Review of
The United States Department of Agriculture
Animal Plant Health Inspection Service
Biotechnology Regulatory Services

By
The National Plant Board

February 15, 2006

Executive Summary:

The USDA, APHIS, Biotechnology Regulatory Services (BRS) unit requested that the National Plant Board (NPB) gather state input regarding biotechnology issues. BRS wanted this information to help them revise their current regulations to better address the needs and concerns of state regulatory officials. Forty-three States responded to a questionnaire that gathered input in eight major areas:

- Implementation Roles,
- State and Local Legal Authority,
- Communication and Coordination,
- Information Access,
- Education,
- Compliance and Inspections,
- Process, and
- Public Perception.

As the committee summarized and analyzed the data, the following emerged as overarching issues:

- Communication,
- Roles and Responsibilities, and
- Education

The primary authority for biotechnology regulatory activities in the United States is based on the Executive Office of the President, Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology. This framework was developed in the late 1980's and depends primarily on the existing statutes. This committee focused on the existing authority within the USDA, APHIS Plant Protection Act for this document. In addition, several states have enacted laws providing state regulators authority for biotechnology. Those states not having specific laws have limited biotech regulatory authority. The survey indicates that most states desire to be routinely involved in BRS permitting and inspection activities. There is a need to develop a mechanism to identify state and federal responsibilities, in order to deal with such interactive issues as compensation, training, access to information and potential liability.

Relative to Authority, the appropriate role of states and local government to participate with BRS in regulating genetically modified organisms is not clearly defined. The majority of states feel the permit conditions stipulated by USDA are adequate, but the lack of availability of Confidential Business Information (CBI) and its protection were identified as concerns by a number of respondents. The vast majority of respondents stated that BRS should extend its scope to cover more organisms. About 75% of the states felt that BRS authorization for interstate movement and importation of regulated articles is desirable and 50% of the states support automatic authorization as long as BRS is notified prior to the movement of the regulated articles. However, most states are not supportive of exempting whole classes of modified organisms.

Communication and coordination between state plant regulatory officials (SPROS) and BRS are viewed as essential to the successful operation of the biotechnology regulatory program. Approximately half of the respondents felt the level of communication was not adequate for addressing both state specific issues as well as general program information. Over half the states indicated that they did not receive the necessary information to review permit applications or assist in inspection and enforcement activities. The majority of states said they preferred to have secured access to BRS information electronically. CBI access and security may limit a state's participation in the review process.

Education and training for state cooperators involving basic biotechnology principles and the duties and responsibilities of BRS are viewed as critical to state's continued participation. It is clear from the response that periodic, face-to-face training is essential. Most state officials believe their level of expertise is not sufficient to thoroughly evaluate the technical aspects of applications for permits. Comments received indicate a need for additional training tools to better address the educational needs of the various target audiences including policymakers, stakeholders, and the general public.

Responses to State-Federal communication and cooperation of inspections indicated varying levels of understanding and the need for additional training and interaction. States were split on the level of familiarity of the inspection procedure. State officials are pleased with the current BRS initiative to work more closely with SPROS. States want to be aware of the inspections in their states, invited to participate, and receive final results of compliance activities.

States often are placed in the position of advocating for the health and safety interests of agriculture and citizens. Most states conduct stakeholder meetings with grower groups, consumers, legislators, and environmental organizations to maintain a sense of the social and economic concerns. Respondents expressed the desire to proactively address public concerns through research and outreach activities.

Recommendations are provided for each of the eight major areas of the survey as well as for the three overarching issues in attached documents. This review committee wishes to recognize the assistance of the BRS staff for their contribution to this report

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Respectfully submitted by the National Plant Board Biotechnology Committee –

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Summary of Findings

In May of 2004, the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulatory Services (BRS) expressed an interest in working with the National Plant Board (NPB) to gather State input prior to drafting amendments to current biotechnology regulations. A committee of NPB members was organized to address this request. Questions were developed to gather information from State agencies relative to current biotechnology activities, needs, and concerns. As a part of the process, Cindy Smith, Deputy Administrator of BRS, proposed a series of questions she felt needed to be addressed. These questions were incorporated into the survey. Forty-three States responded to the questionnaire, providing specific information, concerns, and recommendations.

