Overview

The American Seed Trade Association appreciates the opportunity to provide information about the U.S. seed system and regulatory environment. The U.S. seed system has science-based, predictable, transparent laws and regulations for intellectual property, seed health and trade, and innovation. The system supports the rights of the breeder, reduces pest risk, and fosters innovation and market-based competition among seed companies. The U.S. industry and government actively participates in global fora for the development and harmonization of international seed standards.

The U.S. seed industry must comply with all phytosanitary, labeling, and seed movement requirements as outlined in the Federal Seed Act. Furthermore, the industry complies with regulations related to intellectual property, biotechnology, seed treatment, and foreign regulations for exported seed as outlined in detail below.

Companies' internal policies for seed quality management often extend beyond the scope of federal and state regulations. If a company cannot deliver quality seed to a customer, the company risks losing their business due to market competition.

The U.S. seed industry works closely with relevant U.S. government agencies to ensure regulatory compliance, and to provide information to the government in the development of transparent, science-based regulations that the ensure safety, innovation, and growth of the U.S. seed industry. Communication between the industry and government agencies is critical to ensuring the system operates successfully.

Question list

1. Protection and utilization of Germplasm Resources

The U.S. system to access and protect germplasm resources is transparent and ensures global access to publicly available varieties. The national system is designed to maintain, document, evaluate, and distribute plant germplasm for use in breeding and to maintain food security.

USDA/ARS National Plant Germplasm System (NPGS)

The USDA/ARS National Plant Germplasm System (NPGS) conserves plant germplasm in research and breeding. It is one of the largest national genebank systems with more than 596,000 samples of more than 16,000 plant species. The NPGS plays an important role in preserving plant crop genetic diversity and maintaining food security.

It holds collections of the major staple crops important to U. S. and world agriculture including large holdings of crops without major collections at international agricultural research centers, e.g., cotton, soybean, various horticultural and "specialty" crops. Collections are housed in 20 locations in the U.S.

The Germplasm Resources Information Network (GRIN) documents animal, microbial, and plant collections through informational pages, and searchable databases. Anyone in the world can submit an order online and GRIN will distribute a sample for research purposes or breeding, sent for free to the destination. NPGS annually distributes an average of about 250,000 samples to researchers worldwide.

An average of about 70% are distributed domestically, and 30% internationally. https://npgsweb.ars-grin.gov/gringlobal/search.aspx?

The role of the gene banks are to acquire maintain, document, evaluate, and distribute plant germplasm. In some cases, scientific research is conducted on the collections. In 2015, genotyping by sequencing, a low-cost, high-throughput sequencing technology (GBS) was used to genotype the entire USDA soybean genebank collection of nearly 20,000 accessions. – 50,000 SNPs on 20,000 accessions – that is 1 billion data points. The genetic resource provided by this dense marker set on a broad array of genotypes is a powerful new tool for soybean breeders.

The National Laboratory for Genetic Resources Preservation is part of the National Plant Germplasm System. The National Laboratory, located in Fort Collins, Colorado, has the capacity to store between one and 1.5 million accessions, depending on the size of the propagule, in storage vaults cooled to -18 degrees C (conventional storage). In addition, the NCGRP has a 220 cryotank capacity, with each cryotank holding about 3,000 seed accessions. Each accession contains about 3,000 to 5,000 seeds. Germplasm comes from all over the world and it is donated by collectors, breeders or experts in systematics who locate material with unusual or interesting traits that may eventually be useful in agriculture.

International Treaty for Genetic Resources for Food and Agriculture

The U.S. joined the International Treaty in 2017. Most of the NPGS's genetic resource collection was placed within the Treaty's Multilateral System for Access and Benefit-sharing, continuing the U.S. tradition of facilitating access to plant genetic resources for conservation, research, and breeding.

The U.S. has no regulation for Access and Benefit Sharing, but we comply with the International Treaty for Plant Genetic Resources for Food and Agriculture for germplasm to be used in the context of the multilateral system (SMTA). To acquire plant genetic resources from the U.S. National Plant Germplasm System (GRIN database), the requestor will have to sign a Standard Material Transfer Agreement (SMTA) in compliance with the Treaty if it is a plant genetic resource for food and agriculture. Furthermore, the SMTA will restrict what the germplasm can be used for.

U.S. National Plant Germplasm System - Overview – YouTube link

2. Seed products and technology

What policies and systems are adopted in seed products and technology import & export to ensure effective understanding of related information and avoid any negative impact on the development of seed market in its own country?

