POLICY IMPLICATIONS OF BIOTECHNOLOGY RESEARCH*

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Introduction

Since having agreed to discuss the topic assigned to me, I have concluded that I felt much more comfortable with my last years topic, "A Technology Assessment for Commercial Corn Production in the U.S." In fact, I not only don't know many of the answers for this years assigned topic, I'm not sure I even know the most important questions to ask. But, perhaps I can at least stimulate our discussion of the topic which has already been opened up earlier by Busch, Kalter, Rogoff and others at this seminar.

First, although I don't want to be definitive to the point of excluding important issues, I do think that some definition of the term "biotechnology" is in order. One such definition is "the use of living organisms in agriculturally related processes on farms and in industry." But, by that definition, we have had biotechnology applications in agriculture for a long time. And, it is the more recent applications which are of particular interest to the topic at hand. The Division of Agriculture's Committee on Biotechnology of the National Association of State Universities and Land Grant Colleges, "NASULGC," (Progress Report III, November, 1984) identifies these new techniques in biotechnology to include "... plant and protoplast culture, plant regeneration, somatic hybridization, embryo transfer and recombinant DNA approaches

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*Discussion prepared for Agricultural Research Policy Seminar, North Star Inn, Minneapolis, MN , April 18, 1986.

including gene identification, characterization, splicing, replication, regulation and transfer." And, although this list may not be exhaustive, these are probably the major techniques that should be on the agenda for our discussion on biotechnology here. Lest we be unduly constrained in our perspective, however, we might keep in mind the contention of Rifkin (1983) and others that "Biologists now view living organisms as information systems" and that "DNA is the depository and distributor of information." Such a perspective which was even broadened some by Rogoff earlier in this seminar opens up a dramatically large field of biotechnology research with a host of future policy issues waiting in the wings.

In 1982 an estimated 283 faculty FTES from the State Agricultural Experiment Stations in the U.S. were reported committed to biotechnology research. This number increased by 90 in 1984 and was projected to increase another 151 by 1986. If this projection is realized, the number of SAES scientists working on biotechnology will have almost doubled over only 4 years (NASULGC, 1985). As evidenced by Kinney earlier in this seminar there has also been a major and rapid increase in biotechnology research in USDA. And the private sector is funding biotechnology R & D like it has never funded research in any other technology area. Thus there is little question that the topic of this session (the policy implications of biotechnology research) is already a relevant one. And policy issues will almost certainly increase rapidly in number in the future.