The NPB Biotechnology Committee has reviewed survey responses and this document is a summary of issues and recommendations by significant category, e.g. Implementation Roles, State and Local Authority, Communication and Coordination, Information Access, Education, Compliance and Inspections, and General Process Questions. The committee has summarized the issues and findings in this document.

I. Implementation Roles

Introduction: The primary authority for biotechnology regulatory activities in the United States is based on the Executive Office of the President, Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology. This framework was developed in the late 1980's and was based on existing regulatory authority within federal agencies, such as the USDA APHIS Plant Protection Act. This section focused on the interaction of federal and State roles, States' level of involvement in biotech regulation, appropriateness of current timeframes for state review and comment on applications, ranking of important oversight aspects, and identifying States' desired role.

Several States have enacted laws providing State regulators authority of biotechnology. Those States not having specific laws may have limited biotech regulatory authority based on State Plant Pest Laws. States usually participate, at least minimally, in biotech regulatory activities via State authority and/or by participating with APHIS as they implement federal biotech regulatory authority. The careful implementation and coordination of these federal and State activities is essential.

Issue: State interest in participating in BRS permitting and inspection activities and factors limiting participation

Findings: The response to the survey strongly indicates that most States desire to be routinely involved in BRS permitting and inspection activities. The factors limiting State participation are lack of technically trained staff, access to CBI, and potential liability issues. States express a strong desire to be knowledgeable of biotech regulatory activities underway within their States and value the opportunity to provide their State's perspective to BRS on these issues.

Recommendation: Develop a model cooperative agreement identifying the anticipated federal and State responsibilities. This model agreement should include:

- Availability of State and federal resources, including staff expertise;
- Access to CBI;
- Statement of liability limits;
- Training of staff – preliminary and ongoing;
- Clarification of responsibility for responding to press inquiries; and
- Flexibility to address the wide variety of State needs.

II. State and Local Legal Authority

The appropriate role of States and local governments in regulating genetically modified organisms is not clearly defined. State specific statutory authorities deal with citizen access to public records, ability to enter into cooperative agreements - and at least one State has specific authority to oversee genetically modified organisms. This section sought to delineate the State perception on appropriate roles in coordinating with BRS on regulating biotechnology.

Issue: Need for legal basis for cooperation with BRS for States to perform needed work.

Findings: The responses to this question are summarized as follows:

- Many States have laws that regulate GMO's, though many commented that their regulatory authority is attributed to state plant pest laws, organic certification, seed laws, and pest management.
- Several States believe they have MOU's in place, or at various levels of completion.
- Most States (20) do not allow local governments to regulate biotechnology; the actions taken by those that do are not enforceable as they are in conflict with the Plant Pest Act. Many (15) did not know if state laws allowed regulation of biotechnology at the local level and a few (5) indicated that regulation of biotechnology at the local level was allowed.
- A few scattered counties and municipalities currently regulate through ordinances.

- Over four-fifths of surveyed states want regulations that are either parallel to, or in collaboration with USDA.
- If BRS expands its purview, States are concerned about workload, that all activities are based on science and transparency, and whether these expansions would take authority away from the State.

Issue: Confidential Business Information needs to be protected

Findings: Several States were concerned about their ability to protect CBI because of perceived conflict between State and federal Freedom of Information Act (FOIA) laws. A number of State laws would need to be changed in order to protect CBI. However, some States have laws that currently allow protection of CBI.

Issue: Compliance, permit conditions and information interchange with BRS

Findings: States felt that risk evaluation, compliance, and the need to include priority oversight for some genetic constructs in the prioritization process of compliance activities, such as inspections, are important. Well over half the States felt that current permit conditions are adequate. Several States questioned the adequacy of current separation distances - and the need for increased distances needed between the field trial and commercials related/same crop plantings. There is concern that pharmaceutical and industrial crops not be grown in areas of commercial production. The majority of respondents indicated having concerns related to locations and isolation distances in field trials. Certain crops do not have established isolation distances or the distances are not defined. Pollination distances may not be adequate, insect pollinators may not have been taken into consideration on some crops. States appear to be frustrated at the inability to resolve these issues with BRS.

