

**Testimony of
Michael R. Taylor***
Before the

**Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives**

**Hearing on
Food and Cosmetic Provisions of the "Food and Drug Administration
Globalization Act" Discussion Draft Legislation
April 24, 2008**

Mr. Chairman, Mr. Deal, members of the subcommittee, I appreciate this opportunity to testify on the food and cosmetic provisions of the Chairman's "Food and Drug Administration Globalization Act" discussion draft.

Introduction

I applaud the subcommittee for tackling the modernization of our food safety laws. 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

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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.

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 subcommittee 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. The subcommittee's leadership will be essential to achieving these outcomes.

In my testimony today, I will outline what I believe are the core policy elements of a successful strategy for improving food safety, and I will comment on how these elements are addressed in the discussion draft of the “Food and Drug Administration Globalization Act of 2008” released on April 18 by Chairman Dingell. I will also touch on the need to provide FDA an adequate and stable funding base for its food safety program and to unify and elevate the organizational elements of the program so that FDA can once again provide food safety leadership, nationally and internationally.

In general, I find the discussion draft to be very much on the right track. It recognizes that food safety is a farm-to-table and global challenge and that FDA’s program must be based not only on reacting to problems but on enforcing the duty of the food industry to prevent them. The draft legislation’s core requirement that companies have food safety plans – and that the plans be based on the concept of preventive process control and be designed to satisfy government-established performance standards – is central to any meaningful modernization of the food safety system. The draft also contains innovative provisions to address the safety of imported food.

I will offer some suggestions for improving these and other provisions of the draft, and I will note some additional legislative needs I recommend the subcommittee consider.

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.

This broader understanding of the food safety challenge – and the need to act in a comprehensive, integrated way to meet it – applies with full force to the growing volume of food imports.

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, however, 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, HACCP 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.

Comments on the Discussion Draft

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. I will organize my major comments and suggestions concerning the discussion draft around these five elements.

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

As I understand section 102 of the discussion draft, it would apply the requirements for a food safety plan and preventive controls to all facilities that process or store food for the U.S. market, whether domestic or foreign. It thus strengthens and modernizes standards for food safety in these critical facilities and recognizes, properly, that U.S. food safety standards should apply to imported food just as they do to domestically-produced food.

The discussion draft also takes an important step in section 103 toward bringing agricultural producers more fully into the food safety system by making the food safety plan and preventive control requirements applicable to the production of fresh produce, subject to FDA being able to spell out how producers can comply for specific types of produce. I agree that, within FDA's jurisdiction, produce deserves the highest priority in setting standards for on-farm prevention of food safety problems. I also agree that the measured approach taken in the discussion draft is appropriate, given the wide range of large- and small-scale growers involved and the relative inexperience of many in this sector with preventive process control.

My only suggestion with regard to the produce provisions of the discussion draft is to include a clear directive to FDA to prioritize the types of produce that are most in need of preventive controls to ensure food safety and to move forward promptly with the needed regulations. In addition to produce, FDA has jurisdiction over on-farm food safety practices for eggs and has proposed regulations that would require preventive measures for egg safety. FDA should be directed to finalize those regulations.

The subcommittee should also take note of the fact that animal production practices can be an important risk factor for produce safety, as well as the safety of meat and poultry products. In the case of produce, failure to prevent access of animals to fields where crops are grown or to manage manure in a way that prevents water- or air-borne transmission of pathogens increases the risk of contamination with E. coli O157:H7 and other dangerous bacteria. USDA and FDA both have roles to play in addressing animal production practices that affect food safety, but USDA has no authority to regulate on the farm for food safety purposes, and FDA's mandate and authority in this area are at best murky. Congress thus needs to take a comprehensive look at how to improve the government's ability, working in collaboration with the agricultural community, to strengthen food safety practices on the farm.

While the discussion draft addresses the on-farm and processing segments of the farm-to-table spectrum, it does not address the critical retail sector, which includes both restaurants and grocery stores. State and local agencies play the frontline role in setting

and enforcing standards at the retail level, and there is a long history of collaboration between these agencies and FDA, through the FDA's Food Code and other efforts, to help ensure that state and local oversight reflects up-to-date science and is reasonably consistent nationally. This collaboration needs to be strengthened through training, technical assistance, and federal incentives for state and local agencies to adopt updated standards for retail food safety and implement them effectively.

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

The central strength of the discussion draft is that it would direct and empower FDA to implement a food safety system that is based on the public health principle of prevention. That is what the food safety plan and process control requirements in section 102 are all about, and I hope the subcommittee and Congress will adopt this essential reform.

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

The discussion draft embraces the key principle that the primary duty for prevention rests with the food industry by requiring in section 102 that the operators of all facilities have food safety plans based on preventive controls.

The draft also reflects the modern understanding of the key elements of preventive process control for food safety, which include hazard analysis, validation of the specific controls selected to address the hazards, monitoring and verification that the controls are working as intended, proper recordkeeping, and procedures for correcting problems when

they do occur. It is important that, in codifying the food industry's prevention duty, Congress spell out these basic principles.

As section 102 recognizes, in-process and end-of-process testing can be important tools for verification that preventive controls are working properly. The nature of the company testing that is appropriate and useful for this purpose will vary substantially, however, based on the nature of the food and process involved. I believe the role of testing as a process control verification tool deserves serious discussion, with the goal of fostering such testing by companies when it can contribute to food safety, while preserving the flexibility for companies to adopt testing approaches that make sense in their particular operations.

Section 107 calls specifically for end-of-process testing of food shipments to ensure compliance with applicable food safety standards, with the approach to testing depending on whether facilities are certified or not under the discussion draft's certification provision in section 106. I interpret section 107 as being intended, at least in part, to provide incentives for facilities to seek and gain certification. I have some concerns and suggestions concerning the draft's approach to certification, which I will note below. I see a need for discussion, however, of how section 107 testing relates to testing conducted under a food safety plan. Among other things, care needs to be taken to ensure that the nation's testing infrastructure is not swamped with testing – such as for baked bread, dry cereals, and low-acid canned foods – that may not contribute to food safety.

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

From a public health and consumer protection perspective, food safety plans and preventive controls are valuable only to the extent they are designed and implemented to achieve acceptable food safety outcomes. Section 102 of the discussion draft adopts this principle in two critically important ways: (1) it explicitly directs FDA to examine food safety plans to ensure they meet “relevant regulatory and food safety standards,” and (2) it authorizes FDA to establish by regulation and to enforce performance standards that define for specific hazards the level of food safety performance a facility must meet. These are essential elements of the needed modernization of FDA’s food safety legal authority.

I have one suggestion with regard to FDA’s role in setting standards. I recommend FDA be given an affirmative directive to identify the most significant hazards in the food supply, prioritize hazards with respect to the need for performance standards to prevent food safety problems, and to implement a program to systematically develop and adopt standards for the highest priority hazards. Without a mandate to set priorities and act preventively, the crisis-of-the-day reality in which FDA operates will keep it mired in reaction, rather than leading on prevention.

While I think the discussion draft is basically sound in authorizing FDA to set standards, I have some concerns and suggestions about how the draft approaches FDA’s ability to hold companies accountable for meeting the standards. And standards benefit food safety

only to the extent compliance is achieved. I'll touch here on the basic enforcement mechanism for food safety plans, preventive controls, and performance standards; the role of civil penalties; and the proposed certification program.

I see no enforcement provision in the discussion draft for the requirement that facilities have food safety plans based on preventive controls and that they meet hazard-specific performance standards. I assume this is a drafting oversight. I recommend that the legislation make it a prohibited act for a facility to fail to have a food safety plan that complies with the new requirement or to ship a product that fails to meet a hazard-specific performance standard. Products that fail to meet a hazard-specific standard should also be deemed adulterated.

I support the availability of civil penalties as a tool for holding companies accountable for prevention. The prevention value of food safety plans and preventive controls depends on their being implemented successfully on a continuing, daily basis. This will happen only if a facility's managers have in place not only a satisfactory written plan but the systems to ensure the plan is implemented properly. Many companies need no incentive from government to have such systems, but many do. For the shift to prevention to work in practice and be credible to the public, FDA needs accountability tools that provide incentives for these companies to work in this new way.

Under current law, FDA's most commonly used remedies for dealing with food safety problems are voluntary recalls and judicial seizure actions. In both cases, FDA is able to

act only against the food itself, rather than the behavior that gave rise to the food safety problem. FDA can also seek court-ordered injunctions to control future behavior and criminal penalties to punish past conduct, but pursuing these remedies is extremely cumbersome and costly.

Civil penalties provide FDA an efficient remedy for situations in which companies have failed to act preventively by having and successfully implementing a proper food safety plan. A civil penalty provision should be crafted carefully to recognize that the implementation of a food safety plan is never perfect and that the success of a plan lies not in preventing every problem, but in minimizing problems as much as reasonably possible and responding well to contain problems when they do occur.

I think the discussion draft's approach to certification of food facilities in section 106 deserves careful consideration and thought. I see the value of certification in the import situation as a way to bolster the assurance that products offered for import to the United States have been produced under conditions that meet U.S. standards. I think this can help compensate for the reality that the United States cannot possibly provide the same level of inspection and compliance oversight in foreign facilities that it can provide in U.S. facilities. I think it is even more fundamentally important, however, to clarify and strengthen the duty and accountability of U.S.-based importers for ensuring the food they import meets U.S. food safety standards.

I also see the potential value of certification for domestic facilities as an element for FDA to consider in guiding the risk-based allocation of its inspectional resources, which I think is critical to the long-run effectiveness and efficiency of the federal food safety program.

I have a number of specific concerns and suggestions about the certification proposal in the discussion draft, of which I will mention two here.

First, certification should be done only by independent third parties, which, in the case of imports, could include foreign governments. I do not think FDA should be the certifying party. FDA should accredit certifiers, but not grant certifications itself.

I base this view largely on my experience at USDA, where the granting of the government stamp of approval creates a commonality of interest between the agency and the company and erodes the independence and objectivity of the agency in assessing the company's future problems and behavior. I'm also concerned that, if FDA is put in the certification business, that will become a dominant focus of the agency's food safety managers, rather than setting and enforcing food safety standards. This is a particular concern because certifications are based on a snapshot in time, while the preventive approach to food safety depends on the continuing successful implementation of food safety plans and compliance with performance standards.

Second, the discussion draft is not clear on how "compliance with applicable requirements" is to be determined for purposes of granting certification. Is it sufficient to

have an adequate written plan? Does the plan's successful implementation have to be demonstrated in practice over time? Does compliance with applicable performance standards have to be demonstrated?

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

The discussion draft directs FDA to conduct research on testing methods, with a priority to be accorded development of methods to detect intentional contamination. This is good as far as it goes, but, as outlined earlier, I recommend that FDA be given a broader mandate to drive problem-solving food safety research; build a more integrated, national food safety system; and provide system-wide leadership for risk-based priority setting and resource allocation, as called for by GAO and NAS.

Resources and Structure

Beyond a modernized statute, the other key ingredients for FDA's future success on food safety are adequate and stable resources and a unified and elevated organizational structure.

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. Staffing levels are declining, and 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.

FDA needs an adequate and stable resource base for its food safety program. The discussion draft addresses this need primarily through annual facility registration fees. This is, obviously, a controversial topic. I am one of many who believe that public health and regulatory programs of the government should, ideally, be financed through normal appropriations rather than fees. The primary value at stake here, however, is that FDA must have an adequate and stable funding base. If appropriated funds are not realistically going to meet this need, registration fees are probably the least objectionable alternative, because they spread the cost widely and do not involve a direct quid pro quo between FDA and the industry.

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 appointment in the Office of the Commissioner of an Associate Commissioner for Food Safety does not solve the problem. This position lacks budget or

line authority for programs and thus in some ways 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.

I recognize that these organizational issues are beyond the scope of the discussion draft and that solving them requires careful thought and planning, but I hope that the subcommittee will see the need to tackle them as part of a continuing effort to equip FDA to do its food safety job. In my view, the solution lies in 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. And I would be happy to discuss with your staff further details on the discussion draft.

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Major Points

- The discussion draft is on the fundamentally right track in mandating food safety plans and preventive process controls for all food facilities, domestic and foreign.
- The establishment and enforcement of performance standards is a key element of prevention oriented reform, as contemplated by the discussion draft.
- The process for setting and enforcing performance standards needs to be strengthened, including the judicious use of civil penalties as an incentive for compliance.
- The application of the food safety plan and preventive controls requirement to fresh produce is a positive and important step toward a “farm-to-table” food safety system, but the legislation should also address improving oversight at the retail level.
- Certification can be useful to bolster confidence in imports and guide risk-based resource allocation of domestic inspection resources, but FDA should accredit certifying bodies, not grant certifications itself.
- To ensure FDA’s success, Congress needs to address not only its legislative authority but also FDA’s resources and organizational structure.