Crop Biosecurity: Are We Prepared?

White Paper

Developed by the Public Policy Board
of the American Phytopathological Society (APS)

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EXECUTIVE SUMMARY

Overview

In response to growing concern about bioterrorist attacks on American agriculture and the need to quickly respond should one occur, the Public Policy Board of The American Phytopathological Society (APS) convened a two-day workshop in Washington D.C. on March 20-21, 2003, entitled *"Crop Biosecurity: Are We Prepared?"* This white paper is the result of this workshop, which was financially supported by USDA's Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES). After listening to presentations on five broad topic areas and discussing the implication of these issues to crop biosecurity, participants developed a list of recommendations as well as immediate, near-term, and longer-term priorities for the recommendations.

1. Defining an Event

Efforts to date to combat crop bioterrorism have focused primarily on prevention, with significantly fewer resources dedicated to preparing for the aftermath of such an event. Although a strong prevention program is necessary, an over-dependence on prevention with little attention to preparedness could create a false sense of security. A balance between prevention and preparedness is needed.

Recognizing a potential epidemic early in its course is a difficult task. Determining whether such an event is an accident or deliberate act is even more challenging. It is also important to determine whether the causal agent is a high-risk, non-indigenous pathogen or a new or more virulent strain of an existing pathogen. Major outbreaks could occur in the U.S. from non-indigenous pathogens that are minor problems elsewhere in the world or could be initiated by unknown or unidentified pathogens.

2. Current and Planned Infrastructure for Biosecurity

Efforts are currently underway by the federal government in conjunction with other federal, state, and local organizations and groups to bolster the current surveillance infrastructure and to develop additional biosecurity capabilities. The recent establishment of the National Plant Diagnostic Network (NPDN), which will link diagnostic laboratories at the Land Grant Universities (LGUs) through five regional "hub" laboratories, is an important first step toward finding a balance between prevention activities and building a preparedness infrastructure. This network can serve as a foundation to facilitate communication and response, as appropriate, between the laboratories at LGUs, APHIS, and state and private industry diagnostic laboratories. However, significant additional support will be needed before this system becomes fully operational. In particular, there are few training programs for first responders and field staff, inadequate early detection systems, and a significant gap in essential knowledge of plant pathogen genetics. It is important to continue to strengthen and expand efforts such as the NPDN and to clearly define the roles of LGUs, Federal, State, and private industry diagnostic efforts to prevent unnecessary duplication of efforts.

3. Threats and the Role of Genomics in Biosecurity

The APS Ad Hoc Emerging Diseases and Pathogens Committee currently is developing prioritized lists of threatening pathogen species, which are needed by a variety of Federal and state agencies, including the USDA, the Department of Defense, the NPDN, and the intelligence community. The Committee has identified five different threat scenarios and has created a subcommittee to address each. In assessing threats, the Ad Hoc Committee will concentrate on potential pests and pathogens for the crops considered of highest priority based on strategic value, total value, and vulnerability.

The study of the genomics of plant pathogens also has significant potential value for crop biosecurity because it allows the sequencing, assembly, and analysis of long stretches of DNA, including entire pathogen genomes. In addition, it allows investigators to determine the structure and function of proteins encoded by these genes. Unfortunately, genomic information is available for only a few plant-associated microbes, few of which are among the organisms that pose the greatest risks to crop security. To optimally exploit genomics for biosecurity there is an urgent need for a stepped-up sequencing program.

4. Policy and Practices for Assuring Biosecurity

Protection against high-threat microbial agents and toxins must include prevention of accidental release, and theft by or diversion to those intent on misusing them. Current USDA biosecurity measures require BSL-3 level facilities for those handling microbes and toxins with the potential to cause serious human, animal, and plant disease and have high transmission potential (72 pathogens and/or toxins have been identified as high risk). However, despite the Federal Government's current laboratory construction program, capacity for the containment of BSL-3 and BSL-4 biothreats and for analysis and countermeasures research is insufficient. In addition, although many federal agencies currently are pursuing programs in biosecurity, there has been little coordination of these efforts.

The Department of Homeland Security (DHS) recently established the National Biodefense Analysis and Countermeasures Center (NBACC) at Fort Detrick, Maryland, to integrate national resources for homeland security, drawing on resources from public health, law enforcement, and national security. NBACC's mission is to provide a unique, interdisciplinary capability to better defend against the full range of human, animal, and plant BSL-3 and BSL-4 biothreat agents. To this end, NBACC will contain four primary centers including: 1) the Biothreat Assessment Support Center, 2) the Bioforensics Center, 3) the Bio-Countermeasures Test and Evaluation Center, and 4) the Biodefense Knowledge Center.

