

United States Department of Agriculture
Biotechnology Risk Assessment Grants (BRAG) Program
&
AFRI Social Implications of Emerging Technologies
2018 Annual Project Director's Meeting



USDA APHIS-BRS
Riverdale, Maryland
May 22, 2018



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 & AFRI Social Implications of Emerging Technologies 2018 Annual Project Director's Meeting

Welcome to the 2018 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 2014, 2015, 2016, 2017. In addition, the BRAG program has invited the 2017 awardees from NIFA's Agriculture and Food Research Initiative (AFRI) Foundational Program: Agricultural Economics and Rural Communities – Social Implications of Emerging Technologies (A1642) to attend this PD Meeting.

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 In the Food, Conservation, and Energy Act of 2008 (i.e., 2008 Farm Bill), the authority was not repealed, so the BRAG program continued its role in supporting risk assessment research related to biotechnology.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 AFRI Foundational Program area of Agriculture Economics and Rural Communities supports rigorous social science projects, including behavioral and experimental economics research and analysis that informs decision making and policy design to enhance the sustainability of agricultural production systems. In FY 2017, the A1642 program supported projects that aim to assess the broad social, ethical, and legal impacts that gene drive/genome editing technologies may pose for society, agricultural markets, consumer preferences, and other domains.

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 and AFRI 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 and AFRI Foundational program areas, as well as to continue the recent trend of increased Congressional budget appropriations to USDA competitive grant programs. 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 these programs 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 and AFRI awards. In addition, it is expected that improved communication among BRAG and AFRI 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 and AFRI awards.

Respectfully,

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TABLE OF CONTENTS

Description	Pages
AGENDA	5
PROJECTS AWARDED BY YEAR	7
QUESTIONS FOR DISCUSSION.....	12
APPENDIX	14
ATTENDEE LIST	16

United States Department of Agriculture (USDA)

Biotechnology Risk Assessment Grants (BRAG) Program & AFRI Social Implications of Emerging Technologies

2018 Project Director's Meeting

May 22, 2018

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

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|-------------------------|--|
| 8:30 - 9:00 AM | Arrival and Poster Setup |
| 9:00 - 9:20 AM | Welcome
Ibrahim Shaqir, BRS Associate Deputy Administrator – USDA-APHIS; Shing Kwok, National Program Leader – USDA-NIFA |
| 9:20 - 9:40 AM | USDA Biotechnology Coordinating Group
Fan-Li Chou, Biotechnology Coordinator – USDA-ARS |
| 9:40 - 10:00 AM | Finding Engineering-Linked Indicators (FELIX)
Amanda Dion-Schultz, Program Manager - IARPA |
| 10:00 -10:50 AM | Poster Session #1 – Odd Numbered |
| 10:50 - 11:00AM | Break |
| 11:00 - 11:20 AM | An Assessment of Genetic Breakdown in a Transgenic Insect Conditional Lethal System
Alfred Handler – USDA-ARS, Florida |
| 11:20 - 11:40 AM | Demonstration of Horizontal Gene Transfer from Genetically Engineered Cyanobacteria to Wild-Type E. coli
James Lee – Old Dominion University |
| 11:40 - 1:00 PM | Lunch – On Your Own |
| 1:00 - 1:20 PM | Comparison of mutation rates in soybean following transformation, mutagenesis, tissue culture, and conventional breeding
Peter Morrell – University of Minnesota |

- 1:20 - 1:40 PM** **Developing An Inducible Sterilization Technology to Genetically Contain Farmed Fish**
Ten-Tsao Wong, University of Maryland, Baltimore County
- 1:40 - 2:00 PM** **Nutritionally-mediated variation in *Helicoverpa zea* susceptibility to Bt transgenic crops**
Gregory Sword, Texas A&M University
- 2:00 - 2:40 PM** **New information about pollen dispersal, hardiness, and crop-weed hybrids improve ecological risk assessment for *Camelina sativa***
Carol Auer, University of Connecticut
- 2:40 - 3:40 PM** **Panel Discussion with Regulatory Agency Staff**
- 3:40 - 4:00 PM** **Break**
- 4:00 - 4:50 PM** **Poster Session #2 – Even Numbered**

