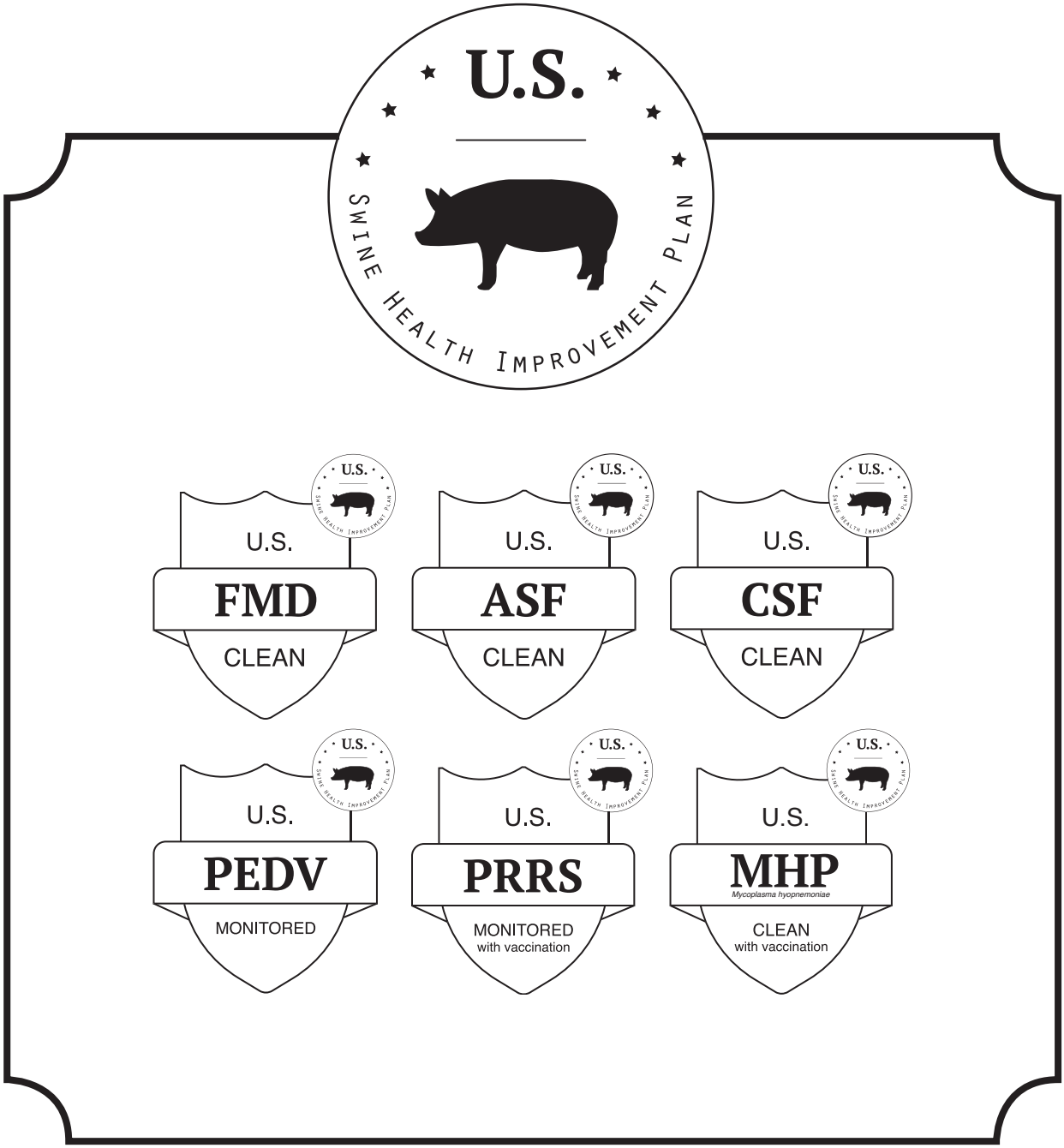
Case Study: Is it Time for an NPIP like Program for the US Pork Industry?



R.G. Main, P.K. Zaabel, K. Leedom-Larson, J.A. Roth, and J.J. Zimmerman
College of Veterinary Medicine, Iowa State University, Ames, Iowa

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Executive Summary

The US pork industry has long believed in "continuous process improvement" for all aspects of pork production, and the search for better nutrition, genetics, facilities, welfare, and health has driven the evolution of the industry over the decades. As a result, today's US pork industry is a world leader in production efficiency, product quality, and competitiveness. However, recent events have exposed two threats to this leadership position: (1) pathogens endemic to the US that resist traditional control strategies and (2) pathogens (trade impacting diseases) whose detection within our borders would immediately cause a ban of US pork from global markets and result in a seismic shift and economic hardship across the entire US pork industry.

Benjamin Franklin's words seem written for these circumstances: "By failing to prepare, you are preparing to fail." That is, it is our responsibility to prepare for the risks that threaten our future. But how should the industry move forward? Initiated in 1935, the National Poultry Improvement Plan (NPIP) is a poultry industry-driven entity designed to promote health and control targeted diseases among participating US poultry producers and slaughter facilities, and presents a possible model for the pork industry to learn from and consider. A study was commissioned by the Swine Health Information Center in 2018 with the aim of understanding the NPIP and assessing the potential for an NPIP like program to support the US pork industry. While there are many species- and industry-specific considerations, in the opinion of these authors, the findings of this study suggest that a "US Swine Health Improvement Plan," modeled after the NPIP, could provide an effective platform for addressing the major swine health related challenges, opportunities, and risks confronting the 21st century US pork industry.

Key Points:

- NPIP functions to safeguard, improve, and assure the health of US poultry and egg industries and enhance the position of the US poultry products in domestic and global markets.
- Participation in NPIP is voluntary and almost universal among commercial poultry and egg operations throughout the US.
- NPIP coordinates industry, state, and federal partners to address targeted poultry health issues. That is, NPIP brings together the expertise, capabilities, and influence of stakeholders and subject matter experts to determine the best strategy to achieve industry goals and establish industry standards.
- NPIP guidelines and health status classifications are used by US poultry and egg industry participants to represent their animals' health status and demonstrate freedom from specified trade and non-trade impacting diseases at points of sale, exhibition, interstate movement, and in support of international trade.
- Decisions on NPIP program content and direction are established through a majority vote of a congress of industry stakeholders at the NPIP Biennial Conference, approved by USDA APHIS leadership, and then published in the Code of Federal Regulations (9 CFR) and NPIP Program Standards document, i.e., a voluntary program recognized by Federal and State authorities across all 50 states. The 9 CFR and NPIP Program Standards document are updated as needed according to the decisions made at each NPIP Biennial Conference.

- Poultry and egg producers, hatcheries, slaughter facilities, and states determine their participation and which NPIP certifications they choose to pursue and obtain. Each state has an NPIP Official State Agency that is structured and operates in a manner that best meets the needs of the poultry and egg industries within their respective state.

- Globalization, multi-site production, and a marked dependence on export markets have changed the landscape of swine health and the impact of disease incursion on the US pork industry. In particular, trade impacting disease risks and recurring endemic diseases of high consequence are substantial challenges. Scalable solutions to these major and well-recognized challenges are largely beyond the immediate control or influence of any individual producer, processor, existing entity, or state.

- "Next generation" animal health assurance and area regional disease control solutions are needed to secure the future of the highly mobile and export-centric US pork industry. Experience affirms that solutions offered by government or industry, each acting independently, will not be timely, capable, or robust enough to keep pace with industry needs. State and federal animal health agencies lack the resources, capacity, and industry-specific know-how, while industry only solutions lack the coordination and authority to establish official standards and health status certifications across legally recognized areas, states, regions, or by well-defined segments of the commercial pork industry.

- NPIP's unique industry, state, and federal partnership provides a platform wherein industry stakeholders play a direct and on-going role in establishing poultry health standards, definitions, and policies across the US poultry and egg industries. The basic tenets and approach used by the NPIP could serve as a road map for pork producers and packers (slaughter facilities) interested in more directly and systematically addressing the major swine health issues of high consequence and better positioning the future of the US pork industry in the domestic and global marketplace.

Introduction

The National Poultry Improvement Plan (NPIP) is an industry, state, and federal partnership that has long played a central role in bettering the health of US poultry and improving the competitiveness of the US poultry and egg industries.[1] The objective of this communication is to report the findings of a case study of the NPIP undertaken in 2018. The primary aims of the study included: 1) seeking a more in-depth understanding of the NPIP, 2) clarifying how NPIP differs from and complements the Secure Food Supply Plans for the US poultry and egg industries, and 3) assessing the needs and potential applications for establishing a similar program for the US pork industry (e.g., "US Swine Health Improvement Plan"). Over the course of this study, it became apparent that–with the exception of those working inside the US poultry and egg industries, USDA APHIS (Avian Health Program), and state animal

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health officials–most animal agriculturalists and animal health specialists in the US know little about the NPIP. Herein, we provide a summary of findings, thoughts, and considerations for US pork industry stakeholders. Our hope is that this case study report can serve as a foundation for learned dialogue on this topic and question raised (i.e., Is it time for an NPIP like program for the US pork industry?) amongst US pork industry stakeholders.

Figure 1.

National Poultry Improvement Plan (NPIP) logo.

Figure 2.

Sampling of NPIP health status classification shields.

Overview of the National Poultry Improvement Plan (NPIP)

What is the NPIP?

NPIP is a cooperative industry, state, and federal program that serves to safeguard, certify, and represent the health of US poultry (Figure 1). NPIP health status classifications are the officially recognized standard by which US poultry and egg industry participants demonstrate freedom from domestic and trade impacting diseases (Figure 2).

The NPIP is an active and continuously evolving program implemented across all segments of the US poultry and egg industries.[1-6] The NPIP is coordinated by USDA APHIS Veterinary Services. It is informed and driven to meet the needs of the industries served, updated every two years by a formal congress of US poultry and egg industry stakeholders, administered by NPIP Official State Agencies, and implemented by NPIP program participants. NPIP approves diagnostic test methods, determines requirements for specified NPIP health status classifications, and certifies laboratories.

NPIP participants utilize the program to certify the health status of poultry flocks, slaughter plants (i.e., supply chains), products (i.e., eggs and chicks), and states in accordance to the definitions and standards set forth in the NPIP. NPIP health status