Homeland security personnel recently have expressed concern about the public release of scientific information regarding plant pathogens that is not designated "classified" but might be considered "sensitive." Because the definition of "sensitive" has not been determined, many in the scientific community are concerned that national security objectives may hamper important scientific research, which thrives on openness and collaboration. In an effort to balance homeland security concerns with the need for scientific openness and collaboration, APS has recently adopted new manuscript review policies, adapted with permission from the policies of the American Society for Microbiology, which stipulate that: 1) authors may alert reviewers to the presence of sensitive information in their manuscript, 2) reviewers may "flag" potential sensitive information in a manuscript, and 3) those articles that have been flagged will receive extra attention by the reviewers.

5. Models of A National Plant Health System

The National Seed Health System (NSHS) was presented to illustrate how an existing, coordinated program on seed health addresses many elements relevant to preventing the rapid spread of plant diseases in the U.S. NSHS works to implement diagnostic methods that have been evaluated and proven to be accurate, reproducible, and capable of detecting pathogens at a defined level of sensitivity. The function of the NSHS is to accredit private and public organizations to carry out testing for phytosanitary certification. The NSHS also works to resolve phytosanitary issues that adversely affect international trade and exchange of seeds produced in the U.S. and conducts research in the development and standardization of seed health testing methods.

The APS presented a proposal for the development of a National Center for Plant Disease Prevention and Control (NCPDPC), which would build on, enhance, and provide leadership and coordination of the multiple national efforts for documenting, monitoring, and protecting American crops, forests, and rangelands against new or emerging plant diseases. This NCPDPC could conduct surveys of new and emerging plant diseases; develop "gold standards" for diagnostics; function as a regional center for communication among multinational companies and institutions; maintain databases on national expertise, sources of reference cultures, and global diversity and population dynamics of pathogens; and provide centralized public relations in cases of national emergencies.

Recommendations

Near-Term Priorities:

- Develop a better rating system for plant threat levels
- Build on the existing National Plant Diagnostic Network
- Increase education of potential first-line responders so that they know what to look for and who to contact and develop incentives for agencies and individuals to report potential threats
- Coordinate and share resources and promote collaborations, refine processes to be optimally effective at the local level, and integrate efforts among regions

- Seek opportunities to enhance research in conjunction with all homeland defense plant health efforts
- Develop germ plasm screening systems with worldwide applicability
- Provide resources to support isolate collections and preservation
- Better utilize genomics in designing diagnostic tools
- Support use of peer review for screening sensitive information
- Establish a multi-disciplinary study group for the development of a National Center for Plant Disease Prevention and Control, as a follow-up to the recent National Research Council report on crop vulnerability
- Educate the public and policy makers on benefits/risk of open communication of science

<u>Intermediate Priorities:</u>

- Develop a better balance between prediction and preparedness for agents of concern
- Develop enhanced communication systems and strategies to reduce the time between pathogen introduction and response
- Develop a plan for 24/7 diagnostics capability and a policy for rapid redirection of resources in the event of an introduction
- Gather sufficient information to understand the breadth and depth of pathogen organisms' genomic sequence and to permit traceability
- Establish a formal process for assessing threats of organisms
- Ensure that databases become accessible to the wider scientific community in a timely fashion
- Educate the public and policy makers on basic biology as it relates to plant health
- Develop appropriate national and international alliances and provide a common risk assessment analysis protocol
- Develop linkages to the veterinarian community and the private sector
- Create a position for a National Program Leader for plant health
- Appoint a Chief Scientist for agriculture at an administrative level comparable to that of the Chief Economist in the Secretary's (USDA) office

<u>Long-term Priorities:</u>

- Improve capability for pre-symptom disease detection, standardize diagnostic methods, and institute an accreditation process for diagnostic laboratories
- Develop policies for timely redirection of resources
- Build capacity in plant health R&D and concurrent education/extension (Example: NSF doctoral program in plant health)
- Work toward broad-based, durable resistance against important pathogens

Overview

In light of the September 11, 2001, attacks on the World Trade Center and the Pentagon and the subsequent anthrax attacks on the U.S. Capitol, there is an increasing awareness that a potential exists for a terrorist attack against agriculture in the United States. In fact, most experts agree that it is not a matter of "if" but "when" a microbe will be used against the American public through agriculture. Because of that concern, the Public Policy Board of the American Phytopathological Society (APS) convened a workshop in Washington D.C. on March 20-21, 2003, entitled *"Crop Biosecurity: Are We Prepared?"* The APS is an international scientific organization that includes among its 5000 members worldwide the scientific leadership and expertise to mitigate the impact of intentionally or naturally introduced plant disease agents.[1]

This white paper is the result of the two-day workshop, which was financially supported by USDA's Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service (ARS), and the Cooperative State Research, Education, and Extension Service (CSREES), and moderated by John L. Sherwood, Ph.D., Professor and Head of the Plant Pathology Department in the College of Agricultural and Environmental Sciences at the University of Georgia, and Chair of the APS Public Policy Board. The workshop was attended by plant pathologists and field experts from state, Federal, and private agencies as well as representatives of the funding agencies, the Department of Homeland Security, and the intelligence community. After listening to presentations on five broad topic areas and discussing the implication of these issues to crop biosecurity, participants developed a list of recommendations as well as immediate, near-term, and longer-term priorities for the recommendations.

