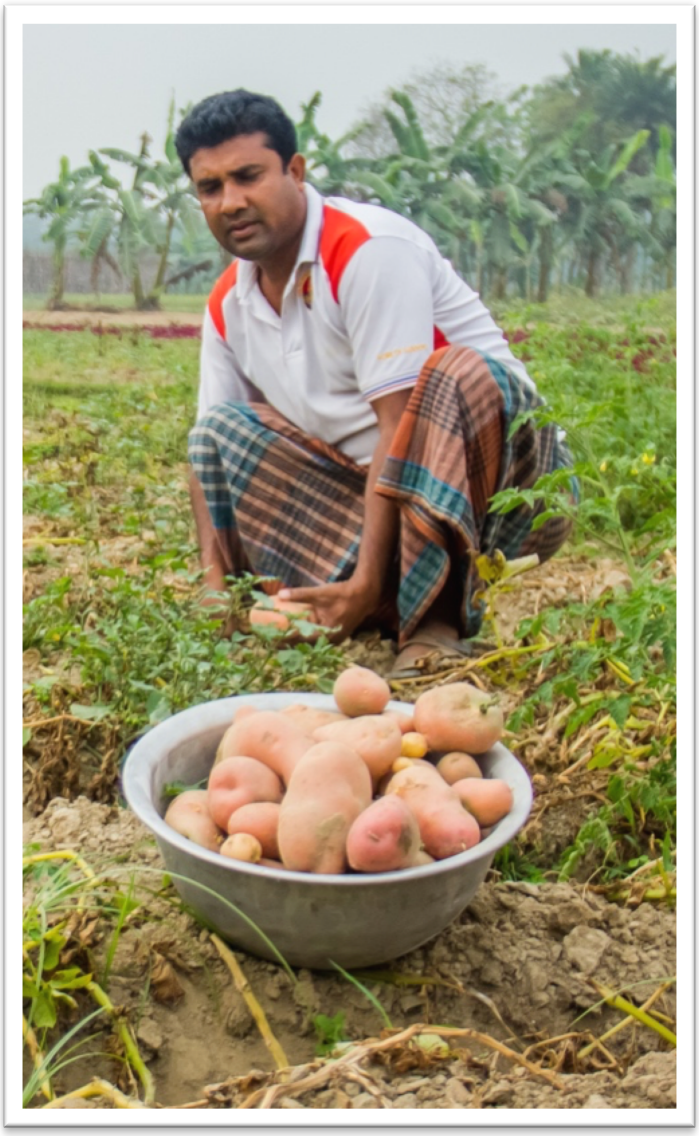
FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative

BIOTECHNOLOGY POTATO PARTNERSHIP
Science Based Answers to Sustaining Farmers, Solving Hunger and Securing our Planet



ANNUAL REPORT 2017

ACTIVITIES AND ACCOMPLISHMENTS

USAID FROM THE AMERICAN PEOPLE
UNIVERSITY OF MINNESOTA
Simplot
MICHIGAN STATE UNIVERSITY

"Hunger is not an issue of charity. It is an issue of justice."

– Jacques Diouf, Senegalese diplomat and former Director General of the United Nations' Food and Agriculture Organization

Feeding our world is the responsibility of all humankind. It is an ever changing, ever growing uphill battle. According the UN, current world population is 7.6 billion and is projected to reach 9.8 billion in 2050, and 11.2 billion by 2100. Our world adds 83 million new mouths to feed, minds and bodies to grow, each and every day.

America's initiative to combat global hunger and poverty, Feed the Future, was born of the belief that global hunger is solvable. Partnering with bright minds and passionate hearts around the world to create greater global food security through innovative research in agriculture, Feed the Future is fighting hunger with science and technology.

The Feed the Future Biotechnology Potato Partnership is a five-year, $5.8 million, cooperative agreement with USAID to introduce bio-engineered potatoes in farmer and consumer preferred varieties to smallholder farmers in Indonesia and Bangladesh. These biotech potato products, developed through gene insertion and gene silencing methods, offer broad-spectrum resistance to Late Blight (*Phytopthora infestans*), the most devastating potato disease in the world.

The Feed the Future Biotechnology Potato Partnership is multi-institution collaboration between USAID, Michigan State University (MSU), the University of Minnesota (UMN), the University of Idaho, and the J.R. Simplot Company. The partnership includes in-country collaborators the Bangladesh Agricultural Research Institute (BARI), the Indonesian Center for Agricultural Biotechnology Genetic Resources Research and Development (ICABIOGRAD), the Indonesia Vegetable Research Institute (IVEGRI), and the International Potato Center (CIP). The Feed the Future Biotechnology Potato Partnership also provides strategic human and institutional capacity building support to in-country partners to ensure sustainable use of agricultural biotechnology for future generations.

