Rolling Back the Border:
America's New Strategy for Import Safety

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Introduction

In May 2008 Secretary of Health & Human Services (HHS) Michael Leavitt called for a "new strategy" for import safety that would "roll back the borders."[1] The call for a more global approach to import safety followed a year of import safety scares that shook Americans' confidence in the products they consume. Secretary Leavitt's recommendation summarized an Interagency Working Group (IWG) report that called for fundamental changes in how the U.S. regulates food and product safety. The report called for reforms at both the legislative and agency levels.

Regulatory agencies have begun implementing a series of policy changes that will have profound implications for how business is carried out throughout the world. Summer 2008 has already seen the launching of a pilot third-party certification system for food products and the passage of groundbreaking product safety legislation. Major security initiatives are set to take effect in within a year. The new approach to import safety promises to be more invasive and more collaborative, creating both new challenges and new opportunities.

This paper reviews the import safety reform plans of U.S. Customs and Border patrol (CBP), the Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC). Together these three agencies are responsible for the safety of most imported consumer goods. The FDA, CPSC, and CBP have been uniquely challenged by the expansion of international trade, and these agencies are at the core of the IWG's plan for import safety reform.

Import Safety

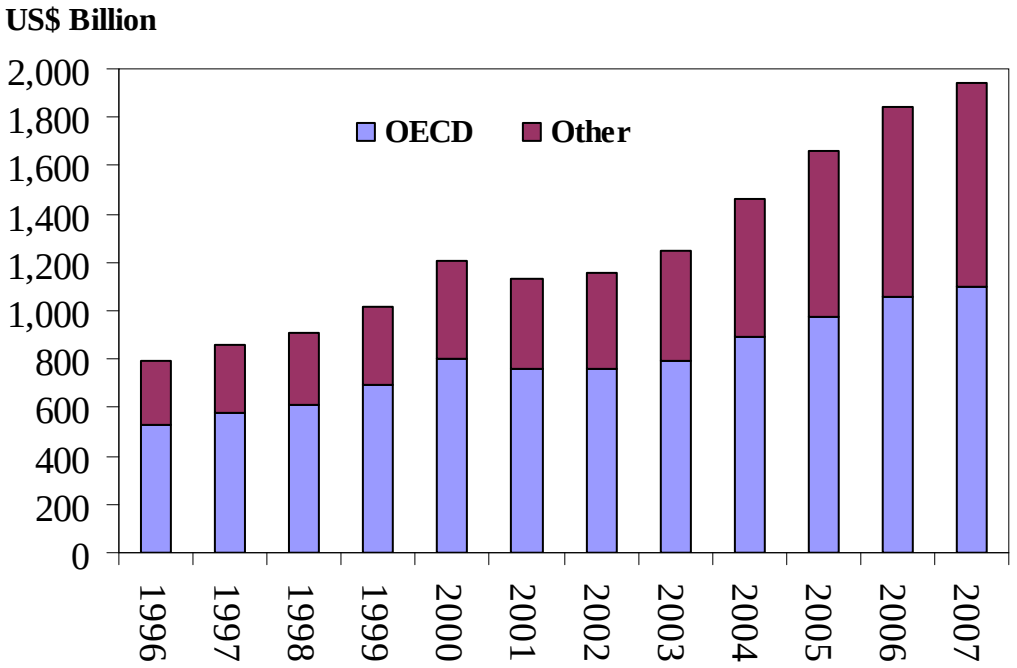
The United States enacted the Federal Meat Inspection Act and the Pure Food and Drug Act in 1906, laying the foundation for the United States' food safety regulatory system. That same year, U.S. imports reached

[1] Michael Leavitt, Secretary. "Remarks as Prepared to the Target Corporation's Worldwide Vendors Conference", May 12, 2008. http://hongkong.usconsulate.gov/uscn_others_2008051202.html.

a record $1.3 billion.[2] In 2007, a century later, U.S. imports hit another record: $1.94 trillion. These imports were brought into the U.S. by over 800,000 importers through 300 ports of entry.[3] These staggering figures will likely only grow in years to come. With this growth comes the challenge of ensuring imported goods meet U.S. safety standards.

Developing countries account for much of the growth in trade in recent years. Imports from non-OECD members more than tripled between 1996 and 2007 (See graph below).[4] Today, two of the United States' three largest trading partners, Mexico and China, are developing countries. The shift of trade flows towards developing countries, which may have less advanced food and product safety systems, adds an additional level of complexity to the challenge of ensuring import safety.

U.S. Imports by Country of Origin



Import safety is an issue of critical importance. Imported products account for the majority of consumer product recalls in the U.S.[5] The CPSC estimates that "{d}eaths, injuries and property damage from consumer

[2] "Foreign Trade in 1907," *New York Times*, January 18, 1908. The import figure is not adjusted for inflation.

[3] Secretary Michael Leavitt. "Safety at the Speed of Light," July 9, 2008, at 4.

[4] U.S. International Trade Commission Dataweb statistics. http://dataweb.usitc.gov.

[5] Consumer Product Safety Commission. *Import Safety Strategy*, July 2008, at 3.

product incidents" cost over $700 billion a year in the U.S.[6] In addition, imports now account for 15% of the U.S. food supply and 75% percent of seafood, a high-risk product.[7] The U.S. Center for Disease Control estimates that six million Americans become ill every year due to food borne illnesses, resulting in 325,000 hospitalizations and five thousand deaths.[8] While many of these illnesses are attributable to domestically produced products, import safety is a necessary part of ensuring the safety and health of all Americans.

Ensuring import safety is therefore not only increasingly complex, it is critical for the health and prosperity of the U.S. The growth in international trade and globalization of supply chains is forcing governments and companies around the world to rethink how they approach import safety.

