

Genetic biocontrol of invasive species

- The Minnesota Department of Natural Resources (DNR) is interested in exploring the issues related to genetic biocontrol of invasive species with partners and potentially affected interests.
- At a working group-sponsored meeting in June 2019, participants learned about genetic biocontrol research, regulatory processes, and public engagement, and identified potential next steps for individuals and organizations interested in genetic biocontrol of invasive species.
- Genetic biocontrol technologies are currently in the research stage in Minnesota, but some technologies are in field trials outside of the state.

Why talk about genetic biocontrol now?

Researchers are developing genetic biocontrol technologies that could be used to control individual invasive species. The general term “genetic biocontrol” may refer to a range of approaches to modify the genes or gene expression of an organism for the purpose of reducing populations, including genetic engineering, gene drives, RNA silencing, and other methods.

The Minnesota Department of Natural Resources invasive species program recognized that we and others have questions about the application of genetic biocontrol technologies to invasive species control. We have an opportunity to be proactive by beginning these discussions now, because genetic biocontrol technologies that might be used for invasive species control in Minnesota are probably years away from release into the environment.

Working group-sponsored meeting to identify next steps

To begin this conversation, the Minnesota Department of Natural Resources worked with partners at the University of Minnesota, the U.S. Fish and Wildlife Service, and the U.S. Geological Survey to organize a meeting about the scientific, legal, and public participation aspects of genetic biocontrol technologies. The meeting took place June 25-27, 2019, in St. Paul, Minnesota. The meeting was supported by Great Lakes Restoration Initiative funding administered by the U.S. Fish and Wildlife Service. Meeting participants included 56 individuals from natural resource management agencies, regulatory agencies, and research organizations. About half the participants traveled from outside Minnesota to attend.

Over the course of three days, meeting participants heard presentations on emerging technologies that apply to invasive species control, regulatory processes at U.S. federal and state level, public engagement, and legal considerations from the local to international scale. Small- and large-group

discussions also helped participants to further develop these themes of science, regulatory frameworks, and public engagement. Participants used a “workbook” during the meeting, which included readings suggested by presenters, key points from speakers, discussion questions to help participants move between presentations and discussions, and opportunities for participants to provide feedback directly to the meeting design team. The workbook may be a useful model for other individuals or groups interested in hosting a conversation about genetic biocontrol technologies. (A copy of the workbook is available on request; contact Kelly Pennington.)

At the June 2019 meeting, these experts presented on the following topics:

- Michael Smanski, University of Minnesota, talked about “synthetic genetic incompatibility” approaches being developed to control common carp and spotted-wing drosophila
- Kurt Kowalski of the U.S. Geological Survey spoke about their work developing species-specific approaches to manage non-native *Phragmites*
- Stas Burgiel, Acting Director of the National Invasive Species Council Secretariat, shared an introduction to the Coordinated Framework for Regulation of Biotechnology in the U.S. and other policy considerations relevant to invasive species control
- Abigail Walter from the U.S. Department of Agriculture (USDA) presented on the role of USDA’s Biotechnology Regulatory Services (BRS) in regulating certain products of biotechnology
- Laura Epstein of the U.S. Food and Drug Administration (FDA) talked about the FDA’s Center for Veterinary Medicine role in regulation of animals with intentionally altered genomic DNA
- Chris Wozniak of the U.S. Environmental Protection Agency (EPA) presented on how the EPA regulates genetic technologies for population suppression
- Minnesota state agency personnel presented several hypothetical genetic biocontrol scenarios to illustrate the current regulatory frameworks at state agencies
- Jason Delborne from North Carolina State University presented on public engagement and genetic biocontrol technologies for invasive species
- Stephanie Otts, Director of the National Sea Grant Law Center at the University of Mississippi School of Law, talked about international and local policy considerations

How you can get involved

The Minnesota Department of Natural Resources is interested in continuing discussions about genetic biocontrol for invasive species. For example, we are co-organizing a symposium on this topic at the 2020 Midwest Fish and Wildlife Conference.

We invite other organizations interested in this issue to stay involved in the ongoing discussions.

