The USDA Small Business Innovation Research Program: Vision, Challenge, and Opportunities

William R. Goldner
USDA
Washington, DC

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The Small Business Innovation Research (SBIR) Program is a national competitive funding program, authorized by the United States Congress in 1982 to stimulate and facilitate research and development by US-owned and operated for-profit small businesses. All executive-branch departments with extramural research budgets exceeding $100 million are directed by legislation to provide a 2.5% set-aside to fund SBIR programs. Small businesses are defined as having 500 employees or less.

The United States Department of Agriculture (USDA) Cooperative State Research, Education, and Extension Service (CSREES) manages the SBIR Program. The USDA-SBIR Program awards only grants. It is a three-phase program. Phase I is a feasibility (proof-of-concept) study, and for FY2007 the grant may be for eight months for up to $80,000. Successful Phase I award winners are eligible to apply for Phase II funding. Phase II proposals are for a full R&D project leading to the development of a working product, process, or service that will be ready for final commercial application in the private sector. For FY2007 Phase II awards are for up to 24 months and up to $350,000. Phase III is the actual commercialization phase and no federal funding is used. Historically, companies winning SBIR grants have been successful in leveraging the SBIR seed money and the technical credibility conferred by a confidential and rigorous peer-review process to attract additional investment dollars from private sector entities. Almost half of the companies receiving USDA-SBIR Phase II awards have gone on to have some level of commercial sales based on their project.

The USDA-SBIR Program strongly encourages the participation of university and government scientists in SBIR projects. These scientists may serve as consultants or subcontractors with funding not exceeding a third of Phase I awards or a half of Phase II awards. A public-sector scientist may serve as the principal investigator on an SBIR grant by reducing employment at her/his home institution to 49% for the duration of the grant and if the SBIR research is performed someplace other than her/his lab. It is usually not acceptable for a university or government scientist to serve as a consultant and have all the research proposed for the grant done in her/his lab.

The funding level for the USDA-SBIR Program FY20006 was $19.17 million (Table 1). In 2006, 650 Phase I proposals were received and approximately 16% (101) were recommended for funding (Table 1). During the same year thirty-three of sixty-one Phase II proposals were funded (54%, Table 1).

Table 1. USDA-SBIR Program funding history.

Year	Budget ($million)	Phase I	Phase II
1999	13.3	84[1]/425[2]	32[1]/56[2]
2000	15.6	89/480	36/59
2001	16.3	90/480	37/63
2002	15.7	86/449	39/68
2003	17.7	88/656	38/67
2004	18.2	99/582	38/65
2005	19.2	93/557	40/79
2006	19.2	101/650	33/6`

[1]Proposals funded. [2]Proposals submitted.

Investigator-initiated concepts make up the bulk of the proposals received by the USDA-SBIR Program. The Program has twelve broad topic areas that are outlined in the request for applications (RFA) form (accessible at http://www.csrees.usda.gov/fo/sbir). Of these topic areas, nine routinely field biotechnology proposals (Table 2). This presentation will focus on opportunities and challenges facing researchers submitting biotechnology proposals to two USDA-SBIR topic areas, Plant Production and Protection – Biology and Industrial Applications.

Table 2. Biotechnology-relevant USDA-SBIR Topic Areas

Forest & Related Resources	Aquaculture
Plant Production & Protection–Biology	Industrial Applications
Animal Production & Protection	Animal Manure Management
Water & Soil Resources	Plant Production & Protection–Engineering
Food Science & Nutrition	

Plant Production and Protection–Biology

SBIR Topic Area 8.2, Plant Production and Protection–Biology (P^3B), has three main subtopics:

- Improved Crop Quality and Yield Utilizing Innovative Applications of Plant Breeding, Molecular Biology, Genomics, and Cell and Tissue Biology;
- Development of New Crops as Sources of Food, Fiber, or Industrial Products; and
- Crop Protection from Insects, Disease, and Abiotic Stress.

The USDA-SBIR web site (http://www.csrees.usda.gov/fo/sbir) provides access to abstracts of funded research and success stories that are illustrative of the scope of projects receiving funding in this topic area. From FY2005–2007 "specialty crops" have been a special focus of the P^3B topic area solicitation. Examples of specialty crops are fruits, vegetables, nuts, ornamental nursery or greenhouse crops, and forest trees (*e.g.* American chestnut). Typically, specialty crops have a much lower per-crop market value than the major row crops (*e.g.* corn, soybean). However, taken together they make up fully half of the US annual agricultural output, ~$50 billion (Jerardo, 2005). The P^3B topic area encourages submission of FY2007 proposals in four specialty-crop focus areas:

- improved plant-disease diagnostics;
- improved disease resistance in specialty crops;
- biological approaches to improve floriculture and ornamental nursery production; and
- rapid diagnostic methods for weedy and invasive species.

