

WOAH Collaborative Centre Reports Activities 2023

Activities in 2023

This report has been submitted : 25 juin 2024 18:02

Centre Information

Title of WOA Collaborating Centre	Vaccine Evaluation in the Americas
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Name Director of Institute (Responsible Official):	James A. Roth: Matthew M Erdman
Name (including Title and Position) of Head of the Collaborating Centre (WOAH Contact Point):	James A. Roth, Executive Director: Matthew M Erdman, Science Advisor
Name of the writer:	Jane Galyon: Elizabeth Latcham

TOR1 AND 2: SERVICES PROVIDED

1. Activities as a centre of research, expertise, standardisation and dissemination of techniques within the remit of the mandate given by WOA

Category	Title of activity	Scope
Disease control (true)	Preparedness Resources	Deliver a variety of foreign animal disease preparedness resources at: www.cfsph.iastate.edu/emergency-response Deliver infection control resources at: www.cfsph.iastate.edu/infection-control
Training, capacity building (true)	Transboundary and Emerging Disease of Animals online course	Online course used by all US veterinary schools to provide training on transboundary animal diseases and required for initial accreditation training in the U.S.
Diagnosis, biotechnology and laboratory (true)	Inspection and Compliance activities for international veterinary biologics manufacturers.	Various products were imported from a total of nine countries (France, New Zealand, Canada, Argentina, Spain, Israel, United Kingdom, The Republic of South Korea, and Serbia) and were evaluated for market release within the United States for a total of 287 lots for over 500 million doses.
Vaccines (true)	Veterinary Biologics Training Program	Annual 5-day in person training program in partnership with the USDA APHIS Center for Veterinary Biologics on the USDA regulatory process for assuring the purity, safety, potency, and efficacy of veterinary biologics

<p>Training and Capacity Building (true)</p>	<p>Fact Sheets for transboundary animal diseases</p>	<p>Technical Fact Sheets 148 English fact sheets, downloaded 421,089 times in 2023; 138 Spanish fact sheets downloaded 539,479 times in 2023; 44 Portuguese fact sheets downloaded 61,691 times in 2023; and 11 French fact sheets downloaded 3,831 times in 2023 One Page Fact Sheets for the Public 88 English: Downloaded 158,411 times in 2023 67 Spanish: Downloaded 101,347 times in 2023 Annotated Images of Animal Diseases 410 annotated images: 59,214 views (English) and 14,698 views (Spanish) in 2023</p>
<p>Disease Control (true)</p>	<p>Secure Food Supply Plans</p>	<p>Work with federal, state, and industry officials on plans to avoid interruptions in animal product/animal movement to commercial processing from farms with no evidence of infection during a foreign animal disease outbreak. www.cfsph.iastate.edu/secure-food-supply/</p>
<p>Disease Control (true)</p>	<p>Certified Swine Sample Collection Program</p>	<p>Worked with partners at the National Pork Board, Iowa State University and USDA to develop a program for Category II accredited veterinarians to train producers, caretakers and industry partners how to properly collect samples from swine for diagnostic and surveillance purposes. A standardized curriculum is used to ensure all sample collectors are consistently trained and certified. During an outbreak, state animal health officials will determine when collectors will be authorized to collect samples and provide guidance on testing protocols. This program increases the number of individual qualified to collect samples. Resources also translated into Spanish with funding from the National Pork Board. https://www.securepork.org/training-materials/disease-monitoring-sample/</p>
<p>Disease Control (true)</p>	<p>ASF Eradication planning</p>	<p>With funding from the National Pork Board, developed a white paper titled "Factors to Consider in a Potential Eradication Plan for African Swine Fever in the U.S. This 62 page paper covers background information on ASF, characteristics of the swine industry and feral swine in the U.S., current eradication and mitigation efforts. Factors to consider in designing an eradication plan are also presented, along with a plan to designate the ASF status of production sites and states, and approaches to regaining pork exports during an ASF eradication program. https://www.cfsph.iastate.edu/pdf/asf-eradication-plan-white-paper</p>
<p>Disease Control (true)</p>	<p>Framework for Interstate movement</p>	<p>The Framework for Interstate and Intrastate Movement Decisions During a Foot and Mouth Disease Outbreak in the U.S. is the result of a two-year effort to build consensus and develop criteria for making animal movement decisions in the event of a Foot and Mouth Disease outbreak in the U.S. The document focuses on interstate and intrastate movement decisions by State Animal Health Officials; however, the recommendations may also be useful for movement decisions by producers and packers. https://www.cfsph.iastate.edu/emergency-response/fmd-framework-for-interstate-movement/</p>
<p>Vaccines (true)</p>	<p>Veterinary Immunology and Vaccinology online courses</p>	<p>Online courses providing an overview of veterinary immunology and vaccinology</p>

