BIOTECHNOLOGY INDUSTRY ORGANIZATION

James C. Greenwood
President & CEO

December 6th, 2011

Mr. Mike Stebbins
Assistant Director, Biotechnology
Office of Science and Technology Policy
Executive Office of the President
725 17th Street Room 5228
Washington, DC 20502

Dear Assistant Director Stebbins:

Biotechnology companies are working every day to solve the greatest challenges facing our society — whether it's finding a cure for cancer, protecting against bio-terror threats, or creating renewable energy sources. Yet despite the urgent need for scientific breakthroughs in these areas, some current government policies are holding back the potential and promise of biotechnology.

Only by transforming the policy environment can we create a robust innovation economy that helps America compete globally by maintaining our position as world leader in biotechnology research and development. And only by investing in biotech today can we unlock the scientific potential that resides in the thousands of American biotech companies and unleash the promise of biotechnology into the breakthrough cures, treatments, enhanced agricultural products, vaccines to defend against bioterrorism and revolutionary biofuels that can transform society.

To this end, BIO began a process in 2010 of interviewing thought leaders within and outside of our industry for the purpose of envisioning game-changing strategies. We contracted with Dr. Elias Zerhouni, former Director of the National Institutes of Health, to conduct an analysis of the challenges we face and a more comprehensive survey of medical experts, academic researchers, and other life science leaders to suggest out-of-the-box, big ideas to significantly advance biotechnology's chances to succeed.

Over the past year, we worked with BIO Board members and staff to review these ideas, debate their merits, and offer alternative and additional approaches to develop a comprehensive national policy strategy.

The policy agenda detailed in the accompanying materials is the result of this rigorous policy development process. It reflects the input and suggestions gathered throughout this process from biotech CEOs, venture capitalists, current and former government officials, academic and medical researchers, patient advocates and other experts. Our recommendations reflect the big, bold and daring thinking required to create new models to encourage investment in innovation and to speed up the discovery of scientific breakthroughs. In short, this agenda will enable the biotechnology industry to fulfill its promise to help, heal, fuel, and feed the world.

We are pleased to share these recommendations with you and look forward to working with the White House to create a bioeconomy blueprint for the 21st Century.

Sincerely,

James C. Greenwood
President and CEO
Biotechnology Industry Organization

Cc: Greg Nelson, White House Office of Public Engagement
Mary Maxon, White House Office of Science and Technology Policy

Introduction

In the last century, technological know-how (human capital) and physical capital have replaced land, labor and natural resources as the primary drivers of economic growth. Governments that have 1) invested in scientific research and technology development and 2) created policies and institutions to encourage the growth of scientific understanding and technological innovation have profited from their investments. The overall economic well being of their citizens has improved, as has their longevity, infant mortality rates and quality of life.

Science-based technology development accelerates economic growth through its effects on industrial productivity. New technologies create new products and processes; stimulate the creation of new companies and even new industries; improve existing products and processes; and lower manufacturing costs. They also provide researchers with tools and techniques for discovering new products.

In the past two centuries the primary scientific drivers of technology development were physics and chemistry. Technological innovations rooted in these sciences were key components of the Industrial Revolution, Information Age and Green Revolution, all of which transformed the nature of our economies and structure of our societies.

Society now finds itself on the threshold of an era dubbed the Biology Century by a number of authors. In the 21st century, a deep and rich understanding of the fundamental mechanics of life processes and its molecular components will lay the foundation for the development of an array of biologically-based technologies. This set of technological tools, collectively known as biotechnology, will be the predominant force fueling innovation, stimulating economic development and transforming our lives.

Biotechnology is not a single technology but a collection of technologies. The common thread uniting these technologies is their foundation: they are based on living cells and biological molecules. They capitalize on the cell's capacity to reproduce itself; manufacture biological molecules precisely and repeatedly; degrade a variety of substances; and respond to environmental factors.

These are the very same capabilities humans have relied on for centuries and that have provided the foundation for many well-established industrial sectors, such as agricultural production, food processing, pharmaceutical manufacturing and waste treatment. The success of these industries has always hinged on effectively expropriating the biochemical processes of living organisms and shaping them to specific purposes. However, only recently have scientists uncovered the underlying mechanisms of the biological processes that industries relied upon. With today's biotechnologies, companies co-opt these same cellular capabilities knowingly and purposefully.

All of the biotechnologies in Table 1 can be used by the many industrial sectors listed in Table 2 to conduct basic and applied research; identify and solve problems; improve processes; and create new products and services. Consequently biotechnology, like all technologies developed in the last two centuries will stimulate economic growth by increasing industrial productivity.

This infiltration of biotechnology into many industrial sectors will serve as the foundation of the bioeconomy

Biotechnology capitalizes on unique cellular properties

The fundamental problems confronting people today are essentially the same problems they have faced for centuries - growing crops, treating diseases, getting energy - but the technological tools brought to bear on these problems have improved, especially during the last century. By using cells and biological molecules as the foundation of a technology, companies can develop products that capitalize on innate properties of life at that level: specificity, unity and reproducibility. These cellular properties impart unique characteristic to the products and processes developed through biotechnology that make them superior to earlier, comparable technologies that addressed the same problems.

Specificity, precision and predictability

Cells and molecules exhibit extraordinary specificity in their interactions, so the tools and techniques of biotechnology are quite precise and can be tailored to operate in known, predictable ways. As a result, the products of biotechnology should represent improvements over earlier, comparable technologies by being better targeted to solving specific problems; generating less severe side effects; and having fewer unintended consequences.

The specificity of cells and molecules also enables biotechnology-based detection/disgnostic techniques to identify substances that occur in minuscule amounts and, once identified, to measure them faster and with great accuracy.

Unity, flexibility and leveraging

Cells and molecules from very diverse organisms display remarkable similarity. Because all cells

1. work with essentially the same set of molecular building blocks;
2. use similar processes to manufacture and breakdown molecular building blocks; and
3. are able to read and implement the genetic instructions from virtually any other cell

the technologies based on cells and biomolecules allow great flexibility in developing products and solving problems. By working at the level of cells and molecules, all of nature's immense diversity becomes accessible, providing an unprecedented number of options for designing technological solutions to specific problems.

In addition, because of the unity of life, every research dollar spent on understanding the molecular basis of a cellular structure or process in one organism is capable of informing research and enhancing understanding of other organisms.

Reproduction, renewable resources and sustainability

Fossil fuels provide the energy and feedstock chemicals that currently drive the engines of economic growth. However, fossil fuels are non-renewable resources and a major contributor to greenhouse gas emissions. Processes based on fossil fuels generate unwanted by-products, some of which are hazardous pollutants. Continuing to base economic growth on fossil fuels is not sustainable because the resource base is nonrenewable and their use degrades the quality of essential resources. Depletion and degradation or essential resources are inconsistent with the concept of sustainability – meeting society's current needs without sacrificing the ability of future generations to meet theirs. We must find a way to continue to grow the economy, but it must be done sustainably.

Because organisms contain molecules similar to those in petroleum, they can be used as sources of energy and material inputs in manufacturing processes. As a result, biotechnology could help replace fossil fuels with renewable resources, such as biomass. In addition to being renewable, these resources could lead to the creation of products and processes that generate less solid waste or pollution. If the products are composed of biological molecules, they will be biodegradable due to the unity of life principle just described.

