USDA APHIS/U.S. Seed Industry Biosecurity Framework

The detection and abatement of Cucumber Green Mottle Mosaic virus (CGMMV) in 2013 identified a problem in the APHIS seed import regulations and requirements: lack of protection against the introduction of seed transmitted pathogens. These pathogens can occur within the seed and can be transmitted to the resulting seedling upon germination, thereby posing risk for introduction and potential establishment. Seeds harboring pathogens usually exhibit no visible symptoms especially when infected at low levels. Current APHIS import regulations either prohibit certain seed species or allow seed in with minimal scrutiny; those that are not prohibited are usually allowed entry into the U.S. subject to proper documentation and only a visual inspection at the port of entry.

Besides CGMMV, there are a number of other seed transmitted pathogens of potential concern. Although there is a need to develop a response specific to CGMMV to prevent future introductions, a system needs to be developed that will address all possible threats caused by seed transmitted pathogens. Unless a holistic system is established, the seed industry will potentially be faced with having to comply with individual requirements for a growing number of seed pathogens. The traditional approach of establishing requirements for individual seed pests will result in tremendous expense, delays, and bureaucracy to the industry. It has also become increasingly difficult and resource-intensive for APHIS to establish and enforce new regulations.

The seed industry is very concerned about seed transmitted pathogens and other seed pests as is APHIS. The driving force in the industry is seed quality. Competition both at the national and international levels is driven by the ability of companies to consistently produce seed that performs according to label claims and is pure, which also means free of unwanted extraneous material in the forms of seed pathogens, weed seed contaminants, plant debris and soil. In addition, companies are often held liable by their customers when their seed is responsible for poor yields as well as disease introductions. Most companies have quality management systems (QMS) in place to ensure high seed quality. Many QM systems are ISO certified and accredited through programs such as the National Seed Health System (NSHS). Included in these QM systems are traceability programs that document where the seed originated, was increased, where it is/was in storage, and where it was ultimately sold. These systems also document seed health inspection and testing as well as sanitization and treatments applied to the seed. These QM systems are very sophisticated and are usually based on Hazard Analysis and Critical Control Point (HACCP) approaches and principles. Many companies involved in the seed business on an international level move seed routinely into, through, and out of many countries; every time seed is brought into a given country, it must comply with the phytosanitary import requirements of that country, so phytosanitary concerns are already built into their QM programs. Some companies have quality management systems and routinely test; this effort should focus on those seed importers that do not have programs in place and make sure that anyone who is importing seed is doing the appropriate testing.

A comprehensive biosecurity framework that prevents the introduction of seedborne and seed transmitted pathogens and other pests of phytosanitary concern can best be achieved through a partnership between USDA-APHIS and the seed industry. The fundamental basis for such a framework should be through a non-regulatory or minimally regulatory approach. The components of this program would include 1) establishment of a baseline monitoring program by APHIS and the states (National Plant Board) for pathogens/pests of major concern; 2) establishment of a federal system/program for voluntary accreditation of seed companies and seed brokers that have QM systems in place that reduce or minimize overall phytosanitary risk; and 3) a seed health testing network comprised of accredited private, state, university (NPDN) and federal laboratories that are certified to perform testing for pathogens included in the baseline monitoring program. In addition, prevention and response plans need to be jointly developed for each pathogen of phytosanitary concern.

Baseline Monitoring Program: Samples from incoming seed shipments need to be taken randomly at a baseline frequency based on a reasonable probability of detection, and tested for pathogens of concern. Specifically, shipments of seed coming from countries that present the highest risk of these pathogens occurring need to be targeted. (At the recent APHIS seed summit APHIS reported that CGMMV is known to occur in 14 countries.) In some cases it may be feasible to take official samples at a port of entry, but it may be more feasible to partner with the states (through AASCO?) which have seed control agents that routinely sample seed prior to sale for Federal Seed Act purposes, to pull samples from warehouses, storage facilities, etc. prior to final sale. Samples could be sent to designated, including internal accredited company laboratories, in the network that are accredited to perform that particular test. Over time, a database can be developed that will be of value to more accurately determine sampling frequencies, and conduct pathway and pest risk analyses for pathogens of concern. For those lots sampled there should be a timeframe established to receive the results back and release the lot for sale.

Accreditation of Seed Companies for Phytosanitary Risk Management: The National Seed Health System (NSHS), an APHIS program administered through the Iowa State University Seed Science Center, currently accredits entities (seed companies, private and state laboratories, crop improvement associations) to perform certain functions (phytosanitary field inspections, seed visual inspections, seed sampling, phytosanitary seed testing) that support issuance of export certificates. Based on information provided, the certificates are either issued by APHIS officials or state officials under delegated federal authority. A new category of accreditation could be established under the NSHS for private sector QM programs that significantly minimize phytosanitary risk. This accreditation would cover all aspects of international seed movement, such as, for example, seed testing overseas by companies that have that capacity for seed destined for the U.S. The architecture for this accreditation could begin with the ASTA Guide to Seed Quality Management Practices, which is a general guide used by ASTA member companies to evaluate or establish their company-specific QM systems . This guide identifies 7 stages in seed production beginning with bringing germplasm into a research/breeding program all the way through commercialization. A HACCP framework is set in place for each of the 7 stages.

