

**United Fresh Government Relations Council**  
***Food Safety Working Group***



Food Safety Policy White Paper  
*December 20, 2008*

**Introduction**

Food safety is the produce industry's top priority. The men and women who grow, pack, and market fresh produce are committed to providing consumers with safe and wholesome foods. We are constantly working to enhance and improve our performance in growing crops in the field, carefully harvesting and handling them for distribution, packaging and processing commodities into convenient, ready-to-eat products, and maintaining the safest possible delivery chain all the way to the consumer's table.

However, recent events have led to the produce industry considering what role the federal government should play in managing food safety requirements for produce. For produce, the primary bills under consideration include creating a preventive control standard for produce that is based on risk. In other words, for produce that has a high risk profile for microbiological contamination, FDA would set a standard that will reduce risk from these contaminants. Testing and inspections from farm to table would be used to measure against a preventive standard while additional enforcement and penalty authorities would be granted to FDA. In addition, other areas where produce would be impacted include import requirements, third-party certification, recall authority, food facilities, and traceability requirements.

It is clear to many that in 2009, Congress and President Obama will be supporting a comprehensive review and overhaul of our food safety laws. While the timing of this debate is unclear, it is critical that the industry address how to best manage produce food safety with a united front in what could be a challenging political environment. In particular, this effort must be industry driven to achieve maximum success, rather than be buffeted by competing and conflicting view points.

With this context, in September of 2008, the United Fresh Government Relations Council and then the United Fresh Board of Directors approved a resolution calling for a food safety working group to be formed that would provide a comprehensive overview of the key food safety policy priorities for United Fresh. Therefore this white paper has been developed by the United Fresh Government Relations Council ad hoc *Food Safety Working Group* to provide a clear roadmap to pursue on a set of policy recommendations that will bring us closer to a comprehensive food safety program that will achieve our goals of a stronger fresh produce industry.

## KEY FOOD SAFETY POLICY ISSUES

### PRODUCE SPECIFIC PROVISIONS

#### OVERVIEW

None of us can deny that our fresh produce industry faces a different business world today than we did two years ago. Each time any fruit or vegetable is implicated in a foodborne illness outbreak, we all suffer from lost consumer confidence in our industry as a whole. In the long run, this is simply not sustainable and certainly not acceptable.

First and foremost, the fresh produce industry has been at the core of developing comprehensive food safety programs for many years. In fact the first *Food Safety Guidelines for the Fresh-Cut Produce Industry* was published 16 years ago in 1992, and was just updated by FDA in February 2008. The industry also developed industry Good Agricultural Practices (GAPs) in the mid 1990s to minimize on-farm microbiological food safety risks for fruit and vegetables, and worked closely with FDA as the agency published its overarching GAPs document in 1998. This has led to multiple commodity specific food safety guidelines programs for tomatoes, melons, sprouts, and leafy greens. Put simply, food safety has been at the forefront of our industry's commitment to serve the American public for many years.

In addition, it is clear through current law and regulation, that FDA is responsible for ensuring the safety of all domestic and imported fresh and fresh-cut fruits and vegetables consumed in the United States. We believe that responsibility is at the very core of the discussion today with Congress. FDA has the legal responsibility to assure American consumers that their produce meets all acceptable safety requirements. Our industry must and will do all we can to grow, pack and process the safest possible products. But no matter what steps we take as an industry, the law requires, and the public demands, that FDA as an independent, public health agency be the final arbiter of what is safe enough. In that vein, we believe FDA already has strong regulatory authority by statute to achieve these goals. In particular, FDA has the authority to promulgate rules and regulations, issue guidance that compels industry action, enter into agreements with states to allow for field investigations, and generally set standards to protect the public health.

Lastly, we believe one of the most important issue for produce is whether FDA is adequately funded, has sufficient staff with scientific training and experience in our sector of the food industry, has research dollars available to address key questions, has strong working agreements with the states to provide support as needed, and has the commitment of the President and full support of Congress.

