



Genetic Biocontrol- potential regulatory implications

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Great Lakes Panel on ANS

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Michigan's regulations

Part 413. Transgenic and Nonnative Organisms, Natural Resources and Environmental Protection Act, Act 451 of 1994, as amended

324.41305 Introduction of prohibited or restricted species, or genetically engineered or nonnative bird, crustacean, fish, insect, mammal, or mollusk, or aquatic plant; prohibition; exceptions.

Sec. 41305. A person shall not introduce a prohibited species, a restricted species, a genetically engineered or nonnative bird, crustacean, fish, insect, mammal, mollusk, or aquatic plant unless the introduction is authorized by 1 of the following, as applicable:

- (a) For a fish, by a permit issued by the department of natural resources under section 48735.
- (b) (b) For a plant or an insect other than a wiggler, by a permit issued by the department of agriculture and rural development under section 41306. (c) For any other species, by a permit issued by the department of natural resources under section 41306



Michigan's regulations

(e) "Genetically engineered" refers to an organism whose genome, chromosomal or extrachromosomal, is modified permanently and heritably, using recombinant nucleic acid techniques, or the progeny of such an organism.

(l) "Recombinant nucleic acid techniques" means laboratory techniques through which genetic material is isolated and manipulated in vitro and then inserted into an organism.



Michigan authorities- just a start

Department	Division	Authority	Subject
Natural Resources	Fisheries Wildlife	NREPA Part 413	Transgenic and Nonnative Organisms
Agriculture	Pesticide and Plant Pest Management	NREPA Part 413	Transgenic and Nonnative Organisms
Natural Resources	Fisheries	NREPA Part 487	Fish stocking
Agriculture	Animal Industry	Aquaculture Development Act 199 of 1996	Aquaculture
Environment	Water	NREPA Part 31 Rule 97	Materials applications not subject to standards
Environment	Water	NREPA Part 31 NPDES	Pesticide application
	?	?	?



Genetic biocontrol for invasive species

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Minnesota DNR Invasive Species Program

Genetic biocontrol – term

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, gene silencing, and other methods.



Minnesota Invasive Species Advisory Council calendar for
December 2020

Key points

- Genetic biocontrol technologies are being developed for control of invasive species
- Minnesota is beginning to build our capacity
- A June 2019 working group meeting revealed some existing regulatory frameworks and needs for better coordination



Acknowledgements

- Great Lakes Restoration Initiative grant administered by the U.S. Fish and Wildlife Service
- University of Minnesota – Minnesota Aquatic Invasive Species Research Center and Minnesota Invasive Terrestrial Plants and Pests Center
- U.S. Fish and Wildlife Service
- U.S. Geological Survey



Working group meeting – themes

Themes to begin conversation:

- genetic biocontrol technologies for invasive species
- U.S. federal and state regulatory frameworks
- public engagement

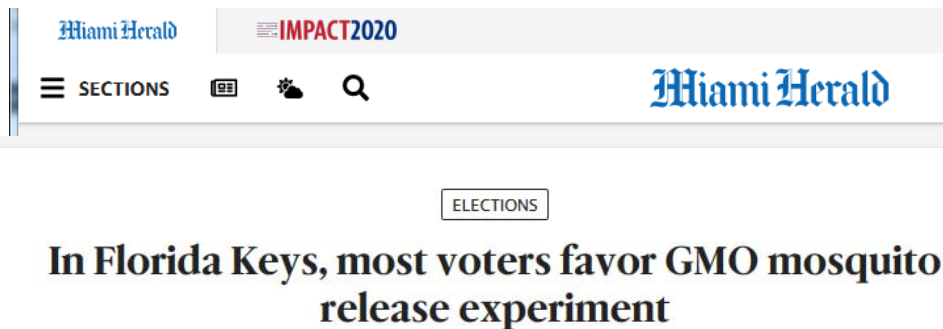
U.S. federal regulatory framework

“Coordinated framework”

- U.S. Environmental Protection Agency: Federal Insecticide, Fungicide, and Rodenticide Act
- U.S. Food and Drug Administration - Center for Veterinary Medicine: Federal Food, Drug, and Cosmetic Act
- U.S. Department of Agriculture - Animal and Plant Health Inspection Service (APHIS): Plant Health Protection Act

Other governance frameworks

- Tribal governments
- Transboundary harm
- International governance bodies (Convention on Biological Diversity, IUCN)
- Local communities



Scenarios: Minnesota state agencies

- Interagency coordination
- Discussed relevant authorities and processes, focusing on three scenarios:
 - Common carp
 - Spotted-wing drosophila
 - Nonnative *Phragmites*



Scenarios

The scenario presentations by Minnesota state personnel are:

- Hypothetical, future scenarios based on a preliminary analysis of current authorities and processes by program staff in Minnesota state agencies.
- For your information: they are not an official or legal position of the DNR or another agency. They are offered only to facilitate preliminary discussions.
- Nothing in these scenarios should be taken to imply that the state or any state agency does not have authority, or that authority is otherwise limited to the matters discussed herein.

Scenario 1: common carp, 2029



Department of
Natural
Resources:
Invasive
Species,
Fisheries,
Environmental
Review

Scenario 2: spotted-wing drosophila, 2024

Minnesota
Department of
Agriculture and
Environmental
Quality Board



Scenario 3: nonnative Phragmites, 2019



Department of
Natural
Resources –
cafeteria
conversation

Working group meeting – take-aways 1

“The regulatory framework for genetic engineering technologies is still very much in flux.”

“Regulatory process at federal level appears to be straightforward for GE mosquitoes.”

“Regulation and permitting focuses on final product.”

Working group meeting – take-aways 2

“Regulation is prioritized by risk (i.e., low-risk things may be exempt from regulation, high-risk things get most attention).”

“It is probably a good idea for researchers and developers to contact regulators as early as possible in the process.”

“States have unique concerns and processes that may not be covered by federal review.”

“...concerns about efficiency, transparency, and effectiveness of the...process.”

Next steps – already underway

- Aquatic Nuisance Species Task Force
- Great Lakes Panel on ANS
- Webinars to increase awareness
- Midwest Fish and Wildlife Conference
 - January 2020, Springfield Illinois



MISAC calendar 2020

Questions?



Thank You

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