

EMBARGOED UNTIL SEPTEMBER 10 AT 2PM



Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

A Report to the President

**Interagency Working Group on Import Safety
September 10, 2007**

**Interagency Working Group
on Import Safety:**

Department of Health and
Human Services

Department of State

Department of Treasury

Department of Justice

Department of Agriculture

Department of Commerce

Department of Transportation

Department of Homeland
Security

Office of Management and
Budget

United States Trade
Representative

Environmental Protection
Agency

Consumer Product Safety
Commission

*The world is changing, and in order to make sure
that we can continue to have the confidence of our
consumers, we will continually review practices and
procedures to assure the American consumer.*

-- President George W. Bush
July 18, 2007

September 10, 2007

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

The Interagency Working Group on Import Safety is pleased to submit this initial report, *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety*, in accordance with your Executive Order of July 18, 2007. The report outlines an approach that can build upon existing efforts to improve the safety of imported products, while facilitating trade.

Americans benefit from one of the safest food supplies and among the highest standards of consumer protection in the world. Our task is to build on this solid foundation by identifying actions for both the public and private sectors that will help our import safety system continually improve and adapt to a rapidly growing and changing global economy.

Approximately \$2 trillion of imported products entered the United States economy last year and experts project that this amount will triple by 2015. The federal government cannot and should not attempt to physically inspect every product entering the United States. Doing so would not only bring international trade to a standstill, but would also distract limited resources from those imported goods that pose the greatest risk. Instead, we have to be smarter about what we do.

While we acknowledge it is not possible to eliminate all risk with imported and domestic products, being smarter requires us to find new ways to protect American consumers and continually improve the safety of our imports. We recommend working with the importing community to develop approaches that consider risks over the life cycle of an imported product, and that focus actions and resources to minimize the likelihood of unsafe products reaching U.S. consumers.

This will require shifting from reliance on “snapshots” at the border to interdict unsafe products, to a cost-effective, prevention-focused “video” model that identifies and targets those critical points in the import life cycle where the risk of unsafe products is greatest and verifies the safety of products at those important phases. Such a risk-based, prevention-focused model will help ensure that safety is built into products before they reach our borders.

EMBARGOED UNTIL SEPTEMBER 10 AT 2PM

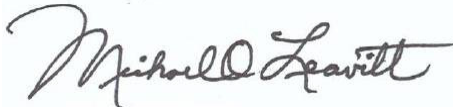
Import safety is a public-private responsibility and some agencies and private parties are leading the way towards a more preventative system. There are important roles for the private sector, foreign governments, the U.S. government, and state and local governments. As with domestic products, recognizing best practices and incentives within the private sector and building consensus among the public and private sector are cost-effective and proven ways to minimize risks.

Supporting this model are six building blocks: 1) Advance a common vision, 2) Increase accountability, enforcement and deterrence, 3) Focus on risks over the life cycle of an imported product, 4) Build interoperable systems, 5) Foster a culture of collaboration, and 6) Promote technological innovation and new science.

Over the coming weeks, we plan to solicit extensive comments and recommendations from the public, and we will provide to you a follow-on Action Plan by mid-November. The Action Plan will be based on this Strategic Framework and will lay out a road map with short- and long-term recommendations for improving import safety.

On behalf of all members on the Interagency Working Group on Import Safety, I thank you for this opportunity to serve our great country.

Respectfully,

A handwritten signature in black ink, reading "Michael O. Leavitt". The signature is fluid and cursive, with the first name "Michael" being the most prominent.

Michael O. Leavitt
Secretary, Health and Human Services and
Chair, Interagency Working Group on Import Safety



Table of Contents

I. Introduction 2

II. Background 4

III. Existing Environment 6

IV. Strategic Framework 11

V. Conclusion 22

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

Introduction

On July 18, 2007, President Bush issued Executive Order 13439, establishing an Interagency Working Group on Import Safety (Working Group). The Working Group, chaired by Health and Human Services Secretary Michael O. Leavitt, is comprised of senior officials from 12 federal departments and agencies,¹ each with unique and critical import safety responsibilities. This Executive Order and call for review was prompted by the recent dangers found in some imported apparel, pet food ingredients, toys, seafood, and other products.

The Executive Order defines the Working Group's mission as: (1) reviewing or assessing current procedures and methods aimed at ensuring the safety of products exported to the United States, including existing cooperation with foreign governments, foreign manufacturers, and others in the exporting country's private sector, (2) identifying potential means to promote all appropriate steps by producers and the U.S. importing community to enhance the safety of imported products, and (3) surveying authorities and practices of federal, state, and local government agencies regarding the safety of imports to identify best practices and enhance coordination among agencies.



The U.S. import system faces challenges from a changing world that are driven in large part by consumer demand. The volume and value of U.S. imports continues to grow due to the increasing demand by American consumers for goods that

come from access to global markets, including goods that are only available from such markets, such as the year-round availability of seasonal fruits and vegetables.

Americans must be able to purchase goods with confidence in the safety of, and knowledge of the risks posed by, the product, whether the product is from a domestic source or imported. Incidents over the past several months, however, have highlighted the need for our present import system to keep pace with this changing world and to continue meeting the expectations of the American people. These incidents are not simply signaling the need for additional resources and authorities, although additional resources and authorities may be needed and may be recommended by the Working Group after public input is received. Rather, these incidents are telling us that aspects of our present import system must be strengthened to promote security, safety, and trade for the benefit of American consumers.

¹ The Working Group includes the Department of Health and Human Services, the Department of State, the Department of Treasury, the Department of Justice, the Department of Agriculture, the Department of Commerce, the Department of Transportation, the Department of Homeland Security, the Office of Management and Budget, the Office of the United States Trade Representative, the Environmental Protection Agency, and the Consumer Product Safety Commission.

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

The Strategic Framework presents a new import safety strategy that emphasizes a cost-effective, risk-based approach. It is a strategy that considers risks at the points they are most likely to occur, and then targets the application of controls to those critical points to minimize the likelihood of unsafe products reaching U.S. consumers.

The strategy shifts the primary emphasis from a “snapshot” assessment at the border to a life-cycle “video,” working with foreign producers and the importing community to ensure that identified risks are addressed and any risk mitigations are verified at the most appropriate points of production and distribution.

The Working Group has held initial consultations with the private sector, reviewed and assessed current import safety procedures and methods, surveyed the authorities and practices of federal government agencies, and worked with the importing community to begin identifying best practices. This initial report begins the process of identifying the necessary action steps to enhance the safety of imported products consistent with domestic requirements and without unduly burdening international trade or increasing costs.

This Strategic Framework is based on information provided to the Working Group by each of the member departments and agencies. It also is informed by a nationwide fact-finding mission by members of the Working Group, and initial discussions with private sector entities representing different components of the importing community.

This Strategic Framework will be followed by an Action Plan in mid-November 2007, which will take into account information gathered from discussions with individuals and leaders representing all aspects of the importing and consuming communities and written comments from the public. The Action Plan will set out a road map with short- and long-term recommendations for improving import safety.

