

DOCUMENT RESUME

ED 251 305

SE 045 255

TITLE Science and Policy Issues: A Report of Citizen Concerns and Recommendations for American Agricultural Research.

INSTITUTION National Agricultural Research and Extension Users Advisory Board (USDA), Washington, DC.

PUB DATE Jul 84

NC 74p.

PUB TYPE Reports - Descriptive (141) -- Viewpoints (120)

EDRS PRICE MF01/PC03 Plus Postage.

DESCRIPTORS *Agriculture; Developing Nations; DNA; *Economic Factors; *Federal Regulation; Futures (of Society); *Genetic Engineering; *Government Role; Higher Education; International Trade; *Policy Formation; Research Projects; Scientific Personnel; World Problems

IDENTIFIERS Biotechnology; Farm Policy; *Food Production

ABSTRACT

Two areas which will have far reaching consequences for the future of United States agriculture are discussed: (1) biotechnology; and (2) critical economic research in world trade and commodity supply management. Topics in the first area include: controversies related to biotechnology; the relative importance of health, safety, and environmental regulations affecting the commercialization of biotechnology; the relative importance of targeting policies affecting the commercialization of biotechnology; and the expansion of federal responsibilities in biotechnology. Also included are recommendations related to the relative importance of public perception affecting the commercialization of biotechnology, and to scientific expertise and manpower. Topics in the second area include the world food system of the 1970s (examining factors influencing the demand for and consumption of food) and the outlook for the 1990s (considering how population, economic growth, and government policies will affect world agriculture). These topics and recommendations related to conducting critical macroeconomic research and attracting and retaining economic research expertise in the U.S. Department of Agriculture can help in assisting policymakers who develop long-term goals and formulate the new farm bill. Supporting documentation (including a list of existing federal responsibilities regarding agricultural biotechnology by agency and function) is included in appendices. (JN)

 * Reproductions supplied by EDRS are the best that can be made *
 * from the original document. *

Science and Policy Issues:

Report of the Committee on Science and
Policy Issues of the National Academy of
Sciences

ED251305

U.S. DEPARTMENT OF EDUCATION
NATIONAL INSTITUTE OF EDUCATION
EDUCATIONAL RESOURCES INFORMATION
CENTER (ERIC)

- This document has been reproduced as received from the person or organization originating it.
- Minor changes have been made to improve reproduction quality.

• Points of view or opinions stated in this document do not necessarily represent official NIE position or policy.

SE015255

2

Contents

v	Preface
1	Breaking the Species Barrier with Biotechnology
3	New scientific advances bring controversy
6	The relative importance of health, safety, and environmental regulations affecting the commercialization of biotechnology
7	The relative importance of targeting policies affecting the commercialization of biotechnology
9	Expanding Federal responsibilities in biotechnology
14	Recommendations
14	The relative importance of public perception affecting the commercialization of biotechnology
17	Scientific expertise and manpower development
23	Economic Research, World Trade, and Farm Policy
23	The world food system of the seventies
28	Outlook for the decade ahead
34	Recommendations
34	Conducting critical macroeconomic research
37	Attracting and retaining economic research expertise in USDA
40	Appendixes
40	Existing Federal guidelines and regulations that may impact the development and testing of genetically engineered products
46	Federal responsibilities regarding agricultural biotechnology, listed by agency and function

Contents—continued

- 58** **Responsibilities and Structure of the
Users Advisory Board**
- 60** **How the Users Advisory Board Functions**
- 61** **The Board's Accomplishments in 1984 and
Agenda for 1985**
- 66** **Call for Comments**
- 67** **Participating Board Members**

**Washington, D.C.
July 1984**

Science and Policy Issues: A report of citizen concerns and recommendations for American agricultural research

Preface

Historically, agricultural technology has made agricultural production more efficient. Biological research substituted relatively inexpensive capital and energy for labor. The yield per unit of land was maximized. Efficient producers who applied these technologies increased yields at an annual rate of 2 to 3 percent. Sales were high in the seventies. Domestic feedgrain markets were strong. In addition, export sales expanded because developing nations experienced real population growth.

Today current real farm income is low and surpluses high because of unforeseen events. Chief among the causes are the following factors:

- Consumer preference change from red meat to poultry and fish.
- Worldwide economic recession.
- Foreign countries shift from being net food importers to food exporters.
- Export programs sponsored by foreign governments.

Consumer preference has shifted from red meat to poultry and fish. About 7 to 8 pounds of feedgrains are required to

produce a pound of red meat, but only 2 to 3 pounds of feedgrains are needed to produce a pound of poultry. World markets for excess domestic red meat production are limited because of the worldwide economic recession and trade barriers. Competition for world grain markets has heightened as many nations have expanded agricultural production to gain export revenues. The conduct, structure, and performance of world markets have changed because of government-sponsored programs used by U.S. competitors. The result is that traditional markets for U.S. agricultural products have declined.

This report focuses on two issues which the Users Advisory Board believes will have far reaching consequences for the future of U.S. agriculture: First, the science of cellular and molecular biology, commonly called biotechnology, and second, the need to exploit the potential for expanding U.S. and world agricultural markets. Actually, these two issues are interrelated. One promises a more bountiful and efficient agriculture in the United States and other countries as well. The other will determine whether the United States can sell its surplus production.

The agricultural capacity of the United States will remain far in excess of at least domestic needs for many years to come. Our food, fiber, and feed supplies have improved quantitatively and qualitatively. We simply can grow more food than peoples have the money to buy for the foreseeable future. Critical economic analysis of the factors which influence export markets would help the

agricultural sector achieve its economic vitality and production and profit potentials. Over the past 30 years, the central objective of crop research has been to substitute relatively inexpensive capital and energy for labor to maximize yield per unit of land. Today, this objective needs to be reviewed. In recent years, the cost of capital, energy, and land increased tremendously. Increases in yield alone cannot restore profitability to a battered agricultural economy when the dollar is strong and free trade is constrained. Agricultural research should use molecular genetics and molecular biology to reduce input costs.

In July 1983 and February 1984, the board addressed the potential benefits of biotechnology as a means of reducing input costs. Although new advances are still at some distance from achieving all of our hopes, there is already ample evidence of the benefits of biotechnology. Even so, we certainly need clearer guidelines, policies, and legislation for research, safety, licensing, sales, and the distribution of bioengineered products. The potentially pervasive nature of these new technologies means that a large number of Federal agencies will probably play many roles.

Without public confidence, the commercial use of agricultural biotechnology will be slowed by litigation at local, State and Federal levels. The spirit of these regulations should be cooperative and reflect a constant influx of new knowledge.

Currently, public and private research organizations are acting responsibly. But the American public deserves the assurance that this work is progressing responsibly. Federal attention will provide the guarantee.

The second section of this report identifies critical economic research in world trade and commodity supply management. This information can help to assist in providing policymakers who develop long-term goals and formulate the new farm bill.

William E. Marshall

WILLIAM E. MARSHALL
Chairman

Donavon C. Loeslie

DONAVON C. LOESLIE
Vice Chairman

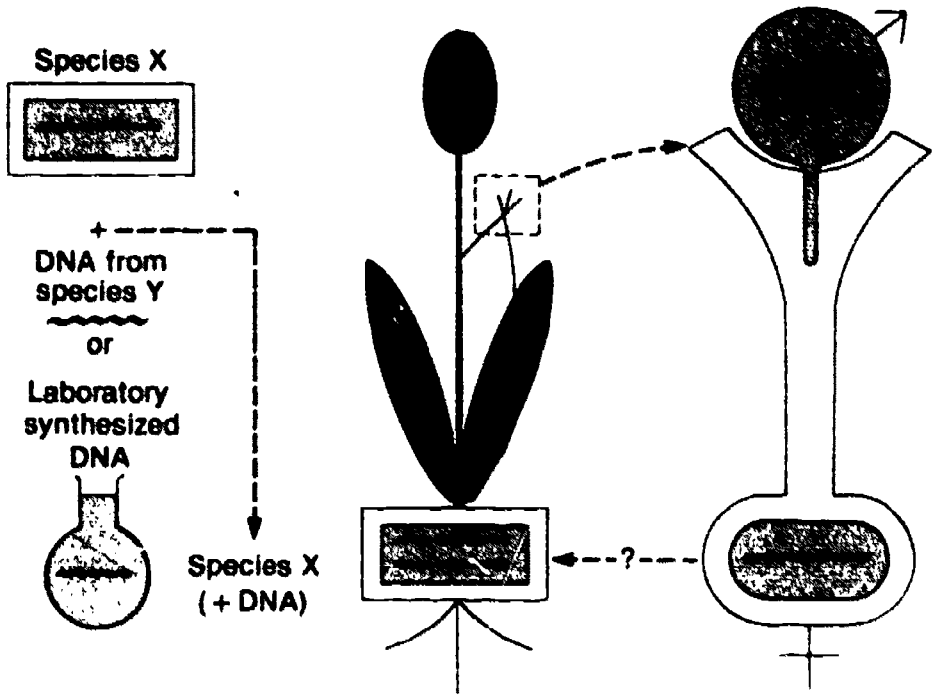


Breaking the Species Barrier with Biotechnology

For thousands of years, humans have manipulated nature for their own benefit. In the scientific age, wild plants and animals have been selected and bred to produce superior food and fiber products for many human generations. Most of these accomplishments were achieved by the artificial movement of naturally occurring genes within the same genus. In recent times, plant breeders created wheat, rice, and hybrid corn with high-yielding, fertilizer-responsive, and disease-resistant characteristics. They have spread around the world to create the "green revolution."

What is new, however, is that by genetic manipulation scientists can place human genes in yeast cells and animal genes into plants, bridging a barrier that now exists in nature. Someday researchers may synthesize genes. Biotechnology is thus setting the stage for an even more dramatic agricultural change than the green revolution. Scientists believe that genetically improved crops will soon tolerate a wider range of temperatures, drought, saline soils, and other stressful growing conditions. These improved plants will ignore certain herbicides, resist diseases and pests, and could reduce farm input costs while maintaining or increasing yields.

Chart 1: Bypassing the sexual reproductive process



Source: Institute of Food and Agricultural Science; University of Florida.

Genetic engineering using recombinant DNA is a new tool that will be used to produce new food additives, animal feed and drugs, chemical and microbial pesticides, and improved plant and animal species. Genetically engineered microorganisms are already producing insulin, growth hormone, interferon, and other new products to improve human health or combat disease. Breakthroughs in plant science are occurring at a faster pace than anticipated, particularly in the microbial area.

Biological control methods developed by scientists have been beneficial in preventing or arresting the damage done

by plant and animal pests and diseases. These control methods enhance the ability of plants and animals to withstand other detrimental effects that follow biological and environmental stresses. More of these advances will be developed through biotechnology research. With the advent of genetic engineering, it is possible to modify the genetic material of virtually any living organism to a greater extent than occurs through conventional breeding techniques. Products produced with this scientific tool can affect all aspects of food and fiber production, processing, and distribution.

