

APHIS Perspective on Risk Management Associated with Agricultural Disease Control

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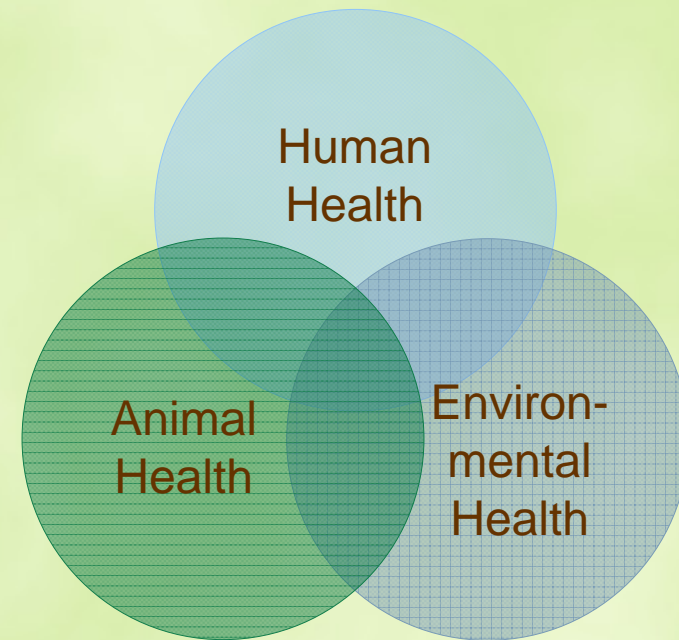
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Types of Disease Outbreak Risks

- Regulatory/legal liability
- Health
 - Agricultural
 - Human Health
 - Environmental



One World, One Health

Disease Outbreak Regulators

- U.S. Department of Agriculture (**USDA**)
- U.S. Environmental Protection Agency (**EPA**)
- U.S. Department of Transportation (**DOT**)
- U.S. Occupational Safety and Health Administration (**OSHA**)
- U.S. Centers for Disease Control (**CDC**)
- States

WHO REGULATES WHAT?



<p>Plant Diseases</p>	<p>APHIS eradication State eradication</p>	<p>APHIS movement control State movement control</p>	<p>APHIS disposal methods State disposal methods Local permits</p>
<p>Foreign Animal Diseases</p>	<p>APHIS quarantine, culling State quarantine, culling</p>	<p>APHIS movement control DOT packaging, labeling, transport State movement control</p> <p>HAP</p> <p>HAP</p>	<p>APHIS disposal methods State disposal methods Local permits Owners conditions</p> <p>HAP</p> <p>HAP</p>
<p>Zoonotic Diseases</p>	<p>APHIS quarantine, culling CDC public health OSHA safety, biosafety State quarantine, culling Local Health Depts. Public health</p>	<p>APHIS movement control DOT packaging, labeling, transport OSHA safety, biosafety State movement control Hlth. Depts. Public health</p>	<p>APHIS disposal methods EPA Med/Infectious waste OSHA safety, biosafety CDC public health State/Local permits Owners conditions</p> <p>HAP</p>

USDA-APHIS Regulations

Geared Toward Protecting Agriculture

- 9 CFR 50.7(a): Livestock to be destroyed because of **tuberculosis** must be shipped direct to slaughter ... or be **disposed of by rendering, burial, or incinerating** ...
- 9 CFR 51.6(c): Animals Destroyed Because Of **Brucellosis; Swine**. ... In cases where the swine are destroyed other than at a slaughtering establishment, the carcasses of the swine shall be **disposed of by burial, incineration, or other disposal means authorized by applicable State law...**
- 9 CFR 53.4(a): **Foot-And-Mouth Disease, Pleuropneumonia, Rinderpest, and certain other** Communicable Diseases Of Livestock Or Poultry; ... animals infected with or exposed to disease shall be ... **disposed of by burial or burning, unless otherwise specifically provided** by the Administrator, at his or her discretion.
- 9 CFR 54.7(b): Control Of **Scrapie**; The carcasses of animals destroyed in accordance with this section are authorized by the Administrator to be **buried, incinerated, or disposed of by other methods** in accordance with local, State, and Federal laws.

