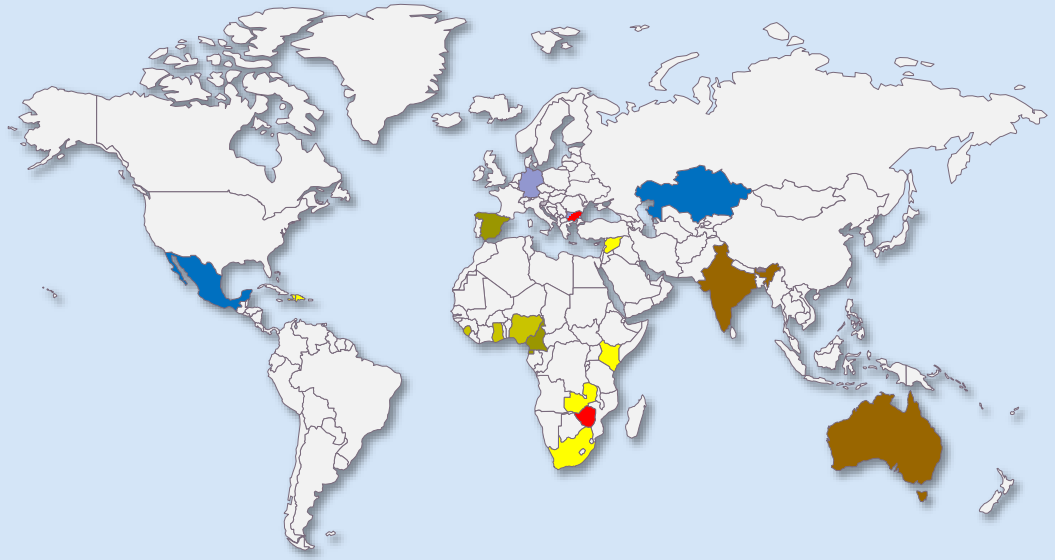
The COVID-19 pandemic has underscored the importance of strong national capacities for infectious disease surveillance, diagnosis, and response. International cooperation and assistance play a critical role in building these capacities. Our governments have partnered openly and transparently through the Biological Threat Reduction Program, which is a part of the U.S. Department of Defense Cooperative Threat Reduction Program. These partnerships are devoted exclusively to peaceful purposes; they have nothing to do with weapons. These partnerships protect the health of humans and animals in our countries, including in the prevention, detection, and control of infectious disease outbreaks, and in enhancing laboratory biosafety and biosecurity. As partners in this program, we each have firsthand knowledge of its relevance to our shared goal of cooperating to strengthen global health security and reduce the impacts of infectious diseases on our societies. Our governments strongly affirm the common view that such cooperation should not be undermined, but rather promoted and reinforced. Pursuant to Article X, we encourage all Biological Weapons Convention States Parties to work together, including at the forthcoming Review Conference, in support of this goal.

Ebola outbreak 2022



an Ebola disease outbreak in Africa in 2022 (Sudan ebolavirus)

Epidemic situation for extremely hazardous and dangerous human diseases (2022-2023)



Number of cases:

- **Marburg fever:** *Spain (1), Cameroon (2), Equatorial Guinea (25)*
- **Lassa fever:** *Ghana (14), Nigeria (116), Sierra Leone (15)*
- **Q fever:** *Bulgaria (7), Germany (2)*
- **Anthrax:** *Bulgaria (1), Zimbabwe (61)*
- **Brucellosis:** *Kazakhstan (283), Mexico (5)*
- **Japanese encephalitis:** *India (1,331), Australia (45)*
- **Cholera:** *Syria (84,607), Zambia (42), Kenya (16), South Africa (2), Haiti (28,901), Dominican Republic (47)*

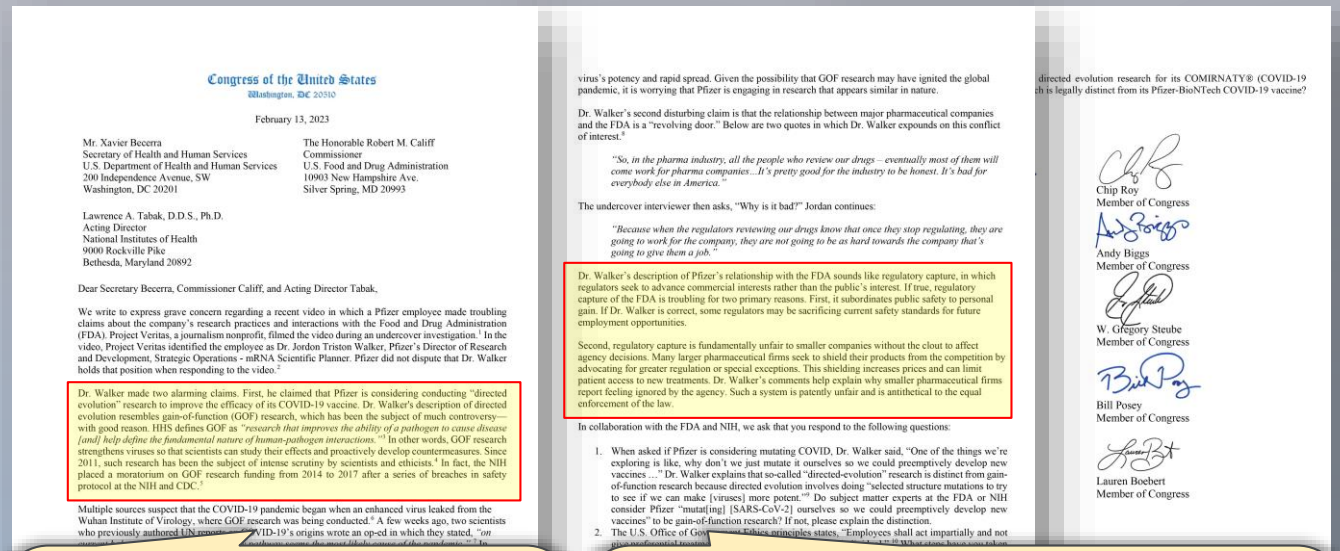
Epizootological situation for economically significant animal diseases (2023)

Number of foci:

- **African swine fever:** *Hungary (35), Germany (2), Greece (2), Italy (51), Latvia (35), Moldova (4), Poland (168), Russia (2), Romania (72), Serbia (15), S. Macedonia (1), Czech Republic (2), Bhutan (1), South Africa (4)*
- **Highly pathogenic avian influenza:** *Austria (48), Belgium (29), Germany (7), Hungary (7), Ireland (1), Italy (3), Luxembourg (1), Moldova (1), Netherlands (3), Poland (49), Romania (11), Russia (3), Serbia (1), Spain (1), UK (26), Slovakia (1), Slovenia (1), France (73), Czech Republic (13), Switzerland (2), Sweden (7), Israel (3), Japan (12), South Africa (1), Bolivia (2), Honduras (1), Canada (1), Costa Rica (1), Mexico (1), Panama (1), USA (14), Ecuador (7)*

Big Pharma's 'directed evolution' research

Request from the U.S. Senate regarding Pfizer's 'directed evolution' research



Congress of the United States
Washington, DC 20510

February 13, 2023

Mr. Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Lawrence A. Tabak, D.D.S., Ph.D.
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Secretary Becerra, Commissioner Califf, and Acting Director Tabak,

