WORKSHOP RECOMMENDATIONS

HERBICIDE TOLERANCE IN CROPS

Concentrating on four priority issues and goals, this workshop made the following recommendations:

HTCs and herbicide use—There was general agreement that the primary goal of research should be to ensure that HTCs result in the safer use of safer herbicides. Additionally, farmers must learn how to integrate the various options for weed control into the best management plan for their farms.

Conduct field research studies that compare alternative weed control strategies, including how HTCs will affect the overall production system.

Focus HTC research on herbicides with the following attributes: low toxicity to non-target species, including humans and wildlife; low residues in the environment, including groundwater, surface water and air; nontoxic residues in crops and food; low use rates; appropriate degradation to benign breakdown products; cost effectiveness; compatibility with alternative weed management strategies; compatibility with technology improvements in the way herbicides are applied; and increased reliability of weed control accompanied by improved crop yields.

Health and environmental risk assessment—There was agreement that any risks need to be identified, and criteria to assess these risks developed. The federal government should:

Evaluate environmental data for HTCs on a case-by-case basis and in a reasonable timeframe.

Use public funds to construct a data base from information obtained from small scale field trials.

Provide guidance to ensure that seed companies and other institutions developing HTCs ensure the food safety and quality of the crops.

Socioeconomic Impacts—Government institutions that currently deal with socioeconomic concerns should:

Consider the impact of HTCs and, if appropriate, mitigate any impacts.

Foster public discussions on the impacts of HTCs, including socioeconomic impacts.

It was agreed that socioeconomic impacts of HTCs should not be a "fourth criterion" for regulatory approval of a product for commercialization—the products should be judged on three criteria: human and environmental safety, quality and efficacy.

Regulatory Policy—Participants felt that the impact of regulations on the cost of products and the development of minor versus major crops must be considered. A fair, timely process clarifying or establishing regulatory policy is needed. The federal government should:

Articulate a policy stating what is regulated and who regulates by January 1, 1992. Within a reasonable time after a regulatory policy has been articulated, it should be "tested" with a specific HTC ready to go through such a process. Three general criteria for this process were set: 1- provide meaningful opportunities for public input; 2- allow industry to proceed in a fair and timely manner; and 3- as appropriate, responsible health and environmental safety reviews should be conducted.

BIOLOGICAL CONTROL OF PESTS

Out of four subgroups identified, (technology, regulation, commercialization and adoption), four issues emerged as important for the development and increased application of biological control in the coming years.

First, because of a *lack of leadership,* biological control must get on the national agenda. For this to happen, advocacy is necessary from academicians, legislators and other public policy makers.

Second, *effective and reasonable regulatory procedures* are needed.

Third, a *tax on pesticides* should be established to provide government revenues for the promotion of biological control applications.

Fourth, an *increase in government funding* in the public arena (research and extension) and the *establishment of (financial) incentives for* an increase in supply (industry) and demand (farmers) of biological control is necessary.

Each subgroup in the workshop developed specific recommendations:

Technology—Establish and maintain basic and applied research programs to address scientific issues. In order of priority, research programs should focus on: 1- host-pest biocontrol agent interactions; 2-ecological relationships between the target pest, its environment and biological control agent; 3-host resistance mechanisms; and 4-compatibility

of biological control agents with chemical agents in integrated pest management programs.

Provide public funding and incentives for 'public good' (commercial products) types of biological control.

Provide incentives for 'private good' types of biological control. Among the variety of options discussed with no consensus: diverting money from the Clean Water Act; a pesticide tax; an "Orphan Drug Act" for small market biopesticides; R&D tax credits; lowering capital gains taxes to help R&D investments; and regulations for field testing and registration of biocontrol agents that are clear and concise.

Regulation—In order of priority:

Redefine regulatory procedures by defining agency responsibility for organism groups; define criteria/characteristics representing risks and benefits, and establishing a fixed time for regulatory decisions to on-field test applications.

Improve communication by facilitating access to federal and state regulatory procedures, by establishing voluntary mechanisms to share the results of safety tests between investigators and between federal and state authorities (such as the National Biological Impact Assessment Program (NBIAP)data base in the USDA).

Commercialization—Incentives to increase use of biolocies and minimize the current barriers are necessary:

Set up national research centers to develop biological control methods with locals and cooperatives, and create a clearinghouse for basic and applied information on the delivery of biological control agents.

Modify crop support programs to encourage diversification and provide insurance premiums against crop loss to farmers who use biological control agents.

