An Assessment of Food Safety Policies and Programs for Fruits and Vegetables: Food-borne Illness Prevention and Food Security

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Introduction

On September 13, 2006 the Centers for Disease Control and Prevention (CDC) alerted the U.S. Food and Drug Administration (FDA) of a multi-state Escherichia coli (E. coli) O157:H7 outbreak that appeared to be associated with the consumption of bagged spinach. The FDA subsequently notified the California Department of Health Services, Food and Drug Branch (CDHS). The FDA San Francisco District Office and CDHS working jointly as the California Food Emergency Response Team (CalFERT), initiated an investigation to determine the source of the contaminated spinach.[1] By the time the out break was contained 227 people had become ill across the United States, 104 had been hospitalized, 31 had developed serious complications from hemolytic-uremic syndrome and 3 had died (Figure 1). In addition to the toll on human health the fresh spinach industry experienced significant negative economic effects despite the fact that the outbreak could only be conclusively linked to spinach grown in one field in California (Figure 2).

The recent outbreak linked to spinach is not unique. Over the past 12 years 22 leafy green outbreaks associated E. coli O157:H7 have occurred. Of the 12 that have been traced, all 12 indicate a California source of the leafy greens.[2] Other products, both domestically produced and imported, have also been linked to other food-borne illness such as salmonella and hepatitis. Since the mid 1990's outbreaks have occurred that were linked to raspberries, green onions, and strawberries. In part as a reaction to these events increased efforts to enhance food safety have been undertaken by the government and associated industries groups. Efforts have focused on increased scrutiny of imported products and the improvement in domestic standards.[3] In some cases product standards have been establish tolerance levels for certain pathogens, in other cases process standards have been adopted that address activities related to the production and handling of products designed to reduce the potential for contamination.[4] In this paper I focus on the role of process standards.

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[1] California Emergency Response Team. "Investigation of an E-coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach", Final, March 21, 2007.

[2] Cassens, Barbara. "Produce Safety An FDA District Office Perspective", 2008 Ag Safe Conference.

[3] Calvin, Linda. Produce, Food Safety, and International Trade, AER-828, USDA, ERS, November, 2003.

[4] For example California pistachio growers imposed standards on aflatoxin limits within the context of a marketing order in August, 2005. Alston, et. al "Economic Consequences of Mandated Grading and Food Safety Assurance: *Ex Ante* Analysis of the Federal Marketing Order for California Pistachios", Gianni Foundation Monograph, No. 46. In another example the requirements for the pasteurization of Almonds is a case where process standards create a product standard.

A great many resources continue to be invested to establish system standards to address concerns regarding food safety and food protection at all levels of the supply chain. However, at the present time the proliferation of these standards, guidelines and certification programs has created a situation some have likened to an “arms race” to prove who is providing the safest food and hopefully capitalize on a perception of related consumer preferences. In the absence of one universally accepted set of standards producers and food providers are often faced with having to comply with a different set of standards for different customers resulting in increased costs with little evidence of a corresponding increase in compensation in the form of higher product prices.

The current labyrinth of food safety and protection standards being promoted by international organizations, national governments, private sector retail food sales, food processors and producers has a common foundation. All of these standards apply to four basic areas and how agricultural producers and handlers accommodate potential biohazards related to them: soil, water, animals and people. To better understand the complementarities and conflicts it is useful to look at how each approaches these four areas.

The paper then focuses on the plight of the producer within this environment. I first provide an overview of issues facing producers operating within a variable food safety standards environment. Next an illustration of variations across standards in guidelines for the handling of generally accepted hazardous components is provided. A brief discussion of the role of traceability systems in food safety process standards is then provided. The costs associated with compliance with the various process standards and guidelines are then discussed.

The paper concludes with a summary of the current situation for the North American fresh produce industry from the multi-layered attempts to enhance food safety and security through the adoption of and/or imposition of alternative product and process standards. Conclusions on areas where work is necessary to minimize existing and/or potential areas of confusion and conflict and suggestions regarding possible courses of action are provided.

Implications of Conflicting Process Standards for North American Agricultural Producers

The current maze of alternative process standards is a concern. An example of the situation currently characterizing the conflicts within the new programs and policy proposals for the produce industry are summarized by Tom Nassif, president and chief executive officer of Western Growers. A consortium of major produce buyers, the Food Safety Leadership Council, set of food safety standards, many which exceed current practices under California's Leafy Greens Agreement. For instance, the council advocates a minimum buffer between grazing livestock and growing fields. It requires concentrated animal feedlots to be separated from produce fields by a minimum one-mile buffer. Nassif responded to the council’s ideas in a Nov. 6 letter to Garry Bergstrom of Publix Super Markets. "We believe that the new standards are unreasonable, excessive and

scientifically indefensible and will require produce suppliers to submit to redundant, expensive and unnecessary food safety inspections and audits," Nassif wrote.

Nassif took issue with a wide range of council actions and asked Bergstrom to explain in greater detail the purpose and justification for them. "Your effort marks the beginning of a destructive food-safety 'arms race,' where different groups of produce buyers, in an effort to claim that they have safer produce than the next, will impose on fresh-produce suppliers ever more stringent, expensive and scientifically indefensible food safety requirements without even the implication that the additional costs will be reimbursed", Nassif stated.

An example of the costs of compliance associated with programs required by some private standards is provided by Jack Vessey, Vice President and Marketing Director for Vessey & Company, a grower packer shipper in Coalinga and El Centro California established in 1910. Pointing out just one element of processors requirements, tapping stations, Mr. Vessey illustrates the cost of doing business in today's market. For one processor there is a requirement to have a rodent trapping station every 50 feet. For a 7,500 acre vegetable operation such as Vessey & Co. that would equal 16,000 stations at $30 per station, or an investment of $480,000. In addition each station is required to be monitored twice weekly and a log kept of rodent activity. Overall Vessey estimates that the trapping station requirement alone cost around $100 acre, representing a $0.15 per pound increase in the cost of spinach and spring mix and a minimum of $1.25 per carton on other items.

An example from Grimmway Farms, a leading California produce company, demonstrates the lengths that companies currently go to insure credibility in the minds of customers with regard to their compliance with food safety standards. Grimmway reports it is a founding member in the USDA Qualified Through Verification Program, has third party audits from AIB, Siliker Labs, Scientific Certified Systems and Davis Fresh Technologies. Their good agricultural practices reportedly include monthly self-audits, quarterly third party program audits, and an annual intensive 3 day third party audit. Each field is audited prior to harvest. All new contracted growers must complete a self-audit as part of their contract. Audit reports may be reviewed by an additional third party. Mock recalls are completed and documented often, with one of five most probable scenarios. And a new isolated Pathogen Laboratory for environmental testing provides us with results in 24 to 48 hours.