Contact Kelly Pennington, Aquatic Invasive Species Prevention Consultant, at kelly.pennington@state.mn.us if you are interested in learning more about this project.

Last updated November 6, 2019

For more information: see attached pp. 3-8, “Genetic biocontrol of invasive species: next steps”

Genetic biocontrol of invasive species: next steps

Participants at the June 2019 working group-sponsored meeting identified “key take-aways”, including next steps that they or others might take to advance the work of building capacity to address the issue of genetic biocontrol for invasive species. Key ideas that emerged from the meeting have been organized by the following themes:

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| A. Federal Regulatory Frameworks | G. Need for Interdisciplinary Approach |
| B. State Regulatory Frameworks | H. Developing Technologies to Application |
| C. Coordination and Communication among Agencies | I. Need for Investment in Research |
| D. Public Engagement | J. Terminology Concerns |
| E. Tribal Governments | K. Suggestions for Next Steps for Organizations |
| F. Ethical Issues | L. Examples of Next Steps for Individual Participants |

These themes are summarized below, supported by selected direct quotes from participants.

A. Federal Regulatory Frameworks

Some participants identified a need for “regulatory streamlining”. Others identified that some federal agencies, for example the U.S. Fish and Wildlife Service, do not seem to be as involved in the process as they may need to be given their role in section 7 and 10 of the Endangered Species Act.

- “Strong need for regulatory streamlining that includes coordination at the federal and state levels, including different authorities and jurisdiction, as well as incorporating various perspectives to ensure impacts are viewed holistically instead of the viewpoint of a specific agency.”

Several participants observed that the public and the regulated community would benefit from increased transparency and clarity about regulatory frameworks; for example:

- “Federal and state agencies should be engaged early in the development of new products. However, it is not always clear which agency is most appropriate to contact and what all of the steps are that must be followed. Thus, we would likely benefit from clarity and guidance – either from the agencies themselves or from an outside source.”
- “National regulatory processes can be a black box in terms of time frames, expectations, etc. It will be key that regulatory processes are transparent and have accountability.”
- “Regulatory...process is not well defined... ‘talk to us, then we will decide.’ Transparency/consistency would be helpful.”

Other participants identified specific needs related to regulatory frameworks, such as:

- “A matrix or flow chart is needed for regulators, proposer and the public to navigate state and federal permitting and the environmental review process.”

- “Who monitors the university labs or their biocontainment protocols? Need to make those rules well known and understood by both the scientists and public so that the public can be secure in the knowledge that there are no unintended releases of organisms.”
- “Consider necessary elements (especially where we’ve identified gaps or grey areas) that would need to be addressed by a regulatory system (this may not be a model law, but a best management practice checklist).”
- “Regulatory ambassadors that are either hired by university or state/federal agency to interface with researchers.”
- “Transboundary harm – both between nations, states, and tribal governments – is a critical issue. It’s not being dealt with in the U.S. on a state-to-state or a state-tribal nation level, based on legal precedence by the Supreme Court.”
- “Genetic controls being studied are species-specific, location-specific (i.e. we haven’t tested how they work in hot or cold extremes, different background conditions, etc.) and may require multiple applications for the same area. This situation warrants consideration of whether each time (release) would require separate permitting/approval/registration/risk assessment...”

Several participants commented on international frameworks related to genetic biocontrol:

- “...need for an international panel to address transboundary transfer of this technology.”
- “[the] U.S. should become a signatory to international agreements on biodiversity.”

B. State Regulatory Frameworks

Some participants recommended work focused on state regulations, including sharing information between states that do have regulatory frameworks that may address genetic biocontrol technologies.

- “[Minnesota Department of Natural Resources] staff can discuss how we follow research and regulations updates related to this field”; “DNR may want to have more detailed conversations and presentations from researchers...developing technology to potentially deploy in Minnesota.”
- “Need to consider how these technologies fit into existing state regulations and processes...Are statute/rule/procedural changes needed?”
- “An inventory of state regulations regarding genetic biocontrol would be very interesting and be a nice springboard for improving states’ readiness.”
- “Even in MN, where the state agencies are highly aware and communicative, there are gaps. Suggest MN model be described and shared so states can adapt. Perhaps an annual regulatory agenda meeting across agencies?”
- “States should be proactive and develop laws and policies to facilitate review before projects proposed.”
- “State review should not duplicate federal review but rather complement it with any necessary local perspective.”

