1. Introduction

Food regulations in the U.S. are at a crossroads, because current regulations are inadequate to deal with issues surrounding rapidly increasing trade, more incidents of economic adulteration, and unstable global markets. In addition, increasing public concern is directed toward large outbreaks of food borne illness that have been linked genetically, and traced to contamination at one or a few operations. A collaborative project at the University of Wisconsin—Madison, “Managing the Challenges of Import Safety in a Global Economy,” was directed toward development of both public and private regulatory mechanisms to ensure the safety of globally-sourced imported food commodities and supplements.

The project began with numerous seminars and benefited from a two-day conference in the first year titled, “Food Import Safety: Systems, Infrastructure and Governance.” The conference approached this topic with a multi-disciplinary, systems-based perspective on problem solving. Speakers and attendees represented the food industry, government regulatory agencies, scientific service companies, the legal community, and academics from a variety of areas. Attendees included representation from the European Union, Mexico, Canada, and China.

The scope of the problem is global and covers both accidental contamination (where education, standards development and certification, and infrastructure investment would help with prevention efforts), and intentional contamination (fraud and economic adulteration), for which monitoring, traceability, and information sharing might discourage opportunism. A number of examples are cited, and advice for the way forward includes approaches at the global, national, and local levels. Recommendations include: improved local enforcement; private certification of suppliers; monitoring; traceability; education; information sharing at all levels; expanding both public-sector and private use of risk analysis; expanding the reach of the European Union rapid alert system; improved communication and oversight (including border inspection); and maintaining strong private accountability for contamination.

Safety of globally-sourced imported food commodities and supplements, and the development of public and private regulatory mechanisms to ensure their safety, were the subject of a broad-based collaborative project at the University of Wisconsin—Madison. The problems are complex and require a multi-disciplinary, systems-based perspective. The project began with numerous seminars and benefitted from a two-day conference in the first year. Many of the insights in this paper were originally inspired by presentations and discussions from that conference with attendees representing the food industry, government regulatory departments, scientific service companies, the legal community, and academics from a variety of areas. Attendees included representation from the European Union, Mexico, Canada, and China.

The problems are complex and require a multi-disciplinary, systems-based perspective on problem solving. Speakers and attendees represented the food industry, government regulatory agencies, scientific service companies, the legal community, and various areas of academia. After two years of further work, we offer our findings, woven with threads from the conference.

Prevention and detection of food adulteration, contamination, and fraud clearly requires cooperation in order to achieve positive public health outcomes and cost-effective solutions. The origins of adulteration and contamination in developing economies are examined, as well as risk-based approaches to regulate the safety of imported foods, and supplier-qualification programs to manage the quality and safety of imported ingredients. Technical issues, such as
effective sampling schemes, advances in detection technology, and testing limitations, are also discussed. Finally, possible strategies for the way forward, including global approaches to food protection, alternative forms of governance, public–private partnerships, and third-party oversight, are considered, followed by policy recommendations emerging from our collaborative project for protecting food supplies.

2. Summary of current concerns

2.1. Contamination and fraud

The underlying reasons for problems with imported foods vary greatly. Contamination and adulteration may be unintentional, occurring because farmers or food processors are unfamiliar with the importance of certain practices for maintaining the wholesomeness and safety of foods, or are not aware of which additives or packaging materials are approved for use in the U.S. For example, in 1990, Mexico was the largest exporter of cantaloupe to the U.S. with 30% of the market (Boriss, Brunke, & Kreith, 2006). However, following a U.S. Food and Drug Administration (FDA) investigation of illness associated with these fruits a few years later, Mexican cantaloupes were banned from the U.S. because of unhygienic conditions in the fields, packing houses, and shipping, which had facilitated contamination of the fruit with Salmonella (US FDA 2011b). Similarly, raspberries from Guatemala, contaminated with Cyclospora in spray water, caused several food borne outbreaks in 1996–98 (Powell, 2000). The concern over beef and beef products imported from the EU or Canada, which might be contaminated with Bovine Spongiform Encephalopathy (BSE) prions was a new disease originating from poor oversight in the UK (Vos & Wendler, 1996). Illegal colors, sweeteners, antibiotic residues, and high levels of sulfites and heavy metals have been detected in some imported foods in New York (Buzby, Laurian, Unnevehr, & Roberts, 2008; Corby, 2009). Other imported foods may not include required information on labels, such as the presence of allergens (Corby, 2009). Many of these violations are presumably due to lack of knowledge on the part of food producers and exporters.

In other cases, food adulteration is intentional. Usually, the motive is economic. In developing countries, such as China, food production systems are often extremely price competitive and decentralized. For example, there are over 500,000 food production/processing businesses in China and 70% of them employ fewer than 10 people (Ellis and Turner, 2008). Slim profit margins may drive some food processors to cut corners and use cheaper ingredients, such as melamine as a fraudulent substitute for the nitrogen in protein in dairy products and pet food, and diethylene glycol as a substitute for glycerin (Jiang, 2009). Other examples include diluted infant formula with insufficient nutrients and unapproved red dyes added to duck eggs to improve their appearance (Jiang, 2009). Although the intent of food adulterers is usually just to give their products an economic advantage, these substitutions can have serious, even lethal, effects on consumers.

Criminal food fraud is a growing problem that includes some products with limited distribution and others that are produced on an industrial scale. The scope of food fraud includes adulteration, counterfeit product or labels, comingling, and substitutions (Spink, 2009). Examples include watering down or adding inert ingredients to products such as infant formula and drugs, relabeling products that have passed their expiration date, relabeling to change country of origin (e.g., honey laundering, America On Line News, 2010), and substituting cheaper species of fish for more expensive ones (U.S. Government Accountability Office, 2009a). Combating food fraud is an ongoing struggle because counterfeiters are smart, well-informed people who adapt to circumvent new control strategies (and have been known to attend anti-counterfeiting conferences) (Spink, 2009).