Develop programs to change the lack of tolerance for imperfections at all levels of the marketing system.

Adoption and Implementation—Establish a national program promoting biological control which includes developing educational and informational materials and their distribution, and establish demonstration projects on farms.

Establish programs to reduce the initial cost disadvantage of biological control agents over traditional pest management techniques, possibly including taxing pesticides!users and use of the revenues for these programs.

Four general areas were identified for discussion:

Unintended and unwanted consequences —Listed were: 1- the impact on genetic diversity, animals as disease vectors and effects upon wild populations as well as pollution that maybe associated with animal production; 2- the well-being of the animals themselves, both in terms of their health and their ability to lead relatively tranquil lives; and 3- consequences not readily anticipated.

Conduct animal genetic research to enhance human and animal well-being at an acceptable risk to animals, humans and the environment. Strategies expected to achieve this goal: 1- sufficient public funds to conduct research in the area of transgenics, thereby reducing the pressure to rush to market and to support research on risk; 2- the use of peer review panels, such as current animal care committees, to assure proper procedures are used by researchers and the public is made aware of these procedures and has the opportunity to express concern to the appropriate bodies; and 3- the development of model systems to anticipate both unwanted and beneficial outcomes of transgenic research.

Socioeconomic concerns—In order to *minimize the negative and maximize the positive socioeconomic impacts of transgenic animals and their products at the local, national and international levels,* four key steps were identified: 1- determine the type of transgenic animal or product, the time frame in which it will be developed and adopted, and where and how it will be used; 2- identify direct economic consequences (good and bad) of adoption, including downstream second and third-order consequences; 3- identify possible associated environmental benefits/costs; and 4- identify segments of world society that are affected by transgenic animal technology.

Funding—Since transgenic technology is merely a tool, it should not be singled out as a special priority for funding. Rather, *basic animal genetic research funding should be increased in order to increase the genetic knowledge base.*

Food safety and consumer acceptance—Participants felt that the existing research and regulatory systems need to be more effective in building public communication, confidence and acceptance of food derived using biotechnology. To this end:

Meet consumer needs with enhanced quality and safety of products.
Consult the public early in the research and production process to determine consumer acceptance of products.
Use biotechnology to assure food safety and quality.
Enhance the credibility of the regulatory system.
Expand dialog with the public and in K-12 and college classrooms.
Discuss the results of safety and socioeconomic research publicly.

ANIMAL GROWTH PROMOTANTS

While workshop participants identified several important issues and goals, there was a divergence of opinion on how they might be addressed. The following recommendations were presented:

Assess the broader social impact of animal growth promotants (and all new technologies). There was disagreement as to how, what, by whom and when. This was the most controversial issue discussed.

Assess the process by which AGPs are regulated for human, animal and environmental safety for possible improvement. The methodology proposed to accomplish this goal includes: 1- identifying the concerns of the different constituencies, possibly in a meeting or via a survey; 2- briefing these groups on the regulatory process as they each may not have a complete overview of the process; 3- developing a white paper that reflects the concerns of the groups with subsequent feedback in order to reach a consensus; and 4- developing solutions for the concerns identified.

Make information available on the risks and benefits of AGPs. The methodology proposed included: 1- research to determine potential risks and benefits; 2- public education to disseminate this information; and 3- public policy set to insure that relevant, credible, objective, non-proprietary information would be available to all.

Eliminate international regulatory disparities with a goal of (free/fair) trade. To accomplish this: 1- establish an international dispute settlement mechanism such as GATT; 2- conduct research in a neutral, independent setting such as an international research center; establish objective international standards such as CODEX; and 3- educate consumers possibly using UN/FAO funds.

TYING IT ALL TOGETHER

As I reflect aloud for the next few minutes on my impressions of the meeting that we have just been through together, I ask that you reflect on your impressions as well. Obviously, our reactions to the meeting come out of the experience and perspective that we bring to the meeting and your reactions will be somewhat different from mine.

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I want to do two things. First, to review the theme of the meeting, *agricultural biotechnology at the crossroads* and use that to talk about what we have heard and said together; and second, to spend a few minutes reflecting on the actual way in which we met together and the quality of our communication.