#### POLICY STATEMENT

*Any new food safety legislation that is directed at the fresh produce industry by the 111<sup>th</sup> Congress should be based on the best available science, be risk based, and consider that fresh produce is a raw agricultural commodity. In that regard, any new legislation should aim at reducing the incidence of foodborne illness by minimizing the risk of adulteration. It is imperative that it is understood that most fresh produce is not sold as ready-to-eat commodities and should not be held to RTE standards. Any food safety effort should, however, encompass the entire supply chain regardless of size, location or operation type.*

#### SPECIFIC POLICY RECOMMENDATIONS

- Must allow for a commodity-specific approach, based on the best available science. We believe produce safety standards must allow for commodity-specific food safety practices

based on the best available science. In a highly diverse industry that is more aptly described as hundreds of different commodity industries, one size clearly does not fit all. For example, the food safety requirements of products grown close to the ground in contact with soil are far different from those grown on vines or trees. And, the large majority of produce commodities have never been linked to a foodborne disease. In fact, a recent FDA federal register notice in 2007 confirmed that five produce commodities have been associated with 80% of all foodborne disease outbreaks in the past 10 years, and that is where we must direct our resources.

In addition, government and industry alike must be careful that broad strokes do not result in requirements that should not apply to specific commodities, and do nothing to enhance safety. Taking a general approach would be far too easy to add regulatory costs and burdens to sectors where those requirements are unneeded, without doing anything to enhance safety where most critical. Finally, as part of this commodity specific approach, FDA must develop a rule-making procedure that establish risk and science-based regulations for the production, handling and distribution of those types of fruits and vegetables for which the Secretary determines such standards are necessary to minimize the risk of microbial illness.

- Must be consistent and applicable to the identified commodity or commodity sector, no matter where grown or packaged in the United States, or imported into the country. We believe produce safety standards must be consistent for an individual produce commodity grown anywhere in the United States, or imported into this country. Consumers must have the confidence that safety standards are met no matter where the commodity is grown or processed. Because of the variation in our industry's growing and harvesting practices in different climates and regions, flexibility is very appropriate and necessary. For example, some production areas use deep wells for irrigation while others use river water supplied from dams. Some farms use sprinkler irrigation, others use a drip system laid along the ground, and still others use water in the furrows between rows of produce. But the common factor must be that all uses of water for irrigation must meet safety standards that protect the product. That must be true whether the produce is grown in California, Florida, Wisconsin or Mexico.
- Must be federally mandated with sufficient federal oversight of compliance in order to be most credible to consumers. We believe achieving consistent produce safety standards across the industry requires strong federal government oversight and responsibility in order to be most credible to consumers and equitable to producers. We believe that the U.S. Food and Drug Administration, which is the public health agency charged by law with ensuring the safety of the nation's produce supply, must determine appropriate nationwide safety standards in an open and transparent process, with full input from the states, industry, academia, consumers and all stakeholders. We are strong advocates for food safety standards based on sound science and a clear consensus of expert stakeholders.

We also believe FDA must have relationships with other governments, USDA, and state agriculture and regulatory officials to ensure that compliance is taking place. Cooperative agreements between FDA and the states have been extremely effective in providing oversight of food safety standards. In particular, USDA has been a strong ally and has offered a number of means to assist the produce industry in safely growing, handling and processing fresh produce. For example USDA through AMS offers several auditing programs that assist the industry in measuring good agricultural practices, good handling practices, and HACCP programs in processing plants. These are good education and training programs, as well as a means to measure individual operators' understanding and implementation of food safety practices.

However, HACCP is not the equivalent of a food safety program, as HACCP is merely a component of an overall food safety program and cannot be established without prerequisite programs such as GAPs, cGMPs, and sanitation standard operating procedures (SSOPs) being in place. Conversely, it is unclear if HACCP can or should be used as a component of a food safety program for production agriculture as these types of programs are well defined and may function well within the control environment of a food processing plant. This does not mean that process hazards should be ignored but simply that the risks and hazards associated with a process need to be dealt with via an alternative mechanism. For production agriculture, in particular produce, risk reduction and mitigations programs such as GAPs, are considered an essential element in controlling and minimizing food safety risk.