Background

According to a recent report from the National Academy of Sciences' National Research Council (NRC),[2] cropland in the United States is highly vulnerable to agricultural bioterrorism. Furthermore, the NRC found that the United States does not currently possess the capacity to rapidly detect and identify many pests and pathogens foreign to the U.S., whether they are intentionally or naturally introduced. The NRC committee that developed the report warned that a large-scale bioterrorist attack against American agriculture could potentially "overwhelm existing laboratory and field resources."[3]

Although the NRC report stated that such an attack on U.S. agriculture is unlikely to result in widespread famine or malnutrition, it nevertheless has the potential to inflict significant harm on the nation's economy. As the recent outbreak of foot-and-mouth disease in cattle in the United Kingdom has demonstrated, the sudden outbreak of a highly infectious disease can be devastating. In 2001, the U.K. foot-and-mouth epidemic

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[1] http://www.apsnet.org
[2] Countering Agricultural Bioterrorism. Committee on Biological Threats to Agricultural Plants and Animals, National Research Council 2002.
[3] Better Plan Needed to Protect U.S. Agriculture From Bioterror Attack. NRC press release. http://www4.nationalacademies.org/news.nsf/isbn/0309085454?OpenDocument

led to the destruction of more than six million animals and is estimated to have cost as much as £4 billion.[4]

Because biological agents that could be used to harm crops or livestock are widely available and easily transported and dispersed, the NRC report urged development of a comprehensive plan to defend against agricultural bioterrorism. According to the report, part of the plan should be to "enhance our basic understanding of the biology of pests and pathogens so we can develop new tools for surveillance and new ways to control an outbreak."

However, a number of steps must be taken in conjunction with the development of such a plan. It also is necessary to:

- Define a "biosecurity" event,
- Improve existing infrastructure for early pathogen detection and disease diagnosis,
- Develop policies and practices for assuring biosecurity, and
- Develop a model for a national center for guidance and coordination of regional diagnostic and response activities.

1. Defining An Event

Prevention versus Preparedness

Efforts to date to combat agricultural bioterrorism have focused primarily on prevention through: 1) increased border protection, 2) tightened security for research labs, and 3) greater research secrecy, including limits on scientific openness.

The U.S. government's current border protection against foreign pests and pathogens consists of inspecting for familiar carriers/sources of plant pests and pathogens (e.g., plants and plant products). This system is largely focused on threats that come from outside our borders and requires the voluntary cooperation of the public. However, an agricultural bioterrorist threat could come from within our borders. Furthermore, terrorists are not likely to cooperate with the system.

Therefore, an over-dependence on prevention with little attention to preparedness could create a false sense of security. Rather, a balance between prevention and preparedness is needed, the latter of which is dependent upon: 1) scientific openness, 2) teamwork and networking, 3) communication at all levels, including between first line responders, scientists, law enforcement, and the public, 4) anticipatory research programs, and 5) useful investments for agriculture.

The recent establishment in the United States of a network of five regional plant diagnostic laboratories—the National Plant Diagnostic Network (see below)—is an

[4] http://news.bbc.co.uk/1/hi/uk/2686041.stm

important step toward finding a balance between prevention activities and building a preparedness infrastructure. However, many other critical issues must also be addressed before the network is optimally effective. These include the need for well-founded policies for imposing reasonable restrictions on the possession and handling of threatening agents, including assurance that pathogens not posing a serious threat to U.S. agriculture are not restricted. It also is necessary to significantly reduce the time elapsed from the initiation of a crop bioterrorist attack to its discovery so that law enforcement can quickly gather any potential evidence and take appropriate steps to confine, eradicate, and manage the outbreak. In addition, there is a critical need to prepare for the reactions from the public and the media, which are likely to be intense, particularly if there is intentional introduction of a novel plant pathogen into the environment. Indeed, if a plant pathogen were released deliberately, it is likely to have a significantly greater psychological and social impact than if it occurs accidentally or naturally. In the worst-case scenario, the United States must prepare for the possibility that an attack on a particular commodity may mean that it can no longer be economically produced in the this country in a sustainable manner or that consumer confidence in the safety of that commodity may be irreversibly damaged.

Identifying an Intentional Introduction: How Will We Know?

