

August 2009

# CONSUMER SAFETY

## Better Information and Planning Would Strengthen CPSC's Oversight of Imported Products



GAO

Accountability \* Integrity \* Reliability



Highlights of [GAO-09-803](#), a report to congressional committees

## Why GAO Did This Study

The growing volume of consumer products imported into the United States has strained the resources of the Consumer Product Safety Commission (CPSC), challenging the agency to find new ways to ensure the safety of these products. The Consumer Product Safety Improvement Act (CPSIA) mandated that GAO assess the effectiveness of CPSC's authorities over imported products. GAO's objectives were to (1) determine what is known about CPSC's effectiveness in using these authorities, (2) compare CPSC's authorities with those of selected U.S. agencies and international entities, and (3) evaluate CPSC's plans to prevent the entry of unsafe consumer products. To address these objectives, GAO analyzed CPSC and other agencies' and entities' authorities, reviewed literature on consumer product safety, and compared CPSC's planning efforts with criteria for effective planning practices.

## What GAO Recommends

GAO recommends that CPSC (1) ensure expeditious implementation of key CPSIA provisions; (2) take several actions to strengthen its ability to target shipments of unsafe consumer products, such as resolving issues with CBP for obtaining more data on incoming shipments; and (3) develop a long-term plan for ensuring the safety of consumer products entering the United States, including long-term plans for international engagement. CPSC agreed with these recommendations.

[View GAO-09-803 or key components.](#)  
For more information, contact Alicia Cackley at (202) 512-8678 or [cackleya@gao.gov](mailto:cackleya@gao.gov).

## CONSUMER SAFETY

### Better Information and Planning Would Strengthen CPSC's Oversight of Imported Products

#### What GAO Found

GAO found broad consensus that CPSC's authorities over imported consumer products have the potential to be effective. However, CPSC has made limited progress in measuring the effectiveness of its authorities, and CPSC's ability to implement these authorities has been constrained by competing priorities and limited resources, as well as by delays in implementing key provisions of CPSIA. CPSC's presence at U.S. ports is limited and, in order to identify potentially unsafe products, it must work closely with U.S. Customs and Border Protection (CBP), which faces pressure to quickly move shipments into commerce. CPSC does not have access to key CBP import data it could use to target incoming shipments for inspection, and it has not updated its agreements with CBP to clarify each agency's roles and responsibilities. CPSC's activities at U.S. ports could be strengthened by better targeting incoming shipments for inspection and by improving CPSC's coordination with CBP. Otherwise, CPSC may not be able to carry out key inspection activities efficiently or to effectively leverage its enforcement priorities with CBP.

Select federal agencies and foreign governments provide lessons for strengthening CPSC's implementation of its authorities, particularly with respect to border surveillance and information sharing among countries. Both USDA and FDA have more robust border surveillance activities than CPSC because they obtain more data on incoming shipments, have more staff working at U.S. ports, use more developed programs to target risks, and use information technology systems that are integrated with other agency-based and CBP systems to effectively leverage their enforcement priorities with CBP. Other agencies have found that timely CBP import data integrated with other agency surveillance data is useful in screening incoming shipments for potential safety violations. In addition, officials at FDA and USDA have found that efforts to educate overseas industries and governments on U.S. safety standards could reduce the number of unsafe products that reach U.S. consumers. GAO also found broad consensus that continued coordination and information sharing among governments and multilateral organizations can improve the effectiveness of product safety frameworks. CPSC has increased its efforts to coordinate with these other entities, particularly China, but lacks a comprehensive plan for international engagement.

CPSC has established annual plans, but lacks a long-term plan with key goals to prevent the entry of unsafe products. CPSC has not yet updated its agencywide Strategic Plan to reflect new authorities granted in CPSIA. This may inhibit CPSC's ability to appropriately allocate any potential increases in agency resources or to address the safety of imported products through international means. An updated Strategic Plan may also help to ensure that CPSC has the requisite compliance and analytical staff to support the full range of CPSC's international efforts.

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**Abbreviations**

ACCC	Australian Competition and Consumer Commission
AIS	Automated Import Information System
APEC	Asian-Pacific Economic Cooperation
APHIS	Animal and Plant Health Inspection Service
AQSIQ	General Administration for Quality Supervision, Inspection, and Quarantine
CBP	Customs and Border Protection
CCC	China Compulsory Certification
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CIQ	Customs, Inspection and Quarantine
CNCA	Certification and Accreditation Administration of China

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CPSC	Consumer Product Safety Commission
CPSIA	Consumer Product Safety Improvement Act
DG SANCO	Directorate General for Health and Consumers
ETSI	European Telecommunications Standards Institute
EC	European Commission
EU	European Union
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GPSD	General Product Safety Directive
ICPHSO	International Consumer Product Health and Safety Organization
ITDS	International Trade Data System
METI	Ministry of Economy, Trade, and Industry (Japan)
MOU	memorandum of understanding
NHTSA	National Highway Traffic Safety Administration
OASIS	Operational and Administrative System for Import Support
OECD	Organization for Economic Cooperation and Development
PHIS	Public Health Information System
PREDICT	Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting
USDA	U.S. Department of Agriculture
USTR	Office of the United States Trade Representative
WTO	World Trade Organization

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United States Government Accountability Office  
Washington, DC 20548

August 14, 2009

The Honorable John D. Rockefeller IV  
Chairman  
The Honorable Kay Bailey Hutchison  
Ranking Member  
Committee on Commerce, Science, and Transportation  
United States Senate

The Honorable Henry A. Waxman  
Chairman  
The Honorable Joe Barton  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The growing volume of consumer products—such as toys, household appliances, and children’s apparel—imported into the United States has strained the resources of the Consumer Product Safety Commission (CPSC) and is challenging the agency to find new ways to ensure the safety of these products. From 1998 to 2007, the value of consumer products imported into the United States increased about 101 percent, with products from China (which includes Hong Kong) nearly quadrupling over that same period to constitute about 42 percent of all imported consumer goods. In addition to the growing value of imports, the number and variety of consumer products have been increasing. Consumer products are becoming more technically complex and sophisticated, and they increasingly are not “from” any one place but rather consist of parts and components from any number of countries.

Increasing imports of consumer products gained national attention in 2007. During that year, CPSC announced 473 recalls, the most in 10 years, and 389 of the recalls (or about 82 percent) involved products imported into the country. As a result, 2007 became known to some as “the year of the recall.” The number of product recalls in fiscal year 2008 was even higher. These record numbers of recalls have raised the issue of whether CPSC can ensure the safety of products that are increasingly manufactured overseas.

While the number of consumer products imported into the United States has been increasing, CPSC has become progressively smaller in terms of staff and resources. The commission has not had a full slate of five

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commissioners since 1986 and has not been authorized to fund more than three commissioner positions since 1993. In fiscal year 2008, CPSC had 396 full-time employees, compared with 480 full-time employees in fiscal year 1997. CPSC's fiscal year 2008 appropriation totaled about \$80 million, and CPSC's fiscal year 2009 appropriation was not passed until March 2009—about 6 months into the fiscal year 2008—due to a congressional continuing budget resolution.

In response to the high-profile recalls of imported products in 2007, as well as concerns that CPSC was inadequately staffed and funded to enforce existing product safety laws, Congress passed the Consumer Product Safety Improvement Act (CPSIA), which became law on August 14, 2008.<sup>1</sup> CPSIA was intended to update and strengthen CPSC by authorizing expanded funding, mandating increased staffing subject to available appropriations, and enhancing existing CPSC authorities, including those regarding product safety standards, recalls, reporting, and administrative penalties. In addition, CPSIA introduced several new statutory tools to address the safety of imported products. Because Congress was concerned that there may be remaining gaps in U.S. product safety law or unforeseen consequences of CPSIA with respect to imported products, CPSIA mandated GAO to review a range of issues regarding CPSC's authorities to prevent the entry of unsafe products into the United States.<sup>2</sup> Because CPSIA was recently passed, and CPSC has not had time to implement it fully, we responded to the mandate by (1) determining how CPSC assesses the effectiveness of its authorities in preventing the entry of unsafe consumer products and determining what is known about CPSC's effectiveness in using these authorities, (2) comparing certain aspects of CPSC's authorities with those of selected U.S. agencies, (3) comparing CPSC's authorities with those of selected international entities, and (4) evaluating CPSC's plans to prevent the entry of unsafe consumer products in the future.

To determine the effectiveness of CPSC's import safety authorities, we examined CPSC data and interviewed CPSC officials to learn how the agency measures and assesses its own effectiveness. We conducted extensive document reviews on consumer product safety generally and import safety specifically. We interviewed legal professionals and

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<sup>1</sup>Pub. L. No. 110-314, 122 Stat. 3016 (Aug. 14, 2008).

<sup>2</sup>See Consumer Product Safety Improvement Act of 2008 § 225, Pub. L. No. 110-314, 122 Stat. at 3070.

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consumer and industry representatives to obtain their perspectives on the effectiveness of CPSC's authorities. We also interviewed officials from other federal agencies involved in product safety at the international level, including U.S. Customs and Border Protection (CBP), the Office of the United States Trade Representative (USTR), and the Departments of State and Commerce. We visited a U.S. port of entry to observe CPSC import surveillance activities and CPSC's interaction with CBP staff at the port. We also visited CPSC's Product Testing Laboratory in Gaithersburg, Maryland, to observe laboratory testing that supports import safety activities. Furthermore, we conducted a comparative analysis of CPSC's authorities to prevent the entry of unsafe consumer products to similar authorities of selected U.S. federal agencies and selected countries. For our comparative analysis of U.S. federal agencies, we selected agencies that regulate the safety of products used by consumers and that possess recent, relevant experience with import safety. Specifically, we selected the U.S. Department of Agriculture (USDA), the Department of Health and Human Services' Food and Drug Administration (FDA), and the Department of Transportation's National Highway Traffic Safety Administration (NHTSA). We conducted interviews with agency officials and reviewed agency statutes, regulations, and other documents. For our comparative analysis of other countries' product safety authorities, we selected Australia, Canada, China, the European Union (EU), and Japan for review.<sup>3</sup> We developed a set of questions concerning consumer product safety authorities, practices, and procedures and worked through the U.S. Department of State to distribute the questions to appropriate contacts at U.S. embassies overseas and, in some cases, to foreign embassies in Washington, D.C. We conducted interviews with product safety officials from Canada, the EU, and Japan, and with U.S. officials at the embassies in Australia, Canada, and China. We received written responses to our questions from the U.S. embassies in Australia, Canada, and China; from officials with the Embassy of Japan in Washington, D.C.; and from consumer product safety officials in the EU. We also reviewed documents regarding product safety in the selected countries and reports on consumer product safety prepared by the Organization for Economic Cooperation and Development (OECD). To evaluate CPSC's plans to prevent the entry of unsafe products in the future, we reviewed CPSC's 2010 Performance Budget Request and compared CPSC's planning efforts with guidance GAO has developed to assess implementation of the

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<sup>3</sup>The EU is a customs territory, but we refer to it as a country in this report for ease of reference.



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Government Performance and Results Act. Appendix I provides a more detailed description of our objectives, scope, and methodology.

We conducted this performance audit from October 2008 to August 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

CPSC was created in 1972 under the Consumer Product Safety Act to regulate consumer products that pose an unreasonable risk of injury; to assist consumers in using products safely; and to promote research and investigation into product-related deaths, injuries, and illnesses.<sup>4</sup> The Consumer Product Safety Act consolidated existing federal safety regulatory activity related to consumer products within CPSC. As a result, in addition to general responsibilities for protecting consumers against product hazards, the duties and functions under the following four statutes were transferred to CPSC:<sup>5</sup>

- the Flammable Fabrics Act, which among other things, authorizes CPSC to prescribe flammability standards for clothing, upholstery, and other fabrics;<sup>6</sup>
- the Federal Hazardous Substances Act, which establishes the framework for the regulation of substances that are toxic, corrosive, combustible, or otherwise hazardous;<sup>7</sup>

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<sup>4</sup>Pub. L. No. 92-573, 86 Stat. 1207 (Oct. 27, 1972) (classified, as amended, at 15 U.S.C. §§ 2051 et seq.).

<sup>5</sup>See Consumer Product Safety Act § 30, Pub. L. No. 92-573, 86 Stat. 1207, 1231 (classified, as amended, at 15 U.S.C. § 2079).

<sup>6</sup>Act of June 30, 1953, ch. 164, 67 Stat. 111 (classified, as amended at 15 U.S.C. §§ 1191 et seq.).

<sup>7</sup>Pub. L. No. 86-613, 74 Stat. 372 (July 12, 1960) (classified, as amended, at 15 U.S.C. §§ 1261 et seq.). Under the act, CPSC is authorized to declare a substance to be a hazardous, and to regulate the labeling of substances which are declared to be hazardous. 15 U.S.C. § 1261(f)(1)(B) and § 1262.

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- the Poison Prevention Packaging Act of 1970, which authorizes CPSC to prescribe special packaging requirements to protect children from injury resulting from handling, using, or ingesting certain drugs and other household substances;<sup>8</sup> and
  - the Refrigerator Safety Act of 1956, which mandates CPSC to prescribe safety standards for household refrigerators to ensure that the doors thereof can be opened easily from the inside.<sup>9</sup>

CPSC has also subsequently been charged with administering the Virginia Graeme Baker Pool and Spa Safety Act, which establishes mandatory safety standards for swimming pool and spa drain covers, as well as a grant program to provide states with incentives to adopt pool and spa safety standards.<sup>10</sup> In addition, CPSC has been charged with administering the Children's Gasoline Burn Prevention Act, which establishes safety standards for child-resistant closures on all portable gasoline containers.<sup>11</sup>

Thus, CPSC's jurisdiction is extremely broad, covering thousands of types of products. According to CPSC, this jurisdiction covers over 100,000 different manufacturers and generally includes all consumer products except food, drugs, and cosmetics, which are regulated by FDA; pesticides, which are regulated by the Environmental Protection Agency; automobiles and other on-road vehicles, which are regulated by the Department of Transportation; flotation devices, which are regulated by the Coast Guard; and firearms, tobacco, and alcohol, which are regulated by the Department of Justice.

The Consumer Product Safety Act established CPSC as an independent regulatory commission. The rationale for establishing independent commissions such as CPSC includes these assumptions: (1) long-term

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<sup>8</sup>Pub. L. No. 91-601, 84 Stat. 1670 (Dec. 30, 1970) (classified, as amended, at 15 U.S.C. §§ 1471 et seq.).

<sup>9</sup>Act of August 2, 1956, c. 890, 70 Stat. 953 (classified, as amended, at 15 U.S.C. §§ 1211 et seq.). Under the act, it is unlawful for any person to introduce or deliver for introduction into interstate commerce any household refrigerator, unless it is equipped with a device enabling the door to be opened from the inside and which conforms with the standards prescribed by CPSC. 15 U.S.C. § 1214.

<sup>10</sup>Pub. L. No. 110-140, Title XIV, 121 Stat. 1492, 1794 (Dec. 19, 2007) (classified at 15 U.S.C. §§ 8001 et seq.).

<sup>11</sup>Pub. L. No. 110-278, 122 Stat. 2602 (July 17, 2008) (classified as a note to 15 U.S.C. § 2056).

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appointment of commissioners would promote stability and develop expertise, (2) independent status would insulate the commissioners from undue economic and political pressures, and (3) commissioners with different political persuasions and interests would provide diverse viewpoints. The act provides for the appointment by the President of five commissioners for staggered 7-year terms. However, no more than three commissioners have served at one time since 1986, and the commission has been led by two commissioners since 2006.<sup>12</sup> One of these commissioners is designated the Chairman, who directs all the executive and administrative functions of the agency.

CPSC was designed as a complement to tort law, under which one may seek compensation for harm caused by another's wrongdoing. The threat of legal action under tort law plays an important role in assuring that companies produce safe products. However, tort law is primarily a postinjury mechanism, and foreign manufacturers are usually outside of the U.S. tort law system. Therefore, CPSC has certain authorities intended to prevent unsafe consumer products from entering the market in the first place.

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## CPSC Protects Consumers Primarily through Product Safety Standards

Under several of the acts that it administers, CPSC primarily protects consumers from unreasonable risk of injury or death by issuing regulations that establish performance or labeling standards for consumer products. These standards are often referred to as "mandatory standards."<sup>13</sup> CPSC issued 38 mandatory standards between 1990 and 2007. If CPSC determines that there is no feasible standard that would

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<sup>12</sup>CPSC has not been authorized to receive appropriations for more than three commissioners since fiscal year 1993. See Pub. L. No. 102-389, Title III, 106 Stat. 1571, 1596 (Oct. 6, 1992). Section 202(b) of CPSIA repealed this provision, effective August 14, 2009. We have previously found that CPSC could benefit by changing to a single administrator because some of the basic assumptions about the need to have commissioners had not been realized. See GAO, *Consumer Product Safety Commission: Administrative Structure Could Benefit from Change*, GAO/HRD-87-47 (Washington, D.C.: Apr. 9, 1987).

<sup>13</sup>Products subject to such mandatory standards are often referred to as "regulated products." Regulated products that do not comply with mandatory standards are often referred to as "violative products."

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adequately protect the public from danger, CPSC may issue regulations to ban the manufacture and distribution of the product.<sup>14</sup>

Many consumer products are subject to voluntary standards. These voluntary standards, which are often established by private standard-setting groups, do not have the force of law.<sup>15</sup> However, many voluntary standards are established with input from consumer groups and industry and, as a result, are often referred to as “consensus standards.” In addition, the 1981 amendments to the Consumer Product Safety Act require CPSC to defer to a voluntary standard—rather than issuing a mandatory regulation—if CPSC determines that the voluntary standard adequately addresses the hazard and that there is likely to be substantial compliance with the voluntary standard.<sup>16</sup> Between 1990 and 2007, CPSC worked with industry and others to develop 390 voluntary standards related to consumer products.

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## Import Safety Responsibility within CPSC

CPSC’s policy on imported products states that the commission will seek to ensure that importers and foreign manufacturers, as well as domestic manufacturers, distributors, and retailers, carry out their obligations and responsibilities under the five acts. The commission will also seek to establish, to the maximum extent possible, uniform import procedures for products subject to the acts the commission administers.<sup>17</sup>

Two CPSC staff offices have primary responsibility for carrying out this policy: the Office of International Programs and Intergovernmental Affairs

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<sup>14</sup>See 15 U.S.C. § 2057; 15 U.S.C. § 1262; 15 U.S.C. § 1193; and 15 U.S.C. § 1472. Banned products include unstable refuse bins, extremely flammable contact adhesives, lead-containing paint, consumer patching compounds containing asbestos, artificial emberizing materials containing asbestos, and lawn darts. See 16 C.F.R. §§ 1301-1306.

<sup>15</sup>Although voluntary standards do not have the force of law, every manufacturer of a consumer product must inform the commission if they obtain information that reasonably supports the conclusion that the product is defective such that it presents a substantial product hazard, as defined below. 15 U.S.C. § 2064(b). Such a report may include information the manufacturer obtained about a product outside the United States if it is relevant to products sold or distributed in the United States. 16 C.F.R. § 1115.12(f).

<sup>16</sup>15 U.S.C. § 2056(b)(1).

<sup>17</sup>16 C.F.R. § 1009.3(a). When it appears that application of this policy is unduly burdening the free flow of goods, the commission states that it may consider modifications that alleviate such burdens, but not those that do not assure the consumer the same protection from unsafe foreign goods as from unsafe domestic goods. 16 C.F.R. § 1009.3(i).

