

**Written Testimony of the Honorable Cal Dooley
Grocery Manufacturers/Food Products Association
President and Chief Executive Officer**

**Before the
Committee on Energy and Commerce Subcommittee on Health
“Food and Drug Import Safety Act”
September 26, 2007**

I am Cal Dooley, President and CEO of the Grocery Manufacturers /Food Products Association. I am here today to discuss an issue of paramount importance to our members—ensuring the safety of imported foods.

Food producers have an abiding interest in safe food. Maintaining consumer confidence in our products, our brands, and our companies is the single most important goal of the food, beverage, and consumer packaged goods industry, and product safety is the foundation of consumer trust. My industry devotes enormous resources toward this goal, and effective regulation and oversight by federal regulatory agencies such as the FDA are critical and complementary elements of the fabric of consumer protection.

This month, GMA/FPA issued “*Commitment to Consumers: The Four Pillars of Food Safety*,” a comprehensive proposal designed to protect consumers by strengthening, modernizing, and improving the system governing food imports. Our proposal envisions new mandatory requirements for the food industry to assure the adequacy of foreign supplier food safety programs and new responsibilities for FDA. Other elements include a new program to help identify and prioritize imports of potential concern, new efforts by FDA to help enhance the capacity of foreign governments to prevent and detect food

safety issues, improvements to FDA's scientific capabilities and its use of information technology, and a significant increase in FDA resources.

Underlying this comprehensive set of proposals is a fundamental emphasis on prevention.

Let me put the challenge before us in plain terms. As the volume of imported food steadily increases, the FDA's job at the border can be compared to trying to find a needle in a haystack. We need to approach this task from different angles: (1) by reducing the number of needles to find; and (2) by reducing the size of the haystack in which to find them.

A complete copy of the "Four Pillars" proposal has been submitted with this written testimony. Before I provide comments on the Food and Drug Import Safety Act introduced last week, I will take just a few minutes to briefly outline each of the four pillars for you now.

Pillar One: Mandatory Foreign Supplier Quality Assurance Program – Under this pillar, all importers of record would be obligated to adopt a foreign supplier quality assurance program that assures that all imported ingredients and products meet FDA food safety and quality requirements. Food companies would utilize FDA guidance to adopt food safety programs and practices needed to ensure food safety, such as audits, testing, good manufacturing practices, good agricultural practices, HACCP plans, food defense programs, product management systems, and recall programs. Requiring importers of

record to ensure the safety and quality of their supply chain – and giving FDA the authority to review the effectiveness of these programs – would reduce the number of needles in the haystack.

Pillar Two: Voluntary Qualified Importer Food Safety Program – To help prioritize FDA resources and to relieve congestion at ports, we further propose that importers of record who are able and willing to meet additional standards and conditions than those required under Pillar One could voluntarily participate in a program entitling them to expedited entry at U.S. borders. This is similar to the Safe and Secure Food Importation Program Chairman Dingell has proposed in the Food and Drug Import Safety Act introduced last week and builds upon the C-TPAT program currently in place. In addition to demonstrating the presence of well-designed and implemented food safety systems, importers could demonstrate a secure supply chain and conduct and share additional testing and program data with FDA to be eligible for expedited entry. By permitting expedited entry for imported foods that pose no meaningful risk, Congress can reduce the size of the haystack needing closer scrutiny by the FDA.

Pillar Three: Build the Capacity of Foreign Governments – FDA would work with foreign governments to improve their capacity to prevent and detect threats to food safety. FDA would work with foreign governments to expand training, accelerate the development of laboratories, ensure the compliance of exports with U.S. regulations, permit appropriate FDA inspections of foreign facilities, and ensure adequate access to data and test results conducted abroad. In addition, FDA would be encouraged to use

Codex to harmonize requirements among countries. The food industry has long supported international harmonization through Codex, and we believe that FDA must once again provide international leadership towards the adoption of strong, science-based international food safety standards. All of these foreign capacity building steps would further reduce the likelihood of contamination and thereby further reduce the number of needles for FDA to find at the border.

