Testimony

Food Marketing Institute

Food and Drug Administration Globalization Act of 2008

To

Subcommittee on Health,
House Committee on Energy and Commerce Committee

May 13, 2008

Introduction

Chairman Pallone and Members of the Health Subcommittee, the Food Marketing Institute (FMI) is pleased to present testimony and suggestions on the recently released discussion draft of the "Food and Drug Administration Globalization Act of 2008". FMI's statement addresses the following areas:

- Introduction
- Restoring Consumer Confidence in the U.S. Food Supply
- Assessing the Food and Drug Administration Globalization Act
- The Retail Industry and Food Safety
- Importance of Supermarket Programs
- FMI Supports Key Components of the Draft Legislation
- Initiatives FMI Cannot Support
- Recommended Improvements in a New Draft

FMI is a national trade association that has 1,500 member companies made up of food retailers and wholesalers in the United States and around the world. FMI members operate approximately 26,000 retail food stores with combined annual sales of $340 billion, representing three quarters of all retail food store sales in the United States. FMI's retail membership is composed of national and regional chains as well as independent grocery stores. Our international membership includes some 200 companies from more than 50 countries.

The most important goal of America's food retailers and wholesalers is to ensure that the products they sell are safe. As the purchasing agent for the consumer and the final link in the supply chain, the supermarket continually seeks ways to make the nation's food supply safer. As a result, the American consumer enjoys unmatched choice and convenience, as well as safe, abundant food year-round.

Retailers and wholesalers have a long history of anticipating and responding to food safety and defense challenges. They constantly strive to strengthen food safety on many fronts by working on many fronts. For example, retailers and wholesalers work with suppliers globally; implement rigorous best practices in supermarkets and warehouses; ensure that store managers and their associates follow the recommendations of the *FDA Food Code*; and through extensive public outreach campaigns, help teach consumers to follow the most important food safety practices.

Restoring Consumer Confidence in the U.S. Food Supply

Research shows that consumer confidence in food safety swings widely depending on events in the marketplace. Media coverage of recent outbreaks, recalls and food safety scares have contributed to a decrease in consumer confidence and revealed new challenges to ensuring the food supply is safe in an ever-changing marketplace. In 2007, consumer confidence in the safety of food they purchase in supermarkets dropped to its

lowest point since 1989. FMI's survey of consumers, presented in the annual *U.S. Grocery Shopper Trends* report (*Trends*), found that consumer confidence declined from 82 percent in 2006 to 66 percent in 2007. This same survey revealed that consumer confidence in restaurant food was even lower at 42 percent.

In 2008, with the federal government and private sector working together to improve food safety, consumer confidence rebounded: 81 percent of those responding to the 2008 *Trends* survey said they are "completely" or "somewhat confident" in the safety of the food bought in supermarkets. But this confidence is fragile. Only 11 percent of respondents are "completely confident," while 70 percent classify themselves as only "somewhat confident."

We realize that restoring consumer confidence and strengthening our food safety system is of paramount importance. We understand and support the goals in the discussion draft. Enhancing the safety of the food supply requires the active effort and aggressive support of the business community — such as food wholesalers and retailers – as well as government. This includes our work with suppliers, especially those beyond our borders, our commitment to train our own people, and our outreach to consumers. It is a farm-to-table challenge that needs a farm-to-table solution. It is both a domestic and an international problem we must address together.

Assessing the Food and Drug Administration Globalization Act

Many of the proposals in Chairman Dingell's discussion draft are consistent with our thinking on food safety but we must be sure that any changes to current practice meet certain criteria. They must:

- Be supported by science;
- Have measurable benefits;
- Be affordable;
- Be realistic; and
- Be implemented without unintended consequences.

Furthermore, two things are imperative when we think about the type of legislation that is needed to make our food supply safer:

- We must use mitigating risk as our guiding principle, and
- We should consider what actions will have the greatest impact in reducing foodborne illness.

The Retail Industry and Food Safety

All points in the supply chain play an important role in food safety. As retailers, we have a responsibility to sell the safest food possible. And our customers expect the foods they

purchase to be safe, whether store produced, manufactured or farm grown. Supermarkets have many prevention programs in place to protect our customers, such as consumer education campaigns, employee food safety training, extensive sanitation programs, and food safety management systems. But all of these prevention programs at the retail level cannot ensure that we deliver safe food to our customers if the food coming into our stores isn't already produced and processed to the highest standards.

