

FOOD REGULATION AND SAFETY

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FOOD REGULATION AND SAFETY

4.1 INTRODUCTION

The United States enjoys the safest food supply in the world, not by accident but rather due to the current laws and regulations protecting the health and safety of the American public. However, even a system that ensures the safest food supply can become outdated and inefficient if it does not keep pace with emerging threats and technological advances.

Today's consumers demand a food supply that is safe from all hazards, including microbial, chemical, and physical threats. Many of the hazards associated with foods are not detectable through traditional inspection techniques, although current laws and regulations often depend upon these regulatory methods. New technology is emerging that allows regulatory agencies new, more effective options for ensuring the safety of food. New knowledge and research about food safety has shown us how a system can be strengthened even when resources are limited.

The U.S. food safety system should be consistently reviewed and updated. Reform should be based on risk, as well as the best available, scientifically-proven technologies, such as irradiation. It should eliminate duplication and improve efficiency. It should ensure consistency between federal agencies, and afford state regulators and industry a forum in which to seek clarification when information is inconsistent. Reform should also retain those elements of current laws which meet the current-science standard, and which have assured the U.S. the safest food supply to date.

4.2 "FARM TO TABLE" FOOD SAFETY SYSTEM

The production of wholesome food for consumers is a cooperative effort between the food industry and governmental agencies. A "farm to table" food safety approach ensures that each partner involved in handling food, from the producer to the consumer, is a responsible part of the food safety continuum. Characteristics which define this food safety system should include the following:

- System based on trust and respect for the capabilities of all partners, with clearly stated goals, defined roles, and effective information sharing.
- Minimum uniform standards that provide state flexibility, harmonization with international standards, and considers laboratory standards, certification and accreditation.
- Funding to support, in whole or in part, activities of state and local officials that are judged necessary or appropriate to enhance food safety.
- A centralized national data base with timely information on epidemiological studies, foodborne illnesses, sample test data, and recalls.
- An effective compliance program that consists of progressive enforcement which is coordinated, uniform, and consistent; outlines intervention strategies; provides education and training; and deputizing authority.
- Provides seamless program delivery by reallocation of responsibilities for federal, state, and local entities, and removal of obstacles such as non-amendables.
- Effectively communicates food safety issues and messages to the public.

4.3 THE SCIENCE OF RISK ASSESSMENT

No subject is a greater source of misinformation and public confusion than the assessment of relative risk to human health, safety, and the environment. The mathematics of probability is not easy to understand. It is difficult to distinguish the relative difference in the degree of risk between a probability of one in 10,000 and a probability of one in 1,000,000. The issue is further complicated when seemingly qualified scientists dispute the underlying data and assumptions upon which risk calculations rest. Even when the science of risk assessment is crystal clear, there are still value judgments to be made about which risks deserve the highest priority and how safe is safe enough.

Generally, when public health issues are ranked by experts, microbial threats are a greater problem than chemical hazards. However, both chemical and biological hazards present separate potential public health problems that must be addressed in the nation's food safety policy. While microbial threats are often manifested in immediate, acute reactions ranging from gastrointestinal upset to death, chemical threats may take a lifetime to manifest themselves as disease or genetic changes that affect the next generation. Both problems demand a diligent and effective response from state and federal governments.

Putting Risk Into Perspective — Risk is often put into perspective using numerical estimates, such as “a one in one million chance” of an accident occurring. How are these numbers derived? Many statistics, such as the average person's risk of dying from accidents and violence, are based on hard actuarial data. In contrast, the human cancer risks resulting from low-level chemical exposure in air, food, and water are rarely based on direct observation of human populations. These figures are typically based on high-dose animal studies, which are then extrapolated to determine risks to humans from exposure to low doses.

Very conservative risk assumptions, which are intended to err on the side of health protection, may frequently result in substantial overestimates of risk. There is a need for improved methods of estimating potential foodborne disease in order to prevent and reduce foodborne illness, while ensuring a strong and viable food industry.

Within the field of environmental health, some risks are far less speculative than others. The risks of childhood lead poisoning, indoor air pollution, and occupational exposures to chemicals are relatively well understood by citizens and policy makers. Some of the non-cancer health effects from pollution, ranging from aggravation of asthma to neurobehavioral effects, have a stronger technical foundation than is commonly realized. In contrast, many of the traditionally popular and expensive environmental protection programs have a weak foundation in risk analysis.

Decisions Based on Sound Science — No magic risk number can substitute for informed and thoughtful consideration by accountable officials who work with the public to make balanced decisions. Public officials play a key role in determining which involuntary threats to human health are unacceptable and which are acceptable based upon the best available science and not just perception.

Risk Analysis in Food Safety & Security Regulation — NASDA supports the development of uniform food safety regulations and policies that also permit a certain degree of state flexibility to promulgate regulations that address circumstances that may be unique to that state. In general these regulations and policies should be applied in a consistent manner across federal, state and local agencies. However a necessary first step in the introduction of uniform nationwide food safety policy and the prioritizing of resource allocation is the need to develop sound scientific information on which to base that policy.