Pillar Four: Expand the Capacity of FDA – Expanding FDA resources – including personnel, equipment, laboratory capacity, and scientific expertise – is an essential component of an effective food safety system. FDA resources have not kept pace with the demands posed by rising imports and current food safety challenges. To meet these needs, Congress must provide significant new funds to dramatically improve FDA’s analytical testing capabilities, to increase and target inspections conducted by FDA, to obtain real-time test results, and to enhance communications during crisis events. With additional resources that are well-deployed, FDA should be much better positioned to find any remaining needles before they cross the border and enter U.S. commerce.

We believe that the adoption of these four pillars of food safety will result in significant improvements in our food safety net. By focusing our efforts on prevention – and by expanding and improving our ability to detect threats to public health – we believe that our proposal will do far more to ensure the safety and quality of imported food products and ingredients than would the adoption of many of the provisions of the Food and Drug

Import Safety Act and will build upon the partnership between FDA and the food industry.

Food companies recognize that growing food imports pose new challenges and we share the same goal as the Committee: to continually improve the safety and quality of food products and ingredients. We are grateful for the opportunity to work with you to develop comprehensive imported food safety legislation which makes the prevention of contamination the cornerstone of our food safety net.

While inspecting products at the border is an important element of a comprehensive approach to food safety, we believe that inspections alone will not provide enough improvement to the safety of our food supply. We strongly agree with your desire to find more resources for FDA, which needs to restore its scientific base as well as its capacity to conduct an appropriate level of inspection and examination. However, we strongly oppose the user fee provision in the Food and Drug Import Safety Act. We have five significant concerns with the user fee.

One, we believe that the benefits of a safer food supply accrue to the public generally, much like the benefits of a strong national defense, and believe that the costs of providing FDA with sufficient resources to perform the various responsibilities to protect the public health that have been given to it by the Congress should come through taxes, not user fees. As you know, a user fee is appropriate when the benefits of the government service flow to an individual (such as postage stamps, recreation fees, or public transportation) or

to a particular business (such as harbor maintenance fees, accelerated review of prescription drugs, or bankruptcy filing fees). The benefits of inspection and research clearly flow to all Americans, not simply to food companies.

Second, the proposed user fees would impose significant financial burdens on U.S. companies, not just on importers. This is especially true for companies with facilities in both the U.S. and Canada, for example, where there is a steady flow of ingredients and finished products, all of which would be subject to import user fees. We are in the process of collecting data to estimate the added costs to U.S. businesses, but we have reason to believe they would be substantial.

Third, the imposition of the user fee on imported products and ingredients could create an incentive for companies to locate production facilities outside the United States. Let me provide an example of why this is so. Suppose a company makes a product in the United States that consists of 20 ingredients, half of which are imported. Under the user fee proposal, a fee would be imposed on ten of those ingredients each time they are imported. If, on the other hand, the production facility was located in Mexico or Canada, for example, the fee would only be imposed once: when the finished product was brought into the United States.

Fourth, we are concerned that a user fee on imports would violate our trade commitments by creating a preference for domestic sources of food products and ingredients. We're also concerned that such a fee could invite other countries to place similar fees on our

food exports. Finally, we are concerned by the mechanics of the user fee. By charging \$50 per line of food, the user fee in the Food and Drug Import Safety Act places an unfair burden on importers of many distinct products.

We strongly agree that FDA needs more resources to increase inspectors, improve its scientific capabilities, and meet other critical needs. For the past year, GMA/FPA has worked with the Coalition for a Stronger FDA to substantially increase FDA funding. In our view, FDA does not simply need “more” resources, but needs the “right” resources. In particular, we believe that the agency needs additional resources for both its “science” and its “compliance” activities. The agency cannot operate effectively without both. Our goal is to double FDA’s food-related spending over five years, and we applaud Chairman Dingell for his efforts to seek additional FDA spending.

We have other major concerns with the Food and Drug Import Safety Act and we look forward to working with the committee to address these and other challenges.