Biotechnology Risk Assessment Grant Program - Project List

Poster #*	Award Year	Investigator	Institution	Title	Project Report Link
1	2017	Bagavathiannan, M	Texas A&M AfriLife Extension Service	Towards Understanding and Mitigating Gene Flow Between Crop Sorghum (<i>Sorghum bicolor</i>) and Its Wild Relative Johnsongrass (<i>S. halepense</i>)	Brief Full
2	2017	Brito, I.	Cornell University	Monitoring and inhibiting interspecies gene flow in a OneHealth context	Brief Full
3	2017	Jander, G.	Boyce Thompson Institute for Plant Research	Evaluating off-target effect of RNAi Transgenes that limit the growth of phloem-feeding insects	Brief Full
4	2017	Kerns, D.	Texas A&M AgriLife Extension Service	Risk Assessment for Transgenic Bt Crops from Bt Resistant <i>Helicoverpa zea</i>	Brief Full
5	2017	Krupke, C.	Purdue University	Neonicotinoid seed treatments in Bt maize: balancing contributions to insect resistance management with impacts on soil health	Brief Full
6	2017	Lindquist, J.	University of Nebraska	A Risk-Assessment Model and Population Genomics Tools for Monitoring Herbicide-Resistance Evolution in Weedy Sorghum	Brief Full

7	2017	Parker, K.	Washington University	Environmental Fate of RNA Molecules from RNA Interference (RNAi) Agricultural Biotechnology	Brief Full
8	2017	Strauss, S.	Oregon State University	CRISPR/CAS9 mutagenesis for genetic containment of forest trees	Brief Full
9	2017	Teets, N.	University of Kentucky	Impact of Genotype and Environmental Variables on Transgene Effectiveness for Conditional Lethality Systems in Insects	Brief Full
10	2017	Thilmony, R.	USDA-ARS, Albany CA	Development of a Transgene Biocontainment System for Switchgrass	Brief Full
11	2017	Van Eenennaam, A	University of California, Davis	Comparative evaluation of the phenotype, genome and animal products derived from offspring of a genome edited, hornless bull and controls	Brief Full
12	2016	Burke, J.	University of Georgia	Short-term experiments as predictors of long-term patterns of gene introgression in crop-wild hybrids	Brief Full
13	2016	Busov, V.	Michigan Technological University	Utility of STERILE APETALA (SAP) for development of a sterility transgenic containment technology in poplar	Brief Full

14	2016	Egan, S.	Rice University	Monitoring the Dispersal of Genetically Engineered Organisms and Their Byproducts Using Light Transmission Spectroscopy II	Brief Full
15	2016	Fritz, M.	University of Maryland, College Park	Improving Bt Risk Assessment and Management by Genomic Monitoring	Brief Full
16	2016	Hunt, T.	University of Nebraska, Lincoln	Evaluating the Efficacy of Insect Resistance Management Plans for Delaying the onset of Bacillus Thuringiensis Toxin Resistance in Western Bean Cutworm Populations	Brief Full
ORAL	2016	Lee, J.	Old Dominion University	Designer Algae Biotechnology Risk Assessment	Brief Full
17	2016	Liu, W.	University of Tennessee	Bioconfinement of Camelina sativa as a sustainable oilseed crop via cleistogamy	Brief Full
18	2016	Scott, M.	North Carolina State University	Development and evaluation of safeguards for conditional suppressive gene drives for spotted wing Drosophila and the New World screwworm	Brief Full
19	2016	Wang, K.	Iowa State University	A Data-Driven Approach to CRISPR Design for Reduced Off-Target Activity in Plant Genome Editing	Brief Full

ORAL	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
ORAL	2015	Handler, A.	USDA-ARS, Gainesville, FL	Assessment and mitigation of genetic breakdown of transgenic conditional lethality systems in insect pest species	Brief Full
ORAL	2015	Morrell, P.	University of Minnesota	Comparison of mutation rates in soybean following transformation, mutagenesis, tissue culture and conventional breeding.	Brief Full
20	2015	St. Leger, R.	University of Maryland, College Park	Consistent Risk Assessment of Genetically Modified microorganisms in the Field	Brief Full
ORAL	2015	Sword, G.	Texas A&M University	Nutritionally-mediated variation in <i>Helicoverpa zea</i> susceptibility to Bt transgenic crops	Brief Full
21	2015	Van Eenennaam, A.	University of California, Davis	Genetic containment in livestock via CRISPR-mediated gene knock-in	Brief Full
ORAL	2015	Wong, T.	University of Maryland, Baltimore County	Developing An Inducible Sterilization Technology To Bio-Contain Transgenically Engineered Tilapia	Brief Full
22	2014	Dunham, R.	Auburn University	Targeted Gene Knockout of Reproductive Genes of Catfish with Hormone Therapy to Restore Fertility	Brief Full
23	2014	Reisig, D.	North Carolina State University	Impact of transgenic Bt crops on <i>Helicoverpa zea</i> ecology and subsequent resistance risk	Brief Full

24	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
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AFRI Foundational Program: Agricultural Economics and Rural Communities – Social Implications of Emerging Technologies (A1642) Program - Project List