A national risk assessment model must be developed at the federal level for use in conducting risk assessments of commercial food handling operations from farm to retail. The model should be suitable for use in assessing the risks associated with both accidental and intentional contamination of our food supply

and should take into account both food safety and food security. Standardized risk management procedures based on risk assessment results should be used to weigh policy alternatives and to develop and implement the appropriate regulatory response. An active risk communication network should be established to facilitate the exchange of information among those in industry and government who are assessing risk or developing methods to mitigate or manage risk.

A voluntary Model Food Security Code should be developed to ensure that states have the tools necessary to close gaps identified through risk assessments. The development of standardized food safety protocols embodied in the Model Food Code have enabled jurisdictions at all levels to establish a uniform system of regulation to ensure that food is safe for consumers. The very real threat of an attack on the food supply demands that additional measures be taken to ensure that food offered for sale has been handled under the most secure conditions from farm to table.

4.4 A SEAMLESS FOOD SAFETY SYSTEM

The President's Council on Food Safety has drafted a Food Safety Strategic Plan with the overarching goal: "To protect public health by significantly reducing the prevalence of foodborne hazards, thereby reducing acute and chronic illnesses and injuries through science-based and coordinated regulation, inspection, enforcement, research, and education programs".

The National Academy of Sciences report entitled, "Ensuring Safe Food from Production to Consumption," found that an effective food safety system "recognizes the responsibilities and central role played by the non-federal partners (state, local, industry, consumers) in the food safety system."

In September 1998, the U.S. Food and Drug Administration convened the 50 States Meeting in Kansas City, MO, to identify means of improving interagency collaboration. Participants identified 13 obstacles to a truly integrated national food safety network.

Six tasks groups were formed to develop specific action plans to address the points identified. Each task group included representatives of local, state and federal food safety agencies. The groups met during the winter and spring months of 1998-1999 and outlined the vision for a National Food Safety System (NFSS) that is fully integrated.

NASDA supports the development of a seamless food safety system for the United States. A priority in the development of a seamless food safety system must be the development and application of uniform science based regulations and policies across federal, state and local agency lines. However, state and local governments must retain flexibility in order to address circumstances which may be unique to a particular state or locality. Other key ingredients in a seamless system include the coordinated use of laboratory resources, the sharing of laboratory data, the accreditation of federal, state and local laboratories, and the sharing of inspection and investigation results. A comprehensive surveillance program should also be developed integrating federal, state & local resources by expanding participation in initiatives such as "Pulsnet" and "eLEXNET".

NASDA recommends a new and clearer delineation of roles between federal and state agencies. Federal agencies should exercise oversight for training, certification, risk assessment, program evaluation, imported foods, research, science, standards, lab practices, additives and funding. States should receive resources in the area of inspections, investigations, complaints, sampling, analysis, compliance and enforcement that fully reimburse the cost of implementing national programs and developing national standards.

Coordination and cooperation between federal, state and local agencies is in many ways of more consequence to food safety than the structure of the federal agencies. As our nation crafts the optimum response to biosecurity threats and potential broad scale food contamination, NASDA calls upon HHS and CDC to recognize and incorporate the large number of food safety programs that are located in states' Departments of Agriculture as well as the current incorporation of the food safety programs in states' Departments of Health.

A critical component of the coordination and cooperation between federal, state and local agencies charged with food safety and security is the sharing of information about: vulnerabilities in the food protection system, ways to reduce risks of an intentional attack on the food system, and specific threats of terrorists against any component of the food system. NASDA strongly recommends that appropriate security clearances be provided to state and local agencies so that confidential information about any of these matters that is obtained at the federal level may be shared with state and local food safety partners.

Furthermore, in light of the capacity and capability of local and state agencies to provide field surveillance and laboratory support for food safety and security, the results of state and local inspections and laboratory analyses found to be consistent with federal requirements should be recognized as equivalent to federal inspections and analyses.

Either a consolidated single federal food safety agency or the reorganization of existing agencies to utilize common procedures and statutes across agency lines would be acceptable. However, in light of growing threats from bioterrorism, the latter approach is preferable at this time to the massive upheaval a reorganization into a single agency would create.

4.5 HACCP AND HACCP PLANS

The production of wholesome food for consumers is a cooperative effort between the food industry and governmental agencies. In order to be successful, a sincere spirit of cooperation between the food industry and the government is essential. The incorporation of HACCP plans into the industry must change the way the Secretary of Agriculture allocates resources for inspection. In order to provide efficient utilization of current resources, risk assessments must be made in all segments of meat, poultry, exotic, and aquatic food production, and resources should be allocated in areas where significant risks to consumers can be reduced.

Modernization of the nation's meat, poultry, and seafood inspection system must be based on the principal idea of reducing the risks of foodborne disease to consumers. Inspection programs should provide oversight that focuses on prevention of food safety hazards. Risk-based inspection will lead to overall safer products by focusing scarce inspection resources in areas with a greater risk potential. Government resources can then more efficiently be directed at ensuring that the hazard control procedures achieve the program's objective through monitoring and verification of the industry's activities.

The main value of a Hazard Analysis and Critical Control Point (HACCP) system is prevention rather than detection. The HACCP system involves determining points along the food production chain where contaminants can occur. Safeguards are then developed for these critical control points to prevent food safety hazards. Records are kept to help trace problems to their origin. Verification systems are established to ensure that the program is effective.