PROJECT GOALS

The Partnership aims to achieve the following goals within our target countries of Bangladesh and Indonesia:

- Produce, deregulate, and commercialize farmer-preferred varieties of potatoes transformed with a three-gene stack of late blight resistance genes.
- Increase institutional capacity in biotechnology, biosafety and product stewardship within governmental agencies.
- Implement a communications strategy to inform the public and stakeholders of the benefits of the late blight resistant (LBR) potato and genetically modified crops.
- Develop international biosafety standard operating procedures for commercialized genetically modified (GM) potato seeds produced through the project.

The social impact of the project will contribute to the goals of:

- Improving health and reducing malnutrition.
- Reducing the use of harmful pesticides.
- Reducing pre-and post-harvest losses.
- Improving the social and economic standing of women.
- Catalyzing economic growth.

PROJECT HIGHLIGHTS

The Partnership continued to gain traction in fiscal year two and made progress in implementing 11 main activities of the grant. These activities focused on networking, developing and executing formal agreements, and strengthening project management communication. Technical progress included testing, validating and deregulating biotech potato materials. Capacity building focused on the design, implementation and training for biotech, regulatory, and product stewardship.

TECHNICAL

The development of genetically modified potatoes is a multi-step process where specific gene(s) are inserted into the DNA of preferred varieties. This gene modification introduces a single gene to achieve a desirable trait. For example, the gene may provide disease resistance, insect resistance, nutritional enhancement, drought tolerance, etc. Introducing multiple genes can result in a more sustainable desirable product.

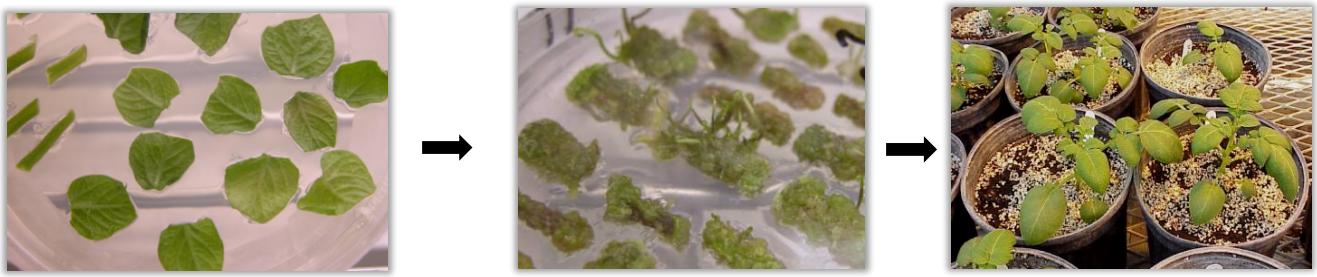
Genetic modification includes many steps. The first step is the identification and selection of the desired gene(s). A vector construct must then be engineered to deliver the identified genes into the plant properly. This insertion of the vector into the target cell is called transformation.

The technical team made great strides in many areas during the last fiscal year. Early in our project we completed a vigorous selection of R-genes, completed vector construct engineering and used input from partner countries to identify varieties to receive the transformations. We immediately began potato transformation. Hundreds of transformations were made in each variety. The transformed plants were grown in the greenhouse and underwent further testing including detached leaf bioassays (DLB). DLB involve taking leaves from a plant and exposing them to a pathogen or insect, in our case, late blight isolates. The exposed leaves are monitored for a period of time and analyzed to determine if the plant is susceptible or resistant.

Visual effects of late blight disease.

This year a selected number of transformations were then grown in confined field trails. These trials provide insight into how the modified plants will perform in the field under conditions that are ripe for late blight. Further studies are required in the development of our products and we will be completing them in the upcoming years. For example, additional molecular characterizations will be performed on the selected transformations. These characterizations identify the difference between the genetically modified plant and its conventional counterpart. This characterization confirms that the transformation occurred as intended. Additional field trials and product safety testing will be completed to ensure environmental and human well-being.

Development of a Genetically Modified Potato



Potato transformation process (Agrobacterium)

Greenhouse evaluations

Confined Field Trials

Product safety evaluations

During this fiscal year, the technical team focused on four potato events:

1. SIMPLOT 3 R-GENE LBR POTATO

The Partnership, conjunction with our private sector partner, Simplot Plant Sciences, developed, evaluated, and selected the best multi-gene construct with three different Late Blight resistance genes that will provide superior and durable resistance to the disease.

2. LEGACY POTATO

At the request of USAID, the Partnership is continuing work on the Legacy potato, a single R-gene late blight resistant potato developed under a previous USAID project with Cornell University's Agricultural Biotechnology Support Project (ABSP) II (now relabeled as the Legacy Potato). A major accomplishment was the completion of the full molecular characterization of the Legacy potato event. Understanding the genetic makeup of the transformed potato will provide key information in making future decisions on the release of this potato.