New Scientific Advances Bring Controversy

"One may also imagine that in criminal hands radium might become very dangerous, and here we may ask ourselves if humanity had anything to gain by learning the secrets of nature, if it is ripe enough to profit by them, or if this knowledge is not harmful. The example of Nobel's discoveries is characteristic: powerful explosives have permitted men to perform admirable work. They are also a terrible means of destruction in the hands of great criminals who lead peoples toward war. I am among those who think, with Nobel, that humanity will obtain more good than evil from the new discoveries."

Pierre Curie, at a Nobel Prize Ceremony, 1903

Controversy, of course, is inevitable when people confront a new scientific advance. The debate about the safety of recombinant DNA research began almost as soon as the first experiments were reported. In 1971 a molecular biologist proposed to combine DNA (deoxyribonucleic acid) from a monkey tumor virus, known as SV40, with a plasmid from the bacterium *E. coli*. Fears were immediately raised among some scientists that the modified virus might somehow infect humans and cause cancer.

Although unlikely, these concerns could not be dismissed for several reasons. First, *E. coli* commonly reside in human and animal intestines. If the recombinant molecule were ingested by a human or animal, it might establish itself in the intestine. Second, although the virus has not been known to cause cancer in humans, it has produced cancer in mice and hamsters and caused human cells in culture to grow abnormally. The biologist finally voluntarily deferred the experiment.

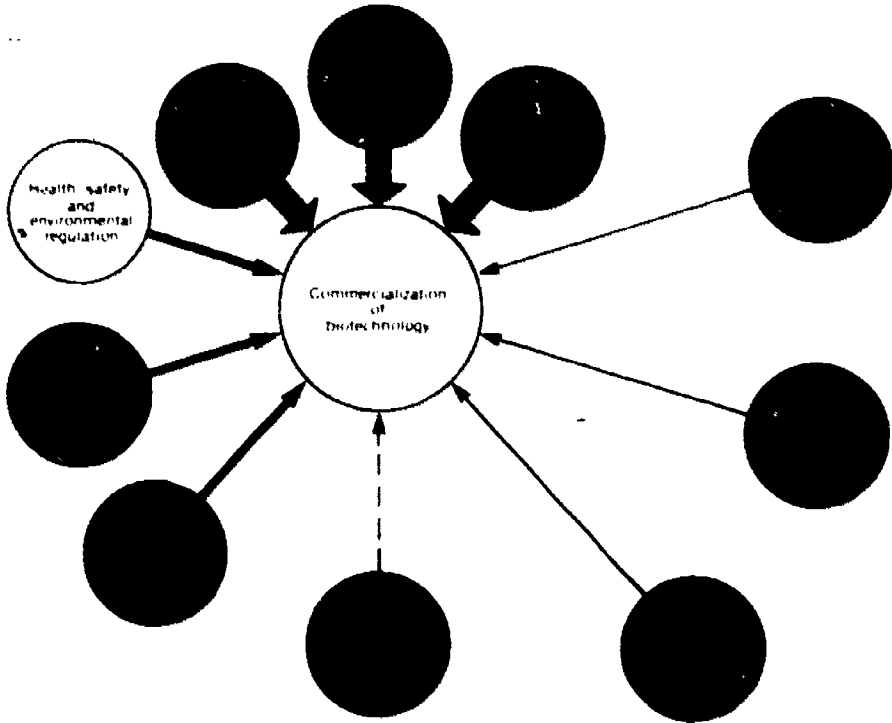
When a small group of molecular biologists met at the 1973 Gordon Conference, they discussed the potential hazards of recombinant DNA experiments. After the meeting, they wrote to *Science* magazine to alert the scientific community of their concerns. They urged the National Academy of Sciences to investigate the potential hazards of using this new tool. In 1974 an academy committee said that until the safety hazards could be assessed, a worldwide moratorium should be observed for work with certain types of

recombinant DNA, such as those that would introduce viral genes into bacteria or genes that confer antibiotic resistance to bacteria. They also recommended that the National Institutes of Health establish an advisory committee to develop safety guidelines for future recombinant DNA research and that an international conference be held on recombinant DNA research. All three suggestions were followed.

A committee of the National Institutes of Health, now known as the Recombinant DNA Advisory Committee (RAC), responded to the recommendations suggested by the scientific community. Their guidelines, adopted in 1976, specify the physical and biological containment conditions under which recombinant DNA experiments may be performed. The guidelines are binding only for federally funded research. To date, industry has voluntarily complied with these guidelines, following the suggested procedures for obtaining project approvals.

The guidelines provide for an institutional monitoring of recombinant DNA experiments supported by Federal grants through institutional biosafety committees at each university. Committee meetings are not open public forums where social, ethical, and environmental concerns of citizens can be addressed prior to conducting new research. A USDA group called the Agricultural Recombinant DNA Research Committee (ARRC) monitors USDA's laboratory and field agricultural research and provides guidance to the USDA representative to HHS-NIH RAC.

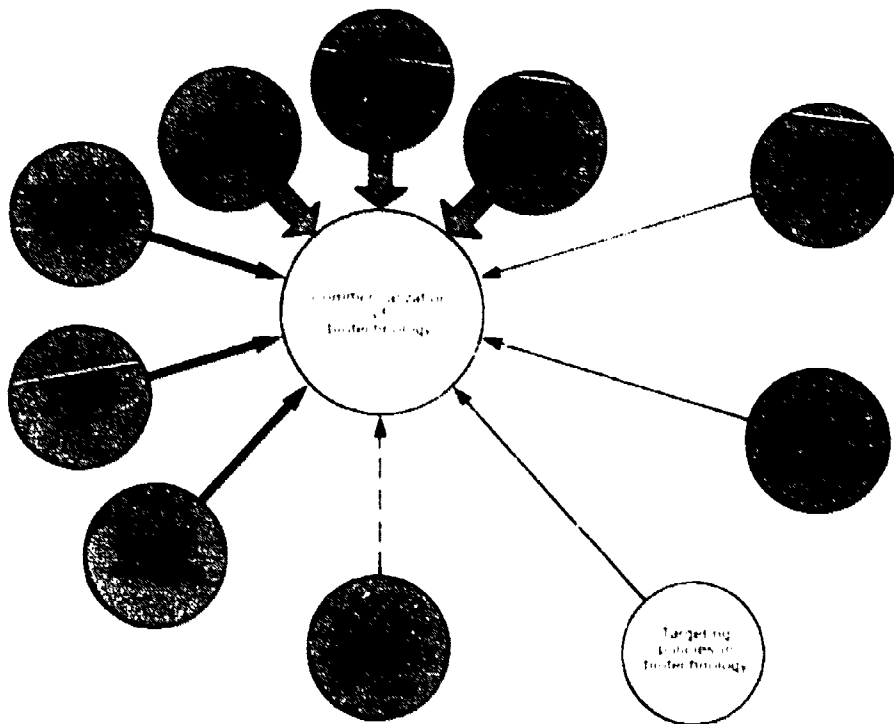
The relative importance of health, safety and environmental regulation affecting the commercialization of biotechnology



Source: Office of Technology Assessment

The Centers for Disease Control and National Institute of Occupational Safety and Health have another advisory committee that develops safety guidelines for workers who create industrial applications of recombinant DNA. Occupational safety laws require employers to provide a safe work area, free from known significant risks. This committee is concerned about any possible risk posed by genetically recombined organisms and products. Although the group supports physical containment of recombinant DNA materials, they recommend medical surveillance of workers' health.

The relative importance of targeting policies affecting the commercialization of biotechnology



Source: Office of Technology Assessment

Agricultural, food, and environmental laws also apply to experiments and products as well as scientific and worker safety guidelines. Each Federal agency's mission and goals shape the data requirements for conducting research, assuring product performance, maintaining medical surveillance, making toxicological and residue analyses, noting hazards to nontarget organisms, and protecting ecosystems. Agricultural research has produced thousands of new plant and animal foods and agricultural inputs which have satisfied Federal regulatory requirements. Current Federal guidelines and regulations have a

significant influence on conducting laboratory research, field trials, and commercializing genetically engineered products. USDA's Food and Safety Inspection Service, Agricultural Marketing Service, and Animal and Plant Health Inspection Service operate under more than a dozen authorities.

The U.S. Environmental Protection Agency is responsible for protecting the environment from chemicals, pesticides, and pollutants. The U.S. Food and Drug Administration is responsible for establishing standards for food additives, human food, animal feed and feed additives, and veterinary medicines. However, standards for veterinary biologics are the purview of USDA's Animal and Plant Health Inspection Service. Neither USDA nor the Food and Drug Administration have developed useful plans for monitoring active biologics in the food supply.

Environmental legislation has also affected recombinant DNA research. The National Environment Policy Act, enacted by Congress in 1969, was designed to insure that the Federal Government would undertake no major programs or projects without first considering the potential environmental consequences. The act is a promise that the Federal Government will evaluate all potential environmental hazards of its activities. This is to occur in open public forums before embarking on courses of conduct that could significantly affect the environment.

Expanding Federal Responsibilities in Biotechnology

Progress in biotechnology research and development is occurring rapidly. It is outstripping the capacity of existing regulatory agencies to deal with many emerging issues. As presently constituted, Federal regulatory agencies have not provided the level of guidance and policy direction needed by public and private institutions. The private sector is unsure of the most direct pathway for commercial clearance.

The myraid of agency guidelines and regulations which may be relevant is overwhelming. The public's best interest is perhaps no longer best served when regulators and manufacturers meet agency by agency mandates rather than government-wide standards. A summary of current Federal guidelines and regulations relating to agricultural biotechnology appears in a later section of this report.

Adequate Federal laws for regulating biotechnology may already be in place and perhaps a simple regulatory road map is required. At present, the regulations are part of a patchwork system of guidelines and Federal health, safety, and environmental laws. Subtle changes in Federal procedures and regulations could exert needed guidance, policy direction, and streamline red tape. It may be feasible to reduce regulatory costs associated with product release if there is adequate Federal coordination

for compliance with test requirements. Policy issues which must be addressed include the following:

- How will the international flow of genetically engineered products be controlled?
- How will molecular biological scientific expertise be consulted as regulatory agencies establish research protocols?
- How will up-to-date scientific expertise be brought to bear on individual submissions without release of trade secrets?
- How will entry of active biological materials in the food supply be assessed and by what agency?
- How will research guidelines be established for additional biotechnical techniques beyond recombinant DNA?
- Will the HHS-NIH RAC determination, based upon scientific information that the agricultural product is not unique from parent or related products, be considered as any other organism for product registration?

The President's Cabinet Council on Natural Resources and Environment recently brought together 14 Federal agencies to develop the basis for regulating biotechnology. The working group on biotechnology, headed by White House science advisor Dr. George Keyworth, is charged with developing a unified policy. We support this effort. However, the Cabinet Council does not

provide an open public forum to discuss and resolve the diverse interests of scientists, industry, and the general public.