General Perspectives

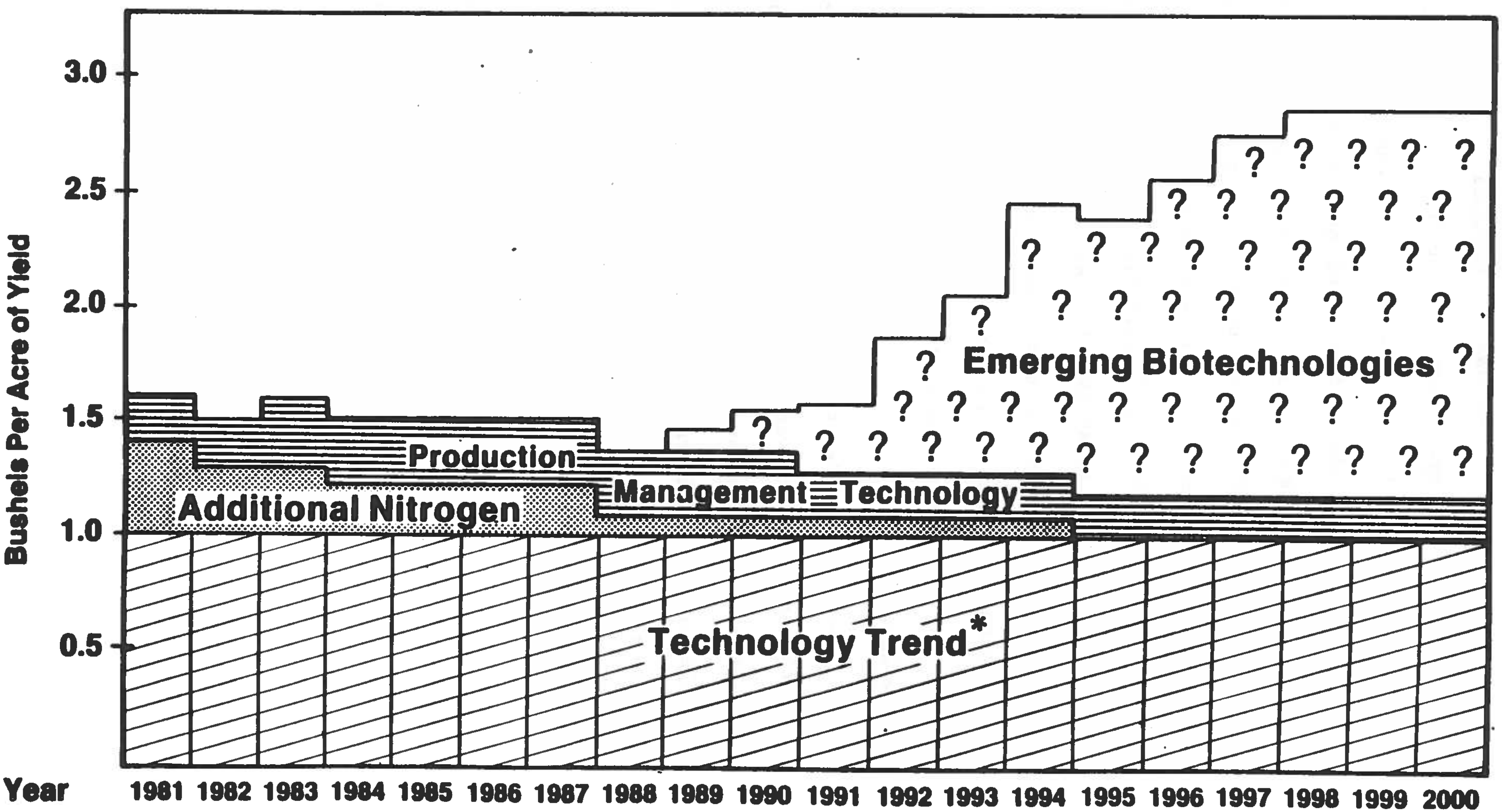
Several years ago, I was involved in a technology assessment for maize in the U.S. (Sundquist, Menz and Neumeyer, 1982). And as we tried to project the importance of various technologies into the future, the emerging biotechnologies took on a major but highly uncertain role. And, the role of existing technologies, except for technology trend associated with conventional plant breeding took on a declining future role (Figure 1). This is probably the case for other commodity areas as well. Although I believe that biotechnology may play a proportionally much smaller role in the developing world than in the U.S. over the next 10-15 years, it could well be a major source of potential total productivity gain there as well.

It is already clear that the major policy issues surrounding biotechnology research vary greatly depending on the personal interests and value perspectives of the individuals involved. For example, most agricultural scientists (and many general biological scientists) see the application of new biotechnology techniques to agriculture as a potential "bonanza of opportunity." Jeremy Rifkin (1983) and others, particularly many individuals and groups with strong environmental concerns, on the other hand, see it in a very negative context. And, as is the case for most major policy issues, there are certainly some trade-offs involved. Let's look first on the positive side of future biotechnology applications.

The Office of Technology Assessment (1984) identified 10 factors important in determining the future position of the U.S.

FIGURE 1

Projected Marginal Impacts on Corn Yields by Various Technologies, 1981-2000



* Includes conventional plant breeding and other highly correlated trend factors such as plant population and moisture control.

and other countries in the commercialization of biotechnology:

1) Financing and tax incentives for firms.
2) Government funding of basic and applied research.
3) Personnel availability and training.
4) Health, safety and environmental regulation.
5) Intellectual property law.
6) University/Industry Relations.
7) Antitrust law.
8) International technology transfer, investment and trade.
9) Government targeting policies in biotechnology.
10) Public perception.

All 10 of these factors have policy implications although OTA considers the first 3 to be most important, the next 3 of moderate importance and the last 4 of least importance. However, not all of the 10 factors relate centrally to biotechnology "research," as such.

