

Agency Responses

Secretary's Advisory Committee on Animal Health Recommendations

Foot-and-Mouth Disease Preparedness

SACAH Recommendation #1: The Committee supports the procurement of a fully functional FMD antigen vaccine bank but does not support the use of private or matching funds for procuring the FMD vaccine bank. While an uncontrolled FMD outbreak would be devastating to producers, the impacts would be felt across the entire U.S. economy. The vaccine bank is a public good and it should be paid for by public funds.

SACAH Recommendation #2: The Department asked the Committee to consider whether or not the USDA should contract for the procurement of a fully functional FMD vaccine bank. The Committee favors this approach. The additional flexibility of a contract vaccine bank would allow it to be more functional and lower cost than owned and managed by USDA.

SACAH Recommendation #3: Committee members reiterated their support for all of the recommendations previously submitted to the Secretary in its March 2015 report.

AGENCY RESPONSES

The United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the recommendations of the Secretary's Committee on Animal Health and appreciates the opportunity to respond.

Agency Response to SACAH Recommendation # 1: With regard to the Committee's first recommendation, VS notes that the APHIS Administrator has given clear direction that VS needs to continue exploring public-private partnerships for expanding the FMD Vaccine Bank. VS is working to follow this direction.

Agency Response to SACAH Recommendation #2: With regard to the Committee's second recommendation, APHIS is beginning to implement changes to the North American Foot and Mouth Disease Vaccine Bank (NAFMDVB) with respect to vaccine antigen concentrate procurement, storage, length of service, and buy back that substantially meets the recommendations to modernize the NAFMDVB.

VS respectfully asks the committee for further discussion and definition regarding its recommendation to implement further reliance on "contracting out" the FMD vaccine bank. Contracting out the role of government would lead back to a public – private partnership and cost sharing with the industry, depending on the scope the Committee intends.

Agency Response to SACAH Recommendation #3: VS thanks the Committee for its ongoing interest in working with APHIS on foreign animal disease issues, and is continuing to study the Committee's earlier recommendations.

Background

- 1,000,000 swine are in transit daily in the United States with 400,000 to 500,000 destined for slaughter.
- An additional 400,000 cattle are also in transit per day, with an unknown number of susceptible livestock (sheep, goats, and others) being exhibited or sold at markets or fairs.
- U.S. beef, dairy, and pork exports have grown dramatically in the past decade with beef valued at \$6.2 billion, dairy at \$6.7 billion, and pork at \$6 billion.
- An outbreak of FMD in the U.S. would undoubtedly put an immediate halt to most interstate livestock movement and export markets would immediately react in an unfavorable manner. A study published by Oladosu, Rose, and Lee in 2013 estimated the economic impact of an FMD outbreak linked to an act of bioterrorism to be \$37- 228 billion.

It was further related that, in all likelihood, a widespread or catastrophic FMD outbreak would necessitate the use of FMD vaccination, either through a stamping-out strategy (modified with emergency vaccination) or a vaccinate-to-live strategy without stamping out. In order for the U.S. to be able to respond quickly and effectively to an FMD incursion and to protect the \$100 billion a year animal industry, Dr. Roth recommends the procurement of 31 million doses of each of the 17 FMD strains deemed to be highest risk to the U.S. (or approximately 530 million doses).

To provide the Committee a concrete scenario, APHIS used the swine and cattle populations of Iowa and Texas as examples. Iowa's swine population is around 20 million animals. The current capacity of the North American Foot and Mouth Disease Vaccine Bank (NAFMDVB) would only enable us to vaccinate 2.5 million (13%) of those animals. With a Texas cattle population of 10.9 million, current NAFMDVB capacity would allow the immediate vaccination of only 22% of those animals.

One estimate to expand the country's FMD vaccine capability to full capacity would cost approximately \$150 million per year for five years and \$70 million per year to maintain.

The Committee discussed the pros and cons of voluntary and non-voluntary check-offs as well as the possibility of user fees to partially fund the project. The Committee opposed all of these approaches and favors Congressional and/or Department action to fund this project.

Swine Enteric Corona Disease (SECD)

The Committee recommends Veterinary Services take the following actions related to SECD.

