AMERICAN ASSOCIATION OF EXPORTERS AND IMPORTERS

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Testimony before the House Subcommittee on Health of the Committee on Energy and Commerce
"H.R. 3610, the Food and Drug Safety Import Act"

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A. Introduction and Overview

Chairman Dingell, Ranking Member Barton, Ranking member Deal, and Members of the Committee, my name is Hall Northcott and I am President and CEO of the American Association of Exporters and Importers (AAEI). AAEI appreciates the opportunity to offer its comments on your effort to address import product safety in the "Food and Drug Import Safety Act of 2007" (H.R. 3610)

AAEI is a trade association comprised of U.S. and multinational manufacturers, distributors, retailers, freight forwarders, insurers, brokers, foreign trade zones and ports across the country, each engaged in the import and export of merchandise to and from the United States. In one fashion or another we truly represent the scale and scope of America's supply chain. We have helped educate and then externally represented the trade community in domestic regulatory, legislative, and public policy arenas since 1921 and in recent years have moved to assertively represent American import and export interests in multiple international forums.

AAEI's primary focus has long been "getting things in and out of the United State in the most efficient, practical and responsible manner seen worldwide.". In this we have long been a strong supporter of supply chain integrity and security as well as facilitation throughout the full-range of trade community issues affecting customs and international commerce. In short, AAEI believes that it is vital for the government and the trade community to work closely together and coordinate supply chain security, facilitation and import product safety for the United

States to maintain a critical balance between the free flow of legitimate trade and safe and secure goods. However, we are not expert in food product safety matters and thus are to here to support the committee in its efforts impacting supply chains, trade processes and those multiple aspects of today's global trade reality with which we are very familiar. It would be our pleasure to support, assist and encourage the Committee in these efforts.

It is indeed a privilege to appear before you on behalf of Chairman Charlene Stocker, our Board of Governors, and our members, found in every industry nationwide. Our testimony reflects the trade community's eagerness to work with the Committee to ensure that the Nation's product safety measures work – for consumers, the government, manufacturers, importers and exporters. In particular, we hope that we can assist you in your efforts to advance product safety by both fully exploring and thus utilizing all the current trade related statutory and regulatory tools available.

Since 9/11, AAEI and the U.S. business community have worked diligently with the Department of Homeland Security, U.S. Customs and Border Protection and multiple government agencies at the federal, state and local levels to develop programs designed to maximizing homeland security protection primarily through reducing the likelihood that the global supply chain could be used by terrorists as a delivery system for weapons of mass destruction. Frankly, we have long been and remain concerned that many important trade facilitation functions can be relegated to secondary status in the press of today's critical security environment. Thus, it has been our intent to assist in ensuring that robust security practices enhance the flow of legitimate trade such that the twin goals of trade security and trade facilitation are mutually complementary. In this, while we often have significant disagreements as to details and applications, we would strongly commend the efforts and personnel of the CBP and related DHS leadership for their commitment to vital national goals.

In relation to the above trade and supply chain concerns, we have recently begun to explore, in depth, related product safety issues and believe that ensuring product safety and integrity should be viewed as an important "third leg of a stool" which strengthens the other two legs – security and facilitation. Although balancing these interests is unquestionably a difficult task, we believe that H.R. 3610 has provisions of great value in further structuring the overall framework. We look forward to working with you to safeguard achieving this productive balance between these roles is a vital national interest and those U.S. policies and programs critically important for the United States to remain competitive in the global marketplace. In this we will support your efforts to further encourage the growth of our nations reliable, efficient and successful international trade system. This system must remain healthy if our Nation is to retain and enhance its position at the head table of global commerce.

B. Setting a Framework for Import Product Safety Difference

AAEI's testimony on Setting a Framework for Import Product Safety touches upon four topics which we understand to be of particular interest to this Committee 1. Low risk and account-based management works and can be used to enhance import product safety; 2. trade security and product safety are different and are based on divergent principles including different risk tolerances; 3. Interagency cooperation, particularly data exchange through the International Trade Data System (ITDS), is essential; and 4. Enhancement of manpower and resources for multiple agencies both directly and through third parties should be approached with an eye to significantly enhanced capabilities.

