Addressing Cross-Sectoral Health Issues: A Collaborative Approach

Proposed Solutions

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REAGAN-UDALL FOUNDATION FOR THE FDA

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA (Foundation) is an independent 501(c)(3) created by Congress to advance the mission of the FDA to modernize product development, accelerate innovation, and enhance product safety. The Foundation works to advance regulatory science, support development and dissemination of reliable information, and facilitate engagement and information exchange.

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I. Introduction

At the request of the U.S. Food and Drug Administration (FDA), the Reagan-Udall Foundation for the FDA (the Foundation) led the project: *Advancing FDA Mechanisms to Address Complex Cross-Sectoral Health Threats*. This project aimed to identify opportunities to strengthen the Agency's capabilities to address cross-sectoral health issues, particularly at the intersection of human and animal health.

Examples of cross-sectoral health issues include:

1. Highly pathogenic avian influenza (HPAI)[1] – addressing avian influenza in poultry and dairy cattle while also protecting human health
2. The emerging threat of xylazine in the human non-medical drug supply[2] – measures to address xylazine in the human non-medical drug supply (e.g., scheduling as a Schedule III drug) could affect veterinary access to xylazine and animal health

The objective of this project was to generate actionable recommendations from FDA partner perspectives to strengthen preparedness and coordination across public health, agriculture, and regulators and to enable the FDA to improve its contribution to the efficiency and effectiveness of a cross-sectoral response. Responses include both short-term (e.g., an outbreak) or longer-term concerns, such as addressing emerging contaminants. To inform this effort, the Foundation conducted stakeholder interviews and roundtable discussions with experts actively engaged with FDA in previous cross-sector health issues, focusing on key challenges and potential solutions (Appendix B: Methodology). This report explores how to better integrate animal health and human health, and how to foster collaboration across organizations that support such cross-sectoral goals. Key issues are described in Section II and potential solutions are discussed in Section III.

The 1906 Pure Food and Drugs Act that gave rise to the FDA is rooted in collaboration between the FDA and the U.S. Department of Agriculture (USDA). Dr. Harvey Washington Wiley, named Chief Chemist of the USDA Bureau of Chemistry in 1882, oversaw investigations on the purity of food, and tested the impact of adulterated foods on human health. Dr. Wiley strongly advocated for the creation of the FDA, saw it materialized in the 1906 Act, and became its first Commissioner. This historic coupling is echoed today in the establishment of various integrated rapid response for all-hazards human and animal food emergencies, like the FDA Rapid Response Teams (RRT) Program (see Box 11) and the Coordinated Outbreak Response and Evaluation (CORE) Network (see Box 12). By name,

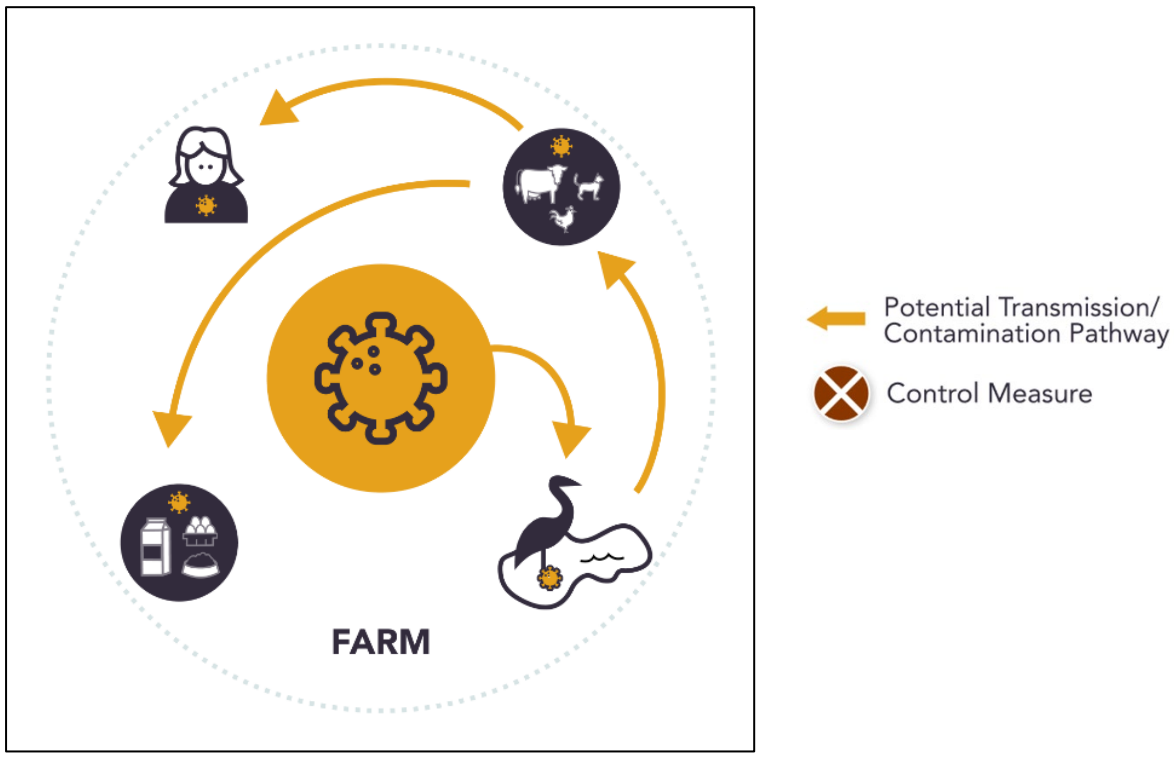
[1] U.S. Department of Agriculture (USDA). Avian Influenza. Animal and Plant Health Inspection Service. www.aphis.usda.gov. Published February 4, 2025. Accessed August 21, 2025. https://www.aphis.usda.gov/livestock-poultry-disease/avian/avian-influenza

[2] National Institute on Drug Abuse (NIDA). Xylazine. https://nida.nih.gov. Published April 21, 2022. Accessed August 21, 2025. https://nida.nih.gov/research-topics/xylazine