Import/Export Requirements Overview:

The U.S. government facilitates the import and export of the seed from the U.S. using a science and risk-based system to prevent the introduction of plant pests into the U.S., and to meet the requirements of the importing country. USDA Animal and Plant Health Inspection Service (APHIS) manages the development of seed health regulations and protocols for imported seed. The Federal Seed Act also outlines specific sampling and inspection requirements for imported seed and inter-state commerce. Import protocols are executed via partnership with U.S. Customs and Border Protection agricultural

specialists at maritime ports, airports, and land borders. CBP agricultural specialists conduct risk-based sampling and visual inspection at ports of entry. If additional inspection is required, the seed is referred to a trained entomologist or pathologist at the port, or sent to one of 16 regional plant inspection stations operated by APHIS.

All requirements to import seed into the U.S. are found in the APHIS Plants for Planting Manual (https://www.aphis.usda.gov/aphis/ourfocus/planthealth/complete-list-of-electronic-manuals). The Plants for Planting manual is a public document providing detailed requirements for each taxa. The manual lists plant taxon and the regulated plant part (seeds or all propagules). It lists any countries where the plant taxon is not authorized or prohibited from, and provides any specific requirements or restrictions (if any) related to import.

There are very few specific import requirements for commercial seed. If a seed is not prohibited or restricted, the seed import requires a phytosanitary certificate from country of origin. Certain agricultural and vegetable seed must meet additional labeling requirements under the Federal Seed Act. The Federal Seed Act requires accurate labeling and purity standards for seeds for planting and prohibits the importation and movement of adulterated and misbranded seeds.

Federal Seed Act seeds are identified as FSA-A (Federal Seed Act Agricultural) or FSA-V (Federal Seed Act Vegetable) in the Lists of Plants for Planting. In addition to the plants for planting regulations, seeds in this category require each lot to be accurately labeled as to kind, origin, variety, and lot designation, and for treated seeds to identify the substance on the label. See answer 4 for additional information.

For exporting seed from the U.S., the companies need to meet the requirements of the agency issuing the phytosanitary certificate (state or federal). The agency will issue the phytosanitary certificate according to the importing country's requirements. The APHIS Phytosanitary Export Database (PExD) https://pcit.aphis.usda.gov/PExD/faces/ViewPExD.jsp provides seed and country specific import requirements. It is important that foreign governments share new import requirements with APHIS so that the database remains up-to-date. Additional seed certification programs focused on germination, purity, quality, etc. are optional. These programs include OECD Seed Schemes or Association of Official Seed Certification Authorities. Following the requirements above ensures the safe and efficient movement of seed into the United States and across state borders.

Additionally, APHIS is also working with trading partners to implement electronic phytosanitary certificates (e-Phytos) following the the International Plant Protection Convention (IPPC) guidance. The IPPC ePhyto Solution is an initiative to encourage the implementation of electronic certification by IPPC Contracting Parties to facilitate safe trade in a more expeditious, transparent, reliable, digital and paperless manner.

Controlled Import Permits (CIPs) to Import Plants or Plant Products for Experimental, Therapeutic, or Developmental Purposes

Special permits are required to import prohibited or restricted materials. Guidance for obtaining permits (called controlled import permits) is on the APHIS website (https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/plants-and-plant-products-permits/prohibited/cip-containment-guidelines) and in the Plants for Planting manual

In some cases, APHIS may approve a commercial or research containment facility for use with a controlled import permit. In other cases, the restricted or prohibited seed must be imported to the National Plant Germplasm Inspection Station in Beltsville, MD for propagation.

A Controlled Import Permit (CIP) may be issued by APHIS Plant Protection and Quarantine Division to authorize the importation of an article whose importation is prohibited or restricted, according to the Plants for Planting Manual. To identify if a plant is prohibited/restricted look in the Plants for Planting Manual. CIPs are intended for plants imported for:

- Experimental purposes: Scientific testing to collect data and perform analytical processes under controlled conditions;
- Therapeutic purposes: Specific scientific processes designed to eliminate, isolate, or remove potential plant pests or diseases;
- Developmental purposes: Evaluate, monitor, or verify plant material for plant health risks and/or the adaptability of plant material for certain uses or environments.

Taxa listed under Not Authorized Pending Pest Risk Analysis may only be imported with a CIP. The intended use of the imported plant material determines risk. CIPs are authorized for destructive analysis, for limited propagation where the imported material is destroyed at the end of the trial, and for propagation followed by release of the imported material from quarantine. A containment facility may be required for importation of the regulated material. The facility will be evaluated before the permit is issued.

Process to Request a CIP:

Applicants requesting a CIP must submit a PPQ Form 588 application. There is no fee for a CIP and no phytosanitary certificate is required.

The time to process an application depends on various factors including the number of applications in the queue, the application completion status, the imports intended use, if the material will be destroyed or released, if a containment inspection is required, the condition of the containment facility, the pest risk, the country/commodity combination, and whether prior permits exist. Upon evaluation of your facility, APHIS may determine that you need to perform upgrades in order to be an approved containment facility; if this is the case, an inspector will inspect your facility after the upgrades are performed. This could cause delays in the processing time. Most applications that provide sufficient information can take 30 to 45 days, as the complexity of the import increases and with the need for additional clarification and information the processing time can be extended to 120 days or longer. APHIS makes every attempt to thoroughly understand the considerations for CIP request to ensure pest risk reduction and meeting the requests of the importer.

