

Secretary's Advisory Committee on Animal Health

Committee Report June 18 – 19, 2014 U.S. Access Board Washington, DC

Executive Summary

The USDA Secretary's Advisory Committee on Animal Health met at the U.S. Access Board in Washington DC on June 18 -19, 2014. A quorum of the Committee attended the meeting in person as well as several members who participated by phone. Presiding over the meeting were the Committee's Chair, Don Hoenig, Designated Federal Official, RJ Cabrera, and Facilitator, Anne Dunigan.

Dr. Hoenig began with welcome remarks, followed by Dr. Jack Shere, who addressed the Committee on Dr. John Clifford's behalf (the nation's Chief Veterinary Officer was unable to attend due to foreign travel). Dr. Shere introduced other USDA senior staff members who gave overviews of their respective units. Committee discussion and deliberation continued with the following topics: (1) animal disease traceability, (2) foreign animal disease zoning, (3) non-regulatory approaches to disease control and eradication, (4) antimicrobial resistance, and (5) emergency preparedness and planning.

Mr. Neil Hammerschmidt, USDA, APHIS Veterinary Services, briefed the Committee on the current status of ADT noting that the country does not currently have a full traceability system of animal identification since we do not have record of all the points of co-mingling between birth and slaughter. What we have is a bookend plus system. He also told the Committee that ADT is one of the APHIS Administrator's (Kevin Shea) top 10 priorities. In response to a Committee member question, Mr. Hammerschmidt noted that there is no timeline for Phase 2 of the ADT rule (i.e., identification of feeder cattle over 18 months of age).

Dr. Jonathan Zack, USDA, APHIS, Veterinary Services, briefed the Committee on the current stage of foot and mouth disease (FMD) preparedness, noting that there are 90 million cattle and 60 million swine in the U.S. and that there are approximately 1 million pigs on the road in the U.S. every day. The National Veterinary Stockpile is currently not adequately funded.

Dr. James A. Roth, a guest speaker from Iowa State University, concluded the first day's presentations with a white paper on surge capacity in the event of an FMD outbreak wherein he also described the status of manufacturing and acquiring FMD vaccine. This included a discussion of the North American FMD Vaccine Bank.

The Committee concluded its discussion of FMD preparedness on June 19 and began with the next agenda item: antimicrobial resistance. Dr. William T. Flynn, a guest

speaker from the U.S. Food and Drug Administration, reviewed FDA's recent action regarding Guidance Document 213 that places future restrictions on the use of growth promoting antibiotics as well as increased veterinary oversight. Dr. Alicia Naugle, USDA, APHIS, Veterinary Services, disclosed that the USDA drafted an action plan on antimicrobial resistance and that plan was receiving its first public viewing on that day. Drs. David Dargatz and Bruce A. Wagner, USDA APHIS, Veterinary Services, continued with reviewing the new National Animal Health Monitoring System research and sampling program, which is both voluntary and confidential.

Dr. Kelly Rhodes, USDA APHIS, Veterinary Services, then presented the USDA's proposed zoning plan with the Canadian Food Inspection Agency (CFIA). The plan is to jointly, with CFIA, define a list of highly contagious diseases (such as FMD) and develop a proposal for zoning between both countries to facilitate trade in the event of a highly contagious disease outbreak.

The final item on the agenda was non-regulatory approaches to disease control and prevention. Dr. Jack Shere told the Committee that the issue for the USDA has been how long it takes to promulgate a rule. The agency is interested in pursuing non-regulatory solutions to emerging issues and he used the National Aquatic Animal Health Plan as an example. The agency is trying to determine where they can or should interpret existing regulations more flexibly.

The Committee spent the remainder of the day discussing its plan for developing recommendations. The Committee was assigned by subgroup to draft recommendations on (1) ADT, (2) antimicrobial resistance, (3) zoning, and (4) emergency preparedness and response (FMD vaccine). Subgroup leaders were later assigned as: Hoenig (FMD); McGeary (ADT); Parr (Zoning); and Wagstrom (Antimicrobial Resistance). The Committee agreed to conduct business electronically via FoodSHIELD webinars and through a series of teleconferences to finalize its report and recommendations. The Committee decided that it did not have adequate time or information to discuss and prepare any recommendations regarding non-regulatory approaches and would therefore defer further discussion of that issue to a future meeting.

Recommendations of the Secretary's Advisory Committee on Animal Health

Antimicrobial Resistance

The USDA requested that the Committee:

1. Provide feedback on the current and proposed USDA activities that address antimicrobial resistance (AMR).
2. Identify how USDA could best collaborate with their constituent industries to supplement and sustain these activities; and
3. Recommend actions USDA could take to promote acceptance and support among State and industry stakeholders for USDA activities related to the AMR issue.

Committee Discussion

The main themes of committee discussion on antimicrobial use/resistance included general research and scientific needs to provide guidance for action. The discussion focused on methods of surveillance for AMR, including in people who work with livestock, collection of antimicrobial use data, educational outreach, and stakeholder input. There are important overarching questions about drug use practices; why antibiotics are used in livestock production; what uses are prudent; the impact of removing use on some production systems and in some circumstances. Committee members suggested that USDA can address these questions through surveillance of antimicrobial usage and resistance, research, educational outreach, and collaboration with stakeholders.

Recommendations for Antimicrobial Resistance

Surveillance and Research

1. A stakeholder advisory group on surveillance of antimicrobial use and resistance should be convened to set objectives, design surveillance methods, identify cooperators and build trust between the industries and the agencies.
2. The committee recommends that research and surveillance activities such as NAHMS and NARMS that help to inform the science of antimicrobial resistance could, and should, be enhanced and that the budget should be reflective of these needs. VS and ARS should prioritize funding for these activities.
3. USDA should consider the NAHLN as a valuable resource in antibiotic resistance surveillance testing.

4. More information should be provided to stakeholders on the APHIS-FSIS MOU, addressing trace back and any potential contribution that may have on antibiotic use and resistance surveillance, including the type of data that may be collected under this MOU.
5. The committee recommends that Agricultural Research Service should prioritize resources for AMR research. The following areas were considered important and promising:
 - Alternatives to antimicrobials including probiotics, prebiotics, bacteriophages, lytic enzymes, essential oils and more effective vaccines.
 - Design of advanced food animal husbandry and production practices that favor health and reduce the need for antimicrobials.
 - Determine if there is a relationship between the amount of drug used, type of drug used, and the purpose of the drug used and the risk for AMR in either food animals, animal products or human illness.

Educational Outreach

1. Extension should work with organized veterinary medicine (e.g. AVMA) to develop and deliver key grassroots outreach on AMR topics to veterinarians, producers and other stakeholders.
2. USDA should promote judicious use of antimicrobials that preserves animal health.
3. Veterinary accreditation modules should be developed to educate veterinarians on the Veterinary Feed Directive rules and USDA should promote that education at food animal veterinary meetings

Stakeholder Input

1. USDA should work with FDA and AVMA to summarize the input they received at the VFD listening sessions and outline policies that were developed based on those sessions.
2. USDA should publish their AMR plan and provide an opportunity for stakeholder comment on it. USDA should outline a process for review and revision of the plan.
3. USDA should interface with FDA on a process to revise the Guidance 152 Appendix A taking into account changes in both human and animal importance of some classes of antimicrobials.