In a recent decision, Judge John Sirica ruled that since an environmental impact statement, as required by the National Environmental Policy Act was not filed, a federally supported field trial on ice nucleating bacteria should not be conducted. The plaintiffs in the case—the Foundation of Economic Trends—brought to the court the uncertainty of a risk posed by the intentional release of novel organisms into the environment. The major risk is whether these organisms will disrupt the balance of the ecosystem where they are released.

Sirica's court decision raises the public policy questions of which Federal agency should review such research projects and what procedures should be established to conduct field trials. The debate has now gone beyond the scientific and environmental communities and the public is increasingly concerned about safety issues and ethical implications of the new technology. The entry of the courts into the decisionmaking processes regarding biotechnology indicates the need for the prompt development of sound public and science policies. Scientists now have the tools to precisely manipulate genetic materials. Many people, including some scientists, question whether scientists can responsibly exercise this capability. Another concern is who should decide these issues—scientists, the public, or perhaps both?

In 1980, a Presidential commission began to study ethical problems in medicine and biomedical and behavioral research and address concerns that had been expressed by three major religious associations. They stressed that no Governmental body was addressing fundamental ethical questions or exercising adequate oversight and control on the direct human uses of gene splicing. The commission found that the perceptions of religious leaders were well founded. The commission's report attempts to clarify concerns about genetic engineering and provide a basis for an improved public understanding of the capabilities and potential of the technique. To minimize risks and ensure that changes occur within an acceptable range, the report concludes that an open public forum should be established to evaluate potential social and ethical implications before initiating new research activities.

Recognizing the potential hazards and public concerns about them, we advocate that practical and effective guidelines be developed for regulating research activities. These should include the development and testing of potential products and processes in the laboratory, farm, and field and the monitoring of products and processes throughout each phase as they are adapted for commercial use. Issues of overlapping jurisdictions and conflicting interests among various Federal

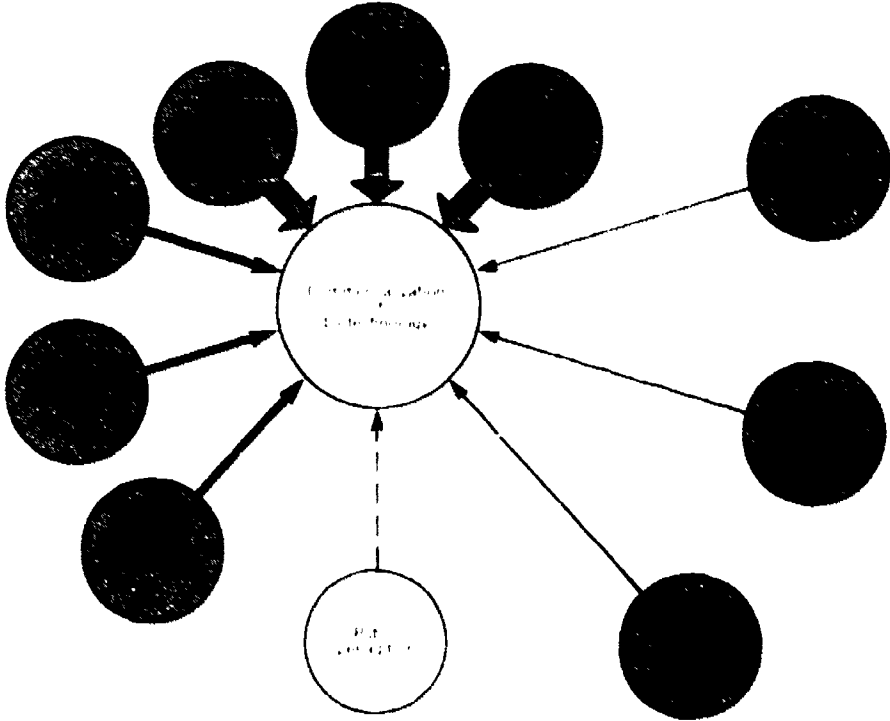
agencies must be addressed. Also, biotechnology guidelines and regulations must be harmonized throughout the Federal Government in a manner which optimally serves the public's best interest. Otherwise, important scientific and public policy issues in biotechnology will be determined by courts of law, an unnecessary, time-consuming, expensive alternative.

Specific Federal guidelines must be established for biotechnology research, field testing, and commercial production and should be—

- **Affordable and applicable to both the public and private sectors, large and small companies.**
- **Promoting scientific development.**
- **Constantly evolving because of new scientific knowledge.**
- **Adaptable by foreign governments on a worldwide basis of cooperation.**
- **Promoting the collection of risk assessment data.**
- **Understandable to the public.**
- **Promoting reduction of known hazards to investigators and workers.**

Recommendations

The relative importance of public perception affecting the commercialization of biotechnology



Source: Office of Technology Assessment

To allow for the rational development of agricultural biotechnology, it is imperative that clear guidelines and policies be implemented soon. This is in the best interest of the general public, scientific, regulatory, and industrial communities.

A temporary national Biotechnology Regulatory Coordinating Commission should be established to guide the shaping of the Federal role in biotechnology. Because of the broad

overlapping effects of the use of genetic engineering techniques in the medical, defense, and agricultural fields, the Commission should represent a broader spectrum of skills and interests than just food and agricultural concerns. The commission should have general responsibility for preparing independent advisory opinions on proposed regulations for laboratory and field tests, as well as on regulatory guidelines for commercial products. Members of the Commission should be responsible for—

- **Serving as consultants to the President by reviewing short- and long-term Federal laws; national policies, priorities, and strategies for research; staff expertise; regulatory guidelines; and patent rights and by preparing a public report on these topics not later than July 1, 1985.**
- **Assessing the social, ethical, economic, and environmental effects of conducting biotechnology research and releasing medical, industrial, and agricultural products.**
- **Recommending interagency lines of jurisdiction and authority in formulating regulatory guidelines for research, development, and product registration.**
- **Assessing the private sector's biotechnology research and the nature of its relationship with federally supported research.**

-
- **Outlining a procedure for resolving future unanticipated issues relating to more than one agency.**
 - **Identifying current and new opportunities or developing problems related to international research, development, and regulatory activities.**

The commission should report to the White House Office of Science and Technology Policy. Members should represent the diversity of all users. Specifically, approximately 18 citizens should represent the multiple interests of the following groups:

- **Public and private sector scientists.**
- **Consumers.**
- **Ecologists.**
- **Physicians-public health and safety.**
- **Theologians.**
- **Lawyers.**
- **Organizations involved in programs in developing countries.**
- **Macroeconomists.**
- **World Trade Corporation Representatives**

The general issues outlined for the commission must also be addressed by the U.S. Department of Agriculture to determine the agricultural implications of biotechnology. The Secretary of Agriculture should provide relevant

guidance to the Biotechnology Coordinating Commission from the agricultural community. Representatives of many of the interest groups who already serve on USDA advisory boards could be brought together in a conference or challenge forum to debate these issues and assist in developing consensus positions.

Scientific Expertise and Manpower Development

Federal agencies responsible for the various aspects of biotechnology must build their scientific expertise quickly. The Food and Drug Administration has already started building its expertise for regulating the pharmaceutical industry. The Environmental Protection Agency must follow up quickly by increasing its ability to administer effective and science-based regulations for agricultural biotechnology. Recognition of the Department of Agriculture's scientific expertise has not been established within the Executive Branch policymaking process. The current needs for scientific expertise must be evaluated and plans made to fulfill future manpower requirements within all its agencies.

The U.S. Department of Agriculture has contracted with the National Academy of Sciences, Board on Agriculture, to develop a national strategy for biotechnology and evaluate the level of competency of USDA's research personnel. These two studies should then be expanded to prepare a joint report on manpower needs, scientific qualifications, recruitment process, and organizational delegations of authority

needed to establish sufficient biotechnology scientific expertise. It is increasingly difficult to attract bright, competent personnel to Federal science and public policy positions. Academic freedom associated with university positions, the frequently higher-salary rewards of non-Federal jobs, and the public's diminished regard for civil servants pose major barriers to fulfilling Federal scientific expertise needs. A thoughtful solution to the problem of USDA's scientific staff will be important to USDA's future role in formulating and directing Federal guidelines and regulations for agricultural research and application.

USDA's Competitive and Special Grants Programs are useful manpower training mechanisms. Countries in which science for agriculture is strongest are those nations whose agriculture will have the dominant market share. It follows that the availability of a sufficient number of educated, high-quality scientists is crucial. Thus the main reason for use of public funds to support basic research in universities should be to ensure a steady stream of such people. As the need for specialized biotechnology manpower continues to expand, competitive and special grants can provide the critical funding in the key scientific disciplines that underpin this concern.

The Competitive Grants Program was established in 1978 to provide support for high-quality, significant, basic agricultural research, regardless of the affiliation of the research institution. The program also provides training

opportunities that attract superior young scientists to work on agricultural problems. More first-class scientists who can successfully compete for basic research funds provided under the Competitive Grants Program should be recruited to conduct basic biological research for USDA, regardless of the institutional affiliations of the scientist. The work of perceptive researchers who can focus their energies on developing frontier scientific tools and techniques should continue to be supported, and the Competitive Grants Program should be reauthorized by Congress. The Competitive Grants Program should be restricted to only basic research instead of basic and applied research as the law currently allows. The restrictions should be made by amending Section 2(b) of the Act of August 4, 1965, Public Law 89-106, as amended by Section 1414 of Public Law 95-13 [7 U.S.C. 450l(b)].

Congress also needs to refocus and fund USDA's Special Grants Program. A new focus is needed to achieve the following objectives:

- **Strengthen the scientific capacity of the state agricultural experiment stations.**
- **Support institutional affiliations which stimulate rapid use of emerging scientific techniques to reduce agricultural input costs for seeds, fertilizers, pesticides and fungicides, labor, fuel, water, farm machinery, and interest.**

-
- Provide increased attention to high-priority biological and economic science for agriculture by supporting this work with competitive funding for major projects in special scientific areas.

Section 2(c)(1) of the Act of August 4, 1965, Public Law 89-106, as amended by Section 1414 of Public Law 95-13 [7 U.S.C. 450 2(c)(1)], should be revised to establish a Centers of Excellence Program as follows:

The Secretary of Agriculture is authorized to provide competitive grants for periods not to exceed 5 years to state agricultural experiment stations to stimulate research on high-priority agricultural questions. These grants must strengthen the scientific capacity of state agricultural experiment stations and promote research partnerships between the state agricultural experiment stations and nonagricultural basic and economic science departments of land-grant universities, other colleges and universities, other research institutions and organizations, corporations, and high-venture capital firms having demonstrable capacities in the food and agricultural sciences.