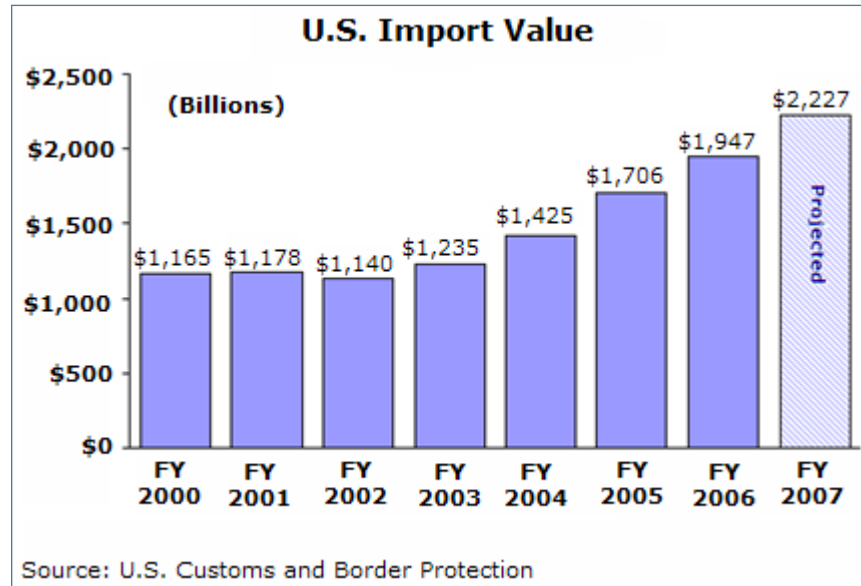
The United States has one of the safest food supplies and among the highest standards of consumer protection in the world. However, the rapid growth in the volume of imports, as well as the number of importers and exporting countries, present challenges to the current system and require a new Strategic Framework to promote the safety of products that are consumed and used by Americans.

Protecting American Consumers Every Step of the Way:

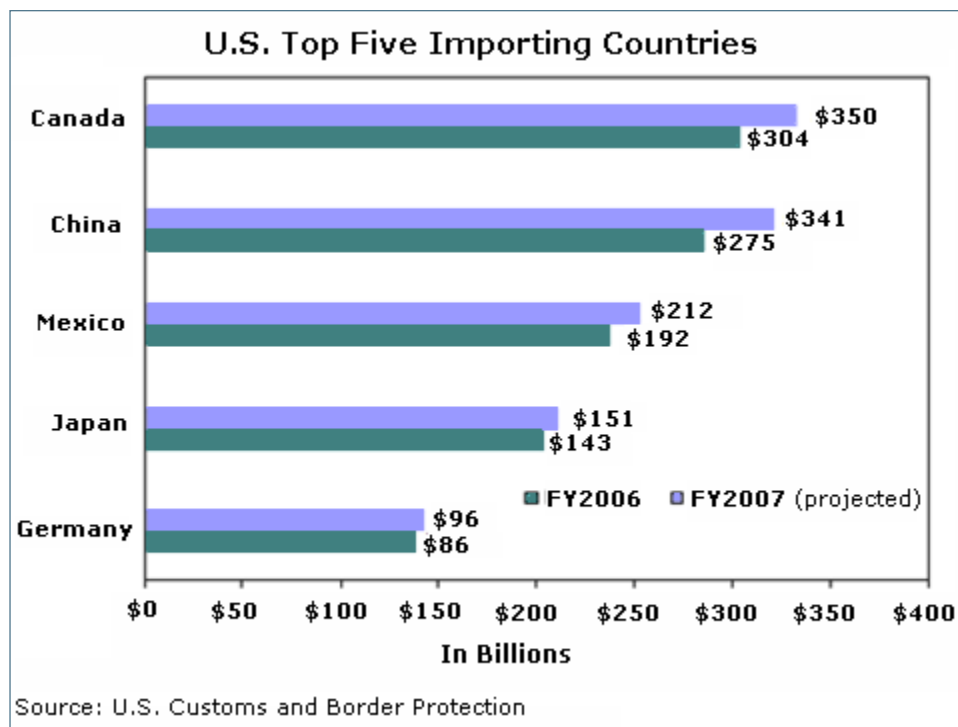
A strategic framework for continual improvement in import safety

Background

The United States currently imports approximately \$2 trillion worth of products annually from more than 150 countries. Experts project that this amount will triple by 2015, as American consumers continue to demand foreign products. The growth in imports since 2003 is steady and rapid:

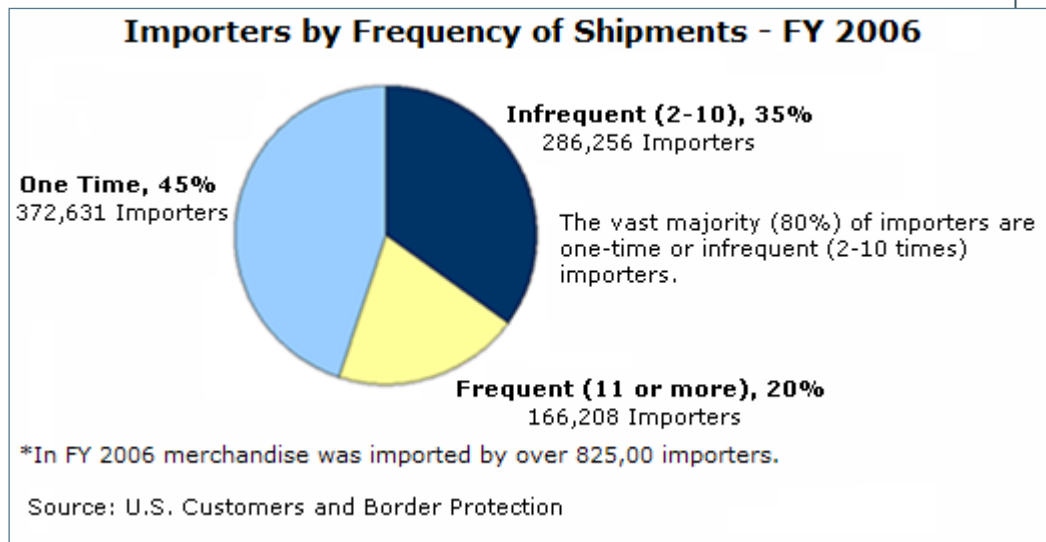


- The value of all imported shipments increased by 67 percent between FY 2000 and FY 2006, from \$1.17 trillion to \$1.95 trillion.
- The number of imported shipments increased by 33 percent between FY 2000 and FY 2006, from 23.5 million to 31.3 million shipments.



In FY 2006, more than half of all imports to the United States originated from five countries: Canada (\$304 billion), China (\$275 billion), Mexico (\$192 billion), Japan (\$143 billion), and Germany (\$86 billion).

