Foodborne Disease Outbreak Response: Assessing the Legal and Institutional Framework for Interagency Information Sharing
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Executive Summary

Foodborne illness is a serious public health issue. The 2011 Food Safety Modernization Act (FSMA) aims to create an integrated food safety system. The free flow of information is vital to reaching the goal of such a system, but, unfortunately, information sharing among federal, state, and local agencies faces policy and legal obstacles. Federal and state privacy laws and enforcement laws sometimes prevent the timely two-way sharing of information.

Through this project, ASTHO sought to improve our understanding of the legal and institutional framework impacting information sharing during a foodborne disease outbreak. Through our legal research, ASTHO created an appendix of state laws and regulations relating to state health agency (SHA) authority to protect non-public information from public disclosure. In addition, ASTHO used a survey and qualitative research methods to obtain extensive information from the states and District of Columbia to deepen our understanding of state practices with regards to information sharing with federal and state food regulatory agencies.

SHAs receive confidential food safety information from several sources, including federal partners (FDA, USDA, and CDC), other state and local agencies, and companies. This confidential food safety information is shared through vehicles such as FDA’s commissioning process and information sharing agreements (e.g., FDA’s 20.88, USDA MOU for recalls), and can help SHAs gain access to federal agency information that aids their investigation. However, the majority of SHAs don’t have mechanisms in place to receive confidential food defense information from federal agencies like DHS or FDA.

ASTHO’s analysis of the state Freedom of Information Laws (FOILs) revealed that all states allow individuals to request the disclosure of information collected by state agencies. Upon receipt of the request, the state agency is required to disclose the information, but, nearly all states have laws setting out exemptions to disclosure. A few of the state disclosure exemptions relate directly and specifically to information about food or agriculture, while a number of states exempt disclosure of information that is confidential under or prohibited from being disclosed by federal law. Other state disclosure exemptions (e.g., for trade secrets, proprietary or commercial information, public health data) could be interpreted to protect non-public food safety information from disclosure. Most states also have disclosure exemptions related to law enforcement, criminal investigations, or terrorism which could be utilized during an intentional outbreak.

ASTHO drew three major findings with regard to information sharing between federal and state agencies: 1) federal, state, and local partnerships are important; 2) information sharing agreements can be limited; and 3) state food defense programs face challenges. Based upon our findings, ASTHO recommends promoting the development and participation of state agencies on joint taskforces or advisory councils; promoting information flow by getting key state food safety staff commissionered...
and hold a national security clearance; developing and sharing with federal agencies a directory of state food safety officials that are allowed to receive confidential food safety and defense information; developing internal communication plans for handling confidential food safety and defense information; and strengthening relationships with local law enforcement.

**Abbreviations**

- ASTHO: Association of State and Territorial Health Officials
- CDC: Centers for Disease Control and Prevention
- DHS: U.S. Department of Homeland Security
- FDA: U.S. Food and Drug Administration
- FOIA: Freedom of Information Act
- FOILs: Freedom of Information Laws
- FSIS: Food and Safety Inspection Service
- FSMA: FDA Food Safety Modernization Act
- HSIN: Homeland Security Information Network
- MOU: Memorandum of Understanding
- NACCHO: National Association of County and City Health Officials
- NASDA: National Association of State Departments of Agriculture
- SEHD: State Environmental Health Director
- SHA: State Health Agency
- SHO: State Health Official
- USDA: U.S. Department of Agriculture
Acknowledgements

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The views and conclusions contained in this document are those of the authors and should not be interpreted as necessarily representing the official policies, either expressed or implied, of the U.S. Department of Homeland Security or the Food Protection and Defense Institute.

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Background

Need

Foodborne illness is a serious public health issue. Foodborne diseases sicken one in six Americans each year, resulting in an estimated 128,000 hospitalizations and 3,000 deaths, at an annual cost of $152 billion.¹ In fall 2011, 146 people were infected with strains of *Listeria monocytogenes* after consuming affected cantaloupes, resulting in 30 deaths. In addition, one woman pregnant at the time of illness had a miscarriage.² This was the deadliest outbreak of foodborne illness in the United States in 100 years. During the same year, President Barack Obama signed the FSMA into law. FSMA, the most sweeping reform of food safety and defense laws in more than 70 years, aims to create an integrated food safety system.

The free flow of information is vital to any integrated, systemwide effort to improve food safety. Unfortunately, information sharing among federal, state, and local agencies faces policy, bureaucratic, and legal obstacles. Laws created for well-intentioned, non-food safety purposes can pose problems for state agencies seeking food safety-related information from federal agencies and other states. For example, in both active surveillance programs and outbreak investigations, privacy laws aimed at protecting the identities of foodborne illness patients can slow or even block the flow of epidemiological information between CDC and state food agencies. This can reduce surveillance data’s value to parties working to prevent foodborne illness and make it more difficult for outbreak investigations to proceed quickly and efficiently.

In food recall or market withdrawal situations, FDA may cite the Freedom of Information Act (FOIA) as the basis for not routinely sharing industry distribution lists with state and local agencies, stating that they constitute commercially valuable business information that is protected from disclosure under FOIA. On occasions when states are able to obtain such information, typically by executing a confidentiality agreement or a memorandum of understanding, they are usually prohibited from sharing this information with their local counterparts or the public. This legal barrier to information sharing can hamper state and local agencies’ ability to quickly remove tainted foods from grocery shelves. FOIA-based concerns about protecting confidential business information may also prevent federal agencies from sharing full establishment inspection reports with states and localities.