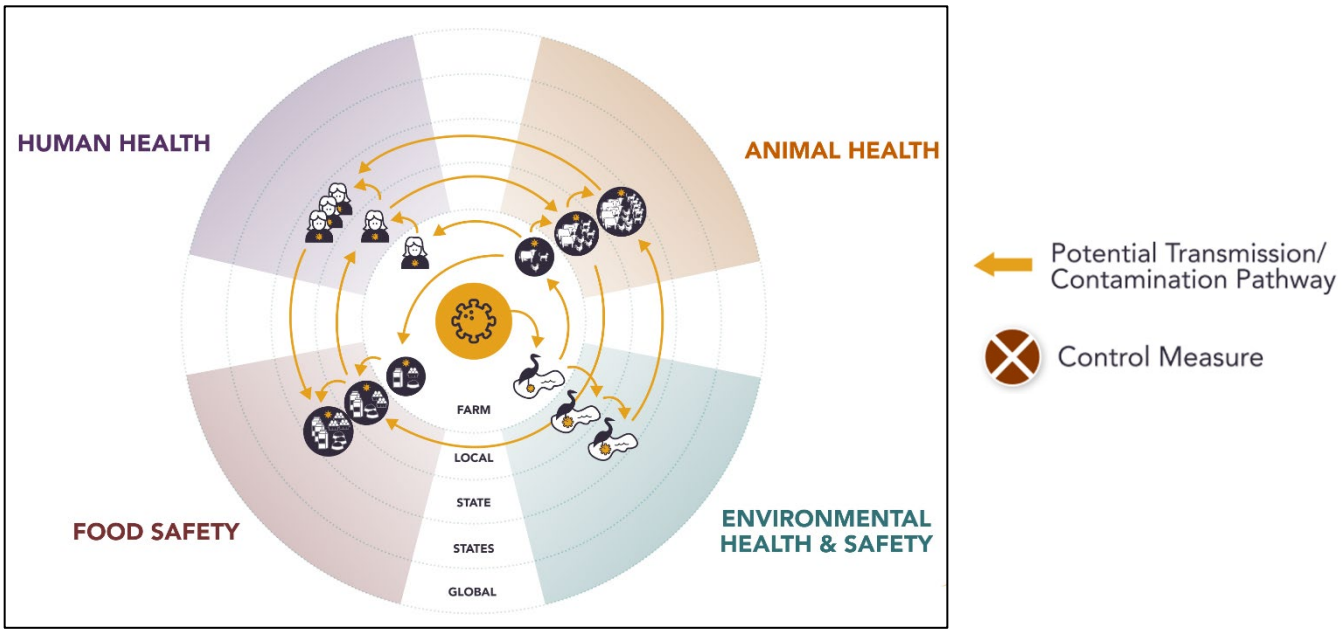
cross-sectoral events involve multiple sectors and FDA's response does not occur in a vacuum. As illustrated in Figure 1, upstream actions in one sector can have downstream consequences that affect not just that sector, but other inextricably linked sectors. While certain solutions are targeted for FDA, this document includes solutions that extend beyond the FDA's direct scope. This is intentional, reflecting the perspectives and challenges shared by all interviewed partners.

Figure 1. Cross-Sectoral Outbreak Response & Impact
Where Actions in One Sector can have Consequences in Another

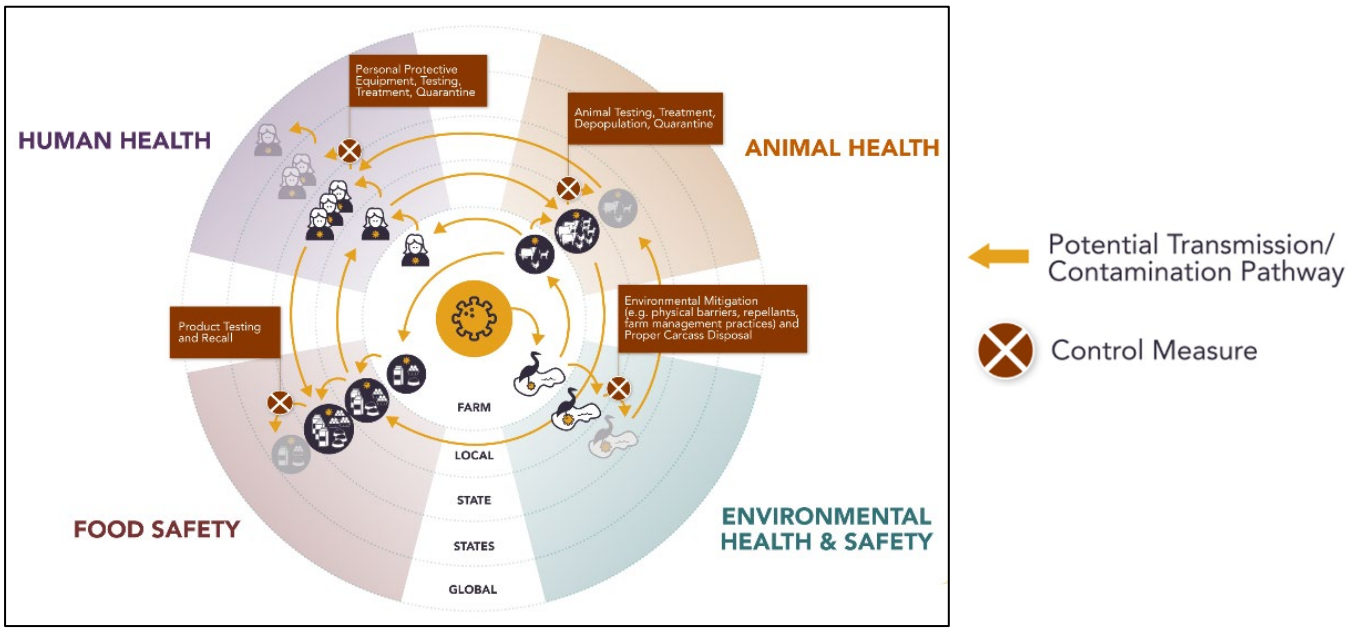
These figures illustrate multiple points of intersection across animal and human health. Upstream actions in one sector can have downstream consequences that affect that index sector, as well as others across multiple geographies. It illustrates the path a disease-causing agent and associated responses might take. It is not meant to depict any specific pathogen, transmission pathway, or noninfectious pathogen.



