



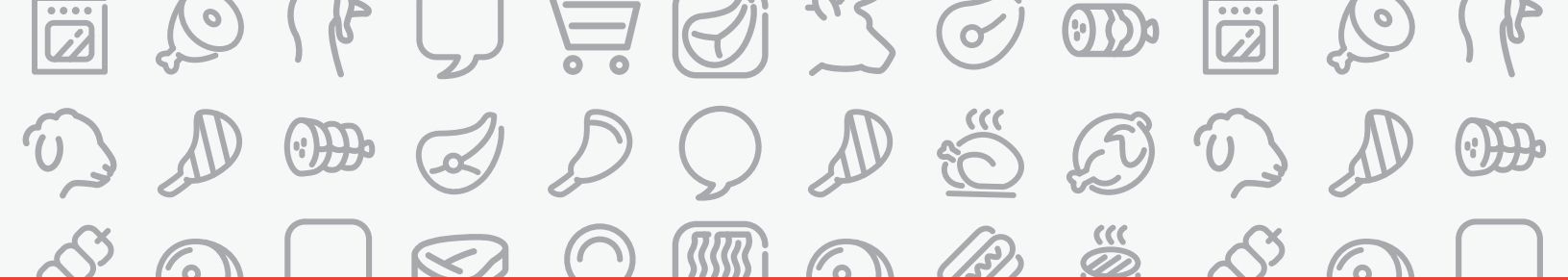
Recommendations to Modernize the Meat and Poultry Oversight System in the United States

Developed by the Meat and
Poultry Dialogue Group



Meridian Institute

Connecting People to Solve Problems



Contents

ABOUT THE MEAT AND POULTRY DIALOGUE	1
EXECUTIVE SUMMARY	2
INTRODUCTION AND CONTEXT SETTING	7
DESIGN PRINCIPLES	9
RISK-BASED OVERSIGHT SYSTEM	11
DATA	13
PRE-HARVEST (FARMS AND FEEDLOTS)	15
HARVEST (SLAUGHTER)	17
PROCESSING AND FURTHER PROCESSING	21
ENFORCEMENT AUTHORITY	23
POST-PLANT-OF-ORIGIN SUPPLY CHAIN	24
RISK COMMUNICATION	26
HEALTH CARE AND PUBLIC HEALTH	29
CONCLUSION	30
GLOSSARY OF KEY TERMS	31
LIST OF ACRONYMS AND ABBREVIATIONS	34
NOTES	35
WORKS CITED	36
APPENDIX A: MEAT AND POULTRY DIALOGUE GROUP PARTICIPANT LIST	38
APPENDIX B: PAST LEGISLATIVE PROPOSALS TO IMPROVE MEAT AND POULTRY SAFETY	39



ABOUT THE MEAT AND POULTRY DIALOGUE

Beginning in early 2013, representatives from The Pew Charitable Trusts (Pew) and Cargill, Inc. (Cargill) met periodically to discuss the feasibility of launching an initiative to modernize the United States meat and poultry legislative and regulatory system. Pew and Cargill had been working together in a stakeholder forum on implementation of the FDA Food Safety Modernization Act (FSMA) since 2011. Their positive experience in this effort led both organizations to believe that the most effective approach to kick-starting a meat and poultry modernization effort would be through a multi-stakeholder dialogue process, focused on developing recommendations to improve the food-safety oversight system for these food products. These recommendations could then provide the foundation for legislation and support changes in applicable regulations and policies developed by the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS)¹ as well as relevant policies at the state and local level.

Pew and Cargill enlisted Meridian Institute to design the process and facilitate the dialogue in conjunction with a core Steering Group. The Steering Group was comprised of representatives from Pew and Cargill as well as from the meat and poultry industry, retail food sector, consumer advocacy community, and academia.

Between October 2014 and February 2015, Meridian conducted 30 confidential interviews with key stakeholders from different industry sectors (i.e., beef, pork, and poultry) across the production chain (farm, slaughter, processing, further processing, and retail); consumer advocacy organizations; academics/scientists with relevant expertise; public-health groups; trade associations; and other interested/affected parties. The interviews explored the substantive, political, economic, and technical issues underlying the meat and poultry oversight system; gathered preliminary suggestions about

the kinds of policies that would improve public-health outcomes; identified possible members for the multi-stakeholder dialogue group; and created a foundation for a shared vision across the range of interests concerned with meat and poultry safety.

The Steering Group initially identified 21 participants for the core Meat and Poultry Dialogue Group (Dialogue Group), based on results from the interviews and the individuals' knowledge of and role within the meat and poultry system. A list of Dialogue Group members is presented in Appendix A. The Dialogue Group held its first meeting in April 2015 and continued to meet regularly until the end of 2016. The Dialogue Group's discussions focused on major aspects of the production system for beef, pork, and poultry, including: the "pre-harvest" period (i.e., while animals are bred and raised on farms and feedlots); "harvest" (i.e., slaughter); processing and further processing; "post-plant-of-origin" supply chain (e.g., storage, distribution, retail, and foodservice); and risk communication to consumers and other stakeholders. It also considered the roles of the public-health and health-care systems. Critical overarching issues discussed by the Dialogue Group included how best to assess risks and how to ensure all of the relevant data are collected and shared.

The recommendations included in this report are organized along the "farm-to-fork-to-physician continuum" beginning at the farm (i.e., pre-harvest level) and continuing through slaughter and processing, and then to the "fork" (i.e., the consumer). But, as noted above, it extends to the "physician," (i.e., the public-health and health-care systems, which treat, track, and prevent foodborne illnesses). As you will read in this report, the Meat and Poultry Dialogue is recommending significant changes to the federal oversight system.

This report represents the consensus of a diverse group of organizations and individuals including meat and poultry companies, food retailers and restaurants, consumer advocates, academics and scientists, public-health groups and a labor union. Individual members of the Dialogue Group may differ on particular recommendations, but the group is in consensus on the entire set of recommendations as an integrated whole.

EXECUTIVE SUMMARY

This report was drafted collaboratively by the Meat and Poultry Dialogue Group (Dialogue Group), which is a multi-stakeholder dialogue process focused on developing a set of recommendations to improve the food-safety oversight system for meat and poultry. The goal of the Dialogue Group's recommendations, set out in this report, is to transform the current system into one that is more science- and risk-based, protective of public health, and able to address the entire "farm-to-fork-to-physician continuum" of the meat and poultry production system. The recommendations specify the direction and characteristics of system modernization and the necessary changes to achieve it. Recommendations are directed to all players in the system, including Congress, U.S. Department of Agriculture's Food Safety and Inspection Service (USDA-FSIS), state and local regulators, the meat and poultry industry, retailers, and academic, health-care and public-health institutions.

In convening the Meat and Poultry Dialogue, Cargill, Inc. and The Pew Charitable Trusts identified the following four reasons for believing that the time was ripe for this initiative:

- (1) public-health-based: while there has been some progress, meat and poultry products remain significant vehicles for foodborne illnesses in the United States;
- (2) science-based: the inspection system developed more than 100 years ago does not employ the most science-based means to protect consumers from pathogenic contamination;
- (3) fiscal: taxpayers spend \$1 billion each year on an inspection system that cannot effectively assure the desirable level of safety; and
- (4) political: the FDA Food Safety Modernization Act was enacted in the first two years of the Obama Administration with the support of a broad

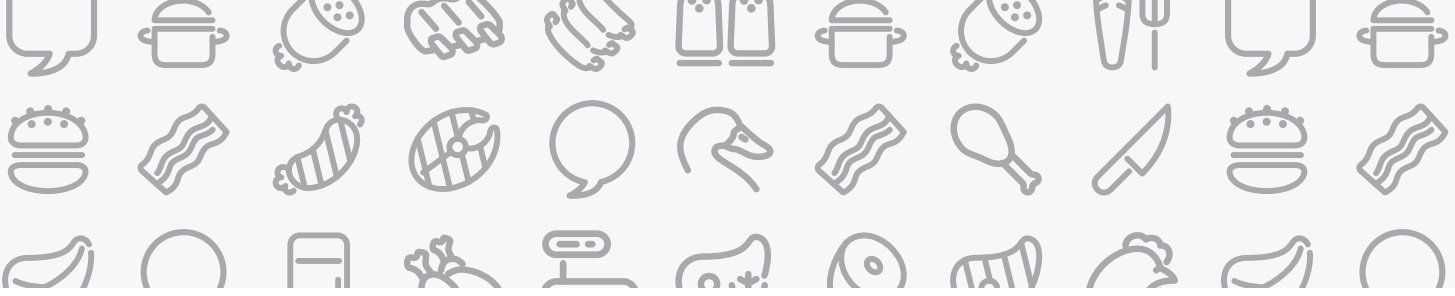
coalition of stakeholders, and the beginning of the Trump Administration may provide an opportunity for a broadly supported, meat and poultry modernization effort.

The hope is that these recommendations can provide the foundation for federal legislation to update the meat and poultry laws, and to support changes in the applicable regulations and policies developed at the federal, state and local level.

Risk-based Oversight System

A modernized oversight system must be based on risk to human health. A risk-based system must identify the risks to be addressed and the process by which they are identified. The Dialogue Group believes that the best approach to achieve this is through the creation of a new, independent food agency focused solely on risk assessment. Congress should establish a new, independent government entity, the Food Risk Assessment Authority (FRAA), by combining the staff responsible for completing risk assessments from USDA-FSIS and U.S. Food and Drug Administration (FDA). For consistency across the food supply, the FRAA would address all foods – both those regulated by USDA-FSIS and FDA – and would be responsible for performing the risk assessments that should be the basis of the regulatory performance and process the standards and policies that are developed and enforced by the regulatory agencies, the risk managers. In developing its risk assessments, the FRAA should rely on an "appropriate level of protection" (ALOP) for each pathogen-food combination, determined by the FRAA based on the advice of a multi-stakeholder advisory group.

The FRAA should prepare both annual and multi-year work plans; conduct systematic peer reviews of existing science; respond to urgent requests for advice from the regulatory programs; monitor and analyze information and data on biological hazards and chemical contaminants; and track food consumption and emerging risks. In particular, it should establish relationships between prevalence and levels of contamination to update risk assessment models, and validate the risk of illness and outbreaks of illness associated with various levels of contamination.



Data

Risk-based decision-making relies on a strong foundation of data that is: collected across the food-safety system; accessible and protective of privacy; transferrable; and comparable. Data collection systems relevant to meat and poultry oversight should be modernized so that they are automated and linked to improve efficiency and reduce errors during data transfer. Modernization of the data collection system should occur simultaneously with the modernization of the risk-based oversight system to ensure alignment and utility, and data should be expanded to include animal-welfare and worker-safety-related data to determine their connection to food safety. The Dialogue Group recommends that a public-private partnership be established to operate the shared data infrastructure and that a multi-stakeholder advisory group should provide advice on data needs. Voluntary data sharing between the public and private sectors should be incentivized.

Pre-harvest (Farms and Feedlots)

In order to have a true farm-to-fork approach to food safety, the government, academia, and the meat and poultry industry must collaborate to develop effective pre-harvest interventions and practices that mitigate the risk of foodborne hazards and protect public health. Congress should grant one federal agency – whether an existing agency within USDA or a new one – clear authority over pre-harvest food safety; this authority would cover all parts of live animal production that are relevant to food safety, including production animals, elite or nucleus herds, farms and ranches, feedlots, feed mills, sale barns, hatcheries and live transport. This agency should have the authority to set science-based, species-specific, minimum pre-harvest food-safety standards to be met by farms and feedlots raising food-producing animals, including minimum requirements regarding biosecurity and management practices. Compliance with these pre-harvest standards would be verified through voluntary on-farm audits or other equivalent means. Congress should also create a voluntary certification program that would operate like USDA Agriculture Marketing Service (USDA-AMS) process-verified programs, that would certify the use of

science-based, effective interventions such as vaccines and probiotics. Congress should also fund additional research on pre-harvest interventions.

Further, retailers and foodservice companies should provide incentives for their meat and poultry suppliers to use validated pre-harvest interventions that can be verified by third-party auditors.

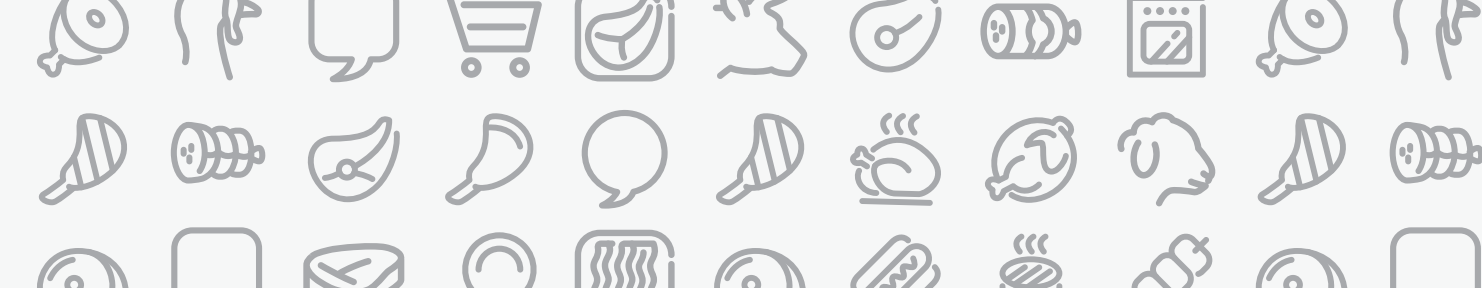
Harvest (Slaughter)

The current approach to inspection at slaughter should be modernized to assure that the tasks performed are risk-based, public-health-focused, and aligned with current technology. It should be based on ALOPs that are specific to the particular pathogen, species, product and consumer, both at the time of slaughter and also at the time of consumption. This modernized inspection approach should address risks posed by chemical and physical hazards as well as pathogens; should move from a task-based oversight architecture to one that is systems-based; and should provide increased incentives to improve public health.

Congress should amend the meat and poultry laws to provide that the nature and frequency of slaughter inspection be based on the associated public-health risk. It should direct the FRAA to establish the relevant ALOPs, determine the data needed from producers, and define the sampling and testing methodology when testing is done.

Congress should direct USDA-FSIS to set performance standards that are science- and risk-based, based on information provided by the FRAA, and related to public-health outcomes (e.g., Healthy People 2020) and the relevant ALOP. These standards should verify that a facility's process control measures are working adequately to produce safe food.

Congress should create two types of inspectors at slaughter: 1) gatekeeper inspectors, whose job is to keep animals unfit for consumption out of the food supply; and 2) plant inspectors, whose focus should be on system verification activities to assure that the slaughter facility is operating in a way that controls contamination.



USDA-FSIS should ensure that inspection activities are related to public health and inspector variability is minimized. It should create multi-stakeholder bodies at the district level to verify the scientific validity of an establishment's Hazard Analysis and Critical Control Points (HACCP) plan and process standards. It should work with small and very small plants to create guidance documents that outline acceptable processes to achieve the relevant ALOPs. USDA-FSIS should also fund additional research to close data gaps that are important to the foundation of a risk- and science-based system. The agency should work with state regulators to better align inspection training and education requirements for federal and state inspectors.

The meat and poultry industry should implement, based on the relevant ALOPs, preventive practices, microbiological testing, monitoring activities and mechanisms for corrective action as necessary.