CIPs initially issued to an applicant are valid for a period of one year. Prior to the expiration of a CIP and if permit conditions are not violated, the permittee may request an expiring permit to be renewed for up to an additional two years.

Containment Facility Guidelines:

One of the purposes of Plant Protection and Quarantine (PPQ) permits is to prevent the entry and spread of plant pests into and within the United States. APHIS PPQ will only issue permits when the

receiving facility has the appropriate measures to adequately contain potential pests that could be associated with the growth of imported plants. Adequate containment of imported plants is required to prevent the potential introduction and dissemination of pests and diseases into the environment in the United States. Many foreign pests and pathogens can go undetected until it is too late to contain, control and remediate the problem, resulting in greater potential for damage and losses to U.S. agricultural production.

A facility inspection may be required before a Controlled Import Permit (CIP) permit is issued. An APHIS PPQ containment specialist will evaluate the documentation submitted with the permit application, and determine if the facility is adequate. The applicant will be informed if their facility must be inspected as part of the permitting process. A PPQ inspector will document aspects of the facility to determine if the facility and equipment are adequate for containment of organisms and pests that may be associated with the imported plants. The applicant is required to provide information about the containment facility where the imported plants will be grown. APHIS PPQ may schedule an inspection of the containment facility to confirm that it will adequately safeguard pests and diseases should they occur.

Outlined below are the documents that may be requested or steps involved in evaluation of the facility:

Step 1: Standard Operational Procedures (SOP):

Submit a Standard Operational Procedures (SOP). Document outline is found here: https://www.aphis.usda.gov/plant_health/permits/downloads/containment_sop_outline.pdf

Step 2: Greenhouse containment questionnaire

If plants will be grown in a growth chamber or greenhouse then the applicant will be asked to complete a Greenhouse questionnaire. Sample questionnaire found here: https://www.aphis.usda.gov/plant_health/permits/downloads/cip-greenhouse-containment-questionaire.pdf Upon receipt of responses, the greenhouse questionnaire will be evaluated by the permit scientist

Step 3: Facility Evaluation and initiation of on-site inspection

Based on evaluation of the greenhouse questionnaire, APHIS PPQ may conduct a facility inspection.

The applicant's containment growing facility should be ready for APHIS inspection within 30 days after the submission of the application. Containment facilities are subject to random compliance inspections post-permit issuance.

Factors to Consider for the Containment Facility:

Water: Water for plants must come from publicly approved deep wells, municipal water or water from other sources purified by filtration through reed-bed systems and slow sand filters in combination with ozonation, ultraviolet irradiation, peroxide or chlorination. Runoff water in the greenhouse should drain to a municipal water system or receive treatment before being reused.

Soil/Growing media: Used in the greenhouse for imported plants. Must be sterilized and not have been used previously for other plants. Soil that comes into contact with the imported plants must not be reused.

Greenhouse Security: The area where imported plants/seeds are maintained must be secure and only accessible to persons who are directly responsible for the plants or who maintain the plants. Doors must be lockable and access must be limited.

Greenhouse containment: All vents and openings must be sealed or covered by insect proof mesh. The ventilation system cooling pads, and or evaporative pads must be covered with insect proof mesh to prevent insects from entering or leaving the greenhouse.

Greenhouse flooring and benches: The floor and bench surfaces must be constructed of an impervious material that may be easily cleaned and effectively decontaminated. Benches for plants must be at least 24 inches from the floor.

Pest control: A pesticide program and or pest surveillance program must be in place to control insect pests. The treatments must be recorded.

Plant Pathologist: A plant pathologist (who is not the applicant) must perform a surveillance of the imported plants for pests and diseases once a month and record the findings. The plant pathologist must be someone within driving distance of the containment facility who can be reached if there is an emergency disease outbreak.

Plant and Soil Waste: All plant material that is not used, or plant waste and soil/potting media that comes into contact with the imported plants must be either autoclaved or double bagged and incinerated, or double bagged and taken to a municipal landfill.

Not Authorized Pending Pest Risk Analysis (NAPPRA):

The Plants for Planting Manual designates some taxa as “not authorized pending pest risk analysis.” Importers who wish to import small quantities of plants or plant material on the NAPPRA list for experimental, therapeutic, or developmental purposes may apply for a controlled import permit (CIP).