Poster #*	Award Year	Investigator	Institution	Title	Project Report Link
25	2017	Bain, C.	Iowa State University	Identifying Gaps in Public Trust and Governance Recommendations for Gene-Edited Foods	Brief Full
26	2017	Galesic, M.	Santa Fe Institute	Formation of beliefs about scientific issues: The case of GM foods	Brief Full
27	2017	McFadden, B.	University of Florida	Determining Antecedents to Consumer Acceptance of Scientific Information to Develop Educational Approaches on Gene-Editing Technologies	Brief Full
28	2017	Portney, K.	Texas A&M University	Gene Drive Applications to Agriculture in Texas: Knowledge, Perceptions, and Values	Brief Full

*ORAL = Presenter on agenda

QUESTIONS FOR DISCUSSION

GENERAL

1. As someone new to the program, I am curious how the federal regulators prefer access to the results of our research (i.e. through published manuscripts, annual reports, presentations at PD meetings, etc.)
2. What additional data is needed to determine if each transgenic event needs to be regulated separately?
3. What is the reality (re. evidence, experience) re. speed of approvals for additional events with the same or similar constructs at USDA? Are there similar expedited processes at FDA and EPA?

RNAi

4. At EPA, is there an expedited approval or exemption process for RNAi-GE ("PIP") crops in development given its extreme specificity compared to most all other pesticides?
5. Several different sequences of dsRNA have been proposed for use as biopesticides/plant incorporated protectants. How will the regulatory data collected for the first dsRNA-based biopesticide to go through regulation be applied to these potential future products of different sequences?
6. How in addition to comprising different sequences, dsRNA plant incorporated protectants may be expressed in different crop species? How are differences among crop species (which may result in different tissue concentrations and exposure routes) incorporated in risk assessment?

GENOME EDITING

7. What is the status of gene editing regulation/rule development for gene editing at USDA, FDA, and EPA, particularly if the guide RNA and Cas9 are no longer present in the genetic background?
8. When does FDA plan to finalize/clarify their draft guidance #187?
 - Is there any further ability for scientific input before this guidance is finalized? Is there a way for researchers to determine if their proposed gene edited animal product is a "new animal drug" without submitting a

new animal drug application to the FDA? (i.e a process analogous to the "am I regulated" letter that goes to APHIS for edited plants?)

- Could the FDA please clarify exactly what hazards they are anticipating that are uniquely associated with intentional genetic alterations that introduce no novel DNA sequences, and how they suggest off target alterations should be distinguished from spontaneous mutations and sequencing errors?
9. Why has the Aquabounty issues not been resolved and how will they be resolved? How will such delaying tactics aimed at FDA decisions be avoided in the future?

QUESTIONS FOR AWARDEES

10. For those persons conducting research on genetically engineered or gene edited animals, have you contacted the FDA Center for Veterinary Medicine with regard to opening an Investigational New Animal Drug (INAD) file or a Veterinary Master File (VMF)?
11. Are there areas of research/development you avoid due to the state of regulations of biotech products? Examples?

APPENDIX: Appropriate Acknowledgment of Your USDA BRAG Award

The Biotechnology Risk Assessment Grant (BRAG) program and the AFRI Foundational program: Agricultural Economics and Rural Communities – Social Implications of Emerging Technologies play an essential role in fulfilling the mission of the United States Department of Agriculture (USDA). Proper acknowledgment of your USDA BRAG and AFRI 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/NIFA support, as appropriate:

'This work is supported by Biotechnology Risk Assessment Grant Program competitive grant award no. #####-#####-##### from the U.S. Department of Agriculture' or 'This work is supported by Agriculture and Food Research Initiative (AFRI) Program competitive award no. #####-#####-##### from the USDA National Institute of Food and Agriculture.'

For details regarding acknowledgment of NIFA's support, please see the following webpage: <https://nifa.usda.gov/acknowledgment-usda-support-nifa>

We also expect that you will use our agency's identifier in all of your slide and poster presentations resulting from your BRAG or AFRI award. Please see: <https://nifa.usda.gov/resource/official-nifa-identifier>, for details about the appropriate identifier to use.



**United States
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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.

APPENDIX: Appropriate Acknowledgment of Your NIFA Award

The Agriculture and Food Research Initiative (AFRI) plays an essential role in fulfilling the mission of the National Institute of Food and Agriculture. Proper acknowledgment of your USDA-NIFA-AFRI funding in published manuscripts, presentations, press releases, and other communications is critical for the success of our Agency's programs. This includes proper acknowledgment of the Program and agency, as well as that of the Department and grant number.

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

"This work was funded by the Agriculture and Food Research Initiative Competitive Grant no. XXXX-XXXXX-XXXXX from the USDA National Institute of Food and Agriculture."

We also expect that you will use our agency's identifier in all of your slide and poster presentations resulting from your AFRI award. You may find the NIFA identifier shown below in the link (<https://nifa.usda.gov/resource/official-nifa-identifier>)



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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.

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