The scale and complexity of the import network is vast, with over 825,000 importers bringing shipments into the U.S. in FY 2006 through more than 300 seaports, land border crossings, postal facilities, and other ports-of-entry. Approximately 80 percent of these shipments are by one-time or infrequent (2-10 times) importers.



This changing environment, fueled by consumer demand, has wide-ranging implications. Imports allow consumers to enjoy the benefits of a greater variety, availability, and affordability of goods in the marketplace.

The growth of imports, combined with an increased focus on security, places a greater burden on border officials. These officials must manage larger volumes of imports from countries which often have less-developed regulatory systems. In addition, they must consider more complex risk scenarios, use more sophisticated screenings and examinations, and employ new technologies to ensure product safety.

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

Existing Environment

The Working Group reviewed current authorities, procedures, and methods of federal government agencies, as well as their cooperative relationships with foreign governments, foreign industry and manufacturers, the U.S. importing community, and state and local governments, that are aimed at ensuring the safety of products entering the U.S. This review helped identify some of the challenges and limitations of our current intervention-focused approach – that of relying primarily on inspections, examinations, other border interactions, and enforcement against violators. It also led to a better understanding of what the importing community and other private entities, such as certifying bodies (e.g., Underwriters Laboratories and ASTM International), are already doing and what else they can do to enhance the safety of the products they bring into the country.

Historically, federal agencies have relied on inspections, examinations and other interactions with imported goods at a port-of-entry to determine whether or not a product can enter the U.S. This provides a one-time, sometimes incomplete, assessment of whether imported products meet U.S. safety requirements.

Americans have reason to be confident in many components of our current import system. For example:

- The Department of Homeland Security (DHS) screens all cargo imported into the U.S. for security threats before the cargo reaches the U.S. and in the vast majority of cases before the container leaves a foreign port. DHS scans nearly all shipments arriving by truck and sea containers for illicit radiological and/or nuclear materials with Radiation Portal Monitors at U.S. ports-of-entry.
- The U.S. Department of Agriculture (USDA) approves foreign countries for the export of meat, poultry, and egg products to the U.S. and inspects every imported shipment of those products for safety.
- The Food and Drug Administration (FDA), part of the Department of Health and Human Services (HHS), electronically and/or physically screens every shipment of food, drugs, biologics, medical devices, radiation-emitting electronic products, and cosmetics for compliance with applicable safety and other requirements. For food regulated by FDA, the agency receives information prior to arrival that helps to identify high-risk imported products.
- Before a pesticide can be imported into the U.S., the Environmental Protection Agency (EPA) requires that a registration (license) be obtained.



U.S. Customs HCV Mobile Cargo Screening Unit

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

- The U.S. Department of Transportation (DOT) approves the foreign suppliers of imported aircraft, aircraft engines, propellers, and certain aviation components. U.S. companies must maintain an inspection system for all supplied aircraft parts. Foreign supplier facilities are subject to audit by the Federal Aviation Administration (FAA).

These practices are indicative of, and contribute to, the safety that Americans benefit from today. There are also the many actions taken by producers



and the importing community to ensure product safety. The private sector has a strong financial interest in selling safe products to its customers and protecting its brands. For example, FedEx's Offshore Radiation Screening Program screens all of its cargo destined to the U.S. for radioactive materials. The Working Group will receive additional information on the private sector's actions through outreach efforts leading up to the Action Plan.

Although the current import safety system has served the public well for many years and is among the most effective in the world, parts of the system will need to be strengthened to meet the challenge of an increasingly global economy.

Deficiencies and challenges associated with the current system include:

- **Comprehensive consideration of risk** – Today's import system does not always result in agency decision makers and importers getting all the best information to address import safety because the system often focuses on intervention at ports-of-entry. Government officials and importers may be left making determinations based on a "snapshot" of information about the safety of products, without a comprehensive consideration of the risk associated throughout the import life cycle of a particular commodity. A one-size-fits-all approach to imports – without consideration of risks associated at the various stages of the import life cycle – will not effectively address the issues of concern or use our resources wisely.

In today's world, processes addressing safety and security threats are complementary. To ensure the safety of imports, our actions must be coordinated.

Some agencies and members of the importing community have already begun to shift to a risk-based preventive approach that includes verification. Others have nearly completed the transition. However, the shift needs to rapidly encompass all who participate in the import supply chain.

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety



- **Security and safety relationship** – Protecting American consumers from security threats or contraband disguised as legitimate imports (import security) and imports that are not intended to cause harm but are unsafe (import safety) are complementary endeavors. Significant overlap occurs in the tools used to combat security and safety risks. Investment in one may pay dividends to the other. A comprehensive approach to import safety requires that both security and safety measures be coordinated to allow decision makers to most effectively leverage resources to solve problems.
- **Need for additional authorities** – In some cases, federal government officials lack the authority to identify or effectively address products found to be unsafe, to punish bad actors, or to implement effective preventive measures across the import life cycle.



For example, under the Consumer Product Safety Act (CPSA) – the enabling statute of the Consumer Product Safety Commission (CPSC) – it is currently legal for entities to sell a voluntarily recalled consumer product even after the public announcement of the recall. Amending the CPSA to make it unlawful for anyone to knowingly sell a voluntarily recalled product after the date of public announcement of the recall would create the proper incentives for retailers and distributors to halt sales of recalled products more quickly.

- **Insufficient data** – Advance cargo information transmitted to border officials does not provide adequate detail to make safety determinations. At the time of entry, the importer provides a Harmonized Tariff Schedule (HTS) number and a description of the goods, yet this HTS number does not always provide enough identifying information to determine the proper jurisdiction and regulatory review required to make determinations of admissibility. Insufficient product information can lead to erroneous decisions about jurisdiction, which in turn can cause the U.S. Customs and Border Protection's (CBP) automated system to incorrectly refer items to agencies without appropriate jurisdiction. This inadequate description often results in more products being held for documentation and examination and thus delays product entry into domestic commerce. Increasing border officials' access to advance data would allow them to better target shipments for safety purposes.
- **Siloed systems** – Federal and state agencies use multiple, non-integrated automated systems and currently cannot adequately share information on import transactions.

For example, during the Working Group's fact-finding mission, border officials noted that in order to process cargo, they have to use multiple passwords to access multiple systems rather than a single password to access a single system.

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

Another example was found in the USDA's import inspection data system for meat, poultry, and egg products, which has no connection to CBP's Automated Commercial System (ACS), the data system used



Meat imports undergoing
USDA inspections

to clear all import shipments for entry into domestic commerce. Because of this lack of connectivity, USDA must use summary information from CBP, including the port arrival time and responsible importer, to track shipments of foreign meat, poultry, or egg products to ensure compliance. This lack of connectivity between the CBP and USDA systems has created the possibility, which is now being addressed, for imported products to enter domestic commerce without being inspected in accordance with federal requirements.

- **Circumvention** – Companies and individuals may engage in circumvention to avoid U.S. restrictions on imports of certain merchandise from a particular country, inspection requirements, or refusal of entry. Circumvention often materializes in the form of: 1) transshipping imports through a third country and claiming the third country as the merchandise's country of origin, 2) misreporting the identity of the merchandise, or 3) "port shopping" by attempting to enter previously refused merchandise through a different port to avoid detection.