<u>The NAPPRA Process</u>

If scientific evidence indicates that a taxon of plants for planting is a quarantine pest or a host of a quarantine pest and has little or no recent import history, APHIS will publish a proposed notice in the Federal Register proposing the taxon as NAPPRA. The notice will cite the scientific evidence APHIS considered in making this determination, and give stakeholders the opportunity to comment on our determination. If the comments we receive do not lead us to revise our determination, APHIS will add the taxon to the NAPPRA list. A plant taxon is added to NAPPRA for the listed pest and for all other quarantine pests for which the taxon is a host. This process allows APHIS to take prompt action in response to evidence that the importation of a taxon of plants for planting may pose a risk while allowing public participation.

<u>Federal Import Order</u>

A Federal Import Order is a legal document issued in response to an APHIS decision that emergency regulatory action is necessary to protect American agriculture or to prevent the entry and establishment

of a pest or disease in the United States. A Federal Import Order may add taxa to the list of plants that are Not Authorized Pending Pest Risk Analysis (NAPPRA) or may impose restrictions such as pest mitigation measures on the import of host genera from countries that have a significant import history of those plants with the U.S. and are exempt from NAPPRA.

Requesting a Pest Risk Analysis

Importers who wish to import plants or plant materials on the NAPPRA list must submit a request. Upon receipt of a completed request, APHIS will develop the Pest Risk Analysis (PRA). Based on the PRA results, APHIS will either remove the taxon from the NAPPRA list from the country or countries for which APHIS had conducted the PRA, and then allow its importation subject to general requirements, allow its importation subject to specific restrictions, or continue to prohibit its importation.

3. Intellectual property rights of seed industry

Seed is the vehicle for many forms of innovation, such as improvement in germplasm, specific genetic and agronomic traits, seed treatments and coatings. Each cycle of innovation adds to the knowledge base and is critical for the continued development of new and better crops that benefit farmers, growers and consumers. The research and development necessary to create and introduce new plant varieties often requires 5 to 15 years and millions of dollars in investment. Effective intellectual property protection reinforces the value and importance of scientific and technological innovations, helps to spur further innovation and provides benefits to society as a whole.

Effective Intellectual Property Protection

Intellectual property protection is most effective when there is a variety of IPR tools available to encourage a wide range of innovations and when there is robust enforcement of those forms of protection. ASTA believes that, worldwide, affordable intellectual property protection systems should be accessible so that innovations can be protected, as determined by the developer. These systems include:

- Plant Breeders Rights (PBR)/Plant Variety Protection (PVP)
- Patents
- Trade Secrets
- Contracts
- Trademarks

Robust intellectual property enforcement not only protects investments but also ensures that the farmer and society as a whole receive the full benefit of innovation. Enforcement should be:

- Fair and equitable
- Timely
- Effective
- Consistently applied
- Reasonable and accessible

The Benefits of Intellectual Property Protection

Supporting the needs of an increasing world population in a sustainable fashion, while protecting the environment, requires ongoing innovation in all agricultural cropping systems, including seeds, that supports improved productivity and nutritional content.

One of the key drivers of innovation within any industry is the capital that is invested in research and development. Robust intellectual property protection attracts the size and scope of investment necessary to develop improved seed varieties. These investments are generally long-term; may require significant amounts of capital resources; and entail large financial risks. Investments in research and development by the seed industry are directly related to the effectiveness of the intellectual property protection. These investments allow the public and private sectors the employment of skilled professionals, the development of new tools, rational land use, and access to specialized equipment–all of which will enable them to continue bringing innovations in the form of improved seed varieties for farmers and new products for consumers.

Effective intellectual property protection through PVP or patents is important as a driver of innovation, and provides a discrete period of protection and choice of protection types. Intellectual property protection of an improved seed variety supports the fundamental concept of a social contract made by the intellectual property right owner when the improved seed variety enters the public domain upon expiration of protection. This balance of protection and access contributes to achieving a wide diversity of improved varieties for farmers, resulting in increased agricultural productivity with resultant benefits to consumers and improved environmental sustainability.

Farmers are allowed to save seed for use on their own land, as long as it only has Plant Variety Protection (PVP) protection, the seed IP has expired and there are no additional contractual terms or restrictions. Farmers that want to use seed without restrictions can obtain public varieties through USDA's National Plant Germplasm System or land grant universities. Different seeds have different requirements. Seed dealers are knowledgeable about specific requirements for varieties sold.

Intellectual Property Rights Tools in the United States

Plant Variety Protection

An application for Plant Variety Protection can be filed with USDA. Anyone who is the breeder of a unique variety of a sexually or asexually reproduced plant or tuber propagated plant may apply for plant variety protection. The applicant may be an individual, a public institution, or a corporation. To apply, the applicant submits information to show that the variety is new, distinct, uniform, and stable. The information is submitted by completing forms located on the PVPO Website: www.ams.usda.gov/PVPO

For seed, a deposit is required of 3,000 viable untreated seeds of the variety; additionally for hybrids, 3,000 seeds of each parent needed to reproduce the variety. Deposit of propagating material for asexually reproduced plant varieties is a new requirement from 2020. The deposit requirement is delayed until January 6, 2023. The applicant is required to make a declaration that the propagating material will be maintained at a specific location, subject to PVPO inspection. When and if requested by the PVPO, the applicant has 90 days to provide the germplasm or risk losing protection.