### **THIRD-PARTY CERTIFICATION**

#### **OVERVIEW**

Currently, most third-party certification programs do not ensure compliance with FDA requirements specifically, but rather with their own sets of audit standards. The basic reason that current programs do not ensure compliance with FDA requirements is that FDA has not clearly established the standards that it believes must be audited against. This leaves open to interpretation to a wide range of competing interests – market players, auditing companies, etc. – to develop their own standards. Also, many produce audits currently overemphasize documentation and testing, which seems designed more to satisfy private commercial liability concerns than compliance with FDA food safety standards. Finally, most other third-party certification programs measure a wider range of practices that might be of interest to the person requiring the audit. For example, many audits measure procedures and practices outside of FDA food safety requirements, thereby diluting the assessment of a facility's compliance with those requirements.

#### **POLICY STATEMENT**

*We believe there may be potential benefits to FDA, the industry and consumers by use of certain 3rd party certifiers under specific conditions. However the process must overcome many obstacles we see in implementation of such programs today, as well ensure a consistent, science-based, and credible certification system in the future that garners the widespread confidence of consumers, industry and government. Because of these concerns, we propose three specific policy recommendations for third-party certification programs currently being considered by Congress.*

#### **SPECIFIC POLICY RECOMMENDATIONS**

- FDA must retain a definitive role in setting fair and appropriate audit fees initiated by third-party certification programs to demonstrate compliance with FDA standards. Currently, produce industry food safety certification programs range in cost (auditor/certification fees alone) from a few hundred dollars per audit (generally by the not-for-profit organizations) to tens of thousands of dollars (generally by the more complex certification bodies like SQF or ISO). Yet, we do not have evidence that the increased costs of some audits result in better evidence of compliance with standards or better evidence of safer food. The tremendous range in audit fees can have a significant impact on the ability of particularly small businesses to participate. If exorbitant audit fees were required, we fear that many producers would be financially challenged to comply with these requirements.

- A third-party certification program should be based on a harmonized set of FDA endorsed standards, and have industry-wide public recognition to preempt additional redundant audits. Today, the produce industry faces multiple, redundant audits, which in most cases are not interchangeably acceptable to different buyers. Most buyers will only accept the results and certification of certain certification bodies, thus leading to proliferation of different audits for different buyers. In some cases, the same auditor will visit a facility multiple times to perform different audits to verify compliance with different and potentially conflicting standards. In addition, inconsistencies in audit standards among the different certification bodies have created frustration and confusion, have unnecessarily increased operational costs, and may create an obstacle to training in food safety practices. To date, every effort to create a harmonized set of produce food safety audit standards has only added another set of standards to the list. If third-party certification programs are to be successful, there must be a system in place that requires buying companies to recognize and approve the results of these audits without requiring their own duplicative audits to recognize the same results.
- USDA/state department of agriculture GAP audits should be designed to certify against FDA standards. Most current audit programs do not ensure compliance with FDA requirements specifically, but rather with their own sets of standards. If given authority, training and adequate oversight, we believe that USDA/state department of agriculture GAP audits could be designed to certify against FDA standards, although most would be considered more educational and benchmarking tools for individual growers at present. Perhaps the one audit program that most closely ensures compliance with FDA standards today is the California Leafy Greens Marketing Agreement (LGMA).

## **TRACEABILITY AND OUTBREAK INVESTIGATIONS**

### **OVERVIEW**

The produce industry is committed to the capability of effectively and quickly tracking the source of our products from retail stores and restaurants back to their original farm source.

The Bioterrorism Act of 2002 requires mandatory record-keeping 'one-step-up' and 'one-step back' of all foods, with the ability to provide such records within 24 hours. The industry is committed to full compliance with these requirements, and urges FDA to rigorously enforce the requirements of this law. We know of no instances where FDA has taken any regulatory action to cite a produce company or its customer for failure to provide adequate records as required by the Act. Rather, we hear generalized concerns about adequacy of records, without specific examples with specific companies where compliance is inadequate. The produce industry stands ready to work with the Agency to ensure full and total compliance with these requirements.

