

IOWA SEED & BIOSAFETY

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THE NEWSLETTER OF THE SEED SCIENCE CENTER AND BIOSAFETY INSTITUTE FOR GENETICALLY MODIFIED AGRICULTURAL PRODUCTS

WHY BIGMAP? *by Manjit Misra, Director, BIGMAP*

Dramatic changes are occurring in the national and global food system due to the introduction of genetically modified agricultural products (GMAPs). In addition to providing more and healthier food for the world's population that has surpassed 6 billion people, GMAPs hold great promise for enhancing quality of life through non-food applications, such as value-added industrial products, clean energy, nutritional products, and pharmaceuticals.

The rise of GMAPs has not come without challenges. Consumers and public groups have raised concerns about safety, quality, traceability, and societal consequences of genetically modified products. Trade barriers have been imposed by importing countries based on both these concerns and on politics rather than science-based risk assessment. Society has placed increased emphasis on preserving the natural resources from which the food system originates. Clean air, clean water and productive soil are recognized as important as safe and nutritious food. The development and diffusion of GMAPs also raise ethical issues that present special challenges to scientists and policy makers.

Attempts by various groups to lend a credible voice to the development and diffusion of GMAPs have been inadequate. Activists opposed to biotechnology place little value on potential benefits of GMAPs. Industrial organizations are often perceived as biased with insufficient concern about consumer and environmental interests. There are questions about the ability of public regulatory bodies to avoid bias. There is an urgent need for unbiased, science-based and independent evaluation of the risks and benefits of genetically modified plant and animal products to the consumer and to the environment. Iowa State University established the Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP) to meet this need.

The Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP) at Iowa State University will develop tools and methodologies for expert risk/benefit analysis of genetically modified plant and animal products.

The institute will also provide strategies for mitigating the risks to safeguard consumers and the environment. It will communicate the results of these activities to key policy and regulatory groups, private entities and the public.



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NEWSLETTER RETURNS

The Iowa State University Seed Science Center is bringing back its newsletter. News from the Biosafety Institute for Genetically Modified Agricultural Products (BIGMAP) will be included. See our "Why BIGMAP" article for a description of the scope of the new Institute. Paul Christensen will be the editor.

Please send us your email addresses if you would prefer to get the newsletter by email. We will be adding new names to the distribution list. If you would like to remove your name from the distribution list, or change the way that your copy of the newsletter is addressed, please send us an email at seedsci@iastate.edu.



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Paul Christensen
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Paul Christensen started at the Seed Science Center in late 2003. He is developing an on-line graduate curriculum in seed science, technology and business management and participating in BIGMAP.

Paul has broad experience in the international seed business and international agricultural development. He has worked as a seed industry consultant, and for Monsanto Company, DEKALB Genetics Corporation, Funks Seeds International, and Purdue University. His specialty was hybrid testing, development and commercialization. He has selected corn varieties for markets on 6 continents. His academic training is in plant breeding and genetics. He has also worked with the evaluation and regulatory approval of traits derived through the use of biotechnology. Paul combines global seed experience with understanding of the contribution of technology and business to wellbeing in many kinds of communities.

Paul played the lead role in writing *Confined Production Processes for Non-Food Corn*. See our article called "BIGMAP and Biopharma." He used his experience with seed industry processes to describe processes that are designed to meet USDA requirements for the production of plant manufactured pharmaceuticals.

We will have an article on the new Seed Technology and Business curriculum in our next issue.

Jeff Wolt
*BIGMAP
Plant Risk
Assessment*



Jeff Wolt joined the staff of BIGMAP in early 2004. He is a Professor of Agronomy at Iowa State University where he has a joint research and extension appointment. He also serves on the faculty of the interdepartmental program in toxicology.