Plant diseases, which are caused by a variety of microbes (pathogens) including viruses, fungi, bacteria, and nematodes, cost the United States $20 - $33 billion each year. These costs result from reductions in crop production, the costs of management, disruptions to trade, effects on human health, and disruption of rural economies. Some of the primary obstacles to early detection of these potentially devastating pathogens include the inadequate sensitivity of current detection techniques and the ability to provide surveillance on a very small percentage of crop or forest plants at any given time. Hence, when a new pathogen is introduced a period of time passes before it is prevalent enough to be detected. The situation can be exacerbated if the pathogen is incorrectly identified or the disease is misdiagnosed.[5] In regards to pathogens currently considered to have significant potential impact on U.S. crop production, rapid, accurate, sensitive, and low-cost methods of detection have not been developed and deployed to diagnostic laboratories. In addition, epidemics vary in character, with diseases such as beet yellowing, oat rust, chestnut blight, sudden oak death, citrus canker, and plum pox having completely different pathological and epidemiological profiles. Nevertheless, through actions of widespread dispersal, many of these pathogens can spread quickly and devastate entire crops.[6]

At a given time, on a given crop, and in a given region of the United States as many as 10 to 15 plant diseases can occur that must be monitored and managed annually for that crop to brought to market. In addition, for any given crop there are typically several potential

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[5] Wheelis, M., Casagrande, R., and Madden, L. V. 2002. Biological attack against agriculture: low-tech, high-impact bioterrorism. BioScience 52: 569-576.
[6] Madden, L. V., and M. 2003. The threat of plant pathogens as weapons against U.S. crops. Annu. Rev. Phytopathology 41: (in press).

pathogens from elsewhere in the world that have not yet arrived in this country. Although recognizing a potential epidemic early in its course is a difficult enough task in itself, distinguishing such an event as either an accident or deliberate act is even more challenging. It is also important to determine whether the causal agent is a high-risk, non-indigenous pathogen (e.g., plum pox virus) or a new or more virulent strain of an extant pathogen (e.g., potato blight and wheat rust). As epidemics caused by indigenous pathogens vary tremendously from year to year as affected by climate, cultivation, and presence of the pathogen, it is especially difficult to determine if a major outbreak is something new or due to an acceptable variation in disease occurrence and severity. Major outbreaks in this country could also occur from non-indigenous pathogens that are minor problems elsewhere in the world but for which plants in this country have no natural immunity (e.g., chestnut blight which essentially eliminated a whole species of tree as a significant component of the forest ecosystem in this country). Finally, outbreaks can occur from unknown or unidentified pathogens.

One of the major findings of the NRC report, *Countering Agricultural Bioterrorism*, is that intentional introductions of agricultural pathogens may differ substantially from unintentional introductions. The report also suggested that terrorists have the advantages of selecting unanticipated and covert means of introduction, the time and place of introduction, and the option of simultaneous release of multiple pathogen species.

In addition, although the basic infrastructure for detecting introductions currently is in place, significant additional support will be needed before the infrastructure becomes fully operational and can distinguish between deliberate and accidental introductions of new disease agents and contain them. Specific needs include greater surveillance capacity, more extensive and more rapid diagnostic services, improved communication among diagnostic labs, improved diagnostic capabilities, increased knowledge of disease prevalence and epidemiology, and greater knowledge of the genetic structure and phylogeny of pathogens in different regions of the world.

Recommendations:

- Provide essential training to first-line responders (i.e., people in the field) so that they know what to look for and who to contact
- Develop a better rating system for plant health "threat" levels
- Develop a balance between prediction (prevention) and preparedness
- Develop enhanced communication systems and strategies to reduce the time between pathogen introduction and response
- Develop better diagnostic tools for exotic pathogens
- Develop incentives for agencies and individuals to report potential threats

2. Current and Planned Infrastructure for Biosecurity

Current and Planned Infrastructure at the National Level

Efforts are currently underway by the Federal Government in conjunction with other Federal, state, and local organizations and groups to bolster the current surveillance infrastructure and to plan for the development additional biosecurity infrastructure. These components will eventually contribute to an effective safe-guarding system, which include an effective off-shore risk management, effective detection measures at the 126 legal points of entry around the United States, quarantine, pest detection, eradication, and control.

The USDA is making strides in advance preparation activities for potentially devastating pathogens that have not yet arrived in the United States but are likely to arrive very soon. APHIS, for example, has substantially increased funding for advanced pest detection capabilities by adding Federal positions and increasing funding for states. APHIS' Offshore Pest Management System also is exploiting international infrastructure already in place, focusing on listed target pests, quickly identifying new threats, and reporting regularly to cooperators and stakeholders on a near-real time basis. APHIS also developed a pool of expert personnel, the Emergency Response Cadre Members, to respond to emergencies.

However, to optimize advance biosecurity preparation, it is important for USDA to both provide leadership and more effectively collaborate with traditional stakeholders (e.g., farmers), industry, environmental organizations, crop consultants, and targeted public groups. To this end, the USDA is currently working with a number of organizations, including APS, the Entomological Society of America, the Weed Science Society of America, the American Malacological Society, the Society of Nematologists, and the Acarological Society of America, to develop lists of potentially harmful pests and pathogens. These lists will significantly improve surveillance capabilities.