Although there is great opportunity for small businesses to use the tools and methods of biotechnology to create valuable new specialty-crop genotypes, there are significant challenges, as well. One aspect of the pre-commercial development of any new biotechnology-derived crop is navigating the regulatory process, which may involve interacting with as many as three federal agencies [USDA-Animal and Plant Health Inspection Service (APHIS), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA)]. The time involved and the financial expense of developing a complete dossier for seeking regulatory approval (deregulation) can be daunting. To date, only a small number of transgenic biotechnology-derived specialty crops have been deregulated and allowed to proceed to market (Goldner *et al.*, 2005). Even more troubling is the trend in research to develop specialty crops. Field-trial requests to APHIS for transgenic vegetables peaked in the mid-late 1990s with as many as 120 requests, but by late 2004, it had fallen to approximately twenty (Figure 1). US taxpayers have invested heavily in agricultural biotechnology through the USDA Agricultural Research Service (ARS) and through funding provided to land-grant universities, other public and private universities, and small agricultural biotechnology companies through USDA CSREES. Where is the return on that investment (McHughen, 2005)?

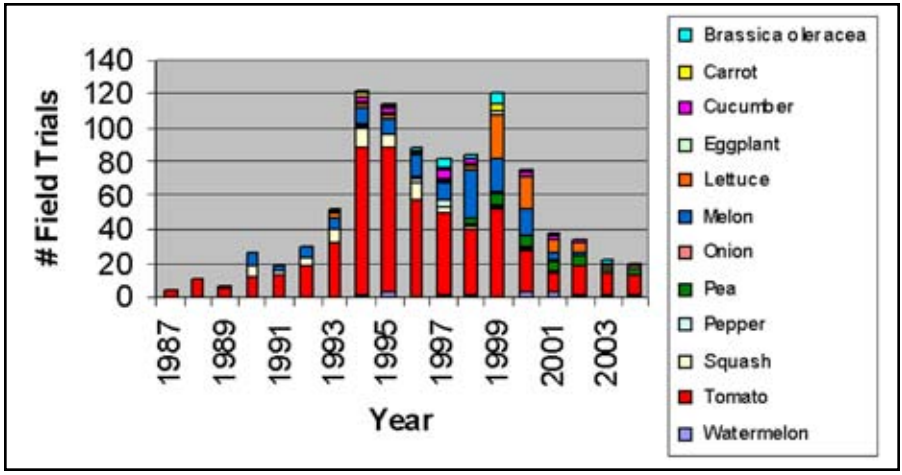

Figure 1. US transgenic fruit and vegetable field trials 1987 to October 2004 (Redenbaugh, 2005)

Biotechnology grants funded by the SBIR Program from FY1998 through FY2006 are shown in Figure 2. One to five Phase I grants in plant biology (P^3B) have been funded during that period (Figure 2). However, Phase II awards in plant biotechnology receiving peaked in FY2000 (three), with single awards funded in FY2001 and FY2003 (Figure 2). Since 2003, no Phase II award has been granted to a transgenic-technology project in plant

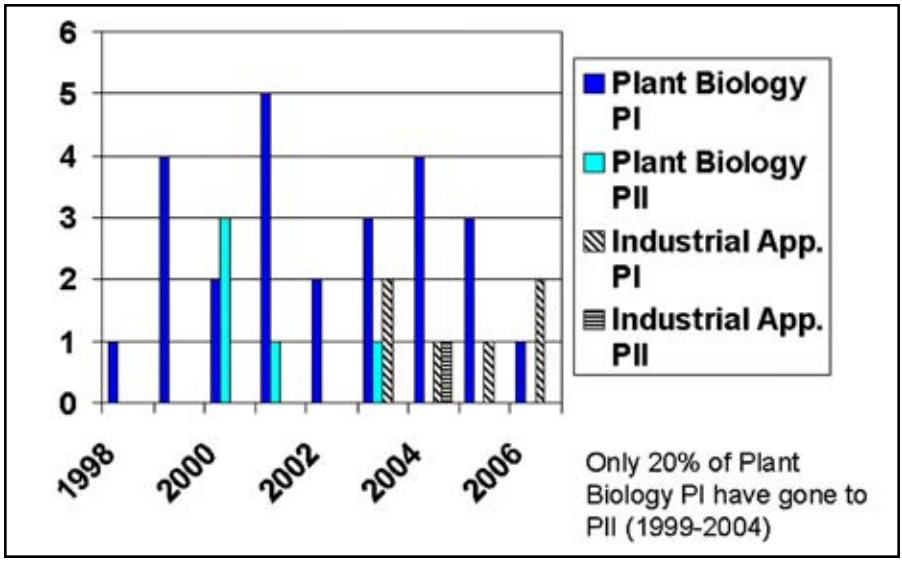

Figure 2. USDA-SBIR biotechnology grants.