USDA-APHIS Regulations (cont.)

7

Geared Toward Protecting Agriculture

- 9 CFR 55.3(e): Control Of **Chronic Wasting Disease**; The carcasses of any cervids destroyed in accordance with this part are authorized by the Administrator **to be incinerated, destroyed in an alkaline hydrolysis tissue digester, or disposed of by any other method authorized by an APHIS employee** and in accordance with local, State, and Federal laws...
- 9 CFR 56.5(b): Control Of **H5/H7 Low Pathogenic Avian Influenza**; ... Disposal methods ... may include one or more of the following: **Burial, incineration, composting, or rendering**. Regardless of the method used, **strict biosecurity** procedures must be implemented and enforced for all personnel and vehicular movement into and out of the area in accordance with the initial State response and containment plan to prevent dissemination of the H5/H7 LPAI virus.
- 9 CFR 121.6: Animals and Animal Products; Possession, Use, And Transfer Of **Select Agents And Toxins; Exemptions** for overlap select agents and toxins; (e) The Administrator may exempt an individual or entity from the requirements of this part for 30 calendar days if it is necessary **to respond to a domestic or foreign agricultural emergency involving an overlap select agent or toxin**. The Administrator may extend the exemption once for an additional 30 days. An individual or entity may apply for this exemption by submitting APHIS/CDC Form 5. A written decision granting or denying the exemption will be issued.(f) Upon request of the Secretary of Health and Human Services, the Administrator may exempt an individual or entity from the requirements of this part for 30 calendar days if the Secretary of Health and Human Services has granted an exemption **for a public health emergency involving an overlap select agent or toxin**. The Administrator may extend the exemption once for an additional 30 days.

EPA Regulations

Geared Toward Protecting the Environment

- EPA delegates regulation of medical/infectious waste to the States

EPA Definition of Medical Waste

- The Medical Waste tracking Act of 1988 (40 CFR 259, now expired) defines medical waste as "any **solid waste** that is **generated in** the diagnosis, **treatment**, or immunization **of** human beings or **animals**, in research pertaining thereto, or in the production or testing of biologicals."
- **Treatment**, when used in the context of 40 CFR 259.30(a), **means** either the provision of medical services or the **preparation of** human or **animal remains** for interment or cremation.

EPA Definition of Medical Waste (cont.)

The EPA-sponsored guidance document on medical waste management for States^[1] defines medical waste as sharps...[and] animal waste...[where] animal waste includes, “contaminated animal carcasses, body parts, fluids and bedding of animals that have been afflicted with suspected zoonotic disease or purposely infected with agents infective to humans during research, in the production of biologicals, or in the in vivo testing of pharmaceuticals.”

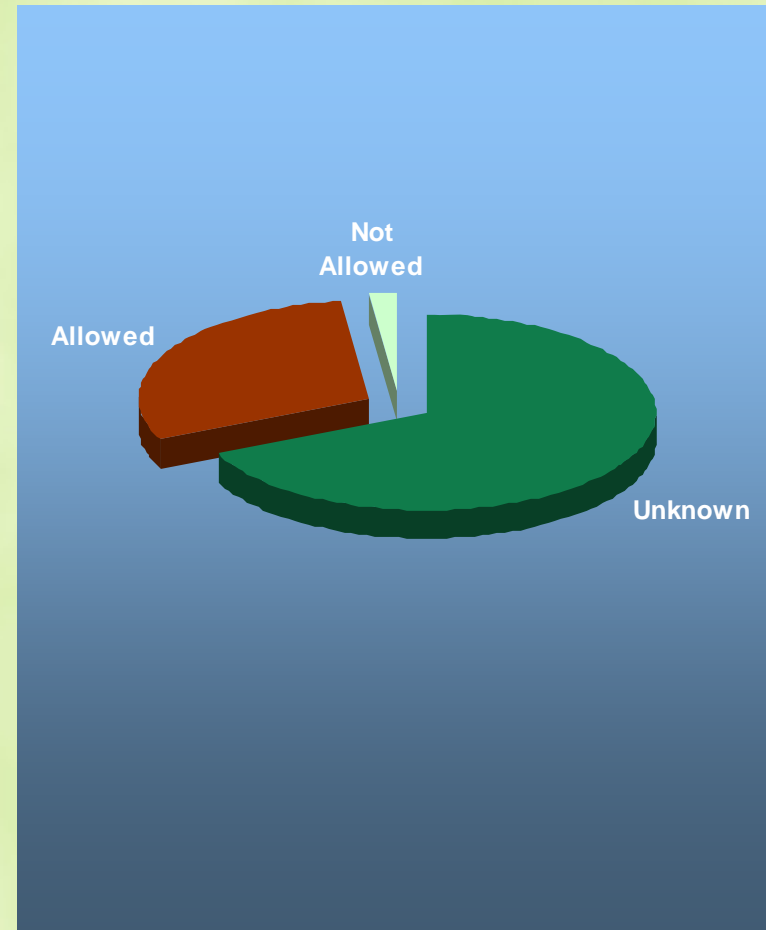
^[1] Model Guidelines for State Medical Waste Management, Council of State Governments and USEPA Office of Solid Waste. (1992)