In addition, outbreak investigations are multi-disciplinary processes, with tracking of product records only one element of successful investigations. FDA, CDC and the states must enhance their epidemiological work to identify which foods are associated with illness; must enhance their understanding of and/or access to expertise on produce industry distribution patterns; and must enhance the expertise of individual investigators. The produce industry has publicly committed to work cooperatively with FDA to help the agency better understand existing industry traceability and recordkeeping practices, and to better understand any areas where the agency believes we could improve those practices.

Concurrently, a number of produce companies throughout the entire distribution chain have begun to adopt a standardized system of case coding for all produce sold in the United States,

including bar codes that contain source information and lot numbers, which will then be scanned and stored by subsequent buyers through the distribution chain. This Produce Traceability Initiative is a multi-year effort to standardize the broad adoption of state-of-the-art processes across the industry. As more in the industry adopt this initiative, it will maximize the effectiveness of industry's current traceability procedures, improve our internal efficiencies, and assist the Agency greatly in its work.

## **POLICY STATEMENT**

*Strong FDA enforcement of existing record-keeping laws, together with work by industry to ensure full compliance today while continuing to enhance the efficiency of tracking systems, provides the public with assurance that produce items can be effectively tracked in an outbreak investigation. Therefore until the current federal law is proven to be deficient, we oppose any additional mandatory legislative or regulatory requirements for traceability as premature and unwarranted.*

## **SPECIFIC POLICY RECOMMENDATIONS**

- Congress should consider how to put in place a command-and-control structure with a clear chain of command. Take guesswork out of who's in charge, and drive real authority and accountability into the process. Whether this can be achieved in a multi-agency cooperative agreement, or requires new government structures, is something that Congress must review. The diffuse responsibility for public health in outbreak investigations is something that Congress must look at intensely. Local and state governments are usually first to discover illnesses, and are free to draw their own conclusions and issue press releases at any time. The diffuse responsibility continues at the federal level, even within the Department of Health and Human Services. CDC has the "official" responsibility to determine what food vehicle is the cause of an illness. FDA must wait on the scientists at CDC to make that call, only after which FDA staff are responsible for the traceback investigation. Lack of a true chain of command brings lack of accountability, and a rush to protect one's own turf or reputation. Even in the investigation itself, field investigators are all over the map. Some are FDA field staff employees, some CDC, some state, some local. Suffice it to say, outbreak investigations today do not resemble a well-prepared, well-organized, or well-drilled team operating as a cohesive unit.
- A stronger crisis preparedness and transparency needs to be developed by FDA and CDC. One of the most important parts of an investigation is the original work by states and CDC with food recall surveys among ill people. However, as we saw in the *Salmonella* Saintpaul outbreak this summer, CDC's first case control study that showed the strongest association with fresh tomatoes, and its second case control study showed a greater association with jalapeños. Today, these facts are all open to second-guessing, not only because we now know tomatoes were not the sole cause of illness (or perhaps any cause at all), but because no one outside of CDC knows how these studies were conducted outside of the state of New Mexico who did the initial work. Could there not be consistent food survey protocols set in advance, peer-reviewed by expert epidemiologists outside government, and kept at the ready for a case like this?

Whatever command-and-control structure is put in place for outbreak investigations, plan it, implement it, and test it before a crisis. Take the recommendations from all stakeholders and build a system – in advance – that government and industry alike will follow in the future. Many in the private sector hold workshops on crisis management and many in the produce industry do recall and traceback drills all the time. The

industry stands ready to cooperate with government in planning and testing overall traceback investigations.

