

Animal and Plant Health Inspection Service
Biotechnology Regulatory Services



Strategic Plan FY2015-FY2018

*Protecting plant health through the
regulation of genetically engineered organisms.*



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BRS STRATEGIC PLAN FY 2015 - FY 2018

INTRODUCTION

Since 1987, the Animal and Plant Health Inspection Service (APHIS) has been protecting plant health through the regulation of genetically engineered (GE) organisms. Through its Biotechnology Regulatory Services (BRS) program, APHIS BRS has authorized more than 38,000 permits and notifications for the safe introduction—importation, interstate movement, and environmental release (field testing)—of GE organisms. In that period we have deregulated under the Code of Federal Regulations (7 CFR part 340) more than 100 GE crops after determining they do not pose a risk to plant health.

Consistent with APHIS initiatives, in the years ahead we're committed to developing alternatives to regulation to address regulatory issues when regulatory approaches are not necessary to achieve plant protection. Examples include clear and effective guidance, stakeholder outreach, workshops, compliance assistance, and ongoing review of our existing regulations with an eye toward policy adjustments informed by science and our own experience. In addition, we will work to bring oversight and risk into closer alignment, while still protecting plant health.

As we move forward, we'll continue to ensure that our regulatory actions are supported by the best available science. Our science-based approach allows for the safe development and use of agricultural products derived from new technologies that provide increased production options to agricultural growers around the world. In addition, we will continue to embrace an open exchange of information among government officials, experts, stakeholders, and the public.

This BRS Strategic Plan outlines our strategic goals and objectives to accomplish our mission from FY 2015-FY 2018. It describes our vision, mission, goals, and challenges as we work to protect plant health and aligns with the strategic goals in the USDA and APHIS Strategic Plans. This Plan outlines just one piece of what APHIS does to protect plant health, and ultimately what USDA does to enhance America's ability to safely produce and trade agricultural products.

BRS uses the strategic goals outlined here to develop annual operational goals that keep us focused and accountable. We also use the annual operational goals to identify individual performance goals for each employee so each staff member understands his/her role in achieving our strategic goals. Our Plan also includes the measures we use to assess the overall effectiveness of our program.

As we move forward over the next four years, we will continue to look for ways to improve our operations while maintaining a high standard of excellence and accountability to the American public.

MISSION, VISION AND VALUES

MISSION

Protect and enhance U.S. agricultural and natural resources using a science- and risk-based regulatory framework to ensure the safe importation, interstate movement, and confined environmental release of regulated GE organisms.

VISION

To serve as a global leader in the science-based regulation of biotechnology products through a framework that balances oversight and risk to protect plant health, while facilitating scientific innovation, embracing an open exchange of information, and earning public trust.

VALUES

We embrace the following values and seek to demonstrate them as we carry out our mission:

- **Accountability:** We maintain a standard of excellence and accountability to the American taxpayer by protecting plant health; delivering our services more efficiently; and by reporting our performance measures in a way that is timely, transparent, and accessible.
- **Communication:** We provide clear and timely communication to our wide diversity of stakeholders and the public, and we seek and value the input of all.
- **Coordination:** We coordinate with federal partners and agencies, tribes, states, the international community, and stakeholders in the effort to protect plant health.
- **Flexibility:** We provide flexible oversight that accommodates the evolving nature of emerging technologies.
- **Scientific Integrity:** We consider the best available science when making regulatory decisions.
- **Respect for People:** We value and respect the diverse views of all in our regulatory actions. In addition, we value and respect our staff. We support them in their career development, share information in a respectful way, and address their questions and concerns.
- **Persistence and Perseverance:** We are steadfast in the pursuit of achieving our goals, taking on challenges and doing our jobs to the best of our abilities.
- **Excellence:** We commit ourselves to high-quality performance and continuous timely improvement that produces outstanding results of lasting value.