For example, in 2006, CBP intercepted 45 containers with chicken, chicken parts, pork, and meat products being smuggled into the U.S. as frozen seafood. These meat products were prohibited entry into the U.S. because they were from a country that was not approved by USDA to export them to the U.S. The misrepresentation was a deliberate attempt to circumvent those prohibitions. CBP fed the information on the violators involved with these actions into its targeting system to make it more difficult for those entities to smuggle product without detection.

In summary, while Americans continue to benefit from one of the safest food supplies and among the highest standards of consumer protection in the world, the existing import system will be unable to manage effectively the risks presented by the mounting volume and complexity of imports that will enter the U.S. in coming years. The changing import environment demands a new approach to import safety – a risk-based preventive approach that is more comprehensive, collaborative, and technologically-enhanced, and that stresses accountability.



The largest ships can carry 8,000
containers each 40 feet long

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety



An Overview of the Import Process

Regulations implementing the Trade Act of 2002 require that specific information – such as a six-digit Harmonized Tariff Schedule (HTS) classification, and shipper name and address – be provided for all commercial cargo prior to arrival in the U.S. By law, exporters provide this information electronically to U.S. Customs and Border Protection (CBP) using the automated manifest system for vessels, air and rail, and the Automated Commercial Environment truck manifest for truck shipments. For maritime cargo, this information must be transmitted to CBP prior to the cargo being loaded aboard the departing vessel.

In addition, the Bioterrorism Act of 2002 requires the submission, prior to arrival, of product-specific information, such as grower and product code, for FDA-regulated food consumed by humans and animals. Failure to provide this information can result in the cargo being held at the port upon arrival.

Border officials compare the information received on the imported products with criteria provided by federal agencies and other information in their automated system to determine if the merchandise can be released into U.S. commerce. Cargo that does not meet the criteria may be held for further review and examination by the federal agency having regulatory jurisdiction.

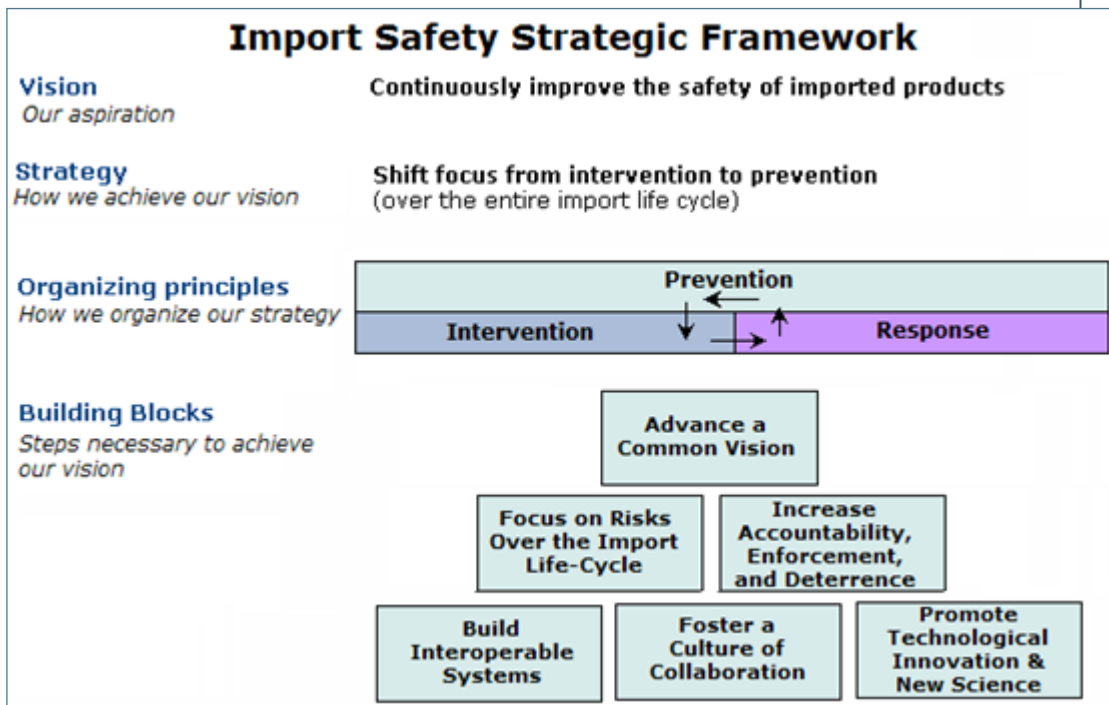
The arriving carrier is responsible for the integrity of the cargo that it transports. Vessel, air and rail carriers are required to maintain carrier bonds that guarantee against unauthorized delivery of cargo. (Carrier bonds are not required of arriving truckers because all truck arrivals are met by a CBP Officer.) Once border officials determine that entry of the cargo may be made, the cargo is conditionally released by CBP and an entry bond is made. The importer is obligated to meet specific requirements (such as payment of duties, filing of complete entry information, and completing review by other government agencies).

In addition, provisions of the importer's entry bond allow for expedited release from CBP custody on the condition that, if the merchandise is found to be in violation of federal requirements, it must be returned to CBP, exported, or destroyed. To take action based on the bond, CBP is required to seek redelivery within 30 days after cargo release unless specific notice is provided to the importer that additional time is necessary. In addition to action under the bond, if circumstances warrant, CBP can take other enforcement and penalty actions that may include seizure of the goods, assessment of penalties, and referral for criminal investigation and prosecution.

Strategic Framework

The challenges presented by the increasingly global economy and growing import volumes require a paradigm shift from an intervention, border-focused strategy to a life-cycle approach that stresses a risk-based approach to prevention with verification that identifies high-risk segments of the import life cycle and verifies the safety of products at those important phases. With this shift, the U.S. import process will change from viewing a “snapshot” of the product at the border to achieving a real-time “video” across the product’s import life cycle at the most appropriate points of production and distribution.

This shift forms the basis of the Working Group’s new Strategic Framework. It envisions the public and private sectors working together to identify risks, and considers new approaches for addressing these risks. Within this Framework, the vision must be to continually improve the safety of imported products. Both the public and private sectors must be vigilant and committed to ensuring that safety is built into the products Americans import in the most cost-effective manner possible.




Three organizing principles are the keystones of the Strategic Framework:

1. **Prevention** – Prevent harm in the first place.