EPA Definition of Infectious Waste

EPA defines infectious waste in its *Guide for Infectious Waste Management (EPA530-SW-86-014)* **as a waste that “contains pathogens** with sufficient virulence and quantity so **that** exposure to the waste by a susceptible host **could result in an infectious disease.** This could apply to both plant and animal waste.

State Regulations

- State regulations vary widely
- 34/50 States don't mention landfilling of diseased animals specifically **HAP**
- 15/50 States specifically allow landfilling
- 1/50 (Arkansas) specifically prohibits landfilling of large animals
- Some specifically exclude diseased animals from medical/infectious waste regulations **HAP**



DOT Regulations

Geared Toward Protecting Transportation

Department of Transportation Hazardous Materials Program Definitions And General Procedures at 49 CFR 105.5(b): Hazardous material means a substance or material that the Secretary of Transportation has determined **is capable of posing an unreasonable risk to health, safety, and property when transported** in commerce, and has designated as hazardous under section 5103 of Federal hazardous materials transportation law (49 U.S.C. 5103).


The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, **materials designated as hazardous in the Hazardous Materials Table (see 49 CFR 172.101)**, and materials that meet the defining criteria for hazard classes and divisions in part 173 of subchapter C of this chapter.


49 CFR 172.101(a) Hazardous Materials Table


Label code	Label name
1	Explosive
1.1 ¹	Explosive 1.1 ¹
1.2 ¹	Explosive 1.2 ¹
1.3 ¹	Explosive 1.3 ¹
1.4 ¹	Explosive 1.4 ¹
1.5 ¹	Explosive 1.5 ¹
1.6 ¹	Explosive 1.6 ¹
2.1	Flammable Gas
2.2	Non-Flammable Gas
2.3	Poison Gas
3	Flammable Liquid
4.1	Flammable Solid
4.2	Spontaneously Combustible
4.3	Dangerous When Wet
5.1	Oxidizer
5.2	Organic Peroxide
6.1 (inhalation hazard, Zone A or B)	Poison Inhalation Hazard
6.1 (other than inhalation hazard, Zone A or B) ²	Poison
6.2	Infectious substance
7	Radioactive
8	Corrosive
9	Class 9

Symbols	Hazardous materials descriptions and proper shipping names	Hazard class or Division	Identification Numbers	PG	Label Codes	Special provisions (§172.102)	(8)			(9)	
							Packaging (§173.***)			Quantity limitations (see §§173.27 and 175.75)	
							Exceptions	Non-bulk	Bulk	Passenger aircraft/rail	Cargo aircraft only
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8A)	(8B)	(8C)	(9A)	(9B)
G	Infectious substances, affecting animals <i>only</i>	6.2	UN2900		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg
G	Infectious substances, affecting humans	6.2	UN 2814		6.2	A82	134	196	None	50 mL or 50 g	4 L or 4 kg

Column (1): Symbols. Column 1 of the Table contains six symbols (“+”, “A”, “D”, “G”, “I” and “W”), where “G” identifies proper shipping names

Column (7), A82 (applies only to transport by aircraft): The quantity limits in columns (9A) and (9B) do not apply to human or animal body parts, whole organs or whole bodies known to contain or suspected of containing an infectious substance. **Does this mean the quantity can be more, or does it mean zero?** 

Column (8A) refers to the section of 49CFR173 containing exceptions to 49CFR172. In this case, it is 49CFR173.134, which says material that cannot cause disease upon exposure (such as treated material) and waste from animal husbandry, is exempt from these labeling requirements. 