ABOUT BRS

USDA's Animal and Plant Health Inspection Service has been regulating biotechnology since 1987, and in 2002, created BRS as a dedicated program to regulate the introduction—that is, the importation, interstate movement, and environmental release—of GE organisms that may pose a risk to plant health. BRS gets its authority from the Plant Protection Act and oversees GE organisms in accordance with APHIS' biotechnology regulations, 7 CFR part 340.

APHIS BRS regulates GE organisms as part of a Coordinated Framework established by the White House Office of Science and Technology Policy in 1986. As part of this framework, we work in partnership with the Environmental Protection Agency, and the Food and Drug Administration to ensure that the development and use of GE products occur in a manner that is safe for plant and animal health, human health, and the environment.

CHALLENGES

We have developed this Strategic Plan in the context of a number of driving forces that provide challenges in the years to come.

Challenge 1: Rapidly Changing Technology

In the rapidly changing field of biotechnology, we are challenged to adapt and find new ways to accomplish our regulatory work, while not inhibiting the development of new products produced with new technologies. In the years ahead, we are committed to developing alternatives to regulation that help us improve our processes in the least burdensome manner possible, while protecting plant health. In addition, we will work to bring oversight and risk into closer alignment, applying our resources where risk is greatest. We will also continue to provide clear and effective guidance and compliance assistance that account for scientific advances.

Challenge 2: Increasing Demands from Stakeholders and Customers

BRS has a wide diversity of stakeholders that hold strong opinions about biotechnology and how we regulate it, and we operate in an environment of budgetary restraint. Our challenge is to deploy resources to maximize effectiveness in achieving our mission. For us this means increasing our data and analytics capacity to improve our operational decision making. In addition, we will become more proactive in engaging our stakeholders to better understand their perspectives and so they can gain a better understanding of our regulatory responsibilities. Improved communication and outreach strategies will contribute to building this mutual understanding.

Challenge 3: Regulatory Climate

In recent years it has become increasingly difficult to gain approval for new regulations as they are often viewed as being an increase in regulatory burden and expense. We will address this challenge by developing alternatives to regulation that may include education and outreach initiatives, better compliance assistance, and flexible and creative approaches to applying existing regulations. We will work closely with our stakeholders to explore these and other alternatives.

Challenge 4: Unforeseen Regulatory Incidents and Threats

BRS has developed and implemented several mechanisms to manage and respond to regulatory incidents and threats. We provide compliance assistance, conduct thorough inspections, and have fast-acting enforcement capabilities to respond to incidents. When regulatory incidents and natural disasters threaten U.S. agriculture, BRS responds to address the emergency. We also take proactive measures to remind regulated entities about requirements to self-report any loss of confinement. BRS has developed strong partnerships with other APHIS programs, primarily Plant Protection and Quarantine (PPQ), and Investigative and Enforcement Services (IES) to assist in inspection, investigative, and enforcement activities. BRS works cooperatively with USDA partners, including Agricultural Marketing Service; Grain Inspection, Packers and Stockyards Administration; and Agricultural Research Service, when incidents or threats involve genetic testing or forensics. We also rely on State Departments of Agriculture to notify BRS when an incident occurs, and to help implement remedial measures. In the years ahead, BRS will work to balance resources and enhance partnerships and preparedness, to increase our ability to respond rapidly to compliance incidents and emergencies.



Challenge 5: Resource Limitations and Workforce Needs

BRS is challenged to work within its available resources, and to attract and retain a highly qualified workforce to ensure the protection of plant health. This challenge requires us to continue to improve and streamline work processes, and to take advantage of information technologies to build productivity. To attract and retain a highly qualified workforce, BRS must ensure that its employees are challenged and valued; assigned where their skills are most in demand; given opportunities for development; provided with the necessary tools and information; and that they receive high-quality leadership and administrative support. In the years ahead, we will focus on these and other issues, including those identified in the annual Federal Employee Viewpoint Survey, a survey that provides employees with an opportunity to provide feedback on work environment and processes.