The U.S. government must work with the private sector to adopt an approach to import safety that builds safety into manufacturing and distribution processes. Producers and the importing community will play a key role in accomplishing this objective by implementing preventive approaches and requiring these approaches from their suppliers. In addition, third-party certifications and testing requirements can play

EMBARGOED UNTIL SEPTEMBER 10 AT 2PM
Protecting American Consumers Every Step of the Way:
A strategic framework for continual improvement in import safety



an important role in this area, as can credible manufacturer supply-chain management programs. Continued enforcement activities will also create incentives by deterring bad actors and encouraging U.S. importers to review their suppliers. The federal government will be prepared to work with the importing community to further develop the tools and science necessary to better identify those imports that pose the greatest risk, and to identify the points in the import life cycle where the most effective intervention can take place to ensure the safety of these products. The federal government will also be prepared to work with foreign governments to oversee manufacturers within their borders to help ensure safe domestic production practices that facilitate safe imports meeting U.S. safety standards and other requirements, such as the enforcement of intellectual property rights.²

2. Intervention – *Intervene when risks are identified.*



Federal, state, local, and foreign governments, along with manufacturers and the importing community, must adopt more effective techniques for identifying potential product hazards. Through risk-based inspections and sampling utilizing science-based detection technology, government officials can more effectively detect potential import hazards. When problems are discovered, government officials must act swiftly and in a coordinated manner to seize, destroy, or otherwise prevent dangerous goods from advancing beyond the point-of-entry. The earlier potential hazards are identified, the greater the likelihood of successful interventions. The private sector's meeting requisite pre-entry documentation and certification requirements also plays a pivotal role in helping to identify potential product hazards.

3. Response – *Respond rapidly after harm has occurred.*

In the event that an unsafe import does make its way into the domestic stream of commerce, swift actions must be taken to limit potential exposure and harm to American consumers. In most instances, existing product recall mechanisms have proven capable in this regard. But we can do more.

We need a more robust, collaborative system of response that leverages information already available to the importing community for the benefit and protection of the consumer. While the response would be led by the federal government, in close collaboration with state and local governments, it would involve the manufacturer, importers, and retailers in order to contain the problem rapidly, recall any products of concern, and inform customers and the general public.



Acoustic Inspection Device

² The continued vigorous enforcement of non-safety related requirements can also play a critical role in promoting safety. For example, products violating intellectual property rights may indicate a significant safety risk. This is certainly the case for imported counterfeit pharmaceuticals.

EMBARGOED UNTIL SEPTEMBER 10 AT 2PM
Protecting American Consumers Every Step of the Way:
A strategic framework for continual improvement in import safety

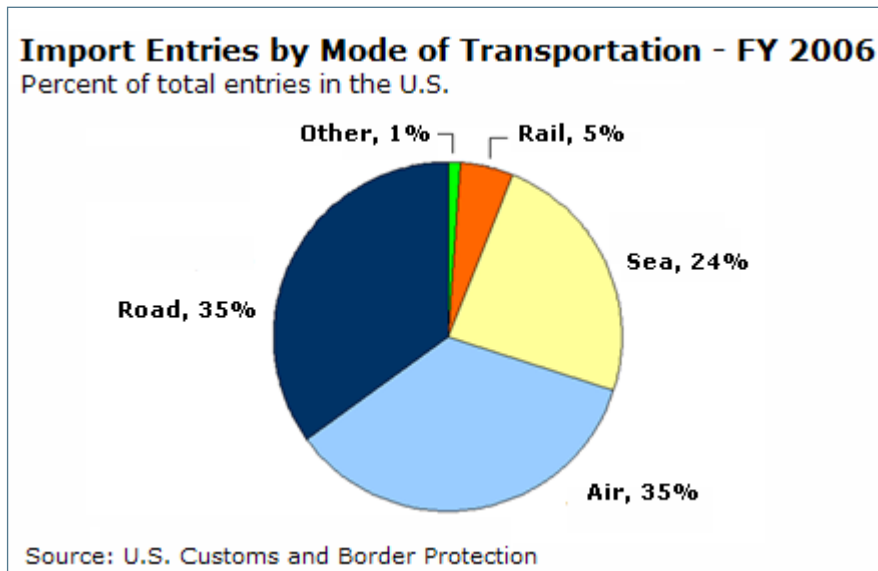


Recalled toys

New and emerging technologies that might assist in more effective response efforts should also be explored and encouraged in both the public and private sectors. Additionally, although the federal government does not have the capacity to prosecute or pursue civil enforcement actions against all wrongdoers, prosecutions will be used strategically to reinforce proper incentives, deter wrongful conduct, and prevent harm.

These keystones provide the organizing principles for continual improvement in import safety that can be implemented using six cross-cutting building blocks: 1) Advance a Common Vision, 2) Increase Accountability, Enforcement and Deterrence, 3) Focus on Risk Over the Life Cycle of an Imported Product, 4) Build Interoperable Systems, 5) Foster a Culture of Collaboration, and 6) Promote Technological Innovation and New Science.

Some building blocks, such as Build Interoperable Systems and Promote Technological Innovation and New Science, can be expected to have a significant impact in a relatively short period of time, while others, such as Advance a Common Vision and Foster a Culture of Collaboration, are more complex and may take more time to implement and show results. The Action Plan that will follow this report will provide a durable road map laying out specific steps that should be taken in both the short- and long-term to implement the Strategic Framework.



Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

Building Block #1: Advance a Common Vision

There should be a shared vision and shared goals across the federal government for promoting import safety. Currently, under their respective statutory regimes, some federal agencies focus on a wide-range of regulatory and enforcement issues, including threats to our national security and safety. The degree to which these agencies focus on the myriad of issues can vary widely. Although each agency has its own role to play in ensuring the safety of imported goods, all agencies should operate under a common vision to strengthen import safety and best leverage federal government resources.

Accordingly, relevant policies and procedures should be reviewed and, where appropriate, revised to ensure that all federal agencies are working together with shared objectives and encourage public and private parties involved in the import life cycle to adopt this common vision. The adoption of this Strategic Framework by all federal agencies involved in import safety would mark an important step towards having a common vision for import safety for the federal government and would also provide clarity to the private sector.



Building Block #2: Increase Accountability, Enforcement, and Deterrence

While it is important to remember that industry has a financial interest to sell safe products to its consumers, all actors involved in the production, distribution, and sale of imports must be held responsible for meeting their obligations to ensure that imported products meet U.S. safety standards. The federal government will continue to work with industry to foster compliance with U.S. standards, but is also prepared to use appropriate criminal and civil enforcement tools to hold companies and individuals accountable and to protect consumers. Targeted investigation and enforcement can send a clear message to the regulated community and, in so doing, provide proper incentives and deterrence. Moreover, the continued vigorous enforcement of non-safety related requirements, such as intellectual property rights, can also play a critical role in promoting safety.

We can improve accountability by developing better tools for linking products to manufacturers, importers, distributors and retailers, and verifying supplier and producer compliance with safety standards.

To further strengthen import safety, the federal government's efforts must be joined vigorously by stakeholders across the import life cycle. From foreign governments, to foreign manufacturers and distributors, to domestic importers, manufacturers and retailers, import safety can be achieved only through shared efforts and responsibility that encompass the entire production process, as well as the U.S. importing process.