Internationally developing countries struggle to implement systems to insure food safety in the face of growing concerns over the quality of imported agricultural products. For example, in China if passed by the Standing Committee of the National People's Congress (NPC) a part of a new draft food safety law will include a legal obligation for all food companies to have a system in place that assigns a unique code to every product, allowing every stage of a product's production and distribution cycle to be tracked. Consumers would be able to get information about the products they buy via the Internet. However, food companies argue that the system will increase their production costs. More than 20 firms, including Nestle, Mars, Coca-Cola and Pepsico, have submitted a

joint petition against the system to the legislative affairs commission of the NPC Standing Committee and State Council Legislative Affairs Office. And more importantly they question if the system will really enhance product safety as it does not deal directly with the quality of raw material inputs.

Despite conflicting views from producers and lack of consistency in the approach to implementation and financing of food safety systems there appears to be a commitment to go forward. For example, the U.S. and Canadian Produce Management Associations have banded together, in cooperation with industry and standards bodies, to focus on developing information standards that will enable a rational transition to whole-chain traceability in North America and internationally. At the heart of this effort is the recognition that true safe and secure food system requires a common language of information across the global supply chain.

Comparison Among Standards: Producer, Industry and Government

Standards applied to farm level activities are built around the establishment risk assessments and foundation programs such as standard operating procedures (SOPs), good management practices (GMPs), sanitation operation procedures (SSOPs), etc. As described earlier these standards can be initiated voluntarily by producer groups, be required as a condition by purchasers or be part of a government imposed mandate at either the state, national or international level. These programs and procedures are required to be documented to allow for an accounting (audit) of how well the firm is performing relative to its established protocols. For example, the Global Food Initiative Guidelines established by the Food Business Forum provide detail information on what should be included in a firm's food safety management system[5]. A CIES conforming food safety management system must: be documented, implemented, maintained and continually improved. In addition, the food safety management system should: a) identify the processes needed for the food safety management system; b) determine the sequence and interaction of these processes c) determine criteria and methods required to ensure the effective operation and control of these processes; d) ensure the availability of information necessary to support the operation and monitoring of these processes; e)

[5] **C**omité **I**nternational d'**E**ntreprises à **S**uccursales **(**CIES) - The Food Business Forum is the only independent global food business network. It serves the CEOs and senior management of nearly 400 members, over 150 countries, with retailers being the largest single group. In May 2000, a group of international retailer CEOs identified the need to enhance food safety, ensure consumer protection and to strengthen consumer confidence. They proposed a program which would set requirements for food safety schemes and improve cost efficiency throughout the food supply chain.

measure, monitor and analyze these processes and implement action necessary to achieve planned results and continual improvement.

In a more recent example, the Food Safety Leadership Council provided the set of on farm food product standards discussed earlier.[6] First among those standards was the requirement that the grower, harvester and/or packer have a documented Good Agricultural Practices (GAPs) program. In addition, growers are required to have a person responsible for the supervision of the programs. Monthly self-inspections to monitor the GAPs and food safety compliance are also required.

The current labyrinth of food safety and protection standards being promoted by international organizations, national governments, private sector retail food sales, food processors and producers has a common foundation. All of these standards apply to four basic areas and how agricultural producers and handlers accommodate potential biohazards related to them: soil and soil amendments, water, animals and people. The level of activity required to be in compliance with these standards is varied. In some cases the standards are recommendations for establishing plans of action, and what they may include. In other cases the standards may include quantitative measures of tolerances that must be met for certain inputs. To better understand the complementarities and conflicts it is useful to look at how the various standard setting bodies approach these four potentially hazardous areas and their interactions.

To provide an example of the differences currently facing agricultural producers the provisions of four different standards were examined. Each set of standards represents guidelines and requirements associated with different levels organizational authority. The guidance for industry provided by the U.S. Food and Drug Administration represents the national level authority.[7] The Commodity Specific Food Safety Guidelines for the Lettuce and Leafy Green Supply Chain provides an example of a voluntary grower, packer, and shipper initiative. The Food Safety Leadership Council On-Farm Produce Standards represent the views of a group of buyers for retail sales group. An international standards perspective is provided by the set of GlobalGap standards.[8] GlobalGap is a pre-farm-gate standard, which means that the certificate covers the process of the certified product from farm inputs like feed or seedlings and all the farming activities until the product leaves the farm. The goal of this section is to help identify the area of commonality among the various processed standards as described in the Knutson and Josling discussion (Figure 3).

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[6] The Food Safety Leadership Council is an industry group composed of Avendra LLC, Darden Restaurants, McDonald's Corp., Wal-Mart Stores Inc., Walt Disney World Co. and Publix Super Markets.

[7] US FDA guidelines for GAPs are recognized as the standards for USDA Qualified Through Verification program. The OTV program is a voluntary program designed to verify the suitability of a firm's Hazard Analysis Critical Control Points (HACCP) food safety system.

[8] GLOBALGAP (EUREPGAP) is an open system, where any producer can apply and receive certification when complying with the objective criteria set out.

Standards Associated with Soil and Soil Amendments

The incorporation of soil amendments that add organic and inorganic nutrients to the soil as well as reduce compaction are a common cultural practice. The composition of these soil amendments often include animal manures that contain human pathogens that may survive for weeks or even months. Soil and soil amendments are a particularly sensitive area because of the vulnerability to contamination of low growing crops like lettuce and leafy greens. These crops may be splashed with soil during irrigation and heavy rainfall or windfalls. Accordingly the need to have an effective set of controls in place to minimize the microbial hazards to the crop from such pathogens is critical.

Standards under the GlobalGap system are ranked in terms of major musts, minor musts, and recommendations. To gain GlobalGap certification 100% compliance of all applicable major must control points is compulsory. For minor musts control points, 95% compliance is compulsory. No minimum percentage compliance statistic is set for all recommendation control points.

With regard to soil management GlobalGap Standards address soil fumigation and the use of soil amendments. When soil fumigants are used a minor must compliance standard requires that there is written evidence and justification for their use including location, date, active ingredients, method of application and the name of the operator. It is also necessary to record any pre-planting interval. In addition, Methyl Bromide use is not permitted as a soil fumigant.