Frankly, at some point in the future, we would welcome the opportunity to discuss with the Committee a number of subjects including 1) the multiple impacts, since 9/11 upon commerce and, in particular, small and medium business of the substantial number of security programs launched, as stand alone efforts, 2) the cumulative affect of proliferating federal agency actions outside of CBP jurisdiction which increases the complexity and cost of the import process, 3)

federal agencies movement towards harmonizing U.S. regulations with international standards, 4) additional compliance requirements, 5) ongoing pressure on agencies to impose new user fees on importers that are, at best, "toll booth taxes" rather than fees for additional government services, and 7) new proposals each year seeking market data demands as well as more transparency and resilience from the global supply chain than can be digested and implemented by the trade community in the short period of time required by statutory deadlines.

1. Low Risk and Account-Based Management is Highly Efficient

    a. Account-Based Management

For many years, the trade community has partnered with CBP and DHS to develop low risk importer programs for both trade security and trade compliance purposes. In regulating over 825,000 importers, CBP had to make strategic choices in deploying its already scarce, and increasingly depleted, resources while the volume of trade continued to increase. CBP's strategy, going back to the 1980's, incentivizes companies with good security procedures and internal controls to join voluntary programs for mutual advantage and, dependent upon the program, a menu of trade facilitation advantages through reduction of processes or complexity of steps required. A critical part of this strategy, as directed earlier by the Congress, is treating importers as an "account" by reviewing the companies' record of compliance for all their importations, rather than individual transactions. By treating importers as an account, CBP is able to quickly determine a company's compliance profile and work with the company to remedy any deficiencies. CBP can then concentrate its resources on companies which do not demonstrate a high level of compliance and present the great risk for violations. In these efforts, CBP serves as an excellent model.

One example of a flourishing public private partnership at work today is found in the risk management operations of a widely accepted account based program now in its 6th year. This

is the Customs Trade Partnership Against Terrorism (CTPAT) program which today, while truly voluntary, has, in many industries become the acknowledged standard upon which business is done. C-TPAT is a government-business initiative to strengthen and improve overall international supply chain and U.S. border security. Those businesses that choose to apply are making a commitment to work toward the goal of creating a more secure and efficient supply chain in partnership with CBP.

One key feature, that we would specifically note for the committees consideration is that, after multiple discussions with industries and Congressional Committees committed to this program's success, CBP did not fall prey to the easy answer of imposing a "one size fits all" approach in this wholly new effort. Instead of the "one size fits all" approach, CBP and DHS succeeded in developing a successful program by recognizing that different products, sourcing regions, and supply chains have different operations and levels of risks. We would strongly urge the committee to explore the many reasons for adopting this approach. In this effort, one vital aspect is the ongoing verification and recertification program. Here, for instance, they issued and used extensively in the ongoing verification process, a Supply Chain Security Best Practices Catalog to provide importers with a compendium of the optimum and most effective efforts developed by other companies. This catalog has helped promote CTPAT's wide acceptance in the trade community as evidenced by the fact that there are over 7,500 certified participants in C-TPAT. As of today, approximately, 5,000 validations have been completed and we expect the remainder will be validated by the end of the year. However, we would hope that any efforts that the Committee might wish to initiate would from date of implementation be adequately staffed for efficiency in implementation.

In a significant precedent, Congress has already accepted and enhanced C-TPAT's risk management approach to security by providing statutory recognition of this program in the Security and Accountability for Every (SAFE) Port Act. In this legislation, they sanctioned its

voluntary nature, and tiered levels of participation linked to specific benefits. For most U.S. companies with global supply chains, C-TPAT membership is a requirement in today's business environment. C-TPAT has also serves as a model for the European Union's Authorized Economic Operator certification for security and the World Customs Organization's (WCO) adoption of the "Framework of Standards to Secure and Facilitate Global Trade" (the Framework of Standards). Here we see an international strategy, based upon clearly established U.S. principles to secure the movement of global trade in a manner that does not impede it, but instead, facilitates the movement of global trade. In this, AAEI has been privileged to support various initiatives in multiple international forums.

2. Trade Security and Product Safety Are Different

AAEI recognizes that though there are important similarities, trade security and product safety are fundamentally different. We have noted and attempted to incorporate those differences in our now four year effort to assist FDA in the development of low risk importer programs which, in our opinion, would have substantially benefited all parties. We remain hopeful that important progress towards this goal can be made through both the regulatory and legislative processes.

It is fair to say that, at its most basic, trade security is primarily concerned with the integrity of the supply chain and ensuring that the "box" (i.e., the cargo container) has not been tampered with during transport so that no weapons of mass destruction or other harmful substances are surreptitiously placed in the box after sealing at the point of stuffing. On the other hand, product safety is focused on the integrity of commodity in the box. Specifically in FDA jurisdiction, we understand there needs to be focus on microorganisms, toxins, pathogens, pesticides and problematic chemicals. In this effort, there is clear recognition that regulated food testing requires examination outside of the containers. In other words it is our understanding your product safety effort is specifically directed to ensure for the Nation the quality, functionality, safety and overall integrity of the product. This is not even comparable.

