

Conference Proceedings

The Office of Science and Technology Policy Blue Ribbon Panel on The Threat of Biological Terrorism Directed Against Livestock

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Preface

About This Analysis

These conference proceedings assess the potential use of biological terrorism directed against U.S. agricultural livestock and lay out the parameters of a future federal defense research and development (R&D) agenda that prioritizes steps needed to safeguard industries associated with this sector. The report is derived from a two-day workshop that was held in Washington, D.C., on December 8-9, 2003 and which was funded by the Office of Science and Technology Policy (OSTP) in the Executive Office of the President. The document may be used, along with other important sources of information, to inform the articulation of federal R&D budgets for mitigating threats to large-scale farming animal husbandry (and related produce) over the near-to-medium term.

This document contains all the papers that were presented at the conference in addition to the narratives and recommendations of four individual breakout groups: Cross-Jurisdictional Surveillance and Information Technology (IT); Infectious Disease Epidemiology; Vaccination and Protection Technologies; and Detection, Diagnostics, and Forensics Capabilities. It should be noted that the papers do *not* represent any findings of the respective breakout groups of the panel as a whole; they merely provide a broader conceptual context for the workshop proceedings.

The report also includes an introductory discussion of the wider threat environment pertaining to agro-terrorism and summation of the main policy recommendations that were extrapolated from the two-day meeting. This section of the proceedings was prepared exclusively by the RAND Corporation's staff and should not be viewed as indicative of the views or opinions of the sponsor or conference participants.

Power Point presentations, conference transcripts, and material received too late for the publication of this report can be accessed on the Web site of RAND's Science and Technology Policy Institute (S&TPI) at www.rand.org/scitech/stpi/Bioagpanel/.

The study will be of interest to agricultural specialists dealing in the general area of animal disease management and control as well as security and policy analysts concerned with the developing structure of U.S. homeland security.

About the Office of Science and Technology Policy

The White House Office of Science and Technology and Policy (OSTP) was established in 1976 to provide the President of the United States with advice on matters of science and technology, both nationally and internationally, and to ensure excellence in federally funded research and development that stays focused on national priorities.

About the Science and Technology Policy Institute

Originally created by Congress in 1991 as the Critical Technologies Institute and renamed in 1998, the Science and Technology Policy Institute (S&TPI) is a federally funded research and development center sponsored by the National Science Foundation. RAND managed the S&TPI from 1992 through November 30, 2003.

The Institute's mission is to help improve public policy by conducting objective, independent research and analysis on policy issues that involve science and technology. To this end, the Institute

- supports the Office of Science and Technology Policy and other Executive Branch agencies, offices, and councils
- helps science and technology decisionmakers understand the likely consequences of their decisions and choose among alternative policies
- helps improve understanding in both the public and private sectors of the ways in which science and technology can better serve national objectives.

In carrying out its mission, the Institute consults broadly with representatives from private industry, institutions of higher education, and other nonprofit institutions.

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Glossary, List of Symbols, etc.

Symbol	Definition
AEC	Agricultural Extension Center
AFBF	American Farm Bureau Federation
AI	Avian Influenza
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
ASF	African Swine Fever
BSE	Bovine Spongiform Encephalopathy
BSL	Bio-Safety Level
BW	Biological Weapons
C&D	Cleaning and Disinfection
CDC	Centers for Disease Control and Prevention
CIP	Critical Infrastructure Protection
CONUS	Continental United States
CP	Conference Proceedings
CSF	Classical Swine Fever
CSREES	Cooperative State Research, Education, and Extension Services
CVM	Center for Veterinary Medicine
D.V.M.	Doctor of Veterinary Medicine
DHHS	Department of Health and Human Services
DHS	Department of Homeland Security

DNA	Deoxyribonucleic Acid
DoD	Department of Defense
DOI	Delayed Onset of Infection
EEE	Eastern Equine Encephalitis
END	Exotic Newcastle Disease
ESA	Emergency Supplementary Assistance
FADDL	Foreign Animal Disease Diagnostic Laboratory
FAD	Foreign Animal Disease
FDA	Food and Drug Administration
FERN	Food Emergency Response Network
FMD	Foot and Mouth Disease
FMDV	Foot and Mouth Disease Virus
FOIA	Freedom of Information Act
GDP	Gross Domestic Product
GIS	Geographic Information System
GMP	Good Manufacturing Practices
HAZMAT	Hazardous Materials
HL7	Health Level Seven
HPAI	Highly Pathogenic Avian Influenza
ISAC	Information Sharing and Analysis Center
IT	Information Technology
LIMS	Laboratory Information Management System
LRN	Laboratory Response Network
MSDS	Minimum Surveillance Data Set
N&H	Nipah and Hendra

N/END	Newcastle and Exotic Newcastle Disease
NAHEMS	National Animal Health Emergency Management System
NAHLN	National Animal Health Laboratory Network
NBACC	National Biodefense Analysis and Countermeasure Center
ND	Newcastle Disease
NEDSS	National Electronic Disease Surveillance System
NHII	National Health Information Infrastructure
NSC	National Security Council
NSS	National Surveillance System
NVLS	National Veterinary Laboratory System
NVSL	National Veterinary Services Laboratories
OIE	Office of International des Epizooties/World Organization for Animal Health
OOI	Onset of Immunity
OSTP	Office of Science and Technology Policy
PCR	Polymerase Chain Reaction
PES	Pre-emptive Slaughter
PHIN	Public Health Information Network
PIADC	Plum Island Animal Disease Center
POC	Proof of Concept
PPE	Personal Protective Equipment
R&D	Research and Development
RFP	Request for Proposal
RNA	Ribonucleic Acid

RP	Rinderpest
RVF	Rift Valley Fever
S&TPI	Science and Technology Policy Institute
SARS	Severe Acute Respiratory Syndrome
SRD	Strategic Research Document
TSE	Transmissible Spongiform Encephalopathy
UK	United Kingdom
USA	United States of America
USAIP	United States Animal Identification Program
USDA	United States Department of Agriculture
VADAR	Virtually Assured Detection, Attribution, and Response
VEE	Venezuelan Equine Encephalitis
VS	Vesicular Stomatitis
WHO	World Health Organization
WMD	Weapons of Mass Destruction

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Dr. John Vitko

Active and Passive Disease Surveillance

Dr. Dorothy Preslar

Agro-Terrorism Modeling and Simulation

Dr. Tim Carpenter

Advanced Animal Pathogen Research

Dr. Gerald Parker

Attacks Further Down the Food Chain

Jean Hellebone

Overview of U.S. Response Capabilities

Dr. Larry Granger

“Pre-Decisional Document: Strategic Research Targets to Protect American Livestock and Poultry from Biological Threat Agents: Report from the WMD Counter Measures Working Group,” Animal Pathogen Research and Development Subgroup, October 31, 2003. [This document can also be accessed at www.usda.gov/homelandsecurity/homeland.html.]

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I. Introduction and Summary

U.S. Agricultural Livestock,¹ Agro-terrorism² and Homeland Security

Over the past decade, the United States has moved to increase its ability to detect, prevent, and respond to terrorist threats and incidents. Much of this focus, which has involved considerable financial outlays, has aimed at upgrading public infrastructure using vulnerability threat analyses designed to maximize both anti-terrorist and consequence management efforts. While many gaps remain, investments in preparedness, training, and response have led to the development of at least nascent command structures that have incrementally begun to span the ambit of potential terrorist attacks, from conventional bombings to more “exotic” biological, chemical, radiological, and nuclear incidents.

Agriculture is one area that has received comparatively little attention in this regard, however. In terms of accurate threat assessments and consequence management procedures, the general farming sector exists somewhat as a latecomer to the growing emphasis that has been given to critical infrastructure protection (CIP). Indeed, agriculture was only incorporated as a specific component of U.S. national counter-terrorist strategy following the September 11, 2001, attacks on the Pentagon and World Trade Center.³

This lack of attention is problematic for three main reasons.

First, agriculture and the general food industry are highly important to the social, economic, and, arguably, political stability of the United States. Although farming directly employs less than 3 percent of the American population, one in eight people work in an occupation that is directly supported by food

¹ This report only addresses threats to U.S. agricultural livestock; it excludes considerations relating to the food chain in general and does not deal with plant-related disease contingencies.

² For the purposes of this report, *agro-terrorism* is defined as the deliberate introduction of a disease agent into livestock herds for the purposes of undermining socio-economic stability and/or generating fear. Depending on the disease agent and pathogenic vector chosen, agro-terrorism is a tactic that can be used to cause mass socio-economic disruption or as a form of direct human aggression.

³ It should be noted that Agriculture and Food Safety is included as one of eight sub-groups of the National Security Council’s (NSC’s) Weapons of Mass Destruction Preparedness Group, which was created in 1998 under the auspices of Presidential Decision Directive 62, “Combating Terrorism.” The USDA serves as the chair of this sub-group.

production.⁴ Cattle and dairy farmers alone earn between \$50 billion and \$54 billion a year through meat and milk sales,⁵ while roughly \$50 billion is raised every year through farm-related exports. In 2001, food production constituted 9.7 percent of the U.S. gross domestic product (GDP), generating cash receipts in excess of \$991 billion.⁶

Second, the agricultural and food industries remain vulnerable to deliberate attacks as well as naturally occurring disruption. Several key considerations exist in this regard, notably:

- the highly concentrated and intensive nature of current American agribusiness, which has worked to increase the potential speed of disease spread
- insufficient agricultural security and bio-surveillance⁷
- a hesitation on the part of agricultural producers to quickly report disease outbreaks at their facilities for fear that doing so will result in uncompensated culling and/or quarantine⁸
- a declining pool of veterinarians and diagnosticians appropriately trained in foreign animal diseases (FADs)⁹
- a continuing (and necessary) focus on aggregate livestock statistics as a result of the movement to larger breeding herds, which has lessened the option of individual animal health observation.

⁴ Agricultural Research Service, "Econoterrorism, a.k.a. Agricultural Bioterrorism or Asymmetric Use of Bioweapons," unclassified briefing given before the USDA, February 28, 2000. See also Henry S. Parker, *Agricultural Bioterrorism: A Federal Strategy to Meet the Threat*, Washington, D.C.: Institute for Strategic Studies, 2002, p. 11.

⁵ Overall livestock sales in 2001 were in excess of \$108 billion. See "Agro-Terrorism Still a Credible Threat," *Wall Street Journal*, December 26, 2001.

⁶ Bureau of Economic Analysis, "Gross Domestic Product: First Quarter 2002 (Advance)," available on-line at www.bea.gov.

⁷ Interviews with U.S. federal and state agricultural officials, Washington, D.C.; Sacramento; Boise, Des Moines; and Omaha, 1999-2003. It should be noted that, in 2002, the Bush administration announced plans to upgrade the screening of workforces employed at food processing plants and packing facilities.

⁸ The USDA is currently considering a review of indemnity provisions specifically related to FMD, which would authorize payments to cover both disinfection costs as well as the full market value of destroyed animals and related products. For a detailed description of the proposed changes, see USDA, "Foot and Mouth Disease Payment of Indemnity, Update of Provisions," [Docket Number 01-069-1], RIN 0597-AB34, November 2002.

⁹ Observations raised during the "American Farm Bureau Federation (AFBF) Commodity Advisory Meeting," Washington, D.C., January 2002.

Third, the capability requirements for deliberately exploiting these weaknesses are not significant. Not only are there a large number of potential pathogens to choose from,¹⁰ but many of these microbial organisms are highly transmissible (something that is particularly true of foot and mouth disease, or FMD) meaning that there is no obstacle of weaponization to overcome.¹¹ Moreover, because most livestock diseases cannot be passed to humans, there is no requirement on the part of the perpetrator to have an advanced understanding of animal epidemiology, nor is there any need for elaborate containment procedures and/or personal protective equipment (PPE) in the preparation of the agent.

Finally, and perhaps most importantly, the ramifications of a concerted bio-assault on the U.S. meat and food base would be far-reaching and could quite easily extend beyond the immediate agricultural community to affect other segments of society.

A large-scale attack would, at the very least, have substantial economic repercussions in terms of containment and depopulation costs, revenue deficits suffered by industries directly and indirectly supported by agriculture, and losses resulting from protective embargoes instituted by major trading partners. As the United Kingdom's 2001 FMD outbreak demonstrated, the extent of the overall fiscal burden associated with emergency disease management can be enormous, running in this case to over 8 billion sterling (roughly U.S. \$14.5 billion at current exchange rates).¹²

Aside from economic considerations, the successful introduction of biological pathogens among livestock could undermine popular confidence and support for government, especially if eradication procedures focus on instituting controversial mass culling and depopulation measures that are unlikely to be understood by the electorate at large. In the event that a zoonotic agent is released, a widespread public scare might also erupt – the psychological parameters of which would be extremely difficult to manage should human

¹⁰ The Office International des Epizooties (OIE) has identified at least 15 “Class A” diseases that have the potential for serious and rapid spread and which pose serious risks to socio-economic stability, public health, and international trade. For further details, see OIE, “Classification of Diseases,” available online at www.oie.int.

¹¹ This is an important consideration as the issue of weaponization is frequently cited as one of the main obstacles mitigating the non-state offensive use of biological agents. For a good summary of the technical constraints associated with bio-terrorism and bio-warfare, see Seth Carus, *Bioterrorism and Biocrimes: The Illicit Use of Biological Agents in the 20th Century*, Washington, D.C.: National Defense University, Center for Counterproliferation Research, 1999, pp. 26–29.

¹² See Iain Anderson, *Foot and Mouth Disease 2001: Lessons to Be Learned*, report presented to the Prime Minister and the Secretary of State for Environment, Food and Rural Affairs, London: Her Majesty's Stationery Office, July 22, 2002, p. 2.

deaths occur. The angst and general fear triggered by the appearance of bovine spongiform encephalopathy (BSE, which has been directly connected to a variant form of the human brain-wasting Creutzfeldt-Jakob disease) in the UK, continental Europe, and, most recently, North America provide just a partial insight into the type of social dynamics that could be unleashed in reaction to a contingency of this sort.

The catastrophic events of September 11 have, to a certain extent, focused greater national attention on some of the weaknesses inherent in the U.S. agricultural sector and the ramifications that would eventuate if these were to be exploited. Reflecting this, increased federal allocations have now been made available to support general emergency management and preparedness in the food and livestock industries. The Agriculture Research Service's (ARS's) counterterrorism budget for FY03, for instance, has been increased to \$5.5 million from a FY02 base that had remained unchanged at \$500,000. This amount is in addition to the \$328 million in Emergency Supplementary Assistance (ESA) that the U.S. Department of Agriculture (USDA) as a whole has received to augment bio-security and surveillance efforts related to intentional attacks against the country's food supply.¹³ More important is the extra funding that has been made available to the Animal and Plant Health Inspection Service (APHIS) – the USDA's main frontline unit when it comes to rapid disease response, containment, and control – which in FY03, amounted to \$146 million.¹⁴ This being said, federal fiscal resources that have been made available to the USDA remain relatively marginal when compared with other areas of homeland security.

The Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock

Motivated by the various concerns discussed above, OSTP, in conjunction with RAND's S&TPI, organized a Blue Ribbon Panel to investigate policy options available for mitigating the potential threat of bio-terrorism directed against agricultural livestock. Key stakeholders and experts in the farming, food, and national security communities-including scientists, academicians, and policy-makers-were brought together for a two-day conference in December 2003 to

¹³ Interview with USDA officials, Washington, D.C., May 23, 2002. See also USDA, *Budget Summary 2003*, available online at www.usda.gov.

¹⁴ USDA, "Agriculture Budget Proposes Increases in Key Areas," news release, no. 0031.02, February 4, 2002; USDA, *Budget Summary 2003*.

identify and prioritize principal needs in the country's agricultural emergency management R&D portfolio for thwarting potential terrorist attack contingencies.

Papers and Power Point overviews addressing several important topics related to the livestock animal disease threat and control were presented during the meeting. These presentations¹⁵ served to provide the context for subsequent breakout sessions tasked with articulating the major components that could become part of a future federal agro-terrorism defense agenda. Four specific groups were organized, covering the following:

- cross-jurisdictional surveillance and information technology (IT)
- infectious disease epidemiology
- vaccination and protection technologies
- detection, diagnosis, and forensics.

Each group was instructed to identify the main research needs in the assigned subject area; to prioritize these requirements; to recommend ways by which current gaps could be addressed from a technical R&D standpoint; and to project estimated timelines and budgets for instituting suggested changes and innovations.¹⁶ The full narratives for each of the four breakout sessions, as well as the membership for each group, are included later in this report. It is hoped that the results of this conference will now be used as an important source of information to help inform future policy decisionmaking in these areas.

¹⁵ This report contains only full papers that were delivered during the conference. The following Power Point presentations and transcripts can be accessed at RAND's S&TPI website (www.rand.org/scitech/stpi/Bioagpanel/):

- a) "U.S. Agriculture, Critical Infrastructure Protection and Homeland Security" (John Vitko, Department of Homeland Security)
- b) "Advanced Animal Pathogen Research" (Colonel Gerald Parker, Department of Homeland Security)
- c) "Attacks Further Down the Food Chain" (Jean Hellebone, Canadian Food Inspection Agency)
- d) "Active and Passive Disease Surveillance" (Dorothy Preslar, Federation of American Scientists)
- e) "Agro-Terrorism Modeling and Simulation" (Tim Carpenter, University of California, Davis, Department of Medicine and Epidemiology)
- f) "Overview of U.S. Response Capabilities" (Larry Granger, APHIS, United States Department of Agriculture).

¹⁶ Only two breakout groups managed to provide estimates of timelines and budgets within the schedule of the two-day workshops – Infectious Disease Epidemiology and Vaccine and Protection Technologies. Both sessions were able to meet this requirement largely because they had the benefit of being able to base their respective calculations on development and financial data bearing off innovations that have been made in the human disease science field.

Key Findings and Recommendations from the Breakout Groups of the Blue Ribbon Panel

Each breakout group reported its key findings and recommendations at the conclusion of the conference. While these respective narratives are discussed in more depth in Part II, we have summarized them here in the form of a primer for the convenience of the reader. This will allow policy-makers and analysts to quickly extrapolate the main themes that came out of the conference without having to go through the entire document. Unfortunately the schedule of the workshop did not allow the full panel to consider each recommendation. While the findings and recommendations were described to the full panel, only each breakout group can be said to have considered them carefully.

It is important to note the section that follows is neither interpretative nor analytical in nature; it merely summarizes the key R&D gaps and associated recommendations that were made by participants in the respective breakout sessions. It also uses the same structure and organization that each of these groups devised, so that the reader may more easily find the related discussion in Section II. The overall purpose of this part of the document is to encapsulate the major findings of the two-day workshop, not to independently assess how they might figure into broader federal government agricultural policy and programs.

Cross-Jurisdictional Surveillance and Information Technology (IT)

Key Weaknesses

1. An inability to electronically track livestock from birth to the slaughterhouse.
2. A dearth of standardized and widely accepted electronic data repositories appropriate for disease surveillance.
3. The lack of established standards and processing methods to integrate and evaluate the utility and relevance of data derived from dissimilar sources.

4. The inability of many agricultural producers, managers, and veterinarians to recognize quickly the clinical signs associated with foreign animal diseases (FADs) and/or uncommon health events.
5. Insufficient incentives on the part of potential disease data suppliers (e.g., zoos, environmental and resource agencies, rendering plants, international and national disease surveillance networks, accredited veterinarians, slaughterhouses, animal research laboratories, port of entry/customs officials) to make this information available to appropriate governmental authorities.

Recommendations

1. Design, develop, and implement a comprehensive national livestock premises and animal identification and tracking system.¹⁷
2. Undertake research and outreach programs to enhance education and awareness about FADs, outbreaks of new infectious diseases, and best practices in the commercial and government sectors when animal disease incidents occur.
3. Support research for a range of issues that contribute to the effective integration of animal disease incident data.
4. Support R&D of programs to bolster government and industry trust in the stewardship of a safe, healthy, and sustainable animal sector.
5. Support research to undertake a cost-benefit analysis of creating a comprehensive animal identification and surveillance system; support additional research exploring cost-sharing arrangements to construct such a system.
6. Provide support to increase the technological capabilities of the National Veterinary Services Laboratory.

¹⁷ After initial start-up costs, the funding for such a system is expected to stabilize at \$122 million per year.

Infectious Disease Epidemiology

Key Weakness

1. Inadequate human and infrastructure resources for conducting epidemiological research and supporting cross-state and regional studies.
2. The lack of end-to-end models that are developed with a practical definition of success and which are: (a) usually restricted to smaller geographic areas and often a particular state; (b) often unconnected to wider human/social behavior, including even basic socio-economic effects; and (c) frequently lacking in terms of mapping the full dynamic of infectious outbreaks, from disease introduction to recovery or reconstitution/repopulation of affected herds and flocks.¹⁸
3. The lack of (or lack of access to) GIS (Geographic Information System) and other data on animal locations and on transport to support the genesis of holistic and appropriately formulated epidemiological models.
4. Insufficient analysis of the negative social impacts of disease outbreaks and the role of risk communication in mitigating these effects.

Recommendations¹⁹

1. The development of a national consortium of ag-bio researchers, funded over a period of at least five years that would meet at least quarterly and would comprise a central hub of management responsible for stipulating requirements for the training and employment of graduate students, interns, and research assistants.²⁰
2. More and better-directed infrastructure investment, including moves to create and fund epidemiological rapid response teams.

¹⁸ This is all needed to ensure modeling results will be useful in helping federal agencies determine response priorities and resource allocation should attacks actually take place.

¹⁹ The list reflects the findings of the Infectious Disease Epidemiology breakout group in their entirety. No aggregation or synthesis of the recommendations was made.

²⁰ The creation of a national consortium of this sort would help facilitate communication, develop expertise, create unified directions for research activities, and allow greater involvement by decision-makers in evaluation and oversight. Such an arrangement could also take advantage of regional differences and integrate specific information from the local and state level into wider national models of disease control.

3. The establishment of an ag-bio equivalent to the World Health Organization (WHO) or Centers for Disease Control and Prevention (CDC) that could serve as outreach agencies to facilitate global networks and accessible research relationships focused on emerging diseases.
4. Greater use of epidemiological modeling that draws on a coarser level of spatial granularity, perhaps to the level of the county and/or zip code.
5. The formulation of alternative data-collection strategies (and appropriate mechanisms for addressing confidentiality issues) that would reduce the current reliance on having the government demand information ahead of time.
6. The development of technology platforms able to support a real-time capacity to build large databases quickly.
7. Better leverage (and possible ownership) of existing corporate industry data relevant to the needs of academic epidemiologists by making more R&D grants available to commercial and other potential stakeholder groups.
8. Increased understanding of how to communicate risk to specific audiences and the use of this knowledge both to build fully inclusive models and to allow more productive uses of their results.
9. More and better use of systematic risk analysis to determine how an individual might intentionally introduce a livestock disease agent.
10. Increased interaction between federal government agencies and epidemiological modelers to improve the range and distribution of resource allocation parameter estimates.
11. More intensive analysis of the social and economic impacts of disease outbreaks to support the development of appropriate “end-to-end” modeling.
12. Suggested levels of research funding:
 - a) expansion and refinement of epidemiological models: \$2 million annually (number of years not specified)
 - b) development of disease introduction and pathway risk analysis: \$1 million annually
 - c) evaluation of current disease interdiction and prevention efforts: \$1 million annually
 - d) development of academic/state/federal/industry research consortia: \$5 million annually per livestock industry
 - e) determination of GIS data needed for epidemiological modeling and response: \$1 million

- f) gathering of, or access to, GIS data needed for epidemiological modeling and response: \$3 million annually
- g) risk communication: \$2 million
- h) determination of socio-economic impacts associated with disease outbreaks: \$2 million annually
- i) development of an international outreach center: \$10 million annually.

Key Weaknesses: Disease-Specific Issues²¹

1. Insufficient understanding of the overall transmissibility – particularly in terms of airborne distance – and environmental survivability of FMD.
2. A lack of knowledge on the cross-species existence and persistence of FMD.
3. The need to understand better climatic factors influencing the emergence and spread of FMD.
4. Inadequate strategies for: (a) disposing of animals contaminated with FMD; and (b) appropriately compensating agricultural producers affected by quarantine and depopulation measures.
5. Uncertainty as to the effects of cumbersome personal protective equipment (PPE) on the effectiveness of first responders dealing with zoonotic diseases.
6. Incomplete research on the general epidemiological dynamics of Nipah/Hendra.
7. Insufficient understanding of Highly Pathogenic Avian Influenza (HPAI) sub-strains and the distribution pathways by which they spread between different species, including factors that have allowed certain serotypes to “jump” to human populations.
8. Inadequate understanding of what causes the development of velogenic strains of Exotic Newcastle Disease (END) and, thus, how they might behave epidemiologically.
9. Inadequate knowledge of the transmissibility of Classical Swine Fever (CSF) and its potential to spread to wildlife populations in the United States.
10. The need to better understand Rift Valley Fever (RVF) wildlife reservoirs (which was seen as especially important given that the agent is essentially a disease of trade).

²¹ The group considered specific diseases in some depth. This is reported between pages 48 and 54.

11. Poorly developed risk communication strategies for allaying public fears concerning the production channels, distribution pathways and overall transmissibility of various types of transmissible spongiform encephalopathy (TSE), which was seen to be especially salient to bovine spongiform encephalopathy (BSE).
12. A lack of basic science regarding the disease reservoirs of pox viruses (such as monkey pox) and the factors that affect their transmissibility among animal populations.
13. The lack of some rapid response capability to respond to emerging diseases, either newly arisen in the wild and so available for subsequent introduction, or perhaps deliberately created or engineered by or for terrorists.

Recommendations: Disease-Specific Issues

1. Increased laboratory experimentation focused on FMD aero-biology.
2. More intensive research to determine rough estimates of FMD survivability on various organic/inorganic surfaces and substances (including potential methods of smuggling).
3. Increased investment in capacity building to support the establishment of centralized rendering centers to dispose of FMD-ridden carcasses (drawing on the work that has been completed in the Netherlands in this area).
4. The provision of funding to develop PPE that is appropriate for handling zoonotic diseases, possibly leveraging off innovations that have already taken place in commercial settings.
5. Enhanced laboratory testing to ascertain the specific disease parameters and epidemiological dynamics of Nipah/Hendra and pox viruses.
6. The initiation of a dedicated R&D program focused on unknown agents and the factors that might cause specific viral families to “jump” the species barrier.
7. Suggested levels of research funding:
 - a. transmissibility: \$10 million annually
 - b. carcass disposal: \$3 million annually
 - c. host/vector range: \$2 million annually.

Vaccination and Protection Technologies

*Key Research Needs: Common Requirements Across Disease Agents Defined as Seriously Threatening to U.S. Animal Health and Agriculture*²²

[Note: This breakout group focused much of its deliberations on animal pathogens highlighted in the following report: “Pre-Decisional Document: Strategic Research Targets to Protect American Livestock and Poultry from Biological Threat Agents: Report from the WMD Counter Measures Working Group-Animal Pathogen Research and Development Subgroup,” October 31, 2003. While this report, hereafter referred to as a Strategic Research Document (SRD), did not explicitly discuss selection of particular agents by terrorists, all members of the group agreed that it presented a generally complete list of seriously threatening diseases. The SRD is available on-line at www.usda.gov/homelandsecurity/homeland.html.]

1. The development of one-time, safe, cost-effective, and easy-to-implement vaccination strategies that have standardized government protocols for FAD suppliers (human vaccine protocols require one U.S. and one non-U.S. supplier).
2. The manufacture of “ideal” vaccines that:
 - a) embrace marker detection mechanisms to differentiate: (i) vaccinated from non-vaccinated animals; (ii) animals that are infected and then vaccinated; and (iii) animals that are vaccinated and then infected
 - b) offer broad serotype protection – preferably one vaccine for all serotypes
 - c) have minimal need for re-application (relevant for delayed onset of infection [DOI] diseases)
 - d) do not make animals unfit for human consumption
 - e) are safe, economical, and easy to manufacture.
3. The creation of vaccine banks complete with appropriate logistical protocols for ensuring effective distribution.

²² The list reflects the findings of the Vaccination and Protection Technologies group in their entirety. No aggregation or synthesis of the recommendations was made.

4. The development of effective, ground-tested implementation procedures to deliver all existing and future vaccination and protection technologies.
5. Consideration and assessment of viable alternatives to vaccination such as stamping out, pre-emptive slaughter (PES), and regionalization.
6. Increased leverage of university and private sector resources, including Requests for Development and Manufacturing Contracts for vaccine formulation, manufacturing, and stockpiling.
7. Providing for specific FAD and zoonotic disease courses (especially with regard to bovine, swine, and avian immunology) in accredited veterinary colleges, possibly to the level of Ph.D.
8. Maintenance of critical infrastructure facilities, such as Plum Island, and the improvement of national resources including the development of bio-safety level four (BSL 4) facilities capable of handling large animals.
9. The institution of an animal equivalent of Bio-Shield within the Department of Homeland Security (DHS) or elsewhere in the federal government.
10. Ensure that attacks against agricultural livestock are treated (and prioritized) as a specific national security issues.

Research Needs for Specific Prioritized Diseases

[Note: Prioritizations assigned to the pathogens listed below were based on seven criteria: (1) economic impacts; (2) virulence and potential for disease spread; (3) zoonotic potential; (4) morbidity or lethality of disease; (5) likelihood disease will spread to other species; (6) ability of terrorists to naturally acquire or otherwise manufacture a particular pathogen; and (7) difficulty associated with weaponization of the pathogen.]

1. FMD (designated as highest priority in terms of R&D because of its virulence, infectivity, potential impact on economic trade, and ease of access):
 - a) the creation of an immediate, “ready-to-go” vaccine bank that has at least 6 million doses for all seven FMD serotypes and which can be delivered anywhere in the United States within 24 hours

- b) the creation of a supplemental vaccine bank that can deliver 10 million doses (bulk frozen, but ready for packaging) for all seven FMD serotypes within two weeks
 - c) the capacity to produce new vaccine stocks within a two-to-three-month time frame
 - d) the development of an ideal vaccine, which in addition to the broad criteria listed above, also inhibits persistent infections, prevents pathogenic “shed and spread,” and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)
 - e) the incorporation of effective logistics and distribution protocols for appropriate vaccine disbursement
 - f) funding for additional research on treatments involving cytokines, interferon, and other anti-viral treatments
 - g) suggested level of research funding: \$75-100 million annually over a seven-to-ten-year period (ten years being the time it will take to produce an ideal vaccine and other relevant therapeutics).
2. RVF (designated as high priority in terms of R&D because of its zoonotic potential, possibility of pathogen becoming endemic to the United States if transmitted to domestic animals, and likelihood of success-a vaccine is near completion):
- a) complete development and testing phase of MP-12 vaccine that is currently being researched by the U.S. Army
 - b) the development of an ideal vaccine, which in addition to the broad criteria listed above, also prevents transmission from host to vector and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)
 - c) development of a human RVF vaccine to protect animal workers (relevant given RVF’s zoonotic potential)
 - d) suggested level of research funding: \$20 million annually over a two-year period to establish a base RVF vaccine stockpile.
3. Nipah/Hendra (designated as high priority in terms of R&D because of its zoonotic potential):

- a) continue evaluation of live vaccine currently under development (at both CDC and the BSL 4 facility in Winnipeg, Canada) in terms of safety and efficacy
 - b) examine alternative mechanisms for vaccine delivery
 - c) the development of an ideal vaccine, which in addition to the broad criteria listed above, also offers sterile immunity
 - d) consider the feasibility of constructing a BSL 4 facility with a significant large animal capacity to research existing and emergent highly contagious diseases
 - e) suggested level of research funding: \$5 million for initial proof of concept; \$20 million for the manufacture and stockpiling of a fully developed vaccine.
4. HPAI (designated as high priority in terms of R&D because of its zoonotic potential):
- a) the creation of a vaccine bank containing at least 10 million doses for the two most common neuraminidase types of HPAI sub-strains (H5 and H7)
 - b) the development of an ideal vaccine, which in addition to the broad criteria listed above, also offers sterile immunity and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)
 - c) investigation of means to prevent cross-species transference of avian-to-swine, swine-to-avian, and human-to-swine
 - d) suggested research funding: \$5 million annually for at least five years.
5. CSF (designated as high in terms of R&D because of its morbidity potential):
- a) the institution of appropriate protocols to allow rapid importation of existing vaccine stocks (at least 5 million doses) from overseas banks to facilitate near-term outbreak control
 - b) the development of an ideal vaccine, which in addition to the broad criteria listed above, also offers sterile immunity and is not vulnerable to cross-contamination from vaccine raw materials (particularly those imported from overseas)
 - c) suggested level of research funding: \$10 million annually for five years.

6. END (designated as medium priority in terms of R&D because of its mortality and zoonotic potential):
 - a) modify existing Newcastle vaccine to produce an easy-to-deliver, cost-effective marker vaccine that is also effective for controlling END
 - b) develop appropriate distribution mechanisms that allow for routine use of new vaccine
 - c) suggested level of research funding: \$2 million annually.
7. African Swine Fever (ASF, designated as medium-high priority in terms of R&D because of the uncertainty as to whether the creation of a vaccine is possible):
 - a) increase present efforts to determine whether a vaccine can be created
 - b) evaluate the terrorist potential of ASF (could or would terrorists attempt to harness ASF?)
 - c) investigate additional vector pathways for ASF (ticks, feral swine)
 - d) the development of an ideal vaccine, which in addition to the broad criteria listed above, also prevents pathogenic “shed and spread”
 - e) suggested level of research funding: \$5 million annually.
8. Venezuelan Equine Encephalitis (VEE, designated as medium priority in terms of R&D because of the existing stocks of trivalent vaccine):
 - a) develop an animal vaccine research program that is informed by and draws off current Department of Defense (DoD) studies of human VEE infection
 - b) invest in general protective immunology to protect against VEE strains that have weaponization potential
 - c) the development of an ideal vaccine, which, in addition to the broad criteria listed above, offers sterile immunity
 - d) suggested level of research funding: \$2 million annually.
9. Rinderpest (RP, designated as low-medium priority in terms of R&D because of the near eradication of the disease):
 - a) development of vaccine bank and maintenance of supplies to ensure defenses even in the event that the disease is fully eradicated

- b) research into potential for the known existing RP serotype to mutate
- c) suggested level of research funding: no recommendations.

Detection, Diagnosis, and Forensics Capabilities

[Note: This breakout group focused its deliberations on detection, diagnosis, and forensics for 11 main diseases: Avian influenza (AI), BSE, CSF, Cowdria ruminantium (heart water), FMD, RP, bovine tuberculosis, RVE, END, and alpha/paramyxoviruses (such as Nipah/Hendra). Priority of these pathogens was based on the following six criteria: (1) level of morbidity and mortality; (2) level of disease transmissibility, including to human populations (i.e., is the disease zoonotic?); (3) presence of effective pathogenic vectors and wildlife reservoirs; (4) numbers of animal species susceptible to the disease; (5) availability of suitable control strategies; and (6) ability of the disease to survive in the environment.]

Key Weaknesses

1. A passive disease reporting system that is dependent on farmers and producers who may not have the necessary expertise to quickly “flag” potential FADs or bio-terrorism agents for subsequent diagnostic testing.
2. A lack of laboratories appropriately equipped with a comprehensive set of (positive and negative) diagnostic testing capabilities covering all main agents of concern.²³
3. Diagnostic and testing capabilities that rarely take into account potential wildlife disease reservoirs for specific pathogens.
4. Insufficient funding to support versatile and/or on-going disease surveillance and testing over time.
5. The absence of clearly defined response protocols in the event that disease surveillance systems detect a potential pathogenic outbreak.
6. A lack of robust assay tests that are able to generate data which can assist with attribution analysis in determining the “who,” “why,” “where,” and “when” of a deliberate disease introduction.

²³ The existing National Animal Health Laboratory Network (NAHLN) covers only 12 state facilities. Participants in this breakout group argue that a truly robust system will require the integration of at least 50 facilities in the NAHLN.

Recommendations

1. Strengthen the current passive system for disease detection and diagnosis by:
 - a) addressing staffing needs at all levels to ensure sufficient system capacity
 - b) improving the training for disease recognition
 - c) increasing the availability of sophisticated diagnostics in testing laboratories
 - d) instituting mechanisms to expanded data sharing within the National Veterinary Laboratory System (NVLS)
 - e) increasing funding for diagnostic surveillance of potential agricultural bio-terrorism agents
 - f) addressing IT requirements to improve the effectiveness of current diagnostic efforts.
2. Develop new technologies for active surveillance of FADs by:
 - a) developing and improving field testing capabilities
 - b) developing and fielding environmental surveillance systems.
3. Develop tests for diseases for which diagnostic methods are currently unavailable or inadequate by:
 - a) promoting validation and deployment of prototype test methods
 - b) addressing agents for which practical test methods are currently unavailable
 - c) increasing information provided by specific test methods
 - d) developing test methods that are applicable to different stages of the animal agricultural system
 - e) developing and fielding faster testing methods.
4. Address the specific requirement of forensic applications by:
 - a) validating assay test methods for specific forensic use
 - b) improving laboratory and personnel capabilities for forensic analysis
 - c) addressing procedural and data-sharing constraints associated with criminal investigations.
5. Promote and fund prospective emergency disease research and surveillance capability.

Observations

Several common themes are apparent across the different research areas described above. Most importantly, all four subgroups of the Blue Ribbon Panel fashioned their research initiatives in light of intensely practical concerns. The Cross-Jurisdictional Surveillance and Information Technology (IT) group generally focused on the steps needed to identify diseases and to usefully report them; the Infectious Disease Epidemiology group focused on making its models useful to decisionmakers during an outbreak; the Vaccination and Protection Technologies group focused on the creation of vaccines that are useful in practice, for example, by providing key “markers” to allow unfettered trade; and the Detection, Diagnosis, and Forensics Capabilities group focused on ways to validate current testing for prioritized agricultural bio-terrorism agents and increase their overall efficiency and diagnostic potential. Each of the breakout sessions were, thus, motivated by some precise, practical concerns.

This is an important shift, even for a research community that is already quite applied in its focus. While considerable attention has been paid to the individual needs of U.S. farmers, instituted mainly through the long-established Agricultural Extension Center (AEC), comparatively little research has been directed to the specific requirements of federal, state, and local agencies and departments when attempting to deal with large-scale disease outbreaks. The recommendations outlined above go a long way toward addressing this analytical gap. Thus, for example, the groups call for a comprehensive identification and tracking system for individual animals and for “end-to-end” models of disease spread, so that the various authorities have some basis for choosing one culling or vaccination strategy over another. This shift is important, and consistent with other developments taking place in homeland security as the U.S. government moves to grapple with the unfamiliar problems of terrorism post-9/11.

Other quite specific, practical initiatives abound in the groups’ discussions. These initiatives ranged from the gathering of better geographic data on herds and flocks to the establishment of additional BSL 4 level facilities and the creation of less burdensome PPE for dealing with zoonotic diseases. Such recommendations flow naturally from the focus on providing better options for controlling any outbreak.

Another common theme across these research areas is the need for significant investments in infrastructure. Although several of the above initiatives are currently being considered for extra funding, such as the expansion of BSL 4 facilities, many larger and equally important areas require financing that has yet to be factored into federal budgetary allocations. Notable examples include: the creation of a national consortium of centers on epidemiology, to share results and methods; augmenting the scope and scale of the existing disease surveillance and health information networks; and the establishment of an international organization to both focus on emerging diseases, and allow U.S. researchers and veterinarians the exposure to FADs diseases not present in the United States.

The four groups additionally identified necessary advances in fundamental or basic research that is needed to *enable* important applied steps. In the best tradition of Pasteur's Quadrant,²⁴ these represent basic research tenets that are undertaken for purely practical purposes, ranging from the development of "marker" vaccines (or other appropriate treatments) for specific diseases to investigations of the competence of alternative (domestic) vectors in availing the transmission of pathogenic agents into and across the United States. Perhaps most dramatically, this aspect of the breakout groups' work also elucidated the relevance of the social and economic realms when considering responses to disease outbreaks and the concomitant need to factor these broader environmental concerns into epidemiological modeling. To the degree this work would be performed by other research communities, it will be important for respective funding agencies to keep the practical point of view firmly in mind; as it was this perspective that motivated the genesis of these particular policy recommendations.

Overall, the initiatives proposed by the subgroups represent a good start toward a future homeland security research agenda for making the industries associated with agricultural livestock more resilient to deliberate attack. Over time, and as new aspects become apparent to the research community, this list of policy suggestions will need to be revisited. For example, the existence of a cheap, effective vaccine might remove one disease from concern entirely; alternatively, epidemiological models might show that even more detailed geographic information is needed, which would have implications for data gathering and system development. That said, the recommendations contained in this report provide a useful initial framework for developing and refining tools to blunt bio-

²⁴ For further details see Donald E. Stokes, *Pasteur's Quadrant: Basic Science and Technological Innovation*, Washington D.C.: Brookings Institution Press, 1997.

threats against an industry that remains critical to the economic well-being of the United States and its evolving system of homeland security.

II. Narratives from the Breakout Groups

Cross-Jurisdiction Surveillance and Information Technology Capabilities

Breakout Group Meeting to Identify R&D Needs

December 9, 2003

Table 1 lists the members of this breakout group. Dr. James T. Case chaired the meeting and coordinated the production of these notes.

Table 1: Cross-Jurisdiction Surveillance and Information Technology Capabilities Breakout Group Attendees

James T. Case, D.V.M., Ph.D.	California Animal Health and Food Safety Laboratory, University of California, Davis	Professor, Clinical Diagnostic Informatics
Valerie Ragan, D.V.M	Veterinary Services, U.S. Department of Agriculture	Associate Deputy Administrator
Robert M. Smith, D.V.M, Ph.D.	U.S. Department of Agriculture	National Program Leader for Agricultural Homeland Security
Joseph Lombardo	Johns Hopkins Applied Physics Laboratory	Program Manager, Biomedical Information Systems and Principle Investigator, ESSENCE
Dr. Jean Hollebhone	Canadian Food Inspection Agency	Acting Director, Science Division
Alun Evans	Office of the Deputy Prime Minister, United Kingdom	Director of Civil Resilience
Donald F. Shepard	Chemical Biological Radiological Technology Alliance	Technology Area Manager
Joan Arnoldi, D.V.M	Michigan Department of Agriculture	State Veterinarian
Dr. Patrick McCaskey	Office of Public Health & Sciences	Executive Associate for Laboratory Services
Holly Bratcher	Federal Bureau of Investigation	Forensic Biologist, Weapons of Mass Destruction Countermeasures
David Huxsoll, D.V.M., Ph.D.	School of Veterinary Medicine, Louisiana State University	Professor of Veterinary Microbiology
Derek Vandrey		Veterinarian
Jeff Wilcke, D.V.M., M.S.	Virginia-Maryland Regional College of Veterinary Medicine	Metcalf Professor of Veterinary Medical Informatics
Mo Salman, B.V.M.S., M.P.V.M., Ph.D.	College of Veterinary Medicine and Biomedical Sciences, Colorado State University	Professor of Epidemiology, Animal Population Health Institute
John Parachini	RAND Corporation	Policy Analyst
Scarlett Magee	RAND Corporation	Research Assistant
Scott Layne, M.D.	University of California at Los Angeles, School of Public Health	Associate Professor
Dr. Terry Nipp	National Institute for Agricultural Security	Executive Director
Alfred Montgomery	Food and Drug Administration	Counter Terrorism Coordinator, Center for Veterinary Medicine

The breakout group was charged to examine cross-jurisdiction surveillance and information technology capabilities and prioritized research. The group made the following six recommendations that are listed in order of priority. These recommendations related to components critical to an effective national surveillance system. However, the priority should not be overemphasized because there is considerable evolutionary synergy between recommendations. Many of these recommendations are operational in nature, but their effective implementation may be greatly enhanced by additional research efforts.

The breakout group deemed all these priority areas as immediate or near-term challenges that offered significant payoffs for comparatively modest costs. Few of the group's recommendations included specific budgetary amounts. In contrast to the considerable efforts to enhance disease surveillance capabilities in the human health sector, this remains a comparatively embryonic mission in the areas of animal health and safety. Many of the recommendations urge the government to do what it has proposed, but has not yet been able to implement for lack of financial or political support. The cumulative impact of these recommendations would significantly address existing gaps in animal disease surveillance.

Recommendations for a National Animal Identification System

1.a **Recommendation:** Development of a comprehensive national animal identification system is critical to enhancing an effective animal disease surveillance system.

The breakout group was unanimous about the central importance of constructing a comprehensive animal identification system as a top priority for improving surveillance capabilities. The recent case of bovine spongiform encephalopathy (BSE), which occurred after the breakout group met, serves to underscore the gap in the current system and the potential value of an electronically identifiable digital marking system for every animal, as well as the necessary infrastructure to support the tracking on identified animals.

A comprehensive animal identification system faces a number of issues that warrant additional research.

1.b **Recommendation:** Funds should be allocated to support a cost-benefit analysis of a comprehensive animal identification system. Producers, shippers, and processors of livestock are hesitant to embrace animal surveillance systems that seem to add to their cost of business. A study clarifying the costs of the

system, depicting the potential costs of an outbreak without an effective animal identification system, and exploring the potential advantages to industry of such a system, may help boost confidence of the commercial sector.

1.c. **Recommendation:** Funds should be allocated to support research into possible cost-sharing approaches for a comprehensive animal identification system. The estimates from the United States Animal Identification Plan (USAIP) yield costs of \$78 million to \$131 million per year for five years, stabilizing to \$122 million per year, thereafter with the majority of the cost being the tags themselves. There may be options for sharing the cost between federal and state governments as well as private business. A thorough analysis of different ways to configure the animal identification system to meet the interests of both the government and private producers, shippers, and processors may reveal that the costs of the systems should be shared in a way to give different stakeholders genuine equity in the system.

Recommendations to Address Gaps in Current Surveillance Methods and Capabilities

The group identified gaps in the system from end-to-end. Importantly, the group noted that the acquisition of data needs improvement. Animal disease surveillance in the United States has historically mostly focused on disease eradication programs and passive reporting of foreign animal diseases. While both of these systems have been effective in meeting their established goals at the time, they do not provide a comprehensive overview necessary to appropriately allocate resources, to assure international trading partners of the health of the nation's herd, and to deal with the current globalization and increased threats of the accidental or intentional introduction of foreign animal diseases (FADs). Thus, the entire system needs to be recalibrated to include enhanced surveillance for FADs as well as newly emerging infectious diseases. Significant improvements in disease identification and reporting are needed in the veterinarian, producer, shipper, and production communities.

Early identification of disease outbreaks enables responses that can limit the potential danger of the disease spreading. The lag time in identifying and verifying the outbreak of foot and mouth disease (FMD) in the United Kingdom made the challenge of containment much greater. There is a need to utilize the most basic methods of surveillance to detect potential problems at an early stage.

2.a. **Recommendation:** Courses on foreign animal diseases need to be a basic component of veterinarian medical education curriculums.

Many American veterinarians may have difficulty diagnosing a FAD because they have no experience with them, and FADs are not a standard part of the curriculum in most contemporary veterinarian schools. Additional FAD diagnostic courses should be held at Plum Island to increase the number of practicing veterinarians with FAD knowledge.

2.b. **Recommendation:** Livestock producers and renders need education on the signs of FADs and how such diseases may hurt their business interests.

Livestock producers and processors can serve as a first line of defense against the spread of animal disease outbreaks if they know what to look for and how to report them. On balance, the private sector has significant, but not perfect, knowledge of their animals. Their expertise needs to be shared with state and federal authorities in a more consistent and systematic fashion.

2.c. **Recommendation:** Livestock producers and processors need business confidentiality protections and financial incentives to identify animal disease outbreaks and report them to veterinarians and agricultural authorities.

Given the significant financial implications of the discovery of an infectious disease outbreak, some producers and processors may be reluctant to report problems about animals in their care. The commercial sector needs to understand how early reporting is in their interest. Similarly, they need some guarantee that governmental authorities will handle disease reporting with appropriate confidentiality until a diagnosis is confirmed.

Recommendations to Improve Disease Data Repositories

The next step beyond effectively capturing relevant data is its integration. A wealth of potentially relevant data sources for animal disease surveillance exists, but the grouping, sorting, and integration are critical to enhancing the capacity to detect foreign animal diseases or new infectious diseases.

3.a. **Recommendation:** A survey of existing animal disease data repositories needs to be undertaken to ascertain the existing syndromic surveillance capabilities.

With a baseline understanding of existing data capabilities, assessments can be made about additional data required for effective surveillance depending upon the purpose of the system. The focus should shift from collecting data only on particular diseases to adding “animal health incidents,” such that the scope of

the surveillance system is flexible enough to capture the unexpected and the previously unseen. One of the benefits of creating a new system is that in the process of determining a baseline of existing capabilities and identifying new data sources, there is an opportunity to define the character of data that the system needs to capture. The breakout group suggested that a U.S. Department of Agriculture (USDA) “national surveillance unit,” which has just been created, would be the most appropriate entity to establish data standards to facilitate effective data integration.

3.b. **Recommendation:** Research and development (R&D) support is required to develop methods to effectively exploit data collected by an enhanced surveillance system.

Common data standards for data sources deemed critical to the surveillance system will raise questions about methods to effectively exploit captured incident data. There is currently a patchwork of different reporting systems with different data standards. Harmonization and standardization are necessary to create an effective national system.

3.c **Recommendation:** Research efforts are needed to facilitate data standardization and integration. Currently, there are a variety of relevant data sources that contain data that is not necessarily configured to ensure maximum integration for a comprehensive surveillance system. Effective exploitation of surveillance data is critically dependent on the integration of a range of different data sources.

Recommendations to Improve Laboratory Capabilities for Effective Surveillance

4.a. **Recommendation:** Research support should be provided to explore how to alleviate the tension of conflicting missions in the different components of the animal laboratory system. Many diagnostic laboratories are restricted either by law or commercial purpose to check for certain diseases and nothing else. The narrow focus of these laboratories hinders their ability to contribute to a broader animal disease surveillance system. The research required is technical, economic, and legal in nature.

An all-hazards approach to laboratory testing is good in principle but not presently technically feasible because there are specific tests to identify particular diseases. Many clinical laboratories have a service function and not a syndromic surveillance function. Finally, many laboratories perform only mandated assessments and do not go beyond these tests unless they are directed to do so.

Broadening the mission of some laboratories has cost implications that need to be considered.

Recommendations Concerning the Producers and Disease Surveillance

5.a. **Recommendation:** Research funds should be allocated to explore ways to increase the active participation of producers in the full spectrum of activities that enhance disease surveillance. The breakout group noted a profound producer distrust of government. One member noted how industry reporting in the poultry sector ceased after an alleged disease outbreak.

5.b. **Recommendation:** Research into technologies and methodologies that enhance reporting confidentiality may help increase industry's willingness to voluntarily report suspicious incidents. Producers must either be compelled to report possible diseased animals for fear of heavy fines or have an incentive to comply voluntarily. Producers fear that government agencies will prematurely and incorrectly make diagnoses about animal cases they report, and then they will suffer adverse financial consequences. Producers may be more willing to report cases if they receive a guarantee of the confidentiality of the information they turn over to authorities. Additionally, a system of indemnification should be assessed to compensate producers if confidential information is disclosed or if incorrect assessments are made about reported disease cases.

5.c. **Recommendation:** Research support should be provided to explore possible incentive systems to encourage the private sector to report suspicious incident information. A disease surveillance system will be more robust if producers have incentives to report any suspicious animal health incidents. The breakout group argued that producers are more likely to voluntarily comply if they believe that they will benefit in some fashion, or at least not be uniquely penalized, from the information collected. Research dedicated to identifying information of a dual-use nature (good for animal health surveillance and commercial purposes) is yet another element that may contribute to the design of a comprehensive and effective animal health surveillance system.

Recommendations Concerning Laboratory Accreditation and Uniformity in Diagnostic Laboratories

Despite the modest confusion about the various accreditation standards for laboratories, the breakout group did not have a consensus view on changes to make in the current system. However, there was some consensus that laboratories contributing to a national animal disease surveillance system should be accredited in some fashion.

6.a. **Recommendation:** Research support should be provided to ascertain what level of accreditation is appropriate for laboratories approved to participate in a national surveillance system. Ultimately, this research task will entail defining practices and procedures including reporting protocols for laboratories.

Summary of Recommendations

Table 2 summarizes the recommendations of the Cross-Jurisdictional Surveillance and Information Technology Capabilities breakout group. It is intended to both provide a concise description of the recommendations above and allow comparison with the other breakout groups. Because of the differences in scope and available information, not all the table entries are filled out for all the breakout groups.

Table 2: Agro-Terrorism Research Priorities: Cross-Jurisdiction Surveillance and Information Technology Capabilities

Agro-Terrorism Research Priorities: Cross-Jurisdiction Surveillance and Information Technology Capabilities									
Research Plan						Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far Term Research Needs (3-7 years)	Overall *Priority	JTC Rankings (see comments)	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Animal Identification: Develop comprehensive national animal identification system		Cost-benefit analysis of comprehensive national animal identification system; Analysis of possible cost-sharing strategies for system		1	1				
Disease Identification and Surveillance: Improve data acquisition procedures and recalibrate surveillance to include functions for emerging infectious diseases		Add courses on FADs to basic veterinary medical education curriculum; Educate producers and renders on the signs of FADs and their risks; Develop confidentiality protections and financial incentives for producers and processors to report animal health incidents		2	2				

Agro-Terrorism Research Priorities: Cross-Jurisdiction Surveillance and Information Technology Capabilities

Research Plan						Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far Term Research Needs (3-7 years)	Overall *Priority	JTC Rankings (see comments)	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
		<p>Shift focus from collecting data on particular diseases to “animal health incidents”;</p> <p>Harmonize and standardize the various existing surveillance systems;</p> <p>Configure existing data sources to ensure maximum integration for a comprehensive surveillance system;</p> <p>Identify or develop standards for animal health data and enhancement;</p> <p>Research development of complex disease concept representation, event detection algorithms, real-time data exchange mechanisms and improved security and confidentiality of data</p>		3	3				
		<p>Technical, economic, and legal research into current laboratories’ roles in broader animal disease surveillance system;</p> <p>Explore options for overcoming functional conflicts between laboratories performing service functions and their performing surveillance functions</p>		4	4				

Agro-Terrorism Research Priorities: Cross-Jurisdiction Surveillance and Information Technology Capabilities

Research Plan						Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far Term Research Needs (3-7 years)	Overall *Priority	JTC Rankings (see comments)	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Producer Participation: Explore ways to increase active participation of producers in activities to enhance surveillance		Research into technologies and methodologies to enhance disease reporting in the industry; Research into possible incentive systems to encourage private-sector reporting of suspicious incident information		5	5				
Laboratory Accreditation and Uniformity: Develop system of accreditation of laboratories involved in animal disease surveillance		Ultimately will entail defining practices and procedures for laboratories		6	6				

Infectious Disease Epidemiology

Breakout Group Meeting to Identify R&D Needs

December 9, 2003

Table 3 lists the members of this breakout group. Dr. Bruce Akey chaired the meeting and coordinated the production of these notes.

Table 3: Infectious Disease Epidemiology Breakout Group Attendees

Bruce Akey, D.V.M., M.S.	NY State Dept. Agriculture & Markets, Division of Animal Industry	State Veterinarian/Director (Acting)
Karen Becker, D.V.M., M.P.H.	U.S. Department of Health and Human Services	Senior Health Advisor
Dr. James Bonomo	RAND Corporation	Senior Policy Analyst
Dr. Tim Carpenter	Department of Medicine & Epidemiology, University of California, Davis	Professor, Epidemiologist
Peter Cowen	Public Health, and Population Medicine, NC State College of Veterinary Medicine	Associate Professor, Epidemiology
Noah Engelberg	Office of Management and Budget	Resource Management Officer
Dr. Dave Franz	Midwest Research Institute	Senior Biological Scientist
Jerome Freier	Center for Epidemiology and Animal Health, Center for Animal Disease and Information Analysis Natural Resources Research Center	GIS Research Analyst
Holly Gaff	Dynamics Technology Inc.	Research Scientist
David Hartley, Ph.D.	Department of Epidemiology and Preventive Medicine, University of Minnesota	Assistant Professor, Division of Biostatistics and Bioinformatics
Sebastian Heath, VetMB, Ph.D., Dipl. ACVIM, Dipl. ACVPM	Animal and Plant Health Inspection Service Emergency Programs	Senior Staff Veterinarian
Dr. William Hueston	Center for Animal Health and Food Safety at the University of Minnesota	Director
Thomas G. Ksiazek, D.V.M., Ph.D.	Department of Health and Human Services/Centers for Disease Control & Prevention/National Center for Infectious Diseases/VR	Chief, Special Pathogens Branch
Ellis Mackenzie	National Institute of Health	Staff Scientist
Dr. Gary Smith	School of Veterinary Medicine, University of Pennsylvania	Professor of Population Biology and Epidemiology
John Vitko Jr., Ph.D.	Department of Homeland Security	Director of Biological and Chemical Countermeasures for the Science and Technology Directorate

The group on the epidemiology of infectious diseases determined that the most important needs in this research area were significantly independent of the specific diseases. Instead, the group considered most research priorities and gaps in terms of broader disease classes, such as vector-borne diseases or directly transmissible ones. This strategy would be more inclusive and reflects the common modeling approach of seeking out diseases similar to the one of current concern, and then tweaking existing models to fit the current disease's particular parameters.

In developing the resulting list of the most important research initiatives, the group focused on applied research that could be most meaningful to policymakers and workers in the field. The resulting discussion was largely driven by modeling concerns – what is it about diseases that we need to know to model them? Moreover, how can we get real life data so that robust information systems based on the latest advancements in Geographic Information Systems can be integrated into Emergency Response efforts? The group set particular priority on increasing the applied research capacity, through initiatives such as a national consortium of centers and the establishment of an international outreach center that might perform key research tasks. The group hoped, and expected, that these centers would form the basis of an epidemiology rapid response team for use in emergency outbreaks.

The group on epidemiology also identified significant, needed expansions in the scope and goal of epidemiological modeling – creating true “end-to-end” modeling. This meant first connecting models of epidemiology to simple economic models, so as to understand the costs and implications of alternative control strategies. It also meant incorporating simple constraints on models, such as limiting the number of animals that might be culled if there were shortages of trained personnel. Most importantly, these models should be created so that “what-if” scenarios for disease control options can be constructed and analyzed; only then can alternatives, such as vaccination plans or quarantines, be evaluated for efficacy. All of this requires modeling the full history of a disease outbreak, from introduction through recovery and reconstitution.

In all likelihood, improved models of the sort outlined would rely upon a robust Geographic Information System (GIS) and the data that it contains. Gathering such data, for different industries and in different states, is a major task in its own right, raising important issues of proprietary and property rights. These need to be resolved if epidemiological models are to be truly useful in an outbreak of some disease.

Not all of the research identified was independent of disease, of course. The group began with a list of the ten diseases from “Strategic Research Document: Strategic Research Targets to Protect American Livestock and Poultry from Biological Threat Agents: Report from the WMD Counter Measures Working Group – Animal Pathogen Research and Development Subgroup,” October 31, 2003. Two major considerations motivated the discussion of priority agents: (1) How contagious is the disease? and (2) What would the impact of the disease be? In general, the list of diseases particularly relevant to the epidemiology research initiatives was similar to the initial list, but there were changes. Two diseases were seen as less important (Eastern Equine Encephalitis and Vesicular Stomatitis), while pox viruses, transmissible spongiform encephalopathies (TSEs), and a general “unknown” category were added. The rationale for these changes is described in more detail following this introduction. Not surprisingly, FMD remained a particular concern, and several research initiatives were identified with it in mind, notably one on transmissibility.

The discussion identified a total of 12 specific initiatives that further expand these general thrusts. Much of the logic of the discussion is captured in the discussion that follows, and the initiatives are then summarized in a final table. Very approximate budgets were also estimated; these should be understood as jumping off points for the development of a detailed research plan.

Laying Out the Problem

Defining High-Priority Diseases

The group began with a list of 10 diseases from the list of diseases of high concern for livestock developed by the USDA.

As noted above, two major considerations motivated the discussion on additions and subtractions from this list: (1) How contagious is the disease? and (2) What would the impact of the disease be? The group agreed that a lack of human transmissibility does not equate with a lack of impact or importance. Considerations of impact should include economic and social consequences as well. The issue of weaponization of diseases was also raised, but this was not a major focus for the group in discussing prioritization of diseases.

- Transmissible Spongiform Encephalopathies were added to the list. The group noted the large economic and social impacts that were demonstrated during the recent outbreak in Canada, although some group members felt

that the low transmissibility and other differences from other diseases already on the list made TSEs a relatively low priority.

- Pox viruses were added to the list. Members pointed out considerable media attention on genetic variations, the recent monkey pox outbreak, as well as recent research work on camel pox and goat pox.
- A distinct class of “unknown” or emerging diseases was added to the list. The group expressed a need for the development of research capabilities that could support rapid epidemiological response to new outbreaks, even if particular details of emerging diseases could not be researched ahead of time. This research would address molecular epidemiology, investigation methods, and control strategies.
- Eastern Equine Encephalitis (EEE) was removed from the list. The members felt that past epidemics had resulted in adequate knowledge about disease control. A few members raised the issue of weaponization, but the group agreed that unless the weaponized version was significantly different, this would not affect control issues. A different weaponized version would fall under emerging diseases.
- Vesicular Stomatitis (VS) was removed from the list. Several members raised gaps in knowledge about VS, such as the reservoir, but the group generally felt that VS is endemic in the United States and is therefore not a potent terrorist threat.
- Blue tongue was considered for addition to the list because of the big impact the disease has had in Europe and the existence of exotic strains; however, the group decided that the disease vector is not widespread and that, given limited resources, this was a low-priority disease. The group ultimately did not include blue tongue on its final list.

The group also felt that it might be beneficial to consider research priorities and gaps in terms of broader disease classes. This strategy would be more inclusive and reflects the common modeling approach of seeking out diseases similar to the one of interest and then tweaking existing models to fit that disease’s particular parameters.

Overall, the discussion led to agreement on two lists: high- and medium- priority diseases. Those are shown in Table 4.

Table 4: Prioritized List of Diseases of Concern

High	Medium
Foot and Mouth Disease (FMD)	Rinderpest (RP)
Highly Pathogenic Avian Influenza (HPAI)	African Swine Fever (ASF)
Exotic Newcastle Disease (END)	Venezuelan Equine Encephalitis (VEE)
Classical Swine Fever (CSF)	Transmissible Spongiform Encephalopathies (TSEs)
Nipah/Hendra Viruses (N/H)	Pox Viruses
Rift Valley Fever (RVF)	Unknown/Emerging Diseases

***Bold** denotes zoonotic diseases.

Defining High-Priority Domains

In developing a list of the most important realms of epidemiology for future research, the group focused on applied research that could be most meaningful to policymakers and workers in the field. The discussion was largely driven by modeling concerns – what is it about diseases that we need to know to model them? Moreover, how can we get real-life data so that robust information systems based on latest advancements in Geographic Information Systems can be integrated into Emergency Response efforts? Several group members advocated viewing modeling and epidemiology through a broad lens, to take into account real-world linkages around diseases. They pointed out that, in practical applications, it makes a real difference if, for example, a farmer meets government officials at the farm gate with a shotgun. Modeling can't be a stand-alone exercise that assumes laboratory conditions but should instead seek to incorporate real-world constraints, including human behaviors insofar as these affect the course of a disease and change the parameters in a model.

This discussion resulted in a list of issues in epidemiology that the breakout group felt had to be considered in fashioning a research plan. These are listed in Table 5.

Table 5: Infectious Epidemiology Issues

Major Issues	Subsidiary Issues
Virulence	
Species Susceptibility	(Reservoirs?)
Transmissibility	<ul style="list-style-type: none"> • Infectious dose, infectious period/latency, immunity • Environmental survival • Mode(s) of transmission • Cleaning and disinfection (C&D) • Phylogenetics/phylogenomics
Carcass Disposal	Agent neutralization, mass reduction, recycling
GIS	Datasets, confidentiality
Modeling	Population dynamics, production system effects, pathways
Risk Management	Analysis (includes introduction pathways), communication
Cost/Benefit Analyses	
Control Options	Vaccination strategies, logistics, quarantine options/effects, depopulation, social impacts
Recovery	Repopulation, indemnity
Success Definition	
Infrastructure	People (succession planning, rapid response teams, consortia)

Broad Overarching Issues

Capacity Building

A major theme underlying all of the discussions of specific diseases was the structure of the epidemiological research community and ways to increase capacity for the future. Group members noted a number of difficulties. For example, current efforts at modeling are often quite localized and fail to reflect the potential for widespread geographical impacts of outbreaks. Information and expertise could be shared more effectively. Researchers often wander in their own directions rather than working toward issues that are widely recognized as high-priority. Finally, recruitment and training of future generations of epidemiologists is inadequate.

To deal with these problems, the group proposed the development of a national consortium of ag-bio researchers, funded over at least five years, with a central hub of management; quarterly meetings; and requirements for training and employment of graduate students, interns, and research assistants. This arrangement would help facilitate communication, develop expertise, create unified directions for research activities, and provide involvement by decisionmakers in evaluation and oversight. A national consortium could take advantage of regional differences and integrate specific regional information into national models of disease control.

GIS & Data Issues

A second issue that cut across all diseases and presented a fundamental challenge for modelers was GIS and the availability of data. The challenge is to integrate spatial data into the planning and implementation of emergency responses. Using web-based and handheld information systems for data integration should also be a focus of applied research

One group member pointed out that switching from temporal to spatial modeling yields big improvements but that the mapping data needed to do this—Where are the farms? How many animals? What are the transportation routes?—is not available and is very difficult to get. To understand issues such as transmissibility, modelers need to know about animal density, production transport networks, and so on. Such issues could eventually affect the allocation of resources if modelers are able to predict where diseases are most likely to spread. Members saw several related lines of potential research on improving the data available to modelers.

First, the group felt that it was not yet known whether difficult to gather farm-level data would really be necessary or if modeling at a coarser level of granularity such as the county or zip code level might yield adequate results. Initial research should seek to understand the impact of data granularity of modeling and the constraints and costs and benefits of data collection at different levels.

Second, members argued that more work could be done on alternative data-collection strategies other than having the government demand information ahead of time. It might be possible to work out strategies for addressing confidentiality issues in advance of an outbreak in order to facilitate rapid data collection later. A related line of research should focus on building technology platforms with the real-time capacity to develop large databases very quickly.

Third, group members pointed out that in many cases corporate industry already has the data that academic epidemiologists seek; for example, vertically integrated industries often have models of flow through production chains. This knowledge needs to be better leveraged. Research in social sciences and economics might inform the development of policies to gain greater cooperation between government and academic epidemiologists and producers. An alternate strategy might be to create ownership of GIS modeling problems among industry stakeholders by making more R&D grants to industry and other groups, and through better risk communication.

End-to-End Modeling and Defining Success

A third broad issue applicable to all the different diseases was the scope and goal of epidemiological modeling. Members felt that considerable work could be done on better understanding the full system of a disease outbreak, from introduction through recovery and reconstitution. Pathways for introduction, both accidental and intentional, are often poorly understood or incompletely enumerated; for example, illegal importation of animals and animal products for ethnic restaurants may pose a considerable hazard; similarly, importation of species as pets could present potential pathways for introduction. Development of methods such as failure pathway analysis should be encouraged. Modelers need to understand the level of risk and the worldwide situation that could contribute to outbreaks. One strategy might be to work on risk analysis for all diseases by systematically considering how one might intentionally introduce a disease. Epidemiologists can't prevent everything, but this research might help determine where to monitor, what to look for, or how to catch intentional outbreaks early.

At the other end, since control options often merge into the recovery phase, it is important to consider the ways in which success should be defined. Models should be created so that what-if scenarios for disease control options can be constructed and analyzed. Outbreaks can have redistributive effects on rural wealth, for example, so epidemiologists need to understand what the effects of various control strategies are on the recovery phase and to work with stakeholders so that their efforts are put toward agreed-upon and beneficial end results.

Social Impacts and Risk Communication

A fourth issue that arose in discussions of nearly all diseases was the need to consider social impacts and human behavior in epidemiological modeling. Members pointed out the important role that social factors can play in disease outbreaks. In many cases, the impact of a disease will be determined more by public reaction than by science, so modelers need to understand these effects. For example, the size and scope of disposal problems may be determined in large part by whether the public accepts science on the consumption of meat during an outbreak or not, so epidemiologists need to understand the effects of behavior and social forces. It was also noted that reaction to outbreaks could be quite different in different countries; for example, differences in percentage of exports, media support, previous experiences, and strength of the inspection system between Canada and the United States means that U.S. researchers can't necessarily use experiences from Canadian outbreaks to understand how the U.S. public would respond. Members pointed out that there is a body of knowledge about public reactions to natural emergencies that researchers could draw on to better understand potential social responses to disease outbreaks, as well as psychological models.

It was noted that in some respects, the potential contribution of epidemiology in this broad sense to motivating changes in social factors could be more important than technical advances in modeling. For example, the discussion of social factors led group members to advocate for better risk communication. One member pointed out that, in his state, communication efforts in response to the FMD outbreak in the United Kingdom had increased cooperation among government, industry, and academic players. Risk communication should mean involving numerous stakeholders in the whole process of decisionmaking—getting them involved now, not just after an event. It was also noted that a potential network for better communication with producers already exists through the USDA Cooperative State Research, Education, and Extension Services (CSREES) county extension agent system, but that

researchers, regulators, and higher-level stakeholders could do a better job working with and through the county agents. Finally, members noted on several occasions that the need for better communication could drive research in areas that we otherwise would not be particularly interested. In dealing with public confidence, meat consumption, international trade, etc., the standard of proof has to be quite high, so research has to be very strong and credible.

Prioritization and Resource Allocation

A final broad issue group members discussed was how modelers might help government stakeholders to prioritize actions. Several members representing federal agencies brought up the issue of limited resources and the need to help government sectors in determining priorities and resource allocation. Some parameters in epidemiological models have larger impacts than others, so modelers should help the government to understand what the highest leverage parameters are. Members agreed that epidemiologists may never be able to provide absolute factors, but it would still be important to improve the range and distribution of parameter estimates and to focus on those that will best reduce variability and narrow predictions. Running models of efficacy of control strategies can help to distinguish those parameters that matter the most. Another line of similar work would involve running different models with different modeling strategies in parallel to determine where they agree and disagree.

Disease-Specific Issues

Model Disease: Foot and Mouth Disease

The group began by pursuing a wide-ranging examination of the knowledge gaps on foot and mouth disease. Members discussed FMD in considerable depth to elucidate not only issues particularly relevant to FMD, but also to find knowledge gaps that were likely to be common to a variety of other diseases. Subsequent discussions of other diseases built on this initial discussion and were targeted specifically at finding areas for each disease that were especially different or exceptional from the FMD model. Therefore, the FMD discussion reflects both particular concerns and general issues that apply to nearly all the diseases covered by the group.

Transmissibility

A number of transmissibility issues were raised as important knowledge gaps for FMD. For example, one member argued that more needs to be known about the relative risk of various farming practices. Given the large social impact of closing footpaths in the United Kingdom, for example, it is important to know if such steps are really important. Members also felt that more should be known about the airborne transmissibility distance of FMD and pointed out that this could be done through laboratory experiments on aerobiology, rather than waiting for new outbreaks.

There was some disagreement on how important wildlife transmissibility is for FMD, as some members pointed out that large deer populations could pose problems, while others pointed out that practical experience has shown wildlife transmissibility has not played a large role in past outbreaks, despite academic belief that it should. A more important area for research might be on the persistence of the disease in different species. Questions were also raised about the potential role of flies in FMD transmission.

The role of climate was raised as an area for further research, as FMD seems to cycle with El Niño in South America, but this effect is not well understood.

Another area that raised debate was the potential for transmissibility in meat products. Although some members felt that existing trade guidelines are based on strong knowledge and that there are few gaps to pursue in this area, other members pointed out that the enormous impact of trade made it crucial to have exceptionally solid and credible research as the scientific basis behind our import and export policies. During the UK outbreak, for example, the science was not strong enough to convince the public that meat was safe for consumption, even though science seems to show there was little danger. This created economic disruption and very low morale among farmers. To some extent this is an additional risk communication issue, but the science also needs to be very strong and credible.

In general, the group felt that more work on the survival of the agent in a variety of environments needs to be better understood. For example, understanding what FMD will do on the steel of a transport truck or on the floor of a barn are vital to understanding how the disease will spread and when various facilities might be considered “clean.” One member felt that he could currently make order-of-magnitude estimates of survivability on various surfaces or substances, but more work would improve models.

Carcass Disposal

Neutralization of FMD virus was raised as an area where much is known about existing options, but considerable work should be done on developing and understanding new and better disposal strategies. There are considerable moral and economic questions related to disposal, so the group felt that it was important to focus on practical disposal strategies. One example was work in the Netherlands on capacity building to support regionally centralized rendering centers that could help contain diseases. Recycling was also mentioned as an area to explore further.

Repopulation

Some areas for further research dealt with the repopulation of farms following an outbreak. Methods for repopulation currently exist, but considering the economic impacts created by forced downtime that is not fully compensated, members felt that there is a knowledge gap in terms of optimizing methods and developing new strategies. Basic questions such as the appropriate timing for allowing repopulation of either a previously infected farm or even an uninfected farm within an infected zone need to be answered.

Phylogenetics

One member felt that work in phylogenetics could help with forecasting and predicting disease outbreaks. For example, creating trees of disease genotypes could help researchers understand the sources of a disease and the reasons why it developed as it did. Phylogenetics helped determine when the HIV-2 disease entered the human species, for example, and it has been used to track the spread of Exotic Newcastle Disease (END) and Avian Influenza (AI).

Other issues

Group members felt that from the point of view of disease control, virulence is an unimportant parameter for FMD. They also felt that enough was already known about C&D.

General Issues Relevant to Zoonotics

The group identified personal protection and disposal as issues that are important for zoonotic diseases, particularly direct transmission diseases, but are not particularly important for non-zoonotic diseases. For personal protection, one member argued that it would be important to know that workers could actually handle animals and carry out vaccination or depopulation strategies

despite the potential cumbersomeness of protection equipment. Researchers might look at personal protection systems in commercial settings. Different diseases might also require different levels of protection. Risk communication issues specific to zoonotic diseases are particularly important as the perceived risk is to humans, but the expertise often lies with animal health professionals.

General Issues Relevant to Vector-Borne Diseases

A number of issues were raised that were applicable to all vector-borne diseases. The group members felt it would be important to know whether diseases had direct transmission routes in addition to vector-borne routes; for example, Venezuelan Equine Encephalitis (VEE) and EEE can be transmitted directly from bird to bird. Vector population dynamics and vector competencies were other important parameters to know. Competency rates could be variable, for example, and affected by biting rates, response to temperature, or other factors.

Discussion of Particular Diseases

Nipah/Hendra

Group members disagreed somewhat on the importance of research on Nipah. One member pointed out that we know how to stamp out the disease, so it may not be necessary to prioritize learning more about the basic biology, especially since outbreaks are rare. Other members, however, felt that this was a weak strategy and that we still need to know more about the disease. They pointed out that much could be learned about the parameters in laboratory settings. There was some discussion of potential reservoirs, although the group seemed generally satisfied with current knowledge. The risk of working with live and slaughtered pigs was also raised, but another group member argued that we already have evidence that only live pigs pose a problem. Given that risk, the issue of personal protection gear was especially relevant to Nipah.

Highly Pathogenic Avian Influenza/Avian Influenza (HPAI/AI)

AI is a zoonotic disease. Members pointed out that AI is not just one disease, but numerous different variations. Most members felt that issues of phylogenetics and mutability were more important than issues of virulence. An important area of research is what epidemiological conditions encourage emergence of a new variant and, more important, what conditions encourage the emergence of a variant with substantial potential for human-to-human transmissibility.

A number of questions were raised regarding species susceptibility. Work is being done on the distribution of different types of the virus in different species. Understanding the pathways between species remains challenging as well and may be informed by considering interactions between cultural and biological factors. Epidemiologists also need to understand the zoonotic potential of different H-types and the factors that have allowed some to jump to human populations and could potentially allow others to jump as well.

As a related issue, some members saw a need for work on the integration of monitoring efforts of human and animal populations. With SARS (Severe Acute Respiratory Syndrome), for example, testing animals has been a question. Sampling strategies would need to be developed to facilitate integration.

Exotic Newcastle Disease

The conversion of mesogenic strains to highly pathogenic velogenic strains was mentioned as an area of particular interest in the study of END. An additional area specific to the disease was the issue of pet birds and how control strategies might deal with a pet mind-set as opposed to an agricultural mind-set. There was some debate as to how relevant pet birds were to the issue of agro-terrorism, as some members felt that the issue related to accidental introduction only, while others viewed this pathway as an ideal opening for intentional introduction.

Classical Swine Fever

While transmissibility among commercial animals is fairly well understood, members saw a need for more knowledge on transmissibility among wild animals and the potential for the establishment of wild reservoirs in the United States. Another big issue specific to Classical Swine Fever (CSF) and African Swine Fever (ASF) is introduction through import of contaminated food.

Rinderpest

Although there was a bit of debate, the group members generally felt that Rinderpest (RP) is a low-priority disease. Disease control is relatively easy because of an effective vaccine and a 90 percent mortality rate that contains the spread of the disease. One group member felt that there was nothing new that we need to know about RP, while another thought that the biggest push at this point should be toward global eradication; another member argued that, even with eradication, it would be important to think about how to respond, since the disease would still exist in laboratories and could be reintroduced. A critical factor for RP would be complication of early detection of the disease due to confusion with clinically similar endemic diseases.

Rift Valley Fever

Members felt that Rift Valley Fever (RVF) could have a significant impact because it can spread quite quickly, causes abortion in animals, and is a zoonotic disease. Understanding wildlife reservoirs would be an important line of research, since RVF is a disease of trade; if it goes generation to generation in mosquitoes, it would be difficult to assure trading partners that the disease had been eradicated. The recent experience with the introduction and spread of West Nile Fever into the United States is illustrative of the challenges that would be faced to prevent RVF from becoming endemic as well.

Venezuelan Equine Encephalitis

VEE was identified as an important disease because of its zoonotic potential, debilitating effects in some human populations, aerosol transmission, and potential for horses to be an amplifying host. The group did not raise any particular research areas of specific concern for VEE, though, because there is an effective vaccine available.

Transmissible Spongiform Encephalopathies

Risk communication was raised as the most important area for further improvements in handling TSEs. For example, although intentional introduction seemed unlikely to the group members, the members felt that risk communication could play an important role in allaying public fears in the potential case of a false claim of intentional introduction. Experience with the disease in the United Kingdom and Japan also illustrates the potential for large impacts despite the fact that the disease is not very worrisome to scientists.

Other issues of concern for TSEs include transmissibility and other parameters needed for modeling. TSEs are similar epidemiologically to toxins, but can pass from animal to animal; therefore, they can't be modeled solely like an infection, but may look more like food contamination. For BSE, members felt that it is important to learn more about production channels and potential pathways because this would help with public reassurance. Finally, members felt that carcass disposal, in terms of both neutralization of the agent and dealing with biomass, were particularly problematic for TSEs because the diseases are hard to detect and, once detected, create a large biomass to dispose of in a short amount of time.

Pox Viruses

Members felt that an important line of research on pox viruses would be to characterize the diseases in their natural environment. For example, little was

known about the transmissibility of monkey pox between animals when the disease appeared in the United States, and little was known about the disease reservoirs. Some members argued that studying the disease's natural environment in Ghana would have helped fill these gaps.

Unknown Agents

Learning quickly about the virulence of unknown agents is an important line of research to inform detection and modeling efforts as new diseases emerge. Another idea was to make a concerted effort toward identifying potential zoonotic diseases that we should keep an eye on because they may cause us trouble in the future. This could be done by focusing attention on different cultural groups that interact with different animal species or by looking at different families of viruses to try to identify factors that make things potentially zoonotic. One member mentioned work by the Rockefeller Institute to identify arthropod diseases, but acknowledged that this work may be a bit far a field.

In a later discussion, the group generally agreed that it would be impossible to deal with all unknowns, so the best strategy would be to develop capacity for rapid response through investments in infrastructure. Several members advocated for the development of epidemiological rapid response teams that could quickly descend on affected areas and work up the problems.

A second strategy for infrastructure development would involve creating an agriculture equivalent of the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) that would serve as outreach centers to facilitate global networks and research relationships focused on emerging diseases in the country of origin. As with WHO and the CDC, scientists should be dispatched to sites of outbreaks of animal diseases of high concern wherever they occur, both to provide assistance and to learn more about those diseases in endemic locales. It was noted that terrorists might have access to agents that are endemic elsewhere in the world, so global networks would be important.

One member pointed out that part of the problem has to do with threshold levels and how quickly diseases emerge. West Nile Virus, for example, was able to gain a foothold because it was insidious and already established before regulators or epidemiologists were aware of it. To improve response time, work should be done finding new strategies for detection of rare events in a complex system.

Another strategy advanced by members was to think about tailored diseases and what aspects might make them particularly worrisome.

Summary of Recommendations

Table 6 summarizes the recommendations of the breakout group of Infectious Disease Epidemiology. It is intended to both provide a concise description of the recommendations above and allow comparison with the other breakout groups. Because of the differences in scope and available information, not all the table entries are filled out for all the breakout groups.

Table 6: Agro-Terrorism Research Priorities: Infectious Disease Epidemiology

* Research needs were prioritized by the working group: H+ = highest; H = high; M-H = medium-high; M = medium; and M-L = medium-low

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
<p>Expansion of Epidemiological Models: Develop “end-to-end” models, including limiting factors, effectiveness of quarantine, depopulation and alternative control strategies, repopulation strategies, and economic effects</p>	<p>Basic epidemiology modeling in hand, with and without spatial dimensions; Connection to control measures, constraints, and effects lacking.</p>	<p>Need to develop conceptual models that provide alternative approaches; Two types of models need to be developed: a granular (crude model) developed for the U.S. using crude county-type data and a more refined model using GPS herd data for selected states with such data</p>	<p>Develop or gain access to data needed to transition from conceptual models to refined, specific models that are comprehensive for each disease</p>	H		<p>USDA, DHS, State Departments of Agriculture</p>	Yes	\$2 million/yr
<p>Introduction Pathway Analysis: Define likely pathways for introduction of diseases and the critical control points for those pathways, beginning in the countries endemic for diseases of concern</p>		<p>Begin identifying data needed and develop databases that will be available from now on to modelers and decisionmakers</p>	<p>Build iterative pathway analysis algorithms for each disease that can be constantly updated with changing patterns of disease occurrence elsewhere in the world</p>	H		<p>DHS, USDA, Border state Departments of Agriculture</p>	Yes	\$1 million/yr

Agro-Terrorism Research Priorities: Infectious Disease Epidemiology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
<p>Evaluate Interdiction Efforts: Analyze the effectiveness of current interdiction and prevention efforts, starting in the countries where terrorists would likely acquire the diseases and including both the international borders and within states. Develop improved methods/procedures to enhance interdiction efforts</p>		<p>Create a catalogue of current interdiction methods; Begin developing methods to evaluate the effectiveness of current interdiction methods; Identify and begin collecting data necessary to formulate and evaluate alternative methods</p>	<p>Refine evaluation methods. Support development of new methods of interdiction (biosensors, informatics and etc...),</p>	H		DHS, USDA, Border state Departments of Agriculture	Yes	\$1 million/yr

Agro-Terrorism Research Priorities: Infectious Disease Epidemiology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Academic/State/Federal/ Industry Research Consortia: Develop models that focus regionally or by production compartment rather than on states and that involve actual decisionmakers in exercises of the developed models		Establish commodity specific research consortia to address research on the introduction, spread, control and impacts of diseases of concern for each commodity	Support the development of mitigation, response, and recovery strategies tailored to the production practices and biology of each commodity group	H	Related to, but importantly distinct from, planned DHS-funded academic center on “foreign animal and zoonotic disease defense.” In particular, needs both a regional or “by commodity” emphasis and a practical one, including industry and regulatory decisionmakers	DHS, USDA, State Depts. Ag. Industry	Probably requires federal funding, in whole or in part, to spur any regional center	\$5 million/yr/commodity
Determine the Level of GIS Data Needed for Epidemiological Modeling and Response (premise, zip code, region, animal)	Some data being collected for purely epidemiological models; Needs expansion to other regions, animals, and scales	Develop conceptual models of the impact on the effectiveness of epidemiological modeling of different spatial levels of GIS data	Refine the spatial granularity requirements for use in all phases of modeling as well as for emergency response operations	H		DHS, USDA, State Depts. Ag., Industry	Yes	\$1 million

Agro-Terrorism Research Priorities: Infectious Disease Epidemiology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
<p>Gathering of, or Access to, the GIS Data Needed for the Modeling and Response (locations, animal demographics, production flow and transportation routes); Investigate Confidentiality Constraints and solutions (need for nongovernmental data repositories); Development of Technology Platforms with the capacity to build large spatial databases from private- and public-source data very quickly</p>	<p>Some limited, state-based efforts, such as California or New York dairy farms, or North Carolina pig farms. Some vertically integrated industries (such as poultry) seem to have such data, but it is proprietary</p>	<p>Catalogue available data; Reach agreements with industries for data access; Establish Freedom of Information Act (FOIA) exemption for GIS data; Determine requirements for large spatial dataset platform development</p>	<p>Integrate GIS systems, web-based and handheld technologies into emergency response plans at both federal and state levels</p>	H		DHS, USDA, State Depts. Ag. Industry	Yes	\$3 million/yr
<p>Risk Communication: Develop improved methods for communication of risks, primarily to the public, but also to the governmental leadership and to those directly involved, such as the producers</p>		<p>Develop mental models for intentional animal and zoonotic disease outbreak scenarios</p>	<p>Develop disease-specific communication plans and materials in multiple languages and formats</p>	M		DHS, USDA, State Depts. Ag. Industry	Yes	\$2 million

Agro-Terrorism Research Priorities: Infectious Disease Epidemiology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Socioeconomic Impacts Define psychological, social, and economic impacts of disease outbreaks, their effects on response and recovery operations and formulate mitigation and response strategies to decrease impacts		Develop mental models for intentional animal and zoonotic disease outbreak scenarios	Develop mitigation, response, and recovery strategies that decrease or offset the social and economic impacts of an agro-terrorism incident	M		DHS, DHHS, USDA	Yes	\$2 million/yr
International Outreach Center: Build a global network for research collaboration and for gaining U.S. experience and access to diseases not normally found in the United States		Develop state/federal/academic epidemiological rapid response teams and fund deployment to other countries to study and assist with disease outbreaks	Develop and fund an International Collaborative Research Center to support all areas of R&D with regard to diseases of concern	H		USDA, DHS	Yes, and probably a purely federal responsibility; Some potential for international cooperation with other developed nations or international organizations	\$10 million/yr

Agro-Terrorism Research Priorities: Infectious Disease Epidemiology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Transmissibility: Define modes of transmission for some specific diseases (FMD via aerosol, for one important example), infectious dose, latency period, environmental stability under varying conditions, role of farm management practices		Create a catalogue of gaps in current knowledge for each disease of concern. Develop the bio-secure infrastructure capacity needed to conduct research on these agents on the mainland United States	Identify intervention points and develop methods to exploit critical points for disruption of the transmission of each disease	H	Overlaps in part planned DHS-funded academic center on "foreign animal and zoonotic disease defense"	USDA, DHS, DHHS	Yes	\$10 million/yr
Carcass Disposal: Develop additional cost-effective, environmentally friendly methods for agent neutralization and biomass reduction		Feasibility studies of methods for salvaging protein instead of destruction and disposal; Development of practical and humane mass euthanasia protocols for each commodity species	Development of both portable and regionally-based disposal or recycling methods	H		USDA, EPA	Yes	\$3 million/yr
Vectors/Host Range: Identify the potential vectors and hosts for exotic diseases introduced to the United States, define their ecological extents and population dynamics		For each disease, create a catalogue of likely vectors and wildlife reservoirs in the United States	Create models of the dynamics of the establishment and spread of each disease within the potential vectors/hosts available in the United States	H	Should serve as one research objective of the international centers proposed above	USDA, DHS, DHHS	Yes	\$2 million/yr

Vaccination and Protection Technologies

Breakout Group Meeting to Identify R&D Needs

December 9, 2003

Table 7 lists the members of this breakout group. Dr. James A. Roth chaired the meeting and coordinated the production of these notes.

Table 7: Vaccination and Protection Technology Breakout Group Attendees

James A. Roth, D.V.M., Ph.D.	College of Veterinary Medicine, Iowa State University	Director, Center for Food Security and Public Health; Executive Director, Institute for International Cooperation in Animal Biologics; Assistant Dean for International Programs and Public Policy
John B. Adams	National Milk Producers Federation	Director of Animal Health and Farm Services
Joseph F. Anelli, D.V.M.	U.S. Department of Agriculture, Animal and Plant Health Inspection Service-Veterinary Services-Emergency Programs	Director, Emergency Programs
Gary Cecchine, Ph.D.	RAND Corporation	Natural Scientist
Salvatore Cirone, D.V.M., MPVM	Office of the Assistant Secretary of Defense (Health Affairs)	Program Director, Health Science Policy, Force Health Protection and Readiness
Tom Evans, D.V.M., M.S.	Pfizer Animal Health	Associate Director, Biological Regulatory Affairs, Veterinary Medicine Research and Development
Cyril Gay, D.V.M., Ph.D.	United States Department of Agriculture	National Program Leader, Animal Health and Safety; National Program Staff
Larry Kerr, Ph.D.	Office of Science and Technology Policy	Assistant Director for Homeland Security
Beth Lautner, D.V.M., M.S.	National Pork Board	Vice President, Science and Technology
David Scott McVey, D.V.M., Ph.D.	Pfizer Animal Health	Veterinary Medicine Research and Development
Ed Nuzum, Ph.D.	National Institute of Allergy and Infectious Diseases, National Institutes of Health	Project Officer
Gerald Parker, D.V.M., Ph.D., M.S.	United States Army	Director, National Biodefense Analysis and Countermeasures Center
Paul-Pierre Pastoret, D.V.M., Ph.D.	Institute for Animal Health, Compton	Director
Brian Reed	RAND Corporation	Research Assistant

Introduction

U.S. livestock and poultry are highly vulnerable to the introduction of foreign animal disease agents. The national herds and flocks have no immunity to FADs because they have never been exposed to these agents, and vaccination against FADs is not practiced. If one of the highly infectious FAD agents were introduced into the United States, it is likely that it would spread rapidly, unless it was immediately detected and preventive measures were taken. Preventive measures would include quarantine and slaughter of infected animals if it were a small focus of infection. If the infection had spread, even modestly, it may be highly desirable to employ vaccination and quarantine as opposed to slaughter. The decision matrix that will be used by the USDA when deciding whether to vaccinate in the face of an FAD outbreak has been published (DeHaven et al., *Development in Biologicals*, 114:281–289, 2003).

One of the important factors in determining whether vaccination is a viable alternative to massive slaughter is whether sufficient amounts of efficacious vaccine are available and can be used in a timely manner. This working group addressed the need for development and deployment of vaccines for rapid use in the event of an outbreak of infection with an FAD that threatens U.S. livestock.

Vaccines for the highest priority FAD agents are not produced or used in the United States. Several vaccines for important FAD agents are produced and sold on the world market. The majority of these vaccines are not approved by the USDA APHIS Center for Veterinary Biologics for emergency use during an outbreak because they have not been evaluated for safety, efficacy, potency, or purity according to USDA standards.

In addition, the majority of vaccines for FADs that are produced are based on decades-old technology. Dramatic advances in immunology, microbiology, genomics, and vaccinology have occurred in recent years. This presents a great opportunity to use these scientific advances to develop a new generation of vaccines with improved safety and efficacy for controlling FAD threat agents. The quickest, most efficient way to reduce the vulnerability of U.S. livestock and poultry would be for government, academic, and industry scientists to work together to develop and test new-generation vaccines and to deploy stockpiles for rapid use. This will require a significant investment by the federal government but will greatly reduce the vulnerability of the greater than \$100 billion dollar animal industry in the United States to the intentional or accidental introduction of foreign animal and zoonotic diseases.

Working Group Deliberations and Recommendations

The Vaccination and Protection Technologies working group reviewed the following document and agreed to follow the general outline of this document:

“Strategic Research Document: Strategic Research Targets to Protect American Livestock and Poultry from Biological Threat Agents: Report from the WMD Counter Measures Working Group – Animal Pathogen Research and Development Subgroup,” October 31, 2003.

This document is hereafter referred to as SRD (and is available at www.usda.gov/homelandsecurity/homeland.html) strategic research document. The SRD already provided a list of commonly acknowledged, highly dangerous animal pathogens. The selection of particular agents by terrorists was not explicitly discussed in the document; however, all agents in U.S. and Soviet bio-weapon programs are among the 10 agents considered in the SRD. (Anthrax was not included because it is being addressed by other agencies.)

The discussion of the animal pathogens listed in the SRD spans four major areas related to the development, implementation, and maintenance of technology, policy, and infrastructure needed to implement an FAD vaccine program. The four areas are science and technology, economic and legal considerations, logistics and implementation, and governmental oversight and regulation. Within each of these areas, a variety of significant obstacles were identified. These points should be considered in relation to an FAD vaccine program as a whole and also in relation to the vaccine program strategy for each individual disease.

There was general agreement from the group that a significant investment in education and research will be necessary to enhance our present knowledge of bovine, swine, and avian immunology. Two general suggestions were made to help develop this knowledge. The first suggestion is that FAD and zoonotic diseases should be incorporated and emphasized in the D.V.M. curriculum. The second recommendation is an increase in funding for D.V.M./Ph.D. programs, particularly those with an emphasis on the study of FAD and zoonotic disease.

It was also agreed that new investment in infrastructure will be required to conduct these types of research and develop new technologies. In particular, lack of infrastructure places severe constraints on our ability to perform research, and develop technologies, involving pathogens classified as BL3 or above. The Plum Island facility is inadequate to handle the volume of necessary research on FAD. Furthermore, the United States has no BL4 capable facility for studies in large livestock species.

Improvements in the areas of education and infrastructure should make the goals of vaccine development more attainable. The ultimate goal of all R&D efforts will be to produce vaccines that possess a set of characteristics that represent an ideal vaccine for the control and eradication of an animal pathogen. In general, it is hoped that any vaccine will be safe, economical, and easy to manufacture within the United States. More specifically, the ideal vaccine would combine all the following features to whatever extent possible—marker detection mechanisms, short onset of immunity (OOI), broad protection across relevant strains, prevention of shed and spread, prevention of persistent infections, long duration of immunity, and that the vaccinated animals remain safe for human consumption.

Marker detection mechanisms would be used to identify the following four scenarios—vaccinated animals that are not infected, non-vaccinated animals that are infected, animals that were infected and then vaccinated, and animals that were vaccinated and then infected. The goal is to quickly differentiate vaccinated animals from infected animals. Broad protection would ideally mean that there is only one vaccine for all the relevant strains and preclude the need to quickly develop a new vaccine once the strain responsible for an outbreak has been identified. This would greatly simplify the logistics of treating an outbreak and would make prophylactic vaccination strategies more robust.

Developing a vaccine that meets some or all of the ideal vaccine criteria, as described above, is only one step in a complex process. Such a vaccine is of little use if it cannot be delivered in a timely and effective manner. Thus, technology may not be the only limiting factor in addressing FAD; we must develop effective, ground-tested implementation procedures to deliver all existing and future technologies.

The significance of delivery methods led the working group to suggest that additional funding and research be directed toward the design and implementation of a stockpiling program that will ensure rapid delivery in the event of any sort of FAD outbreak.

The FMD case contains detailed descriptions of stockpiling issues that should be considered when stockpiling any FAD vaccine. Based on the assumption of early detection, vaccines would be needed within a one- to five-day period for effective ring vaccination. The vaccine bank should have doses for all serotypes, in deliverable form (for rapid emergency use), and must meet licensing requirements of the USDA Center for Veterinary Biologics, including considerations for good manufacturing practices (GMP). In addition, there is a critical need for effective logistics and distribution protocols for present and

future stockpiles. A final logistical consideration is the need to develop standardized government protocol for FAD vaccines—currently the human vaccine protocol requires one CONUS (continental United States) and one non-CONUS supplier. The working group recommends that such a policy be considered for animal vaccine suppliers as well.

Finally, consideration must be given to the overarching economic, legal, and regulatory, and policy implications of R&D efforts for vaccines. From an economic perspective, the issue of funding and use of available resources is critical. The working group recommends leveraging university and private-sector resources, including requests for development and manufacturing contracts for vaccine formulation, manufacturing, and stockpiling when possible, rather than attempting to develop new programs from the ground up.

Furthermore, it is crucial that the economic interests of private- and public-sector resources and facilities are understood. Intellectual property issues (biological companies purchasing [and concealing] new and improved vaccine patents to protect market share) and a current lack of demand for technologies minimize interest within industry and academia to address problems. In addition, disincentives exist for livestock producers that prevent them from demanding or purchasing new technology because of real or perceived cost of production increases and/or the stigma of acknowledging or identifying weaknesses in the security of the food supply.

Apart from the more subtle economic and legal considerations are the obvious funding limitations currently faced by the USDA and other agricultural organizations (for example, Plum Island receives only \$3.5 million to study FAD). To meet the challenges of developing and implementing effective vaccination programs, the USDA and other organizations currently engaged in bio-ag security work need to implement new methods. The DoD approach to R&D and procurement was mentioned as an example. If DoD is asked to solve or address a problem, it first determines if it or some other organization has the information, resources, solution, etc. If no resource exists, DoD does the work itself. To make such a method feasible for bio-ag problems, significant funding increases are necessary. As the case of Plum Island illustrates, the working group feels many bio-ag research efforts are sorely under funded.

The likelihood of a biological or agricultural attack and the potential for severe consequences in the event of such an attack obviate the need to address agriculture as a national security issue. As such, the working group recommends exploiting current funding opportunities to strengthen financial support for agricultural R&D. A clear role must be established for the federal

government to direct the recommended efforts for ensuring bio-ag security. The massive R&D, logistics, and funding efforts recommended by this working group require strong central organization. The working group proposes the creation of an animal/plant equivalent of Bio-Shield within DHS/DHHS or elsewhere in the federal government.

The priority assigned to each pathogen in Appendix 6 of the SRD was based on five criteria:

1. economic impact – potential cost to producers and public
2. virulence and potential for the disease to spread
3. zoonotic potential – potential for the disease to infect humans
4. morbidity or lethality of disease within host population
5. likelihood disease will spread to other species.

In the SRD, the bio-terror potential of a pathogen was not explicitly considered as a ranking criterion. In general, the five criteria above implicitly address most of the relevant criteria for use as a bio-weapon. However, at least two other, potentially critical considerations exist:

1. ability of terrorists to naturally acquire, or otherwise manufacture, a particular pathogen
2. difficulty (or necessity) of weaponization of pathogen.

Recommendations for Specific High Consequence Animal Pathogens

It was agreed that the list compiled within the SRD was a generally exhaustive list of seriously threatening diseases. FMD was the unanimous choice for the most serious threat. Consequently, we have treated FMD in a similar manner to the other working groups, designating it as a “model” disease. The recommendations (as well as their number and detail) for FMD should be considered a reasonable upper bound for all other diseases. Thus, the subsequent discussions for each pathogen only highlight characteristics unique to that specific pathogen.

The discussion of each pathogen is broken down into the same categories: research priorities, current research, priority, funding, and additional questions. In addition, the recommendations for FMD include a section about stockpiling which is not included for any other pathogen. Except for instances in which it is

explicitly *not* included, the USDA is directly or indirectly involved in some or all of the existing research programs for a specific pathogen. Nearly all pathogens will have some commentary for each category. In the few cases in which a category has been omitted (specifically, “Additional Questions”) for a specific pathogen, this indicates that the working group has no substantial and/or unique commentary on that particular subject. In general, the assessments provided in each category may be considered as broad recommendations for the same categories relative to other pathogens, except in cases in which one case is clearly inapplicable to another (e.g., concerns about the presence of African Swine Fever in feral swine populations are not applicable to Highly Pathogenic Avian Influenza).

The pathogens are listed in order of priority, highest to lowest. The numeric ordering scheme reflects the general consensus reached by the working group and may differ from the priority assigned in the SRD. For each pathogen, there is a description of the priority—in this case, a more qualitative approach was used, graded Highest, High, Medium, Low.

In addition to the proposed research and development strategies for each pathogen, it is recommended that alternative control strategies be investigated. The recommendations for vaccination alternatives are taken from the decision tree model on slide 5 of Dr. Anelli’s presentation to the Blue-Ribbon Panel, “Foreign Animal Disease Control: Vaccination and Culling.” The various options, stamping out, pre-emptive slaughter (PES), and regionalization should be weighed to determine the most practical and effective method for dealing with a particular pathogen. This provides for a variety of high-level approaches to address a potential outbreak of an FAD. In addition to the culling strategies suggested in Dr. Anelli’s presentation, the working group also recommends research on treatments involving cytokines, interferon, and other antiviral approaches.

Foot and Mouth Disease

Research Priorities

The working group agreed that current FMD research should be directed at the development of an effective strategy to contain an initial outbreak and thereby prevent a major one. Ideally, researchers should attempt to develop a one-time use vaccine (to avoid the need for reapplication), which would be safe to develop and implement, cost-effective, and easy to administer.

Research Currently Ongoing

The working group endorsed the recommendations of Col. Gerry Parker's (DHS) presentation to the Blue Ribbon Panel as reasonable guidelines for near-term research. For long-term research, the working group endorsed the recommendations of the SRD.

Priority

The working group unanimously assigned FMD the highest priority of all pathogens considered. This results from a combination of the severe economic and social impact and the level of devastation that FMD would produce.

Stockpiling Considerations

FMD stockpiling issues should be considered when stockpiling any FAD vaccine.

Based on an assumption of early detection, vaccines would be needed within a one- to five-day period for effective ring vaccination. Ideally, a vaccine bank would have doses for all serotypes in deliverable form for rapid emergency use. Vaccines should employ an adjuvant suitable for use in cattle, sheep, or swine, and must meet licensing requirements of the USDA Center for Veterinary Biologics, including considerations for GMP. Finally, there must be a method to describe surge capacity to gauge subsequent production in the event of an outbreak.

Specific FMD vaccine bank distribution requirements:

1. Six million doses of all seven serotypes should be deliverable within 24 hours, anywhere in the United States. These doses must be packaged ready-to-use.
2. Delivery of 10 million doses of all seven serotypes within two weeks. These could be stored in frozen bulk ready to package.
3. New vaccine must be produced within two to three months (+/- depending on reapplication needs).
4. Include delivery devices and devices to identify vaccinated animals within the stockpile.

Additional Questions

1. Will an ideal vaccine be used as a prophylactic?

2. What is the proposed level of involvement and potential role of universities, private sector, foreign governments, etc.?

Funding

For the same reasons that FMD was assigned the highest possible priority, it will require the most substantial expenditures for development and implementation of programs capable of addressing the needs identified by this working group. Consequently, the working group recommends substantial funding increases required for existing programs, and additional funding will be required to stimulate university and private-sector involvement (possibly in the form of request for proposals [RFPs]). The working group recommends an initial investment of \$75–100 million/year for seven to ten years. It is estimated that development of an “ideal vaccine” (as described above) will require close to ten years. During this span, the working group also recommends that funds and other resources be allocated to study antivirals and other therapeutics. These monetary figures also include approximately \$10 million/year for D.V.M./Ph.D. education. These funds are intended to remedy the dearth of qualified veterinary and animal health professionals and to better prepare these same individuals for the challenges of combating FMD and all other foreign animal diseases.

Rift Valley Fever

Research Priorities

Develop an effective strategy to contain or prevent major outbreak of RVF. This is necessarily a two-step approach – an effective vaccine must be developed, and an implementation strategy for the resulting vaccine must be devised. A one-time approach (hoping to avoid reapplication) would be ideal; the solution also should be safe to develop and implement, cost-effective, and easy to implement. RVF is a unique pathogen because a vaccine is attainable soon – a modified live version could be attained within a few years. The working group endorses the course of action outlined in the SRD, specifically an evaluation of the MP-12 vaccine developed by the U.S. Army.

Research Currently Ongoing

For the near term (one to three years), the working group endorsed the SRD recommendations for RVF research, including a recommendation to complete the development and testing phase of present technology – the Army’s MP-12 vaccine. The far-term goals are to improve existing technology if necessary.

Additional Questions

Some additional questions remain for RVF. Because of its zoonotic potential, it is a necessary but potentially difficult problem to determine who will administer vaccinations if an outbreak occurs. Furthermore, because someone must be designated to administer the vaccine, this will necessitate the development of a human vaccine to protect those charged with administering the animal vaccine as well as animal workers who may be at risk for contracting the RVF virus.

Priority

The priority of RVF was designated high for at least three specific reasons, zoonotic potential, likelihood of success (a vaccine is near completion), and RVF could become endemic if it is transmitted to domestic animals because competent insect vectors for this virus exist in the United States.

Funding

The USDA is the primary agency charged with funding and administering the R&D efforts for an RVF vaccine. The working group proposes the establishment of an interagency working group for zoonotic disease involving collaboration of USDA, DHS, and DHHS. The purpose of such collaboration would be to draw from a larger pool of available resources and expertise; furthermore, it would help to ensure that the vaccine and policies developed are suitable from the perspectives of the agricultural, economic, and homeland security sectors.

These proposals require substantial funding increases for existing programs and stimulation of university and private-sector involvement (RFPs). It is recommended that there be an initial investment of \$20 million/year (development) for two years, with the possibility of needing additional funds for stockpiles, etc., based on initial two-year results.

Nipah and Hendra

Research Priorities

The primary goal is to develop an effective strategy to contain or prevent a major outbreak of Nipah and Hendra (N&H). The recommendations for vaccine research are once again aimed at development of a vaccine that will satisfy as many of the criteria of an ideal vaccine as possible, as described above.

To this end, the working group recommends the continued study of the live vaccine currently under development. This vaccine uses two genes from Nipah provided by CDC and is delivered using canary pox and human adenovirus vectors. It was also suggested that some research be aimed at examining alternative delivery mechanisms and validation of the marker technology.

Research Currently Ongoing

Current research involves testing and improving the candidate live-vectored vaccines. A candidate vaccine is in the queue for challenge trials at the Winnipeg BL4 facility. In the near term, the working group endorses the SRD recommendations, and it emphasizes the need to determine safety and efficacy of the vaccine(s) currently under development. In addition, new vaccination and treatment techniques (e.g. antiviral) should be researched and tested.

Additional Questions (N&H)

In addition to the necessary vaccine research, N&H underscore the importance of assessing U.S. strategy regarding BL4 pathogens. Specifically, can a U.S.-led/controlled BL4 facility, with significant large animal capacity (greater than one cow and more than five swine), be established and constructed in the near future? This consideration is also relevant for *any* newly emergent deadly zoonotic pathogen.

Priority

The working group has assigned N&H a high priority for a variety of reasons. In particular, it is a BL4 pathogen and it is zoonotic. Also, N&H has only recently been identified, so there is comparatively little knowledge about either disease.

Funding

The working group agreed that significant funding increases are necessary for the USDA and all other related organizations. The increased funding would be directed toward existing programs and the task of stimulating university and private-sector involvement. As such, the working group recommends that approximately \$5 million is needed in the near term for initial proof of concept (POC). Upon success of a POC, an additional \$20 million for manufacture, stockpiling, etc., will be required. The working group also recommends the formation of an interagency working group. This working group would likely constitute another division of the working group that was proposed for FMD and RVE.

Highly Pathogenic Avian Influenza

Research Priorities

The primary goal is to develop an effective strategy to contain or prevent a major outbreak of Highly Pathogenic Avian Influenza (HPAI). The recommendations for vaccine research are once again aimed at development of a vaccine that will satisfy as many of the criteria of an ideal vaccine as possible, as described above.

Research Currently Ongoing

In the near term, the working group recommends the strategy recently implemented in Italy of vaccinating with a homologous hemagglutinin type and a heterologous neuraminidase type. This will allow antibody to the homologous neuraminidase type to be used to detect infected birds. To enable the use of this strategy, the working group recommends developing a stockpile of 10 million doses for the two most common neuraminidase types of both the H5 and H7 strains.

Over the long term, approximately three to seven years, the working group consensus was that significant research is needed. The working group endorses the recommendations of the SRD to serve as a guideline for this research.

Additional Questions

Is it possible to prevent cross species transference – avian to swine; swine to avian; human to swine – and, if so, by what methods?

Priority

The working group assigned HPAI a high priority because of its zoonotic potential. In addition, the general organization and methods of the poultry industry make HPAI a particularly dangerous threat.

Funding

The working group recommends substantial funding increases to support existing research programs and to stimulate university and private-sector involvement. The working group suggests a preliminary figure of \$5 million/year for at least five years.

Classical Swine Fever

Research Priorities

The primary goal is to develop an effective strategy to contain/prevent a major outbreak of CSF. The recommendation for vaccine research is to pursue the development of a vaccine that will satisfy as many of the criteria of an ideal vaccine as possible. Unique to the case of CSF is that vaccines currently exist outside of the United States. Consequently, research should be aimed at improving this technology and establishing a reliable domestic and foreign supply.

Research Currently Ongoing

In the near term (one to three years), the working group recommends having APHIS CVB inspect and preapprove foreign facilities to allow rapid importation of existing vaccine for near-term outbreak control (approximately 5 million doses). Additional domestic research could be performed as needed. Seropositive animals would be slaughtered as a near-term alternative to widespread vaccination.

The long-term ideal approach is to develop a new and improved vaccine domestically per recommendations of SRD. In particular, a high efficacy marker vaccine is desired.

Priority

The working group agreed that CSF should be assigned a high priority.

Funding

The working group recommends substantial funding increases. This funding would be designated accordingly for validation and importation of the available foreign vaccines, support of existing research programs, and the stimulation of university and private-sector involvement. The working group suggests a preliminary figure of \$10 million/year for five years.

Newcastle and Exotic Newcastle

Research Currently Ongoing

The present vaccine for Newcastle has shown efficacy for END. The working group proposes that near-term research investigate the current Newcastle vaccine and vaccination practices for efficacy in controlling END. For the long term, the working group endorsed the SRD recommendations. These recommendations include an effort to modify the existing vaccine to produce an easy-to-deliver, cost-effective marker vaccine that is also effective for controlling END. To improve efficacy and limit exposure to Newcastle and Exotic Newcastle Disease (N/END), there should be a concerted effort to ensure routine use of a new vaccine.

Priority

The working group assigned N/END a medium to high priority.

Funding

The working group proposes a funding increase of \$2 million/year to initiate and continue the proposed course of research.

African Swine Fever

Research Priorities

It is currently unclear whether the creation of a vaccine is possible. Research efforts must resolve this question. If it is found that a vaccine can be developed, this approach should be taken. If it is not possible to develop a reasonably effective vaccine in the relatively near future, the research that led to this conclusion must inform an alternative approach.

The epidemiology of ASF must be better understood. In particular, there must be an improved understanding of the impact of ASF on domestic feral swine populations. Eradication may be impossible because of feral swine populations. Stamping out is currently the most widespread tactic.

Research Currently Ongoing

At present, there are programs devoted to researching ASF. For the near term, the working group has endorsed the SRD recommendations. In particular, the working group proposes increasing current efforts to determine whether a vaccine can be created. A genomic approach is recommended as the most likely avenue of discovery. If a vaccine can be developed, the long-term recommendations of the working group are to focus on vaccine production and improvement. If a vaccine cannot be developed, research should be aimed at alternative control strategies.

Additional Questions

Research that is not directed toward vaccine feasibility or development should address the following concerns: Can domestic ticks serve as a vector? Can (or would) terrorists attempt to harness ASF? Should there be concern about infection from domestic feral swine?

Priority

The working group designates the priority for ASF to be medium to high.

Funding

The working group recommends an increase of \$5 million/year to address the proposed aspects of ASF research.

Venezuelan Equine Encephalitis

Research Priorities

A trivalent vaccine exists for Eastern, Western, and Venezuelan forms, but it is not often used because it lacks maximum profile. This suggests that one avenue for research would be to increase the efficacy of current vaccine technology. DoD currently has a program to study human infection, but there is no animal program. Because horses are an amplifying host, and there is zoonotic potential, there is a need to focus on the animal infection. Consequently, the working group recommends the formation of a program to address equine infection.

Research Currently Ongoing

For the near term, the working group endorsed the recommendations of the SRD. In particular, there is a need to focus attention on the animal infection.

Additional Questions

The working group generally felt there was a need for investment in general animal immunology. In particular, there is a substantial need to consider general protective immunology—to defend against VEE strains that may be weaponized.

Priority

Equine encephalopathies were assigned a medium priority because of the combination of zoonotic potential and relative ease of weaponization.

Funding

At present, DoD is engaged in VEE research, but, as mentioned above, this research only focuses on human infection. The USDA is not presently involved in any research programs focused on VEE.

The working group recommends increases in funding for both near- and long-term research needs. In particular, funds are needed to establish a research program for animal infection. The working group has proposed a tentative figure of \$2 million.

Rinderpest

Research Priorities

RP was unique among the pathogens considered by the working group because the disease is nearly eradicated. Consequently, no vaccination research has been recommended. Instead, emphasis was placed on alternatives to vaccination and approaches designed to fully eradicate and prevent resurgence of the disease. RP is easy to control because it is transmitted only by direct or close proximity contact, and there is only one serotype. Furthermore, infected animals exhibit obvious, severe symptoms, which uniformly result in death. Thus, the working group recommends a strategy of maintaining vigilance to prevent resurgence (and to monitor the emergence of new serotypes) and an attempt at complete eradication.

Research Currently Ongoing

The working group focused only on the near-term actions – believing that continued successful implementation of current methods will result in eradication. Consequently, the working group concurs with the recommendations of the SRD. This includes stockpiling vaccine *and* maintaining supply to ensure defenses exist even after disease is eradicated.

Additional Questions

The goal of eradicating RP appears feasible in the near term. However, the assessment of feasibility and its associated timetable are contingent on the fact that there is only one serotype and that this serotype does not mutate. To validate the eradication strategy, and to maintain proper vigilance for all contingencies, the working group recommends monitoring and/or conducting additional research to ensure that only one serotype exists and that this serotype does not mutate.

Priority

It was generally believed within the working group that the priority for RP should be low; however, because it is so nearly eradicated, the working group thought it was important to concentrate near-term efforts to ensure eradication. Thus, it was assigned a medium priority.

Funding

Because RP is nearly eradicated, and the efforts to control it are well developed, the working group made no specific recommendations about changes in funding levels.

Summary of Recommendations

Table 8 summarizes the recommendations of the working group on Vaccine and Protection Technologies. It is intended to both provide a concise description of the recommendations above and allow comparison with the other working groups. Because of the differences in scope and available information, not all the table entries are completed for all the working groups.

Table 8: Agro-Terrorism Research Priorities: Vaccination and Protection Technology

* Research needs were prioritized by the working group: H+ = highest; H = high; M-H = medium-high; M = medium; and M-L = medium-low

Agro-terrorism Research Priorities: Vaccination and Protection Technology								
Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far Term Research Needs (3-7 years)	Overall *Priority	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Research on Vaccination and Other Alternatives for FMD		Endorsed recommendations of Col. Parker's presentation and document	Endorsed recommendations in SRD; Develop "ideal vaccine" (marker detection mechanisms, short OOI, broad serotype protection, prevention of spreading and shedding, prevention of persistent infections, minimal need for reapplication, vaccinated animals safe for consumption, economical/easy to manufacture in United States, monitoring of raw materials for cross-contamination)	H+		USDA	Yes, substantial funding increases req. for existing programs; Yes, initial funding req. to stimulate university and private-sector involvement (RFPs)	\$75-100 million/year, 7-10 yrs; \$10 million/year included for D.V.M./Ph.D. education
Research on Vaccination and Other Alternatives for RVF	MP-12 vaccine	Group endorsed SRD recommendations; Complete development and testing phase of present technology	Improve existing technology, if necessary; Develop "ideal vaccine" (see characteristics above)	H		USDA	Yes, substantial funding increases req. for existing programs; Yes, initial funding req. to stimulate university and private-sector involvement (RFPs)	\$20 million/year (development) for 2 yrs; Additional money needed to stockpile based on 2-year results

Agro-terrorism Research Priorities: Vaccination and Protection Technology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far Term Research Needs (3-7 years)	Overall *Priority	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Research on Vaccination and Other Alternatives for Nipah and Hendra	Testing and improvement of existing vaccine candidate is in the queue for challenge trials at Winnipeg BL4 facility	Group endorsed SRD recommendations; Determine safety/ efficacy of vaccines currently under development; Research on antivirals, etc.; Challenge study of current vaccine at BL4 facility in Winnipeg, Manitoba	Develop "ideal vaccine" (see characteristics above)	H		USDA	Yes, substantial funding increases req. for existing programs; Yes, initial funding req. to stimulate university and private-sector involvement (RFPs)	\$5 million for initial proof of concept; \$20 million for manufacture, stockpiling, etc.; Develop interagency working group
Research on Vaccination and Other Alternatives for Highly Pathogenic Avian Influenza		Follow strategy recently implemented in Italy; Need to stockpile 10 million doses for the two most common neuraminidase types of both the H5 and H7 strains	Significant research needed; Group endorses the recommendations of the SRD; Develop "ideal vaccine" (see characteristics above)	H		USDA	Yes, substantial funding increases req. for existing programs; Yes, Initial funding req. to stimulate university and private-sector involvement (RFPs)	\$5 million/year for at least 5 years

Agro-terrorism Research Priorities: Vaccination and Protection Technology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far Term Research Needs (3-7 years)	Overall *Priority	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Research on Vaccination and Other Alternatives for Classical Swine Fever		Have APHIS CVB inspect and preapprove foreign facilities to allow rapid importation of existing vaccine for near-term outbreak control (approximately 5 million doses); Seropositive animals would be slaughtered	Develop a new a improved vaccine domestically per recommendations of SRD; High-efficacy marker vaccine is desired; Develop "ideal vaccine" (see characteristics above)	H		USDA	Yes, substantial funding increases req. for existing programs; Yes, initial funding req. to stimulate university and private-sector involvement (RFPs)	\$10 million/year for 5 years
Research on Vaccination and Other Alternatives for Newcastle and Exotic Newcastle Disease	Present vaccine for Newcastle has shown efficacy for END as well	Investigate current Newcastle vaccine and vaccination practices for efficacy in controlling END	Group endorsed SRD recommendations; Modify existing vaccine to produce an easy-to-deliver, cost-effective, marker vaccine that is also effective for controlling END; Insure routine use of new vaccine	M-H		USDA	Yes	\$2 million/year
Vaccination research for African Swine Fever	Active programs exist	Group endorsed SRD recommendations; Increase present efforts to determine if a vaccine can be created (genomic approach is recommended as the most likely avenue of discovery)	If a vaccine can be developed, proceed; Develop "ideal vaccine" (see characteristics above)	M-H		USDA	Yes	\$5 million/year

Agro-terrorism Research Priorities: Vaccination and Protection Technology

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far Term Research Needs (3-7 years)	Overall *Priority	Research Already Funded or Funding Pending?	Agency/ Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Vaccination research for Venezuelan Equine Encephalitis		Group endorses SRD recommendations; Focus on the animal side (DoD has current program to study human infection, but there is no animal program)	Group endorsed SRD recommendations	M		DoD	Yes, substantial funding increases req. for existing programs; Yes, initial funding req. to stimulate university and private-sector involvement (RFPs)	\$2 million/year
Vaccination Alternatives for Rinderpest		SRD recommends stockpiling vaccine and maintaining supply to ensure defenses even after disease is eradicated; Some monitoring or additional research may be needed to ensure that only one serotype exists and that this serotype does not mutate		M-L		USDA	None	None

Detection, Diagnosis, and Forensics Capabilities

Breakout Group Meeting to Identify R&D Needs

December 9, 2003

Table 9 lists the members of this breakout group. Dr. Linda Logan chaired the meeting and coordinated the production of these notes.

Table 9: Detection, Diagnosis, and Forensics Capabilities Breakout Group Attendees

Linda L. Logan, D.V.M., Ph.D.	Texas A&M University, College of Veterinary Medicine	Professor
Noah Engelberg	Executive Office of the President, Office of Management and Budget	
Rocco Casagrande, Ph.D.	Abt Associates	Homeland Security Program
Dr. Rebecca Walker	FBI, Hazardous Materials Response Unit	
Larry Granger, D.V.M.	United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services	Associate Administrator of Emergency Programs
Robert Heckert, D.V.M.	Agricultural Research Service, United States Department of Agriculture	National Program Leader, Animal Health
COL Scott Severin, D.V.M.	Department of Defense Veterinary Service Activity	Acting Director
Alfred Montgomery, D.V.M.	Surveillance & Compliance Office, Food and Drug Administration	Veterinary Medical Officer
CAPT James Burans	National Biodefense Analysis and Countermeasures Center	National Bioforensics Analysis Center
Brian A. Jackson, Ph.D.	RAND Corporation	Physical Scientist
Peter Chalk, Ph.D.	RAND Corporation	Political Scientist
David Adamson, Ph.D.	RAND Corporation	Research Communicator

The goal of the breakout group was twofold: (1) to identify shortfalls in capabilities to detect, diagnose, and analyze potential agricultural bio-terrorism agents, and (2) identify corresponding research and development priorities to address those shortfalls. The discussion was aimed at developing an understanding of:

- a. currently available diagnostics;

- b. the steps necessary to validate current tests and increase their efficiency and diagnostic potential;
- c. the different requirements for tests and application strategies before, during, and after an outbreak; and
- d. tests currently in development and any necessary steps to move them into validation and production.

Agents of Concern

In initial discussions, the breakout group was guided by the agents of concern highlighted in the document entitled “Strategic Research Document: Strategic Research Targets to Protect American Livestock and Poultry from Biological Threat Agents: Report from the WMD Counter Measures Working Group–Animal Pathogen Research and Development Subgroup” from the WMD Countermeasures Working Group–Animal Pathogen Research and Development Subgroup released in October 2003, which focused on vaccine development. Although the 10 agents discussed in that report provided a valuable starting point, the group concluded that the agents of highest priority for vaccine development were not necessarily the same as those of highest priority for diagnostic testing research.

With respect to animal agents, the group concluded that diseases of highest concern should be identified based on their attractiveness to a potential bio-terrorist in combination with their potential impact if released. In this context, criteria relevant to assessing agricultural diseases include

- level of morbidity and mortality caused by the disease
- level of the disease’s transmissibility
- presence of effective vectors of the disease
- number of animal species affected
- whether or not the disease is zoonotic
- availability of control strategies
- presence of wildlife reservoirs of the disease
- ability of the agent to survive in the environment
- availability of diseases to adversaries
- technical constraints on deployment of the disease agent by adversaries
- presence of natural diseases that might confound detection of intentional release or be confused with the agent.

The agents judged to be of particular concern, and that served as the basis of the subsequent discussion of research and development needs, were AI, BSE, CSF, heart water, FMD, RP, bovine tuberculosis, RVF, END, alphaviruses, and paramyxoviruses (e.g., Nipah and Hendra).

Diagnostic Testing Concerns

Because diagnostic tests are only operationally effective when there is a system to trigger appropriate testing of suspect samples or livestock, discussion within the breakout group took as its starting point the status quo for disease detection within the U.S. animal agriculture system. That system is essentially passive in nature. Individuals at the farm or feedlot who recognize the signs of disease most often provide the first identification of a potential outbreak. This initial detection then triggers involvement of local veterinarians who, if they judge it necessary, submit samples to diagnostic laboratories at the state or federal level. At each level, the system is dependant on samples being flagged as potential foreign animal diseases or bio-terrorism agents to ensure that the necessary diagnostic tests are run.

Because of the concentration of expertise and resources needed for the most sophisticated testing, not all testing capabilities are available at all diagnostic laboratories. Rapid diagnosis therefore also depends on samples reaching laboratories that have the appropriate capabilities to test them; if samples are sent to labs that cannot test for all agents of concern, detection of an outbreak could be delayed for multiple days or missed entirely. Because many veterinarians would not recognize the symptoms of many foreign diseases that are potential bio-terrorism agents, the potential for such delays could be very serious.

Beyond the specific issues related to diagnostic testing, the group also raised several broader issues related to the effectiveness of detection systems for animal disease surveillance. These were not issues that led to specific recommendations for research or program changes, but were highlighted for consideration in future technology development and deployment efforts:

- The primary focus of the discussion was detection of disease “on the farm” or “at the feedlot.” Because many diseases of concern can affect wildlife populations, they must be included in planning as well. Such populations could provide introduction pathways or reservoir species for either terrorist or unintentional spread of animal diseases affecting agricultural animal populations.

- Participants highlighted the important interdependencies between diagnostic and detection capabilities and the topics discussed in other workgroups. For example, resolving the animal identification and data sharing issues discussed in the information technology workgroup is critical to making the information from diagnostic tests useful and actionable.
- The group emphasized that the way that disease surveillance programs are structured and funded can have a significant effect on their potential for success. For example, if resources are earmarked for a particular disease or are only available for a short time, it is difficult to develop versatile testing capabilities or to support an ongoing effort of disease surveillance over time.
- The participants also emphasized the importance of putting clear response protocols in place in the event that detection and surveillance systems detect a potential disease outbreak. Diagnostic testing does not stop an epidemic. Actions must be taken to quarantine, trace, and treat infected animals. In many cases, improvements in testing may allow faster identification of a potential outbreak. However, if the related systems that must act on the information are not prepared to rapidly judge the validity of the test result and act decisively, any advantage provided by faster or more sensitive testing could be lost.

Recommendations

The breakout group developed a range of recommendations aimed at improving disease detection, diagnosis, and forensic capabilities. Some of the recommendations focus entirely on research and development opportunities to improve these capabilities. Some are primarily operational or programmatic in nature, but with significant research and development or technology components. The recommendations address five main areas:

1. strengthening the current passive system for disease detection and diagnosis
2. developing new testing technologies that allow active surveillance for animal disease
3. developing tests for diseases where methods are currently unavailable or inadequate

4. addressing the specific testing requirements of forensic applications
5. building a more robust *prospective* emerging disease research and surveillance capability.

The specific recommendations in each of these five areas are described in greater detail in the following sections.

Strengthen the Current Passive System for Disease Detection and Diagnosis

The current passive detection system for animal disease depends on people: the individuals at the farm or processing plant level who identify sick animals, the veterinarians or other professionals who diagnose them, and the laboratory scientists who perform diagnostic testing. As a result, the effectiveness of the system relies on the number of individuals fulfilling each of these roles, their training and knowledge, and their capability to make rapid and accurate assessments of animal health. It is also dependant on the decision processes that lead to the right tests being performed on samples rapidly enough to allow action to contain an outbreak. A number of measures could strengthen the capabilities of this system:

1.a. Recommendation: Address Staffing Needs at All Levels to Ensure Sufficient System Capacity

Since the current system depends on people detecting and responding to potentially ill animals, increasing the number of people available to carry out each role would increase capability. The number of large animal veterinarians available to see animals has fallen over time, and inspectors are not always present to assess animals at slaughter and processing plants. Similarly, the capability of laboratories to perform diagnostic testing on suspect samples is also tied to the number of trained technician and clinical scientists available.

1.b. Recommendation: Improve Training for Disease Recognition

Detection of disease depends on the skill and intuition of individuals making diagnoses at the pen and plant level. Just as concerns existed about the ability of doctors to recognize the signs of smallpox and other human-targeted bio-terrorism agents, many individuals in the animal agriculture system may not recognize the signs of foreign animal diseases. Their ability to recognize the signs of potential threat agents could be improved through training. Of

particular importance are potential agricultural bio-terrorism agents that may present similar symptoms to other more common diseases.

1.c. Recommendation: Increase the Availability of Sophisticated Diagnostics in Testing Laboratories

Increasing the availability of the relevant diagnostic tests could increase the speed of detection of agricultural threat agents of concern. Not all laboratories have the capability to test for all diseases; as a result, detection of an outbreak may be delayed until a sample reaches an installation that can run the needed tests. Multiple strategies exist that could contribute to achieving this goal. Doing so could simply be a technology deployment issue; however, research and development to make tests more straightforward to carry out, less dependant on specialized facilities, or more cost effective could make wider use more practical.

1.d. Recommendation: Institute Mechanisms to Ensure Data Sharing Within the National Veterinary Laboratory System

Because the movement of animals in the agriculture system can make even a local outbreak of disease into a national problem, data coordination can be particularly important for both assessing trends and tracking action at the national level. Funding mechanisms that only pay for equipment in local laboratories may not support actually running tests or linking laboratories for data sharing. This can limit their potential contribution to national-level surveillance activities. One mechanism discussed in the breakout was state or local laboratories providing testing services for agents of concern to the federal government on a “fee-for-service” basis, including the requirement that data be shared.

1.e. Recommendation: Address Cost and Funding Issues in Diagnostic Surveillance for Potential Agricultural Bio-Terrorism Agents

The costs of diagnostic tests are particularly important in the context of a national effort to monitor for agricultural bio-terrorism. When an animal becomes ill, individual farmers or ranchers pay the costs of diagnostic testing. Given that most animal illness is a result of common diseases, performing tests for these currently low-probability agents is not cost effective for those individuals. This builds a disincentive into the system to run the tests and limits the ability to carry out any systematic national-level surveillance for these diseases. Policy research could contribute to better understanding appropriate funding and support mechanisms to address the difference in the national value of systematic testing and the individual value of running tests for low probability diseases. Similarly, research and development to reduce the costs of

testing to limit the impact of such cost issues in system design could also be beneficial.

1.f. Recommendation: Address Information Technology Requirements to Improve the Effectiveness of Diagnostic Efforts

To guide what tests are run on particular samples or to support outbreak investigation activities, it is critical that available information on a test sample—descriptive data on the animal’s condition, any epidemiological information available, etc.—be linked to the sample. In some cases, current systems do not ensure that such information is passed from laboratory to laboratory with samples. Improved information technology capabilities could address these needs.

Develop New Technologies for Active Surveillance for Animal Disease

To increase the probability that any instance of agricultural bio-terrorism is rapidly detected, the nation’s surveillance system should ideally transition from the current passive system to a more active monitoring and testing approach. Two technological strategies could support such a transition:

2.a. Recommendation: Develop and Improve Field Testing Capabilities

Detection speed of potential outbreaks could be significantly increased by providing individuals at the “pen side” or in the processing plant quick and straightforward ways to test for diseases of concern. Basic and inexpensive test kits allowing veterinarians or inspectors to obtain preliminary test results within a few minutes could allow more rapid containment decisions, direct samples for confirmatory or detailed testing to the appropriate labs, and increase the probability that an individual outbreak would be detected.

2.b. Recommendation: Develop and Field Environmental Surveillance Systems

Existing technological systems, such as those currently deployed for human diseases in the Biowatch program, would provide another strategy to detect outbreaks of foreign animal diseases. Such constant ambient monitoring for the presence of diseases of concern would provide an alternative approach to relying on the current diagnostic system to recognize the presence of exotic diseases. Development of such a system would have to address many of the same issues as the Biowatch program—such as minimization of system costs to allow broad

deployment, as much automation as possible to reduce the active maintenance and human involvement required for system functioning, and protocols for addressing response if a positive detection occurs.

Develop Tests for Diseases for Which Methods Are Unavailable or Inadequate

Although good tests exist for many agents of concern, they are not available for all relevant diseases. Prion diseases pose a particular problem—made all too apparent in the recent detection of BSE in the United States—because of the lack of good detection capabilities. The absence of practical test methods is critical not just in an actual outbreak, but for detecting and addressing the potential of a terrorist hoax. In some cases, available tests need to be validated for broad use or tests need to be developed for different strains of a disease. FMD was cited as an example where comparative information for different strains of the disease is particularly needed.

3.a. Recommendation: Promote Validation and Deployment of Prototype Test Methods

Workshop discussions touched on a number of cases in which tests are available for key diseases but currently exist “only in the research laboratory.” Diseases that were highlighted where test validation was critical included heart water, FMD, RP, and END. In some cases, such as polymerase chain reaction (PCR)-based testing for FMD, these validation efforts are already well under way or near completion.

Similarly, cases were cited in which relevant tests are available for human medicine but have not been adapted for use in veterinary applications. Examples included paramyxoviruses, alphaviruses, and RVF. Efforts to validate these assays for deployment are required to ensure sufficient performance and usability for routine diagnostic application.

3.b. Recommendation: Address Agents for Which Practical Test Methods Are Currently Unavailable

BSE was cited as the primary example of an agent in which no practical test methods are currently available for surveillance and detection purposes. Experiences of other nations, and most recently our own, underscore the importance of tests to monitor for incidence of the disease and to support response activities if it occurs.

3.c. Recommendation: Increase Information Provided by Test Methods

Depending on design, the result of a diagnostic test may confirm the presence of an agent but provide no further information about the outbreak. When possible, development of tests that provide as much information as possible, as early as possible, could benefit response activities. This may require the combination of multiple technologies or lines of research. The example was cited of distinguishing high pathogenicity AI or Newcastle from lower pathogenicity strains. Molecular level indicators may not be sufficient to make the determination and further fundamental research in the determinants of pathogenicity is needed.

Research is also needed to provide better ways to distinguish vaccinated animals from exposed or infected animals. The inability to distinguish the two limits some response options in the event of an outbreak. AI was cited as a disease in which this was a particular problem.

Similarly, multiplexing testing for foreign animal diseases with other higher probability diseases, and specifically with domestic diseases that may present similar symptoms as threat agents, could improve the potential to detect outbreaks caused by bio-terrorism.

3.d. Recommendation: Develop Tests Methods Applicable to Different Stages of the Animal Agriculture System

To provide a comprehensive capability to detect agricultural bio-terrorism, test methods are needed that are applicable to all stages of the animal agriculture system—i.e., capabilities to test the environment for agents at a farm or processing plant, the live animal, the animal after slaughter, and in the finished product. BSE and AI were cited as examples of diseases in which this was needed. In addition to providing a more robust capability to trace and control an outbreak, such capabilities are particularly relevant for zoonotic agents that could also affect workers in the agricultural system or consumers of agricultural products.

With respect to testing food products for biological agents or toxins that could potentially harm consumers, it should be noted that the sensitivity of test methods is very important. While a test might be performed on a small volume of a product, an individual consumer might consume many times that amount. As a result, methods must be sensitive enough to ensure protection of consumers.

3.e. Recommendation: Develop Faster Test Methods

In controlling a possible outbreak of disease, getting information faster can provide increased flexibility for response options. Test methods for some agents require lengthy culture techniques to determine the presence of disease. Because delay in disease detection can increase the potential impact of an incident, more rapid testing technologies should be pursued. Bovine tuberculosis was cited as an example of a disease in which a faster test method would be beneficial. Rapid tests are also critical because they make it possible to more easily provide surge capacity for testing in the event of a major epidemic of a disease.

Address the Specific Requirements of Forensic Applications

In the event of a suspected agricultural bio-terrorist incident, the ability to perform testing to determine the source and individuals responsible for the attack will be of utmost importance. Participants cited the issues encountered in the anthrax attack investigation as an example of the roadblocks that exist for effective criminal investigation of biological events. If an event is confirmed to be an intentional introduction of a disease, it will also be necessary that investigators perform diagnostic tests in such a way that their results are admissible in court to support prosecution of those responsible.

4.a. Recommendation: Validate Test Methods for Forensic Use

Test results that will potentially be used in prosecution must meet a particularly high standard for accuracy, precision, and validity. Test validation for these applications is exceedingly important for the results of agent identification, genetic fingerprinting to associate the agents with particular people or laboratories, or other analyses to be useful.

There are not currently validated tests available for many diseases in the forensic context, which could make it particularly difficult to respond after an outbreak has occurred. Participants stated that, from a forensic perspective, it is very important to have at least two complementary technologies that can provide solid positive results.

4.b. Recommendation: Improve Laboratory and Personnel Capabilities for Forensic Analysis

Investigation requires personnel and appropriate facilities to examine evidence and determine the source and individuals responsible for an outbreak. Such an investigation would include not only testing of the agents involved through genetic and other biochemical approaches, but also traditional forensic

investigation (fingerprint examination, trace evidence, chemical analysis, etc.) on likely contaminated samples. Participants noted that current capabilities for such investigation will likely be inadequate in the event of a large bio-terrorist incident.

4.c. Recommendation: Address Procedural and Data Sharing Constraints Associated with Criminal Investigation

Although rapid sharing of information is important for responding to an animal disease outbreak, an ongoing criminal investigation may require restrictions on what information can be shared and with what parties. Such constraints have the potential to complicate response to an agricultural bio-terrorism event. To ensure that the agricultural system can effectively respond to an outbreak where terrorism is suspected, these issues must be addressed before such an event occurs. Such information sharing constraints can be particularly acute for events in states at or near international borders.

Need for Prospective Emerging Disease Research and Surveillance Capability

Although the capability to test samples suspected of particular diseases must be an important component of a system to protect U.S. animal agriculture, it is an inherently reactive approach to the threat of bio-terrorism and foreign animal disease. In addition to such a capability to watch for and respond to recognized threats, participants also highlighted the potential utility of institutions that could take a more proactive approach to protecting animal agriculture from disease. One model that was discussed was the support of one or more centers of excellence on emerging animal disease in which samples from the national laboratory network could be sent and studied for broader research purposes. Such an effort could provide a more proactive surveillance component to U.S. animal agriculture system by seeking out unrecognized animal disease threats before they have the opportunity to have a major impact.

Summary of Recommendations

Table 10 summarizes the recommendations of the breakout group on Detection, Diagnosis, and Forensics Capabilities. It is intended to both provide a concise description of the recommendations above and allow comparison with other breakout groups. Because of the differences in scope and available information, not all the table entries are filled out for all the breakout groups.

Table 10: Agro-Terrorism Research Priorities: Detection, Diagnosis, and Forensics Capabilities

* Research needs were not ranked by the working group

Agro-terrorism Research Priorities: Detection, Diagnosis and Forensics Capabilities								
Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Strengthen Current Passive System for Disease Detection and Diagnosis, Staffing: Address staffing needs at all levels to ensure sufficient system capacity		Assess the total number of people needed in the detection and response to potentially ill animals; Examine policy approaches to ensuring necessary levels of trained individuals are available						
Strengthen Current Passive System for Disease Detection and Diagnosis, Training: Improve training for disease recognition		Improve and ensure the ability of individuals in the agricultural system to recognize the signs of foreign animal disease						
Strengthen Current Passive System for Disease Detection and Diagnosis, Diagnostics: Increase the availability of sophisticated diagnostics in testing laboratories		Determine best strategy to increase the availability of sophisticated diagnostics; Perform research to make test methods more straightforward, less expensive, and easier to transfer to new laboratories						

Agro-terrorism Research Priorities: Detection, Diagnosis and Forensics Capabilities

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Strengthen Current Passive System for Disease Detection and Diagnosis, Data Sharing: Institute mechanisms to ensure data sharing within the National Veterinary Laboratory System		Explore potential mechanisms to enhance data coordination in trend assessment and tracking at the national level						
Strengthen Current Passive System for Disease Detection and Diagnosis, Funding: Address cost and funding issues in diagnostic surveillance for potential agricultural bio-terrorism agents		Policy research could contribute to better understanding of the appropriate funding and support mechanisms to address the difference in the national value of systematic testing and the individual value of running tests for low probability diseases						
Strengthen Current Passive System for Disease Detection and Diagnosis, Information Technology: Address information technology requirements to improve the effectiveness of diagnostic efforts		Develop strategies to ensure that all available data is linked to a sample						
New Technologies for Active Surveillance for Animal Disease, Field Testing: Develop and improve field testing capabilities		Develop basic and inexpensive test kits allowing veterinarians or inspectors to obtain preliminary test results within a few minutes						

Agro-terrorism Research Priorities: Detection, Diagnosis and Forensics Capabilities

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
New Technologies for Active Surveillance for Animal Disease, Environmental Surveillance: Develop and improve field environmental surveillance systems		Develop system for constant ambient monitoring of the presence of diseases, similar to those currently used for human diseases in the Biowatch program						
Development of New Tests, Prototypes: Promote validation and deployment of prototype test methods	PCR-based testing for FMD already under way	Further validation of tests currently existing "only in the research laboratory" (e.g., heart water, FMD, RP, exotic Newcastle) and, in particular, for prion diseases (e.g., BSE); Move forward on the adaptation of relevant human tests for use in veterinary applications (e.g., paramyxoviruses, alphaviruses, RVF)						
Development of New Tests, Alternatives to Testing: Address agents for which practical test methods are currently unavailable		Develop practical test for BSE						

Agro-terrorism Research Priorities: Detection, Diagnosis and Forensics Capabilities

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
<p>Development of New Tests: Increase information provided by test methods</p>		<p>Increase the amount of information provided by a test by combining multiple technologies or lines of research (e.g., distinguishing high from low pathogenicity strains of disease);</p> <p>Develop better ways to distinguish vaccinated animals from exposed or infected animals;</p> <p>Develop test methods in which assays for common diseases can be multiplexed with testing for potential bio-terrorism agents to allow broader and more cost effective surveillance for FADs</p>						
<p>Development of New Tests, Stage-Specific Testing: Develop test methods applicable to different stages of the animal agriculture system</p>		<p>Develop test methods for agents of concern that are applicable to all stages of the animal agricultural system (e.g., testing live animals, in processing plants, finished products). Such tests for BSE and AI are particular priorities</p>						

Agro-terrorism Research Priorities: Detection, Diagnosis and Forensics Capabilities

Research Plan					Funding			
Defined Research Need	Research Currently Ongoing	Near-Term Research Needs (1-2 years)	Far-Term Research Needs (3-7 years)	Overall Priority*	Research Already Funded or Funding Pending?	Agency/Agencies Involved	Increase/Initial Funding Required?	Suggested Increase or Funding Level
Development of New Tests, Speed: Develop faster tests		Refine test methods for diseases in which quick response is key to controlling an outbreak and to increase surge capacity. In particular, develop faster test methods for the detection of Bovine tuberculosis and methods beyond reverse transcriptase PCR for other diseases.						
Specific Requirements of Forensic Applications		Validate test methods for forensic use; Improve laboratory and personnel capabilities for forensic analysis of contaminated evidence and potential agro-bio-terrorism agents; Address procedural and data sharing constraints associated with criminal investigation						
Prospective Emerging Disease Research and Surveillance Capability		Investigate potential models for cost effectively providing proactive detection capabilities for new FADs or agro-bioterrorism agents.						

III. Submitted Papers from Presentations

Opening Remarks

December 8, 2003

John Marburger,
Director, Office of Science and Technology Policy
Executive Office of the President

Good Morning. Thank you for joining us in this effort to address the important issue of the safety of the nation's livestock and food supply.

President Bush has said that "Farming is our first industry; the industry that feeds us, clothes us, and increasingly provides our energy. The success of America's farmers and ranchers is essential to the success of America's economy."

The National Strategy for Homeland Security identifies agriculture as one of the critical infrastructure sectors that must be protected from a terrorist attack. The same document also describes science and technology as a unique American strength that provides a foundation for the National Strategy. As far as agricultural bioterrorism is concerned, you represent that strength. American scientists and agricultural experts, such as yourselves, are essential to the task of seeking out vulnerabilities in the agricultural sector and examining strategies to address these gaps. This workshop is of course only a beginning.

The agriculture and food industry forms a significant part of the U.S. economy. It contributes \$1 trillion to the economy and one-sixth of our gross national product. One of every eight Americans works in the agricultural sector, which includes farmlands, feedlots, processing plants, warehouses, research facilities, factories for food preparation and packaging, and a distribution network that transports animals and food across the nation and around the globe via almost every mode of transportation. From their paychecks to the safety of the food that they eat, millions of Americans rely on the stability of our agricultural economy.

Economic impacts of agricultural bioterrorism would include direct loss of crops, livestock and assets; secondary losses in upstream and downstream markets; lost export markets; significant price effects; and a reduction in economic growth caused from a reallocation of resources. Other effects of such an attack include environmental problems and social and political impacts such as reduced confidence in government, reduced confidence in food safety, and social disruption resulting from fear. Recent naturally occurring outbreaks of Avian

Influenza and Exotic Newcastle Disease, in Virginia and California respectively, have cost hundreds of millions of dollars to control and eradicate.

According to the National Defense University, which conducted the agro-terrorism simulation Silent Prairie, even a limited outbreak of foot and mouth disease on just 10 farms could have a \$2 billion financial impact and wide-ranging effects on society, including the impairment of military deployment.

We know that the best way to minimize the economic impacts of such outbreaks, intentional or unintentional, is through early detection and an organized response plan. We hope this Panel will identify vulnerabilities and gaps in plans to deal with them, and help to improve our responses.

Importance of R&D in Preparedness/Prevention

The past few years have seen an increased focus on animal health and food safety and security. Many programs have been implemented that contribute to the U.S. ability to prepare for and respond to natural or intentional introductions of animal disease, or another agricultural bioterrorism event. Here are some examples:

Through their research and regulatory programs, the USDA, and the Food and Drug Administration (FDA), provide the foundation for national agricultural animal and plant health and for public health. The USDA has established programs on foreign animal diseases; zoonoses; endemic domestic animal diseases; vectors and reservoirs of animal and human disease pathogens; plant/crop diseases; and food safety. It has worked with university and private sector partners to put in place a stronger rapid detection and response network that provides redundancy and surge capacity as part of the National Animal Health Laboratory Network. The Emergency Management Response System has been used to coordinate the efforts to control Exotic Newcastle Disease in California and other western states.

The FDA also has a strong research program to address food safety and security concerns. The FDA Center for Veterinary Medicine (CVM) has instituted measures to prevent an attack through the animal feed supply. These measures include establishing and maintaining the Feed Contaminant and Tissue Residue Compliance Programs which play an important role in the early detection of chemical and biological contaminants in the animal feed supply and developing analytical methods to detect the presence of toxic substances that could be introduced into U.S. animal feed supplies. Once developed and optimized, these methods would be used to detect toxic substances in animal feed.

The Department of Homeland Security (DHS) works with the USDA and the FDA to enhance the homeland security focus of certain efforts. Plum Island Animal Disease Center (PIADC) became a part of the DHS Security on June 1, 2003 and the Science and Technology Directorate of DHS is involved in collaboration with the USDA's Animal Plant Health Inspection Service (APHIS) and Agricultural Research Service (ARS) to continue the research and training programs carried out by the agency. The Office of Research and Development, part of the Science and Technology Directorate, is responsible for the National Biodefense Analysis and Countermeasure Center (NBACC). NBACC is dedicated to protecting health and agriculture by advancing the scientific community's knowledge of bioterrorism threats and vulnerabilities. Biodefense threat and capability characterizations, bioforensics and agricultural security are the key programmatic thrusts of NBACC that are executed through PIADC and four other research and operations centers. [Biothreat Assessment Support Center, Biodefense Knowledge Center, Bioforensics Analysis Center, Bio-Countermeasures Testing and Evaluation Center]

Such efforts by the USDA, FDA and DHS are important steps towards preparedness for an agricultural bioterrorism event, but there are still many more steps that must be taken before we are fully prepared. New vaccines and diagnostic technologies are in various stages of development, but are not yet validated, tested, approved or available for widespread use. The National Animal Health Laboratory Network has strengthened the capabilities and communication systems at 12 laboratories, but there are still many laboratories in need of enhancement. Sophisticated models have predicted countless methods for how to best handle outbreaks of foreign animal diseases, but additional information could greatly improve the information supplied by these models.

Several previous works have formed the foundation for this workshop, including the National Academy of Sciences "Countering Agricultural Bioterrorism" and the "Animal Health Safeguarding Review" by the National Association of State Departments of Agriculture.

The interagency coordinating function of my office applies to science and technology for homeland security as well as for other Executive Branch functions. Under the *National Science and Technology Council's* Committee on Homeland and National Security, we have formed a Weapons of Mass Destruction Medical Countermeasures Subcommittee in partnership with DHS, DOD and HHS. This 12-agency subcommittee works with the relevant partners to understand and fill gaps in medical preparedness for biological, chemical, radiological and nuclear threat agents. The group collaborates on vulnerability and gap analyses, and works to define countermeasures to eradicate those gaps.

Through the interagency process we continue to establish the requirements and acquisition plans to expand the national stockpile of the best antibiotics, antitoxins and vaccines we have. It is through such committees that OSTP is able to articulate research needs to the scientific community, and shape the R&D agendas and budgets for the future.

The Animal Pathogens subgroup of the Weapons of Mass Destruction Medical Countermeasures group which I will mention in a moment has provided this group with an excellent “straw man”, a document around which the vaccines and protection technologies breakout group can build their discussion.

The insight and priorities generated by this panel will be extremely helpful to the U.S. government and the OSTP as it coordinates the development of a federal research and development agenda to address key threats to U.S. animal agriculture. We expect the information collected from this panel to contribute to the development of a National Science and Technology Council task force charged with investigating these gaps and implementing solutions.

Thank you for taking the time to lend your expertise to this national cooperative effort. Your honest and candid input will contribute greatly to the efforts to highlight and address these gaps in agro-terrorism research and development.

U.S. Agriculture in Context: Sector's Importance to the American Economy and Its Role in Global Trade

Beth Lautner, D.V.M., M.S. and Steve R. Meyer, Ph.D.

Since the terrorist attacks of September 11, 2001, Americans including government officials and Congress have looked carefully to discover and quantify vulnerabilities in their lives and our economy. Due to its importance to the U.S. economy and as part of the diet of most Americans, animal agriculture has been identified as a potential target for terrorists. This paper provides:

- A brief overview of the importance of U.S. agriculture to the U.S. economy and trade status;
- Potential impacts of natural or intentional Foreign Animal Disease (FAD) outbreaks on both the economy and trade;
- Global economic and trade ramifications of a FAD outbreak in the U.S.;
- Research/policy gaps that might negatively effect the U.S. economy, economic recovery and return to trade; and
- Potential solutions to the identified gaps in research and policy.

The Important Role of Agriculture in the U.S. Economy

In 2002, about 57 million of the United States' 288 million people lived in non-metro areas that depended to one degree or another on the agricultural economy. Almost 23% of the 29.4 million jobs held by these non-metro residents were either farm or farm-related (Table 11). Perhaps more importantly, 14.9% of the 167.5 million total jobs in the U.S. in 2000 were farm or farm-related. Clearly, the jobs created by the U.S. food and fiber system are critically important to the U.S. economy.

Table 11. Percent of U.S. Employment in Farm and Farm-Related Jobs

	U.S.	Metro	Non-metro
Production	2.0	0.9	7.0
Farm Inputs	0.3	0.2	0.8
Processing & Marketing	2.0	1.5	3.9
Wholesale & Retail Trade	9.9	9.9	9.9
Total	14.9	13.2	22.9

Source: USDA (1)

The agricultural production sector's output in 2002 accounted for \$217.2 billion. This output represents \$98.4 billion of value added to the value of production inputs by crop, animal and forestry production. Agricultural sector employment compensation in 2002 amounted to \$18.9 billion. Total farm assets were valued at \$1.304 trillion while total farm debt was \$193.3 billion. Farm equity at the end of 2002 stood at \$1.111 trillion. It is quite obvious that the livelihoods and nest eggs of millions of Americans depend upon the health of agriculture.

Table 12 shows the top ten U.S. agricultural products in terms of value. Five of the top ten are either livestock or poultry products with a total value of \$85.8 billion. These five products represent about 45% of the total value of U.S. agricultural production. Livestock and poultry production's importance to U.S. agriculture goes beyond these direct value measures, however, as these enterprises are the main users of feed grains and oilseeds in the U.S. as well. USDA estimates that 62.4% of the U.S. corn crop, 42.7% of the sorghum crop and 7.8% of the wheat crop went to feed usage. In addition, 49.7% of the soybean crop was used to produce soybean meal that went to domestic uses. The vast majority of this meal was used in livestock feeds.

Table 12. Top Ten U.S. Agricultural Products by Value of Farm Receipts

Rank	Product	Value of Receipts*	Pct. Of Total	Cumulative Pct.
1	Cattle and calves	\$37,968,464	19.7	19.7
2	Dairy products	\$20,546,980	10.6	30.3
3	Corn	\$17,488,834	9.1	39.4
4	Greenhouse/nursery	\$14,275,285	7.4	46.8
5	Soybeans	\$13,473,213	7.0	53.8
6	Broilers	\$13,434,783	7.0	60.7
7	Hogs	\$ 9,625,708	5.0	65.7
8	Wheat	\$ 5,541,001	2.9	68.6
9	Hay	\$ 4,634,726	2.4	71.0
10	Chicken eggs	\$ 4,262,664	2.2	73.2

*Thousand dollars

Source: USDA (2)

The Important Role of U.S. Agriculture in U.S. Foreign Trade

Exports of U.S. agricultural products in 2002 were valued at \$53 billion dollars and represented 8.4% of total U.S. exports of \$629.6 billion. Perhaps more important, however, is the fact that U.S. agriculture year-in, year-out runs a trade surplus while the U.S. as a whole runs a large and growing trade deficit. The agricultural trade surplus in 2002 was just over \$11 billion (down dramatically from \$26.8 billion in 1996 before the Asian economic crisis reduced the purchasing power of some of our largest export customers). Still, any sector of the U.S. economy that can offset a portion of the \$536 billion non-agricultural trade deficit is very valuable to our economic stability.

The flip side of the importance of agricultural exports to the U.S. economy is that the U.S. agricultural sector is extremely reliant on export markets. Compared to the rest of the U.S. economy, agriculture is twice as dependent on overseas markets and this dependency is rising at a faster rate. Agriculture's export reliance, measured as the ratio of agricultural exports divided by farm cash receipts rose from 22 to 26% during the 1990's. This measure was 27.6% in 2002.

The effect of bovine spongiform encephalopathy (BSE) in Canada underscores the risk associated with high dependency on export markets and the threat of animal diseases. Prior to May 2003, Canada (3) exported half of the cattle sold in Canada as either live animals or meat. In 2002, this level of exports was worth about \$4.1 billion. Those exports came to an abrupt halt after the discovery of a single cow with BSE. Canadian beef and cattle supplies began to back up and beef and cattle prices fell. Canadian packing plants reduced their chain speeds or idled shifts. Placement of cattle in Canadian feedlots fell dramatically thus causing the number of cattle on feed to fall. Jobs were lost or at least idled at every level of the Canadian beef sector.

But the impact went well beyond the Canadian cattle-beef sector. Reduced cattle feedlot inventories reduced the demand for inputs such as feed grains, forages, pharmaceuticals, and veterinary and trucking services. Lower beef prices encouraged higher beef consumption and this product substitution caused the demand for pork, and consequently hogs, to fall. Hog slaughter plants reduced operating rates and exports of market hogs to the U.S. increased for the first time since late 1997.

Bulk commodities have long depended on export markets. About half of the U.S. wheat and rice crops, one-third of soybean, tobacco and cotton production and 20% of the corn crop are exported. The big change since 1990 is that high-

value U.S. products such as fruits, vegetables and animal products are becoming more and more dependent upon export markets as well. Exports of beef, pork, veal and lamb and products derived from them accounted for \$5.114 billion dollars in 2002 and are expected to total over \$5.5 billion dollars in 2003. Poultry meat and poultry products valued at \$2.172 billion were exported in 2002. Other significant animal product export categories in 2002 were hides and skins (\$1.777 billion), dairy products (\$1.034 billion), fats (\$850 million) and live animals (\$804 million).

Exports of high-value products create considerably more economic impact than exports of bulk commodities due to the processing and packaging they require. USDA research (4) estimated that each dollar of bulk commodity exports generated an additional \$0.92 in business activity while each dollar of high-value exports (such as meats and animal products) generates an additional \$1.55 in business activity. Thus, the \$11.751 billion in animal product exports cited above generated additional business activity of \$18.214 billion.

Potential Impacts of a Foreign Animal Disease Outbreak on Both the Economy and Trade

There are several key sources of the economic impact of a foreign animal disease (FAD). They include: loss of production, loss of exports, loss of U.S. consumption, losses to related industries, the direct costs of control (fair market value for animals destroyed for disease control or depopulated for animal welfare reasons, costs of federal and state personnel for administering the disease control program, carcass disposal, vaccination, disinfection, surveillance, etc.) and indirect losses (business interruption for producers, suppliers, and processors, wildlife effects, tourism losses, etc.). The scope of the impact of a foreign animal disease outbreak in the United States depends upon a number of factors. These include:

- Whether the disease introduction is intentional or accidental and how quickly it is detected;
- The location(s) of the outbreak
- The specific disease in question;
- The number of species the disease affects, and
- Whether the disease poses a direct human health risk.

Due to the many variables that will affect the severity and scope of a FAD outbreak, wide ranges are given in any estimates of the economic impact of a FAD in the U.S.

Intentional or Accidental Introduction

Foot-and-mouth disease (FMD), unless some type of altered virus is developed, will behave like foot-and-mouth disease regardless of how it is introduced. Mode of introduction may, though, affect the scope of the disease outbreak and the reaction of governments and the U.S. population and, quite likely, the intensity of their efforts to quell the impact of the disease.

The scope of the outbreak could differ dramatically between an intentional or accidental introduction. Any intentional effort would likely be carried out on a larger scale, perhaps affecting different regions of the country simultaneously. Such a widespread introduction would tax and could overwhelm (at least initially) the resources available to control the outbreak. On the other hand, an accidental introduction would more likely have a single starting point and may be more easily handled by planned emergency response mechanisms and resources depending on time to detection.

Perhaps there would be different effects from an intentional introduction on the psyche of the American people and thus the resolve of the government and population to deal with the FAD outbreak. An intentional introduction would be an attack upon the United States that could well elicit the same kind of patriotic, duty-driven responses that followed the terror attacks of September 11, 2001. The difference could be dramatic. Federal and state governments could be more willing to allocate resources to fighting the outbreak. Citizens may view cooperation with a containment and eradication plan as a duty. The public perception of destroying animals in the wake of an intentional introduction could be different as well – it would be “their” fault that these animals had to be depopulated to prevent the disease from spreading, not the fault of the government or farmers who were protecting their economic well-being.

However, consumer confidence in the safety and security of the food supply and the ability of the government and industries to protect them may be shaken and this may also have economic impacts. Consumers may still fear potential human health effects in spite of public health officials’ assurances to the contrary. It must be noted that consumers have many choices for protein sources and substitutions may be made. These substitutions may be short-term or could be sustained and permanently alter the per capita consumption of meat or poultry products. In a recent economic analysis by Purdue and USDA (5) of a FMD outbreak in the U.S. similar to the 2001 outbreak in the United Kingdom, the loss in farm income was \$14 billion with an assumed 10% decrease in consumption of red meat and dairy products. However, if there was no adverse reaction by consumers, the loss in farm income was only \$6.8 billion. A 20% decrease in

consumption caused the loss in farm income to increase dramatically to \$20.8 billion.

The Location(s) of the Outbreak

If the outbreak is in an area that is not densely populated with the susceptible species, the disease may be quickly contained without considerable spread. In a densely populated area, many more herds may need to be depopulated to control the disease or vaccination may be needed. If a market or other type of concentration point is involved in the outbreak, a large number of herds in a variety of locations may be exposed by the time of the first diagnosis.

The Specific Disease Manifestations

The effect of a FAD will be highly dependent upon whether the disease affects more than one species, is highly contagious or has direct human health implications. There is considerable difference in the type of response needed to respond to a highly contagious, multi-species disease like FMD vs. a species-specific disease like avian influenza. When there are direct public health ramifications such as in the Nipah virus outbreak in Malaysia in 1998-99, the response must be altered to protect personnel as well as protect other susceptible animal species.

Economic Losses

Producer losses include decreases in market prices, lost sales due to mortality, productivity inefficiencies, the inability to move animals to market, and costs associated with disease control measures. Many producer issues would need to be addressed including market value determination, availability and timeliness of indemnity funds, restricting movements between production facilities and markets, the need for welfare depopulation due to movement restrictions, and the psychological impact on producers of losing their herds and livelihoods.

Agricultural-related businesses such as the feed industry, livestock markets, packers, pharmaceutical companies and private practitioners would have significant business losses. One of the most severe economic consequences of an incursion of a FAD into the U.S. is the immediate halt to exports. As noted above, U.S. animal industries are becoming increasingly dependent on export markets. The U.S. was the second largest exporter of beef in 2002, ranking

between Australia and Brazil (6) and the third largest exporter of pork between ranking behind the European Union and Canada (7).

Estimates of the Economic Costs of FMD in the U.S.

USDA's Economic Research Service (8) has estimated the potential cost of an outbreak of both FMD and BSE in the U.S. FMD poses the most immediate and largest threat to the U.S. livestock industry because it is highly contagious and affects multiple species.

FMD can cause productivity losses of 10-20% when the disease is allowed to run its course in infected livestock. These losses are deemed too high to be accepted by U.S. livestock production sectors that usually run on narrow profit margins. But the costs of FMD go well beyond these productivity losses or even the loss of livestock that will have to be depopulated for disease control. The costs and challenges of disposing of dead livestock will be significant. Depending upon the region where the disease occurs and the degree of success that animal health officials have in containing the disease, the U.S. livestock sector may take years to recover. Producers will lose years of time and energy that were invested in developing specific genetics and establishing an efficient production flow. Lengthy periods without income would have to be endured. Support industries, both on the input and the processing sides, will have fewer animals with which to work resulting in lower employment, higher per-unit costs and lower profits.

Price Waterhouse Coopers estimated that the 2001 FMD outbreak in the United Kingdom would eventually cost the equivalent of \$3.6 to \$11.6 billion (9). About 3.2 million sheep (over 11 percent of the total sheep inventory), 640,000 cattle (5.5 percent of the total inventory and 160,000 pigs (about 2.3 percent of total inventories) were destroyed (8). When divided by the number of animals destroyed, Price Waterhouse Coopers estimate of economic impact was \$1,389 to \$4,477 for each of the 2.6 million head of livestock on which indemnities were eventually paid. If the same percentages of U.S. inventories were affected as were affected by the U.K outbreak, FMD in the U.S. would cause the loss of about 5.3 million cattle, 1.4 million hogs and 800,000 sheep. Assigning the range of impacts above to those 7.5 million animals would mean that an U.S. FMD outbreak could have a total impact on the U.S. economy of \$10.4 billion to \$33.6 billion. Of course, the proportions of the different species affected in the U.S. would be very dependent upon the location of the initial break of the disease.

These total economic impacts are much larger than the value of the livestock in question because of the many, many other industries both inside and outside of

agriculture that will be affected. Fewer livestock available for marketing and processing will obviously affect the livestock and meat processing, production input supply, animal services and transportation sectors. Restrictions on movement, though, will severely impact tourism and transportation as well. In fact, the impact of FMD on tourism in the United Kingdom was estimated to be more costly to the economy than the losses to the livestock sector. Table 13 shows employment and sales data for sectors that would be negatively impacted by a FMD outbreak in the United States.

Table 13: U.S. Employees and Sales That Could be Affected by a Foot & Mouth Disease Outbreak.

<i>Sector</i>	Number of paid employees	<i>Shipments, sales & receipts</i> (Billion dollars)
Agricultural Support Industries		
Meat Product Mfg	459,709	\$151.77
Dairy Product Mfg	121,912	\$86.93
Animal Feed Mfg	45,898	\$29.95
Leather & Allied Product Mfg	82,611	\$10.55
Truck Transportation	1,293,790	\$141.23
Other Industries		
Accommodations & food	9,451,226	\$350.40
Amusement and recreation industries	964,166	\$51.86
Museums, historical sites, etc.	7,281	\$0.48
Scenic and sightseeing transportation	23,907	\$1.89
Air transportation	89,125	\$20.25
Transit and ground passenger transportation	339,579	\$13.79

Source: USDA (8)

Ekboir (10) looked at the potential impacts of a FMD outbreak in California. The estimate of losses in this study ranged from \$8.5 billion to \$13.5 billion. Of significant note is the study result that approximately \$6 billion of the total impact was due to the loss of export markets for U.S. livestock products.

Estimates of the Economic Costs of BSE in the U.S.

USDA's Economic Research Service also estimated the impact of BSE being found in the United States and found that the economic threat of BSE would be smaller but more complex. It would be smaller because BSE directly affects only cattle, takes several years to cause clinical losses, and is not highly contagious and thus does not warrant the restrictions on animal and human movements that would be necessary in the case of FMD.

The impact of BSE is more complex because the disease has been linked to a new variant of Creutzfeldt-Jakob Disease in humans and thus has the potential to significantly impact beef demand as it did in Britain. British beef consumption has returned to its trend of the early 1990s but has done so only at prices 31 percent below pre-outbreak levels (8). Conversely, the discovery of BSE in Canada has apparently had little negative impact on beef demand in Canada as Canadians have actually substituted cheaper beef (cheaper due to large domestic supplies resulting from prohibited exports) for pork and chicken.

Finally, the human health risk and latent nature of BSE has led some countries to impose absolute exclusion policies toward beef exports from a country where BSE is known to exist. Most countries with such policies appear hesitant to relax them, so the effect of BSE on a country's beef exports may be quite long run in nature. The current situation between the U.S. and Canada may set a new precedent with regard to trade with a country that presents minimal risk. Nonetheless, all U.S. beef and beef by-product exports (\$4.9 billion in 2002) could be prohibited by the discovery of BSE and the prohibition could last for a significant period of time.

The breadth of the effect of a BSE case in the U.S. will depend on many factors. If an infected animal was imported, the effect may be rather small. If, though, it is a native animal, the potential to find more infected animals exists. The age of the animal in relation to the implementation of the ruminant feeding ban will be critical to the potential economic impact.

Other Examples of the Economics of FADs

The economic consequences of the classical swine fever outbreak in the Netherlands for direct costs related to depopulation for disease control and welfare purposes, business interruption costs for producers, and allied industries losses were calculated to be \$2.3 billion (11). It should be noted that 37% of the losses consisted of compensation paid for pigs that were depopulated for welfare reasons resulting from movement restrictions.

Global Ramifications of a FAD Outbreak in the U.S.

The effects of a foreign animal disease outbreak in the U.S. on U.S. agricultural exports have been discussed above. But what would such a situation mean to the rest of the world?

The first, most important and possibly most lasting impact would be on the buyers of U.S. exports. These buyers would lose a major source of supply and thus could be in a precarious position in their home markets. The reputation of the U.S. as a dependable supplier would suffer as we would simply not be able to meet our commitments to our customers. Higher prices, dissatisfied customers or, even more significantly, hungry citizens will cause importing countries to re-think their reliance on food from the U.S. The reaction will be either to establish relationships with other exporting countries or to become more self-reliant for food in general and the prohibited-import product in particular.

If alternative exporting countries are sought, either the quality of the product may go down, the cost of the product may go up or some combination of those two may happen. There was a reason the country was buying from the U.S. Forcing them to buy from another supplier is suboptimal. Depending on the expected length of the disruption of U.S. exports, output may grow in the new exporting country and regaining market share after the FAD is controlled will be a challenge for U.S. producers and processors.

Becoming self-sufficient will create an entirely different set of circumstances. If the country decides to become self-reliant, product cost will be higher or product quality will be lower or both. The only way for the country to remain self-reliant in the long run will be to protect its market or subsidize its producers or both. So, a possible global outcome of a FAD outbreak in the U.S. (or in any other exporting country, for that matter) could be an increase in trade barriers. Again, depending on the degree of dependence on the imported food product and the severity of the shortage that a disruption of imports causes, these trade barriers may be very difficult to remove.

The result of either scenario may be that the U.S. will never regain access to the market or regain the market share it once held. This would mean permanently lower production of this commodity in the U.S., lower utilization of production inputs and marketing services (processing, transportation, etc.) and lower employment and its subsequent impact on the U.S. economy.

The consequences of the 1997 FMD outbreak in Taiwan can be illuminating with regard to impacts on export markets. Taiwan's pork exports which went almost exclusively to Japan were stopped. They totaled \$1.6 billion in 1996 (12). The costs for diagnosis, surveillance, depopulation, cleaning, disinfection, and other related eradication expenses have been determined to be about \$4 billion. However, cumulative trade losses are estimated to be another \$15 billion (13). Prior to its outbreak, Taiwan controlled 40% of the frozen pork market in Japan

and 68% of the fresh-chilled pork market (14). Other countries have stepped in to fill the supply needs of Japan and Japan has increased its own production. It will be a challenge for Taiwan to regain its previous status in Japan.

Overview of Research/Policy Gaps to Address

The U.S. has been free of FMD since 1929. However, outbreaks of FMD in Taiwan in 1997 and the United Kingdom in 2001 have heightened concerns about the potential introduction and resulting impact of FMD in the U.S. The scope of resources needed to respond to an animal health emergency has been reinforced with the recent outbreaks of avian influenza and exotic Newcastle disease in parts of the U.S.

There are many documents, reports, and presentations at conferences that have reviewed the current status of the animal health emergency management system in the U.S. and made recommendations for improvements. Two of the most recent reports include the Animal Health Safeguarding Review commissioned by USDA and conducted by the National Association of State Departments of Agriculture and the National Academy of Sciences “Countering Agricultural Bioterrorism” report. Reports of the implementation teams for the various recommendations are posted on the USDA: APHIS: Veterinary Services web site.

Recommendations for the most part have been focused on USDA agencies and their programs. The recommendations have been directed to the work of the Animal and Plant Health Inspection Service (APHIS) to prevent entry of pests and pathogens, evaluate risks of FADs, provide FAD training and information, monitor for diseases domestically and internationally, diagnose and respond to outbreaks and to the Agricultural Research Service (ARS) for FAD and biosecurity research priorities.

More recently, the creation of the Department of Homeland Security (DHS) has resulted in the need for close coordination between USDA and DHS in addressing their specific roles and responsibilities for agricultural biosecurity. It is critical that research, program, and policy gaps are identified between the two agencies and plans developed to address them. These coordination efforts are currently underway. The increased emphasis on the risk for intentional introduction of FADs also necessitates a renewed review of previous recommendations and policy decisions. Briefly, some of the research, program, and policy gaps that are being addressed or are yet to be addressed can be divided into the concepts of emergency management: anticipate, prevent, prepare, respond and recover.

Anticipate/Threat Characterization

Global Surveillance

Currently, there are a variety of sources for information on animal health issues and events globally. They include military and other intelligence sources, International Services and Foreign Agriculture Services personnel stationed in-country, news sources, industry interactions, Internet searches, and the Office of International Epizootics (OIE). The robustness of the various sources and the potential for gaps should be reviewed. Recommendations for improvements have been made in the Animal Health Safeguarding Review (see International Information Committee Report). The implementation teams for the Safeguarding Review are currently reviewing the recommendations and how they may be moved forward. An urgent need is for a central collection and analysis point for the various sources of information on global health status that is integrated with intelligence information.

International animal health information is critical to protecting the U.S. livestock populations. Having this information helps anticipate and address risks. Expertise in animal health must continue to be present in U.S. personnel stationed in-country. In addition, providing assistance to countries in addressing their animal health challenges provides additional protection to U.S. livestock and decreases the potential access to agents. However, with limited resources, where this U.S. assistance is provided must be prioritized on the potential for both accidental and intentional introduction. Additional attention is needed to characterize these threats.

International Research Coordination

With very limited resources and expertise devoted to foreign animal disease research, it is critical to coordinate research programs and facilitate scientific exchange globally. The U.S. research program should be developed and implemented with a clear understanding of current and planned research worldwide. Global efforts to fund research at the most appropriate institutions are needed. However, regardless of international efforts, the U.S. must retain core expertise for the most significant diseases and fund and conduct research to address the needs for preparedness and response.

Agent Repository/Bioforensics

A repository of isolates will be needed for forensics and will aid in predicting the scope of an outbreak. USDA retains some isolates due to its international collaborations and relationships. A plan is needed for enhancing this repository.

The repository should also contain information on the epidemiological characteristics of the virus to aid in planning on the potential for aerosol spread, species preferences, virulence, etc. and use in modeling programs during the response phase.

Increased expertise and resources are needed to provide the analyses that can result in attribution in the case of an intentional introduction.

Scenario Planning/Modeling

Modeling programs have been developed by USDA and other institutions such as the University of California that provide for projections based on varying parameters. There has been some international review of these programs. Additional review is needed to determine if they meet all of the potential scenarios that may need to be modeled including accidental and intentional introduction.

Work is also needed to further develop scenarios and what the policy for response would be based on the scenario. The assumptions based on specific diseases should be reviewed. In the event of an actual outbreak, determining which previously reviewed scenario it most closely aligns with could decrease response time for decisions.

Prevent

Import Policies and Inspection Procedures

Pathway analysis provides insights into potential routes of introduction of a foreign animal disease into the U.S. The results should be used to review import policies and procedures for products, people, animals, and equipment. In addition, the August 1998 report *The Potential for International Travelers to Transmit Foreign Animal Diseases to U.S. Livestock or Poultry* by APHIS should be reviewed to determine if any changes in inspection procedures are needed.

There can be a gap between setting forth importation policies for products and animals and verification that these requirements have been met. It is important to verify that import requirements are being met. An annual report should provide information on how these verifications are conducted and the results. Compliance with passenger, cargo, and mail inspection protocols needs to be continually evaluated.

Risk assessment is critical to the development of U.S. import policies. They are conducted to determine the appropriateness of allowing importation from countries requesting entry. Sufficient resources are needed to respond in a timely, yet thorough manner to import requests. In addition, multi-disciplinary teams must be available to conduct these risk assessments.

Agriculture and Food Information Sharing and Analysis Center (ISAC)

Other critical infrastructures have developed processes to share information within the sector that may signal a potential terrorist action and to distribute timely warnings of concerning situations. Efforts are underway in the agriculture and food sectors to develop this time of system and should be supported.

Prepare

Domestic Surveillance

The development of a comprehensive, coordinated, integrated National Surveillance System (NSS) is critical. The NSS needs to include current domestic diseases, emerging diseases and foreign animal diseases. There are 21 recommendations specific to Domestic Surveillance in the Animal Health Safeguarding Review. USDA has recently organized a National Surveillance Unit. These efforts need to be supported.

There are over 50 diseases considered foreign to the U.S. It would be appropriate to review this list and ensure that diagnostic capabilities exist for these diseases and that the list is current. A risk-based surveillance program is needed for the FADs considered to be the most likely to occur in the U.S. This system should include a role for the state diagnostic laboratories in conjunction with the National Veterinary Services Laboratories. The recent creation of the National Animal Health Laboratory Network is an important step to improving

the ability to conduct surveillance. In addition, a surveillance system must be developed to detect emerging diseases even prior to development of a diagnostic test.

Diagnostic Capability and Laboratory Capacity

The National Animal Health Laboratory Network has received initial funding and continued support is important. Continued discussion is needed to more clearly define the role of the laboratories in states. There are two main areas for their involvement—screening for foreign animal diseases especially when there are domestic diseases in the differential and surge capacity after the diagnosis of a foreign animal disease. Rigorous laboratory procedures and protocols are needed to ensure accurate results as well as clearly defined reporting protocols. A tabletop exercise that uses the Laboratory Network in an outbreak situation would be useful in identifying potential problems and issues that could arise.

Reagents can be a limiting factor for surge capacity. The U.S. is not currently self-sufficient for making reagents. Additional emphasis is needed in the area of stockpiling reagents and looking at sources of reagents. Tests that do not have limitations with reagent procurement should be explored.

Some rapid diagnostic tests are currently undergoing validation. Increased efforts are needed to determine how best to use this technology and what further advances in multi-testing are possible.

Vaccine Bank

The Tripartite Exercise in 2000 tested how the Canada, Mexico, and the U.S. would address mobilization and use of the joint FMD vaccine bank. The final report of the Tripartite Exercise contains a thorough review of the issues that surfaced during this test exercise and areas for further work.

Test Exercises

Several exercises have been conducted by Veterinary Services in conjunction with states. The most recent large exercise was the Tripartite Exercise. Several key issues were identified that needed further work to mount an effective response. They included protocols and decision making process for use of vaccines, the vaccine distribution plan, harmonization of standards for disease control zones, and incorporating a decision tree/matrix in country response

plans. More details on the recommendations and identified needs are included in the Tripartite Exercise summary.

A series of broader exercises have been conducted recently. Issues identified included how to implement a national stop movement, vaccination protocols, carcass disposal, indemnity determinations, trade stoppages, and interagency coordination.

Test exercises are critical for the evaluation of emergency response plans and an understanding of roles and responsibilities of stakeholders including various Federal agencies, states and industry. There should sufficient resources available to allow testing of multiple disease scenarios and assistance to states in the development and execution of state-based exercises.

Training and Education

Private practitioners responding to a health concern by producers are likely to be the first to detect a foreign animal disease. There is variation in how much information about foreign animal diseases is provided in veterinary school curriculums. Additional efforts are needed to keep the awareness of the potential for a foreign animal disease in front of veterinary students and practitioners.

Continued training of emergency responders is critical to our country's preparedness. Awareness programs for producers, practitioners, allied industries, policy makers, and the general public are needed to ensure all understand their responsibilities. Continued involvement of animal health officials in FAD outbreaks in other countries is critical to providing "hands on" experience to responders.

Animal Identification

Currently, there is not a single comprehensive, coordinated national animal identification system. Recently, there has been a substantial effort by the Federal government, states and industry to address this. The U.S. Animal Identification Plan has been developed and species specific working groups are now writing their implementation plans. The goal of the national program is to have the capability to identify all premises and animals that had direct contact with a foreign animal disease within 48 hours of its discovery.

Respond

Implementation of Local, State, Regional and National Plans

Various structures have been used by USDA to organize a response to a FAD. Recently the Incident Command System has been utilized for responding to avian influenza and exotic Newcastle disease. With the addition of DHS to the response, it is appropriate to review how the two agencies would interact in a response and their relationship in the National Response Plan. At the state level as well, interactions and templates are needed to sort out roles and responsibilities between state homeland security and agriculture departments.

Considerable effort has been put into emergency response plans at the State and Federal level. It is critical that sufficient emergency management personnel are available to allow these plans to be integrated and coordinated.

Communication

A group of industry communicators that has been coordinating communication plans and messages among the industry groups in the event of a FAD. This Communicators Group is also interacting with USDA to ensure seamless communication in the event of an outbreak. It would seem appropriate to involve DHS and HHS communication specialists in this activity. A common message to the U.S. consuming public is important with regard to the impact on human health of a FAD. As noted previously, consumer reaction can have a very significant impact on the economic impact of the outbreak.

Vaccine Usage

Part of the Tripartite Exercise included the development of a decision tree and matrix for FMD vaccine use. This decision tree and matrix needs to be revisited and the assumptions need to be validated. Novel vaccine technologies and delivery systems need to be researched and the availability and use of antivirals to limit the number of infected animals need to be explored. Differential vaccines or diagnostics are desirable. Strategies such as ring vaccination with or without depopulation need to be reviewed and discussed with stakeholders.

Carcass Disposal/Cleaning and Disinfection

Innovations in carcass disposal options are needed. There is not a strong scientific basis for some of the biosecurity measures that would be put in place or for environmental cleanup of facilities. At the National Planning Workshop on Biosecurity in 2001, a detailed list of research needs was developed. Progress on the research in this area needs should be evaluated.

Recover

Indemnity Funds/Business Interruption

Currently, the Federal and potentially state governments provide compensation for fair market value for animals that need to be depopulated for disease control purposes. A proposed rule for FMD indemnity payments and one for cost sharing have been published and comments received. As noted previously in this paper, there are many costs that are not covered by payments just for destroyed animals.

Many issues have been raised with regard to compensation of producers for the many significant losses due to FADs. As previously discussed, there are significant economic impacts related to movement restrictions, vaccination and disposition of vaccinated animals, pre-emptive control measures, and depopulation for animal welfare reasons. Continued work is needed to clarify Federal and state governments' plans for compensation and opportunities for other types of assistance. In addition to fair market value payments, it is important to develop other risk management opportunities. USDA has been exploring additional options with the Risk Management Agency and these efforts need to be supported. There may be a role for government funding of premiums or other activities to facilitate additional coverage.

Regionalization/Trade Recovery

The National Surveillance System needs to include how surveillance could be conducted in a timely manner to allow for regionalization of the U.S. as soon as possible to minimize the impact on trade losses.

As previously noted, export markets are important to animal producers and the general U.S. economy. Being able to quickly identify unaffected regions of the country is important to allowing trade to resume as quickly as possible. Plans

need to be made now on how unaffected regions could be recognized for trading purposes by other countries. These plans need to be coordinated with the disease control plans but have specific people designated to work in this area. Trade SWAT teams are needed to quickly determine what export market opportunities continue to exist and when markets can be reopened.

Other issues

In addition to the previously outlined issues, there are several overarching issues. For instance, how will resources be allocated for diseases identified as being more likely to be used by a terrorist group vs. diseases with significant economic ramifications but more likely to be accidentally introduced? How would the planned system handle an emerging disease when the actual disease agent itself is unknown and the route of introduction also unknown? What are the roles and responsibilities of USDA, DHS, and Health and Human Services in the event of the intentional introduction of a zoonotic agent? How are research programs and needs addressed for potential zoonotic agents among the different agencies? How would the introduction of a FAD into wildlife be addressed if intentionally or accidental? A critical need is appropriate facilities for FAD research and diagnostic development. What are the future plans to address these increasing needs? How will the need for Biosafety Level 4 facilities with significant domestic animal capabilities be addressed?

It is also imperative that a process for a feedback loop is developed that allows disease control policies and strategies to evolve as the science evolves.

Addressing the gaps

While USDA and DHS increase their interaction and coordination on research and policy issues, there are also many other partners in agricultural biosecurity. It is important to have opportunities for coordination across the various stakeholders. In addition, partnerships have become more important due to many factors including limited government human and financial resources, increasingly complex animal health issues and needs, limits on specialized expertise in both the public and private sectors, and the need to integrate local, national and international perspectives into decision-making. The National Animal Health Emergency Management System (NAHEMS)

Steering Committee is a State and Federal government, industry, veterinary, and academia partnership formed in 1996 to address the various issues related to FADs and other animal emergencies. This Committee should continue to have a

role in facilitating dialogue among the various partners in emergency management.

From an industry perspective, it should be noted that producers and the American public expect there to be a coordinated approach to anticipation/threat characterization, prevention, preparedness, response and recovery for an animal health emergency. They do not concern themselves as much with specific roles and responsibilities of the various agencies which have a role in animal health emergency management. They expect a seamless approach regardless of the agencies involved.

Summary

The occurrence of a FAD in the U.S. would have very significant economic impacts on producers, agricultural-related industries, the national trade balance, and the public. Every effort must be made to minimize the potential for an incursion of a FAD either naturally or internationally.

Due to the importance of animal agriculture to the U.S. economy, gaps in the ability of the U.S. to anticipate, prevent, prepare and respond to a FAD must be adequately addressed. There is an expectation that a comprehensive, integrated, and coordinated system is in place to prevent entry of a FAD, detect it rapidly if there is an entry, and to respond appropriately and quickly. The system must be seamless across the various government agencies and have appropriate resources to accomplish their important tasks.

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Threats and Risks to U.S. Agriculture: An Overview

David R. Franz

Introduction

The U.S. food and fiber industry generates nearly \$1 trillion in revenue annually. Our efficiency in this sector is unsurpassed and serves as a stimulus for the rest of the economy. The greater impact of this industry on the nation was captured by President Jon Wefald of Kansas State University who observed, "Our ability to produce safe, plentiful, and inexpensive food creates the discretionary spending that drives the American standard of living." For many years, we have successfully developed and protected this unique resource and capability. Until recently, our primary concern has been natural or accidental introduction of disease causing agents into our food supply. Our system of federal, state and county inspection and control, although not perfect, has been able to preclude or effectively manage such events. As a result, wholesome food has been widely available and public confidence in the government to protect it is high.

Naturally occurring introductions of disease in the recent past, in Europe and Asia, give us a sense of the potential impact of intentional introductions by a terrorist or group. The 1997 foot and mouth disease (FMD) outbreak in Taiwan, the classical swine fever outbreak in the Netherlands and the 2001 FMD outbreak in Great Britain all came with multi-billion dollar price tags.

Historically, biological warfare programs have considered adversary agricultural sectors as targets. U.S., Soviet and Iraqi state programs developed agents against animals and plants, but they were never used on a large scale.

Before 1990, little thought was given to the possibility of a biological warfare or biological terrorist attack on U.S. cities. Even as recently as 1997, the total U.S. budget for biodefense, all within the Department of Defense, was \$137 million...and it was to protect the deployed force. In 1998, the Centers for Disease Control was first funded (ca. \$140M) and began working to apply the principles of public health to human biological defense. Although we understood the enormity of the Soviet BW program and the modest Iraqi effort in the early 90s, it took 911 and the "anthrax" letters to help us understand the

differences between biowarfare and bioterrorism, and to consider them seriously. Biowarfare requires significant infrastructure and personnel to produce ton quantities of bacterial, viral or toxin agents formulated specifically and disseminated efficiently, typically by fine-particle aerosol, with complex delivery systems over broad areas of a battlefield or adversary territory to cause disease and death in many. Bioterrorism, on the other hand, can involve very small quantities of material of varying quality, delivered by any of a number of means, to cause death or disease in a few or many, but intended to cause fear and panic and even to undermine the confidence of the people in their government. In the 90s, we felt somewhat vulnerable to terrorist attack, generally, and on 11 Sept 2001 (9-11) terrorism became a reality in America. Later that year, after October 4 (10-4), five Americans died of inhalation anthrax, intentionally introduced, and we responded with multi-billion dollar budgets to protect our human population.

In defending our citizens from biological terrorism, the ultimate goal is to save human lives and to limit morbidity. To do this successfully, we can use force stop terrorists from developing weapons---if we can find them. We can deter them by our preparation or by undermining their popular support. We can attempt to develop capabilities to detect an attack before the agent infects humans or detect the exposed humans before or after they show clinical illness. We can directly protect humans with physical countermeasures, prophylactic vaccines or drugs or treat those who show signs of disease. In general, the closer we can come to identifying the index case (first case in an outbreak), the more lives and dollars we can save. Biological terrorism is, fundamentally, a public health issue; chemical terrorism is a HAZMAT issue. As a result of media reports and public education, many more of us now understand these fundamentals and believe that, in the broader sense, preparation for the next emerging infectious disease, which we can be sure will come, is generally a cost-effective way to prepare for the next bioterrorist attack. We also understand that specific measures are needed in addition, to deal with manmade events. Finally, we know that it will not be possible to protect every American from either. The likelihood of bioterrorist attack, on humans or agriculture is probably very low---and risk is almost impossible to measure---but the potential impact is enormous: we can't just look the other way. The questions are, "How much preparation is enough?" and "How much makes sense?"

Since 911 and 10-4, we have improved our ability to protect our citizens from disease or death by bioterrorist attack. We have allocated far fewer resources to protect our agricultural and food industries. Enormous vulnerabilities remain. We must carefully analyze threats, vulnerabilities, potential impacts and attempt

to understand risks. We must decide what risk we will bear. Then we must attempt to cover gaps and to reduce vulnerabilities, but we must do so, conscious of the cost and value of any policy, program or specific countermeasure.

What are the characteristics of our agricultural and food and fiber industries, the threat agents which could impact them and how do these characteristics increase our risk?

1. **Agro-terrorism** might present in three general modes: 1) a direct attack on livestock (FMD virus) or plants (Leaf blight of corn), which does not cause illness in humans but has an economic impact, 2) an attack thorough adulteration of food supplies (botulinum toxin), which causes disease in humans and has an economic impact and 3) introduction of a vector borne disease of humans and animals (West Nile or Rift Valley fever viruses). The third case includes examples of agents which become endemic once introduced into a geographic area, and cannot currently be eradicated, because of wildlife hosts and/or competent insect vectors. It is possible that none of these modes of attack will truly cause terror, although case 1--- especially if multifocal---would be enormously disruptive and could possibly undermine the trust of people in their government.
2. Unlike accidental or natural introduction of disease or pests, intentional introduction might involve multi-focal attacks, possibly in remote areas to confound early detection, and could be done at a time of year which would maximize the likelihood of an expansive outbreak.
3. The agents of agro-terrorism include some which are highly contagious, (Case 1, above) allowing simple point introduction, without "weaponization", to affect a widespread and costly outbreak. The highly contagious, infectious viruses of food animals are typically not zoonotics; they do not cause illness in man. However, unlike the smallpox virus, the highly contagious animal viruses are available somewhere in the world at all times. Not all agents are created equal; their critical characteristics vary widely.
4. The combination of readily available, highly contagious agents and high population densities driven by modern farming methods make us extremely vulnerable to non-zoonotic disease threats. Likewise, low genetic diversity of modern crops and food animals increases their vulnerability to certain pathogens or next-generation threats.
5. Farming and ranching, in the U.S., are characterized by openness and lack of security. Fields, vineyards, orchards and feedlots are operated in isolated areas and along highways, often completely open to human access.

Stockyards and meat-, fruit- and vegetable processing operations often employ low-wage and transient workers.

6. Livestock and food products are transported widely over open highways and by rail within the U.S., making them at once vulnerable to attack and providing rapid dissemination of disease across the nation. Therefore, tracking animals, plants or disease would be difficult during an outbreak.
7. America leads the world in mass-produced, high-quality processed foods. Our success in this field makes our population safer from naturally occurring food-borne disease and intoxication, but---because of product integration and large batch size---it may make us more vulnerable to intentional intoxication of a preprocessed food product.
8. Because profit margins are slim and competition keen, prophylaxis for foreign diseases is currently not economically feasible unless the risk is significant. For FMD alone, unlike anthrax or smallpox in human disease, there are seven serotypes, making simple “one-shot vaccination” difficult or at least not cost-effective today.
9. In a modern, complex economy such as ours, attacks at a single point on the food chain can have wide ripple effects on seemingly unrelated segments. An outbreak of FMD might cause immediate turbulence in the futures market for many commodities worldwide; effect cattle feed prices, stock in fast-food and grocery chains, even land and machinery prices; reduce tourism related income; result in international embargos to U.S. products and potentially undermine the confidence of the public in the food industry or even the government.
10. Unlike a biological attack affecting only humans, an economic attack such as FMD in our livestock herds would have an almost immediate and very personal impact across the country...at the supermarket.
11. As in the case of attacks against humans, early identification of an attack and identification of the disease involved must be the first priority. Currently, diagnostic reagents are not available nationwide for all high-threat agents. Concern about the negative impact of false positive reporting of a case of a contagious FAD such as FMD---and the impact on markets of such a report---has resulted in government control of critical reagents. False positive reporting must be avoided; however, rapid field assays are absolutely essential if disease introduction is to be discovered and response begun in a timely manner.
12. International laws dictate time of reentry into the market after an outbreak of certain diseases such as FMD. How we handle an outbreak could have long-lasting economic implications for the nation and the world.

13. The U.S. imports animals of many species as well as enormous quantities of bulk and processed foods from around the world daily. In addition, animals and food stocks move through our ports 24 hours per day, throughout the year. It is currently impossible to examine or even track the contents a significant number of planes, ships and containers entering the U.S.. Likewise, it is impossible to totally control movement across our borders.
14. The currently accepted approach to dealing with foreign animal (and plant) disease is to diagnose, cull and destroy. In some cases, unaffected herds and flocks must be destroyed to attempt to stop the spread of disease in the broader population. "Surgical excision" of only diseased animals is not possible today. Furthermore, as was demonstrated in the British FMD outbreak in 2001, such activities have untoward psychological impact on owners and generate response from the activist public internationally.
15. We are currently uncertain how best to dispose of 20-30 thousand tons of contaminated carcasses, in an average Midwest feedlot, that would result from an outbreak of a FAD for which cull and slaughter is the only option.
16. The "health-care providers" of agriculture, veterinarians, plant pathologists, entomologists etc., are less familiar with exotic, or "foreign" animal and plant diseases than with those commonly and naturally encountered in the U.S.. Plant pathogens and pests often cause subtle signs of disease, making identification difficult for the layman until it is too late. Furthermore, "doctor to patient" ratio is far lower in veterinary or plant medicine than for human medicine, making it more likely that disease in a population will escape notice until it is established.
17. In a free society, it will be impossible to protect every animal, every tree, every plant and every consumer from the intentional introduction of virus, bacteria, toxin or pest. We must focus on high-consequence, feasible threats and bolster our current system of protecting our agricultural economy from naturally occurring pests and pathogens. Some of what is necessary has begun; we must do more.

What are some options to reduce risk by closing or narrowing the gaps in our defenses?

1. Clearly define responsibility for preparation and response (to include R&D) to bioterrorist attack against our food and fiber system. Coordinate responsibilities across USDA, FDA, DHS and the traditional security community and encourage regular communication among them.
2. Develop an understanding of the impact of the major likely agro-terrorism attacks in order to best prepare to deal with them. The current DHS

approach of building around high-consequence scenarios is a good one. The two currently being used---FMD and a food-borne outbreak---are valuable. If it is not being done, in depth study of these two scenarios should be undertaken by an integrated team of experts and all factors in prevention, attribution, response and recovery considered. A third scenario to be considered might be the introduction of an arbovirus of wild and domestic animals and man (e.g. Rift Valley fever) for which competent vectors are found throughout North America.

3. Define and prioritize a list of threat agents across the categories of concern: 1) non-zoonotic FAD viruses, 2) important plant pathogens and pests, 3) food-borne toxins and pathogens, 4) zoonotic arboviruses and, possibly, 5) next-generation threats.
4. Understand agent pathogenesis, epidemiology of disease and generic approaches to prophylaxis, therapy and control. Complete genomic characterization of the most important agents. Drive basic research from a broad understanding and consensus.
5. Conduct analysis of pathways by which plant and animal disease/pests might enter the country. This will involve commerce, movement of animals, humans, commodities, vectors and fomites. Strengthen links and communication with intelligence and security communities regarding these pathways.
6. Develop systems for tracking livestock movement routinely and for controlling vehicular and human traffic during an outbreak of a highly infectious disease.
7. Based on food-borne agent "threat" list, conduct a systems analysis of vulnerabilities in the food distribution system.
8. Where needed, incentivize industry and academia to develop needed countermeasures. Exploit new technologies and seek means to enhance natural resistance through modern vaccines and antiviral drugs. Seek broad spectrum, non-specific therapies to enhance resistance in susceptible animals to serve as "firebreaks" during an outbreak.
9. Educate farmers, ranchers, feed lot operators, cowboys, extension agents, veterinarians and plant pathologists regarding clinical presentation of the most important threat agents. Develop systems to continually enhance awareness. Develop understanding, among the humans closest to the animals on the hoof, regarding when to report a suspicious case and to whom to report.

10. Develop and field specific and sensitive assays for the major animal and plant threat agents and implement protocols for rapid rule-in and rule-out when these agents are suspected. Devise a policy for making our best field assays available quickly on the farm, yet limiting as much as possible the likelihood of false-positive reporting.
11. Develop a national system of surveillance, reporting and communication which will allow both identification of an outbreak and tracking of infected or diseased plants, grain or animals and potentially contaminated vehicles during an outbreak. Use geographical and wireless technologies, with diagnostic laboratory linkages. Strengthen links between county, state and federal laboratories.
12. Develop widely accessible, easily minable bioinformatics and information bases to support basic research, forensics, epidemiology and response.
13. Develop cases for evaluating risk: and cost: benefit of policies, preparations and countermeasures to agricultural bioterrorism. Seek dual-use solutions which enhance animal and public health in the absence of a bioterrorist attack.
14. Develop and exercise response plans in the context of international (OIE) law.
15. Develop and foster international relationships in research, surveillance, preparation and response.
16. Evaluate physical security as an alternative to more expensive countermeasures for feedlots and other concentrated agricultural systems. For example, poultry and swine operations typically have greater physical- and biological security than other operations.
17. Develop a national advisory team to support responsible agencies during an outbreak. Develop regional advisory teams to deploy to multiple sites in the event of a multifocal or geographically dispersed attack. Prepare teams through working sessions and exercises. Consider replenishment of human resources and the impact of physical and emotional fatigue.
18. Enable state and local response agencies through planning, organizing, equipping, training and exercising. Integrate national, regional and state plans.
19. Develop efficient systems for disposal of 10s or 100s of thousands of tons of animal carcasses at a single feedlot site. Consider environmental, political, public policy/regulatory, economic, psychological, public relations, animal welfare, engineering, public health and specific agent issues.

20. Develop eradication strategies and tools. Consider insect vectors, wild and domestic hosts, stability of organisms in the environment, decontamination (of facilities, vehicles, equipment, people, and carcasses), etc
21. Develop government indemnity plans before the crisis occurs. Consider policies that reduce animal movement and epidemiologically counterproductive behavior by owners and operators.
22. Understanding the modus operandi of the attackers may allow us to stop subsequent attacks. Develop forensic capabilities now, using genomics and information technologies. Coordinate activities of security, agricultural and public health agencies in planning preparation. Plan and prepare for sampling, agent packaging and chain of custody, classical and genetic screening. Designate or develop identification laboratories for large numbers of samples; these could be dual-use, used routinely to screen for emerging diseases and be dedicated to response at the time of human or agricultural attack.
23. Develop public education plans and capabilities before an attack occurs. As with any terrorist event, the gap between the public perception and the truth will be filled by fear and panic, unless it is addressed. "Can my child get FMD?" "I ate at McDonald's. Will I get the disease?" ...and similar questions from the uninformed public must be addressed quickly during an outbreak.
24. Develop policy and opportunities which encourage young people to chose careers as plant and animal health specialists, entomologists, epidemiologists, public health specialists, wildlife biologists, food crop and food animal production specialists and other disciplines which support animal and public health in normalcy and in crisis.
25. In implementing policies and developing technologies, consider a "Total Security Management" approach. Understand the risks broadly and evaluate the countermeasures carefully. Do what is technically sound and economically reasonable. Understand the long-term concepts of operation before investing deeply in new technologies.

The agricultural bioterrorism threat is primarily an economic threat. Although the cost in dollars could be overwhelming, the "terror effect" will likely be less than anthrax or a smallpox attack on our human population. On the other hand, introducing Foot and Mouth disease into our livestock population or Rift Valley fever into North America would be far easier than attacking the human population with anthrax or smallpox. We can't protect every herd, flock, field, orchard and vineyard; however, we can greatly reduce the impact of an introduction and possibly even make our valuable resources "harder" or less

desirable targets through careful evaluation of the vulnerabilities and judicious use preparation to reduce our vulnerabilities and enhance our ability to respond. Many of the technical and policy fixes proposed have dual-use application. Focusing on those, where possible, will positively affect our economy and way of life, even if we never have an intentional attack. There is a spectrum of agents, a spectrum of targets and a number of possible modes of attack. The several unique differences between the threats to humans and agriculture underscore the importance of 1) education and awareness, 2) physical security and 3) far-forward diagnostics, surveillance and communication in protecting our food and fiber industries. We must fully exploit America's research and development capabilities in bio- cyber- and electronic technologies to help reduce our vulnerabilities over the long term, as we consider simple and practical steps that can be taken today.

The Bio-Terrorist Threat to Agricultural Livestock and Produce

Peter Chalk
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Introduction

Over the past decade, the United States has moved to increase its ability to detect, prevent and respond to terrorist threats and incidents. Much of this focus, which has involved considerable financial outlays, has aimed at upgrading public infrastructure through the development of vulnerability threat analyses designed to maximize both anti-terrorist contingencies and consequence management modalities. While many gaps remain, investments in preparedness, training and response have helped with the development of at least nascent incident command structures that have incrementally begun to span the ambit of potential terrorist attacks, from conventional bombings to more “exotic” biological, chemical, radiological and nuclear incidents.

Agriculture is one area that has received comparatively little attention in this regard, however. In terms of accurate threat assessments and consequence management procedures, the industry exists somewhat as a latecomer to the growing emphasis that has been given to critical infrastructure protection (CIP) in this country. Indeed the sector was only incorporated as a specific component of U.S. national counter-terrorist strategy following al-Qaeda’s attacks on the Pentagon and World Trade Center in September 2001.

This paper aims to expand the current debate on domestic homeland security by assessing the vulnerabilities of agriculture and the food chain to a deliberate act of biological terrorism. For the purposes of this testimony, agro-terrorism will be defined as the deliberate introduction of a disease agent, either against livestock or into the general food chain, for the purposes of undermining national stability and/or engendering public fear. Depending on the disease agent and vector chosen, it is a tactic that can be used either to generate economic, social and political disruption or as a form of direct human aggression.

The Importance of the U.S. Agricultural and Food Sector and Its Vulnerability to Sabotage

Agriculture and the general food industry are highly important to the social, economic and, arguably, political stability of the United States. Although farming directly employs less than three percent of the American population, one in eight people work in an occupation that is directly supported by food production. Cattle and dairy farmers alone earn between \$50 billion and \$54 billion a year through meat and milk sales, while roughly \$50 billion is raised every year through farm-related exports. In 2001, food production constituted 9.7 percent of the U.S. GDP, generating cash receipts in excess of \$991 billion.

Unfortunately, the agricultural and food industries remain vulnerable to deliberate disruption. Critical considerations in this regard include:

The Concentrated and Intensive Nature of Contemporary U.S. Farming Practices

Agriculture is both a large-scale and intensive business in the United States. Most dairies in the country can be expected to contain at least 1,500 lactating cows at any one time, with some of the largest facilities housing upwards of 10,000 animals. Unlike humans, these animals exist as highly concentrated populations and tend to be bred and reared in extreme proximity to one another. The outbreak of a contagious disease at one of these facilities would be very difficult to contain, especially if it was airborne in nature, and could well necessitate the destruction of all exposed livestock—a formidable and highly expensive task. Indicative of this was the recent outbreak of Exotic Newcastle Disease (END) in late 2002, which by October of this year had led to the slaughter of over three million chickens in several counties across California.

The Increased Disease Susceptibility of Livestock

U.S. livestock has become progressively more disease prone in recent years as a result of husbandry changes and biotechnology innovations that have been introduced to increase the quality and quantity of meat production as well as to meet the specific requirements of individual vendors. These modifications, which have included everything from sterilization programs to dehorning, branding, crowding and hormone injections, have combined to elevate the stress levels of exposed animals. This has both lowered their natural tolerance to

contagious pathogenic agents as well as increased the “volume” of bacteria that would normally be shed in the event of an infection.

Insufficient Farm/Food-Related Security and Surveillance

A deliberate act of sabotage is simply not something that the majority of the agricultural community has actively thought about, much less physically prepared to guard against. Farms in the U.S. have therefore tended to evolve, not surprisingly, as relatively open affairs, seldom incorporating concerted means to prevent unauthorized access or intrusion. This is especially true of outlying fields and feedlots but is also often the case with respect to centralized facilities such as milking stands.

Food processing and packing plants also tend to lack uniform security and safety preparedness measures, particularly those that have proliferated at the lower and medium end of the production spectrum. Thousands of these facilities exist across the country, exhibiting uneven standards of internal quality control, questionable bio-surveillance and highly transient, unscreened workforces. Entry-exit controls are not always adequate (and occasionally do not exist at all) and even basic measures such as padlocking storage rooms may not be practiced. Moreover, many small-scale operations do not keep accurate records of their distribution network, meaning that it may not be possible to trace a tainted food item back to its original source of production.

Inefficient Passive Disease Reporting System

Responsibility for reporting unusual disease occurrences in the U.S. lies with agricultural producers. However in many cases, communication channels between and state emergency management personnel remain underdeveloped, particularly with regards to information frameworks that clearly designate relevant regulatory agencies and primary or secondary personnel that need to be contacted in the event of a serious viral or bacterial outbreak. Equally as important, farmers are often reluctant to quickly report outbreaks of notifiable diseases, fearing that if they do so, they will be forced to carry mass, unrecompensed depopulation measures.

The current operation of the U.S. animal disease reporting system, in other words, does little to avail early pathogenic warning and identification. This is problematic as rapid, confirmed diagnoses are vital to any effective emergency management system, particularly in the case of highly transmissible viral infections such as FMD.

Inappropriate Veterinarian and Diagnostic Training

The number of appropriately trained veterinarians capable of recognizing and treating exotic livestock diseases is declining in the U.S. In part, this reflects the smaller numbers of people actually entering veterinarian science – itself a product of the lack of educational support and financial incentive given to the discipline in the country – and the preference choices of those that do – most of who tend to focus on domesticated pets such as dogs and cats rather than large-scale husbandry (as this is where the most money is to be made). Just as importantly, it is indicative of college curricula that, in many cases, reportedly do not emphasize FADs sufficiently, with the focus directed toward diseases that are endemic to the United States itself.

Capability Requirements for Carrying Out an Agro-Terrorist Attack

Although vulnerability does not equate to risk and there are few recorded instances of terrorists actually using disease agents against livestock, a realistic potential for such a contingency exists. Indeed what makes the vulnerabilities inherent in agriculture so worrying is that the capability requirements for exploiting these weaknesses are not significant and certainly less than those that would be needed for a human-directed bio-attack. At least four factors account for this. First, there is a large menu of agents to choose from, with fifteen “List A” pathogens identified by the Office International des Epizooties (OIE) as having the potential to severely effect agricultural populations and/or trade. Most of these diseases are environmentally hardy – being able to exist for extended periods of time on organic or inorganic matter – and many are not routinely vaccinated against in the United States.

Second, many FADs cannot be transmitted to humans, meaning that they can be handled with no risk of latent or accidental infection. There is, thus, no requirement on the part of the perpetrator to have an advanced understanding of animal disease epidemiology and transmission modes nor is there any need for elaborate containment procedures, personal protective equipment (PPE) and/or prophylaxis antibiotics in the preparation of the agent.

Third, if the objective is human deaths, the food chain offers a low-tech, yet conducive mechanism for disseminating toxins and bacteria such as salmonella, *E. coli* and botulism (none of which require any substantial scientific knowledge to isolate or develop). Developments in the farm-to-table food continuum have greatly increased the number of entry points for these agents, which combined

with the lack of security and surveillance at many processing and packing plants, has helped to augment the technical ease of orchestrating a food-borne attack.

Fourth, animal diseases can be quickly spread to affect large numbers of herds over wide geographic areas. This reflects the intensive and concentrated nature of modern farming practices in the U.S. and the increased susceptibility of livestock to viral and bacterial infections (see above). There is, in other words, no obstacle of weaponization—which is frequently cited as one of the most important barriers preventing non-state offensive use of biological agents—that needs to be overcome in agricultural terrorism as the animals, themselves, become the primary vector for pathogenic transmission.

Impact of a Major Attack Against Agricultural Livestock and/or the Food Chain

The ramifications of a concerted bio-assault on the U.S. meat and food base would be far-reaching and could extend beyond the immediate agricultural community to affect other segments of society. It is possible to envision at least three major effects that might result.

Economic Disruption

Perhaps one of the most immediate effects of a major act of biological agro-terrorism would be economic disruption, generating costs that could be expected to cross at least three levels. First, there would be direct losses resulting from containment measures and the eradication of disease-ridden livestock. Second, indirect multiplier effects would accrue both from compensation paid to farmers for the destruction of agricultural commodities and revenue deficits suffered by both directly and indirectly related industries. Third, international costs in the form of protective embargoes imposed by major external trading partners would manifest. One study from California, which presented eight different scenarios associated with a theoretical FMD outbreak, concluded each day of delay in instituting effective eradication and control measures would cost the state \$1 billion in trade sanctions.

Loss of Political Support and Confidence

A successful bio-attack against the U.S. agricultural sector could also serve to undermine confidence and support in state governance. Successfully releasing

contagious agents against livestock might cause people to lose confidence in the safety of the food supply and could possibly lead them to question the effectiveness of existing contingency planning against weapons of mass destruction in general.

The actual mechanics of dealing with an act of agricultural bioterrorism could also generate public criticism. Containing a major disease outbreak would necessitate the slaughter of hundreds of thousands of animals, particularly in cases where no concerted vaccination was in place. Euthanizing such volumes has the potential to generate vigorous opposition from the general population—not to mention farmers and animal rights advocates—particularly if slaughtering involved susceptible but non-disease showing herds (so-called fire breaker operations) and/or wildlife.

Social Instability

Beyond immediate economic and political impacts, bio-terrorist assaults against agriculture have the potential to create public angst and could, possibly, stimulate socially disruptive rural-urban migrations. Several animal diseases are zoonotic in nature, meaning they have the ability to “jump” species and affect humans. Should an epidemic of any one of these diseases occur in the U.S., it could have severe repercussions in terms of galvanizing a mass public scare throughout the country, particularly if human deaths actually occurred. Terrorists could use this to their advantage, allowing them to create a general atmosphere of fear and anxiety without actually having to carry out indiscriminate civilian-oriented attacks (and “accepting” all this entails in terms of attracting mass reprisals and alienating actual or potential support).

Biological Assaults Against Agriculture and Terrorism Modus Operandi

Despite the ease by which an act of agro-terrorism could be carried out and the severe ramifications that a successful assault could elicit (especially in terms of economic and political fallout), it is unlikely to constitute a primary form of terrorist aggression. This is because such acts would probably be viewed as “too dry” in comparison with traditional tactics in the sense that they do not produce immediate, visible effects. The impact, while significant, is delayed—lacking a single point of reference for the media to focus on (and highlight).

In this light, it is perhaps understandable that biological attacks against agriculture have not emerged as more of a problem. Indeed since 1912, there

have been a mere twelve documented cases involving the sub-state use of pathogenic agents to infect livestock or contaminate related produce. Of these, only two incidents could in any way be termed terroristic in nature: the 1984 Rajneeshee salmonella food poisoning in Oregon and the 1952 Mau Mau plant toxin incident in Kenya.

This being said, agro-terrorism could emerge as favored form of secondary aggression that is designed to exacerbate and entrench the general societal disorientation caused by a more conventional campaign of bombings. The mere ability to employ cheap and unsophisticated means to undermine a state's economic base and possibly overwhelm its public management resources give livestock and food-related attacks a beneficial cost/benefit payoff that would be of interest to any group faced with significant power asymmetries.

The 2001 Foot and Mouth Disease Epidemic In Great Britain

Presentation by Alun Evans, Director, Civil Resilience
Office of the Deputy Prime Minister

In 2001 Great Britain experienced a devastating epidemic of Foot and Mouth Disease (FMD).²⁵ The speed at which the disease took hold and the severity of its effects, particularly in certain regions, meant a social and economic upheaval in those areas on a scale probably not seen since the Second World War.

The last major FMD epidemic in the UK had been in 1967-68. Subsequent improvements and changes in farming practice, together with developments in veterinary science and international cooperation meant that, by 2001, the continued threat to the UK from Foot and Mouth Disease was not considered to be high.

So in February 2001 the discovery of a confirmed case of FMD was totally unexpected. Neither the British Ministry of Agriculture nor the farming industry was prepared for an outbreak on a large scale. The Ministry could not cope with the unprecedented chain of events, which allowed the disease to go undetected for some weeks and, as a result, take hold.

The rate of spread was dramatic and devastating. The first case was confirmed on February 20 in Essex, near London. Subsequent epidemiology showed that the first infection had probably taken place about three weeks earlier. The precise source of the disease has never been proved. It is most likely that illegally imported meat in North East England entered into pig swill via restaurant waste and was fed to pigs at a poorly run farm in Northumberland (near the Scottish border) to where the first (or index) case was subsequently traced. On day 1 of the epidemic it is likely that there were already 57 cases incubating across the country (Slides 1 and 2). Within three days, by which time only five cases had been officially confirmed, it is likely that there were already 119 cases spread across the country (Slides 3 and 4). How had this happened?

²⁵ The homepage for the lessons learned Inquiry into the Foot and Mouth Disease outbreak of 2001 can be found at <http://www.cabinet-office.gov.uk/fmd/index.htm>.

A contingency plan for handling Foot and Mouth Disease was in place, and agreed by the European Union, but the plan had gaps and had not been shared widely or vigorously rehearsed outside the Ministry of Agriculture and the State Veterinary Service. The scale of the outbreak, and the way in which it spread, could not have been anticipated, although senior officials in the State Veterinary Service had, over the previous two years, expressed internal concerns about their readiness for an outbreak of FMD. These concerns were not relayed to Ministers. Warning signs, from the experience of an earlier outbreak of classical swine fever in The Netherlands in 1997 and in Britain in 2000, were not acted upon. The country was not prepared for what was about to unfold.

The first responses to the early cases were not fast enough or effectively co-ordinated. The paramount importance of speed, and especially the rapid slaughter of infected animals, was not given absolute priority early on.

Knowledge within government of changes in farming and farm practices was limited. This was perhaps inevitable given the gap of 32 years – a generation – since the last major outbreak. In particular, the nature and extent of sheep movements, which contributed to the wide dispersal of the disease before its identification, had not been fully recognised. In the three critical days after the disease was first identified on 20 February until midnight on 23 February, when the Government applied a ban on all susceptible livestock movements, the transport of animals – and in particular sheep – between markets continued (Slide 5). This undoubtedly made the spread of the disease much worse as, unlike previous FMD outbreaks, the virus had disproportionately affected the sheep population.

Initially the outbreak was treated as a purely agricultural issue. This was a mistake. The Ministry of Agriculture took the lead within government in managing the response. Almost immediately it came under severe resource pressures but partly as a result of poor management information to senior decision-makers, those resource shortages were not addressed quickly enough. The impact of the disease, especially on tourism and the rural economy following the introduction of bio-security measures and the closure of footpaths, was not recognised early on. The strategic response of government was to see the disease as an essentially an agricultural problem, not a fundamental economic crisis and a threat to the nation.

The scarcity of resources was not only confined to vets. There were important gaps in managerial and logistical skills. The quality of communication was mixed. Mechanisms for joining up government were not brought into play from the start. This put enormous pressure on the Ministry and on the State

Veterinary Service. People worked long and hard, under very difficult circumstances, to try to contain the disease and limit the consequences but without success.

The disease, by now, had a firm grip on many parts of the country, although some areas remained unaffected. Within 20 days of the crisis on 12 March there were 181 confirmed cases with probably 459 in total. (Slide 6 and 7) By 16 April there had been 1371 cases confirmed and 1461 estimated (Slide 8 and 9). From then on the epidemic began to tail off as the control measures finally began to take effect. But it was another five months before the disease was eradicated, with the 2026 – and final case – being confirmed on 30 September 2001.

Only when the Government's emergency crisis centre (known by its acronym of COBR) was opened on 22 March – 31 days after the first case had been confirmed – and with the personal intervention of the Prime Minister, did the crisis begin to come under control. COBR brought to bear the full capabilities of Government resources in tackling the disease. The military were deployed in support of local responders and made an impressive contribution, providing leadership, management and logistical skills. A few days later, and 35 days into the crisis, a scientific advisory group gathered for the first time under the chairmanship of the Chief Scientific Adviser to the Government.

A network of Disease Control Centres was set up in those areas where the infection was at its worst. These Centres, each run by a senior Regional Operations Director, made major contributions to controlling the disease.

But communications to the rural communities affected was poor. Changes, in particular to animal culling policy, were introduced at short notice. Often they were poorly communicated, if at all. Large parts of the farming and wider rural community became mistrustful of government. The public and the media – which had initially been broadly supportive of the Government's approach – turned against it. In particular, the policies of culling apparently healthy animals became very unpopular, despite their contribution to disease control. Management of carcass disposal was a major concern, particularly in the early stages of the outbreak when animals were burned on mass pyres, but improved significantly after the armed forces became involved.

The issue of vaccination assumed a high profile, not least in the media and amongst animal welfare groups. But the arguments for and against its use were not well explained by the Government or widely understood by the public. By the time it was agreed that vaccination should be used to help control the disease amongst cattle in Cumbria (the worst affected region in the north of England),

the outbreak had passed its peak. In the event vaccination was not used, largely as a result of opposition by the farmers' unions and parts of the food industry, concerned that the public would not accept milk products from vaccinated cows.

As the intensity of the outbreak finally declined, an exit strategy was developed. This included targeting resources to the areas of residual disease, coupled with a robust use of biosecurity and a programme of blood testing. The disease probably peaked on or around 27 March. The last confirmed case – on 30 September – was 221 days after the start of the outbreak.

The overall costs to the UK economy were enormous, with official estimates putting the figure at around £3 billion, or \$5 billion dollars. Others put the figure higher. Millions of animals were slaughtered. Different sectors of the economy were affected in different ways. Farmers were compensated for animals that were culled for disease control purposes and for welfare reasons. Rural and tourist businesses however received little recompense. Farmers whose stock was not culled, but who were subject to strict movement controls, received no compensation at all.

In the summer of 2001, as the outbreak was coming to an end, the UK Government established an independent Lessons Learned Inquiry. It was chaired by Dr Iain Anderson, an ex Board member of the multinational company Unilever. He had wide experience of crisis management in complex industrial organisations and brought his considerable expertise to bear in handling the work of the Inquiry. I was head of the Secretariat team that worked with Dr Anderson. We visited areas most affected by the virus in England, Scotland and Wales. We also visited The Netherlands, which had an associated outbreak of FMD, to learn from their experience and met with the European Commission in Brussels. We reported to the UK Government in the summer of 2002. Our report contained a series of recommendations designed to help ensure that the chances of exotic animal disease entering the country would be reduced; that the farming industry itself would be less vulnerable to outbreaks of infectious animal diseases; and that, if such a disease did occur in future, then the impact would be minimised.

The lessons we identified are, I believe, as relevant to preparing for a deliberate infection of animals (agro terrorism) as they are to a non-intentional outbreak of the disease.

Our inquiry identified nine major lessons. (Slides 10-18)

Lesson 1

Maintain vigilance through international, national and local surveillance and reconnaissance.

Lesson 2

Be prepared with comprehensive contingency plans, building mutual trust and confidence through training and practice.

Lesson 3

React with speed and certainty to an emergency or escalating crisis by applying well-rehearsed crisis management procedures.

Lesson 4

Explain policies, plans and practices by communicating with all interested parties comprehensively, clearly and consistently in a transparent and open way.

Lesson 5

Respect local knowledge and delegate decisions wherever possible, without losing sight of the national strategy.

Lesson 6

Apply risk assessment and cost benefit analysis within an appropriate economic model.

Lesson 7

Use data and information management systems that conform to recognised good practice in support of intelligence gathering and decision making.

Lesson 8

Have a legislative framework that gives Government the powers needed to respond effectively to the emerging needs of a crisis.

Lesson 9

·Base policy decisions on best available science and ensure that the processes for providing scientific advice are widely understood and trusted.

No amount of effort can eliminate the potential risk of economic damage from FMD or other infectious animal diseases. But speed is of the essence in responding to any outbreak. Co-ordinated and rapid action can limit the risks posed by animal diseases such as FMD. There must be effective systems in place – management systems, information systems and communications systems. And decisions must be based on the best international scientific knowledge available.

(Slide 19: “Speed, Systems, Science”)

The Technical Policy Connection

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Abstract

In solving the problems posed by agricultural terrorism against livestock, what should come first: the formulation of strategic policies or the application of available science and technology? There is no clear-cut answer to this question, nevertheless one can argue that the policy aspects need to be considered first. After this, the available science and technology can be used to support and, if necessary, called upon to enforce strategic policies that are aimed at reducing major threats.

This paper and its associated presentation begin by outlining a short list of bioagents against livestock and looking at the overall distribution and transportation of livestock throughout country. It focuses on foot-and-mouth disease and uses it as a model to identify the types of scientific and forensic information that must be generated before an outbreak takes place and after one occurs.

It then moves on to policies, emphasizing that we need to develop the means to prevent and deter agricultural terrorism against livestock. In the event of an attack, we must be prepared to respond from a national security perspective and also act with swift infectious disease control measures. In looking to the future, such policies will require significantly increased capabilities to collect and analyze samples on an ongoing and emergency basis.

Finally, it addresses the use of available science and technology, emphasizing that we need two different kinds of sample testing capabilities. The first kind enables portable on-the-spot testing of samples in the field and yields simple positive-negative results. The second kind permits high-throughput testing of samples in the laboratory and yields high-resolution forensic information on bioagents against livestock.

Within the next two years, both kinds of available technology could be integrated into a powerful laboratory and informatic system against foot-and-mouth disease. Within the next five years, the system could be expanded to many of the leading bioagents against livestock. Such capabilities would support counterterrorism and nonproliferation efforts that can be summed up as: virtually assured detection, attribution, and response (VADAR).

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Problems

Bioagents against livestock are cheap and relatively easy to produce, transport, and employ. They are anonymous because a comprehensive forensic database does not exist to trace and pinpoint their source, greatly hindering any possible efforts to investigate and apprehend those responsible for such acts. They also pose a significant long-term threat to commercial activities that generate nearly 15% of our national economy.

In the event of a major outbreak involving U.S. livestock, we may find it difficult to determine whether it was due to a deliberate attack, an accidental introduction, or a natural event. The number of sites involved in the initial outbreak may offer the only clue, with multiple simultaneous sites suggestive of terrorism.

The table below lists some of the leading bioagents against livestock. Two of these bioagents – rift valley fever and some strains of avian influenza – have the potential to cause severe disease in humans. The table shows that most of the leading bioagents against livestock have relatively small RNA-based genomes, with the exception of African Swine Fever which has a larger DNA-based genome. As emphasized later, these relatively small genomes will assist in the generation of a comprehensive forensic database, mainly because small genomes can be sequenced rapidly and completely to yield definitive molecular fingerprints.

Bioagents	Genome	Approximate size (kilobases)
Foot-and-mouth disease	RNA	8
Classical swine fever	RNA	11
African swine fever	DNA	180
Rift valley fever	RNA	11
Avian influenza	RNA	13
Exotic newcastle disease	RNA	17

On January 1, 2002, the United States had an estimated inventory of 164 million head of major livestock, including 97 million cattle, 60 million hogs, and 7 million sheep. The flows of such livestock through various multi-state regions are clearly different for each species, giving rise to crisscrossing and rather complex patterns. Maps of such flows make it evident that millions of cattle, hogs, and sheep cross each others' paths on a routine basis as they move from areas that specialize in birthing, fattening, and slaughtering of livestock. Consequently, the exposure of livestock to an infectious agent at one or more sites in these flows could easily result in a rapidly spreading multi-species outbreak.

At present, foot-and-mouth disease is judged by many to be the most threatening bioagent against livestock for several reasons. It infects cloven-hoofed animals, including cattle, hogs, and sheep. It can spread from animal to animal with cycle times as short as 3 days and a single virus shedding animal can infect anywhere from 2 to 70 susceptible animals—leading to swift exponential growth. Infectious viruses can travel in the wind, with described distances ranging from 5 to 100 kilometers, and the spread of infection can be enhanced by favorable weather conditions and high animal densities—leading to geographically dispersed growth. The current livestock production practices in the United States, which are fast moving and concentrated, further serve to magnify the threats posed by foot-and-mouth disease. It is therefore conceivable that an outbreak of foot-and-mouth disease in one region of the country could soon involve many others. The potential economic, environmental, and psychological consequences of such an outbreak would be enormous.

Natural foot-and-mouth disease outbreaks have a worldwide distribution. In 2002, the Pirbright Laboratory in the U.K. (which serves as the world reference laboratory for foot-and-mouth disease) received virus-positive samples from 28 countries and, over the past decade, at least twice this number of countries have experienced outbreaks. Overall, foot-and-mouth disease has seven distinct

serotypes plus multiple subtypes within each serotype. Each serotype is immunologically distinct and various subtypes within each serotype often exhibit varying degrees of cross reactivity. A vaccine repository for foot-and-mouth disease must therefore include stocks against all seven serotypes as well as stocks against the most representative and broadly reactive subtype/serotype combinations.

Like many RNA-based viruses, foot-and-mouth disease virus exhibits rapid rates of mutation. An outbreak involving one particular serotype/subtype may therefore “shift” over time to a new or immunologically distinct subtype. The time over which such shifts can occur is likely to vary and has not been clearly defined. Nevertheless, the possibility of spontaneous shifts represents a complicating factor in the use of foot-and-mouth disease vaccines. If a vaccine is used in combination with slaughter to control an outbreak, it calls for extensive sampling and testing of viruses from livestock in order to guarantee that vaccines remain effective over time.

Different strains of foot-and-mouth disease virus also exhibit variations throughout their entire genomes. The overall pattern of such variations can be used to differentiate one strain from another, distinguish one sample from another, and measure the relatedness of one sample to another. A smaller number of variations between two samples is indicative of closer relations. As with the human genome, the analysis of more variable sites within the foot-and-mouth genome leads to more reliable fingerprints and evidence. At present, enough data exists to conclude that most if not all of the leading bioagents against livestock can be uniquely identified by genetic analyses. As outlined below, bioagent forensics can therefore play an important role in shaping effective policies to prevent, deter, and respond to acts of terrorism against livestock.

Policies

In June 2002, the National Academies published a comprehensive report *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism* and delivered it to the United States Congress and Office of the President. The report offers many far-reaching recommendations, including ones to build high-throughput laboratory and information processing systems against biological terrorism and to develop and coordinate bioterrorism forensics capabilities (see Appendix A). In light of these recommendations and the problems outlined above, how should we move forward with the formulation of strategic policies?

Overall, the United States needs to develop the means to prevent and deter agricultural terrorism against livestock. In the event of an attack, it must be prepared to respond from a national security perspective and act with swift infectious disease control measures.

The ability to prevent an attack requires some form of warning from the law enforcement and/or intelligence communities. It also requires active identification of networks, groups, or individuals who plan to carry out such attacks in combination with swift interventions to halt their activities. At home, it calls for proactive investigations by law enforcement and, abroad, it calls for expanded human intelligence capabilities. When it comes to prevention, the most obvious limiting resource is human intelligence and the associated ability to obtain bioagent samples from guarded sources. In all likelihood, it will take years to build up such capabilities.

The ability to deter an attack requires some form of declaration and/or official notice that swift attribution is likely, if not virtually guaranteed. It also requires that networks, groups, or individuals who plan to carry out attacks are impeded by our posture of swift attribution and the subsequent law enforcement and/or national security responses that would follow. For terrorist networks such as Al Qaeda, however, it is unclear whether such measures will succeed.

The ongoing and active prevention of agricultural terrorism against livestock will be, without doubt, the most difficult objective to achieve followed by ongoing and active deterrence. The potential economic, environmental, and psychological consequences of agricultural terrorism, however, leave us with little choice but to develop the practical means to reduce the most likely threats.

The ability to prevent and deter agricultural terrorism and, in the event of an attack, to respond against the perpetrators and act with swift control measures rests on the ability to collect and analyze a large number of bioagent samples. In the case of foot-and-mouth disease, a world reference laboratory already exists but it relies on the passive submission of samples from outbreak areas and is not geared to test and analyze samples in complete forensic detail. In 2002, for example, the Pirbright Laboratory in the U.K. reported the receipt of only 630 foot-and-mouth samples from 28 countries, which represents only a small fraction of circulating viruses.

The United States must therefore increase the means to collect and analyze bioagent samples on a broad international scale. Out of necessity, such samples would come through a variety of sources, including overt and covert ones. Each sample would be associated with its precise geographic origin and analyzed to

yield its complete genetic sequence (fingerprint) and immunologic serotype/subtype. The only feasible way to achieve this goal is to build a high-throughput laboratory network that takes advantage of automation, precision robotics, and control technologies. Such capabilities would eliminate the errors introduced by human technicians and make it feasible to perform every essential test on every bioagent sample. In conjunction with portable technologies that enable on-the-spot testing of samples in the field, it would also offer much needed surge capacity as outlined below.

Technologies

The science and technology already exists to build a new, powerful, and relatively inexpensive high-speed/high-volume laboratory network that can incorporate two different kinds of sample testing capabilities. The first kind enables portable on-the-spot testing of samples in the field and yields simple positive/negative results. The second kind permits high-throughput testing of samples in the laboratory and yields high-resolution forensic information on bioagents against livestock. The high-speed/high-volume network would be based on a common operating system that interconnects these different technologies, thereby creating a virtual hub-and-spoke capability that can span the country.

Several companies offer portable and rapid testing equipment for on-the spot testing of samples in the field. The equipment produces positive/negative test results and works by amplifying and detecting a small number of sequences that are always present in certain bioagent genomes. This polymerase chain reaction-based equipment can test about 50 individual samples per hour and its overall reliability can be enhanced by using multiple genetic probes for one bioagent, such as foot-and-mouth disease. The equipment can be outfitted with a portable computer to record clinical observations on livestock and a global positioning system receiver that automatically pinpoints its location.

In the event of an outbreak, a large mobile team of veterinarians and trained technicians would use the equipment to transmit clinical observations and positive/negative test results to a central database. In combination with other real-time data on regional weather conditions, prevailing winds, and livestock distributions, high-performance computers would then be used to visualize outbreak sites and predict the most likely patterns of spread. Top agricultural advisors would then use this science-based information to make key decisions on quarantine zones, animal destruction, and resource allocation.

Although the above portable technologies are quite powerful, they have several limitations. They are designed to perform only one type of test. They can generate both false-positive and false-negative test results. They can process only a few dozen samples every hour in the field. In addition, such technologies cannot produce the kinds of exact and complete data that are needed to differentiate one bioagent strain from another and cannot lead to the large volumes of data that are needed to track samples and attribute sources.

The high-resolution analysis of bioagents requires the types of laboratory procedures outlined below, with each producing valuable information.

Sequencing bioagents is needed for:

- tracking specific agents and isolates.
- attributing specific agents and isolates to their sources.
- detecting signs of deliberate biological engineering.

Growing bioagents and testing their proteins are needed for:

- determining susceptibility and resistance to vaccines.
- seeking new ways to overcome resistance.
- detecting signs of deliberate biological engineering.

Archiving bioagent samples in long-term frozen storage is needed for:

- repeating tests at a later time.
- performing new tests as they become available.
- proving samples to other laboratories for independent analysis.
- maintaining physical custody and evidence.

The above laboratory procedures are repetitive, labor intensive, and well suited to high-throughput automation. At present, the largest users of such laboratory automation, precision robotics, and control technologies are biotech companies and large pharmaceutical firms. Their high-throughput screening and drug discovery laboratories can routinely perform a hundred thousand to a million tests per day. Such commercial technologies can also be incorporated into a high-throughput laboratory and information processing system for bioagents against livestock.

The system would permit scientists to connect to the high-throughput laboratory by way of the Internet or secure intranets. A set of process control tools would then be used to program and manage all the necessary steps, such as the design of tests, documentation of samples, submission of samples, analysis of data, and assignment of data access privileges. Altogether, the system would permit scientists to use the high-throughput laboratory in the same ways that they

might use hundreds of skilled technicians. Yet the data would have far fewer errors than is possible with technicians and would also be purely digital and, therefore, easy to retrieve and manipulate by computers.

The proof of principle for such concepts dates back to 1995, when staff members at the Los Alamos National Laboratory carried out the first successful demonstration of a modular high-throughput laboratory system. Each module within the system performed a convenient group of tasks and, within a range of parameters, could be programmed to perform these tasks in a completely customized manner. Since 1995, the number of companies offering modular hardware for high-throughput laboratory systems has grown from a few to nearly two hundred. In addition, in 1999, the American Society for Testing and Materials approved an interconnect standard that makes it easier to integrate commercial hardware into laboratory systems. With this powerful standard, commercial hardware can possess the same plug-and-work features like those found in personal computer devices.

With commercial hardware, it would be feasible to build a flexible high-throughput genotyping system consisting of ten modules. To prepare bioagents for sequencing, it would use a sample input, sample output, barcode printing, plate sealing, liquid handling, incubating, and thermocycling module that work together in any logical order. To generate the actual sequence data, it would include three different kinds of modules that are each the most efficient for different kinds of sequencing tasks. Overall, the genotyping system would be capable of generating up to 5 megabases of genetic sequence data per day. For foot-and-mouth disease, which has an RNA-based genome that is ~8 kilobases in length, the high-throughput laboratory system would have the capacity to generate complete sequences on about 500 samples per day.

For bioagent samples collected internationally through the various overt/covert means mentioned above, the high-throughput genotyping system would be used to fingerprint samples and thereby associate precise genetic sequences to exact geographic origins. In the event of an attack, it would also offer much needed surge capacity that goes far beyond the capabilities offered by the portable on-the-spot technologies summarized above.

With commercial hardware, it would be also feasible to build flexible high-throughput phenotyping and archiving systems consisting of a dozen or so modules. For bioagent samples collected internationally, the high-throughput systems would be used to determine the immunologic serotype/subtypes of foot-and-mouth disease viruses and thereby create information that is essential for maintaining and updating vaccine repositories. In the event of an attack, it

would permit extensive sampling and testing of viruses from livestock in order to guarantee that vaccines remain effective over time. The high-throughput archive would be used to maintain physical custody and evidence.

Building and maintaining credible systems for biological security will require more than purchasing portable testing equipment and high-throughput modules from manufacturers. A larger set of issues must also be taken into account. Below are seven key attributes that can be used to define a virtual hub-and-spoke capability that can span the country.

1. The high-throughput laboratory network should be capable of performing 10,000 to 100,000 or more tests per day. Compared to manual laboratories, it should offer 100 to 1,000-fold improvements in sample processing speeds and volumes.
2. The high-throughput laboratory network should be capable of operating 24 hours per day and 7 days per week. To do this, it must manage a continuous flow of supplies and samples and maintain quality controls on a daily basis.
3. The high-throughput laboratory network should offer remote access and convenient means to submit samples from any geographic location. To do this, it must offer tools that work in conjunction with the Internet or secure intranets.
4. The high-throughput laboratory network should support chain of custody procedures for law enforcement, homeland, and national security efforts. For legally defensible and accurate attribution, the chain must be maintained from sampling integrity to data security.
5. The high-throughput laboratory network should enable interconnectivity with portable equipment and other high-throughput laboratories. To do this, it should utilize a standard interface and operating system that leads to a national virtual capacity.
6. High-throughput laboratory network should adhere to a set of standards and specifications. The various ones relate to: labware, calibrations, communications, data structures, testing protocols, data structures, and data manipulation tools.
7. High-throughput laboratory network should be designed to incorporate technical improvements over time. Much like personal computers, it can be based on plug-and-play and modular architectures that facilitate upgrades in software and hardware.

Timelines

The initial facility housing a flexible and computerized control system, automated and robotic sample preparation and sequencing system, and information processing system could be built within a year. Following this engineering and integration phase, its capabilities would be demonstrated on foot-and-mouth disease over a second year. At the same time, a large number of portable and rapid testing devices could be interconnected by the same computerized control system, thereby creating a virtual hub-and-spoke capability that can span the country.

Successful operation of the above capabilities for foot-and-mouth disease would enable expansion to some of the other leading bioagents against livestock. Such expansion could take place over years three to five and include capabilities to grow, phenotype, archive bioagent samples.

For bioagents against livestock, the overall utility of the high-speed/high-volume laboratory network can be summarized as follows:

- Improve the means to prevent, deter, and respond to agricultural attacks by rogue nations, terrorist networks, and domestic terrorists.
- Produce databases that strengthen criminal investigation and prosecution efforts for the law enforcement community.
- Through intensive sampling and testing efforts, link foot-and-mouth disease strains to their origins worldwide.
- Produce databases that are useful for maintaining and updating foot-and-mouth disease vaccine repositories.
- Provide surge capacity that supports science-based decisions on quarantine zones, animal destruction, and resource allocation.
- Overall, provide rapid, accurate, and complete information on which to make dependable decisions.

In addition to terrorist threats against livestock, there are also terrorist and naturally-occurring threats against humans. The leading list includes smallpox, anthrax, pandemic influenza, and SARS. A high-speed/high-volume laboratory network would have many parallel and practical applications against these infectious disease threats. It would support counterterrorism and nonproliferation efforts that can be summed up as: virtually assured detection, attribution, and response (VADAR).

In summary, what is our national strategy? The United States has plans for other complex and evolving threats. For example, it seeks to limit the proliferation of ballistic missile technology by gathering intelligence information, enacting

export laws, and focusing diplomatic pressure. Nevertheless, if an enemy ever fired a missile at the United States, we would immediately pinpoint its origin with our “eyes in the sky” and act with guaranteed force. That is prevention, deterrence, and response rolled into one. The United States must now have the same sort of capability against agricultural terrorism.

Appendices

A. Report Recommendations

Three recommendations from the report *Making the Nation Safer: The Role of Science and Technology in Countering Terrorism* are particularly relevant for shaping effective policies against agricultural terrorism. They are listed below.

Recommendation 3: Create a global network for detection and surveillance, making use of computerized methods for real-time reporting and analysis to rapidly detect new patterns of disease locally, nationally, and – ultimately – internationally. The use of high-throughput methodologies that are being increasingly utilized in modern biological research should be an important component of this expanded and highly automated surveillance strategy.

Recommendation 8: Develop and coordinate bioterrorism forensics capabilities. Federal agencies with missions in defense and national security should lead in establishing this new multidisciplinary, multilayered field. A comprehensive study should be performed to determine the capabilities of and needs for bioterrorism forensics, and an integrated national strategy and plan formulated.

Recommendation 12: Create an agricultural health reserve system and develop surge capacity. As part of a broader planning process, create a reserve system of veterinarians and plant pathologists (modeled on the military reserve system), and prepare local and regional laboratories for developing surge capacity to supplement and enhance disaster-response capabilities.

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Foreign Animal Disease Control: Vaccination and Culling

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Originally prepared for the Office of International Epizootics in February 2003
as: Factors to Consider When Using Vaccine to Control an Exotic Disease
Outbreak

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Abstract

Recent global events have dramatically increased the attention given to veterinary medical regulatory authorities' responsibility of protecting their country's agricultural interests from the threat of exotic disease outbreaks. A vaccine can be a valuable tool to help curb the spread of an exotic disease epidemic and/or lessen its economic impact. However, the decision on whether or not to use a vaccine during an outbreak may be complex and have far-reaching impacts. The decision must be approached in a logical and orderly fashion, taking into account the scientific, economic, political, and practical considerations that are unique to each individual disease outbreak. A decisionmaking process for the use of a vaccine developed for foot-and-mouth disease and its potential application to help decide on the use of vaccines in other exotic disease outbreaks is discussed.

Introduction

The United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA, APHIS) is charged with the responsibility of protecting U.S. agriculture from exotic diseases. Recent global events have dramatically increased the attention given to this responsibility, not only for USDA, APHIS, but for comparable veterinary medical regulatory authorities

worldwide. Outbreaks of classical swine fever in the European community, the devastating foot-and-mouth disease epidemic in the United Kingdom, and the increased threat of deliberate introductions of animal diseases by terrorists, have caused veterinary medical regulatory authorities to revisit and strengthen their emergency preparedness. Many response plans include the potential for using vaccines to help curb the spread of an epidemic and/or lessen its economic impact. The decision to use, or not to use, a vaccine in the face of an exotic disease outbreak can be complex and have far-reaching socioeconomic consequences. Incorrect decisions or delays occurring during the actual outbreak can be costly. Every outbreak is unique, and it is not reasonable to prepare contingency plans for all possible scenarios; however, a well-structured, logical, and thorough decisionmaking process can, and should, be included as part of any emergency plan.

Such a process was developed and tested for a foot-and-mouth disease (FMD) response plan, as a result of tripartite exercises with Mexico, Canada, and the United States conducted in the autumn of 2000. Although this decision tree/matrix was developed specifically for FMD, little modification is required to adapt it to other exotic diseases.

Decision Process

The process uses a decision tree flowchart (Figure 1), combined with decision matrices, which consider multiple-related factors for individual decisions, which are arranged sequentially. The decision process starts from the top left (Decision Box 1) and proceeds to Decision Box 5 in the bottom right of the figure.

Each decision box is supported by a decision matrix, where appropriate factors are listed for consideration. The factors have been grouped into four pivotal factors that characterize the nature of the epidemic (OUTBREAK FACTORS) and four pivotal factors that describe mitigation measures for the outbreak (MITIGATION FACTORS). Each pivotal factor has numerous subfactors described below:

OUTBREAK FACTORS are:

- Contact Rate
- Host or Species Affected/Species at Risk
- Status of Outbreak
- Environmental

MITIGATION FACTORS include:

- Physical Resources
- Human Resources
- Sociopolitical Factors
- Economic Considerations

Nearly all of these factors are common to all outbreaks of exotic diseases, so the process can be modified to fit many other exotic diseases. The following describes factors that must be considered when deciding specifically whether to vaccinate during a disease outbreak (corresponding to Decision Boxes 1, 4, and 5 in Figure 1):

Can the disease be eradicated using stamping out only?

In this decision box, all outbreak factors and mitigation factors must be considered. For FMD, this is the point of departure from the preferred, traditional policy of stamping out.

1. Contact Rate

Contact rate is a critical factor for modeling a disease outbreak. The contact rate will vary considerably, depending on the methods of disease spread. However, contact rate factors include:

1.1 Kind of Farms—For example, dairies and feedlots tend to have a higher rate of movement in and out, as opposed to other types of operations (e.g., a back yard producer). So, if the affected area has a lot of dairies and/or feedlots, the weight given to this factor should be increased.

1.2 Direct and indirect movement—The movement of animals (direct), people or equipment (indirect), or other possible vectors, such as wildlife, must be considered. The frequency of movement of animals from infected farms is more important than equipment or people. Indirect movement includes fomites, such as equipment, contamination of supply delivery vehicles, veterinarians, and farm workers; it also includes marketing of animal products and by-products. Distance of movements is also important for the spread of the outbreak. This factor should also include an estimate of illegal movements in the outbreak area, as well as past movements.

2. Host

The species affected and species at risk must be considered. Modeling in the USA for FMD suggests that if more than two (2) swine herds are involved at the time of detection, stamping out alone will not be sufficient.

2.1 Domestic livestock – For FMD, swine are crucial because of their ability to amplify the amount of virus that can be spread by airborne means. Sheep and goats tend to have subclinical disease and tend to be less likely to spread virus by aerosol. These types of host-pathogen specific interactions must be considered in all exotic disease outbreaks.

2.2 Game farms, zoos, wildlife – This must include consideration of genetics or endangered species that must be maintained (animals cannot be slaughtered). Additional considerations include the effectiveness of quarantine or isolation methods and the special handling methods that must be used with exotic livestock and wildlife.

2.3 Pathogen tropism – The tropism of the pathogen may not be immediately known. Additional surveillance testing of non-target species will be required.

3. Status of Outbreak

This is an estimation of the extent and duration of the epidemic. For FMD, modeling in the USA suggests that if 5 or more herds are affected, with 2 foci separated by 10 km, stamping out alone will not be successful. Subfactors to be considered include:

3.1 Number of affected flocks/herds – The greater the number, the more likely it becomes that there are undiscovered, or incubating, flocks or herds. A large initial number also could indicate biological terrorism, as would detection of more than a single serotype in an outbreak.

3.2 Number of foci – One focus of infection would be less likely to spread before stamping out could contain the outbreak. Two or more foci, separated by 10 or more kilometers, would indicate that the outbreak has already spread.

3.3 Rate of spread – Rapid spread would be reflected in an increasing number of cases per day or week. Rate of spread estimates, based on epidemiological data, may be used. During the initial phases of any disease outbreak, it is

important to differentiate the true rate of spread from the increased detection of preexisting, but undiscovered, cases as surveillance mechanisms are implemented.

4. Environment

This factor includes cultural and physical geography, as well as climate.

- 4.1 Livestock and farm density and distribution – This evaluates the number of herds/animals per square unit of area. The likelihood of spread increases as the density of animals increases and the area densely populated with animals increases.
 - 4.2 Livestock management – This factor considers whether the majority of affected producers are large corporations/owners on private land, communes, small producers, or back yard subsistence producers, as the predominant management practices are likely to have an impact on the outbreak.
 - 4.3 Casual access – This factor considers the network of transportation corridors in the outbreak area and its simultaneous use by casual human and vehicle traffic.
 - 4.4 Physical barriers – This factor considers whether the outbreak occurs in a naturally isolated area (i.e., desert, island/isthmus, rivers, mountains).
 - 4.5 Climate – Prevailing winds, temperature, and humidity conditions that favor airborne spread (if possible) must be considered.
- #### 5. Physical Resources
- 5.1 Slaughter capacity – Facilities must be adequate to handle the slaughter of all infected and suspect animals. On-farm slaughter may be necessary.
 - 5.2 Transportation capacity – If conditions prohibit on-farm disposal, there must be biosecure methods of transportation available for carcasses and all other exposed materials.
 - 5.3 Disposal capacity – If on-farm disposal is required and available, there must be sufficient heavy equipment for burial or incineration. If off-farm disposal is required, there must be adequate rendering facilities, burn sites, or burial sites.

6. Human Resources

6.1 Emergency response system/movement control— There must be sufficient trained staff (and administrative support) for stamping out and to enforce movement restrictions to limit spread. The level and quality of surveillance must be sufficient to enforce movement controls.

6.2 Epidemic projections— Region-, species-, or cost-specific projections may aid in decisionmaking.

7. Social-Political

7.1 Legislation available— Legislation may be necessary for mandatory depopulation efforts.

7.2 Public opinion/legislative will/appearance of government— The current welfare/ animal rights climate, including public perception of affected animal destruction, should be considered. Regulatory officials must maintain the trust and confidence of the general public through direct, timely, and constant lines of communication. Public opinion must be considered in the decisionmaking process.

7.3 Industry acceptance— The producer organizations should concur with the decision to stamp out the outbreak, so the information on which tracebacks are based is more likely to be credible and fully disclosed. The opinion of non-affected livestock industry sectors also should be considered if the agricultural economy in general is affected by international restrictions.

7.4 Socioeconomic status of producers' region— The sophistication, as well as the sociopolitical influence, of the producers in the affected region should be considered. Care must be taken to ensure equal treatment regardless of status and keep the implementation of control efforts consistent.

8. Economic

8.1 Compensation— There must be sufficient funding for indemnity payments for the potential number of animals that will be eliminated by stamping out. Differential payments for commercial versus purebred herds should be considered, as should compensation for lost production and animal products and by-products.

8.2 Value of exports – The value of the disease-free status of the country in the export market should be considered and compared to the cost of the eradication effort.

8.3 Regionalization – The ability to regionalize the affected area, so that animals outside the infected region may retain their international acceptance, should be explored.

Is vaccination possible?

1. Physical Resources

1.1 Vaccine availability – Efficacious vaccine(s) against the correct disease strains must be available.

1.2 Vaccine doses available – A sufficient amount of the vaccine must be available.

1.3 Vaccine logistics – It must be possible to distribute the vaccine to the field in a timely manner and to store the vaccine under suitable conditions in the field setting. Facilities must be adequate to administer the vaccine to the animals, and recordkeeping practices must be suitable for identifying and tracking vaccinated animals.

1.4 Laboratory capacity – Ideally, it should be possible to distinguish vaccinates from infected animals. If such a vaccine is used, one must consider whether cooperating laboratories have the diagnostic capability and capacity to analyze suspect and surveillance samples during, and after, an outbreak.

2. Human Resources

2.1 Emergency response system/movement control – There must be sufficient trained staff to vaccinate animals and to enforce subsequent movement restrictions.

2.2 Risk of disease spread – Provisions must be made to prevent vaccination teams from spreading the disease as they move from farm to farm.

2.3 Epidemic projections – The possibility of additional outbreaks due to an increased risk of carrier animals or inadequate vaccine coverage must be considered.

3. Social-Political

- 3.1 Legislation available— Legislation may be required for mandatory vaccination.
- 3.2 Public opinion/appearance of government- The current welfare/animal rights climate must be considered, as must the potential for public perception that vaccination leads to an inferior product or trade restrictions. Regulatory officials must maintain the trust and confidence of the general public through direct, timely, and constant lines of communication. Public opinion must be considered in the decisionmaking process.
- 3.3 Industry acceptance— The producer organizations should concur with the vaccination decision, to increase the chances that all susceptible animals will be presented for vaccination. Consideration must be given as to whether the industry would rather avoid vaccination and be compensated at market value or vaccinate their animals and have the livestock market value reduced.
- 3.4 Socioeconomic status of producers/region— Same as 7.4 above.

4 Economic

- 4.1 Cost of vaccination— The cost of vaccination must be considered.
- 4.2 Value of exports— It should be determined whether vaccination will reduce exportation from the country in general. The cost/benefit ratio of the additional time to attain country-free status after vaccination should be considered.
- 4.3 Regionalization— The possibility of regionalizing the affected area should be considered, so that international acceptance of exports from outside the affected region can be maintained despite vaccination.

Are Resources Sufficient for a Vaccination-Slaughter Program?

The disposition of vaccinates is a separate consideration from the decision to vaccinate, but it may be necessary to regain “free” status for international trade. For FMD, the OIE standard for “FMD free without vaccination” status is

achieved 3 months after the slaughter of the last vaccinate, whereas “FMD free with vaccination” status is achieved 12 months after the last FMD case.

For previously FMD free countries choosing to vaccinate in an outbreak and not slaughter all vaccinates, a 6 month period after the last case is required provided that a serological survey based on the detection of antibodies to non-structural proteins of FMDV demonstrates the absence of infection in the remaining vaccinated population. There are international markets whose standards exceed those of OIE. Thus, this is primarily an economic consideration, but other mitigation factors also play a role. Resource, disposal, and compensation factors, similar to those considered in the decision to vaccinate, should be considered before implementing a program to slaughter vaccinated animals.

Discussion

Each disease outbreak is unique, and each disease has unique epidemiological factors. Regardless of the disease, however, the decision to use vaccine in control and eradication efforts must be based on the same scientific, economic, political, and societal factors. Many times the decisions made for control and/or eradication efforts cannot be entirely science-based. For example, a vaccination program may be very effective at eliminating clinical disease, yet cripple a country economically because of the huge losses in exports. Similarly, a genetically-engineered vaccine may be highly effective in eliminating a disease, but if the public will not consume meat from vaccinated animals, the vaccine may have limited value. The ultimate goal of any control procedure should be not only to eliminate the disease, but also to eliminate negative economic impacts of the disease.

Even though a decision whether or not to use vaccine to control an exotic disease outbreak cannot be predetermined, a decisionmaking process can be established ahead of time. Knowing what inputs will be required for such decisions, efforts can be focused now on preparedness. Basic disease research can aid in the development of new, or improved, vaccines and diagnostics. Education programs can prepare livestock owners, consumers, and the general public for what to expect in the event of an outbreak. Legislation can be passed to establish appropriate emergency authorities. Regulators can implement and practice plans for mobilizing quickly and efficiently. Livestock and wildlife population density maps can be established and made readily available. Vaccine sources can be identified and evaluated for capacity and speed of product delivery. Disposal sites and slaughter facilities can be located and mapped for quick access. The required staffing sources can be identified, trained, and tested for

their respective roles during an outbreak. These efforts will increase the probability that fast, appropriate decisions will be made in the face of a disease outbreak and that responses will be coordinated and timely.

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