



**INSTITUTE FOR
INFECTIOUS ANIMAL DISEASES**

A Department of Homeland Security Science & Technology Center of Excellence

***Protecting the U.S. Cattle Herd:
A Workshop Towards Improving Knowledge
of Transboundary and Emerging Priority
Cattle Diseases***

2017 Workshop Report

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Protecting the U.S. Cattle Herd – A Workshop Towards Improving Knowledge of Transboundary and Emerging Priority Cattle Diseases

Executive Summary

This report describes the discussions, key findings and recommendations that arose during a workshop held March 13-15, 2017 in Washington, District of Columbia, *Protecting the U.S. Cattle Herd – A Workshop Towards Improving Knowledge of Transboundary and Emerging Priority Cattle Diseases*. Endemic, foreign animal diseases (FAD), emerging and re-emerging diseases are a priority for both the beef and dairy sectors. Understanding how these diseases move, and education of veterinarians and producers on morbidity, mortality, and diagnosis continue to be critical for prevention, early detection, reduction of disease spread and response. This also highlighted the concern regarding the current shortage of large animal veterinarians.

A major theme of the workshop was that the U.S. needs transition from historical disease-based programs towards the ability to share information pertinent for syndromic and disease surveillance. Breaking down information siloes and integrating data necessary to understand the event and mount more rapid response, control and/or eradication efforts were seen by the participants as being crucial for success. Success or failure of biosurveillance, prevention, preparedness and response depends not only on data, but also on collaboration between industry, industry groups, and state and federal government. Industry depends on the government to know what issues the U.S. is facing. These issues need to be prioritized, ranked economically, and then funds need to be directed to where they are most needed. Funding is always an issue, whether for research, assays that enable surveillance of populations, vaccine development, or for an appropriately funded vaccine bank. An essential concern of industry was that efforts must not hinder business operations or negatively impact the speed of commerce.

Funding for this workshop was provided by the United States (U.S.) Department of Homeland Security Science and Technology Directorate, Homeland Security Advanced Research Projects Agency, Chemical and Biological Defense Division, Agricultural Defense Branch (DHS S&T HSARPA CBD) and DHS Office of University Programs (OUP) under the Institute for Infectious Animal Diseases (IIAD) project, *Coordinate and Enhance the AgroSecurity Enterprise*. Participants/speakers included representatives from the U.S. beef and dairy cattle industries (producers and veterinarians), Canadian beef industry, State Animal Health Officials (SAHOs), U.S. and Canadian academia, U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Veterinary Services (VS), Canadian Food Inspection Agency (CFIA), USDA Agriculture Research Service (ARS), U.S. DHS Customs and Border Protection (CBP), DHS S&T, DHS OUP, a speaker from United Fresh Produce Association (UFPA), and an international keynote speaker (full list of participants in Appendix A).

Workshop Goal

Improve collective knowledge of risks and identify gaps/barriers towards enhancing risk-based prevention/preparedness/response to transboundary and emerging priority diseases affecting the U.S. cattle industry.

Objectives

The objectives of this workshop were the following:

- 1) Improve the collective knowledge of the risk for emerging and re-emerging priority cattle diseases that enables improved U.S. risk-based analysis for prevention and preparedness.***
- 2) Identify needs, gaps, and barriers to improving early warning and detection of transboundary and emerging diseases of cattle in U.S. and North America.***
- 3) Initiate groundwork discussions towards defining appropriate, effective and risk-based priority disease surveillance needs for protecting the U.S. cattle industry.***

These objectives were accomplished and participants concluded that discussions on the issues identified during the workshop should continue. A list of priority FADs and emerging/re-emerging diseases were formulated and participants also agreed that the priority list was not exhaustive, nor static and could be further refined in the future based on new information or changing global disease dynamics. There was consensus on a large number of knowledge, information and technical gaps to improving early warning and detection of transboundary and emerging diseases of cattle in the U.S. Prioritized gaps fell into six different categories, including those impacting national security, diagnostics, policy, standards, new technology and knowledge issue areas. An identified opportunity was to consider how to create an industry focused group with an interest in coordinated global disease monitoring, analysis of health data, and targeted research investments designed to minimize the impact of disease threats (i.e., a cattle version of the swine industry's Swine Health Information Center). Both the priority list of diseases and identified gaps can be found below under Session 1 Breakout Group Discussion section of this report. Additionally, participants responding to the post workshop survey results provided their priorities for addressing three top gaps specific to the U.S. surveillance system for early warning and detection of these diseases (see post survey Question 7 results/analysis in Annex J).

Meeting Overview

The workshop's structure, topics, speakers and breakout questions were developed in collaboration with representatives from the National Cattlemen's Beef Association (NCBA), National Milk Producers Federation (NMPF), the American Association of Bovine Practitioners (AABP), and input from both APHIS Cattle Health Center (CHC) and the Center for Epidemiology and Animal Health (CEAH) personnel. This was the first meeting of this type which combined both beef and dairy sectors focusing on transboundary and emerging priority cattle diseases. Pre- and post-workshop surveys (hardcopy and electronic versions) were made available to all participants (See Appendix E and F, respectively and Appendix G for survey results). An opening reception kicked off the workshop with an international expert keynote

speaker who set the stage for the workshop, which was organized into presentations, panels, plenary discussions and breakout group discussions. Presentations included historical lessons learned, current perspectives and future opportunities, which were intended to provide background and substance for the breakout sessions. Speakers from the Canadian government, beef cattle industry and academia were invited to provide insight from Canada's advanced efforts on several of the workshop topics. Additionally, the U.S. and Canada agriculture, beef and dairy sectors share an integrated market, with private sector agribusinesses frequently maintaining operations in both countries and two-way movement of animals and animal input/output products. The U.S. and Canadian Governments have been bi-laterally engaged on animal health and other topics via the Regulatory Cooperation Council¹, tri-laterally with Mexico and multi-laterally through the "Quads" group of the U.S., Canada, Australia, and New Zealand.

Structurally the workshop was divided into five sessions and 2 breakout discussions:

Session 1: What are we doing? What do we know (and don't know)?

Breakout Group 1 Discussion:

- a) Formulating the list- What priority foreign animal, emerging or re-emerging cattle diseases should the U.S. address, worry about, plan for?
- b) Improving the knowledge and process for transparent risk-based decisions and prevention of transboundary and emerging priority cattle diseases – What are the gaps? What does the U.S. government need?

Session 2: Lessons Learned and Impact/Real Life and Other Factors

Breakout Group 2 Discussion: Biosecurity – Knowledge, Perceptions and Opportunities

Session 3: What do we have and why/What do we need and why?

Session 4: Food for Thought

A Plenary group discussion on surveillance followed Sessions 3 and 4.

Session 5: The Future and Next Steps

A plenary group recap of main workshop themes and priority recommendations for future direction.

Plenary discussions reconciled breakout group lists and the complete agenda can be found in Appendix B.

Background

Various U.S. Federal and State Government, trade association, academic and private sector meetings, workshops, conferences and other endeavors have contributed to extensive planning and preparedness for foot-and-mouth disease (FMD) in the U.S. and most, if not all, of the workshop participants have taken part in state or regional FMD workshops or the development of the Secure Milk or Secure Beef Supply Plans. While this workshop included FMD, there are

¹ <http://www.inspection.gc.ca/about-the-cfia/transforming-the-cfia/regulatory-modernization/regulatory-cooperation-council/animal-health-work-plan-2016/eng/1477315469797/1477315470157>

many other foreign animal (transboundary) and emerging diseases circulating globally that are a threat to U.S. agriculture. Re-emerging diseases such as the recent incursions of New World Screwworm in Florida and the expanding threat of cattle fever tick in the southern U.S. remind us that continuing to be vigilant in surveillance, biosecurity and rapid response – as well as supporting research and discovery investments and maintaining robust international collaborations – all contribute to protecting our nations’ animal and human health.

This workshop’s discussions focused on improving the collective knowledge of risks and identifying gaps and barriers towards enhancing risk-based prevention, preparedness and response to these priority diseases affecting the U.S. cattle industry.

The U.S. government has systems in place to help prevent, detect and respond to these diseases – and private veterinarians, producers, and state and federal animal health officials play important roles in these systems. Transition of DHS- and USDA-funded research activities is critically important for increasing the industry’s preparedness for a high-consequence disease event. Interagency coordination between those who sponsor research and development activities that support the nation’s agricultural infrastructure and the users of those tools, technologies and products is critical to ensuring effective transfer of research knowledge to field use to help support risk identification, diagnostic discovery and surveillance. Identifying current and future directions for these activities over the course of this workshop will help collectively identify 1) what the U.S. government and industry need to be looking for, 2) what programs are needed to find it, 3) what tools are needed to do so effectively and 4) what corresponding infrastructure, resources or policy development is required to enable success.

In today’s world – where daily international movement of humans, animals and animal products are the norm – global spread of disease is inevitable. With USDA programs for tuberculosis and brucellosis being updated this workshop was an opportunity to explore the merits or challenges of more integrated approaches. What new tools and research are needed? How does the U.S. government and industry ensure enabling policies keep abreast with technology advancements? With ever-decreasing state and federal agricultural budgets, how does the U.S. government maintain appropriate infrastructure, prioritize needs and ensure continued protection of the U.S. cattle herd, the rural community, states and the U.S. economy?

The dairy and beef sectors are vital contributors to the nation’s economy and the U.S. is a leader in providing safe, abundant, wholesome, nutritious and affordable beef and dairy products for the global community. According to the USDA National Agricultural Statistics Service, the economic impact of the U.S. beef and dairy industries in 2015 were \$76.641 billion and \$35.7 billion in farm gates receipts, respectively². Canada is a North American partner in disease prevention, control and response, one of the U.S.’s top export markets for beef and dairy, and a

²https://www.nass.usda.gov/Publications/Ag_Statistics/2015/Ag_Stats_2015_complete%20publication.pdf

primary trading partner. The private beef and dairy sectors from both countries work together on issues of common interest and integrated businesses span geopolitical borders. Likewise, the Federal governments of both countries work together via formal mechanisms on issues such as regulatory cooperation, animal health and food safety international standards, and trade. Therefore, this workshop included Canadian colleagues to share experiences and lessons learned.

Each sector represented by participants has a role in protecting our vibrant dairy and beef cattle industries and contributing to animal health, food safety and food security in the U.S. and abroad. Each attendee's daily contributions and participation in the workshop discussions will help build upon our country's strong cattle health foundation and enhance progress towards the future. The breadth, depth and scope of attendees enabled a comprehensive discussion for the U.S. beef and dairy cattle industries.

Discussion Summaries

Keynote Speaker

The keynote speaker, Jan Slingenbergh, DVM, is an international expert with a comprehensive career in improving animal and human health which spans the science behind disease outbreaks to applied solutions in the field, and formulating/implementing regional and global strategies. Dr. Slingenbergh's talk set the stage and gave context for the ensuing workshop discussions. Key points focused on better understanding disease ecology and global drivers of new emerging livestock diseases; technical issues related to disease ecology - especially the drivers and transmission ecology of disease emergence at the human-animal-ecosystem interfaces; some applicable overarching commonalities of the growing number of pandemics; and technical details of major cattle pathogens using a systems approach.

For example, the need to properly understand the interplay of pathogen properties, infection and transmission modes, and match with host environment and husbandry systems would enable improved analysis of threats posed to the U.S. cattle herd by infectious pathogens circulating worldwide in bovines, small ruminants, and herbivore wildlife species as well as in arthropod vectors. Also, there is increasing focus on understanding the driving forces or factors that cause disease outbreaks. Global driver discussions frequently include anthropogenic factors such as the growing pressure on the natural resource base, transformation of the global farming landscapes, deforestation, increase in international travel, trade and traffic, and climate change.

The talk outlined key questions participants should keep in mind during the workshop discussions:

- a) Which livestock species and which production systems attract which types of pathogens?
- b) What types of pathogens are in fact circulating worldwide in cattle?
- c) And a related question: what are the cattle-associated pathogens responsible for zoonotic infections, food safety hazards, and antimicrobial resistance challenges?
- d) Importantly: what are the differences between viruses, bacteria and protozoa in disease emergence?

Dr. Slingenbergh concluded his keynote by outlining the merits in broadening the disease ecology and understanding drivers with a perspective to also consider the collective disease dynamics playing at the human, animal and ecosystems interface (see Appendix C for Dr. Slingenbergh's biography).

Session 1: What are we doing? What do we know (and don't know)?

Moderated by Roxann Motroni, Program Manager, DHS

This session provided an overview of current U.S. government programs and approaches to identifying and preventing foreign animal diseases/transboundary animal diseases (FAD/TADs) and pathogen risks of entry into the U.S. This session also provided workshop participants improved knowledge of trade as it pertains to commodity movement and economic trends that ultimately impact dairy/beef animal health and management decisions, as well as economic viability of the agriculture industries. Session 1 contributed to achieving Objectives 1 and 2.

Common themes from this session included:

- FADs/TADs: Having access to adequate tools and methods to prevent or treat emerging, re-emerging and FAD/TADs; removing barriers to protecting the U.S. cattle herd from these threats; and having adequate communication and coordination amongst federal animal health authorities, state animal health authorities, producers and veterinarians. For example, there were shared concerns regarding the geographic spread of anaplasmosis and cattle fever ticks.
- Conducting timely risk assessments: There was agreement that there is an urgent need for prioritized risk assessments so that government, scientists, veterinarians and producers are aware of pathogens and vectors circulating globally which could pose a risk to the U.S. cattle herd. Risks need to be prioritized economically to facilitate shared awareness of potential impacts from disease introduction. Risk assessments performed by government agencies, including sharing of risk analysis results, should be done in a timely manner in order to best inform current and future actions.
- Best utility of limited funding: To protect the cattle herd, there is a need for sustained, appropriate funding for the issues the U.S. cattle industry is facing (e.g., research, tools, infrastructure for surveillance and response, disease management, vaccine development and vaccine banks, etc.). Approaching these types of issues requires a local response first; therefore, this type of meeting/discussion is timely and important.
- Education of veterinarians and veterinary students and the lack of practicing large animal veterinarians in rural areas.

Collectively, the speakers afforded a more holistic picture that informed the ensuing workshop participants' breakout groups' formulation of a prioritized priority cattle disease list and assisted discussion regarding potential pathogen import risks, and identification of gaps and opportunities.

Presenters were from NMPF, NCBA, AABP, USDA-APHIS and CattleFax. Some common diseases of concern mentioned were tuberculosis, brucellosis, New World Screwworm, cattle fever tick, anaplasmosis, Schmallenberg, FMD, Hobi-like viruses and bluetongue.

Some common questions industry speakers articulated were the following:

- Are we appropriately conducting surveillance in the U.S.?
- What does a national cattle surveillance program look like, especially given the extent and volume of U.S. cattle/livestock and milk movements?
- How do we get appropriate screening assays validated and available for use quickly?
- How does the advent of the Food and Drug Administration's Veterinary Feed Directive potentially change the relationship in disease identification, particularly for smaller herds – is there an opportunity for additional education and disease prevention impacts?

Dr. Michelle Colby, DVM, MS, DHS S&T Directorate, CBD Division, Agriculture Defense Branch Chief provided welcoming remarks indicating that a priority for DHS funding included support for facilitated discussions such as this workshop to improve the nation's response capabilities to TADs and emerging disease and to ensure tools are available for use during an outbreak. Dr. Colby also discussed S&T's desire to get products into the pipeline for commercial production and the Directorate's goal for its research and development projects to remain active with a focus on transition to ensure they are sustained following the program's end.

Overall, this session provided an overview of current U.S. government programs and approaches to identifying and preventing foreign animal diseases/transboundary animal diseases (FAD/TADs) and pathogen risks of entry into the U.S., and provided workshop participants improved knowledge of trade as it pertains to commodity movement and economic trends that ultimately impact dairy/beef animal health and management decisions as well as economic viability of the agriculture industries. Collectively the speakers afforded a more holistic picture which informed the ensuing workshop participants' breakout groups' formulation of a prioritized priority cattle disease list and assisted discussion regarding potential pathogen import risks and gap identification. Session 1 contributed to Objectives 1 and 2.

Presenters were from NMPF, NCBA, AABP, APHIS and CattleFax. Some common diseases of concern mentioned were tuberculosis, brucellosis, New World Screwworm, cattle fever tick, anaplasmosis, Schmallenberg, FMD, Hobi-like viruses and bluetongue.

Industry speakers (NMPF, NCBA, AABP) discussed the need for the U.S. government's sustained commitment for an FMD vaccine bank appropriate to the needs of the U.S. livestock industries – some priority issues included the appropriate antigens, sufficient funding and optimal management. These speakers also emphasized how producers and veterinarians work together at the farm level for optimal herd health and management and that there continues to be concern regarding availability of qualified food animal veterinarians in rural America due to work/life balance, economics and societal changes.

Some other shared industry perspectives highlighted the need for early detection of new and emerging diseases or health anomalies. There is a need for continual education of veterinarians and producers to know what diseases they should be aware of, what clinical signs to look for and what to do, as these activities are the keys to prevention, early detection, reduced spread of disease and rapid, and effective response. Ensuring veterinary curriculum and USDA accreditation modules keep current with respect to disease and policy issues can serve to facilitate essential continuing education. Industry representatives stressed a need for better capturing and gleaning information from morbidity/mortality data which might more quickly trigger red flags or awareness the occurrence of a disease event, and supporting knowledge and tools for early detection are vital. Of importance to both the beef and dairy industries is the untapped potential to capitalize on aggregate commodity sampling (*e.g.*, milk) if validated tests for priority diseases were available; prevention is key, and failing that, early detection is paramount. Particularly for open beef and dairy systems, the lack of scientific knowledge to understand movement and transmission dynamics for many of the diseases currently or potentially affecting the U.S. cattle industry hinders prevention and control efforts even when appropriate biosecurity measures are applied. To protect the cattle herd, there is a need for sustained, appropriate funding for the issues the U.S. cattle industry is facing (research, tools, infrastructure for surveillance and response, disease management, etc.); approaching these types of issues requires a local response first; therefore, this type of meeting/discussion is timely and important.

There were shared concerns regarding the geographic spread of anaplasmosis and cattle fever ticks, having access to adequate tools and methods to prevent or treat these two diseases as well as other emerging, re-emerging and FAD diseases, removing barriers to protecting the U.S. cattle herd from these threats and having adequate communication and coordination amongst federal animal health authorities, state animal health authorities, producers and veterinarians on this topic.

There was agreement that there is an urgent need for prioritized risk assessments so that government, scientists, veterinarians and producers are aware of pathogens and vectors circulating globally which could pose a risk to the U.S. cattle herd and to better understand the vulnerabilities so that gaps can be filled; part of this would include prioritizing risks economically to facilitate shared awareness of potential impacts from disease introduction. Risk assessments performed by government agencies, including sharing of risk analysis results, should be done in a timely manner in order to best inform current and future actions.

The session continued with an APHIS presentation regarding the current challenges to the U.S. posed by TADs. Specific examples included the September 2016 confirmation of New World Screwworm in the Florida Keys and subsequent response/eradication effort. While the response was successful, the fortuitous location helped minimize what could have been a greater negative impact resulting from the slow detection of the presence of the disease. APHIS' investigation indicates that the disease was most likely present in the Key deer at least two months before it was initially reported. Diligence and education are critical to ensure that eradication methods were successful in eliminating the spread of disease. The cattle fever tick vector is a control

program example of how critical it is for cooperation between producers, state/federal agencies and other governments (Mexico). This is the longest standing USDA program and in fact, a major impetus for the creation of APHIS VS. A variety of challenges make eradication strategies for this transboundary vector, and eliminating the potential Babesiosis disease threat to all of the U.S., increasingly difficult. These include pesticide resistance, significant human and financial resources, and limited control options on land and extensive tick movement via white-tailed deer and exotic wildlife. Currently, the vector is expanding back into previously free areas in Texas and a successful effort to reverse this threat will require a mix of both old and new methods for the control program. While a new vaccine seems to be working, more effective management tools and a plan is needed to get the current situation under control and move the vector back within its permanent quarantine line along the Texas/Mexico border, or preferably, even further south.

FMD was discussed as an example of a major TAD for which the U.S. has done extensive preparations. APHIS' goal is to take science- and risk-based approaches to FMD response and control. A good preparedness and response plan has been developed (USDA's *Foot-and-Mouth Disease Response Plan, The Red Book: FAD PReP Foreign Animal Disease Preparedness & Response Plan*). That being said, it is anticipated that the occurrence of FMD in the U.S. would require response plan adjustments specific to the situation and would be an "all hands on deck" event. Risk mitigation and vaccination strategies would also be tailored to the actual event and discussions on these topics, as well as the need for an adequate vaccine supply, continues within the U.S. and with the Quads group (Canada, Australia and New Zealand – for the Quads group agreement to share vaccine capacity if needed). The U.S. sector specific continuity of business plans are in various stages of completion/development and are intended to help mitigate negative impacts in the event of FMD.

Other current TADs of concern noted by APHIS were Hobi-like virus, Schmallenberg, bluetongue virus, Heartwater disease, and antimicrobial resistant (AMR) bacteria. In order to determine if Hobi-like viruses are present in the U.S., VS and ARS conducted a Hobi-virus serosurvey project using samples taken for brucellosis testing in slaughter plants (see Session 4 for more details on results). While evidence of the virus was not found, risk of introduction to the U.S. still remains a concern. Schmallenberg is likely not a huge risk and bluetongue virus is of concern because microclimate change can impact its distribution and because it is vector-borne, it would be more difficult to control. Heartwater disease is currently present in the Caribbean and has the potential to easily emerge into the southern U.S. While AMR is not a TAD, AMR bacteria and how they transfer resistant genetic material is of common concern.

How the U.S. government works to address some of the current challenges posed by TADs was provided by APHIS National Import Export and DHS CBP speakers with an overview of the current federal government import processes, and an APHIS VS speaker who discussed the agency's risk identification/risk assessment approaches for foreign animal and emerging diseases. APHIS VS, APHIS Plant Protection and Quarantine (PPQ) and CBP work together in a

coordinated effort at over 40 ocean and air ports and 30 land border ports. For the importation of animals and products, APHIS uses the World Organisation for Animal Health (OIE) standards for risk assessment and evaluates data dossiers provided by countries as well as public source information to inform risk analysis. All imported agricultural products shipped to the U.S. must meet the agency's entry requirements to exclude pests and diseases of agriculture. APHIS also has built relationships with counterparts in like-minded countries and regional groupings (e.g. Americas region and the Quads – U.S., Australia, New Zealand, and Canada) to work on common perspectives, approaches, and agreements. One example would be to recognize countries or parts of countries (defined by a geographical, political or surveyed boundary) as free of a certain disease. This approach, via regionalization agreements, was successful for the U.S. during the recent Highly Pathogenic Avian Influenza (HPAI) outbreaks to assist in keeping some export markets open to U.S. poultry and egg products. Permits and certifications were required and the U.S. also demonstrated appropriate emergency response, followed OIE surveillance standards, and provided traceability of animals/products during these events for our trading partners. Currently U.S. and global discussions are exploring capitalizing on the concepts of zones or regions, especially among priority trading partners with similar animal health infrastructures. All efforts should be science-based, but it was noted that trade is often hindered by politics or a country's specific standards, irrespective of the science.

Working with APHIS and using risk information, CBP's approximately 2,400 agricultural specialists stationed at 182 ports of entry inspect cargo, commodities, conveyances and instruments of trade. CBP targets shipments of concern, which is part of the overall safeguarding continuum. For example, deer hides continue to pose a large risk, particularly along the southern land border. Empty containers are also examined, as the focus goes beyond the cargo itself to include everything involved in the transport of goods. One example of CBP/APHIS collaboration is with international garbage compliance. On the front end, APHIS issues agreements with entities handling/disposing of waste coming into the U.S. at the borders or on vessels (e.g. ships, airplanes) and CBP enforces these at our border, with heavy consequences for noncompliance. Most waste is handled via incineration. Given the volume of vessels, it is not possible to track all garbage coming through, so these agreements are critical to ensuring a risk-based approach.

While there are continual efforts to ensure CBP agents are aware of current risks via training and U.S. government collaborative situational awareness, challenges remain from often limited information to identify high risk shipments to stay ahead of problems. The sheer volume of people, animals, express consignments, commodities and conveyances moving daily also contribute to challenges. CBP utilizes specifically trained dogs, which increase proficiency of detection in passenger areas (the Beagle Brigade) and continually works toward a more desirable level of compliance from passengers and shippers of goods.

The Risk Identification Unit (RIU) in APHIS VS Center for Epidemiology and Animal Health works to better identify risks to the U.S. by focusing on foreign animal and emerging diseases. Utilizing every source of information available, the unit monitors trends, prepares disease threat dossiers and alerts APHIS leadership when risks are deemed significant enough to be shared.

The RIU works with the other government agencies such as the Food Safety Inspection Service (FSIS), where FSIS condemnations are reviewed in order to identify trends such as increases in condemnation for certain reasons. Observational information such as from industry (e.g. noteworthy milk production drops or unusual feed intake decreases) is also important. Likewise, both diseases and vectors are of interest. The RIU assesses risk of entry or spread by disease and/or vector of concern, performing more formalized assessments of realistic threats using a statistical approach to quantify risk, and includes the recommended mitigation/surveillance strategy to ensure appropriate monitoring is in place for the threat.

It was noted that data threat synthesis is not easy to do, requiring significant human labor investment and data collection and analysis as well as bringing them together to ascertain a meaningful disease risk signal remains a challenge.

A speaker from CattleFax provided a holistic perspective on the impacts of animal disease events along the entire marketing chain, allied industries, and the U.S. agriculture sector as well as to the overall economy. Of the \$12.2 billion in exports, \$1 out of every \$8 generated in the cattle business is tied to exports and everyone must be conscious of trade issues when developing plans for animal health/disease control as this directly impact profitability of producers, U.S. consumers, and the U.S. economy. Trade is historically important, with global stage interactions (politics, climate, and economics) impacting the exports and imports balance, and this becomes even more important going forward. Are there steps producers can take to remove barriers and have a better chance of exporting product? Trade issues are beyond producers' control, especially when countries ban imports for non-scientific reasons.

The long-term trend will be for the U.S. to efficiently produce even more protein to meet the increasing global consumption needs, but production is currently outpacing the growth of markets. As an example of extended trade/economic implications from the discovery of a FAD incident in the U.S. cattle herd, an analysis of the market effects from the December 2003 identification of bovine spongiform encephalitis (BSE) was discussed. It took over a decade for export markets to return to pre-BSE numbers and without that interruption, it is difficult to say where the U.S. would be in terms of global market share. There is a need for policies that better mitigate the shock emerging diseases have on the economic system. For example, with FMD, the flow of cattle/products should be analyzed and the threat assessed, putting assets in place to mitigate the biggest threat.

Ensuing question and answer discussion identified the following crucial points:

- Early detection is key to rapid response and being able to circumscribe an outbreak as quickly as possible, to eradicate the disease and return to normal.
- The wildlife/livestock interface is a challenge for emerging diseases and becomes difficult to control because there are different mandates for livestock versus wildlife authorities. The difficulties are also compounded by the overlapping and grey areas of authority.

- Resource issues are always a concern. Prevention, preparedness, and response for many of the diseases discussed are intense resource drains of both people and dollars. Both state and federal governments currently have normal operational funding and personnel resource challenges and there is a need for improved partnering for better responses to disease events. More frequent and distributed disease outbreaks continue to dilute animal health authorities' ability to respond.
- Specific to FMD, vaccine alone is not a silver bullet and having the right vaccine available in adequate amounts is only one of the significant challenges. Two others discussed were logistics for vaccine delivery and administration, and collection of electronic information when animal are vaccinated for FMD, which can then be used to provide documentation for trading partners.
- There is awareness of what to do with FADs and how to handle historic program diseases, but having an effective response plan for new emerging diseases is a relatively new concept. APHIS has an emerging disease response plan coming out soon which creates tiers of response for emerging disease as well as lays out the communication needed and identifies who responds. It is anticipated that the plan will need to be adjusted per specific events but it should form a good framework for USDA to use as “the guidebook” for the next porcine epidemic diarrhea virus (PEDv).
- Is there a need for a cattle industry corollary to the Swine Health Information Center (SHIC; <http://www.swinehealth.org/>)?
- While mechanisms are in place for new technology policy to move forward, science is changing more quickly than the corresponding policy. This is a gap which must be explored further and resolved.
- There was significant plenary discussion regarding the handling of new diagnostics and capabilities such as multiplex tools and their use for screening, understanding the background as well as the challenges posed for what to do with positives found by improved detection methods.
- New diagnostics are also a challenge because new diseases or expanded host range(s) are being found. Government should continue to work with industry and OIE. And it was noted that APHIS Center for Veterinary Biologics (CVB) is the U.S. regulatory authority for evaluation new testing options/capabilities.

Session 1 Breakout Group Discussion: Priority Diseases and Gaps

Workshop participants were divided into two breakout groups, led by Mike Sanderson, Professor, Epidemiology and Beef Production, Kansas State University and Kathy Simmons, Chief Veterinarian, NCBA. Each group discussed and compiled prioritized disease and gaps lists based on the following questions:

- a) Formulating the list- What priority foreign animal, emerging or re-emerging cattle diseases should the U.S. address, worry about, plan for?**

b) Improving the knowledge and process for transparent risk-based decisions and prevention of transboundary and emerging priority cattle diseases – What are the gaps? What does the US government need?

See Appendix D for the 2015 ARS Top Diseases by Commodity Survey and Appendix H for background handouts provided as hands-on resources during the breakout group 1 session.

During the discussions, participants were advised to consider: 1) epidemic/epizootic potential; 2) economic impacts; 3) impact on trade; 4) morbidity/mortality; 5) potential to infect multiple species; 6) tools to detect disease rapidly; 7) tools to vaccinate; 8) zoonotic potential; and 9) co-infections that have the potential to define the impact of the disease. Following smaller group discussions, the plenary reconvened to reconcile the two breakout groups' prioritized diseases and gaps lists. Participants noted that it was difficult to formulate a prioritized disease list because there are a significant number of knowledge/information gaps that prohibit putting together a well-informed risk-based list.

Participants agreed upon the following:

Prioritized foreign animal, emerging or re-emerging cattle diseases for which the U.S. should address, worry about, and plan for:

1. Priority Foreign Animal Diseases:

- FMD
- Babesiosis/Cattle Fever Tick
 - i. It was noted that the U.S. has both the vector and the disease – these should be kept apart.
- Lumpy Skin Disease
 - i. The occurrence in Europe was noted as a potential threat due to the spreading disease footprint beyond traditional (Middle East) outbreak areas.
- New World Screwworm

2. Priority Emerging and Re-emerging Diseases:

- Hobi-like virus
- Bovine Respiratory Disease (BRD)/Bovine Viral Diarrhea (BVD) throughout the production cycle
- Anaplasmosis expansion
- Vector-borne diseases (e.g., exotic bluetongue, Schmallenberg, Heartwater)
 - i. Hard to anticipate
 - ii. The U.S. has been fortunate to avoid introduction from recent global/European outbreaks to date.
 - iii. The U.S. has nearby geographic reservoirs (Canada, Mexico, Caribbean, and Central/South America)
- Mycoplasma

3. Priority Zoonotic Diseases:

- Shiga-toxin *E. Coli*, Salmonella (particularly resistant strains)
- Prion diseases (e.g., Bovine Spongiform encephalopathy [BSE], Chronic Wasting Disease [CWD])
 - i. Participants agreed that it seems like the U.S. has a better handle on these threats than in the past (*i.e.*, BSE introduction was caught quickly), but more research is still needed to understand prion infection and transmission
 - ii. Participants discussed the unknowns related to any possible potential for crossover between wildlife, livestock, and humans, particularly related to pathways/mechanisms for cross-species transmission or atypical disease presentations.
- Rift Valley Fever
 - i. Participants discussed the need for a better understanding of silent carriers, and species-specific differences in disease presentation
- Tuberculosis, particularly the wildlife reservoir
 - i. Consumer impacts were noted, even if only found in wildlife

Prioritized Gaps List:

Gaps were categorized into national security, diagnostics, policy, standards, new technology and knowledge issue areas.

1. National Security Gaps

- Foreign animal and emerging diseases affecting animal agriculture should be a White House/Administration/Executive Branch priority
 - i. The U.S. is a food secure nation due to the productivity of the private sector/agriculture industries, historical federal investment in agricultural research, and previous federal and state infrastructure investments. This is at risk due to recent years' decreased federal investments in research and infrastructure, prevention and preparedness, and many states' continued budgetary/economic challenges.
 - ii. Congressional appropriators and oversight/policy committees need to conduct improved oversight of federal agencies.
 - iii. Cattle-derived products are critical to our nation's Gross Domestic Product (GDP) and the (beef and dairy) cattle industries represent a significant constituency to U.S. and State Congressional and Executive Branches.
- Government coordination is needed to maintain priority pathogens as a national security/defense issue
 - i. The threat of intentional pathogen/disease introduction cannot be discarded; response will be initially implemented as if catastrophic events are intentional.
 - ii. Food and agriculture is a critical infrastructure, and attacks against it have the potential to impact food security (*i.e.*, availability of food), food safety (*i.e.*,

- contamination or other public health risks), and food defense (*i.e.*, intentional adulteration of food products).
- iii. Sector-specific agencies for food and agriculture have limited experience in national security/biodefense/agricultural defense issues (*i.e.*, not their primary mission area).
- States need assistance at every level (*e.g.*, human and financial resources, infrastructure, and policy)
 - i. Challenges with federal budgets and inter-agency coordination are magnified at the state level, particularly given that states have different resources and processes.
 - ii. Distribution of cattle industry across the U.S. (all 50 states) makes it more difficult to work at the local level, unlike some industries who have geographically concentrated production populations.

2. Prevention Gaps: Diagnostics

- Validated herd-based tests are needed for the following priority diseases (at minimum):
 - i. Mycobacterium, Johne's Disease
 - ii. FMD
 - a. Bulk milk test validation is nearly complete, but the timely progress has been delayed due to accompanying use policy decisions and a prolonged development/validation due to challenges with federal organization and cross-agency collaborations.
 - b. There remains a significant need for a rapid aggregate sample cattle FMD test (*e.g.* oral fluids). Participants discussed that this might be of interest to a global consortium/as a global public good. Rough order of magnitude estimates placed minimum costs at \$4 million (\$2M to develop and \$2M to validate). This should be further discussed.
 - c. Confidence in results is paramount therefore FMD tests should be truly validated and thoroughly evaluated/tested for proficiency/performance in the field.
- Algorithms are needed to determine appropriate sampling strategy to give better confidence in a negative test result for movement during a disease outbreak.
 - i. National Animal Health Laboratory Network (NAHLN) laboratories need to move at the speed of commerce and especially during a disease outbreak, test results should be available in a timely manner (preferably electronically) consistent with allowing safe permitted movement needs of animals and animal products.
 - ii. Private laboratories exist that advertise an ability to "do FAD testing"; however, there is no standardized oversight of personnel, processes, procedures, or equipment. Using them looks attractive during an outbreak, but

may not provide the same consistent and reliable results of NAHLN laboratories without additional validation.

- Access to adequate quantity and quality of reagents for the volume of testing required to demonstrate freedom from disease is essential
 - i. NAHLN laboratories will likely be overwhelmed and sufficient reagents not available if single animal testing is required
 - ii. Continuity of business programs are contingent on a Differentiating Infected from Vaccinated (DIVA) test strategy.
 - iii. Enzyme-linked immunosorbent assays (ELISA) kits, polymerase chain reaction diagnostics (PCR) primers/master mixes all take time and special facilities to produce, particularly since there are no FMD ELISAs currently licensed for production in the U.S., and PCR primers/master mixes can only be made at the USDA Foreign Animal Disease Diagnostic Laboratory (FADDL).
 - iv. If the outbreak is widespread enough, or compounded by other factors (*i.e.*, multiple outbreaks in different species or a concurrent human epidemic), availability of general reagents like gloves, pipettes, plates, etc. may also be in short supply.
 - Acceptance of country of origin testing needs to be better understood or standardized
 - i. Are internationally produced reagents or tests performed in other laboratories using non-U.S. standard operating procedures are good enough safeguards (e.g., lot release testing in the U.S. for fetal bovine serum)?
 - Emerging disease diagnostics
 - i. The U.S. is not testing for known unknowns (*i.e.* diseases for which diagnostic tests are not available).
3. Prevention Gaps: Policy
- Policy needs to keep up with science and technology advancements
 - i. Use the best science available to control/manage FADs/emerging diseases and this should trickle down to improve overall animal health.
 - ii. There is a need for policymakers to understand the “why” of requests for funding and political support for FAD and emerging disease preparedness; the U.S. should be proactive to prevent rather than reactive to respond.
 - Improved interagency policy coordination and acceptance
 - i. Relevant U.S. Departments/Agencies need to improve interagency collaborations and partnerships including systemic coordination, use of personnel resources, and alignment of agency priorities and resources.
 - ii. Champions within each relevant Federal Department/Agency can help improve intra- and inter-agency efforts.
 - Trading partners policy

- i. What is the policy or how are communication messages resolved if a disease is not federally or internationally reportable but is within a State jurisdiction (e.g., bluetongue is reportable in Colorado but not federally or to the OIE)?
- ii. What is the definition of “freedom of disease” when reporting requirements within the U.S. /in endemic areas may vary? This becomes an issue with potentially large trade implications.

4. Prevention Gaps: Standards

- Ensuring appropriate availability of qualified veterinary services’ resources
 - i. Even with funding set aside or readily available for response, there is a concern that an adequate number of trained/qualified personnel to carry out field work in response to a FAD disease outbreak will be inadequate (both for veterinary services as well as surge capacity for diagnostics, reagents, testing, and vaccine manufacturing).
 - ii. There is not an adequate number of personnel trained to conduct FAD disease investigations (e.g., In Colorado there is now a net loss of veterinarians as older veterinarians retire, but there is no one whom to sell their practice).
 - iii. Increased qualified veterinary services are needed in rural areas; there remains the challenge of allocation of qualified new veterinarians willing to practice in rural areas (compounded by issues with student debt and lack of a work/life balance). The demographic change in society to urban centers is U.S.-wide and impacts this as well.
- Data sharing linkages and information technology interoperability is essential to surveillance and response
 - i. Appropriate FAD detection and response requires efficient electronic data capture, sharing and transfer (and in a timely manner at the speed of commerce).
 - ii. Continued linkages between NAHLN laboratories and mechanisms to share results directly from labs to SAHOs are needed
 - iii. Infrastructure capabilities exist within non-NAHLN (private) laboratories but their true capacity cannot be assessed due to lack of oversight and ability to assess quality control.
 - iv. Can learnings be gleaned from any public health models for performing trace backs during a disease event?

5. Prevention Gaps: New Technology

- What is the impact of new genetically engineered organisms (GEO)/genetically modified organisms (GMO) policies on the livestock industries?
 - i. Clustered regularly interspaced short palindromic repeat (CRISPR) technology (among others) may allow for production of smaller animals with improved fat/protein distribution, improved feed conversion, disease resistance, etc.

- ii. Some public sectors may resist but these technologies provide advancement and solutions.
- Proactive surveillance to better capture observations in a standardized format that can be shared
 - i. Leveraging samples coming into diagnostic laboratories could provide valuable information, provided samples are submitted.
 - ii. Certain clinical presentations are rarely submitted to veterinary diagnostic laboratories (*e.g.* abortion workups) and there is a lack of submissions for necropsies. Contributing factors include testing costs (money and time) and the fact that reports may be uninformative, so producers/veterinarians do not perceive any benefit versus financial, labor and time costs.
 - iii. How could this information be shared to the benefit of industry?
 - iv. The U.S. has a strong laboratory network to implement new technologies, once validated and with supporting policy for use.
 - v. There is an opportunity for integrated surveillance plus observational surveillance – leverage samples that are already taken, but improvements are needed in capturing the other information that is available with these submissions (*e.g.*, premises, age, clinical signs) in order to marry this information with the diagnostic results.
 - vi. Cooperative agreements/Memorandums of Understanding (MoUs) can help facilitate improved interagency coordination and public-private partnerships if implemented appropriately to better share information between organizations.

6. Prevention Gaps: Knowledge

- Need information regarding the following:
 - i. Transmission risks
 - ii. Reservoirs that are maintaining pathogens/disease
 - iii. Disease points of origin and associated risks
 - iv. Potential contaminants in feed and their effects
 - a. Protein additives from other countries may induce antibody production, which interferes with surveillance (*e.g.* whey protein additive).
 - v. Baseline prevalence of disease(s) and what “normal” looks like in order to detect “something”.
- The U.S. needs to better determine and then focus on eminent threat(s).
 - i. The U.S. is not particularly good at prevention, control, or response to vector borne diseases and there is a much higher risk of these entering the U.S.
 - ii. No country will ever have the resources (funding, personnel, etc.) to look at all potential threats; therefore it is important to prioritize and better understand eminent threats from lesser ones through improved risk-based assessments and planning.

- Are there areas where the U.S. can help improve pathogen load/disease occurrences globally (which decreases our risk)?
 - i. What are the risks in other countries for these priority diseases?
 - ii. What are the main diseases in other countries and of these, which ones should the U.S. be most concerned? Is the U.S. government fully aware of these – what is our process to better understand risks from other countries to the U.S.?

7. Opportunities:

- Do we need to think about creating a cattle version of the swine industry's Swine Health Information Center (SHIC)?
 - i. Such an entity would provide information aggregation and analysis related to sequencing data, especially with new technologies, and facilitate information distribution on specific serotypes of certain pathogens

Session 2: Lessons Learned and Impact/Real Life and Other Factors

Moderated by Fred Gingrich, Executive Vice President, AABP

This session provided a few lessons learned and other perspectives along the livestock food chain in North America. Animal health events have a ripple effect from farm to consumer and impact a large range of interconnected sectors, each with their own perceptions, consequences, and needs. The beef and dairy cattle sectors operate in open environments, have increased potential wildlife/livestock interfaces as compared to other more vertically integrated livestock sectors, and have a wider range of size and business operation structures. The ensuing breakout group discussion focused on biosecurity and was intended to improve a collective understanding on this complicated topic. Session 2 contributed to improved knowledge based on state responses to foreign animal and emerging diseases, information gleaned from the National Animal Health Monitoring System (NAHMS), and awareness of a major trading partner/integrated market's private and public-sector efforts on developing biosecurity standards, all of which has ancillary impacts on all three objectives of this workshop.

Foreign animal and emerging disease response at the state level is a collaborative partnership between industry, SAHOs, and local government/communities. For example, SAHOs should work with state or local environmental agencies to pre-identify viable options for infected animal carcass disposal, have response plans in place, and understand the agriculture sectors within their states. Understanding (per species and disease) the appropriate algorithms for statistically valid testing and how to evaluate different populations of animals, beyond just active observational surveillance, will assist with more rapid identification of a disease event as well as provide information needed for response and recovery of markets/trade. Lessons learned from recent HPAI experiences can inform gaps, strengths, and improvements for a national event. Local level relationships enable focusing on priorities to rapidly respond to events – this includes being able to locate animals, which allows more quickly ascertaining infected sites, targeting quarantine, depopulation and disposal of infected animals when necessary to minimize spread and economic harm, and containing the event within as small an area as possible. Non-infected and infected farms need to be able to stay in business, despite a disease event. Coordinating with NAHLN laboratories with the proper equipment, adequate surge capacity and the ability to electronically provide accurate, rapid test results back to the states within 24 hours is paramount to allow safe permitted movement within a control zone or from non-infected areas. Data management is crucial both within the state as well as the ability to maintain, visualize, and share data as needed for disease control purposes, business continuity, and commerce. Underpinning all of this is the prerequisite that states need a minimum infrastructure to be able to adequately respond to disease events.

The Canadian Cattlemen's Association (CCA) speaker provided further perspectives from the local level, highlighting that an important aspect of mitigating risk can be implemented at the producer/farm level. Starting in 2009, Canada's poultry, beef, and other livestock industries began work to establish a practical, science- and research-based, voluntary biosecurity standard which is national in scope and is intentionally not prescriptive. Steering groups comprised of

industry, government, and academic expertise were formed to collaborate on these initiatives for each commodity. A literature review and gap analysis of existing practices was conducted prior to development and industry was a vital partner in the process.

Biosecurity encompasses management practices to prevent introduction of disease or to control further disease spread. This concept was viewed as an inherent part of the emergency management process and the guidance is flexible enough to allow adaptation by different operation types and sizes. While foreign animal diseases were the driver, the standards include cost-benefit considerations for each operation. They have to demonstrate value to the national herd, take current practices on farm into account and have practical applications to production limiting diseases as well as FADs. A producer implementation manual was also developed and provides additional information/examples for applying the standard on farms. Completed in December 2011, the Canadian Beef Cattle On Farm Biosecurity Standard has 4 principles and 21 target outcomes. The four key elements are: i) manage and minimize animal movement risks; ii) manage the movement of people, vehicles, equipment, and tools; iii) manage animal health practices; and iv) educate, plan, and record. Since then, CCA has incorporated this National Standard for biosecurity into their sustainability program (Verified Beef Production Plus), along with food safety, animal welfare and environmental stewardship – all of which helps differentiate Canadian beef in the international market.

An APHIS speaker provided continued examples of the importance of private/public sector collaborations and local relationships when discussing lessons learned from the agency's NAHMS as an information source for biosecurity on U.S. cattle operations. For example, multiple previous studies have shown that private veterinarians are the most likely to be consulted by producers as an information source during an FAD outbreak and producers would contact them first when they suspected an FAD on their operation – well ahead of extension personnel, a feed company or milk coop, a state veterinarian, or USDA.

NAHMS was created in 1983 through State pilot projects and in 1990 began national studies on the health and health management of U.S. livestock and poultry populations. While these studies are designed to meet the information needs of livestock industries, as identified through a needs assessment by industry stakeholders, the information gleaned during the roughly every 4 to 7 year cattle studies (dairy, beef feedlot, and beef cow-calf) assists producers, scientists/academic researchers, industry educational programs, veterinarians, allied industry, SAHOs and Federal animal health authorities alike. Some biosecurity-related information that has been collected in previous NAHMS studies includes herd additions - including quarantining practices and required or performed disease testing for new additions; percent/handling of contact with Mexican origin cattle (e.g. fence-line); visitor management; presence of other animals on operations; equipment sharing and cleaning; vaccination protocols and employee contact with livestock when off the operation. Other pertinent biosecurity related information also includes cattle exposure to wildlife; contact with feed by other animals; protocols for travel to shows, fairs, etc.; herd of origin disease status; water sources and employee training. NAHMS has been collecting such

information on biosecurity practices since the early 1990's and continues to respond to stakeholder input on information needs related to this and other topics.

Session 2 Breakout Group Discussion: Biosecurity – Knowledge, Perceptions and Opportunities

Workshop participants divided into two breakout groups, led by Danelle Bickett-Weddle, Center for Food Security and Public Health, Iowa State University, and Dale Grotelueschein, Great Plains Veterinary Educational Center, University of Nebraska-Lincoln. There were no handouts for this breakout session. Each group discussed and compiled answers to the following questions:

1. Review any biosecurity questions results received from the pre-workshop survey.
2. What are the unique challenges for biosecurity in open systems such as in the cattle sectors? (e.g. wildlife, fence line contact, etc.)
 - a) Can we address all of these? If not, how do we address the ones that we can?
 - b) What additional tools do we need to help minimize or manage these?
 - c) What, if any, additional biosecurity challenges would any of the foreign, emerging or re-emerging priority diseases identified by participants bring to these open cattle systems?
3. What are the currently available biosecurity best practices, guidelines, information, etc. available to producers, SAHOs or federal animal health officials? (Ex. BVD, Secure Beef Supply (in process), Secure Milk Supply, BQA, Dairy BQA, OIE, etc.)
 - a) Do we need to build upon these existing resources and/or link them together for every day animal health needs for the beef and dairy sectors?
 - i. If yes, what would be the suggested best process for this?
 - b) Given the currently available resources, for every day animal health or for the foreign animal/emerging/re-emerging priority disease list developed by workshop participants, is there a need for the development of more comprehensive best practices for each part of the dairy/beef cattle chain, and if yes, what would be the suggested best process for this?
 - i. Producers
 - ii. Private veterinarian
 - iii. Livestock markets
 - iv. Cattle transportation industry
 - v. Cattle harvesting plants
 - vi. SAHO personnel
 - vii. Federal personnel
 - viii. Other agency/organization (non-agriculture) personnel assisting in the foreign animal, emerging or re-emerging disease event

Groups began the breakout session by reviewing the three sector specific perception questions contained in the survey. These same questions were included in both the pre- and post-workshop survey. For full context and understanding of these complex issues, the survey analysis in Appendix J should also be viewed. The below discussion is in the context of the breakout groups. This review was intended to better inform discussion on Questions 2 and 3, as well as to allow a

better understanding of pre-workshop perceptions amongst the large and diverse groups attending the workshop (dairy producers, beef producers, veterinarians, wildlife personnel, academia, SAHOs, and federal authorities). Much of the breakout discussion time was spent on Questions 1 and 2 above. Due to the challenging topic, engaged discussion and time constraints, Questions 3.a.i and 3.b. were not answered to any degree.

The ensuing plenary discussion highlighted participants felt that they were generally knowledgeable regarding their own sector and each other sector's willingness to incorporate biosecurity best practices, but deterrents such as financial costs of implementation, inherent challenges with open systems (e.g. so many avenues for pathogen entry), and no guarantee that following biosecurity best practices will not completely negate entry/risk, hinder broad adoption across the entire U.S. beef and dairy value chains. It was generally felt that it may be impossible in these systems to ever do "enough" to move the needle in regards to biosecurity/impacts.

Cost of biosecurity versus understood benefit is not well-realized, especially when consistently implementing biosecurity competes with personnel and financial resources. With limited resources, this might take away from a producer's ability to do other operational inputs, especially small producers. Taking into account the daily pressures of raising commercial livestock, biosecurity can be relatively far down the priority list for attention. While producers recognize the value during a disease outbreak, many other issues (e.g., animal welfare, employment practices, and environmental sustainability) usually are a higher priority due to commercial marketplace pressures.

All of these factors contribute to inconsistent or a mixed application of individual operations implementing biosecurity best practices in the absence of known disease events (i.e. disease outbreaks are drivers for action from a broader spectrum of producers). As with any industry, there is a leading curve of early adopters, a large middle section of "want to do things well", and a small group resistant to change of any kind or additional input costs.

It was noted that biosecurity needs to be adapted to current cattle production systems in order for it to work effectively, and those practices may need to be augmented in the face of an FAD or emerging disease outbreak. Many farms are not biosecure and often personnel/vendors visit many of these farms within a geographic area in a short period of time. Adding in that rendering trucks and feed trucks are on and off multiple premises and employees may have their own personal livestock; biosecurity becomes a significant concern to ensuring adequate protocols to prevent disease transmission and during a disease event.

One challenge to this system is the quantity of U.S. livestock that is marketed (e.g. through order buyers, livestock markets), which makes strict biosecurity difficult to implement because sale barns/markets are significant points of coalescence with unique biosecurity issues. Buyers often want to visually inspect animals and significant numbers of animals are moving through these systems very quickly. A better understanding of how to realistically implement biosecurity

measures for both marketing and exhibitions/fairs, another challenging point of livestock mixing, would be beneficial to the industry.

Implementation of good biosecurity practices will not by itself eliminate risk from endemic, FADs, emerging or re-emerging diseases. The plenary also felt that a better understanding of animal traceability to quickly identify where an animal came from and options for limiting conveyance between involved farms would help limit spread and facilitate disease control. Targeted vaccination may also help in that if we can protect cattle, then we can hopefully protect swine (or vice versa) in shared diseases. Traceability and targeted vaccination, along with validated testing will also assist with the ability to continue to move livestock. It was noted that during a disease vaccination program, we cannot send the same crew from farm to farm, numbers of animals likely involved will be a problem and having to do multiple vaccinations for the same animal will increase challenges. The diversity of operation sizes, different amounts of livestock commingling within/between operations and significant variation even within sectors poses increased challenges.

The Secure Food Supply plans are designed to provide business continuity in the face of a FAD outbreak and all of the plans developed to date or in process, contain a biosecurity component for helping to give confidence to SAHOs in making decisions that facilitate risk-based movement during a disease outbreak. Not letting “perfect be the enemy of the good” and determining, then targeting the critical points likely to cause biosecurity gaps (*e.g.*, feed trucks, conveyances) with best practices (*i.e.* HACCP principles) will likely provide the most consistent results. For example, use of undercarriage truck washes as part of normal protocol could significantly decrease farm-to-farm spread through conveyances (these are now routine at poultry operations in Indiana). The goal would be to make parts of biosecurity an integrated aspect of everyday operations; if we can demonstrate the value of this, then it becomes a reason for producers to follow good biosecurity practices. The workshop participants strongly felt that we should build upon industry-recognized programs and resources for biosecurity best practices that are already in place (*e.g.* Beef Quality Assurance [BQA], Dairy BQA, feedyard assessment tools, etc.); there was discussion that, when appropriate, it seemed logical for self-assessment, an attending veterinarian or a third-party auditor to verify biosecurity practices similar to implementation of industry driven quality assurance programs.

Session 3: What do we have and why/What do we need and why?

Moderated by Elizabeth Parker, Chief Veterinarian, IIAD

This session provided lessons learned from historical U.S. regulatory and voluntary surveillance programs, an overview of our U.S. international obligations as an OIE member country, and lessons learned from the citrus industry. Participants also gained an understanding of current USDA surveillance program structures, technical needs, and perspectives towards the future. Session 3 contributed to Objectives 2 and 3 of the workshop.

Session 3 began with a panel addressing historical U.S. cattle surveillance programs and lessons learned, with a particular emphasis on legacies from Tuberculosis (TB) and Brucellosis regulatory programs, lessons learned from Bovine Spongiform Encephalopathy (BSE) surveillance program, and lessons learned from voluntary programs such as Johne's. Panelists included APHIS, a state veterinarian, two dairy producer/veterinarian association members, and a representative bringing a perspective from Florida's experiences with transboundary citrus diseases.

Main USDA APHIS Cattle Health Diseases/Pest programs include BSE, Brucellosis, Cattle Fever Tick, and TB. Since the program began in 1990, the ongoing U.S. BSE surveillance has always been well above OIE requirements and the U.S. surveillance targets cattle with the highest likelihood to find the disease. This was only one of multiple layers of firewalls the U.S. government put into place as soon as BSE was first identified in Europe. BSE surveillance was significantly enhanced from 2004-2006 to aggressively ascertain presence within the U.S. cattle herd after the first finding (December 2003) of the disease in a dairy cow imported from Canada. The extensive, strategic sampling, combined with other U.S. disease prevention measures contributed to the U.S.'s 2013 OIE designation of "negligible risk" for BSE.

The longstanding Brucellosis (1930), Tuberculosis (1917) and the Cattle Fever (1906) programs have all been in place since the early 1900's and have modified over time, with each facing particular challenges today. The current surveillance system in place for brucellosis is capable of detecting one positive within a million animals. Combined with other program measures (e.g. vaccination beginning in 1941), the U.S. numbers of infected herds went from over 150,000 in 1955 to all U.S. states considered free of the disease in 2009 – with one exception - the disease continues to have some recurring problems in the Greater Yellowstone Area (GYA) at the wildlife/cattle interface. This is of significant concern to those states and all U.S. cattle producers. APHIS is currently evaluating the brucellosis surveillance program to see if we can further reduce surveillance in low risk areas but focus on those high-risk animals in the GYA.

TB also has a persistent wildlife/cattle interface challenge with white tailed deer in Michigan. While the national prevalence rate today is at an all-time low of less than 0.002 percent, there are also occasional outbreaks in the country (e.g. CA, TX, SD, etc.), with investigation ongoing for how it gets into those herds. Slaughter surveillance continues in every state, which works well to capture presence of the disease (except for MI due to the deer). TB slaughter surveillance relies on visual lesions and there is a caudal fold test routinely used in the field. The TB program and surveillance is also under review and discussions include improved screening tools needed for identifying TB earlier (e.g. is there a way to screen dairy herds using something similar to a bulk milk tank assay? E.g. More rapid pen side tests for beef cattle versus the caudal fold test?).

Cattle Fever Ticks (*Rhipicephalus [Boophilus] microplus* and *R. Annulatus*) remain a very resource intensive surveillance activity, requiring "boots on the ground" for personnel to individually "scratch" every animal and dipping vats for cattle leaving the permanent quarantine

zone in Texas and coming into the U.S. from Mexico. The ticks were in 16 states when the program began in 1906, transmitting *Babesia bigemina* and *B. Bovis* to cattle, aka Texas Cattle Fever. The eradication program began in 1906 and by 1943 the ticks' footprint was reduced from the southern U.S. to a permanent quarantine buffer zone in South Texas. Wildlife (white-tailed deer and exotic species such as Nilgai in South Texas) present a significant challenge to eradication and the current continued spread of the ticks in Texas is of great concern (see Session 1 notes for more details on eradication etc. tools, needs). Other programs/diseases providing lessons learned are Johne's disease, Trichomoniasis and screwworm. Johne's was a previously federally funded voluntary control program, and while not a surveillance program, it enabled a great deal of new information and at the farm level can result in significant improvements to herd health. However, the results were difficult to measure at the national level and the program is no longer federally funded. Some states and companies/coops/producers remain active in Johne's disease prevention/control/eradication efforts. Trichomoniasis is not a federal program but is an example of a reproductive disease of concern, with difficult management options primarily due to insufficient surveillance tools. While there is currently a concerted effort amongst states and industry to better identify, control and prevent the disease, inconsistent responses and varying state regulations/programs remain a challenge.

New World screwworm is an example of a TAD that can have significant negative impact – especially when a recursion is not prevented or detected early. There is evidence that detection was slow in the recent Florida recursion, and the U.S. was fortunate that the location in the Florida Keys minimized the potential spread during the lag time of recursion and detection. What is the consequence of missing TADS such as this when they get introduced into the U.S. and what surveillance does the U.S. need for TADs to ensure we catch them? What tools do we need and how does the adoption of new technology change surveillance programs? Surveillance is only one piece of an overall FAD and emerging/re-emerging disease plan – an appropriate plan also includes the response for when a positive is found. Policy must keep pace with new technology/surveillance tools and the tools must be validated so that decision makers and industry/markets can rely on the results. With the exception of BSE, APHIS disease/surveillance programs began with large prevalence. As prevalence of endemic diseases (e.g. brucellosis and TB) is reduced or quantified (BSE) and APHIS shifts to do more targeted surveillance, two questions arise: 1) what are the highest risk animals we should surveil and 2) how can we screen lower risk animals without negatively impacting producers or trade? Currently for brucellosis, APHIS has designated surveillance areas (GYA), for TB the national program focuses on slaughter surveillance and State statuses, and BSE surveillance focuses on higher risk animals based on OIE point guidelines.

The APHIS speaker concluded with these main lessons learned:

1. Flexibility – we need to better adapt to changes
2. Efficiency – look for the “bang for the buck”

3. What is the plan when positives are found (e.g. for Johne's testing)? When there is a plan in place for herd management once a positive is found and risks are managed, then improvements in prevalence can be realized.
4. Regulatory programs require commitments from the Federal and State regulatory agencies as well as the industry - these are usually marathons.
5. Low prevalence does not mean absence of risk. Zero risk does not exist. Being able to trace once a positive is found helps, but it is not always possible to ascertain what actually happened, especially when wildlife is involved.

Plenary questions/discussions for APHIS concluded with 2 main points:

- We need improved tests for TB and improved coordination between public and animal health. Some recent dairy TB positive cases using phylogenetic fingerprinting seem to indicate humans as a source – understanding and preventing these cases requires collaboration and coordination between the One Health sectors.
- While many programs are implemented at the state level, there remains a need for federal involvement to provide standardization for testing and information exchange.
- Animal identification for animal health purposes was identified as a consistent need across workshop participants.

The Texas State experience included historical and the expanding CFT re-emerging spread lessons learned. Re-iterating concerns and challenges discussed by previous speakers on CFT, trace outs from the ongoing CFT spread continues and the threat to the entire U.S., and especially southern states was emphasized. The density of the deer populations and a lack of any viable treatment or prevention option for Nilgai sustains tick populations and spread. The need to also continue vigilance on traditional diseases was noted – outbreaks are just waiting for the right conditions. For example, seven cases of TB have been detected at slaughter plants in Texas this fiscal year, with two shown to be from a dairy in New Mexico, and five most likely from Mexico origin feeder animals. Disease investigations were hindered due to the fact that in two of those cases the DNA of the lesion did not match DNA on the identification device. The brucellosis reservoir in the GYA remains a threat to the rest of the U.S. and those GYA states need our support. The state perspective concluded with a reminder of states' needs from USDA – to protect our borders (import/export issues), continue research to better identify new diseases and improved ways to find those we currently have, and invest in diagnostic capabilities.

The first of the two producer panelists provided lessons learned from the Johne's program as well as information on today's consumers, who are asking more sophisticated questions about the milk they purchase and the supply chain. Having dairy industry personnel who understand critical process issues such as risks and early detection for process deviation is more vital than ever. The FDA's Food Safety Modernization Act (FSMA) is also influencing the system to go beyond historical Hazard Analysis Critical Control Points (HACCP) to increasingly risk-based preventative control programs.

Johne's disease has proven to be a difficult disease to eradicate and given this, there are questions among producers on whether eradication efforts are worth the cost-benefit. There remains concern that this disease could become a marketing issue because it is difficult to guarantee zero risk of exposure. Successful efforts on this disease require collaborative interaction between veterinarians, field staff, and dairy cooperative members to understand the risk assessment for each operation and sector. Despite the challenges, the past efforts with Johne's surveillance have had positive impacts beyond just the individual organism. For example, activities/systems put in place to address Johne's have also helped with salmonella prevention/control. Most importantly, the risk assessment process for the voluntary Johne's program – the way it was structured and led personnel through each aspect of a dairy operation – was one of the best models for getting individuals to understand and implement preventative control and further, how to implement these activities into business practices. The process provides regular reminders through the chain, back to dairymen, which creates the opportunity to maintain a more robust system. Looking forward, this would also be beneficial for biosecurity best practices issues.

The final producer/veterinarian panelist provided a personal experience of what happens on the farm, to the producer and families when a FAD is found, including the short and longer-term impacts to the operation. The negative impacts of the first finding of BSE in the U.S., from an imported Canadian dairy cow, were significant - yet despite being the farm with the index case, silver linings were found. The direct impacts to the farm are severe and the collateral damage was widespread for BSE – both short-term and long-term. However, the wide range of local, state, and federal personnel descending on the farm to respond to the event, do epidemiology and perform trace outs had a corps outlook – it was a team effort working together with the producer, for a common goal. Pre-planned BSE communication providing consistent messaging across industry, SAHOs and federal authorities to the public significantly contributed to U.S. consumer confidence rebounding very quickly. The lag time in BSE between exposure, detection and, response can be a problem even in a non-infectious disease, but for a contagion, the spider graph created by this can be overwhelming. Trace backs can be manageable but trace forwards are not, and we really have not improved this capability. Risks continue to present themselves and the list of disease agent threats continues to grow. Are we diligent enough? The threat to our resources, particularly our human resources, is as critical as the threat of the disease.

Generally, there is a tendency to not fully appreciate the risk because animal disease threats in the U.S. have been mitigated and response effective. Likewise, the consuming public is food secure and has been for decades. Losing this blanket of security, such as the incursion of another major FAD, would be devastating, yet there does not seem to be the political pressure to force policymakers into prudent leadership to address the gaps. Also, the parallels between diminishing land grant mission (e.g. investment in research and extension) and diminishing animal health mission (e.g. investment in infrastructure, prevention/preparedness/response planning, technology tools, etc.), creates a vulnerability. Key issues of public good in the animal health mission should be a priority for the government. The dairy industry also has a responsibility to contribute and public/private partnerships for some of these issues could be

explored. A final reflection was, if we expect strategic resources to be publicly funded, then producers should understand that it is a privilege to be part of that system, part of the combined team.

Concluding the panel, United Fresh Produce Association's speaker provided some lessons learned from the citrus industry's decade plus experience dealing with the introduction of two transboundary diseases which have since become endemic due to a variety of circumstances, despite significant eradication efforts. Citrus canker and citrus greening are very economically damaging diseases to the U.S. citrus industry. While not harmful to animals or humans, citrus canker is a bacterial diseases which causes premature leaf and fruit drop and will eventually render trees unproductive. Blemishes on oranges and public perception about how a product looks, with the associated consumer confidence, impacts the ability to sell. Citrus greening disease or Huanglongbing (HLB) is one of the most serious citrus diseases in the world. This bacterial disease is widespread in Asia, Africa, and the Saudi Arabian Peninsula. It was first reported in Brazil in July 2004, and in August 2005 was found for the first time in the U.S. in Florida. The HLB bacteria attacks the vascular system of plants. There is currently no cure for the disease, and within a few years the citrus trees decline and die.

These diseases demonstrate the difference between disease mitigation and management versus eradication. Sometimes it is not possible to get to the goal with eradication. A concerted effort by federal and state government and industry, with \$1.3 to \$1.4 billion invested on the effort to eradicate Citrus Canker was ultimately unsuccessful due to a variety of factors of out of the control of the program (e.g. homeowner law suits which hindered final infected tree removal and major natural weather events [hurricane] which spread the disease across the state). The homeowner lawsuits are a reminder that public engagement is critical – ultimately if they are not in agreement, then the efforts will not be successful. Engaging the public so that they understand the effort and are supportive of both industry and government activities is vital. Research and resource needs for transboundary diseases are also main factors for success. Established relationships between industry and government agencies such as the USDA before a crisis event has proved to be very valuable. Early detection and early intervention is also key to a successful response effort. Even when the focus is not eradication (as is now the case with citrus canker), a driver should be addressing what can we do to get into a better position sooner. Common points of coalescence were noted – the citrus and cattle industries have overlap in geography, and those states also have significant international borders, which are points of risk for disease introduction – finding common points of advocacy across our the citrus and cattle industries would be beneficial to all.

Session 3 continued with two APHIS speakers, one providing an overview for workshop participants to gain an understanding of current USDA surveillance program structures, technical needs and perspectives towards the future; and the other outlined pertinent OIE surveillance recommendations, which APHIS takes into account for U.S. programs.

Two recent APHIS documents provide some structural context for APHIS' current approach to preparing and responding to foreign, emerging or re-emerging diseases: the July 2, 2014 VS Proposed Framework for Responding to Emerging Animal Diseases in the United States, and the August 2016 Draft Emerging Animal disease and Response Plan. APHIS is also currently receiving comments on the January 2017 updated National List of Reportable Animal Diseases (NLRAD) - National Animal Health Reporting System (NAHRS) Reportable Disease List. (See documents in Annex F.) Intended to help VS respond effectively to emerging diseases, the framework defines the process by which VS will identify, evaluate, and respond to emerging diseases, and the implementation of this process as a VS core business practice.

Surveillance plays a role in all aspects – identifying, evaluating and responding to all disease events. Surveillance includes all of the following steps:

- Obtain sample and information about animals
- Laboratory testing
- IT infrastructure – data entry and management
- Information obtained is analyzed regularly
- Analysis triggers action and decision-making
- Results are provided to stakeholders
- Evaluation of the surveillance

The Comprehensive Integrated Surveillance (CIS) and potential new approaches the agency is currently planning for all livestock industries will maintain diseases specific surveillance. The CIS is intended to be representative, reliably gather accurate information, and be real-time, resourceful/efficient and risk-based. CIS addresses activities for priority diseases (brucellosis, bovine tuberculosis, BSE, cattle fever tick) as well as new and emerging diseases. CIS strives to integrate information from a variety of sources to create a cohesive understanding of what surveillance information can tell us about animal health. The main reasons behind the agency modifying their approach is to be able to rapidly recognize newly introduced (e.g. Hantavirus 1993, West Nile virus 1999, Monkey Pox 2003, Porcine Epidemic Diarrhea Virus 2013) emerging or re-emerging diseases (e.g. Old World Screwworm 2016), improve understanding of naturally occurring (endemic) diseases, and provide improved support to trade or assist in re-opening markets. There is also a need to improve surveillance efficiency and a goal for more flexibility and to broaden the scope of what can be done.

There are several key components to disease surveillance including defined purposes and objectives, sampling strategically to optimize disease detection, obtaining reliable information, having an efficient and sustainable process, availability of diagnostic tests, and having a robust infrastructure for managing and analyzing the information. The CIS for cattle is proposing activities that align with these components. For example, the agency is evaluating existing programs and looking to identify efficiencies. The agency is continuing to develop the U.S. Animal Movement Model, to support strategic sampling. This model was created using a sampling of data from certificates of veterinary inspection (CVIs). The continued

implementation of the APHIS Animal Disease Traceability rule is related as individual cattle identification is an essential part of reliable surveillance information that would be used in a disease event to trace past movements and provide information such as age, type and location. The CIS must maximize efficiencies and logistics and be sustainable and current planning towards this includes: i) use existing surveillance (e.g. can blood samples taken for an existing program disease be utilized for other disease surveillance?); ii) leverage places of animal congregation; iii) should not negatively impact business practices; and iv) integrate surveillance activities across livestock species (*i.e.*, can cattle TB evidence be used to support status for other spillover species?)

The availability of diagnostic test whose performance is well characterized is critical to many aspects of successful surveillance, such as determining the number of samples required to ascertain a certain level of prevalence. The final key component of the CIS is information flow, data management and analysis. Adequate and appropriate infrastructure is critical for collecting, managing and analyzing data from diverse systems. A VS priority is to improve surveillance information management. Coordination of regional and transnational information management and analysis, especially during an outbreak, is challenging when animal health information is maintained by different entities (diagnostic laboratories, States, national systems). In closing, some current challenges were discussed:

- As surveillance activities are developed for emerging and TADs, program disease surveillance needs to be maintained.
- What is the impact on reduced sample collection as the program diseases have decreased in prevalence to identifying an emerging or re-emerging disease?
- Analysis of current data streams is lacking, primarily because of challenges in information management described above (e.g. animal health information maintained by different entities in different formats), without an interface to look across programs.
- We currently do not have a real-time feedback mechanism to rapidly get the information back out to those who need it.
- Existing programs are integrated with state surveillance.

Session 3 concluded with a brief presentation of OIE Member Country surveillance reporting requirements. As an OIE Member Country, the U.S. is obligated to report disease that are on the OIE list of notifiable diseases. Diseases that are endemic to the country should be notified every 6 months, however, any exotic/new disease that is detected should be reported immediately (within 24 hours of confirmation). The OIE Code Chapter on Disease Surveillance includes guidance on the types of available surveillance and surveys, and considerations on items such as populations to be sampled, time frames, epidemiological units, and testing and validation of results. Surveillance guidance for specific diseases includes parameters for absence, its presence and distribution, disease trends and early detection. For exotic or high impact diseases, early detection, early reporting and rapid response are critical to minimizing or even preventing international spread.

Session 4: Food for Thought

Moderated by Elizabeth Parker, Chief Veterinarian, IIAD

This session provided information on Canada's current efforts regarding animal health surveillance and the experience gained on emerging pathogens such as Hobi-like viruses with lessons learned, focusing on key points of trends. The ensuing plenary group session focused on initiating discussions towards collectively identifying and defining appropriate, effective and risk-based priority disease surveillance needs for protecting the U.S. cattle industry. Session 4 contributed to Objectives 2 and 3 of the workshop.

The Canadian Animal Health Surveillance System (CAHSS) effort was initiated to help address some identified weaknesses in the country's surveillance system, including information and data sharing and organization and decision-making (www.cahss.ca) and to create an environment for collaboration on surveillance. Canada has a wide range of animal health surveillance systems across federal agencies, provinces, and the private sector/industry. CAHSS is a collaborative governance approach to link these independently functioning systems into a federated member driven "network of networks" for effective, responsive, and integrated animal health surveillance for the country. With full participation of all parties involved, the effort has core principles, communal ownership of the entity and is guided by a common Directors Group, enabled by a Champions Group and supported by a Coordinator and Secretariat. Key goals include: advise on national animal health surveillance priorities, facilitate data gathering, help people exchange and use information, help make information easily accessible, and help remove artificial barriers to animal health surveillance.

CAHSS implementation was initiated in January 2015, with the first several months spent establishing Champions and Directors groups, and creating an appropriate infrastructure to encourage collaboration on surveillance. Species/issue specific network groups are being added in a stepwise fashion. In brief, the process is to conduct 2 day workshops with key stakeholders, using Participatory Action Research to help the group develop a common vision, clarify priorities and develop some key action items. Workshops are followed up by regular conference calls with the purpose of putting plans into action. The following network groups have been established: swine, poultry, dairy, equine and antimicrobial use on farm. Beef, wildlife, and aquaculture workshops are anticipated in 2017 with small ruminants in the future.

A work in progress, the collaborative approach embraced by CAHSS is gaining momentum. The endeavor has facilitated awareness and communication, is identifying lessons learned, gaps, efficiencies and developing recommendations. The network groups are action oriented, they are collectively developing projects with a clear focus on addressing surveillance challenges, gaps and irritants. Some lessons learned of note were, everyone along the continuum needs to see benefit from engaging in the collaboration and a single surveillance system is not a successful avenue. Rather, integrating existing data systems, making full use of what is already available and filling gaps, enhancing communication for better exchange and use of information is

preferred. Also, the data and information platform should sit outside the government as this facilitates flexibility and timeliness. CAHSS does have a private side of the website for member groups to share information. Building networks requires trust and improved lines of communication, which is underpinned by human to human relationships.

Dairy Surveillance Workshops, as part of the CAHSS efforts were conducted in February and March 2017. There are many surveillance initiatives across Canada for dairy and the main need identified was to “knit” surveillance activities together and make better use of the data generated. Key priorities identified during these workshops were:

- Build the foundation with strong stakeholder engagement
- Create a national information sharing platform
- Build upon current data resources through data mining and integration
- Expand service across Canada for bulk milk tank screening tests for diseases of interest.

Engaging stakeholders up front and the people on the ground are critical to success. For example, dairy biosecurity is not an easy sell the risk of catastrophic disease entry is low, there are few diseases of major zoonotic consequence and many other daily responsibilities pull attention away from biosecurity issues. While there has been introduction/spread of “new” diseases events in the industry (e.g. digital dermatitis, Acute BVD, Johne’s disease, and Neosporosis) a lack of focus and/or purpose can be a challenge. The National Dairy Study 2015 found that dairy producers want to keep BVD, Johne’s disease and FADs (especially FMD) out of their farms³. The same survey showed the top 3 endemic diseases the industry is trying to control are *Staph aureus* mastitis, Digital Dermatitis, and ringworm.

The Canadian dairy system is supply-managed which provides opportunities as location of each farm is known, along with a large amount of other information that can be helpful in improved surveillance efforts. For example, 75% of dairy herds are enrolled in milk reporting which means linkages already exist to obtain laboratory data back, albeit this is not currently leveraged well for surveillance. Also, there are missed opportunities to readily provide slaughter data back to the producer/veterinarian and this needs to be integrated with other analyses.

There is a cost associated with conducting both active and passive surveillance, so engagement of all stakeholders, starting with producers and veterinarians is essential. It was also noted that technology will never replace “calling a friend”. When dairy practitioners identify the unusual, they will call whom they trust to provide the answers and support they need. Veterinary colleges and extension specialists can play a role here. Also, the emergency FAD simulation exercises done each year provide an opportunity for building communication links, relationships and familiarity.

³ <http://www.nationaldairystudy.ca/>

Session 4 concluded with a presentation on Managing Emerging Pathogens: Experience Gained with Hobi-like Viruses. Emerging viruses are especially concerning due to their propensity for genetic mutation/recombination, which increases virulence. They also jump species, and can cause significant losses when newly introduced into naïve populations. Newly recognized Hobi-like viruses is related to BVD and require improved surveillance and new detection methods.

BVD is a name for a wide-ranging assortment of clinical presentations caused by viruses from the pestivirus genus, a genus known for causing immunosuppression following acute infection and immunomodulation (can permanently alter immune responses). These viruses can cause similar clinical presentations in multiple hosts. Phylogenetic studies of viruses isolated following outbreaks of BVD demonstrate multiple species of pestivirus isolated from different outbreaks but they are indistinguishable from a clinical standpoint. Originally BVD was thought to be caused by just one species of pestivirus, referred to as bovine viral diarrhea virus (BVDV). Subsequently, genomic comparisons demonstrated that two distinct species of pestiviruses, BVDV1 and BVDV2, were associated with BVD in the US. More recently an emerging species of pestivirus, referred to variously as HoBi-like virus, atypical bovine pestivirus and BVDV3, has been associated with BVD in cattle in South America, Europe and Asia.

Specific reasons for concern with Hobi-like viruses include the following:

- The viruses are more prevalent globally than previously thought. For example, they may be the most prevalent cause of BVD in India.
- If introduced into the U.S. cattle herd, initial introduction will be costlier than the current significant economic losses due to BVDV1 and BVDV2.
- Fetal bovine serum (FBS) contaminated with the viruses poses significant risk to the U.S. cattle herd. Cell lines in ATCC and human vaccines can be contaminated with BVD because the fetus is not a sterile environment. Globally there is a large demand for North American and Australian FBS and these are more expensive than that produced in South America. There are inconsistent and confusing regulations for FBS and there are no regulations to stop bringing in South American FBS (which is cheaper).
- Current tests and vaccines used for BVDV1 and BVDV2 control are not efficacious against Hobi-like viruses and there are no commercial vaccines or tests available. Current commercial tests do not differentiate and it is difficult to identify representative samples.
- Similar to BVDV1 and BVDV2, Hobi-like viruses create persistently infected animals.

APHIS VS and ARS have a Memorandum of Understanding (MoU) that allowed access to a small number (1972) of serum samples taken at slaughter for brucellosis surveillance. This enabled the U.S. government to conduct a “snapshot” survey to ascertain if the U.S. cattle herd had been exposed to or had the Hobi-like viruses. Permission to use the samples was for research purposes only. The research project compared levels of neutralizing antibodies present against multiple isolates of BVDV1, BVDV2 and Hobi-like viruses. The 3 species are antigenically cross-reactive so comparative ratios were analyzed. There was no evidence that Hobi-like viruses are present in North America but based on serology, the national herd is unprotected. Other

considerations/conclusions from the project elucidated that while differential tests have been developed, they are not commercially available and the tests needed for regulatory activities may not be economically viable for a surveillance program. Also, Hobi-like vaccine would provide protection but would hamper sero-surveillance.

Considerations to protect the U.S. herd from Hobi-like viruses:

- Regulatory and control measures for the U.S. are currently under development. It was noted that there are no existing international standards and OIE does not recognize the viruses.
- Banked serum from U.S. brucellosis program disease surveillance is available. As previously noted, brucellosis surveillance is typically done at slaughter plants, so the banked samples provide a recent, representative source for testing for Hobi-like viruses. Continuing periodic snapshots is suggested.

Session 5: The Future and Next Steps

A very brief plenary discussion highlighted main points of the needs and direction of U.S. cattle surveillance. As APHIS continues planning and transitioning away from historical disease-specific surveillance, input from SAHOS, veterinarians, and producers is vital. Also, there are existing siloes of information that is not currently being shared. There was consensus that being able to share agreed upon pertinent information for disease surveillance and response is vital to understanding the scope of the event, and contributes to more rapid and successful response, control and eradication efforts. The participants agreed that data integration, linking systems together, and timely analysis were essential for success.

The idea of a syndromic surveillance group that gets practitioners together to discuss diseases they are seeing in the field was deemed valuable. The Academy of Veterinary Consultants (AVC) and AABP each have internal member list-servs that currently do this to a limited extent. The swine industry SHIC example was also discussed and a main agreed upon action item was for the industry groups to continue discussing the value of and implementation steps towards this concept for the cattle sector. There was support for conference calls with interested partners to brainstorm on this concept. The example provided via the Hobi-like viruses study, leveraging samples taken for existing endemic disease surveillance programs and utilizing those samples, when appropriate for better identifying emerging, re-emerging or FADs was of great interest to the group. Concern over diminishing TB and brucellosis samples as APHIS modifies those programs was noted.

Participants reiterated the timeliness of the workshop topics and importance of the issues discussed. Endemic, FAD, emerging and re-emerging diseases are a priority for both the beef and dairy sectors. The priority disease list is a good starting place and risk assessments should further inform. The gaps identified in the breakout session 1 were comprehensive and extensive. Biosecurity challenges for open systems such as cattle operations require further discussions, but participants agreed that many industry and other biosecurity guidance resources currently exist

and should be built upon. The human component transcended all topics and plays an important role in the success or failure of biosecurity, surveillance, and all aspects of prevention, preparedness and response programs for cattle diseases. These programs must also not hinder business operations or negatively impact the speed of commerce. Participants concluded with consensus that discussions on the issues identified during the workshop should continue.

Acknowledgements

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Appendix A: Workshop Participants

First Name	Last Name	Organization
Michael	Barnes	Agri-Mark
Melissa	Berquist	Institute for Infectious Animal Diseases
Danelle	Bickett-Weddle	Center for Food Security & Public Health University of Florida, Institute of Food and Agricultural Sciences, RCREC
Raoul	Boughton	MRIGlobal
Joseph	Carrano	USDA APHIS Veterinary Services
Michael	Carter	DHS
Matthew	Coats	DHS S&T HSARPA CBD
Michelle	Colby	USDA – APHIS – VS-National Import Export Services
Michael	David	USDA – APHIS – VS-National Import Export Services
Mark	Davidson	USDA-APHIS-VS-Center for Epidemiology and Animal Health
Chuck	Fossler	American Association of Bovine Practitioners
Fred	Gingrich	Kansas State University
Jean-Paul	Gonzalez	CattleFax
Kevin	Good	University of Nebraska - GPVEC
Dale	Grotelueschein	National Cattlemen's Beef Association
Jimmy	Holliman	Nebraska Department of Agriculture
Dennis	Hughes	Canadian Food Inspection Agency
Cheryl	James	National Milk Producers Federation
Jamie	Jonker	National Milk Producers Federation and Dairy Farmers of America
Karen	Jordan, DVM	University of Guelph
David	Kelton	National Cattlemen's Beef Association
Mary Ann	Kniebel	National Cattlemen's Beef Association
Dan	Kniffen	DHS-CBP-APTL
Romelito	Lapitan	MacArthur Agro-Ecology Research Center, Buck Island Ranch
Gene	Lollis	United Fresh Produce Association
Julie	Manes	Institute for Infectious Animal Diseases
Heather	Manley	Indiana State Board of Animal Health
Bret	Marsh	Kansas Department of Agriculture
Jackie	McClaskey	USDA APHIS Veterinary Services
Brian	McCluskey	Canadian Cattlemen's Association
Rob	McNabb	DHS S&T
Roxann	Motroni	South Dakota Animal Industry Board
Dustin	Oedekoven	USDA - ARS
David	Oi	USDA APHIS Veterinary Services
Kathy	Orloski	Institute for Infectious Animal Diseases
Elizabeth	Parker	Institute for Infectious Animal Diseases
Gerald	Parker	Maryland & Virginia Milk Producers Cooperative
Lindsay	Reames	Kansas State University
Juergen	Richt	Ridpath Consulting
Julia	Ridpath	Colorado Department of Agriculture
Keith	Roehr	Department of Homeland Security
Dana	Saft	

John	Sagle	DHS-CBP-APTL
Michael	Sanderson	Kansas State University
Andy	Schwartz	Texas Animal Health Commission
Jeffrey	Silverstein	USDA - ARS
Kathy	Simmons	National Cattlemen's Beef Association
David	Sjeklocha, DVM	Cattle Empire, LLC
Jan	Slingenbergh	International Expert
David	Smith	Division of Animal Industry, New York State Department of Agriculture and Markets
Bob	Smith	USDA – National Institute of Food and Agriculture
Darrel	Styles	USDA APHIS Veterinary Services
Beth	Thompson	Minnesota Board of Animal Health
Willy	Valdivia	Orion Integrated Biosciences
Jessica	Watson	National Cattlemen's Beef Association
Bill	Wavrin, DVM	AABP/NMPF
Rachel	Whisenant	Institute for Infectious Animal Diseases
Mark	Wustenberg	National Milk Producers Federation

Appendix B: Complete Agenda

Monday, March 13, 2017 | House Committee on Agriculture Room 1300

5:00 Keynote Reception

Tuesday, March 14, 2017 | Potomac Room

7:30 – 8:30 am Buffet Breakfast
8:30 – 11:00 am Session 1: What are we doing? What do we know (and don't know)?
11:00 – 11:20 am Break
11:20 am – 12:40 pm Session 1 Continued
12:40 – 1:00 pm Breakout 1: Group Discussion
1:00 – 1:40 pm Buffet and Working Lunch
1:40 – 2:10 pm Breakout 1: Groups Reports and Plenary Discussion
2:10 – 3:45 pm Session 2: Lessons Learned and Impact/Real Life and Other Factors
3:45 – 4:00 pm Break
4:00 – 4:40 pm Breakout 2: Group Discussion
4:40 – 5:15 pm Breakout 2: Groups Reports and Plenary Discussion
5:15 – 5:30 pm Wrap-up Day 1
5:30 pm Conclude Day 1, Free Evening

Wednesday, March 15, 2017 | Potomac Room

7:30 – 8:30 am Buffet Breakfast | Potomac Room
8:30 – 10:45 am Session 3: What do we have and why? What do we need and why?
10:45 – 11:00 am Break
11:00 am – 12:45 pm Session 4: Food for Thought
12:45 – 1:00 pm Working Break
1:00 – 1:30 pm Session 5: The Future and Next Steps
1:30 pm Conclude Workshop

Session 1: What are we doing? What do we know (and don't know)?

Moderator: Roxann Motroni, DVM, Ph.D., Department of Homeland Security (DHS) Science and Technology (S&T) Directorate, Chemical and Biological Defense (CBD) Division, Agriculture Defense Branch Program Manager

This session is intended to provide an overview of current U.S. government programs and approaches to identifying and preventing FAD/TADs and pathogen risks of entry into the U.S., and provide workshop participants improved knowledge of trade as it pertains to commodity movement and economic trends that ultimately impact dairy/beef animal health and management decisions as well as economic viability of the agriculture industries. Collectively, the speakers will provide a more holistic picture that will inform the formulation of a prioritized priority cattle disease list developed by workshop participants during the ensuing breakout discussion and assist discussion regarding potential pathogen import risks and gap identification.

Tuesday, March 14, 2017 | Potomac Room

- | | |
|-------------------------|--|
| 8:30 – 8:35 am | Opening of Workshop Elizabeth Parker, DVM, Institute for Infectious Animal Diseases (IIAD) Chief Veterinarian |
| 8:35 – 10:00 am | Welcoming Remarks Michelle Colby, DVM, MS, DHS S&T Directorate, CBD Division, Agriculture Defense Branch Chief
Self Introductions Workshop Participants |
| 10:00 – 10:10 am | National Milk Producers Federation (NMPF) Perspectives Karen Jordan, DVM, Chair, NMPF Animal Health Committee |
| 10:10 – 10:20 am | National Cattlemen's Beef Association (NCBA) Perspectives Kathy Simmons, DVM, NCBA Chief Veterinarian |
| 10:20 – 10:30 am | American Association of Bovine Practitioners (AABP) Perspectives Fred Gingrich, DVM, AABP Executive Vice President |
| 10:30 – 11:00 am | Current Challenges Posed by Transboundary Diseases Brian McCluskey, DVM, Ph.D, M.S., USDA APHIS Associate Deputy Administrator |
| 11:00 – 11:20 am | Break |
| 11:20 – 11:45 am | Trade and Economics Kevin Good, Senior Analyst, CattleFax |
| 11:45 – 12:15 am | Overview of Current US Government Import Process
Mark Davidson, DVM, MS, USDA APHIS Veterinary Services (VS) National Import Export Services (NIES) Associate Deputy Administrator |

Kevin Harriger, DHS Customs and Border Protection Agriculture Programs and Trade Liaison/Office of Field Operations Executive Director

12:15 – 12:40 pm

Risk Identification/Risk Assessment for Foreign Animal and Emerging Diseases | Darrell Styles, DVM, Ph.D, USDA APHIS VS Science Technology and Analysis Services Risk Identification/Risk Assessment Staff

12:40 – 1:00 pm

Breakout 1: Group Discussion

1:00 – 1:40 pm

Buffet and Working Lunch

1:40 – 2:10 pm

Breakout 1: Groups Reports and Plenary Discussion

Session 2: Lessons Learned and Impact/Real Life and Other Factors

Moderator: Fred Gingrich, DVM, AABP Executive Vice President

This session is intended to provide a few lessons learned and other perspectives along the livestock food chain in North America. Animal health events have a ripple effect from farm to consumer and impact a large range of interconnected sectors – each with their own perceptions, consequences and needs. The beef and dairy cattle sectors operate in open environments, have increased potential wildlife/livestock interfaces as compared to other more vertically integrated livestock sectors and have a wider arrange of size and business operation structures. The breakout group discussion will focus on biosecurity and is intended to improve collective understanding on this complicated topic.

Tuesday, March 14, 2017 | Potomac Room

2:10 – 2:30 pm	Lessons Learned from Indiana Bret Marsh, DVM, Indiana State Veterinarian
2:30 – 2:50 pm	Market Implications and Consumer Reactions to Disease Outbreaks Angie Siemens, Ph.D, Cargill Vice President of Food Safety, Quality and Regulatory (tentative)
2:50 – 3:20 pm	Canadian Cattlemen’s Association Perspectives on Canada’s On-Farm Biosecurity Standards Rob McNabb, Canadian Cattlemen’s Association General Manager
3:20 – 3:45 pm	National Animal Health Monitoring System (NAHMS) as an Information Source on Biosecurity on U.S. Cattle Operations Chuck Fossler, DVM, Ph.D., USDA APHIS VS Centers for Epidemiology and Animal Health (CEAH) NAHMS Veterinary Epidemiologist
3:45 – 4:00 pm	Break
4:00 – 4:40 pm	Breakout 2: Group Discussion
4:40 – 5:15 pm	Breakout 2: Group Reports and Plenary Discussion
5:15 – 5:30 pm	Wrap-up Day 1 Melissa Berquist, Ph.D., IIAD Director
5:30 pm	Conclude Day 1 Free Evening

Session 3: What do we have and why? What do we need and why?

Moderator: Jamie Jonker, Ph.D., NMPF Vice President for Sustainability and Scientific Affairs

This session is intended to provide lessons learned from historical U.S. regulatory and voluntary surveillance programs, an overview our U.S. international obligations as a World Organisation for Animal Health (OIE) member country and lessons learned from the citrus industry. Participants will also gain an understanding of current USDA surveillance program structures, technical needs and perspectives towards the future.

Wednesday, March 15, 2017 | Potomac Room

- 8:30 – 8:40 am** **Brief Recap and Summary of Day 1, Goals for Day 2** | Elizabeth Parker, DVM, IAD Chief Veterinarian
- 8:40 – 10:10 am** **Panel: Historical U.S. Cattle Surveillance Programs and Lessons Learned**
- Michael Carter, DVM, MPH, USDA APHIS VS Surveillance, Preparedness and Response Services (SPRS) Cattle Health Center Assistant Director
 - Andy Schwartz, DVM, Texas State Veterinarian
 - Mark Wustenberg, DVM, Tillamook Vice President of Producer Relations, NMPF
 - Bill Wavrin, DVM, Dairy Producer, AABP, NMPF
 - Julie Manes, United Fresh Produce Association Director of Government Relations
- 10:10 – 10:40 am** **Current USDA Surveillance |**
- Langston Hull, DVM, Ph.D., USDA APHIS SPRS Cattle Health Center Director
- Kathy Orloski, DVM, MS, Diplomate, ACVPM, USDA APHIS Veterinary Services Centers for Epidemiology and Animal Health Epidemiologist/Veterinary Medical Officer
- 10:40 – 10:45 am** **Summary of Pertinent OIE Surveillance Recommendations |**
Michael David, DVM, MPH, USDA APHIS VS NIES Director of International Animal Health Standards Unit
- 10:45 – 11:00 am** **Break**

Session 4: Food for Thought

Moderator: Jamie Jonker, Ph.D., NMPF Vice President for Sustainability and Scientific Affairs

This session is intended to provide information on Canada's current efforts regarding animal health surveillance and experience gained on emerging pathogens such as Hobi-like viruses with lessons learned, focusing on key points of trends. The plenary group will then focus on initiating discussions towards collectively identifying and defining appropriate, effective and risk-based priority disease surveillance needs for protecting the U.S. cattle industry.

Wednesday, March 15, 2017 | Potomac Room

- | | |
|------------------|--|
| 11:00 – 11:30 am | Overview of Canadian Animal Health Surveillance System
Cheryl James, DVM, MS, Canadian Food Inspection Agency National
Coordination of Surveillance |
| 11:30 – 11:45 pm | Canada's Dairy Industry: Surveillance Challenges and
Opportunities David Kelton, DVM, Ph.D., University of Guelph Dairy
Farmers of Ontario Research Chair in Dairy Cattle Health |
| 11:45 – 12:15 pm | Managing Emerging Pathogens: Experience Gained with Hobi-
like Viruses Julia Ridpath, Ph.D., Ridpath Consulting, LLC |
| 12:15 – 12:45 pm | Plenary Group Discussion |
| 12:45 – 1:00 pm | Working Break |

Session 5: The Future and Next Steps

Moderator: Elizabeth Parker, DVM, IIAD Chief Veterinarian

Wednesday, March 15, 2017 | Potomac Room

1:00 – 1:30 pm **Recap of Morning Discussions** | Melissa Berquist, Ph.D., IIAD
Director

Workshop Recommendations | Elizabeth Parker, DVM, IIAD Chief
Veterinarian

1:30 pm **Conclude Workshop**

Appendix C: Keynote Speaker biography

Jan Slingenbergh, DVM retired in 2012 as Head of the Emergency Prevention System for Transboundary Animal and Plant Pests and Diseases (EMPRES) - Animal Health, for the Food and Agriculture Organization of the United Nations (FAO). Over the course of Jan's expansive career, his significant contributions to improving animal and human health have been a holistic and comprehensive approach that ranged from the science behind disease outbreaks to applied solutions in the field, and formulating/implementing regional and global strategies.

Specializing in parasitology and entomology, Slingenbergh's field work initially concentrated on the control of tropical protozoan diseases and insect pests in countries in western, southern and eastern parts of Sub-Saharan Africa. He spent the 1980s in Benin, Mozambique and Ethiopia, where he was involved in a wide range of veterinary/public health topics including laboratory capacity development, tsetse and trypanosomoses, and transboundary livestock disease control.

During the 1990s and 2000s, he coordinated FAO's response to Old World screwworm control and prevention in the Arabian peninsula and acted as FAO's focal point Secretariat of the Programme against African Trypanosomosis, (a global alliance involving FAO, the World Health Organization, the African Union Interafrican Bureau for Animal Resource and the International Atomic Energy Agency). He also worked on clarifying how foot-and-mouth disease, peste des petits ruminants and sheep and goat pox viruses spread through South Asia, the Middle East and the eastern Mediterranean basin.

During this time Slingenbergh also served on the global management team to redress the H5N1 highly pathogenic avian influenza panzootic and he guided the research efforts that established the role of rice-duck farming in the emergence and spread of novel avian influenza viruses in South-East and East Asia. He contributed to the final stage of the Global Rinderpest Eradication Programme - providing strategic leadership which culminated in the 2011 official declaration of global freedom from rinderpest.

An author of more than fifty scientific papers covering infectious and parasitic livestock diseases and now living in Germany, Slingenbergh remains active in efforts to understand disease ecology and global drivers of new emerging livestock diseases. Upon retirement he was editor and main author of the FAO flagship publication entitled '[Changing Disease Landscapes](#)'. He is currently focusing on technical and policy work related to disease ecology - specifically, on One Health and the drivers and transmission ecology of disease emergence at the human-animal-ecosystem interfaces.

Appendix D: Session 1 Breakout Group Handout

Breakout Group 1

12:40 to 1:00 pm

Tuesday May 14, 2017

Blue Group

Location: Potomac

Group Leader: Mike Sanderson, KSU

Scribe: Heather Manley, IAD

Green Group

Location: DuPont

Group Leader: Kathy Simmons, NCBA

Scribe: Melissa Berquist, IAD

Discussion Questions Breakout Group Discussion 1:

a) Formulating the list- What priority foreign animal, emerging or re-emerging cattle diseases should the U.S. address, worry about, plan for?

b) Improving the knowledge and process for transparent risk-based decisions and prevention of transboundary and emerging priority cattle diseases – what are the gaps? What does the US government need?

Top Diseases by Commodity Identified Through the 2015 ARS Survey

Beef

Bovine Respiratory Syncytial Virus (BRSV), Bovine Spongiform Encephalopathy (BSE), Bovine TB, Bovine Viral Diarrhea (BVD), Brucellosis, Coccidiosis, Foot and Mouth Disease (FMD), Infectious Bovine Rhinotracheitis (IBR), Intestinal Parasites, Mannheimia haemolytica, Pasteurella multocida,

Dairy

Bovine Leukemia Virus (BLV), Bovine Respiratory Syncytial Virus (BRSV), Bovine Viral Diarrhea (BVD), Bovine TB, Coccidiosis, Foot and Mouth Disease (FMD), Mannheimia haemolytica, Mastitis, Mycoplasma bovis, M. paratuberculosis (Johnes), Pasteurella multocida

Background Handouts (hard copies available in room):

1. “Emerging Disease Threats to the U.S. Cattle Industry” - AABP Biological Risk Management and Preparedness Committee (BRMP) (pdf)
2. APHIS Jan 2017 National Reportable Disease List
https://www.aphis.usda.gov/animal_health/nahrs/downloads/2017_nahrs_dz_list.pdf
3. APHIS High Consequence FAD & Pest Fact Sheet
4. APHIS VS Proposed Framework for Emerging An Dz’s July 2014
5. APHIS Cattle Health Business Plan FY 2014 - 2018

Appendix E: Pre-workshop Survey

PROTECTING THE U.S. CATTLE HERD:

A Workshop Towards Improving Knowledge of Transboundary and Emerging Priority Cattle Diseases

PRE-WORKSHOP SURVEY

1. What do you hope to gain by attending this workshop?

2. What are your main concerns regarding **the U.S.' cattle health surveillance system(s)' ability to quickly detect a foreign animal, emerging, or re-emerging disease event?**

3. What specific concerns do you have about biosecurity knowledge or practices in terms of **preventing or limiting foreign animal, emerging, and/or re-emerging disease of cattle** in the U.S. and North America?

4. Please rate your knowledge of biosecurity practices **in your sector** prior to attending this workshop:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not at all knowledgeable	Not very knowledgeable	Somewhat knowledgeable	Very knowledgeable	Extremely knowledgeable

5. Please rate your current knowledge of the role of **each of the other sectors'** biosecurity contributions in daily cattle health management and prevention in response to endemic, foreign animal, emerging, and re-emerging diseases:

	Not at all knowledgeable	Not very knowledgeable	Somewhat knowledgeable	Very knowledgeable	Extremely knowledgeable	N/A
Beef Producers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dairy Producers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Private Veterinarians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
State Animal Health Officials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Federal Animal Health Officials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wildlife Authorities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix F: Post-Workshop Survey

PROTECTING THE U.S. CATTLE HERD:

A Workshop Towards Improving Knowledge of Transboundary and Emerging Priority Cattle Diseases

POST-WORKSHOP SURVEY

1. This workshop met my expectations.

Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree

Comments: _____

2. The workshop format was organized into a combination of speakers, breakout sessions, and regroup plenary sessions. In my opinion, this was an effective format for the workshop.

Strongly Agree Agree Neither Agree nor Disagree Disagree Strongly Disagree

Comments: _____

3. To what extent did this workshop contribute to relationship-building across different sectors (beef producers, dairy producers, private veterinarians, state animal health officials, federal animal health officials, academia, etc.)?

To a great extent Somewhat Very little Not at all

Comments: _____

4. Please rate your knowledge of biosecurity practices **in your sector** after attending this workshop:

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Not at all knowledgeable	Not very knowledgeable	Somewhat knowledgeable	Very knowledgeable	Extremely knowledgeable

Comments: _____

5. After attending this workshop, please rate your current knowledge of the role of **each of the other sectors'** biosecurity contributions in daily cattle health management and prevention in response to endemic, foreign animal, emerging, and re-emerging diseases:

	Not at all knowledgeable	Not very knowledgeable	Somewhat knowledgeable	Very knowledgeable	Extremely knowledgeable	N/A
Beef Producers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dairy Producers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cooperatives and Milk Processors	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Private Veterinarians	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
State Animal Health Officials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Federal Animal Health Officials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wildlife Authorities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. After attending this workshop, what are your main concerns regarding the U.S.' cattle health surveillance system(s)' ability to quickly detect a foreign animal, emerging, or re-emerging disease event?

Please list the top 3 gaps that should be prioritized to address these concerns:

1.

2.

3.

7. What other endemic, foreign animal, emerging, or re-emerging diseases should be the focus of future workshops?

8. Please describe ways we can improve this workshop and others like it for future attendees:

Appendix G: Cattle workshop survey results

Methods

A web survey was created for the pre-test to measure knowledge of and concerns about biosecurity practices across industries and identify main concerns regarding the U.S. cattle health surveillance system(s) ability to quickly detect a foreign animal, emerging, or re-emerging disease event. Thirteen (13) completed surveys were received. For the post-test, congruent web and paper surveys were created to allow participants to respond in the format of their preference. In addition to the questions from the pre-test, further questions were added to capture participant satisfaction with workshop format, content, and contribution to relationship-building across industries. Also, participants were asked to identify priority gaps to address surveillance concerns discussed during the workshop and suggest related topics for future workshops. Eight paper surveys and eight web surveys were received, totaling 16. From pre-test to post-test, eight respondents completed both a pre- and post- survey, equating to a retention rate of 62.5%. Eight participants who did not complete a pre-survey submitted a post-survey.

Results

Paired t-tests to compare differences in the scores for pre-test and post-test were performed for Q5 ("Please rate your knowledge about biosecurity practices in your sector...") and Q6 ("After attending the workshop, please rate your knowledge of the role of each of the other sectors' biosecurity contributions..."), with $\alpha=.05$.

For Q5, the results indicate not a significant difference in the scores for pre-survey (M=3.62, SD=0.74) and post-survey (M=3.75, SD=0.46); $t(8)=0.35$, $p=0.18$. This suggests that the workshop did not have an effect on participants' knowledge of their own sectors. This is not unexpected as most respondents felt knowledgeable on their sector prior to the workshop.

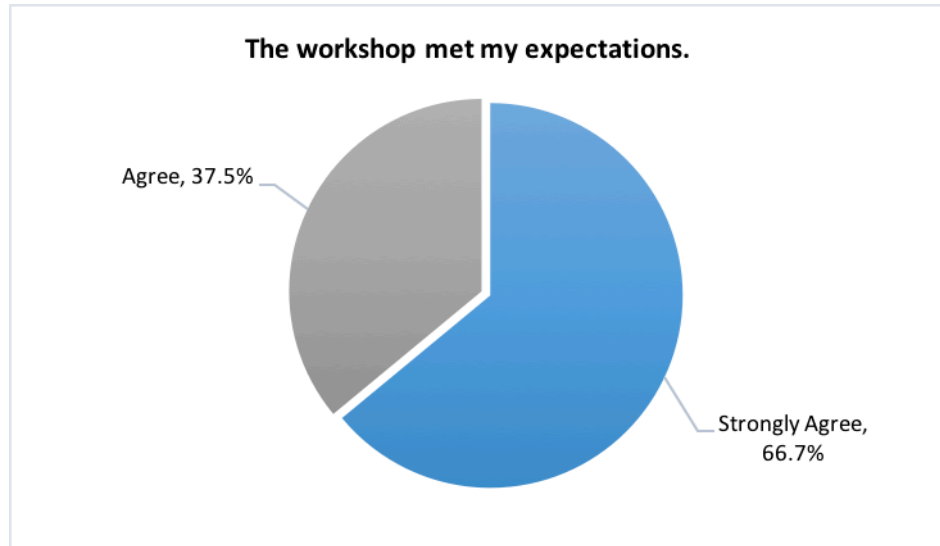
For Q6, results indicate not a significant difference in the scores for pre-survey and post-survey for all industries except for private veterinarians. This suggests that the workshop did not have an effect on each participants' knowledge of biosecurity contributions in daily cattle health management and prevention in response to endemic, foreign animal, emerging, and re-emerging diseases for each of the other defined sectors: Beef, Dairy, State Animal Health Officials, Federal Animal Health Officials, and Wildlife officials.

However, for Private Veterinarians, there was a significant difference in the scores for pre-survey (M=2.88, SD=0.9) and post-survey (M=3.43, SD=0.53); $t(7)=1.92$, $p=0.05$. This suggests that the workshop did have an effect on participants' knowledge of private veterinarians' biosecurity contributions in daily cattle health management and prevention in response to endemic, foreign animal, emerging, and re-emerging diseases.

The tables and figures on the following pages display the results for each question of the survey, comparing pre-survey values to post-survey values, where applicable. Please note that these results are for the entire group of respondents, and therefore may differ slightly from the figures calculated for the paired statistical tests (which are calculated based on the sample of respondents who completed both pre- and post-surveys).

Biosecurity knowledge, surveillance concerns, priority gaps to be addressed and related topics for future discussions provide valuable information for potential future workshops to benefit the U.S. beef and dairy sectors, animal health authorities, research and protection of the U.S. cattle herd.

Q2. This workshop met my expectations.



Response	Response Percent	Response Count
Strongly Agree	66.7%	10
Agree	37.5%	6
Neither Agree nor Disagree	0.0%	0
Disagree	0.0%	0
Strongly Disagree	0.0%	0

Comments:

- Very interesting series of talks. Looks like there are lots of possibilities, now we just have to figure out how to do it.
- A very good presentation of the issues, concerns and significant gaps.
- It was an information-packed day and a half.
- Actually surpassed my expectations.
- Well organized.
- All speakers/topics were important for me, in my role. As we continue the conversation with dairy/beef, much of the information can be used.

Q3. The workshop format was organized into a combination of speakers, breakout sessions, and regroup plenary sessions. In my opinion, this was an effective format for the workshop.

Response	Response Percent	Response Count
Strongly Agree	43.8%	7
Agree	56.3%	9
Neither Agree nor Disagree	0.0%	0
Disagree	0.0%	0
Strongly Disagree	0.0%	0

Comments:

- Maybe not enough time for group discussion. Break outs help but by nature you don't get a full discussion.
- Clearly, while everyone engaged, more time was needed to fully flesh out some of the thinking and ideas.
- Although they added, there was a "maximum" number of speakers - could have held that down some.
- Great speakers and information that can go forth to - USAHA/NIAA.

Q4. To what extent did this workshop contribute to relationship-building across different sectors (beef producers, dairy producers, private veterinarians, state animal health officials, academia, etc.)?

Response	Response Percent	Response Count
To a great extent	62.5%	10
Somewhat	37.5%	6
Very Little	0.0%	0
Not at All	0.0%	0

- I believe industry should have a break out session to discuss industry gaps that might be slowing the process.
- I feel I don't have adequate knowledge of the industries represented to reply here.
- Meetings, especially smaller ones, are always a great forum for relationship building.
- I knew the majority of the people there beforehand, but the group sessions required us to work together and helped to cement those relationships.
- Great interaction between all involved.
- Weather unfortunately interfered.
- Still are some that don't get it.

Q5. Please rate your knowledge about biosecurity practices in your sector after attending this workshop:

Response	Pre-Test	Post-Test
Not at all knowledgeable (1)	0.0%	0.0%
Not very knowledgeable (2)	23.1%	6.3%
Somewhat knowledgeable (3)	23.1%	25.0%
Very knowledgeable (4)	46.2%	68.8%
Extremely knowledgeable (5)	7.7%	0.0%

Comments:

- I know a lot about biosecurity, but I am woefully ignorant of how well it's instituted by the majority of producers.

Q6. After attending the workshop, please rate your knowledge of the role of each of the others sectors' biosecurity contributions in daily cattle health management and prevention in response to endemic, foreign animal, emerging, and re-emerging diseases:

Answer Options	Pre-Test	Post-Test
Beef Producers	3.00	3.00
Dairy Producers	3.25	3.13
Cooperatives and Milk Processors	n/a	3.25
Private Veterinarians	3.17	3.50
State Animal Health Officials	3.55	4.07
Federal Animal Health Officials	3.54	3.80
Wildlife Authorities	2.27	2.54

Q7. After attending this workshop, what are your main concerns regarding the U.S.' cattle health surveillance system(s)' ability to quickly detect a foreign animal, emerging, or re-emerging disease event?

Concern	Pre-Test		Post-Test	
	Frequency	Pre-Test	Frequency	Post-Test
National ID/ Traceability	5	38%	5	31%
Disease Detection	5	38%	2	13%
Lack of Adequate Surveillance systems	2	15%	2	13%
Sufficient Technology	2	15%	1	6%
Communication During Outbreak	2	15%	2	13%
Lack of Workforce	2	15%	1	6%
Testing Capabilities	1	8%	1	6%
Sampling for Disease	1	8%	0	0%
Response speed vs. Rapid spread	1	8%	1	6%
Knowledge/Awareness in Industry	1	8%	1	6%
Lack of Funding/ Resources	0	0%	5	31%

Q8. List the top 3 gaps that should be prioritized to address these concerns:

Gap	Frequency	Percentage
ID/ Traceability	6	38%
Education	4	25%
Information Sharing and Data Transfer/Linkages	4	25%
Research	4	25%
Collaboration	4	25%
Funding	3	19%
Enhanced and Targeted Surveillance	2	13%
Emergency Response Planning	1	6%

Q9. What other endemic, foreign animal, emerging, or re-emerging diseases should be the focus of future workshops?

Comments:

- Maybe not so much anyone disease but focus on approaches to surveillance and new detection methods
- In my opinion, we built a strong list of diseases that we should focus on first. We should build the surveillance system around these and once the system is in place develop a screening process that ranks potential other diseases in risk categories of high, medium, and low. This allows the experts to add to the surveillance program as other are eradicated or surveillance lessens.
- Perhaps form a small working group of individuals that are working on these issues for their particular industry, to come to an agreement on a plan, and formulate recommendations for implementation across the cattle industry.
- While pathogens of concern (known and unknown) are important, it is the system in place to detect them that is critical.
- Parasiticide and antimicrobial resistance. But we shouldn't walk away from the current issues too quickly.
- MDR Salmonellae
- Think you've covered it
- HOBI-like
- Although it would be useful to have updates on many, the next species of interest is swine.

Q10. Please describe ways we can improve this workshop and others like it for future attendees:

Comments:

- I thought that it was very well done. I have no suggestions
- Focus more on how others have solved these issues in their state or country (like Indiana's premise ID program or Canada's health information network). How does the UK/Europe handle these issues?
- I think this workshop was very good for the first one. Things that I would suggest for future meetings are:
 - Lay out a clear set of Objectives and desired outcomes for the meeting.
 - Make sure these goals and outcomes are circulated before the meeting.
 - make sure meeting stays on point and develops toward outcomes desired
 - Have an industry break out
- Keynote speaker should not be on a separate day/location
- If the goal of future meetings is to make advances in planning for implementation, then more time for breakouts with the expectation the breakout groups will develop actionable next steps. An iterative process - with not only face to face meetings, but perhaps also conference calls in between.
- Would suggest the same amount of material ... but dedicating two full days to cover it.
- Just announce it further in advance.

Appendix H: Background/Supplemental Documents used during workshop and provided to Participants

This page intentionally left blank. See subsequent pages for background documents.

Title: Emerging Disease Threats to the U.S. Cattle Industry

Recent outbreaks of disease in the poultry (HPAI) and swine industry (PEDv/PCoV) highlight the need for surveillance and timely control intervention. These disease introductions place the viability of U.S. livestock enterprises at substantial production and economic risk. Early identification and control are essential for maintaining the strength of U.S. agriculture. As such, plans for early identification of pathogens of concern before entry to the U.S. or early after introduction is essential. The AABP Biological Risk Management and Preparedness Committee has considered and discussed future surveillance needs for the cattle industries in the U.S. This report attempts to briefly identify some agents of concern for cattle and issues that need to be addressed and recommends data gap analysis and risk assessment to prioritize agents of concern.

Date: September 16, 2016

Purpose: Identify agents and issues of concern for surveillance of emerging disease threats to the U.S. cattle industries.

Agents of concern:

Known agents of concern for cattle include:

Hobi-like virus imported through either cattle or bovine products particularly fetal bovine serum. Hobi-like virus appears common in South America and has been detected in other parts of the world potentially spread from South America. The magnitude of risk for importation into the U.S. is not known, however fetal bovine serum from South America is a clear risk. Current commercially available diagnostics will not reliably detect Hobi-like virus so a prerequisite of effective surveillance is development of a reliable test that can be used for detection.

Vector-borne diseases are generally of concern. Bluetongue virus (BTV-8) and Schmallenberg virus have emerged in Europe recently and emergence in the U.S. could have substantial impact. Arboviruses in general may be of concern and development of a diagnostic platform that would detect highly conserved "backbone" regions could be valuable for global surveillance and detection.

Lumpy Skin Disease (LSD) is of concern, having emerged from historic sites into central Asia and more recently Eastern Europe including Greece, Albania, Montenegro, Bulgaria, Kazakhstan, Serbia, Russia and Romania. Continued movement of LSD across Europe is of concern.

Endemic agents of concern for expansion of range or prevalence include *Anaplasma* and *Tritrichomonas foetus*.

Unknown agents of concern:

Of concern here are agents that are circulating somewhere in the world but are currently not recognized as threats. Porcine epidemic diarrhea virus (PEDV) in swine is a recent example that demonstrates this concern. Addressing pathogens in this category would require some formal method of monitoring novel or significant disease occurrence world-wide to allow early

recognition and preparation. It is inherently difficult to predict which of these agents might emerge elsewhere. Surveillance needs to include passive monitoring of disease outbreaks (through such avenues as Pro-Med mail, GLEWS, EMPRES) as an early warning system. Subsequent and ongoing Risk Assessment of most likely introductions and potential impact should inform further surveillance and testing.

Issues to address

Initially, a data gap analysis and risk assessment to identify the agents of greatest concern from both an introduction probability and impact of introduction should be undertaken to guide the application of resources to the most important risks. Specifically the risk of entry to the U.S./North America, Risk of establishment (e.g., competent hosts and vectors) and impact of introduction/establishment should be assessed.

If the agents identified by the risk analysis require a testing protocol to manage risk, development of diagnostic assays capable of accurately identifying the agent of concern in surveillance samples will be required if not already available. A clear plan for how positives will be managed including the impact of positives on the trade status of the U.S., possibility of and or criteria for regionalization, should be thoroughly considered prior to implementation of any testing plan.

Specific Agents and Issues:

Hobi-Like Virus

Introduction Probability – potentially significant through fetal bovine serum

Introduction Impact – unknown, potentially substantial

Availability of Diagnostics – BVDV diagnostics do not reliably detect Hobi-like viruses. Commercial diagnostics not available. Research diagnostics have been developed.

Consequence/plan following detection of a U.S. positive

BTV-8

Introduction Probability – unknown

Introduction Impact – potentially substantial

Availability of Diagnostics – Commercially available in EU

Consequence/plan following detection of a U.S. positive

Schmallenberg

Introduction Probability – unknown

Introduction Impact - potentially substantial

Availability of Diagnostics – commercially available in EU, unknown status in U.S.

Consequence/plan following detection of a U.S. positive

Lumpy Skin Disease

Introduction Probability – unknown

Introduction Impact - substantial

Availability of Diagnostics – unknown

Consequence/plan following detection of a U.S. positive



United States Department of Agriculture

**Statement of Kevin Shea
Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture**

Before the Senate Committee on Homeland Security and Governmental Affairs

April 5, 2016

Chairman Johnson, Ranking Member Carper, and Members of the Committee, I appreciate the opportunity to appear before you today to discuss the importance of ensuring that the United States is prepared to prevent, detect, and respond to both natural and intentional biological threats.

Safeguarding against significant plant and animal pests and diseases—ranging from avian influenza to the European grapevine moth—is vital to protecting industry, producers, export markets, and consumers, and ensuring that we have a safe and secure food supply. It remains a top priority for the U.S. Department of Agriculture (USDA), and is something we at the Animal and Plant Health Inspection Service (APHIS) are committed to every day.

Pests and diseases highlight the importance of our “One Health” approach to coordinating efforts across the government to protect human and animal health. According to the Centers for Disease Control and Prevention (CDC), about 75 percent of recently emerging infectious diseases affecting humans originate in animals. And approximately 60 percent of all human pathogens are zoonotic. The work that APHIS and its partners undertake to protect U.S. agricultural health provides benefits far beyond the fields and farms.

The impact of pests and diseases on the U.S. economy can be staggering. The outbreak of highly pathogenic avian influenza (HPAI) last year—which was the largest animal disease outbreak in U.S. history—cost U.S. taxpayers nearly \$1 billion just in response, clean up, and indemnity costs. That didn’t include lost export markets, temporary shortages, or price increases for certain poultry and their products.

Threats to U.S. agricultural health can come from a number of places—hitchhiking pests imported on cargo or ships, a traveler bringing food from overseas, a sick animal or pet being brought from overseas, or even nefarious attempts at agro terrorism. In addition, pests and diseases that enter the country can spread either by people, on commodities and other products, or on modes of transportation, such as automobiles or campers. Regardless of the intent or mode of entry, APHIS’ focus is on putting in place preventive measures to keep pests and diseases out of the country, finding them if they do enter, as well as preparing for these threats, detecting them, and taking emergency action if necessary.

APHIS has a wide breadth of expertise and experience in protecting U.S. agriculture from plant and animal pests and diseases. From our cadre of veterinarians to our plant pathologists, wildlife biologists, entomologists, epidemiologists, and microbiologists, we have a strong scientific infrastructure that informs our decision making and actions. The relationships we have built

with our partners in this effort also serve to strengthen our protections against pests and diseases. We work closely with state departments of agriculture and natural resources, local governments, tribal partners, stakeholder groups, and federal agencies including the Centers for Disease Control and Prevention, Food and Drug Administration, and Department of Homeland Security.

To protect America's agriculture, environment, and food security, APHIS and its partners maintain a comprehensive system of overlapping safeguards that operate overseas, at U.S. ports of entry, and within the United States to prevent foreign pests and diseases from gaining a foothold in our country. While this system supports efforts to protect against both plant and animal pests and diseases, today, I will focus on our animal health protection efforts in each of these areas.

Overseas and Risk Mitigation Activities

APHIS' work to safeguard the health and value of American agriculture begins by preventing harmful pests and diseases from entering the United States. This work starts overseas, in some cases in the field or on the farm. APHIS works with foreign governments, agricultural producers, and shippers to exclude pests at their origin and treat at-risk commodities in the country of origin or on the high seas before shipments get near our shores.

APHIS, with employees stationed in more than 30 countries, collects and analyzes data on foreign pests and diseases from around the world to detect potential trade pathways for accidentally transporting foreign invasive pests. This information helps us make better policy decisions, such as where to focus risk assessments, when to modify port-of-entry inspections, and what pests we should be surveying for at home.

Our work to help our foreign counterparts build their own infrastructures and capacity to respond to emerging pest and disease conditions is another essential component of our safeguarding activities. Through our capacity building programs, we train animal health officials from other countries in developing effective systems to identify and control pests and diseases locally. This serves as an additional safeguard against the transport of pests and diseases.

We also work closely with multilateral organizations throughout the world to promote effective disease surveillance overseas and gain access to information on agriculture health issues worldwide. These include international and regional groups such as the World Organization for Animal Health and the Codex Alimentarius Commission.

Combined with our overseas efforts, APHIS' import regulations work to mitigate the risk posed by agricultural products long before they reach U.S. ports of entry. Before we will allow imports of a specific product from a specific region of the world, our scientists conduct a risk assessment that enables us to make informed decisions about the potential pest or disease risks associated with that specific commodity. Based on these assessments, and based upon public input and additional scientific perspectives we receive through the rulemaking process, APHIS will only allow imports if they can occur in a safe manner.

APHIS also maintains strict, science-based import regulations for foreign agricultural products. We require import permits for a variety of imported agricultural commodities. As appropriate based on pest and/or disease risk, we also require imports to be accompanied by official sanitary or phytosanitary certification indicating that any associated risk has been sufficiently mitigated. USDA may also require that commodities undergo treatment—such as dipping for cattle fever ticks—and/or mandatory quarantine prior to being allowed entry into the United States. As you can see, USDA’s overseas and risk reduction activities play a critical role in helping to mitigate foreign pest and disease risks in the country of origin rather than in the United States.

At Ports of Entry

Through its Agricultural Quarantine Inspection (AQI) program, APHIS works in tandem with U.S. Customs and Border Protection (CBP) to address the risk of foreign pests and diseases entering the country at ports of entry, either through the movement of people or commodities. Under the Homeland Security Act of 2002, USDA maintained responsibility for establishing the regulations, policies, and procedures that govern the import of agricultural products, and CBP became responsible for conducting the actual inspections at ports. APHIS directs CBP on what pests and diseases to look for and which pathways pose the highest risk, shares information on new and emerging pests and diseases, and trains CBP agricultural specialists in how to enforce our agricultural import regulations. CBP inspections target the highest-risk cargo, as well as travelers most likely to be carrying agricultural products. APHIS also stations veterinarians at ports of entry to provide guidance on inspecting animal products to allow for safe entry.

APHIS also operates Animal Import Centers for importations of animals and animal-derived materials to ensure that exotic animal diseases are not introduced into the United States. Animals that are susceptible to or are capable of carrying diseases or pests that could seriously endanger U.S. domestic livestock or poultry must be imported through a U.S. animal import center and are inspected, tested, and quarantined depending on the species and origin. APHIS also has border inspection facilities along the southern and northern U.S. borders for inspecting cattle and other livestock transiting from Mexico and Canada.

Inside the United States

Expanding international trade is good for our farmers, our consumers, our economy, and the world. However, the increasing movement of people and goods means that foreign pest and disease introductions are a very real threat. Outbreaks can halt the movement of agricultural products, having serious economic impacts on farmers, growers, and exporters, and in the case of zoonotic disease, may affect humans.

To counter this threat, APHIS’ efforts to safeguard America’s agriculture and environment continue inside the United States, so that we can quickly detect any foreign pests and diseases that may have evaded our other safeguarding measures. Critical to this effort is the surveillance we and our state partners conduct throughout the country. Early pest and disease detection is important to avert economic and environmental damage; once a pest or disease becomes

established or spreads significantly, the mitigation costs can reach millions of dollars. This is in addition to lost farm revenues, damage to ecosystems, and loss of foreign markets.

Our Veterinary Services (VS) program conducts routine surveillance for foreign, emerging, and endemic animal diseases, including bovine tuberculosis, foot and mouth disease, avian influenza, and scrapie, as well as for disease vectors such as the cattle fever tick. This surveillance is done through a number of surveillance streams, including testing at slaughter facilities, livestock markets, shows, sales, buying stations, on-farm, and at rendering facilities. As an example, in FY 2015, VS tested over 2 million cattle for brucellosis, over 40,000 sheep and goats for scrapie, and over 190,000 swine for pseudorabies.

Consistent with our One Health approach to animal diseases, our Wildlife Services (WS) program also monitors wildlife for diseases that could potentially spread to livestock or impact humans. Their longstanding efforts monitoring for highly pathogenic avian influenza (HPAI) in wild birds were highlighted during the disease outbreak in poultry farms last year. Since last July, they have sampled over 43,000 wild birds in an enhanced surveillance effort, which can serve as an early warning system for HPAI in commercial poultry. This effort was coordinated with the U.S. Geological Survey, U.S. Fish and Wildlife Service and National Flyway Council. Another important effort they undertake is disease testing of feral swine that they remove through the National Feral Swine Damage Management Program. In FY 2015, WS tested over 2,800 feral swine samples for five diseases of national concern, finding, for example, that 18% were positive for pseudorabies, a disease that APHIS and U.S. industry eradicated from the domestic swine population in 2004.

Additionally, although systems of zoonotic and infectious disease surveillance in humans traditionally operate separately from those for animals, we routinely share data during ongoing cluster or outbreak investigations and on an ad hoc basis as the need is identified. For example, CDC and USDA collaborate directly on a number of well-established zoonotic disease surveillance programs including rabies, bovine spongiform encephalopathy, Trichinellosis, swine and avian influenzas, and foodborne diseases.

Laboratory and diagnostic services are another essential components of the U.S. animal health surveillance infrastructure. Our National Veterinary Services Laboratories (NVSL) serves as the only national reference and confirmatory laboratory for APHIS animal health programs, and participated in over 1,000 foreign animal disease investigations last year. To expand our capacity to detect and diagnose pests and diseases and ramp up during emergency situations, we also support the National Animal Health Laboratory Network (NAHLN) of 62 laboratories. The NAHLN is a national network of laboratories managed by State governments and universities, and is a cooperative effort between two USDA agencies—APHIS and the National Institute of Food and Agriculture (NIFA)—and the American Association of Veterinary Laboratory Diagnosticians. It provides animal disease surveillance and testing services, both daily and in the event of a large-scale animal disease outbreak. In FY 2015, NAHLN laboratories performed over 500,000 diagnostic tests in support of APHIS routine surveillance and outbreak testing needs.

We also recognize the risk posed by smuggled or improperly imported agricultural products and address this vulnerability through our smuggling interdiction and trade compliance (SITC) program. Our SITC program is responsible for intelligence gathering and other anti-smuggling activities, such as secondary market and warehouse inspections, that help prevent animal and plant pests and diseases from entering the United States. When SITC personnel identify smuggled product, they not only remove it from the market but also conduct a full investigation to identify and eliminate any illegal pathways. SITC also conducts market surveys and trend analysis and uses various intelligence tools and data systems to track products that have entered through our borders. In FY 2015, APHIS seized over 230,000 pounds of prohibited and/or restricted plants and plant products and meat and meat products and an additional 65,000 pounds of recalled product.

Emergency Response

In conjunction with our prevention and surveillance efforts, we acknowledge the absolute necessity of being able to respond swiftly and in a coordinated manner should a serious pest or disease be detected. APHIS has the authority and the ability to respond quickly and effectively to the identification of new pests and diseases. In addition, APHIS has specific emergency response guidelines for many of the pests and diseases that pose a significant threat to the United States. We've developed these response plans in conjunction with our Federal, State, tribal, and local partners, with whom we conduct exercises to test our preparedness. To ensure maximum speed and effectiveness, we have rapid response teams stationed around the country ready to travel to detection sites to coordinate Federal containment and eradication efforts. In such situations, our goal is to minimize impacts to U.S. producers and disruptions to trade.

We have in place an incident command approach to emergency response. Incident command places teams of emergency personnel and managers directly in the field to coordinate response efforts. By virtue of their placement and size, the teams and their commanders have a high level of autonomy, are able to respond quickly to new or evolving situations, and can provide extremely timely information to decision makers. In addition, teams from various local, State, and Federal agencies all speak the same language -- using standard terminology for positions and having common structures -- when working an emergency and can tap into a wider network of resources. We saw this in January, when APHIS was able to quickly deploy an incident management team to Indiana at the first sign of disease, enabling the Agency and the State to swiftly eradicate an outbreak of HPAI.

Responding to HPAI in 2015 put to test all of our emergency preparedness and response infrastructure and plans. Through our successful efforts in eradicating the disease in 2015, we learned a lot about our disease response plans that will help us be even more successful in the future. Chief among those is the need for rapid depopulation of affected animals so as to reduce the spread of the virus, and the need for all of us to improve our levels of biosecurity.

However, our HPAI response was just a piece of what we do. Of the more than 1,000 foreign animal disease investigations in which we participated last year, the vast majority turned out to be minor illnesses. This shows the vigilance of APHIS and our partners in the states and industry, to quickly respond when there may be a potential threat to U.S. livestock health.

Expanding our Ability to Protect the United States

Safeguarding U.S. agriculture and ensuring that we are prepared for any sanitary or phytosanitary threats against it is a huge undertaking, but it is one to which APHIS and our partners in the federal, state, and local governments, industry, and stakeholders are fully committed. I would like to mention two other initiatives aimed at expanding our ability to be successful.

One of the biggest lessons we learned in responding to last year's HPAI outbreak was that we could build on the Agency's existing capacity to effectively address large animal health events. Unfortunately, our current funding level for animal health activities is below levels that were available to us 10 years ago, and APHIS has seen a reduction of more than 200 animal health professionals since then. The need to rebuild our capacity is critical, and we have requested an additional \$30 million in the FY 2017 President's budget request to address this need. If provided by Congress, we will use most of the funds to hire veterinarians and animal health technicians to rebuild our field force and strengthen our ability to respond to animal health emergencies. To paraphrase a proverb, this request illustrates that an ounce of prevention may well be worth a pound of cure.

Second, to further enhance our ability to respond to emerging disease threats, our Veterinary Services program published a *Veterinary Services Proposed Framework for Response to Emerging Animal Diseases in the United States* in July 2014. The final Framework, which we are working to complete later this year, will describe the activities to be undertaken under the framework, and will outline roles and responsibilities, possible triggers for action, and potential responses to emerging animal diseases, as well as public outreach. Due to the novelty of emerging diseases – either within a geographic area or species – detection and response will depend on close cooperation with producers. For this reason, flexibility is essential, and the framework implementation plan will outline the processes APHIS will use to develop science- and risk-based approaches and systems to respond to emerging animal diseases.

A National Blueprint for Biodefense

We appreciate the effort undertaken by the Blue Ribbon Panel on Biodefense to make recommendations to strengthen the United States' biodefense, and the recognition of the role animal health plays in this effort. I am pleased to say that APHIS is already taking a number of actions related to recommendations made in the Panel's report. I will mention several of them today.

Our Veterinary Services program has a One Health Coordination Center (OHCC) that facilitates the integration of One Health approaches throughout our animal health programs. It is our standard practice to approach our work from a One Health state of mind, and OHCC works to inform and educate USDA employees about this need. OHCC staff also leverage their knowledge and relationships to build better alliances, coordinate between government and industry partners, and network to ensure that animal agriculture is considered when One Health

issues are being addressed. OHCC also identifies unmet needs and opportunities to promote the potential contributions that APHIS can make to One Health activities.

APHIS has also undertaken several efforts around animal health data collection and sharing to help improve collaboration and coordination. We have a data management roadmap initiative to identify strengths and gaps in current data management systems for our animal health surveillance data, with the end goal of finding ways to link the systems to each other and to provide a framework for data sharing between government agencies, universities, and private organizations while maintaining appropriate security of confidential data. We also have tools such as interactive dashboards that allow self-exploration of surveillance information by our federal, state, and industry partners.

In addition, we have a comprehensive and integrated animal disease surveillance approach that includes a variety of surveillance sources of information including wildlife and other vectors. Interagency collaborations are part of this approach, which is particularly important as we address diseases of economic and public health concern. For example, we have a cooperative initiative for Influenza A virus in swine (IAV-S) with the swine industry and NAHLN laboratories to identify unique strains of IAV-S that may be of significance to animal or public health. The CDC is regularly updated on IAV-S surveillance in the U.S. and works closely with APHIS to stay apprised of current influenza issues from a veterinary perspective, linking the human and animal health perspectives into a One Health approach.

APHIS is also developing a U.S. National List of Reportable Animal Diseases (NLRAD) to complement State reportable disease lists. The NLRAD will be a single uniform, science- and policy-based, nationally supported standardized list of animal diseases/agents. The NLRAD will focus on livestock, poultry and aquaculture species. In July 2014, APHIS published the *Proposal for a U.S. National List of Reportable Animal Diseases (NLRAD) Concept Paper*. The NLRAD list was developed in direct collaboration with numerous stakeholders including the United States Animal Health Association (USAHA), American Association of Veterinary Laboratory Diagnosticians and National Assembly of State Animal Health Officials. We are currently looking at issues around laboratory implementation, data management, and confidentiality, as we work towards releasing a draft guidance document this fall. The NLRAD will be implemented through Federal-State cooperation, and will contribute to the assessment and reporting of the listed zoonotic and endemic animal diseases and facilitate response to an emerging disease or issue in the United States, as well as support trade.

In conclusion, APHIS' core mission is to protect the health of U.S. agriculture, which in turn supports public health and food security in the United States. I assure you that my Agency, and USDA, are committed to doing all we can to protect U.S. plant, animal, and human health from the threats posed by pests and diseases. I would be happy to answer any questions.

Cattle Health Business Plan

Fiscal Years 2014 to 2018

Animal and Plant Health Inspection Service Veterinary Services

I. Abbreviations

APHIS	Animal and Plant Health Inspection Service
BSE	Bovine Spongiform Encephalopathy
CDC	Centers for Disease Control and Prevention
EPS	Enhanced Passive Surveillance
FAD	Foreign Animal Disease
FDA	Food and Drug Administration
GYA	Greater Yellowstone Area
IIAD	Institute for Infectious Animal Diseases (formerly the Foreign Animal & Zoonotic Disease Defense Center)
MIM	Mobile Information Management
MOU	Memorandum of Understanding
NAHMS	National Animal Health Monitoring System
OIE	World Organization for Animal Health
PHIS	Public Health Information System
TB	Tuberculosis
VS	Veterinary Services

II. Definitions

Domestic program disease – a disease for which VS has an eradication and/or control program

Emerging disease – a newly identified pathogen or strain, a known pathogen in a new location, or a new presentation of a known pathogen - These disease events may have negative impacts on animal health, public health, and trade. Examples of such events in the United States (U.S.) include infectious salmon anemia, West Nile virus, and porcine epidemic diarrhea virus in the U.S.

Foreign animal disease – a transboundary animal disease not known to exist in the U.S. domestic cattle and bison population



III. Program Description:

A. Program Objectives:

The overall goal of the Cattle Health Program is to partner with State, industry, allied Federal agencies, Tribal governments, and other stakeholders to 1) rapidly detect certain devastating diseases that could affect the U.S. cattle and bison population and harm the economy and human and/or environmental health; and 2) prevent the spread of any detected devastating disease or endemic domestic cattle and bison diseases of concern. Additionally, by conducting surveillance to find animal diseases, the program also verifies and documents for our international trading partners that certain diseases do not exist in the U.S. domestic cattle and bison population, thus facilitating trade. The capabilities developed to respond to cattle and bison diseases may also be utilized to respond to other cattle and bison health emergencies.

Core Objectives:

- Objective 1: Protect domestic cattle and bison health through prevention, preparedness, and communication
- Objective 2: Conduct monitoring and surveillance activities to rapidly detect endemic, emerging, and foreign animal diseases
- Objective 3: Prevent the spread of diseases of concern through rapid response and containment
- Objective 4: Develop and implement strategies for business continuity, mitigation, and recovery in the event of outbreaks of disease

B. Program Components:

Cattle Health Program components include the National Tuberculosis (TB) Eradication program, the National Brucellosis Eradication program, the cattle fever tick (CFT) program, and the ongoing bovine spongiform encephalopathy (BSE) surveillance program. An additional component being developed is a comprehensive cattle health surveillance plan that will provide a roadmap for building upon the existing surveillance system. A comprehensive plan will increase the Agency's ability to detect and prevent the spread of endemic, emerging and foreign animal diseases that could have a severe impact on the health of the U.S. domestic cattle and bison population or economy.

C. Funding Sources:

The Cattle Health Program is funded through the congressionally appropriated cattle health commodity line within the USDA's Animal and Plant Health Inspection Service (APHIS) budget. The fiscal year (FY) 2014 funding level for Cattle Health is \$92.5 million. This funding supports both domestic cattle and bison health activities as well as the APHIS screwworm program.

IV. Value of Program

The domestic cattle and bison health program has been successful in protecting the beef and milk industry valued at \$43.8 billion (NASS, 2010) and \$37 billion (NASS, 2013), respectively, from economic loss by rapidly detecting foreign, emerging, or domestic program diseases and in preventing their spread. For example, preventing the introduction of a foreign animal disease such as foot-and-mouth disease (FMD) from entering the United States would save between \$8.5 and \$13.5 billion in California alone based on a 1999 study conducted by University of California–Davis economists (Ekboir, 1999).

Ongoing BSE surveillance information from APHIS' Cattle Health Program has been instrumental in allowing the United States to maintain its beef export market worth approximately \$5.11 billion per year (ERS, 2012). The BSE surveillance program was also a critical component in the U.S. effort to attain negligible risk status for BSE, which was granted by the World Organization for Animal Health (OIE) in May, 2013.

The Cattle Health Program has also been highly successful in eradicating endemic diseases, such as brucellosis, from domestic cattle and bison. Wildlife in the Greater Yellowstone Area (GYA) remains the last known reservoir of brucellosis in the country. The benefits of eradicating brucellosis have been estimated to be greater than \$18.3 billion (Paarlberg, 2008). An economic analysis conducted by the State of Wyoming indicated that should brucellosis eradication efforts be discontinued, the costs of producing beef and milk would increase by an estimated \$80 million annually in less than 10 years as the disease would become active again (Bittner, 2004). With the successful eradication of brucellosis in domestic cattle and bison, the program is streamlining surveillance efforts while ensuring that surveillance data are sufficient to demonstrate a national disease-free status to trading partners.

The Cattle Health Program also continues to make progress in eradicating TB from domestic livestock. A study conducted by Iowa State University suggests that more than \$13 billion has been returned to the U.S. economy in terms of avoided economic losses since the TB eradication program began (Palmer, 2011). Instead of recommending whole-herd depopulation as the primary option to manage TB affected herds, APHIS now bases its approach on the circumstances surrounding each herd. For those herds where depopulation is not recommended, the herd undergoes a test-and-remove protocol, gaining significant savings of Federal dollars while continuing to eliminate the disease.

Through cooperative efforts between APHIS and the State of Texas, the Cattle Health Program has been 100 percent effective in preventing CFT from spreading within the United States. One study estimates the costs of a relatively small CFT outbreak in the free area of Texas to be \$123 million during the first year of the outbreak (Anderson, 2010).

V. FY 2014-2018 Implementation

A. Objective 1: Protect cattle health through prevention, preparedness, and communication.

Strategy 1: Prevention and preparedness – Design and implement activities to enhance the Cattle Health Program’s ability to avoid the introduction of foreign animal diseases or outbreaks of endemic or emerging diseases of concern into the United States and to maintain readiness to respond.

FY 2014 Activities

- a. Provide foreign animal disease diagnostician (FADD) training for State and Federal veterinarians and accredited veterinarians, the first line of defense against the introduction of a foreign animal disease. These courses provide veterinarians with hands-on experience in observing signs of diseases that are not currently present in the country and provide instruction on sample collection and submission in the event a foreign animal disease is suspected.
- b. Train and accredit veterinarians under the National Veterinary Accreditation Program (NVAP) by developing and providing online training modules and hands-on instruction.
- c. Provide case definitions for foreign animal diseases to local, State, Tribal, Federal, and industry stakeholders.
- d. Continue to review and update plans, standard operating procedures and guidance documents in preparation for responding to endemic, foreign, and emerging disease events impacting domestic cattle and bison.
- e. Prepare and practice animal health and all-hazard response plans in coordination with States, Federal agencies, industry, Tribes, and other stakeholders.

FY 2015-FY 2018 Activities

- a. Continue FY 2014 activities.
- b. Develop, improve, and evaluate, in conjunction with Federal, State/Tribal, and academic stakeholders, new and existing technologies for preventing and controlling diseases in domestic cattle and bison.
 - i. Collaborate with the animal disease traceability (ADT) program by developing pilot projects that utilize the latest technologies in cattle and bison identification devices.
 - ii. Incorporate new preventative and systematic treatment options, including anti-tick vaccines, as they become available, into the CFT program.
 - iii. Provide staff resources and financial support to conduct field trials to collect data to support licensure and approval of developmental brucellosis diagnostic tests and vaccines.
- c. Integrate climate change modeling into preparedness and biosecurity hazard planning to enhance the program’s ability to predict, mitigate, and adapt to adverse conditions caused by climate change.

Strategy 2: Communication – Routinely exchange information with State, Federal, industry, Tribal, and other stakeholders.

FY 2014 Activities

- a. Provide credible, science-based information and educational materials on related cattle and bison diseases and production management practices to U.S. and world stakeholders.
- b. Work with APHIS Legislative and Public Affairs (LPA) to post stakeholder announcements, and use GovDelivery along with other outreach tools to make science-based documents available. Potential documents include:
 - i. Risk assessments for brucellosis, CFT, TB, and other diseases of concern that have a wildlife interface.
 - ii. Business continuity plans, surveillance plans, information management during emergency events.
 - iii. Updated standardized program reports and monthly, quarterly, and/or annual reports for stakeholders. Types of reports include descriptive program reports and annual animal health reports.
- c. Conduct outreach activities for State, Federal, Tribal, and industry stakeholders to facilitate planning and implementation of the new comprehensive bovine brucellosis and bovine TB rule and program standards and comprehensive cattle and bison surveillance activities.
- d. Increase collaborations with other Federal agencies such as the Food Safety and Inspection Service, Environmental Protection Agency, Food and Drug Administration, Department of Defense, Department of Justice, and Centers for Disease Control and Prevention to increase efficiencies and reduce redundancies such as:
 - i. Developing databases that can be integrated with and enhance the national biosurveillance efforts.
 - ii. Continuing FSIS' Public Health Information system slaughter data analysis for identification of emerging diseases and health trends.
 - iii. Continue collaborating with the Institute for Infectious Animal Diseases (IIAD) and State animal health departments on gathering enhanced passive surveillance data.
- e. Collaborate with the OIE on cattle and bison health issues.
- f. Collaborate with other countries on animal disease issues of mutual concern such as brucellosis, TB, and CFT.

FY 2015-FY 2018 Activities

- a. Continue to conduct FY 2014 activities.
- b. Work with State, Federal, industry, Tribal, other stakeholders to develop and disseminate information about disease risk, biosecurity, surveillance and certification activities.
- c. Increase outreach and education to producers concerning endemic, emerging, and foreign animal diseases (with emphasis on FMD) that could affect domestic cattle and bison health, industry productivity, or safety.

- d. Lead discussions concerning cattle and bison health issues with State and Federal animal health officials and other stakeholders through attendance of meetings and conferences and by seeking input in prioritizing cattle and domestic bison health goals.
- e. Conduct or support outreach by partners to promote APHIS cattle and domestic bison health activities, such as the proposed Qualified Accredited Veterinarian program for TB.

B. Objective 2: Conduct monitoring and surveillance to rapidly detect endemic, emerging and foreign animal diseases.

Strategy 3: Monitoring and surveillance – Continue to utilize new scientific information and technologies to transition the current surveillance system to a more comprehensive surveillance system.

FY 2014 Activities

- a. Begin drafting a national cattle and bison comprehensive surveillance plan: To ensure the domestic cattle and bison industry's economic competitiveness, it is essential to identify remaining program disease cases, as well as to quickly detect and address emerging and foreign disease threats. This can be facilitated by implementing comprehensive surveillance that will include strategies for optimizing sampling and minimizing total costs to achieve surveillance goals. Comprehensive surveillance includes: sampling/observing animals for multiple diseases at the same time (common sampling), and combining multiple sampling streams that target high risk subpopulations.
- b. Calculate national baseline values for use in assessing the performance of the traceability program.
- c. Implement cattle and bison surveillance data collection and evaluation through multi-stream enhanced passive surveillance pilot projects in collaboration with the IIAD.
- d. Continue to develop new surveillance approaches and improve tests for BSE, TB and brucellosis.
- e. Maintain compliance with existing performance standards for surveillance of TB at slaughter (i.e., 1 submission per 2,000 adult cattle and bison slaughtered) and achievement of national submission goals (i.e., at least 10,000 granuloma submissions from slaughter).
- f. Conduct national bovine brucellosis surveillance at an appropriate level to detect a 0.001 percent or higher prevalence level (1 or more infected animals per 100,000 adult cattle and bison) among the U.S. cattle and bison population with 95 percent confidence.
- g. Conduct surveillance in domestic cattle and bison at a level that achieves OIE recommendations for BSE surveillance.
- h. Make information technology improvements – evaluate business needs and resource requirements for information and data management, including data acquisition, management and aggregation of data from multiple streams, and access and utilization of data by a range of user types.

- i. Launch a National Animal Health Monitoring System (NAHMS) 2014 dairy study.
- j. Launch a NAHMS ranched bison industry study focusing on the health and management practices in the U.S. bison industry.
- k. Promote ongoing monitoring/reporting via the National Animal Health Reporting System (NAHRS) and continue to implement a national list of reportable animal diseases.
- l. Continue collaboration between NAHMS and the National Mastitis Council on a monitoring system to summarize U.S. milk quality.

FY 2015-FY 2018 Activities

- a. Continue FY 2014 activities.
- b. Publish a white paper describing the diseases/syndromes of cattle and bison that would be addressed in a national cattle and bison comprehensive surveillance plan and surveillance approaches, for stakeholder input.
- c. Finalize a national cattle and bison comprehensive surveillance plan.
- d. Use 2014 initial baseline values to evaluate the progress of the traceability program and to compile reports that provide information on the strengths of the program and the areas that need improvement.
- e. Improve traceability by expanding the capability of mobile information management (MIM) to scan multiple frequencies of ID tags, store them in the MIM software, and collect data on multiple operating system platforms
- f. Consider revising the BSE surveillance strategy to maintain effectiveness while continuing to meet OIE surveillance standards, thus reducing costs: for example, the strategy for classical BSE versus atypical BSE.
- g. Launch a beef NAHMS survey in FY 2016.

Strategy 4: Detection – Implement strategies to decrease the time required to locate diseases, including detecting, characterizing, and transparently reporting disease threats at the earliest possible moment.

FY 2014 Activities

- a. Collaborate with the Department of Homeland Security and other Federal and State agencies and other stakeholders on biosurveillance activities to include active data-gathering in order to achieve early warning of health threats, early detection of health events, and overall situational awareness of disease activity
- b. Conduct diagnostic testing (serology; bacteriologic culture; and identification and genotyping of isolates) for all VS initiatives affecting the U.S. cattle and bison population.
- c. Work with stakeholders to increase the sharing of discrete, essential information to expand exponentially the number of “sentinels” that may detect an incident of national significance.
- d. Provide feedback to shareholders based on information and data that they have provided to VS.

FY 2015-FY 2018 Activities

- a. Continue FY 2014 activities.
- b. Evolve and enhance our national biosurveillance enterprise efforts by:
 - i. Extending electronic reporting of cattle and bison health information, including laboratory results, to rapidly communicate useful information.
 - ii. Leveraging social media and widely available tools to facilitate rapid information sharing domestically and globally. Routine, daily use of such capabilities may be employed to address critical requirements in the context of an emergency.

a) Objective 3: Prevent the spread of diseases of concern through rapid response and containment.

Strategy 5: Response – Rapidly and effectively react to incursions or spread of program, endemic, or foreign animal diseases and vectors to limit negative impact.

FY 2014 Activities

- a. Conduct investigations of potential foreign and emerging cattle and bison diseases.
- b. Respond to incidences of domestic program diseases including cleaning and disinfection, traceback investigations, postexposure monitoring, testing, and disposal of high-risk animals/herds where appropriate.
- c. Conduct epidemiologic investigations of affected herds in accordance with program regulations and standards.
- d. When and where appropriate, eradicate emerging, re-emerging, endemic, and foreign diseases that impact the domestic cattle and bison industries.
- e. Provide indemnity for diagnostic purchases of animals and whole-herd depopulations, when appropriate.
- f. Prevent contact between the diseased and susceptible animals through quarantine of infected animals; movement controls in the infected zone(s) and buffer zone(s); and biosecurity procedures to protect noninfected animals

FY 2015-FY 2018 Activities

- a. Continue FY 2014 activities.
- b. Prevent mechanical transmission of disease by people, material, conveyances, and animals to susceptible animals through biosecurity and cleaning and disinfection measures.
- c. Increase the disease resistance of susceptible animals to the disease or reduce the shedding of the disease agent in infected or exposed animals when needed through emergency vaccination, if a suitable vaccine is available and can be administered in a timely manner.
- d. Maintain procedures for how FMD vaccine will be obtained in the event of an outbreak .

Strategy 6: Containment – Prevent the spread of a program, endemic, or foreign animal disease beyond the area of introduction.

FY 2014 Activities

- a. Continue to work with the GYA States to implement brucellosis management plans for affected herds.
- b. Conduct targeted surveillance around geographic areas where TB has been identified in livestock or wildlife
- c. Continue collaborating with Wildlife Services and other stakeholders in eradicating CFT from the United States through activities such as the inspection and removal of ticks from exotic nilgai in southern Texas.
- d. Complete epidemiological modeling and cost comparison analyses to guide decisions regarding the implementation of herd depopulation versus test-and-remove protocols.

FY 2015-FY 2018 Activities

- a. Continue FY 2014 activities.
- b. Finalize the bovine TB Qualified Accredited Veterinarian program, enabling VS to enforce specific training, oversight, performance, and disciplinary elements of all accredited veterinarians' TB testing activity.
- c. Complete the CFT game fencing project.
- d. When and where appropriate, eradicate emerging, re-emerging, endemic, and foreign diseases that impact the domestic cattle and bison industries.

b) Objective 4: Develop and implement strategies for business continuity, mitigation, and recovery.

Strategy 7: Continuity of business – Develop and implement strategies to minimize the disruption of trade through management of noninfected premises and animals in the event of an FAD outbreak through science-based and risk-based approaches and systems.

FY 2014 Activities

- a. Partner with other Federal Agencies, States, Tribes and industry to develop, maintain, and exercise continuity of business plans and guidance documents.
- b. Support the Secure Food Supply initiatives and efforts by the beef and dairy industries in establishing continuity of business plans for FADs.

FY 2015-FY 2018 Activities

- a. Continue FY 2014 activities.
- b. Conduct proactive risk assessments that consider existing production practices for foreign animal diseases such as FMD.
- c. Utilize new technologies as they become available to improve traceability and information management for movement of nonexposed cattle or bison during an outbreak of disease.

Strategy 8: Mitigation and recovery – Collaborate with stakeholders to reduce the loss of cattle and bison in incidences of endemic, emerging, and foreign animal diseases and to focus on the timely restoration of cattle and bison herds affected by disease.

FY 2014 Activities

- a. Collaborate with stakeholders to develop management plans to decrease the risk for spread of diseases such as brucellosis, CFT, TB, and other diseases of concern between domestic cattle and bison and wildlife.
- b. Provide coordination and oversight of cattle and bison health activities to prevent the introduction and/or spread of program diseases at the national and district levels with continual collaboration and communication among various units within VS, APHIS and the USDA as well as with other Federal and State agencies.
 - i. Complete the GYA brucellosis evaluation that examines the spread of brucellosis in affected wildlife, and State and park service management and vaccination policies.
 - ii. Complete a risk and economic analysis of TB in Michigan and evaluate the effectiveness of mitigation strategies and movement controls.
 - iii. Complete the review of the California TB program, including:
 1. An analysis of the cause of spread of the disease
 2. Emphasis on genetic aspects of the bacteria to help with epidemiological investigations
 3. Revising the MOU
- c. Implement VS Emergency Management Training and Exercise Plan activities and One Health and Global Health endeavors to mitigate and eliminate the impacts of zoonotic diseases on public health, cattle and bison health, and national and international trade.

FY 2015-FY 2018 Activities

- a. Continue FY 2014 activities.
- b. Develop and implement management plans to decrease the risk for spread of diseases such as brucellosis, CFT, TB, and other diseases of concern between cattle and bison and wildlife.
- c. Conduct TB program reviews in Mexico to properly assess disease risks.
- d. Implement mandatory anti-tick vaccination of all cattle and bison herds located within the permanent quarantine buffer zone.

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Emerging Animal Disease Preparedness and Response Plan

**U.S. Department of Agriculture
Animal and Plant Health Inspection Service
Veterinary Services**

August 2016

DRAFT

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To be completed when document finalized

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CHAPTER 1. INTRODUCTION AND DEFINITIONS

1.1 Introduction

The purpose of this plan is to define the processes by which the Veterinary Services (VS) unit of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) will identify, evaluate, and respond to emerging diseases in animal populations, and the implementation of these processes as a VS core business practice. This plan will help VS respond effectively to emerging animal diseases by outlining processes to be used to determine appropriate response activities. The framework for this plan was outlined in 2014 in the [APHIS concept paper](#), "Veterinary Services Proposed Framework for Response to Emerging Animal Diseases in the United States."

Emerging animal diseases have the potential to negatively affect animal health, public health, and trade. Examples of such disease occurrences in the United States in the past 20 years include porcine reproductive and respiratory syndrome, infectious salmon anemia, West Nile virus, and monkey pox virus. More recent examples include the emergence of Schmallenberg virus in Europe and porcine epidemic diarrhea virus in the United States.

Because of the unknown nature of emerging diseases, defining a specific response plan is not possible. Some emerging disease will be reported after an acute impact in a limited number animals; some will be recognized only after a longer term impact on animal health or production. VS plans to work with all stakeholders in implementing appropriate response measures to emerging diseases, with the understanding that emerging diseases – at least when first defined – are clearly different from listed foreign animal diseases. VS has established response plans for foreign animal diseases such as foot-and-mouth disease and highly pathogenic avian influenza.

VS has engaged in emerging disease detection and response as part of its major goals since the 1990's. The "[VS: A New Perspective](#)" document also includes the concepts of identification, analysis, and response to emerging diseases. Rapid detection and response to emerging diseases are critical to animal agriculture as some can spread rapidly, threatening the livelihood of producers and limiting their access to important markets.

Rapid response to emerging diseases can prevent or limit the negative impact to animal health, the economy, food security, and public health. In these cases, having useful situational animal health information can help agency policy makers and the public make informed decisions. VS has an extensive history of working with animal agriculture participants, academic institutions, and State animal health officials. VS intends to apply this collaborative approach to increase awareness of, detect, characterize, investigate, and respond to emerging disease threats as well as provide accurate information to all interested parties. VS will use the activities described in this plan to provide a solid scientific foundation for developing strategic interventions and informing the public of all appropriate actions.

The goals of this plan are to outline four core activities associated with detection and response to emerging animal diseases:

- 1) Undertake global awareness, assessment, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications;
- 2) Detect, identify, and characterize disease events;
- 3) Communicate findings and inform stakeholders; and
- 4) Respond quickly to minimize the impact of disease events.

A fifth goal, addressing recovery from the event, would include strategies that stabilize animal agriculture, the food supply, and the economy, and protect public health and the environment. These activities, including the [secure food supply plans](#), are an extension of this plan and are not detailed here.

1.2 Purpose of Document

This plan provides strategic direction for VS at all levels to detect and respond to emerging animal diseases. It also defines communication activities and possible response measures for an emerging animal disease occurring in the United States.

1.3 Audience

This document is intended for Federal and State animal health officials and industry partners. It provides strategic guidance and outlines roles and responsibilities for detecting, reporting and responding to emerging animal diseases.

1.4 Authority

The Animal Health Protection Act (AHPA), 7 *U.S. Code* 8301 et seq., authorizes the Secretary of Agriculture to restrict the importation, entry, or further movement in the United States or order the destruction or removal of animals and related conveyances and facilities to prevent the introduction or dissemination of livestock pests or diseases. It authorizes related activities with respect to exportation, interstate movement, cooperative agreements, enforcement and penalties, seizure, quarantine, and disease and pest eradication. The Act also authorizes the Secretary to establish a veterinary accreditation program and enter into reimbursable fee agreements for pre-clearance abroad of animals or articles for movement into the United States.

1.5 Definitions

Emerging disease: A disease, infection, or infestation in domestic or wild animals that is a threat to terrestrial animals, aquatic animals, or humans, and meets one of the following criteria:

1. An unknown agent that is causing disease, infection, or infestation in a herd/flock/premises and has the potential to result in a significant animal or public health impact, and applied diagnostic tests have yielded negative or non-definitive results; OR
2. A newly identified agent that is causing disease, infection, or infestation in a herd/flock/premises and has the potential to cause significant animal or public health impact, or is occurring in multiple herds/flocks/premises; OR
3. A previously identified or known pathogenic agent that has a change in epidemiology, such as:
 - a. Increased pathogenicity,
 - b. Expanded host range,
 - c. Change in geography of an agent with the potential to cause a significant animal or public health impact, or
 - d. Unexpected morbidity/mortality

Risk Identification Team (RI team): Group within the VS Center for Epidemiology and Animal Health that has the lead for monitoring the global animal health landscape for potential threats, assessing the risk posed by a possible emerging disease in the United States, and gathering information upon which to base the response.

VS Liaisons: VS Directors who are the first level of review for information assembled and analyzed by the RI team.

VS points of contact (POC). Subject matter experts designated within each group in VS to gather field-level data on possible emerging diseases for further analysis by the RI team.

CHAPTER 2. IDENTIFYING AND CHARACTERIZING GLOBAL AND DOMESTIC THREATS TO ANIMAL HEALTH

2.1 Global and Domestic Awareness and Assessment

The Risk Identification Team (RI team) within the USDA’s Center for Epidemiology and Animal Health (CEAH) Risk Analysis and Risk Assessment (RIRA) unit is responsible for monitoring the distribution of animal diseases domestically and globally to identify potential threats to U.S. agriculture. The team works collaboratively with personnel across VS, with other Federal Government and Tribal agencies, industry, and stakeholders to identify and describe global emerging animal disease risks.

The RI team will identify and characterize animal disease risks using information from VS points of contact (POC), APHIS International Services, and other sources, including the following:

- U.S. Department of Homeland Security’s (DHS) National Biosurveillance Integration Center
- Centers for Disease Control and Prevention (CDC)
- Inter-American Institute for Cooperation on Agriculture
- International Regional Organization for Plant and Animal Health
- Pan-American Foot and Mouth Disease Centre
- World Organization for Animal Health (OIE)
- Food and Agriculture Organization of the United Nations
- World Health Organization

Open-source information available from international agencies and organizations, various media outlets, and peer-reviewed scientific literature will be reviewed daily, to maintain a baseline situational awareness of animal health issues and disease events globally.

Domestically, the RI team uses information available from a variety of resources, including:

- National Veterinary Services Laboratories
- National Animal Health Laboratory Network, voluntary National Animal Health Reporting System (NAHRS)¹
- National Animal Health System Monitoring System surveys
- Mandatory reporting such as that required by the “Reporting, Herd Monitoring and Management of Novel Swine Enteric Coronavirus Diseases Federal Order”
- Data provided by VS certification and surveillance programs

With these systems and previously established relationships with accredited veterinarians; producers; livestock market operations; universities; State and Tribal animal health, public health and wildlife officials; and other Federal agencies. VS can access, share, and evaluate a broad scope of information.

¹ Until the National List of Reportable Animal Diseases is proposed and finalized in the Code of Federal Regulation, the NAHRS system remains the system for reporting diseases in the United States.

Additionally, several industry organizations have implemented systems to gather animal disease information. These commodities include swine (Swine Health Information Center) and equine (Equine Disease Communication Center). VS personnel serve as agency liaisons to these efforts, facilitating communication and collaboration.

2.2 Roles and Responsibilities Overview

Successful emerging disease response requires a collaborative effort among APHIS units, VS, State Animal Health Officials, and animal industries.

VS units. The responsibilities of units within VS is described in general here and further detailed throughout this document.

Science, Technology and Analysis Services (STAS). The RI team, part of CEAH's Risk Identification and Risk Assessment (RIRA) unit, is the primary unit responsible for monitoring domestic and international information sources described in section 2.1, conducting a preliminary evaluation of information pertaining to risks to U.S. animal health, and leading further analyses and data gathering when possible emerging diseases are identified. The team maintains a database of diseases being actively monitored and a time interval for updating information used to assign a risk level to each.

In addition to the RI team, STAS includes other units that will be involved in emerging disease assessment and response. The National Veterinary Services Laboratories (NVSL) regularly interacts with global and domestic animal health and research laboratories. NVSL Directors will designate POCs responsible for communicating knowledge of possible emerging diseases to RI team analysts and assisting with the collection and initial review of information and risk category assignment. In addition, NVSL will designate Directors to serve as liaisons to the RIRA Director to review information prepared by the RI team and their POCs and to assign appropriate subject matter experts within their unit to participate in cross-unit emerging disease teams.

Surveillance, Preparedness and Response Services (SPRS). As the VS unit responsible for implementation of VS surveillance, preparedness and response activities, SPRS staff routinely receive information on potentially emerging animal health issues. Emerging diseases POCs will be designated for each animal commodity, in the National Preparedness and Incident Coordination Center (NPICC), and in the One Health Coordination Center (OHCC). The role of the POC is to communicate information regarding potential emerging diseases to the Risk Identification analysts for situational awareness, to provide subject matter expertise to the RI team to determine a risk category assignment for each agent, and communicate issues up their respective supervisory chains.

In addition, Directors of the Avian, Swine and Aquatic Animal Health Center; Cattle Health Center; Sheep, Goat, Cervid and Equine Health Center; OHCC; and NPICC will serve as liaisons to the RIRA Director to review information prepared by the RI team and their POC on each global agent designated a risk category 3 or 4, domestic agent designated a risk category 1 or greater, or each agent where additional information is required before a risk category can be assigned. The VS liaisons will determine if additional information,

analyses, or field response is required, and will assign appropriate subject matter experts within their centers to participate in the cross-unit emerging disease team to evaluate these needs and make recommendations.

National Import and Export Services (NIES). POCs from NIES will inform the RI team of potential emerging diseases that need evaluation and by providing subject matter expertise to determine preliminary risk category assignments. NIES will also designate Unit Directors as liaisons to review information prepared by the RI team and to assign, as necessary, appropriate subject matter experts within their unit to participate in cross-unit emerging disease teams.

States. States' responsibilities include reporting under the NAHRS². However, States are encouraged to contact the appropriate VS Assistant Director with any unusual disease event in their state to discuss any results of diagnostic testing and available epidemiological information. Further state responsibilities would include issuance of holds or quarantines and participation in any monitoring, control, or eradication activity determined to be appropriate.

Industry. Previously established communication links with industry organizations will be used to communicate information, discuss response options, and address questions related to potential disease risks and concerns. For those industries that have implemented systems to gather animal disease information, such as the Swine Health Information Center and Equine Disease Communication Center, VS personnel serve as agency liaisons to these efforts, facilitating communication and collaboration.

Agency and Non-Agency Partners. Other Federal partners in USDA, DHS, CDC, U.S. Geological Survey, etc., as well as State Animal Health Officials, industry leaders, National Animal Health Laboratory Network laboratories, and accredited veterinarians, will provide information, review and subject matter expertise to the RI team, as needed, to help analyze information and determine the level of risk to US animal or public health posed by emerging diseases. Depending on the situation, partners may provide subject matter experts to participate in the cross-unit emerging disease teams to assist with evaluation and characterization of the disease incident, communications, and other related emerging disease response activities.

2.3 Initial Assessment of Information

1. When the RI team becomes aware of a possible emerging disease risk, the team will work with VS POC to conduct a preliminary analysis and assign the disease to a risk level category (Appendix A):
 - Level 1: Nominal risk to U.S. animal or public health
 - Level 2: Potential risk to U.S. animal or public health
 - Level 3: Impending risk to U.S. animal or public health
 - Level 4: Current risk to U.S. animal or public health
2. The RI team will write a briefing for international emerging disease risks designated at risk level 3, domestic diseases designated at any level, or diseases for which more information is needed before a risk level can be assigned.

² Until the National List of Reportable Animal Diseases is proposed and finalized in the Code of Federal Regulation, the NAHRS system remains the system for reporting diseases in the United States.

3. The RI team will share the briefings with appropriate VS Liaisons for review.
4. If, based on the results of the review, the severity and complexity of a disease incident warrants additional evaluation, characterization, or response. VS Liaisons will identify appropriate subject matter experts to form a cross-unit Emerging Disease Team to determine the additional information, analyses, or field response needed to thoroughly evaluate, characterize, or mitigate the disease incident (Appendix B).

2.4 Evaluation of Disease Incidents and Recommendations for Response

1. When the initial review of information by the RIRA Director and VS Liaisons determines an emerging disease incident requires further evaluation, characterization, or response, VS liaisons, in collaboration RI analysts and VS POC, will identify appropriate subject matter experts in APHIS to form a cross-unit Emerging Disease Team to conduct the evaluation. If the animal disease is associated with human health outcomes, subject matter experts in CDC will be identified to assist with the evaluation and development of recommendations.
2. The RI Team Lead will initially organize and lead the Team to review information, determine gaps in data or preparedness, and outline additional analyses, research, field epidemiological investigations, or mitigations needed to fully characterize and respond to the emerging disease incident.
3. The results of this evaluation, including any recommendations for response, will be documented and provided to VS Liaisons for presentation and decision making by the VS Executive Team (VSET). Recommendations will outline any regulatory issues or financial needs associated with each action.
4. The VSET will approve and authorize resources for the appropriate response measures. Depending upon the scale, scope, and urgency of the situation, the VSET may need to designate responsibility to the appropriate VS unit for each recommendation. For instance, further field investigations would be the responsibility of and coordinated through SPRS; pathway analyses would be the responsibility of and coordinated through RIRA or NIES; and questions about existing surveillance data would be coordinated through and by STAS.

CHAPTER 3. RESPONSE COORDINATION

After an evaluation of an emerging disease incident has been completed, and the recommendations include response options, the cross-unit Emerging Disease Team will take the lead in coordinating the response option(s) assigned by the VS Executive Team. The actions necessary to develop and implement specific responses are outside the scope of this document. However, standard program, regulatory, and budgetary business practices will be followed and will include, as needed, the use of VS Guidance 12001.2 as well as response evaluation tools such as the “Technique for the Assessment of Intervention Options” (TAIO) and Decision Lens.

If the emerging disease impacts a single species, then the appropriate SPRS Commodity Center Director (or their designee) will become the leader of the cross-unit Emerging Disease Team and will be responsible for developing and implementing response options. If a disease impacts more than one commodity, then it will be the responsibility of the SPRS Associate Deputy Administrator to designate a leader for the team. The team leader may request further analyses to clarify response options. Aspects to be considered include impacts to international trade, animal health, public health, food security, agricultural production, and the environment; geographic distribution of disease; political pressures; resource intensity; available subject matter expertise; diagnostic capabilities; regulatory authorities; and the potential for bioterrorism.

Possible responses are listed by risk category below and will depend on the specific situation. Additionally, there may be responses not identified in the document that might be relevant to a certain emerging disease incident.

3.1 Possible Responses to Emerging International Threats

Risk Level 1 (Nominal Risk to U.S. Animal or Public Health):

- Provide continual monitoring of emerging disease incident and situational awareness updates, as needed

Risk Level 2 (Potential Risk to U.S. Animal or Public Health):

- Continue to monitor emerging disease incident and provide situational awareness updates, as needed
- Assess preparedness status for introduction (e.g. presence of valid diagnostic tests, vaccines)

Risk Level 3 (Impending Risk to U.S. Animal or Public Health) or insufficient information available to assign to a risk level

- Work with APHIS International Services personnel in relevant countries to get additional information on disease incident
- Determine need for further evaluation and characterization of incident by an Emerging Disease Team
- Conduct pathways and import risk assessments, and determine data gaps and needs for additional information to inform high risk entry points
- Implement import restrictions or increased surveillance, as needed

- Develop and distribute communication materials to relevant partners and stakeholders

3.2 Possible Responses to Emerging Domestic Threats

Risk Level 1 (Nominal Risk to U.S. Animal or Public Health):

- Contact diagnostician(s), State and Federal partners, and relevant diagnostic laboratories to get additional information and confirmation of disease incident
- Identify needs for and conduct additional research (e.g., animal inoculation studies, additional molecular characterization of pathogen)
- Determine reservoirs, transmission pathways and potential impacts on U.S. animal or public health
- Implement increased surveillance, as needed
- Conduct an investigation on farms meeting an epidemiological or disease based case definition, as needed to characterize incident
- Develop and distribute communication materials to relevant agency and non-agency partners and stakeholders
- Increase diagnostic capacity, as needed

Risk Level 2 (Potential Risk to U.S. Animal or Public Health):

- All options in Level 1
- Increase laboratory diagnostic capacity and evaluation or development of effective vaccines
- Provide guidance to States, industry, and stakeholders for prevention, detection, and response to emerging disease

Risk Level 3 (Impending Risk to U.S. Animal or Public Health):

- All options in Levels 1 and 2
- Develop a case definition for reporting
- Determine need for and establish regulations and/or new policy

Risk Level 4 (Current Risk to U.S. Animal or Public Health):

- All options in Levels 1-3
- Conduct active surveillance (situational dependent) and develop a surveillance plan
- Conduct analytical epidemiologic investigations
- Determine need for and establish regulations for a new program (certification, control, or eradication) or new policies

CHAPTER 4. COMMUNICATION AND INFORMATION SHARING

Throughout the process of developing an emerging disease response, situational awareness and risk assessment information, including the results of disease incident evaluation and characterization, will be shared with States, Tribes, affected industry and other government agencies such as Food and Drug Administration, Food Safety Inspection Service, CDC, and stakeholders. These will be shared in writing and will include the use of Stakeholder Registry Notices that can be further distributed by e-mail to the States, impacted industry associations, and other Federal partners. If a determination is made that a disease poses an actionable threat, VS will engage the National Assembly of State Animal Health Officials, American Association of Veterinary Laboratory Diagnosticians, industry associations, and industry emerging disease groups as appropriate to develop response options. Formal USDA communications around specific response activities, such as investigative studies, eradication, control, or certification programs will be coordinated with APHIS Legislative and Public Affairs.

Communication and collaboration among those government agencies, industries, and stakeholders impacted by a potential or emerging disease is essential to ensure a timely and appropriate response. Communication should flow in both directions to ensure that information is current and analyses/evaluations are well vetted and accurate. This communication, collaboration and information sharing needs to be continuously occurring, allowing emerging diseases to be detected early. These communications will be varied depending on the situation, but will include both written and verbal methods.

It is important to stress that any emerging disease information released by the USDA will maintain the confidentiality of any individual owner.

4.1 Communication within USDA

4.1.1 Situational awareness documentation

A written emerging disease brief summarizing available information and risk level assignment will be prepared by the RI team and VS POCs as needed (see section 2.3). These summaries will be provided to VS liaisons for discussion during regularly scheduled meetings or ad hoc meetings based on the urgency of the situation. Briefs may be further distributed internally and discussed during regularly scheduled VS internal conference calls.

4.1.2 Summary of evaluation and characterization of disease incidents with recommendations for response

When review of emerging disease briefs and other information results in a further evaluation of an emerging disease incident by an Emerging Disease Team, a summary of the evaluation and recommended response options will be provided to VSET for review and decision-making during regularly scheduled weekly or monthly meetings, or during ad hoc meetings as needed based on the urgency of the situation.

4.2 Communication with Federal Partners, State and Industry

VS liaisons are responsible for distributing written situations reports of the emerging disease incident to Federal, State and industry partners. In addition to written notices, conference calls, webinars or face-to-face meetings may be required. The situation report will be updated as appropriate and distributed as additional information becomes available.

4.3 Public Communication

Public communication will be handled at various levels and through multiple written and/or verbal methods. Stakeholder announcements and FAQ websites are a few of the tools that may be utilized. Not all emerging diseases will warrant public communication.

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APPENDIX A: Guidance for Assigning Diseases to a Risk Level

Threat Definitions

	Host Range	Pathogenicity	Current Geographic Range	
			Has not been identified in the U.S. within last year	Disease confirmed in the U.S.
Minimal	Restricted to a single, non-livestock species and/or wildlife species with no public health concerns	Low morbidity/mortality	Local presence in a foreign country with no transboundary spread	Small local presence with no spread, and no recognized high risk transmission pathways
Moderate	Single agricultural commodity and/or a new host species recognized	Moderate morbidity/mortality, or potential to affect public health	Present in a foreign country with minor to moderate spread to neighboring countries or regions	Local presence with limited spread to surrounding counties/parishes, or recognized high risk transmission pathways for spread
Significant	One or more agricultural commodities and/or zoonotic transmission risks	High morbidity/mortality or significant risk to public health	Present in a foreign country bordering the US, or trading partner with a recognized high risk transmission pathway	Multiple emergence points or regional spread recognized

Using Threat Definitions to Assign Diseases to Risk Levels³

Level 1—Nominal risk to US Animal or Public Health:

- Host Range: Minimal to moderate host range for diseases not recently identified in U.S.; minimal host range for diseases confirmed in the U.S.
- Pathogenicity: Minimal to moderate
- Current geographic range: Minimal geographic range for diseases confirmed in the U.S.; minimal to moderate geographic range for diseases not recently identified in U.S.

Level 2—Potential risk to US Animal or Public Health:

- Host range: Moderate to significant host range for diseases not recently identified in U.S.; moderate host range for diseases confirmed in the U.S.
- Pathogenicity: Moderate to significant
- Current geographic range: Minimal geographic range for diseases confirmed in the U.S.; minimal to moderate geographic range for diseases not recently identified in the U.S.

Level 3—Impending risk to US Animal or Public Health:

- Disease not recently identified in the U.S.
 - Host range: Significant
 - Pathogenicity: Moderate to significant
 - Current geographic range: Significant
- Disease confirmed in the U.S.
 - Host range: Moderate

³Threat Definitions and Risk Levels are qualitative, and assignment of individual emerging animal diseases may vary, based on the information available.

- Pathogenicity: Moderate to significant
- Current geographic range: Moderate

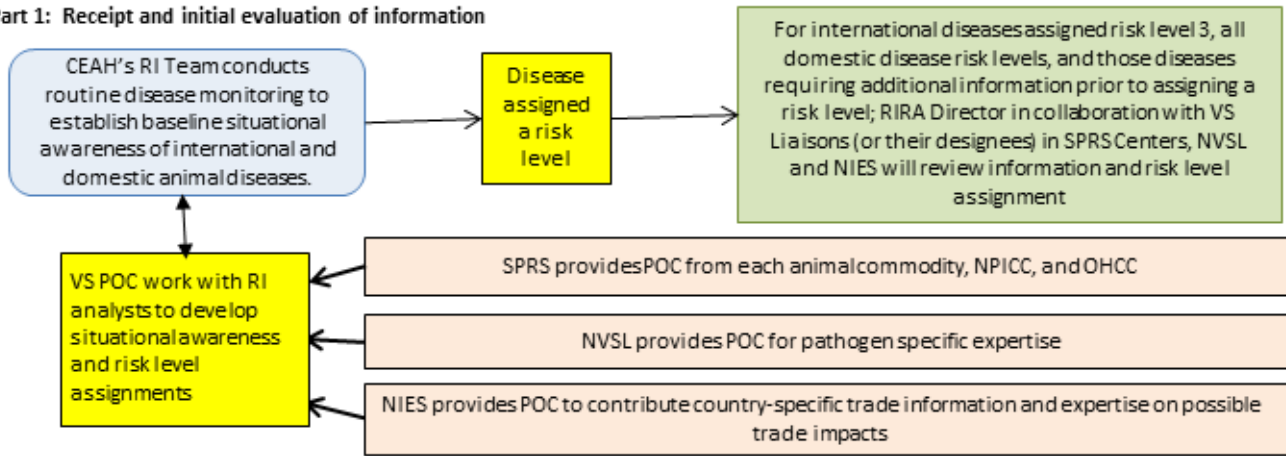
Level 4—Current risk to US Animal or Public Health:

- Host range: Significant
- Pathogenicity: Moderate to significant
- Disease confirmed in U.S. with moderate to significant geographic range

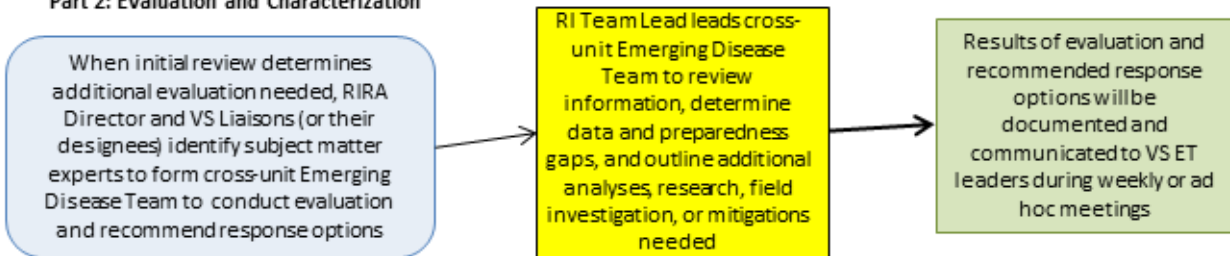
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Appendix B: Emerging Disease Identification, Characterization and Response

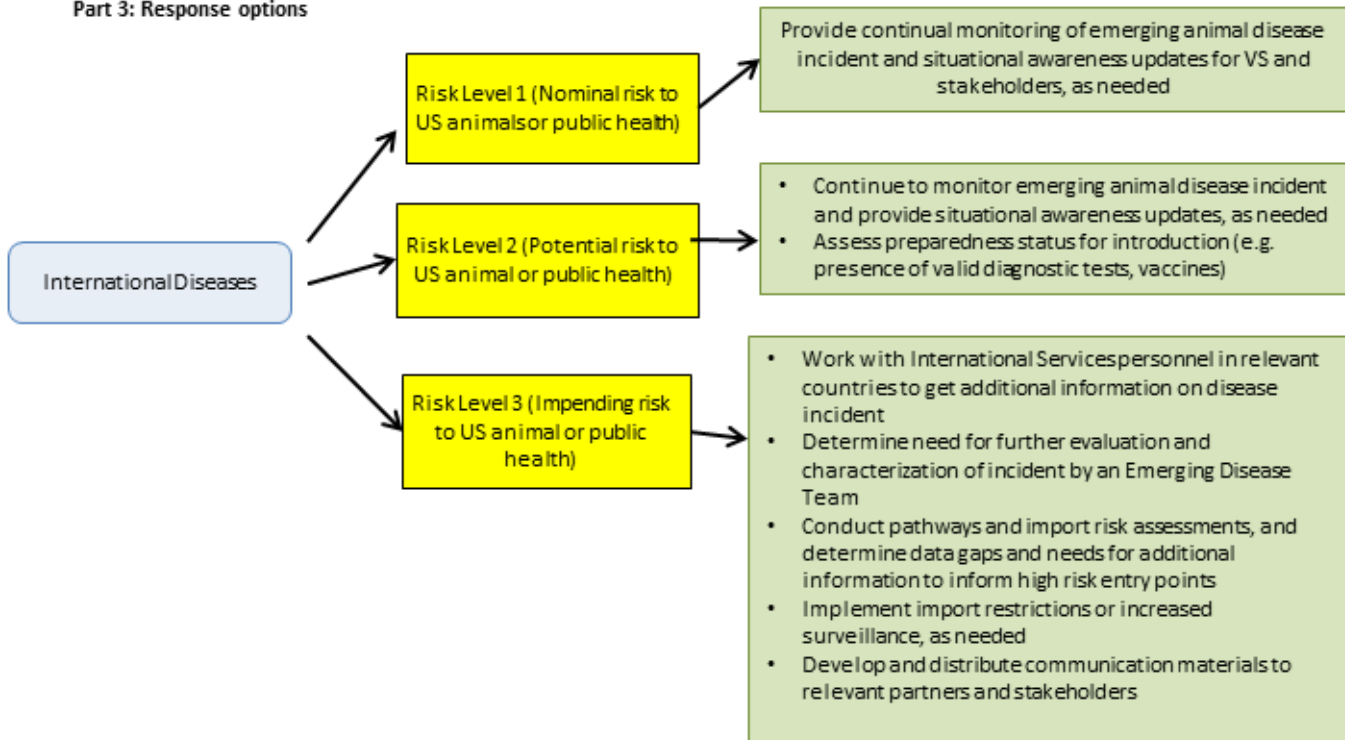
Part 1: Receipt and initial evaluation of information

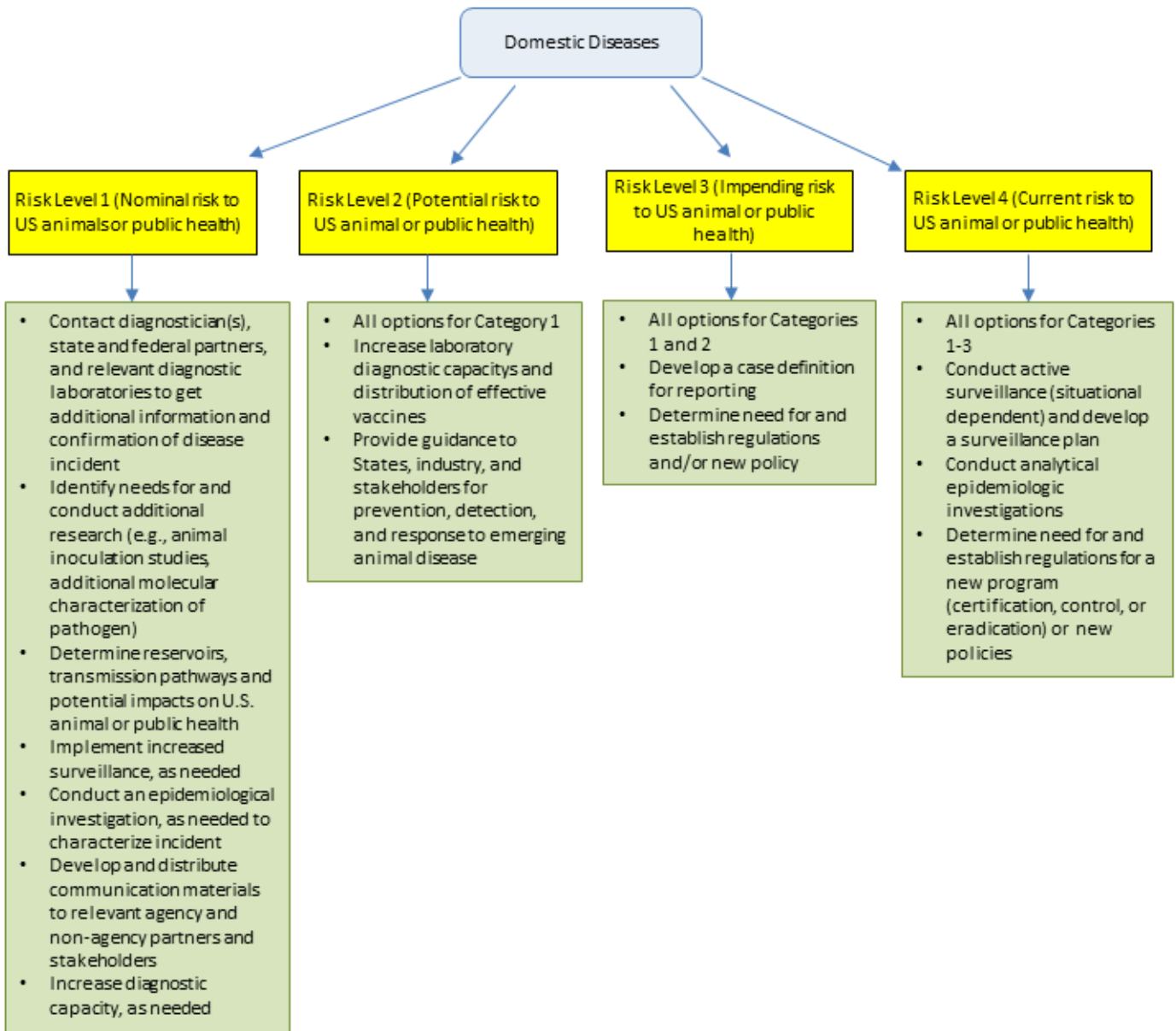


Part 2: Evaluation and Characterization



Part 3: Response options





Acronyms

- CEAH: Center for Epidemiology and Animal Health
- RI: Risk Identification
- POC: Points of Contact
- RIRA: Risk Identification and Risk Assessment Unit
- SPRS: Surveillance, Preparedness and Response Services
- NPICC: National Preparedness and Incident Coordination Center
- OHCC: One Health Coordination Center
- NVSL: National Veterinary Services Laboratories
- NIES: National Import Export Services
- VS ET: Veterinary Services Executive Team

High-Consequence Foreign Animal Diseases and Pests

In carrying out our safeguarding mission, the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) works to ensure the continued health and welfare of our Nation's livestock and poultry populations. One important aspect of this work is emergency preparedness—making sure we are ready to respond effectively when faced with a foreign animal disease outbreak or pest infestation. As part of these efforts, APHIS' animal health officials identify "high-consequence" foreign animal diseases and pests. These are serious diseases and pests that do not currently exist in the United States. If introduced here, they pose a severe threat to U.S. animal health and, in some cases, the economy and human health as well.

The list divides diseases and pests into tiers according to risk level, as described below.

Tier 1

Tier 1 diseases are those of national concern. They pose the most significant threat to animal agriculture in the United States, as they have the highest risks and consequences. This category includes:

- African swine fever*
- classical swine fever*
- foot-and-mouth disease*
- avian influenza (any strain that is highly pathogenic or has zoonotic significance)*
- virulent Newcastle disease*

Tier 2

Tier 2 diseases are transmitted primarily by pests. How quickly these diseases spread and APHIS' ability to control or eradicate an outbreak depends largely on whether these pests are present in the environment and whether they can transmit the disease between

animals. This category includes:

- heartwater
- New World screwworm
- Rift Valley fever*
- Venezuelan equine encephalitis*

Tier 3

Tier 3 diseases and pests pose less risk and fewer consequences than those in Tiers 1 and 2, but still rise to the level of inclusion because of their potential negative impact on animal or human health. This category includes:

- African horse sickness
- contagious bovine pleuropneumonia and contagious caprine pleuropneumonia
- glanders and melioidiosis
- henipaviruses (Hendra and Nipah)*
- rinderpest* and peste des petits ruminants*
- tropical bont tick

What the List Means

These high-consequence foreign animal diseases and pests are of primary importance to APHIS' emergency preparedness officials, guiding many of our program priorities. For example, the list will help inform decisions on how we procure countermeasures to address a disease outbreak and, potentially, funding for research and response activities. The diseases marked with an asterisk are those APHIS has identified as biological threats that need to be considered in program priorities and countermeasure stockpile requirements.

How We Developed the List

APHIS developed this list after carefully considering all foreign animal diseases and pests that could negatively affect livestock or poultry. We also took into account disease agents that are identified in the agricultural select agent program, as well as those that can severely threaten public health or animal health (zoonotic diseases) or the safety of animal products. We did not include diseases and pests that are endemic, or common, in the United States or any disease APHIS

already manages through one of our animal health programs (e.g., brucellosis, bovine tuberculosis, scrapie, etc.).

When developing the list, another overall issue we considered was a disease's potential for introduction into the United States. The eight criteria below also helped guide our decisions on whether or not to designate an animal disease or pest as one of high, negative consequence.

- 1) high epidemic/epizootic potential, or the ability to rapidly spread and infect a large number of animals
- 2) high economic impact
- 3) large impact on trade, both domestic and international
- 4) high animal morbidity and mortality, or the capability to cause disease and death respectively
- 5) high potential to infect multiple species
- 6) inability to detect the disease rapidly
- 7) ability to vaccinate for the disease
- 8) high zoonotic (can be transmitted from animals to people) potential

APHIS animal health officials will review and update this list periodically. In doing so, we will seek broad input from stakeholders to inform our decisions.

Learn More

If you have any questions about the list of high-consequence animal diseases and pests, please call APHIS Veterinary Services at (301) 851-3595. To learn more about animal health emergency management, go to www.aphis.usda.gov/animal_health/emergency_management.

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Veterinary Services Proposed Framework for Response to Emerging Animal Diseases In the United States

Introduction

Veterinary Services (VS) proposes a framework to help it respond effectively to emerging diseases. This framework will help VS identify and evaluate emerging disease events and define the appropriate responses. VS plans to work with all relevant stakeholders in implementing the appropriate responses. This framework document defines the process by which VS will identify, evaluate, and respond to emerging diseases, and the implementation of this process as a VS core business practice.

Emerging animal diseases include occurrences of illness or death in animals caused by a newly identified pathogen or strain, a known pathogen in a new geographic location, or a new presentation of a known pathogen. These disease events may negatively affect animal health, public health, and trade. Examples of such disease occurrences in the United States in the past 20 years include porcine reproductive and respiratory syndrome, infectious salmon anemia, West Nile virus, and monkey pox virus. More recent examples include the emergence of Schmallenberg virus in Europe and porcine epidemic diarrhea virus in the United States. (See Appendix 1 for a further definition of an emerging animal disease.)

VS has long engaged in emerging disease detection and response. Since 2001, VS strategic plans have incorporated identification and response to emerging diseases within their major goals. The “VS: A New Perspective” document also includes the concepts of identification, analysis, and response to emerging diseases.

Rapid detection and response to emerging diseases are critical to animal agriculture. Some emerging diseases can spread rapidly, threatening the livelihood of producers and limiting their access to important export markets. Rapid response to emerging diseases can prevent or limit sudden and negative animal health, economic, food security, and public health consequences by providing useful animal health information to cooperators and Agency policymakers to inform their actions.

VS has an extensive capacity and history of working with animal agriculture participants, academic institutions, and State animal health officials. VS intends to apply this collaborative approach and our expertise to increase awareness of, detect and identify, characterize, investigate, and respond to emerging disease threats, and provide accurate information to all interested parties. VS will use the activities

Rapid detection
and response to
emerging diseases
is a VS core
business practice.

identified in this framework to provide a solid scientific foundation for developing strategic intervention actions and informing the public of all appropriate actions. These may or may not require a regulatory response.

Approach

This document describes four goals for addressing emerging diseases:

- 1) Undertake global awareness, assessment, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications;
- 2) Detect, identify, and characterize disease events;
- 3) Communicate findings and inform stakeholders; and
- 4) Respond quickly to minimize the impact of disease events.

A fifth goal, addressing recovery from the event, would include strategies that stabilize animal agriculture, the food supply, and the economy, and protect public health and the environment. These activities are an extension of this framework and will not be detailed here. They include the secure food supply initiatives (Secure Pork Supply Plan, etc.; see the VS Web site for more details).

Goal 1: Global awareness, assessment, and preparedness

VS recognizes the need to have an enhanced system for detecting emerging diseases in the United States and in other countries. The Risk Identification Unit (RIU) within the Center for Epidemiology and Animal Health (CEAH) is primarily responsible for identifying emerging diseases globally, including those that may pose a threat to U.S. agriculture. The group will work with other areas in VS and the Animal and Plant Health Inspection Service (APHIS), other government and Tribal agencies, industry, and other stakeholders to identify and describe emerging animal diseases.

International emerging diseases will be identified and characterized, in part from contacts established through APHIS International Services and regional and global partners such as the Inter-American Institute for Cooperation on Agriculture, the International Regional Organization for Plant and Animal Health, the Pan-American Foot and Mouth Disease Centre, the World Organization for Animal Health (OIE), the Food and Agriculture Organization of the United Nations, and the World Health Organization.

Domestically, the RIU will use information resources established as part of VS' nationwide Federal system of animal health professionals. This system has direct contact with accredited veterinarians; producers; livestock market operations; diagnostic laboratories; universities; State

VS will evaluate and monitor global emerging diseases and develop science-based options for response.

and Tribal animal health, public health, and wildlife health officials; and other Federal agencies, such as the Food and Drug Administration, the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency, the U.S. Department of the Interior, the U.S. Department of Homeland Security (DHS), and the U.S. Department of Defense. These activities will allow VS to provide a broad scope of information to stakeholders, decisionmakers, and incident responders by incorporating both international and domestic perspectives.

A cross-unit VS team led by the RIU will evaluate global emerging animal diseases, recommend priority status for a disease, and present alternative actions for VS. VS' Science, Technology, and Analysis Services division will assess pertinent issues and develop science-based options for response. In addition, regular meetings or conference calls will be held with stakeholders to gather additional input and to prioritize areas to address.

Goal 2: Detect, Identify, and Characterize

A variety of sources or systems can help detect an emerging animal disease in the United States. These include producers, practitioners, diagnostic laboratories, researchers, internet sources, public health information sources, State and Federal field forces, and active and passive ongoing surveillance and monitoring programs. Consequently, strong partnerships and constant communication among these partners will promote early awareness that an emerging animal disease may exist. Enhanced passive surveillance (EPS) provides a framework for reporting disease events that meet syndromic case definitions or observations without a specific disease diagnosis. An emerging animal disease is likely to present itself in this way. VS is currently collaborating with DHS and other stakeholders on the development of a system for reporting such events through EPS.

Once there is a case definition for reporting purposes, an emerging disease must be rapidly reported if VS and our stakeholders are to consider early intervention actions before the event is amplified. VS, the U.S. Animal Health Association (USAHA), and the American Association of Veterinary Laboratory Diagnosticians (AAVLD) have developed a nationally consistent approach for reporting animal diseases – the National List of Reportable Animal Diseases (NLRAD). VS intends to promulgate regulations which will require that diseases on this list, as well as any newly emerging disease, be reportable to VS as the national veterinary authority.

Through this VS-USAHA-AAVLD collaboration, standard operating procedures have been drafted to approve and maintain the NLRAD. Once VS implements the list and finalizes the reporting parameters, it will consider updates and edits to the NLRAD when amending its

VS will employ passive and active systems to detect emerging diseases, including mandatory reporting.

regulations and guidance documents or the National Veterinary Stockpile list. Updates will also be considered when changes are made to the U.S. Department of Health and Human Services-U.S. Department of Agriculture Select Agent List, the CDC bioterrorism agent list, or the OIE list of reportable diseases; when an emerging issue or condition develops that may require addition to the NLRAD; and on stakeholder request.

Once initial detections of disease are identified and reported, either through confirmed laboratory diagnostics or significant morbidity or mortality events without diagnostic confirmation, VS will launch an investigation. VS Guidance Document 12001.2, *Policy For the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents*, provides VS personnel, State and Tribal animal health officials, and National Animal Health Laboratory Network laboratories specific guidance for conducting investigations and reporting results for emerging animal disease events.

The primary reason for conducting field investigations will be to quickly learn about the source and circumstances that led to the emerging disease. The findings of the investigation will allow VS and our stakeholders to make science-based decisions on how to reduce disease spread, either in animals or, in the case of zoonotic diseases, in humans.

A top priority in addressing an emerging disease is to gather information on key considerations to determine the best options for engagement. These considerations include, but are not limited to, the following:

- Trade impacts (interstate and international);
- Food security impacts (real vs. perceived, transmission via meat products);
- Public health impacts (real vs. perceived);
- Animal health impacts (morbidity, mortality, incidence, clinical signs, species affected, apparent mode of transmission);
- Production impacts (including segment of industry affected);
- Environmental impacts (wildlife susceptibility, disposal issues);
- Geographic scope (local, regional, national, or international, extent and rate of spread);
- Politics;
- Resource intensity;
- Available expertise;
- Diagnostic capabilities (validity of diagnosis, availability of laboratory tests, sensitivity and specificity of diagnostic tests);
- Authorities; and
- Potential for bioterrorism.

VS will collaborate with stakeholders to rapidly investigate and assess emerging diseases.

VS will discuss this information with State and Tribal animal health officials and industry representatives to aid all parties in determining the appropriate level of engagement.

Goal 3: Communicate findings and inform stakeholders

As the Federal Agency responsible for safeguarding animal health, VS must both receive and disseminate, in a nationally coordinated fashion, information about emerging disease events. Throughout and following the initial detection, identification, and characterization phase, VS must serve as the nationally recognized source for official information and must be in regular communication with all relevant stakeholders. The affected industry, States, other Federal Agencies, international trade partners, Congress, and the public expect VS to have consistent, complete, and correct information about an emerging animal disease event. As an event progresses, VS will need to continuously gather and disseminate information.

Data and reporting. During the initial response, VS must collect, analyze, and summarize data on cases by time, place, and host characteristics to suggest a source of the outbreak, type of spread (common source or propagative), and method of transmission. Generating hypotheses is critical, and during later response phases, epidemiological field studies (e.g., case-control; retrospective cohort) should be conducted to test the hypotheses. This analytical epidemiology wave is needed to characterize the magnitude and scope of the problem, and the information can be used to formulate an immediate response. Flexible and available information technology systems are essential to support this analysis and reporting.

VS may develop and share other data, including investigation reports, educational materials, pathway analyses, and predictive modeling. Most importantly, VS should quickly and clearly communicate the actions it will take to answer questions about the threat and impact of the disease, fully characterize the event (past, present, and future), and gather and use information to develop policy if that becomes necessary.

Data security is a critical aspect of information management during an emerging disease event. VS will store, handle, and analyze data within secure Federal information technology systems. Where appropriate, VS will collaborate with States, Tribes, and third-parties to access and analyze data. VS will only publish analyses and reports that contain aggregated data and do not specifically identify producers or individual facilities.

While maintaining appropriate data security, VS will serve as the national repository for shared information on emerging disease events.

Goal 4: Respond to minimize impacts

The response to an emerging disease will likely be different from a foreign animal disease response. The response to a recognized foreign animal disease (e.g., highly pathogenic avian influenza) is well defined and often immediately requires aggressive measures, including depopulation. In these cases, the causative agent is often well known and the disease and its effects are well understood, as are the measures needed to deal with the disease. These have been examined thoroughly.

“Response” to emerging diseases does not always necessitate depopulation.

For emerging diseases, VS will undertake adaptive response measures, rather than a predetermined control action. Unknowns may limit the agency response to understanding the epidemiology and ecology of the disease and pathogen using all available resources, and then to rapidly share accurate information and intervention options with stakeholders. If control or eradication measures are recommended, VS will provide science- and risk-based approaches and systems to facilitate industry continuity of business operations, limit spread of the disease, and prescribe coordinated approaches for eliminating the disease from populations of animals. If control or eradication measures include hold orders or depopulation, VS will work with industries, States, and Tribes to identify appropriate compensation mechanisms.

Assessing response options. With accurate, consistent, and shared information comes the ability to collaborate on appropriate responses. These responses range from information dissemination to full mobilization of resources for rapid eradication. VS will work with the affected industry, States, and other affected stakeholders to determine and implement the appropriate response.

VS will lead the collaborative development and implementation of emerging disease response options.

VS may form State-industry-Federal working groups, deploy rapid response assessment teams, or use the National Incident Management System and incident management teams. Other VS actions may include diagnostics and vaccine development, education, implementation of certification programs, control measures such as vaccination and movement restrictions, and identification of research priorities. VS will assume a leadership role when providing services (e.g., information sharing) to a primary responder; when partnering with industry, States, and Tribes (e.g., epidemiology investigations; surveillance); or when coordinating a response (e.g., coordination of quarantine and depopulation actions; indemnification). VS may also support stakeholder actions by providing human resources, funding, technical expertise, and educational and outreach materials.

Two tools may be used to assess response options. VS is increasingly using TAIO (Technique for the Assessment of Intervention Options), an approach that can engage internal and external stakeholders, reduce complexity, and ensure transparency in evaluating disease

management, surveillance, or response actions. The outcome of TAIO is an assessment of the epidemiological and economic success of selected options. See Appendix 2 for more information on the TAIO process.

Decision Lens is a program that facilitates prioritization and resource allocation that best matches overall strategies. It can combine data inputs and other intelligence to evaluate and support decisions.

Preparedness. An effective collaborative response to an emerging disease requires advance preparation. Preparedness and response planning for emerging disease incidents are crucial to effectively protect public health, animal health, animal agriculture, the food supply, and the economy. VS and our stakeholders—local, State, Tribal, and Federal government agencies, and food and agriculture industries—must collaborate to develop coordinated incident goals, guidelines, strategies, and procedures before an incident.

For any response to an emerging disease, all parties must clearly communicate their goals for managing response efforts. States, Tribes, and industry need a range of options for different situations, and these options must include exercising hold orders or quarantines by State and Tribal animal health officials. Since the industries are affected greatly by any response, industries should develop response strategies for known trans-boundary agents and for situations involving novel agents. Communication and collaboration ahead of an outbreak will reduce the likelihood of unmet expectations, and improve the speed and effectiveness of the response.

Appendix 1: Definition of Emerging Animal Disease

VS defines an emerging animal disease as:

- Any animal disease or infection not known to exist in the United States, including a new strain of a known disease occurring in any animal species, including wildlife;
- An emerging animal disease with zoonotic potential;
- Unexpected and unexplained increase in morbidity or mortality of diseased animals; and
- Evidence of a change in the epidemiology of a known animal disease such as increased pathogenicity, expanded host range, or clinical signs that do not fit the classical picture.

While not diseases, exotic vectors, if identified, should be reported to State and Federal animal health officials for further investigation.

Appendix 2: The TAIO Process

The TAIO process is distinct from other processes used within VS to evaluate potential and existing disease events. A few of the key differences that distinguish the TAIO process from these other analytical processes are:

- The TAIO process integrates economic (benefit-cost), risk assessment, and epidemiological methods into an analysis of disease management intervention options.
- The TAIO process conforms to regulatory requirements for benefit-cost analysis by appropriately framing the objectives of the analysis, establishing explicit performance metrics for the options being assessed, assessing each option in terms of the level of net benefit produced, and expressing the output of the assessment in terms of risk-weighted benefits and costs. The net benefits measured in the assessment are weighted by the likelihood of success of a given disease intervention option in accomplishing its stated objectives.
- The TAIO process provides an explicit evaluation of the proposed intervention options, concluding with a documented explanation as to why the preferred option is being recommended.
- TAIO reduces decisionmaking complexity through a series of organizational questions that eliminate sectors (e.g., species, commodity, region, time) and pathways that are not directly relevant to the determined objectives.
- Throughout the TAIO process, the state of available data is documented and data gaps are identified. The analysis and recommendations are revised as new information becomes available to fill existing gaps.

Top Diseases by Commodity Identified Through the 2015 ARS Survey

Beef

Bovine Respiratory Syncytial Virus (BRSV), Bovine Spongiform Encephalopathy (BSE), Bovine TB, Bovine Viral Diarrhea (BVD), Brucellosis, Coccidiosis, Foot and Mouth Disease (FMD), Infectious Bovine Rhinotracheitis (IBR), Intestinal Parasites, Mannheimia haemolytica, Pasteurella multocida,

Dairy

Bovine Leukemia Virus (BLV), Bovine Respiratory Syncytial Virus (BRSV), Bovine Viral Diarrhea (BVD), Bovine TB, Coccidiosis, Foot and Mouth Disease (FMD), Mannheimia haemolytica, Mastitis, Mycoplasma bovis, M. paratuberculosis (Johne's), Pasteurella multocida

Equine

African Horse Sickness, Piroplasmosis, Vesicular Stomatitis Virus (VSV), West Nile Virus (WNV)

Goats/Small Ruminant

Blue Tongue, Bovine TB, Brucellosis, Coccidiosis, Intestinal parasites, Mannheimia haemolytica, Mastitis, Q-fever, M. paratuberculosis, Scrapie, Toxoplasmosis, West Nile Virus

Poultry – Breeders/Layers

Avian Influenza, Avian Leukosis Virus (ALV), Coccidiosis, Gangrenous dermatitis, Infectious Bursal Disease, Infectious Laryngotracheitis, Marek's Disease, Mycoplasma gallisepticum, New Castle low virulence, New Castle virulent/exotic, Necrotizing enteritis, Poulet enteritis

Poultry – Broilers/Meat

Avian Influenza, Avian pneumovirus (APV), Coccidiosis, Gangrenous dermatitis, Infectious Bursal Disease, Infectious Laryngotracheitis, Marek's Disease, Mycoplasma gallisepticum, New Castle low virulence, New Castle virulent/exotic, Necrotizing enteritis, Poulet enteritis

Sheep/Small Ruminant

Blue Tongue, Bovine TB, Brucellosis, Coccidiosis, Intestinal parasites, Mannheimia haemolytica, Mastitis, Q-fever, M. paratuberculosis, Scrapie, Toxoplasmosis, West Nile Virus

Specialty Species

Anaplasmosis, Bovine TB, Brucellosis, Chronic Wasting Disease (CWD), Coccidiosis, Epizootic Hemorrhagic Disease (EHD), Intestinal parasites, Malignant Catarrhal Fever (MCF), Mycoplasma bovis, West Nile Virus (WNV)

Swine

African Swine Fever (ASF), Classical Swine Fever (CSF), Foot and Mouth Disease (FMD), Lawsonia intracellularis, Leptospirosis, Pasteurella multocida, Porcine circovirus, Porcine Epidemic Diarrhea Virus (PEDV), Porcine Reproductive and Respiratory Syndrome (PRRS), Swine Influenza Virus, Trichinellosis

Turkey

Avian Influenza, Coccidiosis, Gangrenous dermatitis, Infectious Bursal Disease, Infectious Laryngotracheitis, Marek's Disease, Mycoplasma gallisepticum, Necrotizing enteritis, Poulet enteritis

REVIEW ARTICLE

Review of the Global Distribution of Foot-and-Mouth Disease Virus from 2007 to 2014

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Summary

Foot-and-mouth disease (FMD) virus affects livestock worldwide. There are seven different serotypes, each with a diversity of topotypes, genetic lineages and strains. Some lineages have different properties that may contribute to sporadic spread beyond their recognized endemic areas. The objective of this study was to review the most significant FMD epidemiological events that took place worldwide between 2007 and 2014. Severe epidemics were caused by FMD virus (FMDV) lineage O/Asia/Mya-98 in Japan and South Korea in 2010, both previously free of disease. In India, where FMD is endemic, the most important event was the re-emergence of lineage O/ME-SA/Ind-2001 in 2008. Notably, this lineage, normally restricted to India, Bangladesh, Nepal and Bhutan, was also found in Saudi Arabia and Libya in 2013 and has caused several outbreaks in Tunisia and Algeria in 2014–2015. In January 2011, FMDV-positive wild boars were found in Bulgaria, where the disease last occurred in 1996, followed by 12 outbreaks in livestock infected with FMDV O/ME-SA/PanAsia2. In 2012, FMDV SAT2 caused outbreaks in Egypt and the Palestinian Autonomous Territories. Another significant event was the emergence of FMDV Asia1 Sindh-08 in the Middle East. In South America, one outbreak of FMDV serotype O, topotype Euro-SA was reported in Paraguay in 2011, which was recognized as FMD-free with vaccination at the time. Lessons learned from past events, point out the need for an integrated strategy that comprises coordinated global and regional efforts for FMDV control and surveillance. Specific local characteristics related to host, environment and virus that condition FMD occurrence should be carefully considered and incorporated to adapt appropriate strategies into local plans. In this review, we compiled relevant epidemiological FMD events to provide a global overview of the current situation. We further discussed current challenges present in different FMD areas.

Introduction

Foot-and-mouth disease (FMD) is considered one of the most contagious diseases of livestock. FMD was the first animal disease virus ever described (Loeffler and Frosch, 1898), and it is still an important obstacle for agricultural development in endemic countries. Although mortality caused by FMD in infected animals is low, outbreaks result

in significant economic consequences due to direct losses, such as low milk and meat production, treatment cost, loss of draught power, as well as animal and animal products trade limitations (James and Rushton, 2002; Perry et al., 2002; Perry and Rich, 2007; Nampanya et al., 2012). Additionally, FMD is a matter of animal welfare concern due to current requirements for massive culling of infected and potentially 'in contact' animals when outbreaks occur in

FMD-free regions. An example of this was the 2011 outbreak in South Korea, where over 3 000 000 pigs were killed (Park et al., 2013).

FMD is caused by a virus from the *Picornaviridae* family, genus *Aphthovirus*, generically referred to as FMD virus (FMDV) (Brooksby, 1958). Seven different FMDV serotypes have been described, namely, A, O, C, SAT1, SAT2, SAT3 and Asia 1 (Grubman and Baxt, 2004). Notably, serotype C was last detected in Kenya and Brazil in 2004 (Sangula et al., 2011).

FMDV may cause incidental infection in a wide variety of host species, but cloven-hoofed animals (order: *Artiodactyla*) have a crucial epidemiological role in maintaining the virus in the environment (Alexandersen and Mowat, 2005). Livestock species, including cattle, water buffalo (*Bubalus bubalis*), pigs, sheep and goats are susceptible to infection and can spread the disease, whereas the African buffalo (*Syncerus caffer*) is known to be the main wildlife reservoir for SAT serotypes in Africa (Vosloo et al., 1996; Thomson et al., 2003).

FMDV control programmes should be designed based on current knowledge of FMD status at a global level. The distribution of different viruses is relevant to determine targeted surveillance, to tailor control strategies and to decide the vaccine antigens that should be used in each area or region. We have reviewed the global epidemiological

situation of FMD in endemic regions and countries reporting outbreaks over the last 7 years (2007–2014). We collected information from published literature, the reference laboratory network (RLN) reports generated by the World Reference Laboratory for Foot-and-Mouth Disease (WRLFMD) and official reporting to the World Organization for Animal Health (OIE).

FMD distribution overview

Endemic areas have been described in seven geographical FMDV *pools* that share similar viruses. (Rweyemamu et al., 2008; Paton et al., 2009b). These viral *pools* are often the result of ecological similarities, common livestock exchange and cultural traditions. This review describes the epidemiological situation of regions corresponding to each *pool* and the viruses characterized between 2007 and 2014 in Asia, Africa and South America (Fig. 1). Occurrence of FMD in non-endemic areas is also described.

Endemic pools in Asia

Pool 1: South-East Asia–East Asia overview

This pool encloses FMDV in South-East Asia (SEA) and eastern Asia. Incidence and persistence of FMD is heterogeneously distributed throughout *pool 1* (Table 1). Countries

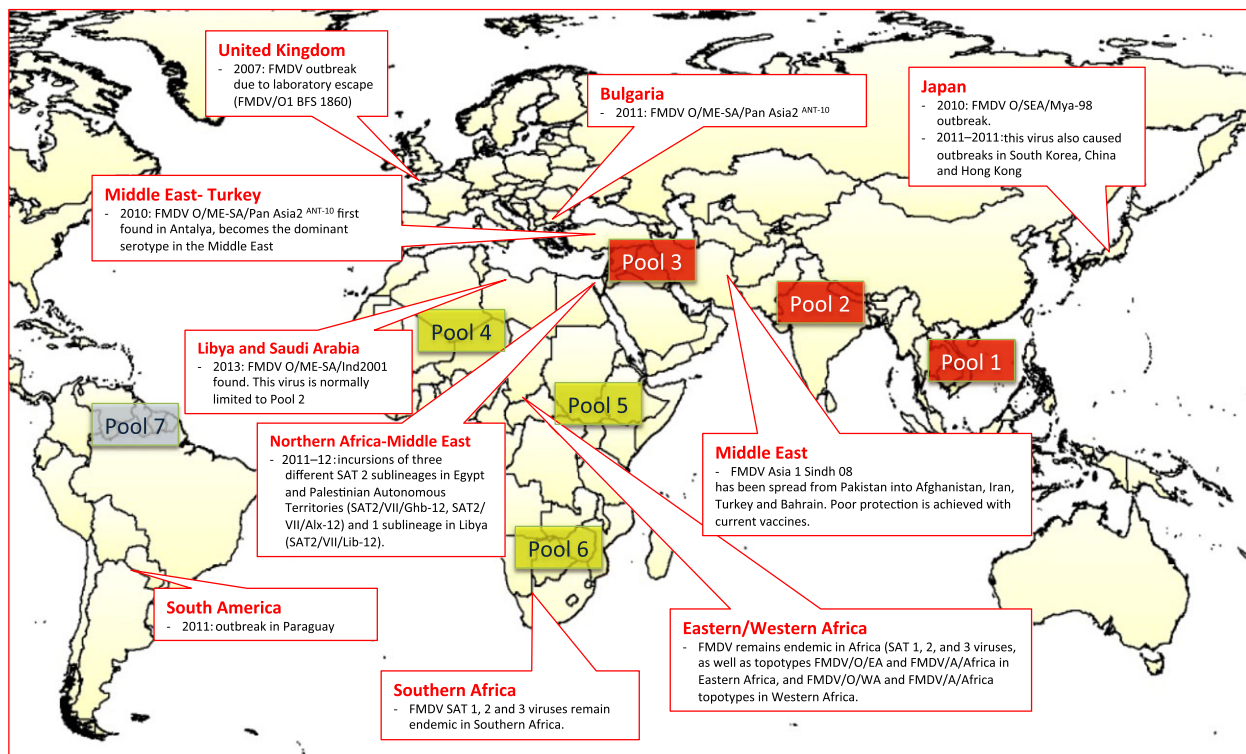


Fig. 1. Major highlights of FMDV events between 2007 and 2014.

known to have had a high incidence of FMD are mainly located in SEA: Myanmar, Thailand, Cambodia, Lao's People's Democratic Republic (PDR), Vietnam and some areas

in China. Control of FMD in SEA is coordinated by the SEA and China FMD campaign (SEACFMD) through the OIE Regional Coordination Unit in Bangkok, which works

Table 1. Foot-and-mouth disease viruses characterized in 2007–2014 in Asia, Europe and northern Africa. Endemic viruses to each *pool* are represented by the colour of the 'pool' column. Incursions of viruses outside their endemic areas are represented with the corresponding colour in the lineage/genotype column. Grey colour represents viruses from sub-Saharan Africa

Pool	Area	Serotype	Topotype	Lineage/ Genotype	Country (year)	Literature		
Pool 1	East Asia	O	SEA	Mya-98	Hong Kong (2010), South Korea (2010–2011, 2014), North Korea (2010), Japan (2010), Mongolia (2010), Eastern Russia (2010), Taiwan (2012), China (2010–2013).	WRLFMD, 2007–2014, Lin et al. (2010), Zheng et al., (2012), Knowles et al. (2012), Hui and Leung (2012), Valdazo-Gonzalez et al. (2013)		
			ME-SA	PanAsia	China (2011–2013), Mongolia (2014), Russia (2011,2012,2014)			
			Cathay	–	Taiwan (2009–2013), Hong Kong (2011–2014).			
	South East Asia	O	A	Asia	Sea-97		South Korea (2010), China (2009–2013), Russia (2013–2014), Mongolia (2013).	
			Asia1	–	Group V		North Korea (2007–2008).	
			SEA	Mya-98	Myanmar (2004–2010), Malaysia (2005–2014), Vietnam (2005–2010), Lao PDR (2007–2014), Thailand (2007–2013)			
			ME-SA	PanAsia	Vietnam (2005–2013), Laos (2006–;2012), Cambodia (2008), Vietnam, Lao's PDR, China (2011) and Thailand (2004–2013)			
				PanAsia2	Malaysia (2009)			
				Cathay	–		Thailand (2012), Vietnam (2005–2008), Laos(2008)	
			A	Asia	Sea-97		Thailand (2004–2014), Vietnam (2010–2013), Malaysia (2011–2013), Laos (2003–2014), China (2009–2013), Cambodia (2008)	
Pool 2	Indian subcontinent	O	ME-SA	Ind-2001	Myanmar (2010) India (2009–2014), Sri Lanka (2013–2014), Bhutan (2009–2013), Bangladesh (2009–2013), Nepal (2008–2014)	WRLFMD, 2007–2014, Sanyal et al. (2010), Loth et al. (2011), Mohapatra et al. (2011a,b), Nandi et al. (2013), Subramaniam et al. (2013a,b), Yuvaraj et al. (2013), Ullah et al. (2014, 2015)		
				PanAsia2	India, Sri Lanka (2011), Bhutan (2007–2008), Nepal (2007–2008)			
				Unnamed	Sri Lanka (2009–2012)			
				A	Asia		G-VII	India (endemic), Bangladesh (2013).
				Asia1	–		G-II	India (2008–2012), Bangladesh (2012–2013)
Pool 3	Southern Asia	O	ME-SA	PanAsia2	Iran (endemic), Iraq (2010), Afghanistan (endemic), Pakistan (endemic)	WRLFMD, 2007–2014, Knowles et al. (2009), Jamal et al. (2011a,b,c), Upadhyaya et al. (2014)		
			Asia	Iran-05	Afghanistan (endemic), Pakistan (endemic), Iran(endemic), Iraq (2009–2013).			
			A	Asia	A-Pak-09		Pakistan (2009)	
			Asia1	–	Sindh-08		Pakistan (endemic), Afghanistan (endemic), Iran (endemic), Iraq (2013)	

Table 1. (continued)

Pool	Area	Serotype	Topotype	Lineage/ Genotype	Country (year)	Literature
	Arabian Peninsula	O	ME-SA	PanAsia2	Saudi Arabia (2007–2012), United Arab Emirates (2010, 2012), Bahrain (2008–2012), Kuwait (2008–2012)	WRLFMD, 2007–2014, Valdazo-Gonzalez et al. (2014)
				Ind-2001	United Arab Emirates (2009, 2014), Saudi Arabia (2013–2014)	
				EA-3	Yemen(2006–2009)	
				Iran-05	Kuwait (2009), Bahrain (2008–2011– at least 3 sublineages)	
				Sindh-08	Bahrain (2011)	
	Western Asia	O	ME-SA	PanAsia	Turkey (2005), Jordan, Israel (2004–2006)	WRLFMD, 2007–2014, Upadhyaya et al. (2014)
				PanAsia2	Turkey since 2007), Israel (since 2007), Jordan (2006), PAT (2007–2013)	
				Iran-05	Israel (2009), Lebanon(2009), Turkey (since 2005), Joradn (2006), PAT (2009–2013)	
				Sindh-08	Turkey (2011–2014)	
				SAT2-Ghb-12	PAT (2012)	
	Central Asia	O	ME-SA	PanAsia2	Georgia(2011), Kazakhstan (2010, 2012)	WRLFMD, 2007–2014
				PanAsia	Kazakhstan (2012), Kyrgyzstan (2012), Russia (2013),Kazakhstan and Kyrgyzstan (2012)	
				Iran-05		
Europe	Europe	O	ME-SA	PanAsia2	Bulgaria (2011), Turkey Thrace (2011)	Valdazo-Gonzalez et al. (2012b)
North Africa	Northern Africa	O	ME-SA	PanAsia2	Libya (2010, 2012), Egypt (2007,2011)	WRLFMD, 2007–2014, Ahmed et al. (2012), El-Shehawy et al. (2014), Valdazo-Gonzalez et al. (2012a), Valdazo-Gonzalez et al. (2014)
				Ind-2001	Libya (2013), Tunisia (2014), Algeria (2014)	
				Sharkia-like	Egypt (2007–2009)	
				EA-3	Libya (2010–2012), Egypt(2012–2014)	
				Iran-05	Egypt (2010–2014), Libya (2009)	
				G-IV	Egypt (2012)	
				G-VII-Ken-05	Egypt (2009)	
SAT2	–	–	VII	Libya (2012), Egypt (2012–2014)		

with national animal health authorities (Madin, 2011; OIE SEACFMD, 2011).

Peninsular Malaysia has suffered sporadic outbreaks (Khounsy et al., 2008; Sumption et al., 2008; Madin, 2011), whereas Sabah and Sarawak (East Malaysia) have been recognized by the OIE and remained as FMD-free where vaccination is not practiced. The Philippines has not reported an outbreak since 2005, and the OIE officially recognized the country as FMD-free in 2011. Similarly, Indonesia, Singapore and Brunei have remained FMD-free without vaccination. Specific efforts based on the feasibility of FMD eradication are focused in defined areas of Myanmar, Thailand and Malaysia, as well as maintaining the FMD-free areas (Wongsathapornchai et al., 2008; OIE SEACFMD, 2011).

Livestock farming is important in this region where most of the animals, mainly pigs, cattle, water buffalo

and chickens, are raised in small households. Buffalo and cattle are not only used for meat and milk consumption, but they are also a source of draught power for farming, an essential practice in this area (Di Nardo et al., 2011; Nampanya et al., 2012). The free movement of animals across country borders contributes to maintenance and spread of FMD. Endemic areas in southern China, Vietnam, Lao's PDR and Cambodia, or further away in India, Nepal and Bangladesh, may act as source viruses to importing regions and markets such as Malaysia and Thailand.

FMDV serotype O in SEA

Three serotype O FMDV lineages have been circulating in recent years in the region, namely O/SEA/Mya-98, O/Cat-hay and O/ME-SA/PanAsia (WRLFMD, 2007–2014; Le et al., 2010b; Lee et al., 2011).

FMDV serotype O toptotype SEA lineage Mya-98 (O/SEA/Mya-98)

O/SEA/Mya-98 endemic to SEA has been isolated in Myanmar, Vietnam, Lao PDR and Thailand. This virus has also been detected in southern China and in sporadic outbreaks in Malaysia (WRLFMD, 2010–2013; Abdul-Hamid et al., 2011).

Over the last 7 years, O/SEA/Mya-98 has caused outbreaks in eastern and central Asia, specifically Hong Kong SAR (2010), South Korea (2010–2011), North Korea (2010), Japan (2010), Mongolia (2010), Russia (2010) and Taiwan (where this lineage was reported for the first time in 2012) (Nishiura and Omori, 2010; Knowles et al., 2012; Zheng et al., 2012). The O/SEA/Mya-98 strain found in Hong Kong was highly adapted to swine hosts and caused high morbidity and severe disease (Hui and Leung, 2012). In 2010 and 2011, whole-genome sequence analysis of O/SEA/Mya-98 viruses from eastern Asia showed the presence of two different sublineages, one of them responsible for outbreaks in the Russian Federation and Mongolia and a different one in China (Valdazo-Gonzalez et al., 2013).

FMDV O/SEA/Mya-98, which is normally restricted to mainland SEA, caused outbreaks in Japan and South Korea. These outbreaks resulted in devastating economic losses to the local industry. The 2010–2011 FMD epidemic in South Korea was the largest ever reported in the country, affecting cattle, pig, deer and goats. Disease control was initially attempted by depopulation only; however, when the number of outbreaks increased, national authorities decided to switch to vaccination strategy. Although South Korea operates a compulsory vaccination campaign, clinical disease has been again reported in 2014 and 2015 (Yoon et al., 2012; OIE-WAHID, 2015).

FMDV O/SEA/Mya-98 also caused a major epidemic in Japan, which affected a total of 292 farms between February and July of 2010 in Miyazaki prefecture. Epidemiological investigation revealed that initial infection occurred in water buffalo approximately 1 month before FMD was detected and spread rapidly thereafter among surrounding farms. Initial control included culling infected and exposed animals, but emergency vaccination was needed due to rapid spread of the virus and lack of readily available carcass disposal facilities. The source of these epidemics remains unknown (Nishiura and Omori, 2010; Knowles et al., 2012; Muroga et al., 2012).

FMDV serotype O, toptotype ME-SA, lineages PanAsia and PanAsia2

In 2011, O/ME-SA/PanAsia lineage, which had previously been introduced into SEA specifically in Malaysia in 2003–2005, became widespread along with the local O/SEA/Mya-98 lineage. O/ME-SA/PanAsia was found during this period in Cambodia, Vietnam, Lao's PDR, China and Thailand

(WRLFMD, 2008–2011). FMDV O/ME-SA/PanAsia was also reported from samples collected in the Russian Federation and Mongolia in 2014, which were closely related to viruses found in Vietnam (WRLFMD, 2014). One sample collected in 2009 in Malaysia belonged to O/ME-SA/PanAsia2 lineage; this virus was most likely introduced from India and Bangladesh into Malaysia in early 2000 and circulated within this country until 2009 (Abdul-Hamid et al., 2011). O/ME-SA toptotype viruses have not been found in Malaysia since 2009 (WRLFMD, 2009).

FMDV serotype O, toptotype Cathay

The O/Cathay toptotype was dominant in Vietnam previous to 2007, but it was replaced by O/SEA/Mya-98 lineage and more recently by O/ME-SA/PanAsia viruses. FMDV O/Cathay was last isolated in Vietnam and Lao PDR in 2008, and in 2012 in Thailand. In eastern Asia, it was isolated in Taiwan (2009 and 2013) and Hong Kong (2011–2014). However, sequences analysis revealed that Hong Kong and Taiwan viruses were not closely related (WRLFMD, 2009–2014; Lin et al., 2010).

FMDV serotype A, toptotype Asia, lineage Sea-97 in SEA and East Asia

In 2008–2009, positive serology for FMDV A was found in Myanmar. Later in 2010, a serotype A virus collected close to the borders with India and Bangladesh was sequenced for the first time in Myanmar. This virus was closely related to recent Indian isolates (WRLFMD, 2011). No further detection of this virus has been reported.

FMDV A/Asia/Sea-97 (also named toptotype Asia, genotype IX) has been consistently reported during the past 7 years, increasing its occurrence in recent years in China (Tosh et al., 2002; Knowles and Samuel, 2003; Le et al., 2010a). Contemporary A/Asia/Sea-97-related viruses have been isolated from outbreaks in Cambodia (2008), Thailand (2007–2013), Vietnam (2010–2013), Malaysia (2011–2012), China (2009–2013), South Korea (2010–2011) and Lao's PDR (2007) (WRLFMD, 2008–2013; Le et al., 2010a; Abdul-Hamid et al., 2011). Furthermore, in 2014, it was found in clinically diseased pigs and cattle from Russia, close to the border with China (WRLFMD, 2014). This lineage was also found in Malaysia in 2011 (WRLFMD, 2011; Knowles et al., 2012).

FMDV serotype Asia 1 in SEA and East Asia

Since 2006, Asia 1 serotype has caused few outbreaks in China in 2008–2009 from which sequences are not available (WRLFMD, 2009; Perez et al., 2011). Among all characterized viruses reported by international laboratories in SEA, FMDV Asia 1 the last sequenced viruses were sampled from Vietnam (2007) China (2006) and Myanmar (2005) (WRLFMD, 2005–2007; OIE SEACFMD, 2011). These

isolates belonged to FMDV Asia 1 group V (Le et al., 2010b; Lee et al., 2011). Asia 1 was also detected in 2007 in North Korea (WRLFMD, 2007–2008).

Pool 2: Southern Asia

Southern Asian countries included in the FMDV *pool 2* are India, Nepal, Bhutan, Bangladesh and Sri Lanka. Serotype O is the causative agent for most of the outbreaks in the region, followed by serotypes A and Asia 1 (Table 1) (Sanyal et al., 2010; Dukpa et al., 2011; Subramaniam et al., 2012). Countries in *pool 2* have remained endemic for FMDV. This area is home to the largest population of cattle and water buffalo globally. In India, cattle are usually used for milk and draught power, but not for meat consumption. In many areas, cultural behaviour originate an overstock of cattle, which is moved and sold at competitive prices in Pakistan, Nepal and Bangladesh (and further into SEA), where they are offered in local markets or slaughtered, resulting in uncontrolled movement of livestock across country borders (Chhetri et al., 2010; Loth et al., 2011). Buffalo from India are also sent for slaughter to Nepal, and meat products are distributed in the Middle East and East Asia. These practices (legal or not) result in FMDV transmission from India to other countries. Spread of endemic FMDV beyond the Indian subcontinent has been observed for serotype O (i.e. FMDV/O/ME-SA/PanAsia, PanAsia2 and Ind-2001), but apparently it is less likely for endemic FMDV A and Asia 1, which are locally restricted (Sanyal et al., 2010; Mohapatra et al., 2011b).

There is a heterogeneous distribution of FMD within India. Outbreaks reported between 2007 and 2011 were caused by serotype O (80%), Asia1 (12%) and A (8%), and clinical disease seems to be most prevalent in the eastern and southern regions (Subramaniam et al., 2012).

Bhutan reported an estimated 15% FMD prevalence in 2009, and more cases occur in areas close to the border with India (Dukpa et al., 2011). A study by Dukpa et al. (Dukpa et al., 2012) reported freedom from disease in one district of Bhutan based on non-structural protein testing. The authors propose the feasibility of FMD progressive control using zoning strategies, given the heterogeneity of viral circulation in different areas of the country. Designation of disease-free areas, buffer areas and high-risk areas to place animal movement restrictions and vaccination strategies can help to decrease disease occurrence and eventually eradicate FMD.

FMDV serotype O in South Asia

In India, all FMDVs serotype O belong to the O/ME-SA toptotype, of which O/ME-SA/Ind-2001, O/ME-SA/PanAsia and O/ME-SA/PanAsia2 lineages, as well as a minor unnamed group have been described in the last 7 years

(Yuvaraj et al., 2013). FMDV O/ME-SA/Ind-2001 lineage, which re-appeared in 2007 in northern areas of India, has been dominant in the area since 2008. It has caused several outbreaks, affecting various species including zoo animals and elephants (J. K. Mohapatra, personal communication). However, O/ME-SA/PanAsia (which predominated until 2006, and was first found in India in 1982) and O/PanAsia2 (which was the dominant virus from 2006 to 2008) are also present throughout the country (Subramaniam et al., 2012; Yuvaraj et al., 2013). O/ME-SA/Ind-2001, which was first isolated in 1997 has been characterized in four sublineages, O/ME-SA/Ind-2001a-d. The latter (Ind-2001d) is the current virus circulating and is more prevalent in southern areas of the country (Hemadri et al., 2002; Subramaniam et al., 2013b, 2015).

Outbreaks caused by O/ME-SA/Ind-2001 were found in Saudi Arabia and Libya in 2013; the virus was closely related to those in India, Bhutan, Bangladesh and Nepal (Nandi et al., 2013; Valdazo-Gonzalez et al., 2014; WRLFMD, 2014).

In Sri Lanka, O/ME-SA/PanAsia2 virus was reported in 2012, and another O/ME-SA toptotype distant to any other FMDV serotype O has been recently described. In 2013, O/ME-SA/Ind-2001 was also isolated in Sri Lanka (WRLFMD, 2012–2014).

FMDV serotype A in South Asia

FMDV serotype A toptotype Asia, genotype 18 has been the only genotype present in India since 2001. This genotype is further classified into the VP3⁵⁹-deletion and non-deletion groups (Mohapatra et al., 2011b; Subramaniam et al., 2011). Genotype 18 has also been found in Bangladesh in recent years (Mohapatra et al., 2011a; Nandi et al., 2013; WRLFMD, 2013). India reported that only 5% of the FMD outbreaks in 2012 and 2013 were serologically caused by serotype A (WRLFMD, 2013).

FMDV serotype Asia1 in South Asia

Serotype Asia1 has historically been endemic in *pool 2*. FMDV circulating in India since 2005 belongs to genotype II, further classified into lineages C (group VIII) and D (group III) (Subramaniam et al., 2013a). Genotype II has also been characterized from outbreaks in Bangladesh (Ullah et al., 2014, 2015). Antigenic characterization suggests that the current local vaccine protects appropriately from this serotype (Sanyal et al., 2010; Subramaniam et al., 2012; WRLFMD, 2013).

Pool 3: Middle East and Eurasia

FMD outbreaks in the Middle East are caused by serotypes A, O and Asia1. Infected cattle and small ruminants owned by nomadic and transhumant pastoralists spread FMD as

they enter susceptible herds, or while they share common grazing or watering areas through their route. This movement of animals within and between countries often follows a seasonal pattern associated with cultural and religious festivals, such as the Eid (Jamal et al., 2010; Di Nardo et al., 2011).

Spread of FMDV outside this pool, as well as introductions from other areas, occurs by an active flow of livestock from south and central Asia into Pakistan, Afghanistan, Iran, Saudi Arabia and Turkey. Livestock exchange with Africa by land through Egypt and Libya and livestock exchange with Africa by sea from Eritrea, Djibouti or Somalia to the Arabian Peninsula are also alternative pathways of virus spread into and outside the region (Di Nardo et al., 2011; Sumption et al., 2008).

Countries within this pool have shown different levels of disease occurrence. The Arabian Peninsula (Oman, Yemen and Kuwait) and eastern countries (Iran, Iraq, Pakistan and Afghanistan) are suspected or known to have high incidence of outbreaks throughout the year (WRLFMD, 2007–2014; Klein et al., 2008; Sumption et al., 2008; Jamal et al., 2010). Control measures are also variable within this area; however, most of the countries reporting outbreaks to the OIE describe the use of vaccination in response to outbreaks (OIE, 2014).

FMDV serotype O in the Middle East and Eurasia

FMDV serotype O is the most prevalent in the Middle East and Eurasia. In 2007, the O/ME-SA/PanAsia strain spread into eastern Mediterranean countries, including Turkey. In addition, outbreaks were reported during this period in Cyprus (2007), where serotype O was confirmed in small ruminants by serological testing, but no virus was isolated (WRLFMD, 2007; Paton et al., 2009a).

Five O/ME-SA/PanAsia-2 sublineages have been distinguished by OIE/FAO RLN molecular reports (PanAsia-2^{SAN-09}, PanAsia-2^{FAR-09}, PanAsia-2^{ANT-10}, PanAsia-2^{BAL-09} and PanAsia-2^{PUN-10}). PanAsia-2^{ANT-10} sublineage is the most widely distributed and consistently reported during recent years in Iran, Iraq, Israel, Saudi Arabia, Turkey, United Arab Emirates, Kuwait, Afghanistan, Pakistan, Libya and Bahrain (Jamal et al., 2011a; WRLFMD, 2011–2014). PanAsia-2^{FAR-09} has been found in Iran, Israel, Palestinian Autonomous Territories (PAT) and Turkey and continues to be reported (WRLFMD, 2014).

In 2009, the United Arab Emirates reported FMD with high mortality in gazelle; this virus was later identified as FMDV O/ME-SA/Ind-2001 (WRLFMD, 2009). In 2013, viruses from this lineage normally restricted to the Indian subcontinent were found from samples submitted by Saudi Arabia and Libya, which were similar to contemporary sequences from India and Bhutan (Subramaniam et al., 2013b; Valdazo-Gonzalez et al., 2014).

FMDV serotype A in the Middle East and Eurasia

Since 2007, lineage FMDV A/Asia/Iran-05 has continued to spread throughout and beyond the Middle East. FMDV A/Asia/Iran-05 lineage incursions, first characterized in Iran in 2003 (Knowles et al., 2009), were widely spread within Iran, Turkey, Bahrain, Pakistan, Afghanistan and have caused sporadic outbreaks in other countries (Kuwait, Israel and PAT). Eleven different sublineages of this virus (Iran-05^{ARD-07}, Iran-05^{EZM-07}, Iran-05^{AFG-07}, Iran-05^{BAR-08}, Iran-05^{FAR-09}, Iran-05^{SIS-10}, Iran-05^{HER-10}, Iran-05^{ESF-10}, Iran-05^{QAZ-11}, Iran-05^{FAR-11} and Iran-05^{SIS-12}) have been characterized, some of them are widely spread, such as Iran-05^{BAR-08}, which was reported in Israel, Lebanon, Kuwait, Iran and Iraq, while Iran-05^{ARD-07} and Iran-05^{EZM-07} have only been found in Turkey (WRLFMD, 2008–2014; Upadhyaya et al., 2014). The different serotype A viruses circulating in Pakistan and Afghanistan have been described in detail elsewhere (Jamal et al., 2011c).

FMDV serotype Asia1 in the Middle East and Eurasia

Before 2009, groups I and VI were present among ruminants in Iran, whereas Pakistan was endemic for groups II and VI (Valarcher et al., 2009). A novel Asia 1 virus, referred to as group VII or Sindh-08 first found in Pakistan in 2008, has recently spread into Afghanistan, Iran, Iraq, Bahrain and Turkey (Jamal et al., 2011b; WRLFMD, 2011–2014; Subramaniam et al., 2013a). This lineage regularly shows poor to no matching with the local vaccine antigen (Asia1 Shamir) and continues to circulate in this region (Jamal et al., 2011b).

FMDV serotype SAT2 in the Middle East and Eurasia

In February 2012, several outbreaks caused by FMDV SAT2 viruses were reported in Egypt and Libya, which were not endemic for SAT serotypes. Two months later, FMDV SAT2 was confirmed in the PAT (Gaza Strip) (Ahmed et al., 2012). Further characterization revealed that FMDV isolated in the PAT belonged to SAT2/VII/Ghb-12 lineage, closely related to one of the FMDVs isolated in Egypt. No further SAT2 viruses were reported in PAT. Additionally, in 2012, a different strain (SAT2/IV/Ken-09) was reported in Bahrain, in cattle held at a quarantine station (WRLFMD, 2012a,b).

Related events in Trans-Caucasus and Central Asia

In the Trans-Caucasus, Georgia reported FMDV O/ME-SA/PanAsia 2^{ANT-10} lineage in 2011. The same sublineage was isolated from an outbreak in Bulgaria that caused clinical disease in wild boar 2 km north to the border with Turkey Thrace, followed by detection of infection in cattle, sheep, goats and swine in 12 outbreaks from neighbouring areas from January through April 2011. This epidemic was controlled by stamping out, quarantine and movement

control, although several serotypes A and O outbreaks were further reported in Turkey Thrace, close to the border with Bulgaria. Bulgaria regained its FMD-free status in August 2012, as did Turkish Thrace in October 2012 (OIE, 2014). Further studies revealed that similar contemporaneous viruses were present in Turkey and Israel (Valdazo-Gonzalez et al., 2012b).

During 2011–2012, Kazakhstan, Kyrgyzstan and Russia reported outbreaks caused by FMDV O/ME-SA/PanAsia, the sequences were similar to viruses in Vietnam and China (WRLFMD, 2012a,b). Kazakhstan also reported outbreaks caused by O/ME-SA/PanAsia-2 viruses from 2007 through 2012 (WRLFMD, 2010–2012). Additionally, FMDV A/Asia/Iran-05^{SIS-10} has recently been found in Russia (2013) and A/Asia/Iran-05^{HER-10} in Kazakhstan and Kyrgyzstan (2012) (WRLFMD, 2013).

Endemic pools in Africa

Serotypes O, A, and the South African Territories (SAT) FMDVs are endemic in Africa; serotype O is the most widely distributed in eastern and western Africa, whereas SAT viruses are mostly found in sub-Saharan Africa. A review by Tekleghiorghis et al., (2014b) provides a comprehensive overview of FMDV occurrences reported until 2013 in Africa (Tekleghiorghis et al. 2014b).

FMDV SAT2 followed by SAT1 is responsible for most livestock outbreaks. Although SAT3 is mostly found in buffalo, it has been serologically detected and isolated from bovine samples (Dhikusooka et al., 2015; Dyason, 2010; Jori et al., 2014).

Within Africa, livestock movement is influenced by the following: (i) dry season when pastoralists and agropastoralists move their animals looking for water sources, (ii) meat prices, (iii) cultural traditions and (iv) social and political disturbances (Rufael et al., 2008; Ayebazibwe et al., 2010c; Di Nardo et al., 2011). In this region, preventive immunization against FMD is practiced in only few counties, particularly in those where vaccination is a requirement for international animal and meat trade.

Because FMD is endemic in this region, most countries report clinical disease to the OIE annually or bi-annually, and detailed occurrence is undocumented. The amount of samples received by OIE/FAO RLN has increased over recent years through a concerted effort of network members. However, there are still major knowledge gaps about circulating viruses, especially in western Africa.

Northern Africa/Maghreb

Northern Africa is a bridge for FMDV exchange between Africa (pools 4, 5, 6) and western Asia (pool 3). Pandemic virus strains originating in Asia have been reported in this

area. In 2012, SAT2 outbreaks were reported in Egypt, Libya and the PAT. Molecular analysis of samples showed that these SAT2 isolates in Egypt and PAT belonged to lineages SAT2/VII/Ghb-12 and SAT2/VII/Alx-12, similar to Sudan isolates from 2010 (WRLFMD, 2012a,b). SAT2 viruses from Libya were different from those found in Egypt that same year (SAT2/VII/Lib-12) suggesting independent introductions of the virus (FAO, 2012; WRLFMD, 2012a,b). In 2012, FMDV collected from PAT belonged to the SAT2/VII/Ghb-12 Egyptian sublineage, while a different FMDV SAT2 was isolated in Bahrain, corresponding to topotype IV and related to viruses isolated from Kenya in 2009. The circulating viruses generally showed a good match with SAT2 Eritrea antigen, but control of disease was compounded due to the multiple serotypes present in the region and a significant number of immunologically naïve livestock (WRLFMD, 2012a,b). Additionally, FMDV O/ME-SA/Sharquia-like, O/eastern Africa (EA) topotypes, genotypes IV and VII, as well as A/Asia/Iran^{BAR-08}, were isolated in Egypt during this period (Valdazo-Gonzalez et al., 2012a; WRLFMD, 2012–2014).

In Libya, several other viruses have been reported during recent years. FMDV O/ME-SA/PanAsia 2ANT-10 sublineage, closely related to those found in Pakistan and Iran in 2011, caused outbreaks in Libya in 2010 and 2011 (WRLFMD, 2011). A/Asia/Iran-05^{BAR-08} was last detected in Libya in 2009. Additionally, in 2013, FMDV O/ME-SA/Ind-2001, normally restricted to the Indian subcontinent, was isolated in Libya and related to contemporaneous FMDV in Saudi Arabia and Bhutan (Subramaniam et al., 2013b; Valdazo-Gonzalez et al., 2014). Additionally, Libya reported FMDV O/Africa/EA-3 in 2012, which was also found in samples from Sudan and Egypt in 2011–2012 and samples from Yemen in 2008–2009 (WRLFMD, 2011–2012).

Regarding FMDV control, Algeria, Morocco and Tunisia started official control programmes in 2013 (DEFRA, 2014; WRLFMD, 2014). However, several FMD outbreaks caused by O/ME-SA/Ind-2001, closely related to those from Libya, have been reported in Tunisia in 2014 and Algeria in 2014 and 2015 (WRLFMD, 2014; DEFRA, 2014; OIE-WAHID, 2015).

Pool 4: Eastern Africa

Most countries in this region are endemic for serotypes A, O, SAT1 and SAT2. Vaccination is reported only in 6 countries, namely Kenya, Ethiopia, Uganda, Somalia, Burundi and Sudan. Serotype O is the most common, followed by A and SAT1. Vaccination is reported to RLN by some countries (namely Ethiopia, Kenya, Somalia, Burundi, Sudan, Uganda, Djibouti, northern Tanzania and Eritrea) as a response to clinical outbreaks and limited to resources

availability. Furthermore, a recent survey of veterinary diagnostic laboratories in eastern Africa revealed that the laboratories assessed did not meet the requirements for appropriate diagnostics (Namatovu et al., 2013a). SAT viruses historically circulating here have been reviewed elsewhere (Sahle et al., 2007a,b). In this region, although the African buffalo population is high, further research is needed to elucidate their involvement in livestock outbreaks.

It is noteworthy that serotype C was last detected in Kenya in 2004 (Sangula et al., 2011), and serological evidence for type C antibodies was reported in a single publication from a survey conducted in 2009 in Eritrea (Tekleghiorghis et al., 2014a), although this may be due to cross-reactivity with other serotypes.

FMDV serotype O in eastern Africa

FMDV serotype O is the most prevalent in eastern Africa. Viruses from this region have been further classified into four different eastern African (EA) topotypes (>15% VP1 sequence divergence among topotypes), referred to O/EA-1, O/EA-2, O/EA-3 and O/EA-4 (Balinda et al., 2010).

Two geographical clusters have been described within this area (Di Nardo et al., 2011), namely the Horn of Africa and the area of the Great Lakes. The area of the Horn of Africa includes Djibouti, Ethiopia and Somalia. O/EA-3 is predominant lineage in this area. Ethiopia has reported EA-2 and EA-4 topotypes circulating in 2008–2014 (WRLFMD, 2008–2014; Negussie et al., 2011). In 2009, Somalia reported O/EA-3 viruses related to sequences isolated from Yemen in 2003–2009 (WRLFMD, 2008; Di Nardo et al., 2011). Political and social disturbances within Somalia may have contributed to changes in the patterns of animal and people movement and thus FMDV transmission through the country borders.

The area of the Great Lakes includes northern areas in Tanzania and Zambia, Uganda, Kenya, Rwanda and Burundi. FMDV/O/EA-2, the dominant virus in this area, was responsible for large outbreaks in 2008–2009 in Uganda, likely originated by movement of live animals across Lake Kyoga (Kasambula et al., 2012). FMDV O/EA-2 was also responsible for almost all recent FMDV O outbreaks in this area, including Tanzania. In Kenya, O/EA-4 and O/EA-1 were found in 2009 and 2010, and O/EA-2 and O/EA-4 in 2010 and 2011. EA-2 has also been isolated from the Democratic Republic (DR) of Congo (WRLFMD, 2009–2010; Balinda et al., 2010; Kasanga et al., 2014; Wekesa et al., 2015). Although FMDV O/EA-2 is the dominant virus, O/EA-1 is traditionally used to formulate vaccines in this area, resulting in low cross-protection with circulating viruses (Namatovu et al., 2013b).

FMDV serotype A in eastern Africa

Serotype A samples from eastern Africa have been characterized as A/Africa/G-I genotype. In Tanzania, A/Africa/G-I was isolated in 2014, which was particularly important because serotype A had not been found in this country in over 30 years (Kasanga et al., 2014; WRLFMD 2014). FMDV A/Africa/G-I was also isolated from Kenya (2008–2009, 2012) and the DR of Congo (2011), whereas historical genotypes III and VIII are thought to be now extinct (Wekesa et al., 2014a). FMDV A/Africa/G-VII, closely related to earlier Kenyan viruses from 2005, was isolated from Ethiopia between 2007 and 2009, and Egypt (2009). Sudan (2011), Eritrea (2007–2009) and Egypt (2012) have reported FMDV A/Africa/G-IV. Vaccine matching studies suggest that there is a need for reformulation of FMDV A serotype commercial vaccines in this region that currently uses A-KEN-05-1980 and A-ETH-06-2000 antigens (WRLFMD, 2007–2009; Negussie et al., 2011; Tekleghiorghis et al., 2014a; Bari et al., 2014; Wekesa et al., 2014b).

FMDV serotypes SAT1, 2 and 3 in eastern Africa

SAT1 and 2 FMDVs were found in eastern Africa during 2007–2014. SAT1 virus was isolated in 2007 for the first time in Ethiopia close to the border with Sudan (Legesse et al., 2013). Molecular characterization showed that this was a different topotype from other SAT1 virus in the region and was consequently named topotype IX (Ayelet et al., 2009). In Kenya, the existing SAT1 topotype I-NWZ has been regularly detected. Topotype I-NWZ was also found in Tanzania in 2010, 2012 and 2013. FMDV SAT1 in eastern Africa was most likely introduced originally from southern Africa (Sangula et al., 2010). In Kenya, in 2010, a serological study of healthy pigs found evidence of FMDV SAT1 (Wekesa et al., 2014a). Serotype SAT3 virus was isolated from a healthy calf in Uganda, different from any FMDV SAT3 characterized before (Dhikusooka et al., 2015).

SAT2 topotype IV FMDVs were found in Tanzania (2012) and Kenya (2009), whereas the SAT2 viruses isolated in Sudan (2008) and Ethiopia (2010) belonged to topotype XIII (Tekleghiorghis et al., 2014a). Other FMDVs found in Sudan were identified as SAT2 topotype VII, closely related to viruses isolated in Nigeria in 2005. This topotype was also responsible for outbreaks in Egypt, Libya and Sudan (SAT2/VII/Alx-12) (Valdazo-Gonzalez et al., 2012a).

Pool 5: West and central Africa

Serotypes that are known to be endemic in western Africa are O, A, SAT1 and SAT2. Guinea and Guinea Bissau have reported no occurrence of the disease based on findings of

their general surveillance programmes, while most of the countries in the region have reported clinical FMD to the OIE during the last 7 years (Couacy-Hymann et al., 2006; Habiela et al., 2010; WRLFMD, 2013; OIE-WAHID, 2015).

FMDV serotype O in western and central Africa

FMDV O/EA-3 was identified from samples from Nigeria (2007, 2009, 2011) and Niger (2007), closely related to earlier viruses collected from Sudan (2005). Other serotype O viruses from the western African topotype were found in Benin (2010) and Mali (2007) (Tekleghiorghis et al., 2014a; Gorna et al., 2014).

FMDV serotype A western and central Africa

Most of the samples analysed in 2009–2013 from Nigeria were positive to serotype A topotype Africa, genotype IV (A/Africa/G-IV), closely related to earlier isolates from Kenya and Cameroon viruses (WRLFMD, 2009–2010). Serotype A topotype Africa FMDV has also been reported in Sudan (G-IV) and Benin (G-VI) (WRLFMD, 2009; Gorna et al., 2014).

FMDV serotypes SAT1, 2 and 3 in western and central Africa

In Nigeria, FMDV SAT2 was isolated in 2007–2008 and 2012. These viruses belong to the VII topotype (WRLFMD, 2008–2012), which have also been sequenced from samples collected in Senegal in 2008. A SAT2 different from any characterized virus was detected in Cameroon in 2013. A serological survey evidenced the presence of FMDV SAT1 and 2 in Chad (WRLFMD, 2008, 2010, 2014). Serotype SAT3 was reported to the OIE from Cameroon in 2007 (OIE-WAHID, 2015), and although it is probably present in the region, no SAT3 characterized virus is available from this area.

Pool 6: Southern Africa

FMD is controlled in some areas of southern Africa, in contrast to other areas in Africa (Tekleghiorghis et al., 2014b). Some countries such as South Africa, Namibia and Botswana have official FMD-free zones, but are constantly threatened by endemic viruses circulating in wildlife within transfrontier conservation areas (TFCA) and neighbouring regions where few or no FMD control measures are implemented. Some have proposed to reconsider restrictions established for international animal trade, to allow commodity-based trade approaches, so that SAT viruses adapted to the wild buffalo population are evaluated differently when assessing trade risks (Thomson, 2009).

The African buffalo is the main reservoir of SAT serotypes and plays an important epidemiological role in FMDV transmission in the region, especially in areas where livestock and wildlife contacts are common (Vosloo et al.,

2007; Jori et al., 2009; Ayebazibwe et al., 2010a,b; Brahmhatt et al., 2012). The recent creation of several TFCAs in SADC directly impacts FMD spread. TFCAs are shared between countries, so it is advisable that plans to control FMD in wildlife should be carefully and jointly addressed, particularly in those areas having large African buffalo populations (Thomson, 2009).

Countries from the SADC that have reported outbreaks to the OIE/FAO RLN during the last 7-year period are Tanzania, Botswana, South Africa, Mozambique, Zambia, Zimbabwe, Namibia and Malawi, whereas Lesotho and Swaziland remained free of FMD (OIE, 2014). South Africa had its FMD-free zone suspended in 2011 and restored 2 years after implementation of containment zones (where vaccination is practiced) and fulfilment of the OIE terrestrial code requirements. Clinical disease has occurred repeatedly after 2011 in the containment zone (OIE-WAHID, 2015). Botswana has consistently reported FMD outbreaks in livestock since 2002; only one zone is currently recognized as FMD-free where vaccination is not practiced (OIE, 2014). Noticeably, in 2009, Tanzania reported an outbreak caused by FMDV serotype A, close to the border with Malawi, being the southernmost area in which serotype A has been detected (WRLFMD, 2009).

FMDV serotype SAT1, 2 and 3 in southern Africa

In southern Africa, SAT1 topotypes I, II and III are endemic and have been characterized from earlier samples from Mozambique (2001–2002), Zimbabwe (2003), Zambia (2005–2006), Botswana (2006) and more recently from Namibia (2011) and Malawi (2008–2009). SAT1 topotype III (WZ) was reported from samples collected in 2006 in Botswana. In Caprivi, Namibia, SAT1 outbreaks have been reported in cattle in 2010 and 2011. In Zambia, a SAT1 topotype III (WZ) not closely related to any other SAT1 virus was characterized in 2012 (WRLFMD, 2008–2013). In South Africa, FMDV SAT1 was reported from outbreaks in 2009–2011 and 2013 (OIE-WAHID, 2015).

Serotype SAT2 is the most prevalent in the area. Topotypes I, II and III have been regularly reported over the last years. SAT2 has caused repeated outbreaks over the past years in Botswana, presumable due to contact with infected wildlife in bordering areas with Namibia, Zambia and Zimbabwe. Topotype I was reported in southern Mozambique (2010) and Botswana (2011). Malawi reported a new SAT2 virus related (<10% nucleotide differences) to viruses previously isolated in the region. In South Africa, SAT2 viruses were reported in Mpumalanga (2008, 2011) and in Limpopo, adjacent to the Kruger National Park (2010). Historically, SAT1, 2 and 3 have regularly been detected in wild African buffalo in South Africa (F. Maree, personal communication).

Endemic pool in South America

Pool 7: South America

OIE-conferred FMD status is quite diverse in South America. Chile, Surinam, southern Argentina (Patagonia) and the State of Santa Catarina in Brazil are FMD-free where vaccination is not practiced. Whereas in Uruguay, most of the Argentine territory, three zones in Bolivia, two zones in Paraguay, two zones in Colombia and 15 Brazilian states (or at least part of them) are disease-free with vaccination. There are also areas formerly known as a high surveillance zone in the borders between Argentina, Bolivia, Brazil and Paraguay where serosurveillance is performed with a high frequency. These zones are now recognized as FMD-free zones where vaccination is practiced. In 2013, Bolivia started a control programme officially recognized by the OIE (WRLFMD, 2013; OIE, 2014). Ecuador has requested early in 2015, the FMD-free with vaccination status to the OIE, which will be officially issued in May 2015.

Progress has been made in the region to control FMD. Consequentially, the disease is presumed to be restricted to specific areas in the continent and the viruses belong to one single pool, referred to as FMDV pool 7, where serotype A toptotype Euro-SA and serotype O toptotype Euro-SA circulate. FMD has caused sporadic outbreaks in Venezuela. Colombia reported FMD outbreaks in June–July of 2008 (serotype A and O near the border with Venezuela) and in July of 2009 (serotype O near the border with Ecuador). These outbreaks were controlled using a combined strategy that included movement control, stamping out and vaccination. FMDV serotypes A and O isolated from 2008 samples from Colombia were closely related to the ones collected in Venezuela between 2004 and 2006. In Venezuela, a genetically divergent serotype A genotype was found in 2007 (Malirat et al., 2012).

Serotype O viruses have been collected and characterized from Bolivia (2007), Ecuador (2007–2008), Colombia (2008) and Venezuela (2007). Venezuelan and Colombian isolates were more closely related to each other than Ecuadorian and Bolivian viruses and genetically clustered in different groups (Malirat et al., 2011).

A molecular epidemiologic study of serotype O FMDVs isolated from Ecuador in 2009 and 2010 found similar viruses circulating in samples collected throughout the country since 2002. These viruses diverged in 3 lineages, of which, only one is still present. This study speculates that adequate vaccine protection was not achieved against the current field strain (Maradei et al., 2011, 2014).

In September 2011, Paraguay confirmed two FMDV/O/Euro-SA outbreaks in the department of San Pedro, affecting cattle. Stamping out, quarantine, movement control, vaccination and surveillance strategies were used to control the outbreaks. This virus belonged to local strains from the

Euro-SA toptotype most closely related to O/Corrientes/Arg/06 (WRLFMD, 2011). Cross-protection studies showed that Vaccine O1/Campos was not protecting against this virus in Paraguay (Maradei et al., 2013). In November 2013, Paraguay regained FMD-free status, and since 2012, when the last FMD cases were reported by Paraguay, no further FMD outbreaks have been officially reported to the OIE or the RLN.

Final remarks and conclusions

Epidemiological challenges to control FMD vary in different endemic regions. In south and South-East Asia, the most important issues seem to be related to the size of susceptible populations, along with the complexity and variability of the market chain. Animal movements outside this region may sporadically spread the virus in most endemic FMD countries, much of the challenge seems to be related to the long standing and ancient traditions for nomadic and transhumant movements of animals between countries (Di Nardo et al., 2011). Furthermore, the natural endemic cycle of FMDV is not well understood, the virus reservoirs between outbreaks remain elusive, and the role of convalescent carrier animals in disease epidemiology remains undetermined.

Successful FMD control programmes in sub-Saharan Africa need to overcome a number of challenges. Ability to impose animal movement restrictions required to contain outbreaks is impaired by the transhumant and pastoralist nature of much of livestock production (Di Nardo et al., 2011). Vaccination has proven to be an efficient control method in Europe and South America. However, control strategies based on sustained vaccination of large proportion of the animal population require economic resources that are beyond some countries in Asia and Africa. There are technical and practical issues that must be addressed for vaccination to be effective (Rodriguez and Gay, 2011). For instance, in Africa, there are only two laboratories that have the ability to diagnose FMDV and carry out molecular characterization of viruses and vaccine matching. Vaccination campaigns need to be organized at a national level and engage livestock holders, veterinarians and the governments (Sinkala et al., 2014). Compulsory vaccination is needed, and a high proportion of animals should have protective immunity to result in disruption of transmission and spread among the population (Rodriguez and Gay, 2011). Vaccination should be performed every 4–6 months, which is the length of protective immunity conferred, depending on the adjuvant and strain (Hunter, 1998; Lets-hwenyo et al., 2004). Additionally, maintaining the cold chain requires training veterinarians and farmers and providing them with appropriate resources for transport and storage of vaccines (Smith et al., 2014). Vaccine cost is pro-

hibitive for many small livestock owners. Furthermore, selection of protective SAT virus vaccine strains is difficult because of high intraserotype variation (Hunter, 1998; Sahle et al., 2007b). In the absence of public or private investment, it is unlikely that the epidemiological situation of FMD will improve in this region. This can be a very onerous endeavour and will only be sustainable as the government, farmers and veterinarians become committed to control FMD.

FMDV strains exotic to northern Africa have affected the region (FMDV/O/ME-SA/Ind-2001, SAT2 G-VII, A/Asia/Iran-05^{BAR-08}), as well as devastating epidemics in eastern Asia caused by the SEA endemic strain FMDV/O/Mya-98, and have highlighted the importance of establishing better surveillance in these areas, including vaccine matching to assure the use of appropriate vaccine antigen and to detect potential emerging lineages and changes in their geographical distribution. In South America, the most important concern to be addressed is the implementation of effective surveillance and vaccination programmes in specific regions in which the disease has persisted for decades, despite the notable progress made throughout the continent.

The task ahead to control FMD worldwide is extremely difficult and requires input from all sides of government, livestock keepers, diagnostic laboratories and animal health organizations to coordinate the initiative. Because livestock-related activities represent an important activity in several countries, international organizations such as FAO and OIE are working in improving awareness of correct application of vaccines, as well as implementing diagnostic methods that meet international standards (Smith et al., 2014).

Although certain regions have made notable progress in the development of regional control, more input is needed, including an urgent need for the support of international comprehensive control and surveillance programmes to evaluate FMDV strain circulation and provision of real-time information and vaccine strain advice.

Throughout the world, political, economic and social instability affect the ability of endemic countries to control the disease. Because of the transboundary nature of FMD, local and global joint efforts such as the OIE/FAO RLN are key aspects to enable realistic control. There is an urgent need to develop programmes that provide benefits to the affected regions and their livestock keepers and that are biologically sound, culturally and socially acceptable and financially and logistically feasible.

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Integrating novel data streams to support biosurveillance in commercial livestock production systems in developed countries: challenges and opportunities

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Reducing the burden of emerging and endemic infectious diseases on commercial livestock production systems will require the development of innovative technology platforms that enable information from diverse animal health resources to be collected, analyzed, and communicated in near real-time. In this paper, we review recent initiatives to leverage data routinely observed by farmers, production managers, veterinary practitioners, diagnostic laboratories, regulatory officials, and slaughterhouse inspectors for disease surveillance purposes. The most commonly identified challenges were (1) the lack of standardized systems for recording essential data elements within and between surveillance data streams, (2) the additional time required to collect data elements that are not routinely recorded by participants, (3) the concern over the sharing and use of business sensitive information with regulatory authorities and other data analysts, (4) the difficulty in developing sustainable incentives to maintain long-term program participation, and (5) the limitations in current methods for analyzing and reporting animal health information in a manner that facilitates actionable response. With the significant recent advances in information science, there are many opportunities to develop more sophisticated systems that meet national disease surveillance objectives, while still providing participants with valuable tools and feedback to manage routine animal health concerns.

Keywords: biosurveillance, syndromic surveillance, veterinary medicine, livestock production, infectious disease, information technology, epidemiology

Introduction

The recent outbreaks of porcine epidemic diarrhea virus (PEDV) in the United States swine industry (1) and Schmallenberg virus in the European cattle and sheep industries (2) highlight the increasing vulnerability of commercial livestock production systems to emerging infectious diseases. Both outbreaks initially started with animals in a small number of isolated herds displaying unusual clinical signs of severe watery diarrhea and high mortality among suckling pigs for PEDV and fever with reductions in milk yields followed later by the birth of animals with severe congenital defects for Schmallenberg virus. However, by the time, the outbreaks were recognized and confirmed through

laboratory diagnostic testing, the viruses had already spread widely across their respective continents due to the high volume of direct and indirect contacts between livestock herds. Conservative estimates of the annual losses from PEDV range from USD \$900 million to \$1.8 billion depending on the level of piglet mortality assumed by the economic models (3). Although less is known about the cumulative financial impact of Schmallenberg virus in Europe, the average cost of treating individual cases has been estimated at USD \$80–\$140 per animal (4). Reducing the burden of these diseases as well as future emerging disease outbreaks will require the development of more effective surveillance systems to minimize the delays between disease introduction, detection, and response.

Current methods for detecting emerging infectious diseases in commercial livestock production systems rely heavily on individual veterinarians observing cases with overt clinical signs, pathognomonic lesions, or atypical presentations in the field and then notifying regulatory officials if there is reason to suspect an outbreak, and/or laboratory confirmation of disease and then notifying regulatory officials (5, 6). This can lead to significant delays in detection if farmers decide not to seek veterinary consultation for sick animals, if the clinical signs mimic those of other common endemic diseases, or if the initial cases are observed by different veterinarians who may not be aware that other practitioners are seeing cases with related presentations. Consequently, there has been growing interest in developing biosurveillance systems to integrate pre-diagnostic animal health data from different sources in the livestock industry in real-time so that they can be monitored for unusual spatial or temporal trends that may indicate the presence of an emerging disease concern (6). While these so-called “syndromic” surveillance systems cannot definitively confirm an emerging disease outbreak, they can signal a sufficient probability of an outbreak and alert regulatory officials to clusters of cases that require further epidemiological investigation (7). Feedback from these systems can also be used to enhance the situational awareness of farmers and veterinarians to disease trends in their local region, which may increase the likelihood of voluntarily reporting suspect cases.

In commercial livestock production systems, the earliest indication that an infectious disease may have been introduced to a farm is often changes in animal health parameters such as feed intake, water intake, activity levels, production levels, reproductive performance, and mortality. This in combination with presence of clinical signs may prompt the farmer to seek advice from a veterinarian. During the farm visit, the veterinarian examines sick animals in the herd, generates a list of differential diagnoses, and then decides whether or not to submit samples for laboratory diagnostic testing. Positive test results may confirm the presence of a known infectious disease agent, while negative test results may indicate the presence of a novel or emerging pathogen. Over the course of this timeline, animals may be shipped to slaughter facilities where the carcasses are examined for lesions as part of routine food safety inspections. Animals that are sold to other farms or slaughter facilities through livestock markets may also be observed by regulatory officials for overt clinical signs of infectious disease as well as may be subjected to further disease-specific diagnostic laboratory testing as part of

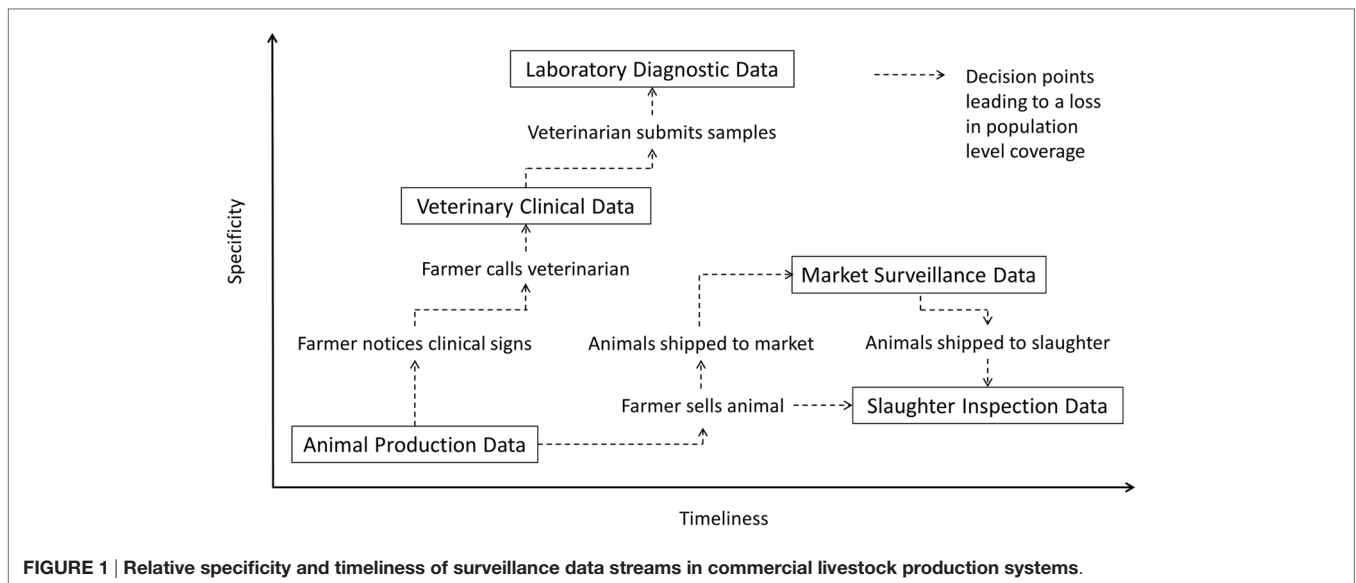
established national disease surveillance programs. Data collected at any point in this continuum can theoretically be monitored using automated outbreak detection algorithms. However, as highlighted in **Figure 1**, there are significant differences in the relative specificity, timeliness, and population coverage of each data stream that must be considered when evaluating their use in surveillance systems.

This paper reviews the five primary data streams (animal production data, veterinary clinical data, laboratory diagnostic data, market surveillance data, and slaughter inspection data) that can be used to support infectious disease surveillance in commercial livestock production systems. Particular emphasis is placed on factors influencing data quality and coverage, methods to facilitate data collection in real-time, and insights from published emerging infectious disease surveillance initiatives. The challenges associated with data collection, standardization, analysis, and dissemination are also discussed along with opportunities to improve biosurveillance systems through innovative technology frameworks.

Data Streams

Animal Production Data

Farmers and/or production managers observe animals in their herds or flocks for evidence of disease on a regular basis as part of providing routine husbandry care. The frequency of these observations can depend on many factors, such as the differences in management practices between commercial livestock species (e.g., multiple observations a day on dairy operations, daily observations in poultry and swine operations, less frequent and seasonally dependent for beef cattle kept on pasture). Disease may initially manifest itself as reduced feed and water intake, decreased growth rates, decreased production levels, increased mortality rates, poor fertility, or abnormal behavior well before the appearance of overt clinical signs. With the intensification of commercial livestock production systems, there have been significant advances in developing automated systems for collecting production data to compensate for the decreased time spent observing individual animals in large herds or flocks (8). For example, audio sensors have been installed in swine production units (9, 10) and cattle farms (11) to successfully capture coughing noises and to distinguish those caused by respiratory illness from those caused by poor environmental conditions. In poultry production systems, audio sensor technology has also been used to monitor the feeding behavior of broilers by the intensity and frequency of pecking sounds in the house (12). Other examples in the scientific literature include the accelerometers fitted to halters or collars of dairy cattle to measure jaw movements as an indication of resting, eating, and ruminating periods (13), passive transponder (RFID) tags attached to pigs (14) and cattle (15, 16) to monitor feed intake at controlled feeders, sensors that attaches to teat cup to measure electrical connectivity, color, and milk yield as early warning for mastitis (17) as well as other clinical disorders (18), radiotelemetry units implanted subcutaneously in poultry to monitor heart rate and body temperature (19), and electronic water flow meters used to detect outbreaks of diarrhea in swine (20). In addition, data on the day-to-day inventories, movements,



and statuses of herds are routinely recorded to support the business processes of commercial livestock production systems. These data typically reside in databases located within individual operations themselves or within databases of third-party data management companies.

Given the low-economic value of most commercial livestock on an individual animal basis, farmers will often attempt to treat simple conditions identified through direct observation of sick animals or through alerts generated by automated monitoring systems themselves before calling the veterinarian for a farm visit (21). The systems for recording this type of animal health data vary greatly between individual farms with some maintaining highly detailed records of all management and health related events for individual animals using commercial production management software and others keeping only simple paper-based records of treatments for sick animals as required by law in most industrialized countries. Frei et al. (22) conducted a longitudinal study of Swiss dairy herds to evaluate the potential for implementing an intensive animal health data recording system. Over a 15-month period, farmers were required to complete paper-based data sheets for every observed animal health event including information on the date, animal identification, event type, whether or not the veterinarian was called, treatment given, costs, and whether or not laboratory samples were submitted. A list of codes was provided to each farmer to standardize data entry. The average time requirement was approximately 15 min/week and the majority of farmers expressed a willingness to participate in future studies if similar financial compensation was provided.

A more recent study by Menéndez et al. (23) compared the animal health records maintained by Swiss dairy farmers to the records maintained by the farm veterinarian to evaluate the quality of farm-based animal health data. Farmers had the choice of recording data on paper-based forms, electronic spreadsheets, or Internet-based journals and similar data to the Frei et al. (22) study was collected with the addition of information on the name,

dosage, and withdrawal time of medications used. There was no difference in the completeness of forms between collection methods with the exception of animal identification being collected less frequently on paper-based forms. Data were missing for approximately 3–7% of the remaining data fields. Farmers recorded significantly more health events than veterinarians (78% compared to 64%); however, the level of agreement (defined as having the same date, event category, and event subcategory) was only 33% on average. The author concluded that it was important to combine farmer data with veterinary data to improve the completeness and accuracy. Other studies have also shown farmers more accurately record data when the events are associated with high treatment costs or significant production losses (24, 25) or during disease outbreaks like the Bluetongue virus epidemic in France (26).

Beltrán-Alcrudo et al. (27) explored the potential for using daily mortality and egg production rates collected from 27 commercial layer flocks in southern California to detect outbreaks of low pathogenic avian influenza (LPAI) faster than through the direct observation of clinical signs, which can be mild or inapparent for many viral strains. Each of the study flocks experienced a confirmed outbreak of LPAI H6N2 during the months of January and February in 2002. Data from 44 other healthy commercial flocks were used to estimate the expected baseline mortality and egg production levels over the production life cycle of a typical commercial layer flock. Alerts were generated when the observed rates exceeded the expected rates by a factor of “*x*” for a single day or by a factor of “*y*” for two consecutive days based on values determined by a previous study in the Netherlands (28). Using low threshold values, the system was capable of detecting all observed outbreaks within 7 days of introduction at the expense of increased false positive signals. Monitoring mortality rates was found to be timelier than monitoring egg production data. However, the authors highlighted the potential for inaccuracies if the mortality data was not collected at a consistent time of day. For example, if mortality data were collected late on 1 day and then at a normal

time on the following day, the observed mortality rates would be falsely high on the first day and falsely low on the second day. The authors also stressed the importance of using historical data from each flock to calculate expected mortality rates to prevent flocks with chronic management and disease concerns from generating false alerts.

Veterinary Clinical Data

Veterinarians visit commercial livestock farms to deliver routine care such as parasite control, reproductive services, regulatory activities (e.g., issue government health certificates), and vaccinations as well as to diagnose and treat animals with clinical illnesses. The frequency of routine visits varies greatly between livestock operations with larger herds and herds using intensive management practices utilizing veterinary services more frequently due in part to the lower average cost of care per animal per visit (29). In addition, commercial livestock operations may also employ a veterinarian(s) within their company. Collecting data from routine visits are important in syndromic surveillance systems to establish that livestock herds are actively being monitored, which can support claims of freedom from disease and be used to calculate denominators in surveillance algorithms (30). The decision to call a veterinarian for clinical illnesses is more complex and based on factors such as the number and economic value of animals affected, previous experience in treating disease, the severity and duration of the clinical signs, and the availability of veterinary services (21, 31–34). This can lead to substantial data loss in veterinary practitioner-based syndromic surveillance systems as well as delays in detecting animals that may be infected with an emerging disease.

Most regulatory authorities require veterinarians to maintain basic medical records with sufficient detail on the animal identification, history, clinical findings, diagnostics, and treatments so that another veterinarian could easily follow the case. Given the remote nature of food animal veterinary work, the majority of practitioners keep medical records in paper format only (35) and must therefore invest additional time in reporting data for surveillance purposes. This has been highlighted as a significant barrier to maintaining veterinary practitioner-based surveillance systems long-term (6). Although some food animal veterinarians use commercial practice management software to maintain electronic records, the software companies may be unwilling to modify their programs to generate automated surveillance data reports since these programs are typically designed for invoice management and not for the electronic transfer of animal health data (35, 36). Furthermore, uptake of these systems has generally been low due to the reluctance of many farmers and veterinarians to modify their existing routines, poor collaboration between software developers, end-users, and data analysts to develop practical interfaces, and the perceived lack of returns on the financial and time investments (37). There is also lack of interoperability between systems that collect similar data (e.g., health certificates, production management information, and laboratory submission forms). In several European countries, veterinarians are also required to submit reports of all bovine farm visits into a national animal health database either through paper-based forms or electronic submissions (38–40). The requirements of veterinarians to enter similar data into multiple systems leads

to a decrease in compliance for providing complete information to these different data streams.

The quality of data submitted by veterinarians is highly variable regardless of whether the surveillance program is voluntary or compulsory. In a retrospective study of data collected from seven veterinary practitioners participating in the Ontario swine veterinary-based surveillance (OSVS) pilot program (41), it was found that veterinarians consistently reported basic visit information (farm code, postal code, visit type, and farm production type) and syndromic information (body systems affected), but were less reliable in reporting information on the production parameters affected, type and efficacy of treatments, diagnostic laboratory submissions, and whether the visit was new or related to an ongoing problem. The discrepancies were partly attributed to veterinarians using different definitions for the variable fields than what was provided in the project documentation. It has also been shown that the way veterinarians interpret clinical signs in patients is also highly variable leading to inconsistencies in data recording (42, 43). When submitting mandatory reports on bovine consultations, it has been shown that the completeness of data fields submitted by veterinarians ranges from 17 to 37% for locomotor disorders (39), 56 to 94% for clinical mastitis (40), and 71 to 88% for metabolic disorders (38). Furthermore, survey data from Sweden has also shown that only 18% of veterinarians only reported the main diagnosis for which the animal received prescribed drugs rather than all diseases present (44). The authors of these studies concluded that the data may therefore not accurately reflect the true incidence of disease in the livestock populations.

Detailed reviews on the design of recent voluntary veterinary practitioner-based surveillance initiatives can be found in other published sources (5, 6, 45). Given the limited timespan of available data, their use as early warning systems for disease has been only minimally evaluated. Amezcua et al. (46) analyzed data from the OSVS project to identify clusters of increased report submission rates by season, year, and geographic location using simple regression models. Compared with laboratory test order data from the same time period, the OSVS project identified a greater number of high-risk periods, which corresponded with disease trends in the province. However, no further investigation was performed to determine whether the cases were epidemiologically linked. The authors noted that veterinary compliance with report submission decreased later in the study period as the outbreaks of porcine circovirus associated disease (PCVAD) and porcine reproductive and respiratory syndrome virus (PRRSV) became more distant. A study by Carpenter et al. (47) using data from a large animal health database in Denmark found that outbreak detection tools could potentially reduce the total number of abortions in dairy cattle by 22.9–0.3% depending on the alarm threshold. However, when the cost of abortions was weighed against the cost of responding to an alarm, there were only a limited number of situations where the surveillance system provided any significant financial benefits to the Danish cattle industry.

Laboratory Diagnostic Data

Laboratory diagnostic testing is frequently used in conjunction with clinical examinations to determine the underlying cause of disease problems in livestock herds. Samples may also be submitted

routinely to diagnostic laboratories as part of national disease surveillance programs, herd health certification schemes, or pre-purchase/movement testing requirements. This data stream has become popular in syndromic surveillance research since most veterinary diagnostic laboratories maintain electronic laboratory information management systems (LIMS). However, the capability to electronically transfer data [e.g., human level seven (HL-7) messaging, web services, custom developed macros] varies greatly between LIMS systems used by the diagnostic laboratories that serve commercial livestock production systems, with LIMS systems used ranging from systems developed in-house to those developed by commercial vendors. Furthermore, many laboratories do not have the information technology (IT) resources and personnel available with expertise to implement this capability, nor have they been fully incentivized so as to have this capability be a mandatory requirement of LIMS systems used. As such, the overwhelmingly majority of laboratory diagnostic data being shared between laboratories and regulatory authorities is done via email and spreadsheets. Those LIMS systems that can be accessed remotely through secure connections to obtain animal health data in near real-time for further analysis most readily support the objectives of syndromic surveillance programs (48).

Veterinarians are required to complete sample submission forms for diagnostic test requests, with the type of information requested on the forms including the date, owner identification, animal identification (age, sex, and breed), relevant clinical and treatment history, specimen characteristics, and diagnostic tests requested. However, there are known issues with the quality and completeness of data recorded on these forms, which are currently primarily paper-based and manually entered into LIMS systems. The test requests can be classified into broad syndromic categories based on the clinical signs associated with the pathogen (49) and monitored for trends that may indicate an increase in the incidence of diseases being observed in the field. Clusters of syndromic cases that test negative for common endemic pathogens may be indicative of an emerging disease threat (50).

The population coverage of laboratory submission data can be influenced by practitioner perceptions and experience (51) as well as the financial and epidemiological state of the livestock industry (52). Based on discussion from a focus group of practicing veterinarians, Robinson et al. (53) found that the high costs associated with performing diagnostic tests deterred sample submission, although producers were more willing to submit samples if the veterinarian was unsure of the diagnosis, if the disease was having a significant economic impact, or if the problem was not resolving with empirical treatment. Similar findings have been reported elsewhere (51, 54).

The likelihood of sample submission also appears to increase if the samples are convenient to collect and the farms are located in closer proximity to diagnostic laboratories (55) and if the diagnostic tests are subsidized through national animal health programs (56). Gilbert et al. (21) estimated that the probability of syndromic cases in the United Kingdom generating an entry in the national laboratory surveillance database ranged from 8.5% for neurologic conditions to 25% for enteric diseases. Outbreaks can also potentially be missed if samples are not of appropriate quality or if the appropriate diagnostic tests are not

requested or performed (30). Furthermore, loss in population coverage can occur on submissions to private diagnostic laboratories or from diagnostic tests performed in-house if these data sources are not integrated into surveillance programs.

Several research studies have reported using historical data from veterinary diagnostic laboratories to retrospectively identify disease outbreaks in livestock populations. Hyder et al. (57) scanned data on cattle submission to a national diagnostic laboratory in the United Kingdom and found six clusters of cases where a diagnosis was not reached through laboratory testing. The authors reviewed the accompanying data from the clinical history to determine whether the cases were epidemiologically linked. One cluster may have been caused by a local outbreak of John's disease, while the others were believed to be false positive signals due to the lack of a consistent case definition. This highlighted the importance of collecting good case history information that is easily accessible to allow analysts to quickly distinguish false positive signals from those that require further investigation. The authors also noted potential biases in monitoring cases with no diagnosis for evidence of an emerging disease threat stemming from practitioners requesting limited or pathogen-specific diagnostic testing on their cases. O'Sullivan et al. (50) collected test information on swine samples submitted to a regional veterinary diagnostic laboratory in Ontario to determine whether a known emerging outbreak of PCVAD could be detected by monitoring the weekly proportion of PRRSV tests (an endemic disease with similar clinical characteristics) that returned negative results. A significant association was found for PRRSV PCR results, but not for PRRSV ELISA results, which was attributed to the greater use of PRRSV ELISA for routine monitoring of herd health status rather than for diagnostic purposes during a suspected disease outbreak.

Market Surveillance Data

Livestock farmers routinely sell animals to maximize the returns on their available farm resources. This includes selling animals that have reached an appropriate market weight for slaughter, animals that are transferred to other livestock operations for further finishing or as breeding replacements, and animals that have been culled from the herd due to disease, poor performance, or surplus stock. Many countries require animals to be examined by an accredited veterinarian prior to shipment to verify that they are free from notifiable infectious diseases. The corresponding certificates of veterinary inspection may contain information on the shipper, receiver, livestock transport company, date of examination, date and purpose of the movement, animal identification (ear tag or tattoo number, species, age, sex, and breed), animal or herd disease status, and any relevant diagnostic testing results. A study by Portacci et al. (58) evaluated the completeness and legibility of paper-based certificates of veterinary inspection used to accompany cattle shipments within the United States. The authors found that date examination were only recorded on 40% of certificates and many certificates were also missing information on animal identification, which inherently limits the use of this data stream for disease surveillance and livestock traceability purposes. However, there are now options for veterinarians to submit electronic certificates of veterinary inspection using web-based (59–61) and mobile

technology platforms (62) to allow for real-time data exchange and improve data legibility and accuracy.

In commercial poultry and swine production systems, farmers often have fixed contracts with other producers and slaughter facilities to transport animals directly between locations when they reach a specified age, weight, and/or production stage. The commercial beef and dairy industries are much less vertically integrated and livestock markets play a more important role in facilitating animal trade. In the United Kingdom, approximately 30% of cattle moved off agricultural holdings pass through livestock markets (63) with a range of statistics reported in countries elsewhere (64–67). Movements of animals through livestock markets are believed to have greatly amplified the spread of foot-and-mouth disease the United Kingdom during the 2001 epidemic (68, 69) and unsurprisingly, there has been interest in developing both active and passive surveillance systems at markets to detect emerging diseases before they become widely distributed.

Van Metre et al. (70) piloted a syndromic surveillance system at a livestock market in the United States, which was based on a trained observer performing visual inspections of animals in each holding pen. Using a paper-based form, data were recorded on the date, the total number of animals in each pen, and the number of animals in the pen showing any of the 12 pre-defined clinical syndromes. Due to privacy concerns, the authors were unable to collect information on the ownership, destination, and demographic characteristics of the animals. Data collection required approximately 2–4 h depending on the volume of livestock entering the market on a given day. Key challenges identified with the system included the difficulty in detecting subtle clinical signs through distant visual observation, inter-observer variability in how animals with clinical signs are categorized into broad syndromic groups, and variation in the production type and demographic characteristics of animals sold on different market days. In a much earlier study estimating the incidence of disease in cattle and swine observed through a livestock market in Saskatchewan, animals with evidence of disease on initial inspection were withheld for a more thorough physical examination to better assess the clinical presentation (71). This may not be feasible at markets with a high volume of livestock trade.

Slaughter Inspection Data

In most commercial livestock production systems, animals intended for consumption are subject to ante-mortem and post-mortem examination at slaughter facilities to identify diseases that may pose a risk to human health. The ante-mortem examination involves inspecting animals for abnormal respiration, behavior, gait, posture, discharge, swelling, and other external lesions that warrant segregated slaughter. Data loss may occur since animals with overt clinical signs of disease are not supposed to be transported to slaughter facilities. In the United Kingdom, it has been estimated that 18% of recorded cattle deaths occur on locations other than slaughter facilities (63). After slaughter, the initial internal and external examinations are typically performed by trained meat inspectors on the slaughter line and any carcasses with suspect lesions are withheld for further examination by a federal veterinary inspector to determine whether the product is fit for human consumption. Slaughter facilities maintain basic records

of the number and origin of carcasses that are fully or partially condemned for the main purpose of calculating penalties against the submitting producers. The reasons for carcass condemnation are also frequently recorded under broad syndromic categories such as pneumonia, arthritis, emaciation, and abscessation (72). When there is reason to suspect a notifiable disease, samples may be submitted to veterinary diagnostic laboratories for pathogen-specific testing (73).

Several studies have highlighted that the rates of carcass condemnation at slaughter facilities can vary based on other non-biological and non-outbreak factors. For example, Alton et al. (74) found that condemnation rates in provincially inspected abattoirs in Ontario, Canada declined when sales prices were above average, which may be attributed to differences in the quality of animals shipped to slaughter. Higher condemnation rates were also found in abattoirs that accepted a larger proportion of older or poorer quality cattle. The authors concluded that it was important to account for animal age and production class when determining the baseline condemnation rates at slaughter facilities for use in automated surveillance algorithms. Thomas-Bachli et al. (75) evaluated factors contributing to lung and kidney condemnation rates in Ontario swine slaughter facilities. There was significant association between the number of hogs processed by slaughter facilities and lower condemnation rates, which may be explained by the effects of processing speeds on the ability of meat inspectors to identify lesions (76) as well as the possibility that larger slaughter facilities receive higher quality hogs. Seasonality has also been found to influence carcass condemnation rates likely due to changes in management and environmental conditions that change the baseline incidence of disease in livestock populations (77, 78).

Syndromic surveillance systems based on monitoring trends in condemnation rates have successfully been used to detect emerging spatio-temporal clusters in disease incidence. In evaluating historical data from Ontario swine slaughter facilities, Thomas-Bachli et al. (79) identified clusters of high condemnation rates in three slaughter facilities that coincided with known outbreaks of PCVAD, PRRSV, and swine influenza virus (SIV) occurring in the province. Due to privacy constraints and the limitations of analyzing retrospective data, the authors were unable to confirm whether the outbreak signal was caused by animals shipped to slaughter from affected farms. However, in comparison with traditional diagnostic data collected by provincial laboratories in the same study time period, the authors suggested that the slaughter surveillance would have provided an earlier warning of the impending outbreaks. Similar findings were reported in a smaller scale study of data from a single federally inspected slaughter facility in Ontario during the reported outbreaks (80).

Challenges

Data Collection

For syndromic surveillance systems to be useful in providing an early warning of emerging disease outbreaks, data must be collected and analyzed in near real-time. This can prove challenging given that the majority of farmers, veterinarians, laboratories, markets, and slaughter facilities still rely on paper-based recording systems

to manually capture animal health data in the field. These data must subsequently be transferred into electronic databases, which can lead to significant delays before the data become centrally available for analysis. For example, in the Ontario Farm call Surveillance Project (OFSP), the average time from farm visit to report submission was 16 days for paper-based submission forms, 13 days for web-based submission forms, and 7 days for submissions through handheld mobile devices with the majority of participating veterinarians (72 out of 98) choosing to use paper-based submission forms (36). The OSVS pilot program reported that the average time to availability of clinical records was approximately 22 days for both the paper-based submission forms and submissions through handheld mobile devices (41). Furthermore, form completeness is less likely when using paper-based recording systems. For example, when researchers in Sweden compared data from farm copies of veterinary consultation reports against the information to the national animal health database (44), it was found that only 76% of records submitted manually through paper-based forms were complete compared to 95% of records submitted electronically. The discrepancy was largely attributed to the presence of incorrect or unreadable information as well as missing data fields, which are common occurrences when using paper-based recording systems. Options to implement electronic reporting over paper-based forms would help improve the efficiency, completeness, and standardization of data collection and timeliness of data availability for analysis.

Data Security and Sharing

Much of the data collected within commercial livestock production systems is considered business sensitive by farmers and veterinarians. In countries without national herd and animal identification programs, there is often reluctance to share identifying farm information with regulatory authorities due to concerns over how the data will be shared and its potential to negatively impact business interests (51, 70). A critical component to the overall success of biosurveillance systems is maintaining the trust of the data providers. Protecting the confidential nature of the data and ensuring that only authorized individuals are provided access to it is essential. Establishing end-user agreements [e.g., memoranda of understanding (MOUs), data sharing agreements] that outline policies for data access, protection, use, sharing, and dissemination can help ensure transparency and enforcement these policies and maintain data confidentiality. An example of this is provided by the United States Centers for Disease Control and Prevention (CDC), which establishes Data Use Agreements with state and local health authorities for data sharing and to conduct syndromic surveillance during peacetime and during health emergencies as part of their BioSense system for public health surveillance (81). In addition, protection of the data within the technology is equally important. Farmers and veterinarians usually prefer their data be housed by a third-party with controlled access to regulatory authorities for surveillance purposes. Having the appropriate mechanisms in place to protect against unauthorized access or accidental release of the data, and to provide access control is necessary. The confidentiality of the data collected must be protected, integrity of the system must be maintained, and system disruptions must be minimized.

Data Standardization

The lack of standardized systems for recording animal health events has been highlighted as a significant barrier to integrating data across multiple data streams and systems (6). Almost every reported syndromic surveillance initiative has collected a different set of variables or used different definitions for the same set or variables. For example, the rapid syndrome validation project for animals (RSVP-A) that collected data from veterinary practitioners in the United States used only 6 syndrome categories (82), whereas a poultry slaughter surveillance program in Brazil recorded 23 common causes for carcass condemnation (78) and a laboratory-based initiative in Canada identified 16 primary syndromic groups based on clinical signs, non-specific diagnoses, or organ systems (49). Previous studies have also found considerable variability in the way different veterinarians interpret clinical cases (42), which may lead to inconsistencies in the types of animal health events that are recorded under each syndrome category. Even in countries with national herd and animal identification programs, it can still be difficult to link animal health databases when the necessary identifying information is not collected appropriately (83, 84). In addition, there is lack of data standardization among diagnostic laboratories, with the naming and coding of the same diagnostic test being highly variable within the LIMS systems among individual laboratories. This makes it difficult for analysts to link information from veterinarians, diagnostic laboratories, markets, and slaughter facilities back to the original farm, prevents the comparability of similar data collected by different systems or within different data streams, and interferes with the calculation of baseline disease incidence rates in outbreak detection algorithms. The sensitivity of the surveillance system for detecting spatial clusters of disease can also be improved when higher granularity data is available for report locations (85–87). Broader usability of the data collected will be enabled by ensuring relevant data fields and categories are standardized or conform to established data standards from other animal health data collection efforts.

Data Analysis

When implemented on a national scale, syndromic surveillance systems are expected to generate large volumes of heterogeneous data that become difficult to analyze using traditional statistical methods. Early changes in disease frequency can easily be masked by the greater natural variation in baseline disease levels observed in large populations (88). The most common solution has been to monitor smaller subsets of data from populations defined by administrative boundaries, geographic locations, or business catchment areas (6). This, however, is also problematic given that livestock disease often spread over wide geographical areas through animal movements (63, 89–91) as was the case during the 2001 foot-and-mouth disease epidemic in the United Kingdom (92). Outbreaks that span across the different monitored data streams may therefore go undetected for longer periods of time. For many outbreak detection algorithms, there are also known issues with accounting for changes in the level of reporting over time due to the recruitment and loss of participants (93), economic and disease factors affecting the industry (52), and changes to the underlying population demographic structure. It has been difficult to

evaluate the sensitivity and performance of different analytical approaches in the context of livestock production systems since most published syndromic surveillance projects did not achieve adequate population coverage or were not in operation during known disease outbreaks with sufficient epidemiological data for analysis (6).

Outbreak Response

Most prospective outbreak detection algorithms operate on the same basic principle that when the number of observed cases exceeds the number of expected cases by a specified amount, the system alerts the analyst to a potential emerging disease threat (94, 95). Setting the threshold levels is challenging because of the many uncertainties in how an emerging infectious disease threat will appear as a signal in the syndromic surveillance data. If the threshold levels are set too high, there may be delays in detecting true disease outbreaks, which can lead to larger outbreak sizes and significantly greater socioeconomic impacts. If the threshold levels are set too low, there will be an increased frequency of false positive alerts, which can lead to user fatigue, resource depletion, and decreased confidence in the system's performance. Furthermore, monitoring multiple data streams simultaneously is also likely to increase the absolute number of false positive alerts generated by the system. A recent review by Rolka et al. (96) highlighted numerous other challenges with monitoring multiple data streams including poor alignment in the coverage and timeliness of different data sources, difficulty in linking data streams to obtain accurate estimates of outbreak size, the theoretical nature of proposed statistical methods for integrating data from multiple sources, and the need for better visual analytics and decision support tools to facilitate rapid outbreak response.

Program Sustainability

With the exception of a few Scandinavian countries, the participation of farmers and veterinarians in syndromic surveillance initiatives has typically been on a voluntary basis. For that reason, many pilot projects have provided incentives such as direct financial compensation (51) or credits toward laboratory diagnostic testing (36) as a means of encouraging participants to submit surveillance reports. Zurbrigg and Van den Borre, (36) demonstrated a significant increase in the timeliness of report submissions in the OFSP during the time period when participating veterinarians were reimbursed for conducting post-mortem examinations on-farm. Follow-up survey studies have also revealed that both farmers (22) and veterinarians (41) believe that financial compensation for the time spent collecting data is essential for long-term project sustainability, although some participants were willing to continue submitting data voluntarily because of the value they perceived in conducting infectious disease surveillance. This raises concerns over the sustainability of large scale syndromic surveillance programs without a continued source of funding or building incentives into the program that benefit farmers and veterinarians so they see value in the system for managing animal health at the farm level. Participants have also expressed frustration that aggregate information on disease trends or significant findings was not made available in a useful format (53) and that the disease

situation of livestock populations has not actually improved despite the significant time and resources being invested in surveillance programs (51).

Discussion

The long-term success of syndromic surveillance programs in commercial livestock production systems hinges on being able to use innovative technology platforms to integrate animal health information from diverse data sources into a common operating picture where it can be used to support emerging infectious disease detection and decision-making as well as efforts to manage endemic diseases more cost-effectively at the farm and industry levels.

A key step toward improving the quality and timeliness of animal health data collected through syndromic surveillance systems will be developing mobile technology platforms that allow participants to capture information electronically as part of their normal work routines (23). The VetPad initiative in New Zealand is one example where veterinarians were provided with an interface for handheld mobile devices that operated as a practice management software as an incentive to submit surveillance reports (97). The main advantage over paper-based recording systems is the ability to standardize data collection by making key data fields required before submission to prevent data loss and by providing pre-determined lists or validation constraints for each data field to ensure consistency in how the information is recorded. Reducing the need for double data entry, such as mobile technology capabilities to allow data collected to be submitted for multiple purposes (e.g., an electronic laboratory submission form being automatically generated from a syndromic surveillance report) and integrating tools to automatically transfer completed reports into a centralized database is also likely to increase long-term compliance by minimizing the time burden on program participants (36). Several commercial herd and veterinary practice management software programs also offer users the option of recording data through interfaces designed to operate on personal digital assistants (PDAs), smartphones, or tablets in the field. However, variability in the type and format of recorded data makes it difficult to integrate into syndromic surveillance initiatives without either making significant modifications to the underlying source code or creating independent software programs that map local terminology into a standardized coding system. This can be addressed using innovative technology solutions that allow for the interoperability, and therefore data integration between different IT systems. This challenge highlights the need to establish national and international standards for reporting animal health information consistently at all stages in the production chain, which includes establishing definitions to standardized terminology and ensuring they are properly understood by program participants. This can be achieved through training and by having this information be easily referenced within the surveillance forms. In addition, evaluations of the data collected should be performed to ensure their use fit intended purposes of the syndromic surveillance system (e.g., assess frequency of use and trends, evaluate training, compare syndromic categorizations with

diagnostic tests results). Data standardization and consistency are also needed within diagnostic laboratories, including the collection, naming convention, and coding of data within LIMS systems. A working group of epidemiologists in Canada recently published a list of minimum data requirements to support disease surveillance using diagnostic laboratory submissions (98). These included the (1) unique laboratory submission identifier, (2) unique premises identifier, (3) sample submission date, (4) geographic location for the premises, (5) species tested, (6) main farm type, (7) production type of animals tested, (8) total population of the species tested on the farm, (9) total number sick, (10) total number dead, (11) diagnostic test(s) performed, (12) disease agent(s) screened, (13) test results, (14) syndromic classification, and (15) final diagnosis. Subjective elements such as risk factors (husbandry practices, farm demographics, animal characteristics), clinical information (clinical signs, differential diagnoses, treatments, laboratory submissions), potential confounders (feed changes, facility issues, environmental conditions), and other case notes were excluded from the list on the basis of being time consuming to collect and highly variable in how they are reported by different practitioners. However, this additional information can be used by analysts to determine whether cases in an identified cluster are epidemiologically linked (57) as well as to provide more useful feedback to farmers and veterinarians on disease management (99). As mentioned above, providing mechanisms for practitioners to electronically submit laboratory submission forms (e.g., online submission forms, mobile applications) would help reduce the time burden of completing these forms and allow diagnostic laboratories to require certain data fields be included on all submissions, such as these minimum data requirements. Education and outreach to practitioners on the value and benefit of providing more information on laboratory submission forms to manage the health of their clients' animals is needed to achieve better compliance, as well as initiatives for diagnostic laboratories themselves play a larger role in syndromic surveillance programs and provide useful information back in a consumable format as a service to their clients.

Another possible solution is to ensure that the different, but complementary information recorded by the various data streams can be linked through either herd or animal identification numbers. Glass-Kaastra et al. (100), for example, used both clinical and laboratory data from the OSVS program to characterize patterns in antimicrobial use and risk factors for treatment failure to help veterinarians select the most appropriate treatments for their patients and to help regulatory officials monitor livestock populations for evidence of antimicrobial resistance. As the use of RFID identification tags on livestock expands, it will also become easier to track production and health parameters on individual animals from birth through slaughter (101). Although some farmers have expressed concerns over sharing identifying information, there are now much more sophisticated technology platforms that can provide relevant summary statistics to key industry stakeholders while still protecting confidentiality. There are several examples in the literature where aggregate slaughter surveillance data from national animal health schemes has been successfully shared with participants for the purpose of benchmarking the performance of their farms against others in the industry (102–104).

The consistent use of herd and animal identification numbers in surveillance reports also facilitates the development of better statistical methods to detect emerging disease outbreaks. In countries where detailed information on livestock movements and farm locations is available through national computerized databases, it may be possible to strategically select space-time windows using network-based approaches to avoid the problem of using artificial boundaries to subset the large volumes of surveillance data. This process first involves reconstructing the contact network by creating links between farms that trade animals or are located in close proximity. These links may be weighted by the volume and frequency of animals traded in the case of movements or by the distance between farms in the case of spatial proximity. Various community detection algorithms can then be used to divide the population of farms into linked networks or communities based on the strength of connections between them (105, 106). Theory holds that if an infectious disease is introduced to a livestock farm, it has a greater chance of spreading to other farms within the community than to farms outside the community. It may also be worth establishing temporary subsets of farms based on their co-attendance at livestock events as markets, rodeos, or shows, since there is high risk of disease being introduced and widely disseminated through these venues (107, 108).

Several methods have been proposed to reduce the error caused by setting arbitrary threshold values. Dórea et al. (109) developed an approach based on aggregating the results from multiple outbreak detection algorithms that were run simultaneously on laboratory submission count data. Rather than setting a single threshold value, outbreak alert signals were assigned a “severity” score based on how far they deviated from the expected baseline values. The severity scores for the different algorithms were then combined and an alert was generated if the overall score exceeded another preset threshold value. This approach may increase the sensitivity of the system to diseases with a slow increase in case counts. Carpenter et al. (110) suggested using a two-level approach to determine the level of response to outbreak signals from data on abortions in dairy cattle. When the difference between the number of observed cases and the number of expected cases exceeds the threshold value once in a given time period, there should be only a limited preliminary investigation into patient risk factors. If the number of observed cases continues to exceed the number of expected cases in consecutive time periods or if the magnitude of the difference is excessively large, then there should be a more involved field investigation and/or outbreak response. A third approach used by Amezcua et al. (46) in the context of swine disease surveillance was to compare trends observed in the syndromic reports submitted by participating veterinarians to the corresponding laboratory submission count data from the same time period. The observation of similar trends may increase suspicion that the alert signal represents a true disease outbreak.

Some of the basic principles from risk-based surveillance (111) may also be useful in setting threshold values for outbreak detection algorithms. Certain farms are known to have a high risk of acquiring and spreading disease based on their connectivity in the animal network, proximity to other farms, demographic characteristics, and biosecurity practices. These factors could be used to generate a risk score for individual farms. The threshold values required to

trigger an alert could then be varied according to the aggregated risk scores for all farms present in the outbreak cluster. The basic premise is to increase the timeliness of response in situations where there is a high risk of disease spreading rapidly from the index farms. Similarly, diseases that present with an unusually high morbidity and mortality or unusually severe clinical signs should trigger an alert at lower thresholds than diseases with mild case presentations. Proper evaluation of these statistical methods will require the development of synthetic datasets to compensate for the lack of data with sufficient population coverage, duration, and superimposed natural disease outbreaks from pilot surveillance projects. In the public health field, there is a growing field focusing on the development of synthetic syndromic surveillance datasets to protect patient confidentiality while still providing researchers realistic enough baseline data to support methodological investigations (112). The veterinary community would benefit from efforts to develop similar synthetic datasets for livestock populations.

With the increasing sophistication of the technology platforms supporting syndromic surveillance efforts, it is also possible to provide participating farmers and veterinarians with customized tools to improve animal health management. This has been identified as an important incentive for continued participation (36). It has also been well established that the use of information management systems can offer significant financial returns through increased productivity (113), which may help farmers see the value in adopting electronic recording systems. In the BOSS project from Australia, which was designed to collect syndromic surveillance data from remote beef cattle herds, researchers developed a Bayesian classification system to provide participating producers with the most likely diagnosis based on the submitted clinical signs (114). A similar system has been proposed to use the clinical signs reported in veterinary practitioner-based surveillance data to identify cases with presentations that are compatible with known transboundary animal diseases such as bluetongue virus (115). Other valuable tools may include the ability to automatically detect herds with a higher incidence of disease or poorer performance than the general population based on established benchmarks, summary reports of disease trends in the surrounding region to increase situational awareness of local disease concerns, and systems that allow farmers and veterinarians to easily track the efficacy of different management interventions

by comparing production parameters before and after change. Establishing the use of syndromic surveillance for purposes beyond emerging infectious disease detection is important for justifying the costs of implementation and ensuring its sustainability (116).

Conclusion

As highlighted by this review, there is still much to be learned about how data collected from farmers, veterinarians, diagnostic laboratories, markets, and slaughter facilities can be used to support infectious disease surveillance in commercial livestock production systems. Each data stream has its own unique challenges associated with achieving adequate specificity, timeliness, and population coverage. However, advances in IT are greatly expanding opportunities to collect and integrate animal health data in real-time for use in detecting emerging infectious disease outbreaks as well as for managing common endemic diseases more cost-effectively than traditional surveillance systems.

Author Contributions

MG conducted the literature review and drafted the manuscript. TB, KB, and LH provided scientific guidance on the manuscript structure and contents. All authors read and approved the final manuscript.

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Detection of foot-and-mouth disease virus infected cattle using infrared thermography

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Abstract

In this study, infrared thermography (IRT) was assessed as a means of detecting foot-and-mouth disease virus (FMDV)-infected cattle before and after the development of clinical signs. Preliminary IRT imaging demonstrated that foot temperatures increased in FMDV-infected animals. The maximum foot temperatures of healthy ($n = 53$), directly inoculated (DI) ($n = 12$), contact (CT) ($n = 6$), and vaccine trial (VT) ($n = 21$) cattle were measured over the course of FMD infection. A cut-off value was established at 34.4 °C (sensitivity = 61.1%, specificity = 87.7%) with the aim of detecting FMDV-infected animals both before and after clinical signs were observed. Seven of 12 (58%) DI and 3/6 (50%) CT animals showed maximum foot temperatures exceeding the 34.4 °C cut-off before the development of foot vesicles. In contrast, only 5/21 (24%) VT animals displayed pre-clinical foot temperatures above this cut-off possibly indicating partial vaccine protection of this group. These results show IRT as a promising screening technology to quickly identify potentially infected animals for confirmatory diagnostic testing during FMD outbreaks. Further evaluation of this technology is needed to determine the value of IRT in detecting animals with mild clinical signs or sub-clinical infections.

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Keywords: Infrared thermography; Foot-and-mouth-disease; Bovine; FMDV

Introduction

Foot-and-mouth disease (FMD) is one of the most significant animal diseases affecting trade. It has been eradicated from many regions of the world where re-introduction has devastating economic, social and environmental effects (Woolhouse et al., 2001). The causative virus, foot-and-mouth disease virus (FMDV), causes vesicles on the foot, mouth, tongue, and teats of cloven-hooved animals and is one of the most contagious disease agents known. FMD is classified as a reportable disease by the Office International des Epizooties (OIE).

Although rarely fatal in adult animals, the appearance of FMD in a disease-free country results in severe trade

restrictions and agricultural losses. For example, the reappearance of FMD in the United Kingdom in 2001 resulted in multi-billion dollar losses associated not only with agriculture, but a wide range of activities including the pharmaceutical and tourist industries (Thompson et al., 2002). In order to re-gain FMD-free status, countries like the UK must demonstrate freedom not only of the disease but also of the virus in their animal population. Therefore, control measures include mass slaughter of animals in premises reporting disease as well as neighboring premises. In 2001, this approach resulted in the slaughter of millions of animals, most of which were not infected, to quickly achieve eradication (Davies, 2002).

Currently, clinical screening for FMD in cattle is time-consuming and labor-intensive since it necessitates the restraint of suspect animals for clinical examination. One of the main problems hampering the diagnosis, control and eradication efforts during the 2001 UK epidemic was

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the need for veterinarians to inspect hundreds, or in some cases thousands of individual animals on suspected infected premises (Davies, 2002). This was particularly difficult as many animals were either at an early stage of infection or not clinically affected by the OUK/2001 FMDV strain.

An often observed sign of FMD preceding development of vesicular lesions is the presence of fever, but in some animals infected with certain viral strains fever can be mild and/or of short duration, or absent. In the absence of overt clinical signs, a pen-side rapid screening test such as infrared thermography (IRT) that measures heat emission could be instrumental in selecting likely infected animals for further testing for FMDV infection either by direct virus detection or using serological methods.

This study was aimed at evaluating IRT as a screening method for FMDV-infected cattle and its potential application in the identification of suspected animals for sampling and confirmatory diagnostic testing during FMD outbreaks.

Materials and methods

Animals and virus

Holstein steers aged 6–8 months of age and weighing 180–270 kg were used in the study. All cattle experiments were performed in biosafety level 3 isolation facilities at the Plum Island Animal Disease Center following protocols approved by the Institutional Animal Care and Use Committee. Infrared images were collected from animals undergoing FMD vaccine trials or pathogenesis studies.

Animals from pathogenesis studies were grouped by route of virus exposure – direct inoculation or contact exposure. Directly inoculated (DI) animals ($n = 12$) were sedated and inoculated intradermally (IDL) at four sites with 100 μL per site of virus suspension containing a total of 10^4 bovine infectious doses (BID_{50}) of FMDV.

Two FMDV serotype O viruses (strains O UKG/2001 and O1-Manisa-Turkey/1969) and one FMDV serotype A virus (strain A24 Cruzeiro) were used for inoculation. Contact (CT) animals ($n = 6$) were introduced in groups of two into the room where two DI animals were housed at 24 h post-inoculation. Cattle that were part of a vaccine trial (VT) ($n = 21$) were directly inoculated as described above. The VT group included animals that were protected, partially protected or unprotected after FMDV challenge. The three study groups (DI, CT, and VT), virus strains, and vaccine treatments are detailed in Table 1.

During inoculation and every 24 h thereafter, animals were sedated and visually examined for vesicular lesions on their feet, nose, and mouth.

Table 1
Treatments, challenge virus strain and number of animals used in this study

Group	Challenge virus (number of animals)	Treatment
Directly inoculated [DI] ($n = 12$)	A24 ($n = 8$) O/UKG/2001 ($n = 2$) O1 Manisa ($n = 2$)	Unvaccinated
Contact [CT] ($n = 6$)	A24 ($n = 2$) O/UKG/2001 ($n = 2$) O1 Manisa ($n = 2$)	Unvaccinated
Vaccine trial [VT] ($n = 21$)	O1 Manisa	Unvaccinated ($n = 3$) Inactivated antigen commercial vaccine ($n = 8$) Ad5-IFN α experimental vaccine ($n = 10$)

A numeric scoring system was used to record clinical scores where a point is assigned for lesions on each of the four feet, the mouth and the nostril. The highest score of 6 indicated lesions in the tongue other than the inoculation site, on each foot, and on/in the nostril.

Infrared thermography

Infrared images were obtained always prior to sedation using one of two cameras, namely a FLIRSystems ThermoCAM EX320 or a Fluke IR FlexCam R1. Images were collected before animal rooms were cleaned in order to avoid temperature variations induced by the presence of standing water. The camera was placed 1.5–2 m from the animals to capture all images. Images were downloaded using ThermoCAM QuickView or Fluke SmartView software for analysis. Cameras were surface-decontaminated between each study by wiping all surfaces with a 5% acetic acid solution and a 70% ethanol solution followed by a 30 min ultraviolet light exposure inside a class II biological safety cabinet.

Confirmation of infection status

Infection status was established by clinical assessment and laboratory confirmation of infection. Viremia was determined by virus isolation as previously described with minor changes (Amass et al., 2003). Briefly, whole blood was collected daily and centrifuged at 800g for 10 min. Sera was harvested and frozen at -70°C . Multi-well plates containing 2 cm^2 monolayers of BHK-21 cells (passage level 62–68) in duplicate wells were inoculated with serum to detect FMDV (sample volume of 200 μL). Plates were monitored for cytopathic effects (CPE) for 3 days. All samples without CPE were frozen/thawed and passed two more times as described above to confirm an absence of infectivity. Samples with CPE were confirmed by real-time PCR as previously described (Callahan et al., 2002).

Data analysis

One hundred and six individual observations were collected from 53 healthy, naïve cows before FMDV exposure to generate baseline foot-temperature data. Multiple observations from each animal were separated by at least 24 h in order to incorporate day-to-day variation. After virus exposure, IRT images were collected daily in order to capture three stages of infection: Pre-clinical (1 day before foot lesions identified), Clinical (the first day foot lesions were identified), and post-clinical (1 day after foot lesions were identified). The single maximum data point from each foot of at least three feet of an animal was collected. The maximum foot temperature was defined as the highest temperature identified by the software program in the area from the bottom of the hoof up to the top of the digits. These temperatures were compared using a 2-tailed Student's t test in Microsoft Excel; $\alpha < 0.05$ was considered significant. Exclusion from the clinical stage analysis occurred if an animal became injured or did not develop lesions, all stages of infection were not captured, or fewer than three hooves were visible in the IRT image ($n = 34$).

The Screening and Diagnostic Tests/Validity Measures option in the Describe program of WINPEPI (<http://www.brixtonhealth.com>) was used to generate descriptive statistics for the maximum foot temperatures (Abramson, 2004). WINPEPI (Programs for Epidemiologists for Windows) is a free, downloadable statistics package that provides a wide variety of statistical calculations. The Describe program computes descriptive statistics from manually entered data sets including the appraisal of screening and diagnostic tests. Cut-off values reported here were determined by utilizing the Youden's index (the percent sum of the sensitivity and specificity of a particular cut-off point minus 100).

The maximum floor temperature between an animal's feet, the maximum eye temperature, and the rectal temperature of each animal were collected alongside the maximum foot temperatures. To determine if correlations existed, the single maximum foot temperature of each animal at each stage of infection was plotted against the floor, eye and rectal temperatures in Microsoft Excel and the Pearson's correlation coefficient (r) was obtained.

Results

Site selection

Preliminary IRT imaging demonstrated temperature differences between FMDV-infected cattle that presented fever and viremia from those that did not before vesicular lesions were observed (Fig. 1). These differences motivated further evaluation of IRT as a screening test for FMDV-infected cattle. To identify the best site for FMD screening, maximum foot temperatures, maximum face temperatures, and rectal temperatures were plotted with clinical scores. Foot temperatures paralleled clinical scores better than face and rectal temperatures in 14/17 (82.4%) vaccinated-unprotected cattle (see example in Fig. 2A). In contrast, the foot temperatures of vaccinated-protected animals remained low, reflecting their protective immune status (see example in Fig. 2B). Further confirmation of the foot as an ideal site to screen for FMDV-infected cattle came from correlation analysis of contact ($n = 6$) and directly ($n = 12$) inoculated animals with maximum foot, eye, and floor temperatures and rectal temperatures. Moderate positive correlations between maximum foot temperatures and rectal and eye temperatures were identified ($r = 0.53$ and $r = 0.60$, respectively) as well as between the rectal and eye temperatures ($r = 0.50$). Conversely, a small positive correlation was demonstrated between the floor temperature and foot temperatures ($r = 0.18$) indicating that foot temperatures detected by IRT were not affected by floor temperature under the experimental conditions of this study (Fig. 3). Based on this evidence, all further analyses were focused on maximum foot temperature as determined by IRT.

IRT as a screening tool for FMDV-infected cattle

Two serotype O viruses (O/UKG/2001 and O1 Manisa) and one serotype A virus (A24 Cruzeiro) were used in this study. Only one serotype O virus (O1 Manisa) was used for

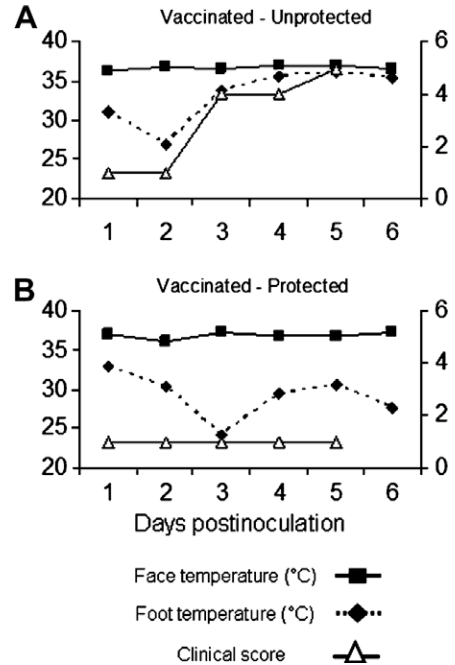


Fig. 2. Example of individual temperatures and clinical sign scores in FMDV vaccinated-unprotected ($n = 15$) and vaccinated-protected animals ($n = 3$). Face and foot temperatures based on IR images; clinical score based on number and distribution of vesicular lesions. Left Y axes indicate temperature in °C, right Y axes indicate clinical scores.

the challenge of VT animals. Among the DI and CT groups, no significant differences between the two serotypes ($P = 0.48$ and 0.09 , respectively) were detected in maximum foot temperatures at the pre-clinical or clinical stages of infection. A significant difference at the post-clinical stage was detected ($P = 0.02$) where animals infected with type O virus had maximum foot temperatures between 39.1 °C and 40.1 °C, while animals with type A virus ranged from 31.6 °C to 39.3 °C. Post-clinical data from DI and CT groups were not available for 3, 2, and 1 animals infected with A24, O1Manisa, and O/UKG/2001 viruses, respectively. For further analysis animals were grouped

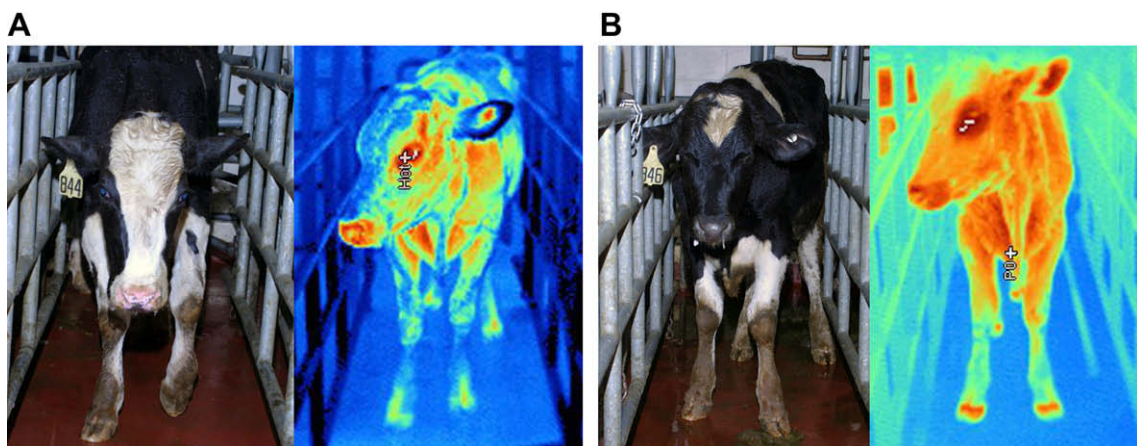


Fig. 1. Digital and infrared images of cattle without (A) or with (B) fever and viremia at 24 h post challenge, before vesicular lesions were observed. Note the lower temperatures (blue–green) in the animal without fever or viremia versus the higher temperatures (orange–red) in the viremic and feverish animal.

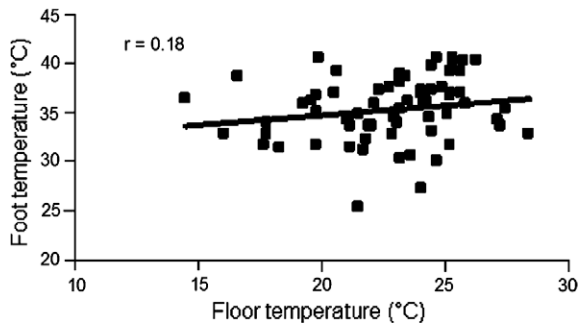


Fig. 3. Comparisons of floor temperatures with maximum foot temperatures observed in 18 FMDV infected animals at various stages of infection.

by route of infection and vaccination status (DI, CT, and VT groups) and temperature differences were observed according to disease stage. The VT group included protected, partially protected and unprotected individuals.

One hundred and six individual baseline observations taken from 53 cows prior to inoculation yielded a mean maximum foot temperature of 30.1 °C (SD 4.1 °C; range 20.3–36.8 °C). Thirty-nine FMDV-infected animals were used in subsequent analyses. After FMDV inoculation, DI animals ($n = 12$) showed a mean increase in maximum foot temperatures of 4.7 °C from the baseline mean to pre-clinical stage and 7.2 °C to clinical and post-clinical stages ($P \leq 0.001$) (Fig. 4A). CT animals ($n = 6$) demonstrated similar temperature differences from baseline with 4.8 °C, 7.5 °C, and 8.9 °C increases at the pre-clinical, clinical, and post-clinical stages of infection, respectively ($P < 0.003$) (Fig. 4B).

The ranges of maximum foot temperatures for each group and stage are shown in Table 2. There were no significant differences between DI and CT animals at any stage of infection (pre-clinical, $P = 0.95$; clinical, $P = 0.81$; post-clinical, $P = 0.21$). VT animals ($n = 21$) showed smaller increases from the baseline mean with 0.5 °C at the pre-clinical stage, 5.7 °C at the clinical stage, and 5.2 °C at the post-clinical stage (Fig. 4C). The clinical and post-clinical means from the VT group were significantly different from the baseline values ($P < 0.001$). Increases in maximum foot temperature occurred regardless of strain and differed significantly ($P < 0.03$) between the VT animals and DI and CT animals at all stages of infection (Fig. 4).

Sensitivity and specificity

Pre-clinical maximum foot temperatures from all animals ($n = 39$) regardless of the route of virus infection or vaccine status were used to calculate a cut-off value using WINPEPI (Abramson, 2004). The cut-off value generated was 33.0 °C (sensitivity [SE] = 62.5%, specificity [SP] = 73.6%). However, this cut-off yielded a number of false positives as illustrated by the large number of baseline animals falling within the 31.4–34.3 °C range (Fig. 5).

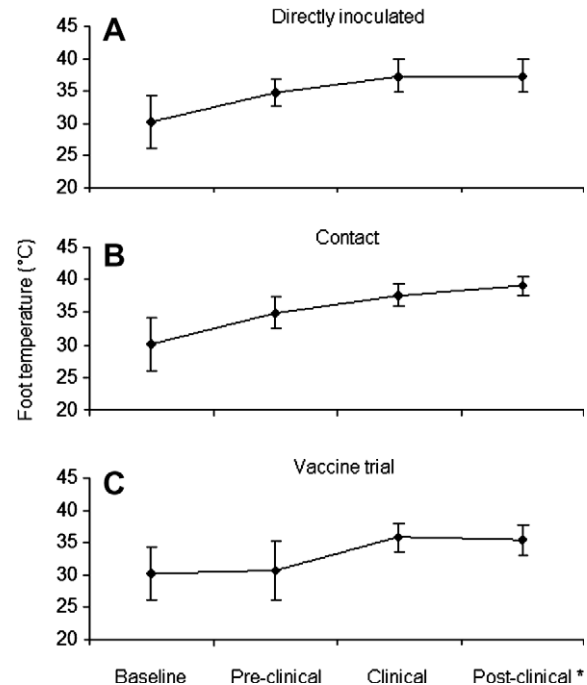


Fig. 4. Mean and standard deviation of maximum foot temperatures at each stage of infection for DI, CT, and VT animals (A, B and C, respectively).

Table 2

Ranges of maximum foot temperatures by group and stage of infection

	Pre-clinical	Clinical	Post-clinical ^a
Contact [CT] ($n = 6$)	31.8–37.1	36.0–40.3	37.3–40.1
Directly inoculated [DI] ($n = 12$)	31.4–38.1	33.9–40.7	31.6–39.5
Vaccine trial [VT] ($n = 21$)	23.1–39.1	31.0–40.6	31.3–42.3

All temperatures are shown in degrees Celsius.

^a Post-clinical stage data missing on 3, 3, and 1 animals from the CT, DI, and VT groups, respectively.

Therefore, we established a cut-off value of 34.4 °C (SE = 61.1%, SP = 87.7%), which correctly identified 58% and 67% of pre-clinical CT and DI animals, respectively, while mistakenly identifying only 12% of baseline animals (Fig. 5). Sensitivity and specificity for IRT detection of FMD-infected animals during the clinical stage using this cutoff were 79.5% and 87.5%, respectively. On the second day of clinical disease (post-clinical stage), the SE and SP were 78.1% and 88.4%, respectively. Animals in the VT group were not considered in this analysis since many of them were partially protected and yielded lower foot temperatures.

Clinical sensitivity of IRT

Utilizing the cut-off value of 34.4 °C, we evaluated the ability of IRT to detect animals that would develop clinical FMD signs. Viremia is often used to monitor FMDV

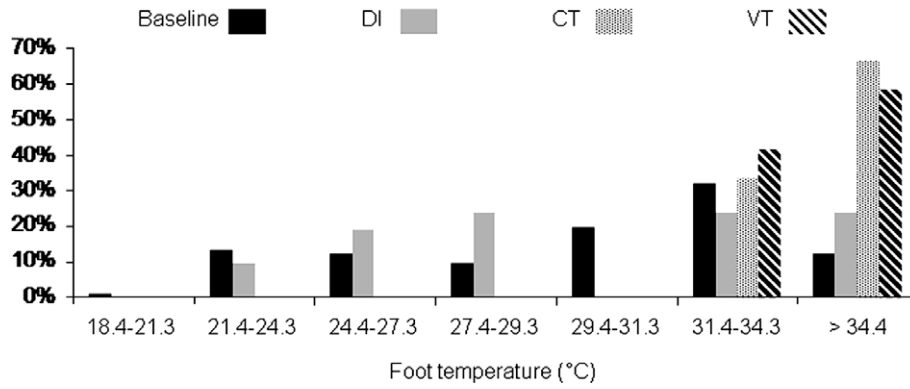


Fig. 5. Proportion of cattle in each foot temperature range from baseline and pre-clinical stage of FMDV infection for the DI, CT, and VT groups.

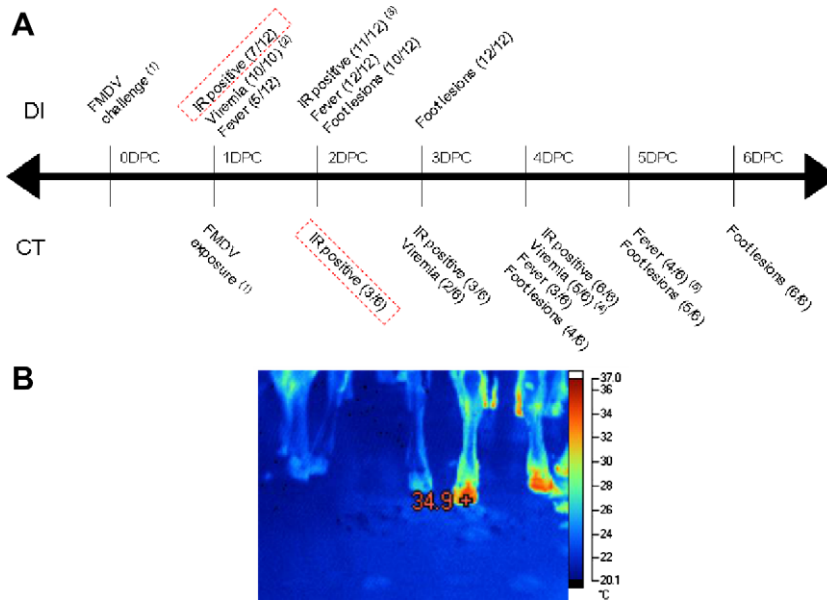


Fig. 6. (A) Timeline illustrating proportion of cattle from DI and CT groups presenting viremia, clinical disease (fever and vesicular lesions) and IRT positive foot temperatures (utilizing a cutoff value of 34.4 C) after FMDV exposure. DPC = days post-challenge. (B) Example of infrared image showing foot-temperature difference between FMDV infected (right) and non-infected (left) cattle.

infection in animals as it frequently precedes the development of clinical signs. In this study, 3/6 (50.0%) CT animals were positive by IRT 1 day prior to having detectable viremia and 2 days prior to the development of foot lesions (Fig. 6A). At 1 day post-challenge (DPC), of the ten DI animals assessed for viremia, 100% were viremic and 7/12 (58.3%) were detected by IRT (Fig. 6A). Foot lesions were identified in these 10 animals the following day. Clinical signs never occurred before viremia for any animals in the CT and DI groups. Eight of 21 (38.1%) VT animals developed viremia and foot lesions by 2 DPC. One animal was detected by IRT at 1 DPC and five were detected the next day (data not shown). An example of a possible application of IRT as a screening test in a group of animals is shown in Fig. 6B where an FMDV-infected animal was easily detected by the increased foot-temperature.

Discussion

Previous studies have assessed the efficacy of IRT for the detection of injury and disease. Human medical applications have included the early detection of breast cancer (Mital and Scott, 2007), quantification of the disease process in herpes labialis lesions (Biagioni and Lamey, 1995), and airport screening for severe acute respiratory syndrome (SARS) (Chiu et al., 2005). Veterinary studies have also been varied. Schaefer et al. identified IRT as a method for early detection of animals infected with bovine viral diarrhea virus (Schaefer et al., 2004) or with bovine respiratory disease using facial scans (Schaefer et al., 2007). Infrared has been identified as a possible detection method for laminitis in lactating dairy cattle (Nikkhah et al., 2005) and chronic pain following tail docking (Eicher et al., 2006). Measurements from IRT have also been used to

recognize orthopedic injuries in dogs and horses (Eddy et al., 2001), rabies virus in raccoons (Dunbar and MacCarthy, 2006), and mange in the Spanish ibex (Arenas et al., 2002). These studies have concluded that while IRT provides an additional perspective on disease and injury, it should complement traditional diagnostics methods. Similarly, the present study assessed the application of IRT as a screening method for identifying potential FMDV-infected cattle for further sampling and laboratory confirmation of infection. This is the first report of IRT as a screening method for FMD in cattle.

Foot temperature was chosen as the area of interest in this study because, unlike face temperature, important temperature changes were seen in animals during the different phases of disease. Although Schaefer et al. (2004) identified increased face temperatures for early detection of bovine viral diarrhoea virus, the data presented here did not support this finding for FMDV. The highest face temperature is often identified in the eye, which is believed to reflect internal body temperature (Kastberger and Stachl, 2003). Interestingly, we did not see a strong positive correlation between face and rectal temperatures. While we were able to identify a positive correlation between foot temperatures and rectal temperatures, increases in foot temperatures consistently occurred prior to the development of fever. Furthermore, the presentation of fever occurs in a wide variety of illnesses in cattle but increased foot temperatures have fewer etiologies. We were unable to identify a large correlation between foot and floor temperatures, strongly suggesting that under the conditions of this study floor temperature did not influence the temperature of the foot.

Interestingly, DI and CT animals showed similar increases in foot temperatures regardless of the viral strain or route of FMDV exposure while VT animals did not show significant increases in foot temperature in the preclinical stage and showed smaller increases than DI and CT animals. This difference might be due to the fact that these animals were partially protected, had less of an inflammatory response and therefore, had lower temperatures in the feet. The 33.6 °C cut-off value obtained using WINPEPI maximized the sensitivity and specificity of this test (SE = 72.2%, SP = 82.1%) but misclassified a number of healthy animals. Since this tool is intended for identifying potentially infected cattle for further testing, a high number of false positives would limit the utility of the test. By increasing the cut-off value to 34.4 °C (SE = 61.1%, SP = 87.7%), IRT was able to more accurately identify infected cattle and reduce the number of false positives.

During the 2001 FMD outbreak in the UK, the decision to cull animals was originally based on laboratory confirmation but changed to clinical presentation as the diagnostic laboratory became overwhelmed by large numbers of samples arriving daily (McLaws et al., 2007). IRT could provide a tool for better selecting animals for sampling, resulting in a decreased number of clinical samples submit-

ted for diagnostic confirmation and easing the strain on veterinarians in the field and laboratory technicians during a large FMD outbreak. One of the main problems during this outbreak was the difficulty of detecting clinical signs in sheep (McLaws et al., 2007). The IRT test would need to be evaluated to determine its utility as a screening test in this species.

As illustrated by Fig. 6A, IRT detected foot temperatures above the cut-off value at 1 DPC for DI animals, which was the same day that viremia and fever were first detected but before any lesions were observed. In contrast, IRT identified increased foot temperatures prior to the detection of viremia and foot lesions in CT animals. The ability of IRT to detect animals infected with FMDV by contact (presumably the mechanism of infection during natural transmission) not only in the pre-clinical but even during the pre-viremic phase provides strong evidence that this technology can be very useful in detecting FMDV-infected animals prior to other evidence of infection. This early detection capability can become critical during an FMD outbreak, particularly when suspect animals need to be identified for diagnostic sample collection. Since two-thirds of pre-clinical and 100% of clinical CT animals in this study had a maximum foot temperature above the cut-off of 34.4 °C, it is likely that at least one animal in an infected herd would be detected by IRT during an FMD outbreak.

FMDV-infected animals in the VT group were not as easily detected by IRT during the pre-clinical phase. The fact that only 8/21 (38.1%) VT animals developed viremia supports the hypothesis that the VT animals developed partial protection to FMDV after vaccination. This partial protection might or might not interfere with the inflammatory process, and may make IRT pre-clinical detection of VT animals more difficult. Infected animals without clinical signs might or might not be detectable through inflammatory responses in the coronary band and resultant rise in temperature. This may or may not limit the usefulness of this test in screening for FMD in countries that use FMDV vaccines and where partially protected animals would be common. Another potential limitation of this technology is the cost of the infrared cameras used in this study. However, it is likely that less expensive equipment can be employed to detect maximum foot temperatures and so allow for rapid screening of suspected FMDV-infected cattle.

Further validation of the technology is necessary as we did not have access to a large number of healthy animals under field conditions. Also, it is well established that other pathologies result in inflammation of the feet, mimicking the 'hot feet' seen here, which makes it important to carry out the field validation of this screening test. Collection of foot temperature data using IRT under a variety of environmental conditions, floor surfaces (i.e. grass, mud, concrete), and other variables is necessary for the validation of this technology. The data collected with the infrared camera included up to 25,000 individual temperatures for

each image generated. Therefore, unique patterns or temperature signatures for FMD could be better defined using computer algorithms.

The purpose of this study was to test the feasibility of IRT as a screening tool for detection of FMDV-infected cattle. The use of a quick and reliable tool to screen large numbers of animals without the need for handling or restraining would allow for a more efficient use of valuable resources. An important issue during the 2001 UK epidemic was the 3-day quarantine for veterinarians after visiting a suspected FMDV-infected premise (Kitching et al., 2005). This limitation could be avoided by having veterinary assistants trained in IRT scan the herds with an IRT camera before veterinarians enter the premises. Furthermore, with existing wireless technology, IR images could be transmitted remotely to incident command centers where veterinarians could pre-select animals for further clinical examination and sampling. Other potential uses of IRT technology could be in combination with rapid pen-side diagnostic tests such as real-time RT-PCR or antigen detection methods. By rapidly identifying potentially infected animals, sampling and testing could be done on-site, cutting the time of detection and allowing for faster implementation of quarantines in the control phase or quarantine release during the recovery phase of an FMD outbreak.

Future research should focus on differentiating foot-associated conditions in cattle and developing computational algorithms that assess signature temperature patterns of specific diseases including FMD. This study demonstrated the feasibility of IRT as a screening tool for FMD in cattle that, in combination with other rapid diagnosis tests, could play an important role during the control, eradication, and recovery phases of an FMD outbreak.

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ORIGINAL ARTICLE

Early Detection of Foot-And-Mouth Disease Virus from Infected Cattle Using A Dry Filter Air Sampling System

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foot-and-mouth disease; foot-and-mouth disease virus; airborne; dry filter unit; air samplers; spread

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Summary

Foot-and-mouth disease (FMD) is a highly contagious livestock disease of high economic impact. Early detection of FMD virus (FMDV) is fundamental for rapid outbreak control. Air sampling collection has been demonstrated as a useful technique for detection of FMDV RNA in infected animals, related to the aerogenous nature of the virus. In the current study, air from rooms housing individual ($n = 17$) or two groups ($n = 4$) of cattle experimentally infected with FMDV A24 Cruzeiro of different virulence levels was sampled to assess the feasibility of applying air sampling as a non-invasive, screening tool to identify sources of FMDV infection. Detection of FMDV RNA in air was compared with first detection of clinical signs and FMDV RNA levels in serum and oral fluid. FMDV RNA was detected in room air samples 1–3 days prior (seven animals) or on the same day (four animals) as the appearance of clinical signs in 11 of 12 individually housed cattle. Only in one case clinical signs preceded detection in air samples by one day. Overall, viral RNA in oral fluid or serum preceded detection in air samples by 1–2 days. Six individually housed animals inoculated with attenuated strains did not show clinical signs, but virus was detected in air in one of these cases 3 days prior to first detection in oral fluid. In groups of four cattle housed together, air detection always preceded appearance of clinical signs by 1–2 days and coincided more often with viral shedding in oral fluid than virus in blood. These data confirm that air sampling is an effective non-invasive screening method for detecting FMDV infection in confined to enclosed spaces (e.g. auction barns, milking parlours). This technology could be a useful tool as part of a surveillance strategy during FMD prevention, control or eradication efforts.

Introduction

Foot-and-mouth disease (FMD) is a highly contagious disease of livestock that has devastating economic and social consequences which are substantially different between endemic and free regions (Grubman and Baxt, 2004; Arzt et al., 2010b). In endemic countries, FMD contributes to food insecurity by causing substantial losses to farmers and rural communities (James and Rushton, 2002; Perry and Rich, 2007). Disease-free countries continuously spend considerable resources in surveillance to prevent introduction of FMD. However, important epidemics still occur

sporadically, such as those experienced in Europe in 2001 (Thompson et al., 2002), Argentina 2001 (Malirat et al., 2007), Japan 2010 (Muroga et al., 2013), South Korea 2010–2011 (Knowles et al., 2012) or Bulgaria 2010–2011 (Valdazo-Gonzalez et al., 2012), among several others.

FMD is caused by FMD virus (FMDV), a single-stranded positive-sense RNA virus from the *Picornaviridae* family, genus *Aphthovirus* (Grubman and Baxt, 2004). When outbreaks occur, FMDV is rapidly and effectively disseminated by various mechanisms including movement of infected animals, fomites and aerosolization of virus. The aerogenic properties of FMDV are important concerns for predicting

and limiting transmission. Pigs are generally believed to be the most effective shedders of airborne FMDV (Sellers and Parker, 1969; Donaldson et al., 1970, 1982; Donaldson and Ferris, 1980; Alexandersen and Donaldson, 2002; Alexandersen et al., 2002a), whereas cattle are believed to be most sensitive to aerosol infection (Donaldson et al., 2001; Donaldson and Alexandersen, 2002). Natural aerosolization of FMDV contributes to the rapidity of spread within and between farms. So that by the time an infected farm is detected, several other farms and animals that are in direct or indirect contact may have already been exposed (Kitching, 2005). It is widely accepted that one of the most important aspects influencing the rapid control of outbreaks is the early detection and rapid deployment of strict quarantines and effective control measures (Christensen et al., 2005; Cottam et al., 2008).

Counter intuitively, the natural aerosolization of FMDV also provides a useful opportunity for prevention and control. It has been shown previously that FMDV may be detected in the environment from air samples in proximity to FMDV-infected cattle (Alexandersen et al., 2002b; Christensen et al., 2011) and pigs (Gloster et al., 2007; Amaral Doel et al., 2009; Ryan et al., 2009; Waters et al., 2014). This manner of detection may be exploited as a rapid and non-invasive system of surveillance at the farm level. Additionally, it has been shown that reducing time between infection and detection significantly decreases the number of outbreaks during an epidemic (Brito et al., 2011; Carpenter et al., 2011).

Detection of FMDV is normally carried out by observation of clinical signs, followed by laboratory confirmation by various diagnostic tests. By the time animals show signs of clinical disease, they have been already shedding the virus (Arzt et al., 2011). Disease detection before clinical signs can be achieved by sampling blood, serum, oral fluid or nasal secretion, but this type of testing requires invasive sampling of several individual animals within a premise, and a visit from a trained professional to detect initial positive cases. In addition, this type of testing is not practical for surveillance of animal gathering premises such as auction barns or slaughter houses, where animals from various regions congregate allowing wider regional surveillance within and without quarantine areas. An important issue during the 2001 UK epidemic was the 3-day quarantine for veterinarians after visiting a suspected FMDV-infected premise (Kitching, 2005). Having additional surveillance tools such as air sampling of barns or milking parlours might help mitigate the loss of surveillance personnel due to quarantines while allowing for wider strategic sampling.

Aerosolized virus emitted by animals is related to the amount of virus present in oral fluid, blood and nasal swabs, which can be detected before clinical signs (Alexandersen et al., 2003; Pacheco et al., 2012). Several devices

have been utilized, and different results have been reported depending on the detection system (i.e. individual animal sniffer, large volume air samplers), collection media (e.g. liquid, electrostatic, dry filter), the viral strain, room setting and length of air sample collection (May and Harper, 1957; May, 1966; Errington and Powell, 1969; Donaldson et al., 1982; Gloster et al., 2007; Ryan et al., 2009; Christensen et al., 2011; Mohamed et al., 2011; Pacheco et al., 2012). A recent publication (Amaral Doel et al., 2009) compares different samplers and describes the method by which samples are processed. They conclude that there is no optimum air sampling instrument which could be successfully employed for all situations. Additionally, over the years, sensitive diagnostic tests such as real-time qRT-PCR or LAMP detection techniques for viral RNA have become more cost efficient, accurate and faster, and more conducive to process automation (Longjam et al., 2011; Waters et al., 2014). New technologies should further allow sending the results remotely to a central location in real time.

The objective of the current study was to measure the detection of FMDV RNA in air from rooms housing individual or groups of cattle experimentally infected with FMDV A24 strains with different levels of virulence, ranging from wild type fully virulent to attenuated mutant viruses that do not cause clinical signs. For this purpose, we utilized a system consisting of continuous air collection in dry air filters. This system had previously been successfully used for detection of FMDV RNA in air from rooms housing infected domestic (Pacheco et al., 2012) and feral pigs (Mohamed et al., 2011). We compared the time and level of detection of FMDV RNA in air relative to that in oral fluid and serum samples, as well as the appearance of clinical signs. The system described herein could be used for detection of FMDV infection in enclosed spaces housing animals such as farms, live animal markets and abattoirs with the goal of early detection and prevention of FMDV spread.

Materials and Methods

Experimental animals, virus, inoculation systems and sample collection

All animal procedures were performed following protocols approved by the Plum Island Animal Disease Center Institutional Animal Care and Use Committee (IACUC), which ensured ethical and humane treatment of experimental animals. All experimental subjects were 9- to 12-month-old Holstein steers weighing 400–500 kg that were obtained from an AAALAC-accredited experimental-livestock provider (Thomas-Morris Inc., Reisterstown, MD, USA). Detection of FMDV in air samples was evaluated in 19 experiments, 17 consisting of a single steer and two group experiments including four steers each, all infected with

FMDV A24 Cruzeiro strains of varying virulence. Routes of inoculation included aerosol, intradermolingual (IDL) and contact, as previously described (Pacheco et al., 2010a). Clinical evaluations were carried out daily, and scores were measured in a scale from 0 to 20 as previously described (Pacheco et al., 2010a). Tampons were used to swab the mouth and then centrifuged to collect oral fluids that were stored at -70°C until further processing. Serum was separated from blood collected from the jugular vein and stored at -70°C . Air sampling dry filters were collected daily following the protocol described below. For most experiments, data were collected for 8–9 days post-inoculation (dpi), but the duration was variable and depending on the primary objective of the individual experiments.

Single-animal experiments

Table 1 describes the details of all the single-animal experiments, which were designed as part of pathogenesis or vaccination-challenge studies at PIADC and most have been published previously (for references see Table 1). Individual animals were kept in 26.1 m² rooms (air volume 95 cubic metres, 13 air exchanges per hour) and inoculated by aerosol with different variants of A24 Cruzeiro at doses ranging from 10^6 to 10^7 infectious doses.

Group experiments

Two separate experiments were performed including 4 animals each inoculated with A24 Cruzeiro wild type, at different doses, and held in a 52.21 m² room (135 cubic metres, 25 air exchanges per hour) For each experiment, two cows were IDL inoculated with low and high infectious doses of, 10^4 TCID₅₀ and 10^7 TCID₅₀, respectively. After 24 h, two naïve animals were brought in direct contact with the inoculated cows for the rest of the evaluation period.

Air sampling

Air sampling was performed as previously described (Pacheco et al., 2012). For the purpose of optimizing air sampling, we used three combinations of pumps and filters in these experiments. The first one was the MRV PSU system from HI-Q that uses a Hi-Q filter holder (Hi-Q Environmental Products Company, San Diego, CA, USA) containing one Fluoropore membrane filter (1.0 µm filter pore size, diameter of 47 mm, Catalogue number FALP04700; Millipore, Billerica, MA, USA). The second system used a Model 1000 air pump developed by the Program Executive Office for Chemical Biological Defense (PEO-CBD), fitted with its original DFU filter assembly holding two separate Lockheed Martin polyester filter discs (1.0 µm filter, diameter 47 mm, Catalogue number DFU-P-24; Lockheed Martin, Washinton DC, USA). The third

system was the Model 1000 pump fitted with the Hi-Q filter holder described above. In preliminary experiments, no differences were found in FMDV detection between the two filter types (Pacheco et al., 2012). The three methods: MRV – HiQ filter, Model 1000 – DFU filter and Model 1000 – HiQ filter had air flows of 4.6, 15 and 144 l/min, respectively. Therefore, to compare across experiments, all the data were standardized by air flow rate for the amount of FMDV RNA detectable per m³ (1000 l). Filters were replaced every 24 h. As a negative control, the air was sampled inside the animal rooms for 24 h prior to FMDV inoculation. After collection, the filters were kept at -70°C until processed for detection of FMDV RNA using real-time qRT-PCR as described below. The humidity of the rooms ranged from 30 to 70% (higher humidity was generally associated to the time when room was washed down for cleaning) and air changes (complete replacement of the air in a room) were 13 and 25 per hour for the small rooms with individual animals and larger group rooms, respectively.

FMDV RNA detection methods

FMDV RNA detection in air, serum and oral fluid samples was performed by real-time qRT-PCR as previously described (Pacheco et al., 2012). Cycle thresholds obtained by qRT-PCR were converted to RNA genome copies per ml of serum or oral fluid or as RNA genome copies per 1000 l of air for air samples, utilizing a standard curve generated from synthetically derived pure FMDV RNA, as previously described (Arzt et al., 2010a).

Statistical assessment of variables associated with FMDV RNA measurement in air samples

To assess the association between FMDV RNA detected in air and in serum or oral fluid in individual animal experiments, we tested for statistical significance of parameters in a repeated-measures mixed model regression. Daily measurements of FMDV RNA in serum and oral fluid, clinical score and rectal temperature were assessed for their association with FMDV RNA detected in air per day after virus inoculation. The animal was added as a random factor, given that animals were challenged with different variants of the virus. The random effects allowed assessment of the variability of measurements of FMDV RNA in air that could be associated with FMDV in serum and oral fluid, while accounting for the variability observed due to the use of different viral strains for each individual animal experiment. This procedure allows working with correlated data, which, in this case would be the different measurements within one animal. The dependent variable was the amount of viral RNA detected in the air sampling device filter, corresponding to FMDV accumulated in the

Table 1. Clinical signs and Foot-and-mouth disease virus (FMDV) RNA copy numbers detected in air or clinical samples obtained from individually housed animals

Animal ID	Virus	Pump type (l/min)	Days of detection in air respect to clinical signs	Days of detection in air respect to serum	Days of detection in respect to saliva	Initial day of clinical signs	Highest clinical score (Maximum = 20)	Air			
								Initial (excluding potential remaining inoculum)		Peak	
								day post inoculation	log ₁₀ RNA CN/1000 l	day post inoculation	log ₁₀ RNA CN/1000 l
9143	A24WT3BPVKV3DYR	144	-3	0	0	5	4	2	2.15	6	6.29
7204	A24-VPG25934	15	-2	1	1	4	20	2	1.85	5	3.36
7109	A24-WT	15	-1	1	1	3	18	2	1.22	5	5.57
7203	A24-L1110	15	-1	2	2	5	18	4	1.16	6	1.99
7205	A24-3'8110	15	-1	1	1	5	20	4	1.69	6	3.07
847	A24-5853	4.6	-1	2	1	5	16	4	2.52	6	5.09
9144	A24WT3BPVKV3DYR	144	-1	1	0	4	16	3	6.42	3	6.42
7198	A24-L1159	15	0	1	1	3	18	3	3.53	5	5.49
848	A24-5869	15	0	2	2	3	20	3	3.21	5	4.35
1 ^a	A24WT3DYR	4.6	0	3	3	4	18	4	2.25	8	3.66
2 ^a	A24WT3DYR	15	0	3	2	4	8	4	2.56	4	2.56
8182	A24-VPG1	15	1	2	2	3	20	4	3.89	6	4.47
7140	A24-L1118	15	N/A	N/A	N/A	No FMD detected		N/A	ND(1) ^b	N/A	ND(1)
763	A24-L1110	15	N/A	1	-3	No FMD detected		3	1.35	8	2.03
7201	A24LL3DYR	15	N/A	N/A	N/A	No FMD detected		N/A	ND(1)	N/A	ND(1)
3	A24LL3DYR	4.6	N/A	N/A	N/A	No FMD detected		N/A	ND(3) ^d	N/A	ND(3)
4	A24LL3DYR	15	N/A	N/A	N/A	No FMD detected		N/A	ND(1)	N/A	ND(1)

All animals were inoculated with 10^6 – 10^7 TCID₅₀ by aerosol as previously described (Pacheco et al., 2010a).

CN, copy numbers; N/A, Not applicable.

^afor these animals clinical signs, air filter and swabs samples were not collected at 3 dpi.

^bND(1): Not detected, below limit of detection of 0.86 log₁₀ RNA copy numbers/1000 l.

^cND(2): Not detected, below limit of detection of 2.69 log₁₀ RNA copy numbers/ml.

^dND(3): Not detected, below limit of detection of 1.37 log₁₀ RNA copy numbers/1000 l.

filter during the 24 h immediately prior to oral fluid and blood sample collection included in the analysis. Additionally, we evaluated whether initial day of detection and

peak of FMDV RNA in serum, oral fluid and air were associated with the amount of FMDV RNA in air. Variables that were significant ($P < 0.05$) were retained in the

Last day collected or detected	Serum						Saliva						Reference	
	Initial		Peak		Last day collected or detected		Initial (excluding potential remaining inoculum)		Peak		Last day collected or detected			
	day post inoculation	log ₁₀ RNA CN/1000 I	day post inoculation	log ₁₀ RNA CN/ml	day post inoculation	log ₁₀ RNA CN/ml	day post inoculation	log ₁₀ RNA CN/ml	day post inoculation	log ₁₀ RNA CN/ml	day post inoculation	log ₁₀ RNA CN/ml		
≥16	3.14	2	5.28	4	7.69	6	4.84	2	8.21	5	9.32	9	6.48	Uddowla et al. (2012)
≥9	2.3	1	3.87	3	5.86	4	5.57	1	5.69	5	7.87	≥9	4.56	Pacheco et al. (2010b)
≥8	4.62	1	4.68	3	7.92	5	5.91	1	5.45	4	9.19	≥9	6.14	Piccone et al. (2010)
7	1.42	2	4.8	6	6.95	8	3.28	2	3.22	5	9.92	≥9	5.79	(Piccone et al. (2010)
≥8	2.35	3	3.97	5	5.44	5	5.44	3	3.65	6	7.79	≥9	5.18	Piccone et al. (2009)
≥10	4.04	2	4.89	4	5.86	6	3.95	3	5.83	5	5.97	≥10	4.64	Pacheco et al. (2010b)
≥10	3.95	2	4.68	4	8.21	6	3.73	3	7.54	5	9.14	≥10	4.74	Uddowla et al. (2012)
≥9	2.12	2	5.65	4	6.22	5	4.15	2	8.43	4	9.32	≥9	6.57	J. M. Pacheco, Unpublished
≥10	3.21	1	4.67	3	7.19	5	5.41	1	5.9	5	10.19	≥10	5.68	Pacheco et al. (2010b)
≥9	1.37	1	4.09	3	7.83	5	3.88	1	5.26	4	8.29	≥9	3.64	Uddowla et al. (2012)
5	1.47	1	3.07	3	8.24	5	4.52	2	7.78	4	9.76	≥9	5.15	Uddowla et al. (2012)
8	3.17	2	4.63	4	7.41	6	4.53	2	4.51	5	10.48	≥9	6.74	Pacheco et al. (2010b)
N/A	ND(1)	6	3.98	6	3.98	6	3.98	4	3.27	9	5.26	≥10	4.43	Piccone et al. (2010)
9	1.82	2	4.4	2	4.4	3	4.18	6	5.13	8	5.23	≥9	4.2	Piccone et al. (2010)
N/A	ND(1)	N/A	ND(2) ^c	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	Uddowla et al. (2012)
N/A	ND(3)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	Uddowla et al. (2012)
N/A	ND(1)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	N/A	ND(2)	Uddowla et al. (2012)

model as variables significantly associated with FMDV RNA in air. We excluded measurements taken ≤24 h after infection due to the difficulty to discern between FMDV RNA from the nebulized inoculum and virus emitted from the infectious host.

Results

Individual animal experiments

All measurements of FMDV RNA in air prior to challenge with FMDV were below detection levels. On challenge day,

a new filter was inserted just before inoculation, and in some experiments, it was removed approximately 30 minutes after inoculation of the animals by nebulization. Foot-and-mouth disease virus RNA was detected in these filters reflecting the virus aerosolized during the inoculation process (results not shown). Air samples collected from 0.5 to 24 h post-inoculation (hpi) consistently showed lower levels of FMDV RNA than those detected during the inoculation period and probably represented residual inoculum virus. Only when viral RNA levels in air increased above the first post-inoculation levels, it was considered to reflect *de novo* viral synthesis in the infected animals (Table 1). Clinical signs (e.g. vesicles in feet or mouth) were observed in 12 of 17 individual animals (Table 1). In these 12 animals showing clinical signs, the first day of *de novo* FMDV RNA detection in air samples ranged from 2 to 4 dpi and peaked by 3–8 dpi (Table 1). In 7 of these 12, FMDV RNA was detected in air samples at least 1 day prior to clinical disease (animals number 9143, 7204, 7109, 7203, 7205, 847 and 9144 in Table 1); in 4 animals detection in air occurred on the same day as clinical signs (animals number 7198, 848, 1 and 2 in Table 1), whereas in 1 animal the detection began the day after clinical onset (animal number 8182 in Table 1). For animals 1 and 2, it was not possible to collect clinical evaluation data, swab or air samples at 3 dpi due to weather-related lack of access to the laboratory. They were both clinically positive, and air samples were also positive on day 4 (Table 1). In the remaining 5 of 17 individual experiments, no clinical signs were detected due to the low virulence of the viral strains. Three of these 5 animals had no detection of FMDV RNA in serum, oral fluid or air samples throughout the evaluation period of 10 days (animal numbers 7201, 3 and 4 in Table 1). Foot-and-mouth disease virus RNA was detected in serum and oral fluids in the remaining two of these subclinically infected cattle (animal numbers 7140 and 763 in Table 1), and FMDV RNA was detected in air only in one of these two animals starting 3 dpi through 9 dpi (animal number 763 in Table 1). When taken together, the results from the 17 individually housed animals with varying disease progression (ranging from uninfected to clinical FMD) showed that FMDV RNA could be detected at 24 hpi in serum and oral fluids as well as in room air, whereas clinical signs could not be detected until 48 h later (Fig. 1).

Group experiments

Air sampling with subsequent FMDV RNA detection was performed during two experiments in rooms housing two steers directly inoculated by the IDL route with either high (10^7) or low (10^4) TCID₅₀ doses of FMDV A24 Cruzeiro, and two naïve steers were introduced 24 h later for direct contact exposure (Fig. 2). At 24 hpi, all directly inoculated

cattle had lesions at the inoculation site (lingual vesicles) and FMDV RNA was detected in oral fluid. Secondary lesions (foot vesicles) were observed at 1 and 3 dpi in the high and low doses, respectively. All contact-exposed animals had FMDV RNA in oral fluid starting 1 day after the start of contact exposure, with development of vesicles between 3 and 5 dpc. Virus was detected in air starting at 1 dpi in both experiments, coinciding with the first FMDV detection in oral fluid in the case of directly inoculated animals and 1 or 2 days prior to clinical disease. Viraemia was detected at 1 dpi in the IDL direct inoculated animals and 2–3 dpc in the contact inoculated animals (results not shown). In both experiments, FMDV RNA was detected in air prior to clinical signs (Fig. 2).

Variables associated with FMDV RNA measurement in air samples

The only significant variable retained in the mixed model to measure association between FMDV RNA detection in air and other samples was the FMDV RNA detection in oral fluid ($P < 0.005$) (Fig. 3). The strength of the association, as suggested by the results of the regression coefficient, suggested a rate of increase of 0.379 (95% CI 0.242–0.526) standardized unit of RNA in oral fluid increase per one unit of RNA detected in air (genome copies/1000 l of air). The model was constructed with air measurements performed from 2 through 9 days post-inoculation. Days 0–1 and >9 were not included because few animals had detectable amount of FMDV RNA in air within these days. The observed values of FMDV RNA detected in air, oral fluid and blood per day are shown in Fig. 3.

Discussion

Conventional invasive screening methods for FMD in cattle are time-consuming and labour intensive as they require restraint of animals for clinical examination and sample collection. During the 2001 UK FMD epidemic, one of the main problems hampering the diagnosis, control and eradication efforts was the need for veterinarians to inspect hundreds or thousands of animals in suspected infected premises (Davies, 2002). This was particularly difficult in animals with subclinical infections (McLaws and Ribble, 2007) or at preclinical stage of the disease. Deployment of systems that enable monitoring of premises and early detection of FMD, particularly in the early subclinical phase of disease, would be extremely useful and could substantially mitigate the impact of FMD outbreaks by allowing the establishment of timely control measures. The use of an effective technique to screen at the farm or abattoir level without the need for handling or restraining individual animals would allow for a more efficient use of valuable veteri-

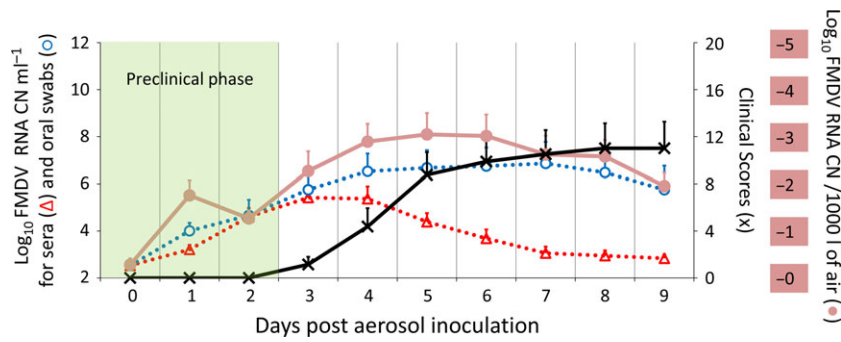


Fig. 1. Mean + SEM of Foot-and-mouth disease virus (FMDV) RNA detection in air samples of 17 individual animal experiments of steers inoculated with FMDV A24 Cruzeiro wild type and mutants. FMDV RNA in serum (red dotted line) and in oral secretions (blue dotted line) is expressed as \log_{10} RNA copy number per ml on the left Y-axes (range from 2 to 12). Clinical scores (black line) are expressed on the right Y-axes (range from 0 to 20). FMDV RNA in air (pink line) is expressed as \log_{10} RNA copy number per 1000 l on the right Y-axes (range from 0 to 5). X-axes correspond to days post-inoculation of aerosol-inoculated steers. Green shaded area indicates period with no clinical signs (pre-clinical phase).

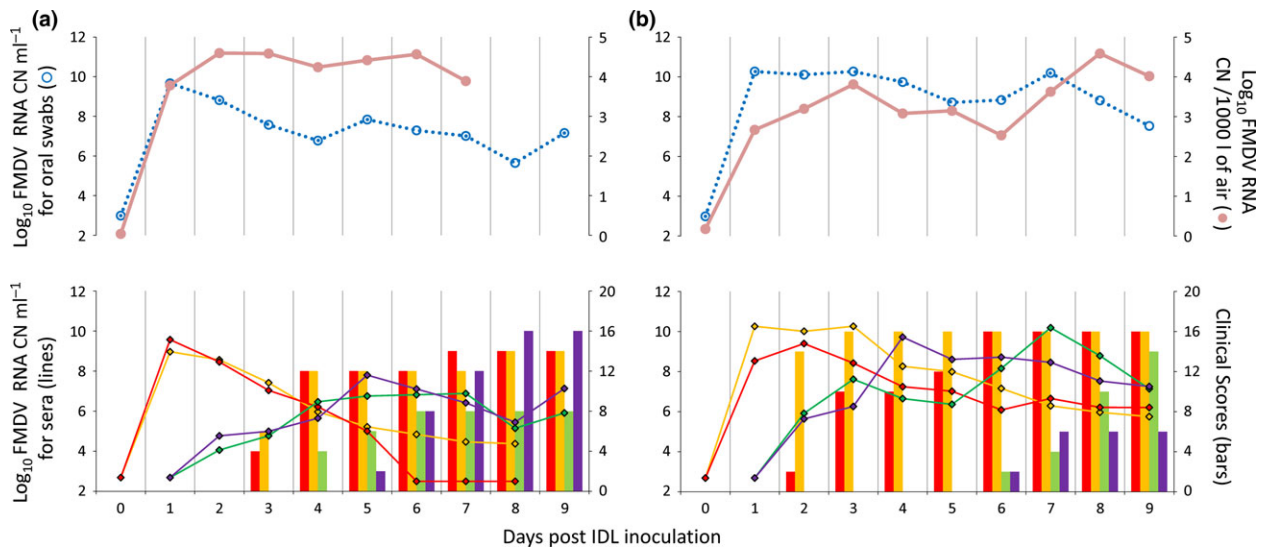


Fig. 2. Relationships between detection of Foot-and-mouth disease virus (FMDV) in air samples and oral secretions in the context of clinical scores of steers inoculated with FMDV A24 Cruzeiro. Left panels (a) correspond to directly-inoculated cows receiving 10^4 infectious units. Right panels (b) correspond to directly-inoculated cows receiving 10^7 infectious units. Top panels show the cumulative levels of FMDV RNA in oral secretions (blue dotted lines) expressed as \log_{10} RNA copy numbers per ml on the left Y-axes (range 2 to 12), together with FMDV RNA in air (pink lines) expressed as \log_{10} RNA copy numbers per 1000 l on the right Y-axes (range 0–5). Bottom panels show individual results, with FMDV RNA in oral secretions shown as lines, expressed as \log_{10} genomes per ml on the left Y-axes (range 2–12), and clinical scores shown as bars, expressed on the right Y-axes (range from 0 to 20). Maximum lesion (clinical) score is 20 for contact inoculated animals and 16 for direct inoculated animals because lesions on the head are not counted in the last group. Animals inoculated by intradermolingual route (IDL) are shown in red and yellow. Animals inoculated by contact exposure are shown in green and purple. X-axes correspond to days post-inoculation of IDL-inoculated steers. No air was collected on days 8 and 9 for low-dose experiment.

nary resources. Several studies have characterized air sampling for FMDV detection in various experimental infections and epidemiological studies (Ryan et al., 2009; Christensen et al., 2011; Mohamed et al., 2011; Pacheco et al., 2012; Chase-Topping et al., 2013; Waters et al., 2014), with some of the studies utilizing hand-held devices held near the head of infected animals. The study described

herein was aimed at evaluating room air sampling using dry filter collection units and real-time RT-PCR testing to detect the presence of FMDV infection in rooms housing infected cattle. This system has been previously utilized to detect FMDV RNA in rooms housing infected domestic and wild pigs (Mohamed et al., 2011; Pacheco et al., 2012). This proof-of-concept system is operationally simple,

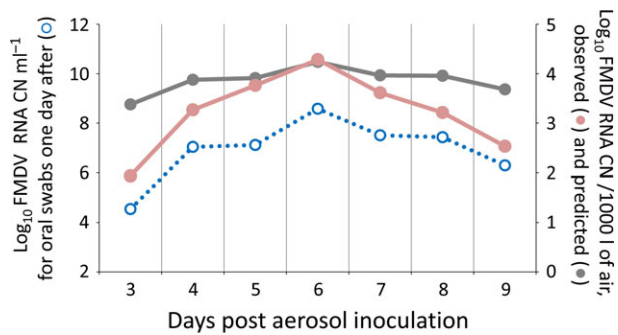


Fig. 3. Predicted and observed values of the repeated-measures mixed model of Foot-and-mouth disease virus (FMDV) RNA detected in air samples and oral swabs one day after. Foot-and-mouth disease virus RNA in oral secretions (blue dotted line) is expressed as \log_{10} RNA copy number per ml on the left Y-axis (range from 2 to 12). Foot-and-mouth disease virus RNA observed (pink line) and predicted (grey line) in air is expressed as \log_{10} RNA copy number per 1000 l on the right Y-axis (range from 0 to 5). X-axis correspond to days post-inoculation of aerosol-inoculated steers.

requires minimal labour investment of trained personnel to collect and replace the dry filters at regular intervals followed by testing by rRT-PCR.

FMDV RNA was detected in air samples of rooms housing cattle at least 24 h before clinical onset of disease in 7 of 12 individually housed animals, and it was also detected in one steer that never showed clinical FMD. In rooms housing groups of animals, FMDV RNA was detected in air 1–2 days before the appearance of clinical signs. Previous studies utilizing breath air samplers (sniffers) placed in close proximity from the animal's head or throughout animal holding rooms for 30 min periods (with the room ventilation systems turned off) also showed that FMDV RNA could be detectable early after infection (Ryan et al., 2009; Christensen et al., 2011). In the current study, the rooms where transmission experiments were conducted had constantly functioning ventilation systems resulting in a continuous high rate of air changes per hour (between 13.7 and 25 air replacement/h). Despite this high rate of air exchange, FMDV RNA was detected consistently prior to appearance of clinical FMD and even in subclinical infections. Although extrapolating the conditions of this experiment to field conditions is difficult, the results suggest that static air is not necessary during sampling for early detection of FMDV infection. The demonstrated efficacy under these air-flow conditions suggests that this is an attainable method for FMDV RNA detection in enclosed spaces; however, extrapolation to open-air field conditions must be carefully assessed.

The utility of the air sampling method demonstrated herein is supported by the simultaneous detection of FMDV RNA in room air and in oral fluids. This is shown in Figs 1 through 3, and although for illustration purposes,

the scales used to represent RNA detection were different (CN/1000 l of air versus CN/ml of fluid), the association between detection in air and oral shedding was seen even when the scales were expressed using the same scale (CN/ml) (not shown). The added advantage of air sampling is that it does not require oral swab testing of large numbers of animals sampling to detect infected premises. Foot-and-mouth disease virus RNA detected in oral fluid was significantly associated with the amount of FMDV RNA detected in air during the first 24 h after infection. This correlation is consistent with the known pathogenesis of FMDV whereby primary viral replication occurs in the nasopharynx reaffirming the sensitivity of the air sampling in detection of early stages of FMDV infection before clinical signs are evident. During group experiments, the amount of FMDV RNA detected in air followed similar patterns as in the individual experiments, and as biologically expected, the method was sensitive enough to detect an initial increase in virus emitted by the IDL-inoculated animals ('donors'). In addition, a peak corresponding with initial virus replication in contact-exposed (recipient) animals was observed (see Fig. 2). Specificity of the air sampling technique was demonstrated by the absence of positive results in rooms prior to inoculation and also in the case of the three animals inoculated with attenuated viruses that did not cause infection or disease and did not have detectable FMDV RNA in serum or oral fluid.

The use of attenuated viral strains in this study provided an opportunity to evaluate the performance of air sampling for detection of subclinical infections. This is a very important aspect of any surveillance programme as subclinically infected animals are often missed by clinical case surveillance. One example of this is the UK epidemic in 2001, caused by serotype O PanAsia strain, where subclinically infected sheep were responsible for FMDV spread (Ferris et al., 2006). In facing an epidemic, early detection methods could significantly reduce the number of outbreaks and help monitor the spread of infection around control areas to refine the exclusion and quarantine zones. Disease surveillance could greatly benefit by incorporating practical sampling methods for early virus detection. Environmental air sampling as part of a comprehensive surveillance system could decrease the number of surveillance sample submissions to the diagnostic laboratories by focusing sampling efforts to infected premises. Air sampling surveillance can also free up valuable human resources such as field veterinarians, laboratory personnel as well as material resources during outbreak response efforts. This can further enhance the efficiency of response during epidemics, when effective labour investment can substantially mitigate the ultimate impact of the outbreak.

In conclusion, the work presented here provides evidence suggesting that air sampling could be a useful tool for

detection of FMDV-infected animals in spaces where animals congregate such as feed lots, slaughterhouses and live-stock markets. Early preclinical detection of FMDV RNA in room air housing infected animals is possible even when animals have mild or subclinical infections. Future experiments including a wider range of FMDV strains, host species and duration of sampling will contribute towards further validation of the utility of this technique.

Acknowledgements

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2010 Priority Topics

Commodity groups addressed during the 2010 Animal Health Stakeholder Meeting were: [Beef](#), [Dairy](#), [Equine](#), [Goats](#), [Poultry-Breeders/Layers](#), [Poultry-Broiler/Meat](#), [Sheep](#), [Specialty Species](#), [Swine](#), and [Turkey](#).

Clicking on any commodity group above will take you to that commodity's list of priority topics.

BEEF

Bovine Respiratory Disease Complex including BVD

- Rationale: Most significant cause of beef production loss, reproductive losses secondary
- Research focus: Host-pathogen interaction/synergy, altered host response, novel preventatives & therapeutics, surveillance for pathogens and host factors for early intervention

Mycobacterial diseases (TB and Johnes)

- Rationale: Disease related to production loss, market barriers
- Research focus: Diagnostics, vaccines, herd management/control programs, wildlife/livestock interface

Vector-borne Diseases

- Rationale: Economic impact due to animal loss, market disruption, loss of consumer confidence
- Research focus: Virus-Vector Ecology & host relationship, integrated approaches to prevent importation of disease, DIVA vaccine and companion diagnostics, improved surveillance and modeling

Infectious Reproductive Disease

- Rationale: Huge economic impact on production despite limited success with diagnostic assays and preventives
- Research focus: Impact of immune status on protecting reproductive function; altered interaction of immune function and endocrine modulator; novel diagnostics, preventives and therapeutics; efficacy of current tools: diagnostics and vaccines

Minimize Impact of Emerging Infectious Diseases

- Rationale: Ensure food security, continuity of business and public health
- Research focus: Biosecurity, evidence for accurate disease transmission assessment, bio-economic decision tools for outbreak response, define & mitigate risks at livestock/wildlife interfaces

DAIRY

Lameness

- Rationale: Rising welfare issue, contributes to high removal rate, predisposes to other diseases
- Research focus: Mechanisms of disease (environment, nutrition, genetic), digital dermatitis, better management of clinical cases (extension)

Johne's

- Rationale: Prevalent, economic impact, food safety
- Research focus: Diagnostics, vaccination, management of infected animals (sub-clinical, extension), disease resistance and genes

TB

- Rationale: Re-emerging threat, potential impact on trade, economic impact
- Research focus: Diagnostics, vaccines, management (wildlife, controls, security, extension), epidemiology (movement issues, political)

Mastitis

- Rationale: Prevalent with high economic impact, reliance on antibiotics
- Research focus: Prevention (vaccines, nutrition, immunomodulation), genetic resistance, management (antimicrobial alternatives, long-term impact), diagnosis (rapid, accurate, cow-side)

Transition cow

- Rationale: Impacts numerous disease states, economic impact, impact on neonate, animal welfare focus
- Research focus: Immune function (define, predict, modulate), nutrition (immune effect, prevent metabolic disease), management (diets transition, behavior, housing, extension), metabolic balance & overall health

EQUINE

Emerging and Re-emerging Diseases

- Rationale: Threaten biological and commercial health of US horse industry, including international and interstate movement.
- Research focus: Epidemiology: identification of risk factors; immune response & vaccine development; diagnostic tests: rapid, accurate, stall-side; Pire (1st), EHV-1, EEE-WEE, CEM, VS, Lyme, EPE, EIV

Non-Infectious Diseases of Economic Importance

- Rationale: Equine health, safety, welfare & utility. Economically critical for industry and the public
- Research focus: Epidemiology to identify risk factors; foundational mechanistic pathophysiology; diagnostics, prevention & therapeutics; laminitis (1), colic (2), lameness/arthritis (3), airway disease

Reproductive and Developmental Health

- Rationale: Improved production efficiency, welfare, utility
- Research focus: Developmental musculoskeletal diseases, foal health (e.g. immunology, diarrhea, reparatory, sepsis), genital tract disease (e.g., CEM; EAV; endometritis/ placenta), infertility & embryonic development

Equine Genomics

- Rationale: Population sustainability & improvement of equine health
- Research focus: Develop novel genetic tools & resources for research, identify genetic mechanisms for diseases, characterize genotypic & environmental effects on phenotype, develop molecular diagnostic tests and pharmacogenomic approaches

Foreign Diseases and Zoonoses

- Rationale: Protect domestic population; prevent disastrous economic impacts from foreign diseases; minimize/avoid trade barriers
- Research focus: Piroplasmosis, BT, AHT; host-vector-pathogen-environment interactions; develop tools (diagnostics, etc) for surveillance, immune response & vaccine development strategies

Nutrition and Metabolic Disorders

- Rationale: Enhancing health & utility, such as reducing equine obesity & associated disease, colic, parasitism, and laminitis
- Research focus: Biology of nutrition, including feed efficiency; pathophysiology of the GI tract; effect of nutrition on GI health-colic, enteritis; parasite control programs (environmental, genetic, anthelmintics)

GOATS

Gastrointestinal Parasites (worms and protozoa)

- Rationale: Reported as top industry priority as part of NAHMS needs assessment; high morbidity, high mortality, high economic impact
- Research focus: Genetics-host and parasite; diagnostics-field typing, molecular diagnostics; vaccines-Haemonchus first priority; discovery and approval of pharmaceuticals and alternatives, including phytochemicals and nutraceuticals; disease control through management-nutritional, grazing management.

Species Specific Approvals for Necessary Pharmaceuticals

- Rationale: Food safety and production issue as it relates to extra-label use due to lack of approved safe and effective medications for goats
- Research focus: Therapeutic antibiotics (for mastitis, respiratory disease, lameness); new classes of anthelmintics; pain and analgesics (for animal well-being during tattooing, dehorning, castration, etc.); biologics (toxoplasma, respiratory vaccines)

Control Measures for Caseous Lymphadenitis

- Rationale: identified as second priority in NAHMS due to production losses and food safety issues
- Research Priorities: vaccine to reduce and/or eliminate CL; improved diagnostic test; identification of host genetic factors associated with shedding; ecology of the organism (host pathogenesis, vectors, fomites, environmental persistence)

Mastitis Control and Treatment

- Rationale: Major economic losses for producers due to decreased production and inability to market milk, food safety, and lack of data on specific issues of mastitis in goats
- Research focus: Management factors (teat dipping, nutrition, housing, equipment, protocols); therapeutics-identification of effective treatments for lactating and non-lactating does; bacterial ecology and animal health (especially coagulase-negative Staph); develop vaccine (emphasis on coagulase-negative Staph)

Q fever (*Coxiella burnetti*)

- Rationale: Zoonotic (select) agent, production losses, potential for mass euthanasia, loss of public confidence in safety
- Research focus: Determine prevalence of coxiella; improved diagnostics (phase I vs. phase II); ecology of the bacteria (transmission, interaction with host genetics, wildlife and interspecies interface); management methods for controlling shedding to reduce zoonotic potential

Eradicate Scrapie

- Rationale: Lack of goat-specific data results in total herd depopulation following scrapie exposure
- Research focus: Identify routes of transmission of caprine scrapie; improved diagnostic testing, especially live animal; identify genetic factors affecting resistance and incubation time; inter-species transmission (including strain variation)

POULTRY-Breeders/Layers

Housing Systems Influence on Health/Welfare

- Rationale: Housing systems influence on health and welfare is poorly understood; economic, political, and consumer implications
- Research focus: Effects on disease incidence (mortality, morbidity, & stress), alternative disease control and treatment methods, internal and external parasite load & control, incidence of SE and overall bacteria load in eggs

Salmonella Enteritidis (SE)

- Rationale: reduction of testing costs, reduction of food-borne illness, vaccine failure on the rise
- Research focus: Evaluate immunity from different live or killed vaccine regimes, evaluate serologic methods to measure immunity, host genetic resistance, evaluate new and emerging isolates

Tumor Viruses

- Rationale: Ongoing evolution of MDV and ALV, cost to industry is ~\$200 million in the US and \$1 billion worldwide
- Research focus: Survey and pathotyping of MDV and ALV field isolates, new and improved MD vaccines, host genetic resistance, improved detection methods of ALV

Colibacillosis

- Rationale: Losses are significant and affects ~30+% flocks, it is the primary bacteriological problem in layers
- Research focus: Develop an effective mass-applied vaccine, determine risk factors for increased incidence of disease, host genetic resistance, non-traditional control and treatment measures

Mycoplasma gallisepticum (MG)

- Rationale: Present preventive measures are either not effective or are pathogenic to non-target species (e.g. turkeys, broilers)
- Research focus: Mass applied and effective vaccines safe for all poultry, surveillance and pathotyping of current MG isolates, rapid and more specific diagnostics/better surveillance, diagnostics to differentiate field strains from vaccines

POULTRY-Broiler/Meat

Functional Genomics for Disease Resistance

- Rationale: In the era of post-genomics, the information needs to be applied for practical uses
- Research focus: Identify how innate immunity influences disease resistance, identify markers of adaptive immunity leading to better immune function, apply bioinformatic tools to analyze genomics data for poultry, improved understanding of host/pathogen interaction

GI Disease/Integrity/Host Microbial Interactions

- Rationale: Gut diseases are the most important economic factor to commercial poultry
- Research focus: Improved vaccines or other controls to prevent coccidia, improved understanding coccidia/clostridial (inc GD) interaction, understand contributions of microbioma to gut health, better understanding of GI immunity

Diseases Affecting World Trade

- Rationale: AIV, NDV, VVIBD, ILT, Salmonella and other diseases that are known to affect trade
- Research focus: Develop vaccines (tools) to prevent transmission, antigenic and genetic characterization of evolving viruses, rapid multiplex diagnostics for poultry pathogens, improved understanding of the epidemiology of the virus

Respiratory Disease Complex

- Rationale: IBV, E.coli, lentogenic NDV, ILTV, Mycoplasma are important players in the respiratory complex diseases of commercial poultry
- Research focus: Improved vaccines, mass vaccination, improved safety, cross protection; better control of E. coli and other secondary bacterial infections; better understanding of emerging viral and bacterial pathogens; role of immune competence in multi-factorial diseases

Vaccines and Their Limitations

- Rationale: Current vaccines are not meeting the needs of the industry
- Research focus: Need for improved immunomodulators for poultry vaccines, improved vaccines to more effectively block pathogen transmission, improved DIVA strategies, improved strategies to overcome maternal antibody

SHEEP

Research on Bighorn/Domestic Sheep Compatibility

- Rationale: Research gaps in the pathology behind bighorn sheep die off, which jeopardizes 80% of domestic sheep industry
- Research focus: Determine normal commensal populations of respective tract in both species; determine etiologic agents in bighorn; determine nutritional, genetic/genomic, stress factors in bighorn; determine preventive/therapeutics for both spp.

Eradicate Scrapie

- Rationale: Ongoing eradication efforts need to be expedited
- Research focus: Develop live animal/preclinical diagnostics, determine how to mitigate environmental contamination by prions, determine transmission potential of new strains, determine whether goats are transmission reservoir

Control and Prevention of Ovine Progressive Pneumonia in Sheep

- Rationale: Significant cause of trade barriers, early culling, mastitis, carcass defects, and production losses
- Research focus: Determine immunogenic markers of disease progression, develop viral molecular and pen side diagnostics, determine mechanism of disease transmission, determine method to block transmission

Prevent Malignant Catarrhal Fever in Bison and Cattle

- Rationale: Highly prevalent, asymptomatic disease in sheep; why is there high susceptibility with high mortality in bison?
- Research focus: Determine pathogenesis of MCF in bison, produce a vaccine for bison and cattle, determine viral shedding factors in sheep, determine genetic factors for disease resistance

Genetic/genomic Solutions to Economically Significant Sheep Diseases

- Rationale: Need alternatives to complement/replace current prophylactic or control measures
- Research focus: Determine markers for internal parasites, sore mouth, foot rot; develop diagnostic tests to detect markers

Improved diagnostics for ovine Johnes, Q-fever, and Brucella ovis

- Rationale: Improved diagnostics would enhance control and management of these endemic diseases
- Research focus: Develop, evaluate, validate molecular and serological diagnostics; standardization across NAHLN labs; develop early detection pen side tests

SPECIALTY SPECIES

Tuberculosis Rapid Diagnostic Tools

- Rationale: Need single application diagnostic that does not require re-handling of animals
- Research focus: Develop rapid diagnostics with high sensitivity and specificity to detect TB, develop reagents for characterization of immune responses, couple rapid diagnostics with epidemiologic tools in infected herds to develop evidence-based knowledge for controlling TB

Prevent Sheep-Associated Malignant Catarrhal Fever in Specialty Farmed Species

- Rationale: MCF causes significant economic losses in specialty farmed species and currently no vaccine and limited diagnostics. MCF can also adversely affect other domestic livestock species.
- Research focus: Develop vaccine against sheep-associated MCF, define pathogenicity and host immune responses, define mechanisms of transmission, develop appropriate diagnostic tools for specialty farmed species.

Epizootic Hemorrhage Disease/Bluetongue

- Rationale: EHD and Bluetongue serotypes are endemic in the US. EHD/BTV causes significant economic losses in specialty farmed species. EHD/BTV are infecting and causing economic losses in traditional domestic livestock
- Research focus: Develop vaccine(s) to protect against EHD and/or BT (DIVA vaccine would be long-term priority), characterize virus persistence in vectors and mechanisms of transmission, develop new diagnostics that allow differentiation of EHD or BTV serotypes, develop mechanisms for vector control that prevent transmission.

Bacterial Pneumonia-Pasturella/Fusobacteria

- Rationale: Fusobacteria and Pasturella are causing significant economic losses (mortality and morbidity) in farmed species
- Research focus: Characterize etiology and pathogenesis of pneumonia, develop vaccine(s) to prevent bacterial pneumonia, comparative genomics to define species differences in susceptibility.

Parasite Control

- Rationale: All specialty farmed species have issues with parasites, lack of approved anthelmintic, effective dosages and regimes, food withdrawal times, and parasite resistance to anthelmintic treatment
- Research focus: Develop anthelmintics and/or treatment regimes that are effective in specialty farmed species to prevent abdominal parasites, characterize residue issues and withdrawal time for for anthelmintic regime, develop new anthelmintics that are effective in specialty farmed species, characterize mechanisms of parasite resistance to anthelmintics.

Tools and Resources

- Rationale: There is a lack of species-specific reagents, genomics, physiology, etc to address disease issues in specialty farmed species
- Research focus: Development and characterization of reagents (cross-reactive or species specific) to allow characterization of immune responses, acquirement of genomic data on species or species-specific pathogens to allow bioinformatics approach to problems, characterization of physiologic responses to drugs, drug metabolism and excretion, and effective dosages related to route delivery.

SWINE

PRRS Elimination

- Rationale: Significant economic losses to pig industry
- Research focus: Vaccine platforms, viral host-cell pathogenesis, immunology; diagnostics, surveillance; ecology, epidemiology; genetics of PRRS resistance/susceptibility

Emerging and Zoonotic Diseases

- Rationale: \$1.6B loss from H1N1 in 2009
- Research focus:: Swine influence, MRSA, etc.; diagnostics, pathogenesis, transmission; microbial genomic, bioinformatics; vaccine platforms, intervention strategies

Optimize Health of Growing Pig

- Rationale: Area of greatest opportunity for improving economics of production efficiency, prevention wastage and animal well-being
- Research focus: Polymicrobial infections; microbial genomics and bioinformatics; vaccine platforms, therapeutics, delivery platforms; diagnostics, surveillance

Periparturient Production Efficiency

- Rationale: High wastage; mortality, morbidity, growth efficiency; carbon footprint
- Research focus: Polymicrobial infection, Immune modulators, Lactation performance, microbiome

Healthy Pig Production with Restricted Antimicrobial Access

- Rationale: Strategies to avoid negative consequence on animal health and well-being as demonstrated in other countries
- Research focus: Microbiome, metagenomics; alternatives to antibiotics/antimicrobials; nutrient utilization and feed efficiency; alternative management strategies

TURKEY

Clostridial dermatitis (Turkey cellulitis)

- Rationale: Consistently, year-to-year several industry surveys indicate that this is the top priority affecting turkey health.
- Research focus: Risk factors for introduction, pathogenesis of infection; prevention; vaccines for breeders and meat birds; other control strategies, probiotics, antibiotic alternatives

Pre-harvest Food Safety

- Rationale: Pre-harvest control of Salmonella and Campylobacter is critical to assuring a safe product for consumers.
- Research focus: Identification of risk factors, control: vaccine development and other mitigation strategies

Influenza in Turkey Breeders

- Rationale: Turkeys are uniquely susceptible to infection with influenza A viruses, particularly breeders.
- Research focus: Identification of risk factors; pathogenesis including immunopathogenesis; within and between flock transmission, interspecies introductions; prevention strategies: vaccination, biosecurity addressing risks

Enhanced Gut Health

- Rationale: Understanding and improving the gut microbiome is critical to health and production.
- Research focus: Develop approaches to microbial community analysis, understanding host/pathogen interactions in the gut, create strategies to manage gut health, developing diagnostics for gut pathogens

Histomoniasis

- Rationale: Blackhead has re-emerged as a significant disease for the turkey industry negatively impacting production and welfare.
- Research focus: Identify risk factors for the disease, develop new therapeutics for treatment, develop prevention strategies and prophylactics

Understanding the Adaptability of Pathogens to Current Treatments

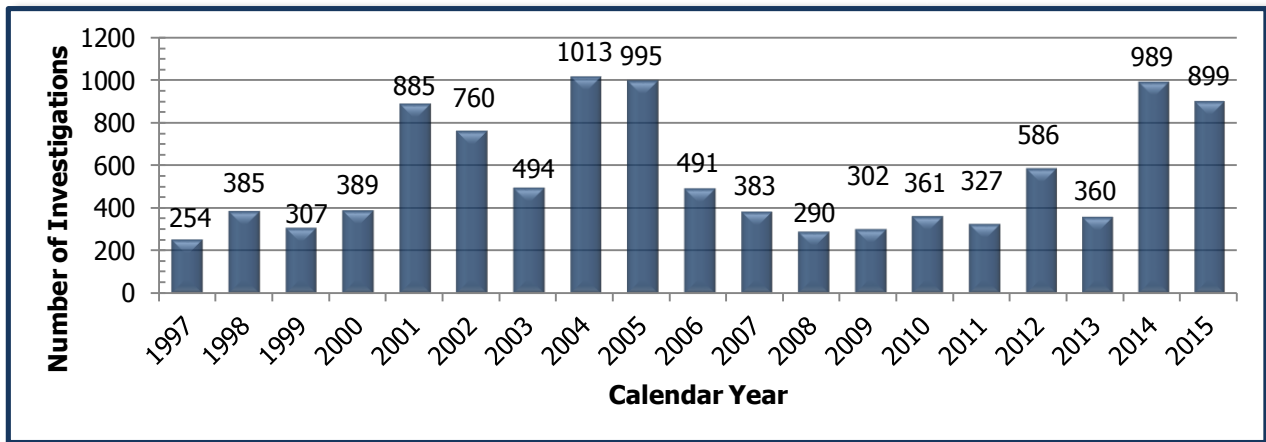
- Rationale: The continuing development of pathogen resistance has resulted in the need for novel strategies to keep animals healthy.
- Research focus: Identifying mechanisms of bacterial resistance to treatment, develop novel antimicrobials , develop strategies for preserving the efficacy of treatments



SUMMARY OF RECENT FAD INVESTIGATIONS

In the past 19 years, there have been over 10,400 investigations conducted on possible foreign animal disease (FAD) or emerging disease incidents throughout the United States, ranging from a yearly low of 254 investigations in calendar year 1997 to a high of 1,013 investigations in 2004 (Figure 1).

Figure 1: FAD Investigations from 1997 to 2015

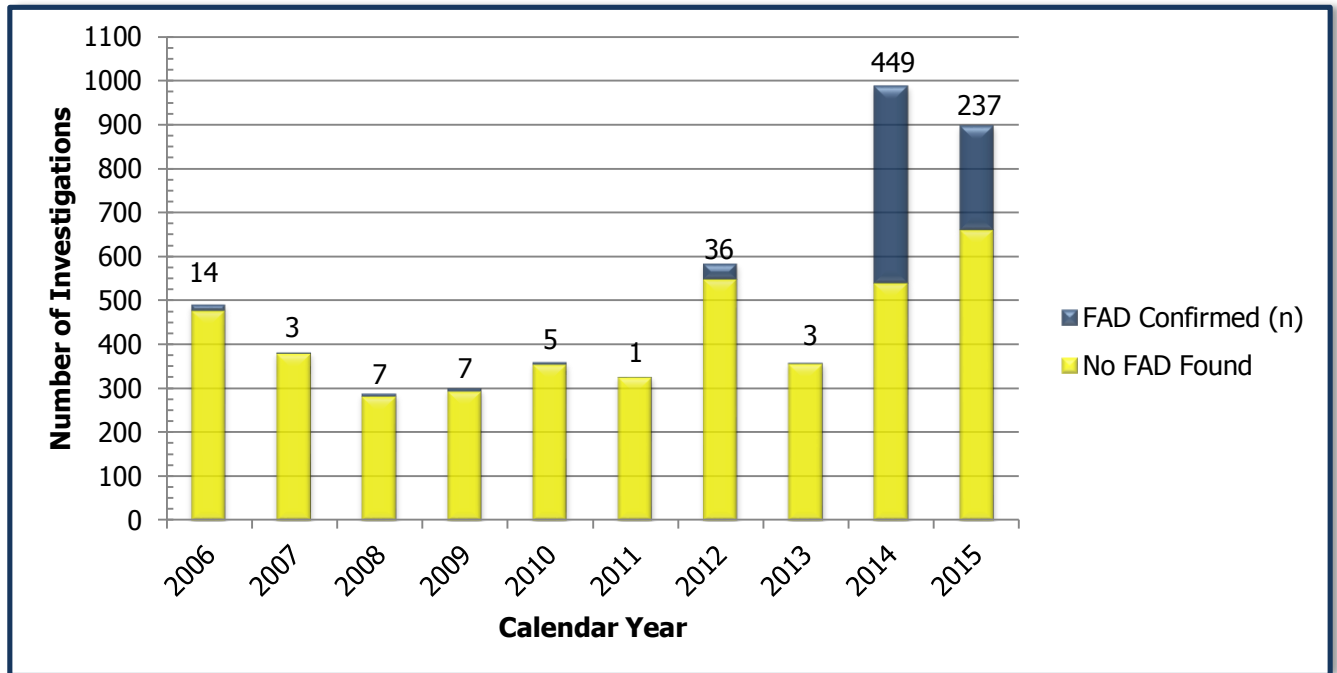


This summary of FAD investigations was compiled from annual reports on animal health in the United States published by Veterinary Services (VS) of USDA Animal and Plant Health Inspection Service (APHIS) (available [here](#)), data from the World Organization for Animal Health (OIE) World Animal Health Information Database (<http://web.oie.int/wahis/public.php?page=home>), and data in the Emergency Management Response System (EMRS) of APHIS VS.

2006 – 2015

From 2006 through 2015, 4,988 possible FAD or emerging disease incidents were investigated by VS and State collaborators. However, only a small percentage of those were confirmed to be actual emerging or foreign animal disease. The exceptions during this period were the occurrences of a widespread vesicular stomatitis outbreak that contributed to the 449 confirmed FAD findings in 2014 and the largest ever U.S. highly pathogenic avian influenza outbreak in 2015 (Figure 2).

Figure 2: FAD Investigations by Result, 2006 to 2015.

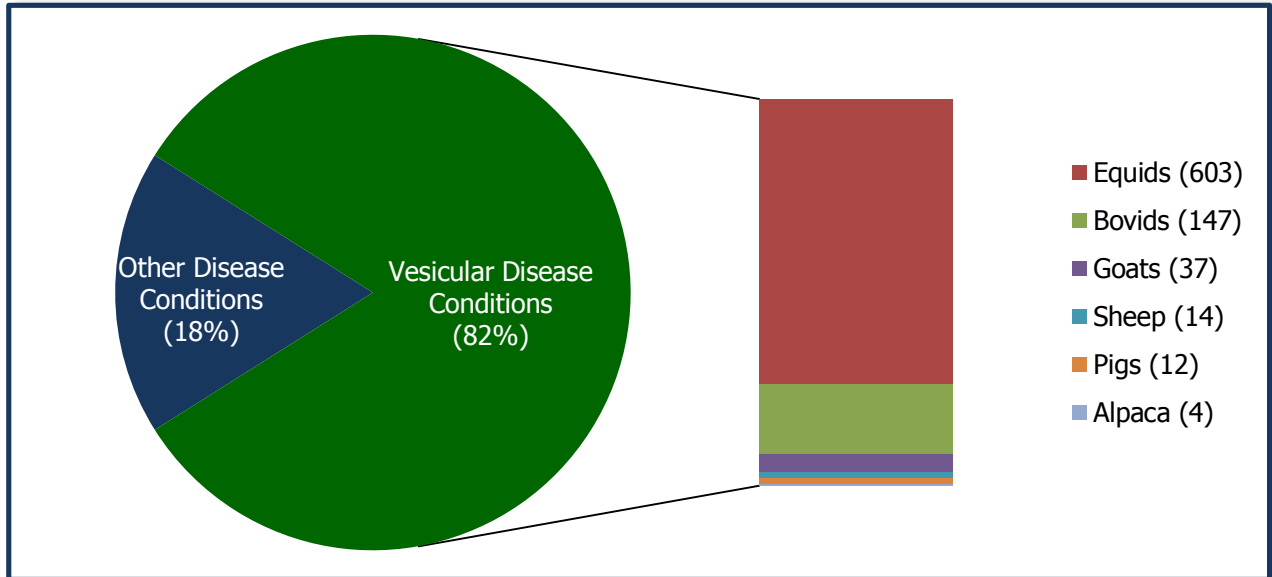


2005

In 2005, VS and State collaborators conducted 995 investigations of suspected FADs in 47 States and Puerto Rico. Colorado, Utah, and Wyoming reported the most investigations (146, 144, and 130, respectively), the majority of which were in response to a vesicular stomatitis outbreak that ultimately was reported in 6 additional States: Arizona, Idaho, Montana, Nebraska, New Mexico, and Texas. Of the 995 investigations, 446 resulted in a confirmed FAD finding, with 445 diagnosed as vesicular stomatitis. The other confirmed finding was a rabbit hemorrhagic disease outbreak.

In 2005, vesicular conditions (painful, blister-like lesions) of the muzzle and feet were the most common complaint investigated. There were 817 vesicular complaints: 603 in equids (horses, donkeys, and mules), 147 in bovids (cattle and bison), 37 in goats, 14 in sheep, 12 in pigs, and 4 in alpaca (Figure 3). Differential FAD diagnoses for vesicular conditions in equids include vesicular stomatitis. In ruminants, camelids, cervids, and swine, vesicular diseases of concern include not only vesicular stomatitis but also foot-and-mouth disease (FMD), which is a highly contagious viral infection that primarily affects cloven-hoofed animals. FMD would have a severe economic impact if it entered the United States.

Figure 3: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2005.

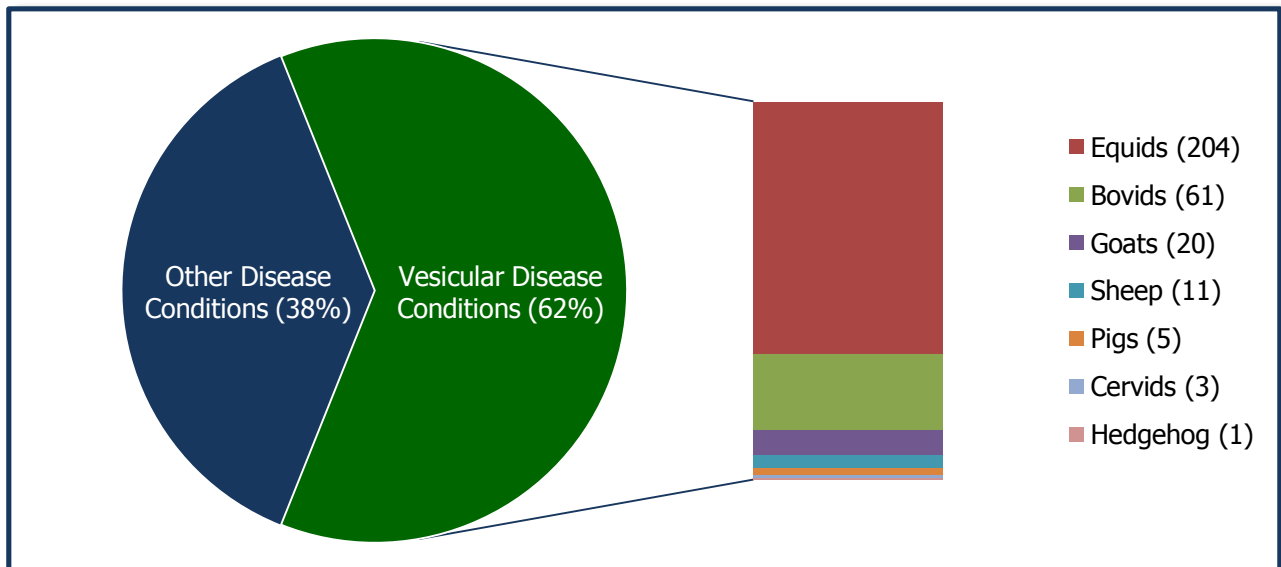


2006

In 2006, VS and State collaborators conducted 491 investigations of suspected FADs in 45 States, Puerto Rico, and the U.S. Virgin Islands. Tennessee and Texas reported the most investigations (46 and 47, respectively). Of the 491 investigations, 14 resulted in a confirmed FAD finding, with 13 diagnosed as vesicular stomatitis and one as contagious equine metritis (CEM), a transmissible, exotic, venereal disease of horses caused by the bacterium *Taylorella equigenitalis*.

There were 305 vesicular complaints for the year, with 204 in equids, 61 in bovids, 20 in goats, 11 in sheep, 5 in pigs, 3 in cervids, and 1 in a hedgehog (Figure 4).

Figure 4: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2006.

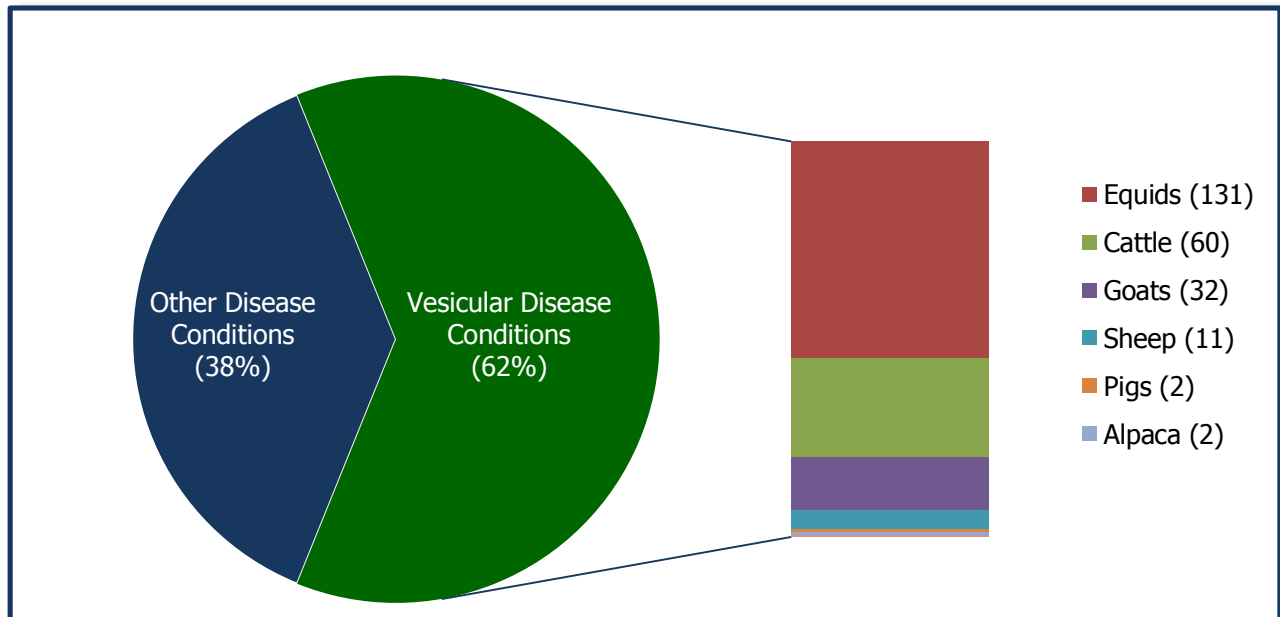


2007

In 2007, there were 383 investigations in 45 States and Puerto Rico. California and Texas reported the greatest number of investigations (31 and 30, respectively). Of the 383 investigations conducted, 3 resulted in a confirmed FAD finding. One FAD investigation of shrimp in Hawaii found white spot syndrome virus (WSSV), another confirmed Old World screwworm in a dog originating in Singapore, and the third found New World screwworm in a dog originating in Trinidad.

As in years past, vesicular conditions of the muzzle and feet were the most common complaint investigated. There were 238 vesicular complaints: 131 in equids, 60 in cattle, 32 in goats, 11 in sheep, 2 in pigs, and 2 in alpaca (Figure 5). In contrast to 2005 and 2006, none of the vesicular disease investigations confirmed the presence of vesicular stomatitis.

Figure 5: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2007.

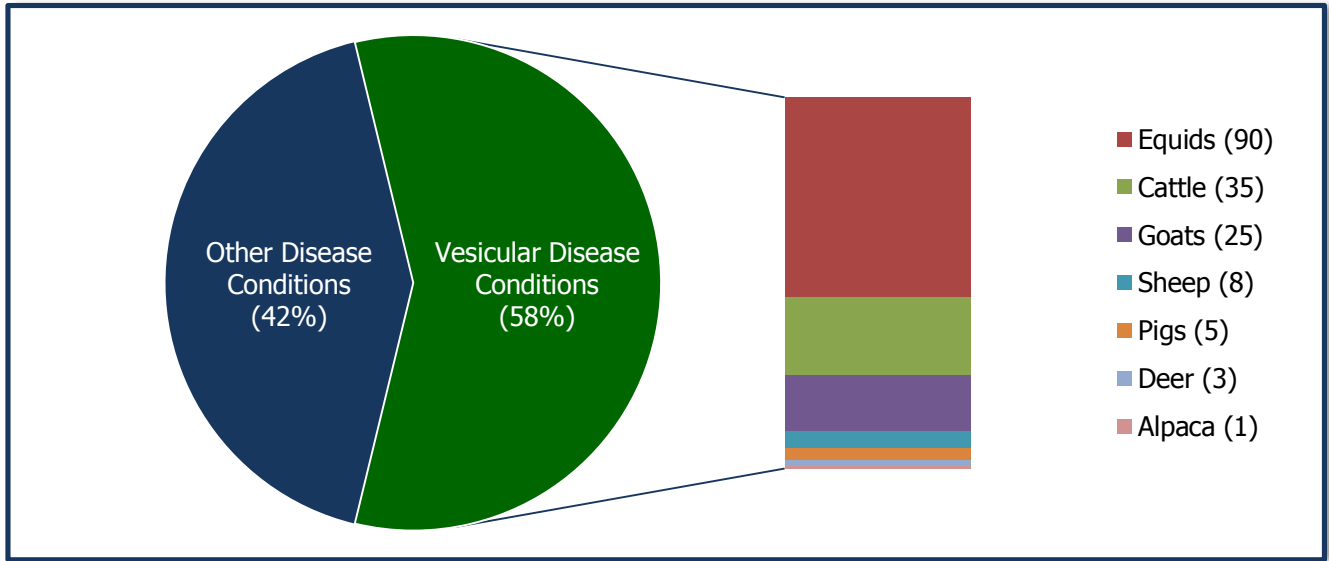


2008

VS and State collaborators conducted 290 investigations in 2008; 7 resulted in confirmed FAD findings. One FAD investigation confirmed equine piroplasmiasis (*Theileria equi*, EP), three found wildebeest-associated malignant catarrhal fever (alcelaphine herpesvirus type 1), one confirmed rabbit hemorrhagic disease, one found WSSV, and another confirmed an outbreak of CEM unrelated to the 2006 finding.

In 2008, vesicular conditions of the muzzle and feet were again the most common complaint investigated. There were 167 vesicular complaints: 90 in equids, 35 in cattle, 25 in goats, 8 in sheep, 5 in pigs, 3 in deer, and 1 in an alpaca (Figure 6).

Figure 6: Proportion of Investigations due to Vesicular Conditions, by Species in 2008.

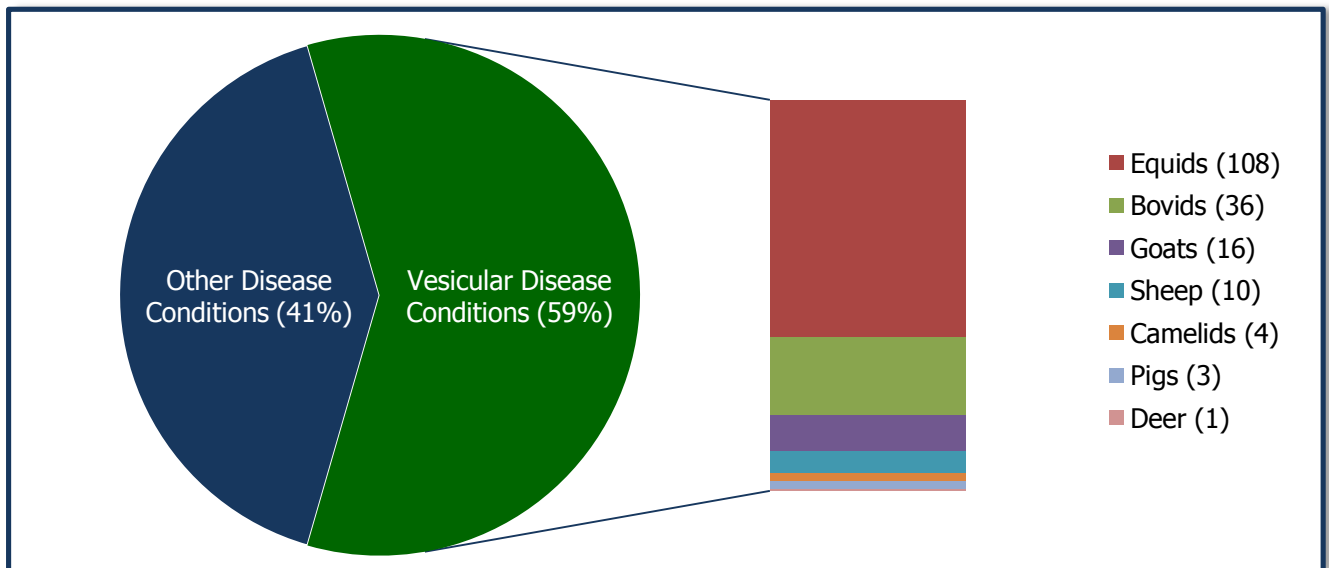


2009

Of the 302 investigations conducted in 2009, 7 resulted in confirmed FAD findings. Two of the investigations found EP and five confirmed vesicular stomatitis.

In 2009, vesicular conditions of the muzzle and feet were once again the most common complaint investigated. Of the 302 investigations in 2009 there were 178 vesicular complaints; of these, 108 were in equids, 36 in bovids, 16 in goats, 10 in sheep, 4 in camelids, 3 in pigs, and 1 in a pudu, a South American deer species (Figure 7).

Figure 7: Proportion of Investigations due to Vesicular Conditions, by Species in 2009.

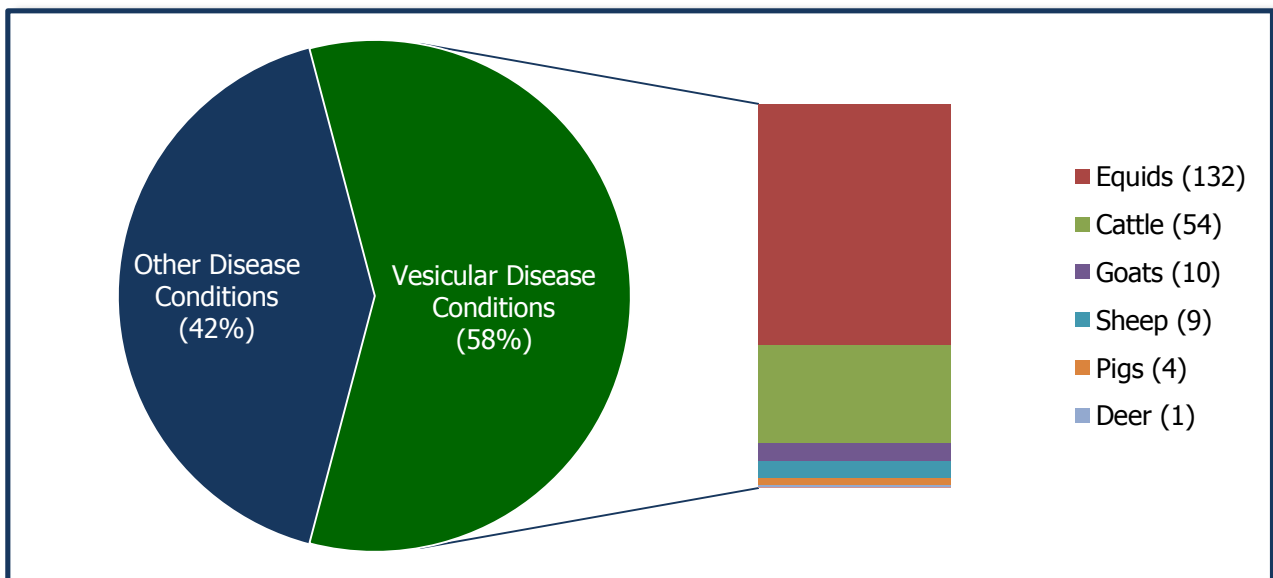


2010

There were 361 FAD investigations in 2010. Investigations were conducted in 44 States, Puerto Rico, and the U.S. Virgin Islands. States with the largest number of investigations were Texas (49) and Arizona (39). Five investigations confirmed the presence of an FAD. Two found vesicular stomatitis, one found rabbit hemorrhagic disease, and one confirmed New World screwworm in a dog originating in Venezuela. The fifth finding was a case of CEM in an imported stallion in California; all in-contact horses were tested and confirmed negative.

Of the 361 investigations, 210 were for possible vesicular disease conditions: 132 in equids, 54 in cattle, 10 in goats, 9 in sheep, 4 in pigs, and 1 in a deer (Figure 8).

Figure 8: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2010.

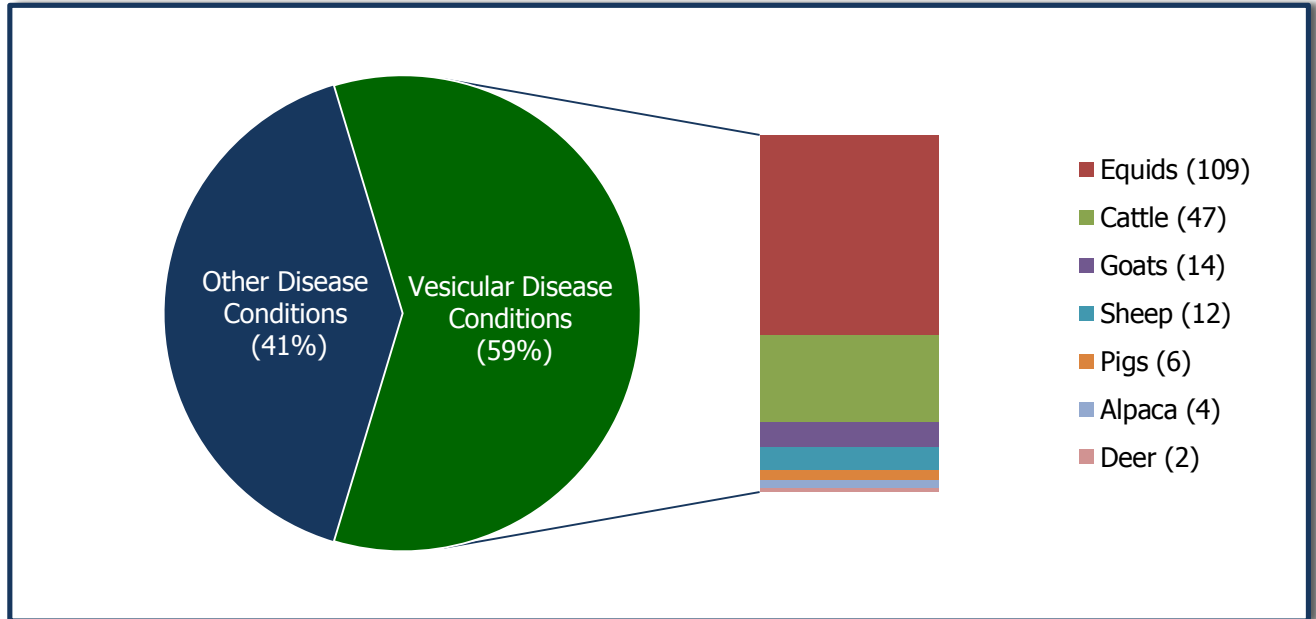


2011

There were 327 FAD investigations in 2011. Investigations were conducted in 45 States and Puerto Rico. States with the largest number of investigations were Texas (41), Arizona (26), and California (26). Only one FAD was found, a case of CEM in an Arabian stallion born in Arizona, not epidemiologically linked to cases in previous years; an in-contact stallion and mares were tested, none had positive results.

Of the 327 investigations, 194 were for possible vesicular disease conditions. Of the 194 vesicular complaints, 109 were in equids, 47 in cattle, 14 in goats, 12 in sheep, 6 in pigs, 4 in alpaca, and 2 in deer (Figure 9).

Figure 9: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2011.

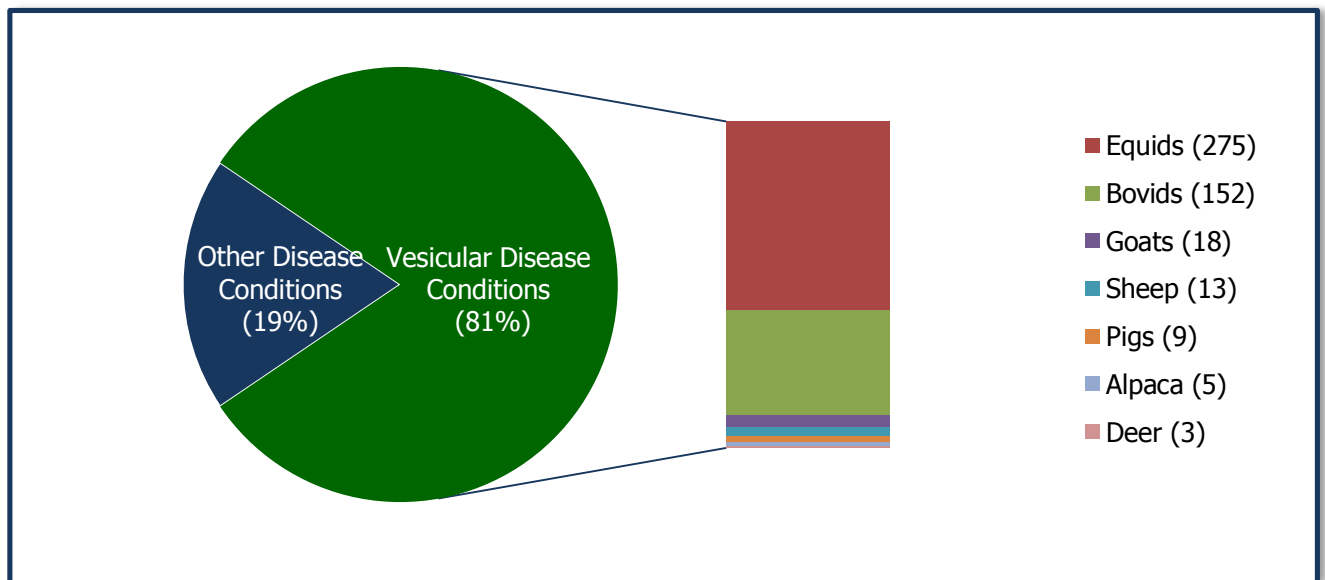


2012

In 2012 there were 586 investigations of suspected FADs in 47 States and Puerto Rico. New Mexico (113), Nebraska (54), and Texas (52) reported the most investigations. Of the 586 investigations, 36 resulted in a confirmed FAD finding. All 36 were diagnosed as vesicular stomatitis.

There were 475 vesicular complaints for the year, with 275 in equids, 152 in bovids (cattle, bison, yaks), 18 in goats, 13 in sheep, 9 in pigs, 5 in alpaca, and 3 in deer (Figure 10).

Figure 10: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2012.

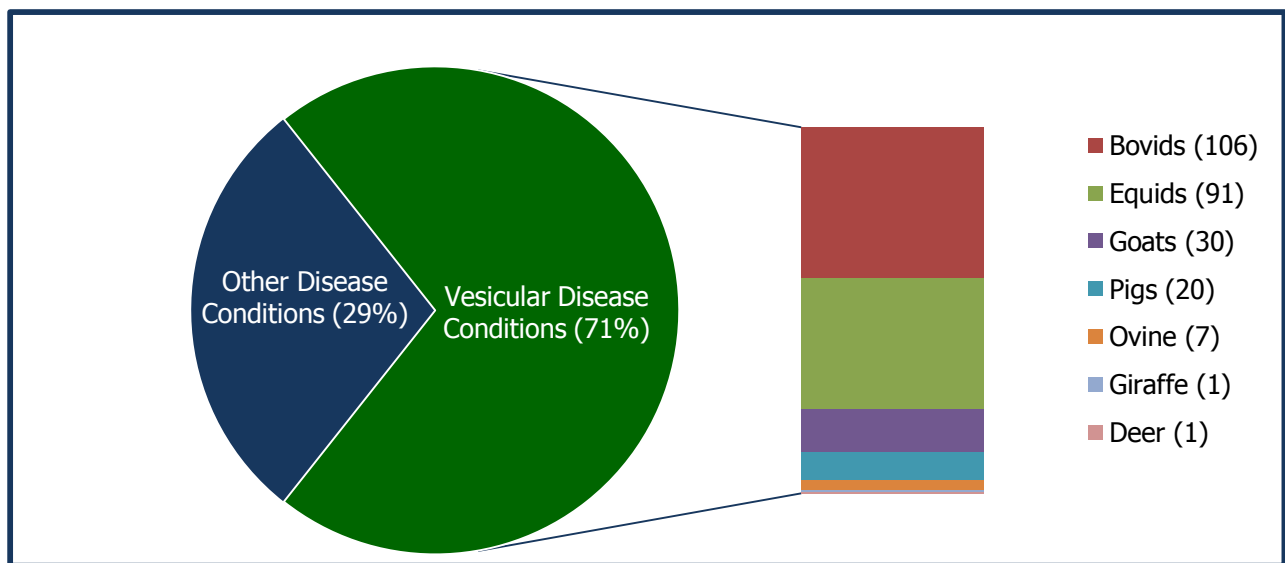


2013

In 2013, VS and State collaborators conducted 360 investigations of suspected FADs in 45 States, Puerto Rico, and the U.S. Virgin Islands. Iowa (41), California (24), and Colorado (23) reported the most investigations. Of the 360 investigations, 3 resulted in a confirmed FAD finding—two were CEM and one was tropical bont tick (*Amblyomma variegatum*).

There were 256 vesicular complaints for the year, with 106 in bovids (cattle, bison), 91 in equids, 30 in goats, 20 in pigs, 7 in ovine (sheep, mouflon), 1 in a deer, and 1 in a giraffe (Figure 11).

Figure 11: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2013.

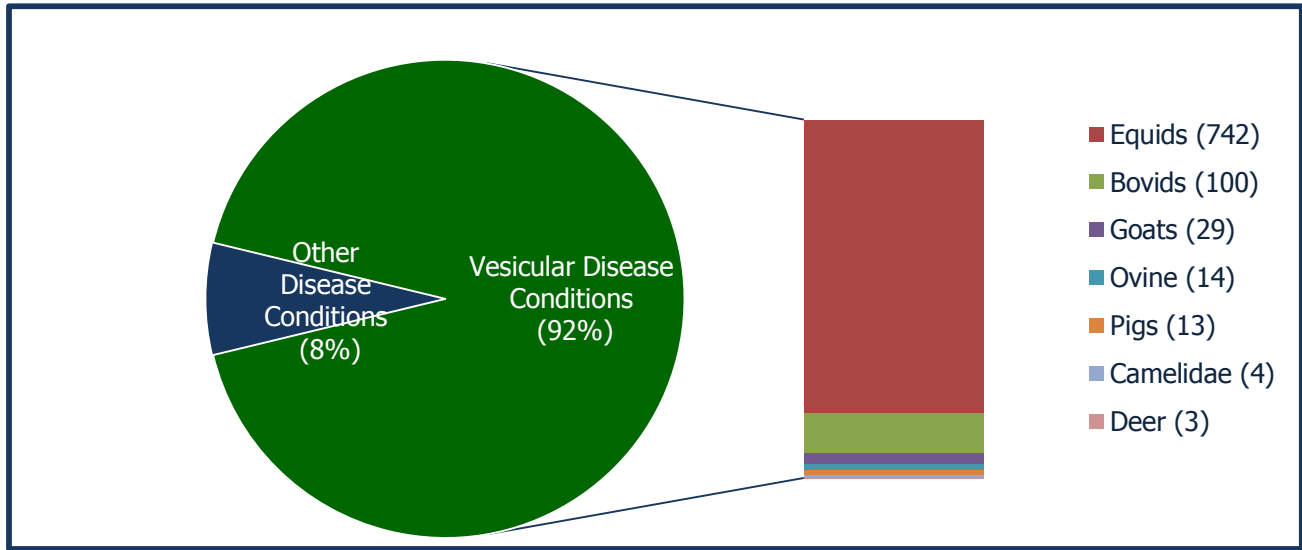


2014

There were 989 FAD investigations conducted in 2014. VS and State collaborators conducted investigations in 46 States and Puerto Rico. Colorado (556), Texas (153), and Georgia (18) reported the most investigations. As in 2005, the reason for the high number of investigations was largely due to a widespread outbreak of vesicular stomatitis virus. Of the 989 investigations, approximately half resulted in a confirmed positive FAD detection—the majority of these findings were vesicular stomatitis-positive diagnoses (433 positive premises in 2014; situation reports [here](#)). Additionally, 2 investigations resulted in the detection of highly pathogenic avian influenza, 13 investigations resulted in the identification of EP, and 1 investigation resulted in the identification of a foreign reptile tick species (*Amblyomma nuttalli* Donitz).

Of these 989 investigations, 905 were vesicular complaints with 742 in equids, 100 in bovids (cattle, bison), 29 in goats, 14 in sheep, 13 in pigs, 4 in camelidae (alpaca, llama) and 3 in deer (Figure 12).

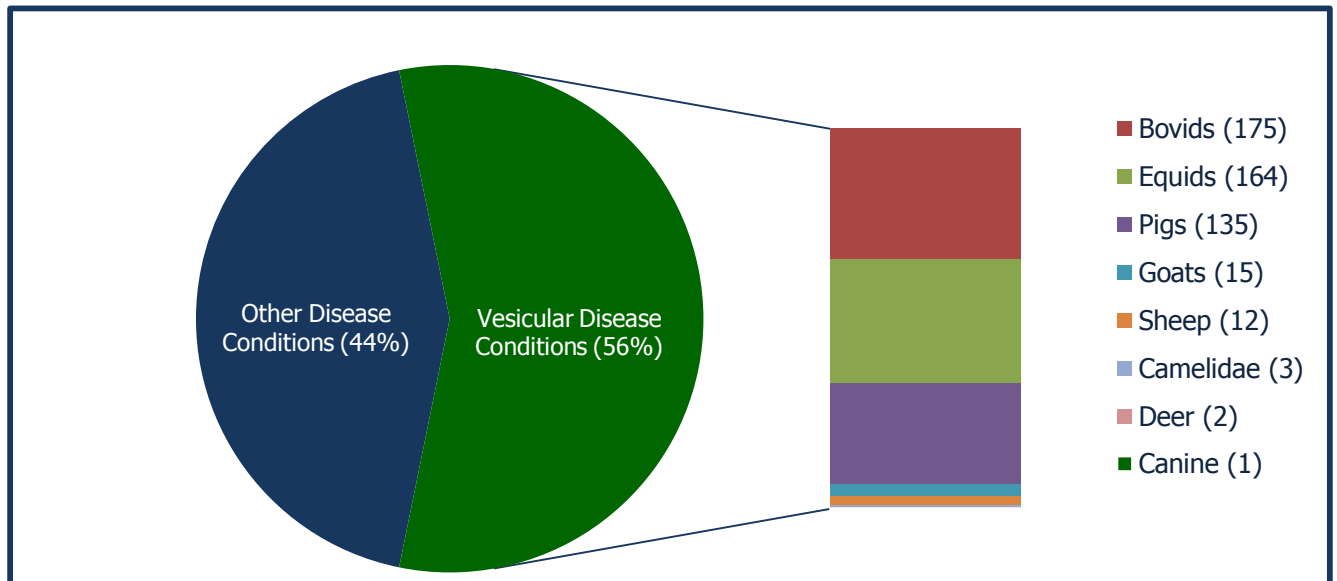
Figure 12: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2014.



2015

There were 899 FAD investigations conducted in 2015. Iowa (110), Minnesota (61), and Colorado (56) reported the most investigations. This year, the high number of investigations was primarily due to the largest outbreak of highly pathogenic avian influenza (HPAI) in U.S. history, focused in the Midwest. During the HPAI outbreak, in CY2015, there were 211 positive commercial premises, 20 positive backyard premises, and 4 positive captive wild birds (please note, the outbreak started in late December 2014). There were also 2 detections of EP. Please note that for CY2015, most vesicular stomatitis investigations are not reported as in prior years as vesicular stomatitis is no longer considered an FAD; however, any vesicular stomatitis investigations in caprine, ovine, cervid, and bovine species are reported in the total FAD investigation number. In addition, there were FAD investigations conducted in equids that included vesicular stomatitis as a differential; these were counted in the totals. For future years, these specific equid investigations will no longer be considered FAD investigations if there is not an FAD differential diagnosis. In these species groups, other FADs, including FMD, must be ruled out through an investigation. Of these 899 investigations, 507 were vesicular complaints with 175 in bovids (cattle, bison), 164 in equids, 135 in pigs, 15 in goats, 12 in sheep, 3 in camelidae (alpaca, llama), 2 in deer, and 1 in a canine (Figure 13).

Figure 13: Proportion of FAD Investigations due to Vesicular Conditions, by Species in 2015.



2017 U.S. National List of Reportable Animal Diseases (NLRAD) - National Animal Health Reporting System (NAHRS) Reportable Disease List

Changes from previous year:

Porcine:

Removed: C801 Swine erysipelas

(Non OIE listed-commodity recommendation)

Equine:

Added: C752 Pigeon fever (*Corynebacterium pseudotuberculosis*, ulcerative lymphangitis)

(Non OIE listed-commodity recommendation)

C753 Strangles (*Streptococcus equi equi*)

(Non OIE listed-commodity recommendation)

Aquatic:

Removed non OIE listed diseases

Added: Crustacean N451 Necrotising hepatopancreatitis (OIE-listed 2016)

BOVINE

A010	Foot-and-mouth disease (FMD)
A020	Vesicular stomatitis (VS)
A040	Rinderpest
A060	Contagious bovine pleuropneumonia (<i>Mycoplasma mycoides mycoides</i>)
A070	Lumpy skin disease
A080	Rift Valley fever
A090	Bluetongue
N001	Crimean Congo hemorrhagic disease
2001	Akabane (congenital arthrogryposis-hydranencephalaly syndrome)
B051	Anthrax (<i>Bacillus anthracis</i>)
B052	Aujesky's disease (Pseudorabies)
B053	Echinococcosis / hydatidosis (<i>Echinococcus granulosus</i> , <i>E. multilocularis</i>)
B055	Heartwater (<i>Cowdria ruminantium</i>)
B057	Q Fever (<i>Coxiella burnetii</i>)
B058	Rabies
B059	Paratuberculosis (Johne's disease - (<i>Mycobacterium avium paratuberculosis</i>)
B060	New World screwworm (<i>Cochliomyia hominivorax</i>)
B061	Old World screwworm (<i>Chrysomya bezziana</i>)
B101	Anaplasmosis (<i>Anaplasma marginale</i> , <i>A. centrale</i>)
B102	Babesiosis (<i>Babesia bovis</i> , <i>B. bigemina</i>)
B103	Bovine brucellosis (<i>B. abortus</i>)
B152	Caprine and ovine brucellosis (<i>B. melitensis</i>)
B253	Porcine brucellosis (<i>B. suis</i>)
B104	Bovine genital campylobacteriosis (<i>Campylobacter fetus venerealis</i>)
B105	Bovine tuberculosis (<i>Mycobacterium bovis</i>)

N117	Bovine viral diarrhoea (BVD)
B108	Enzootic bovine leukosis (BLV)
B109	Hemorrhagic septicemia (<i>Pasteurella multocida</i> , serotypes B/Asian or E/African)
B110	Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis (IBR/IPV)
B111	Theileriosis (<i>Theileria annulata</i> , <i>T. parva</i>)
B112	Trichomoniasis (<i>Trichomonas [Trichomonas] foetus</i>)
B113	Trypanosomiasis (tsetse-transmitted)(<i>Trypanosoma congolense</i> , <i>T. vivax</i> , <i>T. brucei brucei</i> , <i>T. evansi</i>)
B114	Malignant catarrhal fever (specify wildebeest or sheep form)
B115	Bovine spongiform encephalopathy (BSE)
N158	Epizootic hemorrhagic disease (EHD)
C613	Melioidosis (<i>Burkholderia pseudomallei</i>)

CAPRINE AND OVINE

A010	Foot-and-mouth disease (FMD)
A020	Vesicular stomatitis (VS)
A040	Rinderpest
A050	Peste des petits ruminants
A080	Rift Valley fever
A090	Bluetongue
A100	Sheep pox and goat pox
N001	Crimean Congo hemorrhagic disease
2001	Akabane (congenital arthrogryposis-hydranencephalaly syndrome)
B051	Anthrax (<i>Bacillus anthracis</i>)
B052	Aujesky's disease (Pseudorabies)
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B060	New World screwworm (<i>Cochliomyia hominivorax</i>)
B061	Old World screwworm (<i>Chrysomya bezziana</i>)
B103	Bovine brucellosis (<i>B. abortus</i>)
B105	Bovine tuberculosis (<i>Mycobacterium bovis</i>)
B111	Theileriosis (<i>Theileria annulata</i> , <i>T. parva</i>)
B152	Caprine and ovine brucellosis (<i>B. melitensis</i>)
B151	Ovine epididymitis (<i>Brucella ovis</i> infection)
B153	Caprine arthritis / encephalitis (CAE)
B154	Contagious agalactia (<i>Mycoplasma agalactiae</i> , <i>M. Capricolum capricolum</i> , <i>M. putrefaciens</i> , <i>M. mycoides mycoides</i> , <i>M. mycoides mycoides</i> LC)
B155	Contagious caprine pleuropneumonia (<i>Mycoplasma capricolum capripneumoniae</i>)
B156	Enzootic abortion of ewes (ovine chlamydiosis, <i>Chlamydophila abortus</i>)
B158	Nairobi sheep disease
B159	Salmonellosis (<i>Salmonella abortusovis</i>)

B160	Scrapie
B161	Maedi-visna/ovine progressive pneumonia
B352	Tularemia (<i>Francisella tularensis</i>)
N002	West Nile fever
C613	Melioidosis (<i>Burkholderia pseudomallei</i>)
C706	Mange (<i>Sarcoptes scabiei</i> var <i>ovis</i> , <i>Chorioptes bovis</i> , <i>Psoroptes ovis</i> , <i>Psoroptes cuniculi</i> , <i>Psoregates ovis</i>)

EQUINE

A020	Vesicular stomatitis (VS)
A110	African horse sickness
B051	Anthrax (<i>Bacillus anthracis</i>)
B053	Echinococcosis / hydatidosis (<i>Echinococcus granulosus</i> , <i>E. multilocularis</i>)
B058	Rabies
B060	New World screwworm (<i>Cochliomyia hominivorax</i>)
B061	Old World screwworm (<i>Chrysomya bezziana</i>)
B062	Trichinellosis (<i>Trichinella</i> spp.)
B201	Contagious equine metritis (<i>Taylorella equigenitalis</i>)
B202	Dourine (<i>Trypanosoma equiperadum</i>)
N220	Equine encephalomyelitis (Eastern)
N221	Equine encephalomyelitis (Western)
B205	Equine infectious anemia (EIA)
B206	Equine influenza
B207	Equine piroplasmiasis (babesiosis, <i>Babesia</i> [<i>Piroplasma</i>] <i>equi</i> , <i>B. caballi</i>)
B208	Equine rhinopneumonitis (EHV- 1)
B208a	Equine herpesvirus myeloencephalopathy (EHV1 - EHM)
B209	Glanders (<i>Pseudomonas mallei</i>)
B211	Equine viral arteritis (EVA)
B212	Japanese encephalitis
B215	Surra (<i>Trypanosoma evansi</i>)
B216	Venezuelan equine encephalomyelitis
B352	Tularemia (<i>Francisella tularensis</i>)
N002	West Nile fever
W075	Hendra
C613	Melioidosis (<i>Burkholderia pseudomallei</i>)
C752	Pigeon fever (<i>Corynebacterium pseudotuberculosis</i> , <i>ulcerative lymphangitis</i>)
C753	Strangles (<i>Streptococcus equi equi</i>)

PORCINE

A010	Foot-and-mouth disease (FMD)
A020	Vesicular stomatitis (VS)
A030	Swine vesicular disease
A040	Rinderpest
A120	African swine fever
A130	Classical swine fever (hog cholera)

N258	Nipah virus encephalitis
B051	Anthrax (<i>Bacillus anthracis</i>)
B052	Aujesky's disease (Pseudorabies)
B053	Echinococcosis / hydatidosis (<i>Echinococcus granulosus</i> , <i>E. multilocularis</i>)
B058	Rabies
B060	New World screwworm (<i>Cochliomyia hominivorax</i>)
B061	Old World screwworm (<i>Chrysomya bezziana</i>)
B062	Trichinellosis (<i>Trichinella spp.</i>)
B212	Japanese encephalitis
B252	Infection with <i>Taenia solium</i> (Porcine Cysticercosis)
B253	Porcine brucellosis (<i>B. suis</i>)
B254	Transmissible gastroenteritis (TGE)
B257	Porcine reproductive and respiratory syndrome (PRRS)
B352	Tularemia (<i>Francisella tularensis</i>)
C613	Melioidosis (<i>Burkholderia pseudomallei</i>)
2006	Vesicular exanthema
2010	Swine Enteric Coronavirus Disease (SECD) (Porcine epidemic diarrhea virus –PEDV; Porcine delta coronavirus (PDCoV))

AVIAN

A150h	Highly pathogenic avian influenza (reporting of occurrence in all birds)
A150i	Low pathogenic avian influenza (H5 or H7 subtypes)(Poultry only)
A160	Newcastle disease (Exotic)(Domestic birds)
N315	Turkey rhinotracheitis (Domestic birds)
B301	Avian infectious bronchitis
B302	Avian infectious laryngotracheitis
B304	Duck viral hepatitis (Domestic birds)
B308	Fowl typhoid (<i>Salmonella gallinarum</i>)
B309	Infectious bursal disease (Gumboro disease)
B311	Avian Mycoplasmosis (<i>Mycoplasma gallisepticum</i>)
B312	Avian chlamydiosis (psittacosis and ornithosis, <i>Chlamydia psittaci</i>)
B313	Pullorum disease (<i>Salmonella pullorum</i>)
N316	Avian Mycoplasmosis (<i>Mycoplasma synoviae</i>)

AQUATIC

B401	Fish: Viral hemorrhagic septicemia (VHS)
N416	Fish: Infectious salmon anemia (ISA)(HPR-deleted)
N416a	Fish: Infectious salmon anemia (ISA)(HPR0)
B404	Fish: Spring viremia of carp (SVC)
B405	Fish: Infectious hematopoietic necrosis (IHN)
B413	Fish: Epizootic hematopoietic necrosis disease
N417	Fish: Epizootic ulcerative syndrome (EUS) (Infection with <i>Aphanomyces invadans</i>)
N418	Fish: Gyrodactylosis (<i>Gyrodactylus salaris</i>)
N419	Fish: Red sea bream iridoviral disease
N420	Fish: Koi herpesvirus disease

2011	Fish: Infection with salmonid alphavirus
N430	Mollusc: Infection with <i>Bonamia ostreae</i>
N431	Mollusc: Infection with <i>Bonamia exitiosa</i>
N432	Mollusc: Infection with <i>Marteilia refringens</i>
N433	Mollusc: Infection with <i>Perkinsus marinus</i>
N434	Mollusc: Infection with <i>Perkinsus olseni</i>
N435	Mollusc: Infection with <i>Xenohalictis californiensis</i>
N436	Mollusc: Infection with abalone herpes virus
N450	Crustacean: Taura syndrome
N451	Crustacean: White spot disease
N446	Crustacean: Necrotising hepatopancreatitis (Candidatus <i>Hepatobacter penaei</i>)(NHP, early mortality syndrome)
N452	Crustacean: Yellowhead (Infection with Yellowhead virus genotype 1)
N455	Crustacean: Infectious hypodermal and haematopoietic necrosis
N456	Crustacean: Crayfish plague (<i>Aphanomyces astaci</i>)
N457	Crustacean: Infectious myonecrosis
N458	Crustacean: White tail disease
N459	Crustacean: Acute hepatopancreatic necrosis disease (<i>V.parahemolyticus</i> pVA-1 plasmid)

FARMED CERVIDS

A010	Foot-and-mouth disease (FMD)
A020	Vesicular stomatitis (VS)
A040	Rinderpest
A080	Rift Valley fever
N001	Crimean Congo hemorrhagic fever
2001	Akabane (congenital arthrogryposis-hydranencephalaly syndrome)
A090	Bluetongue
B051	Anthrax (<i>Bacillus anthracis</i>)
B052	Aujesky's disease (Pseudorabies)
B053	Echinococcosis / hydatidosis (<i>Echinococcus granulosus</i> , <i>E. multilocularis</i>)
B055	Heartwater (<i>Cowdria ruminantium</i>)
B057	Q Fever (<i>Coxiella burnetii</i>)
B058	Rabies
B059	Paratuberculosis (Johne's disease - <i>Mycobacterium avium</i> paratuberculosis)
B060	New World screwworm (<i>Cochliomyia hominivorax</i>)
B061	Old World screwworm (<i>Chrysomya bezziana</i>)
B103	Bovine brucellosis (<i>B. abortus</i>)
B152	Caprine and ovine brucellosis (<i>B. melitensis</i>)
B253	Porcine brucellosis (<i>B. suis</i>)
B105	Bovine tuberculosis (<i>Mycobacterium bovis</i>)
B114	Malignant catarrhal fever
N156	Chronic wasting disease (CWD)
N158	Epizootic hemorrhagic disease (EHD)
C613	Melioidosis (<i>Burkholderia pseudomallei</i>)

LAGOMORPH (Rabbits & Hares)

- B351 Myxomatosis
- B352 Tularemia (*Francisella tularensis*)
- B353 Rabbit hemorrhagic disease

OTHER DISEASES

- B501 Leishmaniosis
- N502 Camelpox

AMPHIBIAN DISEASES

- N601 Infection with *Batrachochytrium dendrobatidis*
- N602 Infection with ranavirus

BEE (APIARY) (optional reporting requirement as other agencies responsible)

- B451 Acarapisosis of honey bees (Infestation with *Acarapis woodi*)
- B452 American foulbrood of honey bees (Infection with *Paenibacillus larvae*)
- B453 European foulbrood of honey bees (Infection with *Melissococcus plutonius*)
- B455 Varroosis of honey bees (Infestation with *Varroa spp.*)
- 2008 Tropilaelaps infestation of honey bees (Infestation with *Tropilaelaps spp.*)
- 2009 Small hive beetle infestation (Infestation with *Aethina tumida*)