Processing and Further Processing

As with slaughter, there should be risk-based and public-health-focused inspection during processing (i.e., transforming an animal carcass into primal and retail cuts) and further processing (i.e., turning cuts through physical and chemical methods into "value-added" products like burgers and sausages). To achieve this, Congress should amend the meat and poultry laws to provide that the nature and frequency of inspection at establishments doing initial or further processing is based on the associated public-health risk.

Congress should direct USDA-FSIS to set performance standards for processing and further processing that are science- and risk-based, based on information provided by the FRAA, and related to public-health outcomes (e.g., Healthy People 2020) and the relevant ALOP. These standards should verify that a facility's process control measures are working adequately to produce safe food.

USDA-FSIS, based on information provided by the FRAA, should determine laboratory testing requirements

for processing plants, including the frequency of testing, the limit of detection, and the types of tests involved. These requirements should be designed to detect the major food-safety hazards that should be detectable by inspection, and be based on the expected public-health risk.

The role of inspectors in processing and further processing facilities is to assure that a facility is operating in a way that reduces contamination. They should concentrate on food safety, not quality, issues and focus their inspections on the overall operation of the facility.

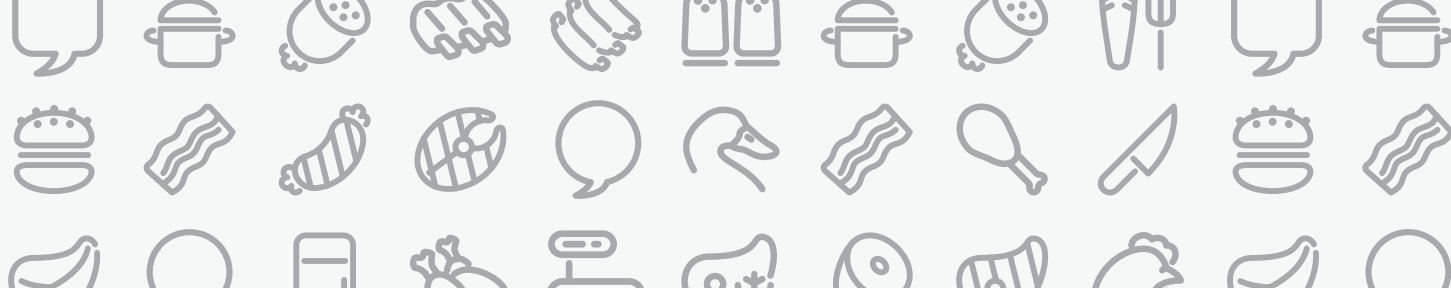
Congress should fund research to determine the most efficient and cost-effective interventions to address the key hazards of concern in processing and further processing and how to best implement them.

Federal and state regulatory agencies should coordinate more closely align their inspection activities, and standardize training and education requirements for federal and state inspectors.

Enforcement Authority

Congress should ensure that the USDA-FSIS's use of its enforcement tools is risk-based and the tools are strengthened where necessary. It should increase transparency and accountability of government and meat and poultry establishments in the context of an enforcement action. It should also ensure that members of the FSIS Recall Committee have the knowledge and training to determine when a recall is appropriate and are able to increase the consistency of decision-making throughout the process. Congress should ensure due process protections are available to meat and poultry companies that are subject to a potential enforcement action.

Congress should strengthen public-health protection and information dissemination and transparency to consumers, while broadening the public-



notification requirements and other corporate requirements associated with recalls and public health alerts. It should improve the quality and speed of communications and information sharing between USDA-FSIS, public-health authorities, and a meat and poultry company before a potential enforcement action or product withdrawal or recall. In addition, Congress should enable government agencies to share information with each other when there is an ongoing investigation.

The statutes should be amended so that establishments regulated by FSIS may not discharge or otherwise discriminate against an employee when the employee reports a violation, testifies in a proceeding concerning such violation, or objects to, or refuses to participate in an action they believe to be in violation of any provision of the meat and poultry statutes or any order, rule, regulation, standard, or ban under them.

Post-Plant-of-Origin Supply Chain

The appropriate authority at the federal, state or local level should perform periodic, risk-based inspections to ensure that facilities storing meat and poultry products beyond the plant of origin have adequate cold-chain management, sanitation, pest control, cross-contamination controls, and security.

USDA-FSIS, FDA, and the U.S. Department of Transportation should develop and implement a coordinated, risk-based inspection and enforcement strategy to assure that vehicles transporting meat and poultry products are in compliance with the FDA Sanitary Transportation rule.

State and local authorities, which are responsible for retail and foodservice oversight, should include in their regulations the key food-safety-related provisions from the most current edition of FDA's Model Food Code that are aimed at reducing the risk of contamination of meat and poultry products as well as those related to sick foodservice workers.

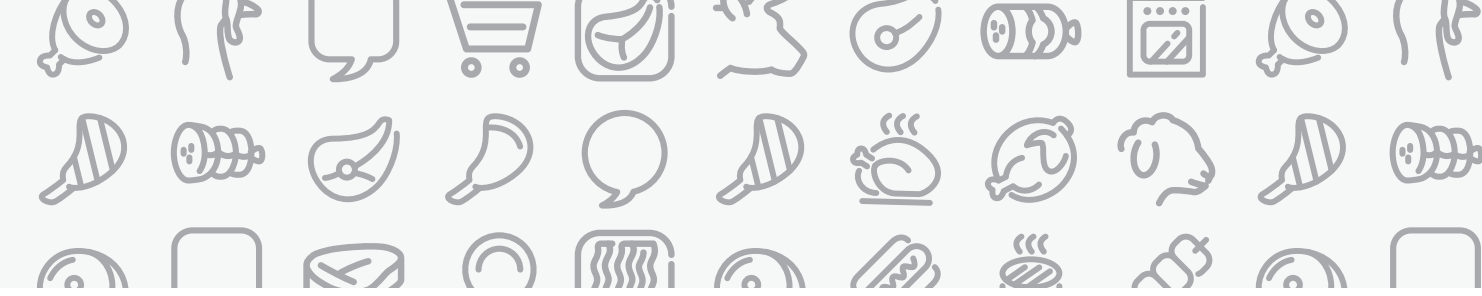
Risk Communication

There must be better risk-communication and food-safety education programs so that stakeholders across the system – including food preparers, servers, handlers and consumers – understand the risks posed by meat and poultry products and follow safe food handling practices when they handle, cook, and serve these products. To achieve this, Congress should allocate more funding to support research on how consumers view different food risks, what risk messages they are more likely to respond to and remember, and the best methods for delivering the information.

USDA-FSIS should establish a risk communication program that clearly communicates the actual risks associated with different meat and poultry products and reflects changes in the understanding of risk. USDA-FSIS and the meat and poultry industry should work together to establish an effective and dynamic communications system that brings research into the public domain on pathogen risks, as well as emerging pathogens, including antimicrobial resistant pathogens.

USDA-FSIS should work with FDA to expand the scope of its Risk Communications Advisory Committee (RCAC) to include food-related communication activities by both USDA-FSIS and the Centers for Disease Control and Prevention (CDC).

Other governmental and quasi-governmental entities responsible for informing and educating consumers about food-safety risks should ensure that their messaging is consistent with the recommendations of the RCAC. In addition, FDA should update the Model Food Code provision requiring a consumer advisory warning about the risk posed by consumption of raw and undercooked meat and poultry products that is included on restaurant menus and signage.



The meat and poultry industry should provide clear and non-misleading information about the risks associated with meat and poultry products, and USDA-FSIS should revise its Safe Handling Instructions label so that it provides more specific, straightforward, and legible information about safe handling practices.

The foodservice industry should better train servers and other staff who prepare and handle food so they clearly understand the risk of foodborne disease and the importance of safe food handling and cooking practices to their customers. Its training of servers and food preparers should also reflect best practices in the risk communication literature and it should better train servers to clearly communicate food-safety information to foodservice customers.

Food risk communicators in the government, academia, and industry should make greater use of social media and other non-traditional channels to educate the public about food safety. Communicators should also reach out to individuals and organizations that have the attention and trust of the general public – such as celebrity chefs and cooking shows – and encourage them to follow safe food handling practices and to provide accurate information about food safety.

Food-safety education must begin at an early age and should be included in middle and high school curricula. This training, analogous to driver's education, must equip students with the safe handling and preparation skills and must teach them that failure to follow simple food-safety protocols can result in serious health consequences.

Health Care and Public Health

Congress should increase funding to state, local, territorial and tribal public-health agencies for investigating foodborne illness outbreaks, with

funding tied to metrics on exposure assessments completed and timely sharing of quality data. Public-health agencies should build their capacity to complement recent advances in laboratory methods and work with the medical community to put a public-health perspective on diagnosing and reporting foodborne illness. Public-health agencies should perform environmental assessments for all foodborne illness caused by enteric pathogens, and build a national exposure assessment tool with a national database that is accessible to the public and researchers.

Government and grantmaking institutions should invest in advanced molecular methods for identifying and linking foodborne illnesses, modernizing surveillance infrastructure and developing databases and information technology systems that can more readily share data. They should also fund training programs aimed at increasing epidemiologic capacity across the public-health system.

Medical and nursing schools should revise their curricula to provide more information on foodborne illnesses, and place more emphasis on them in clinical training and practice, with the goal of improving the diagnosis, treatment and reporting of foodborne infections.

Schools of public health should increase capacity to train foodborne disease epidemiologists by seeking funding for training programs and by partnering with state and local public health agencies to develop hands-on training programs.

Veterinary schools and animal science departments should revise the food animal veterinary curricula to provide more information on foodborne illness and food safety, and place more emphasis on them in clinical training and practice. The schools should incentivize careers in food animal veterinary medicine and increase opportunities for research and graduate training in the area of food safety.

INTRODUCTION AND CONTEXT SETTING

A Short History of Meat and Poultry Production in the United States²

Animal protein has been and continues to be an important part of the American diet. For early settlers, abundant land for grazing meant that meat and poultry – once considered delicacies reserved for royalty – became a regular component of their diet. As the country became more urbanized, stockyards, slaughterhouses, butcher shops, and rendering plants were in every neighborhood – until civic leaders successfully forced butchers and slaughterhouses to move away from residential areas. Eventually, livestock operations moved west into open territory, as consumers, who were relocating to growing cities, still wanted readily available meat products. Thanks to the expansion of railroads, cattle and hogs could be raised far out west, where there was ample land for grazing, and their meat could be shipped back east. The introduction of refrigerated rail cars in the late 19th century allowed for the year-round, nationwide distribution of “dressed” meat (i.e., carcasses containing only muscle and bones).

In the early 20th century, Upton Sinclair’s novel *The Jungle* shocked the public with the poor working conditions and unsanitary practices in meatpacking plants. Public pressure in response to the book led Congress to enact the Federal Meat Inspection Act (FMIA) in 1906, which prohibited the sale of “adulterated” (i.e., contaminated) or “misbranded” (i.e., mislabeled) meat and ensured that animals were slaughtered and processed under sanitary conditions.

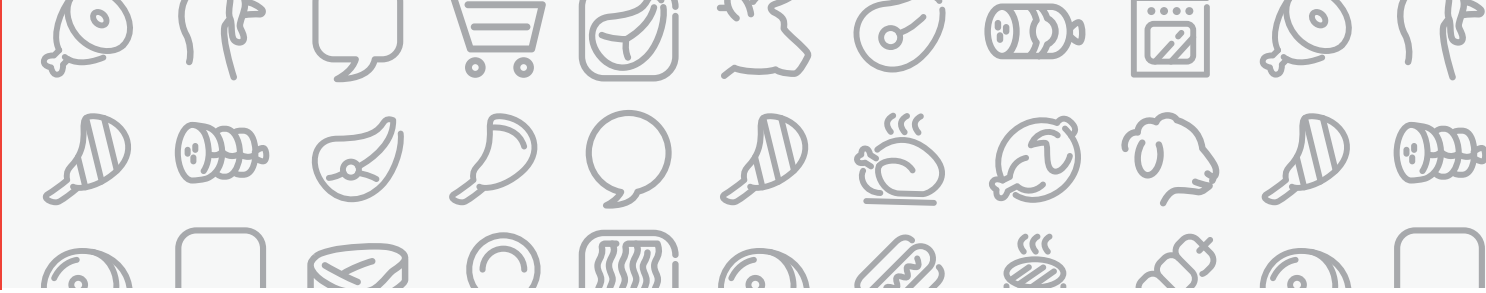
Over the century, livestock producers moved to more factory-like operations that linked farms, slaughterhouses, food processors and retailers in an

effort to keep food costs low. Following World War II, the rapid growth of the federal highway system and the development of refrigerated trucks allowed meatpackers to move out of expensive urban areas. Competition in the meatpacking business led to sophisticated, mechanized plants in less expensive rural areas. A flourishing economy and steadily rising incomes resulted in an increased appetite for meat and poultry. Between 1940 and 1960, meat consumption per capita rose significantly as did the population, which pushed production to the feedlot.

The focus first turned to poultry in 1926, when USDA initially offered a voluntary inspection and grading service to poultry processors. It was not until 1957 that Congress passed the Poultry Products Inspection Act (PPIA), which provides the same mandatory inspection program for poultry that it provides for meat.

Today, the animal protein market continues to become further concentrated; the majority of chicken, beef, pork, and turkey production is controlled by the top four or five companies in each sector. In light of the continuous push towards consolidation and integration, the meat and poultry industry today looks significantly different than it did in 1906 and even 1957.

In 2017, meat remains a significant portion of the average American diet, contributing over 15% to the daily energy intake, 40% of protein consumed and 20% of daily fat intake.³ Looking at recent trends, consumption of chicken continues to increase, while pork and turkey consumption have remained relatively steady in recent years. Beef consumption has seen a relatively steady downward trend over the last five years. The meat and poultry industry continues to be the largest segment of United States agriculture. Total meat and poultry production in 2013 reached more than 93 billion pounds, up by 600 million pounds since 2011. In 2013, the meat and poultry industry processed 8.6 billion chickens, 33.2 million cattle, 239.4 million turkeys, and 112 million hogs.⁴



Safety Concerns with Meat and Poultry Products

If publication of *The Jungle* in 1906 was the first seismic shift to rock the meat and poultry industry, then the second was the Jack in the Box outbreak in 1993, when four children died from infections linked to undercooked hamburgers contaminated with a lethal strain of *Escherichia coli* (Shiga toxin-producing *E. coli* (STEC) O157:H7) bacteria. In addition to these deaths, a total of 732 people were sickened, with 178 of them left with kidney and brain damage, and other serious conditions. With this outbreak, many American consumers learned for the first time that foodborne illness can lead to life threatening conditions and even death.

Both the industry and government regulators responded to this outbreak by improving practices in meat slaughter and processing plants and establishing prevention-based requirements known as the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (PR/HACCP) rule.

Since the mid-1990s, USDA-FSIS has continued to enforce the PR/HACCP rule along with a range of other regulations, guidance documents, and policies, such as classifying certain STEC strains as adulterants, all of which aimed at reducing pathogens in meat and poultry products. At the same time, the meat and poultry industry continues to innovate by developing new processes and interventions to improve food safety. As a result of these actions, the incidence of infections caused by STEC O157:H7 has been cut in half since the mid-1990s. The same, however, has not been true for other pathogens; for example, *Salmonella* contamination in chicken. Therefore, other approaches – including changes in the underlying laws – should be considered in order to achieve more meaningful and sustained reductions in foodborne illness associated with contaminated meat and poultry products.

