Subcommittee on Rural Development, Research, Biotechnology and Foreign Agriculture
Committee on Agriculture
U.S. House of Representatives

Statement of Roger N. Beachy, Ph.D.
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Thank you, Chairman Johnson, Mr. Costa, and Members of the Subcommittee, for holding this hearing. The topic is one of great interest and importance to agriculture and agriforestry, in particular the science and biotechnologies that work to ensure the success of this sector of the American economy while preserving the natural resources that make the industry possible. Our goal is to convey to you the importance of research that brings innovation to agriculture, and of the regulatory processes that are in place to ensure safety of products of biotechnology. I will address most of my remarks to the plant sciences and the technologies and products that are derived from biotechnology.

I come with a background as a teacher and scientist, as an inventor of technologies that are used in agricultural biotechnology, as a former director of the Donald Danforth Plant Science Center, established in part as a mechanism to stimulate innovation and local economy, and as a former director of a federal research agency: I was appointed by President Obama to be Founding Director of the National Institute of Food and Agriculture that was established by the 2008 Farm Bill. I have been an advisor to several venture capital funds, have sat on the boards of two multinational companies, as well as a number of not-for-profit research and education organizations. It has been a privilege to have participated in such a breadth of activities, each of which had a role in bringing me to this table today.

Since the middle of the last century biologists, chemists and biochemists have worked diligently to understand the fundamentals of plants – how they grow and develop, and the nature of the proteins, oils, carbohydrates and the hundreds of thousands of natural products that they produce. The results of these and derivative studies have been used to enhance and improve the agriculture that peoples in America and around the world rely upon for sustenance and livelihood, indeed for their very survival. As agriculture continues to be pressed to be ever more productive and economically and environmentally sustainable, the targets of research are to increase crop yields, develop more nutritious and safer foods, to reduce requirements for water, nitrogen and other inputs, to develop disease resistant crops that require fewer chemical protectants, crops that are used to produce more and better biofuels, and crops that produce useful and valuable materials that will fuel the industrial and pharmaceutical sectors of the future. The goals will result in an agriculture that meets all the criteria for environmental safety and sustainability, ensures rural and urban wealth, contributes to human health and well being, and that seeks to provide global food security. While such goals may seem lofty and far afield from what is often

referred to as ‘agriculture’, they are achievable through science and development of the human potential to exploit the knowledge provided through discovery, innovation, and invention.

The discoveries made in the plant and agricultural sciences in the laboratories of universities, private and public research centers, and in laboratories of the private sector have been nothing short of remarkable. They have led to understanding how and why some plants produce large amounts of oils, or proteins, or carbohydrates while others cannot; how and why some plants are resistant to certain insects or diseases, but not to others; and how some plants make certain types of molecules such as pain killers and cancer-fighting anti-oxidants while other plants do not. As these and other discoveries were made scientists began to look for ways to ‘genetically instruct’ some plants to have specific traits that will increase their value to producers, or to consumers of agriculture products. In many cases researchers have used genetic engineering to accomplish their goal.

While many of the advances in agriculture in the past 25 years have come through classical methods of genetics and breeding, chemical and radiation mutagenesis, and cell and tissue culture-based biotechnologies, some of the most remarkable advances have come through the biotechnologies that comprise genetic engineering. Genetic engineering (GE) brought farmers insect resistant crops that require far fewer chemical inputs than did parental varieties, and tolerance to environmentally friendly herbicides that reduce the use of less safe herbicides and enable farmers to increase no-till agriculture. This can save the farmer fuel and labor costs and increase profits, while increasing the quality and fertility of the land. Similarly, virus resistant crops have reduced the need for the insecticides that control the aphids that transmit the viruses from plant to plant. These discoveries, breakthroughs if you like, have increased the profits of producers, reduced the use of harsh chemicals that can cause illness in farmers and their families as well as to consumers, and enhanced the environmental quality of farming eco-systems. Furthermore, each of the technologies and products that have come to market has an outstanding record of safety for the farmer and consumer as well as the environment.

