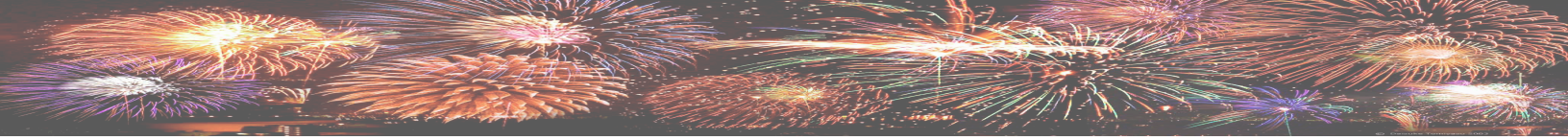

THE CIP REPORT

CENTER FOR INFRASTRUCTURE PROTECTION AND HOMELAND SECURITY

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We are very pleased to announce that this edition of *The CIP Report* marks its 100th issue. We would like to thank you for your dedication to this publication and for your valuable insight. We would also like to thank the numerous individuals and organizations who have contributed over the years. We could not have achieved this milestone without your support.

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In honor of the upcoming Thanksgiving holiday and the food that will be consumed, this month's issue of *The CIP Report* features the Food and Agriculture Sector. This issue highlights the laws and tools that are put into practice to protect the consumers of goods produced by the Food and Agriculture Sector.

First, the National Turkey Federation (NTF) explains the safety measures that are implemented to ensure that everyone enjoys the holiday festivities. Next, we examine the role of public-private partnerships in preparing for a terrorist attack on the Food and Agriculture Sector. The National Center for Food Protection and Defense (NCFPD), a U.S. Department of Homeland Security (DHS) Center of Excellence, then discusses the development of food risk models for the Bio-terrorism Risk Assessment (BTRA). The development and initiation of FoodSHIELD, a program sponsored by National Center for Food Protection and Defense (NCFPD), is also explored in depth.

This month's *Legal Insights* analyzes the U.S. Food and Drug Administration's (FDA) Food Safety Modernization Act, which is currently awaiting votes in the U.S. Senate, and its impact on the Food and Agriculture Sector.

We hope you enjoy this issue of *The CIP Report* and find it useful and informative. Thank you for your support and feedback. We wish everyone a very Happy Thanksgiving.

Mick Kicklighter
Director, CIP/HS
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The National Turkey Federation Thinks Turkey All Year Long: Turkey Industry Takes Proactive Approach to Prepare for Thanksgiving

by Joel Brandenberger, President
National Turkey Federation

While the National Turkey Federation (NTF) thinks of turkey all year long, we recognize that many Americans focus most closely on turkey during the Thanksgiving season.

NTF is the national advocate for all segments of the turkey industry based in Washington, D.C. The federation provides services and conducts activities to help its members provide safe, wholesome, and affordable turkey products. The federation represents its members' interests in legislative and regulatory affairs and also develops consumer education and information resources, including its key tool EatTurkey.com.

Every year, prior to Thanksgiving, NTF takes a proactive approach in preparing its members for the holiday season. There is no denying the fact that on Thursday, November 25, NTF will be "Queen for the Day." All eyes will be on the turkey industry and there are sure to be animal activists who will try to make headlines by targeting the product that is served at the center of the plate during this American holiday. There are literally hundreds of animal rights groups in the United States. Some of the most active groups include, but are not limited to, the Human Society of the United States (HSUS), People for the Ethical Treatment of Animals (PETA), Physicians Committee for Responsible Medicine (PCRM), Animal Legal Defense Fund, and United Poultry Concerns.

Obviously, the industry has a philosophical difference with such groups about the role of animals in society. The reality is that these animal rights groups do not want the turkey industry to change its practices; they want to end the production and consumption of turkey and all other meat proteins. We respect their rights to have an opinion and have no problem with them espousing it so long as they do not spread false information when they do.

The real truth is that the turkey industry has a strong record of raising its birds in a humane, sustainable manner. Our members do it because it is the right thing to do and because it makes good business sense. Research has shown birds subjected to stresses such as poor ventilation, disease, crowding, and excessive heat do not gain as much weight or utilize feed as efficiently as low-stressed birds.

So what does the turkey industry do to promote the truth and protect itself? It remains prepared. NTF ensures its members are clearly focused on the importance of security on the farm and in the processing plant. Below are some important security programs and procedures that NTF recommends to ensure its members, and ultimately the consuming public, have a happy and safe winter holiday season.