While HACCP has primarily been required in the meat, poultry, exotic animal, and aquatic industries, HACCP's application is much broader than just food inspections. HACCP has proved effective in canned food processing, and HACCP or HACCP-compatible systems should be applied to all food production and processing. General guidelines to assist producers, processors, and distributors in HACCP plan development should be available. Testing should be used as a tool to verify the effectiveness of HACCP plans.

HACCP programs can result in enormous safeguarding benefits for the food system, however, it requires a resource commitment on the part of industry. Government agencies should support the movement towards HACCP systems in the food industry. Support could be in the areas of training, research, model plans, and other tools to assist the industry in HACCP implementation.

These HACCP plans must be unique for each operation. Critical control points should be identified, critical limits established, and corrective action procedures developed for processes that are outside of acceptable limits. These plans must be reviewed and updated on a regular basis. Flexibility is necessary in preparation and implementation of these plans. The Secretary of Agriculture and state meat and poultry inspection agencies should monitor the overall effectiveness of these industry plans. A sincere sense of cooperation and collaboration between the industry and the government is essential for a successful risk-based inspection system.

The 7 Basic Principles of HACCP — A HACCP system involves determining points along the food production chain where contamination can occur. HACCP systems vary for all foods, but seven basic principles are universal:

- All potential hazards associated with producing a particular food product are assessed, including growing and harvesting of a product with attention to all raw materials or additional ingredients used. This assessment includes the processing, manufacturing, distribution, marketing, and preparation for consumption of the food.
- Critical points required to control the identified hazards are determined.
- Standards (critical limits) that must be met at each critical control point are established.
- Procedures for monitoring the critical control points are established.
- Corrective action plans are developed to be implemented when a deviation is identified.
- Procedures to verify if the HACCP plan is working correctly are established.
- Record keeping systems that document the HACCP plan are established.

Expanded Use of HACCP Principles — In order to ensure the safest possible food supply, HACCP's application is much broader than just seafood, meat and poultry inspections. HACCP has proved effective in canned food processing, and should be applied to all food production and processing, including shell eggs. For example, general guidelines to assist shell egg processors and distributors in HACCP plan development should be available for processing plant sanitation, proper egg washing, interior quality of eggs and refrigeration. Research should be conducted in food production areas to identify intervention strategies in those areas that would significantly reduce risk. Testing should be used as a tool to verify the effectiveness of HACCP plans. An efficient, cost-effective, science-based, risk-based program should be developed through the cooperation of the responsible federal and state agencies and the industry.

Microbiological Testing — Microbiological testing, as necessary to verify the effectiveness of an establishment's procedures for controlling microbiological hazards, should be an integral part of the risk-based system. This testing should be done to determine if the process is effective and not attempt to establish microbiological standards. The frequency of testing required should be proportional to production volume and frequency of detection, and not based on a calendar schedule.

A significant difference exists between microbiological testing in raw and ready-to-eat foods. Science and technology indicate that it is currently impossible to ensure that raw meats and poultry are free of potential pathogens. As a result, microbiological testing of raw meat and poultry for other than informational purposes and verification of HACCP systems is inappropriate. Microbiological testing in ready-to-eat foods is appropriate and should continue to be mandatory.

Preharvest Food Safety — Pre-harvest food safety relies on activities conducted by livestock and crop producers which prevent or reduce the occurrence of organisms, agents or conditions that pose an animal health or food safety risk. Most current regulatory programs, however, are focused on post-harvest food safety practices (transportation, processing, retail sale). NASDA believes measures can be taken at the farm level to minimize or reduce the potential for foodborne illness further down the processing chain. We believe this because such measures are successfully being taken in many cases.

Many food retailers and distributors are now calling for third-party food safety inspections of their producer suppliers. In these instances, producers engage the services of a third party to verify that plant and animal production is occurring in accordance with a set of standards. The on-farm standards used vary among states, third-party verifiers, buyers, as well as by crop or animal produced. Consistent standards are needed to ensure that food producers can ensure food safety, satisfy consumer concerns, address the emergence of new organisms and satisfy current and potential export markets. On-farm quality assurance standards should be voluntary, well conceived, sustainable over time, flexible, transparent, uniform and include an evaluation mechanism. Many states are already moving forward to design and implement effective producer-oriented quality assurance programs. For example, the California Department of Food & Agriculture is participating in several on-farm quality assurance programs. The structure of the programs and degree of involvement varies by commodity and their unique needs. More basic and applied research, as well as educational efforts, is also needed.

Incentives, technical assistance, and a comprehensive approach can be used to increase the speed and the extent that standards are adopted on farms. Because of the nature of food handling activities on farms, a comprehensive, integrated approach is needed for ensuring that standards are utilized. Verification that food safety standards are being utilized effectively can be accomplished in a number of ways including third party, HACCP, an overarching audit, or by epidemiological indicators.

NASDA supports development of uniform, but voluntary standards for pre-harvest food safety, with input from all parties and a clear articulation of the risks and benefits associated with adoption of those standards. Basic and applied research is needed to define specific interventions that will positively impact food safety, and which can be used in the development of uniform standards. Moreover, pre-harvest food safety efforts should also be integrated with overlapping issues such as nutrient and waste management, environmental protection, rural economic development, and animal health and welfare.