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and the Office of Compliance and Field Operations. The Office of International Programs and Intergovernmental Affairs was created in 2004 to provide CPSC with a more comprehensive and coordinated effort at the international, federal, state, and local levels in developing and implementing consumer product safety standards. The office conducts activities and creates strategies aimed at ensuring greater import compliance with recognized American safety standards. A major emphasis of this program is encouraging foreign manufacturers to establish product safety systems as an integral part of the manufacturing process. The office is also involved in coordinating international consumer product safety efforts with such U.S. federal agencies as the Departments of Commerce and State. It also ensures that CPSC regulatory efforts are consistent with U.S. international trade obligations by coordinating with the United States Trade Representative. As of July 2009, the office was staffed by four full-time employees.

The Import Surveillance Division within the Office of Compliance and Field Operations was created in March 2008 and has primary responsibility for CPSC's product surveillance program at ports of entry. CPSC, in cooperation with other appropriate federal agencies, is required to maintain a permanent product surveillance program for preventing the entry of unsafe consumer products into the commerce of the United States.<sup>18</sup> Previously, CPSC operated the import surveillance program through product safety investigators staffed in multiple regions throughout the country who included among their investigative responsibilities ports of entry in their particular regions. Over the years, the numbers of CPSC regional offices and product safety investigators have been reduced. CPSC states that these product safety investigators continue to support the import surveillance program, operating in 48 locations throughout the country. The Import Surveillance Division marks the first permanent, full-time presence of CPSC investigators at key ports of entry, according to CPSC. As of July 2009, the division was staffed by 11 full-time employees—9 compliance investigators located at seven ports of entry and a Director and Supervisory Compliance Investigator located at CPSC headquarters in Bethesda, Maryland. The compliance investigators are supported by compliance officers, technical staff, attorneys, and other staff at CPSC headquarters. There are over 300 ports of entry in the United States.

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<sup>18</sup> 15 U.S.C. § 2066(h).

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## CPSC Works Closely with CBP at Ports of Entry

CBP notifies CPSC and other regulatory agencies with import safety responsibilities of the arrival of imported products and provides information about those products. Under several of the acts that CPSC administers, CPSC identifies potentially unsafe products and requests that CBP set them aside for CPSC examination. CPSC has implemented programs at some ports for CBP to target certain categories of products based on their Harmonized Tariff Schedule (HTS) codes.<sup>19</sup> CBP has import specialists at major ports who specialize in certain commodities, including consumer products. They analyze manifest, entry, and other import data to identify shipments for CPSC review.<sup>20</sup> In some instances, CBP will independently identify shipments for CPSC examination. Once samples are delivered to or taken by CPSC for examination, CPSC may detain the shipment pending further examination and testing, conditionally release the shipment to the importer's premises pending examination and testing, or release the shipment to the importer outright. Compliance investigators examine the sample to determine whether it

- complies with the relevant mandatory standard(s);
- is accompanied by a certification of compliance with the relevant product safety standard that is supported by testing, in some instances by a third party;
- is or has been determined to be an imminently hazardous product;<sup>21</sup>

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<sup>19</sup>Harmonized Tariff Schedule is an extension of the six-digit Harmonized Commodity and Coding System, the internationally recognized classification system for commodities. The Harmonized Tariff Schedule is a statutory authority codified at 19 U.S.C. § 1202.

<sup>20</sup>A manifest is a document or compilation of documents required by law for most conveyances arriving in United States territory. A manifest provides information describing the cargo on board the arriving conveyance. *See* 19 U.S.C. § 1431; 19 C.F.R. § 4.7; 19 C.F.R. § 122.48; and 19 C.F.R. § 123.4.

<sup>21</sup>An imminently hazardous consumer product is a consumer product that presents imminent and unreasonable risk of death, serious illness, or severe personal injury. 15 U.S.C § 2061(a). CPSC states that it has not used its authority to refuse admission of an imminently hazardous consumer product because it requires filing an action in U.S. District Court, which is a resource-intensive process. Instead, CPSC states that it works cooperatively with the manufacturer to remove the product from the market, which can include seizure and detention of products at the port by CBP, if necessary.

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- has a product defect that presents a substantial product hazard;<sup>22</sup> or
  - is produced by a manufacturer who failed to comply with CPSC inspection and recordkeeping requirements.

If compliance investigators decide that further testing of a sample is necessary, they will send the sample to the CPSC Product Testing Laboratory or to a CBP laboratory.<sup>23</sup> If the sample is found to violate any of the above criteria, CPSC is authorized to refuse admission of the shipment. Consumer products that are refused admission will be destroyed unless the Secretary of the Treasury allows the product to be exported.<sup>24</sup> CPSC may instead instruct CBP to seize shipments upon finding a prohibited act, which according to CPSC is the most common outcome when a violation is discovered. The importer may be subject to civil or criminal penalties.<sup>25</sup> See figure 1 for an overview of CBP and CPSC's current process for conducting inspections at ports of entry.

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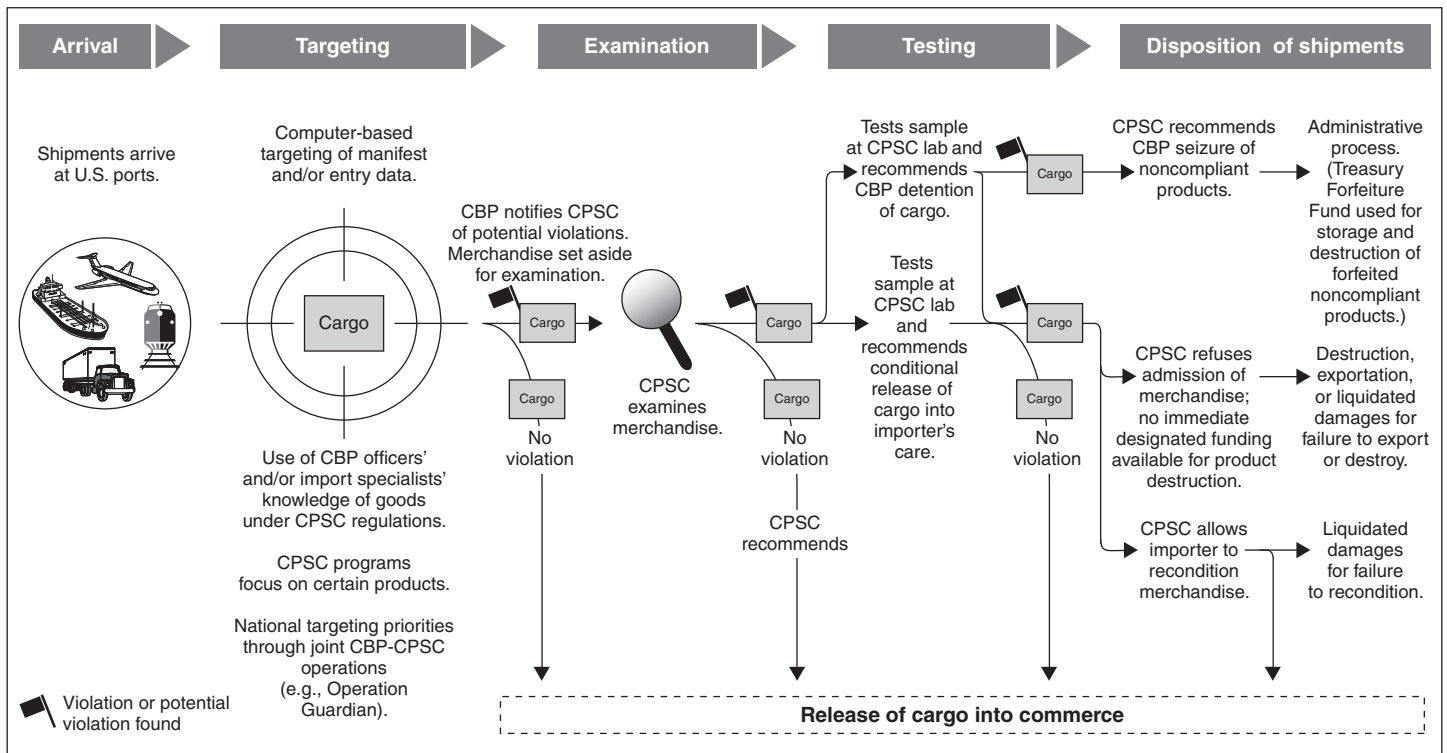
<sup>22</sup>A product may present a substantial product hazard if it fails to comply with a mandatory standard or is otherwise found to have a defect, and if the product creates a substantial risk of injury to the public.

<sup>23</sup>CPSC officials told us that there is statutory authority under the Tariff Act of 1930, revised, that places certain obligations and time constraints on CBP for issuing detention notices and making decisions regarding detained products, but that authority expressly exempts from those requirements detentions made where the decision as to admissibility resides with an agency other than CBP. *See* 19 U.S.C. § 1499. Accordingly, CPSC officials stated, neither CBP nor CPSC is bound by those procedural constraints when merchandise is detained under CPSC authority.

<sup>24</sup>15 U.S.C. § 2066(e). CBP has the authority to supervise the exportation of refused consumer merchandise. *See* 19 C.F.R. § 158.45.

<sup>25</sup>Effective August 14, 2009, the civil penalty maximum amounts are \$100,000 for each individual violation and \$15 million for a related series of violations. 15 U.S.C. § 2069(a)(1). The criminal penalties for a knowing and willful violation of the Acts that CPSC enforces could result in up to 5 years in prison and fines of up to \$250,000 for individuals and \$500,000 for corporations for each offense. 15 U.S.C. § 2070(a).

**Figure 1: Overview of CBP and CPSC's Current Process for Inspections of Consumer Goods at U.S. Ports of Entry**



Sources: GAO analysis of CBP and CPSC information; Art Explosion (clip art).

CPSC relies on CBP to carry out key import surveillance activities at ports of entry. In addition to its numerous antiterrorism and trade responsibilities, CBP faces pressure from the international trade community to quickly move compliant shipments into commerce. Factors such as the high volume of containers, financial incentives for longshoremen to unload ships quickly, and the limited amount of time CBP has to identify and examine cargo contribute to the challenges CBP faces in facilitating commerce.<sup>26</sup> In addition, CBP enforces regulations for 45 other federal agencies. Importers place pressure on CBP to correctly


<sup>26</sup>For example, according to CBP's 2009-2013 Trade Strategy, on a typical day CBP processes over 85,000 shipments of goods worth \$5.2 billion. However, CBP indicated that after steady growth in imports the past few years, the overall value of imports entering the United States has decreased to \$900 billion as of mid-fiscal year 2009, a decrease of \$200 billion from fiscal year 2008. CBP also projects that the value of imports for fiscal year 2009 will decline to as low as \$1.7 trillion, which was the level in 2004-2005.



identify violations because the cost of storing CBP-detained products at privately run container examination stations is high. CPSC surveillance activity with CBP at ports of entry has fluctuated in recent years. For example, as shown in figure 2, the number of samples that CPSC collected for examination dropped from 1,348 in fiscal year 1999 to 710 and 514 in fiscal years 2002 and 2003 and has still not reached the 1999 level, despite an increase in imports of products under CPSC jurisdiction of about 101 percent.

**Figure 2: CPSC Surveillance Activity at Ports of Entry Compared to Imports of Consumer Goods, 1998-2008**

	Import samples collected by CPSC	Total import dollars (in billions) under CPSC jurisdiction and percentage from China and Hong Kong
1998	1,222	22.0% \$318.3
1999	1,348	22.5% 356.1
2000	870	23.1% 413.1
2001	880	24.8% 390.8
2002	710	28.4% 410.8
2003	514	31.8% 442.3
2004	888	34.7% 510.1
2005	685	38.0% 564.3
2006	616	40.3% 603.9
2007	748	42.1% 638.9
2008	1,171	42.8% \$638.7

 Total imports under CPSC jurisdiction  
 Portion of imports from China (which includes Hong Kong)

Sources: GAO analysis of CPSC and U.S. International Trade Commission data.

Note: Data on import samples are reported on a fiscal-year basis. Data on imports under CPSC jurisdiction are reported on a calendar-year basis.

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**CPSC’s Authorities Have the Potential to Be Effective, but Implementation Is Limited by Incomplete Information on Imported Products and Resource and Practical Constraints**

Consensus exists that CPSC’s authorities have the potential to be effective in preventing the entry of unsafe products into the United States. Although CPSC has made limited progress in measuring the effectiveness of its authorities over imported products, the agency believes that new authorities granted in CPSIA should increase compliance with mandatory standards and enhance its ability to monitor compliance with voluntary standards at ports of entry. Private industry sources and others we interviewed generally said that CPSC’s authorities are potentially effective but that implementation is limited by competing priorities and resource and practical constraints.

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**Consensus Exists That CPSC Has Broad Authority over Imported Products, but CPSC’s Assessment of Effectiveness Has Been Limited**

There is consensus among those we interviewed that CPSC has broad authority to prevent the entry of unsafe consumer products into the United States, particularly in light of new authorities that strengthen its ability to enforce mandatory standards and protect consumers from unsafe products subject to voluntary standards at ports of entry. As described above, CPSC primarily protects consumers from unreasonable risk of injury by promulgating mandatory standards and working with private standard-setting organizations to promulgate voluntary standards, and CPSC has broad authority to enforce those standards at ports of entry. In particular, CPSC and other product safety experts believe CPSC’s enforcement of mandatory standards at ports of entry will be strengthened because now all products subject to a mandatory standard under any law administered by CPSC must be accompanied by a certification of compliance that is supported by product testing.<sup>27</sup> In addition, every

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<sup>27</sup> 15 U.S.C. § 2063(a)(1). Section 14 of the Consumer Product Safety Act (classified, as amended, at 15 U.S.C. § 2063) has always required that manufacturers and private labelers of consumer products subject to a product safety standard issue a certificate that certifies that such product complies with the applicable mandatory standard. The certificate must be based on a test of each product or upon a reasonable testing program. However, CPSC told us that they did not enforce the certification requirement at the ports of entry, but rather focused on the compliance of the product with the underlying mandatory standard. Furthermore, the previous certification requirement in the Consumer Product Safety Act applied only to products subject to mandatory standards promulgated under the act rather than each of the laws administered by the CPSC.

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manufacturer or private labeler of a product subject to a children’s product safety rule must have samples of the product tested by an accredited third-party laboratory for conformance with the applicable mandatory standard.<sup>28</sup> For many years, CPSC focused import surveillance activities on enforcement of certain mandatory standards for consumer products, primarily toys, fireworks, and lighters.<sup>29</sup> The new testing requirement puts greater burden on industry to ensure that products comply with mandatory standards. If implemented properly, CPSC should be able to use the testing and certification requirements to strengthen surveillance of regulated products at ports of entry.

Furthermore, CPSC believes its ability to monitor compliance with voluntary standards at ports of entry will be strengthened by new authority to create a “substantial product hazard list.”<sup>30</sup> As described above, many consumer products are produced according to voluntary standards. In addition, many products are subject to no standards. CPSC primarily protects consumers from unsafe products subject to voluntary or no standards by declaring them “substantial product hazards” when the products have a defect that creates a substantial risk of injury. However,

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<sup>28</sup>15 U.S.C. § 2063(a)(2). A children’s product is defined as a product primarily intended for children age 12 and under. 15 U.S.C. § 2052(a)(2). CPSC is in the process of defining rules by which accredited third party laboratories are eligible to conduct testing for conformance with certain mandatory standards; that is, the laboratories do not receive a blanket accreditation from CPSC. CPSC is required to establish requirements for periodic audits of accredited third party laboratories and may withdraw accreditation under certain circumstances. 15 U.S.C. § 2063(d)(1) and (e).

<sup>29</sup>CPSC provided three reasons why surveillance is focused on these products. First, the HTS may not be specific enough to accurately identify specific products subject to CPSC mandatory standards. Generally speaking, the HTS is used to describe all goods in trade. Importers use a code from the HTS to identify goods in shipments. If the code is not specific enough, then CPSC states that it has difficulty targeting specific products. Second, CPSC states that the mandatory standards for these consumer products are written in a manner that allows for easy identification of violative products at the port. Third, CPSC states that fireworks and lighters, as well as toys, are among the most common consumer products imported into the United States, so it conducts increased port surveillance to prevent unsafe products from entering the market.

<sup>30</sup>CPSC may by rule determine that certain characteristics of a product or class of products, by their absence or presence, shall be deemed a substantial product hazard if (1) the characteristics are readily observable and addressed by voluntary standards, (2) the voluntary standards have been effective in reducing the risk of injury, and (3) there is substantial compliance with such standards. 15 U.S.C. § 2064(j). Characteristics of products often used as examples for the substantial product hazard list include the presence of drawstrings in hooded sweatshirts intended for children and the absence of a ground fault circuit interrupter in electric hairdryers.

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CPSC faces difficulty at ports of entry identifying defects in products subject to voluntary or no standards because defects are not always apparent until the product has been used by the public.<sup>31</sup> With implementation of the substantial product hazard list, CPSC will be able to target new shipments and refuse admission of products subject to voluntary standards that it has already determined have a defect constituting a substantial risk of injury.<sup>32</sup>

Despite this broad authority, CPSC has made limited progress in measuring the effectiveness of its authorities to prevent the entry of unsafe consumer products. CPSC measures the performance of its import surveillance program by the number of product samples collected and by the number of samples ultimately found to be unsafe and therefore seized. CPSC is now considering altering this metric so that it will track all shipments that CPSC investigators examine, rather than just those samples collected and tested. Furthermore, CPSC measures the performance of its Office of International Programs and Intergovernmental Affairs by the number of outreach events conducted. These metrics provide measures of the output of program staff but do not necessarily provide accurate measures of the effectiveness of the programs. In the 1990s, CPSC used industry compliance with mandatory standards as an alternative basis for measuring the agency's effectiveness, what it termed the Comprehensive Plan. The plan was designed to examine the compliance of these products with mandatory standards on a periodic basis and then identify problem areas for focusing limited agency resources. CPSC did not continue the Comprehensive Plan after the mid-1990s because the data indicated that compliance was high, and CPSC believed that the plan did not help it address problems with noncompliant products. CPSC sought information from the public in 2008 to develop a new methodology that would replace the Comprehensive Plan. CPSC reported receiving two responses, but

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<sup>31</sup>Pursuant to 15 U.S.C. § 2066(b), an importer may demand a full administrative hearing to contest a refusal of admission made on the basis of a CPSC staff-level substantial hazard determination. CPSC states that this is a resource-intensive process. *See* 16 C.F.R. § 1025. With the substantial product hazard list, CPSC states that if its determination to refuse admission is challenged by the importer, the only issue at the administrative hearing would be whether the product is on the substantial product hazard list.

<sup>32</sup>Products subject to no standards cannot, by law, be included on the list. CPSC staff told us that it is very difficult to judge whether a product is defective when there is no standard with which to compare the product. CPSC staff stated that this is particularly true at ports of entry where there is pressure to move products quickly into commerce. Moreover, manufacturing or design defects in products are not always readily apparent and can take some time to surface, sometimes only after consumers have used the product.

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commission staff stated that they did not pursue further work because the responses did not address their needs for developing new performance measures. While CPSC recognizes the need for outcome-oriented performance measures and has taken steps to develop new measures, without these measures, CPSC may not be able to determine how effective its authorities are for preventing the entry of unsafe products.