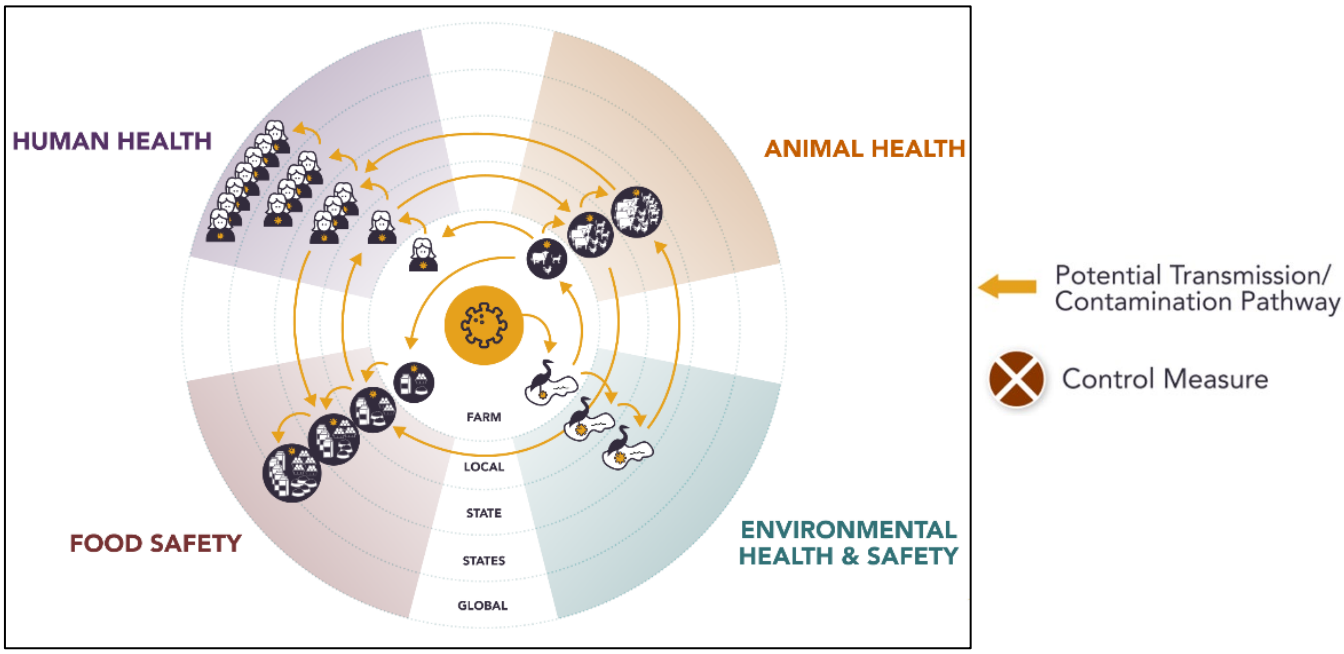
In this example is a farm with standing water. Following the gold arrows, an infected **migratory bird** can introduce a disease agent to the **farm environment.** A **hen** can come in contact with the contaminated environment, become infected, and lay contaminated **eggs.** At the same time, a farm **worker** may become infected from the infected hen during close contact in the work environment. This illustrates connections across **all four** sectors.



In zoonotic disease, humans are as important a transmission vector as they are a susceptible species. Infected workers can transmit (either directly or indirectly) to other humans or animals or contaminate food products. Humans may also become infected by food products or animals, or from the environments in which they work. The interests, incentives, and disincentives for all sectors must be considered when deciding which actions to take and when to support animal health, environmental health, human health, and business continuity.



For each of the sectors, control measures can have impacts that cross local and state lines and other sectors. *Food safety*: Control measures can limit the introduction of contaminated foods into the food supply. These include proper personal protective equipment for workers to prevent contamination of the food supply; and testing, surveillance, and quarantine to reduce infection and spread among affected and ancillary animals, humans, and environments. Food products need to be tested and if found unsafe, recalled to ensure that the available supply is safe and of high quality.



When no controls are present, spread is ongoing and continues impacts across sectors and geographies.

II. Challenges to Effective Cross-Sectoral Responses

The interconnectedness of human and animal health, along with shared environmental and food safety concerns, encompasses a range of perspectives. In response to health threats that cross multiple sectors and jurisdictions, different sectors have unique objectives, organizational cultures, incentives, disincentives, and governing rules. The complex regulatory frameworks involving multiple agencies at federal, state, and local levels lead to a challenging structure for addressing these cross-sectoral threats. This complexity can hinder collaboration, coordination, and clear, consistent communication. Conflicting objectives from various sectors, ambiguous roles and responsibilities, and ineffective communication strategies can undermine trust among stakeholders involved in responding to cross-sectoral incidents. A lack of trust can severely limit the effective planning and execution of a coordinated and successful response.

Addressing cross-sector health threats requires focused and coordinated strategies, evolving knowledge-sharing, collaboration, and contingency planning. For example, limited understanding of the epidemiology of a disease-causing agent can hinder surveillance and response efforts; insufficient knowledge about the effectiveness of protective measures can compromise the very individuals supporting surveillance and response. Knowledge sharing and collaboration can be further stymied by inadequate infrastructure and the presence of siloed, disparate data systems that hinder information sharing and reporting.

Responding to cross-sectoral health threats requires strategic and critical thinking and decision making under pressure. Tensions are naturally high during emergency situations as events unfold rapidly and there is pressure to provide accurate, effective, and defensible response. As such, if missteps occur, information is not always forthcoming; when transparency is lacking, trust can quickly erode.

Partner interviews explored the cross-sectoral complexity of the H5N1 outbreak response of 2024 as a case study. Gaps and challenges, both real and perceived, identified through partner interviews include:

1. Collaboration barriers and stakeholder engagement gaps contributed to a trust deficit.
2. Regulatory misalignment and limited utilization of authority appeared to slow the response.
3. Challenges with surveillance, testing, and data sharing exacerbated the trust deficit.
4. Industry hesitancy and suboptimal use of trusted messengers appeared to slow the response.