Frankly, with apologies, in the contrast of “inside the box” and “outside the box,” we must point out that these are, as my niece has said, simply apples and zebras. One element which this Committee could appropriately explore is an import safety is current company or independent testing policies at FDA. Currently, AAEI is unaware of any variety or method of internal testing which a company can do to reduce processing and inspection time for food, drugs and medical devices. However, it is important to note that would be a fundamental change in culture and resource requirements for FDA to fully implement a programs which take advantage of ongoing extensive domestic industry efforts. Thus, any efforts which the company makes do not help without agency facilitating product delivery. Perhaps the nearest match to product safety requirements in today’s business environment is in the quality assurance process (QA) – which so many American companies excel in and can help by providing valuable lessons for the Committee’s use in crafting language.

3. Interagency Cooperation Is Essential – ITDS is a Vital Tool

In fostering necessary interagency cooperation, and thus effective and efficient import and export programs, the Congress made an important first step in strongly encouraging what has become known as “One Face at the Border.” The effort has been designed to eliminate lack of coordination and even agency cross purposes, at our land, air and sea ports. Achievement of this goal was initiated in the creation of the Department of Homeland Security. Over the past several years, AAEI has testified to the importance of both preventing restoration of and further eliminating the extraordinarily burdensome and inefficient processes which have been suggested by a variety of special interests.

Increasing the government-wide focus on product safety, including CPSC leadership and multiple agency participation in the enforcement of Intellectual Property Rights protection, along with tracking financial transactions that may be financing terrorism are extremely worthy

goals. Unprecedented cooperation and formal coordination of efforts, whether legislative or Administration driven, would make all the difference.

In this, AAEI and the trade community have long supported the government's multi-agency automation efforts and the use of data to provide more transparency to the supply chain and import clearance process. One of our top priorities in the passage of the SAFE Port Act was the inclusion of a provision mandating federal agency participation in the International Trade Data System (ITDS). ITDS is intended to be a "single window" of trade data for government agencies to advance electronic access trade data provided by the importer in order make the import clearance process a seamless process for importers, CBP, and other federal agencies that license imported products or have "release and hold" authority for regulated imports. In a rough analogy, ITDS is the air scoop on the hood feeding vital data to the engine of the Automated Commercial Environment System (ACE).

We continue to believe that interagency cooperation and, at minimum, data exchange through the ITDS is essential. While full data sharing may not always be possible, alignment of agency goals with our nation's regulatory framework is crucial. In sum, use of the ITDS tool, if fully supported by vital agencies and bureaus, is highly beneficial for all involved and its maturation should be a much higher priority. We are gratified that the President's Interagency Working Group on Import Safety highlighted the importance of ITDS by recommending the acceleration in the development of ITDS in its initial report to the President, "Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety," issued on September 10, 2007. We hope the Committee can take advantage of this important tool in development of its overall legislative strategy to improve product safety.

a. U.S. Business Data Confidentiality

Among the emotionally charged issues that the U.S. trade community and AAEI's member companies have confronted in today's evolving environment are the extensive and substantial concerns regarding the confidentiality of proprietary business data submitted to government agencies. In crafting this testimony, we wish to recognize the Committee's dedication to preserving and even expanding individual data privacy and we hope that the Committee will recognize that for business this is an effort which should be preserved with equal vigor. Frankly, commercial data is property and inadequate protection is a "give away" to the bad guys. We need not look far to see a repugnant record of foreign firms and interests engaging in grand scale industrial espionage. In trade policy terms, these concerns are driven both by private sector competitiveness issues and international business ownership and management. In addition, we are deeply concerned about some federal agencies' dismal record of compliance with the Federal Information Security Management Act (FISMA). We would ask that the Committee carefully examine the breadth of concerns we convey today and support further study in this area.

The immediate issues which we ask you to consider exploring and incorporating into your efforts are driven by several "real world" competitiveness concerns. Among business community concerns are: 1) the increasing range, depth and amount of total data that is being requested by multiple federal, state and local agencies often without cooperation and certainly without integration; 2) the federal sharing of "sensitive" data with an ever widening range of domestic and international trade bodies where neither a devotion to crafting future program requirements nor a tradition of confidentiality (or record of advanced training programs) or have even been apparent to the private sector; and 3) the federal government's increasing reliance on unproven electronic systems to manage confidential commercial data including product entry and risk assessments about products based on such data.