4. USDA should work with poultry/livestock industry stakeholders to develop objectives for a plan to collect and report more accurate antibiotic usage data for food animals, including indications for use, and use of the antibiotic classes considered most important in human medicine.

Emergency Preparedness and Response

The USDA requested Committee feedback on the following topics and issues in emergency preparedness and response:

FMD Vaccine

1. How should APHIS and its stakeholders modernize FMD vaccine capabilities?
2. What should be the minimum quantities of vaccine available, and the minimum time to delivery, to provide an effective response?
3. Can there be cost-sharing or public-private partnerships to modernize FMD capabilities?

Continuity of Business

1. How should the Secure Food Supply plans be evaluated before an outbreak?
2. How should these plans be “accepted” or adopted by States before an outbreak?
3. Should plans be implemented by Memoranda of Understandings between States? Through rulemaking? Or should other processes be used?

Committee Discussion

The Committee’s discussion on Emergency Management and Preparedness expanded from a primary focus of FMD to include recommendations that other FADs be considered as well. The discussions covered a broad range of topics on the issues, with Committee members brainstorming on a long list of possible actions to improve prevention, surveillance and response.

During the discussion, various members of the Committee mentioned the following concerns and perspectives:

- Protecting the borders through interdiction of risk materials at the ports.
- The need to carefully assess risk of policies allowing importation of products from countries that either have FMD or who have had FMD and been declared negative through vaccination. Committee members disagreed as to whether to recommend no imports from countries that were controlling FMD through vaccination.
- Improving the threat perspective of potential FMD carriers by recognizing that most of the world’s animal holdings are not held in farms. A visitor walking

around on the streets of Addis Ababa, Ethiopia can easily carry the FMDV back to the United States. Surveillance and monitoring should be restructured to meet such an occurrence.

- Addressing surge capacity for laboratories, vaccines, and workforce.
- Laboratory capacity issues include sufficient testing reagents, training for personnel, fast communications (perhaps electronic) with USDA and others involved in outbreak response efforts and cooperation between the National Animal Health Laboratory Network (NAHLN) and Foreign Animal Disease Diagnostic laboratories (FADDL).
- Laboratory capacity also implicates the protocols needed to prove a negative to our trading partners, detecting vaccinated animals, and serology work during the recovery phase.
- Animal identification, particularly of vaccinated animals versus non-vaccinated, could be important to the speed of response efforts.
- For vaccination efforts, members raised concerns about the speed of obtaining vaccine in the United States, the quantity of vaccine available, and funding for vaccines.
- The options for different vaccine technology, including those that do not require the whole virus, differ in how they affect availability and where the vaccine can be manufactured.
- Humane euthanasia and safe disposal of carcasses was raised, with some members urging greater consideration for vaccination options.
- The on-farm workforce, for preliminary diagnoses and sample submission, is a concern.
- Workforce issues include both the number of people and having training, materials, and protocols ready ahead of time.
- Sufficient funding underlies most of these issues, with various Committee members urging the recognition that funding to ensure that we can address an outbreak is necessary *before* the outbreak occurs.

The issue of thresholds for response was discussed at some length. The Committee members differed on how to decide when depopulation, vaccination, or some combination would be the appropriate response. Some members advocated for a clear, specific numerical threshold, while others proposed a more situation-specific approach.

Recommendations for Emergency Preparedness and Response

The Committee urges the Secretary to take the following steps so that the U.S. is prepared with facilities, people, vaccines, diagnostics and money to address an outbreak of FMD or other highly contagious animal disease.

The Committee supports a fully functional FMD antigen bank to support a “vaccinate-to-live” response strategy to include appropriate serotypes and quantities for immediate use in an FMD outbreak, as well as concomitant diagnostic capability to identify disease and prove freedom from disease. The Committee recommends the following actions:

1. Pre-approve all FMD vaccines approved for use in original European Union member states for emergency use in the U.S.
2. Convene a stakeholder working group to: (a) determine stakeholder needs for preventing or responding to an FMD outbreak; (b) conduct an assessment of the current state of preparedness in the U.S.; and (c) identify the most important preparedness gaps.
 - a. With respect to vaccines, the working group should include experts capable of evaluating existing and new FMD vaccine/diagnostic technologies to identify those that can best meet the needs for emergency response in the US. The group should evaluate the multiple approaches that can be employed to assure surge capacity for FMD vaccines in the immediate, short-term, and long-term time frame.
 - b. The working group also should evaluate various funding options for the necessary surge capacity, including public-private partnerships. The role of NAHLN laboratories in providing the necessary testing of samples during an outbreak should be determined and communicated to stakeholders in all states. The working group should include individuals representing livestock producers of each susceptible species, including small-scale producers; heritage breed owners; large-scale producers; private veterinarians; laboratory diagnosticians; livestock markets; processors and other potentially impacted business entities; the Extension Education Disaster Network; State Animal Health Officials; U.S. Animal Health Association; the Institute for Infectious Animal Diseases; National Institute for Animal Agriculture; the Department of Homeland Security; and the USDA.
3. Form a standing advisory committee whose purpose is to provide recommendations on the optimal use of vaccine, before, during, and after an outbreak. Members of the committee should include individuals with a wide range of expertise and perspective, including: FMD vaccinology, FMD epidemiology, diagnostics; production agriculture, heritage and rare-breeds, small-scale production, economics, and animal health emergency response.
4. Ensure that regular exercises with States occur to address potential FMD and other disease outbreak scenarios, and publish a copy of the USDA's exercise schedule.
5. Fully fund the NAHLN at \$25 million. The NAHLN is composed of federal, state, and university veterinary diagnostic laboratories. It has established the framework of a surveillance and emergency response system that provides critical and ongoing resources for laboratory testing, surveillance, information management, including data analysis and sharing, quality assurance, and the development of and validation of new diagnostic tests. The NAHLN enables laboratories to test for economically devastating diseases, such as FMD, and serves as the nation's

early warning system for emerging and foreign animal diseases. Funding for the NAHLN is currently at \$10 million through multiple parts of the USDA budget, which allows it to function at baseline levels. The SACAH recommends that the NAHLN be fully funded by providing the additional \$15 million authorized in the Farm Bill. This is essential for bringing the operational level of the NAHLN up to the required state of readiness, with the capabilities and capacity for surveillance of and response to disease outbreaks. In order for the nation to adequately respond to, and recover from an incursion of a foreign animal disease, the NAHLN needs to be fully funded.