There also is a need for significantly more educational and outreach activities on events that have not yet happened but are likely to occur. Furthermore, advance preparation is needed to define the desired outcome and provide ways for measuring progress. State-of-the-art technology and research and the better utilization of human resources also are extremely important to preparedness.

The diagnostic capacity in the United States has significantly increased recently due to additional support for USDA-ARS, USDA-APHIS, and the newly established National Plant Diagnostics Network (NPDN), which encompasses diagnostic laboratories at the land grant universities (LGUs). Linkages are beginning to be developed between USDA, state Departments of Agriculture, labs at LGUs, and private companies to coordinate this diagnostic capacity. The NPDN,[7] which is funded by the USDA-CSREES and the Department of Homeland Security (DHS), is a network of 5 regional "hub" laboratories

[7] http://npdn.ppath.cornell.edu/

located at major LGUs. The NPDN is designed as a regional network because each region has a different crop and agricultural profile, and each state must be able to address the needs of its clientele with as much local control as possible. The objectives of NPDN are to provide leadership of state laboratories within a region, coordinate regional diagnostics resources, enhance interregional communication, establish a national uniform reporting protocol, and utilize the National Agricultural Pest Information System (NAPIS) located at Purdue University as the central repository for archiving select data from the five regions.

LGUs were chosen as sites for these hub laboratories because most have an operational plant disease diagnostic laboratory, are linked to the county extension service, and have a history of trust with farmers and the public. The NDPN hub laboratories will be responsible for providing the other laboratories in their network with up-to-date information concerning potential plant pests in their region, developing a rapid notification system linked to state and Federal regulatory agencies in every county in the United States, collecting and analyzing data, developing communications systems, and reporting. The NDPN also will enlist and provide training to first-line detectors so that they will know what to look for and where to report such information.

Three of the five hub laboratories, encompassing 29 states, have formed the Plant Diagnostic Information System (PDIS). One benefit of the PDIS is the potential for collaborative diagnostics, as researchers in many locations can view the same specimen through web-enabled microscopes. The PDIS, which is Internet-2-based, has video conferencing and resource sharing capabilities, including a common data base and web server. Another important PDIS asset is a rich set of diagnostic resources (e.g., digital images, literature libraries, etc.), which can be used for training, teaching, extension, and rapid response programs.

<u>Recommendations</u>:

- Coordinate and share resources and promote collaborations, refine processes to be optimally effective at the local level, and integrate efforts among regions
- Develop a plan for 24/7 diagnostics capability and a policy for rapid redirection of resources in the event of a pathogen introduction
- Develop greater intellectual capacity in diagnostics
- Improve capability for pre-symptom disease detection, standardize diagnostic methods, and institute an accreditation process for diagnostic laboratories
- Invest in facilities development (e.g., nationwide distribution of secure high containment laboratory capability sufficient to work on plant pathogens)

3. Threats and the Role of Genomics in Biosecurity

Plant Pathogens of Greatest Concern and Their Identification

The APS Ad Hoc Emerging Diseases and Pathogens Committee currently is developing prioritized lists of threatening pathogen species, which are needed by a variety of Federal

Government and state agencies and the intelligence community. The Committee has identified five different threat scenarios and has created a subcommittee to address each.

In assessing threats, the Ad Hoc Committee will concentrate on potential pests and pathogens that threaten the top commodity crops according to strategic value, total value, and vulnerability. The process will begin with the development of a survey instrument for each of the host plant species, which will be administered to experts in the plant health community. The goals of this process are to rank pathogens of high priority and to develop a numerical rating for each pathogen within a host group. The numerical ratings will be used to generate master lists of pathogens that cut across scenarios. The ratings could also be used to generate customized lists by scenario.

Strengths and Voids in Current Diagnostic System

Although the recent formation of the NPDN, with its linked resources and wide array of technical capabilities, is a major step forward in strengthening the current diagnostic system, there are many voids in current capabilities. In particular, there are few training programs for first responders and field staff to recognize disease and insect problems. A void also exists in the early detection system, which should have the capacity to monitor pest occurrence in real-time and to track specific diseases as they spread. There is also a significant gap in knowledge of plant pathogen genetics, a deficit exacerbated by the recurring loss of pathogen collections. The loss of collections is due, in part, to new regulations for registration, permits, and security measures that make maintaining collections of select agents beyond the capabilities of many laboratories. Even without such new regulations, many laboratories lack the basic resources to maintain the collection when the “curator” retires or leaves for another position. It is, therefore, important to continue to strengthen and expand efforts such as the NPDN by fostering collaborations, increasing financial support, and providing real-time linkage from field inspectors to the diagnostic labs of the NPDN.