We write to express grave concern regarding a recent video in which a Pfizer employee made troubling claims about the company's research practices and interactions with the Food and Drug Administration (FDA). Project Veritas, a journalism nonprofit, filmed the video during an undercover investigation.[1] In the video, Project Veritas identified the employee as Dr. Jordon Triston Walker, Pfizer's Director of Research and Development, Strategic Operations - mRNA Scientific Planner. Pfizer did not dispute that Dr. Walker holds that position when responding to the video.[2]

Dr. Walker made two alarming claims. First, he claimed that Pfizer is considering conducting "directed evolution" research to improve the efficacy of its COVID-19 vaccine. Dr. Walker's description of directed evolution resembles gain-of-function (GOF) research, which has been the subject of much controversy—with good reason. HHS defines GOF as *"research that improves the ability of a pathogen to cause disease [and] help define the fundamental nature of human-pathogen interactions."*[3] In other words, GOF research strengthens viruses so that scientists can study their effects and proactively develop countermeasures. Since 2011, such research has been the subject of intense scrutiny by scientists and ethicists.[4] In fact, the NIH placed a moratorium on GOF research funding from 2014 to 2017 after a series of breaches in safety protocol at the NIH and CDC.[5]

Multiple sources suspect that the COVID-19 pandemic began when an enhanced virus leaked from the Wuhan Institute of Virology, where GOF research was being conducted.[6] A few weeks ago, two scientists who previously authored UN reports on COVID-19's origins wrote an op-ed in which they stated, *"on*

virus's potency and rapid spread. Given the possibility that GOF research may have ignited the global pandemic, it is worrying that Pfizer is engaging in research that appears similar in nature.

Dr. Walker's second disturbing claim is that the relationship between major pharmaceutical companies and the FDA is a "revolving door." Below are two quotes in which Dr. Walker expounds on this conflict of interest.[9]

"So, in the pharma industry, all the people who review our drugs – eventually most of them will come work for pharma companies…It's pretty good for the industry to be honest. It's bad for everybody else in America."

The undercover interviewer then asks, "Why is it bad?" Jordan continues:

"Because when the regulators reviewing our drugs know that once they stop regulating, they are going to work for the company, they are not going to be as hard towards the company that's going to give them a job."

Dr. Walker's description of Pfizer's relationship with the FDA sounds like regulatory capture, in which regulators seek to advance commercial interests rather than the public's interest. If true, regulatory capture of the FDA is troubling for two primary reasons. First, it subordinates public safety to personal gain. If Dr. Walker is correct, some regulators may be sacrificing current safety standards for future employment opportunities.

Second, regulatory capture is fundamentally unfair to smaller companies without the clout to affect agency decisions. Many larger pharmaceutical firms seek to shield their products from the competition by advocating for greater regulation or special exceptions. This shielding increases prices and can limit patient access to new treatments. Dr. Walker's comments help explain why smaller pharmaceutical firms report feeling ignored by the agency. Such a system is patently unfair and is antithetical to the equal enforcement of the law.

In collaboration with the FDA and NIH, we ask that you respond to the following questions:

1. When asked if Pfizer is considering mutating COVID, Dr. Walker said, "One of the things we're exploring is like, why don't we just mutate it ourselves so we could preemptively develop new vaccines …" Dr. Walker explains that so-called "directed-evolution" research is distinct from gain-of-function research because directed evolution involves doing "selected structure mutations to try to see if we can make [viruses] more potent."[10] Do subject matter experts at the FDA or NIH consider Pfizer "mutat[ing] [SARS-CoV-2] ourselves so we could preemptively develop new vaccines" to be gain-of-function research? If not, please explain the distinction.
2. The U.S. Office of Gov… Ethics principles states, "Employees shall act impartially and not

directed evolution research for its COMIRNATY® (COVID-19 …ch is legally distinct from its Pfizer-BioNTech COVID-19 vaccine?

Chip Roy
Member of Congress

Andy Biggs
Member of Congress

W. Gregory Steube
Member of Congress

Bill Posey
Member of Congress

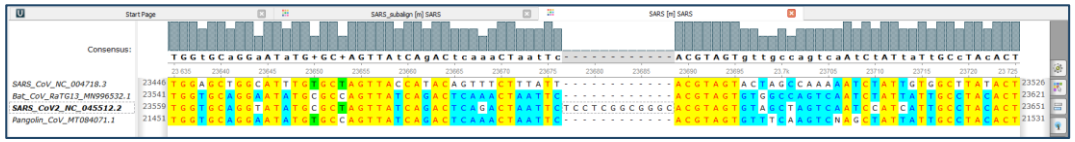
Lauren Boebert
Member of Congress

'…Pfizer is considering conducting "directed evolution" research to improve the efficacy of its COVID-19 vaccine… Dr. Walker's description of directed evolution resembles gain-of-function (GOF) research…'
'…In fact, the NIH placed a moratorium on GOF research funding from 2014-2017 after a series of breaches in safety protocol at the NIH and CDC'.

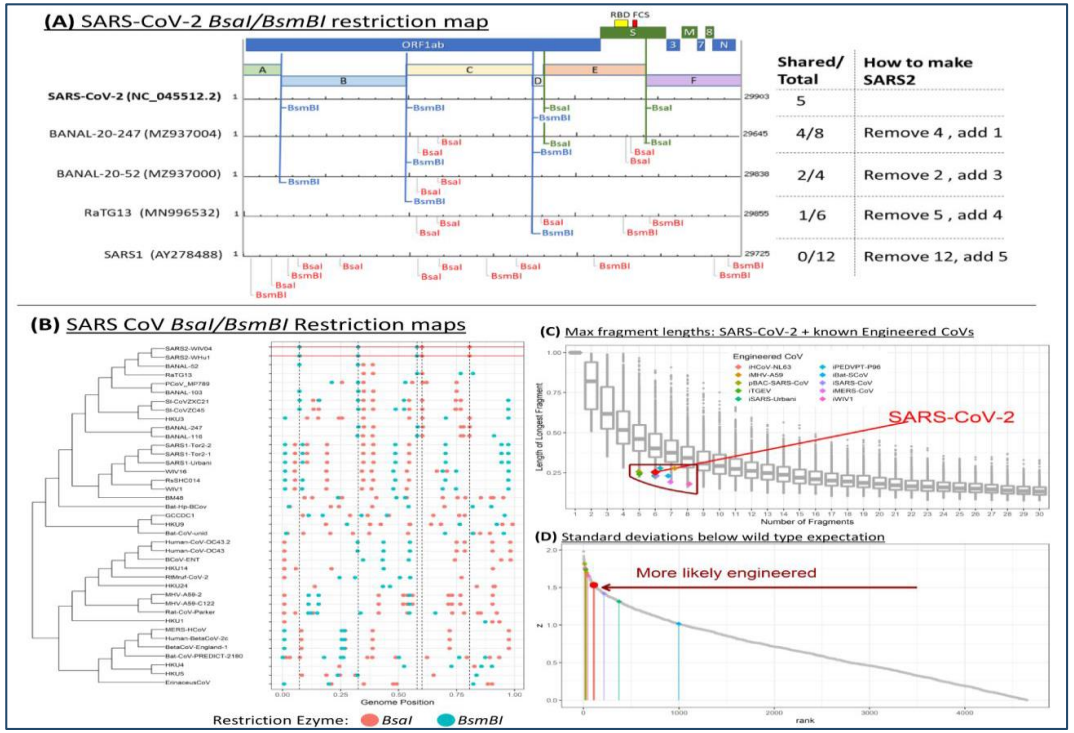
'…Dr. Walker's description of Pfizer's relationship with the FDA sounds like regulatory capture, in which regulators seek to advance commercial interests rather than the public's interest…'
'…First, it subordinates public safety to personal gain. If Dr. Walker is correct, some regulators may be sacrificing current safety standards for future employment opportunities.'
'Second, regulatory capture is fundamentally unfair to smaller companies without the clout to affect agency [FDA] decisions.'

Pfizer Executive: 'Mutate' COVID via 'Directed Evolution' for Company to Continue Profiting Off of Vaccines … 'COVID is Going to be a Cash Cow for Us' … 'That is Not What We Say to the Public' … 'People Won't Like That' … 'Don't Tell Anyone'

Modification of SARS-CoV-2 genome by synthetic biology methods



Results of mammalian coronaviruses' gene alignment (SARS-CoV, Bat-CoV, SARS-CoV-2, Pangolin-CoV)



Map of SARS-CoV-2 restriction sites
(*Bruttel M. Endonuclease fingerprint indicates a synthetic origin of SARS-CoV-2 / Bruttel M., Washburne A. // bioRxiv. – 2022. – P. 1-17*)

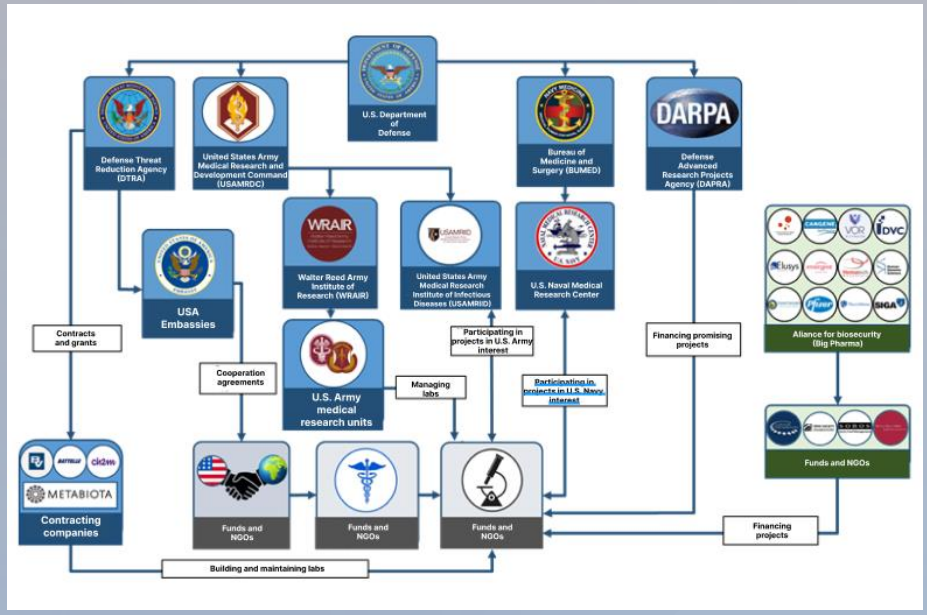
Several researchers believe that SARS-CoV-2 may be a product of directed evolution, as it has a set of unique restriction sites typical for synthetic viruses

US methods for developing global biosecurity regulations

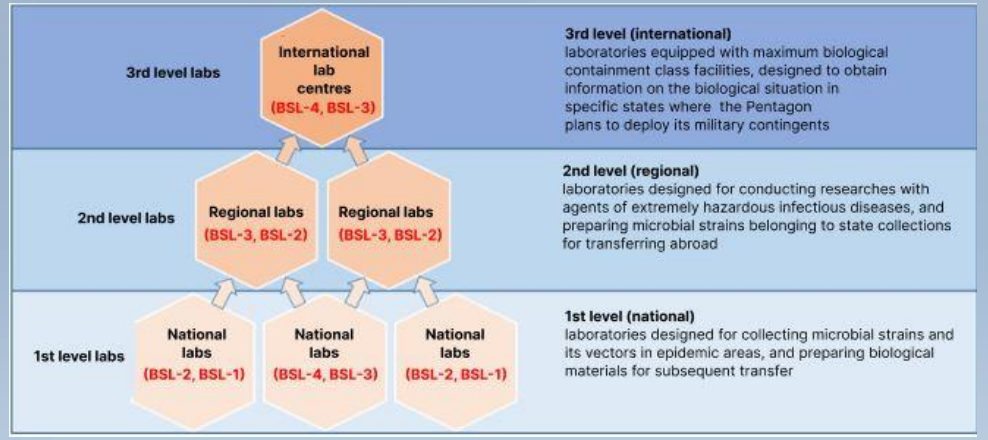
Objectives stated by U.S. biological programme
1. Monitoring of the biological situation
2. Assistance to developing countries
3. Development of means and methods of biological protection

Signs of the USA conducting research bypassing the obligations under the BTWC	
INDIRECT	DIRECT (IN VIOLATION OF THE BTWC)
1. Construction of military laboratories around the borders of geopolitical opponents	1. Violation of article IV of the BTWC
2. Collection of strains of particularly dangerous microorganisms endemic to certain territories	2. Failure to take the necessary measures at the national level to prohibit and prevent the development, production, accumulation, acquisition or preservation of biological weapons
3. Increasing the number of works on the artificial creation of dangerous microorganisms with specified properties	
4. Participation of the military department in the financing of research projects	3. Conclusion of agreements allowing the work to be carried out in violation of Article I of the BTWC
5. Increased funding of biological programs (including in the field of synthetic biology, paleogenomics, etc.)	4. Preservation of measures in national legislation that allow the development of biological weapons
6. Human testing of toxic drugs	5. Patenting of technical means of delivery and use of biological weapons
7. Collection of biological material of "mono-ethnoses"	

Global biothreat prevention, response, and neutralisation architecture for the USA



Division of US laboratories under construction and recomposed into levels of functionality



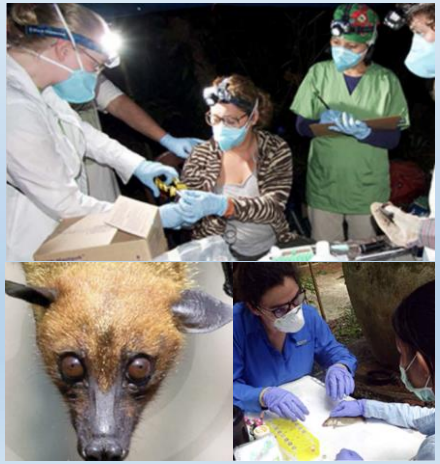
Failure of US regulatory authorities to enforce control over biological research

NIH National Institutes of Health

The National Institutes of Health is the U.S. Department of Health agency responsible for health and medical research. It consists of 27 institutes and research centres

EcoHealth Alliance

EcoHealth Alliance is an American non-governmental organisation dedicated to research aimed at preventing pandemics and promoting environmental conservation in hotspots around the world



US Department of Health Office of Inspector General Audit Report

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

THE NATIONAL INSTITUTES OF HEALTH AND ECOHEALTH ALLIANCE DID NOT EFFECTIVELY MONITOR AWARDS AND SUBAWARDS, RESULTING IN MISSED OPPORTUNITIES TO OVERSEE RESEARCH AND OTHER DEFICIENCIES

Inquiries about this report may be addressed to the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Christi A. Grimm
Inspector General

January 2023
A-05-21-00025

Report in Brief
Date: January 2023
Report No. A-05-21-00025

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Why OIG Did This Audit
OIG initiated this audit because of concerns regarding the National Institutes of Health's (NIH's) grant awards to EcoHealth Alliance (EcoHealth), NIH's monitoring of EcoHealth, and EcoHealth's use of grant funds, including its monitoring of subawards to a foreign entity.

