Session VII: Part I
Feral Cats: New Regulatory Pathway, New Approaches
By Dr. Kathy Fagerstone

ERAL CATS: NEW REGULATORY PATHWAY, NEW APPROACHES

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National Wildlife Research Center

What Federal Agency Regulates Contraceptive Products?

<table>
<thead>
<tr>
<th>FEDERAL AGENCY</th>
<th>PRODUCTS REGULATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Agriculture</td>
<td>Disease vaccines</td>
</tr>
<tr>
<td>Environmental Protection Agency</td>
<td>Contraceptives for wildlife and feral animals</td>
</tr>
<tr>
<td>Food and Drug Administration</td>
<td>Contraceptives for domestic livestock, companion animals and zoos</td>
</tr>
</tbody>
</table>

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Federal Insecticide, Fungicide and Rodenticide Act

- Pesticide products must obtain an EPA registration before manufacture, transport, and sale
- Registration based on a risk/benefit standard
- Grants EPA authority to require data
  - Product Chemistry
  - Hazards: Wildlife and Aquatic Organisms
  - Hazards: Humans and Domestic Animals
  - Environmental Fate
  - Residue Chemistry
  - Product Performance

EPA Regulatory Review

Bait Delivered Oral Contraceptives
Minimum Data Requirements

<table>
<thead>
<tr>
<th>Standard Conventional Pesticide Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Chemistry</td>
</tr>
<tr>
<td>Toxicology</td>
</tr>
<tr>
<td>Nontarget Hazard</td>
</tr>
<tr>
<td>Environmental Fate</td>
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<tr>
<td>Product Performance</td>
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<tr>
<td>Worker Protection</td>
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<td>Residue Chemistry</td>
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</table>
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**EPA Regulatory Review**

**Injectable Contraceptives**

**Abbreviated Data Requirements**

<table>
<thead>
<tr>
<th>Category</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Chemistry</td>
<td>Standard with waiver requests</td>
</tr>
<tr>
<td>Toxicology</td>
<td>Waiver + acute toxicity data from literature</td>
</tr>
<tr>
<td>Nontarget Hazard</td>
<td>Probable waiver</td>
</tr>
<tr>
<td>Environmental Fate</td>
<td>None – waiver requests</td>
</tr>
<tr>
<td>Product Performance</td>
<td>Laboratory and Field Efficacy</td>
</tr>
<tr>
<td>Worker Protection</td>
<td>Precautionary label language</td>
</tr>
<tr>
<td>Residue Chemistry</td>
<td>Submit FDA HFS review</td>
</tr>
</tbody>
</table>

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**Federal and/or State Regulatory Authority**

- Products are registered nationally with the EPA (FIFRA Sec. 3)
  - Gonacon™

- Then each state decides whether they will register the product

- States may register an additional use for a product under a Special Local Need (FIFRA Sec. 24c)
  - For different species
  - For different use patterns
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Label Requirements
- General/Restricted Use Box
- Target Species/Active Ingredients
- Treatment Statement
- Precautionary Statements
  - Signal Word:
    - Caution: Low Toxicity (>500 mg/kg, oral)
    - Warning: Moderate Toxicity (50-500 mg/kg)
    - Danger: High Toxicity (<50 mg/kg)
  - Environmental: Wildlife, Water
  - Chemical Hazards
  - Endangered Species
- Directions for Use
  - Use Restrictions
  - Application Directions
  - Labeling Attachments
- Storage/Disposal

What is a Label?
- The written, printed, or graphic matter on, or attached to, the pesticide or any of its containers or wrappers
- It is a violation of FIFRA to use a pesticide product outside label directions

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RESTRICTED USE PESTICIDE
DUE TO NON-TARGET INJECTION HAZARD
For use by state or federal wildlife or natural resource management personnel or persons working under their authority.

GONACON™
IMMUNOCONTRACEPTIVE VACCINE
Intramuscular contraceptive vaccine for use in selected species

Directions for Use
- Immuocontraceptive vaccine for use in cervid species
- For use by state or federal wildlife or natural resource management personnel or persons working under their authority.
- GonaCon™ will render a treated female infertile for multiple years with only one vaccination. However, vaccinating more than once will increase the duration of infertility with no known adverse health effects.
- A single vaccination (1 ml) of GonaCon™ should be administered at least two to three months prior to the rut for full contraceptive effect.
- For longer contraceptive effect, a second vaccination may be given 30 to 60 days after the first injection or the following year.
- Over a period of a few years, treated females may once again become fertile and require re-immunization with GonaCon™.
- GonaCon™ can be administered by either hand or remote injection.
DIFFERENCES BETWEEN EPA AND FDA REGULATIONS

REGISTERED PRODUCT AND USE FOR MULTIPLE SPECIES

- **FDA**—New Animal Drug Approval (NADA)
  - NADA (allows for use on one species: Ex, GonaCon for Cervids)
  - Use for other species:
    - “Extra-label” provision allows for use on other species without FDA notification.
- **EPA**—Registration
  - *Active Ingredient or Technical Registration* (100% capsaicin—red pepper)
  - *End Use Product*—Label lists species and use patterns (ex., 5% capsaicin in a spray for repelling bears). Cannot use for other species.
  - *Special Local Need* (FIFRA Sec. 24c)
    - State registration for different species or for different use patterns
  - 2ee—if same rate and use pattern, can use for another species without EPA notification

DIFFERENCES BETWEEN EPA AND FDA REGULATIONS

HOW ARE USES RESTRICTED?

- **FDA**—NADA
  - RX (Veterinarian prescription)
  - Over-the-Counter
- **EPA**—Registration
  - Restricted Use (Use by certified applicator)
  - General Use (Can be sold directly to the public)
  - Further restrictions allowed
    - Ex., for use only by persons trained in bird control
    - Ex., for use only by USDA/APHIS/WS personnel
DIFFERENCES BETWEEN EPA AND FDA REGULATIONS

MANUFACTURING PRACTICES

- FDA—NADA
  - Good Manufacturing Practices required, as well as characterization of the product and product stability

- EPA—Registration
  - Not GMP
  - EPA requires characterization of the product, including storage stability

DIFFERENCES BETWEEN EPA AND FDA REGULATIONS

TESTING

- FDA—NADA
  - Investigational New Animal Drug (INAD)

- EPA—Registration
  - Less than 10 acres (no regulatory requirement)
  - Experimental Use Permit
    - Requires a basic data package

STATE AUTHORIZATIONS

- FDA—NADA
  - None?

- EPA—Registration
  - Individual States have authority over use in their state