This is true sustainability of agriculture; this is sustainability that is quantifiable, is defined by science-based criteria, not a ‘sustainability’ based on a philosophical approach that critics and the media too often bandy about in criticizing conventional agriculture. It is an agriculture that is the goal of many scientists around the globe, and those around this table today. These applications of biotechnology to agricultural are thus bringing to life the vision Rachel Carson put forward in the last chapter of Silent Spring:

> "A truly extraordinary variety of alternatives to the chemical control of insects is available. Some are already in use and have achieved brilliant success. Others are in the stage of laboratory testing. Still others are little more than ideas in the minds of imaginative scientists, waiting for the opportunity to put them to the test. All have this in common: they are *biological* solutions, based on understanding of the living organisms they seek to control, and of the whole fabric of life to which these organisms belong. Specialists representing various areas of the cast field of biology are contributing -- entomologists, pathologists, geneticists, physiologists, biochemists, ecologists -

- all pouring their knowledge and their creative inspirations into the formation of a new science of biotic controls.[1]

Scientists and technicians have in past decades made discoveries through the use of genetic engineering that will, if approved for commercial release, produce crops that are even more remarkable: for example crops that require less irrigation under drought conditions, and that have higher nutrient value than the parent varieties, among other traits.

Yet this is only the beginning of reaching the potential for agriculture – an agriculture which must feed more people not just more calories, but more nutrient-rich calories; agriculture and agriforestry that requires fewer chemicals to protect them from insects and diseases; agriculture that delivers more and better biofuels; and agriculture that meets the growing demands for the natural chemicals that will fuel our pharmaceutical and industrial factories, all while fulfilling conservation pioneer Wallace Stegner's command that we learn to "tread more gently on the land."

Science-driven agriculture can be the means through which the United States remains competitive with the rest of the world. U.S. agriculture will increasingly be challenged by scientific advances being made by talented scientists and innovators in other countries, including in Brazil and China, whose work is projected to contribute half of the new biotech plant varieties brought to market between now and 2015[2]. Furthermore, many of the discoveries represent the underpinning structure of global food security as scientists in advanced countries share breakthroughs in with those in developing economies whose local crops need similar advances to meet the growing food and nutrition needs of their communities. Productivity of crops such as cassava, sweet potato, sorghum, millets, and pulse grains, which provide nutrition for hundreds of millions in developing economies, will be increased via advanced technologies. It is a moral imperative to assist in achieving global food security by building local capacity in agriculture in order to meet the needs of a growing and demanding world population.

This is an exciting period of time in discovery and innovation. Unfortunately, it is not an exciting time for delivering new products of agriculture biotechnology to consumers or to those who would invest in the future of agriculture. While not all discoveries lead to innovation and new products, there are a growing number of examples of new inventions developed through genetic engineering that have good likelihood of success and that continue to be delayed in reaching the marketplace because of regulatory processes that are ill-defined and/or unpredictable, sometimes irrational, and always costly. This is an area for significant concern to inventors and entrepreneurs, and is worthy of attention and reform. These are delays that are not imposed on crops that are improved by chemical or radiation mutagenesis or through mutagenic cell cultures, or through advanced molecular breeding.

Some of the discoveries that fall in this category have been made in our land grant colleges and universities; others have been made in the elite universities and research institutions that previously

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[1] Rachel Carson, "The Other Path", Silent Spring, Houghton Miflin, New York. 1962. p.278.

[2] Alexander J. Stein & Emilio Rodriguez -Cerezo, 2009. The global pipeline of new GM crops: Implications of asyncrhonous approval for international trade. European Commission Joint Research Centre, Institute for Prospective Technological Studies. EUR 23486 EN - 2009.

focused on achieving breakthroughs in biomedical sciences. Others are made in the start-up companies that are attempting to turn discoveries into innovations, such as those that will fuel the bio-based economy of the future. Many of the discoveries are made with horticultural crops such as tomato, cucumbers, lettuce, potato, and other fruits and vegetables. Other examples include applications that are relevant to industrial crops such as the perennial grasses and rapidly growing trees that will provide the 2nd and 3rd generation biofuels and biopower for energy. Still others would result in specialty and industrial chemical feedstocks that will feed a green economy.