It is also important to clearly define a role for private industry in the network. During the APS workshop, attendees heard about early detection efforts at Pioneer Hi-Bred International’s 35 diagnostic laboratories around the world. Pioneer utilizes hand-held GPS systems to collect plant disease data (including digital images) in the field. Such resources could be particularly helpful to the NPDN to help it quickly identify potential outbreaks and to better track the spread of crop diseases or pests.

Priorities for Genomics Biosecurity

It is becoming increasingly clear that genomics has significant potential value for biosecurity applications because it allows the sequencing, assembly, and analysis of long stretches of DNA, including entire genomes. It also allows investigators to determine the structure and function of proteins encoded by these genes. Unfortunately, genomic information is available for only a few plant-associated microbes, almost none of which are among the organisms that pose the greatest risks to crop security.[8]

To optimally exploit genomics for biosecurity purposes there is an urgent need for a stepped-up sequencing program. Genomics will help determine the function of the sequenced genes and how they interact with the host plant. There also is a need for more comparative genomics, which employs strategies to compare the genes from plant-associate microbes to other known genes. This type of information is important for assessing the likelihood that a pathogen will spread and how aggressively it will spread. It can also help investigators determine the toxins a pathogen may produce and whether has been genetically modified. These data also will be useful in the development of resistant crop cultivars and management practices. Finally, there is an urgent need for trained scientists who can conduct these studies and analyze the data.

In April 2002, the APS convened a workshop in Washington D.C., entitled "Genome Analysis of Plant-Associated Microbes." A white paper developed from this workshop[9] estimated that approximately $500 million over five years is needed to adequately exploit genomics for addressing just the 9 plant pathogens that have been targeted by APHIS as potential high-risk threats. This is considerably less, however, than the estimated $20 - $33 billion in losses to producers caused by these pathogens each year. The $500 million would be targeted to four specific areas: 1) sequence analysis, 2) functional analysis, 3) standardized bioinformatics and data base systems, and 4) training.

Recommendations:

- Make better use of genomics in designing diagnostic tools
- Increase resources to support culture and isolate collections
- Develop germ plasm screening systems with worldwide applicability
- Establish a standard process for assessing threats to organisms
- Gather enough information to understand the breadth and depth of an organisms' genomic database and to permit traceability
- Ensure that databases become accessible to the wider scientific community in a timely fashion
- Enhance research to develop broad-based durable resistance in host plants

4. Policy and Practices for Assuring Biosecurity

Biosafety Guidelines for Working with Plant Pathogens of Concern

There is a distinction between biosafety and biosecurity. Biosafety refers to the development and implementation of administrative policies, work practices, facility design, and safety equipment to prevent transmission of biologic agents to workers, other

[8]To see a list of the completed microbial genomes and those in progress, see http://www.tigr.org/tdb/mdb/mdbcomplete.html
[9] http://www.ismpminet.org/Final_Plant_Associated_Microbe_Genome_Initiative.pdf

individuals, or the environment. With regard to biosafety, the Center for Disease Control and Prevention (CDCP) provides guidance on containment through its Biosafety Level (BSL) classification system, which rates those agents not known to cause disease in healthy human adults as BSL-1 organisms and those associated with life threatening diseases, high risk of transmission, and no known treatment as BSL-4 microbes.

Biosecurity, on the other hand, involves protection against high-threat microbial agents and toxins or critical relevant information against theft or diversion by those who are intent on misusing them. Because prior regulations were directed mainly toward biosafety, in 2002 Congress passed the Agricultural Bioterrorism Act to address the lack of security procedures in many laboratories across the country. This led to the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which instructed the CDCP and APHIS to establish regulations for the possession, use, and transfer of 72 agents and toxins posing a severe threat to human, animal, and plant health. The Patriot Act of 2002 went further by instructing the CDCP and APHIS to establish measures to ensure proper training for handlers of these agents, the use of proper containment facilities, and the development of appropriate safety and security measures to prevent unauthorized users from gaining access.

The USDA-APHIS requires BSL-3 level facilities (i.e., those handling microbes and toxins that cause serious human disease and have high transmission potential) for all 72 agents identified as high risk, and has established security policies for them.[10] These facilities must address risk/threat assessment, physical security issues (e.g., access control), personnel security (e.g., worker screening, identification), inventory accountability, agent transfer, and emergency response. In addition, a new BSL-3 level designated BSL-3-Ag, has been created, which stipulates that laboratories working with BSL-3 plant pathogens and toxins must filter their exhaust gases, decontaminate their sewage, require personnel to shower upon leaving, and provide ongoing facility integrity testing.

