Regulatory Framework for Genetic Biocontrol

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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


  - “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 be submit an NADA to FDA.
Would EA/EIS be required?

- Again, might depend on species released. If non-food species, could potentially qualifies for a CE.

- However, given the unprecedented nature of the release of GE animals for biocontrol and the controversy surrounding GMOs, its 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?

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