For soil amendments GlobalGap major must requirements include that the methods used to sterilize amendments be documented including the date, name and location where sterilization takes place, etc. As with fumigants the pre-planting interval must also be recorded.

In contrast to the GlobalGap standards the US-FDA provides little direct specificity in its guidance to industry regarding soil and/or the use of soil amendments. The FDA addresses the use of manure or biosolids, including solid manure, manure slurries, and manure tea. In their recommendations FAD suggest GAPs for their use includes treatment to reduce pathogens and maximizing the time between application and harvest. However, within the broad recommendations for what constitutes GAPs with regard to soil and soil amendments are quite specific rules and regulations that apply from other agency controls.

For example, the maze of regulatory authority and oversight regarding acceptable practices is illustrated by the FDA guidelines for application of biosolids in crop production. The FDA defers to the U.S. Environmental Protection Agency.[9] Under EPA regulations land application of biosolids are subject to strict requirements concerning

[9] Under the authority of Section 405(d) of the Clean Water Act as amended, the U.S. Environmental Protection Agency (EPA) promulgated, at 40 *Code of Federal Regulations (CFR)* Part 503, Phase I of the risk-based regulation that governs the final use or disposal of sewage sludge.

levels of pathogens and nutrients in the material, the determination of agronomic application rates, in all the application of biosolids is subject to an extensive set of standards included in a 105 page guide for land appliers.[10]

The FDA handles guidelines for good agricultural practices for manure management in a more direct manner. The FDA suggests a variety of treatments that may be used to reduce pathogens in manure and other organic matter. Passive treatments such as making sure products are well aged and decomposed before being applied to fields are suggested. Active treatments such as pasteurization, heat drying, anaerobic digestion, alkali stabilization, aerobic digestion or a combination of these practices are addressed. Providing specific time and temperature specifications that should be followed in composting and other manure treatment operation is declared to be beyond the limits of the agency.

The guidelines required by companies who are signatories of the California Leafy Green Products Handler Marketing Agreement (LGMA) are more rigorous than those provided by the FDA but less detailed than EPA standards governing the use of biosolids. The LGMA begin with suggestions regarding the performing of a pre-plant assessment of production fields and surrounding areas. Best practices are provided that include prohibition on the use of raw manure or soil amendment that contains un-composted, incompletely composted or non-thermally treated animal manure on fields used for lettuce or leafy green production. Composted soil amendments are approved for use only prior to the emergence of plants. Composting heat, time and processing procedures are detailed in the guidelines. To use composted soil amendments the specific tolerances for fecal coliforms, salmonella and e. coli must be met. In addition to acceptable criteria, recommended testing methods, sampling procedures, testing frequency intervals, application intervals and appropriate documentation procedures are outlined in the standards.

The Food Safety Leadership Council On-Farm Produce Standards (FSLC) has a variety of requirements that pertain to the fields where crops are to be grown. For example, the standards call for fields that have been used for purposes other than growing produce to be tested and be documented to be within unspecified EPA, state or local regulatory limits for contaminants.[11] Where fields are flooded, the product is not to be harvested for human consumption. Documented monitoring programs are required to insure that fields and surrounding areas are free of miscellaneous trash and debris.

With regard to soil amendments the FSLC provides a detail set of requirements. Raw or incompletely composted manure, biosolids or leachate from raw manure must not be used. For manure to be used it must be composted or aged per the Code of Federal Regulations 40 CFR 503.32. Acceptance criteria for composted soil amendments outlined in the standards are consistent with those outlined in the LGMA standards. One exception is the standard for fecal coliform which is < 10 MPN/gram compared to the

[10] EPA/831-B-93-002b

[11] No lists of specific contaminants or corresponding tolerance levels are provided.

LGMA standard of < 1000 MPN / gram. The FSLC prohibits the use of biosolids as a soil amendment for the production of lettuce and leafy greens. Conditions for application intervals of >45 days before harvest are consistent with LGMA standards.

Standards Associated with Water

There is a major emphasis on the role of water quality management across all sets of standards due largely to the inherent potential for pathogen contamination during the numerous field operations involved in crop production (e.g., irrigation, application of pesticides and fertilizers, cooling and frost control). While crops can be contaminated from exposure to water of inadequate quality during production or during the packing and/or processing stage the focus here is on irrigation water. Results from the investigation of recent foodborne illness outbreaks confirm that it is difficult to identify with certainty the cause of contamination. However, there is research that suggests contaminated irrigation water can increase the frequency of pathogen transfer in crop production.[12]

GlobalGap acknowledges that water quality must be determined to be fit for irrigation based on local authority standards. If there are no local standards a major must criteria states that then a test from a laboratory capable of performing chemical and/or microbiological analyses up to ISO 17025 level or equivalent standards is required.[13] The results of the test must be available and show that the water complies with the criteria established by the World Health Organization Health and Guideline for the use of wastewater in Agriculture and Aquaculture. Untreated sewage water is not permitted for use as irrigation water. A minor must requirement calls for an annual risk assessment to consider the potential microbial, chemical or physical pollution for all sources of irrigation/fertigation water. Where corrective actions were required records of those actions must be maintained.

The FDA standards for water quality begin with a recognition that it is important to consider the source and distribution of water used including rivers, streams, irrigation

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[12] Solomon E.B.1; Pang H-J.1; Matthews K.R. Persistence of Escherichia coli O157:H7 on Lettuce Plants following SprayIrrigation with Contaminated Water Journal of Food Protection®, Volume 66, Number 12, 1 December 2003 , pp. 2198-2202(5) International Association for Food Protection; Marina Steele1; Joseph Odumeru1Irrigation Water as Source of Foodborne Pathogens on Fruit and Vegetables Journal of Food Protection®, Volume 67, Number 12, December 2004 , pp. 2839-2849(11) International Association for Food Protection; Norman, N.N. and P.W. Kabler, Bacteriological Study of Irrigated Vegetables. Sewage and Industrial
Wastes 25:605-609, 1953. 6. Dunlop, S.G. and W.L.L. Wang. Studies on the Use of Sewage Effluent for Irrigation of Truck Crops. Journal of Milk Food Technology [24:44-47, 1961.]