Existing practices within the import life cycle sometimes make it a challenge to link unsafe products to importers and manufacturers that may close or rename

their businesses to avoid accountability. Greater reliance on prevention-focused mechanisms, such as third-party certification and testing schemes and manufacturer supply-chain management, may be useful for ensuring that production inputs and processes comply with safety requirements throughout the import life cycle.

We can improve accountability by developing better tools for linking products to manufacturers, importers, distributors, and retailers, and verifying supplier and producer compliance with safety standards. This step would enable more timely investigations and interventions, help prevent potentially dangerous goods from entering the stream of commerce, and make possible stronger and more effective enforcement actions. Promptly sharing this information with foreign governments can help them take steps needed to protect public health and the environment within their countries.

Ultimately, any private entity that stands to benefit from access to U.S. markets owes a duty to the American public to ensure that the products they export and sell comply with all applicable safety standards. Accountability for ensuring that these standards are met rests with all stakeholders across the import process, both public and private.

Building Block #3: Focus on Risks Over the Life Cycle of an Imported Product

Rather than merely trying to identify unsafe products at the border, the new approach must focus on the most important safety considerations affecting imported goods throughout their import life cycle – from overseas production through U.S. ports-of-entry to final consumption or use in the U.S. A key element is developing the ability to identify and manage the greatest risk at critical points along the import life cycle. Rather than being the primary line of defense, intervention at the U.S. border must become one part of a network of interconnected measures that facilitate the entry of safe, lawful imports and protect the American public.

The federal government should move to a risk-based, cost-effective approach to identify and mitigate risks posed by imported products. Principles of hazard analysis and risk management have long been applied in manufacturing as a method of minimizing risks and maximizing quality in production processes. These principles enable the targeting of resources to areas of greatest risk.

Within America's food processing industries for example, Hazard Analysis and Critical Control Points (HACCP) principles are applied voluntarily by manufacturers and processors, and, in some areas, as a regulatory

Key Features of a Risk-Based Approach

Risk assessment

- *Information gathering*
- *Surveillance and detection*
- *Information integration*
- *Risk analysis*

Risk management

- *Improving compliance*
- *Preventing entry of unsafe imports*
- *Mitigating risks*
- *Risk communication*

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

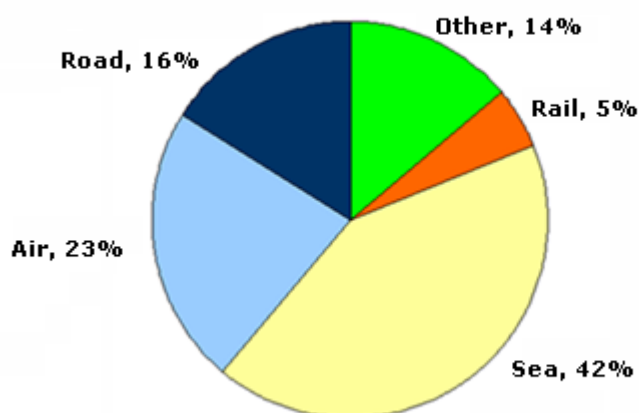
requirement to ensure that only safe products reach the marketplace. Identification of risks at the points they are most likely to occur, and the targeted application of controls at those critical points, helps to minimize the likelihood of producing an unsafe product. Controls are verified to ensure they are working as intended. Surveillance and detection are fully integrated into each step of the import life cycle.

These same principles of risk management should apply to the import supply chain – from the point of foreign origin to domestic consumption or use. All entities

involved in the import life cycle – foreign growers and manufacturers, foreign governments, foreign exporters, U.S. importers, manufacturers and retailers, testing and certification bodies, and regulatory authorities at the federal, state, and local levels – should work together to support prevention with verification and mitigation of risk in products entering the U.S. marketplace. Determining the scientific methods and tools for identifying, characterizing, and

Import Value by Mode of Transportation - FY 2006

Percent of total value of imports in the U.S.



Source: U.S. Customs and Border Protection

mitigating risk will help improve decisions regarding the safety of imported products and the capacity to act on them.

In addition, the science-based measures that we put in place for both domestic- and foreign-made products must comply with our international trade obligations, including obligations related to product safety and intellectual property protection. In this manner, we hold ourselves accountable to the same expectations that we place upon our trading partners.

Building Block #4: Build Interoperable Systems

Interoperability is the ability of one system to communicate with another. Too often, we build sophisticated data systems without ensuring the systems' ability to interface with one another. We need to finalize implementation of interoperable data systems, already under development, that facilitate the exchange of relevant product information among parties within the global supply chain to ensure import safety.

Government agencies should share the information they collect about activities occurring along the global supply chain to prevent, identify, mitigate, and respond to product safety hazards. Manufacturers test products to ensure that they comply with relevant performance and safety standards; government agencies inspect and

test products to ensure that they meet regulatory requirements associated with public health, environmental safety, and consumer protection. Marketplace recalls are conducted to remove faulty or unsafe products from commerce. Information about these activities is often collected and recorded, and should be shared among individual actors in the import life cycle or aggregated and analyzed as a whole.



Screening and Tracking Technologies

Information technology has improved the availability and exchange of information on imported products. The import entry process is one area where information technology is being used to improve the exchange of import supply chain information. Throughout most of U.S. history, a revenue-centric import system focused largely on the collection of customs duties on imported goods. In the post-9/11 environment, however, government and industry have recognized the need to expand the focus of the import system to encompass security and safety. This involves integrating additional information, including import inspection and clearance activities conducted by other government agencies, into the customs entry process.

The International Trade Data System (ITDS) is a key component to improve systems interoperability. The recently enacted Security and Accountability for Every (SAFE) Port Act of 2006 established a requirement for an electronic interface among all federal agencies that monitor or control the movement of imported products in domestic commerce. The ITDS will create a single-window environment in which importers, transportation carriers, and government agencies can exchange information on imported products. When fully implemented, ITDS will facilitate the processing of legitimate import transactions, improve how imported products are identified and classified, strengthen entry screening capabilities, and help to target inspection resources to areas of greatest risk.

Building Block #5: Foster a Culture of Collaboration

We must develop a culture of collaboration that will permeate the relationships among federal agencies as well as our relationships with external partners. All parties (federal, state, and local governments, foreign governments, foreign producers, and the importing community) involved in the import life cycle need to work together to prevent unsafe products from entering the U.S., and to take swift and effective action if such products do enter domestic commerce.

Federal departments are working towards a common vision to advance import safety. For example, federal agencies recently collaborated to interdict and eliminate products containing melamine, a toxic chemical compound illegally added to wheat gluten, a primary ingredient in the manufacture of pet food. The U.S. Department of Agriculture, The Department of Health and Human Services, Department of Commerce, Environmental Protection Agency, and Department of Homeland Security coordinated risk assessment, testing and enforcement activities to identify the scope and scale of the problem, contain its spread, and, in collaboration with the pet food industry, implement targeted product recalls.

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

This will require a new era of collaboration, as we find better ways to work with all import life cycle parties. Specific steps to improve collaboration include: the establishment, communication and enforcement of standards, sharing of relevant safety information, leveraging resources among the agencies in the U.S. government, and seeking state, local, and international cooperation as a force multiplier.

