



Regulatory Framework for Genetic Biocontrol

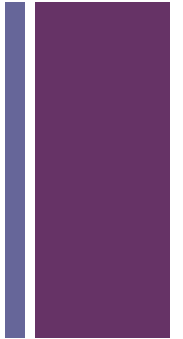


Stephanie Showalter Otts
Director, National Sea Grant Law Center

International Symposium on Genetic Biocontrol of Invasive Fish
Minneapolis, Minnesota • June 24, 2010



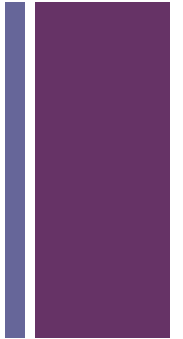
Triploid Grass Carp: A Potential Model?



- Most states require a permit to release triploid grass carp for aquatic weed control.
 - A few states exempt releases from permit requirements if carp were bought from licensed dealers and stocked in private ponds.
- Almost every state requires that triploid grass carp be certified as such by the U.S. Fish and Wildlife Service or another recognized source.
- Permit conditions commonly imposed to prevent escape from research area, such as installation of barriers.



Coordinated Framework for Regulation of Biotechnology



- Announced June 26, 1986
- Three agencies with primary authority
 - APHIS (Livestock/Plant Pests)
 - EPA (Pesticides)
 - FDA
- Existing laws governing traditional genetic modification techniques “would address regulatory needs [for products obtained with new techniques] adequately.”



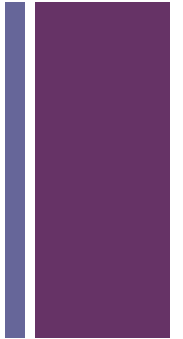
FDA's Authority



- FDA regulates GE animals under New Animal Drug provisions of the federal Food, Drug, and Cosmetic Act.
 - “Drug” – “articles (other than food) intended to affect the structure or any function of the body of man or other animals.”
- rDNA construct is the “drug”



New Animal Drug Application



- Generally, a new animal drug is deemed unsafe unless the FDA has approved a New Animal Drug Application (NADA) for that particular use.
- NADA's must include either an Environmental Assessment or a claim for a categorical exclusion pursuant to FDA's regulations implementing the National Environmental Policy Act.
 - Categorical exclusion available for drugs intended for use in nonfood animals.
 - Exclusion doesn't apply, however, if "extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment."



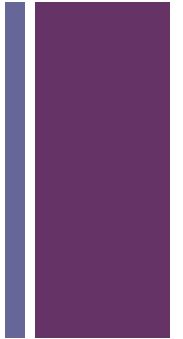
Issue #1: Trade Secrets Act



- NADA is protected from public disclosure by Trade Secrets Act.
 - Because EA is submitted as part of an NADA, environmental analysis would not be available for public comment until after the new animal drug was approved.
- Significant concerns that secrecy would prevent full analysis of all potential environmental impacts.
 - Also undercuts a primary purpose of NEPA which is public participation.



Issue #2: “Enforcement Discretion”

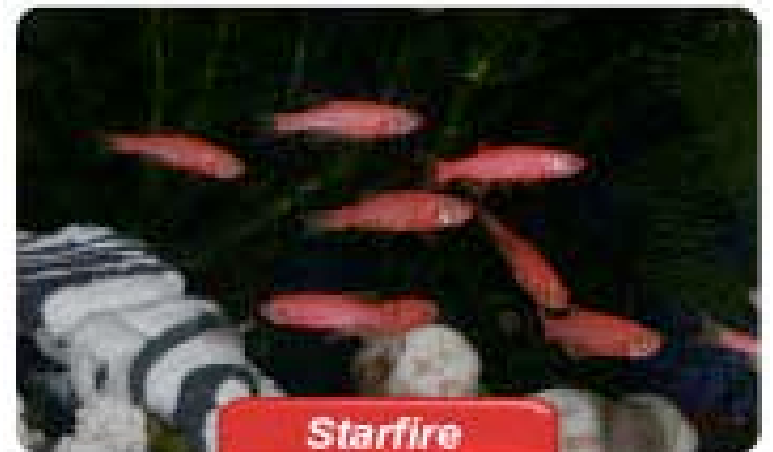
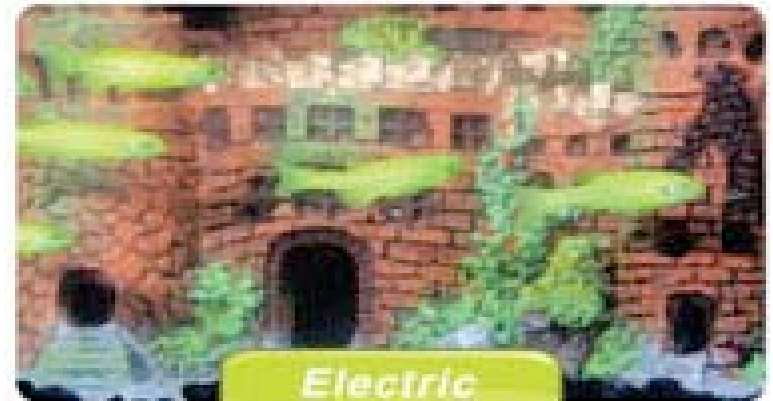