In today's environment, we are quite concerned with the development of policies within international bodies where multiple U.S. data streams are provided to merge and commingle with other Nation's data. In this we applaud recent Department of Commerce's initiatives toward data security for the Automated Export System (AES). In any instance, sharing of data regarding "risk analysis" must be done in such a fashion so as to avoid commercial implications as much as is humanly possible.

Notably, it is the practice of a number of foreign governments, which are traditional and significant U.S. trade partners, to subsidize certain industries which compete directly with their U.S. counterparts. In many of these governments, both in developed and developing nations, it has been AAEI's experience that the US tradition of data confidentially and specific agency retention of data, is both absent, and frankly, unwelcome. This is particularly true of a significant number of competitive nations which have neither sufficient customs nor enforcement capacity. Thus, internationally, we particularly encourage the Committee to explore development of policies to address the sharing of sensitive information with other governments, in particular foreign customs and business promotion agencies.

In noting that a variety foreign governments have substantially invested finances, national pride and whole industrial development strategies in industries and specific business enterprises that compete directly with the U.S. private sector, we must also note that, as the Committee is well aware, significant commodity supports are found globally. Clearly our concern here is in the impact of government subsidies and credits among other financial commitments may have upon the absence of appropriate prohibitions, or regrettably the apparent "blind eye" to data misuse or abuse.

In addition, a significant concern here is, the apparent lack of controls or restrictions to be imposed upon these foreign governments by any international body on a commerce driven

mandate, particularly, as noted, those which may have a financial interest in such a competitor to a U.S. company or which lack important legal safeguards restricting the use and dissemination of trade data belonging to U.S. companies necessitate AAEI's concern. To be candid, those FDA regulated U.S. businesses which are of interest to you today must have firm assurances that information potentially to be supplied to foreign governments for safety, and related, purposes would not be used against them in a competitive business context. At present, AAEI member companies are not sufficiently convinced that their proprietary trade data in multiple industrial sectors will be secure.

4. Allocation of Manpower and Resources – Both Direct and Through Third Parties

Among vital areas the significant enhancement of manpower and resources for multiple federal, and perhaps state and local, agencies through third parties should be carefully considered by the Committee. As noted earlier, this may be the time to review existing FDA lack of recognition or benefit from internal testing and controls.

We look to you, in those areas of your concern, for potentially significant changes in the way government provides for and otherwise supports import safety, risk management and control and thus imports writ large. We would be happy to discuss CBP's significant under funding and lack of sufficient manpower in the face of expanding responsibilities, but this is not the proper forum. In specific program terms, our experience has demonstrated that the CBP model for gaugers and, more recently third-party validations for C-TPAT certified partners' shipments from China, may prove useful to the Committee along with the Environmental Protection Agency's long-standing program of licensed importers and Coast Guard's periodic regulatory inspections.

AAEI believes that a fundamental element in the design of such systems must be the economic impact upon small and medium size enterprises. However, the overall impact upon small businesses nationwide; of implementing multiple trade-related approaches to enhanced product

safety is subject to the unforgiving rule of unintended consequences. “To do no harm” is a difficult mission when, even for a vital purpose, modifying long-established importation and distribution patterns and requirements will be part of the mission. It is indeed necessary, but the Committee may wish to explore the use of an incremental approach.

B. Concerns with H.R. 3610

AAEI’s testimony on specific provisions of H.R. 3610 touches upon the following seven topics: 1. Inspection at Port of Entry; 2. User Fee on Imported Food and Drugs; 3. Restricted Ports of Entry; 4. Country of Origin Labeling; 5. Safe and Secure Food Importation Programs; 6. Penalties; and 7. Recall Authority; and 8. Inspections.

1. Section 2 - Inspection at Port of Entry

   a. We believe that emphasis on inspection at the border goes against the current Administrations ‘push out the border’ policy that has been embraced by Congress with respect to trade security and must be considered in development of this approach to food safety. However, those amendments which have already been suggested to simply adopt the pattern of current homeland security policy, ie to push the borders back- to foreign soil is problematic in foods. It is our belief that to prevent any or all FDA regulated product from ever being loaded into U.S. bound containers- to certify the safety of products- has huge supply chain implications for customer access and pricing.

      In addition, though we are not experienced in USDA matters, we certainly appreciate the value of their current system of labs and import safety. However despite this appreciation,, we suggest that trying to take a limited volume and scope ‘system’ which works well for certain kinds of goods and apply it across the board, sends U.S. policy in altogether new directions. As we will discuss shortly, we find a number of these possible directions problematic.