Vaccines (true)	Approvals	The Center for Veterinary Biologics (CVB) approved the conditional use of licensed, inactivated, H5 highly pathogenic avian influenza (HPAI) vaccine for use in the highly endangered species of California condors.
Vaccines (true)	Consult and testing	Provided consultation Kazakh Committee for Veterinary Control and Supervision on anthrax vaccine issues. Provided product testing support.

TOR3: HARMONISATION OF STANDARDS

2. Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the main focus area for which you were designated

Proposal title	Scope/Content	Applicable area
Secure Food Supply Plans	Discussions on avoiding interruptions in animal product/animal movement to commercial processing from farms with no evidence of infection during a foreign animal disease outbreak. Presentations at state and national meetings. These plans cover pork, beef, milk, poultry and sheep and wool	health management
Framework for Interstate Movement	Movement decisions in an FMD outbreak	health management
ASF Eradication	Considerations for developing an ASF eradication plan	health management
Certified Swine Sample Collector Program	Training individuals to collect samples during a foreign animal disease emergency	health management
Veterinary Biologics Training Program	Training on the US process for regulating veterinary biologics and diagnostics	Veterinary products
Veterinary Immunology and Vaccinology online courses	Online courses on veterinary immunology and vaccination	Training and education
Harmonization of Title 9 Code of Federal Regulations (9CFR) and Good Manufacturing Practices (GMP)	Working to demonstrate the 9 CFR regulations for U.S. Veterinary Biologics have the same results as Good Manufacturing Practices (GMP) regulations utilized by many foreign trading partners by addressing "quality" in U.S. regulations. This will make it easier for trading partners to find specific GMP requirements to help facilitate the export of biologics.	Veterinary products

3. In exercising your activities, have you identified any regulatory research needs* relevant for WOA?H?

Yes

Research need : 1

Please type the Research need: Validation of milk bulk tank PCR and virus isolation tests to detect HPAI virus in dairy cows

Relevance for WOAH Disease Control,

Relevance for the Codes or Manual

Field Diagnostics,

Animal Category Terrestrial,

Disease:

Avian influenza

Kind of disease (Zoonosis, Transboundary diseases) Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer:

Research need : 2

Please type the Research need: Validation of virus PCR and antibody tests of oral fluids in swine for diagnosis of ASF and FMD.

Relevance for WOAH Disease Control,

Relevance for the Codes or Manual Manual,

Field Diagnostics,

Animal Category Terrestrial,

Disease:

African swine fever

Kind of disease (Zoonosis, Transboundary diseases) Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer: For both African Swine Fever and Foot and Mouth Disease

Research need : 3

Please type the Research need: Validation of water trough samples from cattle, sheep, and goats using FMD PCR for diagnosis.