Our objectives were to determine whether NIH monitored grants to EcoHealth in accordance with Federal requirements, and whether EcoHealth used and managed its NIH grant funds in accordance with Federal requirements.

How OIG Did This Audit
We obtained a list of all NIH awards to EcoHealth and all subawards made by EcoHealth during Federal fiscal years 2014 through 2021 (audit period). Our audit covered three NIH awards to EcoHealth totaling approximately $8.0 million, which included $1.8 million of EcoHealth's subawards to eight subrecipients, including the Wuhan Institute of Virology (WIV).

Our audit methodology was designed to address NIH and EcoHealth's policies, procedures, and internal controls in place to monitor, manage, and use grant funds. We selected and reviewed 150 EcoHealth transactions totaling $2,578,567 across the 3 NIH awards comprised of different types of cost categories for allowability.

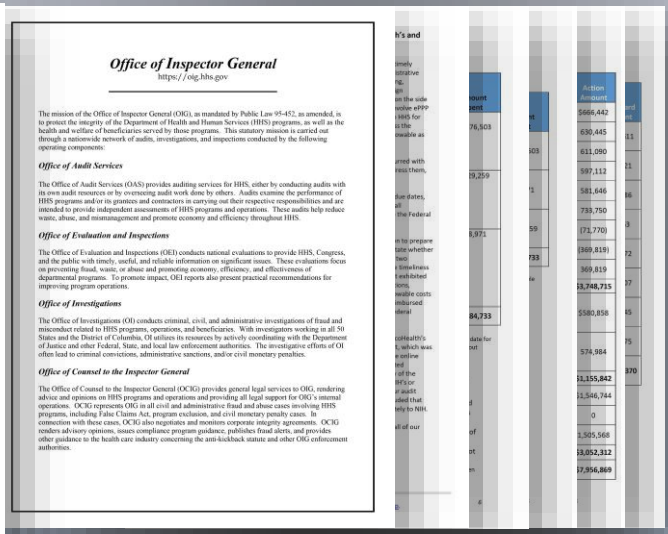
The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies

What OIG Found
Despite identifying potential risks associated with research being performed under the EcoHealth awards, we found that NIH did not effectively monitor or take timely action to address EcoHealth's compliance with some requirements. Although NIH and EcoHealth had established monitoring procedures, we found deficiencies in complying with those procedures limited NIH and EcoHealth's ability to effectively monitor Federal grant awards and subawards to understand the nature of the research conducted, identify potential problem areas, and take corrective action. Using its discretion, NIH did not refer the research to HHS for an outside review for enhanced potential pandemic pathogens (ePPPs) because it determined the research did not involve and was not reasonably anticipated to create, use, or transfer an ePPP. However, NIH added a special term and condition in EcoHealth's awards and provided limited guidance on how EcoHealth should comply with that requirement. We found that NIH was only able to conclude that research resulted in virus growth that met specified benchmarks based on a late progress report from EcoHealth that NIH failed to follow up on until nearly 2 years after its due date. Based on these findings, we conclude that NIH missed opportunities to more effectively monitor research. With improved oversight, NIH may have been able to take more timely corrective actions to mitigate the inherent risks associated with this type of research.

We identified several other deficiencies in the oversight of the awards. Some of these deficiencies include: NIH's improper termination of a grant; EcoHealth's inability to obtain scientific documentation from WIV; and EcoHealth's improper use of grant funds, resulting in $89,171 in unallowable costs.

OIG oversight work has continually demonstrated that grant-awarding agencies' oversight of subrecipients, whether domestic or foreign, is challenging. The shortcomings we identified related to NIH's oversight of EcoHealth demonstrate continued problems. Compounding these longstanding challenges are risks that may limit effective oversight of foreign subrecipients, which often depends on cooperation between the recipient and subrecipient, and the countries in which the research is performed. Although WIV cooperated with EcoHealth's monitoring for several years, WIV's lack of cooperation following the COVID-19 outbreak limited EcoHealth's ability to monitor its subrecipient. NIH should assess how it can best mitigate these issues and ensure that it can oversee the use of NIH funds by foreign recipients and subrecipients.

The full report can be found at https://oig.hhs.gov/oas/reports/region5/52100025.asp.



Office of Inspector General
https://oig.hhs.gov

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

Office of Evaluation and Inspections

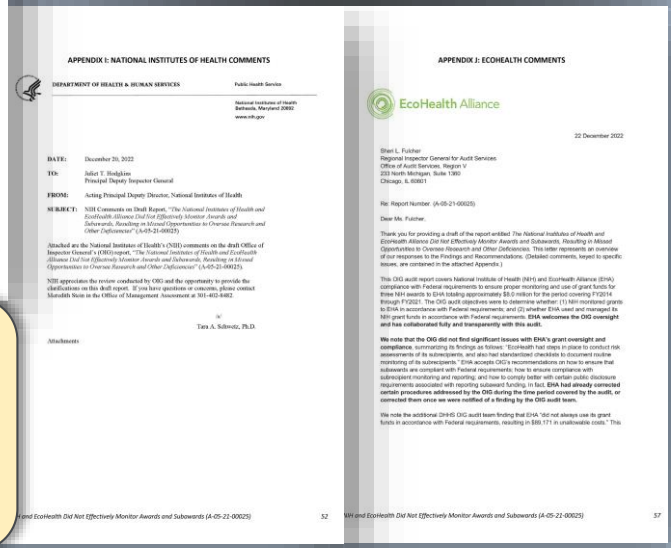
The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

Office of Investigations

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.



APPENDIX I: NATIONAL INSTITUTES OF HEALTH COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

DATE: December 20, 2022

TO: Juliet T. Hodgkins
Principal Deputy Inspector General

FROM: Acting Principal Deputy Director, National Institutes of Health

SUBJECT: NIH Comments on Draft Report, "*The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*" (A-05-21-00025)

Attached are the National Institutes of Health's (NIH) comments on the draft Office of Inspector General's (OIG) report, "*The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*" (A-05-21-00025).

NIH appreciates the review conducted by OIG and the opportunity to provide the clarifications on this draft report. If you have questions or concerns, please contact Meredith Stein in the Office of Management Assessment at 301-402-8482.

/s/
Tara A. Schwetz, Ph.D.

Attachments

APPENDIX J: ECOHEALTH COMMENTS

EcoHealth Alliance

22 December 2022

Sheri L. Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

Re: Report Number (A-05-21-00025)

Dear Ms. Fulcher,

Thank you for providing a draft of the report entitled *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*. This letter represents an overview of our responses to the Findings and Recommendations. (Detailed comments, keyed to specific issues, are contained in the attached Appendix.)