Increasing the international harmonization of product safety standards, without lowering the high-level of protection afforded by existing U.S. standards, can in many instances help strengthen import safety. Often, greater international consistency in safety standards facilitates compliance and permits mutually reinforcing enforcement activities. Harmonization of product safety standards will also help producers that export to multiple countries avoid the burden and complications of having to adjust their practices to meet divergent standards depending on where their products are to be sold.

Building Block #6: Promote Technological Innovation and New Science

Developing and applying new science and technologies will be instrumental to improving the effectiveness and efficiency of the U.S. import safety



Radiation Detector

system. Implementation of innovative technologies will afford the opportunity to screen larger volumes of imported products at the ports-of-entry. These screening procedures will help evaluate and subsequently target high-risk commodities, increasing analytical efficiency and total numbers of imported products tested. Research into the causes of risk, such as the conditions that lead to contamination of foods with certain pathogens, can help government and industry identify vulnerable points in the import life cycle for specific products. The development of innovative technologies to identify and to mitigate risks, such as new field tests for toxins, can help government and industry detect specific contaminants

and take appropriate steps to reduce risk at those vulnerable points in the life cycle.

Because the return on the investment for such technological innovations varies, the federal government can play a significant role in helping to advance this new science. Smart use of technology can also speed and enhance communications among participants in the distribution chain of imported products.

The Strategic Framework in Action

Recognizing the need to strengthen America's existing import system, several federal agencies, and the commercial sectors they regulate, have already made the shift to a risk-based import safety approach that focuses on prevention with verification, while others have begun to make the transition. Below are some examples.

Cooperation with Importers and Foreign Exporters

The National Oceanic and Atmospheric Administration (NOAA) within the Department of Commerce operates the fee-based Seafood Inspection Program. One service under this program provides in-plant inspection of foreign seafood facilities. At the request of the U.S. seafood importer or the foreign seafood facility, NOAA audits the facility to ensure that it complies with the Hazard Analysis Critical Control Point (HACCP) Quality Management Program. This service also includes the training of facility personnel in sanitation practices, hazard analysis and other procedures, and assisting the facility in writing and implementing a HACCP plan. Finally, the program includes training in product grading and quality evaluation to the standards set by the U.S. and the International Standards Organization for food safety and manufacture.



FDA has worked both with importers and exporters, as well as CBP, to streamline the prior notice submission process by allowing the use of one data stream via CBP's automated system.

Domestic manufacturers of aeronautical products maintain a list with the Federal Aviation Administration of their foreign suppliers, and each manufacturer attests that their respective suppliers are capable of producing aeronautical products sufficient to satisfy technical and quality standards. The manufacturing facilities of foreign suppliers are inspected by the U.S. company purchasing their products and are subject to audit by the FAA. For some aircraft components, U.S. companies employ inspectors at the foreign supplier's facility to ensure that parts for export conform to approved specifications. All parts and services purchased by U.S. aeronautical companies are traceable to their site of manufacture. FAA requires companies to maintain inspection records that document materials used in production, product sampling, and type of inspection performed to assure conformity with required specifications.



Through its personnel stationed overseas, the Department of Agriculture (USDA) works with foreign exporters to ensure that fruits and vegetables are free from agricultural pests and diseases prior to export to the United States. U.S. bound shipments that have passed these USDA pre-clearance inspections may receive expedited clearance at U.S. ports-of-entry and may qualify to enter otherwise restricted U.S. ports.

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

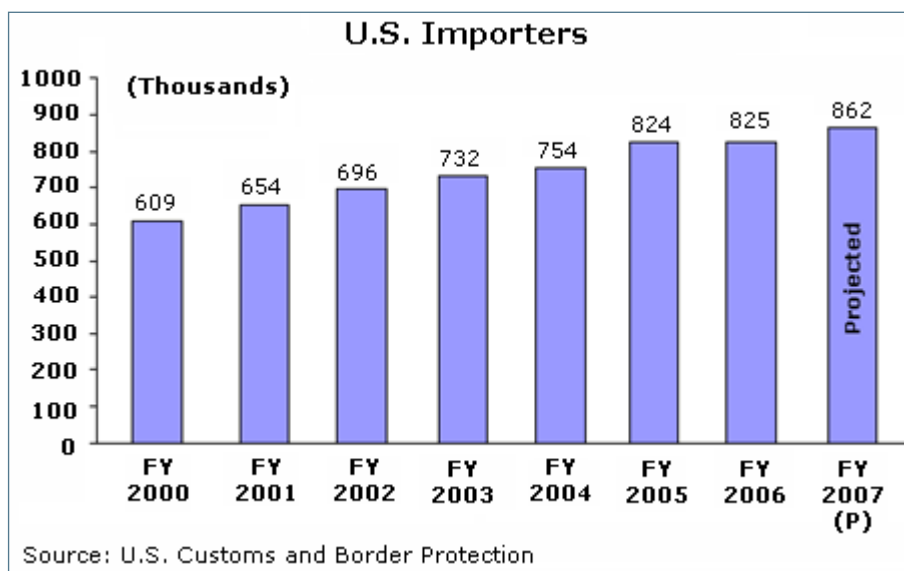
Cooperation with Foreign Governments and International Organizations

FDA has completed 34 confidential arrangements with 31 foreign counterpart agencies in 17 countries that permit FDA to share and receive not only approval, inspection, adverse event, and emergency information for products manufactured in a partner's territory, but also information relating to common regulatory experiences with key third countries. Under these arrangements, FDA is averaging more than two such exchanges each work day.

USDA, as required by statute, makes determinations about the eligibility of foreign countries to export meat, poultry, and egg products to the U.S. Through an assessment of government-run inspection systems, USDA determines whether these countries enforce standards that provide the same level of public health protection as the U.S. inspection system. Only countries with an affirmative USDA determination of eligibility may export meat, poultry, and egg products to the U.S. These countries' governments must certify to USDA those exporting facilities that satisfy U.S. requirements. Only these facilities may ship product to the U.S. market. USDA auditors review a selection of foreign inspection programs and certified facilities annually to verify that they continue to meet U.S. requirements.

The FAA has agreements with 30 foreign governments regarding the importation of aeronautical products into the United States. These agreements define how each foreign government will enforce compliance with U.S. requirements and certify products destined for export to the United States.

The Consumer Product Safety Commission has signed more than a dozen Memoranda of Understanding with its counterpart agencies, including with Canada, Mexico, China, and the European Union. These agreements strengthen the working relationships between the agencies, provide a formal mechanism for a greater and more significant exchange of information regarding consumer product safety, and typically include plans for informational seminars and training programs.



Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

The Environmental Protection Agency participates in the Organization for Economic Cooperation and Development's (OECD) Working Party on Waste Prevention and Recycling. This multinational group helped to develop an agreement allowing shipments of hazardous waste for recycling between members of the OECD, and addressed issues related to the import and export of waste as well as environmentally sound methods of handling wastes.