- Congress and the agencies should find a proper and transparent way to bring industry and other outside expertise into its outbreak investigations. The government's failure to use industry's expertise in outbreak investigations is one of our most important lessons today. First and foremost this needs to be transparent, supported by consumer groups, and completely open to all interested parties. There is an abundance of knowledge in the produce industry about specific commodities, growing regions and handling practices, and specific distribution systems that can be used to protect public health in an outbreak. FDA and CDC should also welcome outside expertise not just from industry, but also from academia, from USDA experts who certainly better understand produce distribution systems, and even from the states themselves

We recommend a broad group of stakeholders be convened to look at all potential options and provide recommendations to Congress and the agencies. We also specifically recommend that a group of experts in major produce commodities be selected and vetted by government well ahead of time, perhaps through a process similar to gaining a security clearance. Then, at a moment's notice, these pre-cleared experts could be assembled with government investigators to provide counsel in their areas of expertise.

- Congress needs to empower FDA and CDC to look at risk management decision-making in advance of an outbreak, and develop transparent guidelines for when to take specific action. Every health or safety regulatory decision requires an assessment of risks and benefits. Agencies make risk management decisions every day that attempt to balance risks and benefits broadly to society, whether in automobile design, toy manufacturing, airline safety, or even FDA approval of food additives. Yet in the case of foodborne disease, FDA and CDC seem ill-prepared to grapple with any risk management approach other than "all or nothing." We simply must develop risk management systems that can distinguish those producers or distributors who can assure the safety of their produce in the marketplace from those who cannot. FDA must find appropriate ways to advise consumers that the legal responsibility for food safety assurance lies with individual companies who offer food for sale, not the federal government. How can a grower of summer tomatoes in Michigan maintain his livelihood selling to local retailers? How can a fast food chain that knows every detail of where and how its tomatoes are grown maintain the option to keep sliced tomatoes on its burgers? How can a produce company that invests hundreds of millions of dollars in food safety stay afloat when its business is shut down the same as others who never made those investments? The unintended message to industry is don't bother investing in food safety, if you're going to be tarred with the same brush and face the same costly consequences in every single outbreak.
- Risk communication must be a central part of an overall crisis management structure, and well planned in advance. As the agencies develop overall management plans, one single office must have authority and accountability for public communications, with one single officer designated as the media spokesperson for the investigation. The principle of timely and candid communication with the press and public cannot be compromised. Yet, any risk communications expert would also advise precision and care in communicating exactly what you want to say, and not speculating beyond what is known. This also comes back to our recommendation about a clear chain-of-command – someone has to be in charge of talking with the media. Good risk communication is not just an art; it is a science, and a science that needs to be studied in advance and rigorously followed in outbreak investigations.

## IMPORT REQUIREMENTS

### OVERVIEW

Food imports in general and fresh produce imports in particular have increased in recent years where there have been dramatic changes in the volume, variety, and complexity of FDA-regulated products arriving at U.S. ports. The United States trades with over 150 countries/territories with products coming into over 300 U.S. ports. In the last decade, the number of food imported items has tripled. According to the USDA Economic Research Service, approximately 15 percent of the overall U.S. food supply by volume is imported. However, in certain food categories a much higher percentage is imported. For example, approximately 60 percent of fresh fruits and vegetables consumed in the U.S. are imported, which fills the gap when U.S. domestic production is inadequate or out of season (e.g., bananas, tropical fruits, etc.).

FDA primarily relies on an electronic screening process to review imported produce at the border--typically only inspecting foreign produce firms for cause, such as a potential link to an outbreak of foodborne illness. The basic import process consists of two stages--prior notice and food safety evaluation. In the first stage, FDA must receive prior notice before a food shipment arrives in the United States. Prior notice information is screened electronically by FDA's import database, the Operational and Administrative System for Import Support (OASIS), for potential risks associated with intentional contamination. Once the prior notice review has been completed, the food safety evaluation is conducted. For this evaluation, OASIS screens each entry line--or portion--of the shipment for risk factors associated with unintentional contamination to determine whether the shipment may proceed automatically or whether it requires further review.

According to FDA officials, import alerts are the agency's primary mechanism for keeping products with a history of violations out of the country, and they use them regularly. Through the use of import alerts, the agency may detain potentially adulterated products at the border without a physical exam. Additionally, import alerts place the burden on the importing firm to demonstrate that the product is safe. During 2002 through 2007, FDA detained 0.15 percent of all imported fresh produce lines on the basis of import alerts. According to a GAO report published in September 2008, FDA officials attributed the small proportion of imports covered by import alerts to the fact that FDA only samples a small portion of imports and only issues an import alert after it finds a problem.