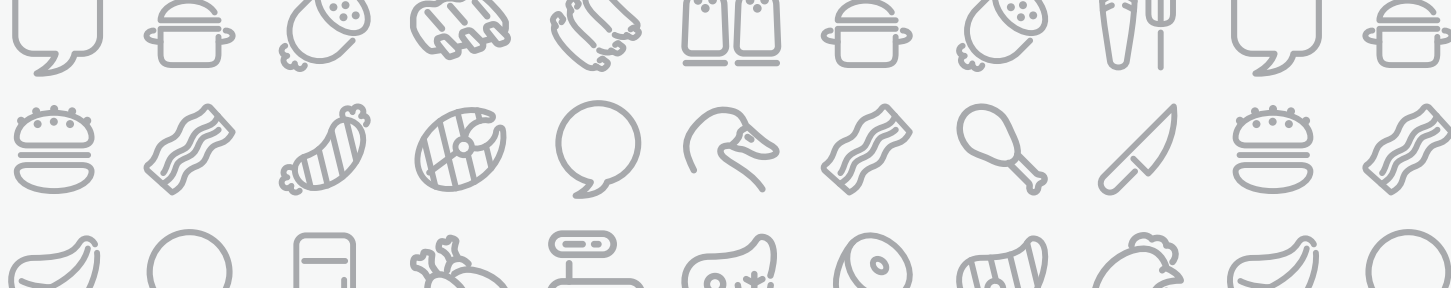
Many critics of the current meat and poultry oversight system believe that these laws are the major obstacles to significant reductions in foodborne disease linked to meat and poultry because they are outdated and

inflexible. The FMIA was signed by President Theodore Roosevelt, Jr., one year before the Ford Motor Company introduced the Model T. In 1957, when President Dwight D. Eisenhower signed the PPIA, Elvis Presley's "All Shook Up" was the best selling song. Both the FMIA and the PPIA established approaches to slaughter inspection ("carcass by carcass") and inspection of processed products ("continuous") that are now considered antiquated because they use an early 20th century "organoleptic" (i.e., employing the senses) approach to inspection, which is not capable of detecting today's human health risks.

The Dialogue Group was convened at this particular point in time for four compelling reasons.

The first reason is public-health-based. Nearly 25 years after the Jack in the Box outbreak, after both government regulators and meat and poultry companies have implemented measures to reduce contamination, meat and poultry are still major vehicles for foodborne illnesses in the United States. An analysis focusing on 14 of the most important foodborne pathogens in the United States determined that beef, pork, and poultry products are responsible for 2.8 million Americans getting sick each year, with an annual cost exceeding \$5.7 billion.⁵ The CDC estimates that meat and poultry commodities account for 22% of all foodborne illnesses, and poultry is associated with the largest number of deaths.⁶

The second reason is science-based. The oversight system created by the FMIA and PPIA was designed to address diseases of concern in the early 20th century. These diseases – tuberculosis in particular – are no longer the public-health threat they once were in the United States. By contrast, diseases that are key food-safety concerns today – infections caused by pathogens like *Salmonella*, STECs, and *Campylobacter* – are not detectable through traditional, organoleptic meat and poultry inspection activities because they do not manifest themselves through visible or palpable defects, such as lesions. Moreover, many of these pathogens infect food animals before slaughter and, therefore, an effective approach to reducing contamination cannot begin at the slaughterhouse, but, rather, must be initiated at farms and feedlots, where contamination could be mitigated.



The third compelling reason for considering measures to improve the federal government’s oversight system for meat and poultry is fiscal. There is increasing pressure to reduce the size of the federal budget and to ensure that agencies use their funding effectively. Each year, USDA-FSIS receives approximately \$1 billion to operate the existing meat and poultry inspection system, which, as discussed in this report, may not be using the most modern, science-based approach to protecting consumers from preventable risks. We should develop other, more science- and risk-based methods that give taxpayers a better public-health “bang for their buck.” At the same time, however, decisions on which new approach to choose cannot be budget driven, but must be matched by a proper allocation of resources to achieve the desired public-health outcomes.

The fourth reason for developing the recommendations in this report is political. FSMA was signed by President Obama in 2011 at the beginning of the second year of his first term. This landmark bipartisan legislation, the first comprehensive update of the FDA food-safety authority since the Great Depression, was developed with input from and strongly endorsed by a wide range of stakeholders, including the food industry and consumer advocacy groups, who worked hard to get it passed.

Since the Jack in the Box STEC outbreak, a number of bills have been introduced in Congress to modernize specific aspects of the meat and poultry safety oversight system, but they received little or no legislative action. (See Appendix B for a chart outlining these bills.) Now, at the beginning of the Trump Administration, the time may be ripe for updating the meat and poultry laws, which is the next logical step in improving food safety.

The recommendations crafted by the Dialogue Group are informed by the work of many food-safety experts over the past 30 years who have identified the characteristics of a modern food-safety oversight system. Such a system should be risk-based, science-informed, and data-driven. It should focus on preventing contamination and resulting illnesses, not just responding to outbreaks. It should facilitate and incentivize continuous improvement in the safety of the food supply. The relevant laws and policies should provide both the government and industry with flexibility to focus on the food products,

processes, and facilities that pose the greatest risk to human health. To the extent possible, a modern food-safety oversight system should reflect the “One Health” concept, which recognizes that the health of people is connected to the health of animals and the environment. A One Health approach is important particularly in light of the fact that six out of every ten infectious diseases in humans are spread from animals.⁷

DESIGN PRINCIPLES

The following list of design principles for a modern food-safety system was developed at the first meeting of the Dialogue Group to help guide their discussions. These design principles reflect the range of perspectives in the Dialogue Group and informed the recommendations in this report. The design principles provide that the modernized system be:

- Risk-based and, to the degree possible, focused on where the risk is best and most effectively addressed and, when appropriate, treat the risk holistically. As such, it should:
 - Concentrate on preventing contamination and resulting illnesses, not just responding to them; and
 - Facilitate and incentivize continuous improvement in the safety of the food supply.
- Rationally related to achieving public-health objectives by incorporating additional tools (e.g., the “One Health” approach).
- Systems-based (i.e., an approach that emphasizes the interdependence and interactive nature of elements within and external to the system). As such, it will require that there is:
 - Culture change, in the short- and long-term, throughout the system (i.e., among the food production and preparation industry as well as the regulatory agencies and inspectors) to effectively implement a risk-based, food-safety system rooted in shared responsibility and focused on prevention.

- Able to make risk-based and science-informed resource-allocation decisions among competing priorities.
- Able to follow a farm-to-fork-to-physician approach, where on-farm practices and public health surveillance systems would be integral parts of the oversight system.
- Effective at maximizing transparency and accountability for government agencies to all stakeholders, including both regulated companies and consumers.

RISK-BASED OVERSIGHT SYSTEM

Background

Beginning in the late 1990s, there has been a growing consensus that food-safety oversight by the government should be both science- and risk-based. This view was articulated in the 1998 Institute of Medicine (IOM)/ National Research Council (NRC) report "Ensuring Safe Food: From Production to Consumption"⁸ and is reflected in subsequent government and non-governmental reports, most recently the 2010 IOM/NRC report "Enhancing Food Safety: The Role of the Food and Drug Administration."⁹

As explained in the 2010 IOM/NRC Report, the term risk-based "implies the existence of an underlying science base; however, it goes a step beyond to encompass use of the tools of risk and decision analysis to create systems that optimize the ability to prevent and control foodborne illness and improve public health."¹⁰

Noting that many groups have defined "risk" and "risk-based," the 2010 IOM/NRC committee agreed on the following working definition for a risk-based approach: "a systematic means by which to facilitate decision-making to reduce public-health risk in light

of limited resources and additional factors that may be considered."¹¹ The committee identified the following as key attributes of a risk-based, food-safety system:

- Is transparent in its decision-making process.
- Is proactive and based on a strategic management plan.
- Is data driven.
- Is grounded in the principles of risk analysis.
- Employs analytical methods to rank risks based on public-health impact and to prioritize the allocation of limited resources to manage risk most effectively.
- Considers other factors, such as consumer perception, cost, controllability, public acceptance, environmental effects, and market impacts, in decision-making when appropriate.
- Employs measures to evaluate the efficacy of the risk management program on a continuous basis.
- Performs all of these functions in a systematic and transparent manner with the involvement of stakeholders.¹²

The 2010 IOM/NRC committee noted: "A risk-based system should be grounded in risk analysis, with risk assessment, risk communication, and risk management as the essential basis for establishing a sound public-health protection capability."¹³ The recommendations included in this section of the report are focused on the first component of a risk-based system, risk assessment. Recommendations related to risk management (the role of USDA-FSIS) are addressed in Sections 7-11, and risk communication is discussed in Section 12.

There are two points to keep in mind in this section and those that follow. First, while we focus primarily in this report on pathogens such as bacteria and viruses, the modernized oversight system must address all hazards in the food supply (i.e., microbial as well as chemical and physical). Second, the Dialogue Group recognizes that risk-management decisions are often based on public-health as well as non-public-health considerations (e.g., feasibility, time constraints, and costs). To maintain trust in the system, it is important that policy decision-making be transparent so that stakeholders understand the rationale that led to specific decisions.

Recommendations

Meat and poultry safety oversight must be securely anchored in the risk that consumption of these products poses to human health. The first step in developing a risk-based system is to identify the risks to be addressed and the process by which they are identified. There are a number of possible models for how to achieve this; the Dialogue Group believes that any approach chosen must include these fundamental elements: there must be a clear separation between risk assessment and risk management functions; the approach must be data-driven; and it must be grounded in solid risk analysis. The Dialogue Group's recommendations included below spell out what it believes to be the best approach to this process: the creation of a new, independent food agency focused solely on risk assessment. A similar recommendation, to create of an independent risk analysis and data collection center, has been included in numerous reports by the Government Accountability Office that outline options for restructuring federal food-safety oversight.¹⁴

A. Congress should:

1. Establish a new, independent Food Risk Assessment Authority (FRAA), which would be the foundation of a more transparent, risk-based, food-safety oversight system.
2. Direct USDA-FSIS and FDA, the relevant regulatory authorities, to use the risk assessments developed by the FRAA as the basis of their performance and process standards, policies, and resource allocations. These agencies should provide transparency in decision-making by providing the public with clear documentation of their decisions, including the scientific evidence on which they are based.
3. Require the FRAA to:
 - a. Be a government entity, independent of USDA-FSIS and FDA, and should be the expert food-related science and risk-assessment body. It should not have regulatory authority; the regulatory role (i.e., risk management) should remain within USDA-FSIS and FDA.
 - b. Address all foods, including those regulated by USDA-FSIS and FDA; because a consolidated risk assessment authority would better ensure consistency across the food supply in the foundational function of risk assessment.
 - c. Conduct risk-assessment modeling for various pathogen-food combinations and potential interventions. The risk assessments should take into consideration the full farm-to-fork-to-physician continuum. The outcomes of these assessments will be used by USDA-FSIS and FDA for prioritization and risk mitigation.
 - The ALOPs should reflect the residual public-health risk for a given food-pathogen pair that would be acceptable to society, with the understanding that while risk can be reduced, zero risk cannot be achieved.
 - ALOPs should be established based on specific factors such as the particular pathogen, species, product and consumer, both at the time of slaughter or processing and also at the time of consumption.
 - Once an ALOP has been established, it should be periodically re-evaluated in light of newly available data and other relevant changes.
 - In developing its risk assessments, it should utilize in decision-making the ALOP for each pathogen-food combination, developed with input from a multi-stakeholder advisory group.
 - d. Conduct risk assessments in conjunction with a network of academic partners in order to build capacity and leverage resources. The FRAA should undertake scientific work on its own initiative, in particular to examine emerging risks and new hazards and to update its risk-assessment methods and approaches. In particular, it should directly establish relationships between prevalence and levels of contamination to update risk assessment models, and validate the risk of illness and outbreaks of illness associated with various levels of contamination.
 - e. Collaborate with CDC, USDA-FSIS, and FDA (e.g., through the Interagency Food Safety Analytics

Collaboration) to develop foodborne-illness, source-attribution estimates using outbreak as well as non-outbreak data sources.

- f. Prepare both an annual and multi-year work plan.
 - It should seek input from the multi-stakeholder advisory group and from other stakeholders in developing its work plans.
 - Its plans and priorities should take into account available resources.
- g. Produce systematic peer reviews of existing science and respond to urgent requests for advice from the regulatory agencies. FRAA staff shall also monitor and analyze information and data on biological hazards, chemical contaminants, and food consumption.
- h. Undergo periodic review by independent external evaluators and implement recommendations related to its work and practices, when appropriate.

DATA

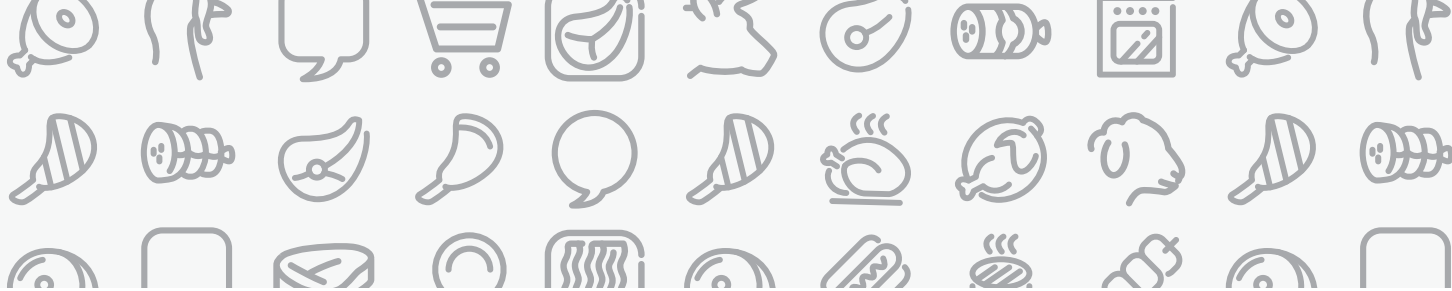
Background

Risk-based decision-making relies on a strong foundation of data that are: 1) ideally collected across the food-safety system; 2) accessible in ways that also protect privacy; 3) transferrable; and 4) comparable. Currently, the data needs of the food-safety system are being met through a patchwork of diverse data collection systems and networks, and there is no strategic approach to identify the information needed to support risk-based decision-making.

Data sources tend to be isolated, with limited access within and between sectors, making it difficult or impossible for decision-makers to access the right information at the right time. For example, many government agencies collect data across the food system but are reluctant to share data with third parties, including other government agencies.

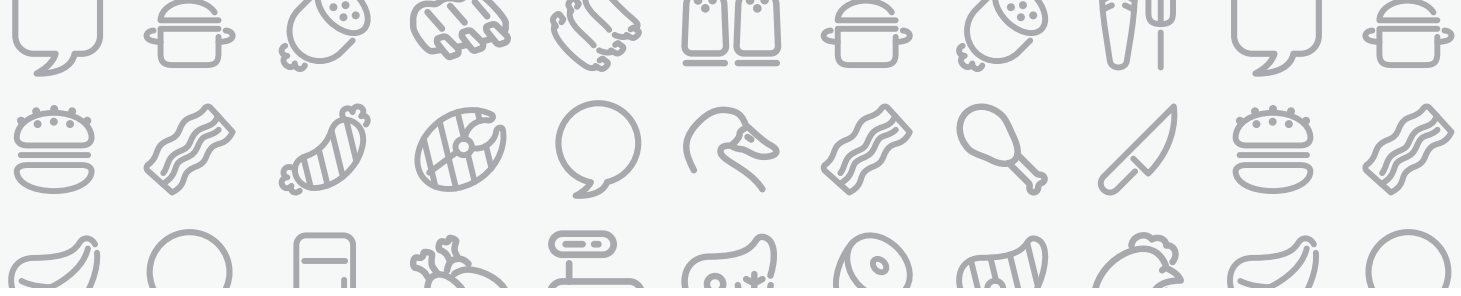
Similarly, food companies collect substantial amounts of data, everything from testing results to personal information from shopper loyalty cards and distribution data, which could be leveraged to assess food-safety risks and identify effective interventions. However, the food industry has been reluctant to share data with regulatory agencies because of potential regulatory ramifications and the desire to protect trade secrets and confidential business information. Future data collection efforts need to focus on gathering the right information from the right parties with an eye toward data sharing, while respecting appropriate concerns regarding confidential business information. That data then needs to be used proactively, in real time, to understand what is happening in the system so that necessary actions can be taken.

The Dialogue Group recognized the need for data that are relevant for the intended purpose, and are collected for many different purposes and in varying formats that may limit use for other purposes. For instance, free-text data may be adequate for recording observations in a single plant and may provide appropriate information during inspection of said plant, but such data is not very accessible for other uses (e.g., estimation of a nationally representative baseline). In addition, the usefulness of data often relies on meta-data that provides information on how the data was collected. For example, meta-data related to the results of microbiological testing could include the laboratory methods used to analyze the sample and its limit of detection, or how and when the sample was collected. Therefore, the usefulness of data for risk analysis, including operational data that may exist within individual facilities, may be limited. In addition, some data may be proprietary or contain confidential commercial information. Standards are needed to assure data meet minimum quality standards and are interpreted appropriately. Ideally, future data systems would allow for almost real-time data sharing between industry and regulatory agencies, and pre-agreed upon data standards would govern how data sources may be used appropriately.



Recommendations

1. Data-collection systems should be modernized to allow for automation and interoperability across systems, and to improve efficiency and facilitate timely and seamless collection and integration. Barriers to timely collection and sharing of data need to be identified; current IT infrastructure within and across agencies should be critically reviewed; and a strategy for modernizing and harmonizing data collection systems should be developed. Aggregating and linking of diverse data sources on a central platform would also support trend analysis, risk assessment, and decision-making.
2. Stakeholder analyses should be conducted to:
 - a. Identify data needs and gaps;
 - b. Determine if existing data sources are “fit-for-purpose” for meeting regulatory science needs;
 - c. Assess opportunities and barriers to increased data sharing; and
 - d. Develop recommendations for establishing a framework that supports the ongoing, systematic sharing of data to meet regulatory science needs.
3. The design of the modernized risk-based oversight system and updated data-collection systems need to occur simultaneously to better ensure that they are coordinated.
4. Modernized data-collection systems should facilitate the real-time exchange of data to the greatest extent possible.
5. Data collected during regulatory inspections can provide valuable insights for risk assessments and the development of ALOPs.
 - a. Information that is collected by inspectors during the inspection process should be standardized and collected on data forms, not text boxes, in order to facilitate data analysis and make the data more readily accessible for other users;
 - b. The data-collection system used for inspection records should be compatible with other data platforms; and
 - c. Data guidelines should be developed for confidential or proprietary data in inspection records.
- d. A holistic approach should be taken towards data collection to evaluate connections between food-safety outcomes and potential risk factors (e.g., production practices, animal welfare, and worker safety).
6. The types of data collected by agencies and industry should be based on the goals and expectations that the system is working to support; for example, if the Healthy People 2020 targets are the goal, then the data needed must support the necessary criteria to determine if the goal is being met.
7. A partnership should be established between the food industry and government agencies to increase data sharing between the public and private sectors. This partnership should, among other aspects, require data infrastructure that assures both confidentiality of the submitted data and sufficient granularity to generate useful data.
8. A public-private partnership may be the most appropriate entity to control the data infrastructure, and a multi-stakeholder advisory group would provide valuable recommendations related to infrastructure design. The public-private partnership, in consultation with the advisory group, the FRAA and the regulatory agencies, should establish clear and binding guidelines about data access and confidentiality. These guidelines should specify:
 - a. What industry-provided data the FRAA can use in risk assessments and how that data can be disclosed.
 - b. How confidentiality issues of concern, are resolved; this includes trade secrets for industry data and limitations under the privacy protections of the Health Insurance Portability and Accountability Act for clinical data.
 - c. How some proprietary data is protected from disclosure. The guidelines should clearly specify the criteria for determining if a given data set may be proprietary, and how proprietary data may be used and disclosed.
9. Incentives to maximize data sharing should be developed because they are central to the success of a voluntary data-sharing approach through a



public-private partnership. The regulatory agencies as well as FRAA should evaluate potential incentives for industry to share relevant data sources.

10. If voluntary data-sharing approaches prove unsuccessful, and the resulting lack of data significantly impacts the FRAA's ability to perform required risk assessments, the regulatory agencies, in consultation with the FRAA, the public-private partnership, and the advisory group should consider alternative approaches. These alternatives could include mandating data collection and sharing, or working with academia to fill in data gaps.

PRE-HARVEST (FARMS AND FEEDLOTS)

Background

Under existing law, USDA-FSIS's jurisdiction begins at the slaughterhouse and extends through the processing plant; as a result, primary regulatory focus is on reducing contamination during and right after "harvest" (i.e., slaughter and processing). However, to better protect public health, a comprehensive approach to meat and poultry safety is needed, one that begins at the farm and feedlot level, where the animals are bred and raised and much of the contamination that makes people sick originates. Currently, multiple agencies are responsible for various aspects of live animal agriculture, including FDA, USDA's Animal Plant and Health Inspection Service (USDA-APHIS) and USDA-AMS, but no one entity has clear jurisdiction over pre-harvest operations as they relate to food safety.

There are a range of pre-harvest interventions, measures aimed at improving public health by reducing contamination in food animals and, thereby, in the meat and poultry products produced from them. For example, biosecurity measures (e.g., quarantine, access restrictions, and vermin control), and best management practices (e.g., adequate housing, feed and water

hygiene for food animals) can be used to prevent the introduction and spread of foodborne pathogens on farms and feedlots.

Additionally, vaccines, probiotics, and bacteriophages have been developed to reduce carriage of potential foodborne pathogens. The approval process for these products, however, can be burdensome and confusing. While FDA's Center for Veterinary Medicine regulates veterinary drugs under the Federal Food, Drug and Cosmetic Act (FFDCA), biologics (such as vaccines) are regulated by USDA-APHIS under the Virus-Serum-Toxin Act (VSTA). The regulatory requirements and processes under these two statutes differ dramatically, as do the types of claims permitted. Moreover, it is often not clear before the fact whether a product should be regulated as a drug or a biologic.

In general, the use of antimicrobial drugs as pre-harvest interventions has not been demonstrated to be effective. International experts appear to agree that antimicrobials are not recommended as pre-harvest interventions for poultry,¹⁵ and use of several antimicrobials in cattle as pre-harvest administrations has not been shown to have a significant impact on fecal shedding or carcass contamination.¹⁶ In addition, reports on antimicrobial drug use among pigs have revealed varying effects. There is broad consensus that antimicrobials should not generally be used as a pre-harvest intervention against *Salmonella* in pigs. In fact, a meta-analysis of intervention studies found limited efficacy and potential harmful effects (i.e., increased fecal shedding prevalence) associated with tetracycline use, even though results were highly heterogeneous across studies, the number of studies was small, and studies raised quality concerns.¹⁷

Moreover, a major consideration with use of these drugs on farms and feedlots is the worldwide problem of antimicrobial resistance, which each year results in an estimated two million human infections with resistant bacteria and more than 23,000 deaths in the United States.¹⁸ Use of medically important antibiotics in animal agriculture is considered to be a contributing factor to this problem, even though the exact contribution has not yet been quantified.

Recommendations

A. Both USDA and animal producers should:

1. Adopt an approach to food safety that encompasses pre-harvest food safety to ensure that meat and poultry products are safe.
2. Collaborate to develop effective pre-harvest interventions and practices that diminish the risk of foodborne hazards and protect public health.

B. Congress should:

1. Grant USDA clear authority over pre-harvest food safety. This responsibility could be provided to USDA-APHIS or some other agency within the USDA. It should extend to production animals as well as breeding herds, farms and ranches, feedlots, feed mills, sale barns, hatcheries and live transport. The pre-harvest, food-safety agency at USDA should approach pre-harvest food safety from a One Health perspective. Specifically, Congress should:
 - a. Provide this agency with authority to establish science-based, species-specific, minimum pre-harvest food-safety standards to be met by farms and feedlots raising food-producing animals.
 - b. Specify that compliance with these pre-harvest standards can be verified through voluntary on-farm audits or other equivalent means.
 - c. Direct this agency to work with FDA and USDA-APHIS to improve the approval processes for pre-harvest interventions.
2. As an initial approach to encouraging the use of pre-harvest interventions, create a voluntary certification program, like the process-verified programs run by USDA-AMS, for the use of effective, science-based pre-harvest interventions, administered by the agency with pre-harvest authority. This agency should:
 - a. Consider including in this program comparable private-certification and quality-assurance programs.

- b. Review similar programs in other countries, such as Canada, when developing this pre-harvest certification program.

- c. Recognize the need to be size and scale appropriate in such programs.

- d. Assess, after three to five years in operation, the effectiveness of this approach by determining whether there has been a decrease in pathogen loads at slaughter and consider alternative approaches if the voluntary approach is not effective. The impact of pre-harvest interventions on the environment should also be considered.

- e. Develop new training programs to assist and encourage small producers to use pre-harvest interventions.

3. Fund additional research on pre-harvest interventions, which should include epidemiological studies that assess potential risk factors for increased microbial contamination.

C. Animal producers should:

1. Adopt strategies that reflect a range of approaches to reducing pre-harvest contamination, addressing species-specific needs.
2. Invest more money and commit to collaborating in research, including the sharing of data, to identify effective pre-harvest interventions and practices.
3. Disclose to the public and be more transparent about what actions are being taking to minimize pre-harvest contamination levels, including use of effective, science-based, pre-harvest interventions and practices.

D. Retailers and foodservice companies should:

1. Provide incentives for meat and poultry suppliers to employ scientifically validated pre-harvest interventions, the use of which is verified by a third-party audit.

HARVEST (SLAUGHTER)

Background

Inspection

Currently, the USDA-FSIS deploys approximately 7800 inspectors (1000 of which are veterinarians) in 6400 meat and poultry establishments around the United States.¹⁹

Inspection at slaughterhouses is important to assure food safety, to detect foreign animal diseases, such as classical swine fever or foot and mouth disease, and to identify any violations of animal welfare protections. In terms of food safety, there are two goals: (1) to keep animals unfit for human consumption out of the food supply; and (2) to verify that the slaughter operation has a system in place that minimizes the contamination that results in human illness. Current inspection activities, however, in which inspectors primarily rely on their senses of sight, smell and touch during examination (an approach known as traditional or organoleptic inspection) do not align with these two food-safety goals.

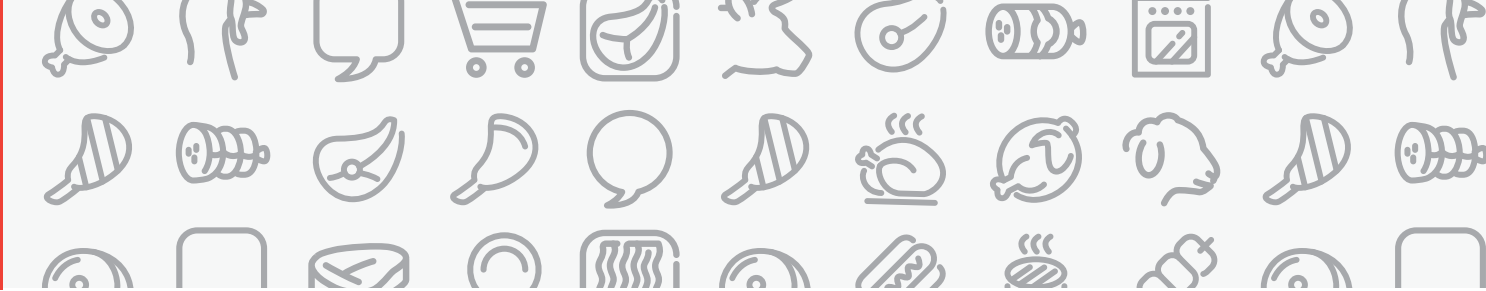
The current inspection activities, which are the same ones performed over a century ago, were actually risk based at that time; the largest food-safety risks at the beginning of the 20th century were tuberculosis, brucellosis and trichinellosis, all of which can be readily detected organoleptically. Fortunately today, none of these diseases pose major food-safety risks in the United States; the diseases that do present important risks (e.g., infections caused by *Salmonella*, STEC, and *Campylobacter*) rarely cause morphological changes in animals and, therefore, cannot be detected and controlled through traditional meat inspection protocols. Numerous scientific studies on the effectiveness of traditional inspection in detecting food-safety problems have been conducted in a variety of countries, primarily for swine (e.g., comparing traditional and visual only inspection), but

also for other species.²⁰ Some findings from these studies are transferrable to the United States, in particular:

1. Foodborne pathogens that can cause important human health impacts and that can be readily detected by organoleptic meat inspection (e.g., *Mycobacterium tuberculosis*, *cysticercus*) have become exceedingly rare in most developed countries.
2. Many of the morphological changes that cause carcasses to be deemed unfit for human consumption during meat inspection (e.g., granulomatous process in lymph nodes) are rarely associated with the presence of foodborne pathogens or risks.
3. Even for hazards that can be detected through organoleptic inspection, this inspection approach is often not sufficiently sensitive to detect all lesions that could cause a human health impact (e.g., *cysticercus* lesions, though detectable by organoleptic inspection, may be overlooked).
4. The most common pathogens associated with foodborne illness (e.g., *Salmonella*) rarely cause pathological changes that can be detected by traditional meat inspection.

There is a clear recognition that inspection tasks can and should vary based on the actual risks to human health associated with individual animals and species. For example, the risk for *Toxoplasma gondii* differs between pigs raised in outdoor versus indoor housing systems and inspection methods should take this into account. In addition, information from ante-mortem (pre-slaughter) inspection, as well as food-chain information, such as a producer's history of food-safety problems, should be used to determine risk.

One activity undertaken as part of inspection is microbiological testing; it is used to verify that a facility is adequately controlling bacterial contamination during and after slaughter, and involves sampling and testing a certain number of carcasses. While testing can be used to detect pathogens in each individual carcass, detection is unlikely to occur, given that contamination is heterogeneous and prevalence is generally low. For this reason, using microbiological testing as the primary mechanism for ensuring the safety of individual meat



and poultry products is impractical because it would require extremely large sample sizes and would be very expensive.