A somewhat different perspective from the "commercialization goal" one of OTA is taken by some people in the scientific community who see biotechnology as "The Age of Intervention." This intervention refers to the expanded use and modification of other life forms for human ends. Regal (1985a) provides a well reasoned perspective that "the challenge with biotechnology will be to maximize its benefits to society and to minimize health and environmental hazards and other costs." Regal goes on to say that "a most critical need is for better information-flow between those seeking profits and those seeking to understand the implications of the new creations, as well as those seeking to insure the effectiveness and safety of the new power." The latter statement gives considerable prominence to policy issues related to trade secrets, intellectual property law, health and safety considerations, antitrust law and University/Industry relations (including public versus private research), etc., which were given somewhat lower priority than commercialization in the OTA perspective.

An additional perspective provided by Kalter earlier in this seminar and by a recent OTA study (1986) is that the emerging biotechnologies will speed up the structural change in U.S. agriculture to fewer and larger farms.

One could go on to other references and to other general perspectives, but perhaps it is more useful at this juncture to narrow down on some of the policy implications stemming from agriculturally related biotechnology research.

Policy Implications

Perhaps a better heading for this section of my discussion is that of "policy issues" rather than policy implications since it is difficult for me to come to strong conclusions about all or even most of the policy implications of the emerging biotechnologies. And, perhaps the best approach to the topic is to try to categorize major policy issues into several major groups while recognizing that many of these categories are highly interdependent and overlapping.

Genetic Modification and Diversity

Embodied in the notion of the "age of intervention" is the implication of a major shift to genetic engineering rather than "mutation and natural selection" as the mechanism by which the evolutionary process is guided. To quote Robert Sinsheimer (1983), "In the hands of the genetic engineer, life forms could become extraordinary tinkertoys and life itself just another design problem." It would appear that such a process, if it develops, could result in a major decline in the incentives for maintaining natural genetic diversity unless public policies are developed to deliberately ensure the preservation of existing germplasm. And, major varietal performance gains via genetic engineering could result in excessively heavy dependence on (vulnerability for) these new "genetically engineered" lines should major pest or environmental problems emerge.[1] Moreover, such new superior genetically engineered lines could exert very heavy pressure on existing "natural" lines. In any event, there does seem to be a potential for forgetting the importance of natural genetic diversity and thus a new imperative for policies which encourage the preservation of such diversity. Also important is the continuation of conventional plant and animal breeding programs

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[1]In addition to major disease and insect problems, are the potential hazards of acid rain, the "greenhouse" effect of increased atmospheric CO_2, increased salinity and toxic salts on irrigated lands, etc.

which draw on this naturally existing gene pool as well as incorporating the genetic inputs from biotechnology. Thus, biotechnology is not a substitute for conventional breeding work. Our research funding policies need to recognize this latter fact.

Health and Safety Implications

According to Regal (1985b), "It is safe to say that contrary to other implications, no scientist ... will now claim that all or even most recombinant DNA organisms will be categorically dangerous. This is a dead scientific issue in 1985." But, in another context, "there is a ... oversimplification of ecological issues in the claims that it will be quite safe to release essentially any genetically engineered form into the environment."

In brief, the safety debate appears to have shifted from one of concern about genetically engineered forms becoming dangerous "rogue" organisms and thus being "dangerous cannons loose on the deck" to one of concern for responsible testing and safety regulations. The very recent controversies regarding the field testing of "ice minus" bacteria and a genetically engineered vaccine for pseudorabies suggest that agriculturally related biotechnologies will be in the forefront of safety issues. Some of you are aware that on March 24, EPA suspended the permit for field testing of the ice minus bacteria signalling that this agency will enforce its regulatory policy regarding biotechnology experiments.

Human health issues will almost certainly be of crucial importance for biotechnology applications in the food processing industry. And, there clearly are already a large number of biotechnology applications in this industry with more to follow.

Although the Federal Food and Drug Administration has rather clear cut responsibilities in the food health and safety area, the line of responsibility in ensuring safety in crop and livestock related applications is still being sorted out. As of this date, industry leaders are stepping up pressures for federal and state governments to forge a regulatory apparatus to ensure that agricultural biotechnology experiments can go forward without excessive delays and clearance costs. In response, EPA and USDA were expected to unveil their regulatory matrix this week. There appears good reason to believe that key regulatory issues relating to product field testing and release may be reasonably worked out. But these regulatory issues will be a major policy arena over the next decade or more. And, it is already clear that agricultural applications of biotechnology will not be given the open ended license of their predecessor agricultural technologies. Neither, however, should they probably be subjected to excessive regulatory delay or to such product safety requirements as the "zero tolerance" constraints of the Delaney clause.