NASDA encourages continued work on the Federal/State National Auditing Alliance to verify good agricultural practices and good handling practices. NASDA also supports the concept, similar to the approach used for environmental protection efforts, to provide federal support and incentives to producers who voluntarily establish verifiable pre-harvest food safety programs. NASDA proposes a Food Safety Quality Assurance block grant program, administered by the states, to facilitate the adoption of innovative food safety assurance programs on farm. In addition, there is a need for uniform education regarding the national program to Retailers and International Market Buyers of the USDA Federal State Program. NASDA requests that USDA AMS Fresh Products Branch begin an educational campaign to inform retail buyers of the program and the advantage of the uniformity provided by the Federal State Auditing Program.

Tracebacks — An effective preharvest quality assurance program should contain a feedback loop whereby food producers and food processors share relevant information on disease agents and disease incidences, diagnostic procedures and intervention strategies. The various segments of the industries can work together through an effective quality assurance program to identify and implement effective intervention strategies to achieve a safer food supply for consumers.

The Secretary should have some oversight of preharvest activities and authority to trace disease agents through all points of production to the place of origin, or at least to the last point of production. In order to make such tracing of organisms and agents possible, the Secretary should have the authority to require appropriate identification of individual animals and plant material. Such identification can lead to a more effective, rapid recall of potentially contaminated food products along the entire food chain, as well as minimization of illness and/or death resulting from exposure. Such a system also provides increased consumer confidence, while possibly minimizing the economic loss to industry in the event of a product recall. Plant records should identify the grower, and such identification could be coded.

Traceback of foods that are inapparent carriers of potential human pathogens should be for the purpose of developing ecological, epidemiological, diagnostic and intervention information and strategies. Quarantine of farms, however, is inappropriate for potential foodborne pathogens that have a number of host species, are found in the environment, and for which there are no effective preharvest diagnostic procedures or intervention strategies. Should quarantine authority become necessary it should continue to reside with state animal health agencies. Seizures/embargo authorization is necessary to halt the movement of adulterated products in commerce.

The federal government should work closely with state governments and industry to develop an identification system that will address the diversity of production, marketing and distribution mechanisms for fresh and processed food products.

Harvest — Harvest activities include the conversion process from a live animal to a carcass, the removal of plant material from its growing media, and the harvesting, picking, or collecting of a raw agricultural product or seafood. NASDA supports requiring those facilities involved in animal harvest to develop and implement written HACCP plans, which identify and control public health hazards for products of animal origin during harvest. The plans should encompass ante-mortem and post-mortem procedures in addition to other identified critical control points (i.e. dressing procedures, sanitation, facility requirements, etc.). Once a facility's plan has been satisfactorily implemented, the Secretary of Agriculture should focus efforts on verifying the effectiveness of the facility's plan and the facility's compliance with it. The intensity of government oversight should depend upon many factors including the risks presented by particular products and slaughter operations, the effectiveness of a facility's plan, and each facility's compliance with the plan. In facilities that slaughter a uniform, high quality animal, produced under an effective, well documented quality assurance program, the Secretary should not be required to provide 100 percent evaluation of the animals for disease or aesthetic defects (organoleptic inspection). The facility should assume this responsibility as a part of its HACCP plan. A HACCP system developed and implemented by the establishment which could include government verification and minimal inspection oversight would be superior to continuous organoleptic inspection used alone. Facilities harvesting animals that are not uniform and/or of high quality or originate from farms that do not have an effective quality assurance program should still be subject to 100 percent evaluation of animals by the Secretary for disease or aesthetic defects. Facilities involved in plant material harvest should follow HACCP-compatible good agricultural and sanitation practices.

Processing — The most significant reduction in risk of foodborne disease can be made by controlling the processes that occur during post harvest production. Processing includes the wholesale and retail handling and modification of plant and food products after the harvest phase and prior to consumption. Wholesale

processing includes meat and poultry processing, egg product processing, and further processing of other food products for wholesale and distribution in commerce. It also includes cooking, baking, heating, drying, mixing, churning, separating, extracting, cutting, freezing, or otherwise manufacturing a food or changing the physical characteristics of a food, and the packaging, canning or otherwise enclosing such food in a container, but does not mean the sorting, cleaning, or water-rinsing of a food. Retail processing includes the handling of foods at restaurants, retail stores, vending operations, and other institutions. The steps that are taken at these facilities pose risks to consumers.

Wholesale Processing — Mandatory HACCP plans should be required for all post harvest wholesale processing operations. Each wholesale food processing facility should develop a HACCP plan to control, monitor, and verify the critical processes that are conducted in that operation. Plant operators and plant employees should be responsible for implementing these plans and taking control of the food production processes in their operations. The Secretary of Agriculture and states should monitor and verify the implementation of those plans.

Retail Food Service — The retail processing of food (the food service and retail arena) is the last step before consumer handling and consumption. This is the last opportunity to apply a “kill step” that could render harmless any pathogenic organisms that have survived previous HACCP controls. It is also, however, a prime opportunity to introduce and incubate new pathogens to a product that was previously safe. This reintroduction and incubation can be accomplished through a myriad of breakdowns in the critical control points. A single inexperienced or untrained worker can nullify all HACCP controls prior to this point. The Center for Disease Control (CDC) has determined that the following are the main risk factors that are utilized in assessing risks at retail operations:

- Improper holding temperatures,
- Inadequate cooking,
- Poor personal hygiene,
- Contaminated equipment.