Stakeholders perceived significant gaps in coordination and communication among federal, state, and local agencies. Common observations included a lack of transparency, a trust deficit among involved parties (government and private sector), and hesitancy in response. These common observations serve as foundations for the solutions proposed in Section III.

The FDA alone cannot strengthen a response, as many of its actions are implemented through the states. A truly cross-sectoral response is inherently multi-agency, and therefore this document includes solutions that extend beyond the FDA's direct scope. This is intentional, reflecting the perspectives and challenges shared by all interviewed partners.

III. Proposed Solutions

The following proposed solutions aim to strengthen trust, collaboration, and communication across sectors while addressing the regulatory complexity involved in coordinated responses to cross-sectoral issues. The solutions aspire to leverage existing tools as a starting point to incorporate the unique combinations of partners (e.g., federal, state, local, industry) and situations presented by cross-sectoral health threats. Many proposed solutions can be implemented before a health threat emerges, establishing (or in some cases, strengthening) a foundational structure that can later be adapted to meet the specific needs of an evolving situation.

Solutions may be relevant across the following phases of a response:

- Pre-incident: Establishing frameworks, protocols, and relationships in advance
- During incident (early and active phases): Coordinating actions and sharing information in real time

- Post-incident: Applying lessons learned, improving systems, and restoring public confidence

Some proposed solutions will be specific to a particular phase, while others may span multiple phases to support a continuous and adaptive response.

We provide call-out/text boxes throughout the document to highlight solutions that are tied to existing frameworks and best practices.

It is essential that the culture of trust, collaboration, transparency, and communication be set early in any response effort. Goals and objectives should be clear and stated at the outset and leadership structure should set the tone for the collaboration, communication, surveillance, and research activities pre-, during, and post-response.

A. Understand, Clarify, Articulate, & Leverage Existing Regulatory Authorities & Intersections

Proposed Solution

1 Recognizing the inherent tension of multiple regulators at multiple levels, clarity and collaboration are essential. Existing authorities and intersections (i.e., agency authorities and where those authorities overlap within federal, state, and local jurisdictions) should be interpreted to foster flexible leadership and co-regulation across federal, state, and local levels for all response activities, including command, operations, planning, communications, surveillance, and research.

Where possible, reduce administrative burdens by suspending requirements that may impede a response (see Box 1). Consider adopting a more proactive approach, rather than a restrictive one, during urgent or emergency situations.

Box 1

Example of regulatory flexibility and declaration of emergencies in New York State: https://www.hanys.org/emergency/planning/docs/healthcare_emergency_guidebook.pdf

- Declaration of Emergency:
  - based on imminent peril to public safety (p. 53) – Local Declaration
  - based on Local governments unable to respond adequately (p.57) – State Declaration

Suspension and Modification of State Requirements (p.59)

Potential Pre-Incident Solutions

- Map legal authorities and responsibilities at the federal, state, and local levels and explore how those authorities can be employed during an outbreak response. Identify where Rapid Response Teams (RRTs) or similar structures are in place and tailor planning efforts to local capabilities, RRT connectivity, and regulatory contexts. In states lacking RRTs or similar frameworks, establish similar teams.
- Develop an inventory of federal and state requirements that may impede response efforts, such as the Paperwork Reduction Act.[3] Prepare an exemption proposal for consideration, outlining the circumstances under which these mandates could be lifted. Focus on reducing the administrative burden related to contracting and biosafety regulations, which could delay inspections.
- Refine existing federal and state frameworks for response activities, including testing, containment, quarantine, and release procedures. Utilize appropriate authorities to ensure more consistent implementation and enforcement. Establish and maintain a centralized inventory that is regularly updated with federal, state, and local legal authorities pertaining to testing, containment, quarantine, and release strategies.
- Develop a coordination protocol that defines expectations for testing, data sharing, and communication among federal, state, and local entities, aiming to promote consistency and accountability. Consider creating a designated coordinating body to oversee the dissemination of information, assessments, and data sharing to support proactive alignment between federal, state, and local agencies, as well as enhance future emergency preparedness.

Across Phase Solutions

Regulatory authorities and intersections should support the evolving needs of cross-sectoral health threats and facilitate coordination among local, state, and federal regulators. If there is no clear regulatory authority to facilitate this coordination, new regulatory pathways should be established. These pathways should create a flexible framework that allows for support among regulators, ensuring responsiveness to the evolving challenges posed by cross-sectoral health threats.

[3] About the PRA | a Guide to the Paperwork Reduction Act. pra.digital.gov. Accessed August 14, 2025. https://pra.digital.gov/about/

B. Sector Considerations

Proposed Solution

2

Cross-sector health issue response efforts should incorporate non-government agencies, organizations, and public health experts as key informants. Ensure that relevant and important non-federal entities are included. Consider establishing an industry advisory group that creates "sector snapshots."

Include public health and agriculture partners at the federal, state, and local level as key informants and collaborators in response efforts. Identify stakeholders with appropriate expertise across different animal and health sectors and jurisdictions. Adopt a posture of early engagement of partners. Leadership at the federal level should consider state or local jurisdiction structures.

At the Start and During an Incident

- Explore and understand sector-specific contexts quickly, at the start of an incident, and map key stakeholders, supply chains, and co-regulators.
- Develop a 'sector snapshot' to capture baseline knowledge of the impacted species or product sector (see Box 2).
- At the initial identification of an issue, consider impacts to animal and human health and their shared environment and emphasize a co-regulatory structure. Identify and leverage relevant industry associations, and sector experts within FDA and other federal agencies, for information-gathering and information-sharing.

Box 2

Stakeholders emphasized the importance of building rapid understanding of involved animal sectors during an emerging issue. A proposed early-stage "sector snapshot" process would help regulators navigate the practical realities of specific industries: Map stakeholders, regulators, and supply chains (e.g., animal movement, production cycles); Grid relevant regulatory structures and the operational culture of the sector; Use structured question sets, routed through trusted associations, to gather insights.

C. Resources

3

Proposed Solution

Leverage existing resources (e.g., funding, staff, tools, playbooks, templates) and collaborate across jurisdictions. Continue to invest in response preparedness.

