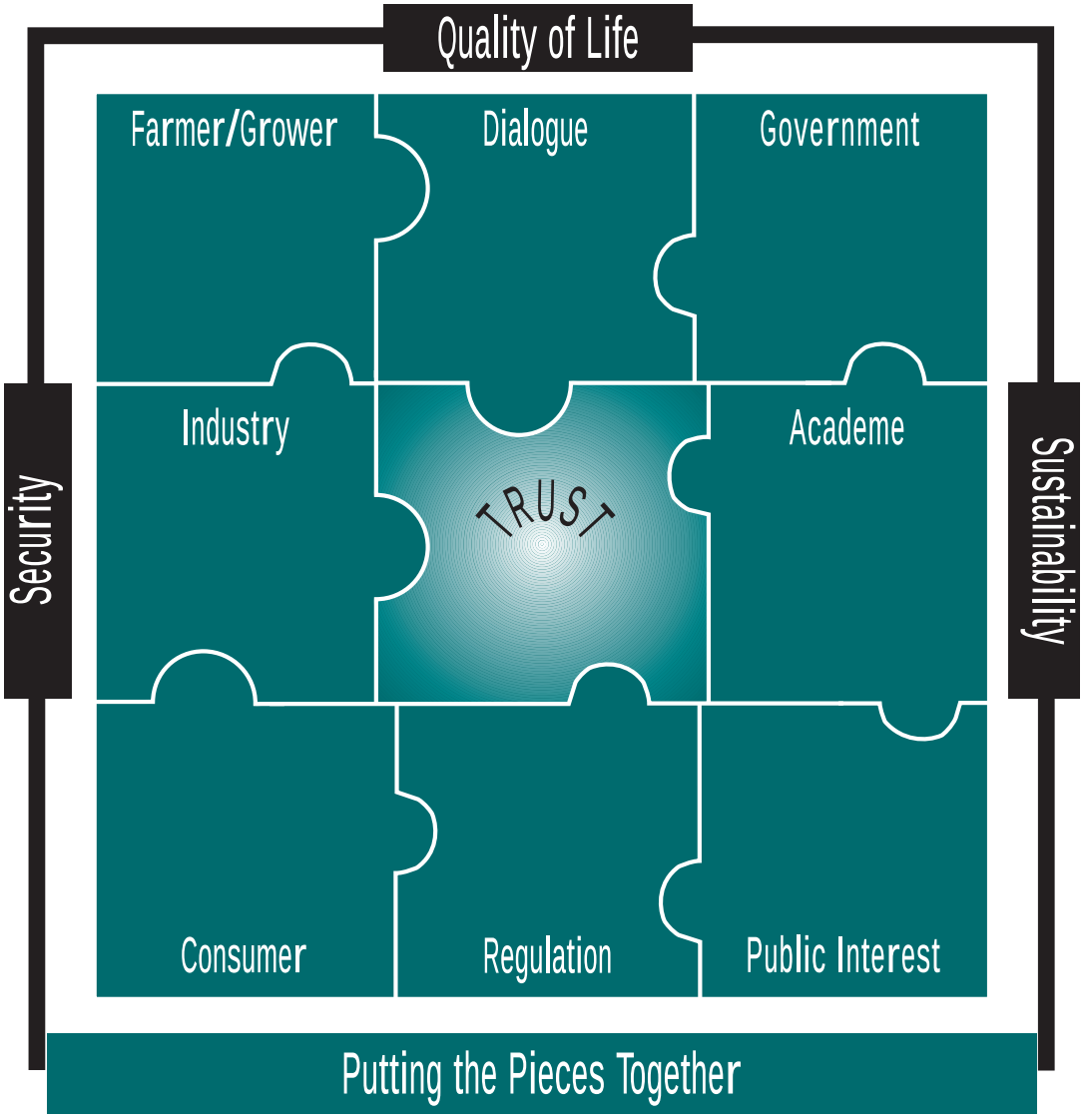
NABC Statement 2000 on Agricultural Biotechnology:

Promise, Process, Regulation, and Dialogue



Prepared by the National Agricultural Biotechnology Council

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The National Agricultural Biotechnology Council (NABC) is a consortium of 30 major agricultural not-for-profit research and education institutions in the US and Canada. The NABC has a ten-plus year record of providing the only annual open forum for all stakeholders — farmer/growers, academe, agribusiness, government agencies, public interest groups, and any other interested individual — to speak, to listen, and to learn on the issues of agricultural biotechnology. The published proceedings of these fora are freely distributed worldwide. These publications are a most complete record of the dialogue on the key issues of agricultural biotechnology over an extended period, and we invite interested and concerned organizations and citizens to use them. Support for the NABC comes solely from the not-for-profit member institutions and foundations.