SACAH Recommendation #1: Improve the reporting mechanisms so that duplicate reporting to APHIS and SAHO are not required, streamline the disease reporting officer process, and clarify Federal reporting requirements for emerging diseases, such as SECD.

SACAH Recommendation #2: Encourage continued adoption of processes for electronic messaging between laboratories, including PIN and premises type, on laboratory submission reports.

SACAH Recommendation #3: NAHLN laboratories should deploy standard tests that perform consistently between laboratories. Testing protocols should be communicated across laboratories, and with stakeholders, so that results generated by any of the NAHLN laboratories can be considered equivalent to results from the other NAHLN laboratories.

SACAH Recommendation #4: Support the Federal-State-Industry PED Strategic Task force. The committee supports the continuation of the task force and supports the recommendations determined by these subject-matter experts. The task force should determine the timeline for, and industry interests in, future plans for addressing SECD (control vs. eradication).

SACAH Recommendation #5: Support for APHIS to continue funding for SECD testing until the task force determines goals (control vs. eradication). Encourage additional epidemiological analysis of the information collected to date, and the ability to use that data in the case of potential control programs.

SACAH Recommendation #6: Consider if feral swine are potential reservoirs for SECD and determine what risk that may have for the domestic herd.

AGENCY RESPONSES

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) appreciates the Committee recommendation and the opportunity to provide an update on the current thinking and actions related to these topics.

Agency Response to SACAH Recommendation # 1:

VS currently has guidelines related to responding to an emerging disease; i.e., VS Guidance 12001.1 “Policy for the Investigation of Potential Foreign Animal Diseases/Emerging Disease Incidents (FAD/EDI).” This guidance standardizes investigation response and communication. Dual reporting, generally no more onerous than a second phone call, assures that both Federal and State governments are informed simultaneously and assures their ability to initiate rapid and coordinated response activities critical to successfully controlling high-impact diseases.

The disease reporting officer process was designed to reach back to veterinarians and producers to characterize the severity of the disease, gather limited epidemiology data, and confirm positive laboratory results. The utility of the data for studies and future disease management depends not only on timeliness, but also on the completeness of information. APHIS welcomes further discussion and collaboration with industry groups to more efficiently achieve these goals.

In 2015, APHIS formed a joint working group composed of members from the National Animal Health Laboratory Network (NAHLN) Coordinating Council and National Animal Health Reporting System Steering Committee to help develop implementation details for a National List of Reportable Diseases (NLRAD). The working group broadly represents stakeholders from the American Association of Veterinary Diagnostic Laboratories, State animal health officials, and industry groups as well as VS business units. The group members provide input to VS for clarifying specific requirements for reporting and managing emerging diseases as well as case definitions. Input from the group members and public comments on an NLRAD white paper published in 2014 will be compiled and available in 2016.

Agency Response to SACAH Recommendation # 2:

VS also values the practice of producers sharing premises IDs (PINs) and premises types with laboratories and subsequently enabling the data to electronically transfer from the laboratory to the appropriate VS data systems. The PIN and premises type information is used for a number of purposes, including general high-level reporting, in depth epidemiological analyses, and accounting and laboratory reimbursement for testing. Further, VS continues to prioritize electronic messaging of laboratory data for a number of diseases. Currently all of the major NAHLN swine laboratories are messaging SECD results to VS. These six laboratories account for 70 percent of the overall SECD testing in U.S. NAHLN labs. The SECD progress for implementing electronic messaging of laboratory results and the importance of including PINs has also enhanced VS' response and preparedness for the HPAI outbreak.

Agency Response to SACAH Recommendation # 3:

The NAHLN uses standardized testing protocols across the network to ensure consistency between laboratories for regulatory disease and VS disease programs. As SECD was neither a regulatory disease nor a program disease, and the testing had been handled in the NAHLN laboratories in the same manner as other production diseases for many months prior to USDA involvement, it was not practical to introduce new protocols once the Federal Order was issued. However, in June 2014, the NAHLN laboratories conducting the majority of the SECD testing shared their PCR protocols and validation data with the National Veterinary Services Laboratories (NVSL) and participated in an equivalency test using their protocols. Based on the results of the equivalency test, the Diagnostic Virology Laboratory at the NVSL was confident the laboratory protocols were comparable and would achieve similar results in detecting the SECD agents. NAHLN laboratories that later added SECD testing were referred to the NAHLN laboratories that participated in the 2014 equivalency test and the NVSL, which were all quite willing to share the SECD PCR protocols.