[13] ISO/IEC 17025 is the main standard used by testing and calibration laboratories. Originally known as ISO/IEC Guide 25, ISO/IEC 17025 was initially issued by the ISO in 1999. There are many commonalities with the ISO 9000 standard, but ISO/IEC 17025 adds in the concept of competence to the equation. There are two main sections in ISO/IEC 17025 - Management Requirements and Technical Requirements. Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory. Technical requirements address the competence of staff, methodology and test/calibration equipment.

ditches and open canals; impounds such as ponds, reservoirs, and lakes; groundwater from wells; and municipal supplies. The general assumption is that ground water is less susceptible to contamination than surface water. Specific standards or statistical compliance measures for agricultural water are not provided. The FDA guideline document suggests that there are a number of gaps in the science upon which a microbial testing program and such test may be of limited usefulness.[14] The guidelines suggest that growers may elect to test their water supply for standard indicators of fecal pollution such as E. coli, noting that bacterial safety does not necessarily indicate the absence of protozoa and viruses. Rather, growers are urged to first concentrate their attention on good agricultural practices to maintain and protect the quality of their water source.

Good agricultural practices to address agricultural water concerns suggested by the FDA guideline include a review of potential sources of water contamination from existing conditions such as animal pasturing in growing areas, manure storage adjacent to crop fields, leaking or overflowing manure lagoons; uncontrolled livestock access to surface waters, wells or pump access, and high concentrations of wildlife. Other areas of concern are local rainfall patterns and field topography that might result in runoff from animal feed locations into water sources. All potential hazards must be assessed and to the extent possible control measures established.

The LGMA guidelines for water used in production and harvest include a mix of suggested good agricultural practices and specific statistical tolerances for certain test results to measure water quality. The best practices call for the preparation of a water system description that communicates the location of all permanent fixtures and the flow of water through the entire system. Permanent fixtures include wells, gates, reservoirs, values, returns and all things that make up a complete irrigation system. With the help of the system description the guidelines that irrigation water and water used in harvest operations be tested as close to the point of use as possible. Test results are subject to specific numerical tolerances and documentation of test results and/or Certificates of Analysis are to be retained for inspection for a period of two years.

The specific tests and tolerances required under the LGMA include a test for generic E. coli, where a 100ml sample is to be taken at the point of use such as one sprinkler head per water source for irrigation or water tap for pesticides, etc. Samples should be collected at least monthly. For wells and municipal water sources if generic E. coli test are below detection limits for five consecutive samples, the sampling frequency may be reduced to once every six months. Such test are to be conducted using the 15 tube MPN (FDA BAM) or other U.S. EPA, AOAC, or other method accredited for quantitative monitoring of water for generic E. coli. The acceptance criteria is ≤126 MPN/100 mL (rolling geometric mean n=5) and ≤ 235 MPN/100mL for any single sample.[15]

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[14] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition, "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, page 12, October, 1998.

[15] Most Probable Number (MPN); Bacteriological Analytical Manual (BAM); Association of Official Agricultural Chemists (AOAC)

If water testing indicates that a crop has been directly contacted with water exceeding the acceptance criteria, the products are to be sampled and tested for E. coli O 157:H7 and Salmonella. If the crop testing indicates the presence of either pathogen the crop shall not be harvested for human consumption.

The standards imposed by the FSLC guidelines for irrigation water are similar to those adopted by the LGMA, however some statistical tolerances are more restrictive. The FSLC guidelines also call for a mapping of all water sources along with the development of a written SOP that outlines the process of sampling all irrigation water that includes requirements that each water source be tested within 60 days of its first seasonal use, with samples taken as close a possible to the point of use and continued to be sampled every 30 days. Water that fails to meet FSLC standards can not be used for irrigation or used to deliver foliar sprays. In addition, water used to control dust on dirt roads within the growing area must also meet these standards.

The specific standards imposed by the FSLC for irrigation well water indicate that a test result for generic E. coli of ≤ 1.1 MPN/100 mL is acceptable. Well water with test results of ≥ 1.1 MPN/100 mL is unacceptable and requires immediate documented corrective and preventative action, the water is not to be used for irrigation. Such test are expected to be conducted in accordance with the Standard Methods for the Examination of Water and Wastewater, 21st Edition, publish by the American Public Health Environment Association, American Water Works Association & Water Federation, 2005.

Standards for irrigation water from surface sources are based on a rolling geometric mean sample with testing five consecutive days with at least 18 hour intervals between samples and monthly routine testing to follow. Water is acceptable with generic E. coli test results of < 1.1 MPN/100 mL. Water with test results that fall in the interval of ≥ 1.1 MPN/100 mL but <126 MPN/100 mL and negative for pathogens is conditional and requires immediate corrective and preventative actions. If test results are ≥ 126 MPN/100 mL or positive for pathogens the water may not be used for irrigation or dust control.

Standards Associated with Animals

The potential environmental risk factors involving animals, domestic and wild, in the transfer of pathogens such as E. coli O 157:H7 are for the most part linked to runoff from animal feeding operations or large concentrations of grazing livestock, and/or the presence wild species such as deer or feral pigs which deposit feces in growers' fields, exposed surface waterways and in the proximity of irrigation wells. Standards and regulations to minimize such risks take the form of guidelines for good agricultural practices rather than statistical compliance standards as in the case of water and soil amendments. However, in some cases the requirements imposed may be significantly restrictive in terms of where crops may be grown and at odds with policy goals related to the promotion of wildlife habitat and/or riparian buffers for erosion control and promotion of biodiversity.

GlobalGap standards for crop production do not directly address potential hazards associated with animals. It is assumed that critical control points where animal intrusion may result in environmental contamination are covered in standards related to specific controls on water quality, handling product contaminated by fecal matter, etc.

The FDA recognizes the potential hazards associated with animal waste and suggest that growers conduct an initial assessment of existing practices and conditions to determine the likelihood of significant amounts of uncontrolled deposits of animal feces in growing fields. If such conditions exist the FDA guidelines provide several suggested good agricultural practices to assist in minimizing the potential risk. It is recommended that domestic animals, such as cows or sheep, be prevented from entering fields either by being confined in pens or yards or by means of physical barriers such as fences. If an assessment of the surrounding areas reveals the potential for cross contamination during heavy rains physical barriers such as ditches, mounds or other means should be considered as possible measures for protection.

The FDA is less helpful in providing potential solutions to possible problems associated with the presence of wild animal population. Good agricultural practices suggested include visual, auditory, or physical deterrents to redirect wildlife such as deer or waterfowl and/or growing border crops or maintaining buffer areas between growing fields. It is pointed out that any measures undertaken be in compliance with Federal, State, or local animal protection requirements.

The LGMA standards provide more specifics regarding measures growers should utilize to minimize the risk associated with animal activity, wild or domestic, in a field. The LDMA guidelines also point out the need to be cautious when using general measures such as fencing, vegetation removal and destruction of habitat due to possible conflict with local, state, and federal laws regulating riparian habitat, restrict removal of vegetation or habitat, or restrict construction of wildlife deterrent fences in riparian areas of wildlife corridors.