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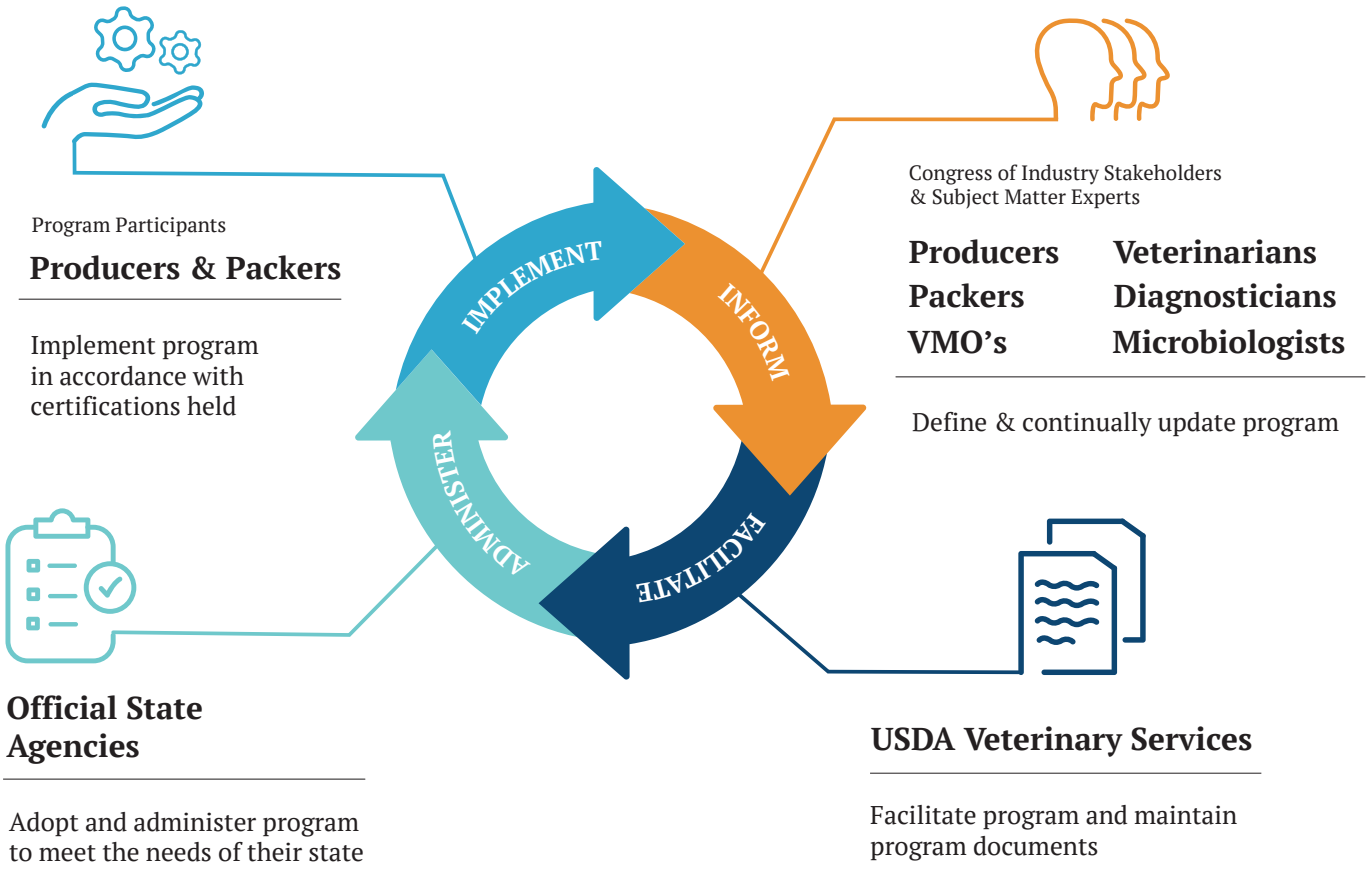
classifications are commonly referenced, used, or required at points of sale, exhibition, interstate movement, and in support of international trade. Participation in the NPIP is voluntary and almost universal among commercial operations across the US. Participant names and NPIP classifications held are listed on the NPIP website (www.poultryimprovement.org, see the NPIP Participants by State/Territory and the H5/H7 Avian Influenza Monitored Program tabs).

Why does NPIP work?

Figure 3, entitled Partnering to Safeguard and Better Animal Health, is our best effort to most succinctly describe NPIP's ongoing system of operations across the US poultry and egg industries. A formal congress of industry stakeholders and subject matter experts define and continually update the program. USDA APHIS Veterinary Services coordinates the program and maintains program documents.

Figure 3. Partnering to Safeguard and Better Animal Health



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NPIP Official State Agencies adopt and administer the program to meet the needs of the industries in their state. Program participants (i.e., producers and slaughter facilities) implement the program in accordance with certifications held. The circular nature of the relationships between the congress of industry stakeholders and subject matter experts, USDA Veterinary Services, NPIP Official State Agencies, and program participants provides for the continuous improvement and updating of the program over the course of time.

In these authors' opinion, this broadly inclusive and forward-looking operational structure has been a critical element to NPIP's success, relevance, and ability to meet the changing needs of the US poultry and egg industries. NPIP's operating structure enables the breadth and depth of species and industry specific know-how that exists across the full-spectrum of industry participants (e.g., producers, slaughter facilities, veterinarians, diagnosticians, microbiologists, and epidemiologists) to be utilized in deriving practical standards, definitions, and policies that serve to better poultry health and competitiveness of the US poultry and egg industries.

Participation in the NPIP has grown over time to now being almost universal among commercial operations. This critical mass of participation is unquestionably another essential element of NPIP's long-standing impact on bettering the health of US poultry and associated industries. NPIP's tripartite partnership (industry, state, and federal) and democratic approach used in the decision making process has a well-established record for delivering workable animal health assurance solutions for the US poultry and egg industries. Much of the burden and responsibility for bringing forth, debating, and directly addressing species- and industry-specific animal health issues of industry-wide significance are deferred from the federal and state veterinary medical officials and associated agencies working in isolation, to NPIP's formal congress of industry stakeholders and subject matter experts. This approach lends itself towards a sense of shared ownership in NPIP's officially recognized standards, definitions, policies, and health status classifications recognized across participants, participating states, USDA, and international trading partners.

NPIP's origins, focus, and evolution

During the early 1900s, bacillary white diarrhea, caused by Salmonella enterica subspecies enterica serotype Pullorum (Salmonella Pullorum–also known as Pullorum Disease), killed 80% or more of the chicks in affected flocks in the United States. In 1913, a test was developed that identified infected birds so they could be eliminated from the flock. Individuals in the poultry industry soon recognized that the most effective way to control Pullorum Disease would be through a coordinated, nationwide effort. This effort led to the development of the NPIP which officially began in 1935.

The NPIP initially focused on testing for Pullorum Disease and improvement of breed-based genetics. Testing for Pullorum Disease and a similar disease, Fowl Typhoid (Salmonella Gallinarum), followed by removal of reactors, has been a very successful ongoing segment of the NPIP. Both diseases have been eliminated from the US commercial poultry industry, but this testing remains a cornerstone of the NPIP.[7]

NPIP's primary focus, dating back to its origins, centers on certifying Breeding Poultry as free of specified vertically transmitted diseases of high consequence. The number of diseases within NPIP's scope, and associated health status classifications for Breeding Poultry, has expanded over time (Figure 4).[7] The current NPIP classifications for the various types of Breeding Poultry are shown in Figure 5.[1] These pathogen-specific NPIP health status classifications are broadly recognized and represent the foundation by which the health status of Breeding Poultry and their offspring are characterized at points of sale, exhibition, and for interstate and/or international commerce.

While NPIP's history and mission are deeply rooted in the control and elimination of vertically transmitted diseases in Breeding Poultry, NPIP's scope expanded significantly in 2006 to include an "H5/H7 Avian Influenza Monitored" classification. This classification was the first (and still the only) NPIP classification for Commercial Poultry (Figure 6).[1] A disruptive outbreak of a lowly pathogenic H7N2 Avian Influenza Virus (AIV) in the Shenandoah Valley and North Carolina in 2002, a more isolated outbreak of a highly pathogenic H5N2 AIV (HP-AIV) in Texas in 2004, coupled with increasing AIV-related concerns around the world, and the growing

1935	Salmonella Pullorum
1954	Fowl Typhoid
1965-1966	Mycoplasma Gallisepticum
1974	Mycoplasma Synoviae
1983-1984	Mycoplasma Meleagridis
1989	Salmonella Enteritidis
1999	Avian Influenza
2006*	H5/H7 Avian Influenza Monitored
2016	Biosecurity Principles & Compartmentalization
2018	Exotic Newcastle Disease

* 1st Classification for Commercial Poultry

Figure 4.

Expanding number of NPIP health status classifications and efforts over time.

Figure 5. NPIP health status classifications for Breeding Poultry.

	Multiplier Egg-Type Chickens	Multiplier Meat-Type Chickens	Turkeys	Hobbyists and Exhibition Waterfowl, Exhibition Poultry, and Game Birds	Ostrich, Emu, Rhea, and Cassowary	Primary Egg-Type Chickens	Primary Meat-Type Chickens	Meat-Type Waterfowl
Pullorum-Typhoid Clean	✓	✓	✓	✓	✓	✓	✓	✓
Avian Influenza Clean	✓	✓			✓	✓	✓	
H5/H7 Avian Influenza Clean			✓	✓				✓
M. Gallisepticum Clean	✓	✓	✓	✓		✓	✓	
M. Gallisepticum Monitored		✓						
M. Synoviae Clean	✓	✓	✓	✓		✓	✓	
M. Synoviae Monitored		✓						
M. Meleagridis Clean			✓					
S. Enteritidis Clean	✓					✓	✓	
S. Enteritidis Monitored		✓						
Salmonella Monitored				✓			✓	✓
Sanitation Monitored		✓	✓					

Key: Breeding Poultry

✓ Flocks and Product Requirement

◯ State Requirement

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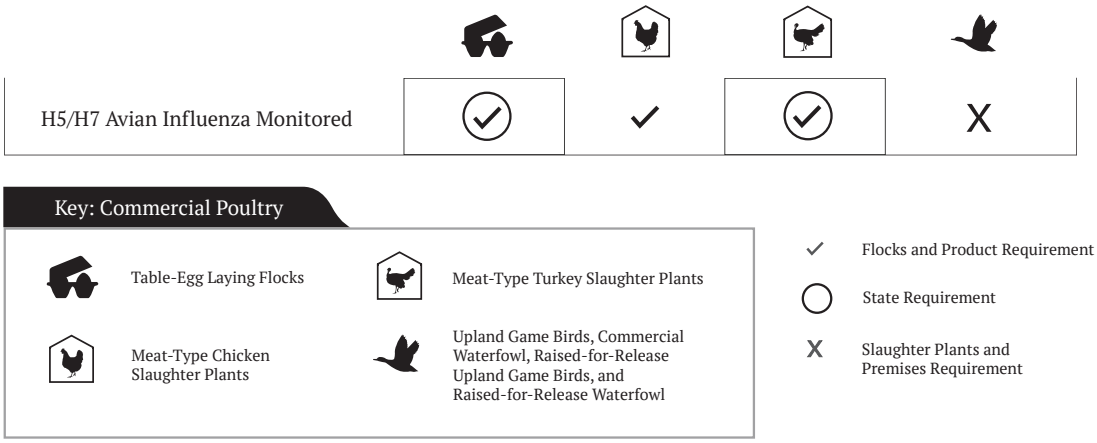


Figure 6.

NPIP health status classifications for Commercial Poultry.

importance and value of export markets to the US poultry and egg industries, each contributed to this substantive change in NPIP's scope.

Because HP-AIV is considered a foreign animal disease, response plans are outside the scope of the NPIP. Nevertheless, the H5/H7 Avian Influenza Monitored classification provides participating Commercial Poultry operations, in states and regions not affected by an AIV event of significance (i.e., HP-AIV or a lowly pathogenic AIV), an officially recognized mechanism for demonstrating freedom from disease. Thus, the H5/H7 Avian Influenza Monitored classification held by meat-type chicken and turkey slaughter plants, commercial table egg laying operations, and states have played a primary role in helping sustain export markets and interstate commerce from unaffected regions during times of an AIV outbreak of significance affecting Commercial Poultry in the US.

NPIP has an active, organized, scientific, thorough, and democratic process for vetting proposed modifications and updating the NPIP. Recent updates of significance (Figure 4) include the requirement that commercial operations have a biosecurity plan in place (2016), and more recently, Virulent Newcastle Disease (vND) was introduced into NPIP program language (2018).[8] The first update was prompted by lessons learned from the 2015 HP-AIV outbreaks centered in the upper Midwest, and the latter by concerns over the recent vND outbreaks in California and to broaden the scope of NPIP's compartmentalization efforts.

Consistent with the guidelines set forth by the OIE (World Organization for Animal Health), NPIP has also recently been providing leadership towards developing a pathway for poultry operations to become officially recognized "compartments". Through this effort, a primary breeder operation (Aviagen®) became the first commercial livestock or poultry operation in the US to become an officially recognized compartment (2018). This status positions operations to export their offspring or products during a time of animal health crisis in the US or within their state. Other US primary breeder operations that distribute poultry genetics domestically and abroad are further exploring the opportunity to become officially recognized compartments to support the future

of their operations. Commercial Poultry are not presently pursuing compartmentalization consistent with OIE guidelines due to the costs, complexities, and feasibility of achieving this high standard. A more complete description of OIE compartmentalization guidelines are available in the OIE's Terrestrial Animal Health Code Chapter 4.4 (Application for compartmentalization) on OIE's website (oie.int). NPIP's management guidelines and protocols for Avian Influenza compartmentalization for Primary Poultry Breeding Companies may also be another compartmentalization reference of interest (see NPIP Program Standards – Subpart F, available on NPIP website, poultryimprovement.org).