Agency Response to SACAH Recommendation #4:

APHIS welcomes input from all stakeholders, including the PED Strategic Task Force, and will continue to participate with this group. The task force represents an important stakeholder channel for APHIS to receive input on industry needs and interests as well as

providing valued subject matter expertise on SECD. APHIS has and will continue to give priority consideration for recommendations from the task force for any future plans for addressing SECD, and appreciates the opportunity to discuss related issues with the veterinarians and producers of the group.

Agency Response to SACAH Recommendation #5:

APHIS currently supports SECD testing through emergency funding, but does not have money to support continued diagnostic testing once emergency funds are expended. On January 4, APHIS issued an updated Federal Order related to SECD. Based on this Federal Order, APHIS has reprioritized its needs and will focus all remaining 2014 emergency funds for SECD towards diagnostic testing. With this modification, the money should cover diagnostic testing through the 2015-2016 winter season.

APHIS encourages and supports discussion on possible options, including focused epidemiological studies with the SECD Task Force as well as other swine industry stakeholders to develop appropriate strategies to control what has now become an endemic disease.

Agency Response to SACAH Recommendation #6:

APHIS agrees that research into the potential for feral swine to serve as a reservoir for SECD viruses could be useful to an eradication program; however, it would not preclude the initiation and progression of a disease control or eradication program. For example, pseudorabies remains a common virus in feral swine but has been eliminated in the U.S. commercial swine population through strict biosecurity and exclusionary measures. Currently, SECD is endemic in the domestic herd and lateral spread from affected farms presents the greatest risk to uninfected herds. Nonetheless, APHIS encourages further dialogue with the swine industry regarding potential control activities as well as risk assessments and research studies that might further the goal of eliminating the disease.

Background

The USDA issued a Federal Order in April of 2014 that required reporting of all cases, while providing funding for diagnostics and biosecurity. The committee was given a summary of the program—including an overview of cases identified to date—and introduced to the reports issued by USDA on a weekly basis. USDA asked for input from the committee in three areas.

1. Provide feedback on the value of the federal mandatory reporting requirements and the information that is shared with the stakeholders from the data collected.
 - a. The State Animal Health Official is an important stakeholder and decision maker, and it is important that information flows back to the SAHO in real time without having to have the labs and/or veterinarians report to both the state and federal authorities.
 - b. The goal of collecting and reporting this data should be to conduct epidemiological studies to assess spread of the virus and identify risk factors.

It is uncertain if the information collected is being utilized for epidemiological purposes, and if not, why not.

- c. Value of the data to help make pig movement decisions is minimal. While there is value in maintaining producer confidentiality, statewide reporting does not provide enough information.
 - d. The Herd Management plan, and the Disease Reporting Officer follow up, seem to be providing very little useful information while using resources.
 - e. Questions were raised on the value of collecting premises identification numbers if there was no traceback or monitoring of animal movements.
2. Provide feedback on the value of the USDA support of diagnostic testing for SECD.
 - a. Requiring the premises identification number on diagnostic submission forms has the potential to provide real value if epidemiology studies are to be conducted.
 - b. Concerns were raised that early in the outbreak NAHLN laboratories were running a variety of diagnostic tests providing inconsistent results from lab to lab. Examples of samples being split and sent to multiple labs, and receiving different results, were given.
 - c. Funding for diagnostic testing was well received, allowed for more testing than would have been done otherwise. With the increased testing, it became easier to evaluate various strategies for attempting to clear a premises.
 - d. Because there was such a large amount of testing, it encouraged the laboratories and APHIS to move to electronic messaging. Only a handful of laboratories are able to send messages electronically, and it has taken many months for them to be able to do so. However, it appears that getting messaging for SECD functioning may have made HPAI messaging easier to implement.
 3. Provide guidance on the future of the SECD control and the role of USDA in these efforts.
 - a. The value of such a program should be in epidemiology, tracing disease, understanding risk, and determining if elimination is feasible. These goals should be considered prior to the development of any mandatory reporting program to maximize the value.
 - b. The Rapid Response Teams should serve as a model for future emerging diseases. A standardized format should be developed for their investigations that allows evaluation of risks, traceback, situation analysis, and provides a basis for decision making. This would allow the potential for more real time traceback and epidemiology, rather than looking back retrospectively as is the case for SECD.
 - c. The concerns with EMRS were expressed, it is a one way flow of data into USDA and no routine data is provided back to states or other stakeholders. It

is uncertain if/how EMRS would be utilized if an eradication program were developed.

- d. Concerns were expressed over the ability of APHIS to deal with more than one disease at a time as demonstrated by HPAD and SECD. Additional concerns were raised that in an FAD situation that resources required for response (e.g., depopulation) may prevent adequate epidemiology to be done in the beginning of an outbreak.

National List of Reportable Diseases (NLRAD)

The Committee recommends the following steps to be taken prior to rulemaking for the NLRAD to promote acceptance and support among State and industry stakeholders:

SACAH Recommendation # 1: The Committee recommends USDA establish a process, possibly forming a task force, to develop guidelines and/or criteria for maintaining confidentiality of producer-specific information, analyze in depth potential trade and other impacts from release of reported information, and specify more clearly persons within federal and state regulatory agencies that will be authorized to receive the reports from all sources.

SACAH Recommendation # 2: The Committee recommends USDA specify the process through which diseases and/or conditions are to be added to the list and also through which they can be removed from the list. USDA should also specify the response strategy for each disease listed including if they are actionable and what those actions may be.

SACAH Recommendation #3: The Committee encourages USDA include provisions that allow accredited veterinarians, producers, veterinary diagnostic laboratories, and others to meet their obligations under the NLRAD through a single complete report to either state or federal animal health officials. USDA should commit to immediate completed reporting to the state animal health officials in the state the premises is located.

AGENCY RESPONSES

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) appreciates the opportunity to respond to the feedback provided regarding the NLRAD. VS has already started to outline plans for processes suggested in the three recommendations.

Agency Response to SACAH Recommendation #1:

APHIS has a long track record of treating sensitive producer information with the respect and security it deserves, and will not treat conditions reportable under the NLRAD any differently. A working group has analyzed the scope of confidentiality issues associated with NLRAD reporting requirements and has assessed the applicable legislative authorities for protecting information. The working group noted that the NLRAD proposal consists of two general categories of reportable diseases: Monitored diseases and notifiable diseases and conditions. VS does not maintain producer information

associated with monitored diseases. The only information associated with monitored diseases VS publicly reports is the presence or absence of disease in a given State; this will not change under NLRAD. Reporting of monitored diseases under NLRAD provides the basis for validating U.S. international reporting, and data assists in trade negotiations.

Notifiable diseases and conditions are categorized into three types of incidents: emergency (foreign animal disease, exotic vectors, etc.), regulated disease, and emerging disease. VS already has procedures to manage producer information during emergency and regulated disease incidents (VS Guidance 12001.1 “Policy for the Investigation of Potential Foreign Animal Diseases/Emerging Disease Incidents [FAD/EDI]”). This guidance will apply to the disease incidents reported under NLRAD.

An NLRAD laboratory implementation plan has been drafted; this plan outlines reporting timelines, specific data standards, reporting mechanisms, and parties receiving reports. Additionally, VS is developing processes for information management and analysis, as well as distribution of emerging disease notices to Federal, State, and industry/commodity stakeholders. VS is coordinating the NLRAD with planning for two other VS initiatives: the Framework for Response to Emerging Animal Diseases and a comprehensive information technology strategy for data management and integration.

Agency Response to SACAH Recommendation #2:

The process for addition to, removal from, and approval of the U.S. NLRAD has been addressed in previous related documents. VS is reviewing feedback on the NLRAD recommendation proposal and will use these comments to develop well-defined guidelines for maintaining and editing the U.S. NLRAD.

Response strategies for many of the NLRAD diseases are already outlined. For NLRAD monitored diseases – primarily endemic diseases, of which the majority are World Organisation for Animal Health (OIE)-listed and reportable diseases – usually no Federal regulatory action is associated with identification. Likewise, VS has guidelines related to responding to foreign animal diseases and emerging diseases (VS Guidance 12001.1). As VS makes plans to implement the Framework for Response to Emerging Animal Diseases, it will review VS Guidance 1200.1 to determine if additional guidance for response to emerging diseases is needed.