This OIG audit report covers National Institute of Health (NIH) and EcoHealth Alliance (EHA) compliance with Federal requirements to ensure proper monitoring and use of grant funds for three NIH awards to EHA totaling approximately $8.0 million for the period covering FY2014 through FY2021. The OIG audit objectives were to determine whether: (1) NIH monitored grants to EHA in accordance with Federal requirements; and (2) whether EHA used and managed its NIH grant funds in accordance with Federal requirements. **EHA welcomes the OIG oversight and has collaborated fully and transparently with this audit.**

We note that the **OIG did not find significant issues with EHA's grant oversight and compliance**, summarizing its findings as follows: "EcoHealth had steps in place to conduct risk assessments of its subrecipients, and also had standardized checklists to document routine monitoring of its subrecipients." EHA accepts OIG's recommendations on how to ensure that subawards are compliant with Federal requirements: how to ensure compliance with subrecipient monitoring and reporting; and how to comply better with certain public disclosure requirements associated with reporting subaward funding. In fact, **EHA had already corrected certain procedures addressed by the OIG during the time period covered by the audit, or corrected them once we were notified of a finding by the OIG audit team.**

We note the additional OHHS OIG audit team finding that EHA "did not always use its grant funds in accordance with Federal requirements, resulting in $89,171 in unallowable costs." This

US Department of Health Office of Inspector General Audit Report on the National Institutes of Health and EcoHealth Alliance (January 2023)

'...NIH did not effectively monitor or take timely action to address EcoHealth's compliance with some requirements. ...anticipated to create, use, or transfer an enhanced potential pandemic pathogens...'

Analysis of effectiveness of U.S. biosecurity interventions

National Science Advisory Board for Biosecurity (NSABB)

National Science Advisory Board for Biosecurity is a federal advisory committee that reviews biosecurity and dual-use research at the request of the US government

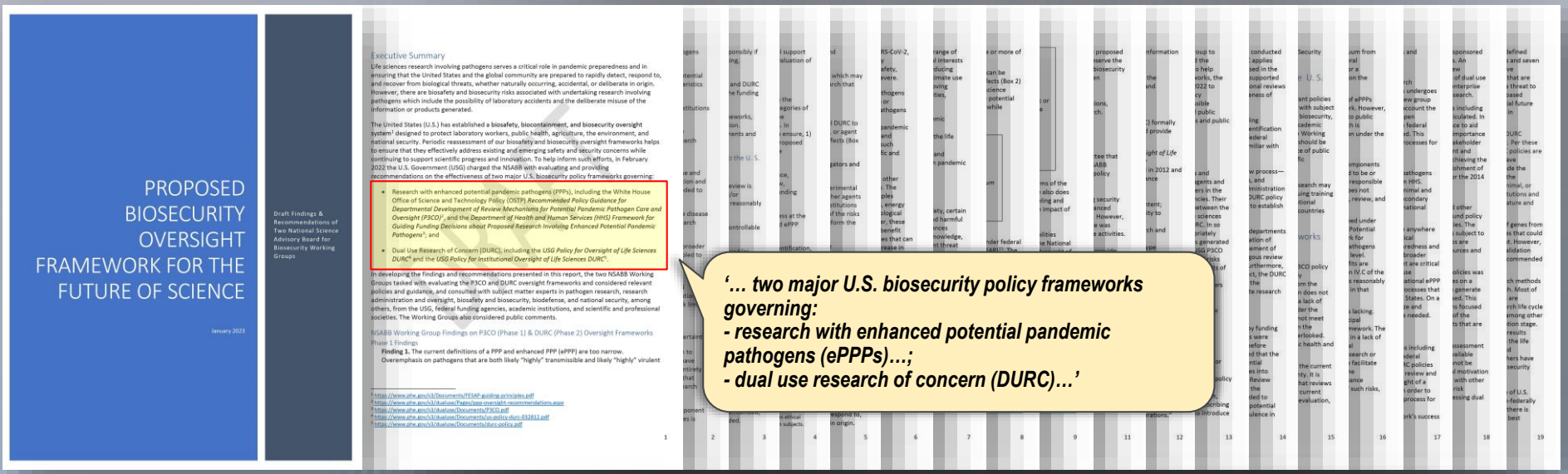
Gerald W. Parker

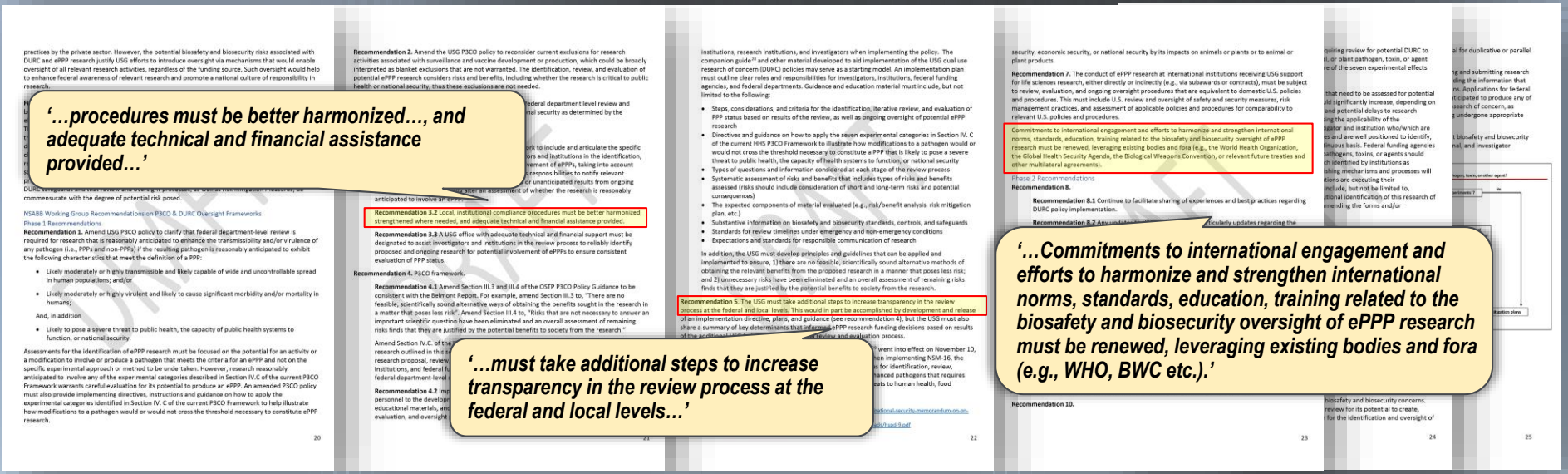
chairman, national scientific advisory board for biosecurity

Associate Dean of Global One Health in the College of Veterinary Medicine and Biomedical Sciences, Director of the Global One Health campus at Texas A&M University, Director of the Pandemic and Biodefense Policy Program at the Scowcroft Institute for International Affairs in the Bush School of Government and Public Service. He is a member of several advisory boards.

He has more than 26 years of service in leading military medical research programmes and organisations. He is a former commander of the US Army Medical Research Institute for Infectious Diseases. He has held senior positions in the Department of Homeland Security, the Department of Health and Human Services (HHS) and the Department of Defense (DOD), including first deputy assistant secretary of state for preparedness and response in HHS and deputy assistant secretary of defense for chemical and biological defense in DOD.

National Science Advisory Board for Biosecurity (27 January 2023)





International reaction to the revelation of U.S. bioweapons programmes

Makabayan Party Initiative to Investigate U.S. Activities in the Philippines

INQUIRER.NET

House urged to scrutinize US-funded lab project in PH

The Makabayan lawmakers also cited reports of other laboratories and research facilities in the Philippines funded by EcoHealth Alliance, a foreign nonprofit organization that received millions of dollars in grants from the US Agency for International Development (USAID).

There are three EcoHealth Alliance projects currently being undertaken in the Philippines, including the Predict project that aims to "identify new emerging infectious diseases that could become a threat to human health," and the Emerging Infectious Disease Repository (EIDR), which seeks to "unravel the origins of emerging infectious disease events."