Employee Screening: During the holiday season, day labor and temporary office help are often needed. NTF recommends screening all new hires as thoroughly as possible, including checking references closely.

Farm Biosecurity: All stages of turkey production require biosecurity to reduce the risks of disease and provide assurance of the healthiest birds possible. Biosecurity on farms begins with the proximity to other sites, landscaping drainage, roads, fences, gates, and signs. All of these security measures are important to ensure that a turkey operation is safe and secure from unwanted visitors, vandalism, or accidental damage that can put the turkeys at risk for injury, disease, or stress. Often there will be "No Admittance" signs on surrounding gates to provide additional security from the public. Many farms also have a security building at the entrance where there is a sign-in log that provides documentation of traffic. If there is

(Continued on Page 3)

NTF *(Cont. from 2)*

an issue, the turkey farmer can easily identify who has been on the farm and in the turkey house. Another way that turkey farmers ensure the health of their turkeys is to require all persons prior to entering the barn to put on clean outer clothing and footwear and some even take the added step of requiring people to shower before going in the facility and showering again upon leaving it.

Turkey Health Security: Turkey buildings are scientifically designed and maintained to prevent disease agents present in wildlife and other animals and birds from coming in contact with the turkeys. All door and ventilation openings are screened to prevent wild birds from entering the buildings. Each turkey house also has rodent protection that is built into the perimeter of the building. Turkey growers conduct an evaluation of each building on a regular basis, along with completing any necessary repairs. Turkey houses also have a biosecurity checklist that is posted for flock caretakers and farm managers. All new employees participate in training programs that include biosecurity procedures prior to entering the farm.

Local Law Enforcement: Since animal rights groups target the turkey industry during the Thanksgiving season, NTF members are encouraged to talk with their local law enforcement authorities about the animal rights threat to the turkey industry. Fake employees, computer system sabotage, and website hacking are just some hallmarks of radical animal rights efforts to stop the turkey industry from conducting business.

Communications Plan: Along with making sure all security systems are in place, NTF recommends its members have a crisis management plan in place. As with any crisis management plan, a designated company spokesperson should be chosen and prepared to speak on behalf of the company.

It is important to communicate that a turkey farmer's number one priority is to ensure the health and wellbeing of his or her flocks so the farmer can provide safe, nutritious, and affordable turkey products to consumers. In fact, on NTF's website, www.EatTurkey.com, visitors can hear from a turkey producer about how he ensures the health and wellbeing of his flock. To listen to this message, please visit http://www.eatturkey.com/consumer/modules/modules_01_welfare.html.

Animal Care Guidelines: The turkey industry has long held that the appropriate treatment of turkeys is a necessary part of production and national guidelines have been in place in the industry since the late 1980s.

To help assist with humane production and slaughter practices, NTF published its science-based Animal Care Guidelines. The guidelines provide the industry with the current state-of-the-art practices and set the stage for enhancement in the future. The document was developed with today's best information and is updated continually in a dynamic way to make sound improvements as new knowledge emerges.

Food Security: Another threat around the holidays is the intentional tampering of turkey products. Therefore, it is essential that NTF members have a food defense plan in place. Food defense should not be confused with food safety. Food defense focuses on protecting the food supply from intentional contamination, with a variety of chemicals, biological agents, or other harmful substances by people who want to do harm. Having a food defense plan in place increases preparedness.

The U.S. Department of Agriculture's Food Safety and Inspection Service provides the meat and poultry industry with a model food safety defense plan. This guide was developed in consultation with various meat and poultry processing establishments in an attempt to ensure that the information presented is beneficial, practical, and achievable.

All of these procedures are crucial in ensuring that the turkey industry is prepared for the holiday season and beyond. Since most of us no longer spend very much time in the kitchen, NTF makes sure that the federation's website, www.EatTurkey.com, has a detailed Thanksgiving guide from purchasing to preparation to pointers for leftovers. It is designed to serve as a comprehensive instructional and recipe manual for the holidays. Beyond the turkey,

(Continued on Page 13)

An Examination of Policy and Organizational Issues Relating to the Role of Public-Private Partnerships in Preparing for a Terrorist Attack on the Food and Agriculture Sector

by Amit Kumar, Ph.D.

This article assesses the state of preparedness of the Food and Agriculture Sector against a possible terrorist attack. In particular, it delves into some key policy and organizational issues with special reference to public-private partnerships in the Sector and their role in preparing for a terrorist attack. Policy postulates that emanate out of this assessment are discussed towards the end.

Food Security under Terrorist Threat

Since September 11, 2001, it has been recognized that the U.S. food supply is vulnerable to attack. The Food and Agriculture Sector is especially vulnerable to attack — the "farm to table" food supply chain comprises farm inputs; domestic farm production; farm product assemblers; food processing plants; wholesalers; retailers; food and agriculture transportation facilities; and consumers. Any of these components are susceptible to terrorist attacks. With the threat of home-grown terrorism more prevalent than ever, it is important to realize that we have to take adequate and urgent measures to ensure our food security. This calls for more robust public-private partnerships.

Existing Model of Public-Private Partnerships

Homeland Security Presidential Directive (HSPD)-7 and HSPD-9 respectively provide the policy blueprint for public-private partnerships in all critical infrastructure sectors, including the Food and Agriculture Sector. Based on these presidential directives, the Government Coordinating Council[1] or GCC (that represents the public sector) for this Sector interacts with the Food and Agriculture Sector Coordinating Council or SCC (that represents the private Food and Agriculture industry) on all strategic and policy issues confronting food and agriculture security.

Furthermore, the National Infrastructure Protection Plan (NIPP)[2] and the Sector Specific Plan (SSP)[3] describe in detail the mechanics of this public-private cooperation.

Information-Sharing Mechanisms

The two main tools employed to facilitate information sharing relating to Food Security are FoodSHIELD,[4] discussed in a later article, and the Homeland Security Information Network (HSIN) (Food and Agriculture), the latter being a public-private information sharing tool.[5] The Federal Bureau of Investigation (FBI) has a web-portal similar to the HSIN (Food and Agriculture) called AgInfraGard which has, in the view of some, many of the same functionalities. This has the potential to create possible redundancies in the public-private information sharing domain. In the risk-based approach to critical infrastructure protection, the risk is determined by mapping

(Continued on Page 5)

[1] Members of the Council include the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS), which together serve as the Sector Specific Agency (SSAs), the U.S. Department of Homeland Security (DHS) as the overall agency charged with coordinating critical infrastructure protection activities for all sectors, and other organizations.

[2] National Infrastructure Protection Plan.

[3] Sector Specific Plan for the Food and Agriculture Sector.

[4] Web-based platform designed to create community between the various laboratories and federal, state, and local regulatory agencies that belong to the Food and Agriculture Sector.

[5] An Internet based platform that enable secure encrypted sensitive but unclassified and for official use communication between SSA and vetted members of the Sector, as well as within and across sectors.

Partnerships *(Cont. from 4)*

threats (information on which is generated by the public sector), against vulnerabilities (information on which is available with the private sector). It is therefore reasonable on the part of the private sector to expect better access to threat information from the government. However, this is not usually the case due to the classified nature of such information and the consequent need for security clearances to gain access to this information. The two-way sharing of information requires trust between the public and private partners and only if both sides are ready to share information can a productive public-private partnership last. Realizing this imperative, in addition to the aforementioned AgInfraGard program, DHS's Homeland Infrastructure Threat Risk and Analysis Centre (HITRAC) provides unclassified alerts, warnings, and information bulletins that are distributed via the GCC and the SCC. Only the government partners, including the Office of Inspector General of the USDA, participate in the FBI-led National Joint Terrorism Task Force, and State and local agencies in the Joint Terrorism Task Force nationwide. Also, the FBI field offices have been asked to develop agroterrorism working groups with relevant stakeholders within their jurisdiction. These working groups are supposed to be engaged in prevention and awareness, intelligence, investigative response, and crisis management. While all of these information sharing mechanisms do cater to an all-hazards threat, including the intentional (terrorist) attack on one or more components of the food-supply chain, it seems that they may not be adequate in response to a terrorist attack. None of these mechanisms are geared to transmit classified intelligence information to the private sector that pertains to terrorist threats and/or notification of actual terrorist incidents.

The Protection of Critical Infrastructure Information (PCII) Program was designed to facilitate sharing of vulnerability information by private sector participants with the PCII office within DHS or the USDA and FDA as the SSAs for the Food and Agriculture Sector, and this information is subject to Freedom Of Information Act exemptions, thus providing an incentive to the private sector to share information with the government. In addition, under Section 871 of the 2002 Homeland Security Act, all interactions between the Food and Agriculture GCC and the SCC are exempt from the provisions of the Federal Advisory Committee Act (FACA),[6] providing yet another incentive to the private sector to share information with the public sector. However, there is a legitimate fear that Section 109 of the Food and Safety Modernization Bill, which is currently up for discussion in the U.S. Senate, would compromise the FACA provision since the interactions of the Food and Agriculture GCC and SCC would have to be made available on the DHS website if the bill is passed in its present form.

Public-Private Collaboration Measures

The picture for public-private collaboration in preparing for a terrorist attack on the sector is not all that grim. The Strategic Partnership Program Agroterrorism (SSPA) initiative, piloted by the FBI, DHS, USDA, and HHS/FDA, has conducted assessments of the Food and Agriculture Sector in collaboration with private industry and State volunteers. This initiative has resulted in threat assessments of certain industry production processes, identification of nodes or process points of highest concern, as well as protective measures and mitigation steps that may reduce the susceptibility of these nodes. In addition, tabletop exercises that focus on response and recovery coordination amongst Federal, State, local, and private stakeholders in the case of an attack are being conducted.

Policy Postulates

The following policy recommendations flow out of this discussion:

1. Section 109 of the Food Safety Modernization Bill should be amended to preclude the possibility of the deliberations between the Food and Agriculture Sector Coordinating Council and the Government Coordinating Council losing their FACA exempt status, and thus jeopardise the public-private information sharing process.

(Continued on Page 13)

[6] Under the FACA exempt status, such proceedings are kept confidential and are not made public.

The National Center for Food Protection and Defense's Development of Food Risk Models for the BTRA (Bio-terrorism Risk Assessment)

by Morgan Hennessey, DVM, MPH, DACVPM, Assistant Program Director, NCFPD
Elizabeth Cunningham, Communications Manager, NCFPD, and
Shaun Kennedy, Director, NCFPD

The National Center for Food Protection and Defense (NCFPD) Background

NCFPD was established as a DHS Center of Excellence in 2004, and its base funding was renewed through a competitive process in 2010. A multidisciplinary and action-oriented research consortium, NCFPD addresses the vulnerability of the Nation's food system to attack through intentional contamination with biological or chemical agents. NCFPD has established a track record of delivering stakeholder-relevant, science based solutions to meet stakeholder needs, and track these needs as they evolve. The team of NCFPD researchers has involved over 25 academic institutions in collaboration with over 30 food system firms, in performing innovative, fundamental, and translational research across a wide range of disciplines related to food defense. NCFPD's consortium of investigators, partners, and stakeholders come from the private sector, national laboratories, universities, other DHS Centers of Excellence, and international non-governmental/inter-governmental organizations. This breadth of stakeholders and partners places NCFPD in a unique position to understand and analyze food system vulnerabilities and potential mitigation strategies.

NCFPD's core vision since its inception has been "Defending the Safety of the Food System through Research and Education." NCFPD-developed tools have already been deployed in the Food and Agriculture Sector. One example is the Food and Agriculture Sector Criticality Assessment Tool (FAS-CAT), which has been used by State agencies for identification of critical infrastructure elements/systems for designation as Level 1/Level 2. The Level 1/Level 2 designation of critical infrastructure systems, subsystems, or assets is a process that occurs every year, as States are required to submit a data call to DHS regarding those critical infrastructure elements that they deem to be most critical to both the State and to the Nation. Level 1 (utmost importance to the Nation) or Level 2 (significant national importance) assets or systems may therefore be eligible for mitigation strategy investment. In the past, this data call has been driven primarily by an asset-centric approach and the designation of systems. Due to this asset-centric approach, nothing in the food and agriculture system had been successfully designated as Level 1 or 2 prior to this year. This year, through a systems-based evaluation of critical infrastructure using the FAS-CAT tool, critical infrastructures, subsystems, and assets in the food system were designated Level 1 or 2 for the first time. Moving forward, the approach for improving this process will be further addressed in a multi-state Federal agency meeting the week of October 18th, 2010. FAS-CAT is just one example among 30 other research projects underway by NCFPD investigators that helps support and inform the efforts on the project described in this article, on developing optimal food models for the Bio-Terrorism Risk Assessment (BTRA) as well as the overall effort on enhancing food system protection.

Food System Background

The global food system that nourishes the United States is likely the most complicated system of supply chains known. This system, from primary production through final consumption, has been optimized to deliver a dizzying array of foods from around the world at the lowest possible cost year round. It was not designed for, and has not been optimized to protect it from intentional disruption or contamination. The systems that are in place do not make such optimization readily feasible. Its complexity and rapidly evolving nature makes development of a detailed model of the entire food system an unattainable goal. Based

(Continued on Page 7)

BTRA *(Cont. from 6)*

on registrants in the FDA's Bioterrorism Registration Database, as of July 15, 2009, there were over 156,000 domestic food firms and over 226,000 foreign food firms registered to produce food for sale in the United States. This wide range of firms eventually end up supplying the over 55,000 individual types of food (stock keeping units or sku's) that are available in an average retail grocery store. The challenges that this complexity and variability present in food contamination scenarios have been highlighted in recent foodborne illness outbreaks, where identifying the food vehicle has presented a significant challenge for both government agencies and for industry.

Through the course of its investigation of the *Salmonella* Saintpaul outbreak associated with produce in 2008, FDA as well as State and local agencies sorted through a pepper supply system that included more than 500 producers in Mexico, 300 importers, and 25,000 shipments of peppers from March through June of 2008. The Peanut Corporation of America product contamination in 2010 led to nearly 4,000 individual recalls, impacting over 200 food companies with dramatically different potential vulnerabilities relative to intentional contamination. These recalls illustrate the complexity of the food system, and therefore the need for a methodology to sufficiently generalize these complex food systems to represent the range of risks evaluated in the BTRA. This is the focus of NCFPD's efforts on this project. DHS is required under statute HSPD-10 to prepare a bioterrorism risk assessment for the White House every two years. This risk assessment assesses all of the potential utilizations of biological weapons of mass destruction and their potential consequences on U.S. infrastructure. This includes an assessment of the overall relative level of risk. The risk is determined as a combination of the threat, consequences, and vulnerability. One of the significant challenges in performing the risk assessment is deciding how to model the potential events that could occur. Prior to BTRA, a limited subset of foods were used that were chosen because of early FDA and USDA risk assessments. The foods chosen did not fully represent the breadth of the food system. The challenge for NCFPD was developing a set of foods that modeled the range of risk in the food systems so that the degree of uncertainty in understanding the overall risk from biological weapons could be better addressed and the uncertainty reduced. The food models developed will be integrated into the overall BTRA, including the uncertainty of the threat component, which is an ever-evolving issue in trying to understand terrorists' motivations and utilizations.

Development of Food Risk Models for the BTRA: Project Objectives

To address this need for a methodology to generalize food systems, NCFPD has undertaken a food risk analysis. NCFPD's objectives for this project are to:

1) Develop clusters of foods that represent similar characteristics with respect to intentional contamination.
2) Develop a metric for selecting exemplary foods from within each cluster.
3) Select the exemplary foods from each cluster.
4) Support the development of a food risk model.
5) Support data collection for the next generation of food risk models.

To develop the clusters of foods, NCFPD considers how those foods would fit into broad categories, from pre-farm inputs through consumption. This includes considering current and potential vulnerabilities, interventions/mitigation strategies, response systems, and recovery strategies.

Approach

NCFPD developed the clusters through subject matter expertise input, review, and collaboration. The fundamental hypothesis is that there are supply chain, processing, consumption, and other specific food attributes that will allow foods to be grouped together. These attributes contribute to an individual food's overall vulnerability and the relative utility of mitigation strategies. The processing characteristics cover the range of processes in food systems, including those that may represent existing mitigation steps such as thermal treatments. Supply chain characteristics include length, complexity, and transportation

(Continued on Page 11)

FoodSHIELD

by Jennifer Pierquet, MPH, Coordinator FoodSHIELD, and
Eric Hoffman, Technical Director FoodSHIELD

FoodSHIELD is a web-based platform that creates community, increases collaboration, and facilitates communication among thousands of public and private entities involved in protecting and defending the U.S. food supply. From laboratories and regulatory agencies at local, county, State, and Federal offices to academia and industry, FoodSHIELD is a central portal where people in all 50 States work collectively to safeguard the national food supply through secure, integrated resources.

FoodSHIELD is sponsored by the National Center for Food Protection and Defense (NCFPD), a DHS Center of Excellence housed at the University of Minnesota. FoodSHIELD support stems from DHS, USDA, FDA, and the Association of Food & Drug Officials.

In 2004, FoodSHIELD was a mere pilot project for NCFPD. The idea for FoodSHIELD developed out of the realization that no one single system could bring all laboratory professionals together to communicate, collaborate, coordinate, educate, and train. This begs the question: why just laboratories? Why not the entire Food and Agriculture Sector? The "farm to table" continuum needed a champion outside of the everyday collaboration norms. In essence, FoodSHIELD is a "new normal" for food sector professionals.

Other systems limited information sharing or did not connect out to other systems with similar or useful information. FoodSHIELD allows a variety of applications to be built onto one platform and reaches out across systems to connect user communities.