The LGMA standards require that growers look for evidence of intrusion by animals by having a periodic monitoring plan in place for production fields with pre-season, pre-harvest and harvest assessments. The list of variables to monitor include physical presence of animals in the field, downed fences, animal tracks in production blocks, animal feces or urine in production blocks and eaten plants. Animals considered to be of particular interest include deer, pigs, cattle, goats and sheep. If evidence is encountered the standards require that corrective action be taken, documented and records maintained for two years.

In addition, the LGMA standards provide direction for how to proceed in the event of the discovery of evidence of intrusion. No crop is to be harvested that has come into direct contact with fecal material. Where fecal matter is detected no crop is to be harvested within a minimum five foot radius buffer from the point of contamination. Where evidence of intrusion in the form of tracks or disturbed vegetation no product should be harvested within a three foot buffer radius.

With regard to concentrated animal feeding operations (CAFO), the LGMA standards recommend a 400 foot buffer between the operation and the growing field.[16] Due to what is called a lack of science, buffer distances are to be adjusted based on judgments regarding relative risk of contamination. Factors to be considered include topography of the crop from the CAFO, possibility of soil leaching, water run off, etc. Grazing land and homes or other buildings with septic leach fields should be no closer than 30 feet from the edge of the crop field. Well heads should be a minimum of 200 feet from untreated manure. Untreated manure should not be located closer that 100 feet to surface water sources in sandy soils, and 200 feet in loam or clay soils (if land slopes away from fields are less than 6% that distance should be increased to 300 feet).

The FSLC standards also contain specific requirements regarding how growers should deal with the threat of contamination from animal sources. A general ban on animals of significant public health concern (domestic or wild including livestock, dogs, horses, pigs, deer, etc) in growing areas is required. If animals gain access to growing fields immediate corrective action is required and a report of that action must be completed and retained for inspection. A minimum ¼ mile buffer zone is required between animal grazing adjacent to growing fields while at least a one mile buffer is required for CAFOs except in cases where a variations are based on a completed risk assessment.

Standards Associated with Worker Hygiene

Most cases of foodborne illness associated with fresh produce have been linked to contamination from contact with fecal material. However, infections diseases are also a potential source of pathogen transfer. Accordingly the importance of worker hygiene and training is a common element in most guidelines, standards and regulations governing best agricultural practices to minimize the risk of pathogen contamination.

GlobalGap standards call for a hygiene risk analysis to be performed, documented and updated annually as a major must condition that contains consideration of human transmissible diseases. Another major must condition is that there is evidence that workers receive training regarding personal cleanliness and clothing, e.g. hand washing, wearing of jewelry, fingernail length, etc. In addition, evidence that workers are provided written (in appropriate languages) and/or pictorial instructions to prevent product contamination is a major must. The presence of fixed or mobile toilets within 500 meters of growing fields is also required as a minor must condition.

The FDA guidelines associated with worker health and hygiene begin with a call for operators (domestic and foreign) to consider the standards contained in the U.S. Code of Federal Regulations (CFR) Title 21, Section 110.10 (21 CFR 110.10) prescription for worker health and hygienic practices within the context of packing or holding of human food when establishing practices appropriate for the agricultural environment. Training is

[16] Animals feeding operations (AFOs), are operations where animals have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12- month period. Concentrated AFO's are those where the number of animals is of a certain size. (over 200 mature dairy cows, 750 swine, etc.).

an integral part of the FDA guidelines. Operators are urged to consider establishing a training program that provides all employees a good working knowledge of basic sanitation and hygiene principles. Operators are also encouraged to become familiar with the typical signs and symptoms of infection diseases.[17] The FDA also emphasizes that good field sanitation helps reduce the potential for contaminating products and that operators should conform to the Occupational Safety and Health Act 29 CFR 1928.110 subpart I in regard to the proper number of toilets to the number of workers, proper hand washing facilities, maximum worker-to-restroom distance and how often such facilities should be cleaned. As described, there is no lack in specificity with regard to government guidelines for good management practices when it comes to worker hygiene related issues.

The LGMA identify the transfer of human pathogens during the harvest process as a potential source of significant public health concern and suggest that it may be additionally difficult to control as workers may be asymptomatic. The best practices identified as appropriate preventative measures concentrate on training and having written standard operating procedures (SOPs) and prevention programs. It is recommended that areas including worker practices, worker physical hazard prevention, worker health and field sanitary facilities be covered by such SOPs. For example guidelines for a field sanitary programs call for addressing issues such as: the number, condition and placement of field sanitation units, the accessibility of the units to the work area, facility maintenance, facility supplies, facility signage, facility cleaning and servicing and a response plan for major leaks and spills.

The FSLC standards are also explicit in their recognition of worker health and hygiene and field sanitation and facilities as major areas of concern in food safety. The FLC standards include 19 specific conditions for compliance related to worker health and hygiene. Requirements include the need for employees to be in "good health" with no obvious signs of open cuts, sores, rash, wounds or communicable disease. Training programs for employees require signed acknowledgement of understanding of company policies regarding personal health, hand washing, field sanitation standards, food safety, food security and good agricultural practices and that failure to comply with such policies will result in disciplinary action up to and including termination. Field sanitation and facility requirements include providing one stationary or portable toilet facility for every 20 employees per gender placed within ¼ mile of all workers. Where there are more than five employees separate toilet facilities for each sex are required. Other areas covered by specific requirements include facility maintenance and handling of waste and rinse water.

Traceability

An additional requirement common to all the different layers of standards just described is the ability to provide information and link certain attributes of the production process to individual products or groups of products. The degree of traceability requirements

[17] Operators are referred to FDA Food Code Ref. 4 pertaining to food establishment inspection for program planning and training on general worker health and hygiene

varies among the standard bodies but in each case it is identified as an essential element for compliance or as part of recognized good agricultural and management practices.[18] One driving force behind the need for such systems in the USA, the Bioterrorism Act of 2002 calls for one-up/one-down traceability for each link in the supply chain.[19] While growers are specifically exempt from the provisions of the Act, the requirements on their buyers puts additional pressure on producers to be able to supply the necessary information.