Jeff's program focuses on the evaluation and communication of the risks and benefits associated with products and processes of plant biotechnology. His research seeks to advance quantitative risk analysis approaches in biotechnology and is currently keyed to confinement of plant biogenic production systems as well as to food and environmental safety issues pertaining to transgenic plants and their products. His outreach activities center on presentations to and consultation with interested and affected parties locally, nationally, and internationally. Jeff earned his B.S. degree from Colorado State University and his M.S. and Ph.D. degrees from Auburn University. Prior to joining Iowa State University, Jeff was an Advisor with Dow AgroSciences where he served as an internal consultant and provided public outreach concerning plant biotechnology. He also has served as an Associate Professor of Plant and Soil Science with the University of Tennessee, as a Visiting Scientist in Tropical Plant and Soil Sciences at the University of Hawaii, and as an Adjunct Professor of Agronomy at Purdue University. Jeff has authored the book *Soil Solution Chemistry*. He has also authored or co-authored over 175 publications. He is a Fellow of the American Society of Agronomy.

Mindy DeVries
Graduate Student



HOME: A farm near Monroe, Iowa.

BACKGROUND: Bachelor's degree from ISU in Agronomy and Seed Science in 2002.

CURRENT: Working on my Ph.D. in Crop Production and Physiology with a specialization in Seed Science (expected graduation in 2006). Dr. Susana Goggi is my major professor.

RESEARCH: Studying the effects of fall frost damage on seed corn production. There are three main aspects

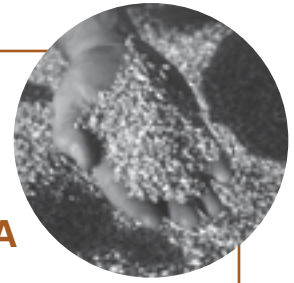
- using a variety of seed quality tests to track viability and vigor of frosted seed lots during short term storage,
- looking at differential expression of mRNA between frosted and non-frosted seed, and
- observing internal temperatures of the corn kernel during an artificial frost cycle.

ACTIVITIES: Mindy has been active with the Agronomy Graduate Student Club (Treasurer in 2003; President in 2004; currently Webmaster) and the Agronomy Department Social Committee. At the university level, Mindy served as the College of Agriculture student representative on the Computation Advisory Committee (2003-2004). Outside of the university Mindy is involved in a community volleyball league and Bridgeway Church.

COMMENTS: I am fortunate to call the Seed Science Center "home". I greatly appreciate the care and guidance I have been given during my time here. The opportunities and experiences that I have been offered are valuable to my overall education.

International Program

HARMONIZATION OF SEED POLICIES AND REGULATION IN SOUTH AMERICA



Seed policies and regulation facilitate trade in seed by assuring that buyers and sellers share some important information, and that sellers conform to some important standards. Phytosanitary regulations protect agriculture from damage caused by the spread of new diseases. Harmonization of seed regulations facilitates trade while providing information and protection. If one assumes that improved varieties are constantly being created and seed quality improved, then increased trade in seed can increase competition, lower prices, improve quality, improve farmer access to better varieties, increase production yields and reduce production cost. Such gains can ultimately lower food costs for the general public.

Variety registration provides some government assurance of the performance of new varieties. The importance of testing and registration depends partially on the testing capacity of the individuals, government organizations and companies releasing new varieties. Requirements for registration reflect the fact that not all breeders may have large testing programs, but some testing can delay introduction and benefits.

The project for the harmonization of seed policies and regulations in six countries of South America (Argentina, Brazil, Bolivia, Chile, Paraguay and Uruguay) had finished with various achievements for the cotton, maize, soybean, wheat, rice, oats, sorghum, beans, ryegrass, alfalfa and sunflower.

- A science-based quarantine pest list. The list started with 50 regulated pathogens for the selected crops and was reduced to 10 for trade within the region and 18 for trade from outside the region.
- Common seed certification and laboratory standards for the eleven crops. (These standards have been also approved by MERCOSUR).
- A seed certification accreditation system for seed companies using a process management tool. (This process manual has been approved by MERCOSUR).
- A common variety evaluation and registration procedure for new varieties reducing the official evaluation trial periods for the registration of a new variety in national list (This technical agreement has yet to be approved by MERCOSUR).

The Seed Science Centers' involvement in the project was supported by Iowa State University and the American Seed Trade Association.