Agency Response to SACAH Recommendation #3:

The National Animal Health Reporting System (NAHRS) is currently the primary method of reporting U.S. NLRAD monitored diseases. NAHRS reporting is through the individual State animal health official, who has primary responsibility to report the occurrence of U.S. NLRAD listed diseases, including monitored diseases. VS does not expect codification of the NLRAD to change the current NAHRS reporting model for endemic disease or increase the reporting burden. VS realizes the majority of reporting for U.S. NLRAD notifiable diseases will occur through laboratories and accredited veterinarians. Consequently, the NLRAD laboratory implementation plan has outlined

specific data reporting triggers and timelines, reporting mechanisms, and parties receiving reports.

The processes outlined in the implementation plan build on existing communication channels to ensure efficient communication between veterinarians, state animal health officials and federal officials, and veterinary diagnostic laboratories. Additional NLRAD reporting needs (e.g., emerging diseases) have been identified, as well as the need to streamline the reporting mechanisms for all diseases included in the NLRAD. Thus, VS is starting to develop national data standards and an effective reporting mechanism with supporting IT infrastructure to collect, analyze, and report critical animal health data. These efforts will include input from Federal, State, and industry/commodity stakeholders.

Background

SACAH responded to the following requests from APHIS on the NLRD:

1. Provide feedback on the strengths, weaknesses, value, and feasibility:

Creation of a NLRAD could serve as a template to promote standardization between the states that often now each have a list unique to each state. The differences in each state's lists currently pose a problem for veterinarians, veterinary diagnostic laboratories, and others that serve livestock in multiple state jurisdictions and often results in non-compliance with existing requirements. The list would likely help address this issue even if the reporting is not made mandatory at the federal level. Making reporting mandatory federally does allow for analysis of trends that may reveal a foreign or emerging disease that might not be apparent when only viewed state by state. Recent events have added credibility to that potential benefit. Unless the system provides for active two-way communication between the states where the events are located and USDA allows for a single report to either the state or federal regulatory officials to meet both requirements, a second layer or reporting requirements will only make the current reporting maze worse.

2. Provide feedback on key issues such as diseases to include in the NLRAD (see list in concept paper), who should be required to report and to whom, what should be reported, timelines for reporting, triggers for reporting emerging diseases, and the process to determine the appropriate response to an emerging disease:

No specific feedback other than that already included elsewhere in this report in response to these questions after hearing the presentation and reviewing the concept paper.

3. Recommend actions USDA could take to promote acceptance and support among State and industry stakeholders.

Notifiable Avian Influenza

Veterinary Services did not pose any specific questions to SACAH on AI. The Committee, however, chose to offer the following recommendations outlined below.

SACAH Recommendation # 1: Provide veterinary and operational support using APHIS and NAHERC personnel to fully address all needs during the current and future NAI outbreaks.

SACAH Recommendation # 2: Provide adequate financial support for all NAI outbreaks.

SACAH Recommendation # 3: Provide financial and personnel support and work cooperatively with State and Federal wildlife management agencies for expanded NAI surveillance of wild birds.

SACAH Recommendation # 4: Provide financial and personnel support for research in NAI epidemiology, biosecurity interventions, and effective vaccination strategies to mitigate disease introduction and spread.

AGENCY RESPONSES

The U.S. Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the role of the SACAH in protecting animal health in the United States and appreciates the opportunity to respond.

APHIS is committed to providing financial support to all NAI events. Funding for the 2014-2015 highly pathogenic avian influenza outbreak was secured through a Commodity Credit Corporation (CCC) request after available appropriated avian health funding was expended. This funding request insured that over \$800 million in indemnity and response costs could be covered. While avian health funding can fund small indemnity and response needs, further large-scale outbreaks will require another request for emergency funding and approval from the Office of Management and Budget.