Column (8B) references the section in part 173 which prescribes packaging requirements for non-bulk packagings. Because large scale animal mortalities are expected to be transported in bulk, this likely would not apply. Regardless, 49CFR173.196 says that body parts, organs or whole bodies meeting the definition of Division 6.2 material must be packaged as follows: (1) In Division 6.2 packaging, as specified in paragraphs (a) and (b) of this section; or (2) In packaging meeting the requirements of §173.197. Division 6.2 packaging includes: (1) A watertight, leakproof primary receptacle; (2) A watertight, leakproof secondary packaging; (3) A rigid outer packaging; and (4) Absorbent material placed between the primary receptacle and the secondary packaging. §173.197 allows bulk outer packagings of metal or fiberglass which are leakproof and weatherproof, up to approximately 60 cubic yards, with plastic film inner packagings of up to 46 gallons, weighing less than 22 pounds each. 

Column (8C) A “None” in Column (8C) means bulk packagings are not authorized, except as may be provided by special provisions in Column (7) and in packaging authorizations Column (8B).

OSHA Regulations

Geared Toward Protecting Worker Health

- 29 CFR 1910.120 Hazardous waste operations and emergency response:** This section covers ... **Emergency response operations for releases of, or substantial threats of releases of, hazardous substances** without regard to the location of the hazard. Emergency response operations for releases of, or substantial threats of releases of, hazardous substances which are not covered by paragraphs (a)(1)(i) through (a)(1)(iv) of this section **must only comply with the requirements of paragraph (q) of this section.**

Hazardous substance means any substance designated or listed under paragraphs (A) through (D) of this definition, exposure to which results or may result in adverse affects on the health or safety of employees: (B) **Any biological agent and other disease-causing agent which after release into the environment and upon exposure, ingestion, inhalation, or assimilation into any person, either directly from the environment or indirectly by ingestion through food chains, will or may reasonably be anticipated to cause death, disease, behavioral abnormalities, cancer, genetic mutation, physiological malfunctions (including malfunctions in reproduction) or physical deformations in such persons or their offspring;**
- 29 CFR 1910.1030 Bloodborne pathogens - Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans.** These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). **[This could apply to zoonotic diseases such as avian influenza and transmissible spongiform encephalopathies (TSEs or prions).]**



OSHA Regulations (cont.)

Geared Toward Protecting Worker Health

- **29 CFR 1910.132 - Personal Protective Equipment (PPE) - General requirements. (d) Hazard assessment and equipment selection. (1) The employer shall assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment. If such hazards are present, or likely to be present, the employer shall:**
 - (i) Select, and have each affected employee use, the types of PPE that will protect the affected employee from the hazards identified in the hazard assessment;**
 - (ii) Communicate selection decisions to each affected employee;**
 - (iii) Select PPE that properly fits each affected employee.**

- **Includes:**
 - Hazard Assessment
 - Training
 - Fit Testing
 - Medical Monitoring



CDC Guidance

Geared Toward Protecting Public Health

- **CDC Interim Guidance for Protection of Persons Involved in U.S. Avian Influenza (AI) Outbreak Disease Control and Eradication Activities**
 - This document provides interim guidance for protection of persons involved in activities to control and eradicate outbreaks of AI among poultry in the United States. Activities that could result in exposure to AI-infected poultry include euthanasia, carcass disposal, and cleaning and disinfection of premises affected by AI.
 - CDC recommendations include Basic Infection Control, PPE, Vaccination with Seasonal Influenza Vaccine, Administration of Antiviral Drugs for Prophylaxis, Surveillance and Monitoring of Workers, and Evaluation of Ill Workers.