Relevance for WOAH Disease Control,

Relevance for the Codes or Manual Manual,

Field Diagnostics,

Animal Category Terrestrial,

Disease:

Foot and mouth disease

Kind of disease (Zoonosis, Transboundary diseases) Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer:

Research need : 4

Please type the Research need: Validation of point of care diagnostics using antibody to detect ASF and FMD viral antigens, similar to the COVID rapid tests

Relevance for WOAH Disease Control,

Relevance for the Codes or Manual Manual,

Field Diagnostics,

Animal Category Terrestrial,

Disease:

African swine fever

Kind of disease (Zoonosis, Transboundary diseases) Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer:

Notes:

Answer: African Swine Fever and Foot and Mouth Disease

4. Did your Collaborating Centre maintain a network with other WOAHO Collaborating Centres (CC), Reference Laboratories (RL), or organisations designated for the same specialty, to coordinate scientific and technical studies?

Yes

Name of WOAHO CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Vaccine Evaluation in the Americas, USDA APHIS CVB	Ames, Iowa	Americas	Worked together as a joint OIE Collaborating Center. Activities included the Veterinary Biologics Training Program and collaborating on answering questions related to vaccination.
International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Outreach Forum	Washington D.C., U.S.	Americas Asia and Pasific Europe	VICH Outreach Forum is a VICH initiative with the main objective of providing a basis for wider international harmonization of technical requirements, improve information exchange and raise awareness of VICH and VICH guidelines with non-VICH countries/regions. The Outreach Forum is composed of countries and regional organizations that have expressed an interest in the work of VICH and are motivated to participate in the activities of the VICH Outreach Forum. Currently approximately 14 countries and 4 regional organizations are participating (or have been invited).
American Committee for Veterinary Medicines (CAMEVET)	Uruguay	Africa Americas Asia and Pasific Europe MiddleEast	The representatives from various regulatory agencies and the industry groups engaged in discussions to evaluate the possibilities of harmonizing biologics policies and test methods.
Council on Biologic and Therapeutic Agents (COBTA)	Illinois, U.S.	Americas	The Council on Biologic and Therapeutic Agents (COBTA): advised the American Veterinary Medical Association Board of Directors in promoting interest in the

			efficacy and proper use of veterinary biologic and therapeutic units.
National Cattleman's Beef Association (NCBA)	Virtual	Americas	CVB representative provided a virtual webinar presentation entitled: "New Vaccine Technologies Webinar: CVB Safety Evaluations of New Vaccines", to the National Cattlemen's Beef Association. A question and answer session followed the webinar
2023 Northeastern U.S. Animal Health Association Annual Meeting	Virtual	Americas	The CVB provided a virtual presentation entitled, "Vaccines for emerging animal diseases Regulatory Tools for Approval of Veterinary Biologics" to the attendees at the 2023 Northeastern U.S. Animal Health Association Annual Meeting
Regulatory Education for Industry (REdI)	Virtual	Americas	The Regulatory Education for Industry (REdI) Program is an FDAled forum that brings together the regulatory educators from the FDA's medical product centers: Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER). There is no cost to register or attend the conference. Their goal is to provide information on the key aspects of drug, device, and biologics regulations.
Research Corporation and Science Advancement (Scialog)	Arizona, U.S.	Americas	This is an interdisciplinary science conference with senior and young scientists from around the USA and Canada which addresses and proposes research ideas to mitigate zoonotic threats.

TOR4 AND 5: NETWORKING AND COLLABORATION

5. Did your Collaborating Centre maintain a network with other WOHAI Collaborating Centres, Reference laboratories, or organisations in other disciplines, to coordinate scientific and technical studies?

Yes

Name of WOHAI CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Animal Disease Surveillance Systems, Risk Analysis and Epidemiological Modeling	Ft. Collins, CO, USA	Americas	Secure Food Supply projects: Business continuity

Collaborating Center			
Biological Threat Reduction	College Station, TX, USA	Americas	Point of Care diagnostics project

TOR6: EXPERT CONSULTANTS

6. Did your Collaborating Centre place expert consultants at the disposal of WOAAH?

Yes

NAME OF EXPERT	KIND OF CONSULTANCY	SUBJECT
James Roth	Advising	
Drs. Matthew Erdman, David White, Connie Shmellik-Sandage, Bruce Carter, Amy Gill, Albert Van Geelan, Chris Tong, Garret Smith, Amy Lock, Matthew Sylte,	Chapter revisions and reviews.	