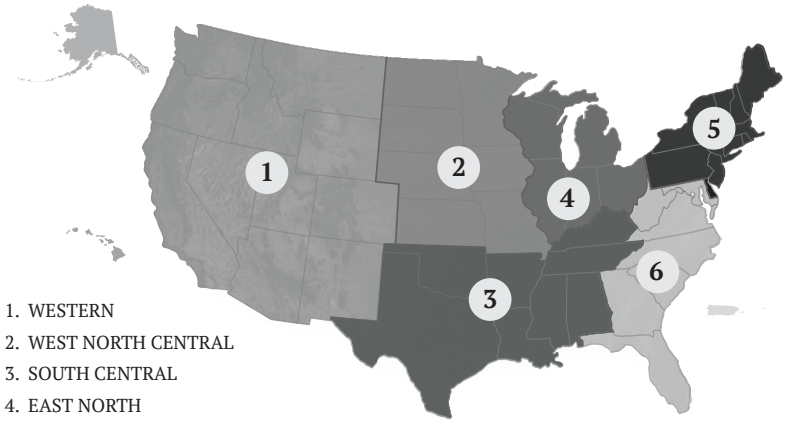
It should be recognized that compartmentalization, which provides a mechanism to demonstrate freedom of disease from specific sites or operations within affected regions, is distinct from, and far more difficult than, regionalization. Regionalization involves demonstrating evidence of freedom of disease in unaffected, or no longer affected, areas, or regions. The US and other trading partners have a history and precedent for respecting and honoring regions within an affected country as free of specified diseases. Disease control efforts within the US, and throughout the world, have long designated health status by region (counties, states, or provinces) over the course of large-scale disease control or eradication efforts.

NPIP administration and implementation

National administration

The NPIP national headquarters and its five USDA APHIS employees are located in Conyers, Georgia. Locating and operating NPIP's small national administrative office in a poultry centric region of the country is an issue of importance to US poultry and egg industry stakeholders. Many international visitors and trading partners visit Georgia (e.g., NPIP national headquarters, Georgia Poultry Lab Network, Poultry Diagnostic and Research Center at the University of Georgia, USDA Southeast Poultry Research Laboratory, and a myriad of commercial poultry operations) to learn and better appreciate the poultry health control programs and poultry and egg industries in the US. The NPIP Senior Coordinator (the senior NPIP administrator) provides leadership for NPIP activities at the national level. The NPIP General Conference Committee consists of elected individuals (one at-large member and six regional representatives) who provide oversight and industry representation in the NPIP administration (Figure 7).

Figure 7. NPIP's General Conference Committee Regions



1. WESTERN
2. WEST NORTH CENTRAL
3. SOUTH CENTRAL
4. EAST NORTH
5. NORTH ATLANTIC
6. SOUTH ATLANTIC

AT- LARGE

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General Conference Committee members are volunteers elected to 4-year terms at the NPIP Biennial Conference and serve as the official advisory committee to the US Secretary of Agriculture on matters pertaining to poultry health. The NPIP Senior Coordinator reports directly to the USDA APHIS Director of Avian, Swine, and Aquatic Health Programs. The national NPIP office provides support to, and coordination among, the NPIP Official State Agencies.

The NPIP Technical Advisory Committee consists of a diverse group of subject matter experts from across the US that play a substantive role in vetting, and in some cases, crafting proposed updates to the NPIP. The Technical Advisory Committee consists of veterinarians, diagnosticians, microbiologists, and epidemiologists and has working groups within it often focused on specific pathogens, health status classifications, or particular areas of the NPIP.

State administration

The NPIP Official State Agency is the state authority recognized by the USDA to cooperate in the administration of the NPIP. Determination for participation in the NPIP is on a state-by-state basis. Currently, all 50 states and one US Territory (Puerto Rico) have a memoranda of understanding with USDA APHIS and participate in the NPIP. Each NPIP Official State Agency must implement the NPIP as stated in the Code of Federal Regulations (9 CFR) and NPIP Program Standards document. However, participating states can adopt and follow additional state-specific poultry health-related requirements that extend beyond the NPIP associated claims, requirements, and standards, in accordance with their state's animal health administrative rules. States commonly reference, adopt, or defer to the definitions and standards set forth by NPIP.

While NPIP is nationwide in scope, each NPIP Official State Agency operates and administers the program in a manner that best meets the needs and interests of their state's poultry and egg industries. This includes working with their respective poultry and egg industry association(s), state animal health officials, and state department of agriculture, to determine an operating and personnel reporting structure that works best for their state. NPIP Official State Agencies are typically housed within the state animal health official's office, state department of agriculture, state poultry and egg industry association, or state-affiliated veterinary diagnostic laboratory. The "heavy lifting" involved in executing the NPIP is done by the NPIP Official State Agencies and NPIP participants. The NPIP Official State Agency maintains a list of active NPIP participants and database of all participants' site-specific information, verifies participants are meeting the specified requirements of the classifications held or being applied for, and maintains an up-to-date list of the NPIP classifications held by each participant in their respective state.

NPIP definitions, program standards, and documents

NPIP program definitions and affiliated documents are housed and detailed in Title 9 of the US Code of Federal Regulations (9 CFR) Parts 56, 145, 146, and 147 and the NPIP Program Standards document. The NPIP maintains links to these documents on its website (www.

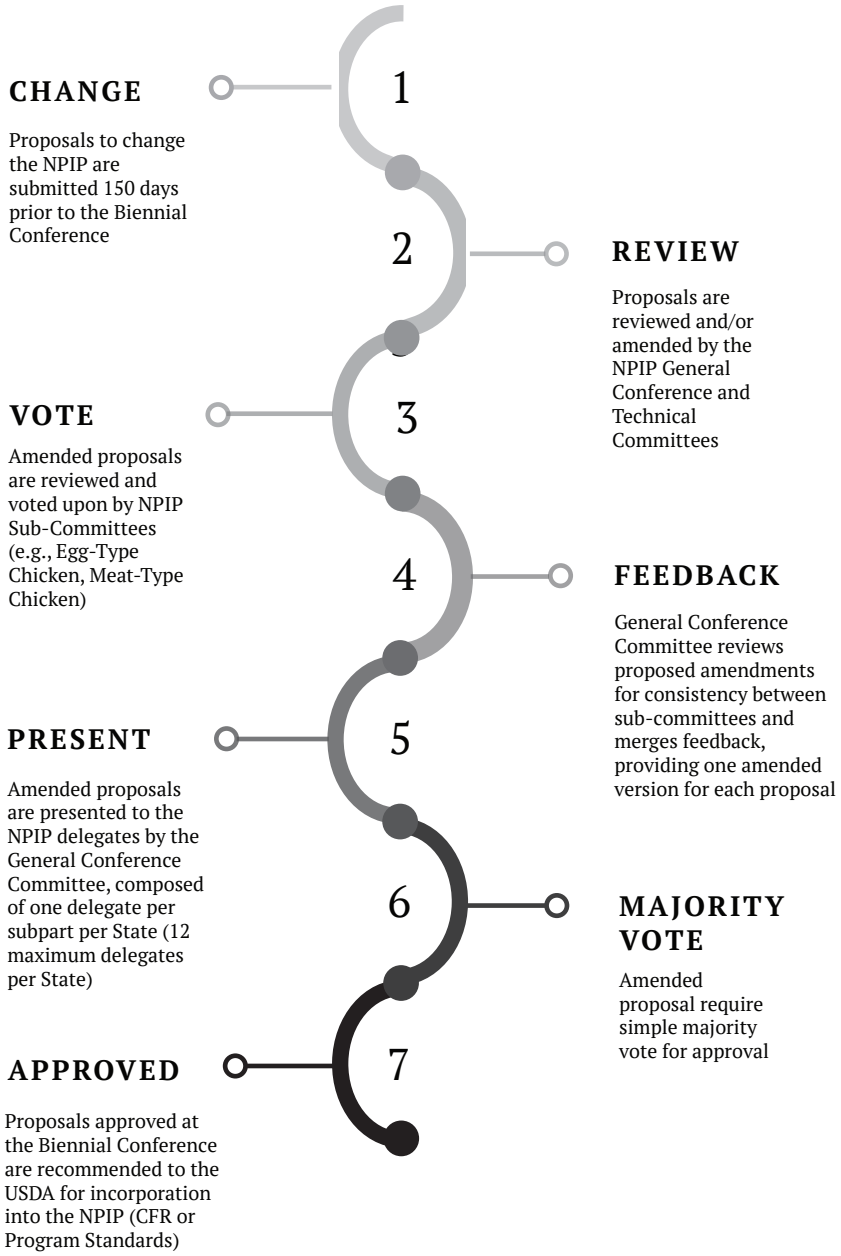
poultryimprovement.org).[1] NPIP program requirements to achieve each of the specific NPIP health status classifications are given in the 9 CFR for Breeding Poultry (Part 145) and Commercial Poultry (Part 146), respectively. The details of the NPIP-approved test methods and NPIP-related sanitary standards have historically been maintained in the 9 CFR (Part 147, subparts A – Blood testing procedures, B – Bacterial examination, C – Sanitary procedures, and D – Molecular examination procedures). More recently, the NPIP Program Standards document was created as a stand-alone document outside of the 9 CFR in an effort to streamline the process of keeping provisions current with the best technologies and practices available.

How is the NPIP updated?

Proposed updates to the NPIP are reviewed and brought forward to a vote by a congress of US poultry and egg industry stakeholders at the NPIP Biennial Conference. Proposed changes must be submitted to the NPIP National Administrative Office at least 150 days prior to the NPIP Biennial Conference. Proposals are shared and reviewed by the NPIP Administrative Staff, NPIP Official State Agencies, NPIP General Conference Committee, and the appropriate subject

Figure 8.

Process for making updates to the NPIP



Overview of National Poultry Improvement Plan (NPIP)

matter experts in the NPIP Technical Advisory Committee prior to the Biennial Conference. NPIP Official State Agencies commonly host stakeholder meetings seeking input on proposed updates of significance within their state prior to the NPIP Conference. Similarly, NPIP Official State Agencies commonly formulate and discuss proposed updates to the NPIP among their peers and the NPIP National Administrative Office prior to the Biennial Conference. To provide some context to the amount of updating to the NPIP that occurs, 42 proposed updates to the 9 CFR and Program Standards were considered at the 2018 NPIP Biennial Conference. Thirty-six passed as amended, 6 proposals failed.[8]

The NPIP Biennial Conference functions as a formal, and extraordinarily efficient, legislative body. State delegates representing one or more segments (subparts) of the US poultry and egg industries consider, discuss, amend, and vote upon proposed changes to the NPIP (Figure 8).[8] The NPIP has various subparts that address provisions specific to a given segment of the US poultry and egg industries. A listing of the various subparts for Breeding Poultry (9 CFR, Part 145) and Commercial Poultry (9 CFR, Part 146) are listed in Figure 9. Voting rights are specified for each state and subpart. Delegates can only cast a formal vote on proposals with a direct impact on the specific subpart of the US poultry and egg industries they represent. A pictorial of the NPIP update process has been included for reference (Figure 10). If industry-related issues arise, the NPIP General Conference Committee can approve proposed changes to the NPIP on an interim basis, in accordance with standards set forth in the 9 CFR. However, all such interim changes are brought forth for official review, consideration, and vote at the next NPIP Biennial Conference.

Figure 9.