More evidence of the importance of traceability and the need to develop consistency throughout the supply chain is highlighted by the ongoing efforts of the Produce Traceability Initiative, an industry-led effort to adopt traceability throughout the produce supply chain, launched in October 2007 by United Fresh Produce Association (United Fresh). Produce Marketing Association (PMA) and Canadian Produce Marketing Association (CPMA). Guided by a steering committee composed of more than 40 companies and eight trade associations, including representation from the buying and selling community, the group is attempting to find a systematic and consistent way to apply a set of common standards across the supply chain to enhance chain-wide traceability beyond the many traceability components of existing standards and individual company programs. At the present time the focus of the U.S. and Canadian effort is the application of global trade item numbers (GTINs) in use on reduced space bar coding applications (GS1 Data Bars).[20] Used in combination the ability to provide a variety of information on an individual product and/or grouping of like products is enhanced beyond the existing Universal Product Code (UPC) nomenclature.

The breath of current standards and guidelines traceability are partially revealed in those reflected by those associated with the authorities reviewed in this paper. The current language in GLOBALGAP requires as a major must that all producers must have a documented recall procedure to manage the withdrawal of registered products from the market which identify the type of event that may result in a withdrawal, persons responsible for taking decisions on the possible withdrawal of product, the mechanism for notifying customers and the and methods of reconciling stock. The procedures must be tested annually to ensure that it is sufficient.[21] Presumably other documentation requirements compliment the system and provide ease of access to detail records on water quality, worker hygiene, etc.

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[18] Additionally in July, 2007 the International Organization for Standards announce its new standard ISO 22005:2007, Traceability in the feed and food chain – General principles and basic requirements for system design and implementation.

[19] Enforced by the FDA Center for Food Safety and Applied Nutrition (CFSAN). The Section 306 Administration and Record Keeping regulation requires that each company in the supply chain keeps information about the company that they received the products from, the company who delivered the product to them, the company who took it away, and the company they gave (sold) the products to.

[20] Reported agreement from steering committee meetings in Atlanta, Ga., February22, 2008.

[21] Global G.A.P., Control Points and Compliance Criteria Integrated Farm Assurance - All Farm, Code Ref.: IFA 3.0-2 CP Version: V3.0-2_Sep07 Section: AF Page: 11 of 16

The USFDA recognizes that the ability to identify the source of a product as an important complement to good agricultural and management practices intended to minimize liability and prevent the occurrence of food safety problems. The guidelines suggest that at a minimum an effective traceback system should have documentation to indicate the source of a product and mechanism for marking or identifying the product from the farm to the consumer. Further the guidelines suggest documentation should include: date of harvest, farm identification and who handled the product from the grower to receiver. The US-FDA's recent experience in the multi-state E. coli outbreak apparently associated with bagged spinach demonstrated the usefulness in effective traceback systems. Product codes available from a limited number of the suspect bags allowed investigators to identify the spinach as being harvested from four fields in two counties in California and eventually to only one of four fields in one country.[22]

The LGMA requires all members to have a traceability process which enables identification of immediate non-transporter source and subsequent recipient; essentially a one-step forward, one-step back approach. The FSLC standards are more inclusive requiring all harvested product to be able to be traced back to a specific field, lot or greenhouse. If the product is taken from there to a packing or cooling shed information on the harvest date and crew must also be included.

Compliance Costs

From a grower's standpoint taking actions they would otherwise not in order to be in compliance with a variety of process standards represents an added cost of doing business. Benefits from being in compliance could accrue to growers in the form of higher product prices, maintaining and growing sales in existing markets, expanding to new markets, reducing potential effects of food recalls, reducing legal liability and insurance costs and improving operational efficiency.[23] The benefits from compliance with food safety process standards may be realized at some time in the future however the costs of compliance is upfront and in many cases is required to participate in a preferred market.[24] Understanding the magnitude of costs associated with process standard compliance helps to provide insight regarding the difficulty facing producers: trying to provide customers with food safety assurance and providing a competitively priced product that returns a profit to the enterprise.

[22] USFDA, California Department of Health Services, Food and Drug Branch. "Investigation of an Escherichia coli O157:H7 Outbreak Associated with Dole Pre-Packaged Spinach, Final", March 21, 2007.

[23] These costs and benefits to the individual firm/grower are also to be weighed against the total annual cost of illness associated with food borne disease in the United States in the range of $5–$10 billion (Crutchfield, et al. USDA,ERS Report No. 755).

[24] Such as the new requirement by Wal-Mart that suppliers of its private label and certain other food items, like produce, meat and fish, must comply with Global Food Safety Initiative standards. Wal-Mart said suppliers will be required to complete initial certification between July and December of 2008, with full certification required by July 2009.

Measuring compliance costs at the farm/firm level is difficult requiring a case study approach. For the most part such costs will be unique to the individual operation. For example, costs associated with Global G.A.P. certification are provided in schedules but vary depending on the scope of the investigation and size of the operation.[25] The costs of third party audits for certification of compliance also depend on size and nature of the operations. Anecdotal evidence from California producers report Primus Labs general ranch audits to be around $450 per ranch, not including the costs associated with correcting any problems revealed in the review. California producers like Metz Fresh, in Kings City California have reported compliance costs associated with LGMA participation in the range of $210 to $260 per crop acre.[26] Arizona producers such as Barkley reported an overall cost increase of four to five percent resulting from initiatives related to enhanced food safety. These same growers report increases in input costs of over 11 percent over the past two years and sales price increases of around two percent.

Formal studies that attempt to quantify the farm level costs of compliance with food safety process standards appear to be limited. One detail example is provided by a World Bank study of EUREPGAP compliance costs for Morocco citrus and tomato producers.[27] This study found that compliance costs associated with attaining the EUREPGAP standard is 8 percent of the total accumulated farm gate costs. After post-harvest, transport, and marketing costs are added, compliance costs represent 3 percent of the total cost. A detail breakdown of the various costs is presented in Table 4 and 5.

In another study and attempt was made to document compliance costs association with a host of regulations including but not limited to food safety issues imposed on producers in Texas, Arizona and California.[28] In that study Texas citrus operators reported a cost of $2.11 per acre ($11,394) for activities associated with Primus Labs and Eurepgap certification. California lettuce producers reported a cost of $1.50 per acre ($4,800) in additional food safety related cultural costs. Arizona lettuce growers reported $3,000 for the inspection of the ranch by Primus Labs, harvest process inspections o $125 per crew and time required in documentation and oversight of $1,190 for an added cost of $1.50 per acre.

