

**United States Department of Agriculture
Biotechnology Risk Assessment Grants Program
Annual Project Director's Meeting**



USDA APHIS-BRS
Riverdale, Maryland
May 24, 2016



United States Department of Agriculture
National Institute of Food and Agriculture



United States
Department of
Agriculture

National
Institute of Food
and Agriculture

USDA Biotechnology Risk Assessment Grants Program Annual Project Director's Meeting

Welcome to the Annual Project Director's (PD) Meeting for the USDA Biotechnology Risk Assessment Grants (BRAG) Program. This year's meeting includes awardees of proposals submitted in fiscal years 2012, 2013, 2014 and 2015.

Authority for the BRAG program is contained in section 1668 of the Food, Agriculture, Conservation, and Trade Act of 1990 (i.e., 1990 Farm Bill) and amended in section 7210 of the Farm Security and Rural Investment Act of 2002 (i.e., 2002 Farm Bill). In the Food, Conservation, and Energy Act of 2008 (i.e., 2008 Farm Bill), the authority was not repealed, so the BRAG program continued its role in supporting risk assessment research related to biotechnology. In accordance with the legislative authority in the 2002 Farm Bill, the BRAG program supports research designed to identify and develop appropriate management practices to minimize physical and biological risks associated with genetically engineered (GE) animals, plants, and microorganisms. The USDA's National Institute of Food and Agriculture (NIFA) and Agricultural Research Service (ARS) jointly administer the BRAG program. The U.S. Forest Service commits additional funding.

The main purpose of the BRAG program is to support the generation of new information that will assist Federal regulatory agencies in making science-based decisions about the effects of introducing into the environment GE organisms, including plants, microorganisms (including fungi, bacteria, and viruses), arthropods, fish, birds, mammals and other animals excluding humans. Investigations of effects on both managed and natural environments are relevant. The BRAG program accomplishes its purpose by providing Federal regulatory agencies with scientific information relevant to regulatory issues.

The overall goal of the PD Meetings is to improve post-award management of competitive grants administered by USDA and encourage an open dialogue between researchers and federal regulatory agencies on emerging topics related to biotechnology research. In turn, this will assist Program Staff in identifying success stories resulting from USDA-

sponsored research in the BRAG program and facilitate the reporting of important impacts resulting from the most successful research through communications with Congress, the Secretary and Undersecretary of Agriculture, USDA administrators, federal regulators, the scientific community, commodity groups and other stakeholders, and the general public. It is critical to identify and highlight these impacts in order to maintain funding in USDA's biotechnology risk assessment program areas, as well as to continue the recent trend of increased Congressional budget appropriations to USDA competitive grant programs that have occurred since 2008. Conducting annual meetings for awardees is just one of several approaches being implemented by USDA to improve post-award management.

A second purpose of this meeting is to foster communication among awardees in this program and federal regulators, such as USDA Animal and Plant Health Inspection Service-Biotechnology Regulatory Service, U.S. Environmental Protection Agency, and the U.S. Food and Drug Administration, which have scientific interests in risk assessment research. It is anticipated that the sharing of information and the ensuing dialogue that will occur in this informal setting will allow all awardees to benefit from the experiences of their colleagues and yield greater opportunity for successful completion of their BRAG awards. In addition, it is expected that improved communication among BRAG awardees will result in better sharing of limited resources and the development of new fruitful collaborations.

We look forward to a highly successful and productive meeting, and we eagerly anticipate continued progress on your BRAG awards.

Respectfully,

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USDA
Biotechnology Risk Assessment Grants (BRAG) Program
Project Director's Meeting

May 24, 2016

USDA-APHIS-BRS Headquarters
Oklahoma Memorial Conference Center
4700 River Road
Riverdale, MD 20737

- 8:30 - 9:00 AM** **Arrival and Poster Setup**
- 9:00 - 9:05 AM** Welcome
Janet Bucknall, Associate Deputy Administrator –
USDA-APHIS-BRS
- 9:05-9:20 AM** BRAG Program Overview
Shing Kwok – USDA-NIFA
- 9:20 - 9:40 AM** Environmental Assessment of GE Animals at U.S. HHS-FDA
Evgenij Evdokimov – U.S. FDA
- 9:40 – 10:00 AM** EPA regulation of plant-incorporated protectants and microbial
pest control agents
Milutin Djurickovic – U.S. EPA
- 10:00 - 10:20 AM** Biotechnology Regulations and Research Priorities
Sally McCammon – USDA-APHIS-BRS
- 10:20 - 10:40 AM** **Break**
- 10:40 -11:00 AM** Assessing the Risk of Transgene Escape via Pollen Flow in Carrot
Jennifer Mandel – University of Memphis
- 11:00 - 11:20 AM** Linking Pollinator Behavior to Gene Flow to Reduce Gene Flow
Risk Over the Landscape
Johanne Brunet – USDA-ARS, Madison, WI
- 11:20 - 11:40 AM** Targeted Gene Knockout of Reproductive Genes of Catfish with
Hormone Therapy to Restore Fertility
Rex Dunham – Auburn University
- 11:40 - 1:15 PM** **Lunch - On Your Own**
- 1:15 - 1:35 PM** Switchgrass Bioconfinement: Delayed Flowering,
Selective Male- And Seed-Sterility, and Conditional Total
Bioconfinement
Neal Stewart – University of Tennessee