1. Sections 3 and 4 – User Fee on Food and Drugs

    a. AAEI is concerned about this proposed user fee on imported food for the following four reasons:

        i. AAEI is opposed to user fees levied against the retail community and other importers when we know that global trade has a positive effect on the United States as a whole. We believe that both existing user fees imposed upon certain commodities (such as medical devices) and future fees under consideration are problematic. We consider that their impact frequently appears to be the kind of unequal burden created when the government agency in procurement or resource allocation among others chooses to treat products differently. The assessment of fees (or tariffs) upon retailers and importers of only specified commodities is said to limit the opportunities to cost effectively bringi9ng in goods of all genres. Frankly though this witness is certainly not an expert on fees versus tax policy it has been our analysis that such fees can unfairly burden certain industries, commodities and communities. Here we note disparate treatment of food and drugs, which are already highly regulated commodities.

        ii. It is our observation that the disparate treatment of imported product safety and domestic product safety is highly problematic in terms of U.S. industry's ability to trade internationally. To prevent serious, unnecessary damage to our huge export economy, U.S. interests must be understood in today's complex WTO environment and our growing framework of trade agreements. With the enormous degree of international competition in food commodity production already facing our companies and industries, we are extremely concerned, as noted earlier, that reciprocal actions, particularly in countries with our U.S. traditions of fair trade, could prove very difficult trade barriers to overcome.

iii. From conversations with our retailer members, it is our impression that fees assessed per line item will disproportionately impact small and medium enterprises (SME's), particularly those that import a wide variety of products currently regulated under the Food Drug and Cosmetics Act. We are informed that these would, as one example, specifically impact, specialty food retailers who may cater to traditional "geographically" based consumers. However, we believe that such data is not yet available and anecdotal evidence is all that we can rely upon at this point.

iv. The possibility exists that the fee amount per line item may actually exceed the value of the good. In this case, importation of the product is likely to dry up regardless of the lack of any domestic production. This diminishes the value of our global economic power in directly benefiting the American consumer and penalizes importers who currently provide low cost food to the average American household.

v. One fine example of this has been provided by an allied trade association in which they pointed out that(MR I think that here we can just Insert NCBFFA Mexico example

2. Section 4 – User Fee on Imported Drug

a. AAEI is concerned about this proposed user fee on imported drugs for the following four reasons:

i. AAEI is opposed to user fees levied against importers when we know that global trade has a positive effect on the United States as a whole. Again, this witness is not expert in the arena of fees assessed.

However, to prevent serious, unnecessary damage to our huge export economy, U.S. interests must be understood in today's complex WTO

environment and our growing framework of trade agreements. Prominent among these have been both the nature of the assessment (tax on value) and constitutional limitations (tax on exports). Frankly, from our preliminary review, it appears that each of the methods commonly discussed does appear to require extensive review so as to avoid unanticipated economic and trade repercussions. To assist in this effort, we suggest that the Committee consider an annual report of all such revenue collected from the spectrum of federal customs-related fees and their allocation in the budget would be of value to the Committee.

ii. The possibility exists that the fee amount per line item may actually exceed the value of the good. This diminishes the value that our global economy has the power to bring to the American consumer and appears to penalize importers who provide low cost food and drugs to the working class families and senior citizens who live on a fixed income. As referenced earlier in this testimony, the impact upon specific niche but very important marketplaces could be profound.

b. It is our understanding that utilization of user fees to pay for government programs and projects reportedly undertaken in the public good, rather than applying primarily or exclusively for the benefit of a specific and defined set of users, would be a significant departure from widely accepted policies. It appears to us that it is simply a tax imposed upon this segment of American industry. Yes, we as a Nation need to gather the resources required, but this is not the way to do it. From our perspective, it is highly prejudicial against imports, falls disproportionately on a variety of industries and impacts most heavily on the ultimate U.S. consumer.

3. Section 5 – Restrict Ports of Entry

a. AAEI believes that restricting ports for entry of food is an unwise choice because our industries trade and logistics providers must always be prepared to adjust to the dynamic economic environment. In fact, any major corporation's supply chain team

can provide you with - virtually on demand - multiple alternate methods and location of delivery with minimal product cost or availability implications. In fact, we all need to keep in the front of our minds the all too real possibility that any number of occurrences (i.e., natural disasters, labor strikes or terrorist attacks) could cripple any one of our major ports for weeks or months. Under this proposal, if that port or ports, since many are located in relative proximity, in the case of natural disasters among other factors were to be closed the options available are markedly reduced and the impacts, while negative, are highly unpredictable.

