

# WOAH Collaborative Centre Reports Activities 2022

## Activities in 2022

This report has been submitted : 14 février 2023 18:24

### Centre Information

<b>Title of WOAHCollaborating Centre</b>	Vaccine Evaluation in the Americas
<b>Address of WOAHCollaborating Centre</b>	USDA, Center for Veterinary Biologics 1920 Dayton Avenue P.O. Box 844 Ames, Iowa 50010 UNITED STATES OF AMERICA
<b>Tel.:</b>	15153376100
<b>E-mail address:</b>	matthew.m.erdman@usda.gov
<b>Website:</b>	<a href="https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics">https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/veterinary-biologics</a>
<b>Name Director of Institute (Responsible Official):</b>	Dr. Matthew M. Erdman
<b>Name (including Title and Position) of Head of the Collaborating Centre (WOAH Contact Point):</b>	Dr. Matthew M. Erdman, Science Advisor, APHIS, Diagnostics & Biologics
<b>Name of the writer:</b>	Ms. Elizabeth A. Latcham, Staff Assistant

### 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 WOAHC

Diagnosis, biotechnology, and laboratory

Title of activity	Scope
<p>Inspection and Compliance activities for international veterinary biologics manufacturers.</p>	<p>Various products were imported from a total of 10 countries (France, New Zealand, Canada, Argentina, Spain, Israel, United Kingdom, The Republic of South Korea, Serbia and Germany) and were evaluated for market release within the United States for a total of 259 lots for over 400 million doses</p>
Vaccines	
Title of activity	Scope
<p>The Center for Veterinary Biologics (CVB) approved a two-year conditional license for Paenibacillus Larvae Bacterin for use in honeybees against American Foulbrood.</p>	<p>The Center for Veterinary Biologics (CVB) approved a two-year conditional license to Diamond Animal Health (the collaborating manufacturer for the developer Dalan Animal Health, Inc.) on December 29, 2022 to produce and distribute Paenibacillus Larvae Bacterin. This is the first conditional license provided by the CVB for use in honeybees against American Foulbrood. The data required to support a conditional license include: 1. The firm must demonstrate that there is an urgent need in the field for such a product. 2. The product has a "reasonable expectation" of efficacy as defined by the agency. 3. The product must meet the same requirements for safety and purity as do fully licensed products. 4. Testing is performed by the firm to ensure batching consistency.</p>

## 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
<p>Harmonization of Title 9 Code of Federal Regulations (9CFR) and Good Manufacturing Practices (GMP)</p>	<p>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.</p>	<p>Veterinary products</p>

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

Yes

Name of OIE CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose

<p>International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Outreach Forum</p>	<p>Washington D.C.</p>	<p>Americas Asia and Pasific Europe</p>	<p>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).</p>
<p>Meeting with the Agricultural Compounds and Veterinary Medicines (ACVM) personnel of the New Zealand Food Safety Authority (NZFSA)</p>	<p>Virtual</p>	<p>Asia and Pasific</p>	<p>Meeting to discuss regulatory structures, information gathering, and international harmonization efforts.</p>
<p>International Association of Biological Standards</p>	<p>Virtual</p>	<p>Africa Americas Asia and Pasific Europe MiddleEast</p>	<p>Meeting with International Association of Biological Standards along with other subject matter experts on high path avian influenza.</p>
<p>American Committee for Veterinary Medicines (CAMEVET)</p>	<p>Virtual</p>	<p>Africa Americas Asia and Pasific Europe MiddleEast</p>	<p>This particular meeting was regarding labelling of veterinary biologics. labelling of veterinary products. CAMEVET is a regional project which aims to facilitate the harmonization of standards, records, and control of veterinary medicines among member countries.</p>
<p>American Association of Swine</p>			<p>The mission of this committee is to review and study the issues and science surrounding the threats to</p>

Veterinarians (AASV) Committee on Influenza	Virtual	Americas	swine and human health by influenza. The committee will assist the Board in the development of policies, position statements and educational resources.
Allen D. Lemman Swine Conference	St. Paul, MN	Americas Europe	Provided a presentation on swine influenza and vaccine options. This conference is an annual educational event bringing swine veterinarians and other professionals working in swine production and animal health management from over 20 countries.
2022 BSL4ZNet International Conference: SARS-CoV-2: Then and Now	Virtual	Americas Europe	Provided an overview of the Center for Veterinary Biologics licensure pathways and flexibilities; and he described the timeline and process for approving the use of a SARS-CoV-2 vaccine for mink in the United States.