Dividing the Research Agenda and Responsibilities

Much biotechnology development requires research inputs from both the basic and the applied sciences. And the public research institutions and the private industrial laboratories can both contribute to the process. But how should the R & D investments be financed? Who should pay the bill? What economic incentives for generating additional private sector R & D will be appropriate?

How will public (and private) interests be protected in the granting of such incentives? What kind of public sector-private sector institutional arrangements (such as joint ventures) should be supported for the development of new biotechnology?[2] How does one ensure, for example, that the basic scientific work which permits the development of new biotechnologies gets done? These several latter questions imply an even broader policy question. How do we draw together the resources and capabilities of the private sector, the research universities, and the government to deliver the biotechnologies which can provide crucial future productivity growth?

Although the private sector generally welcomes the contribution of public research to basic or theoretical science, the development of applied technologies is sometimes a different story. This should not be surprising since it is mainly through the development and marketing of applied technologies that the private sector enters the market economy. Their capacity to do this profitably relates to their ability to develop and protect a market for their product(s). As a result, many private sector firms will oppose any widespread funding of applied research by the public sector. But, they would, if possible, be willing to enlist the services of public sector researchers to assist them in their

[2]A comprehensive prototype legal arrangement for University-Private Sector collaborative arrangements for biotechnology research is contained in Progress Report III of the Division of Agriculture Committee on Biotechnology, NASULGC, "Emerging Biotechnologies in Agriculture: Issues and Policies," November, 1984.

product related R & D. And, although a number of large private sector firms can undertake to do basic and theoretical science, the preponderance of private sector firm's cannot afford to do so.

The question of public versus private research did not have its origin with the emerging biotechnologies. Rather it has been around in one form or another for a long time. In recent years, for example, the question of whether or not the public sector (USDA and the State Agricultural Experiment Stations) should be involved in developing crop varieties for farmer use has been a continuing issue. This policy issue will become even more intense when genetic engineering begins to play an important role in applied plant breeding (varietal development). Yet it seems somewhat of a policy imbalance to ask the tax paying public to support only basic research in the public sector and to turn their results over the private sector firms for them to exploit the potential for economic gain via the application of biotechnology techniques.

These several issues of public-private research division probably focus mainly on three key mechanisms of public policy (Sundquist, 1983):

1. establishing constructive mechanisms for joint public-private sector planning for R & D priorities and conduct of R & D work,
2. providing funding and other support services for public sector research, including private sector funding for research universities, and

3. granting proprietary rights and tax benefits to private sector firms.

Appropriate developmental strategy should capitalize on the interests, capabilities, and comparative advantages of both private sector firms and public sector institutions. For example, the comparative advantage of the USDA/State Agricultural Experiment Station System lies in its extensive and widely dispersed research base (both professional staff and facilities), its extensive feedback system (particularly with producers), and its training capabilities (particularly at the graduate level). The comparative advantage of the private sector centers on its unique profit incentives and its vast capabilities to develop biotechnologies and to market the resulting products.

One of the critical issues relating to the balance of public and private research is the stagnation of public funding of agricultural research (actually declining real public research budgets since the late 1970s) and the large infusion of research funding in the private sector. This has resulted in the private sector R & D budget dominating the public research budget by a ratio of about 2:1 (Ruttan 1982). Thus if public research is to play a continuing important role in biotechnology, it will either have to improve its access to funding for that purpose or leave other important research areas without financial support.

Both new and tested mechanisms need to be utilized in the funding of public sector research for biotechnology. Both the traditional federal formula funding for the Agricultural Experiment

Stations and a strong competitive grants program can aid the process. So can a well financed research program in USDA. In addition, key regulatory agencies need funding support for evaluative (technology testing) research.

