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SOME FOLICY IMPLICATIONS FOR AGRICULTURE OF BIOTECHNOLOGY RESEARCH

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SOME POLICY IMPLICATIONS FOR AGRICULTURE OF BIOTECHNOLOGY RESEARCH*

W. Burt Sundquist

Introduction

First, although I don't want to be definitive to the point of excluding important issues, some definition of the term "biotechnology" as applied to agriculture is probably 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 some of 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 including gene identification, characterization, splicing, replication, regulation and transfer." And, although this list is not exhaustive, these are probably the major techniques that should be on the agenda for any current discussion of policy implications for agriculture of biotechnology research and application. Lest we be unduly constrained in 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."

^{*}This manuscript represents a revised version of a discussion prepared for the Agricultural Research Policy Seminar, North Star Inn, Minneapolis, MN, April 18, 1986.

This perspective opens up a dramatically large field of biotechnology with a host of future policy issues waiting in the wings.

Importance of Biotechnology to Production Agriculture

Several years ago, I was involved in a technology assessment for commercial corn production in the U.S. (Sundquist, Menz and Neumeyer, 1982). As we tried to project the importance of various technologies into the future, the emerging biotechnologies took on an increasing but highly uncertain future role. And, existing technologies, except for technology trend associated with conventional plant breeding, took on a declining future role (Figure 1). My current perspective is to push back several years the time line (from that shown in Figure 1) for major impacts of biotechnology in corn production and other major field crops but to recognize the possibility of some major near term impacts in the livestock production sector, particularly in milk and red meat production.

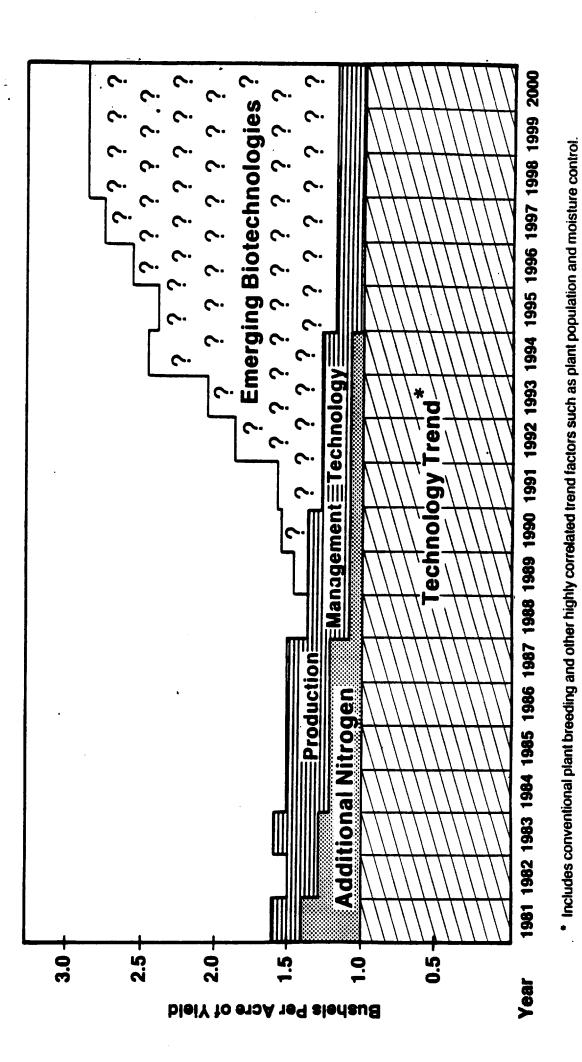
Although it appears that biotechnology may play a proportionally smaller role in the developing world than in the U.S. over the next 10-15 years, it could be a major source of potential total productivity gain there as well toward the end of this period.

Research Resources

From the standpoint of research resources, in 1982 an estimated 283 faculty FTE from the State Agricultural Experiment Stations (SAES) in the U.S. were reported committed to biotechnology research, and a

FIGURE 1

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



high proportion, probably upwards of 80 percent, were in the farm input and production area.¹ This number increased by 90 in 1984 and was projected to increase another 151 by 1986. If this projection was realized, the number of SAES scientists working on biotechnology will have almost doubled over only 4 years (NASULGC, 1985). State Agricultural Experiment Station expenditures for sponsored biotechnology research in 1984 approached \$50 million and there has been a corresponding rapid increase in biotechnology R & D like it has never funded research in any other technology area. Thus there is little question that the topic "the policy implications for agriculture of biotechnology research" is already a relevant one. And policy issues will almost certainly increase rapidly in number in the near future.