In a global environment, it is unwise to place insurmountable restrictions on either specific imported products or individual ports due to the need to maximize the limited remaining flexibility that still exists in the US trades overcrowded and aging infrastructure.

i. For Example, as noted above, if an incident of any kind occurs, it will be extremely difficult to adjust the import clearance and distribution of food product in a timely manner. The lack of pathways, in our current and emerging multimodal environment will restrict the flow of necessary food items to localities that need such products and will inevitably create a backlog in processing shipments through food specific imports. Today, such adjustments for multiple perishable and time sensitive products are routine and often occur overnight.

ii. With respect to the food industry, both a necessity and highly perishable commodity, this is a very dangerous shackle to burden our country with at a time when the need might be at a crescendo. Industry's ability to adjust current import and distribution methodologies in the event of an incident is an essential and highly supported element of today's Homeland Security Strategic planning at the federal, state and local levels. We would urge members of the Committee to consult with those local and state officials most familiar with these concerns to fully evaluate the repercussions.

It is our understanding that application of the USDA restricted port model for individual product imports, food and otherwise, would mean, in very simple terms, that specified kinds of products can only be imported and distributed through certain ports - both land and sea. The impact upon the 50 states and literally hundreds of ports, out of roughly 300, can only be calculated with full understanding of the consequences of economic dislocation in Congressional districts nationwide as well as the anticipatable impact upon land ports along either border. It is important to note that the Congress has, since the Second World War, repeatedly resisted such plans for multiple products and industries. It is our experience that, to date, proposals of such policy for multiple product and industry imports have often been offered by those whose primary concern would appear to ease and simplicity of government processing without equal regard for economic impact.

b. Under such a proposal the added logistical costs for an importer, even assuming that nothing catastrophic occurs, can be prohibitive particularly when – as is very common in this country – a product enters a given port, is transported to a second relatively convenient location for packaging or modification and then delivered to a third perhaps distant market for final distribution and consumption. The implications for the small and medium business owner unable to compete with the large retailers for inexpensive product would be substantial. In terms of industry, as we know there are multiple highly competitive pharmaceutical and food products where profits, under normal circumstances may range for one to four percent. The impact upon these, often generic or house brand products could be highly problematic, if not prohibitive, based upon location of established facilities and long term distribution patterns.

As noted earlier, the reported over-crowding, current massive infrastructure requirements and highly limited expansion or even rebuilding of a number of the ports specified has another side to it. Here, we must be concerned about the impact

upon those areas where labs currently exist or where one of a limited number may be added. As noted, we are looking at the immediate need for substantial infrastructure costs – official structures, roads, tracks, additional docks and many other elements. We are facing immediate and significant congestion and citizen disruption in that virtually all of these ports are contained with major metropolitan areas. We are also looking at potentially substantial overall environmental impact and quality of life concerns. To understand this, we ask that you simply note the enormous volume of product where, at the largest ports, of which these are, roughly 20,000 containers arrive a day. With total current national meat, poultry and egg importation of 2.6 million containers a year being absolutely dwarfed by projected totals coming through each of these ports.

Among many, one particular example of definite concern to the import community would be the Port of Los Angeles. Here the infrastructure requirements, increased congestion and projected, environmental disruption would obviously be of lifestyle concern to those citizen groups and policy leaders already actively engaged in operations and planning.

i. I would like to note, finally, one additional item which may be of interest to the Committee. In conversations with some of our historically minded members I am reminded that, when it was first discussed here in the late 1700s', this concept, apparently known as "Port Goods Selection", might have been a viable option when there were fewer ports around the country, a dearth of well established industries at highly diverse locations and far less global trade flowing through interior ports,. However they suggest that it is certainly not feasible for 2007.

4. Section 6 – Country of Origin Labeling

AAEI is concerned with the burden being placed on the trade with respect to the further development of multiple agency Country of Origin rules. This is, for instance, evident

with respect to CBP and FDA. Today's situation can be roughly described as CBP being harmonized internationally though the WTO and multiple FTA's and FDA having an independently developed and implemented system that lacks even a nexus of compatibility or overlap with CBP's regulatory regime.

