BIOLOGICAL CONTROL
MAKING IT WORK

PART 1: SUMMARY & RECOMMENDATIONS

On April 4 and 5,1991,52 individuals from academia, the private sector and state and federal agencies met to discuss future directions for biological control of pests in the United States. The objective of this meeting was to identify the major steps that need to be taken to expand the availability and use of biological pest controls. The group agreed that the range of available pest control tactics needs to be expanded and that biological controls, broadly defined, need to be more aggressively developed. What emerged from the workshop was a rather lengthy list of actions. While these were eventually combined into four major areas, it seems clear that multiple steps must occur involving a number of organizations in order for biological control to become more effective. There was no single step that alone could produce a major advance, however, there was a high level of certainty that additional investments in addressing the needs would lead to concrete payoffs of considerable advantage to the nation.

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The workshop involved a select group of invited participants representing major interested parties. Since we relied heavily on informal discussions among the entire group and subgroups, the total number of participants was intentionally limited. Four background papers were distributed prior to the workshop, and they follow in this background report.

The workshop consisted of three periods of general discussion among all participants and two breakout sessions where subgroups developed ideas in the areas of technology development, commercialization, regulation and adoption. In the first breakout session, groups identified and prioritized issues that were limiting fuller utilization of biocontrol practices. The second breakout session identified actions that could resolve the limi-

tations. While the subgroups focused on different areas, what emerged were several common areas of concern. Stated as actions, these were:

1— Develop a national agenda, leadership and policy structure including:
- National and state policies encouraging biocontrol practices as part of total pest management.
- Mechanisms to coordinate activities
- Leadership identified in each state
- Regulatory policies different from those for chemical pesticides

2— Aggressively develop bio-based pest control
- Understand fundamental biology of the pest, biocontrol agent and ecological system
- Develop production, storage, delivery and application methods
- Address scientist base, funding structure and other incentives to accelerate programs
- Encourage farmer and extension participation
- Develop and integrated, systems approach in commodity-based programs

3— Expand communication and education efforts
- Improve understanding by scientists of current regulatory procedures
- Encourage more constructive discussions among interested and involved parties
- Respond to specific information needs—fact sheets, demonstrations
- Develop improved extension and consultant training
- Increase public/consumer education about pest-management practices

4— Provide incentives to facilitate adoption
- Need appropriate economic and environmental assessment of different practices
- Address or change cosmetic standards
- Establish clear regulatory environment
- Reduce cost of regulatory compliance for niche products
- Develop universal protocols for risk assessment
- Establish protocols for property rights protection for biocontrol practices

SUBGROUP REPORTS

Four subgroups, in the areas of technology development, commercialization, regulation and adoption, each developed a list of their concerns and potential solutions, which are presented in the following text.

TECHNOLOGY DEVELOPMENT

Generate, expand and improve the appropriate use of genetic resources while maintaining diversity

Plants and soils support a great diversity of organisms with the potential to provide defense of the plants through natural biological control. Different management systems and agroecosystems support unique mixtures of organisms with different potentials to provide biological control. In the past, most attention has focused on genetic diversity, expansion, improvement and appropriate use of plant genetic resources. This effort should continue, but significantly more attention should be given to the genetic resources represented by beneficial organisms and populations of organisms. Associated with the crop, including beneficial plant and soil associated microorganisms, natural enemies of insect pests, nematodes and plant pathogens, or insects and pathogens with potential to attack weeds. To this end:

a. Establish and maintain germplasm of biocontrol agents
b. Genetically assess potential agents
c. Genetically improve biocontrol agents
d. Isolate resistance genes and function of genes from plants and pathogens
e. Screen potential new biocontrol agents

Understand mechanisms of biocontrol at the molecular, genetic, organismal population and ecosystem levels

Basic research is needed on mechanisms of biological control at the molecular, genetic, organismal, population and ecosystem levels as a means to understand and thereby make greater use of biological control. The following phenomena need additional research:

a. community structures
b. timing and phenology of pest and host
c. epidemiology

d. key traits affecting inter-organismal interactions and management
e. gene function(s)

This research could result in changes in cultural practices to favor more natural biological control or a specific introduction (one-time, occasional or repeated as necessary) of a biological control agent or mixture of agents to supplement, expand or create a biological control system. The exact deployment would be determined by the nature and genetic control of the mechanisms deployed. It could include a mechanism(s) deployed in a organism or population or organisms associated with the crop, or when fully understood at the molecular and genetic level, it could be deployed as a transgenic plant.