biology, despite twelve projects being eligible to apply for Phase II in the FY2004–2006 period (Figure 2). Only 20% of eligible P^{3}B Phase I projects went to Phase II in the period FY1999–2004 (Figure 2, Phase I projects awarded in FY2005–2006 are still eligible to apply for Phase II in FY2007). Part of the explanation for the low percentage of Phase I projects competing successfully for Phase II may be the increased emphasis on commercial potential that the SBIR Leadership Team developed beginning in FY2003. If it could not be demonstrated how the results of a project would provide a marketable product, overcoming technical and regulatory challenges, there would be reduced incentive for the reviewing community to recommend investment. The question is, "How can we improve the chances for a broad range of biotechnology-derived specialty crops to reach the market place, where market forces will determine their acceptability to the public?"

The Specialty Crops Regulatory Initiative

Motivated by concerns and circumstances outlined above, a team of public- and private-sector scientists and administrators have been working on a program since 2003, The Specialty Crops Regulatory Initiative (SCRI). The over-arching rationale behind SCRI is to facilitate realization of potential to make available a broader range of biotech options, in a greater diversity of crops, to help meet needs of agriculture, consumers, and the environment. Toward this end, the approach being considered is to develop an organization to assist public-sector and smaller-scale private-sector developers of specialty crops through the existing regulatory approval process. Similar programs have been developed to facilitate small-market orphan drugs (FDA) and small-acreage pesticides (USDA, IR-4). Specialty traits of major crops (*e.g.* industrial lubricants, value-added proteins) share similar developmental challenges with specialty crops (*e.g.* smaller market size). At this time, including specialty traits of major crops under the specialty-crops umbrella has neither been ruled in or out.

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The long-term challenge for SCRI will be to make available a broader range of biotech crop options that create public benefit and meet economic and environmental needs (Goldner *et al.*, 2005). The need for the SCRI is underscored by the diversity of the SCRI steering committee including members from the public sector—USDA-CSREES, ARS, and APHIS, and land-grant universities (1862s and 1890s), as well as technology developers, commodity groups and growers from the private sector. The SCRI steering committee organized and implemented two national workshops to develop the concept and obtain

stakeholder input, and have informed numerous scientific and industry groups about the SCRI model. A significant milestone in the realization of SCRI was recently achieved with the selection and hiring of a consultant, through a contract with the University of California-Riverside. The consultant will serve as project manager to obtain additional stakeholder input and support to develop an action plan for realizing SCRI's potential public benefit. While the SCRI is potentially an important entity for providing guidance and assistance in developing critical data sets for specialty crop developers preparing applications for the deregulation of biotechnology-derived specialty crops under the current regulatory system, the implementation of SCRI remains several years in the future.

Alternative Approaches to Developing Specialty Biotech Crops

Despite the decline in SBIR-funded plant biotechnology projects reaching Phase II in the past 3–4 years, there have been some SBIR projects with technical approaches that partially mitigate risk through the implementation of confinement technologies. Two examples are CEA Systems, Ithaca, NY, and Kuehnle Agrosystems Co., Honolulu, HI.

CEA Systems's technology platform was developed at Cornell University. Essentially, the target production of high-value proteins from transgenic plants in controlled environment hydroponic systems (*i.e.* greenhouse, growth chamber). CEA is using SBIR P^3B funding to understand the effects of environment on protein expression in their target crops. The value of the proteins being manufactured is great enough to create a commercially viable opportunity on a greenhouse scale (small acreage) using controlled environment technology to prevent inadvertent environmental release.

Kuehnle Agrosystems (KA) has developed a system of "green biofactories." Their proprietary genetic transformation technology—magnetophoresis—was developed through funding from SBIR P^3B Phase I and Phase II grants. Magnetophoresis allows specific plant tissues or organelles to be transformed resulting in new or optimized metabolic function. KA received an SBIR Industrial Applications Phase I grant to begin developing the use of magnetophoresis to create green biofactories using transgenic unicellular algae that are grown and contained in controlled environment systems. These algae will be capable of producing high-value proteins and other compounds that will justify their relatively small scale of production. The reduced environmental risk conferred by the KA and CEA controlled-environment approach may facilitate the deregulation of their respective biotechnology-derived genotypes to be used exclusively in these systems.