CDC Guidance (cont.)

Geared Toward Protecting Public Health

CDC Guidance on Animal Disposal Following an Emergency

- People working to **clean up** areas containing **swine or poultry carcasses** should take the following precautions:
 - Wear **protective clothing**, including waterproof gloves, waterproof boots, and protective eyewear (cover any open wounds).
 - Use duct tape to seal tops of gloves and boots to prevent water seepage.
 - Wear **respiratory protection**—an N-95 respirator or better.
 - If you smell hydrogen sulfide (a rotten egg smell), leave the building and call your county extension office.
 - **Clean and disinfect all clothing and boots** after handling carcass-contaminated materials.
 - **Wash work clothes** separately from street clothes.
 - **Wash hands** thoroughly before placing fingers in mouth (nail biting, etc.).
 - **Shower and wash hair** thoroughly after handling carcass-contaminated materials.



Managing Regulatory/ Legal Liability Risks

- Seek clarity from states that have not specified if landfilling is allowed
- Obtain permits/approvals in advance of an outbreak
- Negotiate standards for bulk packagings
- Seek clarity on applicability of OSHA/CDC standards
- Seek industry consensus on differentiating between routine mortalities and diseased mortalities to protect disposal facility personnel

Risks

- Regulatory/Legal Liability ✓
- Health
 - Agricultural
 - Human Health
 - Environmental

Agricultural Risks and Management

1. Spread of Disease

- Economic losses
- Decreased food supply

2. Risk Management

- Countermeasures
- Strict biosecurity
- Secure disposal methods

Human Exposure Risks

- Individual Health
- Public Health – Pandemic

Routes of Human Exposure

- Inhalation
- Dermal Contact
- Mucous Membranes
- Ingestion

Managing Human Exposure Risks

- Waste Encapsulation/Barriers
- Personal Protective Equipment
 - Respiratory Protection
 - Fit Testing
 - Comfort
 - Medical Fitness
 - Training
 - Gloves, Goggles, Suits, Boots
- Hygiene
- Strict biosecurity
- Secure disposal methods

Environmental Risks

- Pathogen Transport Pathways
- Pathogen Survivability
- Disposal Practices

Pathogen Transport Pathways

- Air, Water, Soil
- Fomites
- Vectors

Pathogen Survivability

- Prions - Research at the University of Wisconsin/Madison suggests prions survive and may in fact flourish when buried. It is not known if prions would behave similarly in landfills.



- Bacteria - The publication: "Persistence of Bacillus anthracis spores and Clostridium botulinum and Destruction of Francisella tularensis and Yersinia pestis in Municipal Solid Waste Landfill Leachates" (EXTENDED ABSTRACT # 378 Wendy J. Davis-Hoover National Homeland Security Research Center, Office of Research and Development, United States Environmental Protection Agency, 5995 Center Hill Ave., Cincinnati, Ohio 452224, et al) found that spore-forming bacteria survived in landfill leachate for more than 20 weeks at test temperatures, and non-spore forming bacteria survived for less than 7 weeks.
- Viruses – Recent EPA study found AI virus survived more than 30 days at typical groundwater temperatures of 55 degrees F.



Disposal Practices

- Composting – effective inactivation?
- Incineration – aerial pathogen spread?
- Burial – groundwater contamination?
- Anaerobic Digestion – antibiotic bypass?

GAPS

Minimizing Environmental Risks

- Pathogen Transport Pathways
 - Dust Suppression
 - **Strict Biosecurity**
 - Vector Control
 - Encapsulation/Barriers
- Pathogen Survivability
 - Encapsulation/Barriers
 - Distance to Leachate Collection
 - Leachate Recirculation
 - Aerobic landfill practices (spore formers)
 - **Strict Biosecurity**
- Disposal Practices
 - Minimize Source
 - Minimize Migration Potential
 - **Strict Biosecurity**
 - Used disinfectants

Summary

- There are numerous disease control risks
- Regulatory and research gaps are challenges to risk management
- Effective risk management strategies (especially strict biosecurity) are readily available

Questions