A PVP certificate is granted if the new variety is distinct, uniform and stable. These rights extend for a fixed period of not less than 20 years from the date of the grant of the PVP certificate. At the end of the protection period, the protected material enters the public domain, subject to any other existing and enforceable intellectual property rights.

UPOV 91: ASTA is a member of UPOV 91. The UPOV system as enacted in 1991 provides exclusive marketing rights for a single variety, its harvested material, and, optionally, for products made directly from it. Plant Variety Protection (PVP) provides exceptions for experimental use by third parties for the purpose of plant breeding and new variety development. An exception for farmers permits them to save seed for the limited purpose of propagating for use on their own holdings. ASTA strongly supports the adoption of UPOV 91 by our trading partner governments.

Essentially Derived Varieties:

The principle of essentially derived varieties represented a significant addition to the UPOV Convention's revised Act of 1991 and an important improvement to plant breeders' rights (PBR) and plant variety protection (PVP) across UPOV member countries. The provisions of UPOV 91 establish a balanced form of PBR/PVP so breeders who invest in the development of protected varieties may benefit from additional rights regarding EDVs derived from their protected initial variety (IV). This is because the owner of the PBR/PVP for the IV determines whether an EDV of the IV may be exploited commercially.

Implementation of the EDV principle supports both the intellectual property rights (IPR) of the initial breeder and, at the discretion of the owner of the IV, the commercial interests of those who breed or discover varieties that are essentially derived from the IV. The condition of discretionary ownership to an EDV provides a balance of IPR granted to the owner of the IV and to anyone who subsequently breeds or discovers an EDV under the breeders' rights principle.

The U.S. Plant Variety Protection Office (PVPO) does not participate in the determination of an essentially derived variety. The U.S. PVPO is solely accountable to determine if a new variety qualifies for plant variety protection and is not accountable to determine whether a variety is or is not essentially-derived from a protected variety. The U.S. PVPO only determines whether a new variety seeking PVP protection is distinct, uniform and stable (DUS). No consideration is given to the economic value or agronomic importance of the new variety in its evaluation.

The owner of the IV is accountable to evaluate new varieties commercialized by others and to make a preliminary determination whether a new variety has been potentially derived from the breeder's protected IV.

The owner of an IV may determine predominant derivation by comparing characteristics used by the U.S. PVPO to determine distinctness, by assessing any other morphological characteristics and physiological traits, and/or by DNA-based genetic analysis. Predominant derivation is most meaningfully measured using DNA-based genetic analysis with sufficient genome coverage and with proven discriminative ability to distinguish cultivars, including those closely related by pedigree or differing by a few or a limited number of phenotypic characteristics being used to determine distinctness. A distinct variety exhibiting a higher than average genetic conformity for the species, when compared to a PBR/PVP protected variety using DNA-based genetic analysis,

is likely to be predominantly-derived from the latter even while differing in multiple characteristics.

If the owner of a PVP/PBR protected variety believes a new variety is predominantly-derived from his/her variety and could therefore be an EDV, the IV owner may at his/her discretion inform the possible EDV owner that there is a strong indication of essential derivation and whether a commercial license is required and available. If the parties are not able to reach agreement, the owner of the IV may choose to pursue one or more of the following options in order to assert his/her rights against the EDV owner.

- The IV owner may seek to prove the new variety's EDV status by undertaking a formal review and decision with an independent technical panel using a framework and criteria established by the national seed law and/or seed association.

- The IV owner may request an arbitration panel, convened by a national or international seed industry association, to mediate and resolve a dispute with an EDV owner.

- The IV owner may bring his/her finding, assertion and complaint to the appropriate judicial body for review and judgment.

ASTA is only aware of a few public disputes over EDVs, which led to judicial or arbitration cases. An industry-wide[i] EDV Survey (2019) found a majority of breeders understand the EDV concept and respect the principle of EDV. Additionally, breeders reported they follow internal breeding guidelines to avoid developing EDVs. If an EDV should result, breeders responded that they usually contact the owner of the IV to seek a commercial license.

Utility Patents

A Utility patent can be used to protect single varieties in the United States as well as specific plant traits, methods and processes. Unlike, Plant Variety Protection, utility patents in the United States do not provide for a research exemption. There is no exemption that allows farmers to save seed in the case of using a utility patent to protect a single variety. A patent is granted if the invention is shown to be novel, nonobvious, and is adequately described (enabled). The term of protection for a utility patent is a fixed period of 20 years from the date on which the application for the patent was filed. At the end of the protection period, the protected material enters the public domain, subject to any other existing and enforceable intellectual property rights.