The call to the meeting elaborated the theme of the meeting. To remind you, "In the late 1970s, several published reports emerged extolling the benefits of biotechnology, predicting the outcome of exciting new research agenda, anticipating the potentially vast benefits.. .Biotechnology became the byword of the 1980s, with new techniques for mediating the determinants of heredity, almost anything seemed possible. These new techniques were expected to raise agricultural productivity while reducing chemical use in agriculture, thus leading to a cleaner, healthier environment. These predictions reflected the tenor of the times, in which biotechnology was widely held to be a technology that would revolutionize the coming decades." Not surprisingly, this point of view was expressed optimistically. It was a critical juncture, I would assert, a time when we were trying to interest investors of all types in the promise of these new technologies. We (scientists) were going to Congress and to the public, and quite unusually, to venture capitalists. The science of molecular biology was giving rise to these new technologies but the question remained "Could the resources be found to de-

velop these technologies?" Promises were made at this juncture and like many promises, they sometimes come back to haunt us.

I am reminded of a story Garrison Keillor told the other day. He was talking about a particularly life threatening critical juncture and he found himself beginning to pray. "God, if you will just help me out of this problem, *alive,* then remember those promises I made to you back in Chicago at O'Hare when the landing gear didn't go down on the airplane...?" Thus the old promises came back to haunt him.

One speaker, Roger Salquist, disputed the premise that the promises have failed to develop as predicted. Instead, he asserted that biotechnology to date has met the knowledgeable predictions that were made 10 years ago and that we are now on the verge of having an impressive portfolio of products.

The call to the meeting went on to say, "Clearly, complex, unforeseeable biological, institutional and socioeconomic changes have emerged that place biotechnology in a new context. Today, constraints and incentives create an environment for research and application that is very different from the rules and regulations perceived to constrain both scientific and public policy development ten years ago. This Third Annual Meeting will assess the reasons why many biotechnology innovations have failed to develop as predicted, identify and evaluate the constraints and incentives that currently drive research, commercialization and acceptance of biotechnology products and seek ways to assess their appropriateness or inappropriateness."

Appropriate to the theme of the meeting, several crossroads have been set before us. As we meet these crossroads, the question is "Will the direction we choose give fulfillment to the promise that biotechnology will indeed revolutionize the era ahead?" or, "As we meet these crossroads will we find that we were wrong about the promises of biotechnology?" During the last two days, several types of crossroads were discussed, not just the major one suggested by the call to the meeting, but several smaller crossroads within that. Some of the larger intersections are behind us. It is always good to reflect on the roads crossed in the past and the decision made to take a certain direction. I would assert that we have already crossed at least three crossroads.

CROSSROADS PASSED

Ten years ago, there were many different definitions of biotechnology. The word was used to signify different kinds of activities and enterprises and was used in many different ways. During the last two days, several people offered definitions as if they still wanted to clarify, but their definitions agreed. There was a consensus that biotechnology is a set of technologies, a set of tools, a set of methods and not a monolithic entity.

Another crossroad we have passed is the question of whether or not these technologies will be used in agricultural science. We have lots of evidence that we are beyond that question—they are being used now and they will be used in the future.

A third crossroad that we have passed is the question of whether or not to regulate the products of biotechnology. Ten years ago, some people said "They are like natural products, don't bother to regulate." and there were others who said, "They are VERY unnatural products, regulate everything about biotechnology.. .the process, all the products, etc." We have come to that crossroad and for a variety of reasons are agreeing that we will regulate only the products of biotechnology. No longer is there any sizeable voice suggesting no regulation at all.

FUTURE CROSSROADS

There are several crossroads we still face. We have come upon them, but we have yet to make decisions on which way to go. Over the last two days, a major crossroad permeating much of the discussion at all levels from the general to the highly specific was the question of whether biotechnology will drive our future. Are we going to be led by the technology, caught up in it, or carried along by it? Or, as some of our speakers have asserted, will other forces set the direction for us and determine the way in which we use these technologies that we call "biotech"? Which will be the driving force?

Forces proposed were economic forces of varying types, including international trade; the risk-benefit issues for farmers, consumers, etc.; and the developing and overriding environmental concerns in our society today. The question is "What other factors will be allowed to drive biotechnology if we do not allow the technology to determine our future?" There is no agreement yet. Some would say the technology should have free reign, while others would say that economics should be the overriding

concern. Still others would say there are social concerns which must then modify our economic system. It seems there is considerable disagreement arising from the differing values we bring to the table, as to what the role should be of these other forces which may determine the future use of biotechnology.

