

Food Safety: Issues and Strategies for Efficient Risk Reduction

Growing concern over the use of pesticides in agriculture and potential pesticide residues harmful to human health was rising during the 1980s. The illegal use of the insecticide aldicarb on watermelons in California in 1985 resulted in more than 1000 cases of probable or possible human pesticide poisoning.¹ This event was followed by the release of a landmark report by the U.S. National Research Council (NRC) that presented overstated estimates of potential human cancer risks from pesticides in the diet resulting from the use of worst-case human exposure assumptions (NRC, 1987).² In 1989, the Natural Resources Defense Council (NRDC), an environmental advocacy group, issued a report alleging “intolerable” risks to children from exposure to residues of neurotoxic and cancer-causing pesticides in food.³ Consumer awareness of potential food safety hazards spiked with the “Alar Apple Crisis” in February of 1989, the result of unfounded accusations made in this report and broadcast on 60 Minutes by CBS, followed by a campaign of misinformation propagated by NRDC on the Phil Donahue show and others.⁴

A subsequent report by the U.S. NRC, published in 1993, concluded that the U.S. pesticide regulatory system did not adequately address the potential differences in exposure and susceptibility to pesticide residues of infants and children relative to adults, and recommended significant changes in pesticide risk assessment practices and pesticide regulation.⁵ The public policy framework changed dramatically, with an expansion in programs to assess potential pesticide risk to humans, including an emphasis on children and infants, culminating in the passage of the Food Quality and Protection Act (FQPA) in 1996. Throughout these years many food safety scientists insisted that pesticide residues in the food supply were negligible, and not a significant risk to public health. Many scientists argued that when placed into perspective with other food safety risks, the dietary risks from pesticide residues were far lower than microbial contamination, nutritional imbalance, environmental contaminants, and even naturally-occurring toxins.⁶ Their claims were buttressed as more foodborne microbial outbreaks were documented, and in the 21st century microbial food safety is receiving much greater attention and resources.

The Problem

The vast majority of food consumed in the United States is safe and the incidence of foodborne illness is low. Nevertheless, foodborne illness continues to present a public health challenge and societal expectations increasingly call for less risk and even greater safety than the current system provides. The Centers for Disease Control and Prevention (CDC) estimates that 76 million people become sick, more than 325,000 people are hospitalized, and 5,000 people die from foodborne illness in the United States each year. The estimated economic cost of foodborne illness in terms of pain and suffering, reduced productivity, and medical expenses is substantial, around \$10 billion annually. As traceability of products from farm to fork improves, the liability for a mistake is increasingly being assigned to the responsible party, increasing the incentives for avoiding actions that may cause harm to consumers.

Despite the federal government focusing significant resources on reducing foodborne illness from all sources over the past decade, there is a “food safety gap” relative to safety levels that U.S. official policy has recognized as desirable and achievable in the initiative *Healthy People 2010* approved by the Department of Health and Human Services (DHHR) in January 2000.⁷ The initiative calls for the attainment by 2010 of 457 specific public health objectives divided into 28 focus areas, one of them food safety.

Table 1 shows for the years 1997 and 2006 the incidence (rates per 100,000 population) for five foodborne illnesses and the frequency of outbreaks associated with two pathogens. Relative to 1997, the 2006 data generally show a food safety improvement (notable for *Campylobacter* species), and yet relative to the target rates set out in *Healthy People 2010* the safety gap remains substantial in all but one case. For example, the extant incidence of *Salmonella* infections is more than twice the target rate, and the clear implication is that current regulatory efforts (whether the content of regulations or their enforcement or both) are insufficient or inadequate to attain the target rate.

Table 1. Key Pathogen Rates, 1997, 2006, Target Rate 2010, and Food Safety Gap, (Between 2006 and Target Rates), and Outbreaks of *E. coli* O157:H7 and *Salmonella* Serotype Enteritidis

Foodborne Pathogen	Rate 1997	Rate 2006	Target Rate 2010	Safety Gap*
<i>Campylobacter</i> species**	24.6	12.7	12.3	-3.1%
<i>Escherichia coli</i> O157:H7**	2.1	1.31	1	-23.7%
<i>Listeria monocytogenes</i> **	0.47	0.31	0.24	-22.6%
<i>Salmonella</i> species**	13.6	14.81	6.8	-54.1%
HUS***	1.8****	1.63	0.9	-44.8%
Outbreaks <i>Escherichia coli</i> O157:H7 (number of cases)	22	26	11	-57.7%
Outbreaks <i>Salmonella</i> serotype Enteritidis (number of cases)	44	39	22	-43.6%

* Safety gap is the percentage reduction relative to 2006 necessary to attain the target rate in 2010. ** Rate per 100,000 population. *** Rate per 100,000 children ages 5 and under. **** Rate is for year 2000.

Source: Adapted by the author from NCHS, *Healthy People 2010, Focus Area 10: Food Safety, Progress Review December 20, 2007, and Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food—10 States, 2006.*

The Food and Drug Administration (FDA) is responsible for ensuring the safety of roughly 80% of the U.S. food supply, including over \$417 billion worth of domestic food and \$49 billion in imported food annually. The U.S. Department of Agriculture (USDA) has oversight over the remainder (meat, poultry and processed egg products). The recent outbreaks of *Escherichia coli* O157:H7 in spinach, *Salmonella* in peanut butter, contamination in pet food, and potentially harmful drug residues in farm-raised Chinese seafood, highlight the risks posed by the accidental contamination of FDA-regulated food products. For example, according to FDA, the contaminated peanut butter led to more than 300 people ill and at least 50 hospitalizations, while the 2006 California spinach *E. coli* outbreak resulted in 206 illnesses, three deaths, and more than 100 hospitalizations. Industry representatives estimate that economic losses ranged from \$37 million to \$74 million for the spinach incident alone.⁸

Changing demographics and consumption patterns underscore the urgency for effective food safety oversight. According to FDA, shifting demographics mean that the U.S. population will increasingly be susceptible to foodborne illness. The risk of severe and life-threatening symptoms from infections caused by foodborne pathogens is higher for older adults, young children, pregnant women, and immune compromised individuals. According to FDA, these groups make up about 20–25% of the U.S. population. In addition, we are increasingly eating foods that are consumed raw or with minimal processing and often associated with foodborne illness.

Regulatory Framework

There are 15 federal agencies, led by FDA and USDA that collectively administer at least 30 laws related to food safety (GAO). Other agencies include the National Marine Fisheries Service (NMFS) in the Department of Commerce, which conducts voluntary, fee-for-service inspections of seafood safety and quality; the Environmental Protection Agency (EPA) that regulates the use of pesticides and maximum allowable residue levels (tolerances) on food commodities and animal feed; and the Department of Homeland Security, responsible for coordinating agencies' food security activities. This federal regulatory system for food safety, like many other federal programs and policies, evolved piecemeal, typically in response to particular health threats or economic crises (GAO).

The Center for Food Safety and Applied Nutrition, known as CFSAN, is one of six product-oriented centers, in addition to a nationwide field force, that carry out the mission of FDA. CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

In addition, states are involved in food safety regulation and many work both independently and on a partnership basis with federal agencies to report food safety incidents and to conduct activities such as pesticide surveillance programs.

It is beyond the scope of this paper to cover all of the regulatory programs and activities addressing all of the food groups, rather the intent is to highlight some of the key programs and issues affecting food safety regulatory policies and to stimulate discussion on industry participation, impacts and ways to influence regulatory efficiency.

Food Quality Protection Act

With the enactment of the Food Quality Protection Act of 1996 Congress presented EPA with an enormous challenge of implementing the most comprehensive and historic overhaul of the Nation's pesticide and food safety laws in decades. The FQPA amended the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food Drug, and Cosmetic Act (FFDCA) by fundamentally changing the way EPA regulates pesticides. Some of the major requirements included stricter safety standards, and a complete reassessment of all existing pesticide tolerances.

FQPA requires pesticide regulators to ensure that pesticides comply with a "reasonable certainty of no harm" statute before they can be allowed for use on food crops. In the determination of a "reasonable certainty of no harm," regulators are now required to consider the potential increased susceptibility of infants and children, and the exposure to pesticides not only through food, but also water, and residential sources (aggregate

exposure). In cases of families of pesticides that demonstrate a common mechanism of toxicological action, such as organophosphates, the EPA is required to ensure that exposure to the entire family of pesticides (cumulative exposure), rather than exposure to individual members of the family, constitute a “reasonable certainty of no harm.” Large safety factors built into tolerances, assuming human exposure over a lifetime, were often further increased by a factor of 10 in order to avoid any possibility of risk to children.

The implementation of the FQPA dominated the pesticide landscape for several years as the scientific community struggled to develop new risk assessment methodologies and the regulatory community faced the challenges of interpreting the new law. Reassessment of tolerances and exemptions proceeded based on a schedule requiring one-third to be completed by August 1999, one-third by August 2002, and the remainder by August 2006; this schedule was met. In the reassessment process EPA gave highest priority to pesticides that appeared to pose the greatest risk.

This reassessment was an enormous task because more than 450 pesticides and other ingredients have tolerances or exemptions from the requirement for a tolerance. Approximately 9,700 tolerances were in effect at the passage of FQPA. Because a chemical might be used on various food crops, there can be many tolerances associated with it, contributing to the complexity of the review. Several controversial pesticide regulatory decisions were made in the early years of FQPA implementation but most decisions were completed by 2002 when procedures for conducting aggregate and cumulative risk assessments were finalized. In the process many pesticide tolerances were revoked or modified.

FDA Total Diet Study

The Total Diet Study (TDS) program is conducted annually by FDA. The study began in 1961 as an outgrowth of post-World War II concerns about the potential effects on the American food supply of toxic chemicals produced by radioactive fallout. It remains an important part of FDA’s program for monitoring pesticide residues, chemical contaminants, and radionuclides in the food supply. The TDS data collection program includes nutrient intakes as part of the National Nutrition Monitoring System’s assessment of nutrient levels in the U.S. diet.

In its current version, TDS is based on 280 food items that are representative of the major components of the diet of the U.S. population. The study’s approach is to prepare foods as they would be consumed (table-ready), to then measure in the table-ready meals levels of selected contaminants and nutrients. The meals are analyzed to measure the levels of approximately 500 components (referred to as “analytes”) consisting of pesticide residues, toxic elements such as lead, volatile organic compounds, radionuclides and industrial chemicals, and nutrient elements.⁹ The tests used can detect residues at levels 5-20 times lower than conventional analytical techniques. Dietary intakes of these analytes by the U.S.

population are then estimated taking into account consumption patterns in the population. The latest TDS results published included more than 14,000 analytical findings, about 5,000 of which are toxic elements and chemical contaminants.

Findings of toxic elements and chemical contaminants do not entail that the intake levels for human consumption are harmful. The TDS data for the period 1991-96 were analyzed by Egan et al. for ten nutritional elements and four key toxic elements.¹⁰ Average daily intakes were measured by 14 age-sex groups in the U.S. population. This analysis showed that intakes were well below the reference intakes (tolerable daily intakes) for all toxic elements. In 2002, TDS results showed that the five most frequently observed chemicals, DDT, chlorpyrifos-methyl, malathion, endosulfan, and dieldrin, were the same as those observed for many years, and that the level of the residues are well below regulatory limits.