These challenges are not new. Several playbooks attempt to address these issues, some with sample templates for Memoranda of Understanding (MOU), Data Use Agreements (DUA), protocols, and other tools, as well as mechanisms to bridge trust, communication, and coordination gaps.[4] To be effective, such playbooks need to be used, updated, and adapted to address the many potential permutations of cross-sectoral health threats.

Pre-Incident

- Map existing resources and encourage and incentivize the use of existing tools and funding mechanisms.
- Identify potential funding that may aid response efforts.
- Create mechanisms, such as cooperative agreements, to support state and local partners with surge capacity to supplement regular operations during health threats.

Box 3

Administrative processes can be barriers to accessing resources, such as grant funding, quickly or even at all.

During the COVID-19 pandemic, FEMA implemented a streamlined application process for public assistance funding.

Box 4

When engaged in a multi-agency response, to address the need for surge capacity, consider establishing a volunteer corps (see examples from Maryland and Virginia). Also consider what activities may be appropriate for volunteers and collect information regarding volunteer expertise. For example, retired field inspectors may be deployed to collect environmental samples, or the general public may be deployed to conduct surveys and data entry.

[4] FDA Rapid Response Teams. RRT BEST PRACTICES MANUAL Key Components of Effective Rapid Response for Food and Feed Emergencies Developed by the FDA Rapid Response Teams (RRTs).; 2017. Accessed August 14, 2025. https://www.fda.gov/files/newsroom/published/2017-RRT-Best-Practices-Manual-REDUCED.pdf

D. Communications

4

Proposed Solution

Establish a structure before an incident occurs, as part of a cross-agency coordination. During a response, confirm collaborations early, streamline coordination, and communicate early, often, and routinely.

a. Internal Communication

Pre-Incident

- Develop a communication mechanism and establish a glossary of commonly used terms that supports early awareness and facilitates cross-sector information exchange. This should be validated during pre-incident preparations. The communication liaison position should oversee the communication chain and coordinate communications among partners. Regulators should engage in regular interactions with one another and with the industries and sectors they regulate. Coordinate stakeholder calls to enhance efficiency and ensure consistent information sharing. Revitalize proactive and routine interactions among FDA and other federal agencies, as well as between federal and state agencies, and among federal, state, and local regulators and industries.
- Create a communication chain that encompasses federal, state, and local agencies, industry organizations, and technological support personnel. Ensure transparency regarding what information is shared, with whom, and why. The communication chain should be continuously updated as team members join or change. Prioritize inclusivity and ensure that new participants are quickly brought up to speed. Utilize existing long-term personal relationships across agencies, as the trust and communication established within these associations should be considered when developing the communication chain.

Across Phases

- At the start of an incident, emphasize transparency among co-regulators and affected sectors from the beginning. Align on key terminology for information sharing and public messaging early in the response. Share risk assessments and situational awareness, and establish real-time digital tools, such as dashboards, while ensuring the confidentiality of information. Clearly articulate the goals and objectives of the communication strategy.
- Update the goals and objectives of the communication strategy as needed. Illustrate the relevant regulatory structures at the state, federal, and local levels, and refresh this illustration along with the directory of relevant staff. Include ambassadors to help connect people and programs within the directory. Create a structure for real-time information sharing and leverage existing communication frameworks within FDA and other federal agencies and professional organizations.

- During the incident, maintain regular communication among regulators, industry groups, and other affected parties as the situation evolves. Collaborate on unified public messaging and conduct joint media efforts (e.g., briefings and statements) through associations. Response structures should adopt a unified public communication approach. Deploy joint communication plans among all regulators and key stakeholders, utilizing trusted messengers to deliver clear and consistent information to the public.
- Develop science-based messaging using standardized communication frameworks. Set clear expectations for research communications, emphasizing that basic and translational research takes time, and any progress needs to be clearly communicated across partners. Create common talking points regarding research processes, noting that research is a time-intensive and iterative endeavor.
- Finally, plan for post-crisis communication to share outcomes, lessons learned, and recommendations for long-term strategies.

Box 5

Operationalization of a communication framework: FDA CORE – ***Dedicated Communications Team.*** In 2019, CORE created a dedicated, embedded Communications Team to monitor the status of outbreak investigations and work with federal and state partners to determine when public communications are needed. FDA will warn the public when an outbreak is ongoing, when a specific product has been identified as a risk to consumers, and when there is actionable advice to provide.

b. Public Communication

At the Start and During Incident

- Clearly define and periodically update the goals and objectives of the public communication strategy. Communicate current scientific knowledge and related recommendations to the public, acknowledging that information and recommendations may evolve over time.
- When delivering communications on behalf of the response, consider using a consistent spokesperson, such as the communication liaison. Follow established communication channels and maintain collaboration to ensure unified public messaging in all communications. Develop and explore tabletop strategies for effective communication planning.
- In public communications, avoid jargon and translate regulatory and statutory language into easily understood messages. Consider message testing prior to public release to ensure that the messages resonate across audiences and jurisdictions. Leverage the abilities of national associations and nongovernmental organizations to do rapid testing with bidirectional message improvement.

- Maintain consistent messaging across FDA and other federal agencies, states, industries, and jurisdictions. Develop common talking points that emphasize the research process, the iterative nature of science, and how response efforts are based on the latest and most complete information available.
- Utilize trusted messengers. Leverage existing communication structures within regulatory and industry associations and employ trusted local officials to deliver messages effectively. Acknowledge to the public that the situation, along with the available information, will evolve over time.

E. Surveillance, Research & Data Systems

Proposed Solution

5

Create forums to engage partners in creating and adapting surveillance systems and research agendas and support critical thinking. A collaborative, cross-sector research agenda should address the goals of public health, animal health, environmental health, and business continuity. Address siloed data systems and enable information exchange.

Pre-Incident

- Assess the systems being used for collecting and reporting investigation data (e.g., bespoke systems, existing disease reporting systems) and constraints regarding ability to change formats or adapt to the situation. Upon documenting data constraints, develop potential solutions. Involve information technology (IT) teams at the start to map existing data systems, understand facilitators and barriers to data sharing, and data sharing agreements should be in place before an incident occurs. Additionally, adopt common data definitions where possible and develop translations where needed.
- Incentivize innovative approaches to address barriers to data sharing across FDA and other federal agencies, state and local government agencies, and across private and public entities. Identify and leverage existing tools for data sharing. Establish or support data use agreements (DUA) that prioritize data security and privacy at federal, state, and local levels. Understand gaps in data sharing and develop plans to fill those gaps.
- Document and illustrate relevant legal frameworks for data sharing utilizing specific types of use-cases (e.g., surveillance, control measure response, re-opening response, etc.).