## TOR4 AND 5: NETWORKING AND COLLABORATION

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

Yes

Name of OIE CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
African Swine Fever Tabletop Exercise organized by the Iowa Department of Agriculture		Americas	Participated in an African Swine Fever Tabletop Exercise, organized by the Iowa Department of Agriculture and Land Stewardship and the Iowa State Center for Food Security and Public Health. The exercise is meant to be an opportunity for industry stakeholders, regulatory veterinarians, and Emergency Response Officials to discuss several "what-if" scenarios

<p>and Land Stewardship and the Iowa State Center for Food Security and Public Health.</p>	<p>Ames, IA</p>	<p>related to an ASF outbreak in the United States and how the various group would best interact The exercise is meant to be an opportunity for industry stakeholders, regulatory veterinarians, and Emergency Response Officials to discuss several “what-if” scenarios related to an ASF outbreak in the United States and how the various group would best interact.</p>
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## TOR6: EXPERT CONSULTANTS

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

Yes

NAME OF EXPERT	KIND OF CONSULTANCY	SUBJECT
<p>Dr. Melisse Schilling</p>	<p>Reviewed the following Chapters: Aquatic Manual Chapter 2.2.1 Acute Hepatopancreatic Necrosis Disease; Aquatic Manual Chapter 2.2.3 Infection With Hepatobacter Penaei; Aquatic Manual Chapter 2.2.4 Infection With Infectious Hypodermal; Aquatic Manual Chapter 2.3.1 Infection With Aphanomyces Invadans; Aquatic Manual Chapter 2.3.2 Infection With Epizootic Haematopoietic Necrosis Virus; Aquatic Manual Chapter 2.3.7 Infection With Red Sea Bream Iridovirus; Aquatic Code Articles 8.X.3 For Amphibian Disease Specific Chapters; Aquatic Code Chapter 9.3 Infection With Hepatobacter Penaei; Aquatic Code Chapter 9.4 Infection With Infectious Hypodermal and Haematopoietic Necrosis Virus; Aquatic Code Articles 11.X.3 For Mollusc Disease Specific Chapters; Work Plan for the Aquatic Animals Commission</p>	<p>OIE Manual of Standards for Diagnostic Tests and Vaccines</p>
<p>Dr. Connie Schmellik-Sandage</p>	<p>Reviewed and provided comments to chapter on Merek’s Disease</p>	<p>OIE Manual of Standards for Diagnostic Tests and Vaccines</p>
<p>Dr. Amy Gill</p>	<p>Reviewed Chapter 12.7 Infection with Equine Piroplasmosis and Chapter 12.6 Infection with Equine Influenza Virus</p>	<p>OIE Manual of Standards for Diagnostic Tests and Vaccines</p>
	<p>Reviewed Chapter 11.4 Bovine Spongiform</p>	