There are other crossroads which received attention. I had not predicted that regulation would be as pervasive an issue as it was in the last two days. Throughout the workshops, as well as in the informal discussions here together, regulation seemed a compelling topic. I heard agreement on the point that regulations should be fair, timely and there should be a great deal of public trust in it. I heard some agreement that regulation is not perfect yet. I heard much disagreement as to its points of imperfection. Clearly we have had too little dialog on how to regulate, who regulates whom and what. I found a lot of consensus that we should have some regulatory activity to assure safety. We do not seem to agree whether efficacy is an important point in regulation. Currently some products in our market are judged by whether or not they are efficacious, while others are not. Where biotechnology products should lie within the whole regulatory scheme is a point over which we have yet to reach a consensus.

We also disagreed on how well we are doing—I heard one speaker say that he thought there was considerable room for improvement and he focused on the complexity and uncertainty on the multitude of organizations involved in regulation. Another speaker said he thought it was going very well - that his own experience with the regulatory process had been extremely smooth, processing had gone in a timely fashion and that he was anticipating nothing but the best. In the unknown time ahead we will look at the regulation of actual products coming to market, commercialization as opposed to field trials and testing stages of development of products. The commercialization of products will precipitate many difficult regulatory decisions.

In sum, I heard more concerns about points of imperfection in the regulatory system than I heard agreement that it was doing well. Although a lot of regulatory sub-issues were explored in the workshop reports, it would be redundant to summarize them again this morning.

Let me comment on a couple of other areas where I think I heard some agreement. They are old questions. Should we be regulating the science

that is behind these new technologies? There was not quite 100 percent agreement, but a fair consensus that we should not regulate the science *per se*. We should regulate the products of the technology arising from the science, and while we agreed to regulate the products, we disagreed as to the criteria we should use. The unmapped territory ahead has given rise to a lot of uncertainty and feelings of insecurity, heightening the need for more exploration of what it is that we are going to be doing in the process of regulating products as they are commercialized.

Funding was another crossroad that came up throughout the meeting. It was amazing to me that it came up as frequently as it did. Although funding is part of my job, a part of my business, I had not imagined that funding could be so broad a concern as it appears to be in this meeting. Dollars. Whose dollars? There was much discussion about the role of public funding and private funding. The kinds of activities which face us in developing products from biotechnology give rise to the questions, "What should be the role of public funding? What should be the role of private funding? Do they have different roles?" This is not a discussion limited to biotechnology, but the kind of questions that arose suggested that we need much more discussion of funding, especially since there is not an understanding among us about what our position is on the roles of public and private funding. There are many questions about the appropriateness of different kinds of work using public or private funds, as well as questions about how these funds are currently being used. Again there is room for a lot more discussion and a chance to get much more highly specific about what it is that concerns us in these arenas.

Funding for commercialization also came up. I was surprised that it did not come up more often. I had predicted that it would come up more because the press is writing a lot about where we are with regard to funding for biotechnology companies, both biomedical and agricultural biotechnology.

There was a lot of discussion about the myriad lists of critical technologies that are emerging from Washington and related groups; discussion about the current state of competitiveness in biotechnology and what we can expect in the future. Those emerging lists are saying that we are currently very competitive in biotechnology in the United States as compared to the rest of the world, but that funding concerns, especially for commer-

cialization of products, as well as regulatory and other concerns, are giving rise to questions about how long we will remain competitive. These are all popular issues in the press today; however, there was not as much about these issues at our meeting as I had anticipated. "How critical are these issues?" presented another crossroad on which we expect to differ.

Other crossroads.. .what type of research should we be doing? Who decides? *"Who* decides" kept coming up and not getting answered, except "ME, I'll decide." Whoever is talking is the person who wants to decide. It is an important issue, one needing some public understanding and consensus. What decisions are appropriate in the public arena? What are appropriate in the scientific arena? How do those two inform each other as they each make their appropriate decision? Again, we have not had enough dialog on these issues because I heard more questions than I heard any attempts to provide answers or even points of view.