C. Coordination and Communication among Agencies

Several participants identified a need for increased communication and coordination between federal agencies, between states, between state and federal regulatory bodies, and with other jurisdictions

with relevant authorities. Participants mentioned some existing groups that may help serve this purpose, as in the quotes below:

- “We need to improve coordination and collaboration across and between levels of government and levels of “publics” – international/federal/state/tribal/local; publics/stakeholders/communities.”
- “Invest in and build information sharing and communication networks. Increased communication could happen formally or informally: federal task force; working groups within other groups like [the Association of Fish and Wildlife Agencies], governors’ associations, etc.”
- “Interagency bodies do exist at the federal level ([National Invasive Species Council (NISC), Aquatic Nuisance Species Task Force (ANSTF)...Federal Interagency Committee for the Management of Noxious and Exotic weeds (FICMNEW)] that can serve as mechanisms to coordinate and promote this work.”

Some participants identified better communication within agencies as a useful next step:

- “Need to communicate up to commissioners and legislators that genetic biocontrol research is underway.”

A couple participants suggested that a task force or committee could help address this need:

- “...more centralized interagency regulatory process. Ideally this would include some kind of joint committee that would field inquiries and vet applications. ...A clearinghouse for information could also be very helpful....”
- “Suggest a funded task force or committee to assess needs and next steps.”
- “Like the idea of an interagency panel (governmental) to review and digest science and make recommendations/streamline.”
- “Would like EPA/FDA/BRS to create “unified genetic biotech” workgroup/twice-annual meeting to continue discussion and share information. Hire someone to be dedicated liaison on this topic.”

D. Public Engagement

Many participants identified the need for public engagement around genetic biocontrol of invasive species. In particular, participant comments supported: clearly communicating the risks and benefits associated with this complex technology to the various potentially affected interests; investing time and money in public engagement; and involving experts and professionals in this work. However, some people’s comments reflected their uncertainty about how to move forward with effective public engagement, or what outcomes to expect from public engagement. The quotes below are representative of these themes:

- “Genetic biological control is an area that will/can move forward rapidly but the risk associated with the technology is not well understood by the general population. We need to present a clear picture of the risks and benefits from this technology.”

- “What counts as success cannot just be technological approval and deployment. It should include demonstrated impacts on design and technological choice through stakeholder engagement and a successful and rigorous process of public and community endorsement.”
- “Investment is needed in human dimensions and public engagement relative to this issue now!”
- “Public engagement professionals are important and should be included early in the process.”
- “It’s clear that public engagement is going to be key, but I don’t see definite plans emerging...”

E. Tribal Governments

Many participants identified the critical need to consult with tribal governments and consider tribal rights; for example these comments:

- “Tribal issues need to be addressed early when developing technologies that impact their lands or natural resources.”
- “Increased communication with indigenous populations and have their wishes reflected in state/federal legislation.”

F. Ethical Issues

One participant observed that some people may be ethically opposed to any genetic modification technologies and their use for invasive species control would not be acceptable. A few participants identified the specific need to discuss ethical issues related to these technologies; the June 2019 meeting did not address ethical issues, as this participant observed:

- “There was no time or space in this agenda to discuss ethical issues and concerns. This is part of the needed human dimension component.”

G. Need for Interdisciplinary Approach

As a general matter, several people recommended that an interdisciplinary or multidisciplinary approach would be best for tackling issues around genetic biocontrol for invasive species, for example:

- “Multidisciplinary approach needed – including people representing different levels in this issue: researchers, managers, regulators.”

H. Developing Technologies to Application

Participants were interested in knowing more about how these technologies might be scaled up, manufactured, and deployed; comments that demonstrated this theme are, for example:

- “We are missing manufacturing and production side at this meeting. Who will actually make these things?”
- “Scalability and delivery systems for these technologies should be developed/considered simultaneously with development... It’s good to have “new tools” for invasive species management, but if you can’t get the out of the “toolbox,” then is it worth the investment?”
- “When private industry is developing these technologies, will market pressures or biological need drive development[?]”