Cooperation with State and Local Governments

The Electronic Laboratory Exchange Network is a seamless, integrated, secure system that facilitates the sharing of food-related laboratory test methods and test results with the 135 participating laboratories representing multiple government agencies and all 50 states.

EPA regional offices coordinate with state government officials to locate and identify illegal importation of pesticides. Special emphasis is placed on pesticides that may impact children's health.

CBP's Agriculture Programs and Liaison office works with state governments through the National Plant Board, state plant risk committees, and USDA's Animal and Plant Health Inspection Service to identify products, such as fresh fruit infested with Mediterranean fruit flies, which would create heightened risks to U.S. agriculture if introduced into the United States.




Imported counterfeit drugs

Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety

Conclusion



The benefits of international trade are wide-ranging, yet these benefits bring with them new and complex challenges. Although they are of great value to the American consumer, the increasing volume of imports entering the United States creates an urgent need for a new, forward-looking Strategic Framework for import safety that considers risks over the life cycle of an imported product and focuses actions and resources to minimize the likelihood of unsafe products reaching U.S. consumers.

This will require shifting from the current model that relies on “snapshots” at the border to interdict unsafe products to a cost-effective, prevention-focused “video” model that identifies and targets those steps in the import life cycle where the risks of unsafe products is greatest and verifies the safety of products at those important phases. Such a risk-based, prevention-focused model will help ensure that safety is built into products before they reach our borders.

Recognizing that some risk will always remain, and that it is impossible to inspect our way to safety given the increasing volume of products entering the United States, a major component of the Strategic Framework is identifying means for increasing cooperation with foreign governments, foreign manufacturers, importers, and others to ensure that the private sector takes a leading role in effectively and efficiently strengthening the safety of imports both now and in the future.

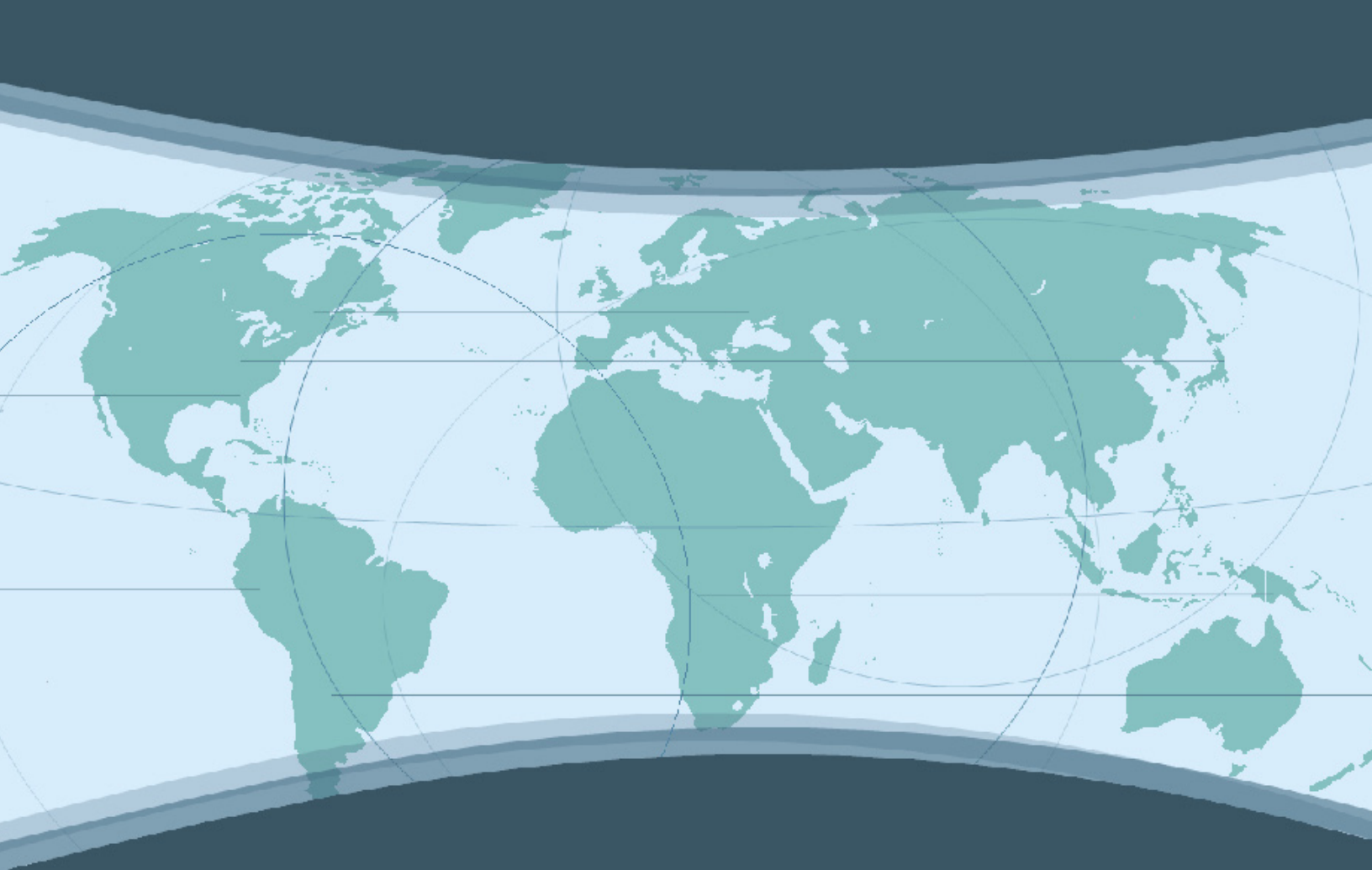
Adopting a forward-looking approach to import safety will require us to find new ways to gather, aggregate, integrate, analyze, communicate, and act upon information about imports from across the import life cycle. As such, the Working Group recommends a Strategic Framework based on the organizing principles of Prevention (prevent harm in the first place), Intervention (intervene when risks are identified), and Response (respond rapidly after harm has occurred).

Supporting these keystones of the Strategic Framework are six building blocks: 1) Advance a Common Vision, 2) Increase Accountability and Enforcement, 3) Focus on Risks Over the Life Cycle of an Imported Product, 4) Build Interoperable Systems, 5) Foster a Culture of Collaboration, and 6) Promote Technological Innovation and New Science.

Americans properly have high expectations for the safety of the foods they eat and the products they use. This Strategic Framework, when coupled with the forthcoming Action Plan, will ensure that as the global economy expands, public and private sector actors will be working to continue to meet the expectations of the American consumer -- not just today, but for years to come.

We need to continually improve our import safeguards to meet the changing demands of a global economy. We must ensure that our food supply and imported products remain among the safest in the world. Our purpose is not just to look at today, but to anticipate tomorrow.

-- Secretary Michael O. Leavitt
Chair, Interagency Working Group on Import Safety
August 6, 2007



EMBARGOED UNTIL SEPTEMBER 10 AT 2PM

www.importsafety.gov