Challenge 6: Global Demand for Agricultural Products

Agricultural industries around the world are looking to biotechnology to help meet the Nation's and the world's need for food security, energy production, carbon offsets, and the economic and environmental sustainability of farms. BRS will maintain the rigorous regulation of GE crops to protect plant health while also enhancing America's ability to trade products of emerging biotechnology that increase global food security. We will identify and consider both regulatory approaches and alternatives to regulation that reduce burdens and maintain flexibility and freedom of choice for the public. As we move forward with our initiatives, we will continue to ensure that our regulatory decisions are based on the best available science.



STRATEGIC GOAL MATRIX

USDA STRATEGIC GOAL 3.2			
Enhance America's ability to develop and trade agricultural products derived from new and emerging technologies.			
↓			
APHIS STRATEGIC GOAL 4			
Ensure the safety, purity and effectiveness of veterinary biologics and protect plant health by optimizing our oversight of GE organisms.			
Objective 4.1			
Ensure that regulated GE organisms will not pose plant pest risks when released into the environment.			
↓			
BRS STRATEGIC GOALS			
Enhance compliance with APHIS biotechnology regulations	Balance regulatory oversight and risk of genetically engineered organisms	Ensure the best science is used in decision-making	Create a highly effective organization
↓	↓	↓	↓
STRATEGIC OBJECTIVES			
<ol style="list-style-type: none"> 1. Enhance compliance through strong regulatory operations. 2. Provide science- and risk-based guidance and assistance to maintain compliance. 3. Respond effectively to emergencies, regulatory events, and compliance incidents. 	<ol style="list-style-type: none"> 1. Advance alternatives to regulation to achieve safeguarding goals, while focusing on greatest risk. 2. Employ a consistent and predictable system for deregulating under 7 CFR part 340 biotechnology products that do not pose a plant pest risk. 3. Advance regulatory approaches that are achievable and focus on greatest risk. 	<ol style="list-style-type: none"> 1. Use high-quality analysis in decision-making. 2. Respond to rapidly changing science. 3. Coordinate with government partners and the international community to engender science- and risk-based regulation of GE organisms domestically and abroad. 	<ol style="list-style-type: none"> 1. Maintain effective and efficient internal processes and procedures. 2. Demonstrate value to taxpayers through responsible management of budget and by monitoring performance. 3. Attract and retain a high-quality workforce. 4. Ensure consistent, timely, and accurate communication to stakeholders. 5. Employ technology to ensure effective business systems.

STRATEGIC GOALS AND OBJECTIVES

Goal 1. Enhance Compliance with 7 CFR part 340

Compliance with APHIS biotechnology regulations is the foundation for protecting plant health. BRS has strong regulatory operations comprised of high quality inspections, prompt and consistent enforcement, clear guidance, and outreach and education. During the next four years, BRS will continue to enhance its regulatory operations, provide science- and risk-based guidance and assistance to regulated entities, and develop emergency response plans for compliance incidents.

OBJECTIVES

1. Enhance compliance through strong regulatory operations.

Through our regulatory operations, we manage authorizations (i.e., notifications and permits); maintain records of notifications and permits; manage compliance inspections; and respond to regulatory incidents and potential threats. During the next four years, BRS will continue to develop documented policies and processes and implement process improvements; increase inspections based on risk; develop new database reporting mechanisms for compliance incidents; enhance federal and state partnerships; and provide updated training to partners, stakeholders, and BRS staff.

2. Provide science- and risk-based guidance and assistance to maintain compliance.

BRS offers several tools to help authorized persons comply with APHIS biotechnology regulations. We know that establishing partnerships with our regulated entities through outreach, education, and guidance strengthens compliance with our regulations and encourages self-reporting. We also provide compliance assistance through our Biotechnology Quality Management System (BQMS) Program by helping regulated entities develop a management system to address critical control points in their work processes. During the next four years, especially as we develop alternatives to regulation, we will continue to provide updated, transparent and effective guidance; deliver compliance assistance and education activities to key stakeholders; and provide compliance assistance services.