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### Implementation of CPSC's New Authorities to Prevent Entry of Unsafe Products into the United States Has Been Delayed

While CPSC has broad authority to prevent the entry of unsafe consumer products into the United States, there have been delays in implementing new authorities CPSC received in CPSIA. According to CPSC, the agency has more than 40 rulemakings to conduct under CPSIA, including approximately 20 rulemakings to initiate or complete by August 2010, which has contributed to the delay in implementing the act. In particular, the two new authorities discussed above—certain testing and certification requirements and the substantial product hazard list—have not been implemented. CPSC issued a stay of enforcement of certain testing and certification requirements until February 10, 2010, delaying implementation of these standards and raising questions among manufacturers subject to this requirement.<sup>33</sup> CPSC stated that it did not complete the rulemaking process because it was unable to respond to innumerable inquiries from industry seeking relief from the testing requirement at a time when the agency faced severe resource limitations because it was operating under the prior year's budget. In addition, to date CPSC has not conducted rulemaking to implement the substantial product hazard list. The effectiveness of CPSC's new authorities will not be clear until CPSC completes its rulemaking and demonstrates the ability to enforce these regulations.

Another factor contributing to delays in implementation of new authorities is the need for CPSC to balance its mission to protect consumers with industry interests. CPSC's mission is to protect the public from unreasonable risk of injury associated with consumer products, and CPSC is also required to work with industry to develop product safety standards, collect information about unsafe products, and conduct recalls. Private companies have expressed concerns about CPSC's implementation of CPSIA, particularly the expanded testing and certification requirements, which, as noted earlier, helped contribute to CPSC's decision to delay

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<sup>33</sup>See "Notice of Stay of Enforcement of Testing and Certification," 74 *Fed. Reg.* 6396 (Feb. 9, 2009).

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enforcement of these provisions. In public comments on CPSIA, several industry representatives commented that the certification requirements are duplicative and could cause them to incur tremendous costs due to the complexity of their business operations. For example, industry representatives stated that large manufacturers produce hundreds of thousands of variations of their products that may require testing and certification, while small manufacturers may have limited product lines across which to spread costs.

In addition to industry concerns, CPSC has also faced concerns from consumers that CPSC's implementation of CPSIA has not, at times, fulfilled the consumer protection goals of the act. In one recent example, consumer groups challenged CPSC's advisory opinion that CPSIA's provisions prohibiting the sale of children's products that contain certain chemicals called phthalates did not apply retroactively to inventories existing prior to the effective date of the prohibitions. These groups were concerned that if the phthalate prohibitions were not applied retroactively, consumers would continue to be exposed to unsafe products in the marketplace. The consumer groups filed suit in a federal district court seeking a declaratory judgment that CPSC's advisory opinion, which was issued at the request of certain wholesale and retail entities, was contrary to CPSIA, and thus violated the Administrative Procedure Act. The district court held that the phthalate prohibitions in CPSIA unambiguously applied to existing inventory and set aside CPSC's opinion.<sup>34</sup>

According to some industry representatives we interviewed, retailers are taking the lead in product testing and certification in response to industry's uncertainty over how CPSC will enforce CPSIA provisions. These representatives believed that retailers are ahead of CPSC in this regard. For example, one industry group said that although CPSC has stayed enforcement of many of its certification requirements, retailers still require suppliers to provide certifications, and some retailers had more stringent lead standards than CPSIA. According to industry groups, U.S. companies, particularly retailers, have an incentive to institute and enforce stringent product safety standards because selling products that cause injury or death can have negative impacts on their brands. The U.S. tort system that exposes companies selling unsafe products to lawsuits also helps to ensure that companies comply with product safety standards. To

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<sup>34</sup>See *Natural Resources Defense Council, Inc., and Public Citizen, Inc., vs. U.S. Consumer Product Safety Commission*, 597 F.Supp 2d. 370 (S.D.N.Y. 2009).

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respond to industry concerns about how to comply with safety standards under current and prior consumer product safety laws, some industry groups have also developed or are developing their own testing and certification programs.<sup>35</sup> CPSC indicated that while these types of programs can help improve compliance with safety standards, there are limits to how well this type of industry self-regulation can be used to protect consumers. They indicated that there is a trade-off between consumer protection and industry cooperation; if the requirements are too onerous, companies might not participate in these voluntary programs. Balancing the interests of both consumer and industry participants adds complexity in completing CPSC's implementation of CPSIA.

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### CPSC Needs Better Targeting Information to Strengthen Enforcement with CBP at Ports of Entry

CPSC needs better targeting information to strengthen its ability to identify risks from imported products and communicate inspection priorities to CBP. CPSC and CBP have a cooperative relationship at ports of entry. That is, while CPSC relies on CBP to carry out key import surveillance and targeting activities at ports, CBP relies on CPSC to communicate the greatest risks and its inspection priorities among consumer products. However, CPSC has not developed formal systems for assessing risks and focusing inspection activities with CBP. Furthermore, CPSC does not have access to information that would enable the agency to effectively target potentially unsafe imported products for inspection.

### Updated MOU with CBP Would Be Useful as CPSC Develops Its Risk Assessment Methodology

In the past, CPSC has generally used informal systems to target risks from imported products and to conduct operations with CBP at ports of entry with some positive results. CPSC has generally been effective using its informal systems to target certain products for inspection, according to several product safety experts we interviewed. For instance, CPSC has targeted imported fireworks for increased inspections during the summer months. CPSC has also had positive results from its participation in Operation Guardian, a multiagency effort to combat the increasing importation of substandard, tainted, and counterfeit products that pose a

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<sup>35</sup>For example, the Retail Industry Leaders Association, a U.S. trade group, has recently partnered with the United Kingdom's retailers association, the British Retail Consortium, to develop global manufacturing standards and risk management practices. In addition, two trade groups that specialize in children's products—the Toy Industry Association and the Juvenile Products Manufacturers Association—have developed their own certification programs. The American Fireworks Standards Laboratory has, for several years, had a testing and certification program for the fireworks industry in response to the failure of over half of all imported fireworks to meet federal safety standards and to CPSC's seizure of these products in the 1980s.

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health and safety risk to consumers.<sup>36</sup> Another program that CPSC stated has produced positive results is an expansion of the CBP Importer Self-Assessment Program that was initiated in October 2008. The expansion, known as the Importer Self-Assessment Product Safety Pilot, aims to prevent unsafe imports from entering the United States by requiring volunteer companies to meet specified internal monitoring criteria in exchange for priority in testing, reductions in the testing conducted, and access to CPSC training programs.<sup>37</sup> However, as discussed above, CPSC targeted relatively few imported consumer products for inspection under its informal system.

CPSIA requires CPSC to establish a formal risk assessment methodology that will require updating the terms of the relationship between the agencies. CPSC and the former U.S. Customs Service (now CBP) established a memorandum of understanding (MOU) in 1990 that serves as the foundation for the working relationship of the agencies for enforcement of CPSC's authorities over imported products. For example, the MOU provides for "the joint conduct of a mutually agreed number of high-visibility, intensive inspection operations annually." This provision is consistent with CPSC's informal system for targeting risks. The MOU is now out of date and does not reflect anticipated changes to CPSC's relationship with CBP required under CPSIA. CPSIA requires CPSC, by August 2010, to develop a methodology for identifying shipments of imported consumer products that are likely to violate import provisions enforced by CPSC.<sup>38</sup> A CPSC official told us that, as part of the agency's work to develop this risk assessment methodology, CPSC plans to create a flowchart of the current product-entry process to identify gaps in any current CPSC authorities to stop unsafe products at the ports. The official noted that CPSC anticipates completing the flowchart later this year. Updating the 1990 MOU between CPSC and CBP and thereby revisiting the

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<sup>36</sup>Through this program, CPSC has worked with CBP and U.S. Immigration and Customs Enforcement, a component of the U.S. Department of Homeland Security that enforces U.S. customs and immigration laws, to implement national programs targeting (1) lighters that do not comply with CPSC's mandatory regulations, (2) holiday lights that pose a fire or electrocution hazard, and (3) toys that do not comply with CPSC requirements. According to CPSC, the agency's involvement in Operation Guardian dates back to December 2007.

<sup>37</sup>So far, two consumer product companies have joined the program—J.C. Penney and Hasbro—and, according to CBP and a trade group, both have had positive experiences thus far.

<sup>38</sup>See Consumer Product Safety Improvement Act of 2008 § 222(a), Pub. L. No. 110-314, 122 Stat. at 3066.



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Better Advance Shipment Data  
Would Strengthen CPSC's  
Targeting Efforts

roles and responsibilities of each agency would be a useful way for CPSC to identify gaps in the current product entry process and speed completion of its risk assessment methodology.<sup>39</sup>

During interviews with CPSC staff and our visit to a U.S. port of entry to determine how CPSC prevents the entry of unsafe products into the United States, we found that CPSC does not have access to CBP data that would provide CPSC with information about products in a shipment before it arrives in the United States. CPSC has access to entry summary data, which CBP generally receives shortly before a shipment enters the United States or, in some cases, as many as 10 days after the shipment has been released into commerce. However, CPSC does not have access to manifest data, which is provided to CBP 24 hours before a shipping vessel bound for the United States is loaded at a foreign port.<sup>40</sup> CPSC and CBP established a second MOU in 2002, which superseded the 1990 MOU, specifying procedures and guidelines for information sharing between the agencies with a particular focus on CPSC access to CBP data systems. The 2002 MOU was intended to allow CPSC access to both entry summary and manifest data. According to a CPSC official, CBP has not provided CPSC with access to manifest data because it believed the data were not specific enough for CPSC purposes. For instance, the manifest data generally do not include the name of the importer and may not have specific Harmonized Tariff Schedule codes to help CPSC identify the merchandise in the shipment. However, CPSC still believes that manifest data will help the agency improve its targeting, as it will give CPSC more timely information on shipments and potentially more specific information as CPSC seeks to revise the Harmonized Tariff Schedule codes to better align them with the categories of products they regulate. CBP also acknowledged that, while CPSC can use the entry summary data to target future shipments for inspection, CPSC cannot place inspection holds on shipments that are about to depart for or are in transit to the United States without the manifest data. In comparing CPSC border surveillance activities with those of other federal agencies that regulate the safety of products used by consumers, we found that FDA has a stronger capability

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<sup>39</sup>Upon completion of its risk assessment methodology, CPSIA requires CPSC to submit a report to Congress within 180 days regarding changes made or necessary to be made to its MOU with CBP. See Consumer Product Safety Improvement Act of 2008 § 222(d)(2), Pub. L. No. 110-314, 122 Stat. at 3068.

<sup>40</sup>The time frames for receiving manifest data for goods entering the United States through other modes of transportation—air, train, or truck—vary.

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to target imports using CBP data (discussed further below). FDA receives advance shipment data from CBP of all entries containing food under FDA jurisdiction that arrive at ports, which FDA then screens electronically against criteria it developed to detect potential violations.

CPSC and CBP state that they have been working together to resolve information-sharing issues. Specifically, in February 2007, CPSC applied for access to the International Trade Data System (ITDS), which CBP intends to be a single source for import and export documentation that is to provide participating agencies quicker access to data and improved ability to identify potentially unsafe shipments of consumer products.<sup>41</sup> As part of the application process, CPSC has submitted to CBP for review an operations plan (a “Concept of Operations” or “ConOps”) and an update to the 2002 MOU with guidelines for the exchange of information.<sup>42</sup> The agencies have had follow-up discussions on these plans; however, CBP has reported that implementation of ITDS has been delayed. As a result, CPSC’s efforts to access more complete import data to help it better target incoming shipments have also been delayed. CPSC staff said that they anticipate this work will not be completed until at least 2011.

In addition to this effort, CPSIA requires CPSC and CBP to improve information sharing and coordination. Specifically, CPSIA requires CPSC to develop, by August 2009, a plan for sharing information and coordinating with CBP.<sup>43</sup> According to CPSIA, the proposed plan is to consider, at a minimum, the number of CPSC staff that should be stationed at U.S. ports and the nature and extent of cooperation between CPSC and CBP at the ports. The plan is also to discuss the nature and extent of cooperation between CPSC and CBP at the National Targeting Center or

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<sup>41</sup>Section 405 of the SAFE Port Act requires all federal agencies with import regulatory responsibility, including CPSC, to participate in the International Trade Data System. Pub. L. No. 109-347, 120 Stat 1884, 1929 (Oct. 13, 2006) (classified at 19 U.S.C. § 1411).

<sup>42</sup>According to CBP, the 2002 MOU will likely need to be updated to reflect changes to the relationship between CPSC and CBP that have resulted from enactment of CPSIA, and updating the 2002 MOU may also help CPSC prepare the risk assessment methodology described above.

<sup>43</sup>See Consumer Product Safety Improvement Act of 2008 § 222(b) and (c), Pub. L. No. 110-314, 122 Stat. at 3067.

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its equivalent.<sup>44</sup> CPSC has not completed this plan, and it is unlikely to do so until it updates information-sharing agreements with CBP.

A CPSC official told us that as part of developing this plan for sharing information with CBP, CPSC is seeking to assign a staff member to a planned CBP targeting center that would focus on health and safety issues. This targeting center, which would be equivalent to the National Targeting Center, would seek to identify shipments of imported products that should be stopped at the ports for further screening and review. A CPSC official said that, in assigning a staff person to this targeting center, the agency would have access to CBP's Automated Targeting System.<sup>45</sup> However, creation of the health and safety planned targeting center has been delayed, so CPSC has not been able to place staff at the center or access CBP targeting information, delaying its ability to better target imported products. A CPSC official explained that the analytical approach that FDA took by creating its own system for analyzing data would require a considerable investment of both time and money. CPSC prefers the option of working with CBP through the planned targeting center to leverage this analytical capability. CPSC believes this option would be more efficient than developing its own system to analyze data.

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### CPSC's Enforcement of Import Safety Authorities Is Limited by Resource and Practical Constraints

CPSC's enforcement of its authorities to prevent the entry of unsafe products into the United States is limited by resource and practical constraints. Specifically, CPSC has few staff at ports of entry and limited analytical and laboratory support. Furthermore, although CPSC has authority to destroy products refused admission, it lacks a source of funding to immediately pay for the costs of destruction. In addition, while CPSC has authority to condition the importation of consumer products based on compliance with CPSC inspection requirements, there are practical constraints on the agency's ability to conduct inspections of foreign manufacturing plants.

CPSC's ability to inspect shipments for potential violations at ports of entry is limited by resource constraints, such as few staff at ports and

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<sup>44</sup>The National Targeting Center is a centralized coordination point for all of CBP's antiterrorism knowledge.

<sup>45</sup>The Automated Targeting System is a system CBP uses to target shipments for further screening and review at U.S. ports of entry. The system contains manifest data on shipments of consumer products.

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limited analytical and laboratory support. In passing CPSIA, Congress recognized the need to strengthen CPSC's resources, including requirements that CPSC increase the number of full-time employees to at least 500 by fiscal year 2013 and that CPSC hire additional personnel to be assigned to U.S. ports of entry.<sup>46</sup> As noted above, CPSC had 9 compliance investigators stationed at 7 ports as of July 2009, as well as 100 product safety investigators in 48 other locations across that country that may help to conduct periodic inspections at ports of entry. CBP staff indicated that having a CPSC compliance investigator collocated at ports has been useful, and during our visit to a U.S. port of entry we saw the cooperative relationship between agency officials. Furthermore, a CPSC official said that currently there is limited analytical support at CPSC headquarters to assist in import surveillance work. According to CPSC, the agency cannot establish a greater presence at U.S. ports without having the requisite analytical support. CPSC also has limited laboratory support for testing potentially unsafe products and has faced significant backlogs at various times. As of April 2009, CPSC had 28 engineers and scientists at its laboratory. CPSC's laboratory facility is located across the country from where a large percentage of imported goods enter the United States. Moreover, fireworks, which are heavily targeted for inspection, must be tested at a separate facility under current procedures. As a result of these conditions, testing backlogs have inhibited import surveillance efforts. In May 2009, CPSC announced that it had secured and was in the process of outfitting a new laboratory with enhanced testing facilities. CPSC also announced that certain support staff from CPSC headquarters would be collocated at the lab to assist the laboratory staff. However, the new facilities still cannot accommodate fireworks testing. Moreover, the new facility does not provide CPSC with a presence on the West Coast, where many consumer products enter the United States. As discussed below, in comparing CPSC's resources supporting border surveillance with those of other federal agencies that regulate the safety of products used by consumers, particularly FDA and USDA, we found that CPSC's resources are much less than those of these other agencies.

According to CPSC and CBP, CPSC can refuse entry for products that violate U.S. laws, but CPSC does not have immediate funding available to subsequently destroy these products if the importers do not destroy or export these products at their own expense. Instead, CPSC generally asks

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<sup>46</sup>See Consumer Product Safety Improvement Act of 2008 § 202(c)(1) and (2), Pub. L. No. 110-314, 122 Stat. at 3040.

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CBP to seize unsafe products, and CBP is authorized to access the U.S. Department of the Treasury's Forfeiture Fund to cover the cost of product destruction. The Treasury Forfeiture Fund is also available to CBP for other enforcement purposes, so that any money CBP uses for destroying seized products reduces the amount of money available to CBP for other purposes. Moreover, CBP is concerned that the costs of product destruction are likely to increase as CPSC fully implements CPSIA. Although CBP requires that formal entries be covered by a bond, which is another funding source that may be used to cover the cost of product destruction, we found that CBP has not pursued bonds for that purpose because they may not cover the full cost of destruction. CPSC officials also noted that bonds are not immediately available for product destruction but may only be recovered to reimburse destruction costs. However, a new mandate in CPSIA requires CPSC to work with CBP to set bond amounts sufficient to cover these costs.<sup>47</sup> CBP and CPSC's efforts to implement this requirement are still in process. Given the limited resources immediately available for product destruction, CBP indicated that CPSC and other federal agencies might explore other funding sources for this purpose. However, we previously found that estimating the cost of destroying consumer products is difficult given the wide range of products CPSC oversees, making it challenging to determine the appropriate size of a dedicated fund. In addition to setting aside enough funds for product destruction, CPSC would have to consider establishing parameters on the use of any funding source it administers.<sup>48</sup>

While CPSC has broad authority to conduct inspections of manufacturers and importers, significant resource and practical constraints limit its ability to conduct traditional inspections of foreign manufacturing plants. CPSC is required by rule to condition the import of a consumer product on the product manufacturer's compliance with CPSC inspection and recordkeeping requirements.<sup>49</sup> CPSC does not conduct inspections in

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<sup>47</sup>Pub. L. No. 110-314, § 224(a), 122 Stat. at 3069-70 (to be classified at 15 U.S.C. § 2088).

<sup>48</sup>See GAO, *Feasibility of Requiring Financial Assurances for the Recall and Destruction of Consumer Products*, [GAO-09-512R](#) (Washington D.C.: Apr. 22, 2009).

<sup>49</sup>See 15 U.S.C. §§ 2065(d) and 2066(g). CPSC has authority to enter and inspect, at reasonable times and in a reasonable manner, a "factory, fire-walled conformity assessment body, warehouse, or establishment where such products are manufactured, held, or transported and which may relate to the safety of such products." 15 U.S.C. § 2065(a). Also, every manufacturer, private labeler, or distributor of a consumer product is required to establish and maintain records reasonably required by the commission to implement the Consumer Product Safety Act. 15 U.S.C. § 2065(b).

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foreign countries, and CPSC and many product safety and international trade experts cite several constraints on its ability to do so. Specifically, these parties state that U.S. inspectors would likely need the consent of both the foreign manufacturer and the foreign government to conduct an inspection. Other experts stated that such consent from a foreign government, if granted, may be accompanied by a request for the same rights to inspect U.S. manufacturing plants. Another constraint on inspections of foreign manufacturers is that such a program would need to be prohibitively large in order to be effective, perhaps larger than CPSC's domestic inspection program. As noted earlier, CPSC had about 100 product safety investigators in 48 locations to conduct its domestic inspections as of July 2009. Also, it is not clear what CPSC would look for when inspecting foreign manufacturing plants given that CPSC evaluates the final product for compliance with product safety regulations rather than the production process. As noted above, CPSC may condition the import of consumer products on cooperation with inspections. However, ensuring that the specific manufacturer's products do not enter the United States would be difficult without detailed knowledge of individual companies' supply chains, which could be gained through inspection of the manufacturer's records.<sup>50</sup> Due to these legal and practical constraints, CPSC stated that expanding its international education and outreach activities rather than conducting inspections of foreign manufacturing plants would more effectively prevent the entry of unsafe consumer products.