6. Increase U.S. laboratory surge capacity in preparation for an outbreak of FMD or other highly contagious animal disease. All possible avenues to accomplish this should be explored including the following:
 - a. Studies evaluating sample pooling for efficient use of test resources should be conducted prior to an outbreak using currently available diagnostic assays.
 - b. Samples not requiring collection from individual animals such as rope and bulk milk samples should be evaluated using currently available diagnostic assays.
 - c. Diagnostic assays using new technology should be developed for both lab and pen-side field applications.
 - d. Test performance of all assays and protocols should be established in endemic FMD areas.
7. Adequately fund the National Veterinary stockpile.

Animal Disease Traceability

The USDA requested that the Committee provide feedback on the following questions:

1. Are there specific areas of the ADT (overall framework and regulations) that industry finds problematic that USDA could work to improve?
2. Are there aspects of traceability that USDA should consider in the future for certain species?
3. What aspects of our traceability system need to be evaluated to ensure the U.S. meets the future demands of trading partners?

Committee Discussion

Part of the Committee’s discussion focused on the issue of interstate Certificates of Veterinary Inspection (iCVIs) and concerns that had been raised by producers and marketers on the new requirements, in particular the question of where the issuing veterinarian must personally record the animals’ identification numbers, or whether the seller could provide a list of the animals’ ID numbers to attach to the iCVI.

Members of the Committee suggested that moving to an electronic-based system could address this issue and provide other benefits. Other members raised concern as to whether moving to an electronic-based system could create new barriers, particularly for veterinarians who are not equipped for electronic-based systems. No consensus was reached.

The Committee also discussed the issue of animal traceability within the context of the porcine epidemic diarrhea (PED) outbreak, and what lessons could be learned from the handling of the outbreak. Discussion included an awareness of the unique learning opportunity presented by this outbreak and the reporting program.

Recommendations for Animal Disease Traceability

1. The SACAH recommends that USDA-APHIS continue to monitor all existing and emerging technology options used in the identification and traceability of transported poultry and livestock. Future consideration of new technology should embrace inter-agency activities and cooperation. Technology options should be critically evaluated for cost-effectiveness and ease of application across the country for all stakeholders—including small-scale, large-scale, and socially disadvantaged farmers/ranchers, as well as livestock-related businesses.
2. The introduction and subsequent response to the PED virus epidemic is a unique learning opportunity. We recommend that USDA conduct a study to evaluate the response to the PED epidemic by the USDA Veterinary Service and the veterinary departments of other federal agencies, states, and tribal areas. The study should include an analysis of how the PED virus spread, the existence of industry traceability programs and the role they played, or could have played, in the response, and the role that the Animal Disease Traceability Program played, or could have played, in the response. This should include evaluation of when information in the ADT program can be accessed and by whom.

Foreign Animal Disease Zoning

The USDA requested feedback from the Committee on the following issues:

1. Provide feedback on strengths, weaknesses, value and feasibility of the U.S.-Canada zoning proposal.

2. Identify potential issues or points of controversy among constituent industries and advise on how to address them.
3. Recommend actions that USDA could take to promote acceptance and support among State and industry stakeholders.
4. Recommend projects and other priorities under the Framework for 2014-2015, focusing on tie-ins with existing venues and planned events.

Committee Discussion

Discussion on the U.S./Canadian disease zoning centered around two themes:

(1) Diseases to include in the zoning arrangement and (2) How the zoning agreement will be implemented. During the discussion, various members of the Committee mentioned the following concerns and perspectives:

- Diseases should be defined so that currently endemic diseases don't trigger the need to zone. The OIE highly contagious list is a possibility.
- It is important that there is agreement and commitment by animal health officials at the Canadian provincial level and by U.S. State Animal Health Officials.
- It is important that surveillance is robust enough that if one country becomes infected we are capable of finding it in the other.
- The surveillance structure needs to be funded now as it is too late to build an infrastructure after an emergency occurs.
- The foreign animal disease zoning plan offers a flexible, non-binding approach limited to highly contagious foreign animal diseases (HCFAD).
- The plan has the potential to minimize negative trade consequences between the U.S. and Canada without significant increase in the risk of further spread of HCFAD in or between either country.
- Canada is likely one of the few countries for which this type framework is feasible. Expanding this framework to include other countries besides Canada would be premature at this time.

Recommendations for Foreign Animal Disease Zoning

1. Conduct outreach to assure buy-in by producers, state and provincial authorities as well as federal authorities. For example, it would be useful to present this concept at the U.S. Animal Health Association annual meeting, to the National Institute for Animal Agriculture, and to other stakeholder regional meetings to get input from States and industry. The actions in the plan are appropriate and should be energetically carried out.
2. It would be desirable that a process for receiving ongoing public input be specified.
3. The committee recommends assuring that there is sufficient funding for surveillance at the level needed to support zoning.

4. Consideration of zoning between the U.S. and other countries must include:
 - a. Adequate surveillance plans and transparency of test results from the foreign country for HCFADs.
 - b. An open and honest assessment of how well what really happens in the foreign country matches the plans and reports e.g., does that country's infrastructure and commitment demonstrate conclusively that surveillance and reporting claims match reality?
 - c. How well the U.S. is prepared to detect and eradicate the HCFAD should it enter the U.S. as a result of a zoning arrangement despite the controls in place, including the necessary appropriations.

Non-regulatory Approaches

Issues that were discussed by the Committee:

1. How long it takes to get a rule promulgated.
2. Consider a different process for a non-regulatory solution to an emerging issue (such as the aquatic animal health plan).
3. Continue to work on issuing more flexible regulations, e.g., approving Eastport, Maine as a port of embarkation.
4. Determine where the agency can/should interpret existing regulations with more flexibility, e.g., southern border ports and potency standards.

Recommendations

Although the USDA did not seek specific recommendations from the Committee regarding non-regulatory approaches, this topic may be further considered during the next face-to-face meeting.



Secretary's Advisory Committee on Animal Health (SACAH)

June 18 - 19, 2014 • 9:00 a.m. – 5:00 p.m.

U.S. Access Board

1331 F Street NW, Suite 800, Washington, D.C.

(Public) Listen-Only Call 800-619-4303 Passcode: 9564942

Day 1

Call to Order & Introductions, 9:00am

- Ms. RJ Cabrera, Designated Federal Officer (DFO)
- Ms. Anne Dunigan, Facilitator
- SACAH Committee Members

Introductory remarks

- Dr. Donald E. Hoenig, SACAH Chair

Welcome and remarks

- Dr. John R. Clifford, Deputy Administrator Veterinary Services
- Dr. Jack A. Shere, Associate Deputy Administrator Veterinary Services
- Dr. Thomas J. Myers, Associate Deputy Administrator Surveillance, Preparedness, and Response Service (SPRS)
- Dr. Mark L. Davidson, Associate Deputy Administrator National Import Expert Services (NIES)
- Dr. Elizabeth A. Lautner, Associate Deputy Administrator Science, Technology, and Analysis Services (STAS)

Presentation: Animal Disease Traceability: An Update

- Mr. Neil E. Hammerschmidt, APHIS Veterinary Services (SPRS)

Break

Animal Disease Traceability (*continued*) , Q&A and Deliberations

Lunch, 12:30pm

Presentation: Emergency Management and Preparedness, Secure Supply Projects

- Dr. Jonathan T. Zack, APHIS Veterinary Services (SPRS)
- Dr. James A. Roth, Iowa State University (Guest)
Center for Food Security and Public Health
Department of Veterinary Microbiology and Preventive Medicine

Break

Emergency Management (*continued*), Q&A and Deliberations

Public comments

Wrap-Up and Adjourn, 5:00pm



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Day 2
Call to Order and Review of Day 1, 9:00am
Presentation: Antimicrobial Resistance <ul style="list-style-type: none">- Dr. David A. Dargatz, APHIS Veterinary Services (STAS)- Dr. William T. Flynn, Food and Drug Administration (Guest)- Dr. Alecia L. Naugle, APHIS Veterinary Services (SPRS)- Dr. Bruce A. Wagner, APHIS Veterinary Services (STAS)
Q&A and Deliberations
<i>Lunch, 12:00pm</i>
Presentation: Foreign Animal Disease Zoning <ul style="list-style-type: none">- Dr. Kelly Rhodes, APHIS Veterinary Services (NIES)
Q&A and Deliberations
<i>Break</i>
Presentation: Nonregulatory Approaches <ul style="list-style-type: none">- Dr. Jack A. Shere, APHIS Veterinary Services
Public comments
Wrap-up and Adjourn, 5:00pm

ATTACHMENTS (4)

ATTACHMENT 1

Summary of the Antimicrobial Resistance Issue and Activities for the Secretary's Advisory Committee on Animal Health—June 2014

Introduction

The U.S. Department of Agriculture (USDA) is asking the Secretary's Advisory Committee on Animal Health for feedback on proposed surveillance, research, and education and outreach activities that the USDA plans to conduct to address antimicrobial use and resistance.

Background

Antimicrobial resistance (AMR) is a global issue affecting both public and animal health. Simply stated, there is concern that bacteria that cause disease in both people and animals are developing more resistance to the important antibiotics¹ used for treatment. There is increasing recognition that AMR is also an issue in animal health though the extent of its occurrence and its impact are largely unknown. Some believe that the use of antimicrobial drugs in agriculture is one of the primary drivers for the emergence of AMR. In reality, our understanding of the factors that contribute to levels of AMR in various settings and the specific role of antimicrobial use in agriculture in the selection for AMR bacteria is incomplete. The issue has become increasingly urgent as the numbers of organisms resistant to antimicrobial drugs has grown, the availability of new antimicrobial drugs has slowed or stopped and global interconnectedness has increased.

The public health and veterinary communities have implemented actions to encourage the judicious use of antimicrobials in people and animals. Judicious use of antibiotics, an integral part of good veterinary and production practices, maximizes therapeutic efficacy and minimizes selection of resistant microorganisms. The Food and Drug Administration (FDA) has finalized two guidance documents for industry (Guidance for Industry [GFI] #209 and #213) which seek the voluntary cooperation of the pharmaceutical industry to remove the label claims for growth promotion on antimicrobials deemed medically important. In addition, GFI #213 seeks to move all therapeutic uses of antimicrobial drugs in feed and water under the oversight of a veterinarian – requiring a Veterinary Feed Directive (VFD) for in-feed products used therapeutically or a prescription for in-water products used therapeutically. FDA has proposed a revision to the VFD regulation that incorporated many of the comments received during five regional listening sessions on the GFI #213 and via other routes. The comment period on the proposed VFD revision has closed and FDA is considering the comments received. However, USDA and FDA work together closely to identify and mitigate emerging threats to America's food supply. USDA has collaborated and provided recommendations to FDA on these guidance documents. Perhaps most importantly, the FDA relies on the science-based information that USDA generates about antibiotic drug use, AMR patterns, and livestock and poultry management practices to inform its policy and regulatory decisions. FDA also taps into USDA's extensive network of collaborative relationships with producers and animal agriculture industry organizations as part of its outreach.

¹The terms *antimicrobial drug* and *antibiotic* are used interchangeably; however, antimicrobial drugs are a broader category since they have activity against more than just bacteria and include synthetic medications such as sulfonamides.

ATTACHMENT 1

Summary of the Antimicrobial Resistance Issue and Activities for the Secretary's Advisory Committee on Animal Health—June 2014

Even though the United States Department of Agriculture (USDA) is not the lead regulatory agency with respect to antibiotic use and AMR, USDA is an important part of the solution to address this challenge. For nearly two decades, the USDA has conducted surveillance, basic and applied research, and education and outreach to assess levels of AMR, develop effective mitigation strategies for AMR, and assist animal producers to implement these strategies. USDA activities have made important contributions to understanding the role of animal production in AMR and to reducing its development and spread.

Current USDA AMR activities include:

- National Animal Health Monitoring System (NAHMS) commodity studies gather information about general farm policy and management practices related to reasons for use, antimicrobial class, and delivery route.
- Agricultural Resource Management Survey (ARMS) is an annual farm-level survey that focuses on farm finances, but includes detailed questions aimed at commercial producers of certain livestock species on production practices, including antibiotic drug use.
- FSIS sampling in slaughter plants for both the National Antibiotic Resistance Monitoring System (NARMS) and the *Salmonella* Pathogen Reduction: Hazard Analysis and Critical Control Points (PR/HACCP) verification sampling.
- Intra- and extramural research to generate science-based data about antimicrobial use, mechanisms of antimicrobial resistance, and mitigations to reduce AMR in food-producing animals and their environments (including alternatives to antibiotics).
- Education and outreach activities on the judicious use of antimicrobials.

However, considerable work remains, and there is a growing sense of urgency to address this problem.

Engaging stakeholders

In May 2012, USDA sponsored a workshop² with stakeholders, Federal partners, and USDA agency staff to review current antibiotic use and resistance monitoring, management practices to reduce antibiotic resistance, and alternatives to the use of antibiotics to treat and prevent diseases or to enhance production in food-producing animals. This workshop identified important knowledge and data gaps, and participants encouraged USDA to develop an integrated, strategic plan to address them.

Input from that workshop serves as the foundation for a draft USDA AMR action plan that has been developed over the past year. The action plan was jointly constructed by a broad group of USDA agencies. This plan and the potential activities have not been shared with stakeholders.

Proposed USDA activities include:

- Enhanced and expanded survey questionnaires, longitudinal studies, and development of improved methods and tools to measure antimicrobial drug use and related production practices by livestock and poultry producers.

² Documents from this workshop can be found online at:
www.ars.usda.gov/research/programs/programs.htm?np_code=103&docid=17547.

ATTACHMENT 1

Summary of the Antimicrobial Resistance Issue and Activities for the Secretary's Advisory Committee on Animal Health—June 2014

- Ongoing biological sampling at various points and locations from the farm through the slaughter plant, harmonized antibiotic susceptibility testing procedures, and targeted on-farm and in-plant sampling to supplement National Animal Health Monitoring System (NAHMS) studies and case investigations will enhance our understanding of the patterns of antibiotic drug susceptibilities for selected bacterial organisms.
- New initiatives aimed at funding multi-institutional/multiagency projects that integrate research, education, and extension.
- Research and discovery to develop innovative antimicrobials that provide alternatives to conventional antibiotics and that are refractory to resistance development.
- Education and outreach programs for various audiences including veterinarians, producers, extension agents, academia, the media and the lay public.

All of the activities in the USDA AMR Action Plan are based on voluntary participation by producers. Although plan was based on input received from stakeholders during the 2012 workshop, the recent development of the plan to date has been internal to USDA. Given the voluntary nature of the efforts extensive outreach is needed to ensure collaborative efforts with stakeholders in developing practical, effective, and efficient solutions to the surveillance, research and stewardship plans.

Committee deliberations

The USDA requests that the Committee:

1. Provide feedback on the current and proposed USDA activities that address AMR.
2. Identify how USDA could best collaborate with their constituent industries to supplement and sustain these activities; and
3. Recommend actions USDA could take to promote acceptance and support among State and industry stakeholders for USDA activities related to the AMR issue.

Emergency Preparedness Summary

FMD Vaccine

APHIS has publicly stated in the “FMD Response Plan: The Red Book” that all response strategies—including those with emergency vaccination—would be considered in a foot-and-mouth disease (FMD) outbreak. This is a significant and necessary change in FMD response policy based on the magnitude and speed of animal agriculture in the United States. For many reasons (including public acceptance, depopulation capacities, and disposal capabilities) stamping-out is no longer a viable option as an exclusive response strategy for anything beyond a very small, focal outbreak.

The North American Foot and Mouth Vaccine Bank (NAFMDVB) was developed by the United States, Canada, and Mexico in 1982 as a capability to conduct a small vaccination to kill campaign. APHIS’ move to a broader FMD response strategy stance raises questions about whether the NAFMDVB is adequate to support a broader response strategy, among them:

- How should APHIS and its stakeholders modernize FMD vaccine capabilities?
- What should be the minimum quantities of vaccine available, and minimum time to delivery, to provide effective response?
- Can there be cost sharing or public private partnerships to modernize FMD vaccine capabilities?

Continuity of Business

Quarantine and movement control are essential to stop the spread of an animal disease. However, these activities are also likely to significantly disrupt typical business operations involving intrastate and interstate trade as well as international commerce. In some cases, quarantines and movement controls can cause more economic damage than the disease outbreak itself.

Recently, much work has focused on continuity of business, also known as managed movement. Plans such as the Secure Food Supply Plans are designed to manage the movement of non-infected animals and non-contaminated animal products from non-infected premises in a foreign animal disease outbreak. This managed movement helps animal agriculture maintain or return to normal business while minimizing the risk of disease spread through careful permitting, detailed biosecurity, and other guidance. This science and risk-based approach therefore minimizes the unintended negative effects of the disease on producers not directly affected by the outbreak.

Continuity of business planning is a complex and multidisciplinary effort. The Secure Food Supply Plans are developed through a public-private-academic partnership, which includes Veterinary Services, industry, and academic centers. Many plans offer specific guidance on permitting, but there is not a clear path to implementation, or ensuring that these plans can be executed in a disease outbreak. This leads to the following questions:

- How should these plans be evaluated before an outbreak?
- How should these plans be “accepted” or adopted by States before an outbreak?
- Should plans be implemented by Memorandums of Understanding between States? Through rulemaking? Or should other processes be used?

Animal Disease Traceability (ADT) Overview

May 2014

Background

Preventing and controlling animal disease is the cornerstone of protecting American animal agriculture. While ranchers and farmers work hard to protect their animals and their livelihoods, there is never a guarantee that their animals will be spared from disease. To support their efforts, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) has promulgated regulations to prevent, control, and eradicate disease. Traceability does not prevent disease, but knowing where diseased and at-risk animals are, where they have been, and when, is indispensable in emergency response and in maintaining disease control and eradication programs.

We have clear indications that higher levels of official identification enhance tracing capability. For example, through the National Scrapie Eradication Program, 92 percent of cull breeding sheep are officially identified at slaughter, primarily using flock identification eartags. In fiscal year 2010, this level of official identification made it possible to achieve traceback from slaughter of scrapie-positive sheep to the flock of origin or birth as part of the scrapie surveillance program 96 percent of the time, typically in a matter of minutes. Other diseases, particularly contagious ones, require that we trace to more than the birth premises. We must search premises where the animal has been after leaving the birth premises but before going to slaughter. This means the scrapie model is not a complete solution for such diseases.

APHIS believes we must improve our tracing capabilities to not only address current concerns, including the increasing number of cases of bovine tuberculosis, but also to respond to new or foreign animal diseases in the future.

On August 11, 2011, APHIS published in the Federal Register (76 FR 50082– 50110, Docket No. APHIS–2009–0091) a proposal to amend its regulations. The proposal set minimum national official identification and documentation requirements for the traceability of livestock moving interstate. The final rule was published on January 9, 2013. The regulations set forth in the rule (now at title 9, *Code of Federal Regulations* (9 CFR) part 86) establish a system that promotes APHIS' ability to trace animals back from slaughter and forward from premises where animals are officially identified. The regulations also help in tracing animals' interstate movements.

The new regulations establish USDA's Animal Disease Traceability (ADT) program and supplement existing regulations in 9 CFR subchapter C containing requirements for the interstate movement of livestock to prevent the dissemination of diseases of livestock within the United States. While APHIS focuses on interstate movements of livestock, States and Tribal Nations remain responsible for the traceability of livestock within their jurisdictions.

Animal Disease Traceability Framework

USDA's ADT program is a coordinated approach to the mandatory identification of animals moving interstate. This approach embraces the strengths and expertise of States, Tribes, and

producers and empowers them to find and use the most effective traceability approaches to identify animals moving interstate nationally. Moreover, this approach builds on the successful use of identification methods in APHIS' disease eradication programs; these have significantly boosted traceability. Our refocused approach builds on the fundamental identification requirements of those programs by reestablishing the use of basic, cost-effective identification methods widely accepted by producers. Specifically, APHIS has established traceability regulations for the interstate movement of farm-raised livestock and poultry. Cattle are the priority because of the void in traceability in that sector.

Fundamentals of Animal Disease Traceability Regulation

The regulations at 9 CFR part 86 establish minimum national official identification and documentation requirements for the traceability of livestock moving interstate. The species covered in the rule include cattle and bison, sheep and goats, swine, horses and other equines, captive cervids (e.g., deer and elk), and poultry. The covered animals moved interstate, unless otherwise exempt, would have to be officially identified and accompanied by an interstate certificate of veterinary inspection (ICVI) or other movement document. The requirements do not apply to livestock moving:

- Entirely within Tribal land that straddles a State line and the Tribe has a separate traceability system from the States in which its lands are located; or
- To a custom slaughter facility in accordance with Federal and State regulations for preparation of meat.

Other exemptions are applied on a species-specific basis.

Official Identification and Interstate Movement Documentation

Livestock moved interstate, unless otherwise exempt, must be officially identified and have an ICVI or other documentation.

- Official Identification

Official identification methods are defined by species in the traceability regulation. Official ear tags serve as a common method of official identification for several species, including cattle. Additional materials explaining official identification methods by species are available on the ADT Web site.



- Interstate Certificates of Veterinary Inspection

ADT relies on interstate movement documents to provide

COMMONWEALTH OF VIRGINIA Virginia Department of Agriculture and Consumer Services Division of Animal and Food Inspection Services 100 Governor Charles S. Price, Jr. Building Richmond, Virginia 23219 Telephone: (804) 699-2200		CERTIFICATE OF VETERINARY INSPECTION For Use Only In Shipping Domestic Livestock and Poultry Certificate Valid After 90 Days Current Import Requirements Can Be Obtained From the State of Destination		CERTIFICATE NUMBER Page _____ of _____ Pages Date of Shipment _____ Entry Permit Number _____	
Point of Origin - Name & Address (DTI Address or Prem. ID Required) State _____ City _____ State _____ Zip _____ Premises Identification Number (PIN) _____ Companion - Name & Address (if Different Than Point of Origin) State _____ City _____ State _____ Zip _____		Destination - Name & Address (DTI Address or Prem. ID Required) State _____ City _____ State _____ Zip _____ Premises Identification Number (PIN) _____ Companion - Name & Address (if Different Than Point of Origin) State _____ City _____ State _____ Zip _____		Rec./Originator - Name & Address (DTI Address or Prem. ID Required) State _____ City _____ State _____ Zip _____ Premises Identification Number (PIN) _____ Veterinarian Name _____ Phone # _____ Signature _____	
<input type="checkbox"/> Cattle <input type="checkbox"/> Equine <input type="checkbox"/> Sheep <input type="checkbox"/> Swine <input type="checkbox"/> Other (One Species Per Certificate)		<input type="checkbox"/> Accredited Prem. <input type="checkbox"/> Free <input type="checkbox"/> Quarantined Prem. <input type="checkbox"/> Other <input type="checkbox"/> Broadhead <input type="checkbox"/> Other PIN: _____ Program: _____ Other: _____		<input type="checkbox"/> Breeding <input type="checkbox"/> Show <input type="checkbox"/> Feeding <input type="checkbox"/> Sale <input type="checkbox"/> Slaughter <input type="checkbox"/> Butchery <input type="checkbox"/> Other Carrier: <input type="checkbox"/> Truck <input type="checkbox"/> Other Carrier Name: _____ Phone #: _____	
Species: _____ State / Area Status: _____ Herd Status: _____ Date: _____ Purpose of Movement: _____ Statement / Comments: _____		Vaccination: _____ TB Injection: _____ Date: _____ Negative Cattle: _____ Date: _____ Lab. Accr. Number: _____ Lab. Stamp: _____ Other: _____ Other: _____ Other: _____		Physical Description/Markings: _____ Other: _____ Other: _____ Other: _____	
<input type="checkbox"/> Owner <input type="checkbox"/> Agent CERTIFICATION: The animals in this shipment are those certified to and listed on this certificate. Name: _____ Date: _____ Address: _____ Phone #: _____ Signature: _____		Veterinarian Certification: I certify, as an accredited veterinarian, that the identified animals listed on this certificate have been inspected by me and that they are not manifesting signs of infectious, contagious, or communicable disease. The vaccination, treatment, and results of tests are indicated on this certificate. To the best of my knowledge, the animals listed on this certificate meet the health requirements of the state of destination and federal interstate regulations. Printed Name: _____ Address: _____ Phone #: _____ Signature: _____		Warning: It is a felony to forge a public record, certificate, or attestation, or to utter a forged public record, certificate, or attestation.	

information on the ship-from and ship-to locations. While ICVIs are not actual reports of animal movements, the information contained on the certificates highly correlates to the resulting movements for the listed animals and is used in ADT to indicate likely interstate movements. Using ICVIs this way provides animal movement information that producers would otherwise need to report.

While use of the ICVI is one of the traceability regulation requirements for livestock moved interstate, certain interstate movements are exempt from the ICVI requirement. Also, shipping and receiving States and Tribes may agree on other movement documents. The ICVI requirements are covered in APHIS' ADT reference material by species.

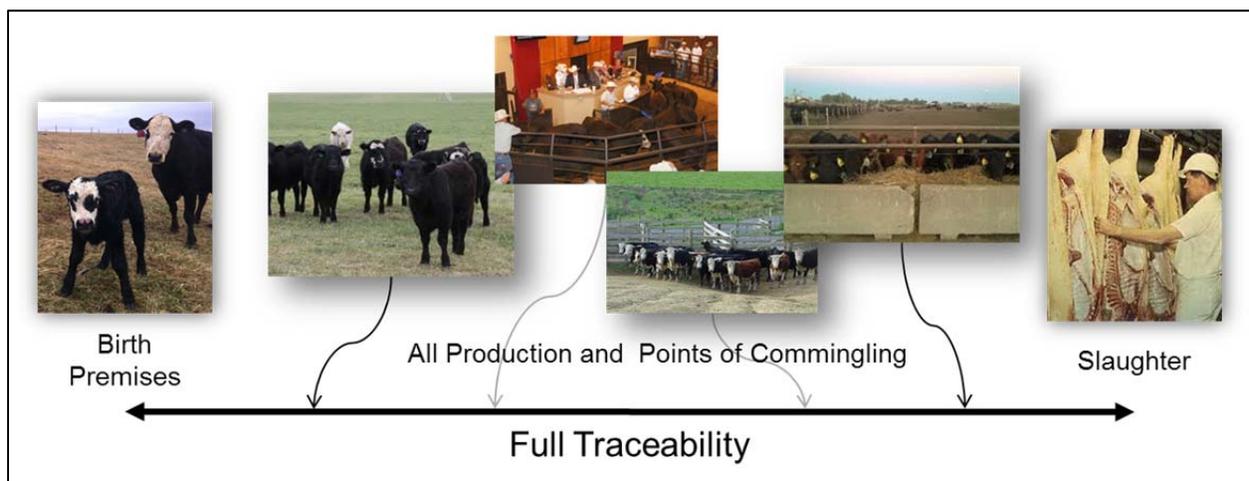
Accredited veterinarians have ultimate responsibility for the proper completion and administration of ICVIs. The requirements regarding the information that must be contained on the ICVI and the administration of the certificates are covered in 9 CFR part 86.

Comparison of Traceability Systems

- Full Traceability

A full traceability system through the preharvest sector traces an animal throughout its life from birth to harvest, through all locations. Many countries with a national identification system have full traceability systems. This includes Canada, Australia, and many European countries. Our former proposed animal traceability system – the National Animal Identification System, or NAIS – included the concepts of full traceability. APHIS tried to implement it as a voluntary program, but received little support. We also learned that the U.S. livestock industry was not ready for a system as elaborate as the one proposed under NAIS, mostly due to the system's cost and overall burden.