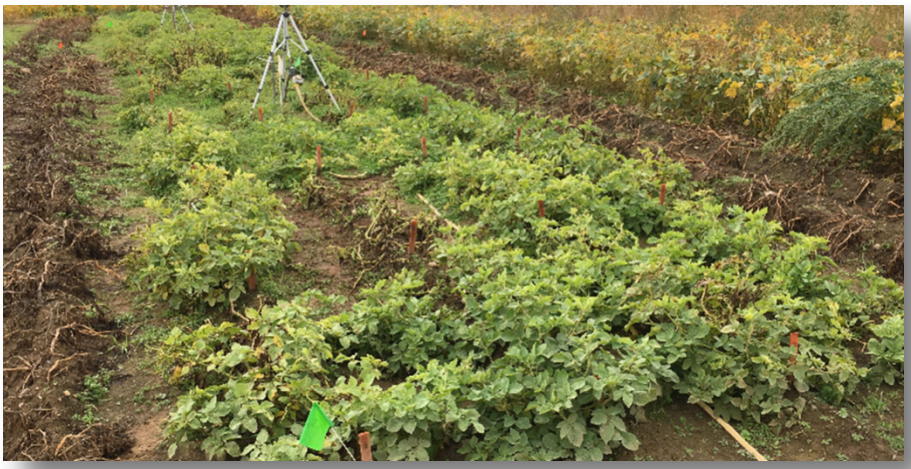
3. CIP'S 3R-GENE LBR POTATO

This year the project also provided leadership in testing and evaluating a 3 R-gene construct potato developed by The International Potato Center (CIP). The MSU technical team transformed the 3 R-gene construct into a Late Blight susceptible variety. Fifteen events were selected and field tested by MSU. The CIP 3R-gene LBR potato showed high levels of resistance to the late blight disease and further testing will continue.

4. VENGANZA'S RNA-I POTATO

Potato events with RNA-I gene silencing technology, developed by Venganza corporation, was also tested for late blight resistance at MSU in field trials and using detached leaf bioassay (DLB). RNA interference (RNAi) is a biological process in which RNA molecules inhibit gene expression or translation, by neutralizing targeted mRNA molecules. RNA is very similar to DNA. The results of this potato's DLB was compared against non-transgenic and the 3 R-gene plants exposed to late blight. The results showed that the Venganza events with the RNA-I constructs did not provide significant resistance to late blight.

Michigan State University Field Trial, Clarksville Research Center in Clarksville, MI



This photo shows two rows (on right and left) of non-transgenic Atlantic variety plants completely succumbed to Late Blight. The center four rows show the 3R-gene potato completely resistant. The affected plants in the middle of this section are the single gene potato which showed little to no resistance.

Non-transgenic Atlantic variety plants devastated by Late Blight.

Single gene plants showing a serious infection of Late Blight.

3R-gene plants showing high level of resistance to Late Blight.

REGULATORY

The regulatory component is critical for any biotech project. International repercussions affecting a nation's trade and economy can be jeopardized if the proper protocols are not in place and followed. The partnership regulatory team ensures that all in-country research and development is carried out in compliance with internationally accepted practices, standards and national biosafety regulations.

Regulatory activities for this project are aligned with the technical activities:

1. SIMPLOT 3 R-GENE LBR POTATO

The Partnership's private sector partner, Simplot Plant Sciences, received regulatory approval in the US for its single R-gene LBR potato (also stacked with other GM traits). The information submitted by Simplot for regulatory approval in the US is being used to inform the planning and development of the regulatory package for the Partnership.

2. LEGACY POTATO

A review of the available regulatory data and information generated from the ABSPII project in both partner countries was completed by the regulatory team. Additional data needs were identified, and plans to collect this data were made in both countries, including plans to collect the additional molecular characterization data of Legacy potato, which was completed by the partnership's Technical Team at MSU.

3. CIP'S 3R-GENE LBR POTATO

Plans were initiated to import the CIP 3-gene material from Kenya for testing in both Bangladesh and Indonesia. Efforts to obtain import approvals from the regulatory authorities are on-going.

In anticipation of project imports and field trials in both partner countries, the reviewing, updating and implementing of standard operating procedures (SOPs) is an ongoing activity for the regulatory team. A series of meetings were held this year with in-country partners to review existing SOPs and draft additional SOPs. The Regulatory Team will ensure that there is a complete set of SOPs and partners are trained before there is a field trial for the project in either country.

HUMAN AND INSTITUTIONAL CAPACITY DEVELOPMENT

The development and deployment of biotech crops require a range of technical skills over the life cycle of this grant and beyond. Enhancing the technical skills of the in-country scientists was the focus of the project's HICD efforts this year.