Issue: Gaps in current or expected regulatory authority

Findings: Roughly three-quarters of respondents indicated no gaps existed. The vast majority indicated that BRS should extend its scope to cover more organisms. Perceived gaps mentioned included noxious weed risks, genetically modified algae, and insects. States responded that whether or not a GE organism is a 'plant pest' is only part of what should be considered when determining risk. Consideration should be given to whether it could be a pest plant (weed), public health hazard, hazard to domestic or wild animals, environmental contaminant, or the possibility of hybridization.

Under the coordinated framework, the product - not the process - is supposed to be regulated, yet the foundation for APHIS regulation is based on the process using non-infectious constructs (bits and pieces of sequences from plant pathogenic bacteria and viruses) in the process as promoters, etc. – these bits and pieces really aren't virulent pathogens.

Issue: Movement of regulated articles and information transfer

Findings: Approximately three-quarters of the States found BRS authorization for the interstate movement and importation of regulated articles to be desirable. About half the States supported "automatic" authorization as long as BRS is provided notice prior to the movement of the regulated articles. There was consensus that information should be available electronically.

Issue: Exemption of whole classes of organisms

Findings: Most of the States responding were not supportive of exempting whole classes of organisms. States offered the following suggestions of characteristics that should NOT be exempt:

1. Crops for which there is no history of release;
2. Modifications involving industrial products, pharmaceuticals;
3. Material that could cause the production of an infectious entity;
4. Material that encodes substances known to be or likely to be toxic to nontarget organisms;
5. Material that poses a risk of creation of new plant viruses;
6. Material that includes nucleic acid sequences derived from animal or human viruses or coding sequences whose products are known or likely to be causal agents of disease of animals or humans;
7. Material for which there is no history of release;
8. Material in plants with wild relatives know to occur in the area of release which could result in the transfer of genetic material which could result in increased weediness, competitiveness, etc.; and
9. Material in plants related to protected native species, controversial species (e.g. wild rice).
10. No exemption should be given for any rice event.
11. Nothing should be exempt if it is flowering or setting seed.

Recommendations:

Harmonize State and federal regulatory authority in the form of MOU's or cooperative agreements that include clear scope and authority as well as liability protection. It is critical that States have legal authority for their actions when interacting with BRS or acting as Federal agents while performing inspections. Two models for consideration are the EPA FIFRA methodology or the FDA medicated feeds program.

Resolve CBI issues via MOUs, cooperative agreements, or a more rigorous framework as needed. The issue of CBI is a foundational aspect to cooperative work between the States and BRS. It is critical that CBI be protected for both the applicants and for the States that receive this information through BRS.

Define a clear process for interaction between State officials, PPQ and BRS to resolve either information gaps or conflict resolution. Currently, the process for States to obtain answers to critical questions is not clear. All States are not aware of the single point of contact (POC) with BRS, or even if a POC exists.

Provide sufficient scientific precedent and some form of regulatory oversight (possibly reduced from current levels) to demonstrate to the State and to the public that the regulated articles do not pose a threat to agriculture, environment, or public health. BRS exempting whole classes of organisms would not alleviate the public concern over this technology. The State must respond to public concerns, and therefore, most of the States responding were not supportive of exempting whole classes of organisms.

Develop a tracking system accessible to the States to enable monitoring of regulated organisms. BRS and States should have the ability to track and monitor the regulated organism if a problem arises. BRS needs to be able to electronically transfer sufficient information to the States so that the States can perform this functional role.

III. Communication and Coordination

As communication and coordination between States and BRS are viewed as essential to the successful operation of the biotechnology regulatory program, several questions were asked concerning the adequacy of the communication and coordination primarily between SPROs and BRS, as well as BRS/SPHD and SPROs/EPA and FDA.

Issue: Need for improvement of communication and coordination among State and federal officials

Findings: Roughly three-quarters of State respondents indicated they had at least intermittent contact with BRS, while half felt the level of communication was not adequate for addressing both specific issues and general program information. More communication and coordination is needed in all areas (BRS and PPQ; PPQ and States; States and BRS). BRS could connect with States at existing meetings and utilize electronic methods.