5. Section 7 – Safe and Secure Food Importation Program

   a. AAEI wholeheartedly supports voluntary programs for security and safety, and was an enthusiastic participant in the development of C-TPAT. As a result, AAEI would, in terms of trade facilitation and security concerns, be pleased to both support and assist in the development of voluntary programs for product safety. However, such a program should be based on risk management principles that are compatible with and enhance both the current and future food security programs.

   b. Foreign exporters of product to the U.S. utilizing non-performance of voluntary standards as a competitive tool against U.S. manufacturers who do adhere to these essential standards - pose a growing problem which must be firmly and quickly addressed. While complex legal issues will arise, the idea that 'voluntary' means that any one player, by virtue of geography, doesn't have to pay attention to them is just plain wrong. Equally, the merits of our current system permitting export of U.S. made products failing to meet domestic agency safety standards will need to be fully explored and addressed.

   c. The Committee should be aware of the enormous complexities, as well as range of other the difficulties, that AAEI members have encountered in dealing with the multiple federal agencies whose regulatory jurisdiction and oversight for certain imported goods overlap with other federal agencies. As mentioned, our member companies have been at the forefront of cooperating with CBP by joining its trade security and trade facilitation partnership initiatives, such as C-TPAT and the Importer Self-Assessment (ISA) Program. We believe that these programs have a valuable role in achieving AAEI's often stated goal of a productive balance between trade

security and trade facilitation, which AAEI believes will be achieved on regulatory issues only when federal agencies work in close partnership with one another and the U.S. trade community.

Regretably, today, many AAEI member companies tell us that they do not receive the full benefit of these partnership programs because they are indeed regulated by multiple federal agencies that neither recognize nor accept the risk-based methodologies of existing partnership programs. They continue to face the kind of d hurdles which should be a thing of the past in today's security environment. Such reluctance affects nearly 36% of the entries for imported goods that are subject to the "release and hold" authority of the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the U.S. Fish and Wildlife Service (FWS), which are the primary federal agencies that impact most of our members potentially impacted by the current proposals.

As you can see the Congress' design for "One Face at the Border" was well founded and based upon concerns to serve land, air and sea port traders with full and equal rights. If successfully implemented it should, and hopefully will, eliminate much of the perceived inequities which have been reported in the past.

d. In this pursuit, AAEI has worked closely with the Congress and has spearheaded private sector efforts to initiate and develop a dialogue and working relationship with these other federal agencies. AAEI is particularly pleased that the earlier referenced industry dialogue with FDA has resulted in some recent initial successes. Most notably, AAEI has provided comments to FDA on its Secure Supply Chain Pilot Program which builds upon the investment U.S. companies have made in C-TPAT since FDA's program requires applicants to be C-TPAT certified at Tier 2 or higher.

e. In the same vein, we are also working with FDA concerning possible adoption of proven and practical risk-based methodologies. One which we believe is worthy of consideration, as a purely voluntary element, is the Importer Self-Assessment program where the foundation of the ISA program is CBP's finding that U.S.

companies which have good internal controls are highly compliant with U.S. customs laws. It is AAEI's experience that ISA member companies are pro-active in meeting their compliance responsibilities for all federal regulatory agencies, not just customs. However, as with other items mentioned, making this program mandatory would have difficult impacts upon the competitiveness of small and medium sized enterprises. Overall, AAEI believes that the Committee's interest in FDA and CBP coordination is an important step toward encouraging coordination and integration of other federal regulatory agencies in maintaining and demonstrably enhancing our efficient and reliable import process.

6. Section 8 – Penalties

    a. Again this is not an area where AAEI has specific expertise but we comment based upon the strong belief of our members that significantly increased and burdensome monetary penalties levied against manufacturers and importers will do little in today's international marketplace to effect change and enhance product safety without implementation of a firm correlation to the level of culpability found during an investigation. We would urge that the apparent lack of delineation in the varieties and levels of company involvement in the introduction of a product for introduction should be carefully evaluated by the Committee. We do not understand the reasoning behind the apparent intent to make no differentiation between those supply chain participants who had no reason to know and those willing and knowingly participating companies. We believe that the bad actors should be punished. Examples of perhaps more useful deterrents which the Committee may choose to explore include tying the fines to certain thresholds of negligence and/or intentional violations.

7. Section 10 – Recall Authority

    a. AAEI supports providing FDA with necessary recall authority. However, as before, we cannot comment upon the specifics of such a provision in light of our focus on import, export and supply chain matters. Nonetheless, we are obviously familiar with

domestic distribution networks and would urge the Committee to examine the full implications of such a proposal. It is, frankly, the velocity with which those products under discussion move through the global supply chain from manufacturer to often independent distribution to multiple retail facilities and ultimately to the consumer that causes our concern. It seems to us that today's rapid and efficient distribution system could well place the importer in the untenable position of chasing down every shipment transported long after delivery to retailers and probable consumption. We suggest that the Committee may wish to recognize that FDA regulated products often move in very different patterns than consumer electronics or automobiles or apparel but are often facilitated by the same players. In this regard, we ask that you examine recall policy, a necessarily reactive remedy for the government, with an eye toward economy wide impact.