A training workshop for members of the Feed the Future Biotechnology Potato Partnership was successfully held at ICABIOGRAD in Bogor, Indonesia in January 2017. Approximately 50 participants from the US, Bangladesh and Indonesia attended.

Intensive follow up training of the technical core teams from Bangladesh and Indonesia was carried out at MSU in summer 2017. The training highlighted a "learning by doing" approach and offered technical and practical laboratory, greenhouse, and field skills to the scientists of both countries. Training was specifically tailored for each individual with the goal of getting them to understand their specific role for delivering the expected outcomes of the partnership. The training featured a strategic mix of lectures, hands-on laboratory and field activities, interactive discussions, knowledge and experience sharing with technical team members

from partner universities. Practical site visits were taken to MSU's CFT trials in various locations in Michigan and to Simplot corporate headquarters in Boise, ID. The training content and materials were also designed so that the scientists can share them with their colleagues in their home countries.

Knowledge and technical skills surveys were collected to help training providers refine follow up activities. Each scientist also submitted post-training or exit survey to indicate skills, knowledge and new information they obtained from the training. Learning and change in behavior or competencies were statistically measured, whenever possible. Free online resources and training opportunities continue to be shared to ICABIOGRAD and BARI scientists as part of the knowledge sharing and capacity building component of the grant.

SOCIO-ECONOMIC DIMENSION

Impact assessments encompassing socio-economic and environmental considerations are important to determine the costs and benefits associated with biotech potato in comparison to alternative technologies and to encourage acceptance of the innovations by farmers in project countries. To support the socio-economic assessment and impact evaluation for biotech potato products, efforts for this fiscal year focused on the development of a survey for evaluation and approval by the Institutional Review Board (IRB) to be implemented by trained and certified surveyors in selected regions of Bangladesh and Indonesia in order to create a baseline against which to measure the impact of the three R-gene late blight resistant potato. These results will provide critical benchmark success objectives.

COMMUNICATIONS

Effective communications, advocacy and strategic partnerships among active players in communicating biotech products are crucial to the ultimate success of the project. Acceptance of biotech products by farmers and consumers, along with a positive media environment for all USAID Feed the Future agriculture biotechnology products is a shared goal. In support of this goal, a strategic communications alliance between the Partnership; Cornell's Alliance for Science, which supports the transgenic Bt brinjal project in Bangladesh; and Seed Stories, private sector communications company; was established.

Communications Workshop, Dhaka, Bangladesh

This new alliance conducted a communications workshop in August, 2017 in Dhaka, Bangladesh. This workshop aimed to identify communication needs and develop a comprehensive communications strategy to support the Feed the Future biotech projects; brinjal and potato in Bangladesh. The workshop featured a stakeholder's meeting attended by more than 45 participants which included representatives from other biotech projects operating in Bangladesh. The communications alliance is looking to expand its membership to include these additional biotech projects.

Timely and effective communications are an essential component of the Partnership. The hiring of the Communications Lead for the last quarter of this year enabled the project to enhance many communications activities. These included a presence on social media, the establishment of regular internal and external communication with team personnel and stakeholders and improvement of the Partnership website.

In addition, a competitive grant proposal featuring the biotech potato and CRISPR-Cas 9 was also developed and submitted to USDA-NIFA for funding. This proposal, when funded, will help in reshaping science communications of emerging plant biotechnologies such as the biotech potato in social environments.

INTELLECTUAL PROPERTY

Biotechnology products, which may or may not be associated with intellectual property rights (IPR) can affect the project's access, use, technology transfer, and commercialization of these products. To better understand how IPR impacts the Partnership, an initial mapping of the various genes used in biotech potato, including their owners, was conducted this year. Working off that framework, material transfer requests were developed to facilitate use of the materials for this project. In cooperation with MSU Technologies, an MTA for the three-gene technology owned by the Simplot Company was drafted, refined and approved by MSU's and Simplot's authorized representatives. Other agreements are also under draft and review.

SUMMARY

Why potatoes? Potatoes feed the hungry! They are the third most important food crop in the world behind wheat and rice. The potato produces more nutritious food, more quickly, on less land, and in harsher climates than any other major crop. They contain no fat, sodium or cholesterol. One potato provides nearly half an individual's daily need of Vitamin C and includes more potassium that a banana.

Food security is more than agriculture, 75% of the world's poor live in rural areas in developing countries. Most of these people rely directly on agriculture for their livelihoods. Smallholder farmers, working less than five hectares of land, make up 2.5 billion people. Studies show that growth in the agriculture sector is, on average, at least twice as effective at reducing poverty as growth in other sectors.

The Biotechnology Potato Partnership will continue to work to provide science based answers to sustaining farmers and solving hunger to secure our planet and future. Year three is expected to provide many exciting advances and accomplishments.

For more information on our project please visit our website at www.canr.msu.edu/biotechpp