"Even if the work of EcoHealth Alliance truly relates to pursuing global health, it is unmistakable that one of the overarching objectives of this USAID grant is to advance US foreign policy," they noted, adding that EcoHealth Alliance also got funding from the DTRA.

philstar GLOBAL

Investigate foreign-funded biolab – Makabayan

MANILA, Philippines — The House Makabayan bloc has expressed concerns over the reported construction of an animal disease diagnostic laboratory in Tarlac City with funding from the United States' Defense Threat Reduction Agency (US-DTRA).

In a joint resolution, Reps. France Castro of ACT Teachers, Arlene Brosas of Gabriela and Raoul Manuel of Kabataan asked House leaders to investigate foreign-funded bio-laboratory projects in the Philippines, including the US-DTRA.

The party-list lawmakers said the $643,000-facility was turned over to the Department of Agriculture in September 2020 to supposedly boost the country's biosecurity efforts against trans-boundary animal diseases.

BusinessWorld

Embassy says US-supported biolabs fully run by DA

THE UNITED States Embassy in Manila allayed concerns raised by opposition lawmakers on US-funded biolaboratories in the Philippines, saying the American government is only providing support to the agricultural department, which operates these facilities.

John Groch, acting spokesperson of the embassy, said the US government, through the United States Defense Threat Reduction Agency (DTRA), extended funding and technical training to the Department of Agriculture (DA).

"DTRA has built, equipped, and trained Philippine government personnel to run laboratories that detect, monitor, and prevent the spread of animal diseases, but the laboratories are run by the Department of Agriculture," he said in a Viber message late Tuesday.

MAKABAYANG KOALISYON NG MAMAMAYAN
MAKABAYAN

Makabayan Philippine party

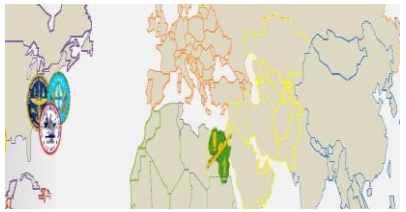
Naval Medical Research Unit Two (NAMRU-2)

NAMRU-2 is a U.S. Navy biomedical research laboratory officially established to study infectious diseases of potential military significance in Asia.

NAMRU-2 had its main laboratory and headquarters in Jakarta from 1991 to 2010, when the Indonesian government requested that it be closed.

A branch in Phnom Penh, Cambodia, was established in 2002 (operating as the main laboratory in the region since 2010).

A branch office in Singapore was established in 2007.



Naval Medical Research – Asia
Naval Medical Research Unit TWO

Host(s): Singapore: Ministry of Defense; Cambodia: Ministry of Health

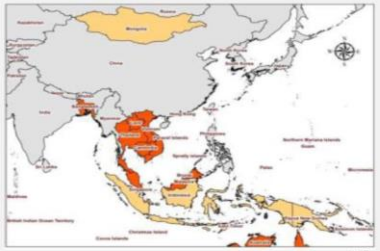
Research Expertise in

- Biosurveillance of infectious diseases
- Pathogen characterization/bioinformatics
- Drug resistant malaria therapeutics

Recent accomplishments

- Established Middle East Respiratory Syndrome-Corona Virus (MERS-CoV) surveillance in SE Asia
- Supports Global Health Security through laboratory upgrade with Cambodia Ministry of Health and Royal Cambodian Armed Forces
- Evaluation of vector control and abatement devices in Laos
- Conducts SMS-based disease surveillance in Cambodia to provide real-time disease trend data
- Conducting Therapeutic treatment efficacy studies to reduce malaria burden in SE Asia

NMRC-Asia HQ in Singapore. NAMRU-2's laboratory in Phnom Penh, Cambodia



18

NAMRU-2 is staffed by four members of the US Navy and more than 90 Cambodian scientists, doctors, technologists, and specialists.

NAMRU-2 collects and characterises more than 5,000 samples a year and quickly disseminates the information to partners in Cambodia and the U.S. government.

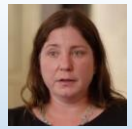
Completion of Lab training at NAMRU-2 for military personnel

U.S. military-biological research figures in Ukraine

Kenneth Myers
DTRA Director (2009–2016)

Robert Pope
DTRA Director (2017–2020)

Rhys M.Williams
DTRA Director (since 2020)



Joanna Wintrol
DTRA project lead

Steven L. Edwards
Black&Veatch CEO

Lance Lippencott
Black&Veatch program director

David Mustra
Black&Veatch manager

Nita Madhav
Metabiota CEO

Mary Guttieri
Metabiota Vice President

Scott Thornton
Metabiota Senior Microbiologist

Anna Gibson
Chief Scientific Officer (Metabiota)

Lewis Von Thaer
Battelle President, CEO

Jeffrey Wadsworth
Battelle former CEO

David Garcia
officer of Military Medical Center (Battelle)

Anthony McQueen
Commanding General, U.S. Army Medical Research and Development Command and Fort Detrick

Thomas R. Frieden
ex-Director of the Centers for Disease Control and Prevention (CDC)

Francis S. Collins
NIH ex-director

Karen Saylors
Labyrinth Global Health Inc. CEO and Co-Founder

Mikael Dolsten
Chief Scientific Officer and President, Worldwide Research, Development and Medical of Pfizer Inc

Colleen Jonsson
lead researcher at the University of Tennessee Science Centre

Tara O'Toole
In-Q-Tel Executive Vice President

Hunter Biden
headed Rosemont Seneca Technology Partners, a leading financial backer of Metabiota

Ashley Lucas
public health advisor at Loyal Source Government Services

Eric Bortz
virologist, Associate Professor, University of Alaska Anchorage

Riza Ikranbegiin
WHO Ukraine Laboratory Officer

Curtis Bjelajac
Executive Director at Science and Technology Center in Ukraine (since 2014)

Andrew Hood
Executive Director at Science and Technology Center in Ukraine (2004–2012)

Eddie Meyer
Board Chairman, European Union's Science and Technology Center in Ukraine

Natalie Pauwels
Board Member, European Union's Science and Technology Center in Ukraine

Sergey Morgun

Head of the Sanitary and Epidemiological Directorate of the AFU Medical Forces Command.

He organised interaction between the AFU and DTRA within the framework of military biological research. Personally supervised UP-8 project, coronavirus and other pathogens research.

Address of residence: [redacted] Borovikovsky Blvd., Kiev

Sergey Litovka

Head of the Central Sanitary and Epidemiological Department of the AFU.

He directly managed the UP-8 project, organized selection of servicemen for biomaterials, prepared reporting materials for DTRA, gave orders for access of U.S. biologists to the facilities of Ukrainian Ministry of Defense
Address of residence: [redacted] Sechevoy Lane, Dnepr.

Vladimir Kurpita

Head of the Public Health Centre of the Ministry of Health of Ukraine.

He provided general supervision and guidance over the interaction between Ukrainian specialists and DTRA. He participated in project No. 68727 EN 02761868.

He also supervised export of 1,000 blood serum samples from different regions of Ukraine.
Address of residence: apt. [redacted] [redacted] Simirenka Str., Kiev

Irina Demchishina

Head of the virology reference laboratory of the Public Health Centre of the Ministry of Health of Ukraine.