Importance of Supermarket Programs

Accordingly, the U.S. retail food industry is actively involved in improving food safety and protecting the health of consumers. We are doing this through four focused programs:

- Safe Quality Food program (SQF);
- SuperSafeMark training (SSM);
- A newly introduced Product Recall Collaboration Portal; and
- The Partnership for Food Safety Education.

Safe Quality Food (SQF)

FMI members, along with other retail, wholesaler and food service buyers, work with their suppliers to ensure that they are following regulatory requirements and globally recognized best practices. To help the retail industry in this regard, FMI has developed a new science-based auditing and certification program for food safety — that can be used by all suppliers, from the smallest farm to the largest manufacturing plant. This program is called Safe Quality Food, or SQF. SQF is one of only five programs in the world that has received recognition from the Global Food Safety Initiative, a group of international food safety experts. In order to become SQF certified, a supplier that has been trained in the SQF standards must carry our a detailed risk assessment of its food production process and establish a food regimen for their process that comprehensively responds to the risks identified. After the supplier has developed and implemented the food safety management system, the supplier's performance is assessed by an accredited third part that will certify the supplier's conformance with the internationally recognized SQF standards only if the supplier's program is deemed sufficient. In order to maintain SQF certification, the supplier must undergo a rigorous series of audits by the accredited third party certification body to ensure that the program continues to meet the standards necessary to produce food that meets or exceeds federal standards.

SuperSafeMark

On the domestic front, FMI trains supermarket employees in safe food handling practices through a program especially designed for retail operations called SuperSafeMark (SSM). SSM offers training programs for all level of store employees and following successful completion of a recognized exam, managers can be certified as food safety professionals. Currently, over 15,000 store managers have been certified and thousands of store employees are trained to the provisions of the FDA Food Code.

A New Recall Portal

FMI members are also working closely with their suppliers to improve communications in food recalls. While the industry responds quickly and efficiently in the event of a recall, FMI members believe that the system can be improved. In a year-long project, retailers, wholesalers and suppliers developed and pilot tested an electronic recall portal, the FMI Recall Collaboration Zone. This portal is powered by GS1, formerly the Uniform Code Council, which oversees the Universal Product Code (U.P.C.) and numerous technological standards and programs for industries worldwide. This portal provides an automated alert system that allows suppliers to send information to retailers and wholesalers rapidly and accurately, 24/7, so they can remove recalled product from the distribution chain and retail shelves as quickly as possible. This portal will be available to all suppliers and retailers, including supermarkets, restaurants, and food service operators.

The Partnership for Food Safety Education

Finally, we provide consumers with practical, science-based advice on food-handling in the home. We do this through The Partnership for Food Safety Education. This is a joint private-public sector project that brings together consumer groups, the FDA, USDA, CDC and a wide variety of other industry associations. FMI's president, Tim Hammonds, is the founding and immediate past chair of the partnership. The Partnership is responsible for the FightBAC campaign to teach food safety to children and others; the Chill Out program to remind consumers to keep their home refrigerators cold to help prevent bacterial growth; and, most recently, the Be Food Safe promotion providing retailers with the tools they need to educate their customers about safe food practices.

Approximately, 6,000 FMI member supermarkets serving some 81 million consumers, have volunteered to implement Be Food Safe through their in-store and external consumer communications programs. The campaign encourages the use of colorful, modular icons and photography to illustrate the basic and most important safe food-handling practices:

- Clean — Wash hands and surfaces often.
- Separate — Do not cross-contaminate foods.
- Cook — Heat foods to proper temperatures.
- Chill — Refrigerate foods promptly.

FMI Supports Key Components of the Draft Legislation

FMI and the retail community are working with suppliers to ensure safer food. At the same time, FMI recognizes that there is an important and evolving role for government to play in assuring that the U.S. food supply remains the safest in the world. The draft legislation contains two important policy initiatives we feel can contribute to this goal and should be implemented as soon as possible.

Expand the Role of Accredited Third Party Certification

We feel all of our suppliers must have rigorous prevention, intervention, and response plans as outlined in the discussion draft. As retailers, we have an obligation to make sure we are sourcing from suppliers who not only have food safety plans in place, but who strictly adhere to them. Many retailers have found that accredited third party certification programs are a sound method for evaluating how suppliers are implementing and managing food safety programs.