Develop implementation technologies

New technology needs to be developed in support of biocontrol implementation for all categories of biocontrol organisms. Current inability to culture and economically mass produce biocontrol organisms limits the development and use of these organisms to control pests. In addition, inconsistency in quality, efficacy and reliability of these products affects producers' acceptance of biocontrol technology. Formulation and storage technology are critical issues and must be improved for the effective distribution and delivery of biocontrol agents or bio-based products. Subsequent to production, storage distribution and delivery comes the introduction and management phase where efforts focusing on the manipulation and management of natural biological organisms and their life cycles must be improved. New ecologically and genetically based technologies must also be integrated effectively with naturally occurring and introduced biocontrol organisms as well as other pest management tactics. Specific needs include: Formulation of agent, mass production, storage systems, quality control, delivery methods and equipment, introduced organism/gene products and the management of natural ecological cycles.

Assess and evaluate technology

Biocontrol agents and strategies must be evaluated for their performance and reliability as well as any consequences of their use across a range of agroecosystems. Consistent and reproducible technologies should be encouraged. The consequences of using biocontrol technology must be evaluated, particularly the technology's impact on non-target organisms as well as the rate and spread of the agent. Additionally, how a biocontrol

technology fits into crop protection practices should be evaluated. For example an analysis of the cost and efficiency of this technology relative to conventional chemical or plant breeding alternatives is necessary. The various producer/consumer groups which will experience benefit or harm need evaluation with respect to: biological and ecological impacts, risk and safety with respect to environment, socioeconomic aspects and general assessments of biocontrol technology.

Complement existing pest control systems and develop long-term alternative systems

In the short term, biocontrol must be integrated into existing pest and disease management technologies, including chemical controls. Biocontrols are also needed in both the short and long term to limit the effects of those pests and diseases for which currently there are no alternatives. Examples include certain virus diseases of plants, especially insect-vectured viruses and soil-inhabiting pests such as nematodes, soil-borne pathogens and soil insects that now are only controlled by uneconomical crop rotations. Gradually, however, within the next 25-50 years, biocontrol technologies must be considered as the main approach to crop protection, including cultural practices to manage natural beneficial cycles of biocontrol.

COMMERCIALIZATION

Put biocontrol on the national agenda

Biocontrol approaches to pest control in plant production, animal production and public health in the United States have not been a high priority issue. Several compelling reasons at this time to give biological control a high priority:

—Pest control procedures with less environmental impact in areas such as toxic chemical residue in groundwater and soils.

—Pest control agents to substitute for the increasing number of insecticides, fungicides and even some herbicides to which pests have developed resistance

—Bio-based pest control agents and procedures to reduce the consumer concern (perceptions) about the risk of chemical pesticides in food

—Biological approaches to discovery needed pest control agents since there is a decreasing rate of discovery of chemical pesticides

—Need to satisfy largely unmet needs for pest control problems such as soilborne pests and sucking insects

—Improve international competitiveness with improved productivity of commodity agriculture crops and new international markets for agribusiness through biological control agents.

—Improve safety of pest control manufacturing workers and pest control applications by replacing synthetic chemicals with biologicals

—New biological technology to facilitate the research and development needs for biological control agents

Actions to put biocontrol in the national agenda:

—Communicate the need for pest control and the potential of biocontrol to national decision-makers

—Forge a coalition of stakeholders for communicating and establishing working relationships

—Implement priority items

Address the paucity of proven biocontrol candidates and fundamental knowledge

To date, only a limited number of candidate organisms have been identified as potential biocontrol agents, a charge exemplified by the fact that less than one percent of the worldwide pesticide market is represented by biocontrols.