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<sup>50</sup>CPSC believes that certifications and tracking labels on consumer products may help in this regard. When implemented, certifications must identify the manufacturer issuing the certificate and the place of manufacture. *See* 15 U.S.C. § 2063(g)(1). Also, the Consumer Product Safety Act requires, as of August 14, 2009, that tracking labels be placed on children's products identifying the specific source of the product. *See* 15 U.S.C. § 2063(a)(5).

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## Authorities of Select Agencies Are Comparable to CPSC's, but FDA and USDA's Border Surveillance Activities and Overseas Presence Provide Useful Information for Strengthening CPSC's Implementation of Its Authorities

CPSC's regulatory authority to prevent the entry of unsafe imports is generally comparable to that of certain other federal agencies with substantial responsibility over the safety of products entering the United States. However, various border surveillance activities of FDA and USDA—particularly with respect to obtaining advance shipment data, allocating staff resources to border operations, and targeting capabilities, as well as efforts to work with foreign governments to educate foreign manufacturers about U.S. safety standards—provide useful information for strengthening CPSC's efforts to prevent the entry of unsafe products.

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## CPSC's Authorities to Prevent the Entry of Unsafe Products Are Generally Comparable to Those of Other Federal Agencies

CPSC's authorities to prevent the entry of unsafe products are generally comparable to the authorities of four other federal agencies: FDA, which oversees, among other things, food, drugs, and medical devices; NHTSA, which, through delegated authority of the Secretary of Transportation, oversees motor vehicles and equipment; Food Safety and Inspection Service (FSIS), an agency of USDA that oversees egg products, poultry, and meat; and Animal and Plant Health Inspection Service (APHIS), an agency of USDA that oversees plants and animals. CPSC's authorities provide it with similar or stronger authority to require or engage in certain activities compared with the authorities of the other agencies we studied.

- *Safety standards:* All of these agencies have authority to regulate and enforce product safety standards or bans relevant to products under their jurisdiction.<sup>51</sup>
- *Border surveillance:* All of these agencies except NHTSA appear to have specific authority to conduct border surveillance activities and broad

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<sup>51</sup>See, for example, 15 U.S.C. § 2056-2057 (CPSC); 21 U.S.C. § 341 and § 360d(b) (FDA); 49 U.S.C. § 30111 (NHTSA); and 21 U.S.C. § 1035, § 1036, § 453, § 456, § 601, and § 608 (USDA).

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authority to refuse entry to items that fail to comply with relevant standards, among other things.<sup>52</sup> NHTSA officials told us that, like CPSC, NHTSA requests that CBP detain and seize products at the border on its behalf.

- *Product certification/testing:* Similar to FDA, manufacturers must certify to CPSC that their products comply with relevant standards, and this certification must be based on a reasonable testing program or, in the case of certain children’s products, the tests must be performed by third parties.<sup>53</sup> Under FSIS, containers of eggs, egg products, poultry, and meat must be labeled as having passed inspection. Although NHTSA authorities require manufacturers of vehicles and equipment to certify that products comply with applicable federal safety standards, these certifications are not required to be based on testing.
- *Temporary hold at ports:* CPSC, FDA, FSIS, and APHIS have the authority to temporarily hold shipments at U.S. ports for inspection.
- *Foreign inspection:* Like FDA and FSIS, CPSC is not expressly prohibited from requesting consent to inspect foreign facilities. Specifically, CPSC may request inspection of foreign manufacturing or distribution facilities, third-party testing laboratories, or conveyances used to transport consumer products in commerce.<sup>54</sup> As discussed above, CPSC does not conduct foreign inspections. Both FSIS and FDA have been successful in obtaining access to foreign facilities for the purpose of inspections or audits where incentives are strong for foreign entities to grant this access. For example, access is generally provided for requests that are tied to applications or audits before products may be eligible for import into the

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<sup>52</sup>See 15 U.S.C. § 2066(b) and (h), and § 2066(a-b) (CPSC); 21 U.S.C. § 381(a), § 381(m) and (o) (FDA); 7 U.S.C. § 7712(a), § 7713(a), § 8303(a), and § 8307(b) (USDA—live plants and animals); 21 U.S.C. § 620(a) (USDA—meat); 21 U.S.C. § 466(a) (USDA—poultry); 21 U.S.C. § 1046(a) (USDA—egg products).

<sup>53</sup>FDA may deny an application to introduce a new drug into commerce in the United States if the application does not include reports of adequate testing by all methods reasonably applicable to show whether or not the drug is safe for use. See 21 U.S.C. § 355(b) and (e). Products under CPSC jurisdiction that are subject to a children’s product safety rule must be tested by a third party. See 15 U.S.C. § 2063(a)(2).

<sup>54</sup>15 U.S.C. §§ 2065(a) and 2066(g).



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United States.<sup>55</sup> FDA officials told us that in practice, if a foreign firm refuses to permit such an inspection, FDA can sometimes refuse admission of products offered for import into the U.S. For example, the refusal to permit an inspection could lead to a product not receiving a required pre-market approval or the refusal to permit an inspection, combined with other information, could support a determination of the appearance of a violation. According to NHTSA, it does not have the authority to inspect foreign facilities for the manufacture of vehicles and vehicle equipment imported into the United States.

- *Consent to local court jurisdiction:* Based on our interviews with officials at the federal agencies we studied, none of the agencies requires foreign manufacturers to consent to the jurisdiction of local courts with respect to enforcement actions. Some agencies, including CPSC, told us they do not see a need for this requirement, as they have been able to effectively carry out their enforcement duties under existing authorities. For example, foreign manufacturers seeking to offer motor vehicles for import into the United States are required by statute to designate a U.S. resident or firm as its agent to receive service of notices and process in administrative and judicial proceedings, and service on the agent is deemed to be service on the foreign manufacturer or importer.<sup>56</sup> Also, FSIS told us that they expect foreign governments to carry out enforcement actions for their manufacturers that are certified to export to the United States. CPSC noted that it has satisfied its enforcement objectives by pursuing the domestic partners—manufacturers, importers, and retailers—of the foreign manufacturer without needing to resort to adjudicative proceedings. For example, in June 2009, CPSC reached a \$2.3 million settlement with Mattel, Inc., regarding the importation of toys made in China that violated a federal ban on paint containing lead.<sup>57</sup> Furthermore,

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<sup>55</sup>In general, imported egg products, poultry, and meat must be manufactured or processed in a foreign country that has obtained certification from FSIS indicating that it maintains a safety compliance program equivalent to that of the United States. *See* 21 U.S.C. § 466(d) and 9 C.F.R. Part 381, Subpart T (poultry); 21 U.S.C. § 620(f) and 9 C.F.R. Part 327 (meat products); 21 U.S.C. § 1046(a)(2) and 9 C.F.R. §§ 590.900—590.970 (egg products). Individual drugs and certain medical devices must obtain preapproval from FDA before they can be introduced, delivered, or marketed in U.S. commerce. *See* 21 U.S.C. § 355(a) and § 360(e).

<sup>56</sup>*See* 49 U.S.C. § 30164; 49 C.F.R. Part 551. As noted in appendix II of this report, notice of an enforcement action is one of the necessary elements for establishing jurisdiction in a U.S. court.

<sup>57</sup>*In re Mattel, Inc., and Fisher-Price, Inc.*, CPSC Dk. No. 09-C0019 (reprinted in 74 *Fed. Reg.* 28030 (June 12, 2009)).

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CPSC also has the ability to settle enforcement actions with foreign parties. For example, in July 2009, CPSC reached a \$50,000 settlement with a Hong Kong corporation with offices in the United States regarding the importation of toys manufactured in China that also violated the commission's lead paint ban.<sup>58</sup> Finally, CPSC staff we interviewed stated that the agency prefers to expand its international education and outreach programs rather than require foreign manufacturers to consent to U.S. jurisdiction to effectively prevent the entry of unsafe products, although they acknowledged that consent to jurisdiction or a requirement of a U.S. agent for service of process would be helpful.<sup>59</sup> Appendix II contains a more detailed discussion of the elements of establishing personal jurisdiction in U.S. courts.

The requirements of the Consumer Product Safety Act appear to demand more from manufacturers than NHTSA with respect to preventing the entry of unsafe imports. NHTSA's key authorities to ensure the safety of imported goods are to prescribe mandatory vehicle safety standards and to require foreign and domestic manufacturers to certify compliance with these standards. However, these certifications are not required to be based on a testing program, unlike CPSC's new certification requirements for children's products, nor are the results of any testing required to be reported to NHTSA as a condition to entry. Appendix III contains a more detailed description of the agencies' key authorities for preventing the entry of unsafe products.

Where key differences exist in these agencies' authorities, they appear to be due to differences in the types of products under an agency's jurisdiction and the particular risks that are presented. As such, these differences are not directly applicable to CPSC as it improves its ability to ensure the safety of imported goods.

- *FSIS's foreign country equivalency:* A major feature of FSIS's framework for ensuring the safety of imported meat, poultry, and egg products is a requirement that foreign countries have a certified food safety system equivalent to that of the United States. As of fiscal year 2008, 34 foreign countries were eligible to import these products into the United States. According to an FSIS budget document, the United States invests

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<sup>58</sup>*In re First Learning Company, Ltd.*, CPSC Dk. No. 09-C0026 (Jul. 8, 2009).

<sup>59</sup>According to CPSC, formal action against a foreign corporation must be served following the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters. 658 U.N.T.S. 163 (November 15, 1965).

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substantial resources, over \$800 million in fiscal year 2008, in the inspection of domestic products.<sup>60</sup> The amount of funds spent on domestic inspection is relevant given that the concept of foreign equivalency is predicated on there being a domestic inspection program. As such, it is unclear how FSIS's country equivalency program could be adapted for CPSC given that CPSC does not have comparable resources for the inspection of domestic products, with a budget of about \$80 million in fiscal year 2008 for all of its activities. Furthermore, the concept of equivalency for meat, poultry, and egg products is established in a 1994 multilateral trade agreement, to which the United States is a signatory.<sup>61</sup> According to the United States Trade Representative, it is not clear whether any WTO Agreement to which the United States is a party specifically precludes application of an equivalency requirement to consumer products.

- *FDA's preapproval of certain drugs and medical devices:* In addition, FDA requires drug manufacturers to obtain prior approval for marketing certain drugs in the United States and for selling certain medical devices.<sup>62</sup> However, FDA's prior approval requirement would be inefficient for CPSC given the diversity of products it oversees and the frequency with which these products change or are updated. CPSC oversees thousands of types of consumer products, and many of the products it oversees, especially toys, change or are updated every year.

Other key statutory differences across agency authorities need not be addressed by providing CPSC with new authorities because CPSC officials have told us they already consider CPSC to have similar authorities.

- *Agreements with foreign governments and overseas presence:* FDA is authorized to participate through appropriate processes with representatives of other foreign countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements, including international agreements such as mutual recognition agreements, agreements to facilitate commerce in

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<sup>60</sup>According to USDA officials, FSIS invested approximately \$19 million in fiscal year 2009 to ensure the safety of imported products, which included costs for determining the equivalence of foreign inspection systems.

<sup>61</sup>Agreement on the Application of Sanitary and Phytosanitary Measures, signed April 15, 1994, Final Act of the Uruguay Round of Multilateral Trade Negotiations, Marrakesh, Morocco.

<sup>62</sup>See 21 U.S.C. § 355(a), § 360b(a), and § 360e.

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devices, and memorandums of understanding, among other things.<sup>63</sup> As discussed below, CPSC already has MOUs with foreign governments, including China and the EU, and is finalizing plans for its first overseas office in Beijing, China, in 2010.

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### Other Federal Agencies' Border Surveillance and Overseas Activities to Prevent the Entry of Unsafe Products May Be Useful for CPSC to Consider

As CPSC considers ways to improve its ability to prevent the entry of unsafe imports, various agencies' border surveillance and outreach activities to foreign governments and industry provide useful information. FDA, FSIS, and APHIS have expansive border surveillance activities based on the amount of data obtained on incoming shipments, number of staff supporting border surveillance operations, and targeting programs and information technology systems that help to integrate data from various sources for use in making border entry decisions. These capabilities enable these agencies to screen incoming shipments for a greater number of risks than CPSC does. According to data provided by CPSC, the agency has generally focused on relatively few categories of consumer products since 2001, specifically toys, fireworks, lighters, and electrical products (such as holiday lights and extension cords).

- *FDA and FSIS have better access to data for screening incoming shipments than CPSC.* FDA receives shipment data from CBP for all entries under FDA jurisdiction that are imported or offered for import, which FDA then screens electronically against criteria it developed to detect potential violations, including information from domestic surveillance and outreach to foreign governments. In addition, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires that FDA be given advance notice on shipments of imported food. FDA allows importers to provide this data no more than 30 days in advance of the date of arrival. This advance information helps FDA determine whether the food potentially poses a bioterrorism or other significant health risk such that FDA should deploy resources to the port of arrival so that an inspection can be conducted before the product enters the United States. FDA officials told us that this information has been so important in screening food shipments for potential violations that they are considering expanding prior notification requirements to all products the agency oversees. FSIS requires by regulation that various information accompany shipments of meat, poultry, and egg products in order to be considered for admission into the United States, including a foreign health certificate. As discussed earlier, while CPSC receives entry summary data

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<sup>63</sup>See 21 U.S.C. §§ 393(b)(3), 383(b), and 360(i)(3).

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regarding shipments already released into commerce, CPSC does not receive data on incoming shipments prior to their arrival at U.S. ports of entry, though CBP receives such data as much as 24 hours before the shipment is loaded in the foreign port. Without advance shipment data, CPSC lacks information that other agencies have found useful in screening incoming shipments for potential safety violations.

- *FDA and USDA have significantly more staff supporting border operations than CPSC.* Federal agencies assign staff resources to border operations to identify and refuse admission to potentially unsafe imported products. NHTSA has no staff dedicated to border operations, but instead relies on CBP to screen incoming shipments and third-party laboratories to test pulled shipments. However, FDA, FSIS, and APHIS assign significantly more staff resources to border operations. According to FSIS officials, the agency physically examines 100 percent of meat, poultry, and egg product shipments presented for import with about 75 inspectors located at approximately 150 facilities near 35 border entry points. In addition, FSIS employed 20 import surveillance officers as of fiscal year 2009. APHIS officials told us 100 percent of plants and animals are inspected in cooperation with CBP. Because of the high percentage of shipments that are inspected, staff resources are accordingly greater. For example, about 1,800 port staff had been assigned to inspect fruit and plants at 139 ports of entry as of 2003. FDA examines approximately 1 percent of food presented for import and has requested about \$382 million for fiscal year 2010 for activities that support import safety. This amount would fund approximately 700 staff supporting import examinations alone, including port operations, of which 78 percent would be field based. FDA personnel cover most ports of entry into the United States, including 297 ports in fiscal year 2008, but for the ports where FDA does not maintain a normal presence, it coordinates with CBP to ensure it is notified of relevant incoming shipments for which examination and/or sampling may take place. FDA's border inspection activities are supported by compliance programs for agency field staff to use in carrying out inspections, sample collections, and analyses, among other things. For food safety alone, there are approximately 25 compliance programs and 12 that cover different imported foods.<sup>64</sup> While FDA, FSIS, and APHIS have significant resources devoted to the port and overseas activities, they still face significant challenges in ensuring that products entering the United

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<sup>64</sup>FDA compliance programs are documents prepared by FDA centers that provide guidance to field staff in carrying out investigations, inspections, sample collections, sample analyses, and regulatory activities in defined program areas, such as domestic seafood and pesticides in domestic foods.

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States are safe for consumers. As discussed earlier, CPSC has 9 compliance investigators at seven ports of entry, as well as about 100 product safety investigators located across the United States who work episodically to support the import surveillance program. Although the missions of FDA, USDA, and CPSC differ, CPSC's staff resources supporting border surveillance are much less than the staff resources of these other agencies and may not be adequate to prevent unsafe products from entering the United States.

- *FDA and USDA have more sophisticated information technology systems and analytical support to target potential risks at border entry points.* FDA, FSIS, and APHIS invest significant resources in information technology systems that support border surveillance efforts. To oversee inspection of plants and animals, CBP created positions in each of its 20 district offices for agriculture liaisons. These liaisons not only advise CBP on border surveillance operations but also report back to APHIS on risks detected at the border for the purpose of expanding targeting operations. These liaisons have access to CBP's Automated Targeting System, a computer system that stores detailed information from cargo manifests and other documents that shipping companies are required to provide before shipments arrive at ports for inspection.<sup>65</sup> This system allows border staff to focus inspections on higher risk cargo. FSIS invests substantially—nearly \$1 billion—in data infrastructure systems to assist its border inspections by linking inspection data with other public health information that is designed for FSIS to quickly and accurately identify trends and vulnerabilities affecting meat, poultry, and egg products. In addition, FSIS has developed a centralized computer system—the Automated Import Information System (AIIS)—that links all ports and tracks prior inspection results from each country and each foreign establishment for use in generating the type of inspection required on incoming shipments.<sup>66</sup> FDA also uses an electronic environment—Operational and Administrative System for Import Support (OASIS)—to screen shipments presented for entry for relative risks and for making entry

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<sup>65</sup>As stated above, all federal agencies with import regulatory responsibility are required to participate in the International Trade Data System, which, according to CBP, is intended to link these agencies to CBP's Automated Targeting System.

<sup>66</sup>FSIS is developing a new risk-based public health inspection program it calls the Public Health Information System (PHIS) that will phase out AIIS. We did not independently review AIIS or PHIS.

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or inspection decisions.<sup>67</sup> OASIS links with other data systems within FDA to leverage the latest information relating to public health. Also, FDA staff manually enter criteria into OASIS from sources such as import alert documents so that products can be flagged as they enter U.S. customs territory for the appearance of violations. According to FDA officials, there are currently about 270 import alerts in effect.<sup>68</sup> FDA officials also told us that the overseas audits and direct communication with foreign governments provide useful information in helping border surveillance agents make entry determination decisions. As discussed earlier, CPSC targets few products for border inspections and has not developed formal systems for assessing risks and providing port staff with risk management tools.

Whereas border surveillance efforts are geared toward intercepting potentially unsafe products at U.S. borders, outreach activities focused overseas may prevent potentially unsafe products from being shipped to U.S. ports. To this end, FDA and USDA assign staff to permanent positions in foreign countries and send staff overseas on a temporary basis to conduct educational workshops, as well as to conduct audits and inspections. Furthermore, some agencies have established cooperative agreements with foreign agencies to facilitate product safety.

- *FDA and APHIS overseas outreach efforts help inform agencies about unsafe products.* APHIS has more than 80 people around the world working with foreign embassies on plant and animal health issues. FDA announced the opening of offices in three cities in China in November 2008, and it has also announced plans to place technical experts and inspectors in four other regions, including Europe, India, Latin America, and the Middle East.<sup>69</sup> These staff would be supported by approximately 8 staff in FDA headquarters in the United States. In addition, FDA has plans

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<sup>67</sup>We did not independently review OASIS. FDA is developing a new screening tool to replace the admissibility screening portion of OASIS it calls the Predictive Risk-Based Evaluation for Dynamic Import Compliance Targeting (PREDICT). The PREDICT screening tool will be different from the legacy OASIS screening module in that it is designed to use multiple factors including automated data mining, pattern discovery, open source intelligence, and database queries of other FDA Center databases to calculate a risk score for import shipments.