Accredited third party certification companies are objective, independent bodies that are highly qualified to evaluate the food safety management systems of manufacturing facilities and primary producers and attest –if warranted – that the supplier meets (or exceeds) all federally mandated food safety standards.

The draft legislation recognizes that these types of programs can provide valuable support to government agencies like the FDA with limited budgets and personnel. Encouraging the use of accredited third party certification programs can supplement government resources as well as increase the depth and quality of the food safety programs mandated in the bill. We would urge the Committee, however, not to make private-sector auditors the enforcement arm of the federal government but rather support certification as a voluntary, industry-driven system for improving food safety management programs. Identification of compliant, third party certified suppliers can be made available without compromising confidential data and protecting proprietary information such as detailed assessment reports. Certification status can be used by regulatory agencies like FDA to determine risk and better allocate scarce federal resources.

The following language is our suggestion for Accredited Third Party Certification programs for incorporation in the Chairman's discussion draft:

"Accredited Third Party Certification Program" refers to an independent auditing and certification program that (1) evaluates the food safety management systems and practices of food producers and processors using recognized auditing standards and (2) attests to the compliance of the food producers or processors with federal food safety standards. In order to qualify as an "accredited third party certification program," the entity performing the auditing and certification of food safety management systems must maintain an accreditation from an independent, internationally recognized third party accreditation body to ensure that the processes and standards used in the auditing and certification program are sufficient to verify compliance of food producers and processors with federal food safety standards.

Require Mandatory Recall Authority and Immediate Notification of Recall

FDA should be given the authority to mandate a recall in those cases where a company found to be responsible for adulterating food does not act promptly to recall a food that presents a reasonable probability of causing serious health problems or death. On November 16, 2007, the FMI Board of Directors approved a policy statement that

supports providing federal regulatory agencies with the authority to require a recall under these circumstances (copy attached). We also believe that suppliers should be required to give retailers immediate notification when a recall action is taken.

In addition, to these primary issues, there are several other initiatives FMI strongly supports:

Rapid Testing

Another area where we are in agreement with the discussion draft is the development of rapid testing techniques for use in inspection of imported foods.

Developing rapid or screening tests should take into account: the seriousness of the threat posed by the pathogen or chemical; how frequently it occurs as a food contaminant; and, the likelihood that a rapid test methodology would be successful. However, lab testing has limitations and should not be used as a definitive pass/fail procedure for food coming into the country. We would also encourage FDA to work with USDA, CDC, and other public and private entities to share expertise, resources and laboratories in pursuing this.

Safe and Secure Importation Food Program

The provision for a safe and secure importation of food program that recognizes those companies that comply with FDA guidelines in exchange for expedited review of their product is a sound idea. This is also an area where the private sector can be of assistance if companies demonstrate their compliance to a food safety standard through an accredited third party certification program such as SQF. SQF requires that a company be in compliance with the regulatory requirements of both the exporting and importing country, in addition to the standards set by the retail buyers. Although not intended to be a substitute for government oversight, the private sector can add an additional layer of oversight for products entering into the U.S. food supply. We still need to see the details of FDA's plan since factors such as tracking compliance, the security of the company's supply chain, etc., need to be taken into consideration. It is also important to understand how FDA plans to coordinate these efforts with USDA, Customs and other regulatory agencies. But the concept remains an important one for the retail industry.

Continued Operation of FDA Field Laboratories

FMI fully supports the continued operation of FDA Field Laboratories. These labs provide needed scientific support and credibility. One consideration for reform would be to determine the capabilities at each of the labs and designate certain ones as a "center of excellence" for a selected type of test or procedure.

Safety Standards for Produce

We support the discussion draft's provisions that direct FDA, states and foreign governments to work together to identify prevention controls for fresh produce. Here

again, supermarkets, may use SQF certification programs to provide an added degree of food safety assurance to consumers.

Institute A Vigorous Hearing and Appeals Process

The draft bill grants FDA extraordinary new powers to suspend or halt the production and distribution process of food products for a variety of reasons. It is essential that these new powers are complemented by a hearing and appeal process that is fair, reasonable and quick.