FoodSHIELD's main attraction is the collaboration portal located behind a firewall. Individuals login to the portal to access online document sharing, web meetings, calendars, discussion boards, and the over 100,000 strong contact directory. The challenge FoodSHIELD encounters working with all types of food system professionals from across the Sector is the way in which each agency organizes their information. Specifically, the contact directory connects colleagues across the Nation by job duties. For example, in Alaska, Minnesota, California, or Florida, the head of the Department of Agriculture may be referred to as the director, secretary, or commissioner. To connect each of these States to another State's agency head requires FoodSHIELD to vet each member and identify their role in their agency.

FoodSHIELD's mission focuses on breaking down silos among the agencies and laboratories knowing each have their own distinct protocols and expertise. FoodSHIELD strives to unite the food-related agencies that need to share information. Users are better able to contain threats to the food supply by identifying the appropriate players, locating them, and immediately conveying information to them. In addition to connecting users for information sharing, FoodSHIELD is being used as a full-scale training platform. For example, the development team converted offline training materials into online modules for USDA to train their inspectors. The trainings contained video, PowerPoint, and live presentation. Normally, coordinating this training would have taken weeks, time away from the office, and more human effort, but with the use of FoodSHIELD's collaboration tools, training for everyone was completed over several days.

A useful tool housed in FoodSHIELD is the Food and Agriculture Sector Criticality Assessment Tool, (FAS-CAT).

(Continued on Page 12)

Legal Insights

S.510, the FDA Food Safety Modernization Act: A Food Safety Paradigm Shift

by Shahin Saloom, J.D.

Introduction

A series of food contamination incidents in the past few years has spurred both the House of Representatives and the Senate to pass food safety laws that plug regulatory gaps; give FDA proactive rather than reactive powers; and bring the security of the Food and Agriculture Sector more in line with the risk management paradigm encouraged by DHS. The House bill[1] was introduced in June of 2009 and referred to the Senate Committee on Health, Education, Labor, and Pensions (HELP) in August of 2009. The Senate introduced their version of the bill[2] in March of 2009, and it will be voted on after the midterm elections. The Senate bill was designed to bridge the gap between the regulatory purviews of FDA and USDA, primarily by granting FDA the ability to proactively avoid compromises of the food system before they occur. This would eliminate situations like the recent recall of eggs contaminated by *Salmonella*. While USDA regulates the *quality* of eggs and has authority to preemptively recall, FDA has authority to regulate the *safety* of those eggs but could not proactively shut down the plant. FDA can only react once a contamination occurs and then only with the cooperation of the egg farm. The bill bridges this gap primarily by requiring food companies to consider, avoid, and document potential hazards and allowing FDA to examine that documentation at any time and to shut down food facilities not in compliance with standards before an actual outbreak. The bill also establishes that all of the new powers and procedures should be designed and executed based on actual and documented risk in the food system, bringing food safety in line with protection paradigms from other critical infrastructure sectors.

Content of the Senate Bill

Food contamination incidents throughout the 2000s spurred the House to react with their bill, and the recent contamination of more than half a billion eggs due to *Salmonella* has put the current Senate bill squarely in the limelight. To bolster their efforts, Congress asked the Institute of Medicine (IOM) to study the food safety situation in the United States and develop recommendations to the existing system to improve food safety. In their June 2010 report,[3] the IOM recommended that FDA adopt a risk-based approach, create uniform standards for investigations and surveillance, and requested that Congress act affirmatively on the recommendations they presented by legislatively bestowing upon FDA more power and responsibilities. Armed with this third party validation, the Senate tracked the general recommendations of the IOM report with the specific provisions of their bill.

The bill, generally, provides for an increase in the authority of FDA to change it from a reactionary agency to a proactive, risk management agency. The popular narrative, supported by the IOM report, of food safety failures in the United States imputes most of those failures to the fact that USDA covers only meat, milk, and eggs while FDA covers everything else but cannot take affirmative action ex post. The increase in power and responsibility of FDA in this bill

(Continued on Page 10)

[1] The Food Safety Enhancement Act of 2009, H.R. 2749.
[2] The FDA Food Safety Modernization Act, S.510.
[3] Enhancing Food Safety: the Role of the Food and Drug Administration, available online at http://www.iom.edu/Reports/2010/Enhancing-Food-Safety-The-Role-of-the-Food-and-Drug-Administration.aspx.

Legal Insights *(Cont. from 9)*

requires a certain toolkit to be effective, and the bill provides that toolkit.

The bill specifically amends the Food, Drug, and Cosmetic Act to expand the authority of the Secretary of HHS. All food facilities that registered pursuant to the Bioterrorism Act of 2002 must evaluate risks and hazards to food safety at their facility, address the risks, as well as document both of these evaluations. The Secretary has the power to subpoena and inspect the records at any time. The Secretary also has the power to immediately and proactively recall or demand the cessation of production of food that he/she has reason to believe does not meet the science-based production and harvesting safety standards this bill compels the Secretary to develop. The bill gives FDA the power to perform this recall on its own, without relying on cooperation from industry. The bill also requires the Secretary to identify and develop preventative practices, regulate food transportation, address and reduce food allergy risks in schools, establish more thorough accreditation of testing facilities, improve tracking of raw agricultural products, and improve the safety of imported food by establishing verification and a qualified importer program. The Environmental Protection Agency is charged with assisting State and local governments in preparing for and recovering from a food safety issue.

An issue has emerged in the negotiations of this bill regarding the different impacts it could have on large and small producers. A $500 registration fee and new safety and documentation requirements are much more easily absorbed into the budget of large corporate food operations than they are for smaller facilities, such as family farms. Pressure from advocacy groups and associations has led to a compromise, allowing State discretion in regulation of small farms, farmers' markets, and roadside stands. However, concern remains due to the mandate that the Secretary promulgates practices and procedures clearly and openly so that State and local food safety entities approach a universal safety scheme. A recent amendment[4] by Senators Jon Tester (D-MT) and Kay Hagan (D-NC) would mitigate these concerns by formally exempting any qualified facilities that make less than $500,000 a year and sell more than 50 percent of their produce within a 400 square mile radius.

Adoption of Risk Management

The bill also incorporates several tenets of the risk management system encouraged by DHS for critical infrastructure protection. While this bill increases the power of the Secretary to take preemptive action, the primary risk reducing activity remains the inspection of food facilities and the promulgation and encouragement of preventative activities. The primary goal of the legislation (and any protective system for critical infrastructure) is to avoid food safety issues through continued vigilance. The goal of effective response is secondary to the goal of prevention. Section 110b of the bill requires that the Secretary of HHS submit a report to Congress, no later than two years after passage, which outlines how he/she has implemented a risk-based approach to resource allocation for both inspection and preventative activities. Similarly, the Tester-Hagan amendment proposed above contains a provision requiring the HHS and USDA Secretaries to conduct a study that establishes the relative risks of foodborne illnesses that arise from different types of food and food facilities. Knowledge of the different risks in a system is a crucial first step to successful risk-based resource allocation.

Knowledge of the actual risk is only possible with accurate and complete information and the bill accounts for this by requiring the Secretary to develop and disseminate science-based preventative standards and practices, to work with the Director of the Center for Disease Control and Prevention to enhance and integrate surveillance and tracking systems, and to improve the accreditation of laboratories used to protect against and identify food contamination. The bill also mandates several supporting programs to bolster this new surveillance and information system, such as facilitating sharing between Federal and State actors, allowing public access to the surveillance data, encouraging scientific research in related fields, and integrating food safety surveillance systems with other public health and bio-surveillance systems.

(Continued on Page 12)

BTRA *(Cont. from 7)*

parameters, among others, that may introduce points of vulnerability. Product characteristics include both food composition and final preparation characteristics that could also represent existing mitigation strategies. In selecting the characteristics for consideration, existing risk, consequence, and vulnerability assessments were utilized. This included each of the assessments conducted through the Strategic Partnership Program Agroterrorism (SPPA) by the FDA, USDA, DHS, and the FBI.

In addition to other assessments made available by FDA, USDA, and private sector partners, an important source of input has been the broad range of FAS-CAT assessments conducted which represent a significant source of supply chain characteristics, system documentation, and potential importance criticality/vulnerability of the assessed systems.

Once the clusters of similar foods were developed, exemplar foods were selected within each cluster that provides the opportunity to model them in detail to support the BTRA. The suite of exemplars then represents the rank of risk types for food used as the delivery vehicle for biological threat agents.

Once these assessments are complete, a more comprehensive picture of the global food system will emerge, enabling much more detailed analysis, a better representation of the risk for biological agents delivered via the food system, and better-informed mitigation strategies. This project is an illustrative example of NCFPD's collaborative approach to food defense, leveraging expertise across the food system to develop the next generation of food risk models, resulting in a safer, better-defended food supply. ❖

Legal Insights *(Cont. from 10)*

Section 110e of the bill explicitly requires the Secretary to describe how he/she has pursued the automation of food safety risk assessments, which are only as effective as the information that animates them. The mandate to allocate resources based on risk and to automate risk assessments has the added benefit of requiring reliable information up front, which creates a positive externality for the primary guarantor of food safety, the ex post inspections, and preventative measures.

Conclusion

This bill, in encouraging the adaptation of a risk-based approach, along with the powers to take proactive risk reducing measures before an incident occurs, brings safety regulation of the Food and Agriculture Sector into line with the general risk management approach to critical infrastructure protection outlined in the 2009 NIPP. This is no coincidence, as Section 108 requires the Secretary to develop and submit to Congress the National Agriculture and Food Defense Strategy, which must be consistent with, among other national planning documents, the NIPP. This mandate to develop and submit plans consistent with the NIPP instills the core tenets of risk management into protection of the Food and Agriculture Sector.

The public recognition that the Food and Agriculture Sector is vulnerable, most recently to human error, revealed enough glaring holes in the system that national security concerns should also spur legislative action. When the 111th congress reconvenes in November, the case needs to be made from both public health and homeland and infrastructure security perspectives; the context of food and agriculture to national security needs to be introduced into this debate to accurately reflect the importance of this critical infrastructure Sector to national security. ❖

FoodSHIELD *(Cont. from 8)*

FAS-CAT measures each State's most vulnerable assets in the Food and Agriculture Sector. The online tool allows data entry, analysis, and reporting to be produced for qualified users. Similarly, the Food Recall Portal provides a secure way to enter data on a recalled product, analyze the recall effectiveness, and produce a hardcopy report on the recall. FoodSHIELD members with access to the recall portal and/or FAS-CAT can share information with others involved in the recall or assessment through e-mail, discussion board, or webinar. Outreach during an event of any kind is important — to be able to find the right person with the right information at the right time — especially during a crisis.

FoodSHIELD continues to provide more functionality to Food and Agriculture Sector professionals as we look to expand our services to mobile devices and offline modes. Currently, food professionals use a variety of technology to protect the food supply from harm. We hope to advance their technology use by providing services that help them do their jobs better, and in effect, making us all safer. ❖

Please contact Jennifer Pierquet, FoodSHIELD Coordinator at jpierquet@foodshield.org with questions.

NTF *(Cont. from 3)*

there are also dressings and stuffing, gravies, side dishes, and dessert ideas. So from the farm to the fork, NTF wants to make sure that everyone takes a role in having an excellent experience with turkey products. ❖

Partnerships *(Cont. from 5)*

2. Membership of the FoodShield information mechanism should be made open to all private industry stakeholders.

3. Private sector players in the food and agriculture industry should be given security clearances on a priority basis, so that they may gain access to classified information pertaining to terrorist threats/ terrorist incidents, after thorough vetting.

4. The all-hazards approach to food and agriculture security needs to be tailor-made towards a special preparedness plan and a response plan geared only towards terrorist attacks. This response plan should comprise of, amongst other components, a communications plan, and arrangements for alternative food supplies in a situation where food shortages may occur as a result of the panic caused by a terrorist attack and/or the actual impact of a terrorist attack on one or more of the components of the food supply chain. Even though a large intentional (terrorist) attack on the food-supply chain has not yet occurred, this does not mean that it cannot ever occur. While the Food Safety Inspection Service (FSIS) is doing a great job at our borders, the possibility of a home-grown attack on our food-supply chain is not that remote and we should take adequate measures against such an eventuality.

5. The formulation and implementation of an appropriate communications plan in the case of an actual terrorist attack should take into confidence the food and agriculture industry in addition to Federal, State, tribal, and local stakeholders including regulators, law enforcement agencies, etc. The industry's participation in the formulation of such a plan is vital.

6. Since the Food and Agriculture Sector is interwoven with other critical infrastructure sectors like transportation and water, it is important that the preparedness and response plans take into account their feedback. Representation of these Sectors in public-private interaction forums specific to the Food and Agriculture Sector is important towards formulating a comprehensive plan to prepare for and respond to a terrorist attack. ❖

The Center for Infrastructure Protection works in conjunction with James Madison Univerity and seeks to fully integrate the disciplines of law, policy, and technology for enhancing the security of cyber-networks, physical systems, and economic processes supporting the Nation's critical infrastructure. The Center is funded by a grant from the National Institute of Standards and Technology (NIST).

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