The whole premise is to begin with clean germplasm and to maintain the purity of that germplasm through each stage in the development and production continuum.

Under this specific program accreditation, similar to the current NSHS processes, an entity would apply for the accreditation and would submit a detailed description of its QM system (under terms of confidentiality as many companies have proprietary components in their programs) based on criteria established for this program. A fee structure for this process would be established by the NSHS. Once accredited, the entity would be periodically audited to ensure that the terms and standards of the accreditation are maintained. APHIS could issue a "seal of excellence" to accredited entities. Accredited companies would use this status as a marketing tool to encourage customers to purchase seed from preferred providers. Such an approach would cause unaccredited companies to create or bring their QM programs up to this standard and therefore seek to become accredited. Accredited entities would be monitored/regulated primarily through audits rather than on a seed lot-by-lot basis. Audits will likely have to be more frequent than the three year requirement for current NSHS accreditations.

Establishment of an accreditation program may not be feasible in the short term as it may require notice and comment rulemaking by APHIS which could take several years to accomplish. APHIS is evaluating whether or not additional rulemaking will be required. An alternative approach may be to develop standards through the NSHS for managing phytosanitary risk for seed pathogens, and then for APHIS to establish compliance agreements with seed companies and other entities (for example, brokers) to ensure implementation of these standards. Again, accreditations and compliance agreements will be voluntary; seed companies and brokers that elect not to become accredited or enter into compliance agreements will continue to be regulated by traditional approaches; however, the baseline monitoring will orient toward seed originating from non-recognized sources.

A key to this approach is a strong, well funded NSHS. Additional sources of revenue for the NSHS need to be considered, but could include 1) application and audit fees paid by the accredited entities; 2) a potential (if industry supported) surcharge of $5.00 to $10.00 for each seed phytosanitary certificate (in 2013 there were over 42,000 seed phytos issued – this surcharge could generate another $200K-$400K annually); 3) additional financial commitment from APHIS. (A separate APHIS/seed industry working group is being formed to identify options for resourcing the NSHS.)

Establish a Seed Health Testing Network. To support the baseline monitoring program as well as have in place a rapid response capability, a comprehensive seed health testing capability needs to be established. This network could consist of: USDA laboratories that have capacity for seed health testing (APHIS, ARS, AMS), NSHS accredited company and third party private laboratories; and those state and university laboratories having expertise and capacity for seed testing that are in the National Plant Diagnostic Network (NPDN). Each laboratory in the network would need to identify which pathogens they are capable of being be accredited/listed for testing. Laboratories that have research capabilities could also help develop new/improved seed testing methods for pathogens of concern. A key element would

be a requirement that each laboratory in the system be accredited through the NSHS and certified for specific tests based on a demonstration of proficiency. A closer, more institutional relationship could be developed with the International Seed Federation International Seed Health Initiative for Vegetables (ISF ISHI-Veg) system and other entities such as the International Seed Testing Association (ISTA) to encourage the development of standardized test methods. A strong, sustainable network based on the NSHS and the NPDN will also significantly benefit APHIS to maintain/enhance its capacity to support its overall biosecurity mission.

Putting All the Pieces Together: Once all the components are established, the framework would function according to the following vision: APHIS, working in conjunction with the seed industry, will identify the seed transmitted pathogens to be included in the baseline monitoring program, beginning with CGMMV. APHIS and the industry will work together to develop prevention and response plans for each pathogen of concern. The focus will be on collecting samples from companies/entities that either are not NSHS accredited or do not have compliance agreements in place with APHIS (consignments from accredited companies may be sampled, but at a significantly lower frequency). In addition, seed consignments from countries where pathogens of concern are known to occur will be targeted. NSHS accredited testing methods should be used as much as possible. Once the sampling protocols and frequencies are set up, samples will be collected and sent to the appropriate laboratories for analysis, with the appropriate seed source company being notified of the action. Turn-around times should be agreed to up front to avoid or minimize having to hold consignments for long timeframes until results are provided. If there is detection of a seed pathogen, it needs to be confirmed using agreed-upon methods. When the testing is completed APHIS will notify the owner of the results. If the seed is confirmed as contaminated, APHIS would 1) notify the owner of the consignment that it has a confirmed detection of pest X, and 2) notify the industry through ASTA and/or other appropriate industry organization (as not all seed companies are ASTA members) and appropriate state officials. Consignments that are contaminated need to be returned to the country of origin, destroyed, or treated (if there are phytosanitary treatments available that are recognized by APHIS) to eradicate the pathogen (verified by subsequent testing after treatment.). Further investigation of that company's inventory may be needed – tracebacks/forwards, etc.As a general comment, shipping the seed back to the country of origin is not a preferred option.