Maintained personal contacts with representatives of Black&Veatch, Metabiota, CH2M Hill, STCU. She personally organised transfer of biomaterials abroad, supervised implementation of UP and TAP series projects. Address of residence: apt. [redacted], [redacted] Antonovycha Str., Kiev

Denis Muzyka

Deputy Director for International Cooperation at the Institute of Experimental and Clinical Veterinary Medicine (IECVM) and Head of the Laboratory of Viral Diseases of Poultry at IECVM.
Performed the bulk of research in the UP-4 project, participated in the P-160 project.
Address of residence: apt. [redacted] Yerevanskaya Str., Kiev

Larisa Pekarskaya

Black&Veatch Finance and Tax Manager.

She worked in international technical assistance management in Ukraine (DTRA, USAID, Millennium Challenge Corporation), dealt with financing of DTRA projects in Ukraine, as well as Black&Veatch related paperwork.

Address of residence: apt. [redacted] [redacted] Kikvidze Str. Kiev; apt. [redacted], [redacted], Balzaka Str., Kiev

Natalia Mikhailovskaya

Manager at Metabiota for research projects and programme implementation in the former Soviet Union, consultant at Labyrinth Global Health, Inc. Assisted in the implementation of the DTRA bioprogramme "Threat Reduction Networks Support" TD-04-03-01. Collaborated with D. Muzyka on implementation of UP-4, UP-9, UP-10 projects and preparation of final reports.
Address of residence: apt. [redacted] [redacted] Yerevanskaya Str., Kiev

Igor Lozinsky

Head of the Laboratory of Natural Focal Infections of the LNMU Research Institute of Epidemiology and Hygiene. He supervised the process of modernisation of the laboratory for military biology research, supervised the work on the UP-8 project. As part of the project, he was the leading specialist in biomaterial analysis and participated in data analysis.
Address of residence: [redacted] Progulochna Street, Lviv

U.S. attempts to continue research at biological laboratories in Ukraine

Kirby's statement on ending US biolaboratories in Ukraine

31 января, 22:49, обновлено 31 января, 23:05

В Белом доме считают необоснованными заявления РФ о работе биолабораторий США на Украине

ТАСС

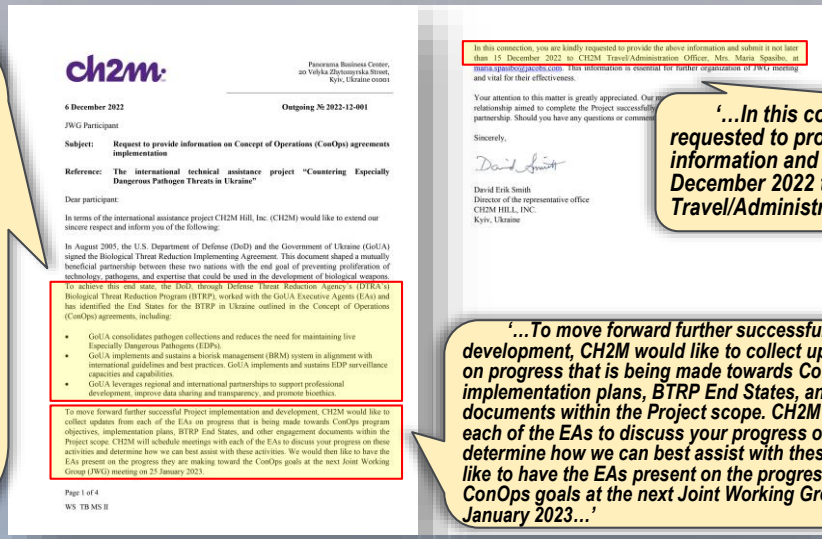
Координатор по стратегическим коммуникациям в СНБ Белого дома Джон Кирби признал, что США действительно "проводили с украинцами некоторые исследования по предотвращению пандемии", но добавил, что все эти исследовательские центры были "покинуты и безопасно деактивированы" до начала СВО

'...abandoned and safely deactivated'

Request from CH2M Hill, Inc. for information on the implementation of the concept of action agreement (ConOps) (6 December 2022)

'...To achieve this end state, the DoD, through Defense Threat Reduction Agency's (DTRA's) Biological Threat Reduction Program (BTRP), worked with the GoUA Executive Agents (EAs) and has identified the End States for the BTRP in Ukraine outlined in the Concept of Operations (ConOps) agreements, including:

- *GoUA consolidates pathogen collections and reduces the need for maintaining live Especially Dangerous Pathogens (EDPs).*
- *GoUA implements and sustains a biorisk management (BRM) system in alignment with international guidelines and best practices. GoUA implements and sustains EDP surveillance capacities and capabilities.*
- *GoUA leverages regional and international partnerships to support professional development, improve data sharing and transparency, and promote bioethics.'*



ch2m:

Panorama Business Center,
20 Velyka Zhytomyrska Street,
Kyiv, Ukraine 01001

6 December 2022 — Outgoing № 2022-12-001

JWG Participant

Subject: Request to provide information on Concept of Operations (ConOps) agreements implementation

Reference: The international technical assistance project "Countering Especially Dangerous Pathogen Threats in Ukraine"

Dear participant.

In terms of the international assistance project CH2M Hill, Inc. (CH2M) would like to extend our sincere respect and inform you of the following:

In August 2005, the U.S. Department of Defense (DoD) and the Government of Ukraine (GoUA) signed the Biological Threat Reduction Implementing Agreement. This document shaped a mutually beneficial partnership between these two nations with the end goal of preventing proliferation of technology, pathogens, and expertise that could be used in the development of biological weapons.

To achieve this end state, the DoD, through Defense Threat Reduction Agency's (DTRA's) Biological Threat Reduction Program (BTRP), worked with the GoUA Executive Agents (EAs) and has identified the End States for the BTRP in Ukraine outlined in the Concept of Operations (ConOps) agreements, including:

- GoUA consolidates pathogen collections and reduces the need for maintaining live Especially Dangerous Pathogens (EDPs).
- GoUA implements and sustains a biorisk management (BRM) system in alignment with international guidelines and best practices. GoUA implements and sustains EDP surveillance capacities and capabilities.
- GoUA leverages regional and international partnerships to support professional development, improve data sharing and transparency, and promote bioethics.

To move forward further successful Project implementation and development, CH2M would like to collect updates from each of the EAs on progress that is being made towards ConOps program objectives, implementation plans, BTRP End States, and other engagement documents within the Project scope. CH2M will schedule meetings with each of the EAs to discuss your progress on these activities and determine how we can best assist with these activities. We would then like to have the EAs present on the progress they are making toward the ConOps goals at the next Joint Working Group (JWG) meeting on 25 January 2023.

Page 1 of 4

WS TB MS II

In this connection, you are kindly requested to provide the above information and submit it not later than 15 December 2022 to CH2M Travel/Administration Officer, Mrs. Maria Sasubo, at maria.rpashkov@accdm.com. This information is essential for further organization of JWG meeting and vital for their effectiveness.

Your attention to this matter is greatly appreciated. Our p... relationship aimed to complete the Project successfully... partnership. Should you have any questions or comment...

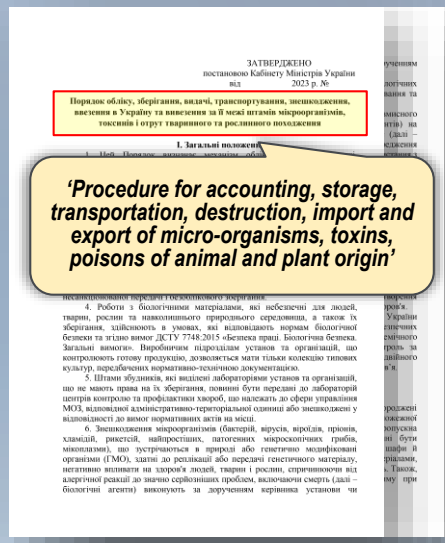
Sincerely,

David Erik Smith
Director of the representative office
CH2M HILL, INC.
Kyiv, Ukraine

'...In this connection, you are kindly requested to provide the above information and submit it not later than 15 December 2022 to CH2M Travel/Administration Officer...'