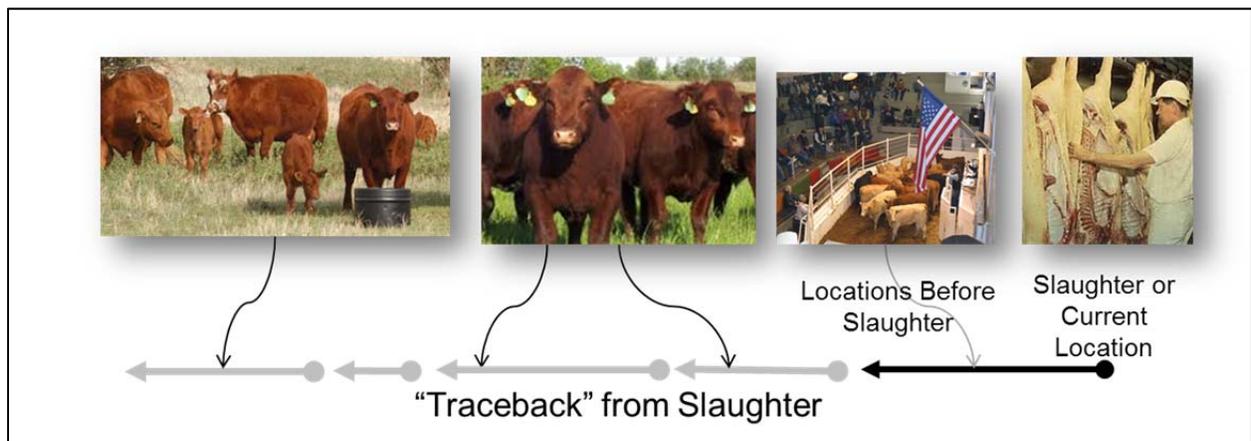
Full Traceability (Preharvest)



- U.S. Traceability without ADT

As we know, APHIS' tracing capability before ADT was inadequate. Without official identification, as was often the case, we used the animal's backtag to trace back from the slaughter plant or last premises where an infected animal resided. Often the traceback led to a market, where the backtag was referenced to the consignor of the animal. The backtag has provided valuable traceability information and will continue to be a vital identification method in ADT. State and Federal epidemiologists continue to work back through farm records to reach the animal's birth premises. As indicated previously, tracing back to the birth premises without ADT can be very time-consuming as frequently there is no official ID. Traces often take 6 months or more. APHIS hopes that will change with the implementation of ADT.

U.S. Traceability without ADT

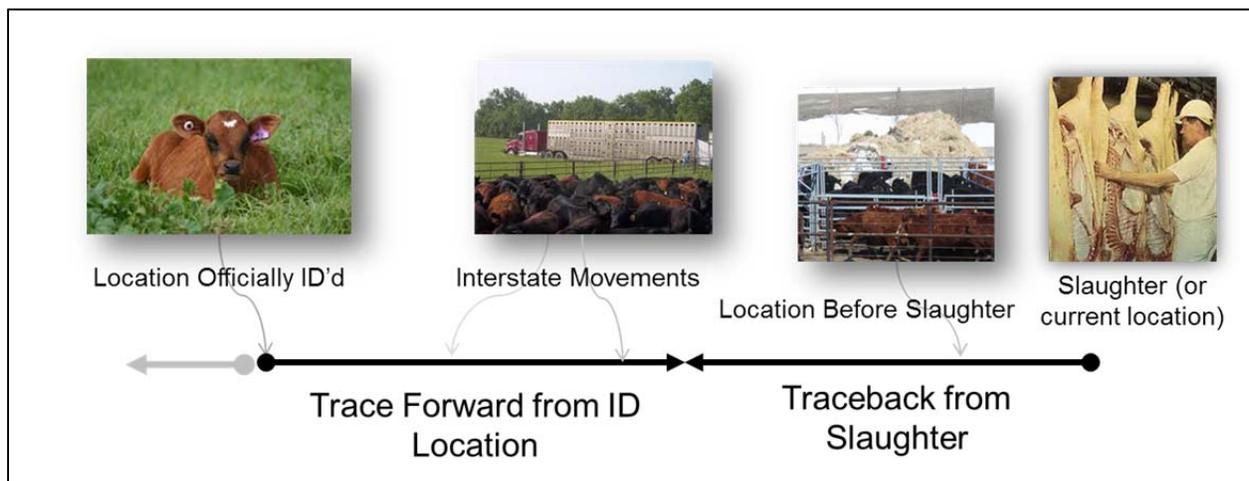


- ADT – Bookend-plus System

Over time, the number of animals officially identified will increase significantly as a result of ADT. This is of particular interest and significant merit in the cattle sector. Under ADT APHIS will continue to initiate a traceback from the slaughter plant or the animal’s current premises. But we will also have the ability to trace forward from the premises at which the animal was officially identified. This is a significant improvement! If ADT is implemented properly, we will often be able to determine this premises within minutes and then start tracing the animal forward from that point. Tracing the animal back from slaughter and forward from the premises of official ID – in a “bookend”-style system – will cut the amount of time required to trace the animal. A true bookend system would only have the start and end points, but APHIS supplements this traceability with information on the animal’s interstate movements. Hence, we reference our approach as a “bookend-plus” system.

This very basic solution advances the anticipated level of traceability. Also, being able to consistently determine where an animal’s location was officially identified has a great return on investment. But this infrastructure has limitations that must be kept in mind. Our trading partners realize our system does not provide full traceability and that a significant sector of the cattle population is exempt from the traceability rule requirements. When APHIS discusses traceability with its trading partners, it will continue to promote the system as adequate based on disease risk. We acknowledge that our trading partners view our system as inferior to those of other countries; industry stakeholders should also realize this. However, we can minimize the concern of our trading partners by successfully implementing ADT. Most importantly, industry will be more inclined to support more comprehensive traceability options if the “bookend” aspect of ADT is launched successfully.

ADT- Bookend-plus System



Monitoring and Compliance

On March 4, 2014, APHIS Administrator Kevin Shea issued a stakeholder announcing the next phase of implementing ADT. While he empathized that APHIS will continue to inform

ATTACHMENT 3

stakeholders of the regulatory requirements of the new regulation, penalties will be considered when an individual repeatedly violates the traceability regulation. Keys to advancing traceability include the proper use of official identification and ICVIs and the collection of ID at slaughter; these areas will receive enforcement priority.

More specific information on the monitoring and enforcement aspects is on the traceability Web site.

Animal Disease Traceability Reference Materials

APHIS provides various reference materials on the traceability regulation and its requirements at <http://www.aphis.usda.gov/traceability/>. Please check this Web site for the most current information.

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Questions:

Are there specific areas of the ADT (overall framework and regulations) that industry finds problematic that USDA could work to improve?

Are there aspects of traceability that USDA should consider in the future for certain species?

What aspects of our traceability system need to be evaluated to ensure U.S. meet the future demands of trading partners?