Policy Perspectives

It is already clear that the identification of major policy issues surrounding biotechnology research and its agricultural applications varies greatly depending on the personal interests and value perspectives of the individuals, organizations and institutions 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." On the other hand, Jeremy Rifkin (1983) and others,

¹ A small percentage of faculty FTEs, no more than an estimated 10-15 percent of the total, were involved in biotechnology applications for food processing and manufacturing.

particularly many individuals and groups with selected environmental and genetic manipulation concerns, see it in a very negative context. And, as is the case for most issues which become major items for policy deliberation, there are substantive areas for disagreement. I turn first to a look at some topics affecting future biotechnology policies from a commercialization perspective.

The Office of Technology Assessment (1984) identified 10 factors important in determining the future position of the U.S. 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. It is probably the case that this list includes most of the major factors which will be involved in policy deliberations vis-a-vis the rate and extent of commercialization of biotechnology processes and products.

There is also a very different perspective from the "commercialization goal" of OTA and others in both the public and private sectors. This is the perspective of those who see biotechnology as "An Age of Intervention." This "intervention" refers to the expanded use and modification of life forms for human ends. Among the basic value questions raised is the one of modifying the human life form itself for other than the correction of health impairing genetic defects. Another concern is for the release of new life forms into the environment and the potential adverse effects of such release.

Regal (1985a) provides the well reasoned perspective (and probably one with rather widespread acceptance) 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 informationflow between those seeking profits and those seeking to understand the implications of the new creations, as well as those seeking to ensure the effectiveness and safety of the new power." The latter statement would appear to give considerable prominence to policy issues related to trade secrets, intellectual property law, health and safety considerations, attitrust law, University/Industry/ Government relations, etc., which were given somewhat lower priority than commercialization in the OTA perspective.

An additional perspective provided by Kalter (1985) and by a recent OTA study (1986) is that the emerging biotechnologies will

probably 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 focus some on the several major policy issue areas stemming from agriculturally related biotechnology.

Policy Issues

One approach to discussion of the policy issues topic, and the one used here, is to try to categorize major policy concerns into several 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. A quote attributed to Robert Sinsheimer is the following: "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 change in the incentives for maintaining natural genetic diversity unless public policies are developed to maintain 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.² Moreover, such new superior genetically engineered lines could exert very heavy pressure on existing "natural" lines. In any event, there does seem to be an inherent potential for downgrading the importance of natural genetic diversity.³ Thus, there arises a new imperative for policies which encourage the preservation of such diversity. Also important is the continuation of conventional plant and animal breeding programs which draw on the naturally existing gene pool as well as incorporating the genetic inputs from biotechnology. In short, biotechnology <u>is not</u> a substitute for conventional breeding and selection 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 an oversimplification of ecological issues in the claims that it will be quite safe to release essentially any genetically engineered form into the environment."

 $^{^2}$ In addition to major disease and insect problems, are the potential hazards of acid rain, the greenhouse effect of increased atmospheric CO₂, increased salinity and toxic salts on irrigated lands, etc.

³ There is, on the other hand, a potential for protecting naturally occurring genetic diversity in anticipation of the capability to utilize this diversity via gene transfer. Both viewpoints, however, would appear to support the argument for protecting naturally existing diversity.

Thus, the environmental safety debate appears to have shifted generally from one of concern about genetically engineered forms developing into "rogue" organisms that can become "dangerous cannons loose on the deck" to one of concern for responsible testing and safety regulations. The 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. In March, 1986, EPA suspended the permit for field testing of the ice minus bacteria signaling that this agency will enforce its regulatory policy regarding biotechnology experiments. This permit was only recently reinstated.

Human health issues will almost certainly be of crucial importance for biotechnology applications in animal agriculture and in the food processing industry. 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 in mid-1986 unveiled their proposed regulatory matrix. There appears good reason to believe that key regulatory issues relating to product field testing and release will eventually be worked out. But these regulatory issues will be a major policy arena over the next

decade or more. And the current status of regulation is not an encouraging one (Science, 1986). Thus, 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 be subjected to such excessive regulatory delay as to virtually ensure their economic failure.