I. Need for Investment in Research

Funding and investment in research related to the development, risk analysis methods, and risk management strategies for these technologies was also a priority for many participants. For example:

- “Significant work on the natural history of some organisms remains to be elucidated; critical for genetic biocontrol.”
- “We need to support...rearing techniques and risk assessments in parallel with technology development.”
- “As always, research on technology development must be accompanied by research on risk.”
- “Mathematical models will need some form of assessment to be considered robust and applicable to environmental risk assessment purposes.”
- “Develop mechanisms to detect and confirm genetic alterations.”
- “Researchers and developers should work on ways to build limited reproduction into genetically engineered organisms as another safeguard.”
- “Need to tightly link existing rush to new genetic technology with equally necessary science to anticipate future challenges/problems.”
- “Risk assessment protocols need to be developed that incorporate the uncertainties of synthetic species.”

J. Terminology Concerns

A number of participants expressed concern that the term “genetic biocontrol” may not be the most useful term when communicating to the public or potentially affected interests; however, no participants advocated for an alternative term. For example:

- “There are challenges with definitions and jargon with this issue; need to find definitions that don’t have problems. E.g., genetic biocontrol – confusion with classical biocontrol....”
- “‘Genetic biocontrol’ has baggage. ‘Synthetic biology’ is broad.”

K. Suggestions for Next Steps for Organizations

Several participants identified more meetings or workshops as good next steps, for example:

- “More interdisciplinary meetings like this to explore the interface between science, regulations, and society (rotate state hosts?).”
- “Develop a national meeting or workshop to examine this issue.”
- “I would welcome quarterly calls with anyone from the meeting to participate. Pick 2-3 concerns or suggestions from the meeting and discuss if any progress has been made or what we can do to foster progress.”
- “Need to have researchers, resource managers, and policy makers continue to meet and stay engaged to ensure the research has management implications and policy can keep pace.”
- “[The Upper Midwest Invasive Species Conference] 2020 might be an opportunity for a symposium on this topic.”

Several participants saw value in using a case study or risk analysis workshop to continue building capacity among researchers, regulators, and other interested parties:

- “A risk analysis workshop where regulators teach researchers exactly how they conduct their risk analysis would be beneficial. This way, researchers can start thinking about their projects from a regulatory standpoint and better design their modified organism.”
- “Identify stakeholders for each relevant technology (similar to gBIRD) and potential site of first application and begin conversations (again could be state, NGO or researcher-driven).”
- “Structured stakeholder/community discussion(s) on concrete problem...and possible responses including advanced biotech tools could be a valuable use case.”

Other participants suggested that online or written resources could also help:

- “Webinars might help make this information available to more people.”
- “Website with some of this information could be helpful.”
- “A review of the different methods of genetic biocontrol would aid both researchers and regulatory agencies.”
- “I’m really looking forward to the [meeting] summary...There may be some interest in turning that into a white paper.”

L. Examples of Next Steps for Individual Participants

Some participants also indicated specific next steps for themselves in response to the post-meeting survey question, “What will you do next related to genetic biocontrol of invasive species?” The examples below demonstrate the range of actions that are already underway as a result of the June 2019 working group-sponsored meeting.

- “...develop a lecture or case study for undergraduate/graduate conflict [management], leadership, and planning class.”
- “I am briefing my leadership and working with Principal Investigators and my Superiors to determine next steps.”
- “Continue to develop federal risk assessment process and work with developers.”
- “Publish genomes as resources for the development of biocontrols.”
- “I plan to finish reading through the materials from this conference, trying to keep up with new developments, and hopefully do an informational session for others in the fall.”
- “I will continue to work on the genetic biocontrol project that we have just started. I will be more aware of the importance of getting many different stakeholders involved, and communicating early with the regulators on the project.”
- “Go back and update my agency's internal Biotechnology working group about this workshop.”

For more information

Contact [Kelly Pennington](#), Aquatic Invasive Species Prevention Consultant, if you are interested in learning more about this project, for a copy of the June 2019 meeting workbook, or for more information about the symposium at the 2020 Midwest Fish and Wildlife Conference.