BIOTECHNOLOGY OPPORTUNITIES FOR SMALL MARKETS

Modern plant biotechnology holds great promise for innovation in the area of food, fiber, feedstock, and pharmaceutical production. In spite of considerable controversy, it appears that many such innovations will be safe for man and the environment. Despite this promise, only two public sector innovations (transgenic flax and papaya) have been deregulated

by USDA-APHIS and only one (transgenic papaya) has proven a commercial success. The costs, complexities, and uncertainties surrounding the successful regulatory clearance and commercialization of genetically-engineered crops have led large commercial enterprises to avoid research and development efforts on small-market opportunities. Developing small-market biotechnology

opportunities that meet the public good is of broad interest to both public sector researchers and small venture firms, but is hindered by limited understanding of the regulatory process and the means for effectively gaining regulatory clearances. The urgency to address this concern has been recognized by recent workshops focused on small-market biotechnology-derived crops.* There is a clear consensus among stakeholders for developing a structure to effectively bridge the public research community to the regulatory process with the vision of empowering a process to rapidly achieve regulatory clearances and reduce the regulatory burden for small-market biotech-derived crops. BIGMAP is well-staged to support this urgent public need through its mission to provide science-based analysis of the risks and benefits of genetically modified plant and animal products and to provide guidance and education to help safeguard consumers and the environment.

BIGMAP is collaborating with a public sector action team to catalyze the key steps that have been identified by stakeholders for empowering the effective regulatory clearance of small-market plant biotechnology innovations.

ISO 9001-2000 LAB ACCREDITATION

The ISU Seed Laboratory is entering its second full year as an ISO 9001:2000 certified seed testing laboratory. The ISU Lab received certification in December 2003 after an 18 month training process by the Center for Industrial Research and Service (CIRAS).



Becoming an ISO 9001:2000 certified laboratory has helped the Seed Lab in its everyday operations. "We are more customer focused, which is the underlying goal of the ISO 9001:2000 system," says Dan Curry, ISU Seed Lab Manager. The Lab has experienced improved internal processes. The third-party verification of the quality system of the lab will ensure that the Lab not only meets, but also exceeds the standard's expectations.

Orion Registrar, Inc, the company that audited the Seed Lab, will continue to periodically monitor the Seed Lab through assessment audits over the next three years. These audits will hold the lab and its staff responsible for upholding the standards associated with the ISO 9001:2000 certification, and also for updating the service practices as standards in the industry change. The staff must inform Orion of changes in their quality practices, and must maintain and report any customer communications.

The Seed Lab was certified in Seed Quality Assurance Services in Germination, Vigor Testing, Purity, Genetic Traits and Seed Health on over 300 species of seeds. The International Organization for Standardization, ISO, is a quality assurance management system that contains procedures, policies and rules considered necessary to assure the quality of a company's services and products. ISO 9001:2000 has a world-wide reputation, and applies to all types of organizations, regardless of size. It can help both product and service-oriented organizations achieve standards of quality that are recognized and respected throughout the world.

This certification assures our customers that we have had our quality system reviewed and that we comply to the ISO system.





Goals of the action team are

- (1) Creating a plan for a network in the public research community that can facilitate regulatory clearances for small-market biotech opportunities.
- (2) Identifying, developing, and advancing peer review white papers addressing current regulatory issues that pose unnecessary impediments to the efficient regulatory clearance of biotech-crops.
- (3) Engaging broad stakeholder involvement and planning for the establishment of research and development priorities for small-market regulatory clearances. Funds are needed to begin the process of building an effective network of regulatory expertise that can move the fruits of public research into the marketplace – these small market concepts will not be successfully commercialized without this support.

** "Impacts of Biotech Regulation on Small Business and University Research: Possible Barriers and Potential Solutions," a workshop sponsored by the Pew Initiative on Food and Biotechnology and USDA-APHIS, 2-3 Jun 2004. "Public Research and Regulatory Review of Small-Market Biotechnology Derived Crops" a workshop sponsored by USDA-ARS, USDA-APHIS, the National Center for Food and Agricultural Policy, and Langston University, 8-9 Nov 2004. In the developing world there have been many studies and meetings relating to the deregulation of publicly developed biotechnology derived crops.*



International Program

HARMONIZATION OF THE PHYTOSANITARY REGULATIONS IN THE ASIA PACIFIC REGION

Phytopsanitary regulations protect agriculture from damage caused by the spread of new diseases. Harmonization of phytopsanitary regulations facilitates trade while providing protection. If one assumes that improved varieties are constantly being created and seed quality improved, then increased trade in seed can increase competition, lower prices, improve quality, improve farmer access to better varieties, increase production yields and reduce production cost. Such gains can ultimately lower food costs for the general public.