Research objectives of private sector laboratories are not the same as those in the public sector. The private sector must provide the greatest possible returns for the investments of shareholders; research agendas are set accordingly. Providing options that can reduce chemical use, for example, may

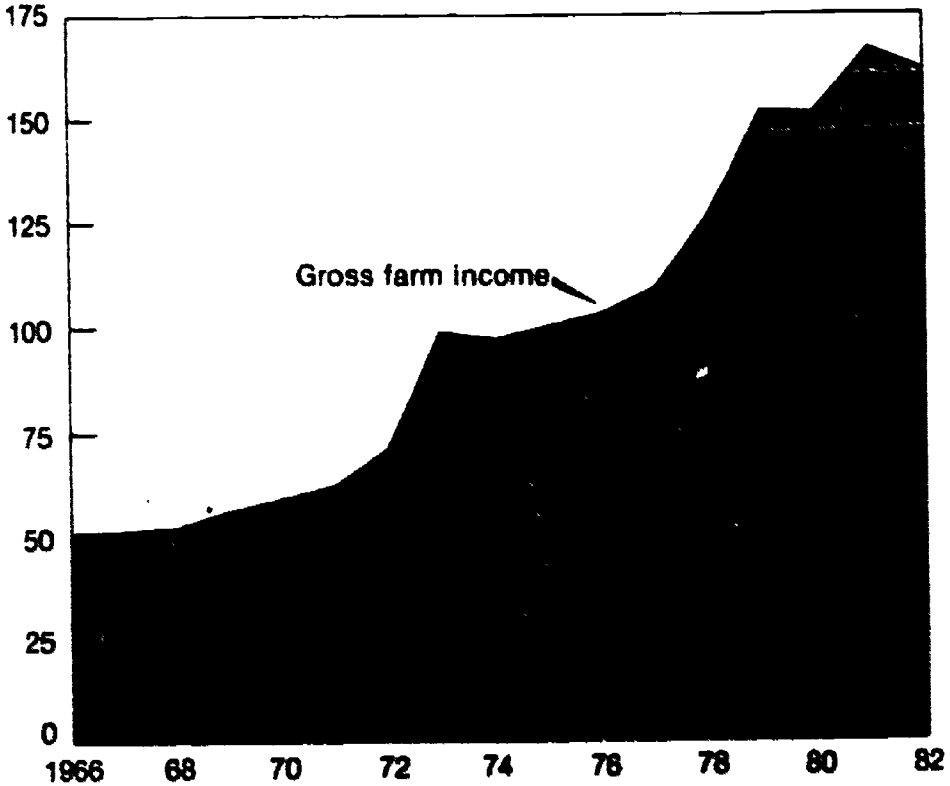
not be in the best interest of some corporations. So the Nation must look to the agricultural colleges and universities to solve those special kinds of problems. Research which continues to focus upon maximizing yield does not ensure producers of food and fiber products a competitive advantage on world markets.

Public supported agricultural research must build the base for reducing farm input costs. Program administrators must have the courage to accept the fact that maximizing yield on plants, animals, and forests for the next thirty to fifty years is a completed task. Our technical goal should be to decrease real production costs at an annual rate of 2 to 3 percent.

The Extension specialist can then develop programs which provide scientific information on the optimum relationship between yields and costs for producers. Production efficiency is critical to put profit back into the farming, processing, transporting, and distributing of agricultural products. We believe the Extension Service can fulfill an important public service to promote state agricultural development by assuring the food and fiber producers an adequate income to remain in production.

Chart 2—Income from farming

\$ billion



Source: 1983 Handbook of Agricultural Charts. USDA, Economics Research Service



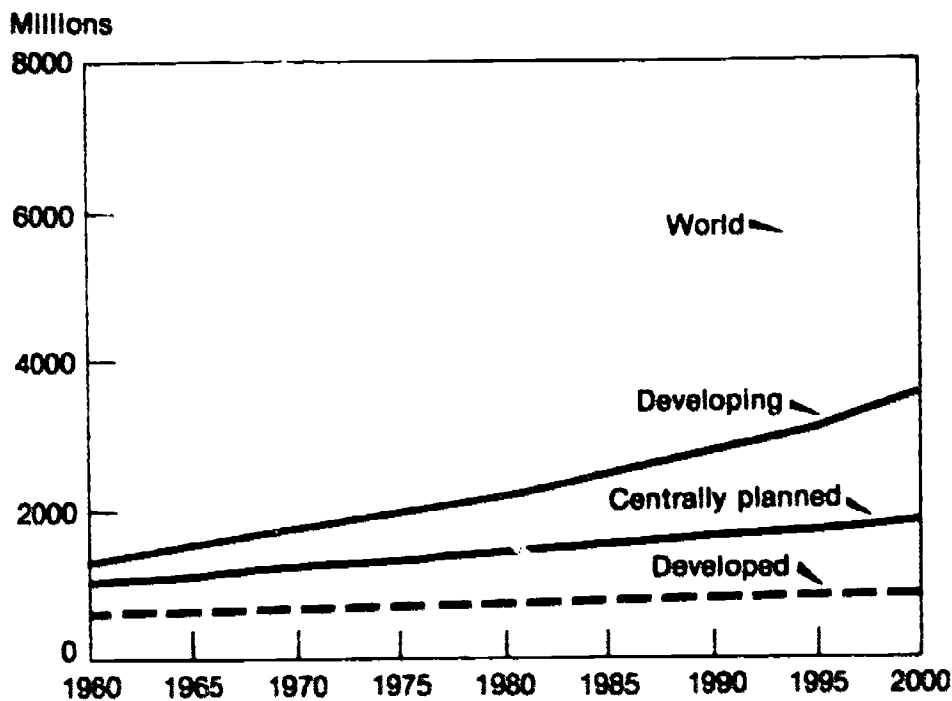
Economic Research, World Trade, and Farm Policy

The world food system is dynamic. Factors that influence the demand for and consumption of food should include the level, growth, and demographics of human populations; the level and growth of incomes; and cultural tastes and preferences.

The World Food System of the Seventies

The past decade was characterized by extreme shifts—from chronic grain surpluses to temporary shortages accompanied by volatile price swings. The most important trend has been the worldwide increase in productivity. World production expanded by 2.5 percent annually during the last decade. But the world's population grew only 2 percent a year. This resulted in a 0.5 percent annual increase in per capita food supplies. However, food and fiber productivity increases have not always occurred in regions where population expanded most rapidly. The result has been significant food deficits and surpluses in different regions of the world.

Chart 3—World population continues to grow, with most of the growth occurring in food-deficit developing nations

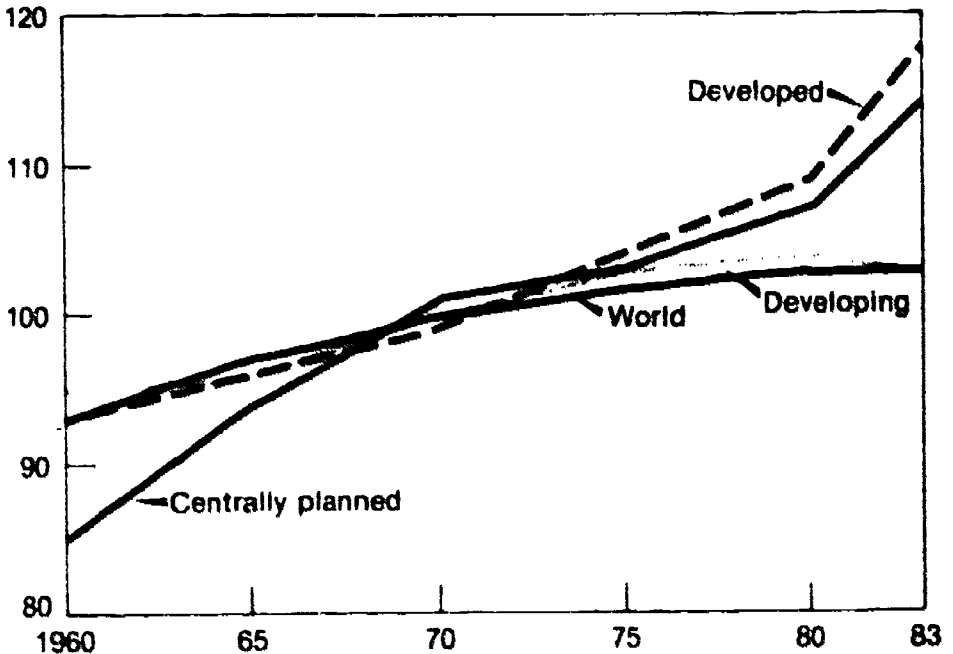


Source: ERS Working Paper, May 1984

Population pressures and declining per capita incomes in sub-Saharan Africa continues to accelerate. Without major economic aid, many countries in Africa cannot maintain their current per capita food consumption levels, which are already low by world standards. The entry of Eastern Europe, the Soviet Union, and China into world trade to supplement their own production shortfalls increased grain demand and also expanded world agricultural trade.

Chart 4—Developed nations achieve substantial gains in per capita food production, while many developing nations show little progress

Percentage*



* 1969-1971 = 100

Source: Economics Research Service, March 1984

The green revolution allowed India and other major importing countries to approach self-sufficiency. Meanwhile, major food surpluses have mounted in North America. In addition, generous government price support policies in other regions, such as the European Economic Community, expanded their agricultural economies and they have become net food grain exporters.

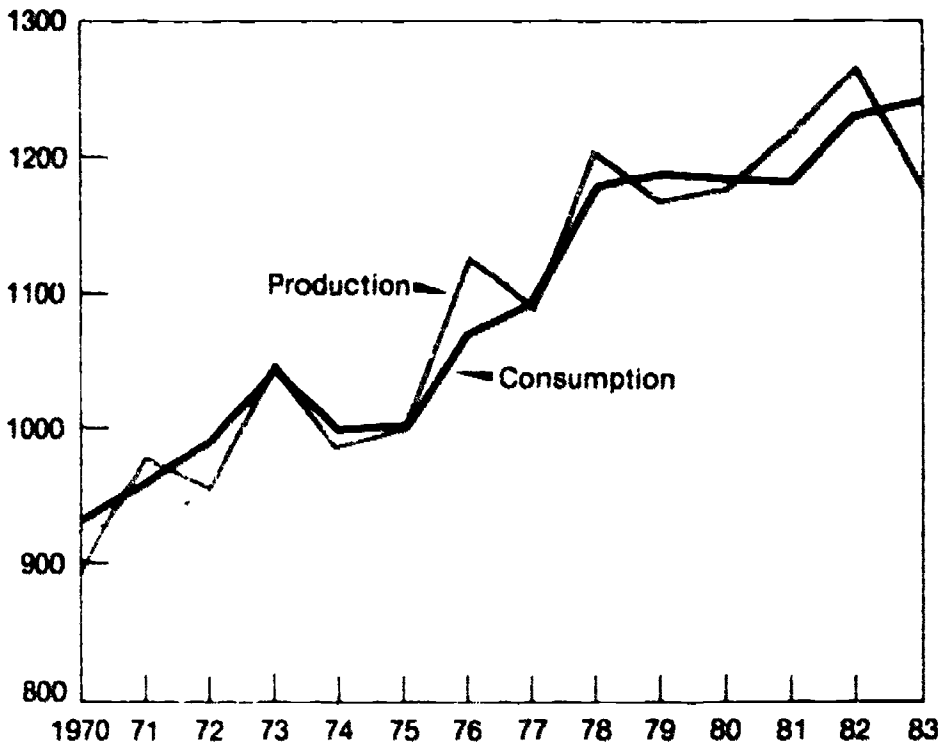
Trade in food is still only a small proportion of global production—8.3 percent for grains. This, of course, means that relatively small changes in production and consumption can have

large short-term influences on the volumes and prices of food commodities traded in the world market. Yet American producers have a growing dependence on export markets.

As a result, world agricultural trade has become increasingly volatile. Farm income was relatively stable in the fifties and sixties compared with the wide fluctuations of the seventies and eighties.

Chart 5—Production and consumption of grains reflect volatile trends, 1970-1983

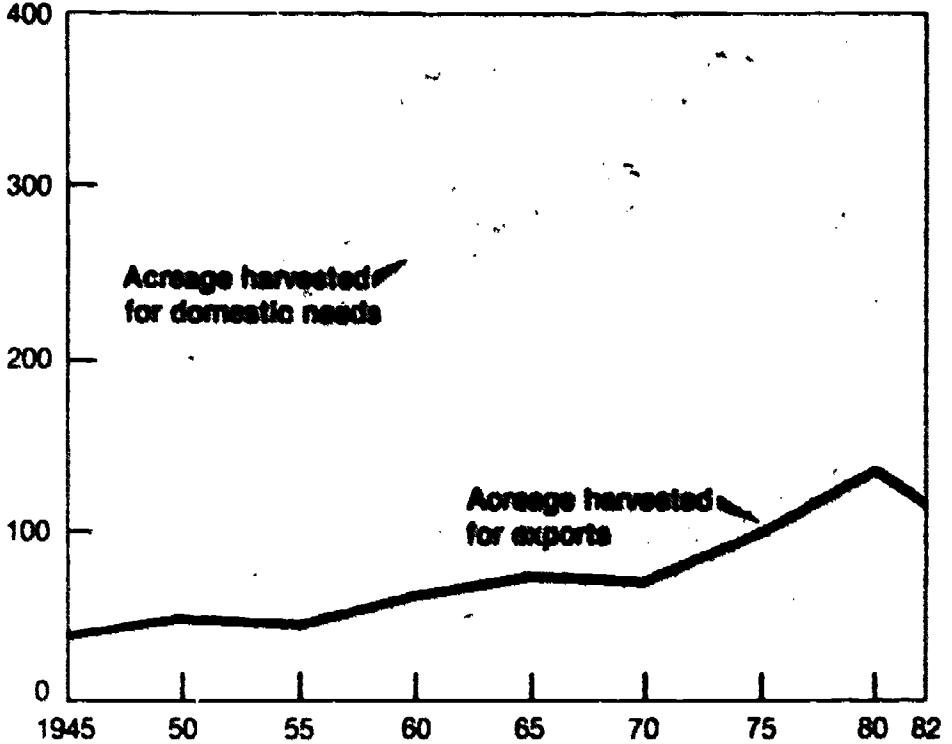
Million metric tons



Source: Chase Econometrics, May 1984

Chart 6—U.S. farm production has grown more dependent on export markets

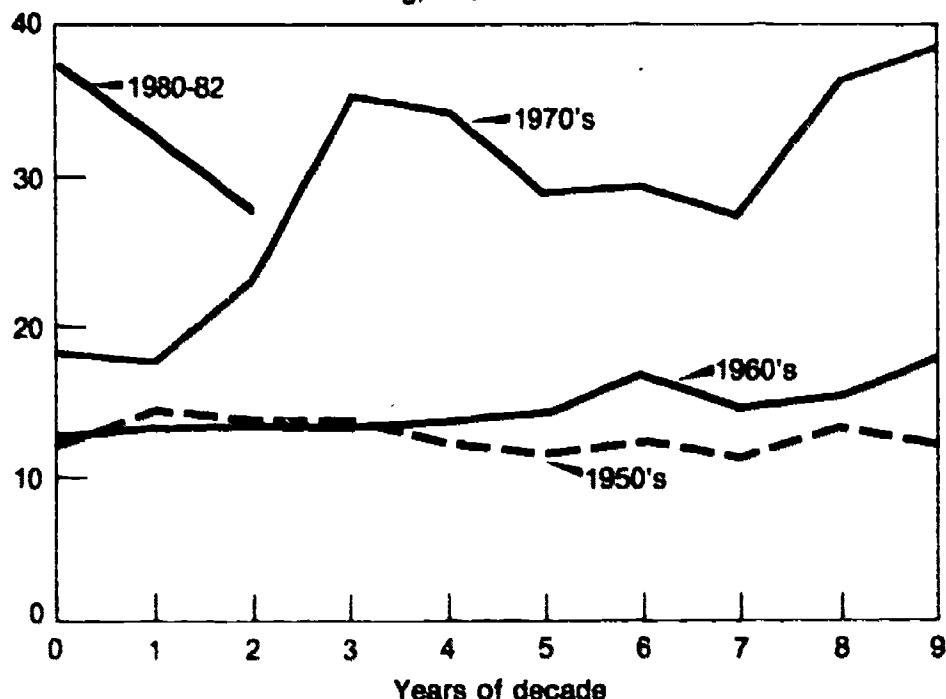
Million acres



Source: Farmline, February 1984, USDA Economic Research Service

Chart 7—Growing dependence on export markets has added considerable volatility to U.S. farm income since the early 1970's

Net cash income from farming, in \$ billions



Source: Farmline, July 1984, USDA Economic Research Service

Outlook for the Decade Ahead

The major forces that will affect world agriculture are population, economic growth, and government policies. In addition, hunger will continue as a serious problem in many parts of the world. Experts say 800 million people need food today. Although world population growth is anticipated to slow to a rate of 1.8 percent a year, compared with 2 percent in the seventies, the total population should reach 5.5 billion people by 1993.

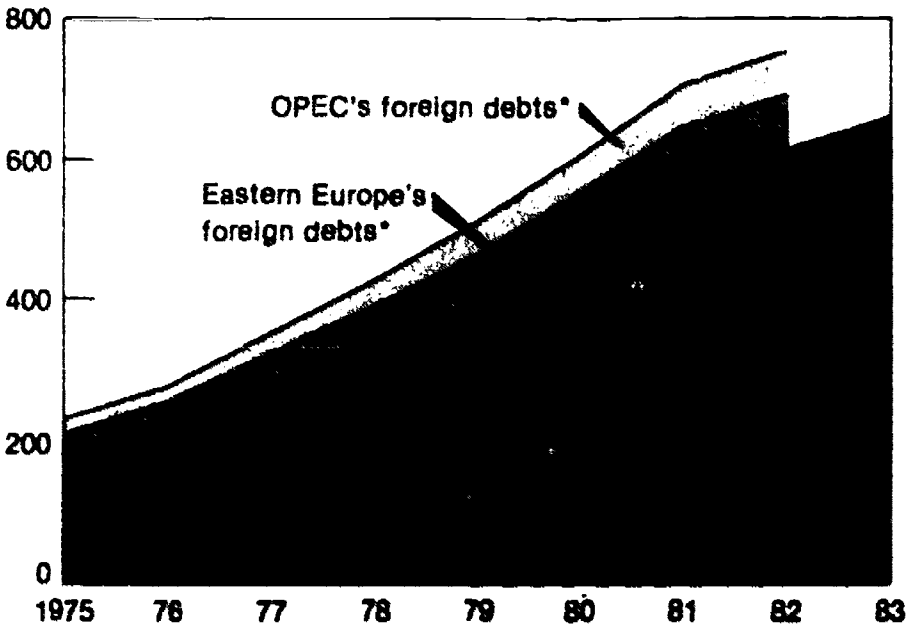
Population growth and hunger, however, represent potential demand for U.S. food and fiber products. Except for

humanitarian assistance, potential demand becomes effective demand only if regions or nations have the economic ability and desire to purchase food for hungry people. Social and economic time bombs may emerge in African and Latin American countries because of their rapid population growth and stagnant economies. Declining food consumption and possibly widespread starvation may result.

Food demand in developed countries is expected to grow slowly. The recent world economic recession, large debt,

Chart 8 — The growing debts of developing nations represent an obstacle in translating potential demand for food into effective demand

\$ billions



* 1983 forecasts not available.

Gross debts do not include assets of debtor nations held as reserves in Western banks.

Source: *Famine*, July 1983. USDA Economic Research Service

and other setbacks in economic growth will restrain the rise in consumer purchasing power in the next decade. In the United States the forecasted economic growth will be only 3.1 percent for the next few years, compared to 4.3 percent during the seventies. Capital costs, as reflected by long-term interest rates, will be higher. The U.S. prime interest rate is expected to average 3 to 4 percentage points above the inflation rate, compared with 2 to 3 percent in the seventies.

This trend will continue to decrease net farm income growth in the eighties. A recent Cornell University study reports that farm revenues decline by \$2 billion for each percentage point increase in interest rates.

Rising Interest Rates Are a Major Concern to U.S. Agriculture

Year	Rural banks	PCA's*	FmHA**
<i>Interest rates***</i>			
1970	8.42	9.38	7.13
1971	8.16	7.20	6.38
1972	8.02	7.03	5.88
1973	8.55	8.90	6.75
1974	9.04	9.80	8.75
1975	8.99	8.56	8.50
1976	9.18	8.12	8.75
1977	9.18	7.93	8.00
1978	9.51	9.15	8.50
1979	11.80	11.00	10.16
1980	13.96	11.99	10.83
1981	18.85	15.71	14.50
1982	16.30	13.80	12.09
1983	14.10	11.82	10.25

* Production Credit Association.

**USDA Farmers Home Administration.

***Rates shown are for fourth quarter of each year.

World diets are anticipated to continue their switch from cereals to meats. However, the annual increase in meat consumption per capita will probably slow to a rate of 0.8 percent, compared with 1.1 percent in the last decade. World food grain demand per capita will probably increase by only half the levels experienced during the seventies. This weak economic outlook, if accurate, would likely result in a slower growth of per capita feedgrain and oilseed demand by an equal amount in the eighties and would thus reduce the volume of world trade.

Simply stated, the choices facing exporting and importing nations alike may be these: accepting the internal costs of adjusting to world interdependence in both up and down markets; or yielding further to pressures for protectionism, self-sufficiency, and isolationism. If too many nations choose the latter path, it could reverse past progress in meeting basic human needs around the globe.

Patrick O' Brian
Economic Research Service

World food and fiber exports have a major influence on economic prosperity in rural America. Although trade generally brings prosperity, it also creates many uncertainties. Export markets are inherently unstable because of world economic cycles, weather variations, and changes in political

environments. The Federal Government has frequently taken steps to mitigate uncertainties facing agricultural producers and to help them adjust to swings in world commodity prices by restricting production. Concerted efforts are urgently needed to expand export markets, as well as to find acceptable ways of modifying food and fiber production levels.