Plants and plant products (but not products developed via food processing) that are developed with the aid of genetic engineering are subjected to regulations and oversight through a process developed in the mid- 1980s, and finalized in 1986 in the Coordinated Framework for Regulation of Biotechnology. Existing processes and authorities of the USDA, EPA, and FDA were brought together to address concerns and potential risks about this new technology: because the types of hazards anticipated with these new products were the same as those with which we were long familiar from other types of agricultural innovation, the determination was made that existing statues were adequate, and no legislative authorities were required by regulators. The history and success of the regulatory process and the products that were released as a consequence of the coordinated framework are now storied in terms of the positive impacts that such products have had on U.S. and global agriculture. It is also reflected in the positive impacts on production agriculture in the U.S. as well as on millions of small holder farmers in developing countries. Genetically engineered cotton, and to a lesser extent maize/corn, have increased yields in India, China, So. Africa and other countries, while reducing the use of chemical insecticides that have caused health problems in poor rural communities.

Today, the regulatory structures that control the production of GE crops are much like they were in 1987 –there have been modest adjustments in the process since that time. And, given sufficient time, financial resources and patience, the process results in the release of some new technologies to the marketplace. The regulatory process has not, however, adapted to the experiences of the past 24 years or to new knowledge generated during this period; as a consequence many other useful products have not made their way to the marketplace. It has adapted poorly in response to the proven safety record and absence of adverse affect on the environment or on animal and human health of GE crops. It has not adapted to changes that have further enhanced the safety of the technologies; and it has not adapted to the needs of the market. The system needs attention, modification, and improvement if the U.S. and global agriculture communities and its consumers are to benefit from the investment in past and current science and technology that can impact agriculture and agriforestry.

Let me put it very simply: Since regulations were first put in place for the products of agricultural biotechnology in 1987, more than 2 billion acres of crops have been grown and harvested in at least 29 countries around the world[3]. These crops have been grown by 15.4 million farmers, 14.4 million of whom are small, resource poor farmers in developing countries. The harvests of these crops have been consumed in billions upon billions of meals by humans and livestock around the world for the better

[3] Clive James, 2011. ISAAA Brief 42: Global Status of Commercialized Biotech/GM Crops: 2010.

part of two decades now. In all this vast experience we have not a single consequence of a novel, negative consequence for health or the environment - not one. In fact, we have seen some of the well known risks of conventional or organic agriculture dramatically reduced: the potential for contamination of food with cancer-causing compounds like aflatoxin in corn has been dramatically reduced through biotechnology; exposure of farmers to potentially dangerous neurotoxins used to control pests has been dramatically reduced, as have been the cases of unintentional exposure with all their health consequences; the quality of runoff from agricultural lands has improved with the widespread adoption of biotech crops as no-till methods of weed control, as carbon sequestration in soils and greenhouse gas emitting consumption of fossil fuels have been significantly reduced. Indeed, as even the Europeans admit,

"… the use of more precise technology and the greater regulatory scrutiny probably make them even safer than conventional plants and foods; and if there are unforeseen environmental effects - none have appeared as yet - these should be rapidly detected by our monitoring requirements. On the other hand, the benefits of these plants and products for human health and the environment become increasingly clear."[4]

There are several consequences if the regulatory burdens faced by innovators are not brought back more closely into alignment with a realistic view of the potential hazards. First, innovation will suffer because of the lack of clarity of the process of regulation and its increasing costs. Currently, the system is geared to big agriculture and to relatively low margin products grown on large acreages. Improved seeds of the major commodity crops corn, soybeans, cotton and canola are the major beneficiaries to date: these GE technologies have benefitted the technology companies, the farmers, the environment and consumers. The few examples of GE crops now on the market that were not developed by a large company include varieties of papaya and squash that were engineered to have resistance to certain viruses. The latter were developed early in the development of genetic engineering technologies when costs and time of deregulation (approval) were less than they are today.

GE seeds for the commodity crops are produced by large companies that tend to be less constrained by cost and time. In contrast, researchers and innovators in the academic community, including those that serve agriculture productivity, and in small companies, have considerably more difficulty in producing or delivering a genetically engineered crop to the market than do large corporations. Indeed, there are fewer than a handful of such products. Researchers in universities and small companies have, since the mid-1980s made discoveries that are relevant to the less lucrative vegetable seed market, and in cutting edge areas that have potential to revolutionize the biofuels and biomaterials industry. Yet, there have been no new products released to the market from universities for more than 10 years, in part because of the time and cost necessary to bring the new product forward.