Pesticide Residue Oversight

While EPA sets the tolerances, FDA enforces them. The use of pesticides in agriculture does not inevitably mean that food residues will result. Even when pesticides are applied directly to food crops, food residues are often not detected. In some cases, pesticides may be applied prior to the development of edible portions of the crop, while in others the rapid environmental degradation of the pesticide between the time of application and the time of harvest may also avoid food residues.

Pesticide residues are illegal when pesticides are detected at levels that exceed the tolerance level or when residues of a pesticide are detected at any level on a commodity for which a tolerance has not been established. During the FQPA re-registration process many chemical companies did not go to the expense of registering pesticides for “minor crops,” often fruits, vegetables, and other specialty crops. This means that many crop/pesticide residue combinations that would have been considered within tolerance, and legal, no longer are, simply due to the loss of registration.

It is important to recognize that illegal residues should not be confused with “unsafe” residues, since pesticide tolerances are most appropriately viewed as enforcement tools to ensure proper application of pesticides at the farm level, rather than as safety standards.¹¹ According to scientific experts, occasional exposure to illegal residues rarely presents a significant health risk, and legal residues comply with the “reasonable certainty of no harm.”

Both federal and state surveillance programs all indicate low levels of pesticide residues in the food supply. Nevertheless, both legal and illegal residues are often pointed to by consumer advocacy groups as an indicator of unsafe food. Hence, it is important to report the evidence.

Pesticide Residue Surveillance Programs

FDA

FDA's pesticide residue surveillance program is an enforcement program rather than a representative sampling of the level of pesticides present in the food system. The composition of the samples changes based on where FDA feels there is higher risk of detecting a problem or there is a history of violation. Therefore, FDA residue findings are expected to be higher than in the food supply as a whole. Sampling may also reflect the need to collect additional evidence on residues of a given chemical to complete risk assessment studies. FDA has traditionally sampled imports at a proportionally much higher rate than domestic production, in part due to lack of control over production processes and regulatory practices and policies abroad.

Since 2003, resource constraints at FDA have prevented it from publishing the results of the annual surveillance programs. Data from 2004-2006 are expected to become available in summer 2008. The data from 1995-2003 made available online were downloaded and compiled to show several potentially noteworthy trends. Exhibit 1 indicates that the total number of samples fell over this time period from 10,113 in 1995 to 7,234 in 2003, with the import share rising from 50% to 68% despite the fact that most food is not imported. The absolute number of import samples was roughly the same at the beginning and end of this time period, so it is the number of domestic samples that fell. An FDA official indicated that the reduction in domestic samples was not strategic, but rather due to a lack of resources. It is easier to collect samples at ports of entry rather than in domestic production regions where FDA officials have to travel to visit producers. Just as the high representation of imports became even more pronounced over this time period, so did the already high share of fruits and vegetables, growing from 72% to 83% of the total samples.

Information on the number of samples and findings by food group are shown in Exhibit 2. Fish/shellfish and other aquatic products are the second most important group sampled, with 395 samples taken in 2003, followed by 369 samples of grains and grain products. Imports performed better than domestic products for all product categories except milk/dairy products/eggs, in terms of the share of samples with no detectable residues. For all food groups 72% of imports had no residues compared with 63% for domestic food samples. In both cases, most of the residues found were legal, as has been true for many years. However, in 2003 there was a significant difference in the rate of violative samples between imports and domestic food, with 6% of import samples violative compared with 2.4% for domestic (Exhibit 3).

Although the percent of violative samples was up in 2003 for both imports and domestic products, the clear trend between 1995 and 2003 is toward a growing gap between the rate of domestic and import violations. Whether or not this is an artifact of a new sampling

process is uncertain, and we will not know if the trend continued until later this year when FDA releases the more recent data. The food groups that had higher than normal violative samples in 2003 were the “other” category, vegetables, and fruits.

These data no longer distinguish between samples that are violative due to exceeding tolerances and samples that in the past were described as incurring in “technical” violations. These are cases where a pesticide residue was found on a product for which it was not registered, but well within the tolerance established for that pesticide on other products. These have always represented the bulk of violations in any sampling program, whether federal or state, whether for domestic or imported samples, and are of lesser concern to regulators. In some cases these residues may be present due to drift or soil uptake even though the pesticide was not applied to the crop.

Over the period 1995-2003 the cumulative number of samples taken was 73,559, of which 58% were of imports, and 2.5% were violative across all food groups. Domestic samples had a 1.1% violation rate compared with 3.6% of import samples.

Pesticide Data Program (PDP)

Since May of 1991 the Agricultural Marketing Service (AMS) of USDA has been conducting an annual pesticide surveillance program. Participation in PDP is voluntary and therefore it is not an enforcement program. In its most recent iteration, 12 states¹² participated in the program’s sampling and/or testing. These states represent about 50% of the U.S. population and include major producers of fruits and vegetables in the country.¹³

The program now surpasses the FDA program in terms of number of samples collected, with a total of 12,554 samples in 2006. However, in this case domestic products represent about 80% of all samples, because the program is designed to be representative of the nation’s food supply. PDP focuses on commodities with high consumption rates, in particular foods consumed by infants and children. Similar to FDA’s program, fruits and vegetables are the largest food group sampled, accounting for roughly 78% of all samples.

The results of its program for 2006 are shown in Exhibit 4. For all food groups for which AMS sampled imports, the imports had a higher rate of samples with no detectable residues than did domestic. PDP reports the data for residues over tolerance and residues with no established tolerance (technical violations) separately. For all food groups, residues above tolerance ranged from 0 to 0.59%, with the highest category being fresh fruits and vegetables, where 0.41% of domestic and 0.59% of imports were above tolerance. Residues with no established tolerance ranged from 0 to 8.2%, with the latter found in domestic samples of wheat grains.

California Department of Pesticide Regulation

In addition to the FDA and PDP pesticide surveillance data, the State of California has long had a pesticide marketplace surveillance program, formerly administered by the California Department of Food and Agriculture, and now by the California Department of Pesticide Regulation (DPR) within CalEPA. During the 1980s, the number of samples taken by California was similar to the number of samples taken nationally by FDA. Some other states with important production volumes and also ports of entry, such as Florida, have longstanding pesticide surveillance programs as well.

In 2006, DPR analyzed 3,590 samples of more than 90 kinds of commodities; 69.4% of the samples were domestic, with the remainder taken on imported product.¹⁴ No residues were detected on 63.5% of the samples, while residues within tolerance were found in 35.2% of the samples. As in recent years, the majority of these residues were less than 10% of the tolerance level. Illegal residues were found in 1.31% of the samples, including 0.28% exceeding the tolerance level with 1.03% residues of a pesticide not authorized for use on that commodity. The violation rate was substantially higher for imports than domestic, with 1% of domestic samples in violation compared with 4% of imports. However, the majority (3.4% of the 4%) of the import violations were for technical violations (no established tolerance) versus over tolerance. The general pattern of low rates of violative samples, the majority of which are technical violations, has been true for many years, going back to the 1980s.

Summary of Evidence from Pesticide Surveillance Programs

The evidence generated by all of the programs indicates that illegal residues are the exception,¹⁵ and even when illegal, generally are present at such low levels as to not constitute a human health hazard. While legal residues are found in a sizable share of samples in all of the programs, these residues are often extremely low, less than 10% of the tolerance levels. Since violation rates have consistently been low for both domestic and imported products, the sampling programs would not support a health concern from products of either origin.

For both imports and domestic products the majority of violative samples are for pesticide residues found on products for which there is no tolerance. This can particularly be an issue for minor use crops, for which chemical companies did not go to the expense of re-registering certain pesticides. While these residues can be due to drift or soil uptake, rather than application, they often do reflect pesticides applied to crops for which they are no longer registered. Since this type of “technical” violation tends to occur more on imported products, domestic producers may raise a concern over whether they are competing on a level playing field. On the other hand, the vast majority of import samples are not violative, lessening this argument.

Microbial Contamination

FDA

FDA conducts few microbial sampling programs, in part due to limited resources and the traditional focus on pesticide surveillance. However, in response to food safety concerns in light of outbreaks associated with fresh produce, FDA conducted surveys on microbial pathogens for imported fresh produce in 1999 with a follow-up in 2001 and for domestic produce in 2000. Additional sampling of imported produce was included in the 2005FY CSFAN work plan but results have not yet been reported.

The imported and domestic produce surveys were designed to provide data to CFSAN on the incidence and extent of pathogen contamination on selected domestic and imported produce. This information is needed in order to develop policy and guidance for the Produce and Imported Food Safety Initiative¹⁶ and to focus education/outreach efforts. The intent was not to draw quantitative comparisons between the incidence of contamination of domestic and imported produce as a larger sample size is needed in order to make these comparisons. However, the surveys were designed to allow the agency to make some qualitative comparisons in order to better understand the potential risks associated with select produce items. In particular, items implicated in earlier food safety outbreaks.

Both imported and domestic cantaloupes were found to have a high rate of contamination in the 1000 sample surveys conducted in 1999 and 2000 (the follow-up 2001 survey had a sample size of 257). Overall, 7.3% of imported cantaloupe and 3.0% of all domestic cantaloupe sampled were contaminated with either *Salmonella* or *Shigella*. The microorganism of primary concern, *Salmonella*, was found on 73% of imported violative cantaloupes and on 80% of violative domestic cantaloupes.

Of the imported produce samples collected during the 1000 sample survey, in addition to cantaloupe, cilantro (9.0%), celery (3.6%), parsley (2.4%), scallions (1.7%), and lettuce (1.7%) were violative. Domestically, in addition to cantaloupe, scallions (3.2%), cilantro (1.2%), parsley (1.1%), and lettuce (.7%) were found to be violative.

Despite recent incidents of actual *Salmonella* contamination in domestic fresh tomatoes, no pathogen contamination was detected on any sample. Imported tomatoes showed no signs of pathogen contamination in the initial imported produce survey. However, in the follow-up imported produce survey, there was one positive out of 169 tomato samples. Imported strawberries had less than a 1% rate of contamination and no domestic strawberry samples were violative.

Centers for Disease Control

The Centers for Disease Control (CDC) are a sister public health agency of FDA within DHHS. Its activities range from education of consumers, the medical profession and educators on healthful food safety practices to electronic surveillance of outbreaks in coordination with state health departments, and monitoring the burden of foodborne diseases and identifying sources of specific foodborne diseases.

CDC programs for identifying and monitoring outbreaks of foodborne illness have been greatly strengthened over the last decade. For example, it is only in the last decade that the country can rely on a national electronic network for reporting foodborne illness that enables CDC officials to identify patterns occurring in different parts of the country on a real-time basis, via the Electronic Foodborne Outbreak Reporting System (eFORS).