At the Start and During Incident

- Initiate investigations at the start of an incident and quickly describe who, what, where, and when people and/or animals are affected. This description should inform the research questions needed to identify appropriate responses (e.g., treatment,

quarantine, recall). Investigation goals must balance the needs of human, animal, and environmental health with business continuity.

- Deploy interoperable (or at least mappable) data systems for coordinated analysis. Establish and support accepted collaboration platforms that facilitate document sharing and development. Align on common data definitions and continue to update shared dashboards for reporting and information sharing across industry, federal, and state partners.
- Revisit, and establish, where necessary, clear protocols and/or DUAs for data sharing and transparency, ensuring that results are shared promptly with relevant parties. Establish data-sharing agreements between federal and/or non-federal organizations to prevent delays in accessing critical information. Recognize that the molecular biology 'revolution,' combined with technology advances, has removed the silos between agriculture (animal health), public health (human health), and environmental health (soil, wastewater).

Across Phases

- Engage multi-sectoral and multi-jurisdictional groups to establish required surveillance needs and to address spotty surveillance. Once the surveillance mission, goals, and objectives are agreed upon, federal, state, and local agencies should partner with the industry being surveilled to establish reasonable actions and expectations.
- Articulate and execute surveillance goals and objectives. Identify who, what, when, and where illness is occurring, including common exposures and context. Update surveillance objectives as more information (through research) becomes available (e.g., number tested, quarantined, depopulated, recovered, dead). Determine minimum data elements and align on a standard reporting format and dashboard.
- Support sector-specific biosecurity[5,6] and biosafety[7] frameworks to ensure consistency across industries. An important driver of research and surveillance is understanding effective infection control measures. Understanding needs related to biosafety and infection control can interplay with activities under the FDA sphere of influence.
- Each partner should define and articulate their research and surveillance objectives, incentives, and disincentives. Involve front-line workers (those at the forefront of the

[5] UN Food and Agriculture (FAO) and World Health Organization (WHO) definition: "biosecurity is a strategic and integrated concept that encompasses the policy and regulatory frameworks (including instruments and activities) that analyse and manage risk in food safety, public health, animal life and health, and plant life and health, including associated environmental risk"

[6] FAO. FAO Biosecurity Toolkit. Food and Agriculture Organization of the United Nations; Rome, Italy: 2007. (accessed on 24 June 2025). Biosecurity Principles and Components. Part. 1; pp. 1–20. Available online: https://www.fao.org/3/a1140e/a1140e.pdf

[7] Beeckman DSA, Rüdelsheim P. Biosafety and Biosecurity in Containment: A Regulatory Overview. Front Bioeng Biotechnol. 2020 Jun 30;8:650. doi: 10.3389/fbioe.2020.00650

incident, e.g., farmers, ranchers) in developing the research agenda to incorporate an implementation perspective.

- Prioritize research that strengthens shared understanding of the issue and improves situation control. Develop a coordinated, cross-sectoral research agenda that includes:
    - Clear research objective(s)
        - Control measures and evaluation approaches for those measures
        - An integrated surveillance strategy
        - Assessment of the impact of disease and control measures on shared environments
    - Case definition(s)
    - Clear outcomes of interest
    - An approach to disseminate results
- Ensure data security. Protect information from unintended disclosures and develop a process for notifying partners and co-regulators of disclosures that may occur in response to Freedom of Information Act (FOIA) requests.
- Collaboratively Interpret results and articulate anticipated use of surveillance and research findings. Be clear about how results will be reported and align on what report(s) will be generated and how research results and reports will be distributed.

Box 6

Adopt a One Health Research Framework* that addresses questions at the intersections of human, animal, and environmental health with a focus on holistic, integrated approaches by multi-disciplinary teams at local, national, and global levels. For example, a Lassa fever prevention intervention which targets the environmental (e.g. improved household sanitation) and animal (e.g. rodent removal) domains may show promise, but omission of the human domain (e.g. education of nurses on disposal of contaminated material in hospitals) may result in a missed opportunity to achieve optimum results. At worst, siloed approaches may lead to unforeseen detrimental effects. In the Lassa fever example, removal of rodent populations may result in increased malnutrition among humans if rodents were a significant direct or indirect (i.e. prey for larger food source animals) source of protein for families living in affected communities. Key to incorporating a multi-sector research agenda on the federal level is including CDC's One Health Office in RRT.

**Lebov J, Grieger K, Womack D, et. al. A framework for One Health research. One Health. 2017 Mar 24;3:44-50. doi: 10.1016/j.onehlt.2017.03.004*

Box 7

Identify and leverage appropriate tools for data sharing as is done in Colorado using MOUs across state agencies. Strengthen interoperability between federal and/or state data systems to facilitate real-time tracking (involves understanding how different partners store data [e.g. legacy systems] and working towards a system that enables a pragmatic approach that minimizes additional effort beyond current workflows).

Ref: https://www.cdc.gov/field-epi-manual/php/chapters/data-collection-management.html#cdc_report_pub_study_section_10-using-routine-electronic-laboratory-reporting-to-support-outbreak-identification-and-evaluation-of-public-health-recommendations

F. Strengthen Response Structures, such as an Incident Command System (ICS)

6 **Proposed Solution**

Using a cross-agency structure, establish collaboration, communication structures, and a strategic communication plan before an incident occurs.

7 **Proposed Solution**

Establish trust. Build a shared understanding among agencies and stakeholders about goals and objectives, regulatory responsibilities, communication channels, and response roles. During a response, confirm collaborations early, streamline coordination, and communicate early, often, and routinely.

The response structure should be the hub of information and knowledge about available resources and the unified and final voice of the cross-sectoral response. It should identify the lead agency in an outbreak based on mission and statutory authority, recognizing that the lead agency might change as the outbreak evolves (e.g., moving from food safety-predominant issue to an animal health-predominant issue).

a. Mission

Establish a shared mission and align on clearly stated objectives. Articulate goals and objectives for the response across different stages of the response and set an expectation of goal setting for any functional working group.