Trade Secrets

A Trade secret covers proprietary information, such as a formula, method, technique or process. This information must have intrinsic value and be economically valuable to the competitors who do not have the information. Reasonable efforts must be made to maintain secrecy by the entity claiming the trade secret. There is no specified protection period for a trade secret.

Contracts

A contract is an agreement between an intellectual property rights owner and another entity. The contract stipulates the parameters under which the other entity may use that intellectual property,

including an agreed payment and conditions of use. Each contract has its own conditions as negotiated between the contracting parties.

Trademarks

A trademark is a word, phrase, symbol, and/or design that identifies and distinguishes the source of the goods, such as seed varieties, of one party from those of others. A trademark is registered to assure its exclusive use by its owner. A trademark cannot be applied to goods or services without permission of its owner.

Developing Intellectual Property Rights Policies

ASTA is strongly opposed to the creation of any regulatory rules that would restrict access to and control the utilization of digital sequence information/genetic sequence data at national and international levels as these would have far-reaching negative effects on basic and applied research and breeding that support the conservation of biodiversity and food security. ASTA believes that regulation of DSI as being envisaged under the International Treaty on Plant Genetic Resources for Food and Agriculture (the "International Treaty") and Nagoya Protocol is inconsistent with the spirit of the Convention on Biological Diversity (CBD).

ASTA recognizes that the issue of DSI is complex in many ways. First, there is no consensus definition for the term "digital sequence information". We agree with many who have stated that non-material information and data are not equivalent to genetic resources as defined in the CBD and the International Treaty. Second, many diverse actors in industry and academia are involved in the generation, storage, curation, dissemination, interpretation and use of DSI. These "users" work in well-functioning systems that have been established for a long time. Many of these systems have operated under the principle of "open access" to promote information exchange, which we believe is a fundamental principle of the International Treaty. Third, the types and extent of uses of DSI are equally diverse, ranging from public and private breeding to essential conservation and phytosanitary work. Beneficial research has been accelerated by public and private actors as sequencing plant genetic resources for food and agriculture (PGRFA) has become more common and affordable. Finally, and with the wider use of sequencing, DSI has become a critically important tool in food security and nutrition especially through faster breeding cycles and more effective control of agricultural pests in farmers' fields.

Within the context of the broader discussion on DSI, ASTA supports having a constructive debate with the goal of enhancing the fairness and equity elements of access and benefit sharing under the International Treaty to promote the conservation and sustainable use of genetic resources like PGRFA. However, ASTA is concerned that the current attempts to create an international DSI regulatory regime will undermine the access and benefit sharing objectives of the International Treaty. We believe that there is also a high likelihood for DSI regulation to disrupt on-going conservation, exploration, collection, characterization, evaluation and documentation of PGRFA, and to create an entry barrier for capacity building for smaller market segments and for new users.

4. Seed quality and quantity

The Federal Seed Act regulates interstate and foreign commerce in seeds, requires truthful labeling of seeds in interstate commerce, and requires standards with respect to certain imported seeds.Seed labels are determined by federal and state seed laws, so they may differ from state-to-state but they all have relatively similar requirements. Truth-in-labeling is the primary rule for all consumer packaging,

which allows seed buyers to make informed choices These seed laws are designed to protect the grower, but they also ensure plant breeders' rights, encourage biodiversity, and ultimately greater opportunity for financial success by the grower community. Seed labels ensure customers are buying what they expect, and therefore assist in the production of a viable and profitable crop.

The USDA Agricultural Marketing Service enforces interstate commerce provisions of the Federal Seed Act (FSA) to ensure that seed can smoothly travel from one state to another.**Here is an overview of the information required on a seed label by the Federal Seed Act:**

- Product name: the brand name and/or species name, so the consumer knows what they are getting

- Pure seed: percentage by weight of the desired seed(s) based on the entire contents of the bag

- Other crops seed: percentage by weight of seeds not considered weeds. If the amount is over 5% (generally) then those species are considered "pure seed" and are to be listed by name. In some cases those species present at 5% or less may also be listed as "pure seed" if so desired by the seller.

- Weed seed: the percentage by weight of weed seeds unless they are considered restricted noxious weed seeds by law where the seed will be sold. If they are restricted noxious weed seeds, then they must be listed individually by name and are limited to the amount in the state law (usually around 0.25%). (NOTE: Prohibited noxious weed seeds are not allowed at all.)

- Inert matter: the percentage by weight of whatever is in the package that doesn't grow (i.e. broken seed that are half or less what was originally there, seed coats, insects, etc.).

- Address: the contact information for the company providing the seed

- Origin: location where the seed was grown

- Lot number: a unique number so that the seed can be traced to its origin
- Test date: month and date that this lot was tested. The date of the standard germination test must be listed, even if it is different from the dates of other tests done.