Many respondents did not know whom to contact with specific questions on permits or for specific information to their State regarding all aspects of the program.

Issue: The need for improvement of communication to inform and educate on a multi-State/national level

Findings: States do not receive sufficient information and education regarding general procedures and policies, regulations, and BRS inspection activities in the States.

Issue: What method is best for information and education from BRS
Findings: In person, in-depth discussion is preferred in conjunction with NPB/regional Plant Board meetings and stand-alone sessions. Electronic communication via email or the BRS website is preferred for other interaction. However, the current email system poses problems, such as attachment size, and limits access/response time when the recipient is out of the office.

Recommendation: Develop an ongoing, meaningful interaction (i.e., a workshop presented by BRS staff in conjunction with a regional plant board meeting) with States. We suggest that emails and the website provide information on appropriate aspects of the program.

Develop a communication plan/flowchart of contacts and information that can be provided to each State for individual questions. This may include a personnel directory of all BRS staff. This information may also be detailed in a cooperative agreement.

Develop an educational/informational program regarding all aspects of the regulatory program, including: scope of the regulations, BRS's view of the State's role, permit reviews, field inspection policies and procedures, coordination with other EPA and FDA, etc. SPHDs and well as SPROS should be targeted for this information.

IV. Information Access

This section focused on the type, and amount, of information provided to States to review associated with permit/notification applications, inspections, compliance/enforcement, and risks associated with biotech crops/plants. Confidential Business Information (CBI) issues were also addressed.

Issue: Is appropriate information being provided to States
Findings: Over half the States responded that they do not receive the right type of information to adequately review permit applications, assist in inspection and enforcement activities, and be informed of the risks associated with biotech plants/crops. Four out of five States replied that more exact information on size, location, and number of field tests is needed. Nearly three-quarters of respondents feel that there is no information that they currently receive that they do not need. Over half of the respondents want information that is not currently being supplied, such as:

- CBI;

- Specifics on containment and disposal plans;
- Basic risk factors;
- High-risk considerations as noted by BRS;
- Contact information;
- Site locations;
- Field activity calendars and notification of planting, harvest, and/or destruction, etc.;
- Possible mitigation actions/emergency response plans;
- Compliance activities;
- Inspections, enforcement, compliance record of applicant, such as scorecard or rating system on applicant performance;
- Whether plantings actually occur, or not;
- More information on phenotype - categories like 'novel protein' are inadequate;
- The BRS biotechnologist who reviewed the permit/notification;
- The research being conducted - an abstract summary of research involved in the trial;
- The "notes" of concern to those who have reviewed the permit to that point;
- Concerns or reasons other States had for accepting the permit or adding conditions or objecting to the permit.

Issue: Information that States receive but do NOT want or need

Findings: Four-fifths of States said that they want or need the information that is currently being supplied. However, comments indicate that CBI-deleted pages that are sent to States are a superfluous, and that the highly-technical nature of some information supplied makes it ineffective to State personnel.

Issue: Secured Internet access to BRS information versus on paper

Findings: Over three-quarters of States prefer to have secured access to BRS information via computer rather than paper. However, comments suggested that the current system of emailing large PDF files is impracticable. States prefer an electronically searchable database of information associated with all biotech permits/notifications. The centralization and searchability (it should include risk assessments, and all applicable data) would allow information to be accessed/manipulated by the year, commodity, by permittee, etc. Email reminders could be utilized to tell States when the system has permits/notifications awaiting State concurrence.

Issue: CBI

Findings: The varied nature of State-to-State open record laws make the CBI issue difficult to summarize. Specific CBI concerns that may limit State's participation in the review process include challenges with States' authority to protect CBI information, as indicated by over a third of respondents; technical comprehension, also one-third; and training and certifying of personnel in proper

handing of CBI, one-third. Frustration was expressed with the State having to request CBI from the applicant. A possible point of confusion among survey States may stem from the wide variance in State-by-State open records laws. There may be a misconception among States that the USDA-training "shields" the CBI data gathered by State employees from open records requests. A secured Internet access point may resolve many of the CBI-security issues. Some commented that maintaining CBI at the state PPQ-SPHD office may solve the problem, but others countered that would be counterproductive as time lost in travel to review information is inefficient.