Additional candidate biocontrol agents must be identified if biological control is to take its potential and proper place as a means of controlling pests and pathogens. An extensive program must be implemented to expand the list and number of potential biocontrol agents and as potential biocontrol agents are identified, they must be characterized as to mode of pest action and the genetic basis of that action. This will result in the basic knowledge required to make genetic improvements of biocontrol organisms. Further, to expand upon the genetic sources of resistance, resistance genes should be identified, isolated and characterized from a variety of sources, including plants and pathogens.

The fundamental knowledge of the action mechanisms of biocontrol agents' at the molecular, genetic, organismal population and ecosystem levels will permit implementation of integrated systems for maximum performance of biocontrol agents. Based on studying community structure, epidemiology, traits affecting interorganismal interactions and man-

agement, gene functions and the life cycles of both pest and biocontrol agent, this basic understanding will permit proper timing of biocontrol agent applications and will result in an integrated systems approach to plant and animal protection and the control of pests impacting public health.

To accomplish these goals, a pool of highly trained technical and business personnel must be available to develop the base technologies, provide the biocontrol products and effectively bring them to market. To initiate this process, all existing biocontrol educational information should be pooled to provide a common informational source to all interested parties.

Insufficient formulation and delivery technology for biological control systems is of concern

The lack of adequate research efforts directed toward formulation and delivery technologies is a major limitation to the implementation of commercial biocontrol products. Although adequate research funding can often be identified for supporting both basic and applied biocontrol research, funding is generally not available for mid-level research. The fundamental differences between chemical pesticide formulation, production and delivery systems and those of biocontrol agents is an additional difficulty.

Research production technology

Research and development for microbes is needed to develop appropriate fermentation technology for "unusual" bacterial and fungal species not typically used by the fermentation industry. Additionally, the focus has to be on production measured by total bio-activity, not simply yield. Research and development for viral agents needs to focus on cost-reduction and generic technologies applicable to many viruses. Research and development on macro—agents needs to focus on the low-cost production and maintenance of viable organisms.

Research formulation technology

Unlike the formulation of chemical pesticides, biological agents need to be formulated in such a way as to maintain visible populations of the agent in a physiologically active state. Ideally, formulations should also be compatible with existing application equipment and consistent with the ecology of the agent. Special efforts should be directed toward the devel-

opment of formulations that will extend the shelf life and storage capabilities of biological agents.

To accomplish the above, appropriate funding needs to be identified in order to train quality individuals in such mid-level technologies. For example, the fostering of industry/academic relationships may lead to the exchange of personnel.

Address the lack of clear, consistent regulations for field testing and commercial registration

A number of regulatory issues impact the field testing, registration and commercialization of bio-based pest control agents. Most importantly, the regulations (risk assessment for field testing and registration) should be based on the end product rather than the process by which the product (pest control agent) was produced. Because an organism is genetically engineered or genetically modified in some way does not necessarily mean it is a higher risk than a naturally-occurring organism.

Approval for field testing should be based on familiarity, containment and risk, as stated in the National Research Council's 1989 report. This would expedite field testing for biocontrol agents, since large data packages may now be required for resting familiar organisms that can easily be contained.

Another issue seriously impacting development of bio-based pest control agents is the inconsistency between state and federal regulations. Harmonizing these regulations would expedite commercialization. At present, regulators have few incentives to adjust the requirements for bio-based pest control agents based on risk, and these incentives need to be identified in order to streamline the regulatory process.