<sup>68</sup>Import alerts indicate particular risks that are screened for at U.S. borders and face potential refusal into the United States. FDA officials told us the agency may issue an import alert based on information from market surveillance, border inspections, or from information they obtain directly from foreign countries.

<sup>69</sup>As of July 15, 2009, the Department of State has denied FDA's request to open an office in the Middle East.

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to hire 20 locally employed staff. FDA staff told us that an in-country presence is useful in preventing the entry of unsafe products because it improves the information border agents have to make entry decisions and allows the agency to train foreign establishments about compliance requirements. As discussed in more detail later, CPSC states that, with increased resources, it plans to open its first overseas office in Beijing, China, to facilitate safety efforts with one of the largest exporters of consumer products to the United States.

- *FDA and FSIS conduct temporary visits, audits, or investigations in foreign countries that help to build foreign awareness of U.S. product safety laws.* FSIS conducts on-site audits of foreign manufacturers as part of its systems equivalence determinations of foreign countries' food safety systems. FDA officials told us that the audits and announced inspections it conducts of overseas manufacturers are very useful in training these manufacturers about U.S. standards. Furthermore, FDA has reported that it has engaged in a variety of efforts with foreign governments to build foreign capacity and provide technical assistance. For example, they report holding regional workshops in Peru and China, participating in a multilateral food safety meeting geared toward developing a rapid alert system, and auditing Chinese government inspectors during their review of 13 Chinese firms to detect drug residues in aquaculture products. As discussed earlier, CPSC does not conduct foreign inspections. However, CPSC staff have conducted visits to foreign manufacturing plants with the permission of the foreign government. CPSC also has plans for conducting three outreach and training events each for foreign government officials and foreign manufacturers in fiscal year 2010, but the agency is limited in its outreach efforts due to limited numbers of staff.
- *FDA and FSIS have actively engaged with foreign governments on food safety.* FDA has actively engaged with foreign governments to develop cooperative arrangements and agreements, including a substantial number of international government-to-government agreements. FDA's Web site indicates a total of 63 MOUs or other cooperative agreements with about 25 different foreign countries.<sup>70</sup> FSIS has also negotiated government-to-government agreements as part of the food safety system equivalency determination process. Specifically, some countries have negotiated alternative sanitary measures to obtain this certification. As of July 2009, CPSC has established MOUs for the purpose of consumer product safety

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<sup>70</sup>As of June 18, 2009, at <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm>.



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with 16 foreign agencies, as discussed later, but this activity has occurred fairly recently and over the last few years.

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## Information Sharing and Cooperation among Countries Provide Way to Bridge Differences and Strengthen CPSC's Implementation of Its Authorities, but CPSC Lacks a Comprehensive Plan to Guide Its Work

Australia, Canada, the EU, Japan, and the United States have some similar authorities for consumer product safety, but institutional structures to implement these authorities vary from country to country, reflecting unique national approaches. Countries also share similar challenges—such as inconsistent laws and standards and ineffective cooperation and liaison among agencies involved in consumer product safety—and national governments' efforts to address import safety challenges have intensified in light of the growing volume of imports and recent consumer safety incidents. Among officials we interviewed, there is broad consensus that continued cooperation among governments, regulators and multilateral organizations can improve consumer product safety policy and enforcement consistency and, ultimately, the effectiveness of import safety frameworks. CPSC's Office of International Programs and Intergovernmental Affairs participates in numerous activities with other countries and multilateral organizations. However, CPSC does not have comprehensive plans to guide its work with these countries and multilateral organizations due to resource constraints and other priorities, according to CPSC officials.

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## While Similarities in Import Safety Authorities and Challenges Exist among Certain Countries, Their Institutional Structures and Implementation Reflect Unique National Approaches

Import safety authorities in Australia, Canada, the EU, Japan, and the United States reflect certain shared values and experiences. According to the OECD, a fundamental objective of consumer product safety policy is to prevent consumers from suffering harm as a consequence of using products that present an unreasonable risk of injury. While these countries have similar authorities, however, the implementation of those authorities may be different. For example, all the countries monitor both domestically manufactured and imported products, and all conduct some type of product testing and/or sampling. However, some of the countries monitor goods on their own initiative, while others operate on the basis of complaints that they receive about particular goods and products.

According to the officials representing the countries we reviewed, none of those countries has the authority to conduct an extraterritorial inspection of the facilities of a foreign manufacturer that exports products to that country. In most cases, these officials stated that the countries have been more successful in working with the exporting country and its manufacturers in order to correct problems that may arise. These officials also stated that none of the countries we reviewed has the authority to

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require foreign manufacturers to consent to local jurisdiction. U.S. Embassy and Australian government officials indicated that, under current law, Australia could ask foreign jurisdictions to enforce Australian consumer product safety laws; however, the Australian government prefers other methods, such as approaching manufacturers directly to raise safety concerns.

The approach countries take to consumer product safety begins fundamentally with how they define “safe” and “unsafe” products. The definitions vary considerably from country to country, as indicated in appendix IV. According to a report by the OECD, most countries apply broad principles to determine whether a product can be defined as safe.<sup>71</sup> For example, according to this report, in some countries (Japan, the United States, and the EU) all products must meet a positive standard—that is, they should be safe for consumers to use or consume prior to market distribution. Businesses selling unsafe goods may be subject to regulatory action, regardless of whether the product has caused a specific accident, injury, or harm to a consumer. In other countries (Australia and Canada), according to the OECD report, products must not breach a negative standard—that is, once the goods are placed on the market they should not carry an unreasonable risk of injury or death. The report notes that producers are held liable for the negative effects of their products once placed on the market.

According to officials, some variations exist with other authorities. They noted that in most of the countries we reviewed only a relatively small number of imported consumer products are subject to mandatory standards. However, according to a senior representative of an industrial association in Europe, the wide variety of product standards among countries, combined with variable concepts and legal interpretations applied by governments makes it difficult for industry to ensure safety and for countries to coordinate enforcement efforts. There are also differences in the case of product certification. Officials stated that neither Australia nor Canada requires certification for imported products. According to Japanese government officials, certain imported and domestic products in Japan are subject to product testing and cannot be sold in Japan without

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<sup>71</sup>In 2008, OECD sent out a questionnaire to its member nations on consumer product safety. The *Analytical Report on Consumer Product Safety*, DSTI/CP(2008)18/FINAL, OECD, 2008, was prepared to facilitate discussion of the questionnaire responses at the Roundtable on Consumer Product Safety, sponsored by the OECD Committee on Consumer Policy on Oct. 23, 2008.

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certification to prescribed standards. In the EU, according to official documentation, businesses must carry out conformity and safety assessments of their products in accordance with the General Product Safety Directive (GPSD),<sup>72</sup> and businesses are required to certify that their products are safe, as defined under GPSD. The documentation indicates that for some products self-declaration is sufficient, but other products require third-party verification.

According to the OECD report on consumer product safety, institutional structures for product safety can also vary from country to country, which can sometimes create challenges for coordination within and among countries and, in many cases, accounts for differences in enforcement and implementation of authorities. The report states that in Canada, consumer product safety policy, development, enforcement, information, and education functions are in one organization, Health Canada, with the provinces retaining some enforcement responsibilities. In the United States, CPSC is the primary agency responsible for implementing and enforcing federal consumer product safety laws and establishing consumer product safety policy. The OECD report further notes that some countries have institutional arrangements that separate policy and enforcement functions. In Japan, for example, policy responsibility is spread across the government in a range of departments, with a central coordinating function in a central policy agency (the Cabinet Office). Certain other countries, such as Australia, have regionally focused policy and enforcement structures for consumer product safety that reflect a division of powers and responsibilities between the national government and states, provinces or regions. In the EU, policy responsibilities lie with the European Commission, the executive arm of the EU responsible for defining and implementing its policies and running its programs. However, individual EU member countries are responsible in their respective territories for enforcement—market surveillance, product monitoring and testing, and possible restrictive or corrective actions.

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<sup>72</sup>GPSD aims at ensuring that only safe consumer products are sold in the EU. According to the EU, GPSD provides a broad definition of a safe product, and products must comply with this definition. In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply. They must take appropriate measures to prevent such risks and be able to trace dangerous products. Under GPSD, the member states are obliged to enforce the requirements on producers and distributors. In addition to the power to impose penalties, the directive gives the surveillance authorities a wide range of monitoring and intervention powers.

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Countries also share similar challenges as they respond to changing demands in the international market place. Similar to the United States, national governments' efforts to address import safety problems have intensified in light of the growing volume of imports entering each country and recent consumer safety incidents. According to the OECD report, many countries face enforcement challenges at both domestic and international levels, including

- finite resources;
- inconsistent laws, regulations, standards, and sanctions within countries and across borders;
- ineffective cooperation and liaison among agencies involved in consumer product safety enforcement; and
- insufficient sharing of injury information across borders.

Governments have taken a variety of actions to address these challenges, including enacting new laws and regulations and, in some cases, they have created new organizations to address new consumer safety challenges. See appendix IV for more information.

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### Engagement among Countries Provides Ways to Address Shared Import Safety Challenges

Officials in Australia, Canada, the EU, Japan and the United States indicate that a mix of bilateral (country-to-country) and multilateral (involving multiple countries) exchanges and agreements among importing and exporting countries has been useful in addressing import safety challenges. The CPSC and its counterparts in other countries have taken a particularly active role in engaging China on consumer safety issues to create more transparent and cooperative relationships.

According to the OECD's 2008 *Report on Consumer Product Safety*, bilateral engagement helps facilitate an exchange of information regarding consumer product safety issues and provides a mechanism for coordinated action against unsafe products. In the United States, CPSC's Office of International Programs and Intergovernmental Affairs administers MOUs between CPSC and consumer product safety entities in other countries, maintains regular contact with key exporting countries, and attends meetings and discussions sponsored by multilateral organizations. According to CPSC, as of June 2009, the office had established MOUs for the purpose of consumer product safety with 16 foreign agencies in Brazil, Canada, China, the EU, Israel, South Korea,

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Peru, Chile, Costa Rica, India, Japan, Mexico, Taiwan, Egypt, Columbia, and Vietnam. CPSC's Office of International Programs also conducts training sessions in various countries to explain U.S. import safety processes and procedures. According to CPSC, staff hold monthly teleconferences with the agency's counterparts in Canada, China, and the EU, and every two months CPSC holds a three-way teleconference with Mexico and China to provide additional opportunities for engagement. In 2008, CPSC created a Chinese-language page on the CPSC Web site and, not long after, a Vietnamese-language page to help facilitate information sharing. The pages provide information about U.S. product safety requirements, including relevant regulations and standards for products bound for the U.S. market, as well as information about the new CPSIA.

Over the last few years, CPSC has increased its bilateral engagement with China. According to CPSC, the first U.S.-China Product Safety Summit was held in Beijing in 2005 and culminated in a joint Action Plan on Consumer Product Safety. CPSC and its counterpart in China, the General Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ), established four working groups focused on fireworks, toys, lighters, and electrical products. According to CPSC, a third summit will be held in October 2009 and will build on the previous two, with the goal of institutionalizing a culture of product safety among Chinese consumer product manufacturers and exporters. In 2005, CPSC established a China Program Plan as a way of managing CPSC's various China-related activities and as the basis for an overall strategy to promote the safety and compliance of Chinese consumer products exported to the United States. Although the plan is to be updated on an annual basis to account for changing conditions and new opportunities for progress, CPSC has not updated the China Program Plan since 2007. According to a senior CPSC official, the fiscal year 2008 and 2009 plans were essentially the same as the 2007 plan. He stated, however, that a revised China Program Plan for 2010 will be submitted to the reconstituted commission and will be published when approved.

Other countries have also established bilateral agreements with China. The European Commission engages in international contacts and cooperation and has, for instance, agreed on a Memorandum of Understanding with China's AQSIQ.<sup>73</sup> According to the EU, one of the key

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<sup>73</sup>According to the EU, half of all dangerous products seized by European customs and product safety authorities in 2008 came from China, and China is the EU's biggest supplier.

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initiatives launched by the EU and China has involved the RAPEX system, the EU's Rapid Alert System for nonfood consumer products.<sup>74</sup> In May 2006, according to EU documentation, the European Commission decided to provide China's AQSIQ with access to the RAPEX system—specifically its notifications on products coming from China. EU officials report that China agreed to investigate all reported cases of dangerous products of Chinese origin and report back to the EU on the results, including withdrawals of export license and other corrective actions.<sup>75</sup> Also, EU officials state that certain individual EU Member States have established limited bilateral contacts with China. According to Health Canada, Canada signed an agreement with China on import safety in 2007. A summit between China, the EU, and the United States occurred in November 2008 to strengthen consumer product safety trilateral cooperation, according to U.S. and EU documents. As a key exporting nation, China has revised some of its own laws, regulations, and procedures in response to high-profile recalls of Chinese-made goods and the consequent international engagement on these issues, according to a senior CPSC official. He indicated that an example of such a change occurred in March 2009, when the Chinese National Institute of Standardization approved Administrative Guidelines for Safe Consumer Product Manufacturing that emphasizes the role of manufacturers in ensuring consumer product safety. In addition, the CPSC official stated that China's AQSIQ had reported to CPSC that it has increased significantly the inspection of paint on export toys and closed down many factories that failed to implement a government requirement of selecting paint suppliers for toys only from a government-approved list.

Multilateral engagement on consumer product safety issues provides other ways to encourage sharing of information and lessons learned on consumer product safety among a larger group of nations. Organizations such as OECD, the Asia-Pacific Economic Cooperation (APEC), and the

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<sup>74</sup>The EU's RAPEX system was established by the GPSD and applies to only nonfood consumer products. It is designed to ensure the swift transfer of information on dangerous nonfood consumer products found in one EU member state to the European Commission and to other member states. The system is intended to promote effective cross-border market surveillance. Once a dangerous product is found and stopped, the national contact point notifies national market surveillance authorities, customs authorities, and the European Commission. The commission validates the notification and then transmits the information to the other countries through the RAPEX system.

<sup>75</sup>Summaries of these reports are publicly available at [http://ec.europa.eu/consumers/safety/int\\_coop/july2009\\_after\\_vi\\_report.pdf](http://ec.europa.eu/consumers/safety/int_coop/july2009_after_vi_report.pdf).

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International Consumer Product Safety Caucus provide additional frameworks for cooperation. U.S. and other officials believe that continued cooperation and coordination among governments and regulators can improve policy consistency and enforcement and, ultimately, the effectiveness of consumer product safety frameworks, particularly since consumer safety enforcement challenges are shared by most nations.

On October 23, 2008, the OECD's Committee on Consumer Policy hosted its first Roundtable on International Consumer Product Safety, with an aim to examine consumer product safety trends and challenges at both domestic and international levels. The Director of CPSC's Office of International Programs and Intergovernmental Affairs attended this meeting, as did other OECD member nation representatives. The final report identified a number of key issues shared by member nations and initiatives for the future.<sup>76</sup> CPSC representatives have also participated in APEC discussions concerning consumer product safety. In 2007, APEC leaders agreed on the need to develop a more robust approach to strengthening food and consumer product safety standards and practices in the region, using scientific, risk-based approaches and without creating unnecessary impediments to trade, according to APEC documents. APEC members reconvened in 2009 to determine future work on consumer product safety. CPSC's Chairman and three staff participated in an APEC regulators' dialogue on toy safety in August 2009 in Singapore aimed at strengthening information exchange among APEC members' product safety officials.

The International Consumer Product Safety Caucus is another platform that facilitates the exchange of information on consumer product safety issues in the area of governmental policy, legislation and market surveillance, with a view to strengthening collaboration and cooperation among governments and regulatory agencies around the world. Current active members include Australia, Canada, China, the EU, Korea, Japan, and the United States (represented by CPSC). The caucus meets at least twice a year.

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<sup>76</sup>The roundtable recommended greater coordination and cooperation within and among countries and multilateral organizations. In addition, the roundtable also recommended that governments take a more proactive approach to product safety failure, make greater efforts to harmonize product safety standards internationally, and work to develop a rapid international information exchange system. See *OECD Roundtable on Consumer Product Safety—Summary Report*, DSTI/CP (2009)1/FINAL, OECD (October 2008).

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## CPSC Has Not Developed Long-term Plans for International Activities

While CPSC participates in numerous activities with other countries and multilateral organizations to establish and strengthen coordinated actions against unsafe consumer products, and has established MOUs with 16 foreign agencies for this purpose, CPSC does not have plans covering its work with these countries and multilateral organizations—except for China. According to CPSC, this is due to resource limitations in CPSC’s Office of International Programs and Intergovernmental Affairs (as discussed earlier, the office has four staff) and because of its focus on China as the single largest source of foreign-made products. A senior CPSC official stated that with the creation of an additional staff position in the Office of International Programs, the office plans to expand its program planning to better address other countries. However, without a long-term plan that incorporates all the office’s activities, it is difficult to accurately assess current and future resource needs and take best advantage of opportunities for future coordination and cooperation among importing and exporting nations that CPSC considers integral to preventing the entry of unsafe products. Long-term planning is particularly important for CPSC’s Office of International Programs and Intergovernmental Affairs because of the diverse nature of its responsibilities and to ensure consistency in CPSC’s policies.

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## CPSC Has Established Annual Goals and Short-term Plans to Prevent the Entry of Unsafe Products, but Lacks a Long-term Plan for the Future

CPSC has established annual goals and short-term plans to prevent the entry of unsafe products but lacks a long-term plan to address the agency’s growing role in import safety. Without a long-term plan, CPSC is not fully prepared to use new authorities granted in CPSIA, nor is it able to effectively address the safety of imported products through international means or to appropriately allocate any potential increases in agency resources.

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## CPSC Has Established Short-term Plans and Annual Goals for Import Safety

In May 2009, CPSC submitted a 2010 Performance Budget Request to Congress, which contains a section called the Import Safety Initiative. This initiative has three key principles: (1) assure that product safety is built into manufacturing and distribution processes from the start, (2) increase enforcement at the border to stop dangerous goods from entering the country, and (3) enhance surveillance of the marketplace to remove unsafe products from store shelves. These three principles are consistent with principles established on a governmentwide basis in 2007. In



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particular, the principles are consistent with those established by the Interagency Working Group on Import Safety, of which CPSC was a part.<sup>77</sup> The working group issued an Action Plan for Import Safety in November 2007 that established three organizing principles: (1) prevention, which means to prevent harm in the first place by working with the private sector and foreign governments to adopt an approach to import safety that builds safety into manufacturing and distribution processes; (2) intervention, which means to act swiftly and in a coordinated manner when problems are discovered to seize, destroy, or otherwise prevent dangerous goods from advancing beyond the point of entry; and (3) response, which means to take swift action to limit potential exposure and harm to the American public in the event an unsafe import makes its way into domestic commerce.

As part of the governmentwide strategy, CPSC developed its Import Safety Initiative, which contains annual goals that are consistent with the initiative's key principles, but it is a short-term plan. For example, to help assure that product safety is built into manufacturing and distribution processes from the start, CPSC states that it plans to conduct three outreach and training events for foreign government officials in 2010 and three outreach and training events for foreign manufacturers. CPSC also has a short-term plan for how it will manage its various China-related activities and states that, for 2010, staff will review and update this plan. To increase enforcement at the border, CPSC states that it plans to increase the number of full-time staff working at U.S. ports and to increase the number of sample products screened at the ports. CPSC's Import Safety Initiative also links goals to requests for increased resources. For example, CPSC states that, with increased resources, it plans to increase its presence at U.S. ports of entry and open its first overseas office in Beijing, China.