The Interagency Steering Committee for Surveillance for Highly Pathogenic Avian Influenza in Wild Birds, consisting of representatives from the Department of the Interior, USDA, Health and Human Services, and the National Flyway Council, developed the “Early Detection and Monitoring for Avian Influenza of Significance in Wild Birds – A U.S. Interagency Strategic Plan”. This plan was finalized in June 2015. We anticipate that, from July 2015 to July 2016, over 40,000 wild bird samples will be collected across the United States and evaluated for the presence of HPAI viruses, and LPAI viruses of interest. As of January 19, 2016, 36,685 samples had been collected with two detections of HPAI although no virus was isolated in either sample. CCC funding is being used to support these efforts. Historically, avian health appropriated funding has supported ongoing HPAI surveillance in birds.

APHIS is committed to supporting analyses, including epidemiological investigations, around animal health events such as the 2014-2015 HPAI outbreak. Analyses produced from this outbreak include “Risk That Poultry Feed Made With Corn Potentially Contaminated with Eurasian-North American Lineage H5N2 HPAI Virus from Wild Migratory Birds – Result in Exposure of Susceptible Commercial Poultry” and three

epidemiologic and other analyses of HPAI-affected poultry flocks conducted in June, July, and September of 2015.

Bovine Tuberculosis

The Committee recommends the following:

SACAH Recommendation # 1: Explore enhance utilization of the Mexico-United States Binational Committee to support tuberculosis eradication efforts.

SACAH Recommendation # 2: Continue supporting the collection of animal isolates to improve and expand the USDA whole genome *M. bovis* sequencing database.

SACAH Recommendation # 3: Work collaboratively with Mexico to encourage additional collection and sharing of isolates, particularly dairy bovine and human cases.

SACAH Recommendation # 4: Continue the monitoring of TB strains from humans-shared agriculture and public health impacts.

SACAH Recommendation # 5: USDA should work with the National Assembly of Animal Health Officials to better engage State Public Health Officials, and should work collaboratively with the Association of State and Territorial Health Officials and Public Health Officials, and potentially with The National Association of County and City Health Officers to enhance understanding and support for collaborative surveillance.

AGENCY RESPONSES

Agency Response to SACAH Recommendation #1:

The United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the recommendations of the Secretary's Committee on Animal Health and appreciates the opportunity to respond. APHIS will evaluate ways to increase the utilization of the binational committee such as increasing emphasis on technology exchange and enhancing research collaborations.

Agency Response to SACAH Recommendation #2:

We recognize this is an important objective. It will remain a priority to sequence isolates recovered in from animals and humans in North America and readily share those sequences with animal and public health officials. APHIS will continue to emphasize the collection and characterization of isolates by whole genome sequencing and are actively pursuing solutions with the Centers for Disease Control and Prevention (CDC) to provide expertise in timely interpreting *M. bovis* outbreaks in humans. We readily share sequences on request by Federal and State officials.

Agency Response to SACAH Recommendation #3:

We recently initiated an APHIS-Mexico agreement to receive granuloma samples from

potential infected dairy cows slaughtered in the Ensenada (Baja California) municipal plant. So far, APHIS has received 153 granulomas which have resulted in over 100 whole genome sequences so far. APHIS plans to continue this agreement in 2016 and receive more cattle granuloma samples from Baja California.

We are also starting a project with the Monterrey regional laboratory in Nuevo Leon to collect 300 granulomas from nonaccredited States/regions. Further, we are working with researchers in Mexico to receive *M. bovis* isolates recovered from humans, and have sequenced nearly 30 isolates.

Agency Response to SACAH Recommendation #4:

We have initiated conversations to sequence or receive sequences from human cases from both the CDC and States. So far, we have commitments to share over 100 isolates recovered from San Diego County. It remains a priority to work with CDC to enhance this collaboration.

Agency Response to SACAH Recommendation #5:

APHIS will keep the National Assembly informed of our progress. We will also accept opportunities to attend meetings with the TB controllers who diagnose and treat patients throughout the United States, especially at the border, so they understand how animal information can inform the epidemiology of *M. bovis* cases.

Background

Mexico Policy and Molecular Epidemiology

In general, there is support for continued advancement of projects and technologies that help illuminate introduction pathways so that actions can be taken to better mitigate the impacts of bovine tuberculosis. There was support for continued advancement and funding for whole genome sequencing and analysis. There was support to continue to develop a genome database that includes isolates from the U.S. and epidemiologically linked countries like Mexico. These isolates should include human cases as well as bovine cases and should be sequenced or otherwise characterized using one method in order to enhance analysis. NVSL was supported as the best entity to be vested with this responsibility. The committee recognized that many suspected human cases do not get adequately cultured and that those that are, go to CDC. However, the State Departments of Public Health may control whether the isolate may be shared outside of CDC. There was general consensus that efforts to work directly with State and Federal human health agencies to stimulate collaboration should be elevated. It was suggested that offering value added information back to public health officials may stimulate continuing cooperation.

Antimicrobial Resistance

Question A

Feedback on USDA's activities that address Antimicrobial Resistance (AMR) and on areas of Departmental investment in infrastructure.

SACAH Recommendation #1: The committee supports the FY 2016 budget request of \$57 million.

SACAH Recommendation #2: An AMR Stakeholder Advisory Group needs to be formed. This will allow vital input and industry involvement in decisions, programs and implementation of ideas.

Questions B and C:

Identify how USDA could best collaborate with industry and other private sector interest to supplement and sustain these activities, and actions USDA could take to promote acceptance.

SACAH Recommendation #3: Hold public meetings with producers during initial program implementation in order to gain producer buy-in to the voluntary program, making sure these meetings are in locations where maximum producer turnout is possible. Stakeholder engagement can be further enhanced by utilizing commodity groups to help educate producers on the options. Consider the use of demonstration farms that will describe how the data is collected and most importantly, how the data is analyzed.

SACAH Recommendation #4: At this point, there does not appear to be any clear definition of endpoints and the Department should clarify these by collaboration with producers in their development.

SACAH Recommendation #5: Consider the health status and welfare implications to livestock and poultry as the era of reduced antibiotic use is phased in. Producer outreach and education will be needed.

SACAH Recommendation #6: The Department will need to be actively involved in providing possible funding and soliciting proposals for research on the implications of reduced antibiotic use.

SACAH Recommendation #7: Protection of personal information of producers will be the key to cooperation and attainment of results.

AGENCY RESPONSES

The United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) recognizes the recommendations of the Secretary's Committee on Animal Health and appreciates the opportunity to respond.

Agency Response to SACAH Recommendation #2: To the extent that Committee members are also members of commodity organizations or groups such as the NIAA and U.S. Animal Health Association, they should be aware of the USDA Action Plan on antimicrobial resistance. This plan, which focuses on surveillance; research and development; education, extension and outreach, was developed with the help of stakeholders as well as our Federal partners such as the Centers for Disease Control and Prevention and the Department of Health and Human Services. We also continue to work with other agencies on the National Strategy for Combatting Antimicrobial Resistance, or CARB, which will allow the United States to work domestically and internationally to prevent, detect, and control illness and death related to antibiotic-resistant bacteria by implementing measures to mitigate the emergence and spread of antibiotic resistance and ensure the continued availability of therapeutics for the treatment of bacterial infections.

Agency Response to SACAH Recommendation #3: APHIS held public meetings in 2012, and contributed to the Food and Drug Administration's public meeting in September of 2015 to address data concerns. APHIS participated in thirteen regional producer/industry/veterinary educational meetings, hosted by the Farm Foundation, that were held in the fall of 2015 and spring of 2016, two of which were webcast. The strategic plan calls for voluntarism to drive producer participation; collection of on-farm information will not be mandatory, so producers will have to voluntarily respond to questionnaires.

Agency Response to SACAH Recommendation #4: The USDA Action Plan has clearly stated goals and objectives.

Agency Response to SACAH Recommendation #5: APHIS has already carried out some producer education and is currently constructing a veterinary accreditation module to further educate cooperating accredited veterinarians on the importance of AMR mitigation.

Agency Response to SACAH Recommendation #6: USDA has limited research funding; neither APHIS nor the Food Safety and Inspection Service received additional AMR-related funding for 2016. APHIS is continuing to work to change that for future appropriations.

APHIS believes that confidentiality concerns associated with AMR response are adequately addressed by the status of the National Animal Health Monitoring System as a statistical unit under the Confidential Information Protection and Statistical Efficiency Act of 2002 as well as protections under the 2008 Farm Bill.