It is essential, in face of this threat to public health, that HACCP principles (whose outlines are in the 1993, 1995, and 1997 Food Code) be made mandatory in the retail food processing (food service and retail stores) industries.

It is also important for consumers and industry, as they move between states, to have the confidence that a consistent and uniform set of minimum standards exists that will ensure the safety of the food they serve and consume. This can be accomplished by having all states incorporate the FDA Model Food Code. The 1997 FDA Model Food Code is a document that provides scientifically based retail food safety advice for food regulatory agencies at all levels of government. It is a living document that will continue to be reviewed and updated on a regular basis through input from state and local food regulatory agencies, industry, academia, and consumers through such forums as the Conference for Food Protection and the Association of Food and Drug Officials. It has received endorsement from USDA, CDC, and various food industry organizations.

4.6 STATE FOOD INSPECTION PROGRAMS

Federal Preemption — Federal preemption of state food regulation under the Federal Food, Drug, and Cosmetic Act should not be allowed. States should retain the right to regulate the food supply in a manner at least equal to or greater than federal standards, and have the authority to regulate food products and food handling establishments not regulated by the federal government. The effect of federal preemption is to take

away states' authority to impose requirements to ensure the safety of the food, drug, and cosmetic supply. States would not be able to impose stricter food safety standards than the federal government.

State Meat Inspection Programs — State food safety programs are important partners of the federal inspection system. The 1967 Federal Meat Inspection Act and the 1968 Wholesome Poultry Products Act established a state-federal cooperative inspection program which requires state inspection programs to be “at least equal to” the federal program. The acts also limit products receiving state inspection to distribution solely within such state. These laws, while stressing the need for cooperation between federal and state authorities, give USDA clear responsibility for setting national standards for meat and poultry inspection.

USDA's Food Safety and Inspection Service (FSIS) certifies that each state inspection program is “equal to” federal inspection standards through review of the annual State Performance Plan. Since passage of the acts in 1967 and 1968, USDA has never unilaterally found that a state inspection program should be discontinued due to inadequacies in its inspection program.

States are allowed to inspect some meat and poultry products for interstate shipment. “Non-amenable” products - such as deer, buffalo, squab, and pheasant - are not regulated by the federal inspection program; therefore, state inspection programs are utilized to ensure that these products can enter interstate commerce. These shipments have been allowed for many years with little or no evidence of any risk to the consuming public. The fact that state-inspected non-amenable products has been safe for commerce and the consumer proves that the prohibition of interstate shipment of state-inspected meat and poultry has little to do with public health and food safety.

Congress has passed the North American Free Trade Agreement (NAFTA) and the General Agreement on Tariffs and Trade (GATT). Passage of these trade agreements allowed foreign-inspected meat and poultry to be shipped into the United States and moved interstate as long as the foreign inspection program is equivalent to U.S. federal standards — the same standard applied to state inspection programs.

The issue of interstate shipment of state-inspected products is a simple fairness issue. Most of the state-inspected meat plants are owned and operated by small business owners. The prohibition of interstate shipment of state-inspected meat — the only such prohibition of any food product — disrupts the free flow of trade and restricts the ability of American small business entrepreneurs to economically compete against foreign producers and large domestic corporations. State-inspected meat products must be allowed to participate in interstate commerce and the Secretary of Agriculture should develop a seamless state/federal meat inspection program.

Amenability — NASDA strongly supports an inspection system that is fair and equitable to all segments of the industry. The system must be based on risk, rather than the point of sale or origin of the product.

Traditionally, the Secretary has assumed authority over various segments of the meat and poultry industry based on the type of operations being conducted such as inspection at wholesale operations but not at retail operations. Inspection of the production of meat and poultry food products has been based on the amount of meat or poultry in a product and not on the potential risks of those products.

A more efficient and effective method of inspection would include a risk assessment of the food safety hazards associated with the type of product or processes involved in production. The percentage of meat or poultry in a product should not be the determining factor in a food safety program. The process used to control, monitor, and verify the production of that food is the most important consideration for consumers.

All food entering commerce, both traditional and non-traditional, aquatic and exotic animals, should be included in the inspection process. Many of the currently exempted items pose the same potential health risks as those presently mandated for inspection. With increased productivity, varying consumer preference, and the lack of a consistent nationwide inspection program, exempting meat and poultry food products from inspection as is currently done under the present system cannot be justified.

Redeployment of Federal Inspectors in Retail — In an effort to re-deploy federal inspection staff, USDA has proposed an "in-distribution" pilot test project. Under this proposal, federal inspectors will expand a presence at retail-level food establishments. State and local food agencies have traditional responsibility at this level.

The National Academy of Sciences, in its August 1998 report, "Ensuring Safe Food From Production to Consumption," stated that the ideal federal food safety system would be "organized to be responsive to and work in true partnership with nonfederal partners. These include state and local governments, the food industry, and consumers." The FSIS is testing the feasibility of using its inspectors in food safety activities outside of federally inspected plants. Many of the activities proposed for the "in-distribution" FSIS inspections have historically been conducted by FSIS compliance officers. Responses by the leadership of the Association of Food and Drug Officials (AFDO) and the Food Marketing Institute (FMI) suggest inadequate FSIS coordination with its nonfederal partners for this initiative.