Utilizing these remarkable and valuable biological properties of molecular specificity, unity of life, and the ability to reproduce will make investments in biotechnology key to the success of a bioeconomy.

The Grand Challenge for Agriculture: Doing More with Less

Throughout history, as human population growth increased the demand for food, animal feed, fuel and fiber, our agricultural production systems kept pace. In the mid-20th century, fears of a population-driven food crisis, primarily in the developing world, led to research and investment to intensify crop production there. From the 1960 – 2000, the Green Revolution increased food production in developing countries almost 200% from 800 million tons to 2.2 billion tons and global food production by 150% from 1.8 billion tons to 4.6 billion tons through the use of high yielding varieties that could resist herbicides and disease, irrigation, insecticides and fertilizers. Although some people, primarily in affluent societies, criticize the Green Revolution's environmental impacts, its methods: 1) saved one billion from famine; 2) halved the global percentage of undernourished people; 3) improved rural economies; and 4) protected approximately 2.2 – 3.8 billion acres of land from being cleared for crop production.

We still face the relentless challenge of feeding an ever-expanding population, which will reach 9 billion by 2050 and require at least a 70% increase in food, feed and fuel production. However, this time the challenge of increasing agricultural production is exacerbated by a confluence of interacting pressures in addition to population growth: increased competition for water and land; rising energy prices; a dietary shift from cereals to animal products; diminishing supplies of fossil fuels – the source of most agrochemicals; resources degraded from past activities; and the global effects of climate change.

The Green Revolution allowed us to produce more with more inputs, most of which are derived from nonrenewable resources. Our current challenge is to produce more with less and to do so in a sustainable fashion. Biotechnology provides a set of precise yet flexible tools for meeting that challenge.

Essentially all of the biotechnologies listed in Table 1 have applications that improve the quantity and quality of agricultural products. The tools that are useful in diagnosing human diseases, such as monoclonal antibodies, can also be used to identify plant and animal diseases. Metabolic engineering technology permits crop developers to improve the fatty acid profiles of the oilseed crops or shunt the plant's energy into producing more roots to enhance drought tolerance. Using insect cell culture we could greatly increase the use of precise biological control agents, such as baculoviruses, in pest control. The list of possibilities is virtually limitless. Identify a problem related to agricultural production, environmental protection, food safety and nutritional value, and one or more of the biotechnologies could be used to develop a solution.

To date, however, most attention has been focused on one biotechnological tool being used to improve agriculture – genetic engineering. Of all of the possible applications of genetic engineering to agriculture, only a few have been commercialized.

Accomplishments in Plant Biotechnology to Date

Biotech crops have already proven they can provide more with less, sustainably, by improving yields without clearing new land, while conserving soil, saving water, using less fossil fuel, both directly and indirectly, and enhancing biodiversity. In addition to environmental sustainability, two other dimensions of sustainability – economic and social – are also enhanced with biotech crops because improved farm incomes have preserved jobs in rural communities

In 2011, U.S. growers once again increased the number of acres they planted in biotech crops. According to the USDA's Economic Research Service, 94% of the soybeans and 88% of the corn grown in the U.S. were biotech varieties[1]. U.S. growers were not alone in choosing to increase their plantings of biotech crops. For the 15th straight year, global acreage of biotech crops saw a double digit percent increase in 2010, as more than 15 million farmers in 29 countries grew 365 million acres of biotech crops. Almost 50% of the biotech crop acres were grown by 14 million small farmers in 19 developing countries. Since being introduced in 1996, there has been an 87-fold increase in the global acreage of biotech crops, making them the most rapidly adopted agricultural innovation in history.[2] The rates of adoption in developing countries have usually been steeper than in industrialized countries. For example, biotech soybeans were first introduced in Argentina in 1996, and by 2001 they accounted for 90% of the soybeans grown there. Biotech cotton was first made available in only two provinces in China, Hebei and Shandong, and within three years 97% and 80% of the cotton crop grown were genetically engineered varieties.[3]

The take-home message is clear: where farmers have been allowed to choose biotech varieties, they have embraced the technology and stuck with it. Why? Economics.

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[1] The primary biotech crops grown today in the U.S. are insect-resistant and herbicide tolerant varieties of soybean, cotton, corn and canola.

[2] By way of comparison, 10% of the corn acres in the U.S. were planted in hybrid corn five years after its introduction; within five years, over 50% of the soybean and cotton acres in the U.S. were biotech varieties.

[3] Neal Van Alfen, UC, Davis. 2004. Agricultural Biotechnology: How Big Is It Globally? In: *Agricultural Biotechnology: Finding Common International Goals*

Scores of studies in different countries have compared the economics of various biotech crops with their conventional counterparts. Not surprisingly, the results show that farmers, who are naturally very risk-averse, switch to biotech varieties because of the economic gains they provide. The magnitude of the benefit varies from study to study, crop to crop, and country to country, but the fundamental - and unsurprising - finding is that farmers, like other business owners, act in their own best economic interest. Why else would farmers continue to choose biotech crops over conventional varieties since biotech seeds typically cost more?

For example, a 2010 National Academy of Sciences (NAS) study found that U.S. farmers who grow biotech crops "are realizing substantial economic and environmental benefits…compared with conventional crops."[4] In their most recent study of global impacts, Graham Brookes and Peter Barfoot demonstrate substantial net economic benefits for farmers of $10.8 billion in 2009 and $64.7 billion from 1996 – 2009, in spite of higher seed costs.[5] Interestingly, the shares of the global farm income gains, both in 2009 and cumulatively (1996-2009), have been split equally between farmers in developing and developed countries, but the economic gains to individual farmers in developing countries exceed that for farmers in developed countries. Carpenter's 2010 meta-analysis of 49 peer-reviewed studies on the economic benefits of biotech versus conventional varieties in 12 countries also demonstrated that the gains for small farmers in developing countries exceed those for farmers in industrialized countries.[6]

The gains that matter most to growers are not global figures, but the improved incomes they experience in their own operations. Studies have shown farm-level gains ranging from a few dollars per acre to significantly more than $200/acre depending on the crop, year, current and past pest levels and control practices, country and region. The economic gains farmers enjoy result from higher yields, lower input costs, or both in some cases. The 2010 NAS study cites "lower production costs, fewer pest problems, reduced use of pesticides and better yields."

Since 1996, biotech traits have added a total of 83.5 million tons of soybeans and 130.5 million tons of corn to global production. The technology has also contributed an extra 10.5 million tons of cotton lint and 5.5 million tons of canola (Brookes and Barfoot, 2011). During the same timeframe, biotech crops have reduced pesticide spraying by 865 million pounds and lowered fuel use. The combination of higher yields and reduced production costs provided for the 1996 - 2009 cumulative farm income benefit of almost $65 billion; 57% ($36.6 billion) was due to yield gains, and $28.1 billion due to lower production costs. James[7] found approximately 25% of global farm-level income increase ($2.7 billion) in 2009 was due to reduced production costs (lower fuel costs, less pesticides used, lower labor costs), and the remainder to yield gains for biotech varieties: 9 million tons of soybeans, 29 million tons of maize, 2 million tons of cotton lint and .67 million tons of canola.