Recommendations:
Create a listing of essential information that needs to be provided to States for the adequate review of permit/notifications. This list may be developed with a focus group of State officials and BRS personnel.

Establish a system of information exchange with States that is a secured, Internet-based system where State concurrence of permits/notifications can occur; and past and current permit/notification data can be accessed - including search capabilities.

V. Education

Biotechnology is a rapidly evolving and complex area of science that can be difficult to fully understand, even for those with a scientific background. If State and federal plant protection responsibilities associated with GMO's are to be effectively carried out, it is important that personnel involved in this process have a good working knowledge of the science that underpins the regulatory process. In addition, there must be a clear understanding of the authorities, purpose, and operating procedures of the BRS office. Therefore, education and effective communication of basic biotechnology principles and the duties and responsibilities associated with the BRS office is viewed as an important part of continued State involvement in the application and field site review process.

Issue: Preferred method for development and delivery of BRS training and educational information

Findings: It was very clear from the responses received that face-to-face, live training held periodically was the preferred option. Using the NPB to determine the frequency and venue of these training sessions was also strongly supported. The use of web-based training was another method that received high marks as a mechanism to effectively communicate and provide training opportunities.

Some of the comments that were received relative to the preferred methods of training development and delivery included:

- We need all the training in this area we can get.

- Use the regional biotechnologist positions to assist with training initiatives.
- Training would assist in building better cooperation and understanding between State and federal employees involved in carrying out this responsibility.

Issue: Quality of the USDA User Guidelines for permits, notifications, and petitions for non-regulated status

Findings: It is noteworthy to point out that with the exception of one commenter, all parties responding indicated they had received no feedback on the user guidelines. Further, the majority was unaware of the guidelines. These two comments lead to the conclusion that the existence and use of the guidelines have not been well publicized or communicated to the parties that may have a need for them.

Issue: Adequacy of BRS website and need for additional educational resources

Findings: Of the respondents, nearly 50% responded yes to the question of website adequacy; however, an equal number indicated they did not know if the site was adequate. A few respondents indicated the site was not adequate.

Key comments on this issue indicated the following:

- The website is not user friendly.
- Many comments indicating they had never accessed the site.
- The site is improving but still needs some work.
- Include some training about the website at face-to-face training sessions.
- Guidance on acceptable protocols needs improvement.
- Add information on performance standards.

Issue: Educational needs for policy makers, stakeholders, and the general public

Findings: The comments received in response to this issue indicated a strong desire for additional training tools to address training/educational needs of the various target audiences. It would be nice to have a range of educational materials to cover everything from the school system (Ag In The Classroom) to consumers to policy makers. Some of the key responses received on this issue are summarized as follows:

- Provide access to available materials via a face-to-face training session.
- Anything to increase awareness of the process, safeguards, and science would be appreciated.
- Develop educational materials that have a public relations component for use with various stakeholders (Information on BRS and how and why GMOs are regulated).
- In addition to training materials, direct contact training is needed.
- Spend more time with State cooperators.

- Include training materials on the website.

Recommendation:
Develop more training and education materials for multiple audiences. For State officials, the preference is for face-to-face training sessions on a national or regional scope with support from Regional Biotechnologists, better web-based training information, as well as video and written materials. The scheduling of regional training sessions around the United States that includes additional clarification of exactly what types of training and educational information is needed. Educational materials will need to be developed for multiple audiences including the general public.

VI. Compliance and Inspections

This section focused on State-federal communication and cooperation on inspections, States' familiarity with inspection procedures, States' confidence in thoroughness of inspections, strengths and weaknesses of current inspection processes, and preferences expressed concerning the level of State involvement with inspections and compliance/enforcement activities.