There has been some concern that these new regulations may be overly burdensome on laboratories working with plant pathogens. BSL-3 facilities are very expensive to build and to keep secure. In addition, few BSL-3 laboratories currently exist, and there are not enough researchers to staff the facilities if more are built. Furthermore, the BSL-3 containment systems are based primarily on animal pathogen protocols, not on those used effectively by plant pathologists. Finally, regulations for such laboratories have had limited external review and have lacked transparency compared to those developed by the CDCP and Veterinary Services, which are very good sources of information for containment of animal pathogens. Hence, the new difficulties facing those whose skills are needed to work on threatening pathogens could mean their access to these pathogens will be limited. This, in turn, could result in fewer scientists having experience with these pathogens and the U.S. being less prepared to deal with their appearance in the field.

[10] http://www.usda.gov/ocio/directives/DM/DM9610-001.htm

Establishing a National Center for Biodefense

Despite U.S. government agencies' current construction program, there exists insufficient capacity for the containment of BSL-3 and BSL-4 biothreats and for their analysis and countermeasures research. In addition, although many federal agencies are pursuing programs in biosecurity, there has been little coordination of these efforts. Therefore, the Department of Homeland Security (DHS) recently established the National Biodefense Analysis and Countermeasures Center (NBACC) at Fort Detrick, Maryland. The NBACC has been established as an essential new approach to integrate national resources for homeland security, drawing on resources from public health, law enforcement, and national security.

NBACC's mission is to provide a unique, interdisciplinary capability to better defend against the full range of human, animal, and plant BSL-3 and BSL-4 biothreat agents. To this end, NBACC will encompass four primary centers including: 1) the Biothreat Assessment Support Center, 2) the Bioforensics Center, 3) the Bio-Countermeasures Test and Evaluation Center, and 4) the Biodefense Knowledge Center.

The Biothreat Assessment Support Center will provide scientific support to the intelligence community in the form of high-security (e.g., BSL-2, BSL-3, and BSL-4) laboratories where human, plant, and animal biothreats and their potential application can be investigated. This center will also train responders in "Red Team" operations scenarios, particularly in novel infectivity and pathogenesis, and evaluate and predict U.S. vulnerabilities. The Bioforensics Center, in partnership with the FBI, will coordinate the Homeland Security bioforensics program, conduct forensic casework for criminal, state, and non-state agencies and participate in applied development and validation of human, plant, and animal biothreats. The Bio-Countermeasures Test and Evaluation Center will test and evaluate new and emerging BSL-3 and BLS-4 technologies, particularly those that are applied and specialized (e.g., aerosol biocontaminant), and offer training in these capabilities. The Biodefense Knowledge Center will serve as the nation's biodefense information clearinghouse, serving as a source of all technical and scientific information, providing data analysis and integration capabilities, developing targeted information dissemination programs, conducting modeling and simulation, and providing innovative training programs.

In the area of agricultural terrorism, NBACC will focus on building partnerships and serve as a facilitator of coordination and cross-fertilization. It will use current centers of expertise and assist in assembling partners based on national strategy, assist in identifying data gaps, develop information links, and identify common technology tools that would allow assessment of a breadth of threats.

Filtering of Scientific Articles and Information

In the past, the dissemination of scientific information regarding research on potential pathogens was regulated by National Security Directive #189, signed by President Reagan in 1985 and reaffirmed in 2001 by National Security Advisor Condoleezza Rice.

Directive #189 stipulates "to the maximum extent, the products of fundamental research remain unrestricted. No restrictions may be placed on the conduct or reporting of federally funded fundamental research that has not received national security classification."

Recently, however, a new term, "sensitive but unclassified," has been introduced into the intelligence community lexicon indicating that there should be control on the dissemination of information on "sensitive" subjects as well as on those that have been formally classified. Because the definition of "sensitive" has not been determined, many in the scientific community are concerned that national security objectives may hamper important scientific research, which thrives on openness and collaboration. To address these concerns, in January 2003, the National Academy of Sciences (NAS), in conjunction with the Center for Strategic and International Studies (CSIS), held a workshop entitled "*Scientific Openness and National Security*" for scientific journal publishers, Federal agencies that support fundamental scientific research, and members of the security community. At the end of the workshop the publishers in attendance issued a final statement reaffirming that scientific publication is "…a vital element in our national life. New discoveries reported in research papers have helped improve the human condition in a myriad of ways: protecting public health, multiplying agricultural yields, fostering technological development and economic growth, and enhancing global stability and security."

However, the publishers also were cognizant that scientific openness, while critical for strong national scientific programs and progress, does create vulnerability in national security. If not dealt with by the scientific publishing community, this vulnerability will be addressed by the U.S. security community. It was acknowledged that new policies are likely to be more reasonable, more effective, and more likely to be accepted by the scientific community, if developed by scientists. The American Society for Microbiology (ASM), the National Academy of Sciences (NAS), and the American Association of the Advancement of Science (AAAS) were among the first scientific publishers to develop new editorial policies for sensitive information.