Subparts of NPIP for Breeding and Commercial Poultry

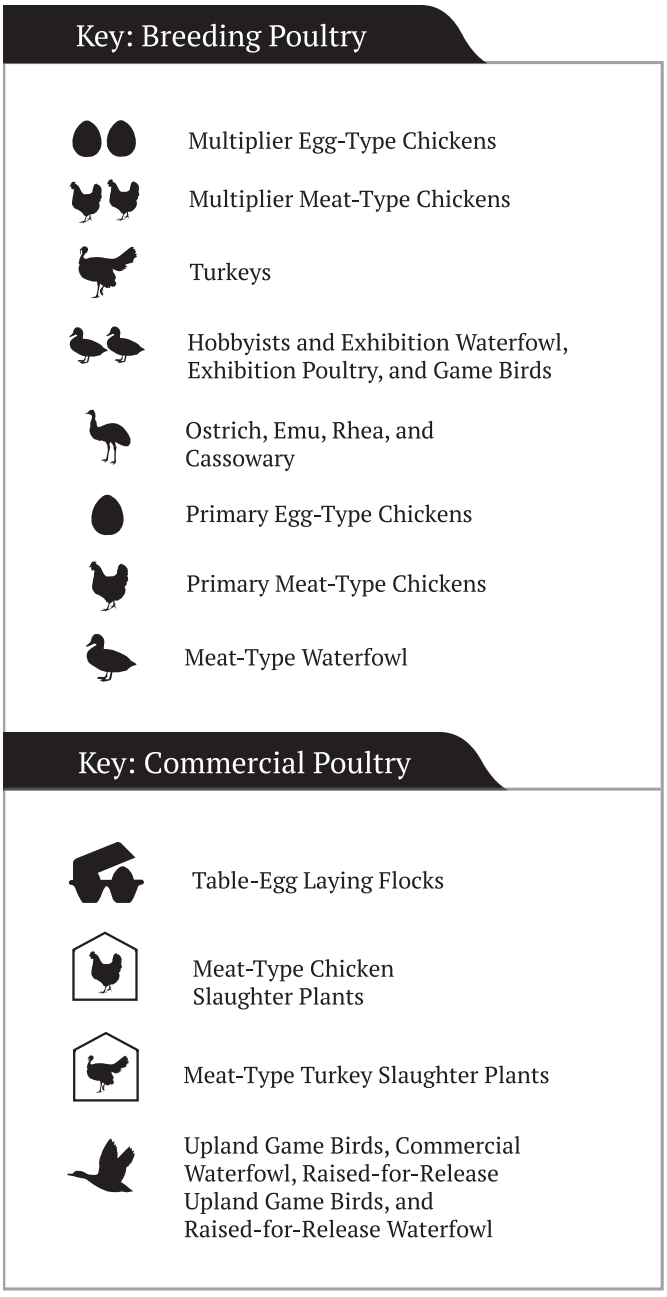


Figure 10.

NPIP Biennial Conference is a formal congress of US poultry and egg industry stakeholders.

Once proposals are approved at the NPIP Biennial Conference, the NPIP National Administrative Office puts together a work plan to submit to USDA APHIS, which is then posted in the Federal Register. The USDA maintains the right to accept or reject the recommendations from the NPIP Biennial Conference. If a proposal is not accepted, USDA's reason(s) for rejection is published in the Federal Register, after which the poultry industry can provide comment. In addition, if USDA approval for a proposal is uncertain, the NPIP, state animal health officials, and poultry and egg industry stakeholders, may push forward a corresponding resolution that supports the proposal through various committees at the annual US Animal Health Association (USAHA) meeting. The acceptance rate of proposed updates to the NPIP approved at the NPIP Biennial Conference is extremely high. Rare instances of non-acceptance may include such things as proposed updates that infer USDA financial commitments that exceed the funds available. Such constraints are generally well known and openly discussed throughout the vetting process prior to, and at, the NPIP Biennial Conference.

NPIP funding

Funding for the administration and implementation of the NPIP within each state (e.g., NPIP Official State Agency program administration, as well as NPIP participant compliance and diagnostic testing-related costs) varies significantly among states, but commonly comes from multiple sources (e.g., NPIP participants, USDA APHIS cooperative agreements, state departments of agriculture, and state poultry and egg industry organizations). While NPIP Official State Agencies vary substantially based upon the size and composition of the poultry and egg industries and maturity of the NPIP program in their respective state, states would commonly have 1 to 3 full-time equivalents

Overview of National Poultry Improvement Plan (NPIP)

(personnel time) involved in administering the NPIP their state.

The NPIP national headquarters and its core administrative functions are funded by federal dollars under the Avian Health Programs budget line for USDA APHIS. It costs approximately $500,000 to run the NPIP national administrative office each year. Federal dollars (usually $50,000 to $150,000) provided to NPIP Official State Agencies through cooperative agreements are commonly used to support some level of NPIP-associated surveillance testing, participant training, and outreach.

There are also some examples of the national industry organizations providing some funding to improve the overall performance and capabilities of the NPIP across the country. The US Poultry and Egg Association recently funded the development of a web-based national NPIP database which is being used by the NPIP Official State Agencies to electronically permit the movement of poultry and hatching eggs between states.

How does the NPIP differ from or complement the Secure Food Supply Plan for the US poultry and egg industries?

The motivation to develop what are now known as the Secure Food Supply Plans (i.e., Secure Poultry, Secure Pork, Secure Milk, and Secure Beef) began with the Iowa Egg Producers' interest in establishing the ability to move and sell eggs from AIV-negative premises located within a HP-AIV control area. Drs. Jim Roth and Darrell Trampel, at the Iowa State University College of Veterinary Medicine, worked closely with the Iowa Egg Producers, Iowa Department of Agriculture and Land Stewardship (Dr. David Schmitt, State Animal Health Official), and the USDA to develop and implement a voluntary program called "FAST Eggs." This pilot program was initiated in Iowa in 2008 and eventually evolved into the current suite of Secure Food Supply Plans.

The Secure Poultry Supply Plan aims to provide flocks within HP-AIV control areas a mechanism to demonstrate freedom from AIV, and safely move non-affected poultry and egg products out of HP-AIV control zones to slaughter, sale, or on for further growing. Specifically, the Secure Poultry Supply Plan provides guidance on testing, biosecurity, and other reporting requirements necessary to demonstrate freedom from AIV at a level of confidence sufficient for state animal health officials to permit movement of poultry or egg products out of a HP-AIV control area. Overall, the Secure Food Supply Plans are technical documents designed for use and reference in preparation for and during an animal health crisis. The scope of the Secure Food Supply Plans for the US poultry industry have targeted foreign animal diseases (FADs), and HP-AIV in particular. The term 'trade impacting disease' (TID) will be used to be synonymous with 'foreign animal disease' (FAD) for the remainder of this document. The Secure Food Supply Plan documents are housed and maintained by the Center for Food Security and Public Health at the Iowa State University College of Veterinary Medicine.

Decisions to use standards set forth in the Secure Food Supply Plans to permit the movement of animals or animal products out of a trade impacting disease (TID) control area during a time

of animal health crisis most generally reside with the state animal health officials (state departments of agriculture) in the affected states, including the states of destination. Such decisions are made on a state-by-state basis and are commonly situation-based decisions made in the midst of the animal health disease crisis. Due to the HP-AIV outbreaks, poultry and egg producers, poultry veterinarians, and state animal health officials in the affected regions (with HP-AIV control areas), are the only segment of the greater US livestock and poultry industries with any first-hand experience in utilizing elements of the Secure Food Supply Plans during a formal trade impacting disease (TID) response. The pre-movement AIV PCR testing requirements, along with a lack of observable clinical signs, have been the primary elements of the Secure Poultry Supply Plan utilized to support the permitted movement of birds or eggs from AIV negative premises in HP-AIV control areas to date.

In contrast to the Secure Food Supply Plans, the NPIP is a long-standing industry, state, and federal partnership (i.e., a working organization with officially recognized documents and health status classifications and a network of ongoing implementation and certification) that provides common definitions and standards toward certifying the health of participating poultry flocks, products, and slaughter facilities across the US. The scope of NPIP health status certifications include both TIDs and non-TIDs. Thus, the NPIP provides a nationally and internationally recognized platform for flocks, slaughter facilities, and states to demonstrate freedom from a growing number of specified diseases in both peacetime and in times of animal health crisis. For example, the NPIP AIV certifications provide the foundation necessary for larger areas, regions, industry segments (subparts) and states to be recognized as H5/H7 Avian Influenza Monitored or Avian Influenza Clean. The recognition of such industry segments (subparts) and regions is a critical element in better positioning US poultry flocks and slaughter facilities in non-affected regions to maintain access to export markets and streamline interstate commerce during a time of animal health crisis in the US.

It should be appreciated that NPIP health status certifications are distinct from (but complementary with) the Secure Food Supply Plans for the US poultry and egg industries. The Secure Food Supply Plans aim to help sustain continuity of business by keeping unaffected animals and product moving through the production cycle and onto market during the time of an animal health crisis. In contrast, the NPIP provides a well recognized platform for demonstrating freedom from AIV across flocks, hatcheries, slaughter facilities, states and regions in support of helping non-affected regions, industry segments (subparts), or states access to export markets and facilitates ongoing interstate commerce. A more complete listing of some key differences, similarities, and synergies between the NPIP and the Secure Poultry Supply Plan are shown in Figure 11.

Figure 11 on next page

Overview of National Poultry Improvement Plan (NPIP)

Figure 11. Differences, similarities, and synergies between NPIP and the Secure Poultry Supply Plan (SPSP)*

ITEM	NPIP	SPSP
Voluntary program	✓	✓
Official USDA health-status certifications recognized by all 50 states and internationally	✓	
Officially recognized industry, state, and federal partnership with program documents in 9 CFR	✓	
Routinely updated by formal congress of industry stakeholders and subject matter experts	✓	
Supports interstate and international commerce on an ongoing basis	✓	
Ongoing system of operations, verification, and certification across all 50 states	✓	
Approves diagnostic assays and sampling regimens to inform health status classifications	✓	
Certifies diagnostic laboratories	✓	
Real-time disease surveillance across participating states	✓	
Provides standards for demonstrating freedom of disease	✓	✓
Biosecurity requirements (Sanitary standards)	✓	✓
Demonstrates freedom of disease from supply chains, areas, and regions	✓	
Demonstrates freedom of disease from individual premises	✓	✓
Trade impacting diseases (TIDs)	✓	✓
Non-trade impacting (endemic) diseases	✓	
Utilized in time of TID crisis	✓	✓
Utilized ongoing in absence of TID crisis	✓	
Utilized in TID control areas	✓	✓
Utilized outside of TID control areas	✓	
Enhanced surveillance requirements for movement at the beginning of a TID		✓
Supports movement of TID negative animals and animal products from TID control areas		✓
Supports commerce outside of TID control areas	✓	

* Secure Poultry Supply Plan for US poultry and egg industries is the equivalent to the Secure Pork Supply Plan for US pork industry.

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What are some key differences and commonalities between the US pork and US poultry and egg industries?

When considering the relevance of the NPIP to the US pork industry, it is important to acknowledge both the key differences and commonalities that exist between the US pork industry and the US poultry and egg industries.

There are many biological and life cycle differences between poultry and swine. Such differences are key drivers in the dissimilarities between poultry, egg, and pork production and in the animal health challenges facing the respective industries. In general, the production cycle is shorter and the economic value of individual animals lower in poultry than in swine or other livestock species. Although there is arguably more diversity among the various types of commercial and non-commercial poultry and egg operations (e.g., layers, broilers, turkey, ducks, upland game birds, hobbyist breeding poultry), the commercial segments of the US poultry and egg industries (Breeding and Commercial Poultry) are generally more consolidated and vertically integrated than the commercial US pork industry. Interstate movement of poultry and swine for further growing and harvest are common and done en masse on a daily basis. However, Commercial Poultry supply chains tend to be more regional compared to their counterparts in the US pork industry.

Endemic diseases of high consequence (most notably viral diseases) are less impactful in commercial poultry operations (Breeding and Commercial Poultry) than in US Breeding Swine. The long-standing NPIP-related efforts to eliminate a vertically transmitted disease of significance from Breeding Poultry and the ability to remove the fertilized eggs from the hens prior to hatching (i.e., offspring are not exposed to infected females) are both significant factors in reducing the impact. Unwarranted lateral introductions of endemic diseases of high consequence into Breeding Poultry are rare events, as compared to the frequency of such episodes in US Breeding Swine.[9] That is, the infectious disease dynamics and risk for the introduction of endemic diseases of high consequence into breeding stock (most notably viruses) differ greatly between commercial swine and poultry operations in the US. The apparent differences in the level of risk and observed occurrences for laterally introducing diseases of high consequence into breeding stock may be one of the most significant health related differences.

However, the US pork industry has evolved in a direction that increasingly shares more commonalities than differences with the US poultry and egg industries. Commonalities include multi-site production, rearing animals in climate-controlled and bio-secure facilities, repeating systems of rearing, production, and inter-premises distribution of animals (supply chains), utilization of population medicine-based approaches towards controlling the health or pathogen status of herds or flocks, and an ever-increasing level of association between the slaughter plants and their suppliers of animals for harvest. The US pork and the poultry and egg industries have observed similar trends in the percentage of domestic production and value derived from exports (most notably in the

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broiler industry). This growth and corresponding dependence on maintaining access to export markets is a common and highly significant issue. The US pork and the US poultry and egg industries are under common social and consumer pressures related to housing standards, production methods employed, and use of antimicrobials. The US pork and US poultry industries are also primary competitors in the domestic and global marketplace.