Issue: State-federal communication and cooperation on inspections
Findings: Nearly three-fourths of the States responded that they participate in some biotech inspections. Survey comments indicated that States defined "some" as anything from knowing inspections are occurring to accompanying federal inspectors on nearly all inspections. States were split down the middle about the level of detail shared with States by USDA inspectors was appropriate. It appears that States are confused as to who and how they are to contact federal personnel with questions on inspection procedures. Roughly a third of respondents said they felt there is a mechanism in place to raise questions, a third said there is no mechanism, and a third answered that they do not know.

Issue: State confidence in inspection procedures
Findings: States were split on their level of familiarity of the inspection procedure. When asked how confident States are with the thoroughness of USDA inspectors, fifteen States were 'confident' with six being 'very confident', seven being 'somewhat confident' and four marked 'not confident at all'. States voiced concerns about inspectors' reliance on protocols and not situation-specific biologic factors and lack of applied background with agronomic practices and equipment.

Issue: Strengths and weakness of current inspection process
Findings: Commonly listed strengths include good communication and collaboration between state PPQ (SPHD) personnel and State officials. States are also pleased with the current BRS initiative to work more closely with State

officials. Commonly listed weaknesses include inspections that are too few in total number as well as too infrequent on an individual site basis; the need for inspection results to be communicated to State partners; USDA reliance on the checklist strategy; the need for more training and resources at both State and federal levels; and lack of communication between BRS/Riverdale and state USDA staff.

Issue: State preferences concerning level of involvement with inspection and compliance/enforcement activities

Findings: States want to be notified in a timely manner of the inspections occurring in their State; invited to attend and participate; receive final results of inspections as well as compliance/enforcement activities; strike a cooperative agreement that defines roles and responsibilities of stakeholders; provide input to BRS on which sites should be inspected; and obtain resources and training to support the States' partnering activities. There appears to be confusion as to what role the State should play in compliance/enforcement issues. States need a statement/protocol which can be provided to the public as to what each agency's role is.

Recommendations:

Develop a mechanism to facilitate timely and effective communication between State officials, state PPQ officials, and BRS officials.

Create a focus group of State officials and BRS inspection supervisors to meet and address specific details of how the inspection process could be improved.

Analyze the procedures within States where the cooperation and communication is working well.

Develop a formal protocol that allows for efficient communication among BRS, PPQ, and State officials on inspection protocols and plans. Define the State's role in inspection and compliance/enforcement procedures.

VII. Process Questions

These questions addressed State procedures for reviewing permit applications and conducting inspections as well as the training State officials have received that enables them to carry out the procedures.

Issues:

Findings: Most States believe their level of expertise is not sufficient to thoroughly evaluate the technical aspects of permit applications. Although Department of Agriculture personnel are the primary reviewers, a number of States rely on university scientists, and other agencies within the State, such as

natural resources and conservation personnel, for assistance. Although half of the respondents indicated that APHIS has provided training, it was noted that inspection training was primarily "how to follow a checklist". There was a strong desire (90% of respondents) for BRS expertise to be made available to States to help them meet their review and inspection needs, in the form of personal interaction and training.

Recommendations:
Provide formal training sessions for SPROs and/or State biotechnology permit reviewers about how and what to review in permit applications, as well as economic, environmental, and health issues associated with the technologies involved. A potential model to consider is the Pesticide Regulatory Education Program (PREP), sponsored by the EPA.

Develop a mechanism (duty officer model, for example) that allows for efficient communication among BRS, PPQ and State officials concerning questions and requests for more information. States desire more readily available BRS expertise to help, as needed, with the permit/notification review and inspections. The ability to reach BRS staff in a timely manner is imperative.

VIII. Biotechnology Issues in the Public's Eye

The States need to advocate for both the health and safety and economic interests of its citizens. This section is designed to determine the sense of social and economic concerns related to biotechnology expressed by the public.

Issue: Approaches to identify public concerns
Findings: Most States reported conducting stakeholder meetings with grower groups, university research and extension agents, consumer groups, legislators, environmental organizations, and others as the most common way of keeping a sense of social and economic concerns. Some States have formal groups established to direct input to the State concerning biotechnology issues.