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[4] National Research Council. 2010. *The Impact of Genetically Engineered Crops on Farm Sustainability in the United States.* http://www.nap.edu

[5] Brookes, G. and P. Barfoot. 2011. GM crops: global socioeconomic and environmental impacts 1996-2009. PG Economics. United Kingdom. PG Economics has published a series of similar studies. www.pgeconomics.co.uk

[6] Carpenter, J. 2010. www.guardian.co.uk/commentisfree/cif-green/2010/apr/21/gm-crops-benefit-farmers

[7] James, C. 2010 Global status of commercialised biotech/GM crops: 2010, ISAAA brief No 42. www.isaaa.org

The follow-on environmental benefits of growing biotech crops are substantial and include preservation of biodiversity[8] and topsoil, while reducing greenhouse gas emissions, fuel use and water loss from soil. According to Brookes and Barfoot (2011):

• Without biotech crops, the 2009 production increases would have required clearing 31 million acres of land for crop production and, as a result, decrease biodiversity.

• Herbicide tolerant biotech crops have facilitated the adoption of no/reduced tillage production systems in many regions, which reduces soil erosion and improves soil moisture levels

• In 2009 alone, less fuel use and additional soil carbon storage from reduced tillage reduced greenhouse gas emissions by an amount equivalent to removing 17.7 billion kg of carbon dioxide from the atmosphere or removing 7.8 million cars from the road for one year.

The Potential for Agricultural Biotechnology to Do More with Less

The past achievements of biotech crops pale in comparison to what agricultural biotechnology could provide, especially in light of the necessity of doing more with less.

The "less" we have already experienced with the existing biotech crops – less fuel, land, pesticides, soil erosion – could be extended to many more crops, including orphan crops essential to subsistence agriculture in developing countries and, as such, key to their food security. For example, genes for the insect-resistance trait developed for corn and cotton, which come from a naturally occurring microbe found in soils worldwide, *Bacillus thuringiensis* or Bt, have been donated to African institutions for use in cowpea, a staple crop in West Africa.

In the U.S. these proven traits could be transferred into minor use or small acreage crops and significantly increase the incomes of famers. This crop diversification not only gives farmers more options but also has been proven to enhance the sustainability of agricultural systems. This flexibility is one of biotechnology's greatest untapped potentials: a genetic innovation developed for commodity crops can be used in any crop, because all plants know how to translate and use the genetic information.

The tools of biotechnology are also being used to develop new crops that use less of other essential resources: water and fertilizers. Drought tolerant corn varieties developed through biotechnology are awaiting approval in the U.S. and other countries, and drought tolerant genes have been incorporated into African corn varieties. A number of crops with the NUE trait (nitrogen utilization efficiency) are also in the pipeline.

"Less" means not only lower amounts of agricultural inputs, but also less severe environmental impacts. The pest control traits of current biotech varieties have had less severe environmental impacts than their predecessors, and therefore less of an impact on biodiversity. The Bt gene is toxic only to a handful of insects, and in order to exert its effect, the insect must eat the crop. As a result, insects that are not crop pests or are beneficial, such as bees and ladybird beetles, are not harmed. The herbicide tolerance traits added to biotech crops, have allowed farmers to switch to herbicides with fewer environmental and health impacts.

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[8] Carpenter, J. 2011. Impacts of GM crops on biodiversity. *GM Crops:*2:1-17.

This same thinking could be applied to crops to control disease, such as those caused by fungi and virus. We have long had the technology to create many virus-resistant crop varieties, but the economics of product development, primarily the costs of regulatory approval, make it unlikely that these will be developed for any but the largest commodity crops.

Just as "less" means more than less inputs, the "more" provided by past and future advances in biotechnology encompasses more than just "more" product. More farm-level income, with its concomitant impacts on rural economic development, could be provided to many more farmers, including those growing small acreage crops in the U.S., if existing biotech traits were incorporated into additional crops, especially small acreage crops.

The "more" provided by biotechnology also entails more nutritious crops, thus enhancing agricultural biotechnology's contribution to public health. A few crop varieties, nutritionally-enhanced through biotechnology, have been commercialized in the U.S. and could help to address the obesity epidemic by shifting the proportion of various oils to healthier types. Similar work is being done with animal food products in which the levels of omega-3 fatty acids, which have many health benefits, in meat and milk are increased. However, much more could be done to improve the vitamin and mineral content, as well as local availability, of fruits, vegetables and other crops, both in the U.S. and globally. Some of these "biofortified" products are currently being field-tested in developing countries, and many more are under development by public sector research institutions. However a number of studies have shown that the high costs of regulatory approval makes ii essentially impossible to create these biotech crop varieties

We already have the know-how to develop the biotech varieties just described that would allow us to do "more with less." We have the necessary genes in hand, have developed the technology to provide them to various crops and, in many cases, have already produced the biotech variety. But having these much needed technologies is not sufficient. We also need government policies that will allow both the public and private sectors to develop these crops.

Realizing the Potential through Regulatory Reform

Agricultural biotechnology holds essentially unlimited potential for improving food and energy security, making food safer and more nutritious, enhancing the sustainability of both agricultural and energy production systems and sustaining rural economies. Unfortunately only a sliver of that promise has been turned into reality. Why? The U.S. regulatory system, which was originally structured to facilitate product development by verifying science-based predictions of product safety, is the greatest impediment to the development of safe, beneficial products. Irrespective of the intent of the U.S agencies in the 1980's (and their verbiage today), our regulatory system is neither risk-based, nor scientifically sound.

Agricultural biotechnology has a sterling safety record, which was anticipated in reports published by scientific bodies from around the world prior to the first field test and has been reiterated often since then.[9] Scientific understanding of biology, food safety and agricultural ecosystems allowed them to predict that the environmental and food safety issues associated with these crops would be the same as those of conventional crops. In other words, the concerns focused solely on biotech crops, such as gene flow and the evolution of resistance to herbicides and Bt crops, are the very same concerns that apply to agriculture, in general.[10] Twenty-five years of testing and experience confirmed the predictions of the scientists, as there have been no documented adverse effects to human health or the environment from biotech crops.[11] None of the hypothetical problems that people raised well before the first crop was planted or eaten has come to pass after over 2 billion acres of biotech crops have been grown and an incalculable number of meals, consumed.

However, as evidence that ag biotech products pose minimal to no risk has accumulated over the last two decades, the degree of regulation, as measured by the amount of data that must be submitted to a U.S. regulatory agency in applications for product commercialization, has increased, not decreased. For example, the attached chart of the U.S. Environmental Protection Agency's data requirements clearly demonstrate the increase in the type and scope of information that must be submitted for registering a crop with a single gene encoding a Bt protein (Table 3). Similar increases in data requirements, accompanied by delays in decision-making, are found at the United States Department of Agriculture regulatory agency, as well.