- 1:35 - 1:55 PM** Silencing of Naturally Occurring Genes Controlling Seed Dormancy to Reduce Fitness of Transgene-contaminated Weedy Rice
Xingyou Gu – South Dakota State University
- 1:55 - 2:15 PM** Assessing the Impact of Gene Replacement and Genetic Modification Methods in a Crop Species at the Whole Genome Level
David Douches – Michigan State University
- 2:15 - 3:00 PM** Discussion
- 3:00 - 3:15 PM** **Break**
- 3:15 - 5:00 PM** Poster Session

2016 BRAG PD Meeting Poster List

#	Name	Institution	Presentation Titles
1	Jurat-Fuentes, J.	University of Tennessee	Extended pest migration in Bt versus non-transgenic crops: impacts on risk assessment and Bt resistance dissemination
2	Reisig, D.	North Carolina State University	Impact of transgenic Bt crops on <i>Helicoverpa zea</i> ecology and subsequent resistance risk
3	Strauss, S.	Oregon State University	Efficacy and ecological impacts of transgenic containment technologies in poplar
4	Yang, Z.	Iowa State University	Genome-wide assessment of off-target effect and removal of transgenes associated with TALEN-based gene editing in plant
5	Schmidt, M.	University of Arizona	Assessing phenotypic variations in soybean seed protein and oil traits using GFP as a reporter in both mutagenesis and transgenomic approaches
6	Lamp, W.	University of Maryland, College Park	Risk assessment for plant incorporated insecticidal products on Non-target aquatic invertebrates
7	Van Eenennaam, A.	University of California, Davis	Genetic containment in livestock via CRISPR-mediated gene knock-in
8	St. Leger, R.	University of Maryland, College Park	Consistent risk assessment of genetically modified microorganisms in the field
9	Handler, A.	USDA-ARS, Gainesville, FL	Assessment and mitigation of genetic breakdown of transgenic conditional lethality systems in insect pest species
10	Wong, T.	University of Maryland, Baltimore County	Developing an inducible sterilization technology to bio-contain transgenically engineered tilapia
11	Carriere, Y.	University of Arizona	Resistance risk assessment for seed mixture refuges with pyramided Bt corn

12	Sword, G.	Texas A&M University	Nutritionally-mediated variation in <i>Helicoverpa zea</i> susceptibility to Bt transgenic crops
13	Morrell, P.	University of Minnesota	Comparison of mutation rates in soybean following transformation, mutagenesis, tissue culture and conventional breeding
14	Auer, C.	University of Connecticut	Improving ecological risk assessments for <i>Camelina sativa</i> through research on pollen dispersal, gene flow and weed populations
15	Durvasula, R.	Biomedical Research Institute of New Mexico (BRINM), University of New Mexico	Antibody-based paratransgenics for Pierce's disease: advanced methods for transmission blocking and environmental monitoring

Biotechnology Risk Assessment Grant Program Projects

Year	Investigator	Institution	Title	Project Report Link
2015	Auer, C.	University of Connecticut	Improving ecological risk assessments for <i>Camelina sativa</i> through research on pollen dispersal, gene flow and weed populations	Brief Full
2015	Handler, A.	USDA-ARS, Gainesville, FL	Assessment and mitigation of genetic breakdown of transgenic conditional lethality systems in insect pest species	Brief Full
2015	Morrell, P.	University of Minnesota	Comparison of mutation rates in soybean following transformation, mutagenesis, tissue culture and conventional breeding.	Brief Full
2015	St. Leger, R.	University of Maryland, College Park	Consistent risk assessment of genetically modified microorganisms in the field	Brief Full
2015	Sword, G.	Texas A&M University	Nutritionally-mediated variation in <i>Helicoverpa zea</i> susceptibility to Bt transgenic crops	Brief Full
2015	Van Eenennaam, A.	University of California, Davis	Genetic containment in livestock via CRISPR-mediated gene knock-in	Brief Full
2015	Wong, T.	University of Maryland, Baltimore County	Developing an inducible sterilization technology to bio-contain transgenically engineered tilapia	Brief Full
2014	Carriere, Y.	University of Arizona	Resistance risk assessment for seed mixture refuges with pyramided Bt corn	Brief Full