The technologies we have been discussing for the last two days are developing extremely rapidly. We are making remarkable progress in biotechnology, but it maybe that the technology has outstripped our basic knowledge with regard to biological systems. What limits us in our ability not only to use these technologies, but to use them wisely, is the fact that we do not have enough knowledge of the biological systems in which we are using them. This limitation came up in many different ways during the meeting. There was a strong call for getting on with the business of understanding these biological systems more clearly so that we can be more thoughtful about what we are doing with technology. There seemed to be a pervasive concern that we have outstripped our ability to assess impacts of the technology. We are not skilled at assessing those impacts. We all say we worry about them, and I think we do. We agree that we worry about the social impacts, economic impacts and other kinds of unforeseen consequences of these new technologies. We are uneasy because we do not know if we can successfully assess the future. We are uneasy because we do not know if we will take the time to do it, and we do not know who will do it. These are points about which we have a great deal of unease. From discussions, it seemed there was more concern and unease than disagreement or conflict. We do not yet know where we each have positioned ourselves within this whole arena. Thus there also looms a crossroads with regard to our research agenda, not only funding or the type of research we are do-

ing, but also what we need to do in order to make ourselves better able to assess the impact of these technologies.

Communication was another pervasive concern, but I do not know if "communication" could ever be considered a crossroads. We almost always refer to it as a two-way street or many two-way streets. Communication is certainly something that everyone was worrying about. We agreed that we wanted to communicate. We agreed that we wanted to communicate *better*. We seem to agree that our communication is not as good as it should be. It is typical of society today that we have this concern. Unfortunately, we did not have the time to explore how we could improve communication. What could we do, specifically, to improve our communications, improve it in the regulatory arena, improve it in the research-decision-making arena, improve it in the funding arena? There were many places where we asked for improvement, but did not really explore what we were doing wrong or not enough of, or should be doing more of, to improve communication. The issue of education came up frequently... education that would provide a more common understanding on which to base our communication and education to improve decision making. There was a strong call for more exchange of information, an open exchange of information and lots more of it.

HOW DID WE DO?

Those are some of the crossroads that I heard being discussed in the last two and half days. How did we discuss them? NABC has the goal of bringing together diverse views, openly discussing and examining those diverse views and in Ralph Hardy's words, "We're coming together to speak, to listen, to learn." How well did we do that? I offer special thanks to the NABC/Joyce Fellows, because I asked them at some length last night how well they felt we had achieved this goal. They had a fairly optimistic answer for me. They seemed to feel that we had a good diversity of views. Here they mentioned two perspectives which they were not sure were represented as well as they should be. Regulators were one group. Another group whose view they thought was missing was the farmers who will actually employ these technologies. But they felt that the discussion had been open and that there had been an exchange of the many views present here. On those grounds, they were rather optimistic about the goal of the meeting being achieved.

I always ask, "How vigorous and how fearless was our examination of issues?" Those of you associated with the University of Wisconsin know about one of the formative statements behind the University which has touched all of us at UW. It is a statement on a plaque in the main administration hall there. It comes from a statement made by the Wisconsin Board of Regents before the beginning of this century: "In all lines of academic investigation, it is of the utmost importance that the investigators should be absolutely free to follow the indication of truth, wherever they may lead. Whatever may be the limitations which trammel inquiry elsewhere, we believe that the great state University of Wisconsin should ever encourage that continual and fearless sifting and winnowing by which alone the truth can be found." I heard some fairly courageous sifting and winnowing in the last two days, although I am not sure it measured up to the standards set by Wisconsin's Regents 100 years ago.

Perhaps we were not completely fearless. We may not have been willing to voice our opinions as strongly and with the conviction that is required to really examine perspectives and to push to a true consensus. We can excuse ourselves, for in two days what can you do? We can excuse ourselves because we are all nice people and we do not want to hurt other people's feelings. We can excuse ourselves for a variety of reasons. However, from a professorial tradition, I would have to say in that regard that I think the best grade we could give ourselves would be a B.

POST MEETING SUMMARY

In a post-meeting session, members of the NABC Council and Operating Committee, NABC/Joyce Fellows and Graduate Fellows, speakers, workshop chairs and session moderators came together to discuss the meeting and its recurrent themes and to develop a follow-up strategy for NABC and its member institutions.

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Following lively debate, three priority action areas were identified:

1 - the need for adequate funding to further develop our national research capacity with strong support for stepwise increases over 5 years to full funding of $500 million for the National Initiative for Research on Agriculture, Food and Environment.

2-the need to include a more substantive social and economic impact assessment in all technology impact assessments of emerging agricultural biotechnology applications.

3 - concern about the need for additional regulatory definitions as well as what the appropriate level of regulation by the federal government should be and the role of individual states.

As an initial step, letters prepared with input from designated attendees were sent from NABC to appropriate Congressional members and agency officials. The strength of these recommendations lies in the backing they have received from participants with different interests and agendas who came together at NABC3 to promote current, specific needs in agricultural biotechnology.