8. Section 11 – Inspections

   a. AAEI remains concerned that merely increasing random inspections, sampling and testing of food imports will not sufficiently enhance food safety because such actions will be done at our borders. We suggest that there are other ways which the Committee could consider in devising solutions. In this effort, one vital step to the ultimate goal of protecting the American consumer from harm will likely lie in the prevention of tainted food and drugs entering the supply chain. However, we believe that the Committee will wish to indicate that the importer's failure to find and obtain products once released, and not "caught by regulators" at entry, will not lead to penalties upon the importer – in particular if there is no finding of intentional distribution . Thus, something that must be done outside the supply chain to ensure that the supply chain does not end up as the dumping ground for any and all catch-all provisions aimed at regulating this complex and sensitive area of trade.

   b. Though the Committee may wish to fully explore providing additional U.S. certification of foreign facilities, it could choose to both augment and take advantage

of the strength of ongoing U.S. efforts to concentrate on development of international harmonization standards. Such efforts, pursued by both the public and private, sectors could provide a model that the Committee could use to assist the promotion of U.S. foods and FDA regulated products.

c. In addition to our export interests we suggest judging the real world impact, upon U.S. consumers. It is vital to note that there are today tens of thousands of foreign shippers to the U.S. which provide critical products and substantial price competition in marketplaces nationwide. We believe that, with the tremendous growth in multiple overseas marketplaces which may not yet or ever choose to impose similar certification regimes upon these very same exporters, American retailers and the consumer could suffer a significant diminution in quality and variety. Despite our attraction as a marketplace the growing sophistication of worldwide consumers could have a major impact.

During our 85 year history, AAEI has a long record of working together with those federal departments and agencies, which have had jurisdiction over customs, trade policy, ports, transportation, tariffs, security, and immigration regarding the variety of other issues that impact the import and export of goods and services to and from the United States. We actively participate in multiple international forums and in support of excellence in this arena. In this light, it is our view that effective models for FDA and trade cooperation should include a wide variety of private sector perspectives – particularly those trade related organizations which have not always been part of the current food and drug related equations. Though independent organizations provide vital information and perspective, one highly instructive model can be based on the foundations of the well regarded Commercial Operations Advisory Committee (COAC). COAC authorized under the Federal Advisory Committee Act (FACA) is a key mechanism to foster and encourage public and private sector interaction. While significant aspects have evolved over time, COAC remains extremely useful and its mission is vital to assisting CBP and DHS craft appropriate trade security and compliance programs that not only do not interrupt the flow of legitimate trade but serve to facilitate trade in

many ways. It is worth noting that the operations and reach of COAC itself were significantly enhanced in last session's passage of the SAFE Port Act and this effort may prove helpful to the Committee.

From our perspective, dedicated private sector organizations and individuals, where appropriate, assisting FDA and related agency consultative efforts could highly productive and organizations can be encouraged which are specifically devised to incorporate the breadth of private sector consumer and trade related voices in their consideration of policy development and implementation. In addition to these groups and other beneficial multiple channels of communications between the public and private sector regarding vital import safety, trade security and trade facilitation issues for both U.S. importer and exporters, a body comprised of private citizens authorized under FACA to confer with FDA modeled on COAC would be a constructive initiative. Such a COAC like body could provide vital support and assist in making these programs both robust and effective. We would ask the Committee to examine options and consider its options in imitating utilization of a federal advisory committee in the development of vital Executive and Legislative branch coordination and direction for these vital trade related issues.

C. Conclusion

In conclusion, we wish to thank the House Subcommittee on Health of the Committee on Energy and Commerce for its invitation to provide our observations, comments, and suggestions about "H.R. 3610, the Food and Drug Safety Import Act." We greatly appreciate the Committee's efforts and hope that we can assist it to ensure that consumer confidence in our product safety regime serves as the third leg of a stool balanced partnership with trade facilitation and security. We strongly believe that the Committee's continued oversight and active promotion of import safety with recognition of existing trade security and trade facilitation programs and initiatives can make an enormous difference.

We hope that our testimony will prove useful as the Committee considers measures to enhance FDA's capabilities in handling imported food and drugs. AAEI looks forward to both supporting this Committee's active involvement and to continuing our partnership with FDA in pursuit of these goals.