> "Just as the volume of trade has changed, so must the strategies to regulate safety. Simply scaling up our current inspection strategy will not work. This is not a problem unique to the United States. It is a fundamental challenge for all nations."
>
> *Secretary Michael Leavitt, "Safety at the Speed of Life"*

INTERAGENCY WORKING GROUP

Public concern over import safety came to a head in summer 2007. Headlines were dominated by reports of deadly dog food and contaminated toothpaste. Product recalls of lead-tainted toys caused parents to worry about the safety of their children. President Bush responded by ordering the creation of an Interagency Working Group on Import Safety (IWG) on July 18, 2007.[9] The resulting IWG report to the President provided the intellectual framework for the regulatory overhaul now in process.

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[6] U.S. Consumer Product Safety Commission. "News from CPSC," August 2, 2007. cityoflansingmi.com/Lansing/pnd/development/fisher_price_recall_notice.pdf.

[7] Food and Drug Administration. *Food Protection Plan*, November 2007, at 8.

[8] Mary L. Nucci, Jocilyn E. Dellava, Cara L. Cuite, William K. Hallman, *The US Food Import System: Issues, Processes and Proposals*, Rutgers new Jersey Agricultural Experiment Station (March 2008) at 4.

[9] The IWG consists of senior officials from the Department of Health and Human Services, Department of Homeland Security, Department of Agriculture, Department of Commerce, Department of Justice, Department of State, Department of Transportation, Department of Treasury, Environmental Protection Agency, and Office of Management and Budget.

At the core of the IWG's recommendations was the need to ensure safety at all points in the supply chain. The report called for a "shift from an intervention, border-focused strategy to a life-cycle approach that stresses a risk-based approach to prevention with verification."[10] This change in strategy requires agencies to be increasingly active outside of U.S. borders. Recognizing the limited resources these agencies possess, the report calls for public-private partnerships to achieve much of this increased oversight. Increased collaboration is to be backed up by enhanced enforcement measures. Such an approach will directly impact all parties involved in the production and importation of goods.

> "All entities involved in the import life cycle – foreign growers and manufacturers, foreign governments, foreign exporters, U.S. importers, manufacturers and retailers, testing and certification bodies, and regulatory authorities at the federal, state, and local levels – should work together to support prevention with verification and mitigation of risk in products entering the U.S. marketplace."
>
> *Interagency Working Group on Import Safety, September 10, 2007*

Reaching beyond borders

The IWG report recommended a series of regulatory and legislative changes to expand the reach of U.S. agencies globally. The IWG proposed that the U.S. government:[11]

- Require importers to submit additional information under the SAFE Port Act and expand reporting requirements to all forms of transportation.
- Expand government offices in foreign countries and increase foreign inspections.
- Authorize the FDA to ban imports from companies who do not fully cooperate with foreign inspections.
- "Make product safety a guiding principle in negotiating future cooperative arrangements with foreign government entities."

[10] Interagency Working Group on Import Safety. *Protecting American Consumers Every Step of the Way: A Strategic Framework for Continual Improvement in Import Safety*, September 10, 2007, at 11.

[11] Interagency Working Group on Import Safety. *Action Plan for Import Safety: A Roadmap for Continual Improvement*, November 6, 2007.

These proposals will increase importers' and foreign manufacturers' exposure to U.S. regulators and place significant new burdens and costs on them. Importers and carriers will face increased reporting and information gathering requirements at an earlier stage. Foreign producers who export to the U.S. will need to be prepared for possible inspections by U.S. regulators. U.S. agencies have already solicited assistance from foreign regulators in enforcing U.S. laws.

Public-private partnerships

The IWG report also called for greater collaboration between U.S. regulators and the private sector. The IWG proposed that the U.S. government:[12]

- Authorize FDA-accredited independent third parties to evaluate compliance with FDA regulations.
- Develop new voluntary certification programs for importers and foreign producers and expand existing programs.
- Incentivize private sector participation by offering expedited clearance and other benefits.
- Expand the use of public-private sector standards programs such as the International Organization for Standardization and the American National Standards Institute.

The collaborative steps proposed by the IWG offer an alternative to a purely "stick" based approach. Companies that choose to participate in voluntary programs will benefit from quicker access to the U.S. market place. U.S. regulators will in turn be able to free resources to more closely scrutinize non-participating companies, improving import safety.

Increasing regulatory requirements

Voluntary public-private partnerships are to be backed up by strengthened enforcement measures. The IWG recommends that the U.S. government:[13]

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[12] Interagency Working Group on Import Safety. *Action Plan for Import Safety: A Roadmap for Continual Improvement*, November 6, 2007.

[13] *Id.*

- Authorize the FDA to require certification of high risk products based on country, region, producer, or product type.
- Expand manufacturer and importer certification requirements under the Consumer Product Safety Act to all products governed by the CPSC.
- Increase penalty caps and allow for the seizure of assets.
- Require importers of record to post larger bonds.

These proposals will raise the cost of noncompliance. Strengthened enforcement measures may make participation in voluntary best practices programs the most cost effective option for companies doing business in the U.S.

Agency Response

Congress and Federal agencies have already begun to implement the IWG's recommendations on import safety. Congress passed legislation reforming FDA in September 2007, providing the agency with additional funds and an expanded international presence. Legislation reforming the CPSC was enacted on August 14, 2008, granting the agency many of the powers it had requested. Both bills passed with broad bipartisan support.

Regulatory agencies have also been quick to respond. CBP began to reform import security measures in late 2001, and some of the IWG's proposals are based on current CBP programs. The FDA issued a Food Protection Plan in November 2007 and the CPSC followed with an Import Safety Strategy in July 2008.[14] All three agencies are currently involved in rulemaking to update import safety measures. These reform efforts are detailed below.

While not covered in this article, other agencies play roles that are just as critical. The U.S. Department of Agriculture ensures the safety of imported meat, poultry, and eggs through a near 100% inspection rate. The National Highway Traffic Safety Administration regulates the safety of motor vehicles in the U.S. The Environmental Protection Agency governs the use of pesticides and other toxins. These, and many other agencies, work constantly to ensure that domestic and imported products alike meet strong U.S. safety standards.

[14] The FDA Food Safety Plan is available at www.fda.gov/oc/initiatives/advance/food/plan.pdf. The CPSC Import Safety Strategy is available at www.cpsc.gov/businfo/importsafety.pdf.

Customs and Border Protection

CBP is at the front line of the fight to ensure import safety. The agency patrols the borders and works to prevent unsafe and illegal goods from entering the U.S. CBP is responsible for enforcing in excess of 400 laws for 40 different agencies.[15] Some FDA and USDA officials have already been relocated to CBP's National Targeting Center to increase coordination over the enforcement of these statutes. Many of the changes recommended by the IWG had already been initiated by CBP in response to post 9/11 security concerns. CBP rulemaking and legislative changes over the past several years have expanded CBP's reach overseas and increased collaboration with the private sector.

In November 2001 the U.S. Customs Service (now CBP) started the Customs-Trade Partnership Against Terrorism (C-TPAT) to encourage companies to voluntarily improve supply chain security. This voluntary approach was extended to trade compliance with the creation of the Importer Self-Assessment (ISA) program in 2002. Overseas inspections were also greatly increased. CBP started the Container Security Initiative (CSI) in January 2002 to pre-screen containerized shipments before they are sent to U.S. CSI is now active in 58 ports around the world. Specifics on individual CBP import safety programs are set forth below.

Customs-Trade Partnership Against Terrorism

C-TPAT was created shortly after the attacks of September 11 to increase supply chain security. C-TPAT is a voluntary program under which companies agree to implement, document and validate an array of supply chain security measures. Information on minimum security requirements for foreign manufacturers, importers, and different types of carriers is available on the CBP website.[16]

C-TPAT is a three tiered program, with increased benefits for companies meeting higher requirements.[17] Benefits include priority processing, reduced inspections, and eligibility for the Importer Self

[15] Self, Jeffrey D. "Southwest Border Division Chief, CBP, Testifies with Other DHS Representatives on the Law Enforcement and Investigative Responsibilities of the Department of Homeland Security," March 11, 2008. http:www.cbp.gov.

[16] Information on C-TPAT minimum security requirements is available at www.cbp.gov/xp/cgov/trade/cargo_security/ctpat/security_criteria/.

[17] Certified C-TPAT members begin at tier one. Companies who undergo validation by CBP may receive tier 2 or tier 3 status depending on the findings of the validation and the risk posed by the imports.

Assessment program. CBP also assigns supply chain specialists to assist companies in improving and validating supply chain security measures. C-TPAT is a voluntary program and CBP does not conduct unannounced validations. Over 8,000 companies currently participate in C-TPAT, slightly over 250 of which are Tier III certified members.[18]

C-TPAT members who trade between NAFTA members are also eligible to participate in CBP's Free and Secure Trade (FAST) program. FAST offers dedicated lanes, priority processing, and reduced inspections for drivers carrying goods into the U.S. from Canada or Mexico. To participate in FAST, all parties involved in the supply chain (manufacturer, importer, carrier, and driver) must be certified under C-TPAT.

Importer Self Assessment Program

CBP conducts focused assessments of importers to monitor trade compliance. In June 2002, CBP introduced the voluntary ISA program. ISA is a public-private partnership in which an importer agrees to implement compliance and record keeping measures in exchange for less CBP oversight. According to the CBP, benefits of joining ISA include "less CBP intrusion," "reduced cargo examinations," and "company control over the process."[19] In order to be eligible to participate in the program importers must be a member of C-TPAT, maintain adequate records on customs transactions, complete an ISA questionnaire, and sign a memorandum of understanding (MOU) with CBP in which the importer agrees to certain reporting and recordkeeping requirements.[20]

ISA marks a shift towards a more collaborative approach with the business community. Companies can now avoid CBP Focused Assessment audits by voluntarily participating in the ISA program. The IWG recommended that agencies expand voluntary best practice programs like ISA, and the CPSC is currently working on developing a similar program for product safety.

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[18] Departmental Advisory Committee on Commercial Operations of the Bureau of Customs and Border Protection, May 9, 2008.

[19] Customs and Border Protection Office of International Trade. "Trade Facilitation & Administration, Partnership Programs, Importer Self- Assessment Program," February 28, 2008. www.cbp.gov/linkhandler/cgov/trade/trade_programs/trade_compliance/importer_self_assessment/c_tpat_seminar.ctt/c_tpat_seminar.pdf.

[20] The memorandum of understanding is available at www.cbp.gov/linkhandler/cgov/trade/trade_programs/trade_compliance/importer_self_assessment/isanotice.ctt/isanotice.pdf.

SAFE Port Act

Congress moved in 2006 to expand U.S. security procedures outside of U.S. borders with the SAFE Port Act. The act ordered the development of testing systems in foreign ports to detect nuclear and radiological material. The Secretary of Homeland Security was given authority to ban imports from ports that refused to cooperate. In 2007 Congress amended the SAFE Port Act to require that all cargo be screened for radiation before it departs for the U.S.

The SAFE Port Act built on CBP's efforts to make private companies the first line of defense for import safety. The C-TPAT program was written into statute and provided with funding through 2012. The Act also directed CBP to increase electronic pre-lading filing requirements for sea shipments to the U.S. This directive was echoed in the IWG's November 2007 Action Plan for Import Safety.

Ten plus two

In 2002 the CBP began requiring importers to submit certain information contained in shipping manifests 24 hours before lading. Dubbed the "24 Hour Rule," this requirement allowed CBP to target high-risk shipments before they left for American shores. CBP, at the behest of Congress and the IWG, is now poised to dramatically expand pre-lading reporting requirements under the agency's proposed "10+2" rule. The proposed rule will require importers to submit 10 additional data elements before lading and sea carriers to submit another 2 (hence 10+2). The period for comment has closed and CBP hopes to issue a final rule in September 2008.[21] 10+2 has been designated a Priority Initiative by Secretary Chertoff.[22]

CBP has estimated that approximately 11 million import shipments and 1,200 carriers will be covered by the 10+2 rule. Official cost estimates for the program over the next ten years range from 2.8-5.3 billion dollars.[23] The 5.3 billion cost estimate assumes a 24 hour delay in the first year of

[21] Departmental Advisory Committee on Commercial Operations of the Bureau of Customs and Border Protection, May 9, 2008.

[22] *Id.*

[23] Industrial Economics, Incorporated. "Importer Security Filing and Additional Carrier Requirements: Regulatory Assessment and Initial Regulatory Flexibility Analysis for the Notice of Proposed Rulemaking," December 3, 2007, at ES-7.

implementation and 12 hour delay for each year thereafter.[24] However, importers have expressed concern that the rule could cost far more. The American Association of Exporters and Importers estimates that the new rules will add three additional days to the wait between when containers are stuffed and when a carrier can leave port.[25]

At present CBP plans to require all importers, including C-TPAT members, to submit the 10 data elements. *See* Table below. Importers and carriers who are found to be non-compliant will face large fines. Under the proposed rule importers who fail to properly submit the 10 required data elements will face liquidated damages equal to the value of the shipment. Carriers will face a maximum $100,000 fine for improperly filing container status messages and a $50,000 for failing to file a stow plan.[26] However, CBP plans to allow importers to report what they "reasonably believe to be true" if they are not "reasonably able to verify such information."[27] CBP has also stated that it will phase in the 10+2 requirements over time.[28]

Additional Proposed Pre-lading Reporting Requirements

Importers	**Sea Carriers**
1) Manufacturer or supplier's name and address 2) Seller's name and address 3) Buyer's name and address 4) First shipment recipient's name and address 5) Container stuffing location 6) Container consolidator or stuffer's name and address 7) Importer of record number 8) Consignee number 9) Country of origin 10) Six digit or higher HTSUS number	1) Vessel stow plan 2) Daily container status messages

[24] Industrial Economics, Incorporated. "Importer Security Filing and Additional Carrier Requirements: Regulatory Assessment and Initial Regulatory Flexibility Analysis for the Notice of Proposed Rulemaking," December 3, 2007, at ES-11.

[25] American Association of Exporters and Importers. "Comments in response to the Notice of Proposed Rulemaking," March 17, 2008.

[26] 73 FR 90.

[27] *Id.*

[28] Departmental Advisory Committee on Commercial Operations of the Bureau of Customs and Border Protection, February 13, 2008.

Consumer Product Safety Commission

The CPSC is the primary regulatory agency governing consumer product safety in the U.S. The agency struggled last year to cope with a series of high profile product recalls and import safety scares. Stung by criticism from Congress and consumer advocacy groups, the Commission is now in the process of overhauling its approach towards import safety. The Commission is working with CBP to better inspect and track imports. A new Import Surveillance Division was announced in March 2008, placing full time CPSC employees at major U.S. ports. The CPSC has increased lead screening and is upgrading its testing facilities. The Commission has charted a path forward for continued reforms with the issuance of its new Import Safety Strategy.

The CPSC has called for greater legislative authority to compliment intra-agency reforms. Commissioner Thomas H. Moore provided Congress with a series of legislative recommendations in July 2007.[29] His proposals included allowing the CPSC to revoke import licenses of repeat offenders, restrict exportation of recalled products, and require manufacturers to place identifying information on products. He also called for the civil penalties cap to be eliminated. Acting CPSC Chairman Nancy Nord included similar legislative recommendation in her July 2007 Product Recall, Information and Safety Modernization ("PRISM") Act proposal to Congress.

Import Safety Strategy

In July 2008 the CPSC issued a four-pronged Import Safety Strategy.[30] The Import Safety Strategy noted that while imports account for less than half of consumer products sold in the U.S., they accounted for over 82% of product recalls in Fiscal Year (FY) 2007.[31] The Import Safety Strategy, echoing themes in the IWG report, calls for increased collaboration with the private sector and foreign governments as well as greater enforcement authority.

The Commission's plans for public-private cooperation mirror efforts by CBP. The CPSC is currently working with CBP to develop a voluntary

[29] The legislative proposals of Commissioner Thomas H. Moore are available at www.cpsc.gov/PR/moore_proposals1.pdf.

[30] The Consumer Product Safety Commission's Import Safety Strategy is available at: http://www.cpsc.gov/businfo/importsafety.pdf.

[31] Consumer Product Safety Commission. *Import Safety Strategy*, July 2008, at 3.

importer safety compliance program in the mold of the ISA program. The CPSC will publish a guide on good importer practices later this year. In addition, the Commission is providing technical advice to the Toy Industry of America in its efforts to create a certification program for toys.

Public-private partnerships are to be backed up by stronger penalties and increased inspections. The CPSC has requested (and received) increased enforcement authority from Congress. The Commission recently created an import surveillance division that will place full-time CPSC inspectors at U.S. ports for the first time.[32] Ten million dollars have been designated for renovating laboratories in order to improve the CPSC's testing capabilities.[33]

However, the CPSC is still operating from a position of weakness. Commissioner Moore testified to Congress in 2007 that the CPSC has less than 90 field investigative staff.[34] In comparison, the Food and Drug Administration has approximately 15 times as many field investigators and still achieves an inspection rate of only 0.7%.[35]

The Import Safety Strategy, recognizing the Commission's limitations, calls for using CBP as a "force multiplier".[36] The CPSC can now use CBP laboratories to test products and use CBP's Automated

CPSC "Key Strategies"

"I. Engage the private sector and foreign governments to foster both compliance with relevant safety standards and adoption of more effective techniques of identifying potential product hazards."

II. Build safety assurances into the production processes by promoting the use of safety standards by manufacturers, and verifying compliance through third-party testing and inspections where appropriate.

III. Prevent unsafe products through strategically redeploying CPSC resources according to principles of hazard analysis and risk management to target surveillance and inspection of the distribution chain.

IV. Identify and quickly remove product hazards in the market and provide real-time communications to consumers, foreign governments, and the private sector."

Import Safety Strategy, July 2008

[32] Consumer Product Safety Commission. *Import Safety Strategy*, July 2008.

[33] *Id.*

[34] Legislative Proposals of Commissioner Thomas H. Moore, July, 2007. www.cpsc.gov/PR/moore_proposals1.pdf.

[35] *Id.*

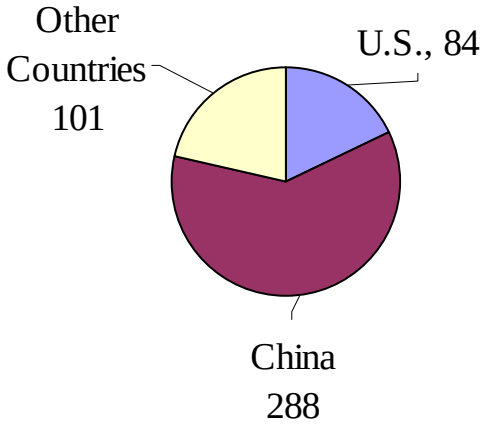
[36] Consumer Product Safety Commission. *Import Safety Strategy*, July 2008.

Commercial Environment (ACE) system to track imports.

The Import Safety Strategy also calls for increased cooperation with foreign governments to prevent unsafe imports from reaching U.S. shores. The CPSC already has MOUs with 15 countries, and the agency is in the process of negotiating new agreements.[37] MOUs with foreign countries allow the CPSC to increase information sharing and coordinate enforcement activities with foreign officials.

China has been the central focus of the CPSC's international outreach efforts. This focus is due to China's position as a top exporter of manufactured goods and the fact that 61% of all recalls issued by the CPSC in FY 2007 were for goods made in China (see chart below).[38] In September 2007 the CPSC and China's General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) signed the Statement on Enhancing Consumer Product Safety.[39] The two agencies agreed to work together to improve the safety of fireworks, toys, lighters, and electrical products exported to both the U.S. and China. AQSIQ agreed to implement a comprehensive plan to eliminate the use of lead paint on toys. The CPSC agreed to provide web-based translations of U.S. product safety regulations in Chinese. CPSC and EU delegations will jointly visit China in September 2008 to discuss further cooperation on product safety.

CPSC Product Recalls by Country of Origin FY 2007



[37] Consumer Product Safety Commission. *Import Safety Strategy*, July 2008.

[38] Consumer Product Safety Commission. *Import Safety Strategy*, July 2008, at 3.

[39] CPSC product safety standards in Chinese can be found at www.cpsc.gov/businfo/intl/newusreq.html.

Consumer Product Safety Improvement Act

The Consumer Product Safety Improvement Act (Pub. L. 110-314) was signed into law on August 14, 2008. The law revises the statutes governing the CPSC for the first time since 1990.[40] The law includes many of the recommendations contained in the IWG's Action Plan for Import Safety and Acting CPSC Chairman Nancy Nord's proposed Product Recall, Information and Safety Modernization (PRISM) Act.[41] The Consumer Product Safety Improvement Act provides the Commission with a large increase in resources. Appropriations for the Commission are increased to $118.2 million in 2010, and the agency is directed to raise the number of its full time personnel to at least 500 by 2013, with some of the new hires assigned to port and overseas facility inspections.

The statutory cap on penalties was raised more than 10-fold from $1.25 million to $15 million for a series of related violations and from $5,000 to $100,000 for a single violation. The Act makes it unlawful to sell products subject to corrective action. In addition, the Act requires for the first time that all products designed for children 12 years or younger be certified by an accredited third-party tester before being imported or released into commerce. The requirement will take effect 90 days after the CPSC establishes and publishes rules for accrediting third-party testers.

Most of Acting Chairman Nancy Nord's legislative requests were adopted in the Consumer Product Safety Improvement Act. Congress declined to make a violation of a voluntary standard a prohibited act. Instead, the Consumer Product Safety Improvement Act requires the CPSC to enact mandatory regulations for certain children's products that are at least as protective as voluntary standards. Congress' approach maintains the delineation between voluntary and mandatory standards. This is consistent with the IWG's recommendation that the government incentivize companies to voluntarily adopt best practices while severely punishing those who fail to meet baseline mandatory regulations.

The course laid out in the CPSC's Import Strategy and Pub. L. 110-314 adheres to the approach taken by the CBP and advocated by the IWG. Public-private partnerships are seen as a way to encourage best practices, while enhanced enforcement measures will be used to deter malfeasance. At

[40] Nancy A. Nord, Acting Chairman. Testimony before the Committee on Energy and Commerce Subcommittee on Commerce, Trade and Consumer Protection, U.S. House of Representatives, November 6, 2007. Available at http://www.cpsc.gov/pr/nord110607.pdf.

[41] The proposed "Product Recall, Information and Safety ("PRISM") Act is available at http://www.cpsc.gov/pr/PRISM.pdf.

the core of this change, however, is a recognition that import security no longer begins and ends at the U.S. border. The fight for import safety is pushing the CPSC and other agencies to extend their regulatory work beyond U.S. borders and collaborate with foreign governments.

Authority Requested by CPSC Chairwomen Nancy Nord Product Recall, Information and Safety Modernization Act	**Pub. L. 110-314**
Ban the sale of voluntarily recalled products	☑
Require manufacturers to test and certify that their products meet all applicable mandatory CPSC safety standards	☑
Increase civil and criminal penalties, including allowing for asset forfeiture	☑
Require importers, retailers, distributors, and manufacturers to provide names and addresses of all parties involved in the production or supply of a product if requested by the CPSC	☑
Expand CPSC's authority to share information with local governments and foreign agencies	☑
Require the CPSC to notify manufacturers 15 days in advance of releasing product safety information[42]	☑
Expand the prohibition on stockpiling to all statutes administered by the CPSC	☑
Allow CPSC to require bonding sufficient the cost of destroying noncompliant products	**X**[43]
Make it a prohibited act to manufacture a product that violates voluntary standards	**X**

Food and Drug Administration

The FDA is responsible for regulating medical products and 80 percent of food products in the U.S. The agency is confronted with challenges similar to those facing the CPSC. High profile import safety scares involving diverse products such as pet food, toothpaste, and the drug

[42] U.S. statute previously required that manufacturers be notified 30 days before the CPSC released product safety information.

[43] Pub. L. 110-314 requires the CPSC to identify products where current bonding requirements are insufficient to cover the cost of destruction and to suggest alternative bonding requirements. The Comptroller General is directed to study whether it is feasible to require bonding sufficient to cover the cost of destruction and to report their findings to Congress by February, 2009.

Heparin have shaken American's confidence in imported food and drugs. Rapid import growth has stretched thin FDA resources, and the agency is able to inspect only a small fraction of imports falling under its authority.[44] The FDA realized that, as with consumer products, a border centric approach towards food and drug import safety is no longer workable.

In May 2007 Secretary Leavitt and Commissioner von Eschenbach called on the FDA to create a comprehensive food safety plan. The result was FDA's November 2007 Food Protection Plan. The Food Protection Plan contained 10 legislative proposals and 38 needed FDA actions. Assistant FDA Commissioner for Food Protection David Acheson explained the change in approach as a shift in "focus from reacting to food safety problems when they occur to preventing them from occurring in the first place."[45]

The FDA's plan included many of the same themes as the IWG report released that same month. FDA officials called for the agency to "push the borders out" by expanding the FDA's presence in foreign countries and increasing cooperation with foreign regulators.[46] The Food Protection Plan proposed greater public-private collaboration by allowing accredited third parties to test and certify products. And, finally, the FDA plan called for enhanced enforcement through improved risk-based inspections, mandatory recall authority, increased fines, and the ability to ban imports from foreign companies who fail to cooperate fully with FDA inspectors.

Third Party Certification

The FDA's most ambitious public-private partnership initiative is its proposed third-party certification program. The Food Protection Plan requested authority to accredit "highly qualified third parties for voluntary food inspections."[47] The FDA issued a Federal Register notice in April 2008 seeking comments on a proposed third-party inspection program for food, feed, and pet food.[48] Many companies have already begun to require

[44] Legislative Proposals of Commissioner Thomas H. Moore, July 2007. www.cpsc.gov/PR/moore_proposals1.pdf.

[45] "New Directions in Food Protection, An interview with David W.K. Acheson, M.D." *Food Safety Magazine*, February/March 2008. www.foodsafetymagazine.com/articlePF.asp?id=2313&sub=sub1.

[46] *Id.*

[47] Food and Drug Administration. *Food Protection Plan*, November 2007, at 18.

[48] 73 FR 1789.

that their suppliers be certified as meeting certain safety standards. The FDA's proposal is designed to officially recognize and build on these efforts.

Third-party inspections will be voluntary, as the "FDA does not have the authority to require third-party inspection."[49] Instead, the FDA hopes to incentivize companies to voluntarily participate in the program. The FDA states that while "certification by an independent third party would not replace an FDA inspection," it will likely speed customs clearance.[50] The FDA is currently working on developing guidance standards for accrediting third-party testing facilities and certification programs.[51]

In July 2008 the FDA issued its first draft guidance for "Voluntary Third-Party Certification Programs for Foods and Feeds."[52] The draft guidance lists twelve attributes required for a third-party to be certified by the FDA. To be certified, third-parties would need to be able to carry out inspections, field audits, and collect and analyze samples. The FDA proposes requiring that third-party inspectors be required to meet the same qualification standards as FDA Consumer Safety Officers. Third-party inspectors would be required to, at a minimum, certify that products meet FDA regulations. To prevent conflicts of interest, third-party certifiers would not be allowed to have shared ownership or financial interests with the companies they inspect.

On July 9, 2008, Secretary Leavitt announced a pilot third-party certification program to "help HHS/FDA learn how to evaluate third-party certification programs and implement them in the field."[53] The pilot program will apply only to farm-raised shrimp. The FDA will work with companies currently certifying foreign seafood processors to assess compliance with FDA seafood regulations.

In addition to voluntary certification programs, the FDA is asking for authority to require certain high risk products be certified before importation. This request is similar to the requirement recently enacted by Congress that all children's products by certified by independent third-parties. It is not clear yet whether Congress is willing to grant similar authority to the FDA.

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[49] U.S. Department of Health and Human Services. "Fact Sheet on Investing in FDA'S Transformation," June 9, 2008. www.hhs.gov/news/facts/fdatransformation.html.

[50] 73 FR 1789.

[51] U.S. Department of Health and Human Services. "Fact Sheet on Investing in FDA'S Transformation," June 9, 2008. www.hhs.gov/news/facts/fdatransformation.html.

[52] The FDA draft "Voluntary Third-Party Certification Programs for Foods and Feeds" is available at www.fda.gov/oc/guidance/thirdpartycert.html.

[53] U.S. Department of Health and Human Services. "HHS Announces New International Programs to Enhance Drug and Food Safety," July 9, 2008. www.hhs.gov/news/press/2008pres/07/20080709a.html.

Twelve Required Attributes for 3rd Party Certification

1. "Authority of the Certification Body"
2. "Qualifications and Training for Inspectors"
3. "Elements of an Effective Inspection Program"
4. "Inspection Audit Program"
5. "Cooperation with FDA and Other Appropriate Government Officials When safety Problems Occur"
6. "Compliance and Corrective Action"
7. "Industry Relations"
8. "Resources"
9. "Self-Assessment of the Overall Certification Program"
10. "Laboratories"
11. "Notification to FDA"
12. Conflict of Interest"

Voluntary Third-Party Certification Programs for Foods and Feeds
July 2008

Enhanced Enforcement

While calling for increased public-private cooperation, the FDA is also requesting enhanced enforcement authority. During a July 1, 2008 press conference, Secretary Leavitt called for the FDA to be granted authority to carry out mandatory recalls of food products and ban imports from manufacturers that deny access to FDA inspectors. The FDA has announced that it will resurrect a rule proposal requiring non-compliant imports to be stamped with the words "Refused Entry into the United States."[54] (The FDA proposed a similar rule in 2001, but the proposal was withdrawn in August, 2002.)[55]

The FDA's legislative proposals (listed below) are consistent with the IWG's recommendations. If enacted, these proposals will increase the cost of non-compliance, expand the FDA's reach overseas, and allow the agency to more easily block or seize non-compliant imports. In addition, mandatory third-party certification and new fees would shift part of the cost of increased enforcement to the private sector. Businesses face the challenge of increasing regulatory requirements and strong penalties for non-

[54] U.S. Department of Health and Human Services. "Fact Sheet on Investing in FDA'S Transformation," June 9, 2008. www.hhs.gov/news/facts/fdatransformation.html.

[55] 66 FR 6502.

compliance. These challenges will provide a strong incentive for companies to adopt best practices and consider participation in public-private partnerships.

FDA Requested Legislative Authority

Enforcement

- "Refuse admission of imports if firm unduly delayed, limited, or denied access to their facilities."
- "Authority to destroy medical products refused admission into the United States."
- "Explicit extraterritorial jurisdiction."
- "Empower FDA to issue a mandatory recall of food products when voluntary recalls are not effective."
- "Asset forfeiture for criminal offenses."

Additional Controls

- "Require preventive controls to prevent intentional adulteration by terrorists or criminals at points of high vulnerability in the food chain."
- "Issue additional preventive controls for high-risk foods."
- "Require food facilities to renew their FDA registrations every two years, and allow FDA to modify the registration categories."
- 'Accredit independent third parties for voluntary food inspections."
- "Require certification of designated high-risk products as an additional condition of importation."
- "Give FDA expedited access to food records during emergencies."

Fees

- "Require new reinspection fee from facilities that fail to meet current good manufacturing practices."
- "Require new food and animal feed export certification fee to improve the ability of U.S. companies to export their products."
- "Allow implementation of a user fee for reviewing Direct to Consumer advertising."

Investing in FDA's Transformation, June 9, 2008
U.S. Department of Health & Human Services (www.hhs.gov)

INTERNATIONAL COOPERATION

FDA officials have launched a concerted effort to increase its presence overseas. The FDA has already received authorization to establish a new office in China and the State Department has issued approval for a FDA office in India.[56] The FDA states that it is also preparing to establish "additional FDA permanent foreign offices over the next two years (such as in Central America, Middle East, Europe)."[57]

At the same time, the FDA is in the process of developing and expanding cooperative agreements with foreign governments and regulatory agencies. HHS signed two landmark memorandums of agreement (MOAs) with China in 2007 to improve the safety of imported food and medical products. The MOA on the Safety of Food and Feed committed HHS and AQSIQ to work together to ensure Chinese exports meet U.S. quality and safety standards.[58] Under the agreement, Chinese exporters will be required to register with AQSIQ and agree to annual inspections to ensure their products meet U.S. standards. AQSIQ will also develop a system to electronically notify the FDA whether shipments are certified by AQSIQ and meet FDA standards.

The second agreement signed with China in 2007 was the MOA on the Safety of Drugs and Medical Devices.[59] HHS and China's State Food and Drug Administration (SFDA) agreed in the MOA to establish a bilateral mechanism to help ensure imported medical products meet standards for safety and effectiveness. SFDA will develop a certification system to ensure exports to the U.S. meet FDA mandatory standards, Chinese manufacturers of certain drugs and medical devices will be required to register with SFDA, and SFDA will notify the FDA if a manufacturer has been determined to be out of compliance with SFDA standards. In addition, the SFDA has agreed to notify the FDA within 24 hours if it determines a product sent to the U.S. could pose a serious health risk.

The FDA and HHS have also pursued agreements with emerging trading partners, such as Vietnam. U.S. agricultural imports from Vietnam

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[56] U.S. Department of Health and Human Services. "Fact Sheet on Investing in FDA'S Transformation," June 9, 2008. www.hhs.gov/news/facts/fdatransformation.html.

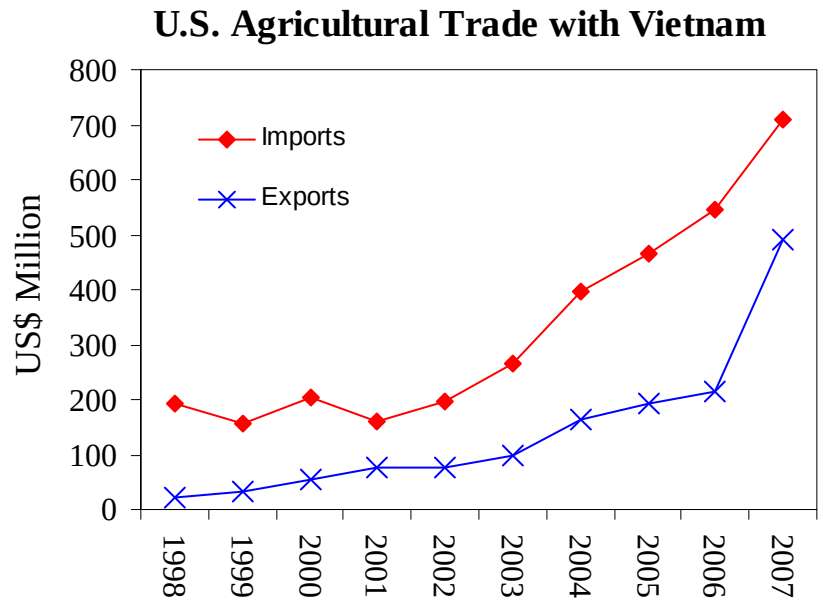
[57] *Id.*

[58] The MOA on the Safety of Food and Feed is available at www.globalhealth.gov/news/agreements/ia121107b.html.

[59] The MOA on the Safety of Drugs and Medical Devices is available at www.globalhealth.gov/news/agreements/ia121107a.html.

grew 266% in the five year period from 2003 to 2007 (see graph below).[60] This period was also punctuated with import safety challenges, and several states restricted imports of Vietnamese catfish in 2005 after finding traces of banned antibiotics. On June 24, 2008, HHS concluded an MOU with Vietnam on food, animal, feed, and medical product safety.[61] Under the agreement HHS and the Ministry of Health of the Socialist Republic of Vietnam agree to share food safety and regulatory information, provide technical training, and continue a review of Vietnamese fishery export safety.

More ambitious cooperative agreements are being pursued with advanced developed countries. On July 9, 2008, HHS Secretary Leavitt announced a new inspection initiative with the European Union and Australia.[62] The initiative will start as a pilot project involving joint inspections of drug-manufacturing facilities. The FDA has stated that if the pilot project succeeds, it may be expanded to cover manufacturers of other products.[63] This initiative has the potential to greatly expand the scope of U.S. collaboration with foreign governments in the area of food and drug safety.



[60] U.S. International Trade Commission Dataweb statistics. http://dataweb.usitc.gov.

[61] The U.S.-Vietnam MOU Concerning Food, Animal, Feed, and Medical Products is available at www.globalhealth.gov/news/agreements/ia062408.html.

[62] U.S. Department of Health and Human Services. "HHS Announces New International Programs to Enhance Drug and Food Safety," July 9, 2008. www.hhs.gov/news/press/2008pres/07/20080709a.html.

[63] *Id.*

THE WAY FORWARD

The overhaul of U.S. import safety regulations called for by the IWG has already begun. The CPSC, FDA, and CBP have all initiated intra- and inter-agency projects to begin implementing recommendations in the IWG Action Plan for Import Safety. Congress recently provided the CPSC with much of the additional authority it had requested. The Food and Drug Administration Act of 2007 provided the FDA with additional authority, and the agency has already provided Congress with a list of additional legislative proposals.

These actions are resulting in a fundamental shift in the United States' strategy on import safety. Agencies are moving beyond U.S. borders in an attempt to strike at the source of import safety violations. Public-private partnerships are being created to better utilize the expertise and resources of the private sector in the fight for import safety. These policies are being backed up by enhanced enforcement measures, including increased inspections and strong penalties for noncompliance.

> "Our new strategy must be to extend our borders and ensure that quality and safety are built into the products we import. We will do this by rewarding producers that have products certified to meet our standards. Their goods will receive expedited entry into our country. We will make clear to those who don't that they can expect enhanced scrutiny."
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> *Secretary Michael Leavitt, Department of Health and Human Services July 9, 2008, "Safety at the Speed of Life" (www.hhs.gov)*

The change in the U.S. approach towards import safety is creating new challenges and opportunities for companies doing business in the U.S. Borders are providing fewer protections from oversight and enforcement action by U.S. regulators. The FDA has already requested "explicit extraterritorial jurisdiction" and authority to ban imports from companies that do not fully cooperate with FDA inspectors. Bilateral cooperative agreements are further increasing U.S. regulators' presence overseas. Programs such as CBP's 10+2 proposal will present companies with additional challenges, requiring importers and carriers to rethink the way they do business.

The challenge of dealing with U.S. regulators' increased presence abroad is made more pressing by enhanced enforcement measures. The Consumer Product Safety Improvement Act increased fines by more than 10 fold and allowed for the forfeiture of assets. The FDA has requested similar authority and both agencies have promised to expand inspections. Third party certification programs and public-private partnerships will allow the CPSC, FDA, and CBP to ratchet up inspections of companies who do not participate in these programs. In this new regulatory environment, having an effective compliance program is more critical than ever.

The regulatory changes also provide companies with new opportunities. CBP has already created a range of voluntary compliance programs such as C-TPAT, ISA, and FAST that allow companies to expedite customs clearance. The FDA is in the process of creating a third-party certification program to allow certified products to move more easily into the U.S. A pilot certification program for farm-raised shrimp was announced this July. The CPSC is also developing public-private partnerships, and is working on a product safety compliance program based on CBP's ISA program. These programs can provide companies a way to sidestep increased inspections and border delays.

The rise in number of voluntary compliance programs, however, raises important questions. Given that most programs offer expedited entry as a primary benefit, it is unclear whether it will become necessary for companies to join all or most programs to enjoy rapid entry into the U.S. Companies will need to carefully assess the costs and benefits associated with joining a wide range of voluntary compliance programs and choose a combination of programs that will allow them to succeed and thrive in the new regulatory environment.

The reforms recommended by the IWG and outlined above are an important step forward in the United States' struggle to ensure consumer safety in a globalized economy. However, the nascent reform effort is not complete. Many of the most innovative and sweeping reforms have yet to be implemented. The challenge for businesses will be to continually adapt to a rapidly changing regulatory environment in coming years while taking advantage of the opportunities inherent in these reforms.

List of Acronyms

ACE	Automated Commercial Environment
AQSIQ	General Administration of Quality Supervision, Inspection and Quarantine
CBP	U.S. Customs and Border Patrol
CPSC	U.S. Consumer Product Safety Commission
CSI	Container Security Initiative
C-TPAT	Customs-Trade Partnership Against Terrorism
EU	European Union
FAST	Fast and Secure Trade
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
HHS	U.S. Department of Health and Human Services
ISA	Importer Self-Assessment Program
IWG	Interagency Working Group on Import Safety
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
NAFTA	North American Free Trade Agreement
PRISM	Product Recall, Information and Safety Modernization Act
USDA	U.S. Department of Agriculture

Major Pending initiatives

Agency	CBP	FDA	CPSC
Program	10+2	3rd party testing	3rd party testing
Participation	Mandatory	Voluntary	Mandatory
What it covers	Importers and carriers	Food and feed	Children's products
Status	September 2008 target date for final rule	Pilot program started for certain products	Takes effect 90 days after CPSC issues relevant rules