Food safety concerns used to focus solely on accidental contamination, but stakeholders are now increasingly concerned about intentional contamination, whereby individuals or entities introduce biological, chemical, or radiological agents into the food supply. Food defense is the effort to protect food from acts of intentional contamination. FSMA sections 103, 105, 106, and 108 specifically reference these efforts, and discuss:

- Identifying and evaluating intentionally-introduced hazards, including by acts of terrorism.
- Issuing regulations and guidance to protect against intentional food adulteration.
• Conducting vulnerability assessments of the food supply and determining mitigation strategies.
• Developing a strategic planning document with USDA and DHS that looks at practical food defense consideration.

In June 2016, FDA finalized the new FSMA rule “Mitigation Strategies to Protect Food Against Intentional Adulteration,” which aims to prevent wide-scale public health harm by requiring companies in the United States and abroad to take steps to prevent intentional adulteration of the food supply. However, information sharing gaps and barriers between federal and state food safety stakeholders still hamper the vision of achieving this truly integrated prevention-oriented system. As stated previously, federal and state privacy laws and regulation/enforcement laws prevent timely two-way information sharing on food safety and defense-related investigations between federal and state governments. In 2007, a DHS report on food defense and critical infrastructure protection emphasized the need for DHS to engage its public and private food sector partners more effectively. According to the report, food sector partners were frustrated by the quality and extent of DHS external coordination in sector governance and information sharing. To enhance food defense preparedness and help the U.S. achieve a fully-integrated national food system, we need an approach that builds cross-sector initiatives and establishes and maintains partnerships among federal, state, and local agencies and organizations.

The delay in sharing food safety inspection and recall information has hampered SHAs critical role in collecting and responding to food safety and defense concerns within their jurisdictions. Although illnesses are often first reported to local health departments, SHAs play an important part in operating state laboratories and understanding the epidemiology and outbreak patterns across the states and territories. The federal government’s national surveillance resources, especially those monitoring intentional contamination threats, are also integral to these investigations. It is critical that the entire governmental public health enterprise works together to successfully protect and promote the public’s health, as no individual component of the system can function effectively without partners.

Oversight

Information Sharing Agreements

There are several types of agreements applicable to food safety and defense information sharing, including commissioning, 20.88 confidentiality agreements (e.g., with FDA) and MOUs (e.g., with USDA). Commissioning is a process that permits state and local officials to conduct examinations and investigations under the authority of the Federal Food, Drug, and Cosmetic Act. A 20.88 agreement permits FDA to share certain non-public information with state and local officials who have signed a written agreement in accordance with 21 Code of Federal Regulations, section 20.88. In this agreement, the state or local government agency confirms that it has the authority to protect non-public information from public disclosure, and it promises not to further disclose such information without
written permission from FDA. When it comes to sharing food defense information, authorizations used to receive information include security clearance, MOUs, or a signed agreement.

There are also different types of non-public food safety information. Deliberative information, also known as pre-decisional information, includes draft rules, draft guidance, and intra-agency or inter-agency communications containing deliberations about potential actions or possible policy decisions, and are exempt from public disclosure under FOIA. Commercial confidential information (CCI) is valuable data or information used in a business and customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the entity to whom it belongs. A trade secret is any commercially valuable plan, formula, process, or device that is used for making, preparing, compounding, or processing of commodities, and it can be said to be the end product of either substantial effort or innovation. Unlike commissioning, FDA cannot share trade secret information under 20.88 agreements. Confidential information in the national security realm in support of homeland security cannot be shared by signing an MOU or via the 20.88 and commissioning process. DHS has established a Classified National Security Information Program for State, Local, Tribal, and Private Sector Entities (STLPS) Program for sharing information in the national security realm. Obtaining security clearance for the STLPS program would require individuals to go through an extensive background check and be sponsored by DHS or a sponsoring agency.

**TYPES OF NON-PUBLIC FOOD SAFETY INFORMATION:**
- Deliberative information.
- Commercial confidential information (CCI) and trade secrets.
- Confidential information (national security realm).

**Federal**

FDA has oversight of 80 percent of the U.S. food supply, but is legally bound to only share certain non-public information with regulatory partners who have signed a nondisclosure and confidentiality agreement. In the case of SHAs, this is usually through the commissioning process. Until an agreement is in place, information may not be shared in a timely manner, thereby preventing effective intelligence gathering and an integrated response to intentional and unintentional food contamination events and foodborne illness outbreaks.