Address the lack of trust for science and technology-based solutions in pest management

Science and technology have greatly advanced our ability to manage pests of human health, food and fiber at low cost and with great safety. Nonetheless, as in all human endeavors, some efforts (such as DDT) have been less successful than others. Unfortunately, public attention has often focused on these missteps rather than successes, leading to a lack of trust for novel technologies in pest management. Particularly with respect to biological pesticides and transgenic plants, the technologies are very abstract and poorly understood by the public, leading to apprehension about the

possible hazards of the technology. All too often, attention focuses on the genetic process rather than the product. In many cases, the criticisms raised about novel pest management tools betray a fundamental misunderstanding of the procedures used in biotechnology. Because no technology can be completely risk-free, it is first essential to educate and communicate with the public about the risks and benefits not only of biotechnological pest controls, but also to compare these with the risks of the technologies that would be replaced. Second, because at least some of this information is highly technical and not all of the interested public will have the time to digest it, there is a need for groups without vested interests but strong technical expertise to publicly give their own appraisals of the technology. Only after these steps have been taken can the public be given an adequate opportunity to make their wishes known

Protect intellectual property

The United States' patenting system is well established for chemically based control systems and therefore provides incentives for investment in research and development by giving the investor a true-limited monopoly on the acquired intellectual property. Similar protection is not well developed for biocontrol agents; the patent office has either been slow processing applications in granting rights, or is not able to grant exclusive rights (macroorganisms, some microorganisms).

Proposed actions:

a. Expedite review of pending patents for inventions deemed patentable.
b. Establish a protective system for biocontrol agents not deemed patentable loosely modeled after the Plant Variety Protection Act. Contrary of PVPA, this act would not contain farmers' rights to propagate.
c. Establish commercial incentives for research, development and commercialization for biocontrol agents with minor use or niche markets modelled after the "Orphan Drug Act."

REGULATION

Support agricultural commodities

Agricultural commodity support policy has to include environmental consideration. Several factors currently create disincentives for adopting more flexible cropping systems that integrate biological control and thus should be eliminated.

The current structure of farm commodity support programs penalizes the adoption of flexible cropping systems that are more conducive to the adoption of biologically-based control of crop pests.

Payments producers receive under these programs is calculated by multiplying deficiency payment *times* program yield *times* base acres. Both program yields and base acres are administratively set as running five year averages of actual yield and acres planted to program crops. There is a strong incentive for producers to l-maximize yields of program crops (which may discourage the adoption of biologically based pest control strategies that may result in lower yields even though these practices may be more cost effective) and 2-maximize acres planted to program crops (which discourages the adoption of rotations, strip cropping, intercropping or other cropping systems that are more conducive to biocontrol).

Current commodity policy should be reformed to eliminate these penalties to adopters of more biologically-based pest control practices.

We recommend that NABC develop a brief position document that explains the way current commodity programs penalize the adoption of cropping systems more conducive to biocontrol. This position document should be submitted to USDA, EPA, OMB and the public to encourage reform of current commodity program regulations.

Increase communication

The communication between different organizations involved in making biological control a viable alternative have to improve.

Communication about the regulatory process and requirements for approval of biocontrols needs to be improved. To improve communication between federal agencies and the scientific community, NABC should identify the information needs of the scientific community, develop materials (such as fact sheets or other primers) and prepare a plan for dissemination of these materials. EPA should develop and disseminate guidance or models for successful data waiver rationales. NABC should investigate opportunities for developing "regulatory" ombudsmen who could serve as sources of expert advice on the regulatory process to the scientific community. In doing this, NABC should consider whether and how such ombudsman positions could be developed within the academic community, scientific and other professional associations, or within government agencies.

Federal and state regulatory agencies need to examine whether their current regulatory processes work effectively together to provide adequate safety evaluations of biocontrols without unduly impeding the research, development and commercialization of these products. The scientific community, industry, public interest groups and regulatory agencies need to examine the existing opportunities and mechanisms for informing the public about biocontrols and providing adequate and effective opportunities for public input in the regulatory decision making process.

In order to achieve these goals:

a. Identify the regulatory information needs of researchers

b. An answer to these questions should be presented, preferably through "easy to use" information; e.g., fact sheets that summarize the regulatory procedures. This could be done by the NABC.

c. Institutions (EPA, USDA,...) provide regulatory models for application procedures.

d. A guide dissemination of their information should be provided.

e. An "ombudsman" could be installed in an appropriate organization to help process the questions, information and applications.

f. The NABC should develop a (short) rationale that explains this point and this should be distributed to the following agencies:

Congress
Environmental Protection Agency, U.S. Department of Agriculture
Office of Management and Budget
farm organizations
public interest groups

Risk assessment protocol is very important

There is a need for the development of a universal and coherent risk assessment protocol for both non-engineered organisms. This would help to reduce existing uncertainty for all parties.