3. Respond effectively to emergencies and compliance incidents.

Over the last 20 years, BRS has responded to numerous regulatory incidents and threats. As a result, we have gained experience effectively managing such occurrences. Each experience helps us improve our processes to ensure the protection of plant health and the agricultural market. During the next four years, we will continue to build on this experience, and to improve regulatory enforcement activities by establishing and enhancing federal and state partnerships and preparedness, identifying and implementing process improvements, developing a compliance incident response plan, and providing training for partners, stakeholders, and BRS staff.

Goal 2. Balance Oversight and Risk in the Regulation of GE Organisms

To deliver maximum value to taxpayers, BRS strives to provide regulatory oversight that is commensurate with plant health risk, so resources are expended where risk is greatest. In the years ahead, we will develop alternatives to regulation to improve our operations, addressing regulatory issues in the least burdensome manner possible. In addition, we will work to bring oversight and risk

into closer alignment, while protecting plant health.

OBJECTIVES

1. Advance alternatives to regulation to achieve safeguarding goals, while focusing on greatest risk.

Within the structure of our existing regulations, we will develop alternatives to regulation based on the best science available, and informed by our extensive experience in regulating GE organisms. They will include evaluating flexible and creative approaches to applying our existing regulations. In addition, we will consider enhanced guidance, and increased educational outreach including workshops and compliance assistance.

2. Employ a consistent and predictable system for deregulating under 7 CFR part 340 biotechnology products that do not pose a plant pest risk.

In FY 2012, BRS implemented a revised process for petitions for deregulation with defined deadlines, resource management and tracking tools, and earlier and more frequent opportunities for public input. During the next four years, BRS will continue the timely processing of petitions using this revised process, with the aim of protecting plant health while producing greater predictability for those seeking determinations of nonregulatory status for GE organisms.

3. Advance regulatory approaches that are achievable and focus on greatest risk.

In 2008, BRS published a proposed rule for its biotechnology regulation, and received more than 66,000 comments. The comments were reviewed extensively and continue to guide our work. During the next four years, BRS will focus our resources on areas of greatest risk, as determined by science and informed by our own 28 years of experience in regulating GE organisms.

Goal 3. Ensure the Best Science is used in Decision-making

As part of our mission to protect plant health, BRS works to ensure that our regulatory actions are supported by the best available science. In the years ahead we will continue this emphasis on high-quality scientific analysis in decision-making through a strong risk assessment framework. In addition, we will coordinate with government partners and the international community to engender science- and risk-based regulation through coordination, outreach, and capacity building.

OBJECTIVES

1. Use high-quality analysis in decision-making.

We employ a science-based risk assessment framework that enables sound decision-making. During the next four years, we will strengthen our risk assessment models to focus even more precisely on those GE organisms that pose a risk to plant health. These analyses will enable us to make decisions that are scientifically sound and earn public trust.

2. Respond to rapidly changing science.

The science of biotechnology is advancing rapidly. Our job is to closely monitor the advancements in science while ensuring that new GE organisms do not harm plants. Our goal of science-based decision-making requires us to keep up with the development of new

technologies, and to conduct science-based policy analysis in consideration of the latest developments. During the next four years, we will continue to stay abreast of scientific innovation, evaluate new technologies, and adapt our regulatory system where appropriate. We will also provide appropriate and timely guidance reflecting the advancements of the science.

3. Coordinate with government partners and the international community to engender science- and risk-based regulation of GE organisms domestically and abroad.

As part of our effort to protect plant health, BRS coordinates with federal and state government partners, tribal partners, and the international community to foster the science- and risk-based regulation of GE organisms. BRS will continue to reach out to a variety of domestic partners and international stakeholders—including tribes, developing countries, key trading partners, and international organizations involved in biotechnology policy and research. We will continue to participate in international standard setting activities, international regulatory developments, capacity building, and work with our federal partners to encourage the safe development and trade of GE organisms, based on the best science available.