2014	Dunham, R.	Auburn University	Targeted gene knockout of reproductive genes of catfish with hormone therapy to restore fertility	Brief Full
2014	Jurat-Fuentes, J.	University of Tennessee	Extended pest migration in Bt versus non-transgenic crops: impacts on risk assessment and Bt resistance dissemination	Brief Full
2014	Lamp, W.	University of Maryland, College Park	Risk assessment for plant incorporated insecticidal products on non target aquatic invertebrates	Brief Full
2014	Reisig, D.	North Carolina State University	Impact of transgenic Bt crops on <i>Helicoverpa zea</i> ecology and subsequent resistance risk	Brief Full
2014	Schmidt, M.	University of Arizona	Assessing phenotypic variations in soybean seed protein and oil traits using GFP as a reporter in both mutagenesis and transgenomic approach	Brief Full
2014	Strauss, S.	Oregon State University	Efficacy and ecological impacts of transgenic containment technologies in poplar	Brief Full
2013	Brunet, J.	USDA-ARS, Madison, WI	Linking pollinator behavior to gene flow to reduce gene flow risk over the landscape	Brief Full
2013	Douches, D.	Michigan State University	Assessing the impact of gene replacement and genetic modification methods in a crop species at the whole genome level	Brief Full
2013	Gu, X.	South Dakota State University	Silencing of naturally occurring genes controlling seed dormancy to reduce fitness of transgene-contaminated weedy rice	Brief Full
2013	Mandel, J.	University Of Memphis	Assessing the risk of transgene escape via pollen flow in carrot	Brief Full

2013	Stewart, C.	University of Tennessee	Switchgrass bioconfinement: delayed flowering, selective male- and seed-sterility, and conditional total bioconfinement	Brief Full
2013	Yang, B.	Iowa State University	Genome-wide assessment of off-target effect and removal of transgenes associated with TALEN-based gene editing in plant	Brief Full
2012	Durvasula, R.	Biomedical Research Institute of New Mexico (BRINM), University of New Mexico	Antibody-based paratransgenics for Pierce`s Disease: advanced methods for transmission blocking and environmental monitoring	Brief Full

QUESTIONS FOR DISCUSSION

1. Can the regulatory agencies provide an update to the modernization/overhaul of the Coordinated Framework on Regulations of Biotechnology that was initiated by the White House, through the Office of Science and Technology Policy (OSTP)? (USDA, EPA, FDA)
 - What has been done for this initiative?
 - What is the timeline of this overhaul?
 - Will there be new regulatory policies put into legislation?
2. How will the National Academy of Sciences study in 2014 (Genetically Engineered Crops: Past Experience and Future Prospects) have on policies/practices of the federal regulatory agencies governing biotechnology products? Is there any sense if and/or how recommendations from that report will be used at the federal regulatory agencies? (USDA, EPA)
3. Can the FDA to clarify the regulation of gene edited animals for food production purposes including gene knockouts and knock-ins. Please clarify the status of surrogate females that have carried a gene edited pregnancy - can these dams go into the conventional food supply? (FDA)
4. How are other countries responding to the non-regulated status of some products?

Also, the "Am I regulated" aspect seems to grab a lot of attention. What is an update on the products they are commenting on and which ones are deemed non-regulated? Will changes in the regulatory agencies address these issues? (USDA)

5. What is the thinking about categorical treatment for directed mutagenesis with CRISPR-Cas or other gene editing methods, when using or not using plant pest sequences, at USDA, FDA, and EPA? Might they be categorially exempt in any way at one or more agencies? (USDA, FDA, EPA)
6. With respect to the above, can the gene editing machinery (CRISPR-Cas for example), in species like trees where removal is difficult, possibly also be considered exempt, or must they be removed even if no plant pest sequences? Any thoughts on if/how this will develop in near future? (EPA, USDA)
7. Is EPA thinking about an exemption or accelerated/abbreviated review, for pest resistance or growth modifying traits using gene editing, RNAi, or cisgenics (markers included or not)? What is outlook? (EPA)
8. How does the federal government decide when to label or not label a product as GMO? How many parties are involved in making the decision of GMO product labeling, and how are the decision made? Are there guidelines for it? Can you describe the recent USDA Non-GMO label process and policy? (USDA).

APPENDIX: Appropriate Acknowledgment of Your USDA Award

The Biotechnology Risk Assessment Grant (BRAG) program plays an essential role in fulfilling the mission of the United States Department of Agriculture (USDA). Proper acknowledgment of your USDA BRAG funding in published manuscripts, presentations, press releases, and other communications is critical for the success of our USDA's programs. This includes proper acknowledgment of the Program and agencies, as well as that of the Department and grant number (Please note that the '####-#####-#####' below refers to your award number and not your proposal number).

We expect you to use the following language to acknowledge USDA support, as appropriate:

'This project was supported by Biotechnology Risk Assessment Grant Program competitive grant no. ####-#####-##### from the U.S. Department of Agriculture.'

We also expect that you will use our agency's identifier in all of your slide and poster presentations resulting from your BRAG award. The identifier is sent to you twice annually for at least 2 years after the termination date of your grant.



**United States
Department of
Agriculture**

Please alert us of significant findings, publications, news releases, and other media coverage of your work. With your permission, we may highlight your project in a national impact story or news release. If your research is featured on the cover of a scientific journal, we can showcase the cover as well.

Examples of these publications can be found at:
www.nifa.usda.gov/newsroom/newsroom.html.