Extremist or terrorist groups may intentionally contaminate food to cause widespread illness and economic upheaval. Although there is no available information suggesting that such an attack is imminent, some documents from terrorist camps abroad indicate that terrorists are interested in attacking food and agricultural targets (Kennedy, 2009). One domestic incident of intentional contamination of food occurred in 1984 in Oregon, when members of a cult group added Salmonella to several items at a salad bar, hoping to sicken enough people that they could win an upcoming election (Homeland Security Newswire, 2009).

2.2. International sourcing

2.2.1. Scope of the problem

The increasing volume of imported food, the increasing percentage of imports from less developed countries, and the complexity of global food supply chains, pose numerous challenges...
to ensuring the safety of imported foods. According to data from the USDA, U.S. food and agricultural imports nearly doubled from $41 billion in 1998 to $78 billion in 2007 (Kennedy, 2009). Consumer-ready products, including fresh fruits and vegetables, meats, seafood, and processed foods, account for most of this increase. U.S. consumer demands for more diverse, healthy, and convenient food products has driven this increase (Brooks, Buzby, & Regmi, 2009; Kennedy, 2009).

Both the number of products and source countries have increased. A total of 330 types of fresh and processed vegetables were imported from 109 countries in 2007 (Kennedy, 2009). Over 90 countries export spices, over 120 countries export fruit and nuts, and over 50 different countries export shrimp to the U.S., according to USDA data (Kennedy, 2009). Approximately 80% of seafood consumed in the U.S. is imported (Buzby et al., 2008). A large fraction of imported foods is comprised of shipments of seasonal produce and products, such as spices and tropical fruits, that cannot be grown in the U.S. Growth in imported processed foods has been stimulated by direct investments in production plants in developing countries, by companies based in more developed countries (Kennedy, 2009). For example, salmon from Alaska and peaches grown in the U.S. are shipped to Thailand for canning and then exported back to the U.S. (Fortin, 2009a, 2009b; Ocean Beauty Seafoods, 2011). Currently, between about 10 and 15% of all food consumed in the U.S. is imported (US FDA 2011a).

In addition to food products, imports of ingredients used in the manufacture of processed foods have also increased significantly in the past decade. A fruit snack bar may contain ingredients from eight or more countries (Kennedy, 2009). Some ingredients are no longer produced in the U.S. and must be imported. For example, China has practically cornered the market for citric acid, wheat gluten, dried vegetables, and liquid vitamins (Kennedy, 2009; Morton, 2009). Ingredients used in processed foods are sourced from increasingly complex food chains, such that there are five or six levels of companies and processors between some original ingredients and the finished product (Kennedy, 2009; Prince, 2009). As the number of processing steps and companies increases, so do opportunities for adulteration and counterfeiting. Further, it is estimated that imports will continue to grow because of the rise of emerging markets, consumer demand (especially for fruits and vegetables out of season), and the increased flow of information, capital, and goods across borders.

The decline in oversight and inspections by U.S. agencies further hinders efforts to ensure safety of imported foods. On an average day, 82,800 shipments of goods approved for entry are processed by U.S. customs (Prince, 2009). However, government agencies charged with ensuring safety of imported food products have seen significant budget cuts in the past decade (Corby, 2009; Fortin, 2009a, 2009b). Despite about 15% of the overall U.S. food supply being imported, and at least a 75% increase in food imports since 2001, the U.S. FDA and other inspection agencies have lost both funding and monitoring and inspection staff (US GAO, 2007; US GAO, 2009b). Following the terrorist attacks in 2001, several hundred port inspectors were hired, but today they are gone (Corby, 2009; Morton, 2009).

2.2.2. Current strategies to prevent and control food contamination and fraud

2.2.2.1. Requirements by importing companies. Outbreaks associated with melanine-contaminated wheat gluten (Dobson et al., 2008) and Salmonella-contaminated peanut butter (US CDC 2009) illustrate the potential for a single unsafe ingredient to severely affect numerous products and brand names. Industries importing food products and ingredients are concerned with the quality and safety of imports they receive, as well as the many aspects of the supply chain influencing this quality. These upstream factors include: adequacy of foreign production facilities, traceability beyond U.S. borders, variations in food-safety regulations and enforcement in supplying countries, counterfeiting, and differences in business culture and practices (Morton, 2009; Prince, 2009; Shebuski, 2009). Nevertheless, companies may not always share information about import problems with each other or with government regulators, for fear of lawsuits or releasing proprietary information.

According to our speakers representing major multi-national manufacturing food companies (Hood, 2009; Morton, 2009; Prince, 2009; Shebuski, 2009) quality and procurement departments have devised risk-management schemes for their suppliers and imported products. These programs include examination of facilities, procedures, and supply chains at overseas plants, targeted testing of products for the most likely contaminants/defects, secure packaging, and investigation of consumer complaints. Financial stability of suppliers, as it affects supply-chain disruption and corporate social responsibility issues, is also considered by some companies. Suppliers are ranked, and those that provide occasional substandard products are audited and inspected more frequently, or no longer used.

A good business relationship, including open and frequent communication between buyers and suppliers, is necessary to prevent misunderstandings and unexpected problems. In some cases, importing companies use third-party auditors and inspectors to evaluate overseas suppliers (Morton, 2009). Due to the efforts of the Global Food Safety Initiative (GFSI), five benchmarked audit schemes: British Retail Consortium (BRC) (BRC, 2010), the International Featured Standard (IFS) (IFS, 2010), Dutch HACCP (Dutch HACCP, 2010), the Food Safety System Certification (FSSC) (FSSC, 2010) and Safe Quality Food (SQF) (SQF Institute, 2011), are accepted internationally. These schemes include standards of good-practice related to agriculture and manufacturing, and examination of business practices that support those safe practices. Examples of the latter include periodic training and ongoing targeted testing of incoming and outgoing supplies. Ultimately, companies are responsible for their own products and must protect their own brands. They cannot depend completely on government inspectors or third-party auditors to ensure authenticity and safety of imported materials (Shebuski, 2009). Of course, good control of the global supply chain depends on all suppliers upstream of the direct exporter, so that audit schemes must be applied to all players in the supply chain (Morton, 2009; Shebuski, 2009).

With the advent of the Food Safety Modernization Act (FSMA) (Olsson, Weeda, Bode, & PC Attorneys at Law, 2010), these practices for imported products become essential. Although regulations are being written as this manuscript is being prepared, importing companies must develop close relationships with ingredient suppliers, manufacturers, packaging vendors, brokers and distributors. Under the Foreign Supplier Verification section of the new FSMA, the importer of record will have responsibility to verify inspection, testing, and trace back.

2.2.2.2. Government regulations and inspections. In addition to state and local agencies, there are eight federal agencies in the U.S. with responsibility for the safety of imported foods (see Fortin, 2009a):

- Bureau of Customs and Border Protection (CBP),
- U.S. Food and Drug Administration (FDA),
- U.S. Department of Agriculture — Animal and Plant Health Inspection Service (USDA/APHIS),
- USDA Food Safety Inspection Service (USDA/FSIS),
- National Center for Import and Export (NCIE) Veterinary Services,
U.S. Environmental Protection Agency (EPA),
• Alcohol and Tobacco Tax and Trade Bureau (TTB),
• National Marine Fisheries Service (NMFS).

However, the following three have primary responsibility and will be discussed below in detail:

• CBP in the U.S. Department of Homeland Security,
• FSIS in USDA, and
• FDA in the U.S. Department of Health and Human Services

CBP uses an automated risk-based targeting system, which incorporates data on the cargo being imported and shipped. However, their primary emphasis is the detection of drugs and human trafficking. On an average day, CBP seizes over 7300 pounds of narcotics and over 4000 shipments of prohibited meat or plant material (Nganje, 2009; Prince, 2009). At land entry points from Mexico, there are concerns about expediting transport across the border of freshly harvested food. To meet this need, government-business cooperative programs inspect shipments at packing and processing plants, and provide certification that the cargo has already been inspected and therefore, border crossing can be expedited (Nganje, 2009). However, there have been cases in Mexico, in which trucks with certified cargo have been diverted, and drugs or people hidden in the trucks. More integrated and intelligent inspection systems may therefore need to be developed (Nganje, 2009; see also chapter 12).

USDA FSIS, but not FDA, is legally empowered to require equivalency of foreign regulatory structures to those in the U.S. to allow importation of meat, poultry, and egg products. In addition, FSIS physically inspects shipments at the border at a rate of 10–11% (James, 2007:2), which is referred to as their re-inspection program (Fortin, 2009a:478). By contrast, the U.S. FDA (which regulates all other food products, including fish) is statutorily prevented from imposing equivalency requirements on foreign regulatory systems, and has been allowed to assure public health and safety only by inspections at the border, although the FSMA will be changing this. FDA inspection rates of food imports decreased to about 1% (by number of shipments) in 2007 (Nelson, 2007:2) and at current staffing and import levels have risen only slightly. In comparison to U.S. inspection rates of imported foods, the European Union averaged about 9% in 2007, which compares favorably to the recommendation by the World Customs Organization of 3% of consignments (Alemano, 2009).

Up until 2011, FDA inspections of imported foods were based on an overall evaluation of risk (e.g., taking into account product documentation and records of previous violations, if available (Buzby et al., 2008; Interagency Working Group on Import Safety (IWGIS), 2007:5)). However, the U.S. Government Accountability Office (U.S. GAO) consistently found that the average 1% inspection level was insufficient (U.S. GAO 1998; U.S. GAO 2001:7; U.S. GAO 2003; U.S. GAO 2008). The recent implementation in all ports of the new software program PREDICT, a program which ranks import consignments by risk for inspection purposes, may improve the situation. However, although the FDA attempts to apply a risk-based approach to targeting its inspections of imported shipments, its ability to do so is limited, because the agency lacks the authority to reach back into the country of origin (Fortin, 2009a), although this too may be changing under FSMA. Thus, it is unable to inspect sources of hazards and risk in the chain of production, or verify the identity of the original exporting company (the latter may have changed names to avoid heightened rates of inspection triggered by large numbers of past violations).

In addition to inadequate border-inspection levels, the U.S. GAO (2007) found that the fragmented nature of U.S. federal food safety oversight results in inconsistencies, ineffective coordination, and inefficient use of resources (Fortin, 2009b). For example, regarding inspection of imported food shipments at 18 ports of entry, the U.S. GAO (2009b) noted that CBP maintains the system importers use to provide information to FDA on food. Although USDA and FDA both inspect, they do not share inspection resources at these ports. In its most recent published report on this subject, the U.S. GAO (2009b) found FDA was expanding efforts to coordinate with other countries. For example, through its initiative, “Beyond our Borders”, the FDA stationed a small number of investigators in China, Europe, and India to provide technical assistance and gather information about food manufacturing practices for the purpose of improving risk-based screening at US ports. However, the U.S. GAO (2009b) found that gaps in enforcement, collaboration, and communication among these three agencies (FDA, USDA, CBP) undermine efforts and increase the risk that unsafe food could enter US commerce without FDA review (particularly at truck ports). Furthermore, U.S. GAO found that FDA has limited authority to ensure importer’s compliance with regulations and that CBP and FDA do not always identify importers with a unique number or identifier.

Moreover, communication among the various federal and state agencies responsible for food safety is hampered by unconnected or incompatible computer systems, and by officials trying to guard their own self interests. Communication of federal agencies with the public, state agencies, and affected companies is also sometimes slow and inefficient (Myers, 2007; Raymond, 2010). However, some collaborative programs, (for example a three year project between FDA and the New York State Department of Agriculture and Markets), developed communication and information-sharing in their inspection programs and screening of imported foods (Corby, 2009).

Food-safety programs in other countries vary in their scope and effectiveness. A recent FDA hearing was convened to inform current FDA rule-making, to learn about efforts in selected foreign countries to ensure the safety of imported foods and animal feed, and to compare food safety practices and food import practices (US FDA 2011a). Selected countries included Australia, New Zealand, Japan, Canada, and the EU. In addition, a US GAO (2008) report compared systems for ensuring import safety in six selected countries. Most of these countries take steps to ensure that certain food imports meet equivalent safety standards, base their import criteria on risk assessment, and have strengthened the responsibility for safe food placed on importers, using prevention and reducing reliance on testing at the border. Another commonality noted in this report in the countries of Canada, Denmark, Germany, Ireland, The Netherlands, New Zealand, Japan, and the UK is that they have at some point in the recent past consolidated their regulatory food safety responsibilities in order to improve effectiveness and efficiency, as well as to reduce costs. Furthermore, all of the countries in the GAO report have mandatory recall authority and some type of trace back system, if only for animals.

On the other hand, food safety programs in some countries may also be underfunded. Developing countries, in particular, may not have the expertise, laboratory resources for testing, and established inspection programs to adequately promote safety of foods (Jiang, 2009). For example, a fragmented regulatory and oversight structure involving numerous government departments at the national level of the exporting country, and little coordination with lower levels of government (which may have their own, differing standards for food products), may cause problems. These countries may be more focused on providing enough food for their citizens than on ensuring minimal contamination levels. Lack of documentation or traceability in the exporting country (e.g., due to lack of suitable standards and enforcement mechanisms, or a fragmented
marketing system dominated by large numbers of small firms handling small volumes of food products, often on a cash basis) can exacerbate the situation (Zach & Bier, 2009). Furthermore, political corruption can be a factor interfering with compliance even in the best safety regulations. Although problems with imported products from China and some Latin American countries have been featured in the news, issues with imports from more developed countries in Europe also occur (Prince, 2009). Exporters of adulterated and counterfeit goods are able to “port-shoot” to choose land/roadway exit and entry points where oversight is lax (Corby, 2009).

2.2.2.3. State authorities and recall issues. Under current limited authority, the FDA and USDA FSIS generally have access to required food supply-chain tracing records only during an emergency situation involving serious threats to health or life. Although the US Centers for Disease Control and Prevention (CDC) analyze public health information on foodborne illnesses, and may request necessary records for trace back through the food supply chain, it does not share this information until it has confirmed the causative agent (Taylor & Batz, 2008). This process can take weeks or months (e.g., in the case of the 2008 incident involving Salmonella in peppers) (Corby, 2009). In addition, federal agencies have limited ability to share key information with state and local levels of government, in spite of the fact that state and local officials perform the bulk of inspection and enforcement activities and are in frequent contact with producers and manufacturers, retailers, food service, and consumers (Corby, 2009; Taylor & Batz, 2008:43).

When the FDA or FSIS is notified of a food recall, the food is traced back through the supply chain, consistent with the Bio-terrorism Act of 2002. Currently, this process is slow; commonly taking two weeks to a month and responses are sometimes electronic but more often submitted on paper, if they appear at all (Corby, 2009). Beyond domestic borders, the trace back process is difficult if not impossible. During this period, the FDA and USDA do not provide distribution and retail information to other levels of government or the public. In response to consumer concerns from the numerous recent multi-state food borne outbreaks, and to speed the commercial recall response, the Food Marketing Institute (FMI) recently piloted and launched a Rapid Recall Exchange (Prince, 2009). This online service enables prompt and accurate exchange of information between retailers/wholesalers and suppliers about food and product recalls and withdrawals. However, only commercial entities may subscribe to this service (for a fee).

The time lag for a product to be pulled from the shelves and information to be disseminated allows more consumers to be exposed to potentially harmful products, as was the case with the Castlberry chili-sauce recall for botulism in 2007 (Corby, 2009). Another example of a slow trace back and recall through a highly complex food supply chain was the Salmonella contamination of peanut butter at the Peanut Corporation of America (PCA) in 2008 (Prince, 2009). PCA shipped contaminated peanut products (peanut meal, paste, granules and more) to hundreds of establishments, including bakeries, manufacturers, and distributors. Over 1800 peanut products were recalled, with more than 250 brands affected (Kenedy, 2009). These complex trace back and recall situations led to the Reportable Food Registry of 2007 (US FDA 2010), which requires that private information about food contamination be reported to the FDA by all players in the food chain, in order to improve oversight (Prince, 2009).

3. Recommendations to improve the safety of imported foods

As the world food supply becomes more interconnected, emerging intentional threats may increase, due to a greater emphasis on value-added exports, supply shortages, economic crises, and the activities of terrorist or extremist groups. Interventions to address these challenges to food safety and security need to consider supply chain issues such as forms of verification programs, better risk assessment for particular commodities, the potential for new economically motivated adulteration, and improved detection methods.

Effective responses to incidents of food fraud and food contamination will require improved flow of information among government agencies, industry, and the public. The rapid alert system in the EU similarly gathers and coordinates information on foodborne hazards and disseminates it rapidly among member states. Companies and government agencies must develop strategies for keeping informed and anticipating future problems (Prince, 2009; Shebuski, 2009). Terrorists and perpetrators of fraud are a moving target so there is a constant need to continuously develop and refine intelligent systems for detection of dangerous and counterfeit products, and share information with all stakeholders (Spink, 2009).

3.1. Inspection and testing

New analytical challenges are constantly arising from food contamination incidents. A wide range of unanticipated contaminants may be used to adulterate foods in the future, if those compounds or materials give producers a cost advantage. For example, melamine contamination of pet foods and infant formula initially went undetected because it was an unexpected additive for which there was no commonly-used analytical method. Sensitive assays to detect 10 parts per million (ppm) of melamine in pet food and 50 parts per billion (ppb) in infant formula were quickly developed in response to the crises (Ellefson, 2009). Likewise, when the Indian government decided to impose a limit of 0.1 ppb for pesticides in soft drinks, extremely sensitive detection methods were developed through a cooperative effort between soft-drink companies and an analytical testing company (Ellefson, 2009; Miller & Milne, 2008). As analytical methods become more sensitive, decisions will need to be made as to what levels of adulterants constitute a public health risk.

Currently, only a small fraction of imported foods is sampled and tested. It may be desirable to do more testing, but increased levels of testing are both expensive and time intensive, slowing importation. Nganje (2009) evaluates current import inspection practices and sampling techniques in order to derive implications for intelligent food protection. Increased testing levels are also physically limited by the capacity of certified laboratories. Despite these challenges, it is becoming more common for suppliers to use analytical methods to demonstrate the authenticity of their ingredients to buyers. Examples of products requiring increased testing include: spices (such as paprika, curry powder and chili-sauce), where synthetic colors disguise quality; honey with chloramphenicol residues; tomato powder adulterated with maltodextrins; juices extended with sugars or adulterated in other ways; and fish species substitutions (Ellefson, 2009). Appropriate sampling techniques of these potentially consolidated lots are critical and additional laboratory methods must be developed and collaboratively shared to keep up with new chemical adulterants and food matrices. Such laboratory methods may need to complement traditional detection of foreign substances, and include screening methods to detect deviations from the characteristic signature signals of the unadulterated material (Ellefson, 2009).

3.2. Special issues in developing countries

Imports from developing countries are often sourced from many small producers, with no brand image to protect and little
investment to lose. Prescribed safety standards may be difficult for them to understand and too expensive to implement; incentives for short-term economic gain may lead to fraud. The growth of cantaloupe production and export from Mexico illustrates this threat (Avedano, 2009). For example, in 2000, nearly 30% of cantaloupes imported into the U.S. originated in Mexico (Boriss et al., 2006). Then, a series of Salmonella outbreaks in 2000–2002, traced to Mexican cantaloupe, sickened more than 150 people in 12 states and four Canadian provinces (Centers for Disease Control and Prevention, 2002).

Following an investigation into growing and storage conditions, FDA issued an import alert banning importation of most Mexican cantaloupes in 2002 (U.S. Food and Drug Administration, 2011b). This resulted in a drastic reduction of cantaloupe exports from Mexico. In 2004, only 4.1% of imported cantaloupes came from Mexico while 41.1% came from Guatemala, and 32.3% from Costa Rica (Boriss et al., 2006). Exports to the U.S. dropped precipitously, as did acreage planted in cantaloupe. In order to obtain an export permit producers and packers were required to demonstrate that Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP) were followed. However, required training in GAP and GMP and the investment in any needed equipment left many smallholders unable to comply with the new standards and therefore shut out of the export market (Avedano, 2009).

3.3. European approaches

The outbreak of “Mad Cow” disease (BSE) in the 1990s, in addition to the dioxin-contaminated livestock feed in Belgium in 1999 precipitated a crisis of consumer confidence in the European food-safety system. The Temporary Committee of Inquiry into BSE, set up by the European Parliament in July of 1996, revealed that the outbreak had been mismanaged. There was little coordination among the responsible agencies, and industrial and agricultural interests had been favored at the expense of public health (Haritz, 2009). In response, the General Food Law was passed in 2002, which describes EU risk regulation of food safety in terms of the new ‘From the Farm to the Fork’ policy. A new independent agency, the European Food Safety Authority (EFSA), was created to scientifically assess risks to the food supply. Trust-enhancing principles became part of the new food protection strategy. This is generally perceived as an improvement, although there is occasional controversy over issues in “attracting excellent, independent scientists and in transparency of operation” (Haritz, 2009).

A Rapid Alert System for Food and Feed (RASFF) was also established to rapidly disseminate information on food safety hazards to all countries in the European Union (EU) and to ensure timely recall of potentially dangerous products. Ireland’s response to dioxin contamination in pork is an example of how this system works. During the last two months of 2008, Ireland experienced a large contamination incident traced to dioxins in pig feed. Dioxin was first detected in November 2008 in a routine pig-fat sample tested for contaminants. Subsequent analyses demonstrated dioxin levels as high as 200 pg/g in some pig fat (EU limit = 1 pg/g), and as high as 5200 pg per gram (pg/g) in some pig feed (EU limit = 0.75 pg/g) (Evans, 2009). A coordinated response to this incident through the European RASFF quickly traced the distribution of pigs from affected farms through slaughtering facilities onwards to export to numerous other countries. Seventeen days after the initial positive test, the decision was made to recall all pork products produced since September 2008. The Irish Food Safety Authority believed that this rapid recall reduced concern over potentially serious health effects, and that open communication with the public quickly restored confidence in Irish pork after resolution of this incident (Evans, 2009).

3.4. Other approaches

Several food safety-related crises in the past decade, including outbreaks of the sometimes fatal E. coli and concern over the BSE crisis have driven a number of countries (for e.g., Canada, Australia, New Zealand, Japan, EU, the UK, Denmark, Germany, Ireland, The Netherlands) to comprehensive reform and consolidation of their food safety and import systems (US GAO 2008). The reasons cited for this legislative consolidation of responsibilities include: 1) to improve effectiveness by making inspections and enforcement more consistent, and clarifying responsibilities, 2) improve the efficiency in the system by reducing duplication and overlap in food safety activities, 3) reduce federal spending, 4) address public concern about food safety stemming from food scares and outbreaks.

Australia and New Zealand both have independent statutory authority through a shared organization, Food Standards Australia New Zealand (FSANZ). The Australian Quarantine and Inspection Service (AQIS) inspects and tests imported food on the basis of FSANZ risk assessments. Under this legislation, importers are responsible for meeting Australia’s food safety standards and food safety laws, which may include tests for a number of contaminants including: pesticides, antibiotics, natural toxicants, food additives, and microbial and metal contaminants (US FDA 2011a). The risk category, based on public health issues, determines the frequency of inspection as well as the appropriate testing regime, with full cost recovery on the inspections due to the identified private benefit. The Australians also have a scheme where importers who qualify may be exempted from import inspection, providing their systems are audited twice per year.

New Zealand has a number of similarities with Australia and was part of the FDA International Comparability Assessment Pilot to examine food safety regulatory practices for shellfish (US FDA 2011a). New Zealand started their risk-based import system for food in 1997, although they have always exercised quarantine and inspection for all animal and animal-derived products and many other agricultural items, as well. Since that time, the import program has changed to meet the following objectives: reduced reliance on testing at the border, improved scientific basis in targeting inspections, and a strengthened responsibility put on the importers with a focus to make sure they import safe and suitable food.

Japan imported 60% of its food in 2007 and comprehensively reformed its food safety system in 2003 through 2005 so that it is based on scientific risk assessments (US GAO 2008). The risk analysis process is split, similar to other countries examined, with the Food Safety Commission assessing risks and both the Ministry of Health, Labor, and Welfare and the Ministry of Agriculture, Forestry, and Fisheries managing the risks. Import controls for sanitation are organized into three inspection stages: the exporting country, at entry into Japan, and through internal distribution.
Japan inspects a high percentage of imported foods at the port of entry based on certain factors: a company's past violations, whether Japan has certified the exporting companies, and information on exporting companies (including the types of agreements they may have with Japan, resource materials, and manufacturing methods). In 2006, for example, Japan required compulsory testing of 100% of Vietnamese shrimp imports after inspectors repeatedly found a banned antibiotic. However, Japan's Ministry of Health, Labor, and Welfare is able to ban importation of a product if violations exceed 5% of goods inspected and if it is expected that violations will continue (US GAO 2008).

3.5. Worldwide standards and organization

The major objective of the World Health Organization (WHO) is to combat disease and promote the general health of people around the world. The WHO implements the International Health Regulations that require countries to report a "Public Health Event of International Concern", which includes unsafe food products. This body coordinates international efforts to monitor disease outbreaks, including major food-related outbreaks, and sponsors programs to prevent and treat diseases. WHO promotes the development of capacities in member states to use and produce research that addresses national needs, by bolstering national health research systems and promoting knowledge-translation platforms.

The Agreement on Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT) are part of an international treaty of the World Trade Organization (WTO), which came into force with the establishment of the WTO in 1995. Under this agreement, the WTO sets constraints on member states' policies relating to food safety (bacterial contaminants, pesticides, inspection and labeling), as well as pests and diseases associated with animal and plant health (through the World Organization for Animal Health (OIE) and the International Plant Protection Convention, respectively). International standards established by the Codex Alimentarius Commission, are used as a benchmark for assessing member states' policies (standards, guidelines, and codes of practice) on food safety, as it concerns trade. The Codex Alimentarius Commission was previously created by the Food and Agriculture Organization and the WHO to protect consumer health, ensure fair trade, and promote coordination of all food-standards work undertaken by intergovernmental and non-governmental organizations (Sperber, 2009). However, even on a collective basis, the WTO, Codex Alimentarius, FAO, and WHO are limited in their ability to ensure the safety of food in international commerce (Sperber, 2008, 2009).

4. Concluding recommendations

Based on two years of collaborative discussion and research, the following recommendations are offered to address both public and private aspects of a coordinated approach to improve the safety of imported products and ingredients.

1. Improve communication, oversight, and resource sharing in U.S. federal oversight

Replace existing U.S. domestic barriers to communication and oversight (U.S. GAO 2009b) with improved, transparent governance promoting consumer trust. This process should include resource sharing among the eight major federal agencies with responsibility for safety of imported food. This may involve consolidating and rebuilding federal food oversight in a similar manner to changes made by the EU after the collapse of public trust due to the BSE crisis (Haritz, 2009; Konig, 2006; U.S. GAO 2008); “The BSE crisis brought about what years of harmonization had not been able to achieve: a start was made on the formulation of a coherent EU policy on food safety, which was to obtain the highest priority.” (Vos & Wendler, 2006).

In addition to resource sharing in the federal arena, resource sharing and communication with state and local government entities is also essential. Haritz (2009) and Evans (2009) commented that this was an important part of the EU system, as well. State and local inspectors work to carry out daily enforcement of federal, state, and local laws, and as such are a vital part of a well functioning system. Corby (2009) outlined such a cooperative information-sharing program between the US FDA and New York State Department of Agriculture and Markets with impressive results.