Goal 4. Create a Highly Effective Organization

BRS recognizes that it must effectively manage its resources to successfully carry out our mission and to accomplish the objectives of its three other strategic goals. We require the necessary tools to carry out our mission, such as software, IT infrastructure, work processes and management systems. In the years ahead, BRS will continue to refine and implement internal processes, and procedures; manage our budget responsibly and track performance; develop and implement strategies to attract and retain a high-quality workforce; continue to ensure consistent, timely, and accurate communication to stakeholders; and employ appropriate technologies to maintain effective and efficient work processes.

OBJECTIVES

1. Maintain effective and efficient internal processes and procedures.

BRS must maintain document and work management systems (including standard operating procedures) that are clear, establish consistency, and support program goals and objectives. BRS will conduct internal quality audits and business process improvement reviews to effectively evaluate and improve business and system processes and workflows. In the next four years, BRS will continually evaluate business processes to improve program delivery ensuring best practices are identified and adopted. We will continue maintenance and support of BRS' International Organization for Standardization (ISO) 9001-2008 Quality Management Systems to ensure compliance with ISO's performance requirements; develop written policies and directives that help promote consistency and quality of service to stakeholders and clearly defined program procedures for employees; develop program resources using Microsoft SharePoint to manage documents; and better align IT support with business informational needs and requirements.

2. Demonstrate value to taxpayers through responsible management of budget and by monitoring performance.

BRS places great emphasis on fiscal responsibility, especially during times of economic uncertainty. BRS measures results and outcomes, and maintains a high level of quality control

and accountability. In an effort to demonstrate accountability to taxpayers, BRS develops annual operational goals in alignment with the strategic goals identified in this document. We also develop quarterly milestones to help keep track of our progress. We measure our progress and program effectiveness with clearly defined measures that directly relate to the work we do every day. In the next four years, BRS will continue to refine its process for tracking performance, including the development of processes and systems for capturing and measuring data. BRS will also continue to identify opportunities for cost savings, including participating in the APHIS-wide initiative to replace our ePermits system with a more robust and cost-effective solution.

3. Attract and retain a high-quality workforce.

In an effort to attract and retain a high-quality workforce, BRS invests in our staff and work environment. BRS must first ensure all employees have the necessary knowledge, skills, and tools to effectively carry out our mission. Additionally, we provide channels for employee feedback, conflict resolution, and develop strategies for change management. We also equip managers with requisite abilities to effectively support employees. BRS also develops administrative policies and processes that are fair and flexible to help employees balance home and work lives. Finally, employees must clearly understand their performance expectations, be held accountable, and be recognized for excellent performance. During the next four years, BRS will develop strategies to address issues identified in the Federal Employee Viewpoint Survey, and examine our performance management platform to ensure that it motivates and rewards employees for high performance in a way that is consistent and fair, and holds them accountable.

4. Ensure consistent, timely, and accurate communication to stakeholders.

Ours is a regulatory system that emphasizes public participation and an open exchange of ideas. In supporting these principles, BRS develops regulatory documents and provides multiple opportunities for stakeholder involvement. We value, respect, and actively seek diverse stakeholder input, and rely upon it to create regulatory documents that consider all relevant issues. Public participation is important for promoting accountability, improving decisions, increasing trust, and ensuring that we have access to widely dispersed information. In the years ahead, BRS will continue to focus on consistent, timely, and accurate communication to stakeholders, to include the public, non-profits, the regulated community, the States, and Federally Recognized Tribes. We will expand our use of technology, providing “virtual” public comment meetings online that enable a geographically-wide range of stakeholders to participate in the process. In addition, we remain committed to providing relevant documents in time for stakeholders to examine them carefully and make fully informed comments.

5. Employ technology to ensure effective business systems.

BRS must have adequate technological infrastructure to carry out our mission. Without high-quality systems, the best policies, procedures, and scientific data cannot be effectively shared with or used by the scientific community, the public, or regulated entities. BRS currently uses the ePermit system for applicants to apply for permits and notifications. In the next four years we will transition to a far more comprehensive and effective system that will provide greater capabilities and management tools to enhance productivity. BRS continually identifies IT needs and ways to improve our current infrastructures to meet the



needs of our staff and stakeholders. These include new SharePoint systems to manage and track petitions and documents.