Industrial Applications

The USDA-SBIR 8.8 Industrial Applications Topic Area provides R&D funding opportunities to companies that are developing enhanced production technology, improved quality control, and new biobased products from agricultural materials and residues. For FY2007, the Industrial Applications program established some specific focus areas: biofuels (*e.g.* ethanol, fuel gas, hydrogen); biobased products improving the economics of the biofuel production stream; and the development of new energy crops. USDA plays a lead role in the development of biofuel feedstocks and biomass-conversion technology. Consequently, the SBIR Industrial Applications program is fertile ground for biotechnology

The USDA Rural Development Agency provides a number of programs supporting bioenergy company development and sustainability.

concepts targeting these areas. Figure 2 shows that Industrial Applications biotechnology projects funded by SBIR are on the increase.

The current interest in renewable energy research and development by SBIR was emphasized at a conference held July 6–7, 2006, at Oak Ridge National Labs (ORNL), Oak Ridge, TN. The Department of Energy (DOE)/USDA-SBIR Energy Summit showcased alternative and renewable energy research-funding and technology-transfer opportunities from ORNL and USDA. Approximately 120 scientists and administrators (seventy from small businesses) attended the 2-day conference. Both ORNL (DOE) and the USDA-ARS have extensive research programs on bioenergy, many of which have strong biotechnology components. Additionally, the USDA Rural Development Agency provides a number of programs supporting bioenergy company development and sustainability. CSREES also funds university bioenergy research programs through the National Research Initiative Competitive Grant Program (www.csrees.usda.gov) and through other funding mechanisms. These bioenergy programs may afford new opportunities for small biotech companies to partner with these public-sector research institutions to bring new technologies into application in the private sector.

Additional USDA-SBIR Program Information

The USDA-SBIR Program releases one annual solicitation (usually June 1) with a closing date usually 90 days after the release (usually September 1). Phase I proposals are reviewed by outside reviewers and funding recommendations are provided by a technical review panel. Proposals are submitted electronically. Each applicant receives a verbatim copy of the review and a summary of the panel discussion.

The twelve SBIR Topic Areas are: Forests and Related Resources; Plant Production and Protection–Biology; Animal Production and Protection; Soil and Water Resources; Food Science and Nutrition: Rural and Community Development; Aquaculture; Industrial Applications; Marketing and Trade; Animal Manure Management; and Small and Mid-Size Farms. The website (www.csrees.usda.gov/fo/sbir) may be used to access program information, the RFA, technical project abstracts, links to the Small Business Administration and other SBIR programs, and USDA-SBIR Success Stories.

Closing Thoughts

- USDA-SBIR projects are effective technology-transfer mechanisms for moving publicly developed technology into private-sector applications that benefit various aspects of American agriculture and rural America.

- Royalties and licensing revenues from many SBIR projects accrue to our university partners and other public technology developers (*e.g.* ARS).
- Agricultural biotechnology projects need to be carefully thought out to be competitive in Phase II (commercialization).
- Opportunities are growing for agricultural biotech applications targeting energy-related industrial applications.

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WILLIAM GOLDNER has served as a national program leader for the United States Department of Agriculture, Cooperative State Research, Education, and Extension Service, Small Business Innovation Research (SBIR) Program since 1999. He is responsible for the *Plant Production and Protection (Biology and Engineering)* and *Industrial Applications SBIR* programs.

Dr. Goldner held positions as: associate biochemist at the Hawaiian Sugar Planters' Association (now Hawaii Agricultural Research Center); research scientist/project manager for Union Camp Corporation (now part of International Paper Company); and technical strategy manager for applied genetics in the Biotechnology Development Group for the Global Agricultural Products Division of American Cyanamid Company (now BASF). While at Union Camp and American Cyanamid, he served for six years as an associate professor in the graduate program in Plant Biology at Rutgers University.

Goldner is a member of a team of government, academic and industry administrators and scientists developing a new Specialty Crop Regulatory Initiative to facilitate the timely, cost-effective, movement of transgenic specialty crops through appropriate regulatory processes. He served as chair (with Ann Marie Thro) for the USDA-sponsored workshop *Public Research and the Regulatory Review of Small-Market (Specialty) Biotechnology-Derived Cops* and a recent related workshop, *The Specialty Crop Regulatory Initiative*. He serves on the Commercialization Subcommittee of the USDA Energy Council and on the USDA Biobased Products and Bioenergy Coordination Council, and chaired the July, 2006, DOE/USDA SBIR Energy Summit at Oak Ridge National Laboratory. Goldner holds a PhD in plant physiology from the Pennsylvania State University.