Does the US pork industry have major animal health-related challenges that extend beyond the immediate influence of an individual producer, packer, or existing organization?

Assessment of industry need is an obvious question. The US pork and US poultry and egg industries share a number of similar species-specific animal industry and veterinary organizations (Figure 12). However, the NPIP has no peer in US animal agriculture. The NPIP is the only industry, state, and federal partnership in the US focused on species and industry specific animal health-related programs, definitions, standards, and rules. The NPIP is also unique in that its program definitions and standards are officially recognized at both state and federal levels.

Trade impacting disease (TID) risks

The US pork industry has grown increasingly dependent on export markets over the past 25 years (Figure 13).[10] TID-related market risks and recurring endemic diseases of high consequence

Figure 12. NPIP is unique and has no peer in US animal agriculture.

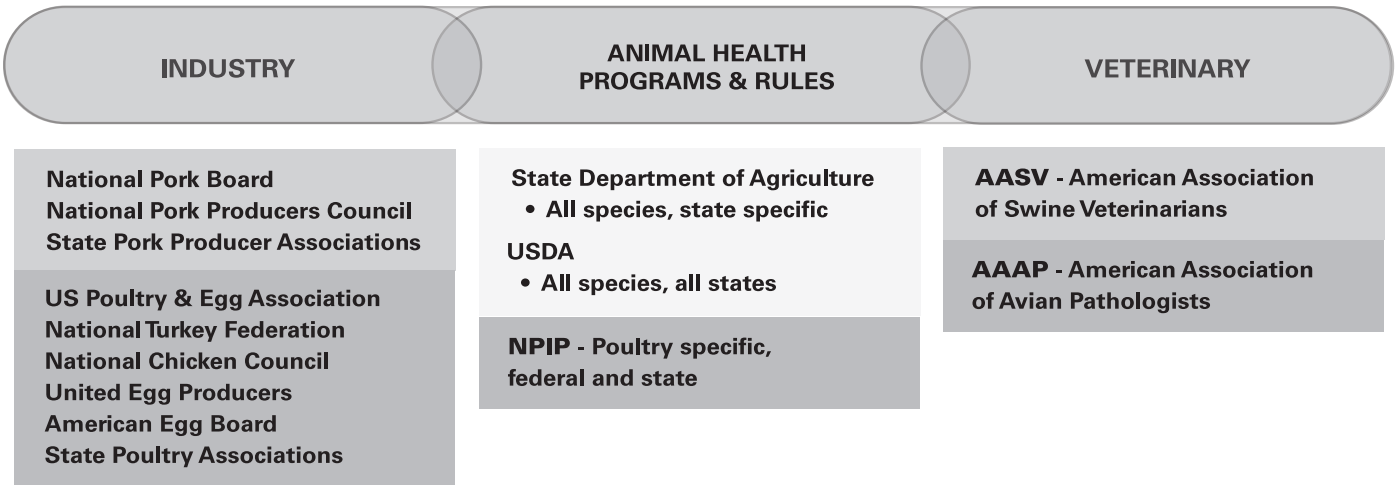
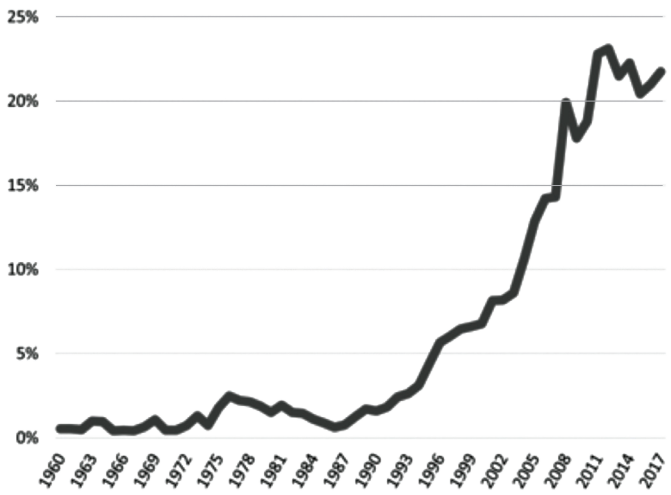


Figure 13.

Percentage of US domestic pork production (on carcass-weight basis) exported.



present major animal health challenges to all segments of today's export-centric US pork industry. While the total amount of pork produced in the US has grown by approximately 100% since the mid-1970s, domestic consumption per capita has remained relatively unchanged.[11,12] Thus, a significant portion of the growth in the US pork industry since the early 1990s has been due to the purchase of pork by consumers outside of the US. Approximately 23% of US pork is exported on a carcass-weight basis, a 10-fold increase over historical averages. This growth in exports not only increases the demand for more tonnage of pork to be produced, but also significantly enhances the value of each pig sold via the distribution of the various parts, cuts, and products for sale to markets throughout the world. Since 2012, exports have represented more than 30% of the market value realized by US pork producers. Exports are one of the most significant factors, outside of demand growth in the US, influencing the overall size and profitability of the US pork industry. Estimates in recent years suggest that export markets add approximately $50 of value to each market hog sold in the US.[13]

The growth in (and resulting dependence on) export markets comes with a markedly different level of TID and geopolitical market risks. While geopolitical risks are beyond the scope of this report, animal health-related risks affecting access to export markets are very real and highly consequential. The internationally-recognized guidelines and standards related to the effect of animal health on the international trade of animal-based food products are established by the World Organization for Animal Health (OIE). OIE standards are widely recognized by willing and interested trading partners throughout the world. African Swine Fever (ASF), Classical Swine Fever (CSF), and Foot and Mouth Disease (FMD) are the three most relevant TIDs for swine. OIE guidelines generally prohibit the exportation of fresh pork products from regions or countries with commercial livestock operations infected with or vaccinated for ASF, CSF, or FMD. Thus, an outbreak of any of these three TIDs in the US can be expected to result in the immediate cessation of fresh pork exports. While each trading partner can make their own decisions on the importation of pork (irrespective of the ASF, CSF, or FMD status of the country or region of origin), the US commonly accepts and follows the standards set forth by the OIE. Likewise, US trading partners are

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likely to follow OIE guidelines for international trade, irrespective of the health status of US swine.

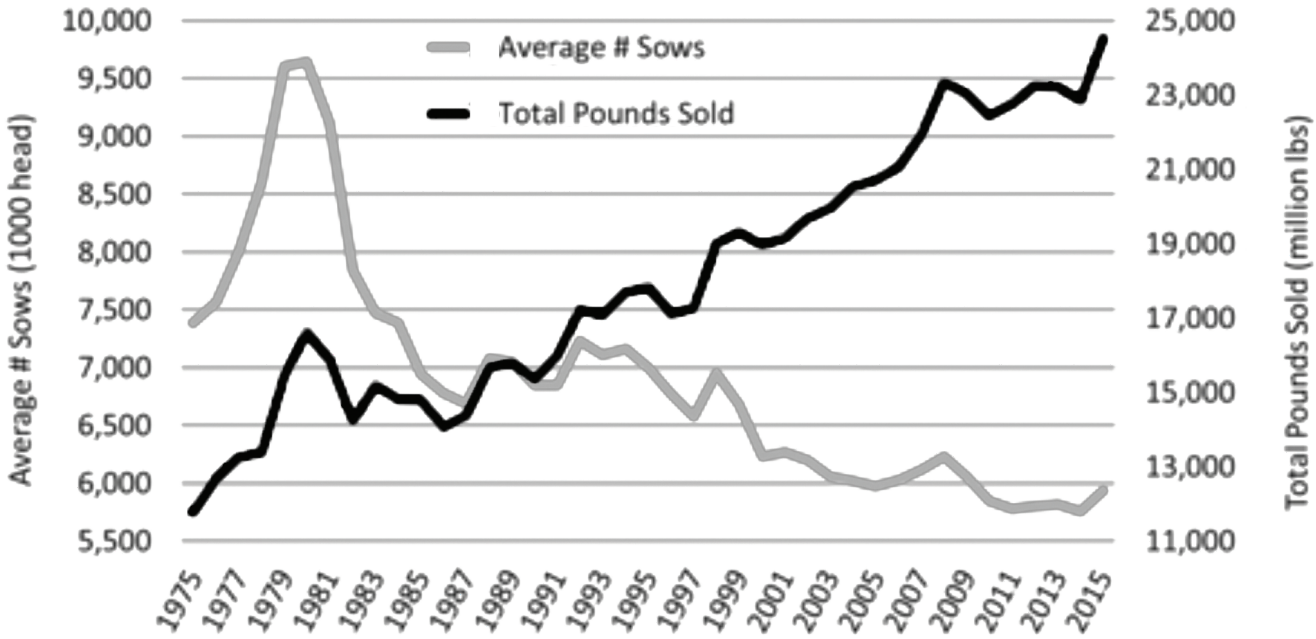
Clearly, a sudden cessation in US pork exports would have a dramatic and far-reaching impact across all segments of the US pork and related industries. Foreign animal disease preparedness is frequently discussed, but rarely results in tangible action(s) or measurable outcome(s). Managing the risk of TIDs is extraordinarily complicated, larger than any single approach, and beyond the ability of any individual, organization, or institution to control. Prevention, Response, and Recovery are each unique and critical components in managing the risk of TIDs. While Prevention and Response get much needed attention, Recovery efforts designed to demonstrate freedom from disease and reestablish export markets in officially recognized regions are often overlooked, despite the fact that Recovery from a TID incursion affecting the US pork industry is far more likely to be measured in months and years than in weeks.

Currently, there is no clearly documented, officially recognized, active (i.e., inclusive of officially enrolled and certified participants and premises), and ongoing program for the US pork industry that is ready to be rapidly scaled-up to support regionalization efforts following the detection of a TID in US livestock. The absence of a pre-existing and officially recognized system ready to establish evidence of freedom from a TID following the initial incursion and throughout the Recovery phase represents a significant risk to the entire US pork industry. Additionally, there is a general lack of understanding, clarity, and/or broadly understood dialogue as to the specifics related to response plans, indemnity eligibility, and payment for the producers initially affected by a TID requiring quarantine or mass euthanasia. Such lack of clarity among industry stakeholders creates an additional level of uncertainty, delays purposeful actions, and contributes to further disease spread because of delays in responding to a TID event.

Recurring endemic diseases (REDs) of high consequence

Levels of productivity in the US pork industry have continuously improved over time. Today, US pork producers generate about twice as much pork with 20% fewer sows than producers 40 years ago (Figure 14).[11,12] Likewise, tremendous progress has been made in the ability to confidently, repeatedly, and cost-effectively control or eliminate diseases of high consequence from individual farms and production networks. Much of this knowledge and capability has its origins in the US pork industry's now 30-year-long effort against the effects of Porcine Reproductive and Respiratory Syndrome Virus (PRRSV). The recent lessons learned from the US pork industry's Porcine Epidemic Diarrhea Virus (PEDV) experience have also been insightful. The myriad of highly collaborative public/private research efforts and information sharing among veterinarians, pork producers, and researchers has greatly enhanced the understanding of the means by which diseases can be introduced into swine farms. In particular, there is a clearer understanding and appreciation for disease movement between farms via means other than the conventional routes of infected pigs and contaminated semen (e.g., transport vehicles, fomites, insects, feed, and aerosol transmission).

Figure 14. US domestic pork production and sow inventory.



Such knowledge has prompted a previously unprecedented investment in biosecurity-related infrastructure and procedural related methodologies. These biosecurity investments have most appreciably been focused on reducing the risk of disease introduction into boar studs, breeding herds, and breeding stock replacement farm sites. Similarly, there have been great advances in the understanding of the shed and spread (circulation and transmission) of pathogens within a given farm site or premises. Such understanding has led to the now common health management practice of coupling breeding herd closure with strict all-in all-out (AIAO) pig flow and good sanitary procedures in farrowing facilities to eliminate a growing number of diseases from stand-alone breed-to-wean farms. In short, the ability to effectively diagnose and eliminate many infectious diseases of high consequence, without having to depopulate the breeding herd, from individual or related farm sites with AIAO pig flow is generally good.