Science-based seed quarantine restrictions are effective when the disease is not present in the destination country, the disease has a significant potential economic impact, the disease is present in the country of origin, and that the disease is seed transmitted.

Under a project with the American Seed Trade Association, Asia Pacific Seed Association, U.S. Department of Agriculture and Iowa State University Adelaida Harris conducted an assessment study in 2002 in China, India, Indonesia, Philippines, Thailand and Vietnam to identify the major constraints in the phytopsanitary area to facilitate the movement of seed in the region. The major constraints identified for the ten crops selected (rice, maize, sunflower, tomatoes, eggplant, hot pepper, cucumber, cabbage, cauliflower and watermelon) were unnecessarily regulated quarantine pests in each country and unclear procedures leading to delays in issuing permits for seed import and export.

To overcome the above constraints, a series of technical workshops were conducted with five countries. They were coordinated by Dr. Joseph Cortes with the following outcomes to date:



- The establishment of a science-based Quarantine Pest List. Starting with 158 pests, the list was reduced to 49 pests for trade within the region and 71 pests for trade from outside the region.
- The development by Adelaida Harris of a Seed Import/Export Procedures Manual utilizing process management provides transparency and clarity to the procedures utilized by the government agencies in the approval of imports and exports of seeds. The manual has combined the requirements of the seed and plant health departments to reduce time and personnel constraints.
- All five participating countries have adapted and developed their own manual.
- The five countries have also confirmed that their respective government offices will effectively implement all points of agreement in mid 2005.

The next step of the project is the implementation of an accreditation scheme for phytopsanitary field inspection and seed health testing again through the development of a procedure manual and using process management as a tool.

The Seed Science Centers' involvement in the project was supported by Iowa State University, the Asia Pacific Seed Association, the American Seed Trade Association, and the United States Department of Agriculture.



TO REQUEST A COPY VISIT:
www.bigmap.iastate.edu

BIGMAP AND BIOPHARMA: FIRST STUDY PRODUCTS ARE EMERGING

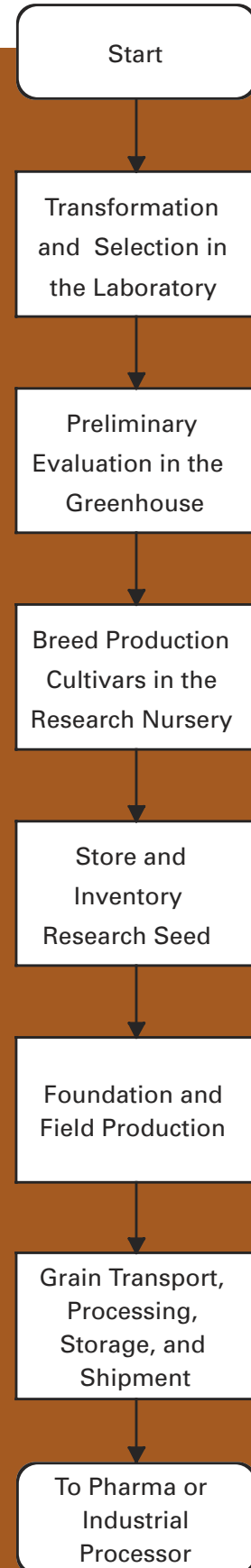
The recently published BIGMAP bulletin, *Confined Production Processes for Non-Food Corn*, presents management schemes for the various aspects of confined production of corn for plant manufactured pharmaceuticals and plant manufactured industrial products (PMP and PMI) in field-confined nursery and large-scale settings. The objective of the bulletin is to outline processes for managing unintended losses of plants, pollen, seed, or grain. We have developed process flow maps, descriptions, and rationale that are based on current practice and experience within the seed industry. These systems incorporate redundant checks to assure compliance with current USDA-APHIS standards for field-confined experimentation and anticipate possible future regulation by the FDA.