Conclusions

Recent experiences with outbreaks of food-borne illness linked to fresh produce and the potential for negative events in the future have resulted in an increase in activities by affected groups to establish process and product standards designed to reduce the risk of such occurrences. The goal of these activities is to reduce the chances of contamination, mitigate the impacts of such events should they occur and provide a measure of

[25] GENERAL_GLOBALGAP_FEE_TABLE_2007.doc/Published on 1st November 2006/

[26] Reported in panel discussion at the 82nd annual meeting of the Western Growers Association in November, 2007 in Maui, Hawaii.

[27] EUREPGAP is the predecessor of the current GLOBAL GAP system. Omar Aloui and Lahcen Kenny The Cost of Compliance with SPS Standards for Moroccan Exports: A Case Study, World Bank, 2005.

[28] Hamilton, Lynn. “Comparing California's Cost of Regulation to Other States: A Case Study Approach for Agriculture”, California Institute for the Study of Specialty Crops, October, 2006.

confidence to potential buyers concerning the safety of their products. It is difficult to measure the benefits of such standards however it is suspected that in light of potentially catastrophic losses in terms of human life, health and product demand, any cost-benefit analysis would likely be significantly positive for society as a whole. Individual farming operations, however, may find the costs of compliance, especially the costs associated with multiple standards, to be burdensome.

Despite likely overall benefits, the nature of the standards, administrative structure and lack of harmonization across sectors in the supply chain may result in confusion and inefficiency in their adoption and application among participants. As a result the consideration of establishing a uniform set of standards that could be adopted within the NAFTA region, if not among a larger set of trading partners would appear to have some merit. Vague guidelines may be too little direction to achieve meaningful gains in food safety assurance. At the same time strict statistical compliance measures may be too constraining given the lack of exact science in such critical areas as generic E. coli irrigation water quality testing. What is needed is a balanced approach to develop a universally accepted set of standards based on currently available sound scientific principals that provides a clear set of good agricultural practices, measurable compliance statistics where possible and is acceptable to all participants along the supply chain.

The challenging tasks will be to establish the public/private partnership necessary to achieve harmonization among existing standards. How much authority will be granted to private sector certification groups, how much of a role federal agencies will play, will buyers have the ultimate say in what level of statistical measures are acceptable, can how will the system compensate growers for significant changes in current operations, how will importers be able to provide assurance that certain process standards have been followed, how will border inspection confirm such compliance, and a host of other questions will need to be addressed.

Absent such an agreement on universal standards the uncertainty regarding food safety will likely increase as the source of food for consumption within North America becomes increasingly global. Food supplies coming from producers adhering to a mixed set of standards with an undetermined amount of consistency regarding how potentially hazardous elements in the process are addressed. The ability of agents charged with assuring public confidence in the food supply, domestically produced or imported, will be a more challenging. Such an environment may lead to a situation where the only option left for harmonization of standards will be government intervention at either the national, regional or global level.

Regardless of how the system ultimately develops one thing is for sure. Without a kill certain technology to eliminate microbial pathogen contamination any system of standards will be one that helps decrease the risk of food-borne illness, it will not make the consumption risk free.

Figure 1. Map of 2006 Bagged Spinach Outbreak Locations

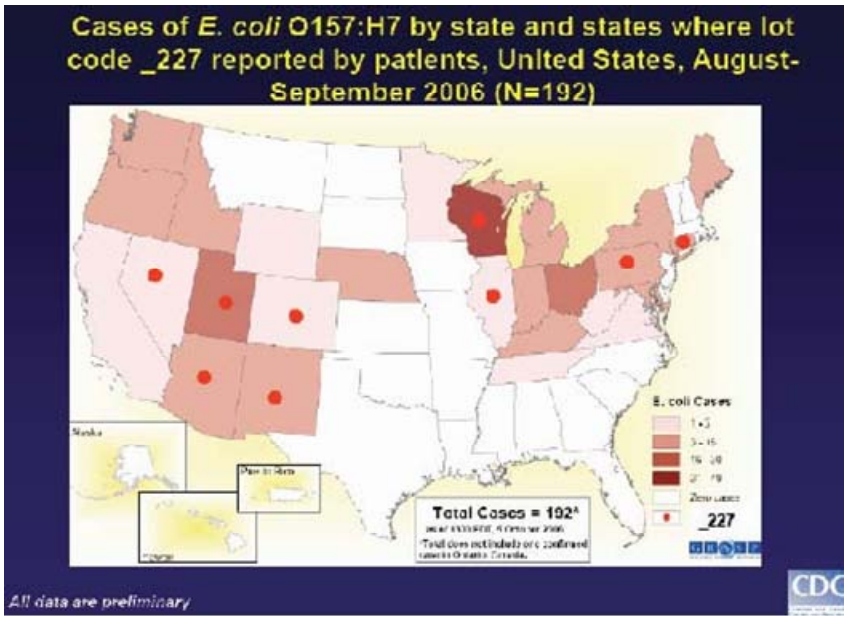
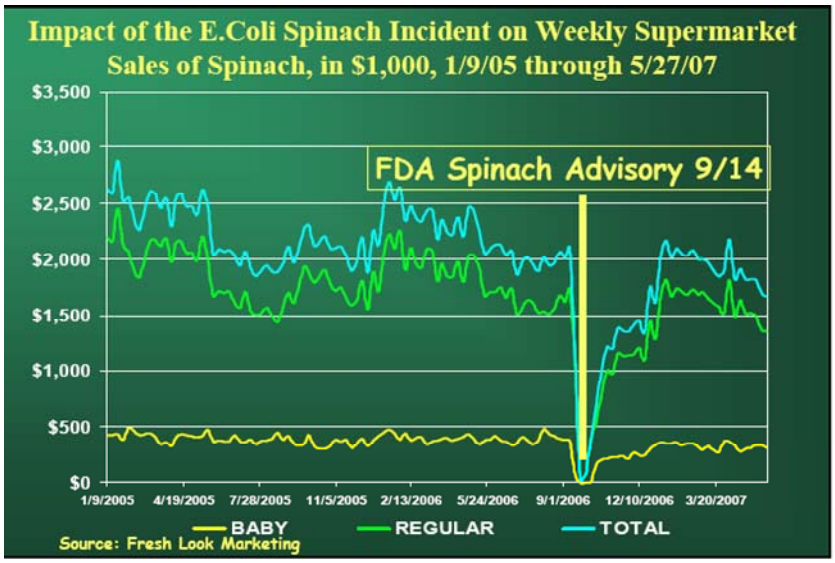


Figure 2.