To verify that a slaughter plant is controlling contamination, inspectors test samples to determine whether establishments are meeting performance standards set by USDA-FSIS. In the food-safety context, performance standards can be based on anything from best practices to defined log reductions in a specific contaminant to even a zero tolerance. Under existing laws and regulations, USDA-FSIS bases most product-specific performance standards on the presence or absence of a particular pathogen in a set number of samples its inspectors collect and test (i.e., these are “qualitative” standards). For example, the performance standard for *Salmonella* in ground chicken is 13 positives out of 52 samples (or 25%); establishments with more than 13 positives in the 52 sample set are considered to have failed the performance standard.

Traditionally, these performance standards have been based on the nationwide average prevalence of bacterial contamination in a specific product, and were designed to ensure that a designated percentage of establishments should be able to meet them. However, because these qualitative standards only measure the presence or absence of particular pathogens in a given sample set, they do not identify those products that are contaminated with very high bacterial loads and therefore, depending on the pathogen, can pose a significant public-health risk. For example, individual products in a sample set that test positive for *Salmonella* can still be sold to consumers without restrictions.

In an effort to further reduce risk, some companies have set their own voluntary “semi-quantitative” performance standards, which do take into consideration the number of carcasses with contamination levels that exceed a threshold based on risk to public health. Quantitative-based performance standards more closely align with a risk-based, food-safety system.

Recommendations

The current approach to meat inspection at slaughter should be modernized to assure that the tasks performed are risk based, public health focused, and aligned with current technology. An important foundational aspect of designing a risk-based oversight system is defining the risks that have to be addressed, and reaching consensus on ALOPs. While zero risk is not a feasible option, it is clear that more can be done to reduce risk. (See Section 5 for our recommendation regarding the establishment of the FRAA and the development of ALOPs.)

The ideal approach to inspection should address risks posed by chemical and physical hazards as well as microbiological pathogens. It should also be based on ALOPs that are specific to factors such as the particular agent, target, animal species, product, and consumer, both at the time of slaughter and also at the time of consumption.

The inspection system at slaughter for meat and poultry should move from a task-based oversight architecture to one that is systems-based and risk-based and should provide increased incentives to improve public health.

A. Congress should amend the meat and poultry laws to:

1. Base the nature and frequency of slaughter inspection on the associated public-health risk. The nature and frequency of inspection should vary depending on a range of factors, including, but not limited to:
 - a. Species;
 - b. Production systems;
 - c. Production practices;
 - d. Past performance (e.g., previous residue violations);
 - e. Destination (e.g., ready-to-eat (RTE) products have a different risk profile than products that will be sold raw);
 - f. Whether effective, science-based, pre-harvest interventions have been employed; and
 - g. Potential impact on public health.

2. Direct the FRAA to:

a. Collaborate with USDA-FSIS to determine:

- Which specific hazards slaughterhouses should be required to control;
- What data (e.g., food-chain information, such as how were animals raised, what treatments were needed) producers should have to provide when presenting their animals for slaughter inspection;
- What activities, or combination thereof, are best suited to validate control of these hazards; and,
- How frequently the individual inspection tasks (verification) should be required.

b. Update risk-assessment models based on enumeration of foodborne pathogen contamination levels in final product samples;

c. Estimate the risk of illness and outbreaks of illness that can be associated with various levels of contamination and set maximum limits consistent with the relevant ALOP; and

d. Collaborate with the CDC to validate risk estimates against reported illnesses and outbreaks to evaluate the effectiveness of the system.

3. Require USDA-FSIS, based on information provided by the FRAA, to set performance standards that are science and risk-based and related to public-health outcomes (e.g., Healthy People 2020) and the relevant ALOP. These standards should verify that a facility's process control measures are working adequately to produce safe food.

4. Create two types of inspectors at slaughter, both of whom are focused on food-safety (not quality) issues:

a. Gatekeeper inspectors, whose job is to keep animals unfit for human consumption, including those with foreign animal diseases or those mistreated in violation of animal welfare protections, out of the food supply and who should:

- Consider the animals' history/risk factors;
- Conduct ante-mortem inspection, preferably with food chain information available;

- Undertake limited post-mortem inspection, as necessary (e.g., for suspect animals only); and
- Ensure that these gatekeeper inspectors, USDA-FSIS employees, are veterinarians, or staff trained by and under the supervision of veterinarians.

b. Plant inspectors, whose job is to assure, by focusing on carcass and verification system activities, that the slaughter facility is operating in a way that reduces contamination. They should:

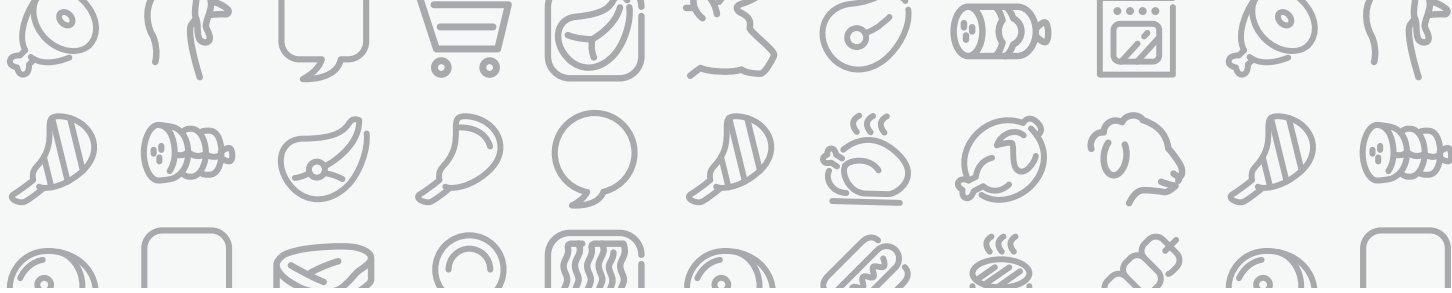
- Conduct inspections to verify sanitary slaughter practices;
- Review establishment records, which should be accessible and maintained in an easily shareable format;
- Evaluate the operations of the facility (e.g., sanitation standard operating procedures and use of interventions); and
- Focus their inspections on outcomes and the overall operation of the facility, and not solely on whether facility employees are completing specific tasks.

5. Direct USDA-FSIS, based on information provided by the FRAA, to verify that an establishment's microbial testing plan, including the frequency of testing, as well as minimum detection levels and methodology, are appropriate. Testing plans should be designed to monitor the presence of food-safety hazards based on the ALOP and expected public-health risk. USDA-FSIS should verify that:

a. Food-safety hazards (e.g., microbiological pathogens, allergens and chemical residues) are controlled by validated processes and that data are provided as evidence that the overall food-safety system is working; and

b. Microbiological or chemical tests performed are effective in assuring that the slaughter facility is producing safe food.

- Depending on factors such as establishment history and product type, some verification testing tasks may be delegated to facility employees.



- If verification testing is delegated to facility employees, then USDA-FSIS should review and approve a company testing plan; if its plan is rejected, the company should modify it to meet requirements for validation, permissible levels of variability, minimum documentation requirements and laboratory accreditation.
- USDA-FSIS should work with the FRAA to develop guidance on testing programs for small and very small slaughter facilities.

B. USDA-FSIS should:

1. Provide, to the degree possible, that:
 - a. Inspection activities are related to public health; and
 - b. Inspector variability is minimized.
2. Create at the district level multi-stakeholder bodies (similar to Institutional Review Boards, which are committees established to review and approve research involving human subjects) that would verify the scientific validity of studies used to support a slaughter establishment's:
 - a. Initial grant of inspection;
 - b. Process control within implementation of a PR/HACCP plan; and
 - c. Process standards.
3. Work with a representative group of small and very small plants to create guidance documents that outline possible acceptable processes to achieve the ALOPs. Each hazard should have clear guidance that explains the ALOP and validated methods of achieving the standard. Plants would then be expected to verify their compliance with validated standards.
4. Fund additional research to close important data gaps and provide the necessary foundation for a risk- and science-based system. For instance, fund research to:

- a. Better understand what microbiological targets to choose for in-plant surveillance and process validation activities; and
- b. When, where and how best to conduct microbial testing, and how these choices may be affected by external factors such as plant type, animal species or season.

C. USDA-FSIS and state regulators should:

1. Coordinate more closely their inspection activities (e.g., individual plants may be inspected by FDA, USDA, and state agencies); and
2. Standardize training and education requirements for federal and state inspectors.

D. Meat and poultry companies should:

1. Determine, based on the relevant ALOPs, how to appropriately manage their supply chains, and meet those ALOPs through:
 - a. Preventive practices;
 - b. Useful and effective microbiological testing (e.g., environmental, process-control and product testing);
 - c. Mechanisms for corrective action, as necessary; and
 - d. Monitoring activities:
 - Find systematic and consistent ways to perform environmental and product sampling in every plant so that data can be compiled and analyzed as a whole;
 - As sampling procedures evolve to become more consistent, provide clear guidance documents regarding changes; and
 - Develop quantitative validation of process controls and use it to determine acceptable contamination levels as animals enter the slaughterhouse in order to assure that relevant ALOPs are being met.

PROCESSING AND FURTHER PROCESSING

Background

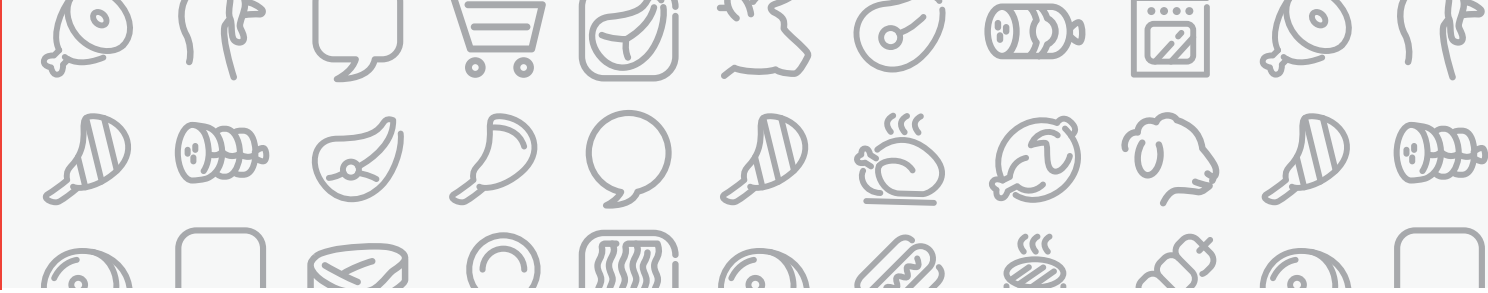
Initial processing in meat and poultry operations involves transforming an animal carcass into large sections known as primal cuts, which are then broken down further into individual retail cuts, which are what you find at the supermarket. Further processing involves taking those pieces of meat and turning them into value-added products such as patties and sausage. Meat processing involves a wide range of physical and chemical treatment methods, normally combining a variety of methods, including: cutting/chopping/comminuting; mixing/tumbling; salting/curing; adding spices or other non-meat additives; stuffing/filling into casings or other containers; fermenting and drying; and smoking.²¹ Further processing can occur in a single facility or be dispersed throughout many different facilities, in which case transportation may be involved. The more links there are in the supply chain, the more opportunities there are for food-safety problems such as temperature abuse and cross-contamination, which may create or exacerbate risks.

The goal for inspection at plants that do processing and/or further processing is to verify that the operation has a system in place that minimizes the contamination that results in human illness. As is the case with slaughter inspection, there is a clear recognition that inspection tasks in a processing environment can and should vary based on the actual risks to human health. Performance standards are set by USDA-FSIS at processing as well as at slaughter. Many believe that the agency should follow a more quantitative approach to setting these standards at processing so that they are more focused on the impact on human health.

Recommendations

A. Congress should amend the meat and poultry laws to:

1. Base the nature and frequency of inspection at establishments doing processing or further processing
 - a. on associated public-health risk. The nature and frequency of inspection should vary depending on a range of factors, including, but not limited to:
 - a. Species;
 - b. Production systems;
 - c. Production practices;
 - d. Past performance (e.g., food-safety record);
 - e. Destination (e.g., ready-to-eat (RTE) products have a different risk profile than products that will be sold raw);
 - f. Whether effective, science-based, pre-harvest interventions have been employed; and
 - g. Potential impact on public health.
2. Direct the FRAA to:
 - a. Collaborate with USDA-FSIS to determine:
 - Which specific hazards processing and further processing plants should be required to control;
 - What activities, or combination thereof, are best suited to validate control of these hazards; and
 - How frequently the individual inspection tasks (verification) should be required.
 - b. Update risk-assessment models based on enumeration of foodborne-pathogen contamination levels in final product samples.
 - c. Estimate the risk of illness and outbreaks of illness that can be associated with various levels of contamination and set maximum limits consistent with the relevant ALOP.
 - d. Collaborate with CDC to validate risk estimates against reported illnesses and outbreaks to evaluate the effectiveness of the system.
3. Require USDA-FSIS, based on information provided by the FRAA, to set performance standards that are science- and risk-based and related to public-health outcomes (e.g., Healthy People 2020) and the relevant ALOP. These standards should verify that a facility's process control measures are working adequately to produce safe food.
4. Inspectors at plants that do processing and further processing should:
 - a. Conduct inspections to verify sanitary practices;



- b. Review establishment records, which should be accessible and maintained in an easily sharable format;
 - c. Review the operations of the facility (e.g., sanitation standard operating procedures and use of interventions); and
 - d. Focus their inspections on outcomes and the overall operation of the facility.
5. Direct USDA-FSIS, based on information provided by the FRAA, to verify that an establishment's microbial testing plan, including the frequency of testing, as well as minimum detection levels and methodology, are appropriate. Testing plans should be designed to monitor the presence of food-safety hazards based on the ALOP and expected public-health risk. USDA-FSIS should verify that:
- a. Food-safety hazards (e.g., microbiological pathogens, allergens and chemical residues) are controlled by validated processes and data provided as evidence that the overall food-safety system is working; and
 - b. Microbiological or chemical tests performed are effective in assuring that the processing or further processing facility is producing safe food.
 - Depending on factors such as establishment history and product type, some verification testing tasks may be delegated to facility employees.
 - If verification testing is to be delegated to facility employees, USDA-FSIS should review and accept or reject a company testing plan; if the company plan is rejected, it should then modify the plan so that it meets requirements for validation, permissible levels of variability, minimum documentation requirements and laboratory accreditation.
 - USDA-FSIS should work with the FRAA to develop guidance on testing programs for small and very small processing facilities.
- B. USDA-FSIS should:**
1. Provide, to the degree possible, that:
 - a. Inspection activities are related to public health; and
 - b. Inspector variability is minimized.
2. Create at the district level multi-stakeholder bodies (similar to Institutional Review Boards, which are committees established to review and approve research involving human subjects) that would verify the scientific validity of studies used to support a processing establishment's:
 - a. Initial grant of inspection;
 - b. Process control within implementation of a PR/HACCP plan; and
 - c. Process standards.
 3. Work with a representative group of small and very small plants to create guidance documents that outline possible acceptable processes to achieve the ALOPs. Each hazard should have clear guidance that explains the ALOP and validated methods of achieving the standard. Plants would then be expected to verify their compliance with validated standards.
 4. Fund additional research to close important data gaps and provide the necessary foundation for a risk- and science-based system. For instance, fund research to determine the most efficient and cost-effective interventions to address the key hazards of concern in processing and further processing and how to best implement them.
- C. USDA-FSIS and state regulators should:**
1. Coordinate more closely their inspection activities (e.g., individual plants may be inspected by FDA, USDA, and state agencies); and
 2. Standardize training and education requirements for federal and state inspectors.
- D. Meat and poultry establishments should:**
1. Determine, based on the relevant ALOPs, how to appropriately manage their supply chains, from farm-to-fork and meet those ALOPs, through:
 - a. Preventive practices;
 - b. Useful and effective microbiological testing (e.g., what type and when, environmental, process control and product testing);
 - c. Mechanisms for corrective action, as necessary; and
 - d. Monitoring activities:

- Find systematic and consistent ways to perform environmental and product sampling in every plant so that data can be compiled and analyzed as a whole;
- As sampling procedures evolve to become more consistent, provide clear guidance documents regarding changes; and
- Develop quantitative validation of a plant's process controls and use it to determine acceptable contamination levels as animals enter the slaughter plant in order to assure that relevant ALOPs are being met.

ENFORCEMENT AUTHORITY

Background

Producers of meat and poultry products have the responsibility to comply with the relevant laws and regulations and produce safe, wholesome, and accurately-labeled food. USDA-FSIS is responsible for and has the legal authority to verify that slaughter and processing establishments are meeting these requirements. The agency protects public health and prevents foodborne illness by inspecting establishments; utilizing its enforcement authorities; conducting public education and outreach to increase safe-food-handling practices; and strengthening collaboration among stakeholders.

USDA-FSIS has a range of enforcement tools to employ when a meat or poultry establishment under its jurisdiction violates the relevant laws or regulations. There are administrative remedies, as well as civil detention, seizure, and criminal prosecution.

A recall can protect consumers after contaminated or potentially contaminated products have left a processing plant. USDA-FSIS does not have the authority to mandate a recall and can only request one. When there is evidence that a recall may be appropriate,

USDA-FSIS convenes the Recall Committee, a standing committee consisting of USDA-FSIS scientists, technical experts, field inspection managers, enforcement personnel and communications specialists, which evaluates all available information and makes a recommendation to the company about the need for a recall. Companies can also independently recall their products without being asked by USDA-FSIS. As an alternative, the agency can also issue public-health alerts to inform the public about potential health risks in cases where a recall has not been recommended. For example, FSIS may issue an alert to inform consumers of a potential risk when it is aware of an outbreak of foodborne illness but the food vehicle has not yet been identified.

Currently, USDA-FSIS's handling of recalls is not satisfying many stakeholders. Consumer advocates complain that USDA-FSIS has failed to request a recall in certain instances when they believe it was justified, thereby putting consumers at risk. Meat and poultry companies criticize the agency for its lack of transparency in the recall process, and note that there have been instances when the agency has impeded them from voluntarily recalling product.

Recommendations

A. Congress should:

1. Ensure that the agency's use of its enforcement tools is risk-based;
2. Strengthen enforcement tools, where necessary;
3. Increase transparency and accountability of government and meat and poultry establishments when there is an enforcement action;
4. Ensure that members of the USDA-FSIS Recall Committee have the necessary knowledge and training to determine when a recall is appropriate and to increase consistency of decision-making throughout the recall process;
5. Ensure due process protections are available for meat and poultry companies subject to a potential enforcement action;

6. Strengthen public-health protection and information dissemination and transparency to consumers;
7. Broaden the public notification requirements and other corporate requirements associated with recalls and public-health alerts;
8. Improve the quality and speed of communications and information sharing between USDA-FSIS, public-health authorities, and a meat and poultry company before a potential enforcement action or product withdrawal or recall;
9. Determine an appropriate way, through enhanced penalties, mandatory recall authority, or other measures, to deal with repeat violators or other “bad actors;”
10. Explore approaches for increasing accountability for USDA-FSIS to its stakeholders, both regulated companies and consumers;
11. Enable government agencies to share information when there is an ongoing investigation; and
12. Explore options to resolving disputes between inspectors and meat and poultry establishments.
13. Amend the meat and poultry statutes to provide that establishments regulated by USDA-FSIS may not discharge or otherwise discriminate against an employee because the employee:
 - a. Provided information relating to any violation of any provision of the meat and poultry statutes or any order, rule, regulation, standard, or ban under it;
 - b. Testified in a proceeding concerning such violation; or
 - c. Objected to, or refused to participate in, any activity, policy, practice, or assigned task reasonably believed to be in violation of any provision of the meat and poultry laws, or any order, rule, regulation, standard, or ban under these laws.

POST-PLANT-OF-ORIGIN SUPPLY CHAIN

Background

While meat and poultry products remain under the control of the establishment where they were produced, USDA-FSIS continues to be responsible for assuring their safety. However, once these products leave that facility, government oversight shifts. Because, at every step in the post-plant-of-origin supply chain, meat and poultry products can be mishandled or contaminated to the point where there is an escalated risk, government authorities at the federal, state, and local levels have established requirements to prevent problems from occurring, and government inspectors are tasked with ensuring that these requirements are being met.

Depending on the circumstances, warehouses and other storage facilities may be inspected by FDA, USDA-FSIS, or state or local authorities. An identification (ID) warehouse, for example, is a facility at which USDA-FSIS provides voluntary identification service for meat or poultry products.²²

The sale of food, including meat and poultry products, via e-commerce is a burgeoning business. However, by using the same distribution channels as conventional sales, these internet sales raise the same safety-related question: Which entity/ies are responsible for ensuring that there is adequate cold-chain management and other protections in place to prevent cross-contamination and tampering while the products are in transit.²³

The Sanitary Transportation of Human and Animal Food rule, which was finalized by FDA as part of FSMA in April 2016, sets requirements for the transportation

of food, including meat and poultry products, by motor or rail vehicle. FDA makes the shipper (i.e., the entity that arranges for the transportation of food by motor or rail vehicle within the U.S.) responsible for determining all necessary sanitary specifications for the carrier's vehicle and transportation equipment to ensure that they prevent the food from becoming unsafe during transportation operations. The shipper may rely on written contractual agreements to assign some of these responsibilities to other parties, such as a loader or carrier. The rule addresses issues such as temperature control, training, equipment design and maintenance. While FDA developed this rule, any one of three agencies – USDA-FSIS, FDA, or the U.S. Department of Transportation (DOT) – has a role to play in ensuring compliance with the rule and implementing the Sanitary Food Transportation Act, as it relates to transportation of meat and poultry products.

Regulators at the state, local, and tribal levels oversee food safety as it relates to foodservice operations such as restaurants, grocery stores (including delis and meat departments), hotels, institutional kitchens, commissaries, and caterers. With input from the Conference for Food Protection, FDA develops the Food Code, model regulations governing preparation and handling of all food products, including meat and poultry, in this sector. The Food Code is updated regularly; between 1993 and 2001, the Food Code was issued every two years and, beginning in 2005, every four. The 2013 Food Code is the most recent complete edition published by FDA. State and local regulators may adopt some or all Food Code provisions from different editions into their own regulations but they are not required to do so.

Recommendations

A. Federal, state and local authorities should:

1. Conduct periodic, risk-based inspections while meat and poultry products are being stored in a warehouse, a distribution center (i.e., short-term storage) or in a long-term storage facility.

The appropriate agency should ensure, through inspections, that:

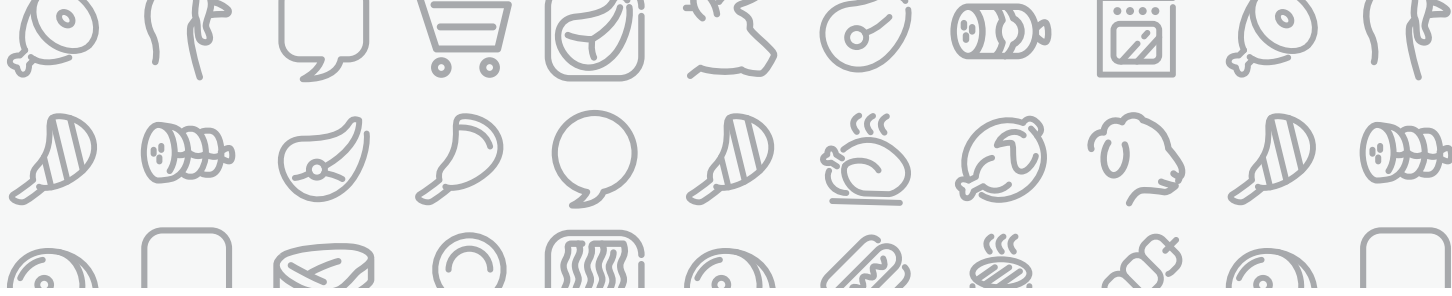
- a. There is adequate cold-chain management/temperature control in the facility;
- b. The storage facility is in sanitary condition;
- c. There is adequate pest control;
- d. Product is stored to minimize possible cross-contamination;
- e. Product is secure from tampering;
- f. Packaging is in good condition; and
- g. If any of these requirements are not being met, the relevant authority should take action to ensure that the facility corrects any problems and, if it does not, then the facility should be closed.

B. USDA-FSIS, FDA, and DOT should:

1. Develop and implement a coordinated, risk-based inspection and enforcement strategy for assuring compliance with the Sanitary Transportation rule and implementing the Sanitary Food Transportation Act, as it relates to transport of meat and poultry products.
2. Regardless of the method of purchase (i.e., conventional store or e-commerce) and distribution (i.e., truck, ship, rail, or plane) ensure that, until delivery to the consumer:
 - a. There is adequate cold-chain management/temperature control for the distribution method;
 - b. The transportation vessel is in sanitary condition;
 - c. There is adequate pest control;
 - d. Product is stored to minimize possible cross-contamination; and
 - e. Product is secure from tampering.

C. State and local authorities should:

1. In order to reduce the risk of contamination and mishandling of meat and poultry products, include in their foodservice regulations the following important food-safety-related provisions from the 2013 Food Code:



ESSENTIAL FOOD-SAFETY PROVISIONS FROM 2013 FOOD CODE TO BE INCLUDED IN ALL STATE AND LOCAL REQUIREMENTS

Issue	Relevant Part or Section
Holding Temperatures for Hot and Cold Food	§ 3-501.16
Cooking Temperatures	§§ 3-401.11 and 3-401.12
Cooling	§ 3-501.14
Preventing Contamination from Hands	§ 3-301.11
Preventing Cross-Contamination	§ 3-302.11
Food Contact Surfaces and Materials	Part 4-1
Cleaning Equipment and Utensils	Part 4-6
Sanitizing Equipment and Utensils	Part 4-7
Consumer Disclosure	§ 3-603.11
Handwashing	§ 2-301.12
Sick Workers	§ 2-201.12
Certified Food Protection Manager	§ 2-102.12
Training Documentation	§ 8-201.14

RISK COMMUNICATION

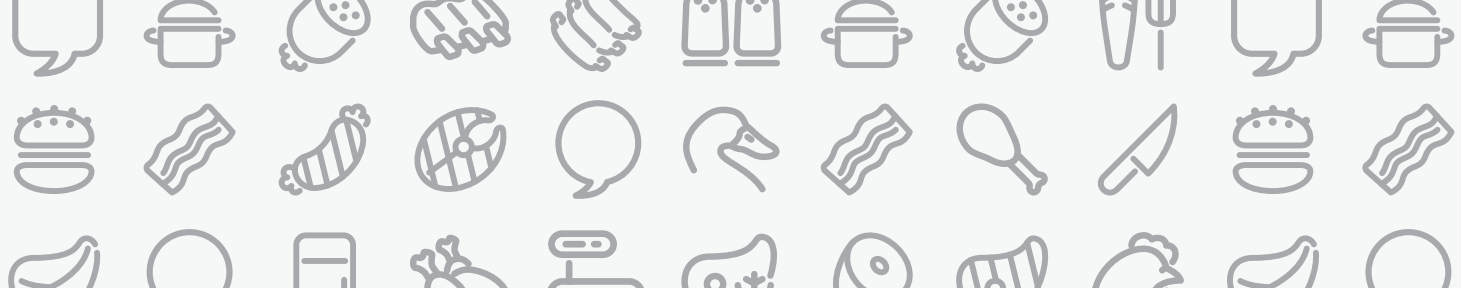
Background

Accurate risk communication with stakeholders is an integral component of a risk-based approach to food-safety oversight. Effective risk communication can also be considered more broadly as a policy tool used by government agencies to better ensure food safety and protect public health.²⁴

Effective risk communication is essential in equipping consumers with the information they need to protect themselves from foodborne illness. Experts note that “messages about food-safety risks and action to mitigate these risks should be rapidly distributed

at appropriate times, tailored to the intended audience, and provide reliable information.”²⁵ In addition, “[f]ood risk information should provide the necessary information for people to achieve a sufficient understanding of risk so that they can decide whether to take measures to protect their health.”²⁶ In order to construct and disseminate information effectively, risk communicators should identify target audiences, convey timely, accurate information from credible sources, be transparent about uncertainties and reach audiences through their preferred channels.²⁷ When practicable, risk communications should be tested on representatives of the intended audience.

One important example of government risk communication regarding meat and poultry is the Safe Handling Instructions (SHI) label. First required by USDA-FSIS in 1994, it was designed to educate consumers regarding the health risk associated with raw and partially cooked meat and poultry. The label has not



been updated in over 20 years, and reflects neither current science nor consumer knowledge. Moreover, information included in the label is not sufficiently specific to help consumers minimize their risk.

One way FDA is working to improve its risk-communication activities is through the creation of a Risk Communications Advisory Committee, which reviews and evaluates proposed strategies and programs designed to communicate with the public about the risks and benefits of products it regulates. It also evaluates research relevant to such communication to the public by both FDA and other entities.

Food preparers, handlers, and servers also need to effectively communicate risk to the consumers they serve, and a recent research study suggests they are not doing a good job communicating the risk of consuming undercooked hamburgers.²⁸ One important communication tool is the consumer advisory regarding the risk of raw and undercooked meat and poultry products that is included on restaurant menus and signage.

Risk communication is transmitted through both traditional and non-traditional channels, including social media. The popularity of celebrity chefs and cooking shows provide one avenue for communicating important information about food safety and safe-food-handling practices. As recent research notes, some cooking shows are not modeling proper food-safety behavior.²⁹

Social media provide opportunities to more widely disseminate information about the risks posed by meat and poultry products and how to mitigate them, and school-based solutions (i.e., reinstating home economics and health classes in middle and high school) are valuable venues for educating students about food safety.

Recommendations

Government agencies and the food industry should improve their risk communication so that stakeholders across the system, including

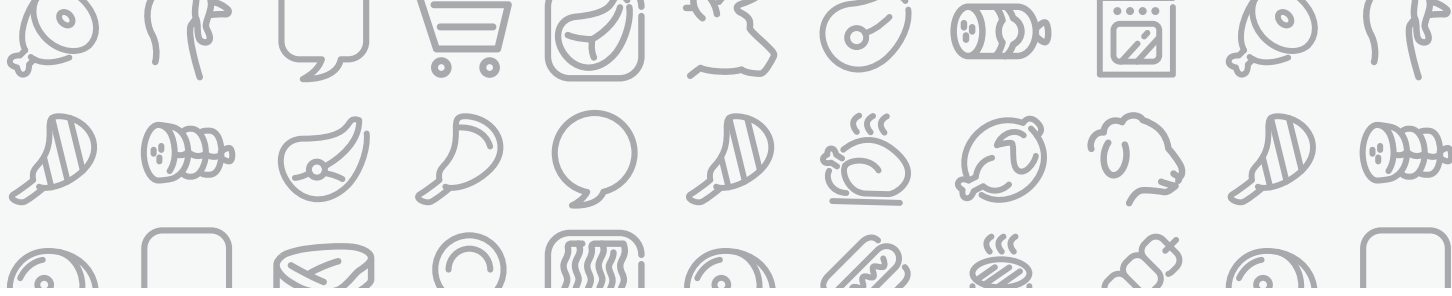
food handlers, preparers, servers, and consumers, understand the risks posed by meat and poultry products and appropriately address those risks by following safe food handling practices when they handle, cook, and serve these products.

A. Congress should:

1. Allocate more funding to support research to examine how consumers view different food risks, what risk messages they are more likely to respond to and remember, and the best methods for delivering the information (i.e., who is delivering the information and in what context). Research should also examine whether there are different responses to risk information based on the food commodity, and whether subgroups within the broad community of consumers view risk information differently.

B. Federal food-safety agencies should:

1. Work together to expand the scope of FDA's Risk Communications Advisory Committee to include, in its food-related work, communication activities by both USDA-FSIS and CDC. This collaboration should help ensure (to the degree appropriate and possible) a consistent approach to risk communication as it relates to food. Other governmental and public-private partnerships that inform consumers about food-safety risks, such as foodsafety.gov, CDC's Vital Signs, and the Partnership for Food Safety Education, should ensure that their messaging is consistent with the recommendations of the Risk Communications Advisory Committee.
2. Ensure that all communication with stakeholders, and in particular consumers, follow best practices for risk communication, providing information about a risk as well as specific instruction regarding what should be done to reduce it.
 - a. Risk communications should be updated frequently to build trust with consumers, making them more receptive to the information that is being shared.
 - b. There is a need to tailor messages to specific audiences with different views of risk, and the proper context for a risk should be provided.



C. USDA-FSIS should:

1. Establish a dynamic risk-communication system that clearly communicates the actual risks associated with different food items, and that reflects changes in our understanding of risk.
2. Bring research into the public domain on pathogen risks and emerging pathogens.
3. Revise the SHI label, consistent with the 2014 recommendations of the National Advisory Committee on Meat and Poultry Inspection. USDA-FSIS should require specific, straightforward, and legible information about safe handling practices including:
 - a. An endpoint temperature in bolded or larger font, for raw and partially-cooked product categories (i.e., intact meats; non-intact meats; poultry), as well as any rest time requirement; and
 - b. Instructions on how to use a thermometer properly to verify that product has reached the recommended internal temperature.
4. Improve communication practices related to recalls to increase their effectiveness, in particular through greater use of social media.

D. FDA should:

1. Revise and update (with input from the Conference for Food Protection) the consumer advisory regarding the risk posed by consumption of raw and undercooked meat and poultry products that is included on restaurant menus and signage.

E. State and local authorities should:

1. Adopt any updated consumer advisory language regarding raw or undercooked meat and poultry products proposed by the FDA.

F. Meat and poultry industry should:

1. Provide clear information on product labels, company websites and other materials and channels, including social media, that is easily understood by the consumers, about the risks associated with meat and poultry products and how to minimize them; and

2. Provide accurate information via social media that is consistent with government messages.

G. Retailers should:

1. Do more to provide information about meat and poultry safety and should promote the purchase and use of meat thermometers.

H. Foodservice should:

1. Align third-party certification programs such as ServSafe to better train food preparers, handlers, and servers so they are provided with an explanation of foodborne illness (how it can be contracted and how serious it can be) and the importance of safe-food-handling and cooking practices to their customers.
2. Reflecting best practices in the risk-communication literature, better train servers to clearly communicate food-safety information to foodservice customers. In particular, they should understand and be able to explain clearly to patrons the consumer advisory regarding the risk posed by consumption of raw and undercooked meat and poultry products included on restaurant menus and signage.

I. Other Communicators should:

1. Make greater use of social media and other non-traditional channels to educate the public about food safety.
2. Reach out to celebrity chefs and cooking shows and encourage them to follow-safe-food handling practices and to provide accurate information about food safety.

J. Educators and School Systems should:

1. Ensure that information about food safety and proper safe-handling practices are integrated into both middle and high school curricula, whether through home economics, health, or science classes. Important aspects of this information should include: hygiene; proper storage and cooking; and the time-temperature relationship of pathogen growth. The consequences of failing to follow safe-food practices should be included in high school courses as a means to emphasize the real-life importance of these practices.

HEALTH CARE AND PUBLIC HEALTH

Background

In a desire to address the meat and poultry safety oversight system comprehensively, the Dialogue Group decided not to stop with the “fork” (i.e., the consumer) but, rather, to also include recommendations related to the physicians who treat foodborne-illness victims and the public-health system that tracks pathogens and investigates illness outbreaks.

Epidemiology serves as the foundation for a risk-based, food-safety oversight system and the information that it can provide drives prevention-based policies. Quick identification of foodborne illnesses and their sources is absolutely essential; this information provides feedback on the effectiveness of existing food-safety systems and offers insights on where government agencies and the food industry should focus their efforts to improve public health. However, public-health agencies at all levels often lack the epidemiologic capacity to effectively respond to and prevent foodborne disease.

There are many obstacles to solving foodborne-illness outbreaks. Few patients seek medical attention for foodborne illness and often blood and stool samples are never collected because they are not viewed as clinically useful, even though they are important to public-health surveillance. A single patient or series of patients could be an early signal of a foodborne-illness outbreak. However, public-health agencies often lack the human resources needed to complete, in a timely manner, interviews of patients suffering from what might be a foodborne illness.

This is the essential first step in an outbreak investigation. As a result, many foodborne illnesses are not identified and, of those that are, few are associated with an outbreak or have an identified food vehicle.

Training and education needed to improve the understanding of foodborne illness span the medical, veterinary, and agricultural spheres. A true One Health approach is needed to assure students grasp the complex interactions between foodborne pathogens, animal health, and human health.

Recommendations

A. Congress should:

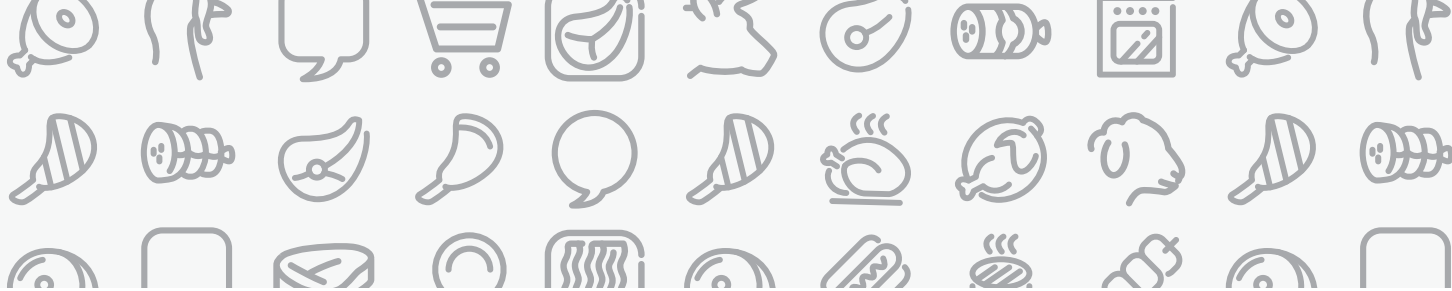
1. Increase funding through CDC’s Epidemiology and Laboratory Capacity (ELC) grants for state and local public-health agencies to investigate foodborne-illness outbreaks, with funding tied to metrics on exposure assessments completed and timely sharing of quality data.

B. Public-health agencies should:

1. Build robust exposure assessment capacity to complement recent advances in laboratory methods (e.g., whole genome sequencing, metagenomics);
2. Work with the medical community to help it understand the importance of public-health surveillance;
3. Develop and implement routine, detailed exposure assessments for all foodborne illness caused by enteric pathogens identified through the surveillance system; and
4. Build a national, exposure-assessment tool and database that is accessible to the public and researchers.

C. Government and grantmaking institutions should:

1. Continue investing in advanced molecular methods for identifying and linking foodborne illnesses. Concurrent investments need to be



made in modernizing surveillance infrastructure, including developing databases and IT systems that can more readily share data; and

2. Fund training programs aimed at increasing epidemiologic capacity across the public-health system.

D. Medical and nursing schools should:

1. Revise their curricula to provide more information on foodborne illnesses, and place more emphasis on them in clinical training and practice, with the goal of improving the diagnosis, treatment and reporting of foodborne infections. Ensure that clinicians understand that individual illnesses occur in the context of community-wide events and that reporting illnesses is the foundation for public-health surveillance.

E. Schools of public health should:

1. Increase capacity to train foodborne disease epidemiologists by seeking funding for training programs and by partnering with state and local public-health agencies to develop hands-on training programs (e.g., State of Minnesota Department of Health's "Team Diarrhea").

F. Veterinary schools should:

1. Revise the food animal veterinary curriculum to provide more information on foodborne illness and food safety, and place more emphasis on them in clinical training and practice. The key goals should be to enhance the veterinary graduate's understanding of foodborne pathogens in order to improve their ability to prevent, detect, treat and control foodborne pathogens in animal agriculture. The role of antimicrobial drugs and antimicrobial resistance should be given particular consideration.

2. Provide incentives for veterinary students to elect a career in food animal veterinary medicine; for instance, through student loan repayment programs. Align these incentives with existing incentive structures to assure that animal producers, including those with minor species, have adequate access to veterinary expertise.

3. Provide increased opportunity for research and graduate training in the area of food safety to ensure the necessary veterinary research capacity is available.

G. Animal science, veterinary technician courses, and science departments should:

1. Revise the food animal curriculum to provide more information on foodborne illness, including how they enter animal agricultural premises and how they can spread on these premises. This curriculum should also include actionable information on how to prevent, detect or treat these pathogens, and what these pathogens mean for public health, food safety and animal agriculture.

CONCLUSION

We sincerely hope our deliberations can contribute to thoughtful policy reform in the future, and we stand ready to assist as appropriate in that process.

GLOSSARY OF KEY TERMS

Agricultural Marketing Service (USDA-AMS): USDA agency responsible for developing quality grade standards for agricultural commodities and administering marketing regulatory programs, among other roles.

Animal and Plant Health Inspection Service (USDA-APHIS): USDA agency established to conduct inspections and regulatory and control programs to protect animal and plant health.

Antimicrobials: Products that kill or slow the spread of microorganisms that include bacteria, viruses, protozoans and fungi in humans and other living beings. Antimicrobial drugs include antibiotics, antifungals, antivirals, and anthelmintics.

Bacteriophage: A type of virus that can invade and kill bacteria. They can be used to treat harmful bacterial infections.

Campylobacter: Pathogenic strains of this bacteria genus can contaminate humans from sources such as uncooked or undercooked poultry. According to CDC, it is one of the most common causes of diarrheal illness in the United States.

Carcass: All parts of any slaughtered livestock.

Cold-chain management: The logistical planning, diagnostics and research to protect the integrity of temperature sensitive products during transportation along a supply chain through thermal and refrigerated packaging methods.

Cysticercus: The larval form of the parasitic tapeworm *Taenia* spp., which from cysts that infect brain, muscle, or other tissue. The tapeworm lifecycle involves humans as a definite host and pigs as an intermediate host. The infection is also known as cysticercosis or taeniasis.

Enteric: Of, relating to, or occurring in the intestines.

Epidemiology: Study of the distribution of disease, or other health-related conditions and events in human or animal populations, in order to identify health problems and possible causes.

Exposure assessment: A component of a risk assessment that characterizes the source and magnitude of human exposure to the pathogen by using a qualitative and/or quantitative evaluation of the degree of intake likely to occur.

Federal Meat Inspection Act of 1906 (FMIA): Requires USDA to inspect primarily cattle, sheep, swine and goats, when slaughtered and processed into products for human consumption. The primary goals of the law are to prevent adulterated or misbranded livestock and products from being sold as food, and to ensure that meat and meat products are slaughtered and processed under sanitary conditions.

Food Safety and Inspection Service (USDA-FSIS): The agency in the USDA responsible for ensuring that the nation's commercial supply of meat, poultry, catfish and processed egg products is safe, wholesome, and correctly labeled and packaged.

FDA Food Safety Modernization Act (FSMA): The food-safety reform law signed by President Barack Obama in January 2011. It modernized FDA'S approach to safety oversight by shifting the focus from reaction to prevention; granted FDA new powers to regulate the way foods are grown, harvested and processed; and granted new enforcement tools, including mandatory recall authority.

Foodborne hazard: Biological, chemical, or physical components that could contaminate food and cause illness or injury, or could otherwise violate established food-safety program criteria if left uncontrolled.



Foodborne pathogens: Disease-causing microorganisms (usually bacteria, fungi, parasites, protozoans, and viruses) found in food. According to CDC, the top five pathogens contributing to domestically acquired foodborne illnesses are *Norovirus*, *Salmonella*, *Clostridium perfringens*, *Campylobacter* spp., and *Staphylococcus aureus*.

Granulomatous: Characterized by granulomas, a compact collection of inflammatory immune cells, usually formed as a result of the persistence of a non-degradable product or as the result of hypersensitivity responses. In meat inspection, granulomas found in the carcass are considered suspect for infections such as tuberculosis.

Healthy People 2020: A national health promotion and disease prevention initiative that provides science-based, 10-year national objectives designed to guide national health promotion and disease prevention efforts to improve the health of all people in the United States.

Indicator organism: Organisms used in a variety of ways in food systems to signal the potential presence of hazardous pathogens; validate the effectiveness of microbial control processes; or otherwise indicate the quality and safety of a food product.

Livestock: Domesticated or semi-domesticated animals reared in an agricultural setting for human consumption, including sheep, cattle, swine, and equines.

Lymph nodes: Part of the lymph system, an important part of the immune system, which carries lymph fluid, nutrients, and waste material between the body tissues and the bloodstream. Abnormalities in the lymph nodes observed during post-mortem carcass inspection are an indicator of infection.

Microbiological: Of microorganisms, including bacteria, fungi and viruses.

***Mycobacterium tuberculosis*:** The bacterium that causes tuberculosis.

One Health: A strategy for expanding interdisciplinary collaborations and communications at local, national, and global levels in all aspects of health care through the prevention of risks and mitigation of effects of crisis that originate at the human, animal and the environment interface. The One Health approach is endorsed by the World Health Organization, the Food and Agriculture Organization of the United Nations, and various physician and veterinary associations.

Organoleptic: Related to or perceived by a sensory organ.

Outbreak: The occurrence of two or more people experiencing the same illness after eating the same food.