- Germination: the percentage of seed in the bag that is expected to grow (based on a lab test)

- Treatment: coatings generally used to enhance germination, protect the seed, or assist in growth

- Other items: any other items deemed necessary by the state, as this list is not all-inclusive.

Example Seed Labeling Requirements

The information on a seed label should be backed up by a test from a seed lab. It is worth noting that growing environments vary in soil type, fertility, fungal & insect population, environmental conditions, etc. Thus, the germination percentage may or may not match field emergence.

In the United States, **Registered Seed Technologists (RST)** examine the seed using standards set by the **Association of Official Seed Analysts (AOSA).** AOSA is an organization of member laboratories dedicated to education and research, including state, federal, and university laboratories from the United States and Canada. AOSA began in 1908, developing rules and procedures for seed testing and the standardization of their interpretation (in conjunction with the Federal Seed Act)

Registered Seed Technologists (RST) may be employed by a commercial lab or seed company, or they can work for a state government agency. RSTs must show evidence of continuing education and proficiency testing to continue their certification.

“Certified Seed” is an extra credential. A bag of certified seed will have an additional tag, also known as a “blue tag.” That tag denotes that it has been certified for genetic purity and varietal identity. Seed certification standards are established by the **Association of Official Seed Certifying Agencies (AOSCA)** and administered at the local level by seed certifying agencies. The end-goal is to enable seed companies to produce and market genetically pure seed. Requirements for producing certified seed include special land requirements, planting eligible stock, field inspections, proper seed labeling and

meeting standards based on complete lab analysis. By purchasing certified seed, you are assured of coordinated, professional and unbiased field inspections and laboratory testing. Seed buyers have assurance that the designated seed has met purity standards related to a known description across seed lots and years of production.

The Association of Official Seed Certifying Agencies (AOSCA) member Agencies are allowed to issue certificates and seed tags that assure customers they are receiving quality seed and crop products that have met AOSCA's exacting production and documentation requirements.

AOSCA member Agencies are evaluated to verify that they are conforming to the Association's standards and this provides a consistent system of participating organizations throughout the United States and in other international members. Member agencies include state crop or seed improvement associations (non-governmental), state departments of ag (governmental).

The major purposes of AOSCA are:

- To establish minimum standards for genetic purity and identity and recommend minimum standards for seed quality for the classes of certified seed.
- To standardize seed certification regulations and procedures, and operational procedures in inter-agency seed certification.
- To periodically review agency genetic standards and procedures to assure compliance with the Federal Seed Act.
- To cooperate with seed regulatory agencies in the determination of policy, regulations, definitions or any procedures relating to the labeling and distribution of seed moving in intra-state, inter-state or international commerce.
- To cooperate with the Organization of Economic Cooperation and Development (OECD) and international organizations involved in the development of standards, regulations, procedures, and policies to expedite movement of seed and encourage international commerce in improved varieties.

Determining Sufficient Seed Supply:

The United States Department of Agriculture provides public information related to crop acreage, yields, harvest, weather, and other production information. USDA provides current, unbiased information on prices, volume, quality, condition, and other market data on domestic and international crops. Monthly crop outlook reports are published for selected commodities detailing global market conditions. The Census of Agriculture, taken every five years, is the most comprehensive source of statistics portraying U.S. Agriculture. https://www.usda.gov/topics/farming/crop-production

The U.S. federal, state, or local governments do not play a role in determining necessary seed supply. Seed companies determine volume of seed to supply based on market conditions and economic analysis.

5. Seed industry investment

The only requirements for foreign investment in the U.S. seed industry is that companies follow the rules of conducting business in the United States. Specifically, companies may be subject to anti-trust guidelines determined by the U.S. Department of Justice and Federal Trade Commission. These

guidelines must be followed equally by U.S. headquartered companies. Anti-trust guidelines include provisions against monopolies, price-setting, and collusion. In some cases, corporate mergers and acquisitions are subject to antitrust review, which review the effects of the mergers or acquisition on specific seed and agricultural chemical markets, prices, and innovation.

Whether a U.S. seed company seeks to acquire another U.S. seed company, or a foreign company wishes to acquire a U.S. company, the same transparent, anti-trust process is conducted. Most recently, the German corporation Bayer AG underwent U.S. antitrust review for its acquisition of Monsanto. The Department of Justice determined that Bayer must divest $9 billion in agriculture business as a condition of the deal and to ensure fair competition in the market. Bayer sold assets to BASF in the largest anti-trust divestiture in U.S. history. The European Union also conducted its own antitrust analysis.

6. Seed inspection and quarantine

Import/Export Requirements:

Question two addresses the phytosanitary requirements for imported and exported seed, including inspection and quarantine procedures, if necessary.