Initiatives FMI Cannot Support

Mr. Chairman, there are a few provisions in the legislation that FMI unfortunately cannot support because of their negative impact on the supply chain and our ability to meet consumer demands for the freshest, safest and most affordable product:

Registration or User Fees for Food and Drug Facilities

Food processing facilities are already required to be registered under the Bioterrorism Act, but we do not believe that charging a fee for this registration is appropriate. We would caution about adding fees that will be passed on to the consumer in the form of higher food prices, especially at a time when consumers are already feeling pinched by rising food prices.

FMI acknowledges that FDA food and drug safety program are woefully under-funded, but increasing FDA funds will not in and of itself minimize food safety risks to consumers. A more effective food safety system needs to be designed before Congress can accurately assess the funds needed by FDA to accomplish its mission.

Moreover, FMI cannot support user fees on imported food and drugs, or on facilities that would have to register with FDA. Not only will this raise the cost of food, but it also ignores the fact that food safety is a public good that offers benefits to all U.S. citizens. Because of the broad focus of these benefits it is appropriate for improvements to be paid for out of general revenue rather than imposing fees that will ultimately raise the price of food for the consumer.

FMI believes that a warehouse that holds food packaged for sale to consumers or packed in cases for commercial distribution for a short period of time and does not process food or drugs should be exempt from such fees like retail establishments are. Many FMI member companies operate warehouses or distribution centers that handle food products, prescription drugs, over-the-counter medications, cosmetics and in some cases medical devices, but are not engaged in any manufacturing or processing activities. Thus registration or user fees should not apply to these types of facilities including facilities that perform reverse distribution functions.

Country-of-Origin Labeling for Food Products

FMI is also concerned that country of origin labeling requirements in the draft legislation duplicate similar provisions currently being debated in the Farm Bill and are in conflict with the Tariff Act of 1930. This draft bill creates an impossible provision requiring manufacturers (presumably including retailers) to put origin information on their websites for every single ingredient in any given product. We expect that many supermarkets would have to forego the prepared foods business if they had to figure out and list the country-of-origin for every ingredient that goes into the prepared foods that they sell at store level. The proposed requirement ignores the fact that during any given day a manufacturer (or a retailer) may have multiple countries of origin for any given ingredient, creating literally thousands of potential combinations for a finished product. The end result is an expensive and inefficient recordkeeping nightmare. In addition, many manufacturers, particularly small ones, may not have websites on which to post this information. If we have a system in place to improve the safety of imports, then such public notification would not be necessary, and despite its potential cost to manage, it will provide no benefit to improving food safety or reducing foodborne illness.

Country-of-Origin Labeling for Prescription Drug Products

The supermarket industry over the past decade has become a major player in the dispensing of prescription drugs to consumers. FMI estimates that our members currently operate 14,000 in-store pharmacies throughout the United States, and they strive to provide consumers with safe and effective medications at the lowest possible prices.

In terms of country-of-origin labeling for prescription drugs, Section 503 of the Food, Drug and Cosmetic Act would exempt drugs dispensed by prescription from the requirements included in the discussion draft. However, we are concerned that the current language could be interpreted to mean that COL must be incorporated into the package labeling that is affixed to the vial or container of the prescription drug that is being dispensed to the patient. If this is true, a COL requirement would pose major operational challenges to a retail pharmacy in order to achieve compliance. Moreover, it may not be physically possible for current package labels that are affixed to a prescription vial to accommodate COL labeling due to space limitations and what is already required to be on the label for the patient, such as the name of the prescribing physician, the patient's name, adequate directions for use, number of refills permitted and other pertinent information. FMI, therefore, urges clarification in the Chairman's Discussion Draft that COL does not apply to the labeling that is affixed on a vial or container of a prescription drug that is being dispensed to a patient.

Restricting the Ports of Entry for Imported Foods

Although we appreciate the Committee revising its earlier proposal to restrict all food imports to a limited number of ports, the new language restricting food from uncertified facilities continues to raise serious concerns for our industry. We understand that the

provision is modeled on a scaled back version of the USDA system, but any significant limitations on ports of entry when applied to the broad spectrum of products under FDA supervision becomes unworkable and prohibitively expensive.