This increase in data requirements has led to a staggering increase in the time and cost of getting a product through the regulatory approval process. [12] A September 2011 study of the six large ag biotech companies[13] involved in product development, conducted by Phillips McDougal in the United Kingdom, revealed the following trends related to ag biotech innovation:

- The cost of discovery, development and authorization of a new plant biotechnology trait introduced between 2008 and 2012 is US$136 million. Of that total, $35.1 million is spent on the costs of meeting regulatory requirements. [14]

- The time from the initiation of a discovery project to commercial launch is 13.1 years on average for all relevant crops. Regulatory science, registration and regulatory affairs

[9] A few of the scientific bodies that have issued scores of statements about the environmental and food safety of biotech varieties are: WHO, FAO, U.S. National Academy of Sciences, OECD, American Medical Association, American Dieticians Association, International Academies of Sciences, Ecological Society of America.

[10] As stated by Dr. Marc Van Montagu of Ghent University in *A Decade of EU-funded GMO Research*, "The current focus on assessing the environmental risks of GMOs in isolation from other agricultural practices defies logic."

[11] For example, a book published by the European Commission in December 2010, *A Decade of EU-funded GMO Research*, summarizes the results of 50 EU projects on the safety of biotech crops: there is "…no scientific evidence associating GMOs with higher risks for the environment or for food and feed safety than conventional plants and organisms."

[12] Those who developed the regulatory system in the 1980's estimated the maximum cost for obtaining regulatory approval of a genetically engineered crop with which they had no familiarity at $500,000. Today, approval for that very same crop, for which we now have decades of experience, is over $30 million.

[13] The September 2011 survey entitled, "The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait", focused on biotech traits in large scale commodity crops that had received cultivation approval in two countries and import approvals from at least five countries.

[14] It should be noted that this study was designed to exclude the costs and timelines for products with multiple events combined by breeding ("breeding stacks"). For breeding stacks, the total timelines are commonly, depending on the crop, 2-3 years longer than what is represented by this data.

> accounts for the longest phase in product development, estimated at 36.7 percent of total time involved. The time associated with registration and regulatory affairs is increasing from a mean of 3.7 years for an event introduced before 2002, to the current (2011) estimated 5.5 years.

A number of unfortunate trends result from the significant increase in costs of obtaining regulatory approval for a genetically engineered crop.[15] The richness of the 1980's-90's pipeline, which was filled with a wealth of different traits, in scores of crops, being developed by the public sector and companies of all sizes, evolved into one containing very few traits in 4-5 crops being developed by a handful of large companies.[16] According to Miller and Bradford,[17] "..innovation in ag biotech was on an exponentially increasing trend during the 1990s, which then abruptly leveled off around 1998 with a decrease in subsequent years." They attribute this precipitous decline in innovation to the increasing cost of regulatory approval for biotech crops that can be recovered only for high volume commodity crops, such as corn and soybeans.

Unfortunately, researchers attempting to develop biomass crops for a bio-based economy have noted a similar stultifying effect of biotech regulations on innovation in that field as well.[18]

The costs of that attrition of safe and beneficial products are many and diverse: consumers do not have access to safer, more nutritious fruits and vegetables; small and large farmers are not able to diversify and profit from value-added crops; and new energy sources and environmental benefits are lost to all.

The other losers are small companies and universities, one of the country's greatest sources of jobs and innovation. Both have been essentially excluded from the ag biotech revolution by a regulatory system in which the degree of regulation is unrelated to the degree of risk.

Recommendation: If the potential of biotechnology is to be realized, the regulatory system must be restructured based on the fundamental principle that the degree of regulation should be proportional to the degree of risk. This might involve excluding classes of crops/traits from regulatory oversight based on familiarity or on science-based prediction of level of risk. This could be achieved by regulatory changes, perhaps in conjunction with minimal legislative language that facilitates and guarantees changes are realized.

The large companies that are able to afford the costs of regulatory approval, irrespective of the system's lack of scientific validity, are now suffering from a different regulatory challenge: the vulnerability of the regulatory-decision making process to litigation and politicization. As a result, rampant regulatory uncertainty is now the norm. Companies no longer can predict how

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[15] Pew Initiative on Food and Biotechnology. *Emerging Challenges for Biotech Specialty Crops*. Workshop Proceedings. (2007).

[16] Graff, G.D., Zilberman, D. & Bennett, A.B. The contraction of agbiotech product quality innovation. *Nature Biotechnology* **27**, 702-704 (2009).

[17] Miller, J.K. & Bradford, K.J. Regulatory bottleneck for biotech specialty crops. *Nature Biotechnology* 28, 1012 – 1014 (2010)

[18] Strauss, S.H., et.al. Far-reaching deleterious impacts of regulation on research and environmental studies of recombinant-DNA modified perennial biofuel crops in the United States. *BioScience* 60, 729-741 (2010)

long regulatory approval will take, which data will be required, what the decision will be, and what the decision will be based upon. The only thing they can be certain of is that it will take 6-8 times longer to receive approval for a crop/trait that would have taken 140 days in 1997.

Recommendation: Regulatory decision-making must be made less susceptible to litigation and politicization so that the regulatory certainty and timeliness return. One way to achieve this is by making regulatory decision-making more immune to attacks based on NEPA and the Endangered Species Act. Successfully achieving this protection will likely involve changes to the agencies' authorizing statutes. Other changes that would improve predictability and timeliness are those that provide additional resources to BRS and making the agencies more accountable.

Table 1. The biotechnologies. Biotechnology is a collection of technologies, all of which utilize certain unique properties of cells and the molecules within them. This list includes only some of the biotechnologies and focuses on commercial applications and not the uses of biotechnology in basic research.

Technology Description	Current and Potential Applications
Monoclonal Antibody Technology Uses immune system cells that make proteins called antibodies. Antibodies bind to substances with extraordinary specificity.	Diagnose infectious diseases Treat autoimmune diseases Detect harmful microorganisms in food Locate and measure environmental pollutants Distinguish cancer cells from normal cells
Bioprocessing Technology Uses living cells, such as bacteria, yeast and mammalian cells, or their enzymes, to manufacture useful products, breakdown molecules or generate energy.	Cleanup toxic waste sites Produce energy from agricultural refuse Manufacture therapeutic compounds & vaccines Produce fermented foods and nutritional additives Manufacture industrial enzymes & feedstock chemicals
Cell Culture Technology Is the growing of cells in appropriate nutrients in laboratory containers or in bioreactors in manufacturing facilities.	Increase use of biocontrol in agriculture Replace animal-testing with cell testing Treat certain medical problems by replacing malfunctioning or injured cells with healthy cells Produce naturally-occurring plant therapeutics
Biosensor Technology Consists of a biological component, such as an enzyme, linked to a tiny transducer that produces an electrical or optical signal when the biological component binds to another molecule.	Measure blood glucose levels Monitor industrial processes in real time Provide physicians with instant test results Locate and measure environmental pollutants Measure the nutritional value & safety of food
Recombinant DNA Technology (Genetic Engineering) Uses molecular techniques to join, or recombine, DNA molecules from different sources.	Treat certain genetic diseases Improve food nutritional value Develop biodegradable plastics Provide new and improved vaccines Enhance biocontrol agents in agriculture Decrease allergenicity of certain foods Increase crop yields & decrease production costs

Microarray Technology Allows analysis of thousands of gene, proteins or other molecules simultaneously.	Detect genes useful in crop production and protection Tailor drug treatment to patient Assess potential toxicity of drug Identify stage of disease progression Find microbes for cleaning up pollution
Protein Engineering Technology Improves existing proteins, such as enzymes and antibodies, and creates proteins not found in nature.	Create novel enzymes Improve catalytic ability of enzymes Develop sustainable industrial processes Improve proteins responsible for bread rising
RNA Interference Technology Decreases the production of specific proteins by blocking the genes encoding them.	Slow food spoilage Control viral diseases Engineer metabolic pathways in crops Treat diseases such as asthma and certain cancers

Table 2. Examples of the industrial sectors affected by the biotechnologies. This summary is not intended to be comprehensive but only suggestive of the potential role biotechnology will play in these industries.