Recommendations:
Proactively address public concerns that are raised through sound science and public outreach. Examples include programs such as Ag in the Classroom. BRS should provide speakers, written publications, and displays for the general public, local and State policy makers, and consumer education materials on biotechnology regulation.

Overarching Issues and Recommendations:

Communication, identification of roles and responsibilities, as well as education and training are critical components of successful interaction among agencies tasked with working together. This is particularly true as BRS initiates new programs, looks to amend regulations, and forges new working relationships with State agencies. As the NPB Biotech Committee analyzed the survey results, these three overarching issues repeatedly surfaced in all sections of the survey. The following is a summary of the overarching issues that emerged during the completion and data analysis of the survey. A series of recommendations focusing on communication, roles and responsibilities, and education emerged from the survey and group discussions. Those recommendations follow a brief description of the overarching issues.

Communication and Coordination

The need for greater communication and coordination was persistent in responses in all sections of the survey. The majority of the comments focused on the communication between BRS and State plant regulatory officials (SPROs), but comments were also received on the BRS/State plant health director (SPHD) relationship. BRS/EPA/FDA coordination also surfaced in the survey results.

Over three fourths of the respondents indicated that they have intermittent or regular communication with BRS while less than twenty percent indicated they have no contact at all. However, when respondents were asked to comment on the effectiveness or adequacy of the communication, half of the respondents categorized the communications as poor.

Another common theme was the lack of clarity as to whom within BRS States are to contact regarding questions and concerns on various issues. The need for specific points of contact was particularly noted when time was short to respond to a permit application. States seek clarity on the structure of BRS, BRS staff responsibilities, contact information, and how to make personal contact as opposed to reaching voice mail. Appropriate methodology, such as a flow chart, should be developed to facilitate prompt and efficient avenues of communication.

Most State officials who have intermittent or regular communication with BRS are contacted through the permit/notification concurrence process. While there are many issues that need to be addressed regarding communication, in the permit review and concurrence process the chief gap revolved around the inspections of field trials. Many States feel they have expertise in this area and are willing to be more involved if effective communication and cooperation could be established.

States identified three types of information desired by States, and thus should be communicated by BRS to the States:

1. State-specific information, such as permit reviews and inspections that are taking place in that State.
2. Information relevant to all States such as the review process for different kinds of permits, inspection protocol and processes, and enforcement processes.
3. General information that is relevant to all States but requires no action such as national statistics, and general biotechnology information.

In regard to communication and coordination outside of issues currently being addressed by BRS and States, several respondents felt BRS should strengthen their relationship with APHIS and particularly the SPHDs. This partnership would assist BRS in information transfer to the SPROs/States since most SPHD/SPRO relationships are strong and there is regular contact. Regarding EPA and FDA coordination of biotechnology issues, no respondents indicated they had any contact with FDA and only a few had contact with EPA. This gap in information sharing highlights the fact that currently unless SPROs get the biotechnology information from BRS they probably are not getting the information.

Key communication/coordination elements identified in the survey responses are noted in the following recommendations:

- Provide a process for interaction between States and BRS to resolve information gaps or conflicts. The process for States to obtain answers to critical questions is not clear. States are not aware of a single point of contact (POC) with BRS or even if a POC methodology exists. Development of a communication plan or flow chart of contacts and information is needed, such as a list of BRS staff and responsibilities.
- Develop a tracking system accessible to the States to enable monitoring of regulated organisms. BRS and the State should have the ability to track and monitor the regulated organism if a problem arises. BRS needs to be able to electronically transfer sufficient information to the States so that the States can perform this functional role.
- Create a listing of essential information that needs to be provided to States for the adequate review of permits/notifications. This list should be developed with a focus group of State officials and BRS personnel.
- Establish a system of information exchange with States that is a secure, Internet-based system where State concurrence of permits/notifications can occur; and past and current permit/notification data can be accessed - including search capabilities.
- Develop a mechanism to facilitate timely and effective communication between State officials, State PPQ officials and BRS officials.

