Testimony of
Michael R. Taylor*
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Mr. Chairman, Senator Enzi, members of the committee, I appreciate this opportunity to testify on strategies to improve food safety and on the Food and Drug Administration's recently issued Food Protection Plan.

Introduction

This hearing is timely and important. For over a decade, the Government Accountability Office (GAO) and expert committees of the National Academy of Sciences (NAS) have been documenting fundamental problems in the nation's food safety system – a system that has evolved over many years without a coherent plan or strategy and that now includes some 20 components of FDA, USDA, EPA, and CDC, and 3,000 state and local agencies.

Among all these agencies, FDA has long been looked to as the natural focal point for food safety leadership in the United States and internationally. It oversees 80% of the U.S. food supply (including an even greater share of imported food) and is the steward of a long tradition of effective, science-based regulation to protect public health.

Unfortunately, FDA's current ability to provide food safety leadership, or even meet its basic food safety responsibilities, is badly constrained by:

- *Obsolete statutes* that date back to the 1930's and focus more on reacting to problems than preventing them;
- *Inadequate resources* that are dwindling in the face of an increasingly complex, global food supply; and an
- *Internally fragmented and ineffectual organizational structure* that makes FDA incapable today of providing effective food safety leadership.

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* Mr. Taylor is Research Professor of Health Policy at The George Washington University School of Public Health and Health Services and chair of the Food Safety Research Consortium. He served formerly as Administrator of USDA's Food Safety and Inspection Service (1994-96) and as Deputy Commissioner for Policy of the Food and Drug Administration (1991-94).

Certainly, FDA could be doing more with its present tools to address some of today's pressing food safety problems. I believe, however, that FDA will continue to fall short of what the public needs and expects from this critical public health institution until Congress provides a modern statutory mandate, an adequate and stable resource base, and an institutional structure capable of national and international leadership on food safety.

And that is why it is so timely and important for this committee to be focusing on how to improve FDA's food safety program. Getting food safety right at FDA is essential to the public's health, to the confidence people want to have in the food they feed themselves and their families, and to the economic success of the food system. This committee's leadership will be essential to achieving these outcomes.

In my testimony today, I will not linger over the litany of what's wrong with the FDA program. I will instead focus on what I believe are the core policy elements of a successful strategy for improving food safety, and I will assess the new FDA Food Protection Plan in light of those elements.

In general, I find that the FDA plan contains many of the policy ideas that experts agree are important to ensuring food safety – and thus provides a platform on which to build. It falls critically short, however, on clearly and properly defining the complementary but distinct food safety roles of the food industry and the government. As a result, the FDA plan does not include actions and recommendations that I think are vital to FDA's success.

I note also that the administration's plan is silent on FDA's resource and organizational problems, but I will focus in this testimony on the core policies that should underlie FDA's food safety strategy and program.

Core Policy Elements of a Successful Food Safety Strategy

The following are the five core policy elements that I consider essential to a successful FDA food safety strategy.

1. *Treat food safety as a farm-to-table, system-wide problem.*

For most of the 20th century, food safety regulators focused largely on basic sanitation in processing plants, chemical contaminants in food, and the safety of chemical additives. It was possible then for FDA to focus on a relatively narrow set of establishments, commodities, and decision processes through which those concerns could be addressed. Over the last twenty years, however, the problem of foodborne illness caused by microbial pathogens has emerged as a central food safety concern and one that requires a broader, "farm-to-table" approach to ensuring food safety.

A farm-to-table approach is required due to the simple reality that dangerous bacteria and other pathogens can enter the food chain at almost any point, from production on the farm through processing, retail sale, and final preparation for consumption; they can grow; and

they can be killed. Thus, whether someone gets sick depends not on any one contamination event but on a wide range of events and behaviors that occur across the entire farm-to-table food system and that, in combination, determine the likelihood dangerous levels of an organism will be present at the point of consumption.

This expanded understanding of food safety makes everyone – from farmers to consumers, as well as government food safety agencies – actors in the food safety system. It creates the opportunity and need for integrated action to minimize food safety risks at points all across the farm-to-table system – wherever pathogens can enter the food and grow or be reduced. FDA's food safety program must recognize and act on this reality, as recommended repeatedly by GAO and NAS.

2. *Make prevention of food safety problems the central focus of the system.*

Prevention is the core principle of public health and should be the central focus of the food safety system. Prevention of problems is certainly what consumers expect of the system, and it's the core principle that drives modern approaches to food safety. Most notably, HACCP (Hazard Analysis and Critical Control Points) is a system of preventive process control that was developed originally by the food industry as a method for anticipating and preventing food safety hazards in particular food production and processing operations.

FDA has adopted HACCP as a regulatory requirement for seafood and juice, but prevention is not an explicit part of its statutory mandate. In fact, FDA's food safety legal authorities are designed primarily for reacting to and correcting problems after they occur, not for preventing them. In an on-going outbreak of foodborne illness, swift reaction and containment measures are important and can reduce the number of illnesses associated with that outbreak, but, to protect public health and meet public expectations for food safety, preventive measures such as HAACP need to be built in to the system so that the risk of food safety problems occurring in the first place is minimized to the greatest extent reasonably possible.

FDA currently pursues prevention of this kind only on a selective and ad hoc basis. A comprehensive, systematic approach to prevention should be a core principle and central focus of the food safety system.

3. *Recognize that the primary duty for prevention falls on the food industry.*

This may be the most crucial point to emphasize in getting roles and relationships between government and industry right. The unavoidable reality is that government does not make food, and government cannot make it safe. That's the food industry's job, and making food safe – doing everything reasonably possible to prevent food safety problems – is the most fundamental duty food producers and processors owe to America's consumers.

Many of our nation's leading food processors and retailers take this duty very seriously, and they make extensive efforts to fulfill it. They know food safety doesn't just happen; it's the result of a plan. So they impose safety specifications on their suppliers to be sure their raw materials and ingredients are safe; they implement HACCP and other preventive control measures within their processing plants; and they test their finished products to verify that their control systems are working. In fact, over the years, much of the food safety innovation in the United States has come from companies that take food safety seriously and have plans for achieving it.

The problem is that many of the nation's 44,000 food manufacturers and processors, 114,000 food retailers, and 935,000 restaurants do not have effective food safety plans. And, at the farm level, systematic planning for prevention of food safety problems is in its relative infancy. This must change.

Any business involved in producing, processing, and marketing food must have a plan for making it safe, based on modern preventive controls. This does not mean a one-size-fits-all approach. It does not mean HACCP per se for every commercial participant in the food system. But it does mean that anyone producing food for today's marketplace should know how they are going to make it safe and should do that consistently, every day.

4. *Focus FDA on setting and enforcing standards that make the food industry accountable for prevention.*

While the food industry is inherently responsible for making food safe by acting preventively, FDA's job as a public health regulatory agency is to set and enforce standards that make the industry publicly accountable for prevention, in accordance with a defined standard of care. Setting standards for prevention means defining the responsibility of food producers, processors and retailers to have and implement food safety plans based on modern preventive controls. It also means establishing performance standards that define the level of protection, or food safety performance, that is to be achieved through preventive controls, such as the levels of chemical residues or microbial contaminants that are deemed acceptable.

Standards protect food safety only if companies comply with them, and it is FDA's job to ensure compliance through inspection and enforcement. For many leading companies, compliance is not an issue: if the government sets a food safety standard, they will organize their systems to comply. In fact, many will go beyond what the government requires in response to the demands of their customers expressed in the marketplace. The food industry is, however, highly diverse, with some companies lacking the market incentive or an internal culture that ensures they meet high food safety standards. That's why government standards and government enforcement are needed, and it's why they are in the interest of both consumers and those in the industry who take their food safety job seriously and do it well.

Government regulation of food safety is essential, but it has to be smart regulation. We have learned that old fashioned "command and control" regulation – in which the government specifies not only the outcome to be achieved but how industry must achieve it – can impose unnecessary costs and stifle innovation. Instead, modern regulation is clear in setting performance standards for companies and flexible in how companies can achieve the standard. Thus, as a regulatory tool, HAACP sets a standard of care for implementing preventive process control but is inherently flexible in allowing companies to tailor their preventive controls to the particular hazards and circumstances in their operations. Performance standards for microbial contamination say what level and incidence are acceptable, but they do not dictate the interventions needed to achieve them.

In a food safety system based on holding the industry accountable for prevention, regulators have a duty not only to avoid stifling innovation but to affirmatively encourage it. This means among other things ensuring that regulatory review of new food safety technologies is done promptly and with an appreciation of the food safety benefits of technological innovation.

5. *Strengthen FDA's mandate and tools for providing national leadership on food safety and managing a science- and risk-based regulatory program.*

While FDA's core role on food safety is to set and enforce standards, it will be effective in this role only if it operates from a position of strength as the nation's leading science-based, public health regulatory agency. To this end, FDA should have a clear mandate to drive research aimed at understanding food safety problems and solutions and setting science-based standards. It should work closely with CDC, other federal food safety agencies, and state and local agencies to build an integrated, national system of food safety protection. And it should provide scientific and policy leadership to develop workable approaches to risk-based priority setting and resource allocation across the food safety system.

Assessment of the FDA Food Protection Plan

The five core policy elements outlined above reflect current thinking about the attributes of a modern, effective food safety system, as that thinking has evolved through the work of NAS, GAO and other experts. The language of the FDA Food Protection Plan is largely consistent with these ideas. It speaks of addressing risks of food "from production to consumption;" it makes prevention and corporate responsibility for prevention central themes of the plan; and it calls for risk-based approaches to inspection and better use of information to improve food safety. For this reason, the plan is a useful basis for discussion.

The shortcomings of the plan lie in the specific actions it proposes – and fails to propose – to implement these broad ideas. While many of the proposed actions are worth pursuing, they do not add up to an effective FDA strategy to improve food safety. In general, they fall short of the action that is needed to establish the food industry's farm-

to-table accountability for prevention. To illustrate this key point, I will review the FDA plan in light of the five core policy elements discussed above.

1. *Treat food safety as a farm-to-table, system-wide problem.*

While stressing the importance of a farm-to-table approach to food safety, the FDA plan proposes no specific actions to improve food safety on the farm or at retail, beyond what it is currently doing.

At the farm level, the plan calls for FDA to meet with food industry representatives to strengthen "voluntary" prevention efforts and for FDA to develop guidelines for industry development of voluntary "food protection plans" for produce and other foods, but FDA has been meeting with the industry about produce safety for the last decade, and in 1998 issued non-binding "good agricultural practice" guidelines to address the microbial safety of fresh fruit and vegetables.

Early this year, an industry trade group, the United Fresh Produce Association concluded that the voluntary approach was insufficient and called for FDA to establish mandatory, enforceable, on-farm standards for safe produce production, but the FDA plan is silent on this idea. And, while the plan calls generally for strengthening FDA's ability to assess and prioritize risks and identify preventive strategies, it contains no specific proposals for driving the research and analysis needed to establish enforceable food safety performance standards on the farm.

On retail food safety, the plan makes several references to the need for dialogue with the states and localities, which play the frontline role on food safety in the nation's grocery stores and restaurants. Such dialogue is important, but is has been ongoing for many years and has resulted in important collaboration through FDA's development and the adoption by many states of the Food Code, which is a model ordinance for regulating food safety at retail. In addition, FDA and the states collaborate on an innovative program to foster improvement in state and local food safety regulatory programs, based on uniform national standards. The FDA Food Protection Plan does not include ideas for improving these core FDA retail food safety programs or recommend any other specific actions to improve retail food safety.

While the FDA plan lacks concrete proposals for new actions to address food safety risks on U.S. farms or at retail, it does call for a number of actions to improve FDA oversight of food imports, including more affirmative efforts to work with foreign governments on food safety, develop knowledge needed to target high-risk imports, and improve FDA's ability to detect problems at the port of entry. These ideas are positive, but, as discussed below, the report does not address the accountability of importers for ensuring that the food they import was produced in accordance with U.S. standards.

2. Make prevention of food safety problems the central focus of the system.

The FDA plan gives great prominence to the concept of prevention, which would be an important and positive shift in emphasis in FDA's food safety program, but the plan's approach is to work collaboratively with the industry to foster voluntary adoption of preventive control plans. Such voluntary efforts can contribute to progress in the near term to the extent those not currently following recognized "best practices" are willing to emulate leading companies that are already implementing state-of-the-art preventive control plans. Such voluntary efforts will not, however, solve the food safety problems posed by companies that lack market incentives or are otherwise unwilling or unable to bring their food safety practices up to modern standards. Furthermore, voluntary approaches do not provide clear public accountability for prevention.

Even more fundamentally, the FDA plan does not address the agency's lack of a statutory mandate to make prevention the central focus of its program. While prevention is clearly the necessary strategy for the future, the basic food safety provisions of the Federal Food, Drug, and Cosmetic Act on which FDA relies to regulate microbial pathogens were enacted in 1938 and are silent on prevention. They consist instead of adulteration and enforcement provisions designed for reaction to problems and correction of them after the fact. To make prevention the central focus of its program, FDA should be calling for a new prevention mandate from Congress and the legal tools to back it up.

3. Recognize that the primary duty for prevention falls on the food industry.

Again, the FDA plan calls prominently for promotion of "increased corporate responsibility to prevent foodborne illness," which is a conceptual step forward, but the proposed implementation of this central concept falls far short.

In fact, rather than recognizing that all those involved in the food business have a prevention duty for which they should be publicly accountable, the FDA plan actually places the burden on FDA to determine case-by-case when preventive controls should be required. Moreover, it calls on Congress to limit FDA's power to require preventive controls to cases in which it can establish through rulemaking that a particular food has been associated with "repeated, serious adverse health consequences or death."

Placing the burden on FDA in this fashion is the opposite of a true prevention strategy. It treats preventive process control as a tool for reacting to problems after they occur rather than a tool for systematically and comprehensively building prevention into the system. And the stringent standard for requiring preventive controls that the FDA plan recommends is a step backward from the legal authority that FDA has under current law and has used already to require HACCP for seafood and juice. It is far from clear whether the Office of Management and Budget would have cleared, or the courts would have sustained, FDA's seafood and juice HACCP rules had they been subject to the standard recommended in the FDA plan.

The plan's lack of follow through on the principle of industry responsibility for prevention is evident also in its import proposals. These proposals focus on what FDA will do to work with foreign governments and to better detect problems at ports of entry, but they do not call for any new accountability on the part of importers to ensure that problems have been prevented up the supply chain to the point of production in the exporting country. FDA will never have enough resources to police and ensure the safety of imports without harnessing the expertise and efforts of the private sector and making a U.S.-based entity legally accountable for ensuring prevention is "built in" for imports, just as it should be for domestically produced food.

4. *Focus FDA on setting and enforcing standards that make the food industry accountable for prevention.*

Other than the provisions for requiring preventive controls on a case-by-case, reactive basis, the FDA plan does not address the need for setting and enforcing standards that make the food industry accountable for prevention. As noted earlier, the plan focuses on encouraging voluntary adoption of preventive controls.

The closest the plan comes to standards and enforcement is in its second core element of "intervention," where the plan calls for "targeted, risk-based interventions to…ensure that the preventive measures called for are implemented correctly." The three "key intervention steps" do not, however, directly address prevention at all, nor do they involve any measure that would create accountability for prevention. The three proposed "interventions" are instead tools for detecting problems after the fact, including risk-based inspection, sampling, and surveillance and improved detection of food system "signals" that indicate contamination. These are all worthy approaches to better targeting the use of scarce resources, but they are more about detection and correction of problems than prevention.

<u>The best way to ensure that necessary preventive measures are implemented is to hold companies directly accountable for prevention in accordance with a defined standard of care</u>.

5. *Strengthen FDA's mandate and tools for providing national leadership on food safety and managing a science- and risk-based regulatory program.*

The FDA plan clearly envisions a food safety leadership role for FDA in relation to the food industry and state and local government, which is positive. The call for closer collaboration with state and local food safety agencies is especially important to building an effective, national food safety program and making good use of all available public resources. On the industry side, however, the proposed FDA leadership role in encouraging voluntary adoption of preventive controls may actually blur rather than strengthen responsibility and accountability for prevention.

The plan's call for FDA leadership on food safety research and on developing the tools for a science- and risk-based approach to setting priorities and allocating resources is an

important strength. The plan also recognizes the need for FDA to take the lead in developing the tools and capacity for knowledge generation and information management to improve food safety, such as enhancement of FDA's Emergency Operations Network Incident Management System, more effective traceback systems, and improved sharing of information across the system. Better collection and use of information is obviously essential to our efforts to improve food safety.

Recommendations for Improving on the FDA Food Protection Plan

FDA's plan has its clear strengths and weaknesses. On policy, the plan's major strength is that it embraces the concept of industry responsibility for prevention and calls for strengthening FDA's capacities in important ways. The plan's major policy weakness is that it fails to call for the statutory modernization and policy change that is needed to implement the prevention concept in a really substantial way and thus leaves FDA still relying too heavily on reaction. The plan does not address at all FDA's problems of dwindling resources and an ineffectual organizational structure for food safety.

With these points in mind, I offer the following major recommendations to augment FDA's Food Protection Plan and equip FDA for success on food safety.

Modernize FDA's Statutory Mandate

Congress should modernize FDA's food safety mandate to, among other things:

- Explicitly make prevention of foodborne illness FDA's primary food safety mission;

- Establish by law a duty for all those in the food business to implement preventive controls appropriate to their particular operation, subject to FDA's implementing regulations and guidance;

- Direct FDA to establish and enforce performance standards that make companies accountable for implementing effective prevention measures;

- Make importers legally accountable for assuring that foreign producers and processors shipping products to the United States are meeting U.S. standards;

- Provide leadership in building an integrated, national food safety system that is science- and risk-based and makes efficient use of available resources to improve food safety.

Provide FDA an Adequate and Stable Resource Base

FDA's resources for food safety have been eroding for years as the agency's food safety challenge gets larger. The total operating budget for FDA's Center for Food Safety and Applied Nutrition – the resources available to take action after the staff and rent are paid

– is down to around $25 million, which is a paltry sum for an organization charged with driving food safety progress across 80% of the American food supply, while also regulating dietary supplements and food labeling, ensuring the safety of infant formula and food additives, and attempting to provide food safety leadership internationally. An agency with all these responsibilities that can't conduct or commission research, adequately equip its staff, or travel simply can't do its job.

Despite this well-documented resource reality, and despite the fact that the FDA plan includes 38 actions to strengthen FDA's food safety program, the plan is silent on resources. Presumably, the President's 2009 budget proposal will include the resources needed to implement the plan.

Congress, however, has a responsibility to act. In addition to meeting FDA's immediate needs through the 2008 and 2009 budget processes, Congress should undertake a serious study of how to establish an adequate and stable funding base for FDA's food safety program for the long-term. Just as it is fair to hold the food industry accountable for doing its food safety job, it is fair to hold FDA accountable for the leadership and effective action we expect from that agency, but only if it has an adequate and predictable resource base.

Congress should explore a range of resource options, including:

- Requiring FDA to prepare for Congress a five-year financial plan and an annual "professional judgment" budget sufficient to implement a modernized statutory mandate.

- Establishing by law a statutory inspection mandate, with consequences built in for failure to meet it, to serve as an anchor for appropriated resources.

- Authorizing FDA to collect establishment registration fees and import fees to provide a steady base of resources for the food safety program.

Unify and Elevate the Organizational Elements of the FDA Food Safety Program

The third key ingredient for the success of any agency – after an appropriate statutory mandate and adequate resources – is an organizational framework suitable for its purpose. For food safety, FDA needs a framework that enables it to provide national leadership on food safety and run a coherent, well-planned program that makes the best use of available resources to improve food safety. For several reasons, FDA lacks such a framework.

First, within FDA, the food program has historically taken a back seat to the drug and medical device programs in the competition for management attention and resources. This is due in part to the intense interest that drug and device companies, health professionals, and patients all have in FDA's "gatekeeper" role for therapeutic products and is reflected in the fact that most FDA commissioners come from a biomedical or

health care background. This strong tilt toward drugs and devices was exacerbated by the drug and device user fee laws, which have further focused FDA management attention, accountability, and resources on the therapeutic side of the agency. History has taught that the job of providing effective national leadership simultaneously on both therapeutic products and food safety is too big a job for any one person.

Second, FDA's organizational structure for food safety is fragmented and lacks a clear focal point for leadership. CFSAN ostensibly has the lead on food safety at FDA, but CFSAN actually shares food safety jurisdiction with the Center for Veterinary Medicine, which regulates pet food and animal drug and feed additive residues in human food, and with the Office of Regulatory Affairs, which manages the majority of FDA's food safety resources through its field force of inspectors, compliance officers and laboratory personnel. The recent establishment in the Office of the Commissioner of an Assistant Commissioner for Food Protection, who serves as a spokesperson and coordinator but lacks budget or line authority for programs, further clouds responsibility and accountability for food safety within FDA.

Finally, food safety leadership at FDA rests at least two bureaucratic layers removed from the Secretary of Health and Human Services. As decisionmaking in the executive branch continues to be centralized at higher and higher levels, with OMB having enormous influence on regulatory policy, the full time leader of the nation's premier food safety program needs to have the greater clout in the system that comes from being presidentially appointed and reporting directly to the Secretary.

The FDA Food Protection Plan did not address these structural obstacles to the success of the food safety program. Congress should address them by unifying the food-related components of FDA into a single organization and elevating that organization within HHS under the leadership of a presidentially appointed official reporting directly to the Secretary.

Conclusion

Thank you again, Mr. Chairman, for the opportunity to testify on these important issues. I look forward to answering your questions and the questions of your colleagues on the committee.