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[4] European Commission, Press Release of 8 October 2001, announcing the release of 15 year study incl 81 projects/70M euros, 400 teams (http://ec.europa.eu/research/fp5/eag-gmo.html and http://ec.europa.eu/research/fp5/pdf/eag-gmo.pdf)

The of cost for regulatory approval GE products that carry a new trait introduced via genetic engineering have been estimated at between $5 million to more $25 million in the U.S.; time to market can be as much as 10 years from product development. Some costs are, of course, related to technology development per se; however, the bulk of the costs deal with the regulation process and achieving deregulated or partially deregulated status for a new product.

Several examples of unjustifiably burdensome hurdles created by the current processes that are required for deregulation can illustrate the problem. One of the steps requires full biochemical characterization of the location of the gene in the DNA of the plant that is genetically engineered. While such characterization no longer has a prohibitive cost, scientific evidence accumulated during the past 20 years indicates that such case-by-case characterization is generally not relevant to the performance or safety of the crops themselves. Indeed, performance is still only meaningfully judged in the old fashioned way, that is, by testing the new variety under field conditions. A second example is the use of genes from *Bacillus thuringiensis* (Bt) to confer resistance to certain insects, such as larvae of certain beetles or caterpillars. Bt proteins from many sources have been tested and shown to be safe for the environment, and for animal (except for the target insects, of course!) and human consumption. It is logical therefore, to begin to exempt from regulation, or at least reduce the review process, for Bt genes. A similar logic can be applied to genes that confer tolerance to the herbicides glyphosate and glufosinate, and to genes for virus resistance.

New technologies that have been developed since the regulations were established raise additional questions about the relevance of some of the regulatory reviews. For example, the use of endogenous host genes to confer a new trait, and genes that produce small interfering RNAs, many of which are naturally found widely in plants, could be exempted from costly approval processes, or considered for reduced regulatory oversight. Endogenous genes and genes that produce small interfering RNAs are used to develop crops and agriforestry varieties with increased resistance to pests and diseases, resistance to heat and drought conditions, improved productivity/yield, improved efficiency in use of water and nitrogen fertilizers, and improved biomass that will serve our biofuels and biomaterials industries of the future.

Other novel technologies, such as use of synthetic chromosomes, and specific proteins that target genetic changes even more precisely than does the older technology, have been developed and tested and proven to be useful to developing new products. It is not known how new technologies such as these, and others of the future, will be regulated, and what the cost of regulatory approval that contain the technologies. It seems likely, from our experience to date, that the costs imposed will not likely be matched by any commensurate increase in safety of the new products. And the lack of clarity as to the regulatory barriers they will have to surmount itself can diminish the prospect of innovation per se, by reducing the incentives for investors to fund such innovations through the R&D process to the marketplace.

What modifications are necessary to change the process of regulation and secure the United States in a position of pre-eminence in the agriculture and agriforestry? The committee is urged to consider the following amongst the changes that it may recommend.

1. **Return to a firm commitment to base regulations on science**, in particular science that addresses issues related to the safety of the product and independent of the process by which it was developed. Regulators need to discipline themselves to focus on what they need to know to ensure safety, and not allow themselves to be distracted into musings on many of the fascinating issues about which it would be nice to know more; questions to which no conceivable answer would shift a regulators' decision one way or another, and thus irrelevant to safety assurance. This will have the effect of reducing the necessity of conducting certain types of analyses of new products and reduce the amount of time and the costs associated with regulation.

2. **Redefine the basis by which products of biotechnology are subjected to regulatory oversight.** The role of APHIS in regulating GE crops is important to maintaining confidence in an approval process; however, the characteristics of the products that would trigger regulation and a relevant mechanism to trigger regulatory oversight should be redefined.

3. **Identify categorical exemptions that can streamline and reduce burdens for products/characteristics experience has shown to be safe.** A process should be developed to thoroughly review the technologies and products that have been developed and commercialized to date and identify those technologies that can be exempted, requiring minimal or reduced oversight. This will reduce the cost of regulation of many new products.