NASDA has urged the USDA, Food Safety Inspection Service (FSIS) to ensure that its food safety initiatives are integrated with food safety activities of its nonfederal partners. Potential impacts if this is not done include:

- Limited federal resources deployed without a systematic evaluation of risk or need
- Duplication of regulatory effort between federal and nonfederal agencies
- Precedent for unilateral federal action without effective coordination with nonfederal food safety agencies.

State Egg Inspection and Quality Assurance — State egg inspection and egg quality assurance programs have worked in cooperation with the table egg industry for many years to reduce the risk of Salmonella enteritidis in shell eggs. As the responsible federal agencies discuss their approach to reducing the public health risk of Salmonella enteritidis in shell eggs, the success and expertise of state programs should be recognized and included. If a mandatory federal program is implemented, the state programs that are equal to the federal program should be accepted. Aspects of quality assurance programs that should be addressed for the egg industry include biosecurity, rodent and pest control programs, environmental and egg sampling, etc.

Dairy Product Safety — As the distribution of dairy products moves from a regional to a national market, it is important that milk regulatory agencies utilize uniform interpretations of the FDA's Pasteurized Milk Ordinance (PMO) and USDA's Milk for Manufacturing Purposes and its Production and Processing Recommended Requirements.

Passage of the GATT and NAFTA agreements are advancing the National Conference on Interstate Milk Shipments (NCIMS) into the area of international trade. State and federal milk regulators and the NCIMS Program must ensure that regulations are uniform and equivalent, providing a safe and wholesome product, while allowing international commerce to progress. Milk regulatory agencies and the NCIMS Program should have the following goals:

- ❑ To produce a safe raw milk supply and provide safe finished products for the consumer.
- ❑ To more efficiently use resources to continue to protect the public health, enhance food safety and accommodate a changing regulatory and industry environment without reducing milk safety.
- ❑ Development of a system to allow the free flow of dairy products both domestically and internationally utilizing equivalent safety standards.
- ❑ To enhance the oversight program through state field audits, program evaluations and when necessary, check ratings. To increase uniformity and ensure product safety.
- ❑ To adopt the most recent edition of the Grade 'A' Pasteurized Milk Ordinance (PMO) and related documents.

Milk Quality: Pasteurization--Inasmuch as apparently healthy cows and goats can shed in their milk organisms which are pathogenic to human beings and may cause diseases such as brucellosis, Campylobacter enteritis, salmonellosis, and tuberculosis; and inasmuch as milk handlers may introduce pathogenic agents during the handling of unpasteurized milk (including certified raw milk), only pasteurized milk, milk products and properly aged cheeses should be sold for human consumption. Sale includes distribution by use of animal or herd sharing, bartering, exchange or agistment. In those states where the sale of unpasteurized milk is authorized, those products should be labeled "Not Pasteurized and May Contain Organisms that cause Human Disease.

As a precondition for the importation of all dairy products (Grade A and Non-Grade A) into this country, the FDA should be required, through legislation or other means, to make a timely determination as to whether a dairy product proposed to be imported meets the sanitary standards of this country. The determination could be made by either (1) inspection of individual plants and farms by FDA or by FDA certified private firms or individuals; or (2) by FDA's determination that the foreign country's dairy inspection system is equivalent to that of the United States.

Verification of Food Safety Programs For Fresh Produce And Citrus — Fresh fruits and vegetables are important to the health and well being of the American consumer. Consumers enjoy one of the safest supplies of fresh produce in the world. However, over the last several years, the detection of outbreaks of food borne illness associated with both domestic and imported fresh fruits and vegetables has increased.

In 1997 the U.S. Food and Drug Administration and the U.S. Department of Agriculture collaborated to produce the "Guidance for Industry" - a guide to minimize microbial food safety hazards for fresh fruits and vegetables. This guidance document (The Guide) addresses microbial food safety hazards and good agriculture and management practices common to growing, harvesting, washing, sorting, packing, and transporting most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. Both domestic and foreign fresh fruit and vegetable producers can use this voluntary science based guidance to help insure the safety of their produce.

The produce guide is guidance, not a regulation. As guidance, and if applied as appropriate and feasible to individual fruit and vegetable production operations, the guide will help to minimize microbial food safety hazards for fresh produce.

The food retail companies have an ever-increasing awareness of the consumer demand for safe food. Due to this awareness, these companies are requiring their suppliers of fresh fruits and vegetables to adhere to the

guidance document and minimize the possibility of microbial contamination to the food supply. The retail food companies are requesting that their suppliers provide verification of their food safety programs through third party audits.

It is the position of NASDA that the concept of third party audits as a means of verification of produce supplier food safety programs, providing the audit programs are science based, and utilize trained licensed federal or state auditors, or suitably licensed private auditors. The third party audit system in no way provides or implies any assurance that suppliers produce is free from microbial contamination. It is only a means to verify that the producers have a system in place to minimize microbial contamination.