The bulletin was developed because understanding process flows and the grounds upon which management systems are developed is a necessary first step in the broader assessment of the consequences of unintended loss to the environment that may result from growing PMP and PMI corn. Our analysis builds on processes and technologies that are currently in practice within the corn seed industry and represents a realistic basis for the assessment of the balance of cost and effectiveness for a variety of practice standards to assure integrity of confined field systems. The association of the Seed Science Center and BIGMAP provides a unique base to address this issue.

This paper was published this spring by Iowa State University. Copies are available on request or at the BIGMAP website.



PMP/PI Production System Processes





GROWING TRANSGENIC AND CONVENTIONAL CORN SIDE BY SIDE

The Iowa State University Agronomy Alumni Newsletter, January 2005 (http://www.agron.iastate.edu/news/newsletter/2005_Agron_Alumni_News.pdf) includes an article related to BIGMAP investigation of confined production of corn.

The article reports on research done by Mark Westgate and Susana Goggi, of the Agronomy Department to learn more about detailed manner in which corn is pollinated. They conducted research on pollen production, created models of pollen production and movement, and studied the effective rates of pollination from neighboring fields.

The researchers developed methods to predict the rate of pollen production from simple measurements of tassel development, and determined how quickly corn pollen loses this capacity as it travels in the air.

The model includes topography factors such as distance, elevation, windbreaks and border rows as well as atmospheric conditions such as wind speed and direction, air temperature and relative humidity. The model works well for predicting pollen deposition at 200 to 600 feet from a source field. Creating models for longer distances

will require more study of pollination at those distances.

The third step of their project was to study the impact of pollen from neighboring fields. Pollen entering from elsewhere must out-compete locally shed pollen to achieve an outcross. This competition is controlled both by physical factors such as local pollen density, and genetic factors such as pollen-silk compatibility. The models predict isolation distances for commercial corn production as well as for seed production where earlier research had focused.

The goal is to provide grain producers a rational and cost-effective method for isolating fields. The modeling software package will provide a new management tool for producers concerned about pollen drift. It will help producers make a prediction of the probability that outcrossing has occurred. This research is supported through grants from the USDA Biosafety Risk Assessment Grants (BRAG) Program and BIGMAP.

FOR MORE INFORMATION VISIT:

http://www.agron.iastate.edu/news/newsletter/2005_Agron_Alumni_News.pdf

SEED WORKSHOPS

The Center's program of Workshops continues for 2005. More Information is available at: www.seeds.iastate.edu

SCHEDULE

Schedule for most workshops
8:00 a.m. - 8:30 a.m. Registration
8:30 a.m. - 4:30 p.m. Workshops

LOCATION

The workshops will be held in the Seed Science Center at Iowa State University.

REGISTRATION

Enrollment is limited in workshops. Registration will be accepted on a first come, fees-paid basis. The coordinator of the workshops reserves the right to limit the number of persons attending per company or institution. If you have questions about registration, contact Terrie Hunter at (515) 294-6222.

ON-LOCATION WORKSHOPS

Special arrangements may be made for the workshops to be held on location at your plant or place of operation if four or more employees are involved.

CUSTOMIZED WORKSHOPS

Special arrangements may also be made for customized workshops designed to suit your company needs. These workshops are held in the Seed Science Center and can vary in duration and content, based on your company's specific needs.



ISU SEED WORKSHOP/SHORTCOURSE SCHEDULE FOR 2005

Workshop Title	2005 Training Dates
Color Sorting	Wednesday, Aug. 3
Gravity Table	Tuesday, Aug. 9
Gravity Table	Thursday, Aug.11
Soybean Conditioning	Monday – Thursday, Aug.15-18
Seed Corn Quality	Tue. Aug. 23
GMO Seed Testing	Wednesday, Aug. 24
Soybean Quality	Thursday Aug. 25
Soybean Conditioning	Monday – Thursday, Aug. 29-Sept. 1
Popcorn Conditioning	Wednesday, Nov.16



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