Through its participation in FDA’s Partnership for Food Protection and the Council of Association Presidents, ASTHO has outlined the need for FDA to expand the number of commissioned personnel in SHAs and increase commissioned personnel’s ability to share reports, inspection schedules, and other important information with non-commissioned personnel. In an effort to improve communication and share data, especially during a foodborne outbreak, FDA’s Division of Federal-State Relations also coordinates 20.88 agreements (discussed above) for state and local government agencies.
According to FDA’s latest estimates, just over half of SHAs are covered under a 20.88 confidentiality agreement or through a commissioning process. In its current form, only specific high-level individuals, including the commissioners of state health and agricultural agencies, are covered by the commissioning process. Because commissioners are often political appointees and serve for a limited time, the commissioning process may prevent state and local governments from continuing their work after their leaders leave office. Legal barriers may also exist in certain states that would discourage or limit state or territorial health officials from entering into confidentiality agreements with FDA and accepting data under specified terms and conditions. In addition, so-called “sunshine” laws or public records laws, also collectively referred to as FOIA laws, may make the federal government unwilling to share classified information with state governments.12

USDA is another federal agency that plays a large part in food safety regulation, especially its Food Safety Inspection Services (FSIS), which monitors state inspection programs and inspects meat and poultry products sold within the state in which they were produced. FSIS’ Office of Data Integration and Food Protection oversees all of USDA’s food defense activities and develops and implements procedures to prepare for, respond to, and recover from intentional and unintentional contamination affecting U.S. meat, poultry, and processed egg products.13 FSIS is also responsible for coordinating all of USDA’s data collection, analysis, and integration activities across program areas. Because it closely collaborates with other FSIS offices, including managing FOIA requests, open communication is essential to its work.

Operating under presidential directives relating to food defense, DHS directs integration and coordination efforts among federal, state, and local agencies, as well as the private sector, to protect critical infrastructure and key resources from intentional attack, including in the food and agriculture sectors. DHS works closely with USDA, FDA, and other federal, state, and local agencies to secure the nation’s food supply through programs aimed at education and prevention, surveillance, threat detection, and rapid response.

State

Most state governments have at least some involvement in food safety prevention and response functions, working typically through both their health departments and agriculture departments. States are the primary link between federal agencies and on-the-ground efforts to respond to illness outbreaks, and they are playing an increasingly large role in inspecting food manufacturing facilities. States conduct the majority of the non-retail food establishment inspections, but meat and poultry inspections are the exception. The 1967 Wholesome Meat Act and the 1968 Wholesome Poultry Products Act require state inspection programs to be “at least equal to” the federal inspection program.14 If states choose to end their inspection programs or cannot maintain this standard, FSIS must assume responsibility for inspections in that state. Currently, only 27 states have meat and poultry inspection programs; the remaining states have given up their meat or poultry inspection programs, or both.15 As a result, states may not receive timely information on meat and poultry-related inspections and recalls.
In recent years, states have experienced the unintended consequences of losing primacy over their meat and poultry inspection programs on their ability to collect and use health information for public health purposes. In two examples, states did not receive some of the critical inspection and recall information related to E. coli outbreaks. This information lapse could have been even more severe if it was an issue of intentional food contamination due to fewer information sharing agreements in place, so it is important for states and the federal government to find ways to improve communication during these incidents.

Methods

ASTHO sought to achieve three objectives when assessing states’ interagency information sharing capabilities. These objectives align with the 2012 National Strategy for Information Sharing and Safeguarding guidance document and one of FPDI’s priority research areas, Aim 4.0 Information Sharing.16

Objective 1: Improve the understanding of the legal framework impacting information sharing during a foodborne disease outbreak.

Objective 2: Raise awareness of information sharing practices between federal and state governments and disseminate resources to policymakers, affiliates and partners.

Objective 3: Build SHA capability to respond to foodborne outbreaks in their states or territories.

Through a qualitative design structure and the activities outlined below, ASTHO assessed the framework of state and federal laws and analyzed their impact on sharing food safety inspection and recall information.

Activity 1: Conduct a systematic review and legal analysis of existing state laws and regulations relating to SHA authority to protect non-public information from public disclosure as necessary under a confidentiality agreement.

ASTHO began this project by developing an appendix of state laws that relate to SHA authority to protect non-public information from public disclosure. To determine the types of laws that would be included in the appendix, ASTHO conducted a preliminary review of the laws of states that participate in ASTHO’s Public Health Law Workgroup. Search terms were developed through conversations with ASTHO’s Public Health Law Workgroup, which consists of state health agency legal counsel for 12 jurisdictions including: Georgia, Kansas, Minnesota, Nebraska, New Hampshire, New York, Puerto Rico, Ohio, Oklahoma, Oregon, Virginia, and Washington. We included search terms to capture both food safety and defense laws.
Search terms included: food, agriculture, Dept. of Agriculture, and animals; health, public health, and Dept. of Health; terrorism, law enforcement, security, and public safety; trade secrets; terrorism, terrorist, antiterrorism, antiterrorist, bioterrorism, and emergency preparedness.

All of these terms were used in conjunction with the term “data”: foodborne disease, foodborne outbreak, foodborne illness, enteric disease, foodborne pathogens, sabotage, fraud intentional adulteration; and disgruntled employee.

ASTHO utilized the legal databases Westlaw, LexisNexis, as well as publicly available state databases, to research laws for inclusion in the appendix. State laws included in the dataset were in place from January 1, 2015 – December 31, 2015.

The legal researchers and environmental health/food safety staff worked in collaboration to determine the focus of the research and the key questions to be coded. The legal researchers reviewed the public records laws that had been collected, including the laws identified by members of ASTHO’s Public Health Law Workgroup, to conceptualize the coding questions. The draft coding questions were shared with staff on ASTHO’s environmental health team as well as the Public Health Law Workgroup. The coding questions were then revised based on the feedback received. When the questions and codes for responses were finalized, the team entered the questions into the MonQcle workspace.

The coding was done by two coders on an individual basis. The coders began coding independently and held discussions to identify divergences and revise questions to the dataset. As necessary, the coding scheme was altered to accommodate newly identified features of the law and reduce ambiguity. Completed states were recoded accordingly. Laws in effect at any time in 2015 were included, regardless of later moratoriums or repeals.

Utilizing the above methods, ASTHO created an appendix of state laws relating to SHA authority to protect non-public information from public disclosure for all 50 states and the District of Columbia. This appendix will be available through ASTHO’s website, and will assist policymakers, public health practitioners, and other stakeholders in assessing their states’ laws for purposes of understanding their authority to protect non-public information from disclosure. Previous research in this area is limited.

ASTHO chose LawAtlas as the platform to display the legal data. This provides a user-friendly interface with maps for easy viewing.
Activity 2: Develop and distribute a survey to all SHAs and the District of Columbia to obtain additional information regarding protecting non-public information from disclosure.

ASTHO used a survey and qualitative research methods to obtain extensive information from the states and District of Columbia to deepen our understanding of state practices with regard to state authority to protect non-public information from public disclosure. ASTHO chose to survey state environmental health directors and state legal counsel based on their tenure in the agency and broad view of these topics.

To start developing the survey questions, ASTHO worked with its subject-matter experts in ASTHO’s Food Safety Advisory Group and Public Health Law Workgroup. ASTHO aimed to address both legal and regulatory issues associated with information sharing, as well as actual public health agency practices. The survey also fed off of the laws and regulations added in the appendix from Activity 1. We included both closed and open-ended questions to elicit the following types of information:

- How do public health officials understand and act within the laws of their jurisdictions?
- Which laws, if any, do officials perceive to be helpful legal tools or constraining legal barriers to 20.88 agreements?
- Which laws, if any, do health officials perceive as necessary, but missing from the legal framework?
- What factors do health officials believe might influence the adoption of new laws and policies within their states?
- Do states have internal policies or procedures regarding protecting non-public information from disclosure?

After developing the survey tool, ASTHO pilot tested the survey instrument with seven states (Arizona, Maryland, Massachusetts, Nebraska, Rhode Island, Virginia, and Washington state) to ensure readability, clarity, and survey quality. We updated the instrument based on their feedback, which helped to strengthen the tool for the official launch. The final survey included both legal questions and those related to food safety and defense. Through the questions, we canvassed existing state laws or regulations as well as perceptions regarding these laws or regulations’ applicability to state agencies.

In spring 2016, ASTHO administered the final web-based survey using Qualtrics software to all states and the District of Columbia via ASTHO’s State Environmental Health Directors and State Legal Counsel peer groups. We were able to solicit various types of information because Qualtrics allows multiple question types (multiple choice, yes/no, open text, and Likert scale), advanced survey logic, and document uploading by respondents. The survey response rate was 36 (67.9%) for environmental health contacts and 19 (33.3%) for legal contacts. The overall response rate for both groups combined was 50 percent. The PDF version of the finalized survey can be found in Appendix A.
Activity 3: Hold key informant interviews.

ASTHO developed an interview guide based on survey responses and individual state laws from Activities 1 and 2, along with input from ASTHO’s Food Safety Advisory Group and Public Health Law Workgroup, to learn more about how current laws impact food-safety related information sharing. Based on survey responses and the appendix created in Activity 1, ASTHO identified state health agency leaders in six states to participate in follow-up interviews. The criteria used to select the candidates for the key informant interviews included:

- Ability to sign on to a confidentiality or information sharing agreement (e.g., FDA’s 20.88 agreement and/or USDA’s MOU).
- A mixture of state health agency governance classifications (e.g., centralized, decentralized, shared, or mixed).
- States that conduct food defense activities.

ASTHO held interviews with both programmatic and legal staff to ensure a wide suite of information. The selected jurisdictions varied in their organizational structure (e.g., centralized or decentralized), size, and geographic dispersion. The interviews were set up to be semi-structured and followed a protocol (available in Appendix B) to ensure more uniform results. Through a limited number of pre-determined and open-ended questions, interview topics spanned how agencies interpret, apply, and seek to change laws affecting confidentiality agreements and disclosure of non-public information. An analysis and key findings from the interviews can be found later in this report.

Activity 4: Prepare key findings and recommendations.

ASTHO’s project team analyzed all of the data collected through the legal research, national survey results, and key informant interviews (Activities 1, 2 and 3) to prepare key findings and recommendations. These findings form the basis for the recommendations in the Key Findings section of the report.
Results

Responsibility for Food Programs

State health agencies differ in their responsibilities for food-related programs (see Figure 1). Some oversee many programs, while others only oversee a few programs. Most have authority over retail food programs, while only a subset of agencies has authority over meat and poultry inspection. According to ASTHO’s 2016 Profile of State Public Health, approximately half of state health agencies have responsibility for food processing, manufactured food, and fish or shellfish programs. This division of authority is important for food-related information sharing because some agencies may not communicate frequently with their federal partners during a food-related outbreak merely because they don’t have authority over that program, not because of any communication barrier. One of ASTHO’s goals was to dig deeper into these communication practices to learn more about the reasons for gaps in communication, whether they be due to jurisdiction alone, communication pipeline barriers, or a combination of both.

![Figure 1: Food-related programs for which health agencies are responsible](image)

Sharing Confidential Food Information

Collecting information is crucial when a SHA investigates a foodborne disease outbreak’s cause and extent. SHAs receive confidential food information from many sources, including federal partners (e.g., FDA, USDA, and CDC), other state and local agencies, and companies (see Figure 2). FDA is the most common source of this information for SHAs, followed by other state agencies and then USDA and CDC. This confidential food information is shared through vehicles such as federal information sharing agreements (e.g., FDA’s 20.88 and/or USDA MOU), and can help SHAs gain access to federal agency information that helps their investigation. The most frequently used authorization to receive confidential food information is through FDA’s commissioning process, followed by FDA’s 20.88 agreements (see Figure 3). Some states also receive information through MOUs or formal agreements with their local counterparts.
The numerous mechanisms for interstate information sharing include informal communication, online platforms, and formal policies. However, the most common mechanism is through informal communication. This method is common in all states (see Figure 4). Examples of informal communication include personal emails or phone conversations with personal or professional contacts. In addition, formal authorizations used to receive information include FDA commissions, FDA 20.88 agreements, MOUs or signed agreements, and contracts with local health agencies.
Surprisingly, prior to taking ASTHO’s survey, 16 respondents were not aware of FDA’s 20.88 information sharing agreements, and 35 respondents were not aware of USDA’s MOU. This is one area where greater visibility of some of these formal mechanisms may help improve uptake of the resources and help enhance communication between agencies.

SHAs also receive information from multiple sources, which can be used to address multijurisdictional foodborne illness outbreaks (see Figure 5). All respondents said that they receive information from FDA, and close to 90 percent of respondents said that they also receive information (always or sometimes) from local health departments, CDC, other state-level departments, and the state department of agriculture.

A multijurisdictional foodborne disease event could involve multiple states and multiple localities within a state. Resources from more than one local, state, territorial, tribal, or federal food-regulatory agency would be required to manage a foodborne disease event such as an outbreak or a contaminated product recall. Information sharing between local, state, and federal food-regulatory agencies is critical to the effectiveness of multijurisdictional investigations.
Freedom of Information Laws

Although there are many avenues for states and localities to share confidential food safety-related information, state freedom of information laws (FOILs), which often require states to disclose information collected by a state agency upon request, may conflict with federal information sharing agreements, which require that shared information remain confidential.

ASTHO’s analysis of state FOILs reveals that all states allow individuals to request the disclosure of information collected by state agencies, which must disclose the information upon receipt of the requests. However, nearly all states have exemptions to this disclosure. Most states have disclosure exemptions for information related to law enforcement, criminal investigations, or terrorism, which could be utilized during an intentional outbreak. Other state disclosure exemptions (e.g., for trade secrets, proprietary or commercial information, or public health data) could be interpreted to protect non-public food safety information from disclosure. While a few state disclosure exemptions relate directly and specifically to information about food or agriculture, a number of states exempt disclosure of information that is confidential under or prohibited from being disclosed by federal law.

According to ASTHO’s survey results, 88.6 percent of respondents indicated that they receive information from state-level departments or agencies in other states when needed (always or sometimes) that is used to address multijurisdictional foodborne illness outbreaks.

Most respondents felt that entering into federal information sharing agreements would be possible under state laws exempting the disclosure of information prohibited from release by federal law, a trade secrets exception, or investigations exemption. Others cited exceptions to disease reporting and health records, but were unsure whether the information would fit under the definitions of disease report or health record. Some respondents maintained that the state disclosure law would be preempted by any federal law requiring the information to remain confidential. This was pointed out by one respondent who could not point to a state law that specifically exempted the information.
When asked about intentional vs. unintentional contamination, 14 states indicated that there would be no change in the legal authority to protect confidential information in the event of an intentional contamination versus an unintentional outbreak. However, some respondents stated that the authority and decision to disclose the information would shift to the state law enforcement agency. One respondent noted that the SHA would have greater authority to not disclose information if the outbreak was intentional.

Food Defense Findings from Survey

In response to our survey, 30 SHAs said that they receive confidential food defense-related information from other agencies. Respondents reported that the most common source of this confidential food-defense-related information is FDA (over 75% of respondents), but other sources include other state agencies (38%), USDA (26%), CDC (15%), FBI (5%), and the others shown in Figure 7.

However, the extent of this information sharing can differ in each state. For example, most states may only be able to share information through one or two commissioned officers, or through a staff member with a secret (or higher) clearance. For states that have task forces or formal food defense programs, however, this may involve a greater number of staff with access to the food defense-related information (e.g., Indiana State Department of Health Food Defense Program and Georgia Committee on Agriculture and Food Defense).  