Human Health Care
Knowing the molecular basis of health and disease can lead to improved and novel methods for diagnosing, treating and preventing diseases. Biotechnology products already on the market include detection tests for many infectious organisms, certain cancers, hormone levels and genetic diseases; therapeutic compounds for rheumatic arthritis, diabetes, cystic fibrosis and other genetic diseases, multiple sclerosis, cardiovascular diseases and many cancers; and vaccines for hepatitis B, meningitis and whopping cough.

Agricultural Production
The agricultural production industry uses biotechnology to increase yields, decrease production costs, diagnose plant and animal disease, enhance pest resistance, improve the nutritional quality of animal feed, broaden the use of biological control agents and provide alternative uses for agricultural crops. Currently marketed products include insect and disease resistant crops, herbicide tolerant crops, healthier oilseed crops and crops that provide renewable sources of raw materials for soaps, detergents and cosmetics.

Food and Beverages
Food processing, brewing and wine-making have always relied on biotechnology to enhance the nutritional quality and processing characteristics of their starting materials – grains, fruits and vegetables - as well as improve the microorganisms that are essential to these industries. All fermented foods and beverages depend on the action of microorganisms, which also serve as the source of many food processing aids, preservatives, texturing agents, flavorings, and nutritional additives, such as amino acids and vitamins. In addition biotechnology-based diagnostic tests are improving food safety.

Enzyme Industry
The enzyme industry and its products are essential to the operations of many of the other industrial sectors, such as food processing, textiles and brewing. Microorganisms have been the essential manufacturing work force of this industry, and their impact will increase in the future as genetic engineering gives new manufacturing capabilities to standard production microorganisms and improves manufacturing process efficiency and production economics.

Forestry/Pulp and Paper
Biotechnology is being used to create trees that are resistant to diseases and insects and to improve the efficiency with which trees convert solar energy to wood production. Extensive research is being conducted on microbes and their enzymes for pre-treating and softening wood chips prior to pulping; removing pine pitch from pulp to improve the efficiency of paper-making; enzymatically bleaching pulp rather than using chlorine; and deinking recycled paper.

Textiles
Many textiles, such as cotton, wool and silk, are naturally-occurring, while others are derived from natural substances, such as wood pulp. Biotechnology should have an indirect impact on

the textiles industry by improving the source materials, as well as a direct impact. Enzymes are currently used in natural fiber preparation and value-added finishing of the final product, such as stonewashed denim genes. Leather manufacturers use enzymes to remove hair and fat from skins and to make leather pliable. Genetically engineered microbes have produced textile dyes, such as indigo, and the protein found in spider silk.

Chemical Manufacturing

Biotechnology can provide cleaner, more efficient ways of manufacturing chemicals than do current methods. Microbes have been used for decades to convert biological materials, such as corn, into feedstock chemicals. Public and private institutions are conducting research on increasing the use of plant biomass and microbial enzymes in chemical manufacturing, because both are likely to generate fewer toxic waste products.

Energy

Before fossil fuels can be used for energy production, sulfur must be removed, and biodesulfurization relies on microbes and their metabolic enzymes. Microbes have also been used to enhance oil recovery from in-ground crude oil formations for more than 30 years. In the future, as fossil fuels become depleted and oil prices increase, we will need to establish alternative energy sources, such as biomass-based fuels like the ethanol that is currently added to gasoline. Advances in biotechnology are making production of ethanol more attractive economically. Other potential areas of energy production include genetically engineered microbes to generate methane from agricultural or municipal wastes or photosynthetic microbes for hydrogen production. However, both will require a number of decades of research before they become economically viable.

Waste Treatment

Microbes have always been essential for degrading organic wastes, whether the waste is generated by humans or agricultural and industrial operations. As the human population increases, supplies of potable water decrease, and the standard of living of people in developing countries improves, we will need to apply biotechnology to improving the efficiency of natural microbial degradation processes. In addition to utilizing microbes to breakdown wastes, we are also turning to microbes to help us clean up soils and water that have become contaminated with environmental pollutants.

Table 3. Past, Current and Future PIP (Proposed 2011) Data Requirements: Registration Applications for Plant Incorporated Protectants[1] (X= required)

(Although not listed in this Table, it is worth noting that in the proposed data requirements rule, the requirements for Experimental Use Permits have increased substantially. The data requirements below now apply to an application for an EUP, with the exception of the following.

- Under human health, the 90-day oral toxicity test, the specific serum binding test, and the hypersensitivity data;
- For nontarget effects, Tier II, III and IV tests;
- For environmental fate, the field persistence data; and
- Product performance and resistance management data.

This is a very onerous list for what could be a very small-scale field testing program.)

Data Category	**Bt Potato 1995**	**Bt Corn 2008**	**2011 Proposal**
Product Characterization			
Biology of the plant			New Requirement
Identification of the event	X	X	X
Identification of the PIP components			Increase Scope
Spectrum of pesticidal activity		X	Increase Scope
Mode of action	X	X	X
Certification of limits		X	X
Characterization of inserted DNA	X	X	Increase Scope
Characterization of protein - Efficacy		X	X
Characterization of protein – Expression levels	X	X	X
Physiochemical characterization of proteins	X	X	Increase Scope[2]
Demonstration of protein equivalency	X	X	X
Human Health			
Acute oral toxicity - Mouse	X	X	X
Allergenicity - Bioinformatics database analysis		X	Increase Scope
Allergenicity – Stability to heat, SGF, SIF		X	X

[1] Both of the crops have a single gene encoding a protein from a strain of *Bacillus thuringiensis.*
[2] Increase in scope is due to possible increase in number and type of proteins doe which data must be submitted (e.g., fusion proteins produced via insertions that inadvertently create new open reading frames), not to providing data on more physiochemical properties of the PIP)