Across Phases

- Establish a shared mission while recognizing the individual missions and statutory authorities of each participating agency and organization. This understanding helps identify where these missions converge and diverge, allowing for effective collaboration toward a common goal.

- Goal alignment facilitates operationalization of processes to achieve that goal and clarifies requirements for surveillance, research, and communications. Articulate the rationale behind regulatory asks, mandates, or response efforts to facilitate uniform understanding of the purpose and goals.

b. Players/Stakeholders & Roles and Responsibilities (Who should be in the room & what they should do)

The response structure should comprise leaders from federal, state, and local agencies, as well as information management and technology specialists. These leaders should be decision makers, who possess relevant subject matter knowledge, though they may not be deeply specialized. These leaders will rely on subject matter experts within the structure. A "Unified Command" enables multiple agencies or jurisdictions to collaborate effectively while maintaining their individual authority. For an effective response structure, it is essential to strengthen the co-regulatory stance and foster a shared understanding among the leadership team, FDA and other federal agencies, and stakeholders regarding the response roles of co-regulators.

Box 8

"The Incident Commander or Unified Command should clearly establish the command function at the beginning of an incident. The jurisdiction or organization with primary responsibility for the incident designates the individual at the scene responsible for establishing command and protocol for transferring command. When command transfers, the transfer process includes a briefing that captures essential information for continuing safe and effective operations, and notifying all personnel involved in the incident."

https://training.fema.gov/emiweb/is/icsresource/assets/ics%20review%20document.pdf

Pre-Incident

Before an incident occurs, several steps can be taken to establish a response structure and ensure readiness for rapid action when needed. By implementing these strategies, the response structure can enhance its effectiveness in managing complex incidents and responses.

- Inventory resources and develop a template for the response structure: Create or update existing templates for a cross-agency, cross-sectoral team that clearly defines leadership roles. Inventory existing expertise, resources, organizations, and jurisdictions to identify who will be involved and outline each position's role and responsibilities. Leverage formal and informal models that are already functioning well.

- Leverage existing best practices and have references at the ready so available when needed. Examples of best practices are provided in the callout boxes.

Box 9

FEMA ICS Manual
https://training.fema.gov/emiweb/is/icsresource/

Box 10

Multi-disciplinary/jurisdictional teams: RRTs are multi-disciplinary and multi-jurisdictional teams that leverage data use agreements (DUAs), memoranda of understanding (MOU), and other collaboration/coordination tools and legal frameworks (e.g. coordinating with the FDA, key state personnel must receive FDA commissions and/or credentials (or be operating under a valid 20.88 agreement) to receive critical information gathered during investigations) across jurisdictions. See the RRT Capacity and Mentorship Framework and RRT Best Practices Manual and RRT testimonials from state leads.

Box 11

Multi-disciplinary/jurisdictional teams: The CORE Signals and Surveillance Team is a multi-disciplinary/jurisdictional team that can be expanded to more fully include the animal sector. CORE "evaluates emerging outbreaks and disease surveillance trends, working in collaboration with CDC, FDA field offices, and state agencies."

Box 12

Internal coordination/collaboration tools: Agency for Healthcare Research and Quality (AHRQ) Situation, Background, Assessment, Recommendation (SBAR) Exercise

- Map Authorities & Responsibilities: Use the mapped authorities and responsibilities discussed in Section A-Potential Pre-Incident Solutions and tailor it to the health issue being addressed by the cross-sector response.

- Establish Common Baselines: Develop a common baseline[8] across FDA and other federal agencies and stakeholders related to regulatory landscapes, communication channels, and response roles to prevent reactive measures and responses. Conduct tabletop exercises involving co-regulators at the federal, state, and local levels to enhance understanding of the jurisdictional complexities involved.
- Identify Gaps: Recognize gaps in authorities and responsibilities across FDA and other federal agencies. Understand where gaps exist and plan how to address them for various types of outbreak responses. Additionally, identify where authority may exist, but inadequate resources hinder action, recognizing that statutory or regulatory authority alone may not be sufficient for an agency to perform its duties.
- Plan for Leadership Transfer: Prepare for leadership transitions with clear hand-offs as the primary concern evolves. Identify who is leading and the circumstances for transitions. Conduct tabletop exercises that simulate transfers of jurisdictional responsibility to level-set various scenarios. Delineate when it's time for one authority to relinquish control and create a threshold map indicating the points at which the leadership structure should change as the incident develops. Understand the indicators for leadership transfer and coordinate the transfer process among agencies.
- Create a Communication Liaison Position: Appoint a communication liaison to oversee the communication chain, which should include federal, state, and local agencies; industry organizations; and technology support personnel.
- Design Flexible Frameworks: Establish adaptable, scalable frameworks that can evolve in response to emerging threats, cover multiple regions, and integrate new stakeholders as necessary. Utilize visual tools like templates and flowcharts to clarify response pathways. Additionally, consider tailored training for regulators on industry-specific topics related to agribusiness, focusing on the economic and logistical factors that drive behavior.
- Institutionalize interagency collaboration through joint exercises and simulations: Tabletop scenarios that include federal, state, and local co-regulators; industry organizations; and other key players in an outbreak response such as producers, growers, and veterinarians. Incorporate scenarios that require information to travel bidirectionally through the chain of communication.

Box 13

Colorado Multi-Agency Coordination Center (MACC). The state of Colorado hosts multi-agency tabletop exercises with both state and federal partners in Colorado. (e.g. HPAI, FMD, PFAS).

[8] The common baseline would capture the regulatory landscape and document who has authority in the specific situation, existing methods for data gathering, data sharing, communication, and dissemination protocols.