A very important program is FoodNet, The Foodborne Diseases Active Surveillance Network, a collaborative project, now with ten state departments of health, the Food Safety and Inspection Service (FSIS) of USDA, and the FDA. FoodNet began in 1996 and has grown from covering 14.2 million persons to 44.9 million (15% of the U.S. population). It quantifies and monitors the incidence of disease caused by enteric pathogens transmitted commonly through food by conducting active, population-based surveillance for laboratory-confirmed illnesses. There are fourteen pathogens that are newly associated with foodborne illness since the mid-1970s and since 1996 FoodNet has made various additions to the pathogens monitored to incorporate evolving science about pathogens of concern.

Preliminary surveillance data for 2006 compared with baseline data from the period 1996-1998 show that the incidence of infections caused by *Campylobacter*, *Listeria*, *Shigella*, and *Yersinia* has declined since the baseline period.¹⁷ Incidence of infections caused by Shiga toxin-producing *Escherichia coli* O157 (STEC O157) and *Salmonella*, however, did not decrease significantly, and *Vibrio* infections (often associated with raw seafood) increased by 78%. CDC reports that the *Vibrio* infection rate in 2006 was at its highest since the FoodNet surveillance system was started in 1996. A CDC report issued in January 2008 indicates that the rate of death and Hemolytic uremic syndrome (HUS) associated with outbreaks of STEC O157 in leafy greens worsened since 2000 when CDC first began to monitor this disease.¹⁸

Policy Initiatives and Government and Industry Responsibility

FDA Food Safety Protection Plan

In 2007 FDA released the Food Safety Protection Plan (FSPP), which includes a request for greater authority on recalls and efforts to coordinate better with USDA including regarding

inspections in other countries, with the aim of shifting more of the enforcement burden to other countries through more pre-shipment enforcement. FDA recognizes that it is not possible to test our way to safety, and that it does not have the resources to bear the full burden of keeping food safe, wherever it is grown. Hence, it is emphasizing approaches that will increase the responsibilities of private companies.

The FSPP integrates a set of strategies that:

- Focus on risks over a product's life cycle from production to consumption
- Target resources to achieve maximum risk reduction
- Address both unintentional and deliberate contamination
- Use science and modern technology systems.

The strategy provides three elements of protection:

Prevent Foodborne Contamination

- Promote increased corporate responsibility to prevent foodborne illnesses
- Identify food vulnerabilities and assess risks
- Expand the understanding and use of effective mitigation measures

Intervene at Critical Points in the Food Supply Chain

- Focus inspections and sampling based on risk
- Enhance risk-based surveillance
- Improve the detection of food system "signals" that indicate contamination

Respond Rapidly to Minimize Harm

- Improve immediate response
- Improve risk communications to the public, industry and other stakeholders

FDA has oversight of more than 136,000 registered domestic food facilities (including more than 44,000 U.S. food manufacturers and processors and approximately 113,000 U.S. food warehouses, including storage tanks and grain elevators (facilities engaged in more than one type of activity are counted in both categories)).¹⁹ It is small wonder that FDA has not been able to keep pace with expanding needs, both for domestic and imported food.

According to a report released by FDA's advisory Science Board, *FDA Science and Mission at Risk*, FDA has insufficient resources to fulfill its regulatory mandate, whether in inspections, enforcement, rulemaking, the ability to respond to foodborne outbreaks in a timely manner, or to keep up with the science needed to prevent food safety problems.

The GAO indicates that USDA, FDA, EPA, and NMFS spent a total of \$1.7 billion on food safety activities in fiscal year 2003, with USDA and FDA accounting for nearly 90% of those federal expenditures. While FDA is responsible for regulating approximately 80% of the food supply it accounted for only 24% of expenditures, with USDA responsible for the bulk of the remainder, despite regulating only about 20% of the food supply. GAO also notes

that there are often overlapping activities between FDA and USDA which could be better coordinated to utilize resources more efficiently.

The need to outsource inspection activities is part of the FSPP integrated strategies. FDA could consider developing a program that utilizes certified third-party inspectors to conduct inspections on its behalf, both at foreign processing firms and domestic importers of seafood, for example. The FSPP requests authority from Congress to accredit third parties to conduct voluntary inspections for foods, and FDA officials envision using third-party inspectors in foreign facilities, where FDA currently inspects little. According to the GAO, this is analogous to FDA's third-party inspection program for medical device manufacturing establishments.

FDA recognizes that globalization of the food system is changing risks and that collaborative approaches, both with foreign governments and the private sector, will be critical to managing and mitigating this risk. In 2007 a twelve-agency working group presented to the President its *Action Plan for Import Safety*. Both the latter and the Food Safety Protection Plan request new legislative authority for enhanced access to a food company's records during food safety emergencies. The FSPP also requests legislative authority to order a recall when FDA has reason to believe that food is adulterated and presents a serious health hazard, to be imposed only if a company refuses or unduly delays a voluntary recall. Currently, food recalls are largely voluntary, and the only federal authority to issue food recalls is FDA's authority to require a recall for infant formula. FDA does have authority, through the courts, to seize, condemn, and destroy adulterated or misbranded food under its jurisdiction, and to disseminate information about foods believed to be a health hazard (GAO). However, government agencies that regulate the safety of other products, such as automobile tires and toys, have recall authority not available to FDA for food.

International Trade

The import share of U.S. food consumption has been growing for many commodity groups. Nevertheless, the import shares of food by major food group are still low, as shown in Exhibits 5 and 6. Shares of volume are typically higher than shares of value, but in most cases for product categories for which the United States has sizeable domestic production, shares of volume are 16% or less.²⁰ The exceptions are fish and shellfish, and fruits and nuts, which include many products not grown domestically, such as bananas, pineapple, and other tropical fruits. These products do not displace domestic production. Hence, while imports have grown rapidly in recent years in response to consumer demand, the vast majority of food consumed in the United States remains domestically produced.

According to FDA, USDA, and food safety scientists, based on the preponderance of evidence, there is no evidence that imports are less safe than domestic production, although this topic is highly debated, particularly among growers and consumer advocates.

Country-of-Origin Labeling, COOL

Many growers feel that consumers would prefer domestic food, in part for what they argue would be a perception of greater safety, if consumers had the information to make a choice. Numerous surveys show that while many consumers indicate a preference for domestic products when asked directly in a survey, if also asked what factors most influence their purchases, origin invariably ranks very low, with quality, appearance, freshness, and price the top factors influencing purchasing decisions.

Nevertheless, a few years ago, beef and fruit and vegetable growers, as well as representatives of some other commodity sectors worked to legislate national country-of-origin labeling. Congress originally approved mandatory country-of-origin labeling in 2002 for beef, lamb, pork, fish, perishable agricultural commodities, and peanuts (food ingredients are excluded). That mandatory measure was delayed for all covered commodities until September 30, 2008, with the exception of wild and farm-raised fish and shellfish, for which country of origin labels have been required since September 2006. The delays are due in part to major opposition from food industry groups such as retailers, which argue that the costs of such a program would be onerous and outweigh any benefits to consumers.

Now, President Bush's proposed 2009 budget calls for USDA to collect fees of \$259 from each of about 37,000 retailers, to pay for compliance reviews for mandatory country-of-origin labeling for meat and other food products. The fees apparently would apply to both the mandatory labeling program that is already approved, and a revised program in the yet-to-be-completed 2007 Farm Bill.

A USDA report examining the economic rationale behind mandatory country-of-origin labeling found little evidence that the market (in the absence of mandatory labeling) is not efficiently meeting the preferences of consumers for country-of-origin information and labels.²¹ It notes that if U.S. origin was so valuable to the majority of consumers and produced a higher return in the marketplace, firms would provide this information voluntarily, and that negates the need for mandatory regulation with costly government oversight and record keeping. The costs are expected to be born primarily by consumers and producers/marketers, given the direct labeling costs incurred by the latter and the ability of retailers to shift costs both upstream and downstream. The authors developed an economic model to measure the impact of COOL which showed that production, exports, and imports of covered commodities would likely decline somewhat, with a small loss in economywide purchasing power resulting.

It is of interest to note that information on product origin has long been provided for automobiles, apparel and shoes, which has not impeded major losses in U.S. market share in these sectors. In the end, consumers make purchasing decisions based on a variety of factors that influence the value proposition for each item. The U.S. food industry has one of

the highest domestic content shares of any industry, despite the lack of mandatory country-of-origin labeling for most commodities, due to its strong overall competitiveness and the value proposition (price, quality, safety and other attributes) it offers to consumers.

China

FDA has recently signed an MOU with China designed to contribute to higher food safety standards and monitoring. China has gone from the eighth most important agricultural trade partner of the United States in 2003 to the fourth with FY2007 imports valued at \$2.8 billion out of \$70 billion in total U.S. agricultural imports. China's difficulties with food safety are noted in the USDA article "Food Safety Improvements in China," by Calvin et al.²² The authors highlight the challenges China faces and note that as China improves food safety the cost of its products will increase, reducing its cost advantage in the global marketplace.

In general, FDA emphasizes working collaboratively with other countries that are important sources of imports into the United States to improve food safety processes and practices, recognizing that resources are insufficient to conduct extensive monitoring at the border. In addition, prevention is a less costly and risky way to impact food safety.

In the meantime, Trader Joe's is taking some of its Chinese food off the menu, announcing on February 12, 2008, that it would phase out the sale of single-ingredient items – such as garlic and spinach – that are imported from China.²³ Concern over the safety of food from China is influencing the sourcing decisions of many firms independent of any government action as firms weigh the costs and benefits, and ingredients for processed food products and animal feed are receiving greater attention.

Self-Regulation vs. Government Regulation and Standards

The experience with self-regulation compared with government regulation and standards is increasingly receiving attention. In the food industry the private sector often develops and implements more stringent standards than existing government standards or self-regulates where the industry sees a void or market failure or an opportunity for product differentiation that may contribute to profits.

Private sector food labeling practices, product quality standards, and buyer requirements to meet specific food safety standards as a condition for doing business have all been proliferating. In some cases these are designed to transfer risk, such as from commercial buyers to suppliers. In other cases they may be designed to inform consumers of the absence or lack of ingredients, farming practices, origin, or other attributes affecting product safety or quality. Suppliers that have identified consumer target groups that value these attributes may find the latter profitable.

In the fresh produce industry most suppliers (frequently grower-shippers) provide year-round supply, often importing during the off-season. In recent years, shippers have been actively working with their growers, wherever they are located, at home or abroad, to insure that all are meeting Good Agricultural Practices (GAPs), and more and more shippers are requiring that all of their growers pass third-party audits. This is not only due to buyer requests and a sincere desire not to harm consumers but also is a strategy for better managing and mitigating food safety risk to protect firm reputation and profits. Increasingly, the global playing field is being leveled and it is a race to the top, not a race to the bottom, as many critics of free trade have charged. All of this is happening in the absence of government mandates, led by normal free market incentives and disincentives.

