

Monkeypox in the United States
A Report to Secretary's Council on
Public Health Preparedness
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Risk Assessment and Risk Management Issues

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Risk Assessment

- Hazard Identification
- Hazard Characterization
- Exposure Assessment
- Risk Characterization



Monkeypox

Risk Assessment Questions

- Is there a significant risk to humans of monkeypox virus infection?
 - Post outbreak
 - Through new imports of exotic species
- What species are associated with the risk?



Monkeypox

Hazard Identification

- Rare, sporadic zoonotic viral illness
- Unknown animal reservoir; likely rodents
- Case-fatality rates of about 10%
- Smallpox vaccination reduces morbidity/mortality in most cases



Monkeypox

Hazard Characterization

- Infections in primates, rodents, and marsupials
- Unknown attack rates among exposed animals
- Duration of infection/infectiousness unclear
- Likely mucocutaneous and respiratory transmission



Monkeypox Exposure Assessment

- No new animal or human cases since June 2003
- 178 (23%) of rodents in original shipment not traced—percent infected unknown
- About 107 (53%) of prairie dogs in IL distribution center not traced—percent infected unknown
- 238 wild mammals trapped near disposal sites not infected
- 23 mammals housed near ill prairie dogs not infected



Monkeypox

Risk Characterization

- Based on data outlined by CDC, probability of identifying new human or animal cases associated with the 2003 outbreak is low, but not zero
 - Need close contact with infected animals
 - No new human or animal cases since June 2003
 - No indication of infections in wild population
- Risk of new importation of infected animals also low, but not zero
 - Import restrictions remain in effect



Risk Management Issues

- Problem definition
- Statutory authority
- Practical, economic, social impacts of response measures
- Other issues



Risk Management: HHS Statutory Authority in the Context of the Monkeypox Outbreak

- 42 USC 264 gives HHS authority to make and enforce regulations to prevent introduction and spread of communicable disease in U.S.
- Under 42 CFR 70.2 and 21 CFR 1240.30, authority given to FDA Commissioner and CDC Director to take actions they believe are “reasonably necessary to prevent” spread of communicable disease when state and local actions are inadequate



FDA Actions Under PHS Act

- Molluscan shellfish (21 CFR 1240.60)
- Turtles (21 CFR 1240.62)
- Psittacine birds (21 CFR 1240.65)
- Human tissue (21 CFR 1270.1-1270.43)



The Interim Final Rule (IFR)

- Clarified and expanded the June 11, 2003 joint order
 - > 600 comments received, from dealers, owners and states; FDA reviewing/preparing response
- IFR may be amended or revoked if FDA concludes that monkeypox is eradicated or adequately controlled
- Preamble to IFR indicated FDA could act as early as 1/20/04 if no new cases or further information warranted extension



Issues in Trade in Wild-caught Imported or Domestic Species

- Vector-specific or disease-specific response vs. systemic prevention/response capacity
- Minimal government resources foster noncompliance
- Coordinated preventive and control measures needed from multiple agencies
- Invasive and exotic animal species pose public health risks distinct from ecological risks posed by plant species



Federal Agencies With Authority Relevant to Imported and Domestic Zoonotic Diseases

- Dept. of Interior, Fish & Wildlife Service
- Dept. of Agriculture, Animal & Plant Health Inspection Service (APHIS)
- HHS, CDC and FDA
- Dept. of Homeland Security, Customs & Border Protection
- Dept. of Transportation



Exotic Animal Regulations

Fish & Wildlife Service

STATUTES	SCOPE	ACTIONS
Lacey Act Amendments of 1981 16 USC 3371 <i>et seq.</i> 50 CFR Pt 16	Wildlife; Violation of federal, state, local or foreign laws	Inspection; Destruction; Enforcement
Lacey Act (1900) 18 USC 42	Injurious animals	Destruction Enforcement
Endangered Species Act (1973) 16 USC 1538d	Endangered species	Enforcement



Exotic Animal Regulations

US Dept. of Agriculture

STATUTES	SCOPE	ACTIONS
<p>Animal Health Protection Act (AHPA) (2002) 7 USC 8301</p>	<p>Pest or disease of livestock</p>	<p>Surveillance, Inspection, Detention, Quarantine, Destruction, Remedial Action</p>
<p>Animal Welfare Act (AWA) (1966) 7 USC 2131</p>	<p>Exhibitors, dealers, handlers of non-livestock animals</p>	<p>Recordkeeping; Licensing; Inspection</p>
<p>Animal Damage Control Act (ADCA) (1931) 7 USC 426 & 426c</p>	<p>“Nuisance” animals; Reservoir Zoonotic Disease</p>	<p>Surveillance Destruction</p>



Exotic Animal Regulations

Health & Human Services

STATUTES	SCOPE	ACTIONS
Public Health Service Act (1942) 42 USC 264; 21 CFR 1240; 42 CFR Pts 70 & 71	Prevention of communicable diseases affecting human health	Public Health Surveillance; Inspection; Detention; Quarantine; Destruction; Enforcement (FDA) Intrastate; Interstate; Import (CDC)



Exotic Animal Regulations

Dept. of Homeland Security and Dept. of Transportation

STATUTES	SCOPE	ACTIONS
Tariff Act of 1930 19 USC 1499; 19 USC 1595a; 18 USC 545; 19 CFR Pt 151	Import prohibited by law	Inspection; Seizure; Destruction; Enforcement
Federal HazMat Transport Law (1994) 49 USC 5101 <i>et seq.</i> 49 CFR Pts 171-180	Hazardous materials	Approval for transport of infected animals; Enforce



FDA's Role in Emerging Infectious Disease Response

- Facilitate the development of reliable diagnostic tools
- Facilitate the development of safe and effective treatments for human infection
- Facilitate the development of safe and effective vaccines for human use
- Help safeguard the blood and tissue supply



Monkeypox

Risk Management Questions

- If the risk of monkeypox is significant, what control measures would be adequate to reduce that risk?
- What other considerations may be relevant in a determination about this risk response?



Risk Management Options

- Education
- Quarantine
- Segregation
- Screening
- Surveillance
- Treatment
- Restrictions



Risk Management Considerations

- Public health considerations
- Other considerations may include economic costs, social costs, and impact on government resources



Summary:

Monkeypox Risk Assessment Questions

- Is there a significant continued risk to humans of monkeypox virus infection associated with:
 - The summer 2003 outbreak in the U.S.
 - Newly imported animals
 - Imported vs. domestic animals?
 - Wild-caught vs. captive-bred animals?
- What species are associated with this risk?



Summary:

Monkeypox Risk Management Questions

- If the risk of monkeypox virus to humans is significant, what control measures would adequately reduce that risk?
 - To what species would each type of control measure apply?
 - How can the effectiveness of these measures be evaluated?
- What other considerations may be relevant in determining whether to impose such control measures?