Dr. Bruce Thomsen	Encephalopathy and Chapter 1.8 Application for Official Recognition by the OIE Risk Status for Bovine Spongiform Encephalopathy	OIE Manual of Standards for Diagnostic Tests and Vaccines
Dr. David White	Reviewed Chapter 6.10 Responsible and Prudent US of Antimicrobial Agents in Veterinary Medicine	WOAH Terrestrial Animal Health Standards
Dr. Pamela Erdman	Reviewed Chapter 1.1.8 Principals of Veterinary Vaccine Production; Chapter 2.3.4 Minimum Requirements for the Production and Quality Control of Vaccines; Chapter 3.1.6 Echinococcosis; Chapter 3.2.1 Acarapisosis Honey Bees; Chapter 3.8.13 Theileriosis in Sheep and Goats; Chapter 3.10.2 Cryptosporidiosis; Chapter 3.10.6 Mange, Glossary	WOAH Terrestrial Animal Health Standards
Dr. Jay Srinivas	Reviewed Chapter 3.1.4 Brucellosis	WOAH Terrestrial Animal Health Standards
Dr. Matthew Erdman	Reviewed Chapter 3.1.8 Foot and mouth disease; Chapter 3.1.14 Nipah and Hendra virus diseases; Chapter 3.9.3 Classical swine fever	WOAH Terrestrial Animal Health Standards
Dr. Matthew Sylte	Reviewed Chapter 3 1 22 Tularemia; Chapter 3.3.9 Fowl cholera	WOAH Terrestrial Animal Health Standards
Dr. Bruce Thomsen	Reviewed Chapter 3.1.X Mammalian tuberculosis; Chapter 3. 8. 11 Scrapie	WOAH Terrestrial Animal Health Standards
Dr. Connie Schmellik-Sandage	Reviewed Chapter 3.3.15 Turkey Rhinotracheitis; Chapter 3.10. 7 Salmonellosis	WOAH Terrestrial Animal Health Standards
Dr. Amy Gill	Reviewed Chapter 3.6.2 Contagious equine metritis	WOAH Terrestrial Animal Health Standards
Dr. Albert Van Geelen	Reviewed Chapter 3.10.1 Bunyaviral diseases of animals	WOAH Terrestrial Animal Health Standards
	Reviewed Chapter 1.1.8 Principles of Veterinary Vaccine Production; Chapter 2.3.4 Minimum	

Ms. Renee Schnurr	requirements for the production and quality control of vaccines; Chapter 3 1.4 Brucellosis; Chapter 3.1.6 Echinococcosis; Chapter 3.1.8 Foot and mouth disease; Chapter 3.1.14 Nipah and Hendra virus diseases; Chapter 3. 1. 22 Tularemia; Chapter 3.1.X Mammalian tuberculosis; Chapter 3.2.1 Acarapisosis of honey bees; Chapter 3.3.9 Fowl cholera; Chapter 3.3.15 Turkey Rhinotracheitis; Chapter 3.6.2 Contagious equine metritis; Chapter 3.8.11 Scrapie; Chapter 3.8.13 Theileriosis in sheep and goats; Chapter 3.9.3 Classical swine fever; Chapter 3.10.1 Bunyaviral diseases of animals; Chapter 3.10.2 Cryptosporidiosis; Chapter 3.10. 6 Mange; Chapter 3 10 7 Salmonellosis; Glossary	WOAH Terrestrial Animal Health Standards
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## TOR7: SCIENTIFIC AND TECHNICAL TRAINING

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

No

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

Yes

a) Technical visit :

b) Seminars :

c) Hands-on training courses:

d) Internships (>1 month) :

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
b,c	Institute for International Cooperation in Animal Biologics (IICAB), World Organization for Animal Health (OIE), Veterinary Biologics Training Program: This program gives participants an overview of the scientific principles of vaccines, vaccination, and the USDA regulatory process for assuring the purity, safety, potency, and efficacy of veterinary biologics. The Iowa State University College of Medicine sponsors this event with the CVB providing the presentations and a workshop. The program is made available to both domestic and international attendees, and is	Argentina 4 Belgium 1 Brazil 2 Canada 2 Malaysia 1 Pakistan 1 Saudi Arabia 1 Singapore 3 & The Republic of South Korea 4 United States 141 These numbers do not reflect how many people attended virtual sessions.	160

	publicized through Iowa State University, the USDA, and the OIE.		
b	A CVB Staff Member provided two virtual presentations on 3R implementation and global harmonization in veterinary vaccine batch-release testing at a webinar hosted by Animal-Free Safety Assessment/Health for Animals/International Alliance for Biological Standardization.	Americias, Asia and Pacific and Europe	
d	2022 BSL4ZNet International Conference: SARS-CoV-2: Then and Now. Overview of the CVB licensure pathways and flexibilities; and he described the timeline and process for approving the use of a SARS-CoV-2 vaccine for mink in the United States.	Americias and Europe	100

## **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 WOA?H?

No

## **TOR9: DATA AND INFORMATION DISSEMINATION**

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

a) Articles published in peer-reviewed journals:

b) International conferences:

c) National conferences:

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

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

12. Additional comments regarding your report: