



Action Plan for Import Safety

A roadmap for continual improvement

A Report to the President
Interagency Working Group on Import Safety
November 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

*We will continually improve the safety of imported products
in a manner that expands global trade and protects the
health and safety of every American.*

President George W. Bush

November 6, 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 *Action Plan for Import Safety: A roadmap for continual improvement*. In it, we detail a roadmap with short- and long-term recommendations and action steps.

This Action Plan represents the culmination of thousands of hours of research and analysis, as well as public comment received from hundreds of stakeholders. The Action Plan takes the form of 14 broad recommendations and 50 specific action steps based on *Protecting the American Consumer Every Step of the Way: A strategic framework for import safety* and the *Immediate Actions Memorandum* presented to you on September 10, 2007.

In the last two months, significant progress has been made on the Immediate Action Items listed in my memorandum to you accompanying the Strategic Framework. The Office of Management and Budget has actively engaged the departments, and all agencies are on track to accelerate their participation in the Automated Commercial Environment / International Trade Data System. In addition, the State Department has led a vigorous international outreach effort to communicate our import safety priorities with our trade partners around the world. The Office of the United States Trade Representative has moved forward with the departments and agencies to explore existing import safety-related agreements with foreign governments and to coordinate future agreements to benefit the United States and not merely individual agencies.

A variety of actions and plans are already underway to improve import safety. Today, the Food and Drug Administration is releasing a new Food Protection Plan. In September, the Consumer Product Safety Commission signed a renewed agreement with the People's Republic of China focused on the safety of toys, fireworks, cigarette lighters and other targeted products. These steps, and other recent actions and current plans, have jump-started our efforts to continually improve the safety of products imported to the United States.

Each recommendation in this Action Plan falls under the organizing principles of prevention, intervention and response and expands upon the building blocks identified in the Strategic Framework. Together, the Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

The information collected and analyzed for this Action Plan reaffirms the essential and integrated import-safety roles of the public and private-sector. Our recommendations pertain to all parties involved in the import life cycle, from production in the foreign country through U.S. ports-of-entry to final consumption or use by American

consumers. The public and private-sectors have a shared interest in import safety, and substantive improvement will require the careful collaboration of the entire importing community.

This Action Plan provides a roadmap that ensures the benefits of the global economy and improves the safety of imported products. Progress will require that we work collaboratively, partner with the importing community and state and local governments, and reach out to foreign producers, exporters and governments. By doing so, all involved will be more prosperous and will continue to benefit from an abundant and safe marketplace.

We recommend that Working Group designees meet within 30 days to assess progress in implementation of this Action Plan, and to discuss how best to collaborate with the private-sector to continue effective implementation.

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

Respectfully,

A handwritten signature in black ink that reads "Michael O. Leavitt". The signature is written in a cursive, flowing style with a large initial "M".

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

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Introduction

On September 10, 2007, the Interagency Working Group on Import Safety¹ (Working Group) presented an *Action Plan for Import Safety: A roadmap for continual improvement* (Strategic Framework) and Immediate Actions² for continual improvement in import safety.³ The Strategic Framework provides the foundation for this Action Plan for Import Safety. Together, the Strategic Framework, Immediate Actions and this Action Plan fulfill the requirements of Executive Order 13439, which established an Interagency Working Group on Import Safety and was signed by President Bush on July 18, 2007.

A careful examination of import safety has been motivated by the recent challenges presented by an increasingly global economy, in which U.S. consumers are purchasing approximately \$2 trillion worth of products that are imported by over 800,000 importers through over 300 ports-of-entry.

In developing the Strategic Framework, Immediate Actions and Action Plan, the Working Group engaged in a campaign to solicit comments and recommendations from the public. Since the release of the Framework, the Working Group has received information and comments from hundreds of stakeholders. Health and Human Services Secretary Leavitt and other Cabinet members traveled throughout the United States and other countries to discuss import-safety issues. They met with federal, state and local officials, producers, importers, distributors and retailers. In addition, they held roundtable discussions and media events to engage the public and importing community⁴ in the activities of the Working Group.

The Working Group also met with Members of Congress and representatives of foreign governments to solicit comments and recommendations. The Working Group issued a Federal Register notice requesting written comment and announcing a public meeting, which was held in Washington, D.C., on October 1, 2007. Representatives from the 12 Cabinet departments and agencies comprising the Working Group listened to comments and recommendations from the importing community and the public on import safety.

Officials from each member department met with



¹ The Working Group includes the Secretaries of the Department of Health and Human Services, the Department of State, the Department of the Treasury, the Attorney General, the Secretaries of the Department of Agriculture, the Department of Commerce, the Department of Transportation and the Department of Homeland Security, the Director of the Office of Management and Budget, the United States Trade Representative; the Administrator of the Environmental Protection Agency, and the Chairman of the Consumer Product Safety Commission. The Food and Drug Administration, Customs and Border Protection and the Food Safety and Inspection Service were active participants on the Working Group as well.

² See Appendix B for the September 10, 2007 correspondence to the President that included these Immediate Actions.

³ See *Protecting the American Consumer Every Step of the Way: A strategic framework for import safety*.

⁴ The term "importing community" is used broadly throughout this document to include all domestic entities in the supply chain.

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scores of their private-sector constituencies to discuss import-safety issues. Texas A&M University convened a Conference on Import Safety Science and Technology on October 18, 2007. Additionally, the Working Group created an import-safety Web site, and utilized novel approaches such as webinars to provide information and to solicit comments and views from the importing community and the public.



The oral comments from the public meeting and the written comments submitted, as well as the input received by the member departments from the public, provided significant input that was used in the development of the recommendations in this Action Plan.

The seminal finding of the Framework was that, to adapt to a rapidly growing and changing global economy, the U.S. government must develop new import-safety strategies that expand and emphasize a cost-effective, risk-based approach. Such an approach identifies risks at the points they are most likely to occur, and then targets the response to minimize the likelihood that unsafe products reach U.S. consumers.

This Action Plan presents broad recommendations and specific short- and long-term action steps under the organizing principles of prevention, intervention and response. Each action item is based on the building blocks identified in the Strategic Framework, released in September 2007. The Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

Implementation of this Action Plan will require expanded legal authorities, improved collaboration and capacity building with our trading partners, improved collaboration with state and local governments and the private sector, increased information gathering and the discovery and application of new science. Implementation of the recommendations will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities.

The Working Group recommends that representatives of the member departments and agencies meet within 30 days to assess progress in implementation of the Action Plan and to discuss possible mechanisms for collaboration with the private sector to continue the effective implementation of this Action Plan.



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Background

This Action Plan builds on the earlier companion report: *Protecting American Consumers Every Step of the Way: A strategic framework for continual improvement in import safety*. That report concluded that the United States must transition from an outdated “snapshot” approach to import safety, in which decisions are made at the border, to a cost-effective, prevention-focused “video” model that identifies and targets critical points in the import life cycle where the risk of the product is greatest, and then verifies the safety of products at those important points.

This Action Plan follows the organizing principles identified in the Strategic Framework – prevention, intervention, and response – and draws on 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.

Public comments on the Strategic Framework show widespread acceptance and support of the organizing principles and building blocks.

The following is a brief summary of the Strategic Framework that forms the foundation of this Action Plan. Readers familiar with the Framework are encouraged to proceed to the Recommendations section.

Summary of the Strategic Framework

The Strategic Framework advocates a strategy that shifts the primary emphasis for import safety from intervention to a risk-based prevention with verification model. It recommends that the public and private sectors work together to identify risks and consider new approaches for addressing these risks. The vision of the Strategic Framework is to improve continuously the safety of imported products.

Three organizing principles form the keystones of the Strategic Framework and the recommendations included within this Action Plan:

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

The U.S. government must work with the private sector and foreign governments to adopt an approach to import safety that builds safety into manufacturing and distribution processes. This effort will reduce the risks to consumers from otherwise dangerous imported products.



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

Federal, state, local and foreign governments, along with foreign producers and the importing community, must adopt more effective techniques for identifying potential product 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. For foreign countries, taking steps to ensure the safety of products exported to the United States will benefit them by facilitating trade.



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

In the event that an unsafe import makes its way into domestic commerce, swift actions must be taken to limit potential exposure and harm to the American public.

Within each of these organizing principles are the cross-cutting building blocks identified in the Strategic Framework that departments and agencies should use to guide their programs.

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Building Block 1: Advance a Common Vision

There should be a shared vision and shared goals across the federal government for promoting import safety. Relevant policies and procedures should be reviewed and, where appropriate, revised to ensure that all federal departments and agencies are working together with shared objectives. Revised measures should encourage public and private parties involved in the import life cycle to adopt this common vision.

Building Block 2: Increase Accountability, Enforcement and Deterrence

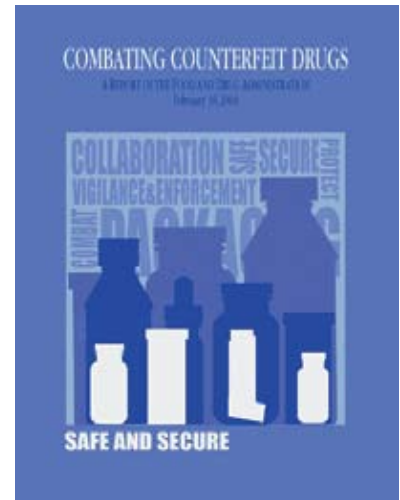
While it is important to remember that industry has a financial interest to sell safe products to its consumers, all actors involved in the production, distribution and sale of imports must be held accountable for meeting their obligations to ensure that imported products meet safety standards⁵ in the United States. The federal government will continue to work with industry to foster compliance with these standards, but is also prepared to use appropriate criminal and civil enforcement tools to hold companies and individuals accountable and to protect consumers.

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

In addition to identifying 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 to U.S. ports-of-entry, through final consumption or use in the United States. A key element is developing the ability to identify and manage risk at critical points along the import life cycle. Rather than the primary line of defense, intervention at the border must become one part of a network of interconnected measures that protect the American public and facilitate the entry of safe imports that comply with U.S. statutes and regulations.

The federal government should move to a more 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.

⁵ “Safety standards” may have a different meaning in different contexts. In this case, we are using the term in a broad sense to refer to recognized standards in the United States that ensure products, including chemical substances and pesticides, are safe for people and animals. By “recognized standards” we are referring to those standards for which compliance is required by United States law or regulation, or for which compliance is voluntary but, if met, is considered by the federal agency with jurisdiction as sufficient to meet federal requirements. These standards can be national or international.



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Building Block 4: Build Interoperable Systems

The federal government needs to finalize implementation of interoperable data systems already under development that facilitate the exchange of relevant product information among parties within the import supply chain to ensure import safety. The International Trade Data System (ITDS) initiative is a key component to improve system interoperability. The ITDS initiative will create a single-window environment for the collection of information and will improve and enhance information sharing among government departments and agencies and the import community.



Building Block 5: Foster a Culture of Collaboration

The federal government must develop a culture of collaboration that will permeate relationships among federal departments and agencies and their external stakeholders. All parties (federal, state, and local governments, foreign governments, foreign producers, foreign exporters and the importing community) involved in the import life cycle need to work together to prevent unsafe products from entering the United States and to take swift and

effective action if such products do enter domestic commerce. This collaboration must build on international multilateral and bilateral agreements to ensure the safety of products imported into the United States without creating unjustified trade barriers. As some unsafe products result from violations of patents and trademarks, the federal government will also work to increase coordination with U.S. industry to enforce intellectual property rights (IPR) and prevent the entry of counterfeit and potentially unsafe products into supply and distribution chains. This will require a new era of collaboration, as the federal government works to identify better ways to engage all parties in the import life cycle.

Building Block 6: Promote Technological Innovation and New Science

A more effective and efficient import-safety system will depend on the development and application of new science and technology. Implementation of innovative technologies will afford the opportunity to screen larger volumes of imported products at points-of-entry. These screening procedures will help evaluate and target high-risk commodities, increasing analytical efficiency and the number 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.

These building blocks and the organizing principles provide the foundation for the recommendations that follow.



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Import Safety Strategic Framework

Vision

Our aspiration

Continuously improve the safety of imported products

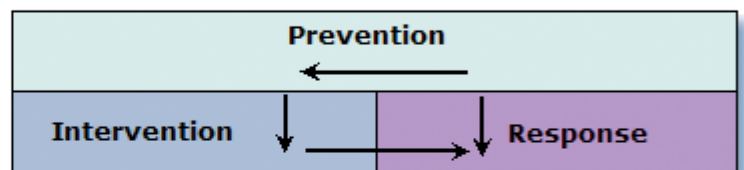
Strategy

How we achieve our vision

Shift focus from intervention to prevention
(over the entire import life cycle)

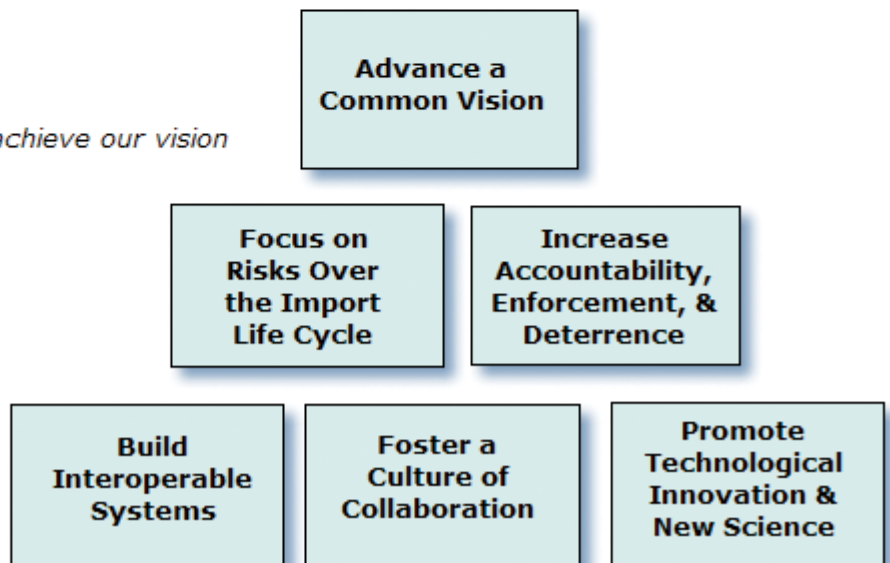
Organizing principles

How we organize our strategy



Building Blocks

Steps necessary to achieve our vision



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Sample Summary of Actions and Current Plans to Protect American Consumers

As directed by the President, all departments and agencies have been reviewing and assessing current procedures, authorities, outreach efforts and international cooperation initiatives to enhance the safety of imported products. Based on these reviews and meetings, the departments and agencies have already taken numerous actions to protect American consumers. Many more initiatives to enhance the safety of imported products are underway and will be completed in the coming months. Here is a sample of significant recent accomplishments and important actions that will be completed within the first 200 days of issuing this Action Plan. A more complete list is shown in Appendix C: Recent Actions and Current Plans to Protect American Consumers.

Safety Standards

- **Food Protection Plan.** The Food and Drug Administration (FDA) has developed a Food Protection Plan that addresses both food safety and food defense for domestic and imported products, including food protection from production to consumption. The Plan will be phased in over the coming months and is integrated with the Administration's Import Safety Strategic Framework and Action Plan.

Certification

- **Seafood Inspection Program.** As of October 24, 2007, the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program has inspected and certified seven seafood processing plants in China and has plans to inspect another 12 plants. A number of other plants are scheduled to be inspected.
- **Seafood Inspectors Stationed in Other Asian Countries.** NOAA is in the process of stationing an inspector full time in Hong Kong, and has plans to put inspectors in other countries that export large volumes of seafood to the United States.

Foreign Cooperation and Capacity Building

- **Safety Agreement with China on Toys, Fireworks, Electrical Products.** Meetings held in September 2007 between the Consumer Products Safety Commission (CPSC) and its counterpart, the General Administration of Quality Supervision, Inspection, and Quarantine (AQSIQ) of the People's Republic of China, resulted in a renewed Memorandum of Understanding (MOU) related to the promotion of safety for target products – children's toys, fireworks, cigarette lighters, and electrical products.
- **Security and Prosperity Partnership (SPP) priority on Safe Food and Products.** In August, President Bush, President Calderon of Mexico and Prime Minister Harper of Canada pledged to strengthen trilateral cooperation and mechanisms within the region, build on current standards and practices and work with our trading partners outside of North America to identify and stop unsafe food and products before they enter our countries.
- **Memoranda of Agreements with China on Food, Drugs, Medical Devices and Animal Feed.** HHS/FDA is negotiating binding agreements with the Chinese government to enhance regulatory cooperation in the area of drugs, medical devices, food, and animal feed. These agreements will protect the safety and health of consumers and animals in the United States and in China.
- **Motor Vehicle Safety Agreement with China.** On September 12, the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) signed a Memorandum of Cooperation with China aimed at increasing cooperation in the areas of motor vehicle regulation and safety. Both sides indicated a willingness to work together to address issues related to the safety of Chinese motor vehicles and equipment (including tires and automotive fuses) intended for export to the United States.
- **Foreign Training on United States Safety Standards for Meat, Poultry and Eggs.** In July 2007, the United States Department of Agriculture (USDA) and FDA conducted a seven-week training program for Chinese inspection officials. The Food Safety and Inspection Service (FSIS) also conducted outreach to foreign government inspection officials regarding FSIS import requirements for meat, poultry and egg products. FSIS provided technical assistance to the Austrian government regarding U.S. import requirements for ready-to-eat products, to Mexico regarding microbiological testing procedures and to the governments of Bosnia-Herzegovina, Namibia and Thailand about U.S. import requirements in general.


Response

- **Marking Rule to Prevent Port-Shopping.** By mid-2008, FDA will issue a proposed rule that would require imported food that has been refused entry to be marked "United States: Refused Entry." Such marking would help prevent the introduction of unsafe food into the United States through port-shopping, a practice whereby importers attempt to gain entry through a port after the goods have been refused at another.

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Recommendations



The current import-safety system in the United States has served the public well for many years and is among the most effective in the world. In this system, the public and private sectors work collaboratively to collect and evaluate pertinent information for all commercial cargo before it reaches the United States. Under U.S. law, cargo that does not meet federal government requirements, including those relating to safety, is not allowed to enter domestic commerce. In a similar fashion, cargo that does not meet the expectations, contractual requirements or safety standards of the private sector jeopardizes trading relationships and compromises business. These legal requirements and market-based measures work together to protect the American public.

The recommendations included in this Action Plan build upon the current import-safety system and activities already being undertaken by the public and private sectors by focusing on cost-effective, risk-based approaches across the entire import life cycle. The Working Group presents 14 broad recommendations and 50 action steps, each with a lead entity and time frame. The recommendations include short- and long-term action steps that should commence immediately.⁶

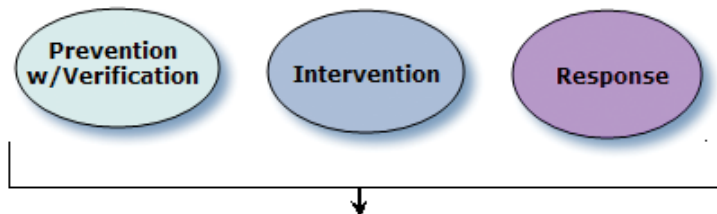
The recommendations are categorized in this Action Plan based on the organizing principles outlined in the Strategic Framework – prevention, intervention and response. Together, the organizing principles, recommendations and action steps create an import-safety roadmap to promote continual improvements in import safety.

We live in a world that is risky. We will not be able to eliminate all risks, but we also need to manage those risks in a way that is smart and efficient.

Dr. Jeff Runge, Acting Assistant Secretary for Health Affairs, Department of Homeland Security

⁶ “Short term” refers to those action steps that can be completed within the next 12 months; “Long term” refers to those action steps that will take longer to complete.

Import Safety Roadmap Organizing Principles



Recommendations

1. Create new and strengthen existing safety standards
2. Verify compliance of foreign producers with U.S. safety standards and U.S. security standards through certification
3. Promote Good Importer Practices
4. Strengthen penalties and take strong enforcement actions to ensure accountability
5. Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities
6. Harmonize federal government procedures and requirements for processing import shipments
7. Complete single-window interface for the intra-agency, interagency, and private sector exchange of import data
8. Create interactive import-safety information network
9. Expand laboratory capacity and develop rapid testing methods for swift identification of hazards
10. Strengthen protection of intellectual property rights (IPR) to enhance consumer safety
11. Maximize the effectiveness of product recalls
12. Maximize federal-state collaboration
13. Expedite consumer notification of product recalls
14. Expand use of electronic track-and-trace technologies

Sample Action Steps

- Establish 3rd party certification
- Make available information about certified firms and importers who only use certified firms
- Increase the dollar amount of bonds
- Expand asset-forfeiture remedies
- Raise the Consumer Product Safety Act (CPSA) statutory civil penalty cap
- Develop capability to exchange information electronically among the federal departments and agencies and with the importing community
- Establish field presence at key foreign ports
- Enhance field laboratory capacity
- Develop best practices for track-and-trace technologies

Footnote: The roadmap includes 50 short- and long-term actions steps. The steps here are a subset of the larger total and illustrative of the recommended actions.

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Points of Clarification

Before presenting the recommendations and action steps, several clarifications are helpful:

- **Shared interest** – The information collected and analyzed for this Action Plan reaffirms the key and integrated import-safety roles of public- and private-sector actors. Both have a shared interest in the safety of imported products and both must continue working together to protect the American consumer. The import-safety chain stretches from the point of foreign origin, both of materials and finished product, to domestic consumption or use. All entities involved in the import life cycle – foreign producers (growers and manufacturers), governments, distributors, exporters, U.S. importers, distributors, manufacturers and retailers, testing and certification bodies and regulatory authorities at the federal, state and local levels – must work together to prevent unsafe products from entering the United States. The appropriate entities in the supply chain must also take swift and effective action when harmful products do enter domestic commerce.
- **Private-sector interest and mechanisms** – The private sector not only has a significant interest in ensuring safety, but also has a wide array of mechanisms to support federal objectives. Likewise, the federal government can learn and benefit from the experience of the private sector. Although the action steps in this Action Plan pertain primarily to the federal government, the Action Plan recognizes the importance of private-sector mechanisms and experience and lays a foundation for ongoing, substantive public-private collaboration.
- **Consumer interest** – The Action Plan recognizes that consumers have a vital interest in the safety of imported products and anticipates active consumer engagement in the implementation of the recommendations and action steps.
- **Risk-based strategies** – This Action Plan is built on the concept that focusing on risk is the most effective way to address safety over the broad spectrum of products imported by the United States. Some areas and products need more attention than others because of the potential risks they could present and because of differences in the product and the production environment. These differences include process controls, the history of compliance, the intended use of the product, the inherent risks of the product and other factors demonstrated by science and experience to be valid predictors of

We believe that the responsibility for safety has to be firmly attached to each link in the supply chain.

Donald Mayes, Consumers Union

It makes sense to focus our limited resources on those shipments that pose the greatest risk.

Josh Green, Panjiva

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risk to the public. The federal government must continue to make choices about where it focuses its resources, and basing those choices on risk means that better and more logical decisions will be made with more effective results. Therefore, there is no one-size-fits-all solution. The recommendations and action steps in this Action Plan reflect this cost-effective, risk-based approach.

- **Accountability** – The Strategic Framework stresses that import safety can be advanced through shared efforts and shared responsibility throughout the entire import life cycle, from foreign governments, producers, distributors and exporters to U.S. importers, producers, distributors and retailers, as well as the federal and state governments. Any private entity that seeks to benefit from access to the U.S. market has the same responsibility domestic producers have to ensure their products meet all applicable U.S. safety standards. For example, producers of drugs and medical devices are expected to meet the standards set by the FDA. Steps to create incentives for foreign firms to ensure this outcome are an important part of the Action Plan. In addition, the U.S. importing community, either as a link in the U.S. distribution chain or as the seller to the ultimate consumer, must share the commitment to ensure that products brought into the United States are manufactured in accordance with U.S. safety standards.

All entities involved in the import life cycle are responsible for ensuring the safety of the products they produce, distribute, export, import or sell. The specific responsibilities of each entity depend on the activities in which they engage. For example, producers are responsible for making products that comply with U.S. safety standards. Importers are responsible for bringing products that meet U.S. safety standards into this country in a manner that does not compromise the safety and, where appropriate, efficacy of the product.

- **Resources** – To implement the Action Plan to its fullest extent will require resources. Federal departments and agencies will coordinate, plan effectively and meet these goals by submitting additional funding needs through the normal budget process.
- **Common mission, varying statutory roles** – While the entire federal government is responsible for advancing import safety, each department and agency operates within a unique statutory framework. The recommended actions do not apply uniformly to all federal entities. Instead

Facilitate Trade but Target High-Risk Imports

The recommendations in this Action Plan are designed to promote import safety while avoiding restrictions on the flow of international trade. Some recommendations provide incentives to foreign producers, suppliers, and importers that will expedite the entry of products that meet U.S. standards. Others lead to greater information about these entities. These incentives and the collection of better information will enhance the capacity of the federal government to focus on those products that may present a risk to consumers in the United States. By improving the management of risk, we can facilitate the trade of safe products and devote more personnel and resources to high-risk products and products of unknown risk.

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they are tailored to product risk and the relevant statutory frameworks serve as tools to improve the safety of imported products on an ongoing basis. Where appropriate, the action steps identify affected departments and agencies.

- **Complementary Findings** – The recommendations and action steps outlined in this Action Plan take into consideration the wide array of other planned or ongoing actions by the federal government and other entities to improve the safety of imported products. The findings of this Action Plan are additive and complement other meaningful changes and programs. Appendix C includes a summary description of recent activities and current plans that expand upon and complement this Action Plan.

The United States import safety system must be a comprehensive, risk-based, preventative approach in which food manufacturers build food safety into their products. Indeed, the changing import environment for our increasingly global food supply demands a new approach to import safety.

John D. Floros, Ph.D.
Institute of Food Technologists

Implementation

Effective implementation will require the concerted effort of all participants in the import life cycle, creating an expanded culture of collaboration. The federal government must lead by example to build each of these recommendations into agency priorities and budgets. To aid in this process and ensure accountability, each action step has a designated lead agency or agencies.

Prevention with Verification

This Action Plan recommends using market-based and regulatory incentives and deterrents to encourage foreign entities to build safety into products destined for the American market and to encourage domestic entities to ensure that the products they import meet safety standards in the United States. This approach holds all participants in the import life cycle, both foreign and domestic, accountable for ensuring the safety of imported products by using a cost-effective, risk-based strategy. It includes:

- Creation of mandatory and voluntary third-party certification programs for foreign producers that are based on product risk to verify compliance with U.S. safety standards,
- Development of good importer practices, and
- Use of strong penalties against bad actors.

Based on their risk, many products may not warrant the establishment of a mandatory or voluntary certification program. The federal government will also work with its trading partners to promote, where needed, the development of the regulatory capacity and legal systems necessary to ensure the safety of the products they export to the United States.

The following recommendations, action steps, lead entities and time frames present a detailed roadmap for further action.

Safety Standards

Recommendation 1 – Create New and Strengthen Existing Safety Standards

An organizing principle of the Strategic Framework is the concept of prevention with verification. This concept is predicated on a philosophy of building assurances of safety into production processes and establishing appropriate supply-chain controls, rather than relying solely on physical inspection and testing of products at ports-of-entry to identify and mitigate safety hazards. Prevention with verification embraces the incorporation of science-based safety standards into production and distribution systems, combined with compliance assessments to ensure these standards are being met.

Industry best practices have long reflected a commitment to the use of risk-based preventive controls as an effective mechanism for assuring product safety. The federal departments and agencies with jurisdiction over imported products should work with industry, standards development organizations and other members of the public to strengthen U.S. safety standards, where needed and appropriate, particularly for products determined to be high-risk. Federal departments and agencies should also increase their participation in international standards-setting organizations to encourage the development of international standards that reflect, to the extent possible, the same level



Safety and Security

Since the United States government bases its decisions about whether or not a product may enter the country on both safety and security considerations, certification programs referenced in the action steps would assess compliance with both safety and security standards. In today's world, certification for import safety and certification for import security need to be closely coordinated. Consideration should be given to merging these two certification processes into one program.

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of protection maintained in the United States. When adopting or developing safety standards, the federal department or agency with jurisdiction should consider the best available science, industry best practices and standards set by credible national and international standards development organizations.

- 1.1 *Extend the mandatory manufacturer/importer certification requirement under section 14 of the Consumer Product Safety Act to all statutes administered by Consumer Product Safety Commission. All mandatory safety standards promulgated by the CPSC under the CPSA require a manufacturer's or importer's certification of conformity to those standards. The other key statutes administered by the CPSC do not contain similar certification provisions for mandatory safety standards. In the CPSC's experience, requiring the certification of conformity improves supplier compliance with mandatory standards. The requirement simplifies and strengthens enforcement at ports because products that are not accompanied by a declaration of conformity must be refused entry. Also, because it is unlawful to issue a false declaration, firms can not easily circumvent the requirement. As a benefit to inspecting officials, the process of checking for a certificate is not burdensome and does not require any additional government testing or evaluation. Extending the existing conformity requirement under the CPSA to other statutes administered by the CPSC would enhance the Commission's ability to ensure product safety.*

Lead: CPSC

Time Frame: Short Term

- 1.2 *Clarify the Food and Drug Administration's (FDA) authority to require preventive controls for certain foods. This action step would strengthen FDA's ability to require, by regulation, preventive control measures to address risks that might occur for domestic and foreign produced foods associated with repeated serious adverse health consequences or death from unintentional contamination. FDA would take into consideration industry best practices, such as Hazard*

Analysis and Critical Control Points (HACCP) requirements.

Lead: HHS / FDA

Time Frame: Short Term

- 1.3 *Provide the FDA with authority to require measures to prevent the intentional contamination of domestic and foreign foods. The FDA would use this authority to issue regulations to require companies to implement practical food defense measures at specific points in the food supply chain where the potential for intentional adulteration resulting in serious adverse health consequences or death to humans or animals is the greatest. This authority would apply to food in bulk or batch form, prior to being packaged.*

Lead: HHS / FDA

Time Frame: Short Term

Apply the Same Safety Standards to Domestic and Foreign Made Products

A product sold to American consumers should be safe regardless of whether it is made in the United States or abroad. These recommendations are aimed at ensuring that foreign producers, exporters and distributors, as well as importers, are held accountable for compliance with the same product safety standards as producers and distributors in the United States. Consistent with international trade rules and longstanding United States practice, any new safety rules will be transparent, will be based on available scientific and technical information and will not discriminate unfairly against imported products over domestic products.

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- 1.4 *Examine food-safety control systems of other countries to determine whether improvements can be made to the operation of FDA's food regulatory program.* The examination would provide FDA with comprehensive knowledge of food safety systems of other countries. FDA could identify elements or components of those systems that are recognized as food safety system "best practices" and utilize them to strengthen and enhance FDA's prevention, intervention and response activities.

Lead: HHS / FDA

Time Frame: Long Term

- 1.5 *Expand the use of public-private sector standards programs.* Standards programs established and administered by the private sector with input from government can provide a generally accepted forum for developing safety standards. Organizations such as the International Organization for Standardization and U.S.-based international standards developers accredited by the American National Standards Institute devise standards that the federal government may subsequently recognize. Greater use of these venues can accelerate the development of needed safety standards. They should be pursued, as appropriate, as long as the standards developed are based on sound scientific information and utilized domestically.

Lead: Department of Commerce

Time Frame: Long Term

Certification

Recommendation 2 – Verify Compliance of Foreign Producers with United States Safety and Security Standards Through Certification

Import certification can augment federal department and agency resources, facilitate trade by expediting the entry of products from certified firms, and assist the importing community in implementing effective Good Importer Practices. As appropriate, certification would include periodic on-site inspections and random testing. Certification would need to be renewed periodically at intervals that could vary based on product risk, such as with greater frequency for high-risk goods. This Action Plan contemplates the use of both mandatory and voluntary certification.

The Action Plan recommends tailoring import certifications to both the product's level of risk and its intended use. Currently, federal departments and agencies use import certifications in a variety of contexts. For example, as a condition for export of meat, poultry and egg products to the United States, the Food Safety and Inspection Service (FSIS) certifies foreign countries that, in turn, certify producers that meet U.S. requirements. Such certification ensures that the products comply with U.S. requirements. While requiring import certifications for all goods is not necessary, in certain circumstances (e.g., high-risk products), this extra step may be warranted. Therefore, the Action Plan recommends mandatory certification for select high-risk products.

The federal departments and agencies with jurisdiction over imported products should work with regulated industry and other members of the public to strengthen U.S. safety standards, where needed and appropriate, particularly for products determined to be high-risk.

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The Action Plan also recommends expanded use of voluntary import certifications for other products. To encourage and assist foreign producers to meet U.S. standards, the federal government should establish voluntary certification programs as appropriate. Voluntary certification programs may provide importers with important compliance information and help them ensure that the products they import meet U.S. standards. If widely used, these programs will also assist the federal government in properly targeting inspection resources to those products of greatest risk. For this reason, we propose incentives to motivate voluntary participation. For example, products made by certified firms would generally receive expedited processing at U.S. ports-of-entry. Furthermore, the federal government will ensure that information about certified firms and importers of record is easily accessible to the public.

Manufacturers will demonstrate compliance with national standards when there is value in it for them, such as recognition at the border by customs, preference by distributors and retailers, and selection by consumers.

Stan Hazan, NSF International

Mandatory Certification

Mandatory certification may be necessary to ensure that imported products are safe in certain circumstances. This would involve safety considerations, including risks associated with the product itself or its place of origin. Generally, in such cases, the only other option available is to deny

the entry of these products into the United States. In requiring that such products be certified, or produced by a certified firm in order to be imported, a mechanism would be provided that allows trade to continue flowing while also enhancing safety.

- 2.1 *Provide the FDA with the authority to require a certification or other assurance that a product under its jurisdiction complies with FDA requirements.* Certification would be mandated based on risk and generally would apply to products coming from a particular country, region, or producer where safety cannot be adequately ensured for these products in the absence of such assurance. This would allow the FDA to redirect its resources to other products. Such import certification programs would be used for designated products imported from countries with which FDA has an agreement to establish a certification program that provides sufficient safety to meet HHS/ FDA standards. FDA would accept certifications from either relevant government agencies or accredited third parties.

Lead: HHS/FDA

Time Frame: Short Term

Voluntary Certification

For foreign producers, the ability to participate in voluntary certification programs could allow products from firms that comply with U.S. safety and security standards to enter the United States more quickly. This would facilitate trade, while allowing federal departments and agencies to focus their resources on products from non-certified firms or for which information suggests there may be safety or security concerns. This would allow federal


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departments and agencies to more effectively target their resources. It may not be necessary to establish certification programs for low-risk products.

- 2.2 *Develop voluntary certification programs based on risk for foreign producers of certain products who export to the United States.* The federal government will work with the importing community and other members of the public to develop voluntary certification programs, as appropriate, based on risk. As part of this effort, the federal government should take into consideration, incorporate or expand upon existing trusted trader partnership programs including CBP's Importer Self Assessment Program (ISA) and programs that relate to security.⁷
Leads: CPSC, HHS / FDA, DHS / CBP
Time Frame: Long Term

- 2.3 *Provide FDA with legislative authority to accredit independent third parties to evaluate compliance with FDA requirements.* To implement the previous action step (2.2), FDA will accredit third party organizations, or recognize an entity that accredits third parties. Third party organizations could be, as appropriate, federal departments and agencies, state and local government agencies, foreign government agencies, or private entities without financial conflicts of interest. FDA would use information from these accredited third party organizations in its admissibility decision-making.
Leads: HHS / FDA
Time Frame: Short Term

- 2.4 *Create incentives for foreign firms to participate in voluntary certification programs and for importers to purchase only from certified firms.* The federal government should establish these incentives, which could include expedited entry, expedited processing of samples for laboratory testing, and access to CBP's account manager program. Utilizing expedited entry, federal departments and agencies with jurisdiction typically would be much less likely to physically examine or otherwise delay products made by certified firms unless the product is examined for auditing purposes, there is information suggesting this product violated U.S. law, is considered high-risk for safety or security reasons, or the importer of record did not provide correct or complete information



In September 2007, the U.S. Toy Industry of America (TIA) announced plans to implement new compliance systems to bolster the safety of toys sold in the United States. The initiative, created in consultation with the American National Standards Institute and the Consumer Product Safety Commission, includes the development of standardized testing procedures and laboratory certification criteria.

The United States is unique to the world in many ways, including the fact that it relies heavily on the private sector for voluntary standards development, as well as product safety testing and certification services.

**August W. Schaefer
Underwriters Laboratories Inc.**

⁷ ISA is a voluntary program for importers who agree to monitor their own compliance in exchange for benefits from CBP. Its primary objective is to maintain a high level of compliance with United States entry requirements through a cooperative partnership and information exchange between the importing community and CBP.

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required by U.S. law. Should samples be taken for testing from a product made by a certified firm, the agency with jurisdiction could expedite processing of those samples. Under CBP's account manager program, the importer of record is assigned a contact person who can answer questions and facilitate the resolution of problems should they arise. The federal government will also consider setting less stringent bonding requirements as an incentive to import products from certified firms.

Leads: DHS / CBP, HHS / FDA, CPSC

Time Frame: Long Term

There are many private sector and government organizations that presently certify products and producers as meeting established national or international standards or accredit certifying bodies. The presence of such certifying or accrediting organizations serves as a ready resource to implement new voluntary certification programs.

2.5 Develop a plan to ensure that information regarding certified firms and importers of record is easily accessible. This will help importers to more easily determine whether or not a foreign firm is certified, and help distributors and retailers to identify importers of record who only handle goods from certified firms. It will also help insurers use this information for determining risk when underwriting importers of record, and help consumers determine whether or not a foreign-made product sold under its own label comes from a certified firm.

Leads: DHS / CBP, HHS / FDA

Time Frame: Long Term

Good Importer Practices

Recommendation 3 – Promote Good Importer Practices.

Although some members of the importing community have established and met their own best practices, the importing community does not have available Good Importer Practices focused on ensuring product safety throughout the supply chain. Developing such practices can assist the entire importing community in taking appropriate steps to ensure the safety of the products they bring into the United States.

To encourage the importing community to take appropriate steps to ensure the products they bring into this country meet U.S. standards, the federal government will work with the importing community to develop Good Importer Practices. These practices should be developed as guidelines, be risk-based and provide concrete guidance to the importing community for evaluating imported products. This evaluation would be based on due diligence and preventive controls principles. These practices will provide a set of factors that can be used by the importing community to evaluate foreign suppliers and products.

Based on this evaluation, the importing community will have greater confidence that the products they import will be in compliance with U.S. laws and regulations. For example, for products with known risks, a key precaution

We owe it not only to our consumers, but, of course, our farmers, ranchers and producers as well. And we must work with our trading partners to share best practices and agree on common standards of science-based approaches for food safety.

Chuck Conner
Acting Secretary of Agriculture

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the importing community could take to ensure safety consistent with Good Importer Practices is to purchase, distribute and sell products made by certified producers. As part of this collaboration, the federal government and the importing community should consider whether and how to foster the development of voluntary third-party programs to certify importers as meeting Good Importer Practices.

- 3.1 *Develop Good Importer Practices.* The federal government should work with the importing community and other members of the public to develop Good Importer Practices and issue guidance with respect to particular product categories. The focus of these practices will be to ensure that imported products meet U.S. safety standards, as well as to promote effective supply-chain management. Development of these practices would help the importing community take appropriate steps to ensure the safety of the products they bring into the United States.

Leads: USDA, CPSC, HHS / FDA, DHS / CBP, Department of Commerce (DOC)

Time Frame: Long Term

- 3.2 *Partner with the importing community to foster the creation of voluntary certification programs for importers.* These programs would be private-sector based and would serve to verify compliance with Good Importer Practices. The federal government would evaluate these programs to determine whether they should be accredited by the federal government and whether certification should be required for importing certain high-risk products.

Leads: CPSC, HHS / FDA, DHS / CBP, DOC

Time Frame: Long Term

Penalties

Recommendation 4 – Strengthen Penalties and Take Strong Enforcement Actions to Ensure Accountability.

To hold both foreign and domestic entities accountable and discourage them from producing, distributing, exporting, importing and selling unsafe products, the federal government will take steps to strengthen penalties against entities that violate U.S. laws. Effective penalties can serve as a deterrent against violating U.S. requirements and will improve compliance with U.S. safety standards and laws.

Rigorous enforcement of U.S. import-safety laws promotes deterrence. Assessing civil and criminal penalties against bad actors creates the proper incentives for all parties across the import life cycle to behave lawfully and responsibly and to build safety into their products to prevent harm to consumers. For enforcement to be an effective tool in the promotion of import safety, however, civil penalties must amount to more than a business expense

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and, for the worst offenders, criminal penalties should apply. Where penalties are weak or lacking, enforcement measures must be strengthened to reflect a meaningful expectation of accountability.

Bonds serve as a guarantee of payment for specific types of penalties levied against the importer. Minimum bond amounts have not changed since 1991 and do not reflect the likelihood that a product may not meet U.S. importing or safety requirements. Compliance with U.S. safety requirements can be encouraged by raising the minimum bond amounts and increasing CBP's authority to consider the risk presented by a product in calculating bond amounts.

As the volume of imported food steadily increases, the FDA's job at the border can be compared to trying to find a needle in a haystack. We need to approach this task ... by reducing the number of needles to find, and by reducing the size of the haystack in which to find them.

Scott Faber,
Grocery Manufacturers Association/
Food Products Association

4.1 Amend the Federal Food, Drug, and Cosmetics Act (FDCA), the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), the Egg Products Inspection Act (EPIA) and the Consumer Product Safety Act (CPSA) to include asset-forfeiture remedies for criminal offenses.

This proposal would allow the forfeiture of all vessels, vehicles, aircraft and other equipment used by bad actors to aid in the importing, exporting, transporting, selling, receiving, acquiring or purchasing of products in violation of the FDCA, FMIA, PPIA, EPIA or CPSA, as well as the proceeds from the criminal offense.

Such penalties would apply only to those actors

who knowingly and willfully violate the act, and the court of record would make the ultimate determination of relief. This action would be wholly administered by the Department of Justice (DOJ) consistent with current practice under many statutes.⁸

Lead: DOJ

Time Frame: Short Term

4.2 Raise the statutory civil penalty cap under the CPSA. Currently, the penalty cap stands at \$1.8 million for any related series of violations under the CPSA. Raising this amount to \$10 million would serve as a deterrent to unlawful conduct and provide the CPSC with leverage to negotiate penalties against violators. In assessing penalties, the CPSC should consider whether a company is a repeat offender.


Lead: CPSC

Time Frame: Short Term

⁸ For example, Congress limited all criminal forfeiture and the civil forfeiture of real property for drug offenses to felony violations of the Controlled Substances Act (see 21 U.S.C 853 (a) and 881 (a) (7)). So, too, could Congress limit forfeiture sanctions to the statutory provisions that require a knowing and willful violation.

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- 4.3 *Strengthen CBP's mitigation guidelines and increase the maximum penalties against importers who repeatedly import products that violate U.S. law.* CBP needs to impose maximum penalties against such parties to provide effective deterrence.
Lead: DHS / CBP
Time Frame: Short Term
- 4.4 *Increase the dollar amount of bonds that importers of record must provide to reflect inflationary increases and risk.* Without an adequate bond, CBP is unable to issue and collect penalties for bad actors in the amount allowable by law.
Lead: DHS / CBP
Time Frame: Short Term
- 4.5 *Authorize FDA to refuse admission of imported products if access--including access to all applicable records, equipment, finished and unfinished materials, containers and labeling--to any factory, warehouse or establishment in which a product for export to the United States is manufactured, processed, packed or held is unduly delayed, limited or denied.* An important tool for the federal government to verify whether a firm complies with U.S. safety standards is to conduct a routine inspection and to review relevant production and distribution records. Domestic firms have an incentive to work with federal departments and agencies with such inspection authority because efforts to delay, limit or deny such an inspection may lead to an enforcement action. However, foreign firms can often deny U.S. officials access to their facilities without any adverse consequence. Having the authority to prevent entry of products from firms that fail to provide FDA access will enable FDA to protect consumers by keeping potentially unsafe products from entering U.S. markets. This authority also will provide a strong incentive for foreign firms to allow FDA to perform inspections, motivation similar to that provided to domestic firms.
Lead: HHS / FDA
Time Frame: Short Term
- 4.6 *Provide authority for the destruction of medical products refused admission into the United States.* The federal government has had limited success in stopping unsafe medical products for personal use from entering the United States because of the statutory requirements that must be met before those products are destroyed. Expedited destruction of these products would address this limitation but would only apply to refused shipments that are valued below a certain threshold or which pose a certain level of risk to humans or animals. This is intended to address problems, such as personal shipments of drugs being re-imported after they have been denied entry.
Lead: HHS / FDA
Time Frame: Short Term



Enforcement plays an important role, not just in remedying past harms, but by providing proper incentives and deterrents, which, in turn, help to prevent harm to consumers in the first place.

John O'Quinn, Deputy Associate Attorney General, Department of Justice

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- 4.7 *Remove the notice requirement for violations of the CPSA.* Under its enabling statute, the CPSC must first provide the offending party with notice of its violation prior to prosecution by the DOJ. Although the notice requirement is designed to ensure that a violating firm was aware of its offense prior to prosecution, the standards for prosecution are such that the DOJ must prove knowledge and intent on the part of the offender. Thus, the notice requirement in the CPSA is unnecessary.

Leads: DOJ, CPSC

Time Frame: Short Term

Foreign Collaboration and Capacity Building

Recommendation 5 – Make Product Safety An Important Principle of our Diplomatic Relationships with Foreign Countries and Increase the Profile of Relevant Foreign Assistance Activities.

In the global economy, import safety begins abroad. While many of our trade partners have active and effective programs, some lack an adequate regulatory regime or legal system, both of which are conducive to maintaining and enforcing adequate product safety standards. U.S. investment in capacity building can benefit developing nations by helping them strengthen their economies, enhance their legal systems and public health infrastructure and ultimately facilitate commerce.

While many federal departments and agencies offer capacity-building support to foreign countries, and many U.S. assistance programs provide training in the rule of law and government oversight of products standards and testing, the United States needs to reinforce the importance of product safety as a priority in our broader diplomatic relationships.

For example, in order to develop foreign regulatory capacity building and accountability, the United States needs to advance import safety when negotiating cooperative arrangements with other countries. Further, the United States needs to build effective coalitions with our trading partners and encourage them to become more involved in identifying solutions to product safety challenges.

In addition to building the regulatory capacity of foreign governments, it is vital that the United States share information with foreign counterparts who have active and effective regulatory programs. There is currently information in the hands of foreign governments — such as foreign inspection results, best practices, adverse event reports and data on recalls and outbreaks — that could be useful to U.S. regulatory agencies to better screen products arriving at the border. For example, FDA has begun an active information-sharing program with many of its foreign counterparts to obtain information about

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product approval, inspection, testing and safety for FDA-regulated food, medical products and cosmetics.

- 5.1 *Direct the federal government to make product safety a guiding principle in negotiating future cooperative arrangements with foreign government entities. To foster effective relationships with foreign government counterparts and demonstrate the importance of product safety in international trade, the United States should make product safety an important component of cooperative arrangements.*

*Lead: Executive Office of the President (EOP)
Time Frame: Short Term*

- 5.2 *Expand and administratively streamline, as appropriate, government inspections in foreign countries and improve collaborative investigation and enforcement activities when negotiating cooperative arrangements with foreign governments. Streamlining bureaucratic processes, such as the visa process for government inspectors, can result in more-timely and less-costly authorized foreign inspections. In addition, as appropriate, federal departments and agencies should provide foreign countries with training and technical assistance regarding U.S. standards and conformity assessment practices.*

*Lead: Department of State
Time Frame: Long Term*

- 5.3 *Review existing overseas programs that target rule of law, regulatory capacity-building and trade capacity-building, to determine how to improve product safety standards and conduct. This would encourage departments and agencies with relevant programs to include product safety standards and compliance, where appropriate, in their capacity-building efforts.*

Existing foreign assistance efforts related to strengthening the rule of law, regulatory capacity-building and trade capacity-building may currently seek to improve product safety standards and compliance. However, there has been no coordinated policy review of these efforts to help policy makers understand if the level of effort is appropriate and effective and to ensure consistency in U.S. policy.

*Lead: Department of State
Time Frame: Long Term*

Strengthen the Capacities of Our Trading Partners

One way to ensure compliance with United States safety standards, if warranted, is to increase the capacity of our trading partners to adopt strong safety standards and regulations and to develop a legal system that is capable of enforcing those standards.

The more data that can be captured early in the supply chain process, the better. If U.S.-based importers, retailers and government agencies can identify product safety problems in the manufacturing or transportation stages before a product reaches the U.S. market, the public will be safer, and enforcement and recall costs will be significantly reduced.

Donald P. Bliss
National Infrastructure Institute

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- 5.4 *Improve U.S. liaison to foreign countries.* For example, establish FDA field presence at key foreign ports of embarkation and a CPSC liaison to certain countries.
Leads: HHS / FDA, CPSC
Time Frame: Long Term
- 5.5 *Develop strategic information-sharing arrangements with key foreign government counterparts.* Through greater information-sharing, such as data on recalls, the federal government can leverage the inspection and regulatory expertise and experience of foreign regulatory authorities to facilitate admissibility determinations, provide advance notice of problems, and enhance enforcement capabilities.
Leads: HHS / FDA, USDA, CPSC, EPA
Time Frame: Long Term

We're working with foreign governments, informing them of our environmental requirements and helping them to strengthen their capacity to comply with U.S. standards.

Stephen L. Johnson
Administrator, Environmental
Protection Agency

Intervention

The second organizing principle—Intervention—recognizes the need to intervene when risks to product safety are identified. These recommendations address the importance of focusing intervention activities throughout the life cycle of imported products, rather than just at the time the goods arrive at the U.S. border. To accomplish this, the federal government will need to put in place automated systems and foster a culture that optimizes both government and private-sector knowledge. The incompatible systems that comprise the current approach must be replaced with interoperable systems that provide all regulatory departments and agencies, as well as the importing community, with the most complete information possible while protecting confidential information. This will allow federal agencies, either prior to shipment, at the port-of-arrival, or at the port-of-entry, to effectively target shipments that may represent a risk if allowed entry into the United States. This would maximize the use of federal resources and facilitate legitimate trade, as well as assist the importing community in meeting its responsibility to ensure unsafe products do not enter the United States.

Common Mission

Recommendation 6 – Harmonize Federal Government Procedures and Requirements for Processing Import Shipments.

Border officials inspect and clear cargo before it enters the United States in accordance with relevant federal laws and regulations. New risk information can complicate efforts to conduct inspections of entering shipments consistent with the applicable admissibility requirements. Better coordination among federal regulatory departments and agencies; cross-training; commissioning of federal personnel in the application of import entry requirements; and the establishment of common inspection, testing and enforcement protocols are needed, in some cases, to ensure that only products that comply with relevant regulations and standards enter domestic commerce, and that federal efforts to achieve this goal are effective and efficient.

- 6.1 Develop uniform interdepartmental procedures, where appropriate, for clearing and controlling shipments at ports-of-entry. These procedures would be used by all federal departments and agencies, where appropriate, and would help streamline the entry process as well as facilitate the exchange of information and intelligence, processing of samples and interagency coordination so that federal resources are used more efficiently and effectively in assuring product safety. As part of this action, federal departments and agencies with border regulatory responsibilities

We're committed at the Food and Drug Administration to continuing to foster the collaboration among other federal agencies and with the states to fully implement the shift to a prevention, intervention and response strategy.

Andrew C. von Eschenbach, M.D.
Commissioner, Food and Drug Administration

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should develop and deliver cross-training, where necessary, to keep the agencies updated on current U.S. import requirements.

Leads: DHS / CBP, USDA, HHS / FDA, CPSC, EPA

Time Frame: Short Term

6.2 *Develop a strategic plan for rapid response to import-safety incidents.*

To implement an effective rapid response requires coordination among all the involved parties. This plan would identify the roles and responsibilities of the federal departments and agencies; include a communication plan with state and local governments, private industry, foreign governments, the media and others; and include a business resumption model, as applicable.

Leads: DHS / CBP, USDA, HHS / FDA, CPSC, EPA

Time Frame: Short Term

6.3 *Co-locate border officials from multiple agencies, when feasible, to enhance targeting and risk-management decisions on import safety.* Border officials can work together more effectively when stationed at the same location. The federal government has co-located border officials in limited locations in the past, including CBP's National Targeting Center (NTC),⁹ resulting in improved coordination and more effective operations.

Leads: DHS / CBP, HHS / FDA, USDA / FSIS, CPSC

Time Frame: Long Term

6.4 *Exercise commissioning and cross-designation authority to leverage federal resources to prevent unsafe products from reaching consumers in the United States.* Under this model, participating agencies would agree that one agency would act under the authority of the other to carry out select activities, such as audits and lab processing, dependent on capacity constraints. Commissioning is particularly helpful when one agency has staff at a location where the other does not.

Leads: DHS / CBP, HHS / FDA, USDA / FSIS, CPSC

Time Frame: Long Term

Interoperability

Recommendation 7 – Complete a Single-Window Interface for the Intra-agency, Interagency and Private Sector Exchange of Import Data.

In Fiscal Year 2006, 31.3 million entries were filed with CBP for import shipments. Today, interactions between the government and importing community frequently involve time-consuming, resource-intensive paper reporting. The Automated Commercial Environment (ACE), which is currently

⁹ The NTC is a CBP facility where federal officials are co-located to enable better risk-assessment and targeting of imported cargo.

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being developed, will provide an automated “single-window” system for processing the entry of import shipments.¹⁰ Information about imported commodities will be collected for all federal departments and agencies involved in the importing of goods. Through ACE, the importing community, CBP and other federal departments and agencies will exchange real-time data about products, compliance and revenue for each import transaction. The federal government would therefore base a decision to clear or reject an import shipment for entry into the United States upon an immediate information exchange. This would facilitate cargo movements as well as more effective risk determinations and enforcement actions.

The Safety and Accountability for Every (SAFE) Port Act of 2006 makes implementation of the single-window concept a mandatory requirement for federal departments and agencies with import and export responsibilities.¹¹ Agencies that license, permit, or certify the importation of products into the United States must establish an electronic interface with CBP’s ACE system as part of the International Trade Data System (ITDS) initiative. ITDS is developing a Standard Data Set (SDS) of data elements to be used in reporting international trade transactions, which will facilitate exchanging data among all parties involved with an import transaction including regulatory and enforcement agencies.

- 7.1 *Require federal departments and agencies by the end of 2009 to have the capability to exchange commercial data and, to the extent allowable by law, communicate electronically with the importing community and other departments and agencies through ACE / ITDS. ACE / ITDS will permit integration of import data collected by federal departments and agencies to facilitate decision-making on the safety of imports. As part of this action step, departments and agencies, in partnership with the importing community, should develop a coding system for imported products and participants in the import life cycle, as well as draft any regulations necessary for implementation. The coding system will provide greater specificity than currently provided under the Harmonized Tariff Schedule (HTS) and will, thus, help identify products more quickly and accurately. The necessary regulations will be issued by the participating departments and agencies with jurisdiction.*
Lead: DHS / CBP and Treasury as executive agents
Time Frame: Long Term

¹⁰ The Immediate Actions Memorandum (September 10, 2007) required that the implementation of ITDS be accelerated. (See Appendix B)

¹¹ The Act permits the Office of Management and Budget (OMB) to exempt certain agencies.



The success of the Food Safety and Inspection Service and other agencies has been the result of the extensive import information that’s available electronically in both ITDS and ACE on imports and importers ... It is a tremendously powerful tool to give you the information you need in order to be able to assess the risk.

**Samuel Banks,
Sandler & Travis Trade Advisory
Services**

ACE / ITDS Data

In 2006, FSIS gained access to data from CBP’s ACE. Since then, detection of illegally-entered meat and poultry products has increased 60-fold. These products have either been destroyed or returned to FSIS for import re-inspection. In all, FSIS has prevented over 3.5 million pounds of illegal meat and poultry products from entering United States commerce.

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- 7.2 *Develop, as appropriate, within the Automated Targeting System (ATS), risk-based screening technologies to target high-risk products in a more effective way and facilitate the entry of low-risk products. Such technologies would use information available through ATS to facilitate risk determinations by federal department and agency officials, thereby expediting the entry of safe and secure products and allowing departments and agencies to better target their resources on high-risk products.*

Lead: DHS / CBP

Time Frame: Long Term

We are finding that the ACE system data are allowing us more efficient collection and analysis of records of incoming consumer products and helping us identify likely shipments of violative products before they can be introduced into the stream of commerce.

Nancy A. Nord
Acting Chairman, U.S. Consumer
Product Safety Commission

- 7.3 *Develop an implementation plan for the integration of the Standard Establishment Data Service (SEDS) module into ACE/ITDS. SEDS would create a centralized service to provide accurate information on the import supply chain. It would provide unique standard identifiers for establishments (to facilitate verification of involvement) and capture a minimal set of establishment violation data from import transactions at the central source.*

Leads: DHS / CBP, USDA, HHS / FDA, EPA, Commerce

Time Frame: Long Term

Information Gathering

Recommendation 8 – Create an Interactive Import-Safety Information Network.

Receipt of advance safety and security data regarding the product, the country of export, the manufacturer, the carrier and the importer prior to export of merchandise allows for a preliminary analysis of import-safety. Analysis of the data is critical to making risk-based determinations on actions to be taken by border officials prior to loading shipments in the exporting country and while they are in transit to the United States. In many cases, making these decisions for further review and examination prior to arrival of the shipment can facilitate the clearance of legitimate trade at the time of arrival in the United States.

For example, the Trade Act of 2002 requires carriers to provide limited data elements prior to loading shipments for export to the United States. The Trade Act provisions apply to all modes of transportation. The 2006 SAFE Port Act allows CBP to collect additional information that is reasonable for security purposes prior to the loading of maritime cargo destined for export to the United States.

- 8.1 *Expand upon existing public-private relationships to seek and share the importing community's recommendations and best practices with other federal departments and agencies for import safety and security purposes, and provide training in accessing this information. The importing community has a great deal of information about the product life-cycle that would assist the*

federal government in its enforcement and compliance actions. Use of this data could allow federal departments and agencies to make early determinations of import risk based on data already being collected.

Lead: DHS / CBP

Time Frame: Short Term

- 8.2 *Identify whether additional information is necessary to enhance import safety as allowed for under the SAFE Port Act. After gaining experience with information gathered under the SAFE Port Act, the federal government, working with the importing community, may conclude that access to additional security information is necessary to make admissibility determinations based on risk.*

Lead: DHS / CBP

Time Frame: Long Term

- 8.3 *Seek legislation that would provide CBP authority to extend reporting requirements for maritime shipments under the SAFE Port Act to all modes of transportation. This would allow CBP to require both importers and carriers to submit additional information pertaining to cargo before the cargo is brought into the United States. The information would improve the ability of CBP to identify and target high-risk shipments in order to prevent smuggling and ensure cargo safety and security. CBP would exercise this authority through notice and comment rulemaking.*

Lead: DHS / CBP

Time Frame: Short Term

- 8.4 *Develop a private-sector import-safety interactive information exchange process. The Department of Homeland Security (DHS) would work with the importing community to address a means for the private sector to report critical import-safety information in a timely manner at one virtual location through existing information-sharing systems. DHS would also use this means to share information with the private sector.*

Lead: DHS

Time Frame: Short Term

New Science

Recommendation 9 – Expand Laboratory Capacity and Develop Rapid Test Methods for Swift Identification of Hazards.

Advancement in the discovery, development and application of science and technology to detect problems in imported products more rapidly is essential for effective intervention strategies. Through research to develop more and better detection tools and to improve the reliability of existing tools, the federal government and the private sector can detect contaminants and defects more quickly and accurately. These tools could include real-time diagnostic instruments and methodologies that allow for rapid, on-site analysis of a

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particular product, especially those that are high-risk. For example, technology that would allow rapid detection of a contaminant could be expanded to cover food types such as produce and dairy products, reducing analysis time from days to minutes and improving the accuracy of test results. New tools would also be developed to identify additional pathogens. Increasing the speed at which federal departments and agencies can detect problems will allow those departments and agencies to take more rapid action, including expediting import entry review decisions and providing critical health information to the public when a problem is identified with a product in commerce.

Laboratory capacity is critical to rapid response to product emergencies. For

Support from the Scientific Community

During the recent event involving melamine contamination of imported gluten-vegetable protein, the National Center for Food Protection and Defense (NCFPD) provided subject matter expertise and real-time data analysis to assist federal agencies in responding. NCFPD also developed a case study including lessons learned and key unknowns, conducted a rapid assessment of imported food risks, and initiated a joint research project on imported food vulnerabilities and solutions with FDA and FSIS.

example, the Food Emergency Response Network (FERN) is a nationwide network made up of more than 130 federal, state and local public health laboratories that support emergency-response activities related to food defense and food safety. FERN also provides training to member laboratories to use new testing methods and provides funding of selected state laboratories through cooperative agreements.

Another example is the Electronic Laboratory Exchange Network (eLEXNET). eLEXNET is a seamless, integrated, secure network that allows multiple federal, state and local government agencies engaged in food safety activities to compare, communicate and coordinate findings in laboratory

analyses by using information technology tools. The system enables U.S. health officials to assess risks, analyze trends and identify problem products. It provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods and enhances the effectiveness of federal-state collaboration.

Ongoing efforts to enhance import safety will benefit from current and future contributions from the academic community. In addition to the obvious role of educating and training the next generation of professionals and experts, academia is an important resource for innovating new solutions for import safety. For example, subject matter experts from the academic community provided advice, incident monitoring, event assessment and the capturing of lessons learned during several recent food and agriculture sector incidents, such as the contamination of pet food with melamine and the recent foot-and-mouth disease outbreak in the United Kingdom.

Because freedom from risk cannot be ensured nor can safety be inspected into products, we agree that the private sector has a leading role in strengthening the safety of imports by building safety into food products.

**John D. Floros, Ph.D.
Institute of Food Technologists**

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Basic research in new technologies, strategies and tools is a natural contribution to import safety from the academic community. Several academic centers are assisting in developing food and agriculture disease and product contamination monitoring tools as well as training tools and programs. The efforts of the academic community in developing new approaches for risk communication and supply chain resiliency can be most effectively tested and further refined via engagement with government. Multiple federal and state agencies, as well as the private sector, already partner with and support research in the academic community.

- 9.1 *Enhance field laboratory capacity for testing and work collaboratively with the public and private sectors to develop analytical tools for enhanced rapid screening of larger volumes of import samples.* This will allow the federal government to detect risks and take actions to remove problem products from commerce more quickly and effectively.
Leads: DHS / CBP, USDA / FSIS, HHS / FDA, CPSC
Time Frame: Long Term
- 9.2 *Increase the capacity and capability of FERN laboratories by developing and validating methods to increase the number of chemical, radiological and microbial threat agents that can be rapidly detected in food as well as broadening the reach of the methods to allow foreign laboratories to provide information.* Ensuring adequate capacity and capability of FERN provides a strong surge capacity that is independent of FDA, USDA and EPA laboratory operations.
Lead: HHS / FDA, USDA / FSIS
Time Frame: Long Term
- 9.3 *Develop rapid test methods for pathogens and other contaminants to ensure that test results are quickly available at ports-of-entry for determining whether or not a product should be admitted into the United States.*
Leads: HHS / FDA, USDA
Time Frame: Long Term
- 9.4 *Increase the quantity and quality of data submitted by participating laboratories to eLEXNET.* FDA would create an automatic data exchange, which would increase the quantity of samples and/or analytes (the components of laboratory tests) a laboratory is able to submit, increase the frequency and timeliness of data submission and ensure a better degree of data integrity as compared to manual data entry. This action would enhance the effectiveness of federal and state laboratory-testing capabilities to protect American consumers.
Lead: HHS / FDA, USDA / FSIS
Time Frame: Long Term

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Intellectual Property Protection

Recommendation 10 – Strengthen Protection of Intellectual Property Rights (IPR) to Enhance Consumer Safety.

Strong IPR enforcement is essential to the protection of public health and safety. Counterfeit trademarked goods purporting to be made and marketed by someone other than the owner of the mark not only pose a threat to public safety, but undermine confidence in the quality of brand name products. These illegal activities also result in billions of dollars of lost revenue, investment, future sales and growth opportunities and harm legitimate businesses and workers who play pivotal roles in creating, manufacturing, distributing and selling genuine and safe products. The public and private sectors must work in concert to identify infringing and potentially unsafe goods and prevent them from entering the domestic marketplace.

If a container is packed with counterfeit goods, there is surely a higher likelihood than average that the goods in that container are dangerous in some way.

**David Spooner
Assistant Secretary for
Import Administration
Department of Commerce**

Patents protect the design, formulae and content of a wide variety of manufactured products, consumer goods and pharmaceuticals. Trademarks protect the brand name of known and trusted companies so that consumers can be sure they are getting the same quality product that they expect to obtain under that mark. When patents are infringed, consumers suffer because infringers create disincentives to the invention of new products and processes. Patent infringement may be accompanied by counterfeiting and trademark infringement. When look-alike knock-off and counterfeit products violate trademarks, consumers cannot be certain of the quality or origin of the knock-off product. In addition, because infringing products are often substandard in quality, they can harm consumers in myriad ways and pose serious health and safety risks. For example, a counterfeit drug may have too little, too much or no active ingredient or contain a toxic contaminant, possibly putting consumers at risk for serious adverse events or worsened health from ineffective treatment of their underlying medical condition.

10.1 Focus the work of the interagency Strategy Targeting Organized Piracy (STOP) and the United States government-private sector Coalition against Counterfeiting and Piracy Initiative on import-safety issues. STOP focuses on empowering American innovators to protect better their rights at home and abroad, increasing efforts to seize counterfeit goods at U.S. borders, pursuing criminal enterprises involved in piracy and counterfeiting, working closely and creatively with U.S. industry and aggressively engaging trading partners to join U.S. efforts.

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The Coalition Against Counterfeiting and Piracy encourages close cooperation between the public and private sectors to effectively secure supply chains and protect consumers and rights holders.

Lead: Department of Commerce

Time Frame: Short Term

- 10.2 *Expand information-sharing about counterfeit and other goods that infringe IPR among relevant U.S. departments and agencies to identify and target products, manufacturers and distributors with potential safety violations.* The International Intellectual Property Enforcement Coordinator, housed at the Department of Commerce, is responsible for disseminating information and coordinating actions on IPR among federal departments and agencies, primarily Commerce, DOJ, USTR, DHS and State. With a new emphasis on ensuring import safety, the Coordinator should extend its outreach and coordination activities to include agencies responsible for import-safety inspections, such as FDA, CPSC and USDA. In addition, with the anticipated increase in private entity certifiers for U.S. safety requirements, it is essential to enhance interagency IPR coordination to include these inspecting agencies.

Lead: Department of Commerce

Time Frame: Short Term

- 10.3 *Encourage companies that have registered trademarks with the U.S. Patent and Trademark Office (USPTO) to record their registrations with CBP.* Industries must record their trademarks with CBP to enable CBP to identify, seize and destroy infringing and potentially unsafe goods.

Lead: Department of Commerce

Time Frame: Short Term

Safety and Intellectual Property

It is critical that the federal government continue to work with trading partners to improve the protection and enforcement of intellectual property rights because counterfeit products can pose significant safety risks.

The end goal must be to create the necessary mechanisms that will allow risk assessment and risk management professionals to actively engage with manufacturers and importers in assessing and reducing risks along their supply chains.

SuiMing (Tomi) Hong
AmeriSci Group

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Response

In the event that an unsafe import does make its way into the domestic stream of commerce and may or does injure consumers or animals, swift actions must be taken to limit potential exposure and harm.

Recall

Recommendation 11 – Maximize the Effectiveness of Product Recalls.

The recall process is the principal tool in the arsenal of response mechanisms to protect consumers from exposure to hazardous products whether the products are domestic or imported. Generally, the manufacturer, distributor, importer or retailer initiates a product recall with the cooperation of the appropriate government agency (e.g., FDA for most foods and CPSC for consumer goods).

11.1 Amend the CPSA to make it unlawful for any manufacturer, distributor or retailer to sell a recalled product knowingly and willfully after the date of public announcement of the recall. Under the CPSA, it is currently legal for such entities to sell a recalled product (other than a product that fails to comply with a mandatory standard or ban) even after the public announcement of the recall. Amending the CPSA will create proper incentives for retailers and distributors to halt sales of recalled products as quickly as possible.

Lead: CPSC

Time Frame: Short Term

11.2 Authorize follow-up recall authority for CPSC. If, after public notice of a voluntary recall, it later comes to the attention of the Commission that products subject to the voluntary recall remain widely available on the market, this provision would allow the agency to act quickly to issue an identical follow-up recall notice without having to consult again with the subject firm. This authority would be particularly helpful in instances of high-volume recalls in which one announcement may prove inadequate to inform the public.

Lead: CPSC

Time Frame: Short Term

11.3 Authorize CPSC to require all recalling firms to provide the name and address of companies that supplied or received the recalled product. Although maintaining thorough and accurate information about product suppliers, manufacturers and distributors is widely viewed as an industry best practice, not all firms maintain such information. Others do not disclose it to the Commission in the event of a recall. With proper authority, the CPSC could require every recalling entity to provide the agency with detailed contact information for all relevant parties across the life cycle

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of the recalled product. Granting the CPSC authority to compel such information in times of recall creates an incentive for firms to adopt strong record-keeping practices as a matter of standard business operations.

Lead: CPSC

Time Frame: Short Term

11.4 *Authorize FDA to issue a mandatory recall of food products when voluntary recalls are not effective.* Currently, FDA lacks the authority to require the recall of food, including food it reasonably believes is adulterated and presents a threat of serious adverse health consequences or death. Although market incentives have made the voluntary recall system generally effective, providing mandatory recall authority to FDA when the voluntary system is not successful would ensure that the agency has the ability to compel action in those instances when firms have refused or unduly delayed a voluntary recall of food. The authority would provide for appropriate due process rights for any firm subject to a recall order.

Lead: HHS / FDA

Time Frame: Short term

Federal-State Rapid Response

Recommendation 12 – Maximize Federal-State Collaboration.

The roles of and the resources used by the federal government and the states in import safety are complementary. States possess legislative authority and resources to respond to unsafe imported products within their jurisdiction.

The federal government can take steps to interdict unsafe imported goods at ports-of-entry. Should an unsafe product enter domestic commerce, federal departments and agencies often work with state authorities to track it down, seize it, notify the public if it has already been purchased by consumers and impose appropriate penalties on domestic entities who violate U.S. law. Also, both the federal government and states may have access to information relevant to protecting consumers that the other does not possess. For example, federal departments and agencies may have relevant information about the foreign source of the imported product and about the importer. This information can help state officials track down an unsafe imported product within their jurisdiction. On the other hand, state officials may identify an unsafe imported product during transport or at the point-of-sale, if the product does get into the country, and can tip off federal officials to prevent future shipments from entering domestic commerce.

To achieve comprehensive coordination, state and local governments also have a vital role and must be fully integrated into overall national efforts.

**Hallock Northcott,
American Association of Exporters
and Importers**

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Several federal departments and agencies already collaborate closely with state authorities to protect consumers. For example, FDA has contracts and cooperative agreements with state governments to share information, conduct joint inspections and collaborate on laboratory analyses. Greater mutual leveraging of state and federal resources can further enhance consumer protection.

- 12.1 *Consider cooperative agreements between the federal inspection agencies and their state counterparts for greater information-sharing.* Such cooperative agreements would not infringe on the statutory authorities of federal or state regulators and would encourage a coordinated effort that would result in a more rapid and effective response. Establishing clear procedures and points-of-contact for information sharing and joint enforcement efforts can further enhance the effectiveness of federal-state actions to limit exposure and potential harm to consumers if an unsafe imported product makes it into domestic commerce.

Leads: HHS / FDA, USDA, CPSC, EPA

Time Frame: Long Term

- 12.2 *Review admissibility policies to improve the use of evidence and laboratory results from state investigations of imported products.* Currently, there are limitations on the use of state-developed evidence in federal court cases due to the gathering, analysis and retention of such evidence by non-federal government entities. Being able to use this evidence would make it easier for federal departments and agencies to take enforcement actions against bad actors.

Leads: DOJ, HHS / FDA, USDA, CPSC

Time Frame: Short Term

Technology

Technological advancements can help industry, as well as federal and state governments, more effectively respond to safety incidents involving imports.

Recommendation 13 – Expedite Consumer Notification of Product Recalls.

After a manufacturer has recalled an imported product because of safety concerns, it is essential for consumers to receive notification of the recall as quickly as possible. While government and industry work largely in cooperation to enact product recalls, the emergence of new technologies may permit an even more rapid and efficient response.

- 13.1 *Develop best practices for the use of technologies to expedite consumer notification of recalls.* With advances in product-tracking technologies, such as integrated circuit cards (Smart Cards) and Radio Frequency Identification (RFID), retailers are increasingly capable of learning and anticipating their customers' preferences, both as individuals and

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cohorts. Information collected at the point-of-sale, provided voluntarily by consumers in exchange for product discounts and other benefits, has significant potential in the realm of product safety. For example, consumers who voluntarily share their personal contact information with a retailer (email address, telephone number, etc.) also can agree to receive instant recall notification from the seller regarding any of the products they recently purchased at that store. To the extent that the private sector can leverage the use of Smart Cards, RFID and other technologies to expedite consumer notification of emerging or existing product hazards while adequately protecting consumer privacy, the government should support such efforts.

Leads: USDA, HHS / FDA, CPSC

Time Frame: Long Term

Track-and-Trace


Recommendation 14 – Expand the Use of Electronic Track-and-Trace Technologies.

Traceability is the capacity to identify and track a product or group of products along the import life cycle, including at all points throughout the sourcing, manufacturing and distribution chain. The ability to identify the product source and points of distribution across the import life cycle is of prime importance for the protection of consumers, particularly in the event of a product recall. If unsafe imports are discovered, effective traceability mechanisms can facilitate timely product recovery and reduce the opportunity for harm to occur. Additionally, the capacity to connect the dots and link import life cycle information back to the point of origin enables both government and private-sector actors to provide consumers with targeted and accurate information concerning implicated products. Traceability is also an effective preventive tool in that post-recall information and feedback can be processed to identify and address weaknesses across the import life cycle.

14.1 Work with foreign and domestic industry to encourage the development of best practices for the use of electronic track-and-trace technologies.

Leads: USDA, HHS / FDA, CPSC, DOT

Time Frame: Long Term



To be effective, tracking requirements must apply at all points along the production continuum, from point of origin to retail sale, and consumers should be given clear information to use to identify recalled products in their home.

**Caroline Smith DeWaal,
Center for Science in the Public Interest**

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Conclusion

This Action Plan creates a roadmap for short-term and long-term improvements in the safety of imported products. The Working Group sets forth 14 recommendations and 50 action steps that are based on the organizing principles and building blocks identified in the Strategic Framework released on September 10, 2007. In addition, at the same time as the release of the Strategic Framework, the Working Group outlined Immediate Actions to be taken by federal departments and agencies to effect meaningful change. Together, the Strategic Framework and this Action Plan provide a national strategy for continually improving the safety of imported products.

Key action steps, which provide the pathway for implementing these recommendations, have each been assigned to lead entities that will be responsible for implementing this Action Plan.

Implementation of the recommendations will require resources, including reallocation of existing resources, as well as trade-offs, to fund these priorities. Additionally, it will require expanded authorities, greater coordination among federal departments and agencies, improved accountability for industry, increased foreign capacity building, greater information-sharing, partnerships with the private sector and the application of new science, to name just some of the activities the federal government must place priority on in coming years. Implementation will also require a collaborative approach by all participants in the import safety life cycle. By doing so, American consumers will be able to continue to enjoy the benefits of the global economy with confidence.

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The recommendations in this Action Plan create a path for the United States to complete the shift from an intervention approach to a prevention with verification, risk-based approach that builds safety into the products that reach U.S. consumers. This shift in emphasis can occur by following these recommendations:

1. **Safety Standards:** Create new and strengthen existing safety standards.
2. **Certification:** Verify compliance of foreign producers with U.S. safety and security standards through certification.
3. **Good Importer Practices:** Promote Good Importer Practices.
4. **Penalties:** Strengthen penalties and take strong enforcement actions to ensure accountability.
5. **Foreign Collaboration and Capacity Building:** Make product safety an important principle of our diplomatic relationships with foreign countries and increase the profile of relevant foreign assistance activities.
6. **Common Mission:** Harmonize federal government procedures and requirements for processing import shipments.
7. **Interoperability:** Complete a single-window interface for the intra-agency, interagency and private-sector exchange of import data.
8. **Information Gathering:** Create an interactive import-safety information network.
9. **New Science:** Expand laboratory capacity and develop rapid test methods for swift identification of hazards.
10. **Intellectual Property Protection:** Strengthen protection of intellectual property rights (IPR) to enhance consumer safety.
11. **Recall:** Maximize the effectiveness of product recalls.
12. **Federal-State Rapid Response:** Maximize federal-state collaboration.
13. **Technology:** Expedite consumer notification of product recalls.
14. **Track-and-Trace:** Expand the use of electronic track-and-trace technologies.

Appendix A: Executive Order

Executive Order: Establishing An Interagency Working Group on Import Safety

By the authority vested in me as President by the Constitution and the laws of the United States of America, and to ensure that the executive branch takes all appropriate steps to promote the safety of imported products, it is hereby ordered as follows:

Section 1. Establishment of Interagency Working Group on Import Safety. The Secretary of Health and Human Services shall establish within the Department of Health and Human Services for administrative purposes only an Interagency Working Group on Import Safety (Working Group).

Sec. 2. Membership and Operation of Working Group.

(a) The Working Group shall consist exclusively of the following members, or their designees who shall be officers of the U.S. appointed by the President or members of the Senior Executive Service:

- (i) the Secretary of Health and Human Services, who shall serve as Chair;
- (ii) the Secretary of State;
- (iii) the Secretary of the Treasury;
- (iv) the Attorney General;
- (v) the Secretary of Agriculture;
- (vi) the Secretary of Commerce;
- (vii) the Secretary of Transportation;
- (viii) the Secretary of Homeland Security;
- (ix) the Director of the Office of Management and Budget;
- (x) the United States Trade Representative;
- (xi) the Administrator of the Environmental Protection Agency;
- (xii) the Chairman of the Consumer Product Safety Commission; and
- (xiii) other officers or full-time or permanent part-time employees of the United States, as determined by the Chair, with the concurrence of the head of the department or agency concerned.

(b) The Chair shall convene and preside at meetings of the Working Group, determine its agenda, and direct its work. The Chair may establish and direct subgroups of the Working Group, as appropriate to deal with particular subject matters, that shall consist exclusively of members of the Working Group. The Chair shall designate an officer or employee of the Department of Health and Human Services to serve as the Executive Secretary of the Working Group. The Executive Secretary shall head any staff assigned to the Working Group and any subgroups thereof, and such staff shall consist exclusively of full-time or permanent part-time Federal employees.

Sec. 3. Mission of Working Group. The mission of the Working Group shall be to identify actions and appropriate steps that can be pursued, within

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existing resources, to promote the safety of imported products, including the following:

- (a) reviewing or assessing current procedures and methods aimed at ensuring the safety of products exported to the United States, including reviewing existing cooperation with foreign governments, foreign manufacturers, and others in the exporting country's private sector regarding their inspection and certification of exported goods and factories producing exported goods and considering whether additional initiatives should be undertaken with respect to exporting countries or companies;
- (b) identifying potential means to promote all appropriate steps by U.S. importers to enhance the safety of imported products, including identifying best practices by U.S. importers in selection of foreign manufacturers, inspecting manufacturing facilities, inspecting goods produced on their behalf either before export or before distribution in the United States, identifying origin of products, and safeguarding the supply chain; and
- (c) 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.

Sec. 4. Administration of Working Group. The Chair shall, to the extent permitted by law, provide administrative support and funding for the Working Group.

Sec. 5. Recommendations of Working Group. The Working Group shall provide recommendations to the President, through the Assistant to the President for Economic Policy, on the matters set forth in section 3 within 60 days of the date of this order, unless the Chair determines that an extension is necessary. The Working Group may take other actions it considers appropriate to promote the safety of imported products

Sec. 6. Termination of Working Group. Following consultation with the Assistant to the President for Economic Policy, the Chair shall terminate the Working Group upon the completion of its duties.

Sec. 7. General Provisions.

- (a) Nothing in this order shall be construed to impair or otherwise affect (i) authority granted by law to a department, agency, or the head thereof, or (ii) functions of the Director of the Office of Management and Budget relating to budget, administrative, or legislative proposals.
- (b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.
- (c) This order is not intended to, and does not, create any right, benefit, or privilege, substantive or procedural, enforceable at law or in equity, by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

GEORGE W. BUSH
THE WHITE HOUSE,
July 18, 2007.

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Appendix B : Immediate Actions Memorandum
September 10, 2007



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

September 10, 2007

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

Re: Interagency Working Group on Import Safety

Dear Mr. President:

On behalf of the Interagency Working Group on Import Safety and in accordance with Executive Order 13439, I am pleased to submit this report, *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety*.

Accompanying this report is a listing of *Immediate Actions* that the Working Group recommends that the Federal government implement without delay to protect American consumers. These recommendations will be followed by an Action Plan in mid-November 2007, which will set out a roadmap with short- and long-term recommendations for improving import safety.

I want you to know of my appreciation for the assistance of all of your designees in this process. Their contributions have been exceptional.

As a Working Group, we provide the Strategic Framework and Immediate Actions with a belief that these changes will make the most effective use of our resources and provide the greatest protection to American consumers over the long term.

Thank you for the opportunity to serve.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael O. Leavitt", with a stylized flourish at the end.

Michael O. Leavitt
Secretary, Department of Health and Human Services

Listing of Immediate Actions

1. Improve collaboration and information sharing with the private sector to improve the safety of imports.

A wide range of products that could potentially threaten the health and safety of U.S. consumers are imported every day. Due to the vast volume of imported products, it is impossible to ensure safety simply by increasing government inspections. Rather, engagement with the importing community must be enhanced to gain insights from the owners and operators of the commercial import infrastructure through which all imported products reach American consumers, and to share best practices among this community.

To conduct this outreach and improve collaboration with the importing community, the agencies should expand on existing public-private relationships, such as COAC (Commercial Operations Advisory Committee), TSN (Trade Support Network), F&ASCC (Food and Agriculture Sector Coordinating Council), ITACs and ATACs (Industrial Trade and Agricultural Trade Advisory Committees), and other groups, to seek and share the importing community's recommendations and best practices with the objective of enhancing import safety and promoting comprehensive supply chain verification.

Recommendations for implementation of this action will be included in the Working Group's forthcoming Action Plan.

2. Interoperability Acceleration – Instruct Executive Agencies to Complete Their Identification of Technical, Business and Legal Requirements for Operating Within the Automated Commercial Environment/International Trade Data System.

The Security and Accountability for Every ("SAFE") Port Act of 2006 requires all Federal agencies that license, permit, or certify imported products to participate in the International Trade Data System (ITDS), a "single-window" system for reporting imports and exports electronically. ITDS will operate as a feature of U.S. Customs and Border Protection's (CBP) trade data processing system called the Automated Commercial Environment (ACE), which is currently under development. Functional capabilities within ACE are being implemented in stages, with full operability expected in 2009. Currently, 34 Federal agencies, referred to as Participating Government Agencies (PGAs), are at varying stages in integrating into ITDS.

In order to accelerate implementation of ITDS, the Office of Management and Budget should issue a directive to PGAs requiring that within 60 days of the directive they establish or refine their Implementation Plan setting deadlines for developing, reviewing and finalizing conceptual operating plans (Concept of Operations),

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memoranda of understanding for the ITDS interface, and a set of technical and business requirements for identifying any program and system modifications needed to support the interface. This would include considerations for the budget process. OMB should give special priority to import safety agencies for this task in the budget process

Further, in order to accelerate implementation of ITDS, the Office of Management and Budget should direct that CBP, within 60 days, establish or refine its Implementation Plan setting deadlines to:

- Include information currently reported by importers and carriers to CBP in the ACE Data Warehouse, where it can be accessed by other agencies.
- Advise other agencies with an import safety mission how they can take full advantage of current ITDS capabilities and deepen their engagement in ITDS development
- Implement World Customs Organization Data Model messages (new international international standard for customs reporting), which could provide a platform for electronic reporting of health and safety information in advance of the current ITDS production schedule.

In addition, all PGAs are instructed to:

- Within their fiscal year 2009 budget submissions, identify the budgetary resources needed to support the ACE/ITDS interface. Within 60 days, designate a senior executive responsible for implementing the ACE/ITDS interface.

Within 60 days, designate a senior executive responsible for implementing the ACE/ITDS interface.

Participating Government Agencies (PGAs)

- AMS - Agricultural Marketing Service (Agriculture)*
- APHIS - Animal and Plant Health Inspection Service (Agriculture)*
- ATF - Bureau of Alcohol, Tobacco, Firearms and Explosives (Justice)*
- BIS – Bureau of Industry and Security (Commerce)
- BLS - Bureau of Labor Statistics (Labor)
- BTS - Bureau of Transportation Statistics (Transportation)
- CDC- Center for Disease Control (Health and Human Services)*
- Census – U.S. Census Bureau (Commerce)
- CPSC – Consumer Product Safety Commission*
- DEA – Drug Enforcement Administration (Justice)*
- EPA - Environmental Protection Agency*
- FAA - Federal Aviation Administration (Transportation)*
- FAS – Foreign Agricultural Services (Agriculture)
- FCC - Federal Communications Commission*
- FDA - Food and Drug Administration (Health and Human Services)*

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- FMC - Federal Maritime Commission
- FMCSA - Federal Motor Carrier Safety Administration (Transportation)*
- FSIS - Food Safety and Inspection Service (Agriculture)*
- FTZB - Foreign Trade Zones Board (Commerce)
- FWS - Fish and Wildlife Service (Interior)*
- GIPSA – Grain Inspection, Packers and Stockyards Administration (Agriculture)
- IA - International Trade Administration–Import Administration (Commerce)
- IRS - Internal Revenue Service (Treasury)
- ITC – International Trade Commission
- MARAD - Maritime Administration (Transportation)
- NHTSA – National Highway Traffic Safety Administration (Transportation)*
- NMFS – National Oceanic Atmospheric Administration / National Marine Fisheries Service, Office for Law Enforcement (Commerce)*
- NRC - Nuclear Regulatory Commission*
- OFAC - Office of Foreign Assets Control (Treasury)
- OFE – Office of Fossil Energy (Energy)
- OFM - Office of Foreign Missions (State)
- State – Logistics Management (State)
- TTB - Alcohol and Tobacco Tax and Trade Bureau (Treasury)*
- USACE - Army Corps of Engineers (Defense)

*Agencies designated by the Board of ITDS as import safety agencies due to their roles in licensing, certifying, and permitting import shipments.

3. **Global Collaboration – Instruct agencies to develop and increase International cooperation and collaboration.**

The Department of State (State) has contacted host governments in 39 countries that are top exporters of food and consumer products to the United States to seek information on how various countries handle import safety issues. In the coming weeks, State, the Office of the United States Trade Representative (USTR), and other interested agencies will analyze the responses to these inquiries and meet to determine appropriate next steps.

As part of these next steps, State and USTR should coordinate with other Working Group members to determine whether appropriate international and regional organizations could be helpful in hosting international conferences or other actions to promote product safety, in order to generate high-level global attention to a worldwide problem. Such events could provide a forum to exchange information on effective product safety practices, identify opportunities for regulatory capacity building, and promote science-based regulation, consistent with U.S. law and our international obligations

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Recommendations for implementation of this action will be included in the Working Group's forthcoming Action Plan.

- 
4. **Agreements with Foreign Governments – Instruct agencies to catalog on-going and planned import safety-related agreements (bilateral and multilateral) with foreign governments. In addition, require agencies to meet within 45 days and then on a regular basis to discuss negotiations underway or that are anticipated and share lessons learned.**

Various U.S. government agencies work with foreign governments to conclude and implement bilateral and multilateral agreements to improve import safety. In many cases, the agency that has expertise in a particular facet of import safety takes the lead in the negotiations. The resulting agreements, however, may affect the jurisdiction, operations, and resources of other agencies. Therefore, coordination among all the relevant agencies is necessary to ensure that all such agreements are as effective as possible and can be fully implemented.

Currently, coordination procedures vary depending on the nature of the agreement. Despite the various existing means for coordination, interagency work on import safety negotiations with foreign governments can be improved. In particular, efforts should be made to increase interagency awareness of agencies' ongoing and planned discussions with foreign governments regarding import safety agreements. In addition, the current coordination processes should be modified to provide a forum for agencies to share successful strategies and approaches with other agencies that could benefit from their experiences. Earlier and improved coordination will help ensure that agreements fully benefit from relevant agencies' experiences, avoid duplicative or counterproductive efforts, and generally improve the negotiating position of the U.S. government.

To this end, as an immediate action, agencies should be required to catalog ongoing and planned discussions with foreign governments regarding import safety. Until the Action Plan is issued, the Department of Commerce should host regular advisory meetings for these agencies to share information about their efforts, experiences and concerns. This process is not a review and would in no way supplant or delay the TPSC and C-175 processes, or any other on-going relevant inter-agency process. International cooperation regarding law enforcement or other similar activities would not be subject to these meetings.

Appendix C: Recent Actions and Current Plans to Protect American Consumers

As directed by the President, all departments and agencies have been reviewing and assessing current procedures, authorities, outreach efforts and international cooperation initiatives to enhance the safety of imported products. They have met with foreign governments, foreign manufacturers and others in the exporting country's private sector, as well as with producers, importers, retailers, trade associations, consumer groups and others in the U.S. importing community.

Based on these reviews and meetings, the departments and agencies have already taken numerous actions to protect American consumers. Many more initiatives to enhance the safety of imported products are underway and will be completed in the coming months. This appendix summarizes significant recent accomplishments and important actions that will be completed within the first 200 days of issuing this Action Plan.

The actions are structured according to the organizing principles from the Strategic Framework and the recommendations included in this Action Plan.

Prevention with Verification

Safety Standards

- **Food Protection Plan.** FDA has developed a Food Protection Plan that addresses both food safety and food defense for domestic and imported products, including food protection from production to consumption. The Plan will be phased in over the coming months and is integrated with the Administration's Import Safety Strategic Framework and Action Plan.

Certification

- **NOAA Seafood Inspection Program.** As of October 24, 2007, the Department of Commerce's National Oceanic and Atmospheric Administration (NOAA) Seafood Inspection Program has inspected and certified seven seafood processing plants in China and has plans to inspect another 12 plants. There are a number of other plants in the queue to be inspected.
- **Improved Compliance with Toxic Substance Control Standards.** EPA's Office of Prevention, Pesticides and Toxic Substances has been developing a Toxic Substance Control Act (TSCA) "Section 13 Import Compliance Checklist" as a compliance assistance tool to help chemical importers and government inspectors better understand import certification requirements. When finalized, the Checklist will be posted on various Web sites and disseminated in other ways.

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- **Seafood Inspectors Stationed in Other Asian Countries.** NOAA is in the process of stationing an inspector full time in Hong Kong and has plans to put inspectors in other countries that export large volumes of seafood to the United States.
- **New Zealand Meat Certification.** USDA's Food Safety and Inspection Service (FSIS) began reprogramming its import inspection data system to enable an electronic data transfer of certifications for meat export shipments from New Zealand. This will constitute verification that importers have presented New Zealand import shipments for FSIS inspection as required by law. Full electronic certificate exchange capability is expected to be operational by the end of 2007 and will be extended to include Australia and Canada during 2008.
- **Accreditation of Private Labs.** FDA will issue guidance by mid-2008 that would set standards for the sampling and testing of imported products, including the use of accredited private laboratories submitting data to FDA to assist in evaluating whether an appearance of a violation may be resolved. Increased confidence in the sampling techniques and methodologies used by accredited laboratories and in the data they submit may allow FDA to base decisions on abbreviated laboratory packages from accredited laboratories, expedite review of the information in those packages and facilitate admissibility decisions.

Foreign Cooperation and Capacity Building

- **Safety Agreement with China on Toys, Fireworks and Electrical Products.** Meetings held in September 2007 between CPSC and its counterpart, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of the People's Republic of China resulted in a renewed Memorandum of Understanding (MOU) related to the promotion of safety for target products—children's toys, fireworks, cigarette lighters and electrical products.
- **Memoranda of Agreements with China on Food, Drugs, Medical Devices and Animal Feed.** HHS/FDA is negotiating binding agreements with the Chinese government to enhance regulatory cooperation in the area of drugs, medical devices, food and animal feed. These agreements will protect the safety and health of consumers and animals in the United States and in China.
- **Motor Vehicle Safety Agreement with China.** On September 12, the Department of Transportation's National Highway Traffic Safety Administration (NHTSA) signed a Memorandum of Cooperation with China aimed at increasing cooperation in the areas of motor

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vehicle regulation and safety. Both sides indicated a willingness to work together to address issues related to the safety of Chinese motor vehicles and equipment (including tires and automotive fuses) intended for export to the United States.

- **Tire Safety Standards Talks with China.** From September 11 through September 18, NHTSA staff with expertise in NHTSA's tire standards and enforcement process attended the Chinese International Tire Exposition in Shanghai and met with China's technical experts on tire issues in Hangzhou. At both locations, NHTSA representatives made detailed presentations on the agency's standards and enforcement process. The presentations were well received by the many representatives of the Chinese tire industry who participated in these sessions. NHTSA's delegation also obtained information that will be useful in designing strategies to help deter and detect the shipment of noncompliant or defective tires from China to this country.
- **Seafood Inspection Agreement with China.** NOAA's National Marine Fisheries Service (NMFS) has begun discussions with China's Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) on an MOU to improve information transfer and to increase the traceability of products. The MOU would establish a notification system whereby each party would alert the other in the event that a problem is detected with seafood being imported from China. Drafts have been exchanged and a final agreement is anticipated in early 2008.
- **Foreign Training on United States Safety Standards for Meat, Poultry and Eggs.** In July 2007, USDA and FDA conducted a seven-week training program for Chinese inspection officials. FSIS also conducted outreach to foreign government inspection officials regarding FSIS import requirements for meat, poultry and egg products. FSIS provided technical assistance to the Austrian government regarding U.S. import requirements for ready-to-eat products, to Mexico regarding microbiological testing procedures and to the governments of Bosnia-Herzegovina, Namibia and Thailand about U.S. import requirements in general.
- **United States-Europe Consumer Protection Talks.** On October 14, 2007, the Trans-Atlantic Consumer Dialogue was held at the State Department. Topics included the review of the respective regulatory impact assessment guidelines on trade and investment and their application, reduction in barriers on trade in chemicals, controlling hazardous toy and consumer product imports, recognition of Supplier's Declaration of Conformity for electrical equipment and other topics of concern in the ongoing trans-Atlantic dialogue.

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- **Security and Prosperity Partnership (SPP) priority on Safe Food and Products.** In August, President Bush, President Calderon of Mexico and Prime Minister Harper of Canada pledged to strengthen trilateral cooperation and mechanisms within the region, build on current standards and practices and work with our trading partners outside of North America to identify and stop unsafe food and products before they enter our countries.
- **Product Safety in Standards Dialogues.** The Department of Commerce is engaging in standards dialogues with key trade partners like Brazil, the European Commission and India. Product safety issues were discussed with India on October 25 and with the European Union on October 29. These dialogues encourage information exchange on policies, procedures and processes to ensure the safety of imported products.
- **International Food Safety Standards Work in Codex Alimentarius.** The Department of Commerce, State, EPA, USDA, FDA and USTR are actively engaged in international food safety standards development work in Codex Alimentarius. Codex already has a significant inventory of standards and guidelines that address food hygiene, food labeling, food import and export certification and inspection systems, contaminants in food and other areas. The United States is considering what gaps exist in food safety standards that Codex might address through new work activities.
- **China Joint Commission on Commerce and Trade (JCCT) Pharmaceutical Task Force.** The JCCT provides ongoing workshops to the Chinese government on anti-counterfeiting and manufacturing best practices for pharmaceuticals. Accomplishments have included direct input into the China State Food and Drug Administration's update of its drug registration review process.
- **China Joint Commission on Commerce and Trade (JCCT) Medical Devices Task Force.** The Department of Commerce and FDA provide ongoing training to the Chinese government on the use of quality systems to ensure the safety of manufactured products, including conducting product recalls for medical devices.
- **Pharmaceutical anti-counterfeiting activity under the United States-India High Technology Cooperation Group's Biotechnology & Life Sciences Working Group.** This group organizes activities to fight the counterfeiting of pharmaceuticals and addresses the regulation of active pharmaceutical ingredients

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to prevent the production of counterfeit medicines. In August 2007, this group discussed with Indian government officials the need to cooperate with the international community in stopping the production and export of counterfeit pharmaceuticals and the need to regulate active pharmaceutical ingredients.

- **APEC Anti-Counterfeit and Regulatory Harmonization Seminars on Medical Devices.** DOC and FDA are organizing a series of capacity-building seminars for Asia and Latin America focused on stopping the spread of counterfeit health products and promoting regulatory harmonization for medical devices. The first anti-counterfeit seminar will take place in Singapore in January 2008; the first regulatory harmonization seminar will take place in Kuala Lumpur in March 2008. Subsequent seminars will take place throughout 2008 and early 2009 in Asia and Latin America. Participants will include pharmaceutical and medical device regulators, custom and law enforcement officials, health professionals and industry representatives.
- **Motor Vehicle Safety Seminars with Chinese Companies.** In late 2007 or early 2008, NHTSA plans to send senior officials to China to meet with the relevant government departments and agencies, trade associations and companies to discuss how NHTSA's standards and enforcement process apply to exports intended for sale in the United States. NHTSA intends to reach those companies already engaged in exporting motor vehicle equipment and those that have announced plans to export motor vehicles to the United States in the next two years. NHTSA will also look for opportunities to enter into more detailed agreements with the Chinese government on cooperative methods to help ensure that imports are compliant with NHTSA standards.
- **Cooperative Agreement with China on Environmental Requirements.** In April 2007, EPA met with China's AQSIQ and other groups and agreed to draft an EPA-AQSIQ MOU to exchange information on environmental requirements and cooperate to help ensure compliance.
- **Cooperation on Enforcement of Environmental Laws in North America.** An understanding was recently reached among EPA, Canadian and Mexican environmental law enforcement officials to share information about noncompliant imports entering the borders of any of the countries.

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- **North American Development of Enforcement Training to Ensure Legal Imports.** In September 2007, representatives from environmental agencies of the United States, Canada and Mexico, reviewed an electronic training module on ozone-depleting substances. At the same time, the officials approved the creation of a similar module for hazardous waste.
- **Outreach on Import Safety through Diplomatic Channels.** The State Department's Bureaus of Economic, Energy and Business Affairs and International Information Programs developed an outreach plan to reach foreign audiences on import safety. To date, import safety articles have already been published in international newspapers; more are expected over the near term. In August 2007, the Department of State sent cables to all overseas posts to provide them with information about import safety and the role of the Interagency Working Group on Import Safety for discussion with governments and the private sector.
- **Negotiation and Capacity Building through Trade Channels.** An integral part of U.S. free trade agreements are commitments to address sanitary and phytosanitary (SPS)¹² issues. In the past year, USTR concluded free trade agreements with Peru, Colombia, Panama and Korea, each of which includes a specific SPS chapter that has as a principal objective the protection of human and animal health. In particular, the SPS chapters provide for the establishment of a standing committee of the parties to enhance cooperation and consultation on SPS matters and improve understanding of each other's SPS requirements. These agreements also provide for capacity building and technical assistance in SPS activities.
- **Anti-Counterfeiting Trade Agreement.** On October 23, 2007, USTR announced that the United States and some of its key trading partners will seek to negotiate an Anti-Counterfeiting Trade Agreement. Anti-counterfeiting efforts will help to improve the safety of imported products.
- **International Dialogues.** The Department of State, Department of Commerce, USDA, USTR, HHS and other federal departments and agencies are encouraging the inclusion of import safety in regional and international dialogues.
 - Import safety will be discussed at the United States-European Union High Level Regulatory Cooperation Forum in November and may also be taken up by the Transatlantic Economic Council, which is also meeting in November.

¹² An SPS measure is generally any measure applied to protect human, animal or plant life or health from risks arising from pests, diseases or adulterants or contaminants in food feed.

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- At the Asia-Pacific Economic Cooperation (APEC) Summit in September, leaders agreed “to develop initiatives in the coming year that effectively address problems related to import safety in ways that do not hinder trade.” There are a number of specific project proposals underway, including one by China to promote information sharing to improve “food safety systems” and another to address Hazard Analysis and Critical Control Points (HACCP).
- USDA has indicated it will fund food safety related workshops for APEC. The primary goal of these workshops would be to raise awareness of, engagement in and compliance with international food safety standards-setting bodies, such as Codex Alimentarius, World Organization for Animal Health (OIE) and the International Plant Protection Convention.
- The Association of Southeast Asian Nations (ASEAN) has endorsed creating a Coordinating Committee on Consumer Protection at its August meeting and is in communication with officials at the CPSC, USDA, FDA and the Federal Trade Commission.

Intervention

Common Mission

- **Enhanced Interagency Cooperation on Animal and Plant Inspections.** USDA’s FSIS and USDA’s Animal and Plant Health Inspection Service (APHIS) continued monthly conference calls to discuss key import and export issues of concern and to resolve technical problems between the agencies. Recently, participation was expanded to include representatives from the Food and Drug Administration and U.S. Customs and Border Protection.
- **Enhanced Cooperation on Egg Product Safety.** USDA agencies (FSIS, AMS and APHIS) coordinated potential product code systems in use by FDA and the Global Safety Initiative that might further identify USDA-regulated animal, egg and plant products in ITDS/ ACE. The agencies currently responsible for regulating the import of eggs and egg products—FDA, APHIS, FSIS, CBP and AMS—are currently identifying product codes to provide clarity in classifying imported products under the Harmonized Tariff Codes.
- **Cooperation on Counterfeits.** DOC’s International Trade Administration (ITA) Office of Intellectual Property Rights is

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collaborating with CPSC to create a Counterfeit Alert System that would refer reports of counterfeits received by CPSC's hotline to DOC's Stop Fakes hotline.

Interoperability

- **Public Health Information System.** On September 27, the Food Safety and Inspection Service (FSIS) awarded a contract for development of a new corporate data warehouse called the Public Health Information System, which will support a user interface for imports and exports. FSIS will develop, test and launch the system. This includes establishing an electronic connection with CBP's ACE/ITDS system and importers for processing imported meat, poultry and egg product shipments.
- **USDA Harmonization with Trade Data System.** USDA's Agricultural Marketing Service (AMS) and APHIS made important progress in establishing an interface with ACE/ITDS. AMS completed import-related business processes, drafted a Concept of Operations and Memorandum of Understanding with CBP and engaged a contractor to identify areas where its connection with ACE/ITDS can be optimized. APHIS submitted its Concept of Operations and Memorandum of Understanding to CPB on October 10. USDA's Grain Inspection, Packers and Stockyards Administration began the ITDS process with CBP on October 30, 2007.
- **EPA Harmonization with Trade Data System.** Building on previous work with CBP and other relevant federal agencies on the development of the single window import-export data system, EPA has accelerated steps in order to become interoperable with ACE/ITDS. EPA is developing business processes and requirements to exchange data between six EPA programs and ACE/ITDS. EPA identified the Chief Information Officer as the executive level representative; assigned EPA's internal Exchange Network Subcommittee as the governance body; established a project management/implementation team structure; is preparing a project implementation plan for submission to OMB on November 12, 2007 and is revising a concept of operations document for submission to CBP in December 2007. EPA is leveraging the Central Data Exchange and Exchange Network technology which the Agency currently uses to exchange data with all 50 states and seven Indian Tribes.

Response

Vigorous Enforcement of Safety Statutes

- **Marking Rule to Prevent Port-Shopping.** By mid-2008, FDA will issue a proposed rule that would require imported food that has been refused entry to be marked “United States: Refused Entry.” Such marking would help prevent the introduction of unsafe food into the United States through port-shopping, a practice whereby importers attempt to gain entry through a port after the goods have been refused at another.
- **Criminal Prosecution of Counterfeit Drug and Illegal Substance Offenders.** FDA, CBP and DOJ are continuing vigorous enforcement of statutes banning trade in counterfeit and illegal products. For example, DOJ recently prosecuted an Ohio man charged in online pharmacy conspiracy for selling counterfeit drugs (Viagra, Cialis, Levitra) shipped from such countries as Pakistan, India and Great Britain. The agencies also collaborated in an international law enforcement operation targeting the underground manufacture of anabolic steroids. The operations have led to 124 arrests nationwide to date and the dismantling of approximately 100 illegal sites that aided in the manufacture and distribution of anabolic steroids, prescription medicines, counterfeit drugs and chemical precursors originating from approximately 30 rogue laboratories in China.



Appendix D: List of Acronyms and Abbreviations

Acronyms

ACE	Automated Commercial Environment
AMS	Agricultural Marketing Service
APEC	Asia-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
AQSIQ	Administration of Quality Supervision, Inspection and Quarantine
ASEAN	Association of Southeast Asian Nations
ASISA	Aviation Safety Information Sharing and Analysis
ATS	Automated Targeting System
COAC	Commercial Operations Advisory Committee
CBP	Customs and Border Protection
CPSA	Consumer Product Safety Act
CPSC	Consumer Product Safety Commission
C-TPAT	Customs Trade Partnership Against Terrorism
DHS	Department of Homeland Security
DOC	Department of Commerce
DOJ	Department of Justice
DOT	Department of Transportation
eLEXNET	Electronic Laboratory Exchange Network
EOP	Executive Office of the President
EPA	Environmental Protection Agency
EPIA	Egg Products Inspection Act
FAA	Federal Aviation Administration
FDA	Food and Drug Administration
FDCA	Federal Food, Drug and Cosmetics Act
FERN	Food Emergency Response Network
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service
GIDEP	Government Industry Data Exchange Program
GSI	Global Safety Initiative
HACCP	Hazard Analysis and Critical Control Points
HHS	Department of Health and Human Services
HTS	Harmonized Tariff Schedule
ICAO	International Civil Aviation Organization
IIP	International Information Programs
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
IPR	Intellectual Property Rights
ITA	International Trade Administration
ITDS	International Trade Data System
MOU	Memorandum of Understanding
NHTSA	National Highway Traffic Safety Administration
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
NTC	National Targeting Center

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OASIS	Operational and Administrative System for Import Support
OMB	Office of Management and Budget
PHMSA	Pipeline and Hazardous Materials Safety Administration
PPIA	Poultry Products Inspection Act
RFID	Radio Frequency Identification
SAFE Port	Safety and Accountability for Every Port Act
SCC	Food and Agriculture Sector Coordinating Council
SDS	Standard Data Set
SEDS	Standard Establishment Data Service
SFDA	China State Food and Drug Administration
SIP	Seafood Inspection Program
SPP	Security and Prosperity Partnership
State	Department of State
STOP	Strategy Targeting Organized Piracy
TACD	Trans-Atlantic Consumer Dialogue
TIA	U.S. Toy Industry of America
Treasury	Department of Treasury
TSCA	Toxic Substance Control Act
USDA	Department of Agriculture
USPTO	U.S. Patent and Trademark Office
USTR	U.S. Trade Representative
Working Group	Interagency Working Group on Import Safety





Appendix E: Working Group Designees and Staff

Interagency Working Group on Import Safety Designees

Secretary Michael O. Leavitt, Department of Health and Human Services,
Chair of the Interagency Working Group

Al Hubbard, Assistant to the President for Economic Policy and Director,
National Economic Council

Dan Price, Deputy National Security Advisor for Economic Affairs

Andrew C. von Eschenbach, Commissioner, Food and Drug Administration,
Department of Health and Human Services

Dan Sullivan, Assistant Secretary for Economic, Energy and Business Affairs,
Department of State

Alan Holmer, Special Envoy for China and the Strategic Economic Dialogue,
Department of Treasury

John O'Quinn, Deputy Associate Attorney General, Department of Justice

Richard Raymond, Under Secretary for Food Safety, Department of
Agriculture

David Spooner, Assistant Secretary for Import Administration, Department of
Commerce

Jeff Shane, Under Secretary for Policy, Department of Transportation

Jeff Runge, Acting Assistant Secretary for Health Affairs, Department of
Homeland Security

Robert Shea, Associate Director for Management, Office of Management and
Budget

Warren Maruyama, General Counsel, U.S. Trade Representative

Jim Gulliford, Assistant Administrator for Prevention, Pesticides and Toxic
Substances, Environmental Protection Agency

Quin Dodd, Chief of Staff, Consumer Product Safety Commission

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Interagency Working Group on Import Safety Staff

Jerry Regier, Executive Secretary for the Working Group, Department of Health and Human Services

Jeff Shuren, Food and Drug Administration

Cathy Saucedo, Department of Homeland Security

John Menard, Department of State

Bob Tuversen, Department of Agriculture

Karen Stuck, Department of Agriculture

Stephen Claeys, Department of Commerce

Bernard Carreau, Department of Commerce

Randy Pate, Department of Health and Human Services

Rob Raffety, Consumer Product Safety Commission

Celesia Gouhari, Department of Health and Human Services

Natalie Gochour, Department of Health and Human Services

Erik Mettler, Food and Drug Administration

John Herrmann, Executive Office of the President

John Cobau, Executive Office of the President



No import-safety system can succeed without collaboration from everyone involved. We share a common interest in import safety and this Action Plan will guide our collective actions moving forward.

Secretary Michael O. Leavitt
Chair, Interagency Working Group on Import Safety



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