The process of granting proprietary and quasi-monopoly rights to businesses for biotechnology by patents, copyrights, and other licensing mechanisms will undoubtedly be an area of active future public policy. So will issues relative to investment tax credits and other tax exemptions or write-offs. In both areas, public policy should be based on an evaluation of trade-offs. But two principles should probably be of overriding public concern. First, the granting of proprietary rights should not be permitted to excessively slow the broad availability of productive new technology or to allow franchise holders to excessively exploit new income streams. In short, excessive monopoly powers should not be granted to technology developers. Second, tax benefits to technology users should generally be granted only for those biotechnologies which have been determined not be have broad based adverse effects.

In summary, it is not difficult for me to identify a more optimal mix than currently exists of mechanisms for joint public-private sector planning of research priorities and conduct of R & D work. In the process the benefits of biotechnology should be more broadly dispersed within the agricultural industry and to other interest groups (environmentalists, consumers, and to the R & D community generally). Moreover, a joint public-private research effort should help accomplish the critical information flow identified by Regal in an earlier section of this discussion.

Intellectual Property Rights, Information Dissemination and Industry Structure

Policy implications of intellectual property rights are already embodied in the previous topic of patents and licenses. The U.S. Board of Patent Appeals, in a reversal of policy, last year ruled that Section 101 of the U.S. Patent Act does indeed apply to seeds, plants, plant parts, tissue cultures, etc. This case, brought by a local firm, Molecular Genetics, Inc., involved a claim made for new corn plants and seeds that contain high levels of the amino acid tryptophan. This decision did for plants what the Supreme Court did for living microorganisms in 1980 by ruling that the latter were patentable products. The full interpretation and impact of these patent rights will undoubtedly be determined still further by future actions in the courts.

While these patentability rulings provide much desired protection for private sector R & D and thus provide incentive for biotechnology development, they raise the specter of adverse consequences as well. The needed improvement in information flow called for earlier by Regal will not be encouraged by patent protection. Also, there is increasing evidence that extensive protection of biotechnology through patenting and licensing rights will result in increased concentration in those agribusiness sectors producing new biotechnology products. Since information on most prior agricultural technologies has been available through the public sector, industrial firms have been able to concentrate the market only if there were major scale economies in product manufacturing or marketing as in the case of major equipment items such as tractors and harvesters. It seems clear that some of the major chemical companies believe that they will be able to capture substantial economic rents in the future through development and control of agricultural applications of the emerging biotechnologies. There can be no other explanation of their widespread activities to acquire farm input firms (such as seed companies) and firms specializing in biotechnology R & D.

<u>Structure of the Farming Sector</u>

Recent analyses (OTA, 1986; Kalter, 1985; Buttel, 1986) suggest that biotechnology applications in the farming sector will result in a continuation of the structural adjustment to fewer and larger farms but will not result in a take over of farming by corporations. These results are exemplified from the OTA report in Table 1. Although most biotechnology applications in farming may be rather scale neutral, they will probably be adopted as part of more technically complex farming systems which will be more easily adopted by commercial farmers than by small or part-time farmers. While the number-size adjustment to the year 2000 shown in Table 1 would probably result in significant increases in agricultural productivity, it will undoubtedly be opposed on several policy fronts. The following quote from the March 23, 1986 issue of the New York Times illustrates the nature of at least some of the expected resistance to commercial release of the Bovine Growth

Table 1. Most Likely Projection of Total Number of U.S. Farms in Year 2000, by Sales Class

Sales class	1982		2000	
	Number of farms (thousands)	Percent of all farms	Number of farms (thousands)	Percent of all farms
Small and part-time	1,936.9	86.0	1,000.2	80.0
Moderate	180.7	10.0	75.0	6.0
Large and very large	121.7	4.0	175.0	14.0
Total	2,239.3	100.0	1,250.2	100.0

SOURCE: Office of Technology Assessment (1986).

Hormone.

> Dairy farmers in Wisconsin, for instance, are organizing to prevent the marketing of a genetically engineered hormone that will raise daily milk production by 30 percent in the average cow. A Cornell University study predicted that the use of this hormone would reduce by half the number of dairy farms and shift the center of production from the Upper Middle West to the Southwest, where farms are much larger and presumably better able to afford new technology. "There is going to be a big fight in farm country over this technology," said Jeremy Rifkin, president of the Foundation of Economic Trends, a Washington-based group. "Farmers are not going to roll over. If they do, they're dead."