Serum binding tests			New Conditional Requirement
Toxins – Protein database analysis		X	X
Non-protein toxicity			New Conditional Requirement
90-day oral toxicity			New Conditional Requirement
Hypersensitivity incidents			New Requirement[3]
Synergistic effects from multiple PIPs		X	X
Environmental – Non Target Organisms			
Soil microbial community acute toxicity			New Requirement
Broiler feeding study –transgenic grain		X	New
Avian oral toxicity – Quail/duck – purified protein	X	X	Increase Scope
Wild mammal – Oral toxicity – purified protein			New Conditional Requirement
Freshwater fish – Toxicity – purified protein		X	Increase Scope
Freshwater invertebrate - Toxicity		X	Increase Scope
Estuarine and marine animal		X	Increase Scope
Honeybee toxicity – Larva and adult	X	X	X
Arthropod toxicity – Ladybird beetle, lacewings	X	X	May Increase Scope
Arthropod – Minute pirate bug		X	X
Parasitic wasp	X	X	X
Non-arthropod invertebrate - earthworm		X	X
Tritrophic testing of selected beneficial insects			New Conditional Requirement
Tier II-IV testing – plant tissue testing; semi-field studies; field studies			New Requirement
Environmental – Environmental Fate			
Plant Studies			New Requirement
Impacts gene flow- sexually compatible plants			New Requirement
Potential weediness			New Requirement
Potential horizontal gene transfer			New Requirement
Field persistence			New Requirement
Soil degradation rate	X	X	Increase Scope

[3] Previously associated with adverse effects reporting (ex post facto). Now seems to be requirement in application submitted for the registration

Resistance Management Data Requirements			
Target organism biology and ecology			New Requirement
Target organism susceptibility		X	Increase Scope
Simulation models		X	X
Potential for cross resistance		X	X
Resistance monitoring plan		X	X
Remedial action plan		X	X
Compliance assurance/grower education		X	X
Conditions of Registration			
Annual Report on CAP		X	X
Annual Report on Grower Education		X	X
Annual Report on IRM Monitoring		X	X
Annual Sales Report		X	X
Other			
Analytical detection method		X	X
Public interest document		X	X

The Grand Challenge for Industrial Biotechnology:
Creating a Biobased Economy

Vision: The vision of the industrial biotechnology sector is the development of a thriving *"biobased economy"* in which the U.S. is no longer dependent on fossil fuels for energy and industrial raw materials, but instead derives much of its fuels, chemicals and materials from renewable agricultural feedstocks converted to higher value products by industrial enzymes and microorganisms or other processes. This vibrant biobased economy would revitalize rural and "rust belt" communities through the creation of high quality *jobs in value-added agriculture and clean manufacturing* of *sustainable domestically produced products*; strengthen the nation's *balance of trade* through exports from increased domestic manufacturing; enhance the country's *energy security* through reduced dependence on imported oil; and improve the nation's *health and environment* through cleaner burning fuels and more efficient manufacturing, which in turn would reduce emissions of greenhouse gases and other pollutants. The biobased economy would be a vital component of a broader "Bioeconomy" based on the innovation and commercial activity of the whole biotechnology industry.

Challenge: Today's fossil fuel-based economy is the product of over a century of private and public investment in fossil fuels. Industrial biotechnology offers a set of tools **(see Appendix A)** which can be used to develop the *fundamental value chains* of a biobased economy; but industrial biotechnologies must compete with mature and entrenched fossil incumbents and the accompanying infrastructure developed over the last century. Innovative industrial biotechnology companies must also have enough capital to vault over the *"valley of death"* that separates emerging technology companies from those that have successfully commercialized biotechnology innovations. One of the largest and most acute hurdles facing the biotechnology sector is the absence of private *financing* for the construction of first-of-a-kind and large-scale commercial *biorefineries.* Another significant hurdle is that a national infrastructure for the production, collection and processing of next generation feedstocks – such as cellulosic crop residues, dedicated energy crops and algae biomass – is lacking. Increased public investment in industrial biotechnology *research and development, and demonstration manufacturing facilities* is also needed to fund future waves of innovation that would proceed in parallel with market development and commercialization efforts. Specific challenges facing the industrial biotechnology sector follow.

R&D Funding. Federal agencies have provided solid funding to industrial biotechnology research, which has led to important innovations and ushered many technologies to the cusp of large scale commercialization. This is particularly true for biofuels, but there are still areas of industrial biotechnology research and development in need of similar attention – particularly for the development of renewable chemical platforms, which are the building blocks for industrial biotechnology. As commercialization proceeds, continued investment in innovation and process improvements will be needed to enhance the economic viability of projects and to continue to expand the industrial biotechnology product portfolio. Public-private research collaborations will continue to be needed to keep the U.S. competitive and maintain leadership in this space. Specific areas in need of ongoing research include synthetic biology, marine biotechnology, industrial biocatalysis (enzymes), feedstock improvement and processing, and development of new renewable chemicals, biobased products, and biofuels.

Specifically prominent among emerging technologies is "synthetic biology," **(see Appendix B)** which aims to apply standardized engineering techniques to biology, thereby creating organisms or biological systems with novel or specialized functions to address countless needs. This highly promising platform merits strong federal investment. The Administration should also strongly consider a dedicated program of research and development to produce a robust, affordable and sustainable supply of industrial building block sugars for conversion to fuels and chemicals.

Financing the construction of first-of-a-kind commercial biorefineries. A new generation of advanced biofuel and renewable chemical products and technologies, such as cellulosic ethanol, drop-in biofuels, and a host of promising renewable chemical intermediates **(see Appendix C, D),** has emerged from the laboratory and is ready for commercial deployment. But, because of the economic downturn, private financing for the construction of first-of-a-kind commercial-scale biorefineries is nearly non-existent. Commercial banks are reluctant to provide financing because they view these technologies as unproven at scale and high investment risk. With the downturn in the economy, venture capital investment has also diminished significantly. A growing list of industrial biotech innovators has exhausted operating capital and is in immediate need of assistance.

Establishing next generation feedstock supply chains. Achieving large commercial volumes of biofuels and renewable chemicals will require a robust and diverse renewable biomass feedstock supply with an emphasis on high-yielding, sustainable biomass sources such as purpose-grown energy crops, including algae. Commercial quantities of these feedstocks do not yet exist. A pathway to widespread adoption of purpose-grown energy crops is needed, including enduring programs to assist farmers in establishing such crops, equipment and infrastructure for collecting, storing and delivering the biomass, and processing technology and infrastructure.

Workforce training. A 2009 report on the "U.S. Economic Impact of Advanced Biofuels Production: Perspectives to 2030" (attached as **Appendix E**) found that advanced biofuel production under the federal Renewable Fuel Standard (RFS) is expected to create over 400,000 direct jobs in the United States by 2030. There are already hundreds of biofuels projects underway throughout the country to meet these requirements, including over 50 existing and planned cellulosic biofuel development projects. Renewable chemicals projects are expected to create tens of thousands of additional high quality jobs over the next decade (see **Appendix F, G**).

These projects are mostly in rural areas and all demand significant manpower in research and development, construction, sales, management, feedstock growth, harvesting, transportation, engineering, distribution, etc. Workforce training in all of these areas will be critical to achieving these targets (see **Appendix H**). In particular, there will be a rapidly growing need for chemical engineers trained to work with biological systems – skills that are already in short supply even at this early stage of deployment.

Regulatory support. Current environmental regulations are geared toward clean-up of end of pipe pollution. Such standards do not reflect the unique properties of industrial biotechnology to prevent pollution through cleaner, more efficient manufacturing processes. Revised regulatory approaches are needed to encourage the adoption of biotechnology processes that can prevent pollution before it ever occurs and can remediate existing pollution. Industrial biotechnology (green chemistry) inherently provides substantial gains in manufacturing of renewable chemicals and biobased products by reducing pollution and waste, decreasing the use of raw materials and water, and reducing the number of process steps.