2. Increase the FDA resources and inspection rate at borders, improve the border-inspection system to focus on the riskiest shipments, and encourage FDA authority to require regulatory comparability/equivalence in the exporting country

Implementation of the PREDICT software system for selection of import consignment inspection, based on risk has been implemented in all sea ports. Selection of consignments for finite inspection resources by risk is an intelligent approach; however the FDA inspection rate at borders should be increased to at least 3%, the level recommended by the World Customs Organization. Further, the U.S. GAO (2007) recommended that FDA seek authority from Congress to assess civil penalties on firms and persons that violate FDA laws, and that the FDA Commissioner explore ways to improve the agency's ability to identify foreign firms with a unique identifier. Implementation of such a permanent, non-transferrable identification for exporters, manufacturers and other entities in the foreign supply chain would facilitate further development of a risk database for firms, making better use of a limited inspection effort. Further, in the EU and the countries of Japan, Australia, New Zealand, among others, the importer bears some of the costs of inspection.

In addition, the FDA plan to develop a regulatory comparability assessment or equivalence in exporting countries is an appropriate preventative tool and a cost-effective use of resources. This concept is somewhat similar to the USDA statutory requirement for regulatory equivalence in import of meat, poultry, and eggs. With this improvement and appropriately frequent audits, border inspection of goods would be effectively a re-inspection for those countries given this comparability status.

Further, in order to assess the status of the food safety and import system, the FDA should be required to audit itself in comparison to other trading partners and to best import practices see the “Audit of the Management of Imported Food Safety” by the Canadian Food Inspection Agency (2010). For this purpose metrics should be developed as a way to measure the effectiveness and cost efficiency of import practices.

3. Expand the FDA systems to be more like an EU-style Rapid Alert System for Food and Feed (RASFF), for informing consumers as well as industry

The European Union RASFF gathers and coordinates information on food borne hazards and disseminates it rapidly among member states. As such, the system involves surveillance and monitoring, trace back, and an alert broadcast for recalls. It emphasizes support for product testing (both local and imported) off local shelves by state and local authorities in addition to testing of imported food and feed at borders and ports. This is because systems for surveillance and monitoring at borders and ports may not always function at peak efficiency. If a violation is found through routine surveillance, as was the case in the Irish pork contaminated with dioxin in 2008, the EU system is designed to alert government officials of all member states, industries within the EU that might buy this as an ingredient, and other entities within the distribution system, both inside and outside of the affected country (Evans, 2009). A similar system in the U.S. would assist with rapid removal of harmful foods and ingredients.
from store shelves and the food supply chain, addressing a weakness of the current U.S. system. Sutton, Welt, and Ollhorst (2010) and Meija et al. (2010) similarly recommended a rapid-response public tracing system for alert and recall situations. (It should be noted that animal feed regulations in the U.S. have been substantially different from those in the EU and are currently being revised in the US under the FSMA (Olsson et al., 2010)).

Implementation of a rapid alert system should include local surveillance, response, and recovery within the domestic food chain, expandable to our trading partners. In addition to border control and inspection, the FDA and USDA would benefit from sharing resources and collaboration with state and local inspectors through ongoing programs for testing and inspection of products at the local level (both domestic and imported in origin). The President’s Food Safety Working Group’s (2009) recommended upgrading the food-safety system by improving response and recovery, prioritizing prevention, and strengthening surveillance and enforcement. Improving response and recovery through improved alerting and trace back is also important for purposes of food protection and defense, which are part of homeland security infrastructure protection.

Requirements of a rapid alert system include:

- recall authority at all levels (national, state, and local)
- funding by the federal government (necessary for situations in which the business of concern goes into receivership)
- support for product monitoring at the state and local levels in addition to the ongoing monitoring at borders
- the ability of federal, state, and local officials (including public health officials) to share information.

4. Evaluate food-import risk from a risk-based perspective

To deal appropriately with import safety, it is important to improve our ability to assess risks quantitatively throughout the life cycles of products, from the foreign point of production to the end use by consumers in the importing nation. We must develop a better understanding of the sources of risk and contamination in exporting countries, including environmental contamination (such as heavy metals), to most effectively deploy limited monitoring, inspection, and interdiction resources, and prioritize training and capacity-building efforts. Improved detection methods, including methods to detect deviations from a characteristic “fingerprint” for unadulterated materials, are essential tools in private qualification programs for risky suppliers. These risk-based approaches would allow producers, importers, and regulators to focus their attention on the parts of the production process or supply chain, that pose the greatest risk. For example, increased testing of the most risk-critical processes or ingredients, coupled with a decreased regulatory burden for less risk-significant parts of the supply chain, could be a win–win situation. Thus, risk-based standard setting and enforcement could complement management-based regulatory approaches (e.g., good-practice standards in production and manufacturing) and performance-based approaches such as finished-product testing (Zach & Bier, 2009).

Coupled with this approach is the use of Hazard Analysis and Critical Control Points (HACCP) and its pre-requisite Good Manufacturing Practices (GMPs) and Good Agricultural Practices (GAPs). In HACCP, plans are developed and tailored to particular establishments, to assess possible biological, chemical and physical hazards, identify critical control points (e.g., processing temperatures), establish critical acceptable limits at these points, monitor procedures, detail corrective actions if limits are not met, and set up verification procedures. Careful record-keeping and documentation is an essential part of HACCP implementation.

These programs are basic to quality-control systems for food producers and processors in the U.S.A. Companies in other developed countries may also often have well-established HACCP plans, and information is available from FDA, USDA, and many trade associations for developing and implementing these plans. However, producers and processors in developing countries may need information and education to establish such programs.

Furthermore, it is common in the U.S. for company procurement departments to develop frameworks to analyze the risks of their largest suppliers. However, this process is time consuming and expensive, and requires continual updating. Reliance on numerous smaller suppliers makes the task even more onerous. Risk analysis directed at comparability/equivalency in regulatory oversight (similar to the USDA) may be an important component in assisting private governance schemes. Prevention-based regulatory approaches, such as risk analysis, are also increasingly used in international regulatory efforts to harmonize legal structures for the food trade.

5. Expand intelligent, cost-effective forms of public–private cooperation

A. Accidental contamination

Public–private partnerships may help small and medium-sized producers to understand new regulations, and provide economic assistance for projects such as irrigation and process-water treatment, and shared packaging facilities (Avedano, 2009). Public–private partnerships can also increase the competitiveness of smallholders by aiding their adoption of new international standards for food quality and safety, pooling resources for processing and storage facilities, and improving standards of living and taxable income for small and medium-sized farmers. This will result in access to a higher-margin export market, and improved standards of food safety (and therefore general public health) in the exporting countries.

Safety issues in the food trade may be approached through unofficial commercial interactions between suppliers and manufacturers to develop safety strategies and facilitate reduction of potential contamination. Such efforts may include grassroots education, engagement, and verification of small producers and suppliers. Buyers of foreign-sourced products may want to explore options for improving communication and problem solving with suppliers in the event that contamination occurs (or that a promised volume is not achieved). Assistance for such options might be built through trade organizations and other advisors.

B. Intentional contamination

By and large, the food industry has come together declaring food safety to be a cooperative rather than a competitive issue. When a food safety incident occurs, the resulting consumer impact is felt across the entire industry, be it pet food, spinach, or peanut butter. However, effective responses to incidents of food fraud, and adulteration are complicated by policies that restrict flow of information among government agencies, the food industry, and the public. Concern about potential lawsuits, proprietary information on ingredients and their sources, and protection of turf by different regulatory agencies can sometimes impede collaboration for solving problems. Information sharing could include results of site inspections and laboratory testing, and might also aid in addressing issues of economic fraud and country of origin.

6. Continue to build private strategies (including supplier-qualification systems for brand protection and third-party inspection using globally-accepted benchmarking schemes) for international partners in the supply chain

An example of such a collective strategy is the Global Food Safety Initiative (GFSI), an industry-led organization to improve food safety for the purposes of enhanced consumer confidence in
retail food and improving trust in global trade. The Global Food Safety Initiative was launched May 2000 at the CIES (Consumer Goods Forum) for food businesses in Europe. The group’s goals include developing a scheme to benchmark food-safety management standards worldwide, promote third-party auditing of food-safety management, ensure integrity in the quality and accreditation of food safety auditors, and benchmark farm-assurance standards. Overall, the Global Food Safety Initiative has worked toward universal acceptance of codes of practice that promote food safety in manufacturing, agricultural, and business management.

Several large multi-national retailers, (including Carrefour, Tesco, Metro, Migros, Ahold, Wal-Mart, Target, and Delhaize, among others), have agreed to reduce duplication in the supply chain through acceptance of any of the GFSI-benchmarked audit schemes. The power of such a global scheme lies in major retailers requesting these standardized audits, not only of their immediate foreign suppliers, but of all suppliers upstream in the food chain. Successful and widespread implementation would improve large portions of the global food supply.

7. Provide global coordination and education through a Global Food Protection Organization

In spite of efforts by WHO and FAO to improve food safety and security, and the WTO agreement for SPS to expand and harmonize free trade, it has been challenging for many countries to implement well-developed food-safety enforcement and monitoring systems (Sperber, 2009). Moreover, these same countries are major suppliers of some foods and ingredients to the U.S. market. For example, until the mid-1980s, there were no significant national food safety regulations or programs in China; even today, food-safety laws are not uniformly well-enforced, due to the lack of personnel and established procedures (Ellis and Turner 2008). Moreover, when safety standards are established and enforced, small stakeholders may not be able to comply with the new standards, because they are too expensive to implement or because technical expertise is not available, as was the case with cantaloupes grown in Mexico (Avedano, 2009). Finally, national boundaries are currently an impediment to trace back and coordination in emergencies, and cooperation is essential, as trace back schemes are slowly implemented.

Establishment of a Global Food Protection Organization would help to develop capacity for food safety around the world through education and verification programs (Sperber, 2008), including laboratory and testing resources (Chyau, 2009). A more proactive organization for global food protection could, for example, eventually require use of HACCP and pre-requisite programs to prevent contamination, and establish uniform audit procedures and traceability systems (Sperber, 2009; see also chapter 14). Such a politically independent organization could coordinate traceability efforts and emergency responses, similar to some projects conducted by the WHO. Finally, the program could work with existing international organizations (including OIE, FAO, and WHO) to reduce friction, misunderstanding, and waste, while enhancing the overall efficiency of the global food-safety system.

5. Conclusion

As the world food supply becomes ever more interconnected, interventions to address food-safety challenges must identify new targets for economically motivated adulteration, and improve supply-chain verification programs, risk assessment for specific commodities, and detection methods. Increased enforcement of the safety of imported foods should level the playing field for domestic producers by holding importers to the same strict standards as domestic manufacturers and producers. Prevention and detection of food adulteration, contamination, and fraud requires cooperation among industry, government regulators, scientists, economists, and the legal profession. A multi-disciplinary, systems-based perspective to problem solving promises to be the most fruitful and dynamic approach to achieve positive public health outcomes and cost-effective solutions. Ultimately, improving food import safety will strengthen free trade and improve the overall global level of food safety and public health.

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