However, the capabilities and advances outlined above have not translated to sustained success in containing or eliminating emerging or recurring endemic diseases (REDs) of significance (e.g., PRRSV, PEDV, and *Mycoplasma hyopneumoniae*) across broad areas or regions of the US. The recurring costs and many challenges associated with mitigating and managing the growing number

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of contagious REDs of high consequence represent a long-standing challenge to the US pork industry. The infectious disease burden and ongoing recirculation of such diseases is most evident in regions with significant growing pig populations. Disease transmission within and between commercial growing pig farm sites is common and provides a reasonable environment for diseases (most notably viruses) to be maintained and indirectly moved both locally and across vast distances to infect susceptible breeding stock.

The applied research efforts conducted by Lowe et al., shed great light as to how much cross-contamination of livestock trailers is occurring at the interface of the trailer and unloading dock at slaughter facilities. In essence, this research found that there were approximately 1.4× (3.35× higher risk if the immediate previous trailer was positive) more PEDV-positive trailers leaving the plant as there were coming into the plant.[14] This work strongly suggests un-sanitized trailers returning from slaughter plants are likely be a significant amplifier of PEDV via the unintended consequences of dragging virus back from the slaughter plants to unsuspecting groups of susceptible finishing pig populations. Such finishing pigs are more than capable of amplifying the virus in great numbers. These late-term finishing breaks of PEDV commonly associated with live haul transportation infections have also revealed the risks that high volumes of virus being shed late in finishing has on the subsequent groups of weaned pigs being placed into the same wean-to-finish facilities, most notably in winter months. It would seem highly probable that this same type of inter-herd transmission associated with finishing pig live haul is also occurring with other diseases of high consequence; albeit the acute clinical consequence of many other diseases in growing pigs (as compared to PEDV) can often be less visually obvious and/or delayed from the actual point of infection.[15] In short, the continuous area/regional spread of endemic diseases of high consequence are a very real and consequential challenge impacting the health of US swine. Such recurring disease challenges contribute to the ongoing investment in biosecurity and other preventative disease measures, increased costs of production, negative impacts on animal well-being, employee turnover, antimicrobial use, and ultimately the longer-term competitiveness in the broader global animal protein marketplace. There is limited historical precedent for the successful containment or elimination of a readily communicable disease of high consequence across broad regions of the US with significant pig populations in the absence of an officially recognized control or elimination program.

Potential roles or applications for an NPIP like program for US pork industry

As noted above, NPIP's primary role since its inception has centered on bettering the health of US poultry through the control and elimination of specific diseases in Breeding Poultry.

Breeding Poultry have long used the NPIP health status classifications as a means of representing the health of their flocks and offspring at points of sale, exhibition, interstate movement, and international trade. The resulting industry expectations,

demands, and requirements for obtaining birds from Breeding Poultry free of the specified vertically transmitted disease of high consequence continues to have a dramatic impact on the overall health and productivity of US Commercial Poultry. NPIP's more recent (2006) divergence and expansion to include the H5/H7 Avian Influenza Monitored classification for Commercial Poultry plays a significant role in mitigating the TID-related market risks for the US poultry and egg industries.

Mitigating TID risks and providing a framework to facilitate larger-scale improvements in the health of US swine at a level beyond the reach or immediate influence of any individual pork producer or packer are potential applications of an NPIP like program (i.e., US Swine Health Improvement Plan) for the US pork industry. Collectively, this aim would serve to enhance the competitiveness and sustainability of the US pork industry in the domestic and global marketplace.

NPIP's approach toward mitigating AIV-related market risks via the establishment of the H5/H7 Avian Influenza Monitored classification for Commercial Poultry and Avian Influenza Clean status for participating states would have significant value to the US pork industry in the event of an introduction of a TID such as ASF, CSF, or FMD. An officially recognized program, with health status classifications and standards to demonstrate freedom of specific TIDs in commercial pork production operations supplying slaughter facilities (supply chains) across states or regions, would be a valuable system to have in place during the Recovery phase of a TID outbreak. It should be understood diagnostic testing, traceability requirements, and sanitary standards are each critical components necessary for demonstrating evidence of freedom across supply chains, industry segments, areas, and regions.

OIE-level compartmentalization is not likely feasible for the vast majority of commercial pork production operations, given the complexity, costs, and requirements of the process. However, there is long-standing precedent domestically and internationally for trading partners to recognize states and regions as free of said diseases in affected countries (i.e., regionalization). The preemptive establishment of a USDA-certified program recognized and supported by participating states could provide the basis for scaling up the necessary testing in the advent of an outbreak to support efforts to demonstrate freedom of disease across specified market segments and legally recognized states and regions (regionalization). As mentioned earlier, well defined traceability and sanitary standards need to accompany the specified diagnostic testing requirements to sustainably support evidence of freedom across supply chains, industry segments, areas, and regions. In the same way as establishing common definitions and standards for establishing officially recognized health status classifications and/or demonstrating freedom of TIDs, a US Swine Health Improvement Plan could also provide the framework to make larger scale progress towards mitigating the effects of recurring endemic diseases (REDs) of high consequence across supply chains, industry segments, regions, and states.

Establishing a US Swine Health Improvement Plan may also be useful in advancing baseline

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traceability and sanitary (biosecurity) practices and standards that indirectly impact all commercial pork production operations in the US. Traceability and baseline sanitary (biosecurity) standards are critical elements in foreign animal disease preparedness (Prevention, Response, and Recovery), as well as in mitigating REDs of high consequence across areas and regions. Systems of traceability and sanitary standards associated with transporting commercial swine for breeding, further growing, or to points of concentration, are hallmark components of similar swine health programs implemented in Denmark and the Netherlands. The systems of traceability and live haul transportation sanitary standards implemented are irrespective of any pathogen specific claims, but represent core elements of their respective swine health programs.[16,17] The Danish and Dutch pork industries are heavily dependent on export markets, have significant populations of pigs in a relatively small geography, and have limited options for the use of antimicrobials.

NPIP provides the US poultry and egg industries a very structured, purposeful, and democratic forum of industry stakeholders, official state agencies, and the USDA to discuss, debate, and address issues of poultry health that have broad impact across the various segments of the US poultry and egg industries. Topics of discussion range from creating officially recognized differentiations between commercial and non-commercial poultry operations, determining the requirements for the various health status classifications, approving officially recognized diagnostic tests or regimens, to updating indemnity policies, eligibility, and payment rates. NPIP's operational structure creates an ongoing forum for substantive and interactive dialogue, learning, awareness, understanding, and informed perspective, on issues specifically related to poultry health across industry stakeholders, states, and the USDA that would not otherwise occur across such a broad and representative body of industry stakeholders. Creating such a forum on US swine health among industry stakeholders, states, and the USDA would be another reason for establishing a US Swine Health Improvement Plan.

Potential structure of a US Swine Health Improvement Plan

The basic tenets of NPIP's operational structure is one option, but a US Swine Health Improvement Plan could be established and operate under a different structure, depending upon the interests and desired outcomes of US pork industry stakeholders. Thus, a US Swine Health Improvement Plan could be developed and operated within the framework of the national and state pork industry organizations, through the creation of a new stand-alone private entity, or approached in a state-by-state manner via collaborative efforts between the pork producers, processors, and state department of agriculture (state animal health official) within a given state.

Developing and operating such a voluntary program within the framework of the existing national and state pork industry organizations or as a new stand-alone private industry entity would most likely provide for the most flexibility. There is clear precedent for facilitating and implementing voluntary pork quality assurance programs within the framework of the national and state based pork

industry organizations.

Similarly, there is a long-standing precedent and history for leaders (e.g., program staff, members, and swine health committees) representing the national and state pork industry and swine veterinary organizations to routinely collaborate with, and provide industry perspective on, issues related to swine health to the respective USDA APHIS and state animal health officials. The swine health committees of the national and state pork industry organizations were intimately involved in collaborating with the USDA and their respective state animal health officials in the development of the program policies and procedures utilized to eliminate Pseudorabies virus (PRV) from the US on a state-by-state basis.

A private entity could be created for such a purpose with a board of directors to provide advisement, and operate the program in accordance with some type of recognized ISO (International Organization for Standard) like standard inclusive of the necessary third-party verifications.

The limitation of either of these "industry only" options is that any such efforts to claim an officially recognized health status across a given state or region (group of counties or states) would ultimately need to be endorsed by the state animal health official (state departments of agriculture) in each state making such a specified claim. The definitions and standards being used to make such claims of status would also need to be recognized by the USDA. State animal health officials (state departments of agriculture) are the responsible entities for representing regional based claims of health status in each state, whereas the USDA is often the responsible party for representing the health status of any collection of states, regions, or the entire US to international trading partners.

Producers and processors, in conjunction with their respective state animal health official (state departments of agriculture), could forge their own state-specific Swine Health Improvement Plans. A state-specific program would carry the benefit of having official recognition and impact within a given state. However, the utility and recognition of such standards, definitions, and health status classifications would likely be limited to and be unique to each state. It should be understood that the vast majority of animal health standards, rules, and authority resides within each state (e.g., state animal health official and state department of agriculture).

Modeling the operating structure of a US Swine Health Improvement Plan after the basic tenets of NPIP's existing structure would carry the benefit of having a precedent and a working model that is well understood within the USDA and across all 50 states (e.g., state animal health officials and departments of agriculture). NPIP's basic tenets include being informed and routinely updated by a democratic forum of industry stakeholders, facilitated by the USDA, adopted and implemented on a state-by-state basis by official state agencies, and voluntary to participants. NPIP's cooperative industry, state, and federal partnership model also lends itself toward having more consistency across states and for having officially recognized health status classifications across supply chains, industry segments, regions, and states that are broadly supported and recognized by state animal health officials, USDA, and international trading partners.

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What would be required to establish a US Swine Health Improvement Plan?

Moving this idea forward would require a collaborative, concerted, and sustained effort by US pork producers and pork processors interested in exploring, creating, and potentially participating in a US Swine Health Improvement Plan. The specific hurdles and milestones would largely depend on the approach (industry only vs. some type of formal industry, state, federal collaboration) and scope (state-specific plan vs. plan for use across states). Interests among pork producers and packing plants (supply chains) in one or more states would be the foundation needed to build this concept. Should there be interest in wanting to claim or defend a specified health status among commercial pork producers and packing plants (supply chains) within a given state or region, targeted outreach and a formal collaboration with the appropriate state animal health officials and the USDA would be critical. Federal and state level legislation would not be required to establish a voluntary program, but a significant push from interested US pork industry stakeholders, a core group of interested states, and approval by USDA APHIS leadership, would be required to move forward with a program officially recognized and/or facilitated by USDA APHIS. Adoption and participation in a USDA-affiliated program would be on state-by-state and participant-by-participant basis.

What would be the potential benefits and liabilities for establishing a US Swine Health Improvement Plan modeled after the basic tenants of NPIP's industry, state, and federal partnership?

Benefits

Reduce trade impacting disease (TID)-related market risks

Establishing officially recognized health status classifications and well-defined systems and standards for demonstrating freedom of TIDs from commercial pork production farm sites and slaughter facilities across states and regions would be immediately helpful in the event of the discovery of a TID in the US. Proactively developing and implementing an industry-informed and functional system prior to a "TID event" would enable participants and states to readily scale up the necessary testing to demonstrate freedom of disease across specified regions and market segments throughout the Recovery Phase. As mentioned earlier, there is precedent for willing trading partners to recognize specific areas (regionalization) as being free of specified diseases within an affected country. Recognizing the health status of commercial livestock by region (counties, states, or provinces) has long been a critical component of making stepwise progress over the course of large-scale disease control or eradication efforts domestically and internationally. Creating such a body and working system to

establish and maintain officially recognized health status certifications across herds, supply chains, processing plants, areas, states, and regions could also provide a means of advancing traceability and sanitary standards across the US pork industry. Traceability and biosecurity are critical elements to all aspects of TID preparedness (Prevention, Response, and Recovery). On-farm biosecurity practices and sanitary standards associated with transporting swine for breeding, further growing, or to or from points of concentration, are critical control points for mitigating the spread of diseases of high consequence into and between farm sites. The infrastructure and systems necessary to consistently sanitize (i.e., clean or decontaminate) the masses of live haul trailers departing points of concentration are a well-recognized and costly animal health infrastructure-related challenge facing the US pork industry. The previously cited applied research completed by Lowe et al.[14] might indirectly suggest that live haul trailer sanitation may be one of the most critical elements in mitigating the unwarranted spread of a TID following an introduction into the US.