U.S. ports are already busy to the point of congestion. And there is increasing concern in the retail community that the growth in port capacity is simply not keeping pace with the growth in demand. Limiting the number of ports food can enter into through legislation will not only aggravate congestion and delays, it could also increase the cost of food for the American consumer. Quite a bit of food that enters the country is perishable and needs to be shipped, sold and consumed in a limited period of time. For example, shipment of fish or avocados cannot be held at a port for an extended period of time. As delays increase, so do food safety risks, waste and — unfortunately — costs. The emphasis should be on increasing programs to prevent adulterated foods from ever reaching our shores. A system to try to monitor and intercept very food product as it enters the country can never be efficient or effective.

Certifying Foreign Governments and Companies

The concept of voluntarily certifying foreign governments and companies by FDA sounds promising as a nod toward a risk-based system. However, such an approach will be very demanding on FDA financial and personnel resources. Before moving forward with this, FDA, USDA and others should map out a plan for how such a system might work.

We agree that foreign governments should be held accountable for demonstrating that they have regulatory systems in place equivalent to those in the U.S.; evaluating other government programs might be a more realistic starting place. Other agencies, such as USDA's Food Safety and Inspection Service (FSIS) and Animal and Plant Health Inspection Service (APHIS) already use this approach. Federal agencies should collaborate to assess and monitor the regulatory systems of other countries. If the federal agencies administer a program for designating those countries with equivalent or acceptable food safety programs, the private sector can supplement this activity by administering accredited third party certification or individual companies within a designated country.

Adequate Testing of Processed Food Products

Providing adequate testing of processed food products post-production presents challenges because there is no scientific way to use testing to ensure food safety. It is more effective to implement and monitor prevention programs, and use testing as a measure for monitoring how well those food safety programs are performing. This approach supports risk-based systems where resources are directed toward making sure products are safe through process control, such as HACCP (Hazard Analysis Critical Control Points) and accredited third party certification programs.

Carbon Monoxide Labeling for Meat, Poultry and Seafood

We do not support the proposed provision for carbon monoxide labeling of meat, poultry and seafood. Both FDA and USDA have recognized that carbon monoxide is generally recognized as safe for its intended purpose. We are not aware of any scientific basis for singling out this one technology for labeling.

Recommended Improvements in a New Draft

There are several other food safety initiatives that FMI supports but were not included in your draft. We would encourage the Committee to take a serious look at these proposals and consider including them in a revised draft of the proposed legislation. They are as follows:

Traceback Systems

FMI supports language requiring systems that will improve the capability of commodity groups to trace back foods to their source and we believe that the government should require such systems. Traceability systems would enable USDA, FDA and the industry to contain foodborne illness outbreaks more quickly and help identify the root causes of food contamination. Each commodity group should be required to create an automated traceback system that is cost-effective and complements current business operations.

Designate a Lead Food Safety Agency

FMI believes that it is time to designate a **lead** food safety agency with responsibility to coordinate the safety of our entire food system. Food safety regulation in the United States is governed by an uneven, and sometimes conflicting mosaic of laws and regulations enforced by multiple federal, state and local agencies, which results in inefficient redundancies in some areas and gaps in others. This system must be redesigned to address the current and future challenges of our rapidly evolving food supply system. The resources needed for such an agency already reside within multiple existing agencies. The challenge is determining how to recognize the responsibilities of the current food safety agencies to make them more efficient, eliminate duplication, share resources and prevent conflicts. Eliminating the duplication that now exists could result in substantial budget savings, improve oversight performance and create a safer food supply.

Rapid Approval of New Technologies

Many new technologies are not approved in a timely manner, thereby preventing the industry from implementing such improvements. Likewise, those companies developing new technologies are often discouraged by the potential multi-year approval process. Although we do not want to compromise safety, there are technologies, such as irradiation, that are already backed by years of safety research and testing. The world's scientific community, USDA and FDA have acknowledged that irradiation is the most effective food safety tool we have in the fight against contamination. FMI supports the expanded use of irradiation to cover a much wider range of fresh and ready-to-eat

products. Congress should amend the food safety laws to expedite the review and approval process for technologies that are proven to enhance food safety with no adverse impact on consumers.

Mr. Chairman, FMI shares the commitment of the Committee to improving the U.S. food safety system. The draft legislation contains a number of significant changes to the current regulatory system that deserve open and full debate. We appreciate the opportunity to submit our views as part of that debate and look forward to continuing to work with you to craft legislation that will help keep America's food supply the safest in the world.