Oversight of Biotechnology:

The U.S. system for oversight of biotechnology emphasizes a science and risk-based process and supports innovation. The system is predictable and transparent with the goals of ensuring food and environmental safety.

The process to develop regulations on biotechnology is transparent, with opportunities for stakeholders to submit comments and feedback before the final rule is drafted. After the regulations are finalized, stakeholders can request a review process for products that is open and transparent.

Within USDA, the Animal and Plant Health Inspection Service (APHIS) is responsible for protecting agriculture from pests and diseases. Under the Plant Protection Act, USDA-APHIS has regulatory oversight over products of modern biotechnology that could pose such a risk. Accordingly, USDA-APHIS regulates organisms and products that are known or suspected to be plant pests or to pose a plant pest risk, including those that have been altered or produced through genetic engineering. These are called "regulated articles." USDA-APHIS regulates the import, handling, interstate movement, and release into the environment of regulated organisms that are products of biotechnology, including organisms undergoing confined experimental use or field trials. Regulated articles are reviewed to ensure that, under the proposed conditions of use, they do not present a plant pest risk through ensuring appropriate handling, confinement and disposal.

USDA finalized the update of its biotechnology regulations under 7 CFR Part 340 (Part 340) on May 18, 2020. Under these revisions, USDA regulates genetically engineered organisms, with a broad definition of what is meant by “genetic engineering” (see below). In the final rule, USDA defines two categories of products that would be exempt from a pre-market review:

- Plants with traits that could have been developed through conventional breeding
- Plants with traits for which USDA has already reviewed

Developers can make the determination of whether a plant meets one of these exemptions or they can choose to go through a voluntary confirmation process.

For those plants that do not meet one of the exemptions, there are two possible options:

- Permitting process for the importation, interstate movement, or environmental release; or
- A "regulatory status review" (RSR) to determine whether the plant should be subject to the Part 340 regulations. Those plants determined not to be subject to the Part 340 regulations would be added to the list of exemptions above.

The revised Part 340 also contains a mechanism for petitioning USDA for future exemptions.

Exemptions

Conventional Breeding:

The following categories of plants are exempt because the modification could be achieved through conventional plant breeding:

The plants have been modified such that they contain a single modification of the following types:

(1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or

(2) The genetic modification is a targeted single base pair substitution; or

(3) The genetic modification introduces a gene known to occur in the plant's gene pool,

or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a

known structural variation present in the gene pool.

The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be initiated by USDA or in response to a request by another party. The timeline for petitioning for additional exemptions is 12 months.

Plant-Trait Mechanism of Action

Plants will not fall under Part 340 if:

(1) The plant-trait-mechanism of action combination has previously undergone an analysis by APHIS and has been determined by APHIS not to be regulated under Part 340, or

(2) The plant-trait-mechanism of action combination found has been determined by APHIS

to be deregulated in response to a petition submitted prior to October 1, 2021.

Am I Regulated Process

Plants will not fall under Part 340 if:

The plant as determined by APHIS to not require regulation under Part 340 during the "Am I Regulated" process. These plants will retain their nonregulated status.

There is a 120-day confirmation process that can be used to determine whether a plant meets one of the above exemptions.

Regulatory Status Review

Any person may submit a request to APHIS for a Regulatory Status Review (RSR). When APHIS receives a request for a regulatory status review of a GE plant, APHIS will conduct an initial review to determine whether there is a plausible pathway by which the GE plant, or any sexually compatible relatives that can acquire the engineered trait from the GE plant, would pose an increased plant pest risk relative to the plant pest risk posed by the respective non-GE or other appropriate comparator. The timeframe for the RSR initial review is 180 days.

If APHIS does not find a plausible pathway for a plant pest risk, the GE plant is not subject to the regulations in this part. APHIS will post the plant, trait, and general description of the mechanism of action on its website. If APHIS does find a plausible pathway for a plant pest risk, the applicant can either apply for a permit or ask that APHIS conduct a further review of those pathways of concern.

Other Information on Stewardship:

Seed associations play a role in sharing industry best-practices including on treated seed stewardship and seed quality management programs.

Guide to Seed Quality Management Practices: The Guide was developed by quality management specialists from ASTA member companies and articulates the normal process that developers take to ensure seed quality. https://www.betterseed.org/wp-content/uploads/Guide-to-Seed-Quality-Management2016.pdf

Treated Seed Stewardship: Provides information to those who treat, handle, transport and plant treated seed. https://seed-treatment-guide.com/wp-content/uploads/2019/04/ASTA_SeedGuide_Farmers_Update.pdf

[i] International Seed Federation (ISF), International Community of Breeders of Asexually Reproduced Horticultural Plants (CIOPORA), Crop Life International (CLI), Euroseeds, Asia and Pacific Seed Alliance (APSA), African Seed Trade Association (AFSTA) and Seed Association of the Americas (SAA)