The industry would then work with APHIS and the state(s) to identify and correct the breach in the system. If the infected seed lot came from an accredited company, traceability and corrective capability should be in place to quickly identify and resolve the problem. If the problem is from a non-accredited entity, the adverse impact to that entity will likely be much greater as it may not have the systems in place to sequester the issue. Seed companies will be encouraged to conduct their own additional testing on all remaining seed lots from the at risk origin countries, and to report positive results and subsequent action to APHIS. Finally, companies would be encouraged to initiate and conduct outreach grower training programs on the pathogens so that they can understand the importance of the disease, and how it could affect them.

Once the program framework is established, those accredited entities having the government "seal of excellence" (based either on the accreditation or compliance agreement) could market themselves as a preferred provider. This alone should be become an incentive for non-accredited entities to seek accreditation. Over time, this will raise the bar across the industry. As those scenarios develop where the source of infected seed is determined to be from non-accredited entities, accredited entities would likely continue to communicate to potential customers the value of purchasing their seed from accredited entities that have QM systems in place to avoid the problem of purchasing lower quality (infected) seed. The net result should be that everyone wins: there is an incentive in the industry to have QM systems in place, there will be voluntary "policing" throughout the industry, fewer introductions will occur, fewer regulations will be needed, and a much stronger, more sustainable laboratory diagnostic infrastructure will be in place for supporting the federal biosecurity mission.

Development of the Standard(s) for Maintaining Seed Imports Free of Seed Borne/Transmitted Pathogens: The seed industry will work collaboratively with APHIS to develop the standard(s) and criteria which will serve as the basis for the accreditation program and/or compliance agreement. These will be structured according to HACCP principles, many of which are found in the ASTA Guide to Seed Quality Management Practices as well as many seed industry QM systems already in place. Those eligible for accreditation /compliance agreement will include seed companies that produce their own seed as well as brokers that purchase and sell seed. In the case of brokers, they will have to demonstrate compliance through their contracting processes with their sources in which requirements for seed inspections and testing are stipulated in their contracts or arrangements for seed testing through third party accredited laboratories are documented. The overall goals are to 1)utilize existing federal regulatory authority without the need to establish additional regulations, existing accreditation programs such as NSHS, and existing internationally recognized seed testing methods (those certified by NSHS, ISHI, ISTA); and 2) recognize existing industry QM programs that already meet the standards)/criteria that will be established.

Elements of the accreditation/compliance agreement will include:

- A system for traceability of all seed lots that are imported into the U.S. as well as increased and distributed within the U.S. Records would include:
    - Dates of importation;
    - Seed commodity and variety;
    - Source of the seed;
    - Amount of seed;
    - Certified laboratory address and contact;
    - Method of importation (air, sea);
    - Destination of each lot.
- Protocols for field inspection of mother plants in the country of origin and/or in the U.S. when the purpose of planting is for seed increase for domestic or export purposes. Field inspections will have to be standardized based on an international standard or by a

system that the NPPO and industry agree upon. Field inspections will need to be documented and these records would accompany the phytosanitary certificate.

- A provision that seed lots (or, if feasible and preferable, mother plants) be tested for pathogen(s) of concern prior to planting in the U.S. Options for testing will include testing by APHIS-recognized laboratories of NPPOs, seed company (NSHS accredited) laboratories that are located overseas or domestically, third party NSHS accredited laboratories, or APHIS recognized Federal or state laboratories. Testing could occur in the country of origin or in the U.S. prior to distribution. Protocols for handling seed lots until after testing is completed could be included in the compliance agreement or accreditation system.
- Facilities having the capability to test for pathogens of concern using established international methods or methodologies recognized by appropriate NPPOs and APHIS.
- Adequately trained staff and facilities to handle exotic plant/seed pathogens on the part of seed companies, third party providers, and/or other entities.
- For seed testing, individual facility quality management manuals for each accredited entity or entity under compliance agreement which will include:
    - Name of contact person who will be responsible for management of the program and oversight of the quality manual;
    - A list of personnel that will perform the testing along with their qualifications and training records;
    - Standard operating procedures used in the laboratory;
    - Testing methods to be used, including the detailed protocol(s);
    - Types of equipment used for testing and associated maintenance/calibration records;
    - Process for receiving, handling, and safeguarding imported seed;
    - System of records that includes test results, source of seed, volume, destination of tested seed;
    - Process for destruction of infected/contaminated seed;
    - System of internal audits;
    - Procedure for notification of detection of pathogen of quarantine concern.

The overall expectations are that all imported seed of species included in this program is appropriately tested by an accredited laboratory for pathogens of concern, and that commercial growers understand the value of, and need for, testing of their seed prior to planting such that they require seed from foreign sources to be tested.

Pilot Program: This framework could be established and tested as a pilot program focusing on CGMMV. A possible path forward would be to develop and submit a joint APHIS/industry proposal for Farm Bill funding. Based on estimates of importations of host seed species for CGMMV, annual costs for a baseline monitoring program for CGMMV and perhaps TASV would be in the $100K-$200K range. Costs for establishing a new accreditation category under the NSHS is yet to be determined. Costs for achieving accreditations and conducting associated audits will be borne by applicants through fees established for this purpose, but will be included

in the Farm Bill proposal for the pilot. Costs for establishing the seed health testing network should be minimal; however, this may be a good opportunity to include some funding for methods development and validation as well as for mock trialing in the proposal.