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?⁴ 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

⁴ Discussion of this topic and 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.

private sector, the research universities, and the government to deliver the biotechnologies which can provide crucial future productivity growth?⁵

The private sector generally welcomes the contribution of public research to basic or theoretical science. And, although a number of large private sector firms can undertake to do basic and theoretical science, the preponderance of private sector firms cannot afford to do so. Thus, a strong case can be made for publicly supported basic research. Private sector reaction to public research on applied technologies is, however, 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 product and process related R & D.

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 SAES) should be involved in developing crop varieties for farmer

⁵ There is a widespread belief that the current prominence of Japan, West Germany and some other countries in world technology and trade is due in part to more effective working alliances between government and the private sector than now exists in the U.S.

use or should leave this to the private sector 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 to the private sector firms to exploit the potential for economic gain via the application of biotechnology techniques.

The several issues of the division of public-private research identified in the preceding paragraphs probably focus mainly on three key mechanisms of public policy (Sundquist, 1983):

- establishing constructive mechanisms for joint public-private sector planning for research priorities and for the conduct of R & D work.
- providing funding and other support services for public sector research, and,
- granting proprietary rights and tax benefits to private sector firms.

Appropriate developmental strategy should strive to 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/SAES 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 biotechnology processes and products and to market the resulting output.

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 new R & D funding in the private sector. This has resulted in the private sector R & D budget dominating the public research budget by a substantial margin (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 with diminished financial support.

Both new and tested mechanisms can be used for the funding of public sector research for biotechnology. Both the traditional (or an improved) federal formula funding for the Agricultural Experiment Stations and a strong competitive grants program can aid the research process. So can a well financed research program in ARS. 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

will have to 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 for technology producers and/or users are appropriate only for those biotechnologies which have been determined not be have broad based adverse effects.

In summary, it is not difficult 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 would 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 could 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, in 1985 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 extensive protection of proprietary products. Also, there is increasing evidence that extensive protection of biotechnology through patenting and licensing rights will result in increased concentration among 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 and/or marketing as in the case, for example, of major equipment items such as tractors and harvesters. It seems clear that some of the major chemical companies now 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.

Structure of the Farming Sector

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. The numbersize adjustment projected to the year 2000 shown in Table 1 would probably result in significant increases in agricultural productivity. It will, however, 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 Hormone.

| | 1982 | | 2000 | |
|----------------------|-----------------------------------|----------------------|-----------------------------------|----------------------|
| Sales class | 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 |

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

SOURCE: Office of Technology Assessment (1986).

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.⁶ And, although concern needs to be realized for impacted dairy farmers

⁶ The only currently identified valid opposition to the bovine growth hormone appears to be in terms of the potential adverse economic impact on some producers. If constraints are imposed on implementation of the technology for economic reasons, it will be the first incidence of technology constraints imposed for that reason alone.

and regional economies, poorly conceived policies could offset a major part of the potential productivity gains from the emerging technologies while providing little or no long term assistance to targeted beneficiaries.

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 in this discussion. 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, the farm and rural business clientele could withdraw much of its support for publicly funded research. The policy issues here relate to retaining or redeveloping an effective technology transfer linkage with this important (mainly rural) clientele group. ARS has instituted a mechanism for routinely reporting their research (technology) achievements through the Agricultural Extension Information System. But this system needs strengthening. I believe also that the Land Grant Universities need to seriously undertake the upgrading of the biotechnology transfer process for their key farm and agribusiness clientele.

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. If

accomplished excessively, this capture 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 information about the relevant new technology which should be transferred 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 an extensive evolving literature on this issue and its importance well justifies its attention in a separate discussion.

<u>In Conclusion</u>

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 policy issues suggests that some are very important and extend well beyond agriculture to basic ethical and human safety concerns. Other issues are simpler but still involve important economic-environmental-structural trade offs. Our understanding of both can profit from good interdisciplinary research.

Although there is a potential for major productivity gains for production agriculture via the emerging biotechnologies, they will

be subjected to much more intensive policy debate and action than has been the case for their predecessor agricultural technologies. And this is probably as it should be if done constructively. The latter requires a good informational base on which to draw.

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