Hazard Analysis and Critical Control Points (HACCP)

Government regulation experienced a substantial change beginning in the mid 1990s. HACCP regulations were adopted for the meat (beef and pork) and poultry processing industries in 1995, for seafood in 1997, and for vegetable and fruit juice and juice products in 2001. The HACCP approach is often described as preventive in nature and as a comprehensive management tool for recurrent food safety improvement. HACCP mandates that plants develop and implement an operating program comprising seven principles described by Unnevehr and Jensen (1996) as follows:

- (a) assess the hazard, list the steps in the process where significant hazard can occur, and describe the prevention measures; (b) determine critical control points (CCPs) in the process; (c) establish critical limits for each CCP; (d) establish procedures to monitor each CCP; (e) establish corrective actions to be taken when monitoring indicates a deviation from the CCP limits; (f) establish record keeping for the HACCP system; and (g) establish procedures to verify that the HACCP system is working correctly.²⁴

Up to the introduction of the HACCP approach, food safety regulations typically required the observance of practices or procedures in the production process (variously referred to as technology, process, or design regulations) or product compliance with a food safety standard (performance regulations). Once a HACCP plan is developed it looks very much like a catalogue of both process regulations and performance regulations, except that the plan is tailored to the specific conditions of a plant, subject to the criteria and requirements contained in the HACCP regulation. Thus, the HACCP approach is sometimes conceptualized as “mandated self-regulations” in the sense that firms develop their own individual food safety plan, with the government playing the role of a meta-regulator that provides generally the aims and objectives that the plans must comply with, and that oversees their appropriate implementation. In practice, FDA has insufficient resources to conduct much oversight.

The record keeping requirements of a HACCP plan are paramount for the approach to deliver ongoing safety improvements. First, as the adage goes “you do what you measure,” so data gathering is in itself an incentive to track closely critical points and to take corrective actions where appropriate. Second, record keeping serves as the basis for smart reengineering of the HACCP plan and becomes a critical input for regulators while assessing compliance and undertaking enforcement actions.

A decade later after their initial adoption, limited empirical evidence is available to assess actual HACCP performance relative to expectations. As mentioned earlier, the rates for most foodborne illnesses have been trending downwards in the last few years relative to their respective rates in the 1990s. Still, as Alberini et al. (2008) have noted for seafood born illnesses associated with *Vibrio*, the rate was 47% higher in 2004 than the baseline rate for 1996–1998. During the comparable period, seafood per capita consumption increased by 12%, so apparently the risk associated with seafood consumption has increased markedly.²⁵

It may be a while before a comprehensive assessment of the benefits derived from the HACCP regulations is available. Such assessments are inherently difficult, as they require causally linking reductions in morbidity and mortality rates associated with foodborne illnesses with the actual implementation of HACCP regulations, net of other contributing factors.

On the cost side of things, HACCP implementation has been the subject of numerous analyses. Antle^{26,27} set out to estimate the increase in production costs resulting from the meat and poultry HACCP regulation four years into its implementation. At the time HACCP was first introduced, FSIS estimated the total annual implementation costs at around \$100 million.²⁸ Antle noted that this estimate did not account for costs resulting from quality and safety controls integrated into the production process, such as removal of contaminated product and the cleaning of the processing equipment. The included costs were limited to features that arguably do not fluctuate with volume of production, such as record keeping, product testing, and some capital equipment. In other words, FSIS implicitly assumed that the HACCP regulation had no impact on production efficiency and variable costs.

Using plant-level data from the Census of Manufacturers, Antle compared the production functions for 377 meat and poultry plants before and after implementation of HACCP. Econometric analyses of that comparison strongly rejected the notion that productivity is unaffected by the quality and safety controls mandated under HACCP. Instead, Antle concluded that the increase in total variable costs following HACCP implementation for all plants was in the range of \$535 million to \$4.8 billion, or 5 to 48 times the estimate originally advanced by FSIS. The difference in cost partly reflects the baseline level of safety practices in plants prior to HACCP.

Estimates with such an enormous range of variation reveal the inherent complexities and uncertainties of cost-benefit studies and underscore the limitations in existing data and models. Yet improvements in cost-benefit methodologies will not be the only factor affecting the course of future food safety regulations, perhaps not even the most important. For various reasons, the demand for greater food safety is growing and that is likely to lead to additional regulatory efforts, whether self-imposed by industry, mandated by the government, or both.

Meat Industry Experience in Addressing the *E. coli* O157:H7 Challenge

Since the early 1990s, the U.S. beef industry has waged a war on the pathogen *E. coli* O157:H7 in fresh beef products. USDA beef sampling data show a sustained decline in the incidence of the pathogen in raw beef products. Likewise, CDC FoodNet data show overall declines in the incidence of human illness associated with the pathogen. This progress was the result of a collaborative effort between government, scientists, and the industry.

But the summer of 2007 brought a new and concerning trend. A slight increase in the incidence of the pathogen in ground beef and a series of beef recalls suggests that it is time for a scientific reassessment and discussion of future strategies to help maintain the progress that has characterized the last decade. The American Meat Institute, the National Meat Association, and others brought together leading experts from industry, academia, and the government to share information and exchange ideas at a January 28, 2008, meeting. Then, in mid-February 2008, a scandal over animal treatment erupted from a meat processing plant in Chino, California, and the biggest meat recall in history took place (Class 2, reflecting the potential risk of, rather than confirmed, contamination), bringing further scrutiny to industry food safety practices, humane animal treatment, and government oversight.

According to Linda Harris, Associate Director of the Western Institute for Food Safety and Security at University of California, Davis, a number of things probably played a role in the progress the meat industry experienced over the last decade.

- After the Jack in the Box incident, *E. coli* was declared an adulterant in raw ground hamburger. To this point, pathogens like *E. coli* and *Salmonella* had been considered “normal” in raw meat products. However, this change in classification meant that detection of the organism in raw ground beef would lead to reprocessing, to a validated kill (if not on the market), or to a recall. This led to changes in USDA sampling to include significant numbers of random samples per year and industry testing in an attempt to prevent recalls. With these practices you can theoretically keep product off the market that would have otherwise caused illness.

- The change to HACCP-based inspection meant that for slaughter processes there was increased attention paid to things that could introduce pathogens into the meat. Much research was done and now animals may be washed before or after slaughter, the carcass may be steamed or sprayed with acids, visible dirt may be steamed or vacuumed or cut off, etc. All of these measures potentially lower initial contamination going into the facility.

Traceability

The current food safety regime was largely designed around the notion of preventing unintentional contamination resulting from lack of proper sanitation and hygiene controls. That rationale is no longer sufficient as the regulatory system now has to contend with the possibility of intentional contamination. Acts of terrorism through food poisoning is now seen as a risk factor, fortunately a risk that has not yet materialized. But there is also the intentional contamination motivated by economic gain, which according to the FDA has recently already occurred in the case of pet food contamination.²⁹ This suggests that the regulatory framework will need to accommodate these new concerns and provide for additional controls to guard against intentional contamination, and to respond quickly and effectively in the event that the preventive controls fail.

The adoption of traceability requirements is one regulatory option that is gaining ground as an effective mechanism to increase food safety and security, a regulatory option that the European Union enacted in 2002.³⁰ Bailey et al. (2002) define traceability “as the ability to track the inputs used to make food products upstream to their source at different levels of the marketing chain.”³¹ Thus, in the event of contamination (unintentional or otherwise) and once the source is located, traceability makes possible the targeted interception from the food supply of intermediate and final products affected by the contaminant. Under that scenario, the efficiency of recalls can improve substantially.

But traceability requirements are desirable beyond their usefulness in the event of a recall. Pouliot and Sumner³² point out that traceability provides an incentive for firms to improve food safety in the first place since it makes firms more accountable for their own food safety violations. If the source of a serious contamination can be reliably identified, the resulting liability (if any) and loss of prestige could fall more on the individual transgressor and less on the industry group as a whole.

Recent experiences with food safety outbreaks in the fresh produce industry have shown that while the firm causing the problem may be held legally accountable, the industry as a whole can be adversely impacted by a reduction in sales for the commodity in question. The incentives for industry-wide responses are therefore growing and apparent.

A traceability initiative in the fresh produce industry was launched in October 2007 by Produce Marketing Association (PMA), Canadian Produce Marketing Association (CPMA), and United Fresh Produce Association (United Fresh). It is guided by a steering committee of more than 30 companies with balanced representation from the buying and selling community, including participants from all segments of the supply chain. In the committee's first meeting on January 9, 2008, it determined the following:

- The traceability standard will be an existing standard, used internationally, GS1.
- An implementation timeline is required.
- Representatives are returning to their companies to ascertain how they can show support, stimulating broad industry participation.
- Case-level traceability will be the initial standard, whereas item-level coding will only be encouraged for now since it is not currently feasible for many commodities.

Fresh Produce and Food Safety

CDC estimates that at least 12% of foodborne-outbreak-associated illnesses were linked to fresh produce items in the 1990s. From 1996 to 2006, 72 foodborne illness outbreaks were associated with the consumption of fresh produce. According to FDA, leafy greens such as lettuce and spinach are the category of produce most likely to be associated with an outbreak (Exhibit 7).

The federal government provides advice on healthful eating, including consuming a diet rich in a variety of fruits and vegetables, through the *Dietary Guidelines for Americans* and the related MyPyramid food guidance system.³³ Annual per capita consumption of fruits and vegetables (processed and fresh) has indeed been rising since 1990, albeit slowly, up 4% to 694 pounds in 2006.³⁴ Given the importance of fresh produce consumption and its central role in a healthy diet, government regulators consider it to be imperative to reduce the incidence of foodborne illness associated with produce.

In 1998, FDA published voluntary guidelines for both domestic and foreign producers on GAPs for reducing microbial contamination. FDA has been very alarmed about the continuing problems in the produce industry and has issued a nearly continuous series of warning letters and initiatives – often directed specifically at the lettuce/leafy green industry – since early 2004. In January 2004, FDA and CDC met with produce industry leaders to discuss their desire for commodity-specific GAPs that would provide additional guidelines tailored to individual commodities, specifically, lettuce, tomatoes, melons, herbs, and green onions. In February 2004, FDA sent the lettuce industry a warning that they needed to pay more attention to food safety concerns.

The produce industry met in June 2004 to consider commodity specific GAPs. Later that month the FDA unveiled its new action plan on food safety, *Produce Safety from Production*

to Consumption. The initiative has four objectives: prevent contamination of fresh produce; minimize the public health impact when contamination of fresh produce occurs; improve communication with producers, preparers, and consumers about fresh produce; and facilitate and support research relevant to fresh produce. FDA adds guidance or restrictions as better information becomes available.

In April 2006, the lettuce/leafy greens industry put out its “Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Greens Supply Chain.” In 2006, FDA took another step to help improve leafy green food safety by developing the Lettuce Safety Initiative. The specific objectives of the initiative are to: assess current practices and any necessary improvements; identify what leads to contamination; be prepared to respond rapidly in case of an outbreak; and consider regulatory action, as appropriate. This initiative has now been broadened to include spinach and other leafy greens.

On August 24, 2006, just at the time people were getting sick from spinach, FDA, the California Department of Health Services, the California Department of Food and Agriculture (CDFA), the industry, and academics were meeting in California to visit lettuce operations and try to understand the contamination problem.