Roberta Cook, November 2007

Figure 3. Convergence of Multiple Process Standards

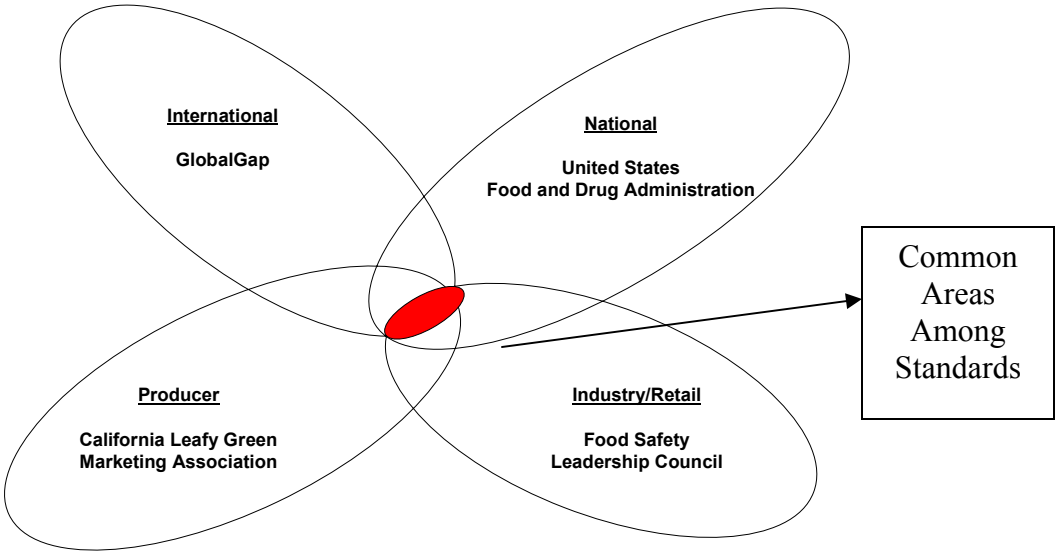


Table 1. Alternative Food Safety Standards by Regulatory Body: Soil and Soil Amendments				
Lettuce& Leafy Greens Selected Cultural Practice Or Activitiy	**Standard Setting Body**			
	Global Gap 1	**USDA/FDA 2**	**LGMA 3**	**FSLC 4**
Documented Plan and Mointoring	Yes	Yes	Yes	Yes
Biosoild Use Allowed	No	No	No	No
Specific Acceptance Criteria	No	Yes	Yes	Yes
Fecal Coliforms		EPA CFR 503	<1000 MPN/gram	<1000 MPN/gram
Salmonella spp		EPA CFR 503	Negative or < DL (<1/30 grams)	Negative or < DL (<1/30 grams)
E. coli 0157: H7		EPA CFR 503	Negative or < DL (<1/30 grams)	Negative or < DL (<1/30 grams)
Generic E. coli		NA	NA	< 10 MPN/gram

1. GlobalGAP Control Points and Complicance Criteria, V3.0-2 Sep 07
2. Guidance for Industry "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, 10-98
3. Commodity Specific Food Safety Guidelies for the Production of Harvest of Lettuce and Leafy Greens, 10-16-07.
4. Food Safety Leadership Council On-Farm Standards, V1.0, 9-10-07

Table 2. Alternative Food Safety Standards by Regulatory Body: Agricultural Water				
Lettuce& Leafy Greens Selected Cultural Practice Or Activitiy	**Standard Setting Body**			
	Global Gap 1	**USDA/FDA 2**	**LGMA 3**	**FSLC 4**
Documented Plan and Mointoring	Yes	Yes	Yes	Yes
Specific Acceptance Criteria	Yes	No	Yes	Yes
Pathogen Presence	≤ 1 per L	- Na -	Negative	Negaitve
Well Water Generic E. coli	Faecal conforms ≤1000/100 ml	- Na -	**≤ 126 MPN/100 mL rolling average ≤ 235 MPN/100 mL any one sample**	**< 1.1 MPN/100 mL** acceptable **≥1.1 MPN/100 mL unacceptable**
Surface Water Generic E. coli	Faecal conforms ≤1000/100 ml	- Na -	**≤ 126 MPN/100 mL rolling average ≤ 235 MPN/100 mL any one sample**	**< 1.1 MPN/100 mL** acceptable **≥1.1 but ≤ 126 MPN/100 mL need corrective action**

1. GlobalGAP Control Points and Complicance Criteria, V3.0-2 Sep 07
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3. Commodity Specific Food Safety Guidelies for the Production of Harvest of Lettuce and Leafy Greens, 10-16-07.
4. Food Safety Leadership Council On-Farm Standards, V1.0, 9-10-07

Table 3. Alternative Animal Related Standards by Regulatory Body: Animal Intrusions				
Lettuce& Leafy Greens Selected Cultural Practice Or Activitiy	**Standard Setting Body**			
	Global Gap 1	**USDA/FDA 2**	**LGMA 3**	**FSLC 4**
Documented Plan and Mointoring	Yes	Yes	Yes	Yes
Specific Acceptance Criteria	no	no	Yes	Yes
Pathogen Presence				
Specific Distance From Growing Fields	No	no	**30 Ft. for Grazing 400 Ft. for CAFO**	**1/4 mile for Grazing 1 mile for CAFO**

1. GlobalGAP Control Points and Complicance Criteria, V3.0-2 Sep 07
2. Guidance for Industry "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, 10-98
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Table 4. Cost of compliance with the EUREPGAP standard (tomato farm) *(US$)*

Items	*Cost for 10 ha*		*Cost/ha/year*	
	US$	*% of total*	*US$*	*% of total*
1. Building and facilities	$33,974	47.8	$170	6.8
2. Equipment	16,959	23.9	339	13.4
3. Technical assistance	5,269	7.4	527	20.9
4. Training	1,317	1.8	132	5.2
5. Monitoring and surveillance	9,221	13.0	922	36.5
6. Consumables	1,493	2.1	149	5.9
7. Certification costs	2,854	4.0	285	11.3
Total	$71,087	100.0	$2,524	100.0

Source: Authors' calculations.
Note: From table 7, used US$1 = 9.11 MAD.

Because companies and large farms are able to afford these charges, they can purchase all of the

Table 5. Share of the EUREPGAP compliance cost to production costs per ha

Items	Value (MAD)	%
Fixed charges 1	119,166	40
Labor 1	43,846	15
Consumables (fertilizers, water, pesticides)1	101,347	34
Other charges 1	9,719	3
Cost of compliance with EUREPGAP2	22,998	8
Total	297,076	100

1Elements 1–4 are from Belcadi 2002.
2From table 7.