CPSC officials have described to us other short-term plans that they developed to respond to requirements and authorizations in CPSIA. For example, as discussed earlier in this report, CPSC's decision to assign additional full-time staff to ports responds to Section 202 of CPSIA, which

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<sup>77</sup>The Interagency Working Group on Import Safety, composed of representatives from 12 cabinet departments and agencies, including CPSC, was formed by executive order in July 2007. The working group issued its *Action Plan for Import Safety* on Nov. 6, 2007, which contained several recommendations designed to improve the safety of imported products. According to a CBP official, representatives from import safety agencies, including CPSC, continue to meet to implement certain recommendations of the action plan.

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requires CPSC to hire personnel to be assigned to duty stations at U.S. ports of entry, or to inspect overseas manufacturing facilities, subject to the availability of appropriations. In its Import Safety Initiative, CPSC requests funding for 10 additional staff to be assigned to ports in 2010. A CPSC official with whom we spoke said that he expects the number of staff assigned to ports to grow from its current level of 9 to about 50 over the next few years. However, CPSC has conducted limited analyses of how it plans to assign additional staff to ports in the coming years, and standard operating procedures that describe compliance investigators' roles and responsibilities at ports of entry have not been updated since 1989. CPSC officials acknowledged the need to update these procedures. CPSIA also requires CPSC, as discussed earlier in this report, to develop a methodology for identifying shipments of imported consumer products that are likely to violate import provisions enforced by CPSC due by August 2010. CPSC, as noted earlier, has taken steps to develop a plan for sharing information and coordinating with CBP, but it is unlikely that CPSC will complete this plan by August 2009, as required under CPSIA, because of delays in updating its agreements with CBP.

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### CPSC Has Recognized the Need for U.S. Consumer Product Safety Policy to Comply with WTO Obligations and International Trade Agreements

In undertaking its planning efforts, CPSC has recognized the need for U.S. consumer product safety policy to comply with World Trade Organization (WTO) obligations and international trade agreements—a positive recognition on CPSC's part. A CPSC official involved in international education and outreach activities said that, in working to address U.S. concerns about the safety of imported products, it is also critical to comply with WTO rules. The official said there are statutory requirements—namely, the Trade Act of 1979—mandating U.S. standards for complying with international trade agreements. He said that CPSC has had a productive working relationship with USTR in the past, and that CPSC is looking to formalize its working relationship with USTR in the future by developing internal standard operating procedures for consulting with USTR. The official said that the procedures would be useful to CPSC in identifying issues that should have USTR's input before they are finalized. CPSC has also recognized the importance of international trade agreements through its work with international groups, such as OECD, as discussed previously in this report. In particular, CPSC has recognized that the WTO Agreements on Technical Barriers to Trade—which establishes rules for preparing, adopting, and applying technical regulations, standards, and conformity assessment procedures—serves to encourage uniformity and predictability in national consumer product safety regimes.

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## CPSC Lacks a Long-term Plan to Prevent the Entry of Unsafe Products

Although CPSC has established short-term plans and annual goals to prevent the entry of unsafe products, the agency has not developed a long-term plan for addressing its import safety work. In particular, CPSC has not updated its agencywide Strategic Plan, which was issued in 2003 and was due for revision in 2006. According to the Government Performance and Results Act, strategic plans help agencies establish long-term goals, including identifying the resources needed to accomplish these goals. The act calls for federal agencies to develop multiyear strategic plans and update them at least every 3 years. CPSC's Strategic Plan does not reflect its import safety work, its plans for international education and outreach activities, its plans to use new authorities granted in CPSIA to prevent the entry of unsafe products, or its plans to respond to mandates in CPSIA to improve its risk assessment and coordination with CBP. CPSC has recently begun efforts to update its Strategic Plan by requesting public comments on revisions to the plan.<sup>78</sup>

In addition to lacking a long-term plan to prevent the entry of unsafe products, CPSC does not have outcome-oriented performance measures to assess the effectiveness of its import safety work. One of CPSC's goals for 2010 is to develop measures of import safety success, according to CPSC's Import Safety Initiative. CPSC reports that, in 2008, staff researched and evaluated information for an enhanced surveillance system, making contact with FDA, CBP, and Internal Revenue Service staff to discuss methods and requirements of their systems. As discussed earlier in this report, CPSC has also requested public input concerning the development of consumer product safety metrics, but it received only two responses, neither of which addressed CPSC's need for developing new performance measures.<sup>79</sup>

CPSC has established short-term plans and annual goals for its import safety work, but it does not have goals for these activities beyond 2010. Without a long-term plan for import safety that contains key goals and performance measures, CPSC may be unable to replicate or enhance its short-term efforts over the longer term. For example, CPSC may find

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<sup>78</sup>See "Consumer Product Safety Commission Agenda, Priorities, and Strategic Plan: Request for Comments," 74 *Fed. Reg.* 109 (Jun. 9, 2009).

<sup>79</sup>We previously reported that when agencies have difficulty establishing outcome-oriented performance measures, they can develop intermediate measures that show how programs are contributing toward end outcomes. See GAO, *Rail Safety: The Federal Railroad Administration Is Taking Steps to Better Target Its Oversight, but Assessment of Results Is Needed to Determine Impact*, GAO-07-149 (Washington, D.C.: Jan. 26, 2007): 39-47.

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insufficient staff to cover meetings and seminars needed to work with foreign governments and foreign manufacturers over the long-term to build product safety into manufacturing and distribution processes from the start. CPSC may also find it difficult to analyze any data it collects through surveillance of the marketplace to strengthen and improve its targeting decisions at the ports. Finally, CPSC may face challenges in ensuring that any further resources it devotes to increasing its port staff and operations are also accompanied by appropriate growth in its analytical and other support staff to help ensure a comprehensive and balanced approach to product safety.

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## Conclusions

Broad agreement exists among CPSC staff, legal experts, industry representatives, and consumer advocates that CPSC's authorities to prevent the entry of unsafe products into the United States have the potential to be effective, but only if they are implemented more fully. With delays in some rulemakings, such as testing and certification requirements, it remains unclear whether CPSC will be able to implement its authorities effectively. Furthermore, CPSC faces significant challenges due to competing priorities and resource constraints. CPSC has taken positive steps to shift its approach to import product safety from one focused on responding to problems after products have entered the marketplace to an approach focused on preventing harmful products from ever reaching consumers. To implement this preventive approach, CPSC states that it is taking steps to enhance surveillance activities, increase enforcement at the ports, engage foreign governments, and educate foreign manufacturers on U.S. standards for consumer product safety.

Our work demonstrates that CPSC needs to strengthen its surveillance activities, particularly its ability to target potentially unsafe products for further screening and review at U.S. ports. CPSC has yet to obtain access to advance shipment data, which FDA's experience suggests could be useful in targeting incoming shipments. In addition, CPSC's agreements with CBP are outdated, which hinders CPSC and CBP's ability to target imports under CPSC's jurisdiction. CPSIA requires that CPSC and CBP work together to develop a methodology to assess the risks of various imported products and to cooperate on CPSC's participation in a CBP targeting center. These joint efforts are a key element for improving CPSC's ability to target shipments for screening and review at the ports and to ensuring consistent enforcement of CPSC's authorities across the United States. Because CPSC relies heavily on CBP for enforcement at the ports, it is imperative for CPSC and CBP to resolve issues concerning their agreements for sharing information and update their procedures for

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operating at the port. CPSC's targeting efforts could be strengthened further through expanded engagement with foreign governments and education of foreign manufacturers on U.S. consumer product safety standards. Such outreach could inform industry of its responsibility for the safety of consumer products entering the United States and provide CPSC with information on manufacturing in the respective countries to assist the agency's development of a risk assessment methodology for imported products. Without improving its ability to target potential risks across a broad range of product categories, it is unclear how CPSC will succeed in preventing unsafe consumer products from entering the United States.

CPSC's inspection of foreign manufacturing plants faces practical constraints and would likely require tremendous resources to implement. CPSC believes strong cooperative relationships between countries to build strong frameworks for consumer product safety are a more effective approach for the United States. As part of its approach, CPSC is in the process of developing such relationships, and current MOUs between CPSC and certain foreign countries primarily address information sharing. CPSC officials state that expanding CPSC's education and outreach rather than inspection of foreign plants could serve to more effectively prevent the entry of unsafe consumer products. Similarly, officials from the U.S. agencies, with the exception of FDA, and countries we reviewed, stated that they do not conduct inspections of foreign manufacturing plants. In most cases, officials we interviewed stated that the countries have been more successful in working with exporters in order to correct problems that may arise. Therefore, we are not recommending any additional authorities be granted to CPSC at this time.

Efforts to expand U.S. jurisdiction to foreign manufacturers for purposes of enforcement action also present unique practical considerations. It may be argued that if foreign manufacturers were required to consent to U.S. jurisdiction, CPSC's enforcement ability would be strengthened because CPSC would have one less hurdle to overcome in pursuing enforcement actions. Nevertheless, CPSC staff stated that, at this time, CPSC does not see the need for this requirement in order to effectively carry out its enforcement duties. To date, CPSC has been able to satisfy its enforcement objectives by pursuing the domestic partners—broadly defined to include those companies along the supply chain to the retailer—associated with the foreign manufacturer. CPSC also has the ability to settle enforcement actions with foreign parties. FDA and USDA officials have found that their efforts to educate overseas industry and governments on U.S. safety standards and the particular risks being screened for at the border could reduce the number of unsafe products

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that reach U.S. consumers. Similarly, CPSC staff we interviewed stated that expanded international education and outreach, rather than expanded enforcement jurisdiction, would more effectively prevent the entry of unsafe products, although they acknowledged that consent to jurisdiction or a requirement of a U.S. agent for service of process would be helpful. Due to the practical considerations associated with requiring foreign manufacturers to consent to U.S. jurisdiction for purposes of CPSC enforcement actions, we make no recommendations for additional CPSC authorities at this time.

CPSC's short-term plans to prevent the entry of unsafe products are consistent with a governmentwide approach taken by the Interagency Working Group on Import Safety in 2007. That group, of which CPSC was a part, established three organizing principles—prevention, intervention, and response—that represent, in our view, a comprehensive approach to import safety. However, CPSC lacks a long-term plan to prevent the entry of unsafe products. CPSC has not updated its September 2003 Strategic Plan, even though the Government Performance and Results Act requires this plan to be updated at least every 3 years. Although CPSC has initiated steps to update its Strategic Plan by requesting public comments, it is important for CPSC to work expeditiously to follow through on its efforts. In addition, while CPSC recognizes the need for outcome-oriented performance measures and has taken steps to develop new measures, it does not currently have such measures in place for its import safety work. Without a long-term plan that contains key goals and measures, CPSC may find it difficult to address its challenges in implementing the new authorities granted in CPSIA to prevent the entry of unsafe products, such as decisions about where and how to allocate any future increases in agency resources.

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## Recommendations for Executive Action

First, to ensure that CPSC is able to exercise its full authority to prevent the entry of unsafe consumer products into the United States, we recommend that CPSC ensure expeditious implementation of key provisions of CPSIA, including establishing the substantial product hazard list and implementing testing and certification requirements that are subject to stay of enforcement until February 2010, and complete its rulemaking as required under the act.

Second, to strengthen CPSC's ability to prevent the entry of unsafe products into the United States, we recommend that the Chairman and commissioners of CPSC take several actions to improve the agency's ability to target shipments for further screening and review at U.S. ports of entry as follows:

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1. To ensure that it has appropriate data and procedures to prevent entry of unsafe products into the United States, we recommend that CPSC update agreements with CBP to clarify each agency's roles and to resolve issues for obtaining access to advance shipment data; and
  2. To improve its targeting decisions and build its risk-analysis capability, we recommend that CPSC
    - a. work with CBP, as directed under CPSIA through the planned targeting center for health and safety issues, to develop the capacity to analyze advance shipment data; and
    - b. link data CPSC gathers from surveillance activities and from international education and outreach activities to further target incoming shipments.

Third, to provide better long-term planning for its import safety work and to account for new authorities granted in CPSIA, we recommend that CPSC expeditiously update its agencywide Strategic Plan. In updating its Strategic Plan, we recommend that CPSC consider the impact of its enhanced surveillance of the marketplace and at U.S. ports as discussed above and determine whether requisite analytical and laboratory staff are in place to support any increased activity that may occur at U.S. ports. Furthermore, we recommend that CPSC's Strategic Plan include a comprehensive plan for the Office of International Programs and Intergovernmental Affairs to work with foreign governments in bilateral and multilateral environments to

1. educate foreign manufacturers about U.S. product safety standards and best practices, and
2. coordinate on development of effective international frameworks for consumer product safety.

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## Agency Comments and Our Evaluation

We provided a draft of this report to CPSC, CBP, USTR, and the Departments of Agriculture; Commerce; Health and Human Services; State; and Transportation; and to EU and Canadian officials for review and comment. CPSC, CBP, USTR, Agriculture, Health and Human Services, Transportation, and EU and Canadian officials provided technical comments, which we incorporated as appropriate. CPSC stated that it concurs with our recommendations.

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We are sending copies of this report to interested congressional committees and the Chairman and commissioners of CPSC. We are also sending copies to the Secretaries of Agriculture, Commerce, Homeland Security, Health and Human Services, State, and Transportation, the United States Trade Representative, and other interested parties. The report also is available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-8678 or [cackleya@gao.gov](mailto:cackleya@gao.gov). Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.



Alicia Puente Cackley  
Director, Financial Markets and  
Community Investment



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# Appendix I: Objectives, Scope, and Methodology

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To determine the effectiveness of the Consumer Product Safety Commission's (CPSC) import safety authorities, we examined CPSC data and interviewed CPSC officials to learn how the agency measures and assesses its own effectiveness. We also conducted extensive document reviews on consumer product safety generally and import safety specifically. We interviewed legal professionals and consumer and industry representatives to obtain their perspective on the effectiveness of CPSC's authorities. We also interviewed officials from other federal agencies involved in imported product safety, including U.S. Customs and Border Protection (CBP), the Office of the United States Trade Representative (USTR), and the Departments of State and Commerce. We visited a U.S. port of entry to observe CPSC import surveillance activities and CPSC's interaction with staff from CBP. We also visited CPSC's Product Testing Laboratory in Gaithersburg, Maryland, to observe laboratory testing that supports import safety activities.

To compare CPSC's authorities with respect to the safety of imported products with the authorities of select federal agencies, we identified key federal agencies with import regulatory authority over other types of consumer goods. These agencies are the Food and Drug Administration (FDA), which oversees the safety of imported food, drugs, cosmetics, and medical devices; the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS), which oversees the safety of imported egg products, meat and poultry; USDA's Animal Plant Health Inspection Service (APHIS), which oversees the safety of imported plants and animals; and the National Highway Traffic Safety Administration (NHTSA), which oversees the safety of imported motor vehicles and equipment. We interviewed officials from each of these agencies, had them identify the primary statutory authorities for ensuring the safety of imports under their jurisdiction, and discussed various agency activities supporting import safety. For FDA, the primary statutory authority is the Federal Food, Drug, and Cosmetic Act. For USDA, the primary statutory authorities are the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, the Animal Health Protection Act, and the Plant Protection Act. For NHTSA, the primary statutory authority is the National Traffic and Motor Vehicle Safety Act, which has been classified, as amended, at Subtitle VI of Title 49 of the U.S. Code.

For our comparative analysis of the product safety authorities of foreign countries, we selected countries that are members of the International Consumer Product Safety Caucus, which is an international forum consisting of product safety officials from member governments to

facilitate the exchange of information on consumer product safety. Specifically, we selected Australia, Canada, China, the European Union (EU), and Japan.<sup>1</sup> We developed a set of questions concerning consumer product safety authorities, practices, and procedures and worked through the U.S. Department of State to distribute the questions to appropriate contacts at U.S. embassies overseas and, in some cases, to foreign embassies in Washington, D.C. We interviewed desk officers for the selected countries from the Departments of State and Commerce in Washington, D.C., and relied on the Department of State to advise us on the recommended approach to take with each country. We reviewed foreign laws and regulations, as well as other documents regarding product safety, provided by U.S. Embassy officials in the selected countries. We did not independently analyze the laws, regulations, or procedures of these countries; instead, we relied on third-party assessments of each country's consumer product safety framework. We received written responses to our questions from and conducted interviews with the U.S. embassies in Australia, Canada, and China. U.S. embassy officials told us that their responses were coordinated with country officials knowledgeable of the respective country's laws, regulations, and procedures. We received written responses to our questions from officials with the Embassy of Japan in Washington, D.C. We received written answers to our questions from consumer product safety officials in the EU. We also received information from the supreme audit institutions in these countries regarding their work on consumer product safety. We conducted interviews with consumer product safety officials from Canada, the EU, and Japan at a conference of the International Consumer Product Health and Safety Organization (ICPHSO) in Orlando, Florida. We reviewed publicly available documents on the Web sites of consumer product safety agencies in each country. We also reviewed and utilized documents provided by the Organization for Economic Cooperation and Development (OECD), including OECD member country responses to a 2008 questionnaire concerning consumer product safety. Department of State officials reviewed a draft of our country summaries and provided comments, which we incorporated.

To evaluate CPSC's plans to prevent the entry of unsafe products in the future, we reviewed CPSC's 2010 Performance Budget Request and

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<sup>1</sup>South Korea is also a member of the International Consumer Product Safety Caucus, but due to resource constraints, we omitted Korea from our analysis. The EU is a customs territory, but we refer to it as a country in this report for ease of reference.

compared CPSC's planning efforts to guidance GAO has developed for implementation of the Government Performance and Results Act. We examined other CPSC data and interviewed CPSC officials to learn about CPSC's future plans. We also interviewed legal professionals and consumer and industry representatives to obtain their perspectives on CPSC's future plans.

We conducted this performance audit from September 2008 to August 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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# Appendix II: Personal Jurisdiction Over Foreign Manufacturers for CPSC Enforcement Purposes

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The Consumer Product Safety Improvement Act contained a mandate requiring that GAO make a recommendation as to whether foreign manufacturers should be required to consent to the jurisdiction of U.S. courts with respect to enforcement actions by the commission. We raised this issue in our interviews with officials at the Consumer Product Safety Commission (CPSC), the United States Department of Agriculture, the Food and Drug Administration, and the National Highway Traffic Safety Administration, as well as officials representing most of the international entities we selected for study—Australia, Canada, the European Union, and Japan. CPSC staff stated that, at this time, CPSC does not see the need for this requirement in order to effectively carry out its enforcement duties.

CPSC has authority to institute administrative or civil enforcement actions against manufacturers, distributors, importers, and retailers. CPSC may opt to negotiate a settlement or consent agreement rather than instituting an adjudicative proceeding in a federal or administrative court. Enforcing product safety standards on foreign manufacturers through an adjudicative proceeding could theoretically pose practical challenges. For example, one important prerequisite to maintaining an action against any defendant in a U.S. state, federal, or administrative court is that the court must have the ability to exert personal jurisdiction over that party.<sup>1</sup> A court's exercise of personal jurisdiction over a party must satisfy the fundamental notions of fairness mandated by the Due Process Clause of the Fifth or Fourteenth Amendments. In the case of a defendant physically located outside the territorial jurisdiction, such as a foreign manufacturer, personal jurisdiction can be established if sufficient contacts exist between a defendant and the territorial jurisdiction where the court sits, and the defendant receives fair notice of the suit. Both requirements are fact-specific and must ultimately be decided by a court, if challenged by the defendant. By requiring foreign manufacturers to consent to U.S. jurisdiction for purposes of CPSC enforcement actions, CPSC's enforcement process could possibly be expedited in that it would eliminate a personal jurisdictional challenge to the enforcement action.