### POLICY STATEMENT

*We believe produce safety standards must be consistent for an individual produce commodity grown anywhere in the United States, or imported into this country. In particular, imports must be treated equitably in all areas of food safety regulation, including similar and equal assessment of imports and domestic production in all areas such as Good Agriculture Practices and Good Manufacturing Practices. Consumers must have the confidence that safety standards are met no matter where the commodity is grown or processed.*

### SPECIFIC POLICY RECOMMENDATIONS

- Food importers should be required to ensure their foreign suppliers meet all U.S. food safety requirements. In particular, Congress should require that all food importers, subject to FDA guidance, document the food safety measures and controls being implemented by their foreign suppliers and should require food importers to make their foreign supplier food safety plan available to FDA. Food importers who demonstrate

their products pose no meaningful risk should be eligible for expedited entry at the border so FDA can give greater scrutiny to high risk imports.

- Build the capacity of foreign governments and enlist the help of the private sector. In particular, Congress should direct FDA to develop a plan to help build the scientific and regulatory capacity of major exporters to the U.S. and should create a registry of private laboratories that meet FDA standards. In addition, FDA should provide for the possibility that official controls and certification are used instead of, or in combination with, third party systems. It would be more efficient for FDA to enforce an appropriate level of protection through administrative collaboration with governments rather than third parties in some cases. Finally, FDA should consider accredited third party certification programs for imports when foreign government food safety oversight capacity is limited. Under these types of programs, third party certification should be able to verify compliance with federal safety standards, foreign supplier safety plans, and identify those imports eligible for expedited entry.

## **MANDATORY RECALL AUTHORITY**

### **OVERVIEW**

Industry has long held that regulatory agencies do not need recall authority, since companies very rarely refuse to conduct one when asked. Moreover, the regulatory agencies have the “power of the press” to issue a public warning indicating the product is adulterated or otherwise harmful AND the company is not cooperating with the agency in getting the product off the market (which can be much more harmful to a business than a recall). The agencies can go to court to seize adulterated product, which takes time, but under the Bioterrorism Act, the agency can also “detain” product to allow time to process a seizure action, or FDA can ask states to “embargo” the product. Moreover, because companies generally do not refuse to conduct a recall, mandatory recall authority is more of a perceived gap in the food safety system than a real one.

One of the biggest food industry concerns has been the criteria to be used by FDA to determine the need for a recall. The key issue is where to draw the line between protecting public health and preventing the unintended consequences of unjustified recalls (should FDA elect to take precautionary action “in the interest of public health”). Congress recently passed new legislation amending the Food Drug and Cosmetic Act, establishing a reportable food registry, which requires reporting of foods for which there is a reasonable probability that consumption will cause “serious adverse health consequences or death” (the same standard incorporated into the Bioterrorism Act and the basis for a class I recall) within 24 hours of determining that a food meets the criterion.

### **Policy Statement**

*Although food companies routinely recall contaminated products, we believe Congress should give the FDA the power to order a recall, subject to due process protections, when a product poses the risk of severe health consequences or death and the company has refused to conduct a recall. In addition, Congress should consider a mechanism to ensure that if FDA issues unsubstantiated recall notice, that impacted companies or producers have an appropriate mechanism for redress.*

## FUNDING

### OVERVIEW

One of the key components to modernizing our food safety laws is the ability to fund these new requirements. The produce industry strongly opposes a food tax related to food facilities or food importers which have been considered in food safety legislation over the past two year. All Americans, not simply food companies, benefit from improvements to our nation's food safety programs. Food safety is a public health issue affecting our entire society and accordingly the cost of any increased federal regulatory oversight should be borne by U.S. general revenues.

