Proposal for Biobased Industry Center Grants Program

Project Title:
Regulatory Encumberments to Deploying Genetically-Engineered Biofeedstock Crops

Project Leadership

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<tr>
<th>Name (PI/Co-PI)</th>
<th>Department</th>
<th>Phone No.</th>
<th>E-mail</th>
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<tbody>
<tr>
<td>Jeff Wolt</td>
<td>Agronomy/BIGMAP</td>
<td>4-6899</td>
<td><a href="mailto:jdwolt@iastate.edu">jdwolt@iastate.edu</a></td>
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Research Priority Addressed by this Project:
Impact of Broader Public Policy

Objectives
1. Describe the regulatory pathway and policy decision milestones for development and commercial deployment of a genetically-engineered biofeedstock crop using relevant current cases.
2. Conduct quantitative policy analysis to forecast costs, times and uncertainties in commercial release for a general case of a genetically-engineered biofeedstock crop.

Approach
Rapid innovation in biofeedstock sources and processing is vital to meeting demands for timely and cost effective expansion of biofuels production. The successful expansion of biobased industry must exploit a vast array of enabling technologies, including genetic engineering (GE). We have been engaged in efforts to analyze and communicate the trade-offs involved in pursuing GE versus non-GE options for development of improved agricultural biofeedstocks (1-3). The propose of this research is to use current relevant cases (GE corn expressing thermostable bioprocessing enzymes) to consider the cost and benefits of pursuing a GE option for improved agricultural biofeedstocks. We will leverage our previous experience with high-amylase corn grain (Syngenta Enogen corn amylase trait) and current effort with high-endoglucanase corn stover (MSU Spartan 1 corn E1 endoglucanase trait) to describe the regulatory path (through USDA and FDA), the public policy pitfalls (impacts of legal challenges involving the National Environmental Policy Act), costs and timing for development and deployment of a GE biofeedstock crop. This analysis will utilize publically available literature and regulatory dossiers as well as interviews with opinion leaders from regulatory agencies (USDA-APHIS-BRS), industry (Syngenta), associations (North American Millers' Association), and NGOs (Center for Science in the Public Interest) to outline and analyze a narrative cost-benefit analysis. This information will be generalized into a quantitative model from which a forecast of costs, times, critical decision points and uncertainties will be developed using quantitative policy analysis tools (i.e., 4).


Workplan and Schedule
The proposed work can be conducted in a timely and effective manner, since the PI has over 15 years industrial experience in the regulatory data package development and defense and public policy issues management including deregulation of GE crops in the US and import approvals in countries throughout the world. In addition, the Wolt Laboratory has a team of graduate students actively engaged in developing methodology for the analysis and regulatory assessment of GE crops, including biofeedstock crops. And our collaborations with ARS, MSU, and NREL provide a critical knowledge base to help in framing key questions and developing answers regarding this research. The effort will be a teamwork approach guided by the PI, conducted by a graduate student, and supported by work group members and collaborators. Work products will include in-progress reports and presentations and a manuscript describing project outcomes.

3Q11  Project ideation, outline, begin assembling and analysis of information
4Q11  Continue assembling and analysis of information, contacts and interviews with opinion leaders, preliminary draft of narrative, conceptual model development
1Q12  Analytical model development, parameterization, forecasts, follow-ups with opinion leaders, revision and reanalysis
2Q12  Complete uncertainty analysis, revise and submit draft manuscript.

Budget (indirect not allowed)

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<th>CATEGORY</th>
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<tr>
<td>Salaries</td>
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<tr>
<td>Benefits</td>
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<td>Sub-total</td>
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<td>Students (1/2-time stipend, 12-mo, AGRON departmental rate)</td>
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*Includes telecomm, computer use, print/copy, honoraria, services/user fees, postage, etc.
JEFFREY D. WOLT

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Education
Ph.D., Soil Chemistry, Auburn University, 1979.
M.S., Agronomy/Soil Science, Auburn University, 1976.
Biology, Case Western Reserve University, 1969-71.

Professional Experience
Professor Agronomy and Toxicology, Iowa State University, 2004-present
Advisor and Issues Manager, Dow AgroSciences, 1988-2004
Adjunct Professor Agronomy, Purdue University, 1993-2004
Visiting Scientist, Agronomy and Soils, University of Hawaii, 1988-1989
Associate Professor, Plant and Soil Science, University of Tennessee, 1979-1988

Research Interests and Responsibilities
Risk and policy analysis for new technologies in agriculture. Biotechnology safety analysis applied to risk management and science policy decision-making. Environmental and ecotoxicological risk assessment. Risk analyst for plant biotechnology; 75% research, 25% outreach. Research centers on quantitative approaches to assessing human health and ecological safety for input and output plant transgenics. Specific areas of research emphasis include risks to non-target organisms; protein characterization in relation to dietary exposure and environmental risk; methods and frameworks for biotechnology risk analysis. Outreach responsibilities center on risk communication and formalized risk frameworks for risk management and public policy decision-making.

Professional and Honorary Societies
American Society of Agronomy (Fellow), American Association for Advancement of Science, Crop Science Society of America, Gamma Sigma Delta, International Organization for Biological Control, International Society for Environmental Biosafety Research, Phi Kappa Phi, Sigma Xi, Society for Risk Analysis, Society of Toxicology, Soil Science Society of America

Relevant Recent Publications (over 150 total)