The Publications Board of APS has received permission from the ASM to adapt its new statement on policies for review of potentially sensitive information. The new APS manuscript review policies relating to sensitive information are that: 1) authors may alert reviewers to the presence of sensitive information in their manuscript, 2) reviewers may "flag" potential sensitive information in a manuscript, and 3) those articles that have been flagged will receive extra attention by the reviewers.

As mentioned, what constitutes sensitive information is still a topic of some debate. The NAS concept for protecting sensitive information is to "create high walls around very narrow areas," and, for plant pathology, this might include studies on plant pathogens on select agents list or plant pathogens modified to become more virulent, more easily disseminated, more difficult to detect, or less amenable to management. However, efforts such as these will not solve the dilemma of how to control the release of sensitive information in pre-publication presentations at conferences, on the Internet, or in manuscripts submitted outside the U.S. or for research conducted outside our borders.

There is, therefore, a great need for a better understanding of what constitutes sensitive information. Continued communication on this issue among publishers themselves, among publishers and the security community, and between scientists, lawmakers, and the public is greatly needed.

Recommendations:

- Support the use of peer review for screening for sensitive information
- Educate the public and policymakers on benefits versus risk of open communication of science
- Educate the public and policymakers on basic biology as it relates to plant health
- Develop appropriate national and international alliances to facilitate mitigation of threats to plant health

6. Models of A National Plant Health System

The National Seed Health System

The National Seed Health System (NSHS) is an existing, voluntary system for private laboratories that addresses many elements relevant to optimizing plant health in the United States. Currently, plant disease diagnostic methods vary from state to state and the facilities, equipment, and personnel training often vary from laboratory to laboratory. To bring greater uniformity to the diagnosis and prevention of contamination of seed stock in this country, the NSHS[11] is authorized by USDA-APHIS to provide standards for laboratory seed health tests and seed field crop inspections.

NSHS works to implement diagnostic methods that have been evaluated and proven to be accurate, reproducible, and capable of detecting pathogens at a defined level of sensitivity. The function of the NSHS is to accredit private and public organizations to carry out testing for phytosanitary certification using defined sets of standards for facilities, equipment, methods, and training of personnel. The NSHS also works to resolve phytosanitary issues that adversely affect international trade and exchange of seeds produced in the United States and conducts research in the development and standardization of seed health testing methods.

Although the NSHS is overseen by the Seed Manager of USDA-APHIS, most of its responsibilities lie within the industry and academic sectors. The Seed Technical Working Group (STWG) is made up of members of the American Seed Trade Association, the National Plant Board, the Association of Official Seed Certifying Agencies, the Association of American Seed Control Officials, and APHIS. The STWG is responsible for establishing policies, procedures, and standards as well as appointing

[11] http://www.seedhealth.org

panels of technical experts to recommend standard methods for laboratory tests and field inspection procedures. Among those who can be accredited by the NSHS are: seed companies, private seed testing companies, private agricultural consultants, certification agencies, state agencies, university laboratories, and other organizations involved in plant seed health. Accreditation options include seed health testing, phytosanitary inspection (field inspection), seed sampling for health testing, and visual inspection of seed for phytosanitary certification.

What Would a Plant Center for Disease Control Look Like?

Beginning in 2002, the APS Ad Hoc Crop Biosecurity Committee initiated a series of discussions and e-mail exchanges regarding the need for a National Center for Plant Disease Prevention and Control (NCPDPC), which would provide leadership for a 21st century infrastructure for documenting, monitoring, and protecting American agriculture against new or emerging plant diseases. The committee provided examples of the responsibilities of the proposed NCPDPC, which could include: conducting surveys of new and emerging plant diseases; developing “gold standards” for diagnostics; functioning as a regional center for communication among multinational companies and institutions; maintaining databases on national expertise, sources of reference cultures, and global diversity and population dynamics of pathogens; and providing centralized public relations in cases of national emergencies.

Recommendations:

- Build on the National Diagnostic Network (urge support of $10 million per year through CSREES, earmarked for the centers
- Establish a multi-disciplinary study group for the development of a National Center for Plant Disease Prevention and Control, as a follow-up to the NRC report
- Develop linkages to the veterinarian community and the private sector
- Create a position for a National Program Leader for plant health
- Appoint a Chief Scientist for agriculture at a similar administrative level as the Chief Economist in the Secretary’s office

Conclusion

There is general consensus that the question is not if, but when, a plant disease that can significantly lessen the quality or quantity of our food, feed, or fiber will be purposefully or naturally introduced into the U.S. If we wish to assure the food security of our nation, the current level of support for pathogen research, diagnostic assay development, and preparation of response tactics will not suffice. Experts predict that there could be a severe reaction to and an extended recovery from such an event. Indeed, with the current level of support for plant health, the likely impact will be an erosion of citizen confidence in a safe and secure supply of food, feed, and fiber. Hence, significant new investments in the infrastructure and resources necessary to protect plant health have the potential for significant social and economic benefit for generations to come.