'...To move forward further successful Project implementation and development, CH2M would like to collect updates from each of the EAs on progress that is being made towards ConOps program objectives, implementation plans, BTRP End States, and other engagement documents within the Project scope. CH2M will schedule meetings with each of the EAs to discuss your progress on these activities and determine how we can best assist with these activities. We would then like to have the EAs present on the progress they are making toward the ConOps goals at the next Joint Working Group (JWG) meeting on 25 January 2023...'

Ukrainian state document on the procedure for accounting, storage, transportation, destruction, import, and export of pathogenic biological agents

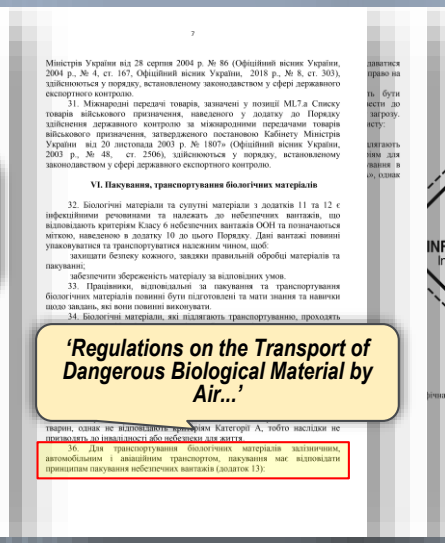


ЗАТВЕРДЖЕНО
постановою Кабінету Міністрів України
від 2023 р. №

Порядок обліку, зберігання, видачі, транспортування, знешкодження, ввезення в Україну та вивезення за її межі штамів мікроорганізмів, токсинів і отрут тваринного та рослинного походження

I. Загальні положення

'Procedure for accounting, storage, transportation, destruction, import and export of micro-organisms, toxins, poisons of animal and plant origin'



Міністрів України від 28 серпня 2004 р. № 86 (Офіційний вісник України, 2004 р., № 4, ст. 167, Офіційний вісник України, 2018 р., № 8, ст. 303), здійснюються у порядку, встановленому законодавством у сфері державного експортного контролю.

31. Міжнародні передачі товарів, зазначені у позиції ML7.a Списку товарів військового призначення, наведеного у додатку до Порядку здійснення державного контролю за міжнародними передачами товарів військового призначення, затвердженого постановою Кабінету Міністрів України від 20 листопада 2003 р. № 1807» (Офіційний вісник України, 2003 р., № 48, ст. 2506), здійснюються у порядку, встановленому законодавством у сфері державного експортного контролю.

VI. Пакування, транспортування біологічних матеріалів

32. Біологічні матеріали та сумутні матеріали з додатків 11 та 12 є інфекційними речовинами та належать до небезпечних вантажів, що відповідають критеріям Класу 6 небезпечних вантажів ООН та позначаються міткою, наведеною в додатку 10 до цього Порядку. Дані вантажі повинні упаковуватися та транспортуватися належним чином, щоб:

захищати безпеку кожного, завдяки правильній обробці матеріалів та пакуванні;

забезпечити збереженість матеріалу за відповідних умов.

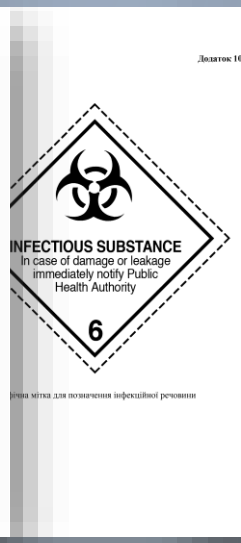
33. Працівники, відповідальні за пакування та транспортування біологічних матеріалів повинні бути підготовлені та мати знання та навички щодо завдань, які вони повинні виконувати.

34. Біологічні матеріали, які підлягають транспортуванню, проходять

тварин, однак не відповідають критеріям Категорії А, тобто наслідки не призводять до інвалідності або небезпеки для життя.

36. Для транспортування біологічних матеріалів залізничним, автомобільним і авіаційним транспортом, пакування має відповідати принципам пакування небезпечних вантажів (додаток 13).

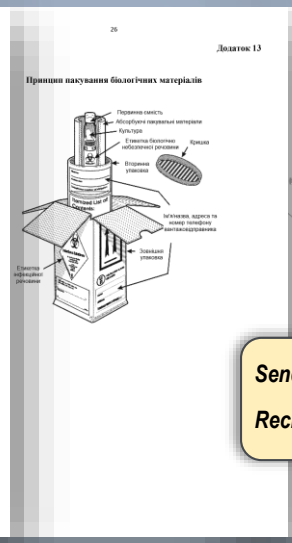
'Regulations on the Transport of Dangerous Biological Material by Air...'



Додаток 10

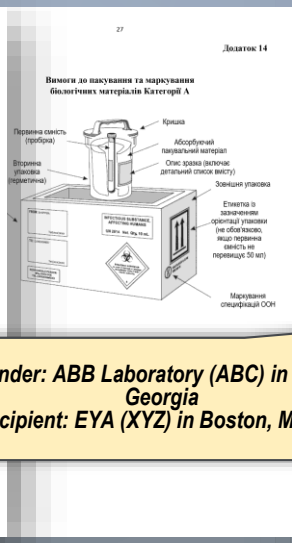
INFECTIOUS SUBSTANCE
In case of damage or leakage immediately notify Public Health Authority

6



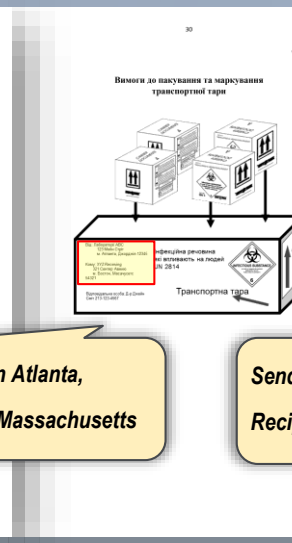
Додаток 13

Принципи пакування біологічних матеріалів



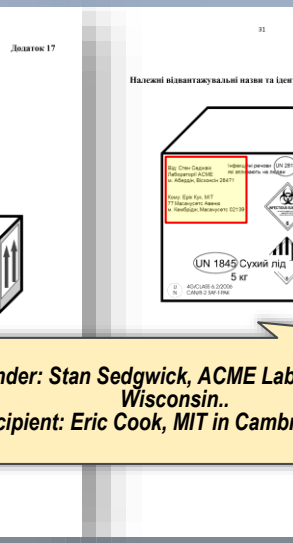
Додаток 14

Вимоги до пакування та маркування біологічних матеріалів Категорії А



Додаток 17

Вимоги до пакування та маркування транспортної тари



Додаток 18

Належні відвантажувальні назви та ідентифікаційні номери ООН

UN 1845 Сухий лід
5 кг

Додаток 20

Sender: ABB Laboratory (ABC) in Atlanta, Georgia
Recipient: EYA (XYZ) in Boston, Massachusetts

Sender: Stan Sedgwick, ACME Laboratory in Aberdeen, Wisconsin..
Recipient: Eric Cook, MIT in Cambridge, Massachusetts