Many factors may play a role in the incidence and reporting of foodborne illness outbreaks that implicate fresh produce, such as an aging population that is more susceptible to foodborne illness, an increase in global trade, a more complex supply chain, improved surveillance and detection of foodborne illness, improvements in epidemiological investigation, and increasingly better methods to identify pathogens.³⁵ However, according to unpublished data from FDA, of the 72 produce related outbreaks previously noted, 25% (18) implicated fresh-cut produce.

Fresh-Cut Produce

The fresh-cut industry grew rapidly since the early 1990s, now approaching an estimated \$15 billion in sales through both retail and foodservice channels. Processing fresh produce into fresh-cut products increases the risk of bacterial growth and contamination by breaking the natural exterior barrier of the produce.³⁶ The release of plant cellular fluids when produce is chopped or shredded provides a nutritive medium in which pathogens, if present, can survive or grow. The processing of fresh produce without proper sanitation procedures in the processing environment increases the potential for spreading contamination through a large volume of product. The potential for pathogens to survive or grow is increased by the high moisture and nutrient content of fresh-cut fruits and vegetables, the absence of a lethal process (e.g., heat) during production to eliminate pathogens, and the potential for temperature abuse during processing, storage, transport, and retail display. Importantly, however, fresh-cut produce processing has the capability to reduce the risk of

contamination by placing the preparation of fresh-cut produce in a controlled, sanitary facility.

In response to these concerns, on February 25, 2008, the Federal Register published FDA's *Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables*. Guidance is intended for all fresh-cut produce processing firms, both domestic and firms importing or offering fresh-cut product for import into the U.S. The guidance does not set binding requirements or identify all possible preventive measures to minimize microbial food safety hazards. FDA recommends that each fresh-cut produce processor assess the recommendations in the guidance and then tailor its food safety practices to the processor's particular operation. Alternative approaches that minimize microbial food safety hazards are permitted so long as they are consistent with applicable laws and regulations. In other words, this is a performance standard with FDA recognizing that there may be alternative processes for achieving the same result.

Leafy Greens, California Spinach, *E. coli* O157:H7, Experience and Response

The average U.S. consumer ate 0.4 pounds per capita of fresh spinach in 1980 compared with 2.5 pounds in 2005 prior to the outbreak and 2.0 pounds in 2006.³⁷ Along with the growth in consumption came a change in product form, in that more spinach is now consumed raw, avoiding a "kill step." The detection of *E. coli* O157:H7 in California spinach in August/September 2006 and the associated loss of life sparked major changes in both the industry and government regulatory frameworks. This incident was followed by two more outbreaks in November 2006 when shredded lettuce was implicated at two unrelated taco chains with separate lettuce suppliers.

For the first time, some industry leaders and trade associations began calling for mandatory government regulation to assure a level and transparent playing field for producers around the United States and for imports. Growers, shippers, and fresh-cut processors all saw clearly the devastating industry-wide consequences of mistakes made by a minority of firms. On the buying side, attitudes began to change as well, with the creation of a number of "dueling" buyer-led food safety initiatives calling for better food safety standards from the industry, some of which appeared unreasonable to many shippers as they evolved.³⁸ On the other hand, much to the chagrin of growers and shippers, many buyers were unwilling to sign up for initiatives requiring them to buy only from qualified suppliers.

The Outbreak

On September 14, 2006, FDA announced that consumers should not eat bagged spinach because of a foodborne illness outbreak of the potentially deadly bacterium *E. coli* O157:H7. The next day it expanded its warning to include bulk spinach. Store shelves and foodser-

vice offerings were immediately cleared of spinach and spinach sales ceased overnight. This is the first time that FDA issued a blanket warning to the public not to eat any of a produce item rather than the product of a specific firm. By the time the outbreak was over, 206 people across 26 states and one province in Canada became ill, 104 were hospitalized, 31 developed the serious complication of HUS, and three died. Eventually FDA determined that the contaminated product was bagged baby spinach grown in transition to organic certification, processed by Earthbound Farms, and co-packed for other firms and that one 2.8-acre field was the most likely source of all the contaminated spinach. FDA could not, however, identify the method of contamination. For details on this incident, please refer to the handout in your binder written by Linda Calvin of the Economic Research Service (ERS) of USDA.

The loss in consumer confidence affected not only spinach sales but also sales of all leafy greens. According to the Perishables Group, scanner data from U.S. supermarkets shows that bagged salad dollar sales declined 5.4% for the 52-week period ending June 30, 2007, compared with increases of 7.7% and 3.9%, respectively, for fresh-cut fruit and fresh-cut vegetables. The rapidly growing fresh-cut produce industry was stagnant in 2007 for the first time in its recent history, as sales growth for fresh-cut fruit and vegetables was not enough to offset the decline in bagged salads, which represent about 48% of fresh-cut sales. According to ACNielsen, baby spinach and spinach blends accounted for 7% of the \$2.8 billion in fresh-cut salad sales through supermarket channels for the 52-week period ending June 2, 2007, and over this period sales of bagged baby spinach fell 19.2% compared with 25% for mature spinach. Hence, industry sales have not fully recovered and the impact goes beyond spinach to the broader leafy green salad category.

Grower, Shipper and Handler Response

Very quickly the industry responded, with a strategy led by the Western Growers Association (WGA) and others to implement industry regulation designed to mitigate risk and rebuild consumer confidence. By March 2007, the industry had developed the California Leafy Greens Marketing Agreement (CLGMA), a voluntary California State marketing agreement with food safety metrics much more specific than the FDA GAPs.

A group of grower organizations and scientists developed the food safety standards and the marketing agreement funds an audit program for those standards, carried out by CDFA auditors. In this way auditors are independent State employees, presumably increasing the objectiveness of the process. By the time preliminary audits began to take place in spring 2007 handlers representing more than 99% of the volume were signatories. An important incentive for some was the decision by Canada to allow only imports from CLGMA signatories.

By the start of the fall 2007 Arizona shipping season, Arizona had put into place a program similar to the California metrics. This process was facilitated by the fact that most of the production of leafy greens in the winter Arizona season is controlled by California firms, all signatories to the CLGMA. CLGMA officials estimate that more than 90% of national leafy green production is covered by these two agreements, given the concentration of production.

The next step advocated by some is to make the metrics national to standardize practices used by firms scattered around other states, usually producing in the summer, whether through a marketing order or agreement. This is a much more difficult goal, given the fragmentation of the last 10% of production, and the incidence of many smaller growers. On the other hand, much of this production occurs in Florida, where the Florida Fruit and Vegetable Association has been considering adopting similar metrics.

But this raises a broader concern for the fresh produce industry as a whole, given the recent growing trend toward more local sourcing by buyers, frequently in regions with short shipping seasons, smaller producers, and often less investment in food safety practices. Many California and Arizona growers are beginning to feel that there is a double standard compared with growers elsewhere in the country. The California leafy green industry is not the only industry to have suffered financial losses due to foodborne illness outbreaks associated with their commodities. The use of marketing programs to improve food safety by the leafy green and other industries is described in Appendix A

While many would like to think that the CLGMA Best Practices are the gold standard for food safety, the science behind many recommendations is not yet fully developed. Only time will tell how robust the recommendations are. In the year following the outbreak linked to spinach there have been a number of cases of leafy green contamination although not any reported illnesses, which the industry points to as demonstration that the system is working. The leafy green industry has also come under criticism for the way the Best Practices were developed. On the other hand, the practices had to be developed under a very short time line and likely would have been delayed by a more open process. The standards were always intended to be flexible and admit new science as it became available. While some California legislators originally pushed for a State law regulating the leafy green industry, the Governor decided to let the CLGMA have a chance to improve food safety first, rather than imposing mandatory standards that might be slower to change as science evolves.

Whoever sets the standards will have the same challenge: to develop science-based practices that reduce risk at the minimum cost. Ongoing scientific research will contribute to this evolving process. In April 2007, Fresh Express, a large bagged salad company, distributed \$2 million of funding to support scientific research on *E. coli* O157:H7 in leafy

greens. Scientists from universities, FDA, CDC, and the California Department of Health Services participated in the selection of the projects. In April 2007, the Center for Produce Safety was established at the University of California, Davis. When the center opened it was supported by initial pledges of over \$5 million from the Produce Marketing Association, Taylor Farms, WGA, the California Farm Bureau Federation, CDFA, and the University of California.

In the meantime, some environmental groups and experts are questioning the impacts of some of the CLGMA provisions on wildlife and natural habitats, as firms attempt to provide adequate setbacks between leafy green fields and riparian and other areas that increase the risk of animal intrusion. Evolving science may enable the industry to define setback provisions more narrowly, reducing cost and potential environmental impacts.

Third Party Certification and Audits

In the meantime, the CLGMA does not seem to have eliminated the problem of different buyers requesting that growers and handlers pay for additional, duplicate third party audits from the auditors of their choice. Firms also point to the lack of oversight of third party auditors and no certification of the certifiers. More firms, in particular, foodservice buyers, are requesting additional final product testing by fresh-cut processors, again a costly procedure for which only some buyers are willing to pay.

The process of final product testing raises several issues. If firms test and do not hold the product and it enters the distribution system before the lab results are received, firms can be faced with issuing recalls in instances of positive samples. Tests are subject to false positives and false negatives, so the more testing that is done, the more both will occur. The California industry has already faced a situation where a firm recalled product in light of a presumptive positive for *Salmonella* that the lab later recognized as erroneous. Another firm tested and held part of the product for a specific buyer but shipped the rest, which was later found to test positive for *Salmonella*. Traceforward records allowed the firm to locate and put holds on more than 90% of the product.

Costs of Compliance and Buyer Dynamics

If the industry is to move to widespread test and hold programs, it will entail significant costs as many firms will need to invest in additional cold storage facilities and incur higher energy costs and the consumer may be faced with less fresh products due to about a three-day lag between processing and shipment, reducing shelf life. Furthermore, many food safety scientists at University of California, Davis point out the low probability of detecting pathogens that, if present, are generally present at very low levels.

The costs of compliance with the CLGMA vary markedly by grower and shipper but can be in the multimillion dollar range, depending on pre-CLGMA food safety practices and

record keeping, firm size, location of fields, and a variety of other factors. Even with a high level of standards already in place, the CLGMA metrics can be quite costly to implement due to requirements such as water testing, fencing, and setbacks from areas with wildlife, animal agriculture, or other areas of increased risk. In addition, many fresh-cut processors have been imposing standards on their growers that go above and beyond the CLGMA metrics.

A letter published in the *Perishable Pundit* on February 22, 2008 paints a picture:

Let me point out just one increased cost out to you: "Trapping Stations."

Some processors are requiring trapping stations every 50 ft. for rodents. I grow 7,500 acres of vegetables. This would equal approximately 16,000 stations. So, 16,000 stations x \$30 = \$480,000. This isn't a one-time cost. Now the stations need to be monitored 2x/week, and logged. I ask you, Mr. Pundit, how many people do you think that will take? I'm pretty sure that will be more than one person!