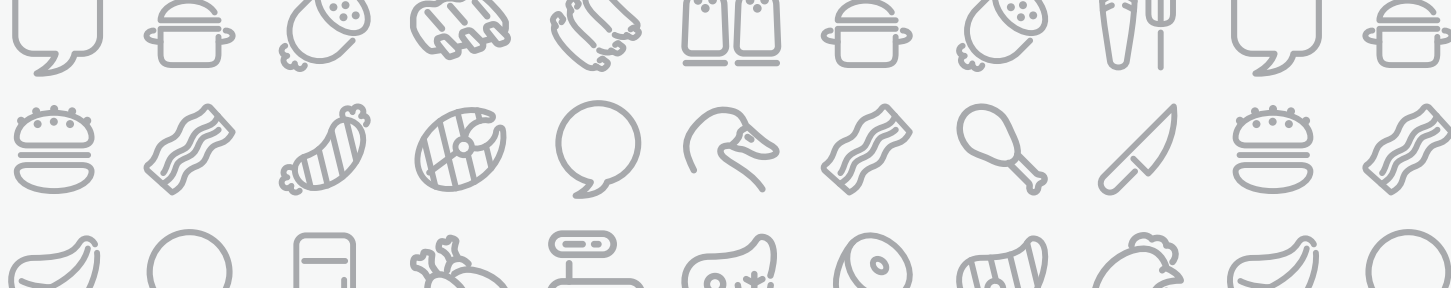
Pathogen: A microorganism (i.e., bacteria, parasites, viruses, or fungi) that is infectious and causes disease.

Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) rule: Regulations finalized by the USDA-FSIS in 1996, which follow a prevention-based approach to minimizing pathogenic contamination in meat and poultry products.

Poultry Products Inspection Act of 1957 (PPIA): Requires USDA to inspect all domesticated birds (e.g., chickens, turkeys, ducks, geese, and guineas) when slaughtered and processed into products for human consumption. The primary goals of the law are to prevent adulterated or misbranded poultry and products from being sold as food, and to ensure that poultry, poultry products, ratites, and squabs are slaughtered and processed under sanitary conditions.

Probiotics: Products that contain live microorganisms, such as bacteria or yeast, that have the potential to confer a beneficial health effect, commonly to the digestive system, when the product is consumed.

Public-health surveillance: The continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public-health practice. In the context of this report, it relates to a system of identifying and investigating foodborne illnesses and outbreaks with the goal of preventing outbreaks and reducing the burden of foodborne illness.



Ready-to-eat (“RTE”): Food that is in a form that is edible without washing, cooking, or additional preparation by a retail food establishment or consumer and that is reasonably expected to be consumed in that form.

Risk: A function of the probability of an adverse effect (e.g., illness) and the severity of that effect.

Risk analysis: The assessment and management of hazards that cause harm/risk to human health and the communication of how those hazards can be controlled, reduced, or eliminated.

Risk assessment: The process of estimating the severity and likelihood of harm to human health or the environment occurring from exposure to a substance or activity that, under plausible circumstances, can cause harm to human health or the environment.

Risk communication: Exchanges of information among risk assessors, risk managers, other stakeholders, and the public about levels of health or environmental risk, the significance and meaning of those risks, and the decisions, actions, or policies aimed at managing or controlling the risks.

Risk management: The process of evaluating policy alternatives in view of the results of risk assessment and selecting and implementing appropriate options to protect public health. Risk management determines what action to take to reduce, eliminate, or control risks, including the establishment of risk-assessment policies, regulations, procedures, and a framework for decision-making based on risk.

Salmonella: A genus of bacteria that is the leading bacterial cause of human foodborne illness among intestinal pathogens.

ServSafe®: A National Restaurant Association program that provides training, testing, and certifications in food-safety management, alcohol service and food handling for food-industry personnel in the United States.

Shiga toxin-producing *Escherichia coli* (STEC):

A strain of *Escherichia coli* bacteria that is particularly virulent and dangerous to humans. Certain strains of STEC, such as *Escherichia coli* O157:H7, transmitted by foods, animal contact, and drinking water, can cause bloody diarrhea and also lead to hemolytic uremic syndrome, a life-threatening condition.

Surveillance: A system of monitoring the health of the population, which is conducted to prevent foodborne-illness outbreaks from increasing. (*see also:* Public-health surveillance)

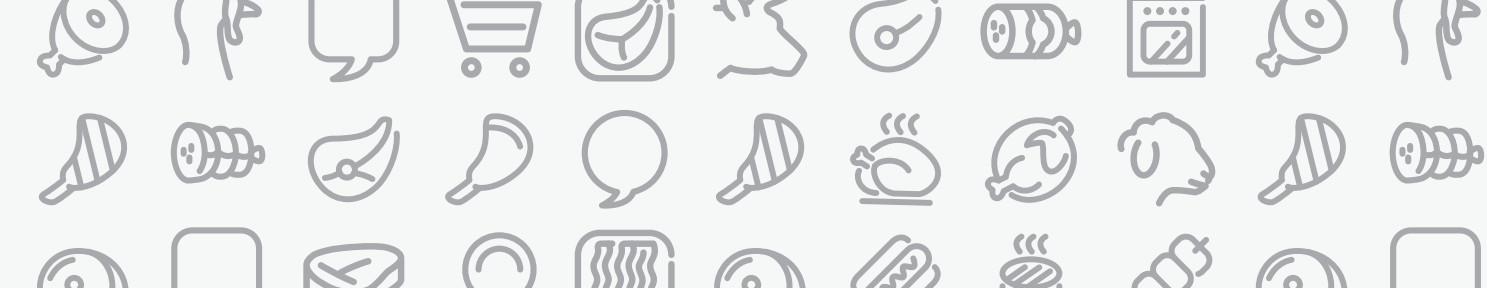
Tetracycline: A class of broad-spectrum antibiotics including doxycycline and minocycline. Increased resistance has made many types of tetracycline less useful.

Toxoplasma gondii: The parasite that causes toxoplasmosis. Humans can become infected by eating undercooked meat of animals harboring tissue cysts or consuming food or water contaminated with cat feces, among other routes of infection.

Vaccine: Product that stimulates the immune system to produce immunity from a disease and can be administered through needle injections, by mouth, or by aerosol. It typically contains an agent that resembles a disease-causing microorganism such as weakened or killed forms of the microbe, its toxins, or one of its surface proteins.

Verification: The use of methods, procedures, or tests to determine if a food-safety system is working to control identified hazards or if modifications need to be made.

Virus-Serum-Toxin-Act: Legislation enacted in 1913 to assure the safe and effective supply of animal vaccines and other biological products addressing the animal immune system. The act and its applicable regulations are administered by USDA-APHIS.



LIST OF ACRONYMS AND ABBREVIATIONS

ALOP	Appropriate Level of Protection
CDC	Centers for Disease Control and Prevention
STEC	Shiga toxin-producing <i>Escherichia coli</i>
FDA	United States Food and Drug Administration
FMIA	Federal Meat Inspection Act of 1906
FRAA	Food Risk Assessment Authority
FSMA	FDA Food Safety Modernization Act
PPIA	Poultry Products Inspection Act of 1957
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point
SHI	Safe Handling Instructions
USDA	United States Department of Agriculture
USDA-AMS	USDA Agricultural Marketing Service
USDA-APHIS	USDA Animal and Plant Health Inspection Service
USDA-FSIS	USDA Food Safety and Inspection Service

NOTES

1. This report addresses only meat and poultry regulation. FSIS also regulates the safety of processed egg products and catfish.
2. This section is based on: M. Ogle, *In Meat We Trust: An Unexpected History of Carnivore America* and the history of the FSIS available at <https://www.fsis.usda.gov/wps/portal/informational/aboutfsis/history/history> (accessed 1/26/2017).
3. C.R. Daniel et al., 2011.
4. See North America Meat Institute, The United States meat industry at a glance, at <https://www.meat institute.org/index.php?ht=d/sp/i/47465/pid/47465> (accessed 5/30/2017).
5. See Batz et al., 2011.
6. See Painter et al., 2013.
7. See the CDC webpage, One Health, at <https://www.cdc.gov/onehealth> (accessed 1/26/2017).
8. See Institute of Medicine and National Research Council (IOM/NRC), 1998.
9. See IOM/NRC, 2010, at 76, citing IOM/NRC (IOM/NRC, 2003), the U.S. Government Accountability Office (GAO) (GAO, 2004a, b, c, 2005, 2007, 2008, 2009a, b), consumer groups (Consumers Union, 2008; Tucker-Foreman, 2009), and Congress (Becker, 2008, 2009; Brougher and Becker, 2008).
10. See IOM/NRC, 2010, at 77.
11. See IOM/NRC, 2010, at 79.
12. See IOM/NRC, 2010, at 80-81.
13. See IOM/NRC, 2010, at 79.
14. See U.S. Government Accountability Office, 2011
15. CITE TO PEW REPORT [NOT YET PUBLISHED]
16. Id.
17. See Wilhelm et al., 2012
18. See Centers for Disease Control and Prevention, 2013.
19. See Becker, 2010, at 4.
20. See Alban et al., 2008; Alban et al., 2009; Blagojevic & Antic, 2014; EFSA Panels, 2011; EFSA Panels, 2012; Fredriksson-Ahomaa, 2014; Hathaway & Richards, 1993; Hill et al., 2013; Jackman & Hathaway, 2011; Pacheco et al., 2013; and Stärk et al., 2014.
21. Further processing is defined in USDA-FSIS regulations as “operations that utilize whole carcasses or cut-up meat or poultry products for the production of fresh or frozen products, and may include the following types of processing: Cutting and deboning, cooking, seasoning, smoking, canning, grinding, chopping, dicing, forming, breading, breaking, trimming, skinning, tenderizing, marinating, curing, pickling, extruding and/or linking.....”. See 40 CFR § 432.2 (e).
22. See 9 CFR § 350.3(a) and 362.2(c).
23. See also Hallman et al., 2015.
24. See IOM/NRC, 2010, at 257.
25. See Jacob et al., 2010.
26. See Oh, 2014.
27. See Powell & Chapman, 2016.
28. See Thomas et al., 2016.
29. See Cohen & Olson, 2016 and Maughan et al., 2016.

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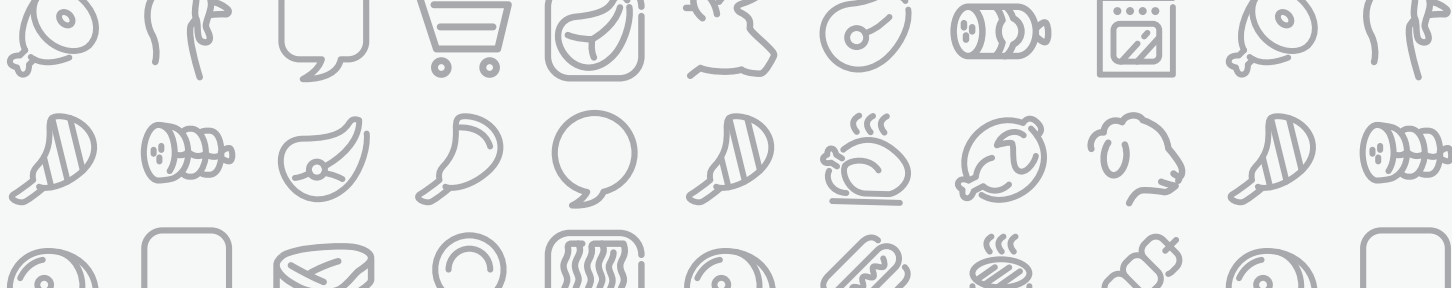
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APPENDIX B: PAST LEGISLATIVE PROPOSALS TO IMPROVE MEAT AND POULTRY SAFETY

	Last Introduced	Sponsor(s)	Civil Penalties	Criminal Penalties	Imports	Inspection	Performance Standards	Recall	Traceback	Whistleblower
(1)	Family Food Protection Act	104th / 1995 Rep. Brown (CA) / Sen. Bradley	≤ \$100k	X	X	√	√	√	√	√
(2)	Meat, Poultry, and Seafood Inspection Reform Act	104th / 1996 Rep. Gunderson	X	X	√	√	X	X	X	X
(3)	Meat and Poultry Products Safety Improvement Act	107th / 2002 Sen. Schumer	X	X	X	X	√	X	√	√
(4)	Meat and Poultry Inspection Accountability Act	108th / 2003 Rep. Lowey	≤ \$100k	X	X	X	X	X	X	X
(5)	Meat and Poultry Pathogen Reduction and Enforcement Act	109th / 2005 Rep. Eshoo / Sen. Harkin	X	X	√	√	√	X	X	X
(6)	Meat and Poultry Products Traceability and Safety Act	110th / 2007 Sen. Schumer	X	X	X	X	X	X	√	X
(7)	Unsafe Meat and Poultry Recall Act	111th / 2009 Sen. Udall (NM)	X	X	X	X	X	√	X	X
(8)	SAFER Meat, Poultry, and Food Act	111th / 2009 Rep. DeGette	≤ \$100k	X	√	√	X	√	X	X
(9)	Safe Meat and Poultry Act	113th / 2013 Sen. Gillibrand	X	≤ 20 yrs; ≤ \$100k	√	X	√	√	√	√
(10)	Safe Food Act	114th / 2015 Rep. DeLauro / Sen. Durbin	≤ \$10k	≤ 3 yrs; ≤ \$100k	√	√	√	√	√	√



Inspection

- (1). Directed an advisory board to make recommended improvements to the inspection system. Failure to comply with the proposed legislation would have resulted in the withdrawal of inspections.
- (2). Included slaughtering facility ante- and post- mortem inspection and verification of livestock, poultry, and seafood; and inspection and verification of meat, poultry, and seafood products and processing facility. The proposed legislation also would have authorized facility self-inspection and provided for facility sanitation and night inspection.
- (10). Creates 5 food facility categories:
 - Category 1:** facility that slaughters animals;
 - Category 2:** facility that processes raw meat, poultry, or seafood without destroying contaminants;
 - Category 3:** facility that processes meat, poultry, or seafood determined to be at high risk for contamination;
 - Category 4:** food processor that is not, by definition, in category 1, 2, or 3; and
 - Category 5:** facility that only stores, holds, or transports food for prior to retail sale.

The proposed legislation directs the administrator of a newly created single food safety agency to establish an inspection program based on the risk presented by each category.
- (5). Following the creation of a list of pathogens that make a significant contribution to the total burden of foodborne disease, the proposed legislation would have required the Secretary of Agriculture to, over the course of five years, establish performance standards. If these and other public-health goals and objectives were not met, the Secretary would have been given the authority to not allow any product produced or processed by the establishment to be labeled as inspected and passed.
- (9). Would have directed the Secretary of Agriculture to establish performance standards based on identified significant foodborne disease pathogens. Additionally, a product testing program and adulterated food tracing protocol system would have been put in place.
- (10). Requires performance standards to be implemented whenever there is a “risk of serious adverse health consequences.” A sampling program is to be designed to ensure compliance.

Imports

Performance Standards

- (1). Directed the Secretary of Health and Human Services to issue regulatory limits for human pathogens and other harmful substances in meat and poultry or meat and poultry food products.
- (3). Called for performance standards for the reduction of microbiological pathogens in meat and poultry and meat and poultry products.
- (5). All meat and poultry capable of use in human food would have been subject to the proposed legislation, including risk-based sampling, testing, and inspection at slaughter or processing in the exporting country.
- (5). Would have directed the National Advisory Committee on Microbiological Criteria for Foods to “ensure the safety of imported food.”
- (8). In the event of an outbreak, the importer would have been held responsible to cease distribution, provide notification to appropriate parties, and recall the product.
- (9). Permitted the Secretary of Agriculture to ban food imports from counties refusing annual inspections.
- (10). Establishes an accreditation system for foreign governments to certify food before importation to the United States.





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