The NABC Council has produced the attached *NABC Statement 2000 on Agricultural Biotechnology: Promise, Process, Regulation, and Dialogue*, and their signatures document their support. Our objective is to provide a concise but comprehensive statement about agricultural biotechnology. Much of the highly publicized media stories, including paid advertisements of recent months, raise "what if" questions and seek to scare rather than provide balanced information. As part of this statement, we invite those organizations with concerns to an open forum discussion of the issues so that society, in terms of quality of life, and security and environmental sustainability, will benefit most at minimum risk. This invitation does not include those organizations that promote or condone sabotage of research plots or facilities.

Darrell Nelson
NABC Chair

Ralph W.F. Hardy
NABC President

"The sorting of genetic characteristics of …corn, making certain groups of them stand alone in individual plants to be fully examined and evaluated and discarded or retained, then recombining the desired traits into truly super kinds of corn . . . This achievement marks, I believe, the greatest contribution which modern science has as yet made to agriculture."

—J. Sidney Cates, "White Magic in Corn," Country Gentleman, 104: 10-11, 61 (1934).

THE PROMISE

Major benefits to our security and quality of life and to global sustainability are expected from biotechnology. Such opportunities are made possible by our expanding knowledge of the principles of biology, an exploding database of information on genomic sequences and gene function, and new tools that enable genetic modification by design at the molecular level. The benefits will result from developments in the biomedical, agricultural, food, and industrial arenas.

- Health products with minimized side effects will be designed for improved efficacy and, even more importantly, treatments for many diseases will become possible. Several novel diagnostic, therapeutic, and vaccine products are already in use.
- Agricultural crops will be self-protected against ever-present pests and diseases with reduced use of synthetic agrochemicals. Corn, cotton, and potatoes protected against insects are being grown; herbicide-tolerant soybeans, corn, and canola now enable the use of short-lived herbicides.
- The devastating effects of periodic drought stress on crops and our global need to use saline and high-aluminum acidic soils to produce food, especially in the developing world, are being helped by biotechnology.
- Biotechnology will help satisfy the global need for increased food production, driven by the still-growing population and demand for higher quality food, including animal products.
- Our food will be more healthful, more nutritious, and even safer.
- The relationship between medicine, plants, and human health will become more seamless.
- Vitamin-enhanced crops, such as rice, can prevent blindness for millions of people in the developing world, and can reduce the impact of ailments that affect the developed world, such as heart disease and some cancers.
- Edible vaccines, made in plants such as bananas, will protect people in both the developed and developing worlds.

The 1998 National Agricultural Biotechnology Council (NABC) *Vision Statement for Agricultural Research and Development in the 21st Century* highlighted a biobased economy. Biotechnology will foster the growth of this biobased economy; energy, chemicals, and materials will be produced from sustainable and renewable agricultural materials rather than from non-renewable fossil fuels. The 1999 National Research Council (NRC) Report on *Biobased Industrial Products* targets 50 percent of liquid fuels, 90 percent of chemicals, and 99 percent of materials from biosources in the 21st Century.

- Regional and global environments will benefit from the use of biobased sources, and the economies of our rural communities will benefit from bioprocessing located near sites of production.
- Our physical security will be improved from much-reduced dependence on foreign petroleum.
- Increased demand for agricultural commodities will help to minimize the periodic economic traumas of over-production and low prices.

Of course, the ultimate benefits from biomedical, agricultural, food, and industrial biotechnology will accrue to the consumer, along with a more sustainable Earth. Crop-yield increases will free fragile land from agricultural use and mitigate the exploitation of tropical forests for agriculture, thus helping to maintain wildlife habitats and biodiversity.

THE PROCESS

Genetic modification over decades, centuries, and even millennia, has helped agriculture meet the food needs of a world population that has grown from 300 million in 1000 AD to six billion in 2000 AD. It is probably impossible to identify a food from a domesticated source that was not genetically modified by humans prior to molecular biotechnology.

Genetic improvement started with selection of organisms with superior traits followed by breeding for additional genetic improvement. (See quotation above.) The power of genetic modification, from 10,000 BC to the present, progressed from selection, to hybridization, Mendelian genetics, quantitative genetics, induced mutation, fusion, and somaclonal variation, to molecular genetics. Molecular methods are the basis of modern biotechnology, providing new tools, not only for more rapid, but also more precise genetic improvement of organisms that are referred to variously as genetically engineered organisms (GEOs), genetically modified organisms (GMOs), or transgenic organisms.

Highly domesticated organisms — bacterial, plant, and animal — are genetically modified for improved end use as a food, feed, or fiber crop, as a microbe for fermentative production of a processed food — for example beer, wine, bread, or miso — or an industrial product, for example fuel ethanol, or as an improved dairy animal, or egg or meat producer. These genetically modified organisms are more fit for our domesticated use and usually less fit for existence in the unprotected world. Our quality of life today is already highly dependent on genetically modified microbes, plants, and animals. Genetic modification is an increasingly major contributor to our capability to provide food for 20 times as many humans in 2000 as in 1000 AD. Our knowledge, data, and tools are enabling us to achieve more-rational and directed genetic changes at the molecular level by transfer of genes and control of their expression.