In summation, "trapping stations" alone would increase my costs by \$100/acre, representing a 15 cents/pound increase on items like spinach and spring mix and a minimum of 12.5 cents/carton on other items. I am not even mentioning any other costs at this point!

– Jack Vessey, Vice President/Marketing Director, Vessey & Company

The subtext of many letters written to the *Pundit* (Jim Prevor) was that the processors were not going to pay any more even though growers are incurring sizeable new costs. Recently, one of the larger leafy green commodity grower-shippers announced that it would no longer sell to fresh-cut processors. If more growers follow suit the commodity leafy green market will likely face excess supply, barring decisions of firms not to plant the acreage they formerly grew for processors.

For their part, processors indicate that many buyers are unwilling to pay price premia for the additional food safety measures. In some cases processors have been able to add a food safety "fee" of around 20-25 cents/carton. This strategy has tended to succeed better for foodservice buyers than retail, in particular large foodservice chains, and may not occur until contracts (often multi-year) are renegotiated. For commodity shippers it has been even more difficult to pass costs along to buyers (compared with fresh-cut processors), as they primarily act as price-takers in the marketplace. All firms are experiencing a large increase in liability insurance costs.

In the longer run the market should adjust as new cost structures affect breakeven grower costs and in turn, supply curves. As always, firms that achieve lowest cost status relative to competitors will have the advantage. Hence, the ability to meet food safety requirements

cost-effectively has become extremely important to the industry, not only in the U.S. but abroad.

Consumer Attitudes about Food safety

Several entities track U.S. consumer attitudes about the safety of the food they purchase. For many years, in national, annual consumer surveys on food shopping, the Food Marketing Institute (FMI) has asked consumers “How confident are you in the safety of food you buy in supermarkets?” Between 1996 and 2006, the confidence level hovered around 80% (extremely or mostly confident), similar to the level shown in surveys done throughout the 1980s. In 2007, consumer confidence declined precipitously to 66% from 82% the prior year. In its 2007 consumer survey FMI also found that 38% of consumers had stopped purchasing some types of food in the prior year due to concern over food safety, compared with 11% and 9% in 2005 and 2006, respectively.³⁹ Furthermore, attitudes changed about the types of foods of most concern. Whereas in 2005, 53% of those consumers who declined to purchase something due to food safety concerns purchased less beef or poultry, only 15% made that choice in 2007. In contrast, 84% of those that stopped purchasing did so for fruits and vegetables, compared with only 12% in 2005.

On the other hand, the Produce Marketing Association (PMA) conducts national consumer surveys on food safety issues specific to fresh fruits and vegetables, finding that the level of confidence in the overall safety of the nation’s fresh produce supply varied between 4.87 in September 2006 compared with 4.84 in June 2007 on a scale of 1-7 (7 most confident).

What are consumers most worried about when it comes to food safety and the grocery store? The national FMI data shows that the number one food-related item considered a serious health concern in 2007 was bacteria or germs, mentioned by 49% of respondents, compared with 37% mentioning pesticide residues as a serious concern, down from the prior decade when pesticide residues were the number one consumer concern. The FMI data show that consumer concern over microbial food safety hazards has continued to rise with outbreaks, while pesticide residues have become less top of mind.

In the meantime, the term “organic” has become a “trustmark” for those consumers most concerned about food safety, in particular pesticide residues. Consumer focus group research done by the author indicates that most people feel that “I always assume that what I buy in the supermarket is safe.” The only food safety-labeling scheme that has attracted a consistent following is organic, while labels such as residue-free, tested to ensure safety, or tested to ensure meets government standards appear to add little value to most consumers.

Enhanced Food Safety

In the near future the regulatory system, particularly self-regulatory schemes, is likely to incorporate enhanced notions of food safety important to consumers. Because of changes in consumer values and lifestyles, in the minds of many consumer groups food safety has become more broadly defined than simply product safety. While still the minority of consumers, increasingly there are more people who care about the attributes of production processes and insist that firms abide by principles in accordance with their values. For example, at the insistence of consumers, red meat food safety standards in the EU incorporate what are called extrinsic qualities of the product (such as assurances about animal welfare). Bailey et al. (2002) define those extrinsic qualities as attributes of the product that without affecting its safety or intrinsic quality, affect their value and appeal to consumers.

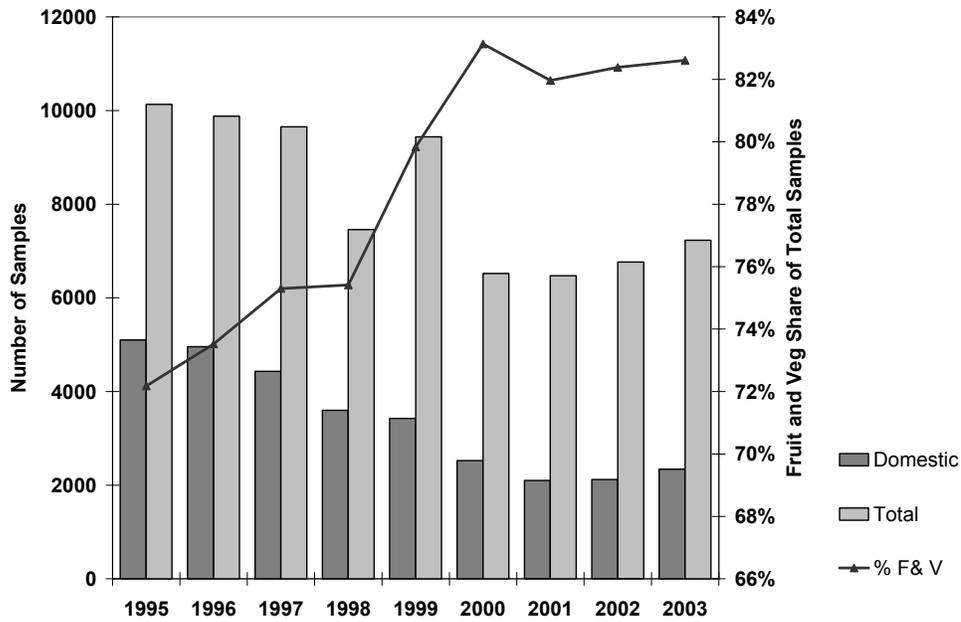
The various reasons identified as drivers of safer food leave little doubt that the regulatory system will have to be responsive in some fashion and accommodate those demands. The choice that industry will increasingly have to face is not between more or fewer food safety regulations, but between smart (efficient) regulations and inefficient ones. The choice is obvious, but the problem is that designing efficient regulations is neither cheap nor easy.

Discussion Questions

- Are mandated self-regulatory approaches, such as HACCP, an efficient way to attain food safety outcomes?
- Should industries continue to attempt voluntary self-regulation to forestall mandatory government regulation or does government regulation, while less flexible, shift part of the liability to government?
- Is it in the interest of the agribusiness community to politicize the issue of food import safety, claiming that imports represent a health hazard to consumers?
- Alternatively, it is in the interest of the agribusiness community to encourage government to work with other countries to improve their food safety processes?
- Should the government intervene to standardize and certify third party food safety audit procedures, taking into account commodity-specific GAPs and GMPs, in order to address the problem of the proliferation of auditors and the nonexistence of any oversight of third party auditors?

- If commodity sectors have voluntary food safety standards, either GAPs or GMPs, supported by complying with a minimum audit standard (such as the CLGMA) should buyers be required to source from only firms meeting these standards?
- Is there a way to transfer part of the cost and food safety risk to buyers, to increase their incentives to procure food only from suppliers meeting standards?
- Should FDA be given greater authority to conduct recalls and other activities?
- Is the FDA strategy for shifting more of the onus for safety on the private sector and other countries likely to succeed in mitigating risk?
- Do we invest enough resources in food safety research and if not, what strategies might increase this, and what is the role of industry versus government?
- Should the agribusiness industry pursue COOL or attempt to delay implementation?
- Will traceability align incentives in the food system in a way that generates better food safety outcomes?
- Given the strained resources of FDA, should industry join forces with consumer advocacy groups to increase its funding to enable it to provide both more food safety research and oversight?
- Should industry consider broader use of marketing orders or agreements as a tool to speed the process of standardized food safety commodity metrics, yet allowing for flexibility in adapting the metrics to different regions?
- Does the Nation need a centralized food safety agency as some advocates recommend or merely better coordination between agencies?

Exhibit 1. FDA Pesticide Residue Surveillance: Number of Domestic and Total (including import) Samples, All Groups, and Fruit and Vegetable Share of Total Samples, 1995-2003



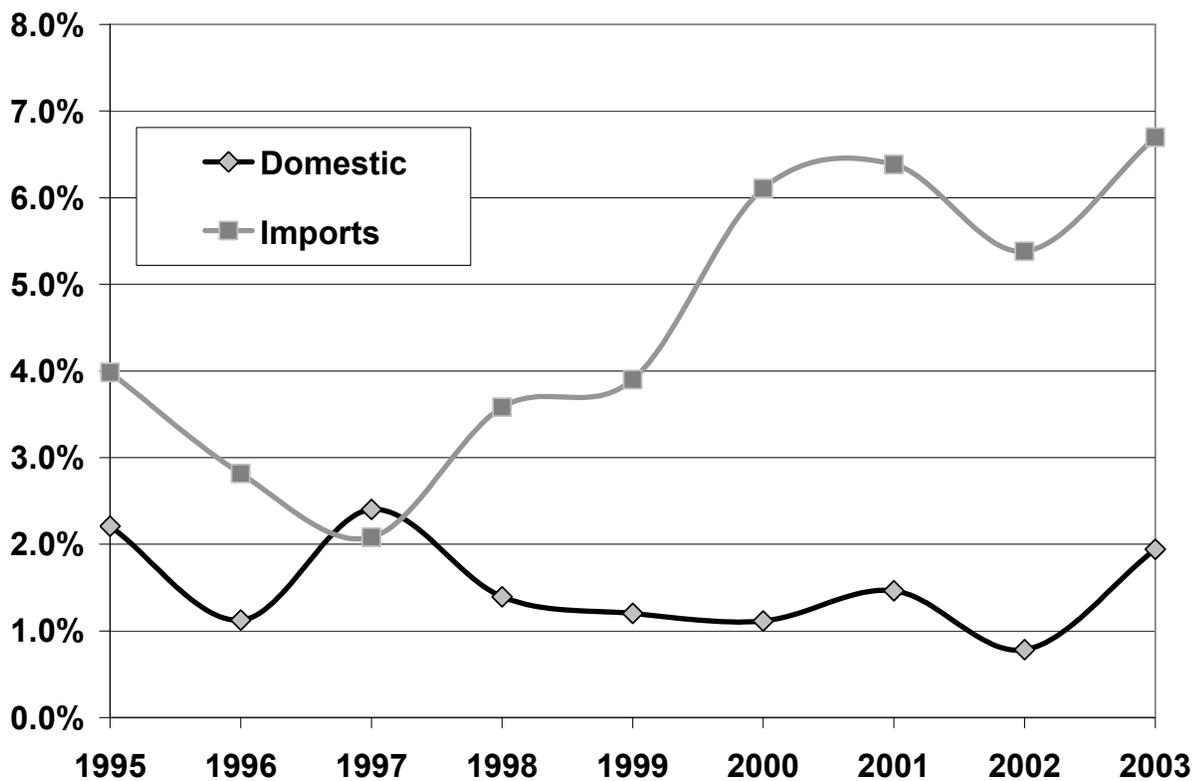
Source: Compiled by the author from FDA, Pesticide Program Residue Monitoring, annual reports 1995 through 2003.