- FDA policy to exercise “enforcement discretion” with respect to certain GE animals.
- Decision whether to exercise enforcement discretion with respect to non-food species is based on evaluation of risk factors.
 - Is anything about the article itself that poses a human, animal, or environmental risk?
 - In the event of an environmental release, does the GE animal pose any more of an environmental risk than its non-GE counterpart?
 - Are concerns over the disposition of GE animals that could pose human, animal, or environmental risks?
 - Are any other safety questions that have not been adequately addressed by the sponsor?



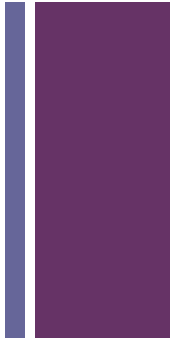
Case Study: GloFish

- GE zebra danio which “glows in the dark.”
- FDA declined to regulate.
 - No evidence that the GE variety posed “any more threat to the environment than their unmodified counterparts.”
 - Intended use was aquarium trade (pet), not livestock or food.
- FDA’s decision avoided NEPA requirements.
 - There was “no federal action” to trigger environmental reviews.
 - Upheld in court in 2006.





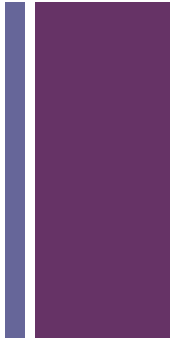
Would NADA be required for use of GE fish for biocontrol?



- Depends on which species. If non-food species, exercise of enforcement discretion is a possibility.
 - But unlike GloFish, these GE fish would be intended for release into the environment.
 - Food species, NADA required – i.e., transgenic salmon
- The key question is likely to be whether the GE fish poses any more of any environmental risk than its non-GE counterpart.
 - If not, FDA may choose not to regulate and the fish could be released without NADA approval.
 - If it does, producer would have to submit an NADA to FDA.



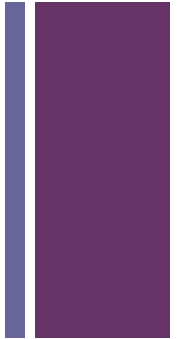
Would EA/EIS be required?



- Again, might depend on species released. If non-food species, could potentially qualify for a CE.
- However, given the unprecedented nature of the release of GE animals for biocontrol and the controversy surrounding GMOs, it's unlikely FDA could legally decline to prepare an EA and/or EIS.
 - *Monsanto v. Geertson Seed Farm*, U.S. Supreme Court (June 21, 2010)
 - Scope of the EIS would depend on the NADA - Is the NADA for use in one specific geographic location; Does the NADA cover more than one target species?
- Depending on scope of EIS prepared and entity carrying out the release, a second EIS might have to be prepared.
 - While redundant, the preparation of a second EIS for the actual release could rectify the NADA public participation problems.



Additional Approvals Required



■ Federal Law

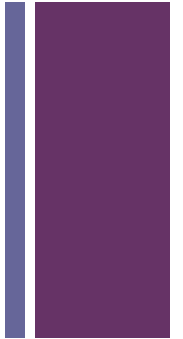
- Endangered Species Act: Fish and Wildlife Service consultation to prevent “jeopardy” and prohibition on “harm.”
- Clean Water Act: Prohibits discharge of pollutants. Fish are considered pollutants, so permit potentially required.
- Lacey Act: Prohibits import and transport of injurious species. No GM species currently listed as injurious. Also, federalizes state wildlife crimes.

■ State Law

- For example, several states in Great Lakes region (Minnesota, Michigan, Illinois, and Wisconsin) have state laws regulating release of GE organisms.



Questions?



Stephanie Showalter Otts, Director
National Sea Grant Law Center
University of Mississippi School of Law
Kinard Hall, Wing E – Room 256
University, MS 38677

(662) 915-7775

(662) 915-5267 (fax)

sshowalt@olemiss.edu