The new molecular approach enables genes — at most a few in any one case — to be moved within and across species with greater facility than occurs naturally. Genomic sequencing is revealing much commonality in genes of bacteria, plants, and animals.

What do we know about environmental and human-health risks from genetically modified organisms? The most important conclusion is that risk from a product is inherent to that product, not to the process by which it is made. If identical products are produced by either molecular or organismal genetic modification, then they pose identical risks. We have substantial experience with organisms modified at the organismal level. In general, such products have been of low risk, but there are a few examples of problems such as the introduction of kudzu, an exotic pasture legume that became an aggressive weed, and widespread use of corn with cytoplasmic male sterility that was subsequently found to be susceptible to southern corn blight. We have less experience — about 10 years — with molecularly modified organisms; however, no substantiated examples of significant risk to the environment or human health, relative to the products being replaced, has been documented by rigorous and replicated scientific evaluation. Of course, we must continue to be watchful for negative effects in order to assure improved product safety.

Our major focus should be on "what is" rather than on the never ending and often untestable "what if."

There are some process characteristics that help guide risk assessment, the most important element of which is asking the right questions. The involvement of only a few genes of known structure and function in molecular genetic modification helps focus risk assessment in contrast to organismal processes that involve, for example, the estimated 30,000 or more different genes of a higher plant. The genetic roulette is much less predictable in organismal than molecular genetic improvement. However, genetically improved products should be evaluated for safety on a case-by-case basis, utilizing all of the available information, including experience, to guide the assessment.

The tools of molecular genetic modification continue to improve, and should reduce further concern over food and environmental safety. Early use of kanamycin antibiotic-resistance, expressed by a marker gene to indicate successful transfer of an accompanying target gene, has been criticized because of a theoretical concern that pathogenic microbes might become resistant to this antibiotic. The FDA reported in 1994 its extensive examination of this risk. Kanamycin is almost never used in human medicine due to its high toxicity and evidence of widespread resistance. Transfer in the human gut of the resistance gene to a pathogenic microorganism from a plant cell is extremely unlikely relative to the transfer of resistance from the much-more abundant antibiotic-resistant microorganisms. Products in the research pipeline, for the most part, do not have an antibiotic-resistance marker gene. Improved tools, such as genomic site-specific introduction, and tissue- and development-stage-specific expression, will make molecular genetic improvement even safer. Other approaches, such as genetic sterility or organelle location of inserted genes, could diminish greatly the concern over gene escape in those areas where there are weedy relatives. Weedy relatives, of course, are not a concern

with most domesticated crops in the U.S., such as corn and soybean.

REGULATION

Three U.S. agencies — EPA, FDA, and APHIS/USDA — have developed and implemented procedures utilizing their authority to oversee the safety of crops and foods that are molecularly improved. The use of existing authorities enabled federal oversight of environmental and food risks from molecularly modified crops, and avoided the difficulty of implementing new regulatory policies and agencies. In the 1980s, the NRC, various professional scientific groups, and congressional hearings provided science-based guidance for the oversight of molecularly modified organisms. For example, the NRC published in 1989, *Framework for Field Testing of Genetically Modified Organisms.* The NABC held an open forum on *Food Safety and Nutritional Quality* in 1990 and broadly distributed the report of that meeting.

Almost a decade of favorable food experience has accrued with fermentatively produced chymosin (FPC), a product of molecular biotechnology used for cheese making. In 1990 it became the first food product approved by the FDA. Today, FPC has an 80 to 90 percent market share in cheese making in the U.S. and Canada. It is approved as vegetarian, kosher, and halal, and is fifty-fold more pure than the traditional product, rennet, from the stomachs of slaughtered calves.

In 1992, the FDA published its policy document *Statement of Policy: Foods Derived from New Plant Varieties.* Its regulatory policy is based on substantial similarity between the molecularly modified product and its unmodified parent. The NABC criticized the implementation process, but not the policy, in letters to the Vice-President, Commissioner of the FDA, Secretary of Agriculture, Administrator of the EPA, and the Secretary of Health and Human Services. The NABC, an organization committed to open dialogue, was concerned about the absence of opportunity for public discussion of the policy prior to its publication. The FDA is holding three sessions across the country to communicate its regulatory process and experience, and to listen to the public to determine if there are significant risks that are not being assessed.

The FDA should make its voluntary consultation mandatory and be as forthcoming as possible, providing information on pre-market approvals, including key safety data, so as to build trust. Its July 1999 *Foods Derived from New Plant Varieties Derived Through Recombinant DNA Technology* is such an example.