Moreover, a governmental policy of recouping inspection costs based on some type of fee generation system would tend to shift fruit and vegetable production in favor of larger, more complex farming operations and away from many smaller, traditional, and local family truck-farms, groves, and orchards. This shift could work against product diversity and support for local agriculture, and act as a barrier to entry for smaller operations that today already contribute substantially to the safe and wholesome supply of fruits and vegetables. Additionally, fees specifically targeting imported produce or facilities handling imported produce will likely be viewed as duties, import taxes or trade barriers and invite retaliatory measures by foreign governments and harm our exports of fresh produce to these countries

### POLICY STATEMENT

*We believe the costs of FDA inspections and research should be financed from general tax revenue, not from taxes imposed on food importers or facilities. While we support increased resources for FDA, we strongly oppose food taxes and "fees" that are not tailored to provide a government service to our industry and that will likely compound food costs at a time of record food inflation. As a matter of public policy, it is much preferred to have direct governmental oversight of such critical matters as the safety of the nation's food supply paid by the general treasury—as opposed to the private commercial companies subject to inspection.*

## FOOD FACILITY REQUIREMENTS

### OVERVIEW

FDA oversees the vast food industry that includes about 46,000 U.S. food processors and warehouses, and comprises a significant segment of the nation's economy. FDA regulated products account for about two-thirds of consumer spending on food, with an annual retail value of \$430 billion. Every year, U.S. food processors spend \$1.4 billion on research and development and introduce 15,000 new products.

Food facilities impose a variety of food safety measures and controls such as Good Manufacturing Practices to ensure the safety and quality of products they process. These regulations cover the basics of producing food under clean and sanitary conditions. The following is just a partial list of matters of concern to the public that are addressed by FDA's food facility regulations:

- Pathogens (bacteria, viruses, parasites)
- Chemical contaminants (pesticides, natural toxins, heavy metals, animal drug and antibiotic residues)
- Loss of wholesomeness (molds, decomposition)
- Mislabeling (false nutrition information or other misleading statements)
- Economic deception (violation of standards, counterfeit foods)

- Safety of food and color additives

As part of the current debate related to food facilities include the cost of new regulatory requirements that provide FDA inspectors with broad authority to review the adequacy of food safety plans, to mandate specific controls for each facility, to establish performance standards for each facility, and to require broad new labeling requirements. Other areas that will be addressed under these provisions include preventive process controls, performance standards, registration requirements, and facility certification among other things.

#### **POLICY STATEMENT**

*While we support the requirement that all food companies have a food safety plan, we believe food facilities should be given the discretion to identify appropriate safety controls and measures beyond those controls and measures already required by regulation. Prescriptive, across-the-board new regulatory requirements will stifle innovation, divert resources from proven food safety measures, and will increase food costs at a time of record food inflation.*

#### **MISCELLANEOUS PROVISIONS**

Export Certification Programs – Several bills introduced in the 110<sup>th</sup> Congress provided FDA with the authority to issue export certificates as the Secretary determined appropriate, and on a fee-basis. This new authority, if adopted by the new Congress, could help some raw agricultural commodities (and processed food) exporters access markets that are currently closed due to sanitary-related concerns by the importing country, e.g., dairy imports to India. FDA certification should be safeguarded, however, so that it does not become a customary requirement by our trading partners, and instead is granted only under special circumstances supported by technical justification. This will help to control costs for our exporters and help ensure that certification does not become a convenient trade barrier.

Food Safety Research – In recent years, federal funding for food safety research has been woefully inadequate, with little to no research focused directly on mitigating risk factors associated with potential field contamination of fresh produce, or to developing effective microbial reduction and elimination techniques after harvest and in processing. While there's no obvious silver bullet around the corner, developing a "kill step" akin to pasteurization while still protecting the natural texture and flavor of our product would be a critical advancement in preventing even rare future illness outbreaks. As a nation, we need your help in driving scientific research to help prevent future outbreaks. Specific produce safety research at FDA that is field oriented and implemented to find practical solutions is critically important, and we urge Congress to include a robust research agenda when considering reforming our nation's food safety laws. We believe that boosting produce safety research is a vital part of reducing risk in the future.

**United Fresh Government Relations Council**  
**Food Safety Working Group**

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