A more formal approach toward actively maintaining a current and up-to-date list of all commercial swine farm premises, and an officially recognized health status for one or more pathogens endemic to US swine, for all commercial farms across a state or sizable region, has not occurred since the PRV eradication program in the late 1990s and early 2000s.[18] The infrastructure for doing so across states has long since diminished. While the information management infrastructure used over the course of the PRV control and eradication effort involved many people and much paper, establishing a working system for maintaining an up-to-date list of premises, officially recognized health status(es), and swine movement information utilizing the information technologies of today, would be of tremendous benefit in any type of disease monitoring, response, control, recovery, or elimination effort. Fundamental and broadly applicable advances in traceability and biosecurity are infrastructure- and coordination-intensive endeavors with no short-term solutions. Instituting an active, working, and continually improving US Swine Health Improvement Plan could provide a platform for tangible progress toward enhancing all three phases of TID preparedness (Prevention, Response, and Recovery) across broad segments of the US pork industry.

Establishing a US Swine Health Improvement Plan would also prove useful in expediting the development and approval of well-informed and practical diagnostic testing regimens for demonstrating freedom of diseases in US Swine. Developing and approving diagnostic tests, sample types, and sampling strategies has long been central to NPIP's mission. Such regimens play the central role in conferring NPIP health status classifications. Establishing and approving well-characterized diagnostic assays and practical testing regimens enhances the quality, consistency, and cost-effectiveness for conferring officially recognized health status classifications. Such efforts create consistency and set broadly recognized precedent and standards for specified health status classifications across farm sites, processing plants (supply chains), states, and regions. The collaborative nature of the industry, state, and federal partnership in approving diagnostic assays and testing regimens through the

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NPIP Technical Advisory Committee, composed of subject matter experts from throughout the US, has a long track-record of delivering practical and cost-effective diagnostic standards for officially-recognized health statuses in the US poultry and egg industries.

Facilitate larger scale efforts to mitigate the impact of recurring endemic diseases (REDs) of high consequence on US Swine

The same systems, structure, and approach for establishing officially recognized health status classifications across individual herds, packing plants (supply chains), regions, and states for TIDs could also be used as a pathway or platform for making stepwise progress toward mitigating the impact of specified recurring endemic diseases (REDs) of high consequence (e.g., PRRSV, PEDV, *Mycoplasma hyopneumoniae*) to US Swine. In addition to area regional or system specific disease monitoring or control applications, establishing officially recognized standards for representing the health status of Breeding and Growing Swine could be useful as a means of representing the health status of the stock at a point of sale or transfer. Similarly, advances in traceability and biosecurity (sanitary standards) would better position the US pork industry for making larger scale progress toward mitigating the impact of endemic diseases of high consequence. Reducing the impact of REDs of high consequence would ultimately improve the health of US swine and longer-term competitiveness of the US pork industry in the global animal protein marketplace.

Create and empower an officially recognized forum to inform and address federal and state agency policies, procedures, programs, or standards relating to US Swine health

Establishing a US Swine Health Improvement Plan modeled after the NPIP would create a formal, structured, and broadly represented democratic forum to engage in meaningful dialogue and directly influence swine health related programs and policies of high relevance to the US pork industry. NPIP has shown that substantive and focused dialogue shared among industry stakeholders (program participants), state agencies, and USDA can create an environment for more informed, timely, practical, and purposeful decisions to be made and industry impacting outcomes achieved.

As stated previously, the NPIP has no peer in US animal agriculture (Figure 12, Page 17). The US poultry and egg industries' long-standing engagement in the NPIP provides a unique position in that this broadly represented group of industry stakeholders (i.e., NPIP participants, NPIP Technical and General Conference Committee members, and voting delegates at the NPIP Biennial Conference) play a very direct role in forming, discussing, and addressing issues, definitions, and policies related to poultry health that have far reaching impact across the US poultry and egg industries. Such an empowered forum creates an opportunity for dialogue, movement, decision-making, and action on poultry health issues that extend beyond the influence of individual producers, processors, or states. The active and highly applied nature of the NPIP continually tests the relevancy of the program and

requires the program to be continually updated and improved to address the changing needs of the industries (subparts) served. Topics can range from those directly included in the NPIP, to tangential poultry health-related items in which the USDA plays a role, such as TID response, indemnity policies, vaccine needs, and interstate and international commerce. NPIP's industry, state, and federal partnership model is also unique in that its outcomes influence both federal and state level standards, definitions, and policies.

In contrast, the absence of an industry-driven and empowered body to establish nationally recognized definitions for swine health sets the stage for a state-by-state patchwork of local standards and definitions. This patchwork lacks the nationally- and internationally-recognized credibility needed to support pork exports from unaffected regions during a time of crisis. In short, the NPIP model of shared governance shifts much of the burden and responsibilities for developing, updating, and implementing swine health related standards, definitions, policies, and rules from the federal and state animal health agencies to an empowered body of industry stakeholders. Based on the history of NPIP, this approach would better position industry stakeholders to influence issues related to safeguarding, improving, and representing the health of US swine.

Outside of the poultry and egg industries, the US livestock industries and federal/state animal agricultural agencies are essentially one generation away from having participated in a large-scale disease control or eradication program. Given the minimal routine interaction between industry stakeholders and the federal and state agencies that exists in the absence of such a program, a "disconnect" and misunderstanding of the resources and capabilities available in such agencies naturally develops. While the US is fortunate in having the service of many capable and committed professionals in our state and federal animal health agencies, their resources are very limited as compared to the capabilities, capacity, and species-specific knowledge that resides in the industries being supported by such agencies. It should also be understood that such agencies are responsible for animal health programs, policies, and capabilities across many species and types (commercial and non-commercial) of livestock, poultry, equine, aquaculture, commercial companion animal breeding operations, and farm-raised cervids, mink, and other minor species. Initiating a US Swine Health Improvement Plan modeled in NPIP's likeness would better leverage the expertise and capabilities that exists among US pork industry stakeholders in addressing the grand animal health related challenges facing the US pork industry.

Liabilities

Time and money

Much of the energies and resources required to develop and implement an NPIP like program for the US pork industry would be additive to the status quo. There may be an opportunity to leverage some of the resources within USDA and participating states' departments of agriculture. Should the development of a US Swine Health Improvement Plan result in stepwise

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improvements in the systems of traceability utilized for monitoring swine movement and keeping premises level information current on an ongoing basis, these would be examples of where existing resources could be redirected, conserved, and improved. One recent success story of traceability-related efficiencies in the NPIP was the US Poultry and Egg Association's funding of a web-based application used by the NPIP Official State Agencies to permit the interstate movement of poultry. However, the vast majority of the work and costs would be additive and borne by the participating states and participants. As stated earlier, NPIP Official State Agencies and NPIP participants carry the primary burden for maintaining, continuously improving, and implementing the NPIP. Initiating and implementing a US Swine Health Improvement Plan would require much industry driven leadership, time, sustained effort, and resources.

Uncomfortable discussions among peers and industry stakeholders

Deriving workable definitions, standards, policies, guidelines, or rules that are agreeable among any group of people in a democratic forum is not easy under any circumstances. Even when its members are all on the same team, share common interests, motivation, expertise, and goals for the long-term success of the industry and stakeholders they represent, democracy is not easy. NPIP's Biennial Conference convenes to make decisions on program definitions, standards, and policies that have ongoing consequences on the health of US poultry and the US poultry and egg industries. The positive aspect is that such decisions are being driven, debated, and decided upon by industry stakeholders that share a common interest in the sustainability and success of the various states and segments of the US poultry and egg industry they represent. Thoughtful debate, compromise, practical and workable decisions, and error on the side of simplicity and flexibility, are common. The NPIP has been called a "democratic regulatory program" in which the producer is both the primary beneficiary and decision maker of the programs content and direction.[19]

Consequences of having requirements, standards, or rules

Obtaining and maintaining a recognized certification or classification that involves an individual or entity to meet or comply with a specified set of requirements has consequences. Consequences of achieving or complying with any type of prescribed minimum standards or rules can be positive, negative, operational, financial, or unintended in nature. The benefits of any decision, standard, practice, or participation in a program with specified requirements ultimately has to be weighed against its costs and consequences.

For most practical purposes, since the eradication of PRV from the US in 2004, there are few examples of specified health status, sanitary (biosecurity) practice, or vaccination related requirements or regulations having a significant impact on commercial pork production operations in the US. Thus, there is limited recent experience with legally binding constraints on day-to-day operations concerning pig movement or particular management practices due to the health status of

individual farm sites or the status of the area or region of origin or destination. Such flexibilities and freedom of choice are highly valued. Over this same time, there has been a previously unprecedented amount of investment, proactive efforts, and management practices implemented by pork producers to protect and improve the health, productivity, and profitability of their operations.

The substantive investments in biosecurity-related infrastructure, siting of breeding stock in less pig dense locations, extensive acclimation and vaccination practices, and pathogen elimination efforts have largely been driven in efforts to reduce the impact of recurring endemic diseases (REDs) of high consequence (e.g., PRRSV, PEDV, and *Mycoplasma hyopneumoniae*) in US swine. These ongoing investments and health improvement practices and initiatives are at the sole discretion of each individual producer. In broad terms, industry-standard biosecurity related practices and efforts to prevent disease introductions into US Breeding Swine are among the highest in commercial livestock production globally. Such investments have come about in efforts to reduce the incidence of unwarranted lateral introductions of REDs of high consequence into breeding stock. Unwarranted lateral introductions of endemic diseases of high consequence outside of the conventional routes of introducing infected animals or semen continue to be significant and ongoing challenge.

Summary and Conclusions

The US poultry and egg industries have long utilized NPIP program standards, definitions, and health status classifications as its primary means for representing, bettering, protecting, and governing the health of US poultry. NPIP is a voluntary program whose primary authority resides at the point of sale or interstate movement. Sanctioned exhibitions involving Breeding Poultry also often require specified NPIP certifications of its participants. While participation in NPIP is open and encouraged for poultry operations of all shapes and sizes, NPIP makes a special effort to differentiate between commercial and non-commercial operations. This differentiation is critical to enable officially-recognized health or program status claims for one or all commercial operations or industry subparts in a given supply chain, area, or state. Participants and NPIP Official State Agencies determine which NPIP classifications or programs to pursue for their operations or state. State departments of agriculture administrative rules related to items of poultry health are generally aligned with and/or reference the requirements set forth by the NPIP. Private entities engaging in the distribution of poultry (live birds or fresh meat products) or eggs across state lines, or internationally, are NPIP's principal participants. The entities responsible for selling or distributing the birds, poultry, or eggs hold the NPIP certifications.

Summary and Conclusions

NPIP's primary emphasis since its inception in 1935 has been controlling and certifying Breeding Poultry as being free of specified vertically transmitted diseases. Poultry breeders, multipliers, and hatcheries use the NPIP health status classifications as an officially recognized means of representing the health status of their flocks, eggs, or chicks to customers, exhibition officials, and state and federal animal health officials and agencies. NPIP's H5/H7 Avian Influenza Monitored classification established in 2006 is the only NPIP certification directly applicable to Commercial Poultry. Participating table egg laying flocks, meat-type chicken slaughter plants, meat-type turkey slaughter plants, commercial upland game birds, commercial waterfowl, and raised for release upland game birds and waterfowl are the principal holders of the H5/H7 Avian Influenza Monitored classification. Participating meat-type chicken and turkey slaughter plants are responsible for ensuring compliance within their respective supply chains. Each NPIP participant is responsible for meeting the requirements of the NPIP certifications they hold or desire to obtain. States can claim an Avian Influenza Clean or H5/H7 Avian Influenza Clean by each respective poultry and egg industry subpart (e.g., type of poultry or egg operation) and participant within their state. Such officially recognized AIV-related health status classifications have played a critical role in demonstrating evidence of freedom of disease, and supporting poultry and egg industry exports and interstate commerce during periods of high or low-pathogenic AIV outbreaks in the US.