One, we are concerned that proposals to limit imports to certain ports and to require the development and implementation of certain tests could create havoc at the border and create costly and unachievable new burdens on FDA and the food industry. In particular, we are concerned that the proposal to limit food imports to ports of entry located in the same metropolitan area where FDA has a laboratory could unintentionally block food imports to many ports. While there are more than 300 ports of entry, there are only 13 FDA labs. As a result, many ports – including all ports in Texas and Florida – would no

longer be able to import food products and ingredients. We believe a better course would be to expand and better target FDA inspectors, as we have proposed in our second “pillar” and Chairman Dingell has proposed in Section 7 of the Food and Drug Import Safety Act, and to expand FDA’s capacity to quickly analyze food products and ingredients.

We are also concerned about requirements to develop rapid tests within three years and to test all processed food products. While we share your desire to make rapid-tests and other sampling methods widely available, we are concerned that requiring the development of such tests within three years may be unrealistic. We are also concerned that a requirement, included in Section 12 of the Food and Drug Import Safety Act, that all processed food be tested to detect substances that make the food adulterated creates an impossible burden: there is simply no way to test for all potential causes of product adulteration. In our view, requiring every importer of record to implement a foreign supplier quality assurance program – and placing the focus of imported food safety efforts on prevention, rather than detection – would significantly improve the safety of imported food to a far greater degree and build upon the strong partnership between food companies, our suppliers, and FDA.

Two, we are also concerned about two new labeling requirements included in the Food and Drug Import Safety Act. First, packaged food products are already required to bear country of origin labeling. Second, we are concerned that the proposal to require country of origin labeling for all food could create huge new burdens on food companies while

providing little or no benefit. Many of our food companies combine ingredients from dozens of countries to create a single product. Would the proposed country of origin labeling requirement mean that each ingredient has to be labeled with its country of origin? We are also concerned that a “safety notice” on meat, poultry or seafood that contains carbon monoxide to affect coloring would needlessly mislead the public. As you know, this practice has been subject to exhaustive testing and has been declared safe by FDA.

Three, we are also concerned that Food and Drug Import Safety Act violates our trade agreements and would invite retaliatory actions by our trading partners. As I mentioned, the adoption of user fees would create a clear preference for domestic food products and ingredients and would invite the adoption of similar fees on our exports. In addition, we are concerned that a requirement that all foreign facilities importing food into the U.S. obtain FDA certification would place enormous new burdens on FDA, would violate our trade agreements, and would invite reciprocal demands by our trading partners. Further, we do not believe that there are likely to be resources available –even with user fees – for FDA to certify tens of thousands of foreign facilities located in about 150 different countries.

Four, there is ample evidence that the current recall system works well. We are concerned that the due process protections that necessarily accompany the recall proposal in the Food and Drug Import Safety Act could actually delay, not accelerate, efforts to address public health threats. As you know, food companies have powerful incentives to

remove adulterated products from commerce as quickly as possible and have worked closely with FDA to implement recalls quickly and effectively. We strongly support efforts to expand FDA's ability to communicate the risks posed by adulterated foods.

In conclusion, we share your commitment to the improving the safety of imported food. We also share your commitment to increase FDA's resources, including resources to increase our ability to detect adulterated food at the border. However, we believe that far more emphasis must be placed on the prevention of threats to food safety throughout the supply chain and look forward to working with you to make a safe and secure supply chain the responsibility of every importer of record and to expand the capacity of foreign governments to detect and deter threats to public health.

Our "Four Pillars" proposal builds on the long history of public-private responsibilities and cooperation in ensuring food safety, while providing new and innovative approaches to the latest challenges to our nation's food safety net. Its focus on prevention would be complemented by an enhanced ability to quickly detect and address public health threats. Meeting the challenges of the modern supply chain requires additional public resources for FDA and related agencies and demands an integrated approach that leverages the significant investment of the private sector in product safety. We look forward to working with the Committee to fashion comprehensive legislation that will address the new challenges posed by rising food imports and will continually improve the safety of our food products and ingredients.