Action plan: Set up a scientific review of the current risk assessment, focusing on the appropriate risk questions, levels of certainty and test requirements.

Examine the decisions made under the current approval processes, including:

Were the questions asked appropriate?

Was the amount of information (data) provided to answer the questions appropriate?

Was the correct level of certainty used in reaching the decision?

Was the correct decision reached?

Categorization is very important:

Define a category of uses of microbial control agents that can be adequately regulated under the Plant Pest Act or that can be exempted from FIFRA and Plant Pest Act regulation.

There is no set of universal protocols for assessing the risk of organisms, natural or genetically modified, for use in biological control applications.

FIFRA, EPA and APHIS, USDA have registered or issued permits for the introduction of biological control agents in the environment. The agencies have reached conclusions that the interdiction poses an acceptable level of risk by reviewing data submitted by the applicants. Each organism or agent has been reviewed and the decision announced through registration documentation (FIFRA) or an environmental assessment (APHIS).

Action: Set up an NABC workshop to come up with this categorization

Under current regulations, microbial biocontrol agents, regardless of their intended use, are regulated under FIFRA statutes. Microorganisms, however, are regulated under Plant Pest Act statutes. This distinction is artificial and not related to risk. Requirements for testing and release of microorganisms under FIFRA are not appropriate for many releases or microorganisms since these regulations are intended to certify the efficacy of a product, determine toxicity to non-target organisms as well as assess the ecological risk of releasing the organism. In many cases, such as release of microorganisms that do not produce toxins, or inoculative releases that are not intended for product development, these regulations are too stringent, and create an impediment for testing and release of microbial biocontrol agents, regulation under the Plant Pest Act would be more appropriate for these kinds and uses of microbial biocontrol agents. We recommend that the NABC convene a workshop to develop a proposal for submission to EPA Office of Pesticides and Toxic Substances that describes the uses of microbial biological control agents that: 1 - Can be adequately regulated under the Plant Pest Act, or 2 - are of a class of uses that in a generic sense meet safety requirements and can be exempted from a registration requirements of FIFRA and the Plant Pest Act.

ADOPTION

Leadership and policy are very important

Formulate national and state policy encouraging biocontrol as a preferred means of pest control.

Coordinate activities within federal agencies, between federal agencies and between state and federal levels.

Promote biocontrol as part of a total pest management program.

Identify leadership in each state to facilitate the development and implementation of biocontrol practices. Encourage the identification of a state coordinator for biocontrol.

Biocontrol includes the introduction of exotic agents and the conservation or augmentation of natural enemies.

Regulate biocontrol practices based on an evaluation of the taxonomy of issues relevant to specific biocontrol practices rather than as pesticides.

Aggressively develop biologically based pest control practices

Long-term observations or chemical free cropping systems

Integrate pest control practices in a whole system complex

Use biocontrol as a starting point for whole system pest management

Facilitate large-scale, on-farm trials

Research production, storage, delivery and application methods

Address scientist base, funding adequacy and other incentives supporting specific research objectives

Encourage Extension and farmer participation in appropriate phases of research

Need more basic information on basic biology of pests (life cycle, phenology, environmental controls)

Extension and education is very important

Develop educational materials and make them readily available

Use at-use-site demonstrations

Enhance education for Extension agents and private consultants

Coordinate fact sheets nationally, develop a clearinghouse (biocontrol institute)

Develop Extension programs which facilitate adoption of biocontrols

Need economic assessment

Improve incentives for adoption

Need appropriate economic and environmental assessment of both

short- and long- term aspects of all pest control practices

Evaluate biocontrol practices with approaches appropriate to the technology—larger plots, longer term, multiple mortalities and controls

Change cosmetic standards

Communicate value of biocontrol practices

Need public and consumer education effort

Biological control training should be part of pesticides applicator training