The possibility of an NPIP like program for the US pork industry (i.e., US Swine Health Improvement Plan) raises considerations for US pork industry stakeholders, state animal health officials, and leadership within USDA APHIS Veterinary Services. Industry needs, the human and financial resources required, and the potential benefits and liabilities must all be carefully considered. It is well recognized that most substantive regional or industry-wide animal health-related undertakings either come out of an industry-changing crisis, fear of such an event based on changing states of risk or knowledge, or other very fundamental shift in a given market or industry.

The US pork industry has evolved, improved, and changed radically over the last two generations of pork producers. Experiences and ongoing risks associated with the intercontinental movement of disease agents, the advent and subsequent widespread adoption of multi-site production methodologies, and an increased dependence on export markets, are among the most significant factors influencing the overall landscape of and impact of swine health on the US pork industry. TID-related market risks and the burden of recurring endemic diseases of high consequence are grand challenges beyond the power or ability of any one approach, strategy, entity, or organization to solve. Establishing a US Swine Health Improvement Plan could provide a tangible, structured, realistic, and industry-driven approach for making stepwise progress in addressing these complex challenges. Proactively establishing the development of working and officially recognized systems, certifications, test methods, and practical diagnostic regimens for demonstrating freedom of TIDs (ASF, CSF, or FMD) across supply chains, areas, states, and regions to support regionalization efforts throughout the Recovery phase following a TID incursion into the US, would be invaluable.

Systems of traceability and routine biosecurity

(sanitary) practices are important components of TID preparedness and in better positioning the industry to mitigate the impact of REDs. Incorporating baseline traceability and sanitary standards into a voluntary health status certification program would have a significant impact across supply chains, states, regions, or entire US pork industry. The same systems, practices, and structure advanced to mitigate TID-related market risks, would also better position the US pork industry to make stepwise progress toward reducing the impact of REDs of high consequence.

Establishing such an officially recognized and broadly represented industry, state, and federal partnership would also provide industry stakeholders a forum to engage in substantive dialogue with state and federal animal health agencies, and most directly influence swine health related program or policy related issues of high relevance to the US pork industry. The NPIP model, built upon developing nationally recognized standards, definitions, and certifications for poultry health that can be adopted by participating producers, slaughter facilities, and states, also carries the benefit of mitigating a patchwork of potentially unwarranted state-by-state variability. The well respected and broadly democratic nature of the procedures involved in continually updating the NPIP–a process that includes representation from subject matter experts, industry stakeholders, and state and federal animal health officials– has proven useful in creating a sense of shared ownership in such decisions and program definitions. This well structured and shared governance approach towards deriving officially recognized certifications, definitions, and standards in the NPIP are also thought to have value in mitigating unwarranted legislative or politically motivated changes to state and federal poultry health related rules or standards.

Developing, initiating, and operating a US Swine Health Improvement Plan would require industry-driven leadership, collaboration, work, and sustained efforts on behalf of industry participants, state animal health officials and respective agencies, and the USDA Veterinary Services. The majority of the work, effort, and resources necessary to establish, maintain, and effectively implement such an effort would largely be additive to the status-quo. While the implementation of such a program would likely be very straight-forward and operational in nature, the process for deriving, defining, and continually updating the programs content and scope via a democratic forum of peers is not commonly a work task of choice among agriculturalists, veterinarians, and scientists.

Crafting program language, definitions, and standards that effectively achieve a primary intent or purpose, while being very practical, broadly applicable, and agreeable across a diverse group of industry stakeholders, is no easy task. Debate, disagreement, and compromise are common in any type of democratic process of consequence. The benefit of the NPIP model is that it is a forum of stakeholders directly responsible for crafting, debating, and deciding upon matters that have a direct impact on their own industry. Albeit not easy or without substantive effort, NPIP's model of shared governance seems to have served the US poultry and egg industries well. Perhaps the largest deterrent for pursuing any type of industry initiated effort to develop more officially recognized definitions, standards, or certifications related to swine health, would arise from concerns

Summary and Conclusions

over consequences that resulting requirements or rules would negatively impinge participating operations. As mentioned previously, attaining any type of officially recognized certificate or standard that causes a participating entity to comply with a specified set of requirements has consequences.

Any specified standard that impacts freedom of a participating entity's choice related to any type of management or biosecurity practice, health status requirement, or that can influence how, where, or under what specified conditions pigs move between premises, across state lines, or to points of concentration, has consequences. In short, the pursuant of having any type of officially recognized certification or program with specified requirements has consequences. The benefits of pursuing and participating in any such officially recognized program with defined standards or requirements has to be weighed against the costs and consequences of participation. Participation and/or the degree of participation (levels of specified certifications) in any type of health status certification program would likely be expected to vary by region, industry segment, and participant.

Sustaining access to export markets, rearing healthy hogs, reducing costs of production, and enhancing the long-term sustainability and profitability of the US pork industry are commonly held objectives across the broad spectrum of participants in the US pork industry. US poultry and egg producers and slaughter plants share similar goals and objectives for their own industries and operations. Such interests, goals, urgencies for continuous improvement, and changing domestic and international consumer demands are unlikely to disappear in the future.

Globalization, multi-site production, and a markedly increased dependence on exports have each contributed to a substantial change in the overall landscape of swine health and TID-related market risks in the US pork industry. It seems arguable that investments in animal health related systems and infrastructure that extend beyond an individual producer's farm gate have not kept pace with the needs of such a highly mobile, interconnected, and export centric industry. The findings of this case study provide US pork industry stakeholders some insight into the NPIP's role in reducing the impact of endemic diseases of high consequence in the US poultry and egg industries, and its more recent expansion and pivot towards mitigating TID-related market risks. The findings of this case study suggest that there are some nuggets of knowledge in the US poultry and egg industries' experience and approach with NPIP that could benefit the US pork industry.

Recommendations

Perhaps the primary question at hand for today's industry that is export-centric, highly mobile, and composed of a complex network of multi-site and multi-state production systems in an ever increasingly globalized world is: Do you believe the legacy systems and approach to animal health control can meet the needs and challenges of the 21st century US pork industry?

Most US pork industry stakeholders are unfamiliar with the NPIP. Therefore, a major aim of this case

Recommendations

study report is to provide an overview of the NPIP and the process by which it coordinates/focuses the energies of program participants, breadth of industry stakeholders, subject matter experts, and regulatory agencies on problems of broad importance to US poultry and egg industries. At its core, NPIP is a platform wherein industry, state, and federal partners address poultry health standards, definitions, and policies. Decisions made at each NPIP Biennial Conference have genuine impact, as evidenced by their inclusion in the Code of Federal Regulations (9 CFR) and publication in the NPIP Program Standards. Given its long history of success in bettering the health of US poultry and competitiveness of the US poultry and egg industries, the question of whether an "NPIP like model" could better protect the current and future interests of the US pork industry is worth consideration by industry stakeholders.

Ultimately, the decision to further explore or pursue something akin to the NPIP for the US pork industry must be determined by pork producers and packers. Pork packing plants (i.e., slaughter facilities) must certainly play an essential leadership role in any such voluntary program that aims to certify the health status or health management practices implemented by its suppliers in support of export market access. Interest, leadership, and participation among some portion of the US pork packing sector would be a foundational element necessary to initiate any type of voluntary program that includes an aim to support export market access for fresh pork in the event of an introduction of a TID in the US. Voluntary animal health or animal health management practice assurance related programs encouraged or required at a point of sale seem to be a common model globally.

History suggests sustainable improvements to the health status of swine herds across large areas, regions, states, and country require industry leaders to set-forth simplistic, practical, strategic, and effective baseline standards of practice that can be widely adopted by commercial pork producers. Industry led leadership, collaboration, adaptability, constancy of purpose, and consistency of execution across the masses have been the hallmarks of historical successes. Experience suggests that the next generation of practical solutions for mitigating the grand animal health challenges facing the US pork industry can only come from the expertise, leadership, and collaborative spirit that resides within the US pork industry stakeholder community. Therefore, to encourage and cultivate this leadership, and introduce the question raised in this case study to a broader audience, the contents of this study should be widely distributed to industry stakeholders in a variety of media: print, narrated video presentation, and podcast. Opportunities to present and further explore this topic at regional meetings throughout the US would provide the opportunity for two way communication (e.g., question/answer, and group discussion) among the broad spectrum of US pork industry participants (producers, packers, veterinarians, diagnosticians, state and federal veterinary medical officials, etc.).

NPIP's more than 80 years of implementation and evolution need to be acknowledged, when determining what would be just the first steps towards establishing a similar program for US swine. Identifying the initial area(s) of emphasis, focus, and tangible first deliverable(s) would be critical when considering the potential for initiating an NPIP like program for the US pork industry. Figure 15 serves to provide a summary

Recommendations

Figure 15. Potential components or areas of emphasis of a US Swine Health Improvement Plan

Evidence of freedom from Trade Impacting Diseases (TIDs) outside of TID control areas

- Pathogens: ASF, CSF, & FMD
- Assays, sample types, and sampling regimens by farm type and type of swine movement
- Traceability and sanitary standards to support a specific certification and demonstrate evidence of freedom by premises, supply chain, industry segment, area, or region.

Health status classifications for Recurring Endemic Diseases (REDs) of high consequence

- Pathogens: PRRSV, PEDV, TGEV, and MHP
- Breeding stock and Commercial farm types
- Traceability and sanitary standards to support a specific certification or demonstrate evidence of freedom by premises, supply chain, industry segment, area, or region.

Traceability standards (irrespective of pathogen)

- Inter-premises swine movements for breeding or further growing
- Swine movements to and from points of concentration
- Necessary to support a specific certification

Sanitary standards (irrespective of pathogen)

- On-farm
- Feed
- Live-haul
- Necessary to support a specific certification

Glossary of Officially Recognized Terms

- Premises Types (Farm and Non-Farm)
- Operation Types (Farm and Non-Farm)
- Pig Types
- Swine Movement Types
- Industry Segments (subparts)
- Diagnostic Specimen Types
- Live Haul Transport Trailer Types
- Live Haul Transport Sanitation Levels

of the primary potential components or areas of emphasis that could be included in a US Swine Health Improvement Plan. Determining the preferred organizational structure and identifying areas of common interest that have both a high and relatively near-term impact would seem like logical place to start.

Beyond the scope of this case study, but consistent with its intent, there would be value in conducting a comparative case study of the various swine health assurance or certification programs being implemented elsewhere in the world (e.g., Denmark, Netherlands, etc.). Similarly, an in-depth review of the primary infrastructure, systems, and practices that would need to change in the event of an extended TID Recovery period in the US would provide context as we prepare for the future, and identify changes and improvements that are needed to support a highly competitive export-centric pork industry well into the future.

Continuous improvement has long been a core principle of the US pork industry. Consistent with that tradition, establishing a US Swine Health Improvement Plan modeled after the basic tenets of the NPIP would be among the more significant swine health related undertakings in the history of the US pork industry. Such a decision presents as an opportunity to create a sustainable pathway to a better, more robust, and less vulnerable US pork industry. Asset preservation, and protecting the opportunities and way of life for the breadth of current and future US pork industry participants and their local communities come to mind. The opportunities, challenges, and animal health related risks in the US pork industry have not likely ever been greater. In these authors' opinion, the primary, macro level (industry wide) swine health related risks, vulnerabilities, and opportunities for improvement are generally well understood. New approaches are needed to address the ever-more complex and consequential swine health challenges (and opportunities) that extend beyond the individual producer's or packer's farm gate. In particular, substantive and systematic improvements are needed to strengthen all three phases (Prevention, Response, & Recovery) of TID preparedness and enhance the industry's ability to control, mitigate, or eliminate REDs of high consequence on a supply chain, industry segment, regional, or industry wide level. While there are no short-term solutions to the major swine health related challenges at hand, making stepwise progress in addressing these major challenges all seems quite doable with the more than adequate diversity of skills, practical know-how, collaborative spirit, and innate pursuit for continuous improvement that exists across the expanse of the US pork industry.

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