At the Start and During an Incident

- Create and maintain a dynamic response structure. Populate the structure template with necessary government actors at the federal, state, and local level. Continue to identify existing expertise and gaps. Upon involvement of a new sector (human health, another animal species) identify and connect with relevant regulators and stakeholders, then integrate them (and their existing regulatory structures and cultures) into the response. Re-engage internal expertise and longstanding partners to avoid duplicative or misaligned efforts.
- Once leadership roles have been established, expand mechanisms like the RRTs[9] to include public health and agriculture partners at the federal, state, and local level to ensure that relevant and important non-federal entities are included. Create a technical working group to manage information and technology resources. Encourage substantive and practical input during decision-making to avoid simple validation of pre-made plans.
- Throughout the response, update cross-sectoral leadership teams and structures to clarify decision-making authority and streamline coordination with clear hand-offs as the primary concern evolves. Ensure that all the stakeholders are informed of any transfer. Along with transfer of leadership, continue to share incident command objectives.

Box 14

There may be a time when, in the spirit of the mission, the assigned lead may believe that another entity should be the lead. For example, when the primary concern in a response shifts from safety of human food to animal health. Such decisions should be documented and communicated to prevent authority gaps.

Box 15

Pressure test a plan by saying "what will fail?" Consider conducting a 'pre-mortem' exercise throughout the response to assess how the response can be improved.

Harvard Business Review. Performing a Project Premortem. https://hbr.org/2007/09/performing-a-project-premortem

[9] Human Foods Program. Rapid Response Teams (RRTs). U.S. Food and Drug Administration. Published 2024. Accessed August 14, 2025. https://www.fda.gov/food/integrated-food-safety-system-ifss/rapid-response-teams-rrts-human-and-animal-foods

IV. Conclusion

This project was intended to develop actionable recommendations to strengthen preparedness and coordination across public health, agriculture, and regulatory systems. The goal is to enable the FDA and other stakeholders to respond more efficiently and effectively to cross-sectoral health threats. Through stakeholder interviews and roundtable discussions with experts experienced in managing outbreak incidents, challenges were identified and potential solutions developed.

By exploring the often-overlooked connections between animal health, environmental health, food safety, and human health, this report underscores the importance of a truly integrated approach to cross-sectoral response. The findings presented here offer potential solutions for improving trust, transparency, and collaboration across sectors to better safeguard public health.

APPENDIX A: Glossary

Biosafety		Safety measures to protect laboratory personnel, the public, and the environment from unintentional harm caused by biological agents. This includes containment, PPE, etc.
Biosecurity		Procedures intended to protect humans or animals against disease or harmful biological agents.
Co-regulatory		A shared regulatory approach.
Cross-agency		Pertains to communications and actions across FDA and federal agencies.
Cross-sectoral		Work that involves multiple sectors, e.g., that involves both human and animal health.
Data Use Agreement	DUA	A contract that outlines the terms and conditions for sharing non-public or restricted-use data between two or more parties.
Incident Command System/Structure	ICS	A standardized, on-scene, all-hazards incident management approach.
Incident Management Group	IMG	A structured group of individuals responsible for coordinating and managing the response to an outbreak.
Memoranda of Understanding	MOU	An agreement between two or more parties outlining their intention to collaborate on a specific project or goal.
National Conference on Interstate Milk Shipments	NCIMS	A cooperative program involving the FDA, state regulatory agencies, and the dairy industry. The main goal of NCIMS is to ensure the safety of the nation's milk supply by establishing and maintaining uniform standards for milk production and processing.
Office of Pandemic Preparedness and Response Policy	OPPR	Leads and coordinates actions related to preparedness for, and response to, known and unknown biological threats and pathogens that could lead to a pandemic or to significant public health-related disruptions in the United States.
One Health	OH	Approach to research that ensures that human, animal, and environmental health questions are evaluated in an integrated and holistic manner to provide a more comprehensive understanding of the problem and potential solutions than would be possible with siloed approaches.
Rapid Response Team	RRT	Multi-agency, multi-disciplinary teams that operate using Incident Command System (ICS)/National Incident Management System (NIMS) principles and a Unified Command structure to respond to human and animal food emergencies.
Regulatory Science		A multidisciplinary field that ensures the safety, efficacy, and quality of products within regulated industries, including pharmaceuticals, medical devices, biotechnology, cosmetics, and food.
State Rating Authorities	SRA	Government agencies that oversee various aspects of state operations, including healthcare, public safety, and finance.
Unified Command		Enables multiple agencies or jurisdictions to collaborate effectively while maintaining their individual authority.

APPENDIX B: Methodology

To inform this effort, the Foundation conducted stakeholder interviews and roundtable discussions with experts actively engaged in previous outbreak responses, focusing on key challenges and potential solutions.

Work was conducted in three phases (Figure B1). During the first phase, twenty-four interviews were conducted with state and federal regulators, veterinarians, industry leaders, and professional societies. In phase two, the Foundation convened three stakeholder roundtables, each focused on a different theme tied to cross-sectoral outbreak coordination. A total of 19 individuals participated in at least one roundtable discussion. The final phase was a broader stakeholder discussion in which participants reviewed key takeaways and potential actionable solutions for FDA and its partners moving forward.

Figure B1

APPENDIX C: Interview, Roundtable, and Stakeholder Meeting Participants

Alcaine, Sam
Baggett, Jessica
Baldwin, Maggie
Ball, Richard A.
Basler, Colin
Beam, Stephen
Boring, Tim
Brihn, Gus
Brown, Jen
Burnsteel, Cindy
Califf, Robert
Chiaia, Lindy
Colonius, Tristan
Costin, Mike
Deeble, Eric
Detlefson, Clay
Feldpausch, Amanda
Fowler, Heather
Freeman, Lori T
Friedrichs, Paul
Fritz, Curtis
Garrison, Oscar
Golab, Gail
Grube, Steve
Hanselman, Miquela
Hansen, Honorata
Heard, Denise
Howard, Katie
Intihar, Tracy
Jonker, Jamie
Kansagra, Susan
Kohnen, Allison
Kromm, Michelle
Marston, Hilary
McCue, Casey
McCoig, Amber
McKinney, Ted
Meidenbauer, Kari
Middleton, Jamie
Mundschenk, Peter
Murphy, Mike
Poulsen, Keith
Prarat Koscielny, Melanie
Reardon, Joe
Rigdon, Carrie
Schroeder, Betsy
Shaw, Sheryl
Sorenson, Alida
Tebbetts, Anson
Thompson, Beth S.
Thornhill, Jonathan
Vander Plaats, Allison
Wagner, Roberta
Wineland, Nora

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