- Analyze the procedures within States where the cooperation and communication is working well.
- Develop a protocol for the efficient communication among BRS, PPQ and State officials on inspection procedures. Define the State's role in inspection and compliance/enforcement procedures.
- Develop a mechanism (duty officer model, for example) that allows for efficient communication among BRS, PPQ, and State officials concerning questions and requests for more information. States desire more readily available BRS expertise to help, as needed, with the permit/notification review and inspections. The ability to reach BRS staff in a timely manner is imperative.

Roles and Responsibilities

Most States desire to be routinely involved in BRS permitting and inspection activities. There are two broad groupings within the Role and Responsibility issues limiting State participation. First, identifying State and Federal authorities while providing a legal basis for State cooperation with BRS is a major concern. States need a mechanism that defines each agency's role in the permitting/notification process. States want to be informed of inspections occurring in their State, be invited to participate, and receive results of compliance and enforcement activities. The second broad area of concern centers on CBI issues. Access to CBI information is critical to decision making however, a number of States need changes in existing laws to protect CBI. This protection may cause a conflict between State and the federal Freedom of Information Act. States express a strong desire to be knowledgeable of biotech regulatory activities underway within their States and value the opportunity to provide their State's perspective to BRS on these issues.

The key BRS roles and responsibility elements that were identified in the questionnaire are noted in the following recommendations:

- Develop a model cooperative agreement identifying the anticipated federal and State responsibilities and authority. Two models for consideration are the EPA FIFRA methodology or the FDA medicated feeds program. This model agreement should include:
  - Availability of State and federal resources, including staff expertise;
  - Access to CBI;
  - Statement of liability limits;
  - Routine training of staff;
  - Parties responsible for responding to press inquiries;
  - Flexibility to address the wide variety of State needs;
- Provide sufficient scientific precedent and some form of regulatory oversight to demonstrate to the general public that regulated articles do not pose a threat to agriculture, the environment, or public health. As the States must

respond to public concerns, it is important that BRS play a supportive role to the States.
- Create a focus group of State officials and BRS inspection supervisors to develop a plan for improving the inspection and enforcement process, with clear definition of the State's role.
- Develop a formal protocol that allows for efficient communication among BRS, PPQ and State officials on inspection protocols and plans.

Education/Training

Biotechnology is a rapidly evolving and complex area of science that can be difficult to understand - even by those with a scientific background. A common theme found in several areas of the questionnaire responses, including an entire section devoted to education, was the need for more training / educational opportunities in the area of the science and biotechnology regulatory process for State cooperators as well as other target audiences.

The key education/training elements identified from the survey responses are captured in the following recommendations:
- Develop an educational/informational program that addresses all aspects of the BRS Program, including the scope of regulations, the States' role, permit reviews, field inspection policies and procedures, coordination with EPA and FDA roles. The training audience for this initiative would be primarily the State and federal employees involved with site reviews and application evaluations.
- Initiate ongoing, meaningful interaction (i.e. a workshop in conjunction with regional or national plant board meetings) between the States and BRS staff. If the State/federal working relationship is to improve and continue to expand, there must be more contact between BRS staff and the SPROs bearing this responsibility.
- Develop additional training and educational materials for multiple audiences. For State officials, the preference was for face-to-face training in conjunction, when possible, with other regionally or nationally scheduled meetings or events. The training would require more than single event short presentations and should include USDA-APHIS regional, biotechnological, BRS staff, and outside expertise. A recommended first-step was to consider holding some broad based training that included a session devoted to determining future specific training needs. The development of web-based training/educational information was also emphasized as an important avenue to provide new and up-to-date information to interested parties.
- BRS should provide formal training sessions for State officials/SPROs/State biotechnology permit reviewers concerning how and what to review in permit/notifications applications, as well as economic, environmental, and health issues associated with the technologies involved. A potential model to

consider is the Pesticide Regulatory Education Program (PREP), sponsored by the Environmental Protection Agency.

- Proactively address public concerns about biotechnology and what the BRS Program provides as safeguards and checks and balances. The science of biotechnology is really very interesting if properly presented. Examples of public outreach opportunities that should be explored include, “The Ag in the Classroom Program,” attractive and well laid out displays and brochures, and a list of speakers who can effectively deliver an interesting presentation. Important audiences include policy makers and consumers.