TOR7: SCIENTIFIC AND TECHNICAL TRAINING

7. Did your Collaborating Centre provide advice/services to requests from Members in your main focus area?

Yes

TEDA

Transboundary and Emerging Diseases of Animals

During calendar year 2023, 4,787 veterinary students used the course along with 652 graduate veterinarians for a total of 5,439 individuals. Not offered for RACE CE credit in 2023.

Website:

Technical Fact Sheets: 148 English fact sheets, downloaded 421,089 times in 2023; 138 Spanish fact sheets downloaded 539,479 times; 44 Portuguese fact sheets downloaded 61,691 times and 11 French fact sheets downloaded 3,831 times.

One Page Fact Sheets for the Public: 88 English fact sheets, downloaded 158,411 times in 2023; 67 Spanish fact sheets downloaded 101,347 times

Annotated disease images: 410 images, 59,214 views (English) and 14,698 (Spanish) in 2023

Secure Food Supply Websites

Page Views

Unique Visitors:

Secure Beef (<https://www.securebeef.org>) 34,697 4,452

Secure Milk (<https://www.securemilksupply.org>) 19,977 3,130

Secure Sheep & Wool (<https://www.securesheepwool.org>) 4,669 1,844

Secure Pork (<https://www.securepork.org>) 43,188 6,542

Poultry biosecurity (<https://poultrybiosecurity.org>) 33,127 8,828

Veterinary Biologics Training Program: 25 international participants, 117 U.S. participants in 2023

Certified Swine Sample Collection Program: 15 states implemented the program and over 400 individuals have been trained. Almost 13,000 page views with 7,252 unique users; Spanish resources: 2088 views and 1063 unique users.

Veterinary Immunology and Vaccination Courses: 45 participants

8. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by WOAAH, to personnel from WOAAH Members?

Yes

a) Technical visit : 0

b) Seminars : 187

c) Hands-on training courses: 400

d) Internships (>1 month) : 0

TYPE OF TECHNICAL TRAINING PROVIDED (A, B, C OR D)	CONTENT	COUNTRY OF ORIGIN OF THE EXPERT(S) PROVIDED WITH TRAINING	NO. PARTICIPANTS FROM THE CORRESPONDING COUNTRY
		Argentina, Brazil, Canada, Egypt, France,	

B	Veterinary Biologics Training Program	Germany, Great Britain, Japan, South Korea, Pakistan, Switzerland, USA, Zambia	142
B	Veterinary Immunology and Vaccination Courses	Canada, Botswana, Costa Rica, Germany, Japan, Mexico, New Zealand, USA, Zimbabwe	45
B	Certified Swine Sample Collection Program	USA	400
C	CVB representatives offered a week of training to a member of the Federal Laboratory for Agriculture Defense in Brazil (in Portuguese: Laboratório Federal de Defesa Agropecuária em Minas Gerais (LFDA-MG).	Brazil	1

TOR8: SCIENTIFIC MEETINGS

9. Did your Collaborating Centre organise or participate in the organisation of scientific meetings related to your main focus area on behalf of WOAHA?

Yes

NATIONAL/INTERNATIONAL	TITLE OF EVENT	CO-ORGANISER	DATE (MM/YY)	LOCATION	NO. PARTICIPANTS
International	FMD Tabletop Exercise	Not applicable	2023-08-29	Manhattan, KS, USA	49

TOR9: DATA AND INFORMATION DISSEMINATION

10. Publication and dissemination of any information within the remit of the mandate given by WOAHA that may be useful to Members of WOAHA

a) Articles published in peer-reviewed journals:

0

b) International conferences:

5

- WOAHA Global Emergency Management meeting- Capacity Building workshop, April 4, 2023 Paris, France. "What does the emergency veterinary workforce need to be effective and efficient?" (M Lee and C Eia)
- American Feed Industry Association (AFIA), June 28, 2023, Vietnam. "Biosecurity Best Practices on the Farm." (M Lee) Virtual presentation.
- World Vaccine Congress, Washington DC, April 5, 2023. "The need for vaccines against transboundary diseases of livestock for pandemic preparedness and food security" (Roth)
- TAFS FMD Conference May 31, 2023, Seoul, South Korea. "Towards a Paradigm Shift on the FMD-Free with Vaccination Status." (Roth)
- Shanghai 2023 Symposium on Veterinary Science and Public Health. Sept 20 – 23, 2023, Sept 20 – 23, 2023. "Low Probability, High Consequence Zoonotic Diseases of Swine." (Roth) Virtual Keynote presentation.

c) National conferences:

11

FMD Framework Tabletop Exercise

Held August 30-31 in Manhattan, KS. Participants worked through a series of animal movement scenarios involving different species and types of movements at different points in time during an FMD outbreak: 73 hours, five weeks, and eight months after the initial detection.

Webinars

- African Swine Fever Eradication Plan Working Group. "Factors to Consider in Designing an African Swine Fever (ASF) Eradication Program." February 14, 2023 (Roth)
- Swine Health Improvement Program General Conference Committee Officers. March 2, 2023. "Factors to Consider in Designing an African Swine Fever (ASF) Eradication Program." (Roth)
- National Association of State Animal Health Officials African Swine Fever Working Group, March 3, 2023. "Factors to Consider in Designing an African Swine Fever (ASF) Eradication Program." (Roth)
- National Pork Board Foreign Animal Disease Research Task Force. March 23, 2023 "Factors to Consider in Designing an African Swine Fever (ASF) Eradication Program." (Roth)
- FMD Framework Working Group. "Framework for Interstate Movement Decisions During an FMD Outbreak in the U.S." March 24, 2023, (Roth)
- United States Animal Health Association Committee on Animal Emergency Management. "Factors to Consider in Designing an African Swine Fever (ASF) Eradication Program." March 30, 2023 (Roth)

- *National Association of State Animal Agriculture Emergency Programs. "Foot and Mouth Disease (FMD) Framework for Animal Movements During an FMD Outbreak" June 21, 2023 (Roth)*

Virtual Workshops on the FMD Framework for Interstate Movement Decisions During an FMD Outbreak in the U.S.

- *Workshop 1 – FMD checked designation, Rapid Surveillance, and training accredited veterinarians on these concepts (FMD Framework Sections 1 & 2 and App D) – June 20*

<https://vimeo.com/840633857/e5e6df6645?share=copy> 36 min

- *Workshop 2 – Vaccination and Animal Identification/Herd Designations (FMD Framework Appendices A, B & C) – June 26*

<https://vimeo.com/840627895/9d0b67f394?share=copy> 41 min

- *Workshop 3 – State Status Designations (Framework Document Section 3) – June 28*

<https://vimeo.com/840642058/686e0e1c45?share=copy> 36 min

d) Other (Provide website address or link to appropriate information):

9

Factors to Consider in a Potential Eradication Plan for African Swine Fever in the United States: A White Paper, January 20, 2023 <https://www.cfsph.iastate.edu/pdf/asf-eradication-plan-white-paper>

Framework for Interstate and Intrastate Movement Decisions During a Foot and Mouth Disease Outbreak in the United States, March 1, 2024

<https://www.cfsph.iastate.edu/pdf-library/FMD-Resources/fmd-framework-for-movement.pdf>

www.cfsph.iastate.edu

www.cfsph.iastate.edu/iicab

<https://www.cfsph.iastate.edu/IICAB/vbtp/>

www.cfsph.iastate.edu/teda-course/

<https://www.cfsph.iastate.edu/diseaseinfo/>

<https://www.cfsph.iastate.edu/secure-food-supply/>

<https://www.securepork.org/training-materials/disease-monitoring-sample/>

11. What have you done in the past year to advance your area of focus, e.g. updated technology?

The CFSPH moved our software that was running on old on-site web server technology to current technologies in the Azure cloud computing platform

12. Additional comments regarding your report: