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**Testimony before the U.S. Senate Committee on Health, Education, Labor, and Pensions
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I wish to offer my sincere thanks to Senator Kennedy, Senator Enzi, and this Committee for providing me the opportunity to testify before you and to discuss the role of state and local government in our country’s food safety system. I have spent my entire working career of over 37 years as a state food safety regulator for the New York State Department of Agriculture & Markets (NYSDAM) beginning as a Food Inspector in 1970. I have witnessed many changes in the manner in which food protection programs are conducted within the country and have also seen the misfortunes of many, especially children, when these programs become weakened and ineffective. I have interviewed victims of foodborne illnesses and listened in great horror to the tragic tales of mothers whose children had succumbed to an illness that was hidden within their hamburger, vegetable salad, or apple cider. In recent years, I began to wonder what food would we next learn could make us sick and what emerging pathogen would now cause such danger and concern for us. It seems to me that this nation is screaming out for leadership and demanding that its government build a seamless food safety system that will restore their confidence in the food supply and in us. This, in my view, is the challenge before us today.

The success of the Food and Drug Administration (FDA) and other food safety agencies at the federal level depends to a large extent on effective coordination and collaboration with food safety regulators and health officials at the state and local level. The more than 3000 state and local agencies involved in food safety have long been on the frontline in conducting foodborne illness surveillance; investigating and containing illness outbreaks; conducting food safety inspections at the processing, warehousing and retail area; and taking regulatory action to remove unsafe products from the market. State and local food safety officials are much closer to consumers than federal agencies and under direct pressure to respond to food safety concerns in their communities, even when the problems originate elsewhere. One need only ask themselves who they or their doctor would call when sickness associated with food strikes them or a member of their family. In almost every circumstance, they call the local health department or the state health or agriculture department. Seldom do they call the FDA. Furthermore, when the media

finds recalled food products still on store shelves months after a recall is announced by the FDA, the media will contact local or state food safety officials and demand to know why.

To many of us in state and local food safety programs, it appears that federal policymakers do not have a clear understanding of the food safety roles of state and local agencies and the issues we face. The need for federal-state-local “partnership” and “collaboration” is well recognized and often voiced, but, absent some affirmative effort, federal food safety reform is unlikely to address the roles and needs of state and local agencies with the specificity required to achieve real progress. This is an important concern because, like many elements of the public health system, state and local food safety agencies operate under disparate and sometimes outdated statutory authorities, face the challenge of working within a complex web of local, state and federal agencies having complementary and sometimes overlapping roles, and are usually underfunded.

Notwithstanding budgetary concerns within the states, there remains a skillful, knowledgeable, and in many aspects untapped resource for the FDA to collaborate with on matters of food safety and food defense. In 2001, the Association of Food & Drug Officials (AFDO), the primary organization that represents government food safety regulators, conducted a survey of state food protection programs to quantify the amount of food safety work performed there. The survey represented all 50 states, with at least one administrator from every state responding. The results clearly demonstrated how huge a role the states play in the overall food safety efforts that exist in this country. Appendix B on the last page of this document summarizes the AFDO survey.

What is most alarming about this data is that the majority of this work identified at the state level may not be accepted or even acknowledged by federal agencies. This is true despite the fact that nearly 50% of the food inspections claimed to be performed by the FDA annually are actually performed by state agencies under contractual agreement. While there may be a number of reasons for this (such as equivalency issues and differences in authorities and laws), in my opinion we do a great disservice to consumers by not better coordinating our overall food safety efforts in this country.

Another unfortunate matter is the fact that over 320,000 food samples collected and analyzed by state food safety programs are, for the most part, ignored by federal agencies. Again, this may be a result of the FDA’s concern for equivalency or how samples are collected and processed by state officials, but it seems very unwise to ignore such a huge amount of important information relating to domestic and foreign-produced foods. Why the FDA does not better utilize this data and recognize its relevance to the protection of public health has remained a mystery to state food safety program managers for some time.

I have had the great fortune of working for an agency that has had the courage to meet food safety challenges very aggressively and the willingness to explore innovative strategies to better deal with these challenges. NYSDAM has gained its national reputation in food protection because we recognize the value in resource integration, partnering with federal agencies, and pursuing a course that recognizes that there is but one food supply to be protected regardless of the number of government agencies involved.

There are certain components of New York State’s food protection program that I believe forge innovative, “cutting edge” partnerships with the FDA and serve as models for other states. Our

“Integrated Food Safety System” is a partnership program with the FDA’s New York District, and perhaps most noteworthy is our Imported Food Initiative agreement we have with that district’s Upstate and Downstate Import Operations.

The purpose of the Integrated Food Safety Partnership is to establish an agreement that coordinates the food protection efforts of NYSDAM’s Division of Food Safety and Inspection and the FDA’s New York District Office. This agreement reduces consumer risk, eliminates duplication, defines regulatory roles and improves channels of communication. All manufacturing food establishments and food storage facilities licensed or inspected by NYSDAM are covered by this agreement and it serves as a pilot to demonstrate the effectiveness of integrating the federal/state responsibility for the food manufacturing and storage industries. The partnership includes data and information sharing, training, recalls, and enforcement strategies. It allows the FDA and NYSDAM to share each other’s resources and authorities. We could have never implemented this partnership program without mutual respect and the recognition that we both play critical roles in protecting New York citizens.

Our Import Initiative pilot is the project of which I am most proud because it is most timely and truly effective in dealing with the overwhelming burden of imported foods. It is very clear that the number of goods imported into this country has increased dramatically, and the majority of these imports are foods (See Figure 1). The FDA’s ability to handle the enormous surge of imported products, however, is increasingly limited; in fact it is estimated that less than 1% of imported products are physically examined (See Figure 2). As a result, the FDA is contracting out more and more domestic inspections to state agencies in order to focus more resources to imported products. Unfortunately, they cannot meet this huge demand, yet little has been done to allow state agencies to play a greater role in the surveillance and inspection of these foods. Imports have essentially remained a role of the federal government through the efforts of U.S. Customs and Border Protection [CBP], the United States Department of Agriculture (USDA) and the FDA. The Import Initiative, however, allows the FDA and NYSDAM to work more collaboratively on imported food oversight.

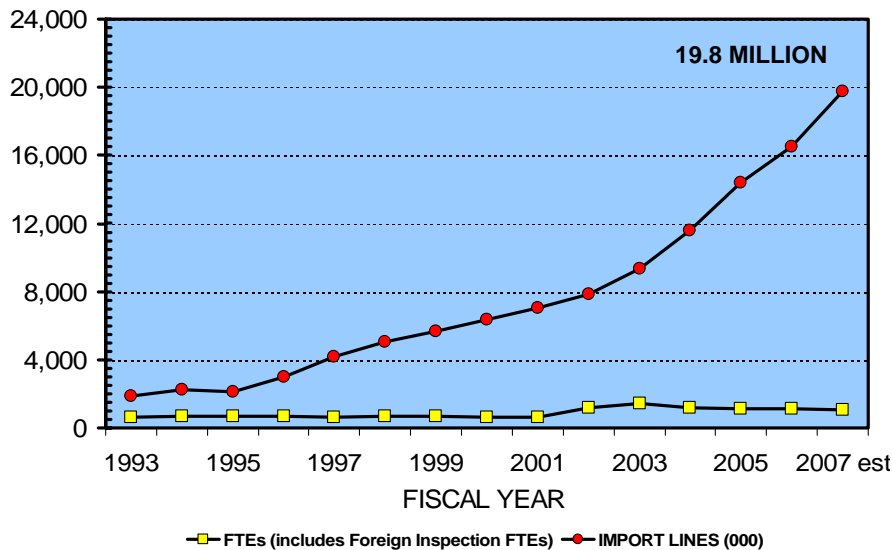
This cooperative effort is essential because approximately 33% of the imports coming into this country enter through New York State. Because of our diverse population, many of these products remain in New York and are marketed domestically here. These domestic channels – which include food warehouses, processing plants, and retailers – are the areas for which state and local food safety regulators are primarily responsible. To summarize, one can conclude that any imported food that makes its way through the scrutiny of the federal government becomes primarily the responsibility of state and local government regulators.

FIGURE 1



FIGURE 2

Import Exams and Entry Review



Note that although large volumes of imported food enter the U.S. via ports of entry in New York State, food of import origin offered for sale at New York wholesale/retail establishments can, and does, enter the U.S. via any of the 400+ ports of entry scattered throughout the country. NYSDAM's surveillance of foods of import origin at the wholesale/retail level not only protects

consumers in New York State, but also provides valuable information to the FDA regarding how the national import program is working. Subsequent joint investigations of violative food product will enable the FDA to determine why the violative food was not detected and detained and take affirmative steps to do so in the future.

A good illustration of the dilemma for state agencies with imported foods is depicted in Figure 3 below. This chart is a 5-year summary of food recalls coordinated by NYSDAM. With a field staff of a little over 100 Food Inspectors, we are averaging over 350 food recalls a year. This number is greater than the number of recalls coordinated by the FDA and USDA annually. Of the 1786 food recalls coordinated in New York since 2002, 1304 of these (or 73%) involved foods of foreign origin. Of that amount, 1030 (or 79%) were categorized as Class I or Class II (health impacted).

FIGURE 3

5 Year Recall Summary 2002- 2006				
Year	Class I	Class II	Class III	Totals
2002	129	187	42	358
	101 Imported	141 Imported	38 Imported	280 Imported
	28 Domestic	46 Domestic	4 Domestic	78 Domestic
2003	101	187	65	353
	54 Imported	122 Imported	52 Imported	228 Imported
	47 Domestic	65 Domestic	13 Domestic	125 Domestic
2004	73	183	102	358
	55 Imported	123 Imported	67 Imported	245 Imported
	18 Domestic	60 Domestic	35 Domestic	113 Domestic
2005	70	192	77	339
	46 Imported	164 Imported	49 Imported	259 Imported
	24 Domestic	28 Domestic	28 Domestic	80 Domestic
2006	23	241	114	378
	15 Imported	209 Imported	68 Imported	292 Imported
	8 Domestic	32 Domestic	46 Domestic	86 Domestic

Rather than ignore the matter or simply forward all of our concerns to the FDA, we decided to be more aggressive in our response. A vision for integrating FDA and NYSDAM resources was developed into a project that would allow NYSDAM to collaborate with FDA in the following three basic areas:

1. *Develop a better understanding of Laws and Authorities for each Agency*

The FDA's strongest enforcement tool with imported food is the "Import Alert" (formerly known as "Automatic Detention"), which authorizes FDA detention without physical examination when suspect foods, which "appear" to be in violation, are presented for entry into this country. NYSDAM's strongest enforcement authority tool is the "Food Seizure" which prohibits the

commercial movement of food anywhere within the state. Merging and utilizing, where appropriate, these authorities have produced influential impact on controlling violative food imports.

2. *Sharing of Resources*

NYSDAM has ample resources in domestic channels, and the FDA has focused resources at New York border entry points. Working jointly on foods of import origin in New York State at both points is optimal and allows the FDA to make better decisions on products to detain for examination at the border.

3. *Sharing of Intelligence and Information*

NYSDAM shares inspection and sampling information relating to foods of import origin in domestic commerce with the FDA. Where possible, we also provide import entry numbers for adulterated imported foods so the FDA can determine which of the 400 border entry points was involved and the mechanism of distribution. The FDA provides immediate notice to NYSDAM of imported food concerns so that state inspectors can take prompt action in domestic channels.

As a result of this imported food initiative, a number of very successful investigations have been conducted. Several of these are worth noting as follows:

1) When a young female child died from choking on an imported gel candy product, NYSDAM received information from the FDA that 18 other children from around the world had met similar fates due to this type of product. We further learned that an ingredient in this food (“konjak”) prevented the candy from dissolving once placed in ones mouth. This information was sufficient for New York and other states to take immediate action against this product. In New York we coordinated around 54 recalls and supervised the destruction of over 60 tons of this product. It would have taken FDA approximately eight months to outlaw the use of this ingredient in these products. The states, on the other hand, were able to respond quickly, and I have no doubt that our actions saved children’s lives.

2) An infant’s sole source of food and nutrition is oftentimes the infant formula provided to them. Without receiving the required nutrition from these products, they can become ill and even die. A scandal existed several years ago with Chinese manufactured infant formula where manufacturers there were producing products absent a number of required nutrients, causing the deaths of a number of Chinese infants. The FDA advised NYSDAM that no entries for this imported infant formula had been listed for the country. Nevertheless, we sent Inspectors into Chinese American neighborhoods, where we found this product. We utilized our food seizure authority, sampled and tested the product, and supervised its destruction following acknowledgement from our Food Lab that the product failed to have much of any nutritional value. A press release was issued through the Chinese media in New York City cautioning anyone who may have purchased the product. Here as well, I believe infant lives were saved.

3) In this country a manufacturer of a Grade A pasteurized dairy product such as fluid milk or cream, yogurt or ice cream can not ship their products out of state or country without verification that their milk suppliers (dairy farmers) and manufacturing facility have received and passed a food safety inspection. Unfortunately, a number of imported Grade A dairy products are allowed to enter this country for marketing without the same requirement being met. States, in most cases, have approved source requirements for foods sold in their states and are able to take action against these foreign dairy firms, which do not have inspection verification. The FDA provides information to NYSDAM of where these products are shipped in New York, and we dispatch an inspector to the warehouse location. Products from foreign firms that are not inspection verified are either exported back to the country of origin or removed from sale here and destroyed.

Our imported food initiative with the FDA has been so successful that we have expanded the program and are now collaborating with other federal agencies involved with imported foods. These include U.S Customs & Border Protection (CBP), USDA's Food Safety and Inspection Service Import Liaison, USDA's Smuggling & Interdiction Trade Commission (SITC), and the Department of Homeland Security (DHS). Our collaborative efforts with these agencies have allowed us to take the following actions:

- 1) Removal of illegally imported or smuggled raw poultry from China (avian Influenza concern).
- 2) Removal of illegally imported or smuggled meats from BSE designated countries (BSE concern).
- 3) Surveillance activities for the illegal distribution and marketing of African "bush meat" (Endangered species/potential human virus concern).

Figure 4 below quantifies our imported food activity we typically conduct.

FIGURE 4

BT Assignments			
			Jan-Oct
	2005	2006	2007
• Imported Feed Samples	55	51	18
• Food Samples	105	233	85
• Physical Examinations	157	362	332
• Import Alerts	6	5	0
• Food Seizures	32	76	28
• Recalls	34	94	14

The other very important element of our initiative has been the development of educational programs for importers, import food distributors, and retail food stores to assist them in protecting themselves from receiving adulterated or misbranded imported foods. These programs are especially useful to small businesses. In October of this year we held a program for the Chinese American business community and have another similar program planned for January with Russian American businesses.

Our goals for this coming year is to train two additional FTE's to perform the inspection and investigational work associated with imported foods. We also hope to develop additional training courses for small businesses and other industry officials that distribute and sell imported foods. These courses will be designed to offer basic assistance of what food safety concerns exist with imported food products so that these firms can set specifications with foreign manufacturers to assure violative products are not delivered into the country. Distributors will further be trained in food labeling matters so they can easily detect violative concerns such as illegal food additives, illegal food colors, and undeclared food allergens and sulfating agents.

We believe our import initiative has contributed to the adoption by the federal and state regulatory agencies of the best available practices for controlling food safety and defense hazards associated with imported foods. The program leverages current federal and state food safety activities to more effectively protect consumers, and it provides a degree of innovation.

This kind of idea is not new, however. A program funded by the FDA beginning in 1998 called the "National Food Safety System" (NFSS) was intended to integrate the food safety resources of government at all levels. A primary objective of that project was to improve food safety through

a collaborative effort of federal, state and local government agencies. It was believed then that a fully integrated, seamless and science-based system would build consumer confidence and address all of our food safety challenges. It would be foolish to ignore some of the progress already in place, which resulted from the activities of the National Food Safety System (NFSS) project. The following are examples of significant NFSS accomplishments that have been achieved since the inception of this project in 1998:

- eLEXNET – A secure electronic data sharing system for food safety laboratory data.
- ISO Accreditation – An internationally recognized laboratory accreditation program aimed at assuring uniform methodologies for federal, state and local laboratories.
- Directory of Laboratory Capabilities – A compilation that identifies federal, state and local laboratory capabilities in preparation for emergency needs.
- AFDO Recall Workgroup – An effort involving state and federal (FDA and FSIS) officials to streamline and better coordinate recalls for increased effectiveness in removal of contaminated product from the marketplace.
- Validation of Laboratory Methodologies – A joint federal/state effort to standardize and develop national rapid detection methods.
- Foodborne Illness Outbreak Coordination Guidelines – Developed to provide uniform investigational procedures and information-sharing protocols.
- ORA-U – Development of a comprehensive national training and certification system to better facilitate uniform food safety activities among all federal, state and local field inspectors.
- Uniform Criteria Workgroup – Development of uniform national regulatory standards.
- Integrated Food Safety Partnership – A pilot program that integrates the food safety functions of a state and the FDA. A pilot of this partnership, as described above, is currently in its early stages of application.

The goals of the NFSS project were to establish a system that would better utilize and leverage all the committed food safety resources at all levels of government, build uniformity and consistency with inspectional, analytical, enforcement and surveillance activities, increase the level of consumer confidence by improving food safety, and encourage the implementation of ONE food safety system. The projected roles for federal and state agencies envisioned in this seamless food safety system were identified as follows:

The federal government would provide oversight in the following areas:

- Training
- Certification
- Risk Assessment
- Program Evaluation
- Imported Foods
- Research
- Science
- Standards
- Lab Practices
- Additives

- Packaging
- Funding

State and local government agencies would share field resources in the following areas:

- Inspections
- Investigations
- Complaints
- Sampling
- Analysis
- Compliance
- Enforcement

Clearly, if we are to have a comprehensive, uniform, seamless and risk-based food safety system for the nation, a development strategy that only examines the federal component cannot be utilized. If it were, then any attempt to correct the deficiencies in the current system or to provide strategic plans for developing a truly effective national food safety system is destined to fail.

The FDA Food Protection Plan and Action Plan for Import Safety are the latest efforts by the agency in setting strategies for protecting the nation's food supply. These plans have great promise and both rely very heavily on working collaboratively with stakeholders including state and local agencies. The Action Plan for Import Safety speaks specifically for considering cooperative agreements with states. The Food Protection Plan uses less specific, more general language such as "collaboration with" and "working closely with" states in several areas of the document. In my opinion, FDA should strive to work more strategically with the states on a variety of functions including food safety inspections, food product surveillance, and imported food evaluations. In order to accomplish this, FDA would need to do the following:

- 1) Accelerate the Manufactured Food Regulatory Program Standards process so more states can participate and demonstrate their equivalency to the FDA. The FDA can then share inspection work plans with state agencies to avoid duplication of efforts.
- 2) The FDA must begin to accept state food laboratory analysis of foods so they can better work with the states on sampling assignments and the sharing of surveillance data. Work performed here should include both imported and domestic products.
- 3) The FDA must improve their presence in foreign countries. By gaining confidence with state and local governments handling most of the domestic burden, FDA should be able to achieve this goal. A number of states are performing inspection verification for foreign dairy manufacturers of Grade A products. FDA should be performing these inspections.
- 4) A number of states are leading the way in mandatory requirements for vegetable growers and packers. California, Florida, and Virginia have all introduced mandatory programs for specific commodities in their states. The FDA should model these programs so they become nationally accepted.

5) There is a huge need to improve our response efforts with food recalls. Recent national recalls for peanut butter, spinach, and chili sauce were confusing and ineffective. North Carolina employed an Incident Command System [ICS] utilizing state and local government officials from a multitude of agencies for the chili sauce recall. They performed more recall audit checks in North Carolina than the rest of the country combined. They also found a large number of these botulism-tainted products in children's camps and other non-traditional food venues ready for sale or service. The FDA needs to review their response efforts with recalls and establish a formalized strategy with state and local government to better deal with recalls.

6) The FDA needs to be granted recall and record review authority by Congress to properly function as a regulatory public health agency.

While the country debates how to best protect our food and what agency and how many will lead this effort, the fact remains clear that whatever strategy is used the states and local agencies must be recognized for the critical role they play.

Developing a new, comprehensive regulatory structure at the federal level will be an enormous task. It must include elements that address human and animal health and nutrition, controls for foodborne pathogens, surveillance of potential hazards, monitoring foodborne illnesses, research and consumer education. Additionally, food safety must now be part of any national security strategy.

Given the scope of the matter and the newfound critical importance of food safety and security, it is difficult to argue against the strategies outlined in FDA's Food Protection Plan and Action Plan for Import Safety. What must not be overlooked, however, is the fact that most of the food safety and food defense activities that occur in this country occur at the state and local levels. The idea that food safety or food defense is somehow only a federal government responsibility is grossly inaccurate and misguided. There is great need for leadership, however, and the FDA, assuming full implementation of these plans, seems well suited.

Thank you for the privilege to present my views on these very important matters.

Joseph Corby
NYS Department of Agriculture & Markets

Appendix B – AFDO national survey

SURVEY SUMMARY

Food Safety Regulatory Activities Conducted by local and State Government Agencies in Year 2001¹

Inspections

Food processing/repacking facilities.....	56,644
Dairy plants.....	7,562
Manufactured milk plants.....	5,956
Dairy farms.....	159,483
Retail food service establishments.....	1,178,348
Institutional food service establishments.....	51,290
Retail food stores.....	516,033
Intrastate wholes sale meat processors.....	418,844
Custom exempt meat plants.....	12,310
Small animal slaughter houses.....	24,395
Feed manufacturers and distributors.....	19,904
BSE inspections.....	3,475
Rendering plants.....	605
Food transportation vehicles.....	9,481
Food salvage operations.....	2,067
Farm productions (GAPS).....	311
Food warehouses.....	20,624
Other.....	15,525
TOTAL.....	2,500,857

Investigations

Foodborne illness outbreaks.....	3,075
Tracebacks (not recalls).....	154
Consumer complaints.....	46,019
Shellfish growing areas.....	20,870
Commercial fishing areas.....	5,251
Farm pesticide residue.....	472
Chemical residue in meat, milk, fish, and eggs.....	7,855
Disasters and/or emergency response.....	2,816
Animal health matters (food safety related).....	204
Other.....	3,199
TOTAL.....	89,915

Do high risk establishments receive more inspections per year than lower risk establishments?

Yes.....	69
No.....	15

Number of licensed/permitted establishments.....755,123

¹ Association of Food and Drug Officials. *State Food Safety Resource Survey, 2001.*

Number of unlicensed/not permitted establishments	60,910
Number of FTEs (field)	3,685
Number of FTEs (administrative and support)	873

Entry Level Requirements

High school	17
Two-year college degree	10
Four-year college degree	65
Other	29

Do you require continuing education for inspectors or investigators?

Yes	55
No	32

Do you require field inspectors or investigators to be registered?

Yes	26
No	52

Do you require field inspectors or investigators to be commissioned?

Yes	20
No	57

Enforcement Activities

Embargo/seizure	13,910
Stop sale	31,546
Health Advisories	90
Monetary penalties	9,878
License/permit revocation	2,899
Injunctions	74
Criminal prosecutions	4,048
Warning letters	36,346
Informal hearings	1,102
Food recalls	660
Other	28,537
TOTAL	128,430

Laboratory Capabilities

Food chemistry	52
Microbiology	63
Pesticide residue	43

Number of samples analyzed

Food chemistry	59,991
Microbiology	252,307
Pesticide residue	15,767
TOTAL	328,065

Number of FTEs (field) 3,685
Number of FTEs (administrative and support) 873

Entry Level Requirements

High school 17
Two-year college degree 10
Four-year college degree 65
Other 29

Do you require continuing education for inspectors or investigators?

Yes 55
No 32

Do you require field inspectors or investigators to be registered?

Yes 26
No 52

Do you require field inspectors or investigators to be commissioned?

Yes 20
No 57

Enforcement Activities

Embargo/seizure 13,910
Stop sale 31,546
Health Advisories 90
Monetary penalties 9,878
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