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<sup>1</sup>The most common means of establishing personal jurisdiction are (1) service of process on a defendant that is physically located within the territorial jurisdiction of the particular court; (2) service of process on a defendant that is not physically located within the court's territorial jurisdiction, but where such service is determined to be fair because the defendant has sufficient "contacts" within the jurisdiction; or (3) a defendant's consent to personal jurisdiction.

However, as noted above, CPSC did not see a need to take such action at this time.

CPSC noted that it can pursue each of the actors in the supply chain, from the manufacturer to the retailer, foreign or domestic. Despite the challenges that could theoretically arise in instituting an enforcement action against a foreign actor, to date, pursuing the domestic partners of such actors has satisfied CPSC's enforcement objectives.<sup>2</sup> Further, CPSC has the ability to settle enforcement actions with foreign parties. In the event a settlement cannot be reached voluntarily, any formal action against a foreign corporation must be served following the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters ("Convention").<sup>3</sup> CPSC also has the authority to file suit against a foreign manufacturer for civil penalties for violations of certain provisions of its statutes, if it can effect service by the Convention or otherwise, and establish that the court has jurisdiction. For example, the Department of Justice on behalf of CPSC recently filed suit against a foreign manufacturer in the U.S. District Court for the District of Minnesota, which was settled in July 2009.<sup>4</sup> CPSC staff we interviewed believe that expanded international education and outreach programs, as opposed to requiring foreign manufacturers to consent to jurisdiction, are preferable tools to effectively prevent the entry of unsafe consumer products, although they acknowledged that consent to jurisdiction or a requirement of a U.S. agent for service of process would be helpful. In addition, each of the U.S. federal agencies and international entities that we interviewed stated that they do not require consent by foreign manufacturers to local jurisdiction with respect to enforcement actions. Therefore, we are not recommending any action at this time.

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<sup>2</sup>For example, in June 2009, CPSC reached a \$2.3 million settlement with Mattel, Inc., regarding the importation of toys manufactured in China that violated the Commission's Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint (Lead-Paint Ban), 16 C.F.R. Part 1303. *In re Mattel, Inc., and Fisher-Price, Inc.*, CPSC Dk. No. 09-C0019 (reprinted at 74 *Fed. Reg.* 28030 (Jun. 12, 2009).

<sup>3</sup>See 658 U.N.T.S. 163 (November 15, 1965).

<sup>4</sup>CPSC announced on August 4, 2009, that Techtronic Industries Co. Ltd., which is a foreign entity, agreed to pay a civil penalty in the settlement of litigation filed by the U.S. Department of Justice (on CPSC's behalf) in U.S. district court. *In re United States v. Wagner Spray Tech Corp. and Techtronic Industries Co. Ltd.*, No. 08 Civ. 6478 (D. Minn. July 23, 2009). Also, in July 2009, CPSC reached a \$50,000 settlement with First Learning Company, Ltd., a Hong Kong corporation with offices in the U.S., regarding the importation of toys manufactured in China that violated the Commission's Lead-Paint Ban. *In re First Learning Company Ltd.*, CPSC Dk. No. 09-C0026 (Jul. 8, 2009).

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# Appendix III: Key Authorities of Select Federal Agencies

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We compared the Consumer Product Safety Commission's (CPSC) key authorities for preventing the import of unsafe consumer products to those of three federal agencies—the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and the United States Department of Agriculture (USDA). Table 1 describes some of the statutory and regulatory provisions of such agencies with respect to various regulatory activities, such as inspecting shipments that are presented for import into the United States.<sup>1</sup> In acknowledgement of the ongoing efforts of the Interagency Working Group on Import Safety, in which these four agencies participate, we present these authorities according to the same principles that are the foundation of the group's strategic framework—prevention and intervention.<sup>2</sup> Although the group uses a third principle—response—we generally did not evaluate agencies' authorities to respond after an unsafe import enters U.S. commerce because the scope of our work was limited to those authorities to prevent their entry.

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<sup>1</sup>This table is not a comprehensive representation of all statutory or regulatory provisions applicable to a particular regulatory activity. In the absence of a primary statutory provision that expressly authorizes or prohibits a particular regulatory activity, we did not undertake an independent analysis to determine whether an agency is authorized to undertake such activity pursuant to a general grant of authority under the relevant implementing statute or otherwise.

<sup>2</sup>Established by the President on July 18, 2007, the Interagency Working Group on Import Safety is composed of senior officials from twelve federal departments and agencies and is organized to continuously improve the safety of imported goods. To accomplish this, the group's strategy is to shift focus from intervention—actions taken when risks are identified—to prevention—actions to prevent harm in the first place.

**Appendix III: Key Authorities of Select Federal Agencies**

**Table 1: Key Authorities of Select Federal Agencies for Preventing the Entry of Unsafe Imports**

	Agency			
	CPSC	FDA	NHTSA	USDA <sup>a</sup>
Product	Consumer products	Food (not including meat, poultry products, eggs, or egg products), drugs, and medical devices <sup>b</sup>	Motor vehicles, motor vehicle equipment	Meat, poultry products, eggs, and egg products; live plants and animals
Primary statute	Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (Oct. 27, 1972) (classified, as amended, at 15 U.S.C. §§ 2051 et seq.) <sup>c</sup> Federal Hazardous Substances Act, Pub. L. No. 86-613, 74 Stat. 372 (July 12, 1960) (classified, as amended, at 15 U.S.C. §§ 1261 et seq.) Flammable Fabrics Act, ch. 164, 67 Stat. 111 (Jun. 30, 1953) (classified, as amended, at 15 U.S.C. §§ 1191 et seq.)	Federal Food, Drug, and Cosmetic Act, ch. 675, 52 Stat. 1040 (Jun. 25, 1938) (classified, as amended, at 21 U.S.C. §§ 321 et seq.)	National Traffic and Motor Vehicle Safety Act, codified as amended, at Subtitle VI Title 49, of the U.S. Code (49 U.S.C. §§ 30101 et seq.)	Federal Meat Inspection Act, ch. 2907, 24 Stat. 1260 (Mar. 4, 1907) (classified, as amended, at 21 U.S.C. §§ 601 et seq.) Poultry Products Inspection Act, Pub. L. No. 85-172, 71 Stat. 441 (Aug. 28, 1957) (classified, as amended, at 21 U.S.C. §§ 451 et seq.) Egg Products Inspection Act, Pub. L. No. 91-597, 84 Stat. 1620 (Dec. 29, 1970) (classified, as amended, at 21 U.S.C. §§ 1031 et seq.) Animal Health Protection Act, Pub. L. No. 107-171, Title X, Subtitle E, 116 Stat. 494 (May 13, 2002) (classified, as amended, at 7 U.S.C. §§ 8301 et seq.) Plant Protection Act, Pub. L. No. 106-224, Title IV, 114 Stat. 438 (Jun. 20, 2000) (classified, as amended, at 7 U.S.C. §§ 7701 et seq.)

**Appendix III: Key Authorities of Select Federal Agencies**

		<b>Agency</b>		
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
<b>Prevention—Authorities to prevent the importation of unsafe products into the United States</b>				
<p>Preapproval, certification, and/or testing of imports prior to entry into the United States</p>	<p>All manufacturers are required to issue a certificate of compliance with all applicable rules, bans, standards, or regulations.</p> <p>Certifications must be based on a test of each product or a reasonable testing program.</p> <p>With respect to certain children’s products, such certification must be based on testing conducted by a third party that is accredited by CPSC.</p>	<p><b>Devices</b></p> <p>Certain devices are subject to premarket approval by FDA.</p> <p><b>New drugs<sup>d</sup></b></p> <p>No new drug may be introduced into interstate commerce unless and until FDA has approved its new drug application. An application may be denied if the application does not include reports of adequate testing by all methods reasonably applicable to show whether or not the drug is safe for use.</p>	<p>Manufacturers are required to certify that vehicles and equipment comply with applicable safety standards. Such certifications may be, but are not required to be, based on testing, and the results of any testing are not required to be reported to NHTSA as a condition for entry.</p>	<p><b>Eggs, egg products, poultry, and meat</b></p> <p>Products must be accompanied by a foreign inspection certificate that includes certain information and representations of the appropriate government official of the exporting country.<sup>e</sup> The inspection must be signed by the authorized foreign government official and, in some cases, bear the official seal of the foreign government agency responsible for inspection of the products.</p> <p>(See also, “Labeling” below.)</p>



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	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
Inspection of facilities located in foreign countries	<p>CPSC is authorized to inspect any factory, warehouse, or establishment in which consumer products are manufactured or held for distribution in the United States.</p> <p>CPSC is required, by rule, to condition the importation of any consumer product into the United States on the manufacturer's compliance with the inspection requirements of the Consumer Product Safety Act (CPSA).</p>	<p>FDA is authorized to conduct inspections of establishments engaged in the manufacture of food, drugs, or devices offered for commercial distribution in the United States.</p> <p>For drugs and medical devices, at the request of FDA, the U.S. agent of the establishment is required to assist in scheduling inspections.</p> <p>In practice, if the foreign firm refuses to permit such an inspection, FDA can sometimes refuse admission of products offered for import into the U.S. For example, the refusal to permit an inspection could lead to a product not receiving a required pre-market approval or the refusal to permit an inspection, combined with other information, could support a determination of the appearance of a violation.</p>	<p>No statutory provision expressly authorizes NHTSA to inspect facilities located in foreign countries.</p>	<p><b>Egg products, poultry, and meat</b></p> <p>Only products from establishments certified by eligible foreign countries are eligible for importation into the United States. In order to be an eligible country, the Food Safety and Inspection Service (FSIS) must determine that the foreign country (1) maintains an inspection system equivalent to that of the United States and (2) ensures compliance with such inspection system.</p> <p>In determining eligibility of a particular country, FSIS will conduct an initial review of the operation of the country's inspection system, and conduct periodic reviews thereafter.</p> <p>The eligibility of foreign establishments to continue to export products to the United States is subject to periodic review, including observations of the foreign establishments by FSIS.</p> <p><b>Live plants and animals</b></p> <p>APHIS may inspect plants and animals for export at international ports or other points of origin.</p>

**Appendix III: Key Authorities of Select Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
<b>Intervention—Authorities to intercept unsafe goods before they enter U.S. commerce</b>				
Product standards/ product bans	<p>CPSC may promulgate mandatory product safety standards, as well as rules declaring a product a banned hazardous product. Currently, there are 33 mandatory safety standards.</p> <p>CPSC may also petition a U.S. District Court to declare a product an imminently hazardous consumer product and grant such relief as may be appropriate to protect the public, such as ordering a recall of the product or ordering the notification of such risk to the purchasers of the product.</p>	<p><b>Food and devices</b></p> <p>Applicable law sets forth the definitions for adulterated and misbranded food, drugs, and devices, including the standards for manufacturing practices.</p>	<p>NHTSA may prescribe motor vehicle safety standards. Currently, there are 45 safety standards for vehicles and 15 safety standards for equipment.</p>	<p><b>Eggs, egg products, poultry, and meat</b></p> <p>FSIS regulates the sanitary operating practices of plants that slaughter or process poultry and meat and sets forth sanitary operating practices of plants that process egg products.</p> <p>Statutes set forth definitions of adulterated and misbranded meat, poultry, and egg products.</p> <p><b>Live plants and animals</b></p> <p>Statute prohibits the import of plants or animals that contain certain pests or diseases.</p>
Labeling	<p>CPSC may require permanent markings (e.g. labels) on products, where practicable, that identify the date and place of manufacture, as well as manufacturing cohort information, such as batch number.</p>	<p><b>Food, drugs, and devices</b></p> <p>Products are subject to labeling requirements such as, depending on the product, its contents, and its proper use.</p>	<p>Manufacturers affix to the motor vehicle or equipment, or to the equipment container, a label, tag, or marking that represents the required certification that the vehicle or equipment complies with applicable safety standards.</p>	<p><b>Eggs, egg products, poultry, and meat</b></p> <p>The immediate containers of eggs and egg products must bear a label printed in English with certain information, including, for egg products, the inspection mark of the country of origin.</p> <p>The immediate containers of imported poultry and meat must bear labels that comply with the labeling requirements applicable to domestic products, except that the label will bear the name of the country of origin and the inspection mark and establishment number assigned by the foreign inspection system and certified to FSIS.</p>

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Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
Registration of foreign manufacturers/ facilities	There is no statutory requirement for the registration of foreign manufacturers with CPSC.	<p><b>Food</b></p> <p>A foreign establishment that engages in the manufacture, processing, packing or holding of food for export to the United States without further processing or packaging outside of the United States, must register with FDA and provide certain information, including a list of all trade names and the name of its U.S. agent.</p> <p><b>Drugs and devices</b></p> <p>A foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or device offered for import into the United States must register with the FDA and provide a list of each drug offered for commercial distribution and the name of its U.S. agent.</p>	Motor vehicles not certified to all applicable safety standards may only be imported by a person registered with NHTSA or by a person who has contracted with a registered importer.	There is no statutory requirement for registration of foreign establishments with USDA.

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Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
Preshipment/prearrival notification	No statutory provision expressly requires foreign manufacturers to provide preshipment notification to CPSC.	<p><b>Food</b></p> <p>Food shipments presented for import must be preceded by prior notice to enable FDA to target food for inspection at ports of entry.</p> <p>Notification must identify the article, manufacturer, shipper, grower, country of origin, and anticipated port of entry.</p>	No statutory provision expressly requires foreign manufacturers to provide preshipment notification to NHTSA.	<p><b>Eggs, egg products, poultry, and meat</b></p> <p>Except for importers of Canadian meat products, importers must make an application for inspection at the port of entry. The application should be made as long as possible in advance of the anticipated arrival of the product to the United States. Importers of Canadian meat products are subject to streamlined inspection procedures.</p>

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Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
Border surveillance	<p>CPSC is required to maintain a permanent product surveillance program to prevent the entry of unsafe consumer products into the United States, among other things. CPSC may inspect consumer products being offered for import. At CPSC's request, CBP will obtain a reasonable number of samples of such product for the purpose of making admissibility decisions.</p>	<p><b>All products</b>            FDA may examine shipments and obtain samples of food, drugs, and devices presented for import to determine whether the product is subject to refusal of admission.             Also, authority provided to prioritize border food inspections, develop tests for the rapid detection of adulterated food, improve border computer systems, and improve links with other federal agencies responsible for food safety.</p>	<p>No statutory provision mandates a border surveillance program.</p>	<p><b>Eggs, egg products, poultry, and meat</b>            CBP notifies FSIS when products from restricted countries are presented for import into the United States.</p> <p><b>Live plants</b>            CBP is to notify APHIS of the arrival of any plant at a port of entry and is to hold the item until it is inspected and authorized for entry or is otherwise released by APHIS.</p> <p><b>Live plants and animals</b>            APHIS may stop and inspect, without a warrant, any person or means of conveyance moving into the United States to determine whether it is carrying any plant or regulated animal.             Also, authorities are provided to improve surveillance at ports of entry and customs and to implement a centralized automated recordkeeping system to better track the status of animal and plant shipments, including those on hold at ports of entry and customs.</p>

**Appendix III: Key Authorities of Select Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
Refusal at ports of entry	<p>CPSC may refuse admission of any consumer product offered for import that</p> <ul style="list-style-type: none"> <li>• fails to comply with an applicable mandatory safety standard or ban;</li> <li>• has been determined to be an imminently hazardous consumer product;</li> <li>• has a defect which constitutes a substantial product hazard;</li> <li>• is not properly certified or labeled; or</li> <li>• is manufactured by a manufacturer that has failed to comply with applicable recordkeeping and inspection requirements.</li> </ul>	<p><b>All products</b></p> <p>Subject to an opportunity to introduce testimony, any food, drug, or device may be refused admission into the United States if it appears from an examination or otherwise that the product</p> <ul style="list-style-type: none"> <li>• is adulterated or misbranded;</li> <li>• is an unapproved new drug;</li> <li>• is forbidden or restricted in sale in the exporting country; or</li> <li>• has been manufactured or processed in unsanitary conditions or out of conformance with good manufacturing practices.</li> </ul> <p><b>Food</b></p> <p>FDA may refuse a food shipment for which advance shipment information has not been provided or is from an unregistered foreign manufacturer.</p> <p><b>Drugs and devices</b></p> <p>FDA may refuse drugs or devices that are not accompanied by a registration of foreign supplier.</p>	<p>Motor vehicles or motor vehicle equipment manufactured after the date an applicable safety standard takes effect shall not be imported unless they comply with the standard and are covered by an appropriate certification of conformance.</p>	<p><b>Eggs, egg products, poultry, and meat</b></p> <p>Eggs, egg products, poultry, and meat that are adulterated, misbranded, or do not comply with standards applicable to equivalent products in U.S. commerce shall not be imported.</p> <p><b>Live plants or animals</b></p> <p>APHIS may refuse admission to plants if determined necessary to prevent the spread of plant pests or noxious weeds in the United States.</p> <p>APHIS may refuse admission of any animal, article, or means of conveyance to prevent the introduction or spread of any pest or livestock disease in the United States.</p>

**Appendix III: Key Authorities of Select Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
Detention/ seizure/ holds pending completion of inspection or further action by owner	CPSC may examine samples of products at ports of entry. CPSC statutes describe prohibited acts, which form the basis for it to instruct CBP to seize products under the Tariff Act authorities. CPSC may also decide to detain the shipment pending further examination and testing, conditionally release the shipment to the importer's premises pending examination and testing, or release the shipment to the importer outright.	<p><b>All products</b></p> <p>Food, drugs, and devices are subject to inspection. The product remains in the custody of CBP, unless delivered to the owner or consignee under bond.</p> <p><b>Food</b></p> <p>FDA may request that a food article that appears to present a health threat be held for a period not to exceed 24 hours for the purpose of inspecting, examining, or investigating it.</p> <p>Food shipments that arrive without adequate prior notice or that are from unregistered foreign manufacturers may be held until prior notice or registration is completed.</p>	No statutory provision; however, NHTSA regulations provide that motor vehicles not in conformity with all applicable safety standards at the time of import may be admitted under a bond to ensure that the vehicle will either be brought into conformity within 120 days, returned to the custody of CBP for export, or abandoned to the United States.	<p><b>Eggs, egg products, poultry, and meat</b></p> <p>Generally, eggs, egg products, poultry, and meat are subject to U.S. inspection at the port of entry and may not be removed from the port of entry prior to inspection. The product remains in the custody of CBP unless delivered to the consignee under an approved bond.</p> <p>FSIS may detain egg products, poultry, and meat for a period not to exceed 20 days.</p> <p><b>Live animals</b></p> <p>APHIS may require that any imported animal be raised or handled under quarantine to determine whether it is affected by any pest or disease.</p>

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Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
Product destruction	<p>Products refused admission into the United States must be destroyed, unless CBP permits the product to be exported from the customs territory of the United States.</p> <p>All expenses connected with destruction must be paid by the owner or consignee. A failure to make such payment shall constitute a lien against future imports.</p>	<p>CBP may destroy any food, drug, or device that is refused admission, unless the article is exported within 90 days.</p> <p>All expenses connected to the destruction of refused goods shall be paid by the owner or consignee. A default shall constitute a lien against future imports.</p>	<p>There is no statutory provision regarding the destruction of nonconforming motor vehicles or equipment by NHTSA.</p>	<p><b>Egg products, poultry, and meat</b></p> <p>Egg products, poultry, and meat that violate federal requirements are destroyed at the expense of the owner or consignee, unless they are exported or brought into compliance (e.g., labeling). The costs of the destruction are either paid directly by the owner or consignee or reimbursed to the government. The failure to make any such reimbursement shall constitute a lien against future imports.</p> <p><b>Live animals</b></p> <p>APHIS may order the destruction or removal from the United States of any animal to prevent entry or spread of any pest or livestock disease. The Secretary of Agriculture may also order owners to disinfect the means of conveyance, an individual, or article involved in the importation of animals ordered to be destroyed or removed.</p> <p>If owner fails to comply with destruction/removal orders, the Secretary may recover from the owner the costs of any care/destruction.</p>



**Appendix III: Key Authorities of Select Federal Agencies**

	<b>Agency</b>			
	<b>CPSC</b>	<b>FDA</b>	<b>NHTSA</b>	<b>USDA<sup>a</sup></b>
<b>Response—Authorities to act on harm, real or potential, after products enter U.S. commerce</b>				
Require foreign manufacturers to consent to local court jurisdiction	No statutory provision mandates that CPSC require foreign manufacturers to consent to local court jurisdiction.	No statutory provision mandates that FDA require foreign manufacturers to consent to local court jurisdiction.	No statutory provision mandates that NHTSA require foreign manufacturers to consent to local court jurisdiction.	No statutory provision mandates that USDA require foreign manufacturers to consent to local court jurisdiction.