4.7 IMPORTED FOOD

International trade agreements have dramatically increased the amount of imported and exported food products to and from the United States. Most trade agreements addressed the issues of non-tariff trade barriers and other mechanisms often used to support domestic production programs. Phytosanitary restrictions, intended to provide safeguards against the importation of new, exotic, or serious pest problems, are still in place and allowable under the trade agreements. However, an issue that has not been adequately addressed is harmonization of food safety standards among trading partners. While the United States has imposed many restrictions on domestic food producers - limiting use of pesticides, mandating production under HACCP plans, mandatory labeling and container requirements - these requirements are not uniformly imposed upon imported products. This creates problems in two areas - uniformity of food safety for United States consumers and economic uniformity among the industry. NASDA strongly encourages the federal government to seek legislative and trade agreement reform that will ensure a uniform standard for food safety on both domestically - produced and imported food products.

All regions of the United States have been faced with significant and continuing problems regarding the safety and threat posed by certain imported foods, and the potential for a bioterrorism threat involving the safety of our foods from deliberate contamination is a reality. NASDA believes the states should not have the responsibility of detecting and correcting problems from imported food items allowed entry into our shores.

FDA & USDA regulations and inspection methods for imported foods should be based on risk-based analysis. The regulations and inspection methods resulting from this process should be applied in a uniform manner by both agencies. Resources allocated for import inspection activities should be distributed equitably across agency lines.

The federal government must assure that all imported food is subject to the same food safety standards required of US food manufacturers. This will require the federal agency with jurisdiction over a particular category of food products to make an equivalency determination in regard to a country's food safety system for that product before imports are allowed into the US from that country. Additionally the federal agency must also establish appropriate auditing and monitoring systems to assure that the food safety system is operating effectively. Furthermore, for those items that are involved in a previous food contamination and food safety incident, a full risk assessment, analytical testing, and certification of food items should be required by USDA and APHIS before importation of those items.

Repeated incidents involving imported foods including four years of food borne outbreaks from Salmonella poona in imported Mexican cantaloupes, recent findings of chloramphenicol residues in Asian shrimp, other seafood species, and honey in the U.S., Canada and Europe, and the findings of Mediterranean fruit fly in Clementine fruit from Spain illustrate the need for heightened surveillance and inspections.

NASDA urges all states to modify their programs to inspect and test for the food safety problems being noted in the marketplace involving antibiotic residues, food borne pathogens, and pesticide residues, and strongly encourages the federal government to provide needed resources to conduct such programs.

NASDA commends APHIS for action to prohibit the entry of medfly infested Spanish Clementine fruit and urges APHIS to continue this prohibition until adequate medfly-free certification criteria can be implemented. NASDA urges the U.S. Food and Drug Administration to establish systems and procedures to prevent the introduction of food borne pathogens, antibiotic residues, and pesticide residues into the food supply from other nations and to prohibit further importation of products involved in known problems until assurances of contamination problems can be resolved.

The United States still imports milk products from foreign countries without regard to whether those countries have equivalent inspection systems to assure the safety of those products, subject only to spot-checking of these products on arrival in the United States, except in cases where state laws have forced state authorities to establish more stringent controls. The Import Milk Act should be amended to extend the prohibitions applicable to the importation of milk to milk products, so that neither may be imported unless the Food and Drug Administration has conducted its own premises inspection, accepted a foreign official's certification of the quality of the product in question, or determined that the shipping country maintains a milk and milk product inspection and control system equivalent to that of the United States.

4.8 TRANSPORTATION

An important component of the “farm to fork” food safety continuum is transportation. It must be recognized that the transportation of food products to retail and wholesale distribution outlets provides one of the greatest hazards to public health. The oversight and regulation of the transportation of food products across our country is one of the weakest links in the food distribution system.

The federal food regulatory agencies need to establish an integrated food transportation oversight and regulatory program. This program should establish the delegation of responsibility and authority to assure that food products are transported under acceptable temperatures, clean and sanitary conditions, and packaged and loaded to prohibit the cross contamination of food products, including fresh produce, meat and poultry, and packaged foods.

4.9 FOOD IRRADIATION

Scientists, food regulators, public health officials, and food industry leaders all strongly support the use of irradiation technology to enhance food safety, quality, and to control pest dissemination. While the regulatory approval process in the United States has been viewed as an obstacle to widespread adoption, the USDA has recently defined uses of food irradiation to include treatment of frozen and refrigerated uncooked meat and meat byproducts. NASDA supports the expanded use of food irradiation to include ready-to-eat meat and poultry products and fruit and vegetable products. As additional approvals are given, USDA must also fund educational efforts in order to provide consumers with accurate information about the technologies used to ensure food safety.

A parallel exists between the current food irradiation debate and the concerns debated during the adoption of an earlier food safety technology – milk pasteurization. Several decades ago, there was a prolonged period when the public was uninformed about the benefits of milk pasteurization and therefore suspicious of adverse health effects associated with consumption of pasteurized products. Consumers were slow to accept this important method of ensuring milk safety in part because public health and agricultural authorities at the time did not publicly advocate its use.

NASDA supports the federal regulatory agencies as they continue to expedite review of food irradiation petitions. FDA should also review current regulation that considers food irradiation as a food additive rather than a food process. We encourage NASDA members to develop partnerships within their respective states

and initiate effective consumer food safety education programs that includes information about the safety associated with the use of food irradiation. And finally, similar to NASDA's biotechnology policy, it is particularly important that food labels convey useful and accurate information in a way that is not misleading to the consumer.