Exhibit 2. FDA Pesticide Residue Surveillance Findings, by Food Group, 2003

Food Group	Domestic	Imports	Total
Vegetables			
Number of Samples	1,132	2,494	3,626
% With no residues	69.2%	72.5%	71.5%
% With residues below tolerance, legal	28.9%	20.8%	23.3%
% Residues, violative	1.9%	6.7%	5.2%
Fruits			
Number of Samples	813	1,537	2,350
% With no residues	48.6%	63.6%	58.4%
% With residues below tolerance, legal	49.2%	31.1%	37.4%
% Residues, violative	2.2%	5.3%	4.2%
Fish/Shellfish other Aquatic Products			
Number of Samples	395	273	395
% With no residues	76.2%	89.0%	85.1%
% With residues below tolerance, legal	23.8%	11.0%	14.9%
% Residues, violative	0.0%	0.0%	0.0%
Grains and Grain Products			
Number of Samples	154	215	369
% With no residues	74.0%	88.4%	82.4%
% With residues below tolerance, legal	26.0%	10.2%	16.8%
% Residues, violative	0.0%	1.4%	0.8%
Milk/Dairy Products/Eggs			
Number of Samples	21	59	80
% With no residues	100.0%	84.7%	88.8%
% With residues below tolerance, legal	0.0%	15.3%	11.3%
% Residues, violative	0.0%	0.0%	0.0%
Other			
Number of Samples	102	312	414
% With no residues	60.8%	78.2%	73.9%
% With residues below tolerance, legal	22.5%	7.7%	11.4%
% Residues, violative	16.7%	14.1%	14.7%
All			
Number of Samples	2,344	4,890	7,234
% With no residues	62.6%	71.8%	68.9%
% With residues below tolerance, legal	34.9%	22.1%	26.3%
% Residues, violative	2.4%	6.0%	4.9%

Source: Compiled by the author from FDA, Pesticide Program Residue Monitoring, annual reports 1995 through 2003.

Exhibit 3. FDA Pesticide Residue Surveillance Samples, Percentage of Samples with Violative Residues, All Food Groups



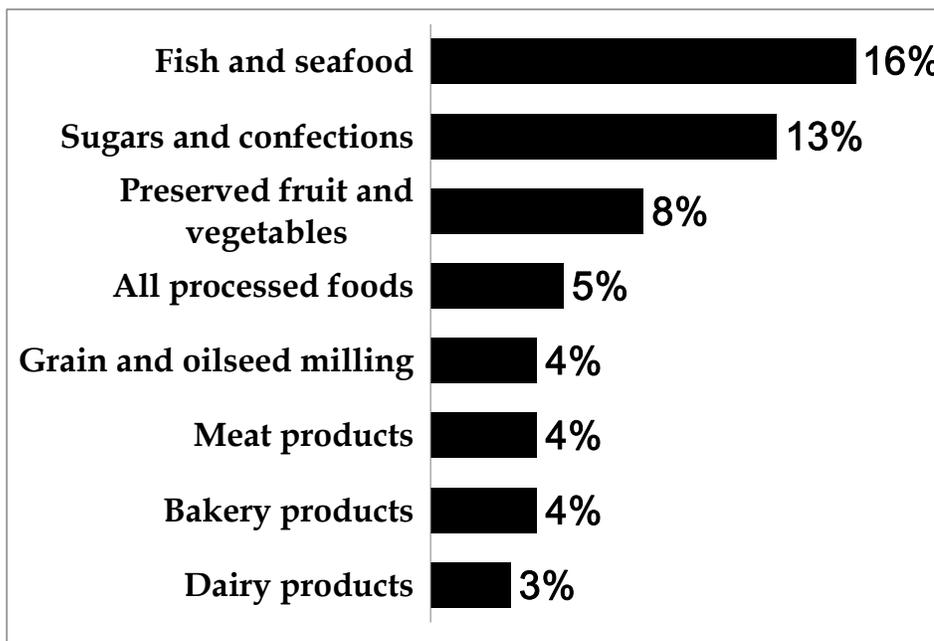
Source: Compiled by the author from FDA, Pesticide Program Residue Monitoring, annual reports 1995 through 2003.

**Exhibit 4. Pesticide Data Program, Marketplace Surveillance
Program Findings, 2006**

Food Group	Domestic	Imports	Total
Fresh Fruits and Vegetables			
Number of Samples	4,393	2,040	6,433
% with no residue	35.9%	37.6%	36.4%
% with residue below tolerance, legal	60.2%	58.2%	59.6%
% with residues and no established tolerance	3.5%	3.5%	3.5%
% with residue above tolerance	0.41%	0.59%	0.47%
Processed Fruits and Vegetables			
Number of Samples	2,968	417	3,385
% with no residue	39.0%	52.0%	40.6%
% with residue below tolerance, legal	58.5%	47.0%	57.1%
% with residues and no established tolerance	2.5%	1.0%	2.3%
% with residue above tolerance	0.0%	0.0%	0.0%
Peanut Butter			
Number of Samples	712	27	739
% with no residue	69.0%	92.6%	69.8%
% with residue below tolerance, legal	31.0%	7.4%	30.2%
% with residues and no established tolerance	0.0%	0.0%	0.0%
% with residue above tolerance	0.0%	0.0%	0.0%
Wheat Grain			
Number of Samples	687	0	687
% with no residue	30.9%	-	30.9%
% with residue below tolerance, legal	60.8%	-	
% with residues and no established tolerance	8.2%	-	8.2%
% with residue above tolerance	0.15%	-	0.15%
Poultry			
Number of Samples	1,310	-	1,310
% with no residue	92.8%	-	92.8%
% with residue below tolerance, legal	3.4%	-	3.4%
% with residues and no established tolerance	3.8%	-	3.8%
% with residue above tolerance	0.0%	-	0.0%
All			
Number of Samples	10,070	2,484	12,554

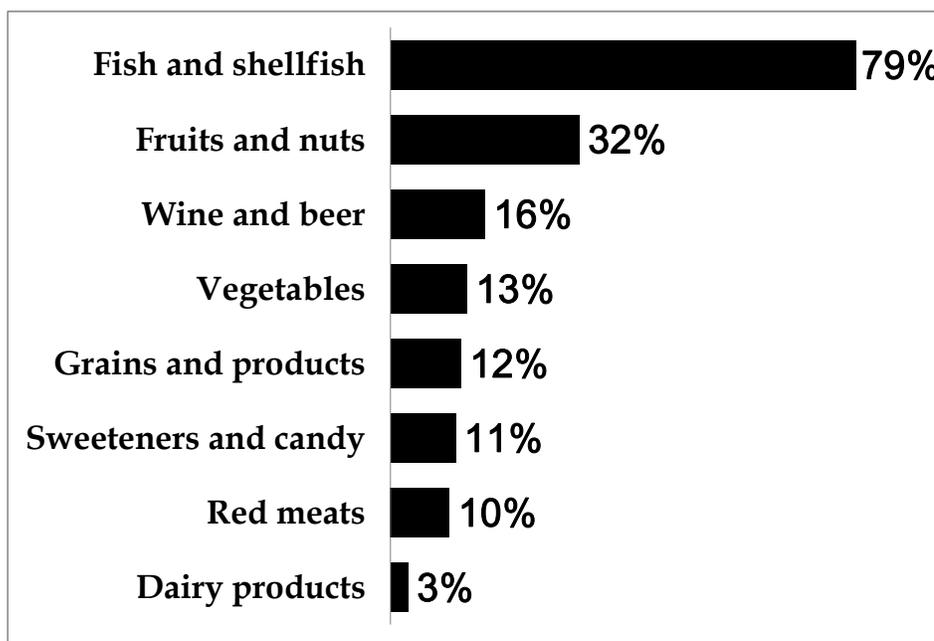
Source: Calculated by the author from 2006 data of the Pesticide Data Program, USDA, Agricultural Marketing Service, Science and Technology Program, December 2007, available at <http://www.ams.usda.gov/science/pdp/Download.htm>

**Exhibit 5. Import Shares of the Value of Domestic Food Consumption
by Key Food Group, 2005**



Source: U.S. Bureau of Census, Annual Survey of Manufactures.

**Exhibit 6. Import Shares of the Volume of Domestic Food Consumption
by Key Food Group, 2005**



Source: USDA, Economic Research Service.

Exhibit 7. Foodborne Illness Outbreaks Attributed to Produce, 1996-2006

Commodity	Outbreaks
Leafy greens	
Lettuce	14
Mixed lettuce	1
Romaine lettuce	4
Spinach	2
Cabbage	1
Basil or mesclun lettuce mix	2
Tomatoes	12
Melons	
Cantaloupe	7
Other melons	4
Raspberries and other berries	6
Herbs	
Basil	4
Parsley	2
Green onions	3
Almonds	2
Mango	2
Green grapes	1
Snow peas	1
Squash	1
Unknown	2
Total	71

Source: U.S. Food and Drug Administration.

Appendix A

Marketing Orders and Marketing Agreements, Old Mechanisms for Addressing Industry Needs, New Uses

Federal and state marketing orders or agreements are tools established in the 1930s to deal with the problems common in that era when farm prices were low and the farm structure was very atomistic, making it necessary to provide mechanisms for joint action. Growers still have open to them both voluntary and mandatory mechanisms for joining forces to pursue common goals. Marketing agreements are voluntary, in that firms are not compelled to participate, but once they sign up to an agreement they must contribute to the costs and requirements of the program. Marketing agreements can be organized at either the state or national level. In addition, there are “mandated-marketing programs,” including federal or state marketing orders, and state marketing commissions. Once these programs are approved by the required amount of growers and share of industry production volume, all firms in the industry must comply with their provisions, making them mandatory.

For a federal marketing program the production area can range from a part of a state to the whole United States; however, a state marketing program can only regulate activities within the state. Marketing orders allow growers to select from a variety of potential options in designing their program. For example, regulating grade, size, quality, packaging, inspection and/or volume handled; provision of production and marketing research, market development, and promotion activities. These are the primary activities for which they have been used, rather than as tools to manage food safety risk. A marketing agreement can cover anything allowed under a marketing order; but since an agreement is voluntary, not mandatory, it is not limited to just those activities, which make it more flexible.