ATTACHMENT 4

Summary of the U.S.-Canada Foreign Animal Disease (FAD) Zoning Initiative for the Secretary's Advisory Committee on Animal Health—June 2014

Introduction

The U.S. Department of Agriculture (USDA) is asking the Secretary's Advisory Committee on Animal Health to deliberate on the U.S.-Canada FAD Zoning Initiative and the *Framework for Implementing and Maintaining the Arrangement between the CFIA and the USDA for the Recognition of Foreign Animal Disease Control and Eradication Zones* (hereafter Framework; attached).

Background

An FAD outbreak in either the United States or Canada could cause major economic losses as a result of both the disease control measures applied and the loss of trade across the common border. Representatives of USDA's Animal and Plant Health Inspection Service (APHIS) and the Canadian Food Inspection Service (CFIA) met in 2007 to discuss zoning for control of FAD outbreaks and the potential for trade to continue or resume quickly from disease-free zones. Both countries have historically recognized each other's zoning decisions for outbreaks of highly pathogenic avian influenza and vesicular stomatitis, but no formal mechanisms exist to ensure that this type of recognition occurs.

As a first step towards developing such mechanisms, APHIS and CFIA evaluated each other's ability to control and eradicate an FAD outbreak through zoning and ensure the sanitary safety of animals and animal products outside of a control zone (evaluations available upon request). The evaluations concluded that each country has sufficient resources and technical capability to establish and maintain an effective control zone in the event of a limited FAD outbreak. For the purposes of international trade, each agency would be able to provide accurate and valid certification that animals and animal products originate from a disease-free zone.

While the evaluations were ongoing, the project became an initiative under the U.S.-Canada Regulatory Cooperation Council (RCC), a high-level program intended to increase regulatory transparency and coordination across the border. There are two action items on the RCC FAD Zoning Initiative workplan:

1. An arrangement for mutual recognition of zoning decisions in the event of an FAD outbreak; and
2. A guidance framework to implement and maintain the zoning arrangement.

Based on the reciprocal evaluations, the United States and Canada entered into an Arrangement in October 2012 to facilitate recognition of each other's zoning decisions if an FAD outbreak occurred.¹ The Arrangement establishes the intent and basic parameters for trade between areas that remain free of an FAD, while safeguarding animal health. For example, the affected country must ensure movement standstill as appropriate, adopt a stamping-out or other effective FAD control strategy, and provide a written description of the control zone and response measures to the other country. The Arrangement also directs APHIS and CFIA to develop a framework to provide guidance on implementation.

Guidance Framework

¹ *Arrangement between the Canadian Food Inspection Agency and the United States Department of Agriculture for the Recognition of Foreign Animal Disease Control and Eradication Zones.*

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Summary of the U.S.-Canada Foreign Animal Disease (FAD) Zoning Initiative for the Secretary's Advisory Committee on Animal Health—June 2014

APHIS and CFIA convened a working group to develop the framework which consisted of subject matter experts in regionalization (zoning), emergency response, and import/export. The Framework was published in the *Federal Register* for public comment on May 13, 2014. It is restricted in scope to highly contagious FAD outbreaks in domestic livestock and does not apply to endemic diseases or to aquatic species, pets, wildlife, or laboratory or research animals. The intent is to provide an operational plan for APHIS and CFIA to implement the Arrangement during an outbreak, establish processes for maintaining the Arrangement over time, and outline a strategy to engage stakeholders in developing the resources and strategies to effectively implement the Arrangement.

Part I—Procedures for recognition of zoning decisions

Recognition of zoning decisions under the Arrangement and Framework would occur administratively and does not involve rulemaking. The Chief Veterinary Officer (CVO) of the affected country must notify the partner country of any confirmed highly contagious FAD outbreak. The partner country may initially prohibit or restrict importation of animals and commodities that could transmit the disease agent, while the affected country is establishing a control zone (aka area of control). Once the CVO of the affected country is satisfied that the area of control is effectively established, s/he would provide the information required by the Arrangement to the partner country, invite one or more qualified staff members to embed in the response, and request recognition of the zoning decision for trade purposes.

The CVO of the partner country would either request additional information or accept the zoning decision and allow trade between disease-free zones (outside of the area of control) to continue or resume. The affected country would notify the partner country of any modifications to the boundaries of the area of control during the response period. The partner country would modify import restrictions as appropriate to safeguard animal health in response or as recommended by embedded staff members. All changes to import policies would occur through notices to the border ports.

In rare instances, a widespread, multi-focal, or rapidly-progressing highly contagious FAD outbreak may temporarily overwhelm the resources of affected country and negatively impact its ability to contain the disease agent through zoning. In this case, the CVO of the affected country would contact the partner country to initiate monitoring by embedded staff members, but—following OIE recommendations for a disease containment zone—would not request recognition of an area of control until two incubation periods have elapsed with no new cases have outside of the area of control.

Part II—Maintaining the Arrangement

Maintaining the Arrangement over time requires both a governance structure and ongoing initiatives to foster the credibility of the Arrangement among stakeholders. The Framework outlines an APHIS and CFIA governance structure consisting of a Steering Committee composed of senior-level representatives and a Working Group consisting of staff members with appropriate and complementary professional, technical, or specialist skills. The Steering Committee has primary responsibility for preserving the concept and intent of the Arrangement; the Working Group is responsible for reaching out to other stakeholders to cooperatively develop the resources and strategies necessary to effectively implement the Arrangement during a highly contagious FAD outbreak.

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Summary of the U.S.-Canada Foreign Animal Disease (FAD) Zoning Initiative for the Secretary's Advisory Committee on Animal Health—June 2014

Projects are specific activities, plans, or tasks led by the Working Group to foster credibility and facilitate implementation of the Arrangement. Examples include bilateral participation in cross-border FAD exercises that include zoning recognition and joint participation of technical specialists in training on FAD response. The Working Group would identify projects in consultation with other stakeholders, taking into account existing venues and opportunities.

Part III—Promoting stakeholder awareness and involvement

Stakeholder engagement is essential to realizing the intent and purpose of the Arrangement. Re-opening trade between disease-free zones during a highly-contagious FAD outbreak will require the support of Federal, State, Provincial, and industry stakeholders. Objections from any of these entities may create delays and/or obstacles to resumption of trade, thereby compounding economic losses.

Under the Framework, APHIS and CFIA would formally solicit feedback at least once per year on existing Working Group projects and priorities, and also solicit proposals for additional projects. The Working Group intends to promote stakeholder engagement through periodic webinars, conference calls, and updates at established forums such as national and regional U.S. Animal Health Association meetings.

Committee deliberations

The USDA requests that the Committee deliberate on the U.S.-Canada FAD Zoning Initiative and Framework document in order to:

1. Provide feedback on the strengths, weaknesses, value, and feasibility;
2. Identify potential issues or points of controversy among their constituent industries and advise on how to address;
3. Recommend actions USDA could take to promote acceptance and support among State and industry stakeholders; and
4. Recommend projects and priorities under the Framework for 2014-2015, focusing on tie-ins with existing venues and planned events.