4.10 RESEARCH

While NASDA supports the use of HACCP programs along the complete “farm to fork” continuum, we recognize that there are major gaps in knowledge and information, making it effectively impossible to implement in some areas. In particular, we know little about effective intervention at the farm production level; therefore it is unwise to mandate HACCP programs. However, with sufficient research we believe it possible to identify strategies that will significantly reduce the incidence of on-farm foodborne contamination. Furthermore, it is critical to have an effective transfer of technology and information to the farm. Coordination of research efforts is necessary between state and federal agencies. Enhanced disease reporting procedures would allow agencies to identify research needs at an early stage.

4.11 SALVAGE FOOD

Food and drug products can become distressed or non-marketable for a variety of reasons that include but are not limited to natural disasters (floods, tornadoes, hurricanes, etc.), shipping accidents, fires, etc. Some food and drug products can be reconditioned or salvaged safely for redistribution and sale to the ultimate consumer. In order to assure that the public health of consumers is protected from the sale or distribution of foods which have become adulterated or misbranded, a fully integrated and uniform system of salvaging and reconditioning of these products is needed. The Model Food and Drug Salvage/Recondition Code to regulate food and drug salvage processing plants and distributors should be offered to and adopted by the states. State and federal agencies should require that HACCP or HACCP-compatible plans are in place for all salvage food operations.

4.12 FOOD LABELING

The United States food supply is rapidly changing as consumers demand diverse and minimally processed foods. At the same time, the number of people at high risk for foodborne illness (pregnant women, individuals with compromised immune systems, the elderly and the very young) has never been higher. Unfortunately, food safety educational efforts have not kept pace.

Consumers frequently can not evaluate microbiological risks when they are purchasing food products. Organisms such as *E. coli* 0157:H7 can cause severe illness when a susceptible individual consumes even a few organisms. Consumers have no way of knowing when low level contamination is present and they must rely on government agencies and the food industry to ensure that the foods they purchase are safe. Although outbreaks of severe illness are relatively rare, when they do occur, they are often associated with consumer feelings of outrage and broken trust.

Warning and safe handling labels are used to inform consumers of potential foodborne illness risks. Food producers are reluctant to have their products publicly linked with foodborne illness and prefer more general food safety educational approaches, such as the “Fight BAC” campaign. A 1996 consumer survey conducted by the Food Marketing Institute suggested that consumers take action to reduce their risks of foodborne illness in response to information contained in safe handling labels. Sixty five percent of consumers participating in the survey indicated the labels made them more aware of food safety issues. However, only 43% reported changing their behavior based on this information. It was not determined if the behavioral changes were maintained over a long period of time. The most commonly reported changes were:

- Increased cleaning/disinfecting for food contact surfaces (41%)
- Cooking foods to proper temperatures (19%)

- Increased handwashing (19%)
- Not thawing meat on kitchen counter (11%).

More effort needs to be placed on finding effective ways to inform consumers of risk without relying solely on warning statements placed on food products. Criteria need to be established on which to base justification for warning statements or any other disclosure about a food product. Food label claims must be both true and not misleading. Labels are powerful ways to inform, persuade, frighten or misinform consumers and care should be exercised to require only information that represents a material fact. Warning information should only be required when warranted by experimental or clinical evidence.

4.13 DISPARAGEMENT OF AG PRODUCTS

Apple growers were financially devastated in 1989 by the highly-publicized Alar scare. It was later determined that disseminators of the sensationalized allegations against apples had no recognized, scientific data to validate their charges. This prompted agricultural interests aggrieved by the apple scare to seek ways to deter such efforts in the future. One option, which several state legislatures have enacted, is to promulgate legislation protecting producers from unfounded scare campaigns.

Biotechnology is an emerging tool that will likely become an important part of agriculture's future, resulting in the development of a host of new food products. This technology and its products are and will continue to be the subject of emotionalized, undocumented, unscientific attacks by certain organizations.

To prevent this situation from occurring, the free flow of agricultural products and the financial security of producers must be protected. Laws and regulations that requiring factual information be used when making allegations against agricultural products and/or producers will protect the industry and enhance the general public welfare by prohibiting the dissemination of false, disparaging, and economically damaging information.

4.14 EDUCATION

The final control in any system of food safety rests with the consumer. Observations in the United States and other countries have demonstrated that the incidence of foodborne illness can dramatically decline as a result of active public education and effective media coverage. Government and industry must share the responsibility for educating consumers on appropriate food handling and cooking practices.

Public education should include a general, science-based food safety program directed toward all consumers and target programs for those persons at high risk for foodborne illness. Consumer education should also provide information on technological advances, such as irradiation and agriculture biotechnology that can enhance the safety of the food supply, to promote wider consumer acceptance of such beneficial progress.

Federal law should also provide consistent information regarding warning labels and other information statements on food products. While it is important to make information available to sensitive populations, statements that are required on some products, but not on other similar products, lead to confusion and misinformation about those products. NASDA would welcome the opportunity to work with federal policymakers on a consistent label and information policy for food products.