The organization seeking to market a new product, usually a company, has the responsibility to obtain data required to show safety, or a favorable benefit to risk, to the regulatory agency. This process, well established for agrochemicals and pharmaceuticals, is used for molecularly modified organisms. Some have suggested the need for more public-sector involvement in food safety research, to assure further the safety of foods from both traditional and molecular biotechnology sources. The public would need to fund such research.

One or more of the previously mentioned agencies regulates all products of molecular biotechnology. At an October 6-7, 1999, hearing on agricultural biotechnology by the Senate Agriculture, Forestry and Nutrition Committee, representatives of the regulatory agencies stated that there was no evidence that any genetically engineered crop is unsafe as a food source. A representative of the Consumer's Union agreed, but stated also that absence of evidence of not being safe is not assurance of safety. The workshops at the 1999 NABC Annual Meeting in Lincoln, NE did not identify concern over food safety as an issue.

At the Senate hearing, the EPA representative stated that they had considered the effects of Bt crops on non-target organisms at the time of approval, and concluded that risk to insects such as the monarch butterfly was not significant in comparison to that from other pest-control methods. They are reassessing the issue and a preliminary discussion of the 1999 data tends to confirm their earlier conclusions.

The network of regulatory agencies has several years of successful experience with genetically engineered crops. There is no evidence of need for significant change of the regulatory system for food sources modified by molecular processes — other than mandatory, not voluntary, consultation and improving communication with a more transparent output. In the view of many academic scientists, it is being overworked for biobased pesticides.

Labeling is a contentious issue. The right to know is important. FDA policy will require labeling of food products with substantial change. For example, products from rice with major increases in beta-carotene or iron content presumably would be labeled because of the substantial change in nutrient composition. Similarly,

foods from plants with an added protein that is a recognized allergen would be labeled, if they were even approved. Should food from plants with no substantive compositional change and no demonstrated beneficial or negative health effects, such as that from genetically engineered plants to date, be labeled? Does such labeling help the consumer select more healthful foods? If a large number of consumers demand labeling of food from sources modified by molecular processes, then a maximum content of that source in the food product would need to be established; for example, the maximum of five percent of non-organic content allowed in organic foods may be appropriate. Without labeling, organic foods, which at this time exclude genetically engineered sources, may be an option for consumers who do not wish to consume foods from molecularly modified sources, albeit at generally an increased cost.

DIALOGUE

The NABC is offering to co-host an open forum meeting with public groups and individuals concerned about the food and environmental risks of molecularly modified foods. Speakers representing the breadth of viewpoints would present background lectures. Workshops with co-chairs from NABC and the public-interest groups would provide the opportunity to speak, to listen, and to learn about specific issues. Areas of agreement and disagreement would be identified, as would the bases underpinning the disagreements. Additional research could help to resolve those disagreements where answers are unavailable from current science. Such open dialogue is key to building trust.

The NABC was formed in 1989 to provide an open forum for dialogue on the safe, efficacious, and equitable development of agricultural biotechnology. All funds to support the NABC operations come from not-for-profit educational and research institutions; in other words, no industry funds are used by the NABC. The NABC procedure identifies key issues of agricultural biotechnology and holds annual meetings on these topics. Plenary speakers representing the various viewpoints (pro and con) provide background lectures. All stakeholders are invited to participate — farmers; consumers; corporate, government and academic representatives; and public interest groups. The major product of an NABC meeting is the published proceedings of the workshops at which all attendees have the opportunity to speak, to listen, and most importantly to learn from each other. In the last decade, the NABC has held open fora on sustainable agriculture; food safety and nutritional quality; socioeconomics; animal biotechnology; risk; public good; gene discovery, ownership and access; novel products and partnerships; challenged environments; environmental quality: gene escape and pest resistance; and industrial consolidation and world food security and sustainability. More than 7,000 copies of the reports from each of these fora have been printed and distributed worldwide. In addition, the NABC supports an annual Bioethics Institute to acquaint university faculty in the non-medical life sciences with ethical theory, to familiarize faculty with strategies for classroom discussions of moral issues and assist them in constructing pedagogical materials such as case studies and classroom exercises.

Recent debate on agricultural biotechnology, as reported in the popular press, is more a monologue than a dialogue. Not considered, for example, is the environmental advantage of the use of herbicides that last in fields for days with herbicide-tolerant crops versus those that persist for months and years with non-herbicide-tolerant crops. The major goal of organizations that are opposed to agricultural biotechnology appears to be the elimination from grocery stores of foods that have any ingredient from an organism genetically modified by molecular process. How deep is the experience base of these organizations in food issues? A public-interest organization with more than a million members in the U.S. and Canada, and a substantial track record in the food area, has concluded that to date, there is no major food risk from the products of agricultural biotechnology.

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