Although it seems unlikely that the release of the bovine growth hormone will be prevented by regulatory constraints, there might well be efforts (of as yet undetermined success) to protect dairy producers via milk quotas or other policy devices. And, although concern needs to be realized for impacted dairy farmers, such policies could offset at least part of the potential productivity gains from the emerging technologies.

Technology Transfer

A number of important policy issues could be discussed under the heading of technology transfer, but I will mention only three which have been indirectly implied earlier. First, the public agricultural research system in the U.S. stands to lose much of its broad based farmer support system if its researchers choose to communicate mainly with private sector firms in the development of new biotechnologies. If this were to happen, farmers could well withdraw their support for publicly funded research. The policy issues here relate to retaining or redeveloping an effective technology transfer linkage with this important farmer clientele group. In this regard I was very favorably impressed by the technology transfer activity described by Administrator Kinney which has been set up by ARS. I believe that the Land Grant Universities too need to seriously consider an effective technology transfer process to their farmer clientele for their biotechnology research.

A second major issue regarding technology transfer relates to the potential for private firms to excessively capture exclusive property rights to biotechnologies via patents and licenses. This could result not only in the economic exploitation of farmers by agribusiness firms but it could also result in the public sector losing its access to the relevant new technology to transfer to farmers. Here the major policy issue relates back to the need to avoid the granting to private sector firms of excessive monopoly rights. A third issue pertains to technology transfer between countries. I have neither the space or the expertise to develop this issue here. But, clearly the issue takes on different dimensions when we are considering transfer between developed countries and between developed and developing countries. There is some evolving literature on this issue and its importance well justifies its attention in a separate discussion.

The above discussion treats only some of the policy implications of biotechnology research and it treats them very lightly. But, even this brief sampling of the policy issues suggests that some are very important and extend well beyond agriculture to basic ethical and safety concerns. Other issues are simpler ones but still involve important trade offs. Although there is a potential for major productivity gains via the emerging biotechnologies, they will be subjected to much more intensive policy treatment than has been the case for their predecessor agricultural technologies. And this is probably as it should be if done constructively.

Selected References

Butler, L. J. and A. A. Schmid, "Genetic Engineering and the Future of the Farm and Food System in the U.S. Leaflet No. 15 in The Farm and Food System in Transition: Emerging Policy Issues, Michigan State University Agricultural Extension Service (1984).

Buttel, Frederick H. "Biotechnology and Public Agricultural Research Policy." Paper prepared for Ag. Science Policy Workshop sponsored by ARI, Spring Hill Center, Wayzata, MN (April, 1986).

Kalter, Robert J. "The New Biotech Agriculture: Unforseen Economic Consequences." Issues in Science and Technology (Fall, 1985).

National Association of State Universities and Land Grant Colleges, Division of Agriculture Committee on Biotechnologies. Progress Reports III (November, 1984) and IV (November, 1985).

Office of Technology Assessment, U.S. Congress. Commercial Biotechnology: An International Analysis, Washington, D.C. (January, 1984).

Office of Technology Assessment, U.S. Congress. Technology, Public Policy, and the Changing Structure of American Agriculture, Washington, DC (March, 1986).

Regal, Philip J. (1985a). "Safe and Effective Biotechnology: Mobilizing Scientific Expertise." Paper presented at AAAS Symposium: Application of Biotechnology: Environmental and Policy Issues. Los Angeles (May, 1985).

Regal, Philip J. (1985b). "The Ecology of Evolution: Implications of the Individualistic Paradigm" in Engineered Organisms in the Environment: Scientific Issues. H.O. Halvorson, et. al. (eds.) American Society for Microbiology, Washington, DC (1985).

Rifkin, Jeremy. ALGENY, Viking Press, New York (1983).

Ruttan, Vernon W. Agricultural Research Policy. University of Minnesota Press, Minneapolis (1982).

Sundquist, W. B. "Technology and Productivity Policies for the Future." Leaflet No. 4 in The Farm and Food System in Transition: Emerging Policy Issues, Michigan State University Extension Service (1983).

Sundquist, W. B., K. M. Menz and C. F. Neumeyer. A Technology Assessment of Commercial Corn Production in the United States, Station Bulletin 546, University of Minnesota Agricultural Experiment Station (1982).