American agriculture is beset by financial troubles that perhaps rival any since the depression of the thirties. To a large degree, Federal policies will determine the extent and speed of economic recovery of U.S. agriculture. Federal farm programs have traditionally provided only short-term solutions for agricultural problems. They have assumed that crop surpluses are temporary. But farm surpluses have been common for more than half a century. Policymakers need an improved research base to help develop long-term goals and formulate the next farm bill. These goals should consider the effects of farm policies on U.S. exports, farm income, domestic food supplies and costs, and Government costs. The Economic Research Service and university economic departments should quickly complete research studies on alternative trade and farm policies which will enhance U.S. food and fiber trade and improve the effectiveness of U.S. farm programs.

Government participation in world food and fiber trade has become more pronounced. However, the preferred and most advantageous system of international trade is one that is as

competitive, market-oriented, and as barrier-free as possible. The general welfare of the United States is best advanced by the freest possible system of trade. But, because the world is unavoidably affected by political as well as economic considerations, more economic research is needed to assist decisionmakers in answering the question, What international market structure and trade policy is the most advantageous for the United States to pursue?

International interests insist that the United States should offer its farm products in world markets at the U.S. support price. At the same time, competing countries sell their farm commodities at the lower world price. They then impose heavy import duties on farm imports and tax their consumers to provide their farmers a fair return.

Mr. Jamie Whitten,
Committee on Appropriations
U.S. House of Representatives

Policymakers and legislators must decide whether the current food and fiber marketing system can operate so as to enable the United States to meet the diverse needs of producers, consumers, and American taxpayers in the eighties and nineties. Trade barriers, tariffs, and intervention of governments have severely reduced free trade as a viable economic model for food and fiber exports.

Changes in world marketing institutions have made obsolete the usefulness of research undertaken earlier on the structure, conduct, and performance of major world food and fiber marketing systems. Research efforts must focus on assessing the efficiency and performance of agricultural institutions, especially those involved in world trade, in the context of today's complex world markets.

Recommendations:

Conducting Critical Macroeconomic Research

First, ERS and university economic departments should assist in determining the type and magnitude of agricultural programs that will maintain a viable U.S. farm economy. Macroeconomic research should be increased in the 1985 ERS budget to research market expansion. Improved and more intensive economic research effort should be focused toward—

- **Conducting research that provides insight into the effect of exchange rates, changes in interest rates and other monetary economic variables, and foreign policy on U.S. food and fiber exports.**
- **Identifying the economic consequences on U.S. exports and world agriculture that result from various price discounts, credits, interest values, long-term bilateral trade agreements, and other sales-incentive programs.**

-
- Identifying the influence of tariffs, quotas, embargos, and nontariff barriers—both in the United States and abroad—on U.S. agricultural export sales.
 - Analyzing the effects of domestic commodity prices on U.S. agricultural export sales including the identification of price elasticities of demand for various commodities.
 - Evaluating the actual and potential benefits of market development activities on U.S. food and fiber exports.
 - Evaluating the potential for increasing value-added exports.
 - Evaluating the potential of expanding U.S. food and fiber exports through improved U.S. grades and standards.
 - Developing a comparative analysis of U.S. crop production costs with farm production costs in competing countries.

Second, assess options for making world food assistance programs more efficient and better oriented to meeting the legislated purposes. To ensure the continued effectiveness of food assistance programs, increased emphasis should be given to research that will—

- Assess the capacity of current or potential food-recipient countries to use food aid effectively. In developing countries, infrastructures especially need to be evaluated in terms of the limits they may place on food aid use.

-
- Evaluate the effectiveness of alternative types of food aid and related assistance programs in developing markets for U.S. agricultural products. Among the program options that might be assessed are concessional credit arrangements, investments to build storage and handling facilities, and technical food and nutrition assistance programs.
 - Analyze ways of minimizing the disincentives of food assistance programs to agricultural development that food aid may create in recipient countries. Determine the long-term effective demand generated by additional U.S. food aid funds.

Third, describe alternative commodity supply management programs which more efficiently and economically balance forthcoming supplies of farm products with changes in demand for agricultural products and which reflect the structural changes in U.S. agriculture since the sixties. Among the options that need greater analyses are:

- Assistance in determining farm policies, goals, and objectives in the eighties.
- Development of alternative farm policy programs that meet the longer term needs of U.S. agriculture.
- Development of supply management programs that are less expensive and more effective in balancing supply with changes in commodity demand.

-
- **Development of alternative farm policy programs which include a coordinated or integrated effort among producing countries.**
 - **Determination of the need for a world emergency food reserve program.**
 - **Determination of the equality of farm programs among different varying program recipients.**

Attracting and Retaining Economic Research Expertise In USDA

In February 1984, the Users Advisory Board said that a strong Federal research system should provide overall direction, stimulation, and support to programs of national importance. Peers at land-grant universities and other institutions expect USDA to provide economic research that directly addresses agricultural production, natural resources, and domestic and international marketing problems. USDA programs should serve as models for other public and private research centers in this country and abroad.

The Federal Government spends about 11 percent (\$18 billion of \$167 billion discretionary or non-entitlement funds) for non-defense research and development. This is an appropriate Federal investment level. However, current funds may not be properly allocated to high-priority programs. Appropriations for USDA's Economic Research Service represent only a quarter percent of Federal funds and less than 5 percent of USDA's research and

development monies. These figures overestimate economic research expenditures since a considerable amount of the agency's manpower is devoted to staff analysis, not economic research, for the Secretary of Agriculture and Congress.

We recommend more funding be redirected toward economic research, specifically designed to expand food and fiber exports and to programs which will assist in developing supply management programs designed to balance U.S. production with changing agricultural demands.

Federal funds must be reallocated to provide a better balance between biological and economic agricultural research. The quality of research is directly related to staff expertise, and administrators should strive for a mix of world-class economists, starting with bright, recently graduated students from outstanding economic departments who can apply their training to agricultural issues. Too often, in recent years, talented individuals have been attracted to university and private industry positions because of high salary levels, good promotion opportunities, and broad professional freedom. Current Office of Personnel Management guidelines classify the economist series as staff support function rather than as research comparable to biological science; this evaluation reduces the agency's ability to attract, retain, and motivate high-performing social scientists. As we stated in our July 1983 and February 1984 reports, we believe the phased civil

service reduction of positions in grades GS/GM 11-15 will be detrimental toward conserving the scientific tool of talent needed for agriculture. USDA administrators and managers must create conditions for a constant renewal of intellectual excellence in their agencies. The importance of economics as a scientific discipline must be recognized and supported if USDA is to attract and retain superior economists.

Existing Federal Guidelines and Regulations That May Affect the Development and Testing of Genetically Engineered Products

Research and Development Activities	Relevant Federal Guideline Activities
<p>1. SAES* scientist proposes laboratory research for increasing pesticide resistance in a feedgrain product using recombinant DNA techniques.</p>	<p>University Institutional Biosafety Committee reviews proposal for compliance with HHS-NIH RAC guidelines for laboratory experimentation and set containment levels for research.</p>
<p>2. SAES* scientist proposes field trial for microbial pesticide in feedgrain.</p>	<p>University Institutional Biosafety Committee monitors project for conformance to HHS-NIH RAC guidelines.</p> <p>SAES and CSRS staff review to determine if guidelines for recombinant DNA federally funded research are being met.</p> <p>University Institutional Biosafety Committee reviews proposal to interpret NIH guidelines; determines that HHS-NIH RAC review is required since a field trial is proposed.</p> <p>HHS-NIH RAC reviews—assessing health, environmental, and worker safety risks and conformance with National Environmental Protection Act regulation.</p>
<p>3. SAES* scientist proposes laboratory research to monitor presence of messenger RNA in feed leaves and grain and use of feedgrain as foodstuff for mice.</p>	<p>USDA ARRC reviews proposal to recommend policy guidelines for field trial of USDA-supported research assessing agricultural and environmental risks.</p> <p>University Institutional Biosafety Committee monitors project for conformance to HHS-NIH RAC guidelines.</p> <p>University Institutional Biosafety Committee reviews proposal for compliance with HHS-NIH RAC guidelines for laboratory experimentation and sets containment levels for research.</p>

*Footnotes and keys are listed at the end of this table.

**Relevant Federal
Regulatory Activities**

Local USDA-APHIS reviews proposal to import exotic organisms in accordance with Executive Order 11987 for exotic organisms and to import foreign seed for scientific purposes in accordance with the Nursery Stock Plant Quarantine Act.

USDA-APHIS reviews proposal to import foreign seed for scientific purposes in accordance with the Nursery Stock Plant Quarantine Act.

EPA reviews experimental use permits or notices concerning field testing of the pesticidal microbe.

Existing Federal Guidelines and Regulations That May Affect the Development and Testing of Genetically Engineered Products—Continued

Research and Development Activities	Relevant Federal Guideline Activities
<p>4. SAES* scientist proposes feeding trial using feedgrain having a recombinant DNA gene which increases pesticide resistance component.</p>	<p>University Institutional Biosafety Committee interpret NIH guidelines; determines that NIHRAC review is required since a field trial is proposed.</p> <p>NIHRAC reviews—assessing health, environmental and worker safety risks and conformance with National Environmental Protection Act regulation.</p> <p>USDA ARRC reviews, develops policy recommendations for field trial of USDA supported research assessing agricultural and environmental risks.</p> <p>University Institutional Biosafety Committee monitors project for conformance to—NIHRAC guidelines.</p> <p>HHS-NIH RAC and USDA ARRC review scientific data to determine whether the food and agriculture is unique or risk-free.</p>
<p>5. Manufacturer proposes commercialization of risk-free pesticidal feedgrain.</p>	

**Relevant Federal
Regulatory Activities**

USDA-APHIS reviews proposal to move animals interstate for research purposes in accordance with animal quarantine laws.

EPA reviews animal toxicity studies associated with administration of the pesticidal microbe.

USDA-APHIS reviews proposal for preparation of shipment and delivery of biological product in accordance with the Virus Serum Toxin Act.

USDA-AMS reviews labeling proposal to ship feedgrain product interstate.

EPA registers the microbe as a pesticide for use in the United States.

Existing Federal Guidelines and Regulations That May Affect the Development and Testing of Genetically Engineered Products—Continued

Research and Development Activities	Relevant Federal Guideline Activities
--	--

6. Manufacturer sales and distribution of risk-free microbial pesticidal feedgrain.

*Industrial research could voluntarily comply with Federal research guidelines; however, compliance is not mandatory if no Federal funds are used to conduct the research.

DOL-OSHA - U.S. Department of Labor, Occupational Safety and Health Administration

EPA - Environmental Protection Agency

HHS-FDA - U.S. Department of Health and Human Services, Food and Drug Administration

HHS-NIH RAC - U.S. Department of Health and Human Services, National Institutes of Health, Recombinant DNA Advisory Committee

Recombinant DNA - To combine DNA (deoxyribonucleic acid)

SAES - State agricultural experiment stations.

USDA-AMS - U.S. Department of Agriculture, Agricultural Marketing Service

USDA-APHIS - U.S. Department of Agriculture, Animal and Plant Health Inspection Service

USDA ARRC - U.S. Department of Agriculture, Agricultural Recombinant DNA Research Committee

USDA-FSIS - U.S. Department of Agriculture, Food Safety and Inspection Service

**Relevant Federal
Regulatory Activities**

**FDA enforcement of EPA
tolerances.**

**USDA-FSIS visually inspects
livestock suspected of having
residue tolerances greater
than FDA standards.**

**DOL-OSHA oversees compliance
with worker safety
regulations.**

Federal Responsibilities Regarding Agricultural Biotechnology, Listed by Agency and Function

Agency	Function and Legislative Authority	Description of Activities
Environmental Protection Agency	<p>1. Chemical substances-- Toxic Substances Control Act (TSCA). 95 Stat. 1686. 15 U.S.C. 2617-2628.</p>	<p>1. Authorizes EPA to acquire information on chemical substances in order to identify and evaluate potential hazards.</p> <p>2. Regulates manufacturing, processing, use, distribution, and disposal of any chemical substance or mixture, excluding items such as drugs, that are regulated under other statutes.</p> <p>3. Manufacturers must notify EPA of their intent to manufacture new chemical substances.</p> <p>4. EPA intends to propose that certain genetically modified organisms are new chemical substances and expects to receive notifications for microbes that are used for such things as:</p> <ul style="list-style-type: none"> a. Toxic waste cleanup. b. Chemical feedstock manufacture. c. Resource recovery applications. <p>5. EPA intends to propose that new biochemical substances produced by microbes will be subject to review under TSCA</p>
	<p>2. Chemical and microbial pesticides-- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). 92 Stat. 183. 7 U.S.C 136.</p>	<p>1. EPA reviews and approves all pesticides prior to use</p> <p>2. Can require the testing of pesticides for health and environmental effects</p> <p>3. Identifies acceptable conditions of use of pesticides through labeling</p> <p>4. 14 microbial agents are already registered by EPA including viruses, bacteria, fungicide, and a protozoan</p>

Benefits	Limitations	Recommendations for Inquiry
<p>1. EPA considers the environmental, economic, and social impact of actions.</p> <p>2. Determination of risk involves an analysis that considers the probability of harm based upon exposure and severity and balances the risks and benefits to society.</p> <p>3. Product development or research with the ultimate hope of making profit is viewed as manufacture for commercial purposes.</p> <p>4. Can mandate testing of chemicals for health and environmental effects, including follow-up authority.</p>	<p>1. Everything in our environment is composed of chemicals. Viewing organisms developed as a result of today's biotechnologies as "chemicals" may be inappropriate. New procedures need to be developed for microbes unless plants and animals are exempt from TSCA interpretation; or unnecessary product testing may result.</p>	<p>1. Are microorganisms chemical substances under TSCA?</p> <p>2. Should regulations focus on the recombinant DNA molecules rather than the organisms containing them?</p> <p>3. Are genetically engineered organisms new chemicals under TSCA?</p> <p>4. Can TSCA be applied to research activities and field trials?</p>
<p>1. Any risks associated with pesticide usage are evaluated against potential benefits.</p> <p>2. Unreasonable risks can be controlled to the extent where the risks of exposure are no longer unreasonable.</p> <p>3. Can review substances at any time from the point of field testing (usually 10 acres or more) through completion of registration and during the life of the registered product.</p>		<p>1. Should data be required on each genetic isolate of an engineered organism?</p> <p>2. Should reviews of novel organisms start with any field trial or should they begin at the current 10 acre limit?</p>

Federal Responsibilities Regarding Agricultural Biotechnology, Listed by Agency and Function—Continued

Agency	Function and Legislative Authority	Description of Activities
<p>Health and Human Services— Food and Drug Administration</p>	<p>1. Human Food Additives— Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) Regulation for a substance that may by its intended use become a component of food or affect the characteristics of food, except substances identified by FDA as generally recognized to be safe by qualified experts (GRAS).</p> <p>2. Human food.</p>	<p>1. Premarket clearance; product sponsor bears burden to show that product is safe.</p> <p>1. Adulterated foods are monitored for:</p> <ul style="list-style-type: none"> a. An added poisonous or deleterious substance which may render it injurious to health b. A naturally present poisonous or deleterious substance that will ordinarily render it injurious to health.
	<p>3. Animal food and food additives.</p>	<p>1. Premarket clearance; product sponsor bears burden to show that product is safe although process is not as elaborate as human food additives.</p>
	<p>4. Veterinary medicines</p>	<p>1. Premarket clearance including exports; product sponsor bears burden to show that product is safe. Drugs must not leave unsafe residues or metabolites in edible tissues.</p>

Benefits	Limitations	Recommendations for Inquiry
<p>1. Provides protection to consumer by developing uniform standard of quality.</p>	<p>1. Unable to confirm safety of most products.</p> <p>2. New surveillance methods difficult to implement.</p> <p>3. Limited qualified staff, particularly with agricultural expertise.</p>	<p>1. Definition in Act not qualified by manufacturing method? Should each genetically engineered product be tested on a case by case basis?</p> <p>2. What are the implications of FDA not requiring compliance with NIH guidelines?</p> <p>1. How will new genetically engineered foods be monitored for active biological substances?</p> <p>1. How will criteria be set to monitor for active biological substances?</p> <p>2. What overlap exists with USDA jurisdiction?</p>

Federal Responsibilities Regarding Agricultural Biotechnology, Listed by Agency and Function—Continued

Agency	Function and Legislative Authority	Description of Activities
<p>Health and Human services— National Institutes of Health</p>	<p>Research guidelines for all experiments involving recombinant DNA in the U.S. or its territories is conducted at or sponsored by an institution receiving any federal funds to support recombinant DNA research. (PHS Act 42 U.S.C., sects. 217a and 241).</p>	<ol style="list-style-type: none"> 1. Provide an administrative framework which specifies the responsibilities of scientists, their institutions and the Federal government. 2. Convenes panels of scientists to review applications for release. Guidelines classify experiments into three categories: <ol style="list-style-type: none"> a. Special review; potentially hazardous experiments may be determined on a case by case basis. b. Exempt (approximately 80-90% of all experiments, i.e., <i>E. coli</i> K-12 EK1, <i>S. cerevisiae</i>, asporogenic <i>B. subtilis</i> in less than 10 liters of culture. c. Contained in accordance with physical and biological containment levels that relate to the level of potential hazard. 3. The Director of NIH is the final decisionmaker who approves research applications.

Benefits

1. Scientifically based
2. Voluntary commercial venture compliance because of negligence liability in law suit.
3. 25 members--public and private sector scientists with agricultural interests represented.
4. Meetings open to the public with published proceedings.
5. Can require host-vector systems data as a condition for receiving grant money.

Limitations

1. No statutory authority. Compliance with guidelines is a contractual condition of receiving research funds.
2. Experienced in laboratory containment review; however inexperienced in field test review.
3. Most member scientists are molecular scientists or experienced in human health; no one is an ecologist.
4. Self-monitoring of guideline compliance by local Institutional Biosafety Committee at institution conducting experiment.
5. Applies only to recombinant DNA research which is only one of the various kinds of technologies that are defined as "biotechnology."
6. Doesn't provide authority to allow adequate field testing of organisms.
7. Doesn't regulate use, movement, sale, and other regulatory aspects of a new technology that has commercial application.

Recommendations for Inquiry

1. Should the scientific expertise be expanded to provide committee membership for ecologists rather than ad hoc subcommittee review?
2. Does the non-regulatory nature of the guidelines provide adequate environmental protection for field tests?
3. Will the agency that regulates commercialization of products accept research data conducted under guidelines as sponsor proof that product is safe?

Federal Responsibilities Regarding Agricultural Biotechnology, Listed by Agency and Function—Continued

Agency	Function and Legislative Authority	Description of Activities
U.S. Department of Agriculture	<p>1. Research guidelines—Agriculture Recombinant DNA Research Committee (ARRC).</p> <p>1983 Secretary of Agriculture Memorandum was issued.</p>	<p>1. Identifies issues with regard to recombinant DNA research and application activities which develop policy recommendations.</p> <p>2. Provides input and assistance to the USDA representative to the NIH Recombinant DNA Advisory Committee.</p> <p>3. Serves as USDA information clearinghouse regarding scientific development, research applications, and regulatory status.</p>

Benefits	Limitations	Recommendations for Inquiry
<p>1. 11 members representing 6 USDA agencies with HHS-NIH and NSF liaison members.</p> <p>2. Strong plant science committee representation with one ecologist. Biosafety at institution conducting experiments.</p>	<p>1. Mandatory with USDA funds only.</p> <p>2. Meetings are not announced to the public.</p> <p>3. Proceedings are not published.</p> <p>4. Self-monitoring of guideline compliance by local Institutional Biosafety Committee.</p> <p>5. Applies only to recombinant DNA research which is only one of the various kinds of technologies that are defined as "biotechnology."</p>	<p>1 Will agency who regulates product release accept research conducted under guidelines as sponsor proof that product is safe?</p>

Federal Responsibilities Regarding Agricultural Biotechnology, Listed by Agency and Function—Continued

Agency	Function and Legislative Authority	Description of Activities
USDA—		
Agricultural Marketing Service	1. Federal Seed Act (7 U.S.C. 1551-1611)	1. Labeling of seeds shipped by interstate (AMS) and foreign (APHIS) commerce.
	2. Plant Variety Protection Act (7 U.S.C. 2521 et. seq.)	1. Granting of patents for sexually reproduced varieties of plants.
Animal and Plant Health Inspection Service	1. Plant pest export inspection—Section 102, Organic Act of 1944, as amended, and the Act of April 6, 1937, as amended (7 U.S.C. 147a, 148, 148a-148e) 7 CFR Parts 300 through 399.	1. Inspection and authority to eradicate, suppress, control, or retard the spread of plant pests.
	2. Plant pest import and interstate commerce—Federal Plant Pest Act, as amended (7 U.S.C. 150aa-150jj; 151-164a, 166-167) 7 CFR Parts 300 through 399.	1. Regulates the importation and interstate movement of plant pests and any products, articles, and means of conveyance which may carry or be infested with plant pests—includes seizure, quarantine, treatment, and disposal authority.
	3. Noxious weed—Federal Noxious Weed Act of 1974 (7 U.S.C. 1801-2813) 7 CFR Part 360.	1. Authorizes seizure, quarantine treatment, destruction, or other disposal of any product or article of any character whatsoever, or means of conveyance, which is moving into or through the U.S. or interstate when a quarantine is established and if control or eradication measures are taken.

Benefits	Limitations	Recommendations for Inquiry
<p>1. Royalties and licensing fees from patents in general and the legal protection of new plant varieties provide a potential source of resources for supporting research.</p>	<p>1. Some overlapping jurisdictions.</p> <p>2. Scientific expertise and facilities.</p>	<p>1. What are the worker safety implications for product handling?</p> <p>2. What are the environmental hazards?</p>
<p>1. Provides a single clearing house for regulatory efforts.</p>		<p>1. Is there a need to restrict recombinant DNA materials?</p>

Federal Responsibilities Regarding Agricultural Biotechnology, Listed by Agency and Function—Continued

Agency	Function and Legislative Authority	Description of Activities
USDA		
APHIS—Cont'd		
	4. Exotic organisms— Executive Order 11987- "Exotic Organisms."	1. Exempts from provisions of EO 11987 the introduction or exportation of exotic species when USDA or the U.S. Department of Interior finds that the introduction or exportation will not have an "adverse effect on natural ecosystems."
	5. Veterinary services— Section 101(d) of the Organic Act of 1944 (7 U.S.C. 430). See 41 CFR 4-4.500 et. seq. (Procurement Regulations)	1. Authorizes purchase and test samples of all tuberculin, serums, anti-toxins, or analogous products of foreign or domestic manufacture that are sold in the U.S. for the detection, prevention, treatment, or cure of diseases of domestic animals.
	6. Biological products— Virus-Serum-Toxin Act (21 U.S.C. 151-158). See 9 CFR Parts 101 through 117 and 122 through 123.	1. Regulates and licenses the importation, shipment, delivery, preparation, sale, and barter or exchange of any virus, serum, toxin, or analogous product intended for use in the treatment of domesticated animals.
	7. Animal quarantine laws— (21 U.S.C. 102-105; 21 U.S.C. 111; 21 U.S.C. 114a through 114h; 21 U.S.C. 115 through 130; 21 U.S.C. 134 through 134h; 21 U.S.C. 135 through 135b).	1. In general, the animal quarantine laws regulate the importation, exportation, and interstate movement of certain animals to prevent the introduction or spread of communicable diseases of animals or of the contagion of any contagious, infectious, or communicable disease of animals.
Food Safety Inspection Service	1. Federal Meat Inspection Act (21 U.S.C. 601 et. seq.) 9 CFR Parts 301.2 (22), 309.16, 311.39.	1. Disposition of livestock suspected of having residue tolerances greater than FDA standards.
	2. Poultry Products Inspection Act 9 CFR Part 391.74.	1. Disposition of poultry suspected of having residue tolerances greater than FDA standards.

Benefits**Limitations****Recommendations
for Inquiry**

1. Will guidelines be determined on a case by case basis?

2. What data will be required on how long the genetically engineered material will survive in the environment?

1. What are the jurisdictional differences between FDA and APHIS?

1. What are the implications for genetically engineered fertilized ovum?

1. Criteria for inspection is visual inspection

1. Do FDA test requirements provide useful visual inspection criteria to monitor for active biological substances?



Responsibilities and Structure of the Users Advisory Board

The National Agricultural Research and Extension Users Advisory Board (UAB) is a statutory committee established by the National Agricultural Research, Extension and Teaching Policy Act of 1977, as revised by the Agriculture and Food Act of 1981, Public Law 97-98.

The Board has the general responsibility for preparing independent advisory opinions on the food and agricultural sciences. Board members are responsible for—

- **Reviewing policies, plans, and goals of research and extension education programs within the Department of Agriculture, other Federal agencies, State agencies, and colleges and universities.**
- **Assessing the extent of agricultural research and extension activities conducted within the private sector and the nature of its relationship with federally supported agricultural research and extension.**
- **Serving as consultants to the Secretary of Agriculture by reviewing short- and long-term national policies, priorities, and strategies for agricultural research and extension and by preparing an annual report not later than July 1.**

-
- **Advising the President; the House Committee on Agriculture; the House Committee on Appropriations; the Senate Committee on Agriculture, Nutrition, and Forestry; and the Senate Committee on Appropriations by appraising the Administration's proposed budget and by submitting an annual report not later than February 20.**

The Board's 25 members represent the multiple interests of all users of the national agricultural science and education system. These citizens represent interests of the following groups:

- **Producers of agricultural commodities, including forest and aquaculture products.**
- **Consumers.**
- **Farm suppliers and food and fiber processors.**
- **Food marketing specialists.**
- **Environmental specialists.**
- **Rural development officials.**
- **Human nutritionists.**
- **Animal health practitioners.**
- **Food transporters.**
- **Food- and agriculture-related labor organizations.**
- **Private sector investors in developing countries.**

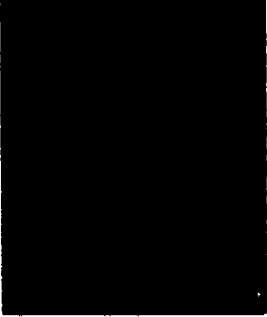
How the National Agricultural Research and Extension Users Advisory Board Functions

1984 UAB Discussions	
Private Sector	
Chicago Mercantile Exchange American Soybean Association Continental Grain Company Iowa Beef Processors, Int'l	Minnesota Wheat Council U.S. Meat Export Federation National Forest Products Association
Public Sector	
European Common Market Canadian Wheat Board U.S. House of Representatives Science and Technology Committee President's Commission on Industrial Competitiveness President's Task Force on International Private Enterprise Environmental Protection Agency Food and Drug Administration National Science Foundation National Institutes of Health	University of Minnesota Virginia Polytechnic Institute and State University University of Florida University of Maryland Harvard University Cornell University University of Georgia
ISDA— Agricultural Research Service Agricultural Marketing Service Cooperative State Research Service Economic Research Service Extension Service Foreign Agricultural Service Forest Service Office of Grants and Program Systems	



UAB Reports	
Agricultural Research and Extension Public Policy and Priority Opportunities report	Report of the President's Council on Agricultural Research and Extension





The Board's Accomplishments in 1984 and It's Agenda for 1985

The National Agricultural Research and Extension Users Advisory Board holds three formal meetings a year to prepare reports required by law. In addition, ad hoc workgroup sessions are held to make indepth assessments of special topics.

The board met in Washington, D.C., February 12-15, 1984, to appraise the proposed 1985 budget for agricultural research and extension. On February 14, work was initiated on the midyear program policies and priorities report with an information-gathering session on the subject of U.S. competition for world agricultural markets. Representatives of the European Economic Community and Canadian Wheat Board discussed trade policies. A panel representing major commodity associations and trading companies was chaired by Clayton Yeutter, President of the Chicago Mercantile Exchange. They discussed world trade issues including market prices, the value of the dollar, and market shares. Finally, the results of the White House Panel on Industrial Competitiveness were discussed and current events in the American steel and automobile industries were compared with those affecting U.S. agriculture.

Board members testified at several congressional hearings in 1984. Testimony was presented to committees of the U.S. House and Senate in support

of the proposed funding increase for a competitive grants program for biotechnology. A statement was delivered by Board Chairman William E. Marshall to the U.S. House of Representatives' Committee on Agriculture, Subcommittee on Department Operations, Research and Foreign Agriculture, regarding the board's recommendations for legislative changes in Title XIV of the Farm Bill. Jack Marvel also testified at a session chaired by Congressman Brown regarding the regulation of research and commercial development of genetically engineered products.

The board met with the National Governors' Conference on Agricultural Innovation on June 3-4, 1984, in Little Rock, Arkansas, to examine critical agricultural research, technology, and innovation issues. Chairman Marshall led a discussion of multidisciplinary approaches; Jack Marvel chaired a workshop on public and private sector relationships; and Jim Williamson participated in the research delivery systems workshop. Governor Bill Clinton of Arkansas and several state commissioners of agriculture informally discussed future directions in agricultural research and extension with members of the board.

After the conference, the board continued to meet in Little Rock, Arkansas, on June 5-6, 1984, to review policies, programs, and goals of agricultural research and extension programs in world trade and biotechnology. Perceptions of the

outlook for world trade and issues related to economic and production agriculture research needs were discussed by Ed Schuh, professor and head of the Department of Food and Agricultural Policy, Trade, and Development at the University of Minnesota; Peggy Kemper of the President's Task Force on International Private Enterprise; and Alvin Riley, manager, Marketing Strategy Evaluation Methods, Campbell Soup Company.

The board also met with Herb Blumenthall, director, Division of Toxicology, U.S. Food and Drug Administration; William F. Helms, Plant Protection and Quarantine, Animal and Plant Health Inspection Service, USDA; Richard Hill, senior science advisor, Office of Pesticides and Toxic Substances, Environmental Protection Agency; Ken R. Hook, Veterinary Science, Animal and Plant Health Inspection Service, USDA; Dyarl D. King, National Program Staff, Agricultural Research Service, USDA; Robert Nicholas, staff director and counsel, Subcommittee on Investigations and Oversight, Committee on Science and Technology, U.S. House of Representatives; David Pimentel, professor of ecology, Department of Ecology, Cornell University; and Sue Tolin, associate professor, Plant Pathology and Virology, Department of Plant Pathology and Physiology, Virginia Polytechnic Institute and State University. Federal policies and regulations were discussed, as well as the scientific, economic, social, and

ethical implications of conducting genetic engineering research and registering products.

Members of the board have also communicated the views of the Users Advisory Board in the following agricultural and food policy forums and in these capacities:

- **Advisory committee for the Office of Technology Assessment's study on "Technology, Public Policy, and the Changing Structure of American Agriculture."**
- **Participant in the American Academy of Science Workshop on Agricultural Policy.**
- **Industrial Research Institute.**
- **Member of the National Academy of Science's Board on Agriculture, study on higher education.**
- **Member of the National Academy of Science's committee on military nutrition.**
- **Members of The Ohio State University's biotechnology advisory panel.**
- **Speaker at the Resources for the Future, Inc., Food and Agricultural Policy Workshop in April 1984.**
- **Agri-Energy Roundtable in Geneva, Switzerland, June 1984.**
- **Development of the Agriculture in the Classroom Foundation.**
- **Member of the Missouri Agricultural Development Commission.**

-
- **Chairman of the Agricultural Research Institute.**
 - **Workshop leaders and speakers at the National Governors' Conference on Agricultural Innovation, Little Rock, Arkansas, June 1984.**
 - **Vice Chairman of the Board on Agriculture, National Academy of Sciences.**
 - **Liaison for human nutrition with the Board of Scientific Counselors.**
 - **Member of the National Forest Products Association's National Forest Research Review Committee.**



Call for Comments

As members of the National Agricultural Research and Extension Users Advisory Board (UAB), we have spent many hours reviewing public and private sector programs, evaluating agricultural policies, and listening to the concerns of other users of research and extension services. We recognize that some of the issues raised probe sensitive areas. Nevertheless, many Federal and State administrators have provided solid responses to our inquiries.

Our objective is to provide recommendations which will promote an efficiently run and effective agricultural research and extension program. **The agricultural science system is sound; we urge that change be made where it is needed and that tradition be preserved when it serves best.**

We ask that policymakers carefully review our recommendations and discuss their merits with as many other users and performers of agricultural research and education as possible. We shall continue to call for comments from all interested persons. Please send comments to:

Dr. Barbara L. Fontana
Executive Secretary
Users Advisory Board
Room 319-A, Administration Bldg., USDA
12th & Independence Avenue, S.W.
Washington, D.C. 20250