**FIGURE 7: AGENCIES FROM WHICH HEALTH AGENCIES MOST COMMONLY RECEIVE CONFIDENTIAL FOOD DEFENSE-RELATED INFORMATION**

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<th>Agency</th>
<th>Percentage</th>
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<td>FDA</td>
<td>76.5%</td>
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<td>Other state agencies</td>
<td>38.2%</td>
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<tr>
<td>USDA</td>
<td>26.5%</td>
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<td>CDC</td>
<td>14.7%</td>
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<tr>
<td>FBI</td>
<td>5.9%</td>
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<tr>
<td>Center for Emergency Preparedness</td>
<td>2.9%</td>
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<tr>
<td>DHS</td>
<td>2.9%</td>
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<tr>
<td>HSEM</td>
<td>2.9%</td>
</tr>
<tr>
<td>Local health agencies</td>
<td>2.9%</td>
</tr>
<tr>
<td>Other states</td>
<td>2.9%</td>
</tr>
<tr>
<td>None</td>
<td>11.8%</td>
</tr>
</tbody>
</table>

Note: There were 34 total respondents for this question because there were multiple respondents from the same state. However, only 30 separate states said that they receive confidential food defense-related information from other agencies.
In addition, based on ASTHO’s survey, states mainly use MOUs or signed agreements, commissioned officers, or individuals with security clearances to receive confidential food-defense information (see Figure 8).

**FIGURE 8: AUTHORIZATIONS USED TO RECEIVE CONFIDENTIAL FOOD DEFENSE-RELATED INFORMATION**

<table>
<thead>
<tr>
<th>Authorization Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOU or signed agreement</td>
<td>30.6%</td>
</tr>
<tr>
<td>Other (e.g., commissioned officers)</td>
<td>27.8%</td>
</tr>
<tr>
<td>Security Clearance</td>
<td>11.1%</td>
</tr>
</tbody>
</table>

However, there are additional avenues for sensitive information sharing that don’t necessarily require a clearance or commissioning. The Homeland Security Information Network (HSIN) is the network for homeland security mission operations to share sensitive but unclassified information with partners. Federal, state, local, territorial, tribal, international and private sector homeland security partners use this network to manage operations, analyze data, send alerts and notices, and generally share the information they need to do their jobs. This network does not require a clearance for information sharing. InfraGard, an FBI-private sector partnership, is an association of individuals who represent businesses, academic institutions, state and local law enforcement agencies, and other participants dedicated to sharing information and intelligence to prevent hostile acts against the U.S. Also, the local FBI weapons of mass destruction coordinator (one in each of their 56 field offices) is tasked with coordinating food defense events in addition to communicating and networking with state and local law enforcement. Finally, the Food Protection and Defense Institute, a DHS Center of Excellence, created and maintains FoodSHIELD, an online information sharing environment that is the product of 10 years of successful inter-governmental collaboration. The FoodSHIELD portal provides a modern interface for creating on-demand, mission-specific workgroups, meetings, events, trainings, conferences, and a private and secure data collection and digital asset management solution. FoodSHIELD offers free membership to any federal, state or local government official working in the arena of food safety and food regulation.
Key Findings and Analysis

Based on the legal scan, survey, and interviews, ASTHO drew three major findings regarding information sharing between federal and state agencies:

Finding 1: Federal, State, and Local Partnerships are Important

Many federal, state, and local agencies share responsibilities for keeping the nation’s food safety system performing at an optimal level. However, regulatory agencies often work independently from one another and operate under different legislative authorities and standards. Different agencies responsible for food safety collect large volumes of data and information that could be mutually beneficial, but such information tends to be siloed within and among agencies because of legal and bureaucratic obstacles.

Some states have created food defense taskforces or advisory councils, either by statute, executive order, or grant. These taskforces or advisory councils bring together multijurisdictional, public, and private stakeholders to provide a variety of food defense activities:

- **Florida** established the Florida Food Safety and Food Defense Advisory Council, composed of representatives from local, state, and federal agencies, the food industry, consumers, the scientific and academic communities, and the state legislature, to serve as “a forum for presenting, investigating, and evaluating issues of current importance to the assurance of a safe and secure food supply to the citizens of Florida.”

- **Minnesota** created a Food Safety and Defense Task Force, composed of representatives from state and federal agencies, research and academic institutions, trade groups, consumers, inspectors, and other food or health professionals and interested parties who are charged with coordinating and serving as a source of information and education regarding food safety and defense, providing advice and coordination to state agencies, and making recommendations to policy makers.

- **North Carolina’s** governor established the North Carolina Food Safety and Defense Task Force. This taskforce, made up of various state designees and representatives of academia, industry, and the public, is responsible for partnering with state and federal agencies to address the vulnerability of the state’s food system to criminal and terrorist acts and make recommendations regarding improvements, legislation, and fiscal issues.

- **Indiana’s** Food Safety Defense Task Force, which consists of stakeholders from the food industry, government, and academia, was formed pursuant to a cooperative agreement with CDC and provides support to the Indiana Food Defense Program.

“A lot of this is about fostering relationships with different agencies and developing trust. The consumer doesn’t care if you carry a local badge, state badge, or federal badge — all they care about is that we ensure the safety of their food.”

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1 ASTHO thanks Pat Kennelly, chief of the food safety section of the California Department of Public Health’s Food and Drug Branch, for his valuable insight and perspectives on food protection information sharing, described on the following page.
**Finding 2: Information Sharing Agreements Have Limitations**

ASTHO’s survey results show that there is a significant lack of awareness of the existence and the purpose of federal information sharing agreements. Crucially, the level of confidential information provided changes depending on the type of agreement. For example, with FDA’s 20.88 agreement, the state agency does not gain access to trade secrets information or, to some extent, product distribution information. The information provided via a 20.88 information sharing agreement is very high level, and may not be helpful for food safety regulatory agents during enforcement cases. In addition, an agency head usually signs the 20.88 agreement on behalf of all the agency employees, and the agency must protect the information to avoid violating federal policy. With the commissioning process, which is a more robust information sharing agreement, only specific individuals who go through a federal background check are covered by the agreement. The number of individuals who are commissioned and have national security clearance is limited, and this could cause a problem with continuity in contacts over the years because of an aging public health workforce or job turnover.

Additionally, entering into a federal information sharing agreement may not be possible if state law is interpreted to not exempt the information shared under the agreement from disclosure. Communication with a state’s attorney about these issues is key. Discussions about the underlying federal law upon which the agreement is based or the types of information that may be shared under the agreement can assist the state’s attorney in concluding whether or not the exemptions to a state’s FOIL would apply to the information to be shared.

“At the program level, 20.88 is just a piece of paper. If you are investigating foodborne illness outbreaks or working on recalls, you need access to trade secrets and confidential business information to do your job. It doesn’t help the boots on the ground for an enforcement case if you don’t get access to all of the relevant information, even if they are trade secrets or confidential business information.”

**Finding 3: State Food Defense Programs Face Challenges**

A majority of SHAs don’t have mechanisms in place to receive confidential food defense information from federal agencies like DHS or FDA. This is partly due to the stringent national security clearance process—individuals have to go through an extensive background check and would need to be sponsored by a cleared contractor or a government entity in order to receive this clearance. At the state level, some SHAs have working relationships with local law enforcement, but there are challenges to working as a cohesive unit because of the perception of SHAs not being a law enforcement agency.

“There is a reluctance of law enforcement in general to talk to non-law enforcement personnel. If you are seen as one of them, it is easier to share information.”
Recommendations

Building upon our findings regarding information sharing, ASTHO recommends the following actions to improve interagency information sharing. ASTHO hopes that government agencies can use these recommendations to improve timely sharing of critical food safety and defense information.

1. Promote development and participation of state agencies in federal information sharing agreements and joint taskforces or advisory councils.

Improving the clarity of disclosure exemptions for information exchanged through a federal information sharing agreement under state FOILs will help ensure that states can enter into the agreements. For those states with federal law disclosure exemptions, clarifying how shared information is confidential or prohibited from being disclosed under federal law would make it easier for states to participate in the agreements. Joint taskforces or advisory councils composed of federal agencies and state agencies increase effectiveness, efficiency, and communications around food safety and food defense investigations. Examples of successful initiatives and taskforces are highlighted below:

**STRATEGIC PARTNERSHIP PROGRAM AGROTERORISM INITIATIVE**

States can volunteer to participate in the Strategic Partnership Program Agroterrorism (SPPA) Initiative, which includes DHS, USDA, FDA, FBI, and private industry. The initiative aims to:

- Identify sector-wide vulnerabilities by conducting critical infrastructure assessments.
- Identify indicators and warnings that could signify plans for an attack.
- Develop mitigation strategies to prevent an attack.
- Validate assessments conducted by the federal government for food and agriculture sectors.
- Provide the federal government and private industry with comprehensive reports that include warnings, indicators, key vulnerabilities, and potential mitigation strategies.
- Provide sub-sector reports for the federal government that combine assessment results to determine national critical infrastructure vulnerability points to support the National Infrastructure Protection Plan and national preparedness goals.
- Strengthen relationships between federal, state, and local law enforcement and the food and agriculture industry.
INDIANA STATE DEPARTMENT OF HEALTH FOOD DEFENSE PROGRAM

The Indiana State Department of Health (ISDH), with funding from a CDC public health preparedness and response to bioterrorism cooperative agreement, carries out the following activities:

- ISDH conducts food defense assessments for Indiana food manufacturers, distributors, and retail food establishments.
- The Indiana Food Protection Program has a food defense program coordinator who has been developing and implementing these assessments.
- Assessment findings are confidential documents and not public record. Finding results are used to make improvements to the food defense system and help reduce the risk of accidental or intentional food supply contamination.
- The food defense program coordinator manages the Indiana Food Safety and Defense Task Force, which consists of stakeholders from the food industry, government, and academia.

GEORGIA COMMITTEE ON AGRICULTURE AND FOOD DEFENSE

In April 2003, the Georgia Committee on Agriculture and Food Defense was formed with support from the Georgia Homeland Security Task Force and the Georgia Emergency Management Agency/Homeland Security. The committee is composed of representatives from state and federal government agencies, academic institutions, and the private sector.

- The group aims to establish better lines of communication between agencies to ensure effective and efficient responses to food contamination, waterborne hazards, and other public health problems.
- The group conducts quarterly meetings to discuss current issues that require a multiagency response.
- The committee has been a national leader in agrosecurity training. (For example, it developed the first agrosecurity awareness curriculum in the U.S.)
- State extension agents from USDA’s Cooperative Extension Office trained in content implementation to help conduct agrosecurity training. The training is provided to people in Georgia who would likely be mobilized in the event of an agricultural emergency, such as law enforcement officers, firefighters, and emergency management and response personnel.
- Regional response capability was developed through state agriculture response teams corresponding to Georgia Emergency Management Agency/Homeland Security areas. During the initial phase of development, teams focused on poultry disease outbreak response and foodborne outbreaks. The teams are multidisciplinary and include members from state and local government agencies, academic institutions, cooperative extension, and the private sector.
CALIFORNIA FOOD EMERGENCY RESPONSE TEAM

To increase food safety investigation efficiency, communication, and effectiveness, the California Department of Public Health, in partnership with FDA’s San Francisco and Los Angeles district offices, formed the California Food Emergency Response Team in 2005. The team comprises state and federal investigators and scientists who are specially trained in conducting foodborne illness investigations. One of the team’s most significant successes is how quickly the joint team is able to conduct streamlined foodborne illness and defense investigations. Prompt responses and team members’ developed expertise have led to more rapid detection of outbreak causes and corrective action.

2. Promote information flow by having key state food safety staff who are commissioned and have received national security clearance.

As mentioned earlier in this report, there are limitations to some types of interagency information sharing agreements, and the information provided may not be helpful for food safety regulatory agents during an enforcement case. Having key staff in an agency who are commissioned and can receive national security clearance makes it easier to conduct food safety-related investigations.

3. Develop a directory of state food safety officials who can receive confidential food safety and defense information and share this directory with federal agencies.

In many cases, there is a lack of awareness in federal agencies and among law enforcement regarding who in SHAs can receive confidential food safety and defense information. Compiling and providing a list of individuals who are allowed to receive confidential food safety and defense information for federal agencies and law enforcement will help improve the flow of critical communication information.

4. Develop internal communication plans for handing confidential food safety and defense information.

FDA’s 20.88 agreement permits the agency to share certain non-public information with various state and local officials who have signed a written agreement. The agreement can be signed by an agency head and covers all the staff in the agency. However, before signing a confidentiality agreement on behalf of all agency employees it would be useful to set up an internal guidance document or communications plan to avoid information leaks that would go against federal regulations.
5. Strengthen relationships with local law enforcement.

Food safety concerns used to focus solely on accidental contamination. However, concerns about intentional contamination by introducing biological, chemical, or radiological agents into the food supply are also on the rise. Having a good working relationship with local enforcement is important in conducting food defense-related investigations.

The California Department of Health Services employs food safety staff with peace officer status to conduct food safety investigations. This law enforcement component within a health agency has helped strengthen relationships with local law enforcement, such as the local FBI and police, who consider the food safety staff as peers and are more willing to share sensitive information.

“The definition of “peace officer” varies by state and jurisdiction. A peace officer generally refers to any employee of a state, county, or municipality (or a sheriff or other public law enforcement agency member) whose duties include arrests, searches and seizures, and execution of criminal and civil warrants, and who is responsible for preventing or detecting crime or enforcing penal, traffic, or highway laws. The peace officer definition may also include those deputy sheriffs whose duties include the care, custody, and control of inmates in a jail setting.”

Limitations

This project was conducted from 2015-2016. Survey respondents included staff from both the programmatic side of SHAs (state environmental health directors) and state legal staff. Although ASTHO feels that these two groups can speak for the agency reasonably well on most of their agency’s practices, there is a chance that the individuals who completed the survey were unaware of a certain practice because they were new to the agency or had a narrower scope than we anticipated, thereby limiting our data collection. In addition, our response rate was much higher for state environmental health directors than for legal staff, so we were unable to get a complete snapshot from every state.

The survey also mainly focused on SHAs and information sharing agreements with federal agencies. Therefore, the survey results are not representative of the entire state food safety system. The survey did not take into consideration the organizational complexity and fragmentation of food safety functions carried out by different state and local governments, such as local health departments, public health laboratories, and agriculture and consumer protection departments.
Conclusion and Next Steps

The free flow of information is vital to any integrated, system wide effort to improve food safety. Delays in sharing food safety inspection and recall information has hampered the critical role of SHAs in collecting and responding to food safety and defense concerns within their jurisdictions. Through this project, ASTHO highlighted obstacles to sharing critical food safety and defense information between governmental agencies. Through a legal and programmatic scan, as well as interviews with key informants within state health agencies, ASTHO analyzed current interagency information sharing practices and gathered information related to successful pathways and mechanisms, as well as barriers faced by agency personnel.

Based upon our findings, the main recommendations to improve the interagency sharing of information include promoting development and participation of state agencies in joint taskforces or advisory councils; promote information flow by having key state food safety staff who are commissioned and have received national security clearance; develop and share with federal agencies a directory of state food safety officials that are allowed to receive confidential food safety and defense information; develop internal communication plans for handing confidential food safety and defense information; and strengthen relationships with local law enforcement.

By developing this resource, ASTHO aims to help federal and state partners develop new processes or polices that enable responsible, timely information sharing and contribute to a more integrated food system. With so many players involved, it is imperative that information sharing is as streamlined and efficient as possible, so as to not hinder communication that may be needed to further improve our food safety and defense system.

Appendix A: Project Survey
Appendix B: Interview Guides
Appendix C: Literature Review
References


7. Ibid

8. Ibid