For example, many proposed federal and state-based carbon regulations fail to adequately account for greenhouse gas emissions savings that can be generated by industrial biotechnology. Combustion of biofuels and other biogenic energy sources recycles CO_2 emissions through renewable biomass feedstocks. If sustainably sourced, such combustion does not result in lasting increases in CO_2 concentrations in the atmosphere. Other uses of biogenic carbon, such as renewable chemicals and bioplastics, may even sequester CO_2, reducing atmospheric GHG concentrations (see **Appendix I, J, K**). Life-cycle based methodologies should start from the premise that all renewable biomass receive full credit for recycling of carbon. Attached please find BIO's comments to U.S. EPA and the California Air Resources Board (CARB) on proper accounting of biogenic carbon (**Appendix L, M, N, O**).

BIO also encourages OSTP to work with industry to ensure that regulation of algae-based fuels and renewable chemicals production is well coordinated among federal agencies and does not impede the development and deployment of this promising emerging technology.

Market access barriers. Biofuels face several barriers to increased market adoption, including ethanol blending limits, regulations and standards that restrict eligible fuel molecules or production pathways, and inadequate biofuel distribution infrastructure. In the case of new "drop-in" biofuel molecules such as biobutanol and renewable hydrocarbons, there are multiple statutory and regulatory barriers to the introduction of these promising new biofuels. A brief presentation summarizing these barriers is attached as **Appendix P**. For biobased products, existing programs to expand market adoption and consumer awareness, such as the USDA BioPreferred Program™, have been very slow to take shape, hindering the growth of these technologies. A short overview presentation illustrating USDA's BioPreferred Program is attached as **Appendix Q**.

Awareness and public opinion. A fundamental challenge for the industrial biotechnology sector is increasing public awareness and support for industrial biotechnology processes and products. Broad support has been established for advanced biofuels, but recent criticism of first generation biofuels (e.g. food vs. fuel; indirect land use change) has negatively impacted the confidence of policymakers, investors, and the broader public in biofuels generally. Awareness of renewable chemicals among policy makers and the public significantly lags biofuels, complicating the case for policy support.

Despite broad support for advanced biofuels, renewable chemicals, and biobased products, federal policies for these technologies have not fully overcome the full set of challenges facing the sector. For example, the impact of biorefinery loan guarantee programs has been limited by overly restrictive implementation; renewable energy tax incentives for other renewable energy technologies have become more generous steering investment to those sectors; and threatened cuts to farm bill energy programs have added to policy and project uncertainty. A new commitment to a biobased economy is needed in Congress and within the Administration to achieve President Obama's goals of economic prosperity, energy security, technology leadership, and environmental health.

<u>Solutions</u>: Strong, sustained, stable federal policy support is critical to overcoming the challenges facing the industrial biotechnology sector to create a biobased economy. BIO's 2011 Industrial and Environmental Section Policy Priorities identify the leading near-term threats and opportunities in federal industrial biotechnology policy. Strong Administration support for these priorities is needed to ensure continued development of the industrial biotechnology sector:

<u>BIO Industrial and Environmental Section</u>
2011 Policy Priorities

<u>Funding/Eligibility</u> - Maintain funding for biomass and biorefinery programs at USDA and DOE, and expand eligibility to renewable chemicals / biobased products

- Cuts to the Biomass Crop Assistance Program (BCAP), USDA/DOE Loan Guarantee Programs (LGP), and DOE Biomass Research and Development Program threaten to derail commercial, demonstration, and pilot biorefinery projects that are finally making progress after two years of credit freeze. As one of the most promising opportunities for high quality domestic job creation, we should be increasing our investment in biorefinery projects, not cutting. BIO's industrial biotech funding priorities for FY12 are attached (see **Appendix R, S, T**).

- As we look to the next farm bill reauthorization, we need to ensure that these programs support the full range of biorefinery products. Some programs, such as the USDA LGP, need new legislative authority to include renewable chemicals and biobased products. Other programs are authorized to support these technologies, but have focused almost entirely on fuels. We need to make sure USDA and DOE ramp up their investment in renewable chemicals.

Farm Bill – Ensure robust energy title in Farm Bill reauthorization

- USDA has rightfully taken a leadership role in helping to commercialize advanced biofuels and biobased products through programs authorized under the farm bill's energy title (Title IX). These programs are just now realizing their full potential after protracted rulemaking (most of the programs only finalized rules late last year). We must ensure USDA has the tools it needs to succeed going forward by further strengthening these programs and identifying other ways USDA can help achieve the biobased economy. BIO's farm bill energy title priorities are attached as **Appendix U**.

DOD – Support DOD's Role in Advanced Biofuels Production

- Transportation fuel security is a national security issue, not just for the American public, but also for America's military. The Defense Department has expressed a desire to help address fuel security by facilitating the commercialization of military-grade advanced biofuels. DOD should be provided with all of the tools necessary to accomplish this mission. A joint letter from the advanced biofuels and commercial aviation industries in support of the recently announced Navy-USDA-DOE Memorandum of Understanding on Drop-in Biofuels is attached as **Appendix V**.

RFS - Support the Renewable Fuel Standard

- The federal Renewable Fuel Standard (RFS) is the fundamental policy supporting the development of the advanced biofuels industry. It provides both market assurance and a price premium for high-performing advanced biofuels, resulting in a strong investment case for advanced biofuels once investors gain sufficient confidence in the technology. BIO's analysis of value proposition for advanced biofuels under the RFS is attached as **Appendix W**. The Administration should reinforce its commitment to the national mandate of 21 billion gallons of advanced biofuels by 2022 as part of the overall RFS goal of 36 billion gallons. To stimulate necessary investment in advanced biofuel technologies, the market needs an unwavering message that the EPA will set annual advanced biofuels volumes at the level mandated in the Energy Independence and Security Act of 2007.

Tax – Incentivize innovation in tax code

- Tax policy can more effectively promote advanced biofuels commercialization by providing the long-term opportunity and flexibility available to other renewables such as wind and geothermal. An enduring package of advanced biofuels tax incentives that extends the cellulosic biofuel producer credit, expands feedstock eligibility, and allows developers to elect either a producer credit or refundable investment tax credit should be pursued aggressively.

- The tax code should also incentivize commercialization of innovative renewable chemicals and biobased products, which have tremendous potential to create lasting, high-quality domestic jobs while revitalizing rural economies, improving balance of trade, and reducing GHG emissions.

BIO's 5-year plan incorporates many of these concepts and adds several additional innovative policy proposals to advance the biobased economy. The executive summary of the industrial biotech chapter of this proposal is included below and attached as **Appendix X**. Administration support of these proposals is strongly encouraged.

BIO Industrial & Environmental Section 5 Year Plan Proposal:
The Biobased Economy Jobs and Development Act

The "Biobased Economy" refers to economic activity and jobs generated by the use and conversion of agricultural feedstocks to higher value products, the use of microbes and industrial enzymes as transformation agents or for process changes and the production of biobased products and biofuels. This proposal seeks to elevate the concept and awareness of the biobased economy and advance the policy priorities of the IES working groups, highlighting the outstanding job creation and rural / rust belt economic development potential of industrial biotechnology and biorefinery commercialization.