4. **Distinguish between real and perceived risks and focus on those that are real.** Processes and methods should be developed to distinguish between real vs perceived risks in establishing safety recommendations; and to consider costs and benefits in risk analysis, including potential costs to the ecological environment from the continuation of conventional agricultural practices. A change such as this will require action by Congress. In providing such guidance to APHIS, Congress should weigh the opportunity costs of regulatory policies that discourage innovations that actually reduce the risks attendant on conventional agricultural production techniques that are already widely used. In this context, it may be helpful to consider the way that current NEPA statues are applied to agricultural biotechnology and to establish specific mechanisms for NEPA compliance in the case of these products that are appropriate for the characteristics and the risks being evaluated.

In concluding these comments, I ask that you consider some of the 'unintended consequences of the overly stringent regulation of products that are developed by genetic engineering. First, by the use of terminologies that falsely imply risk and potential lack of safety, we have created the perception that the technology itself is unsafe and that products derived from the technology are therefore unsafe. Scientific consensus over the past 20+ years has indicated otherwise. It is time to change the verbiage, some of which is embodied in the laws under which we regulate these products.

Second, as a consequence of what many consider overly cautious regulations based on process rather than the safety of the product, many developing countries are reluctant to adopt the technologies and products developed from the technologies. This has the effect of limiting acceptance of products of

American agriculture and the development of crops that could benefit those countries; and, it reduces the opportunity of meeting the goals of global food security, and thus our national security.

We can and must do better.

Respectfully submitted,

Roger N. Beachy

June 21, 2010

Roger Beachy
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Plant Science Center
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Dr. Roger Beachy was appointed by President Obama as the first Director of the National Institute of Food and Agriculture (NIFA) in October, 2009, serving from October, 2009 through May, 2011. He served as Chief Scientist of USDA from January – October, 2010. Prior to this appointment, he served as the founding president of the Donald Danforth Plant Science Center in St. Louis, Missouri. From 1991 to 1998, he headed the Division of Plant Biology at The Scripps Research Institute Professor as Scripps Family Chair in Cell Biology. Dr. Beachy was Professor in the Biology Department at Washington University in St. Louis, and Director of the Center for Plant Science and Biotechnology from 1978-1991. There, his research team, in collaboration with Monsanto scientists, developed of the first genetically modified food crop, a variety of tomato that was modified for resistance to virus disease. His technique has been replicated by researchers around the world and has led to the production of many types of virus-resistant plants.

Dr. Beachy was elected to the U.S. National Academy of Sciences, was awarded the Wolf Prize in Agriculture (2001), and is a fellow in the American Association for the Advancement of Science, the American Academy of Microbiology, Foreign Associate of the National Academy of Science India, the Indian National Science Academy, and The Third World Academy of Sciences, and Fellow in the Academy of Science of St. Louis. He received the Bank of Delaware's Commonwealth Award for Science and Industry (1991) and the Ruth Allen award 1990 from the American Phytopathological Society (1990), among other awards.

Dr. Beachy holds a Ph.D. in plant pathology from Michigan State University and B.A. in biology from Goshen College in Goshen, Indiana.

Committee on Agriculture
U.S. House of Representatives
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House Rules* require nongovernmental witnesses to disclose the amount and source of Federal grants received since October 1, 2008.

Name: Roger Beachy

Organization you represent (if any): _____

1. **Please list any federal grants or contracts (including subgrants and subcontracts) you have received since October 1, 2008, as well as the source and the amount of each grant or contract. House Rules do NOT require disclosure of federal payments to individuals, such as Social Security or Medicare benefits, farm program payments, or assistance to agricultural producers:**
Award to employer on behalf of research in my laboratory through 2011

Source: U.S. Dept. of Energy **Amount:** ~$150,000

Source: _____ **Amount:** _____

2. **If you are appearing on behalf of an organization, please list any federal grants or contracts (including subgrants and subcontracts) the organization has received since October 1, 2008, as well as the source and the amount of each grant or contract:**

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Please check here if this form is NOT applicable to you: _____

Signature: Roger W Beachy

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