The California Leafy Greens Marketing Agreement (CLGMA), a California State marketing agreement, demonstrates many of the principles of a marketing agreement. First, an industry must petition USDA’s Agricultural Marketing Service or state department of agriculture. The industry has to define the regulated commodity, production area, and activities. For example, for the CLGMA the regulated commodity is leafy greens, the production area is California, and the activity is auditing a minimum food safety standard, GAPs with specific metrics. Just as for federal and state marketing orders or agreements, USDA or state departments of agriculture do not draw up the food safety standards. But once they are developed, a marketing order or agreement can be used to audit the standards. Both marketing agreements and orders are administered by committees of representatives that are nominated by the industry and selected by USDA in the case of a federal marketing program and the state department of agriculture for a state marketing program.

For a marketing order, handlers are the regulated entity, but only growers vote to establish the marketing order. If the vote is sufficient (two-thirds of growers by number or volume), all handlers are regulated by the order. For a marketing agreement, the regulated entity is also handlers, but handlers, not growers, express interest in the agreement by signing up to

participate. For a marketing agreement, a particular sector of the industry is identified and if enough firms show interest, the USDA or state department of agriculture gives permission to establish the program. It is a voluntary program; only handlers that sign up for the marketing agreement are held to its rules. However, in the CLGMA case, if growers want to market via handlers who signed up for the marketing agreement they need to meet GAP audits. This is the first time a state or federal marketing program has affected production practices at the grower level indirectly through handlers. Handlers do not necessarily engage in production themselves but they are required to only handle product from growers who pass audits.

The CLGMA is not the first marketing program to be used to promote food safety. Several other produce industries – tomatoes, pistachios, and almonds – have used, or tried to use, Federal and State marketing orders or agreements to address new food safety problems. The process for using marketing programs for food safety is still evolving. The urgency of the California leafy green problem has led to a major shift in thinking with respect to marketing programs, with government officials only beginning to recognize their use as a tool to accomplish food safety objectives.

The first food safety provision in a marketing program for fruit, vegetables, or nuts was testing for aflatoxin in pistachios, a feature of the Federal peanut marketing order since 1967. AMS expanded its definition of quality for almonds to include a treatment (as opposed to testing) to kill *Salmonella*; the absence of this bacterium is considered a key component of quality. Treatment is still a postharvest activity within the purview of handlers. The CLGMA was the first to mandate audits of a production process.

Endnotes

- ¹ Goldman, L.R., M. Beller, and R. Jackson (1990), "Aldicarb Food Poisoning in California, 1985-1988: Toxicity Estimates for Humans," *Arch. Environ. Health*, 45, 141-147.
- ² NRC (1987), "Regulating Pesticides in Food: The Delaney Paradox," National Academy Press, Washington, D.C.
- ³ Natural Resources Defense Council (1989), "Intolerable Risk: Pesticides in Our Children's Food," National Resources Defense Council, Washington, D.C.
- ⁴ In February of 1989, *60 Minutes* did a segment alleging that the use of a hormone, Alar, on apples was causing cancer in children, showing bald children in hospitals undergoing cancer treatment, with the inference that Alar had caused their illness. There was an immediate and dramatic consumer reaction, with apple sales falling precipitously. In reality, research did not support this claim. But the connection between agricultural chemicals and children was drawn, influencing public policy for years to come.
- ⁵ NRC (1993), "Pesticides in the Diets of Infants and Children," National Academy Press, Washington, D.C.
- ⁶ Winter, Carl (2005), "Pesticides in Food," Chapter 11 In: Dabrowski, W.M. and Z.E. Sikorski, eds., *Toxins in Food*, CRC Press, Boca Raton, FL, pp. 251-268.
- ⁷ National Center for Health Statistics (2000), *Healthy People 2010*, Centers for Disease Control, available at <http://www.cdc.gov/nchs/about/otheract/hpdata2010/abouthp.htm>.
- ⁸ GAO (2008), "Federal Oversight of Food Safety: FDA's Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out is Critical," GAO Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, January 29, 2008, 15 pp. All subsequent references to GAO refer to this report, unless otherwise noted.
- ⁹ Egan, S. K. (2005), "U.S. FDA's Total Diet Study," presentation at the National Forum on Contaminants in Fish, September 18-21, 2005, Baltimore, MD.
- ¹⁰ Egan, S. K., Tao, S. S.-H., Pennington, J. A. T. and Bolger, P.M. (2002), "U.S. Food and Drug Administration's Total Diet Study: Intake of Nutritional and Toxic Elements, 1991-96," *Food Additives & Contaminants*, 19(2), 103-125.
- ¹¹ Winter, Carl (2005), "Pesticides in Food," Chapter 11 In: Dabrowski, W.M. and Z.E. Sikorski, eds., *Toxins in Food*, CRC Press, Boca Raton, FL, pp. 251-268.
- ¹² California, Colorado, Florida, Maryland, Michigan, Minnesota, Montana, New York, Ohio, Texas, Washington, and Wisconsin.
- ¹³ Agricultural Marketing Service (2007), "Pesticide Data Program. Annual Summary, Calendar Year 2006," USDA, available at <http://www.ams.usda.gov/science/pdp/Index.htm>.
- ¹⁴ California Department of Pesticide Regulation (2007), "2006 Residues in Fresh Produce," available at <http://www.cdpr.ca.gov/docs/enforce/residue/resi2006/rsfr2006.htm>.
- ¹⁵ Throughout the Total Diet Study's history serious food hazards have been detected and traced to their origin. For example, PCB's in breakfast cereals in 1971, high levels of iodine in dairy products, and in the late 1990s elevated levels of lead in certain baby foods and arsenic in peanut butter.
- ¹⁶ In 1997, then President Clinton announced the Produce and Imported Food Safety Initiative, which called for additional resources to improve domestic standards and to ensure that imports were equally safe.
- ¹⁷ CDC (2007), "Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly through Food - 10 States, 2006," available at <http://www.cdc.gov/foodnet>.

- ¹⁸ Centers for Disease Control (2008), "FoodNet News," *Emerging Inspections Program*, Volume 2, Issue 1, Winter 2008, 4 pp., available at http://www.cdc.gov/foodnet/news/2008/January_FoodNet_News.pdf.
- ¹⁹ Food and Drug Administration (2007), "Food Protection Plan," U.S. Department of Health and Human Services, 25 pp.
- ²⁰ Jerardo, Andy (2008), "What Share of U.S. Consumed Food is Imported?," *Amber Waves*, Economic Research Service of the USDA, Volume 6, Issue 1, pp. 36-37.
- ²¹ Krissoff Barry, Fred Kuchler, Kenneth Nelson, Janet Perry and Agapi Somwaru (2004), "Country-of-Origin Labeling: Theory and Observation," Electronic Outlook Report from the Economic Research Service, USDA, WRS-04-02.
- ²² Calvin, Linda, Fred Gale, Dinghuan Hu, and Bryan Lohmar (2006), "Food Safety Improvements Underway in China," Economic Research Service, USDA, *Amber Waves* 16(5), 16-21.
- ²³ Hirsch, Jerry (2008), "Trader Joe's Halting Some Chinese Imports," *Los Angeles Times*, February 12, 2008.
- ²⁴ Unnevehr, Laurian J. and Helen H. Jensen (1996), "HACCP as a Regulatory Innovation to Improve Food Safety in the Meat Industry," *Amer. J. Agr. Econ.*, 78, 764-769.
- ²⁵ Alberini, Anna, Erik Lichtenberg, Dominic Mancini, and Gregmar I. Galinato (2008), "Was it something I ate? Implementation of the Seafood HACCP Program," *Amer. J. Agr. Econ.* 90(1), 28-41.
- ²⁶ Antle, John M. (1999), "Benefits and Costs of Food Safety Regulation," *Food Policy* 24, 605-623.
- ²⁷ Antle, John M. (2000), "No Such Thing as a Free Safe Lunch: The Cost of Food Safety Regulation in the Meat Industry," *Amer. J. Agr. Econ.* 82, 310-322.
- ²⁸ Roberts, Tanya, Jean Buzby, and Michael Ollinger (1996), "Using Benefit and Cost Information to Evaluate a Food Safety Regulation: HACCP for Meat and Poultry," *Amer. J. Agr. Econ.* 78(5), 1297-1301.
- ²⁹ Pet food products were contaminated with melamine and melamine analogues used as substitutes for more expensive ingredients. The substitution was intentional although it is not clear that it was intended to inflict harm. Nevertheless the incident resulted in the sickness and deaths of cats and dogs, the recall of hundreds of brands of pet food products, and state quarantine or voluntary holds on livestock that consumed suspect animal feed. See Food and Drug Administration (2007), "Food Protection Plan," U.S., Department of Health and Human Services, 25 pp.
- ³⁰ European Union (2002), "Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002." *Official Journal of the European Community* L31, 1-24.
- ³¹ Bailey, DeeVon, Eluned Jones, and David L. Dickinson (2002), "Knowledge Management and Comparative International Strategies on Vertical Information Flow in the Global Food System," *Amer. J. Agr. Econ.* 84, 1337-1344.
- ³² Pouliot, Sebastien and Daniel A. Sumner (2008), "Traceability, Liability, and Incentives for Food Safety and Quality," *Amer. J. Agr. Econ.* 90(1):15-27.
- ³³ U.S. Department of Health and Human Services and U.S. Department of Agriculture (2005), "Dietary Guidelines for Americans 2005."
- ³⁴ Lucier, Gary and Jerardo, Alberto (2007), "Vegetables and Melons Situation and Outlook Yearbook," VGS-2007, Economic Research Service, USDA.
- ³⁵ Center for Food Safety and Applied Nutrition (2008), "Guide to Minimize Microbial Food Safety Hazards of Fresh-Cut Fruits and Vegetables," U.S. Department of Health and Human Services, Food and Drug Administration, OMB Control No. 0910-0609.
- ³⁶ Institute of Food Technologists and FDA (2001), "Analysis and Evaluation of Preventative Control Measures for the Control and Reduction/Elimination of Microbial Hazards on Fresh and Fresh-Cut Produce," available at <http://www.cfsan.fda.gov/~comm/ift3-toc.html>.

³⁷ Economic Research Service (2007), "Vegetables and Melons Situation and Outlook Yearbook," VGS, USDA, p. 86.

³⁸ The Food Marketing Institute, which owns the franchise rights to the Australian food safety program Food Quality Safety (SQF) decided to endorse the CLGMA Best Practices in spring 2007. The National Restaurant Association also decided to endorse the CLFMA Best Practices. In fall 2007, the Food Safety Leadership group, which includes Wal-Mart, Disney, Darden, McDonald's Avendra, and Publix as members, developed an alternative set of food safety standards which are generally considered more costly than the CLGMA Best Practices. There is hot debate over whether these standards further reduce risk. It is not yet clear who may require these standards. If buyers are willing to enter into contracts with firms to provide leafy greens produced to their specifications at a price that is profitable to both sides there is no problem. Growers and handlers have always had to respond to a range of food safety demands from buyers; so the Food Safety Leadership's standards are nothing new in concept, the question is what is the cost/benefit ratio for these measures and who pays for them.

³⁹ Food Marketing Institute (2007), "US Grocery Shopper Trends 2007," available at www.fmi.org/forms/store/ProductFormPublic/search?action=1&Product_productNumber=2168.