SUMMARY

<u>Title I – Agriculture</u>

Biomass Crop Assistance Program – Reauthorization and Enhancement
BCAP is the key program encouraging and facilitating farmers and landowners to produce new purpose grown energy crops (PGECs) for advanced biofuels and biobased products. This section reauthorizes BCAP through December, 2017, and enhances the program by: (1) ensuring funds are directed primarily to production of next generation crops for biofuels and bioenergy; (2) establishing a dedicated funding mechanism for awarded contracts; (3) providing for eligibility of non-food Title I crops; and (4) clarifying eligibility of certain other PGECs.

Federal Crop Insurance for Purpose Grown Energy Crops
While the U.S. Department of Agriculture's (USDA) Risk Management Agency (RMA) is currently studying the feasibility of developing crop insurance programs for certain biofuels and bio-products feedstocks, there is no formal federal crop insurance program available to producers of new PGECs. This section directs the RMA to finalize its research and work with stakeholders to establish by January 1, 2013, a formal crop insurance program that will cover PGECs. Provides such sums as are necessary from the Commodity Credit Corporation to carry out these crop insurance objectives.

Feedstock Sustainability Enhancement Grants
The continued development of domestic sources of energy, including for biofuels and renewable chemicals, depends upon the sustainable availability of consistent, high yield, good quality feedstocks. This section establishes a grant program through the U.S. Departments of Agriculture and Energy to fund demonstration projects that utilize practices to enhance biofuel and bioenergy feedstock sustainability. Authorizes $50 million annually through 2017.

Farm Bill Energy Title Amendments for Renewable Chemicals
Many of the programs in the 2008 Farm Bill's Title IX renewable energy programs are not available to renewable chemicals and biobased products, despite their profound potential benefits to rural America. This section codifies the definition of renewable chemicals; modifies the section 9003 Biorefinery Assistance Program and 9007 Rural Energy for America Program to provide for eligibility of renewable chemicals projects; and expands the USDA BioPreferred program to increase program outreach and education.

Title II – Tax

Tax Credit for Production of Qualifying Renewable Chemicals
Renewable chemicals and biobased plastics represent an important technology platform for reducing reliance on petroleum, creating green US jobs, increasing energy security, and reducing greenhouse gas emissions. By providing a renewable chemicals tax credit, Congress can create jobs and other economic activity, and can help secure America's leadership in the important arena of green chemistry. This section provides a federal income tax credit for domestically produced renewable chemicals. Like current law renewable electricity production credits, the credits would be general business credits available for a limited period per facility. Similar to the operation of IRC section 48C, the Treasury Department and USDA would review taxpayers' applications in a competitive process to ensure conformance with legislative intent. Per calendar year, each taxpayer would be entitled to claim as much as $25MM in renewable chemicals production tax credit associated with production of eligible renewable chemicals.

Advanced Biofuels Tax Reform
Current tax law on advanced biofuels does not provide an ordered pathway toward U.S. energy security. Congress must consider amendments to the current law tax incentives that focus on bringing commercial volumes of affordable advanced biofuels to market in the near term. This section implements several changes to the tax code towards this end: (1) extend the Cellulosic Biofuel Production Tax Credit through 2016 and add eligibility for algal biofuels; (2) allow advanced biofuel facility developers the option of electing to receive an investment tax credit; (3) provide for eligibility of biorefinery retrofit projects; (4) provide eligibility to federal Section 1603 Grants in Lieu of Tax Credits program; and (5) extend and expand eligibility for cellulosic biofuel property accelerated depreciation.

Title III – Defense

Strategic Biorefinery Initiative and Offtake Authority
Substantial energy security benefits would accrue to the Department of Defense from development of domestic sources of renewable biofuels and biobased products. As a major potential customer and as a potential source of funding for biorefinery construction, the Department of Defense is uniquely positioned to help accelerate deployment of these vital products. This section establishes and provides necessary funding for a DoD Strategic Biorefinery Deployment Program to finance construction of the first 5 commercial military advanced biofuel biorefineries. It directs DoD to identify existing funding authority for such projects, and to conduct by January 1, 2012, a biorefinery "fly-off" to identify and fund construction of the most promising projects. In addition, this section provides DoD with the authority to enter into long-term (up to 15 years) offtake agreements for procurement of advanced biofuels for military use.

Title IV – Energy

Repurpose and Retrofit Grant Program
It is widely recognized that repurposing or retrofitting existing idled or underutilized U.S. manufacturing facilities to integrate next generation processes capable of producing advanced biofuels and renewable chemicals and bio-products is one of the most time and cost effective ways to build out the advanced biofuels and renewable chemicals sector. This section establishes a federal matching grant program through the U.S. Department of Energy to fund projects to repurpose or retrofit existing idle or underutilized manufacturing facilities for the production of advanced biofuels and/or renewable chemicals. Provides up to 30 percent of eligible costs. Authorized at $100 million annually through 2017.

Synthetic Biology for Enhanced Sustainability of Biofuels and Renewable Chemicals
The advancing field of synthetic biology has the potential to greatly enhance both the economic and environmental sustainability of fuels and chemicals manufacturing. This section establishes a DOE Synthetic Biology Research and Development (R&D) Grants Program to fund research and development in industrial biotechnology for the enhanced sustainability of biofuels and renewable chemicals produced through synthetic biology technology. This program would support work on biological catalysts and processes that enable the cost-effective sustainable production of advanced biofuels, renewable chemicals and other technologies that reduce or minimize greenhouse gas emissions, including biological processes for removing carbon dioxide from the atmosphere. Authorizes $20M annually for this program through 2017.

Industrial Bioprocess R&D Program
The use of industrial biotechnology for the production of renewable chemicals and biobased products is enabling dramatic improvements in industrial energy efficiency as well as a host of renewable alternatives to traditional petrochemical-based products. This section establishes an Industrial Bioprocess Research & Development (R&D) program through the DOE Office of Energy Efficiency and Renewable Energy (EERE), Industrial Technologies Program (ITP), to fund projects in industrial biotechnology for renewable chemicals, biobased products, and renewable specialty chemicals. Authorizes $150M annually through 2017.

Title V – Environment

EPA R&D Program for Renewable Chemicals
Renewable chemicals can be engineered to provide innovative solutions that save energy, are environmentally preferred, and are a direct substitute or "drop-in" replacement for petrochemicals. Presently, there are no strong standardized metrics to quantify environmental benefits of these innovative products. Standardized metrics would allow renewable chemical companies to demonstrate substantial cost, environmental, and efficiency benefits, further encouraging the development of sustainable products. This section establishes a new Research and Development (R&D) program funded by the Environmental Protection Agency (EPA) that would provide grants to conduct environmental assessments for renewable chemicals and industrial products produced with industrial biotechnology. This program would (1) conduct assessments to provide quantitative data to demonstrate chemical safety and pollution prevention in industrial biotechnology processes; and (2) be followed up with educational and awareness programs for U.S. businesses for the purpose of providing education and data on the environmental and economic benefit of using green chemistry and biological processes in manufacturing. Authorizes $30M annually through 2017.