Source: GAO analysis of agency guidance.

<sup>a</sup>USDA's FSIS oversees meat, poultry products, eggs, and egg products, and APHIS oversees live plants and animals.

<sup>b</sup>FDA oversees other products, including biologics, cosmetics, and radiation-emitting electronic products, but our scope was limited to food, drugs, and certain medical devices.

<sup>c</sup>As stated in this report, CPSC administers other product safety statutes, but these are the three primarily affecting CPSC's ability to prevent the entry of unsafe products.

<sup>d</sup>The term "new drug" does not mean simply a drug that is new on the market; rather, it is any drug, regardless of how old, about which insufficient data exists upon which qualified experts can reach a consensus that the drug is safe and effective. *See* 21 U.S.C. § 321(p). "In other words, a drug is *not a new drug* only if it '(1) is generally recognized, among experts qualified to evaluate the safety and effectiveness of drugs, as safe and effective for its labeled purposes; and (2) has been used to a material extent for a material time.'" *U.S. v. Undetermined Quantities of Cal-Ban 3000*, 776 F. Supp. 249, 256 (E.D. N.C. 1991)(citation omitted)(emphasis added).

<sup>e</sup>For example, with respect to egg products, the foreign inspection official must certify that the products were produced under the approved regulations, requirements, and continuous government inspection of the exporting country. Eggs must be accompanied by a foreign inspection certificate that certifies that the eggs have at all times after packing been refrigerated at the required temperature. With respect to poultry, the foreign inspection official must certify that the product received antemortem and postmortem inspections at the time of slaughter and that such poultry products are sound, healthful, wholesome, and otherwise fit for human food.

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# Appendix IV: Key Authorities of Selected International Entities

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We compared consumer product safety authorities, practices, and procedures for Australia, Canada, China, the European Union (EU), Japan and the United States. Figure 3 identifies the authorities and activities we compared, as well as any future plans for changing the organizations, structures, and/or mechanisms for consumer product safety in the respective countries. Following the figure is a more detailed discussion of the authorities, practices, and procedures. The information in this appendix is based on information we received through U.S. Embassies in these countries, foreign embassies in Washington, D.C., and interviews with country officials. We reviewed documents regarding product safety provided by U.S. Embassy officials in the selected countries. We did not independently analyze the laws or procedures of these countries; instead, we relied on third-party assessments of each country's consumer product safety framework.

**Appendix IV: Key Authorities of Selected International Entities**

**Figure 3: Comparison of Selected International Entities' Authorities with CPSC's Authorities to Prevent the Entry of Unsafe Consumer Products**

	<b>Australia</b>	<b>Canada</b>	<b>European Union</b>	<b>Japan</b>	<b>United States</b>
<b>Key regulatory authorities</b>	Trade Practices Act 1974; various state and territory laws	The Hazardous Products Act and its corresponding regulations  Chemical Management Plan	The General Product Safety Directive (GPSD) (2001/95/EC) sets out the basic requirements on consumer product safety for all EU member states.	- Consumer Product Safety Law - Consumer Basic Act - Product Liability Act - Law for the Control of Household Products Containing Harmful Substances - Food Sanitation Law	Consumer Product Safety Act  Federal Hazardous Substances Act  Flammable Fabrics Act
<b>Organizational structure</b>	Australian Treasury and state/territory offices of fair trading develop policy. Consumer law enforcement is shared between national, state, and territory regulators. Australian Competition and Consumer Commission (ACCC) and state/territory offices of fair trading conduct enforcement and monitoring.	Health Canada is the key policy development and enforcement agency. Provincial governments have jurisdiction over the adoption of the National Building Code, which includes certification requirements for electrical, gas, and plumbing products.	Directorate General for Health and Consumers (DG SANCO) is the primary EU agency responsible for consumer product safety. EU member states are responsible for implementation and enforcement of EU legislation.	METI is responsible for consumer product safety policy. The National Institute of Technology and Evaluation conducts inspections in accordance with METI's instructions and analyzes the cause of accidents. The Cabinet Office provides overall policy guidance.	Consumer Product Safety Commission (CPSC) has national responsibility for consumer product safety policy and enforcement.
<b>Standards</b>	Currently there are few direct consumer safety regulations on most imported goods; however, retailers can face legal action if the goods are faulty. Only a small number of imported consumer products are subject to mandatory standards.	Approximately two-thirds of standards in Canada are voluntary. Some consumer product standards are mandatory legal requirements, others are industry standards developed on a voluntary basis, and some are purely market driven as a particular technology becomes the industry standard.	Imported products must meet the same requirements as domestic products. The EU product safety system is based on voluntary standards. However, for mandatory European Commission standards, products that are manufactured to harmonized standards developed by recognized European standardization bodies benefit from a presumption of conformity with the safety requirements. The safety requirements are expressed in sectoral directives, conformity assessment measures, and, in certain sectors, the availability of European standards. The GPSD fills in the gaps when no sectoral directive exists.	Japanese Standards Association, Japanese Industrial Standards, and the Consumer Affairs Council are responsible for the development of standards. Most standards in Japan are voluntary. Product requirements fall into two categories: technical regulations (or mandatory standards) and nonmandatory voluntary standards.	CPSC may promulgate mandatory product safety standards and rules declaring a product a banned hazardous product. CPSC must defer to a voluntary standard if CPSC determines that the voluntary standard adequately addresses the hazard and that there is likely to be substantial compliance with the voluntary standard. CPSC may ban a consumer product if it determines no feasible standard would protect the public from unreasonable risk of injury.
<b>Product certification / labeling / testing</b>	No requirement for imported product certification. The Productivity Commission has suggested that importers of consumer goods certify that their goods meet applicable Australian mandatory safety standards, but the government has not enacted this suggestion.	No requirement for product certification; however, new legislation seeks to require the furnishing of entry documents and test results at the border.	Member states are required to conduct sampling and safety testing of domestically manufactured or imported products and to follow-up on consumer complaints. Businesses must carry out conformity and safety assessments of their products in accordance with the GPSD and/or specific legislation applicable to their products. For some products, self-declaration is sufficient but other products require third-party verification.	Certain imported and domestic products are subject to product testing and cannot be sold in Japan without certification to prescribed standards. Compliance with regulations and standards is also governed by a certification system in which inspection results determine whether or not approval (certification) is granted.	CPSC requires manufacturers to issue a certificate of compliance with mandatory standards. Certifications must be based on a test of each product or a reasonable testing program. Children's products must be certified by a third party. CPSC may require labels to be permanently marked or affixed to any product, where practicable.

**Appendix IV: Key Authorities of Selected International Entities**

	Australia	Canada	European Union	Japan	United States
Definition of unsafe products	No definition for unsafe products; however, current law allows the Minister for Consumer Affairs to ban or compulsorily recall consumer products in cases where the products "will or may cause injury."	Nothing specific at this time under the Hazardous Products Act. A new act passed by the House of Commons and awaiting action by the Canadian Senate, as of June 2009, will include a definition of "danger to human health or safety."	GPSD defines a "consumer product" and what constitutes a "safe" and "unsafe" product. A "dangerous product" means any product that does not meet the definition of a "safe" product.	Article 1 of the Consumer Product Safety Law defines products as unsafe if they cause threat to consumers' life or health.	Section 15 of Consumer Product Safety Act defines a substantial product hazard as a failure to comply with a mandatory standard or a product defect that creates a substantial risk of injury.
Inspect foreign facilities	The government does not have this authority on product safety grounds. Such authority does exist in certain areas, such as motor vehicles and aircraft, covered by domestic legislation governing the import and licensing of such products.	The government does not have this authority. Instead, Canada works with the exporter and has been successful in using this approach, according to officials.	DG SANCO has no inspection authority. Member-state authorities can review technical product files that all businesses are required to maintain to certify general conformity with product standards.	The government does not have this authority.	CPSC is required, by rule, to condition the importation of any consumer product into the United States on the manufacturer's compliance with the inspection requirements of CPSA.
Border surveillance authorities for imported goods	Australian Customs has responsibility for determining what may enter Australia. Customs generally accepts ACCC recommendations to ban imports of unsafe products.	The Canada Border Services Agency uses a risk-based approach to border management to detect and intercept dangerous goods and to facilitate the movement of low-risk goods. Health Canada does not have full-time port presence and relies on Canada's Border Services Agency for seizure and destruction of products.	The EU recently issued a new regulation to strengthen customs controls. The EU Council Regulation provides the customs authorities with the legal basis and equally applicable and comparable procedures in all member states to suspend, for no more than 72 hours, the release of products that they suspect of posing a serious risk to health and safety.	Japan does not designate consumer products separately in their border and customs authorities. As with CPSC and the EU, Japan imposes its consumer product safety laws on importers, which means that products must be in compliance in order to be imported to Japan.	CPSC is to maintain a permanent surveillance program to prevent the entry of unsafe consumer products into the United States.  CPSC may request a reasonable number of samples from Customs and Border Protection (CBP) to examine products for the purpose of making admissibility decisions.
Require consent to local jurisdiction	Under the current law, Australia could ask foreign jurisdictions to enforce Australian consumer product safety laws. In practice, the Government of Australia prefers other methods, such as approaching manufacturers directly to raise concerns.	The government does not have this authority.	DG SANCO has no jurisdictional authority outside the common market. Within the common market, the regulations apply to the importer, distributor, manufacturer, and retailer. Imported products must meet the same requirements as domestic products.	The government does not have this authority	No statutory provision mandates that CPSC require foreign manufacturers to consent to local court jurisdiction.
Future plans	Under a decision reached by the Council of Australian Governments in 2008, Australia's states and territories are expected to adopt the new Trade Practices Act in its entirety in 2010, providing a harmonized product safety regime with greater federal government control.	On June 12, 2009, Canada's new Consumer Product Safety Act was passed by the House of Commons and, as of the end of June, is awaiting action by the Canadian Senate. The new act will provide better oversight of consumer products by improving the government's ability to take timely compliance and enforcement actions when unsafe products are identified. It will also encourage compliance through higher fines and increased penalties for violators.	Recent EU initiatives aim to improve market surveillance and consistency of enforcement across the member states.	On May 29, 2009, the Japanese Diet approved bills establishing the Consumer Affairs Agency. The agency will be responsible for consumer protection issues as part of a more centralized approach. Approximately 200 staff will move to the new agency from the Cabinet Office; the Fair Trade Commission; the Ministry of Economy, Trade and Industry; the Ministry of Agriculture, Forestry and Fisheries; and the Ministry of Health, Labor and Welfare.	Implementation of the Consumer Product Safety Improvement Act of 2008 is ongoing.

Sources: Official documents from foreign governments and from their official Web sites, from U.S. embassies overseas, and foreign embassies in Washington, D.C.

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## Australia

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### Environment for Consumer Product Safety in Australia

Currently, the dominant issue concerning consumer product safety in Australia is the reorganization of its policy framework. On October 2, 2008, the Council of Australian Governments agreed to a new policy framework for implementation in 2010, comprising a single national consumer law and streamlined enforcement arrangements. This more centralized approach to consumer product safety replaces the current system in which the federal, state, and territory governments all share responsibility for consumer policy and enforcement.

- *Key organizations:* Currently, responsibility for product safety regulation in Australia is shared between the federal, state, and territory governments. The Australian Treasury is the agency responsible for developing consumer policy, and the Australian Competition and Consumer Commission monitors and enforces compliance with product safety laws. In addition, state and territory governments each have their own fair trading agencies that enact and enforce state-based consumer product safety legislation. Such legislation is similar, but not identical, to federal government legislation, which sometimes leads to legislative inconsistencies between jurisdictions.
- *Resources:* Australia has 30 policy staff working in the Product Safety section of the Australian Competition and Consumer Commission and enforcement staff numbering around 150 around Australia. There is no separate international office for consumer product safety. The total combined resources allocated by the Australian Commonwealth (federal), state and territory governments to enforcement in this area of consumer product safety are estimated to be about A\$5 million annually.
- *Consumer advocacy:* Consumer advocacy groups have emerged in Australia over the last 40 years in response to growing interest in product safety issues. Groups such as the Australian Consumers Association supply information on safety issues to consumers and lobby federal, state and territory governments to address the most serious product-related hazards.

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### Regulatory Framework/System

- *Laws and regulations:* Currently, Australia's general consumer product safety system is based on the product safety provisions contained in the Trade Practices Act 1974 and on equivalent provisions in Fair Trade Acts in Australia's eight states and territories. The administration and enforcement of these provisions, along with other nonregulatory activities

conducted by the federal, state, and territory governments, are also part of the system.

The Trade Practices Act 1974 contains general product safety provisions, as well as a product liability regime that enables consumers to seek a range of remedies, including damages for loss or damage caused by a defective product. The act provides the Australian government minister responsible for consumer affairs the power to intervene in markets to ensure product safety, including such activities as

- prescribing consumer product safety and consumer product information standards;
- declaring products unsafe and banning them;
- investigating products to determine whether they will or may cause injury and/or issuing a warning notice of the risk of using the product;
- ordering the compulsory recall of products; and
- obtaining information, documents, and other evidence related to the administration of the safety provisions of the Trade Practices Act.

While in law the general regime applies to all consumer products, in effect this system provides the general legal safety net for products not otherwise protected by specific legislation that addresses more hazardous products.

- *Definition of safe products:* Australia currently has no definition of safe or unsafe products. However, current law allows the Minister for Consumer Affairs to ban or compulsorily recall consumer products in cases where the products will or may cause injury.
- *Standards:* The Trade Practices Act provides the Australian government minister responsible for consumer affairs with the power to establish mandatory standards for a product where it can be demonstrated that it has the potential to cause injury. Standards Australia, an independent, nongovernmental organization, is the sole recognized body for standards development. Only a small number of imported consumer products are subject to mandatory standards, and over half of the standards apply to products that may pose a danger to children. State and territory legislation also allows for the issuance of mandatory standards. At times, the Australia Competition and Consumer Commission, the Treasury, and the

state and territory fair trading representatives have participated in Standards Australia processes.

- *Detection, reporting, and removal of unsafe products:* The current regulatory system relies on governments (federal, state, and territory) to identify and regulate specific product hazards. According to Australia's Ministerial Council on Consumer Affairs, the ability of these governments to address potential safety hazards across a great range of products is affected by limitations on their resources and by the time and effort required to implement, enforce, and review product-specific regulations. Currently, the vast majority of product recalls are undertaken voluntarily by businesses that have become aware of a safety problem concerning one of their products. The Trade Practices Act and many of the state and territory Fair Trading Acts contain provisions that allow governments to order compulsory product recalls when necessary.
- *Business responsibility:* Businesses promote product safety through industry sector associations, which often undertake such self-regulatory activities as business education, the development of industry codes of conduct, and engagement with law enforcement and standards development bodies on enforcement and policy issues. Currently there is no formal requirement for suppliers to monitor the safety of the products they sell, once those products are released to the marketplace. Under the current regulatory system, businesses are required to report voluntary recalls to the Australian government minister responsible for consumer affairs and to the Office of Fair Trading in some other jurisdictions. The Ministerial Council on Consumer Affairs has proposed that suppliers be required to monitor the ongoing safety of the products they sell and report to the government any products that are under investigation for possible safety risks, have been associated with serious injury and death, or have been the subject of a successful product liability claim.
- *Policy enforcement and compliance:* The Australian Competition and Consumer Commission is responsible for enforcing the Trade Practices Act's product safety regime. To ensure that suppliers subject to mandatory standards and bans are responding appropriately, the commission may compel the provision of information, require evidence under oath, undertake random market surveys, enter premises, and seize documents. In situations where suppliers have failed to comply with mandatory standards or bans, the commission can seek orders in the Federal Court requiring such suppliers to recall the noncomplying products. Additionally, the commission may institute civil proceedings or criminal proceedings under the Trade Practices Act. State and territory governments have enforcement powers similar to those of the Competition and Consumer

Commission under their own legislation. The relevant state and territory Fair Trading Acts contain criminal liability provisions similar to those in the Trade Practices Act.

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## Future Plans

On October 2, 2008, the Council of Australian Governments agreed to a new consumer policy framework as proposed by the Ministerial Council on Consumer Affairs. According to the Australian government, the new framework consists of a single national consumer law and streamlined enforcement arrangements. Australia's states and territories are expected to adopt the new Trade Practices Act in its entirety in 2010, providing a harmonized product safety regime with greater federal government control. The council recognized that while Australia's current consumer policy framework has strengths, it is in need of significant improvements to overcome existing inconsistencies, gaps, and duplication in Australia's consumer legislation and its enforcement. The reforms have the following three key elements:

- the development of a consumer law (called *the Australian Consumer Law*) to be applied both nationally and in each state and territory, which is based on the existing consumer protection provisions of the Trade Practices Act 1974, and which includes a new national provision regulating unfair contract terms, new enforcement powers and, where agreed, changes based on best practices in state and territory laws;
- the implementation of a new national product safety regulatory and enforcement framework, as part of the national consumer law; and
- the development of enhanced enforcement cooperation and information-sharing mechanisms between national and state and regulatory agencies.

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## Canada

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### Environment for Consumer Product Safety in Canada

Changing consumer demands, new technologies, and the increasing complexity of global supply chains are the major influences behind Canada's current efforts to modernize its regulatory tools for consumer product safety. According to the Canadian government, the authorities governing food, health, and consumer products in Canada derive from legislation developed in the 1950s and 1960s and, as a result, they are out of step with modern realities and needs. For example, the Canadian



government lacks sufficient authority to issue a mandatory recall of a health or consumer product if it poses a serious or imminent risk to health and safety or to compel manufacturers to take steps to reduce the risk associated with a product. In addition, according to the Canadian government, fines and penalties are low compared with those of other countries. New legislation will update and strengthen Canada's consumer product safety framework.

- *Key organizations:* Currently, Health Canada regulates the import, sale, and advertisement of hazardous products or substances. Health Canada
  - supports the development of safety standards and guidelines;
  - enforces legislation by conducting investigations, inspections, seizures, and prosecutions;
  - tests and conducts research on consumer products;
  - provides importers, manufacturers, and distributors with hazard and technical information;
  - publishes product advisories, warnings, and recalls; and
  - promotes safety and the responsible use of products.

The Canada Border Services Agency is responsible for stopping goods at the border. The agency has a service agreement with Health Canada under which it seeks to prevent prohibited products from entering Canada and facilitates additional targeted inspections of these products, as well as shipments of products from companies with histories of poor compliance. In addition, the agency's Single Window Initiative will give the department access to import and export data that will help to efficiently approve shipments of low-risk products from low-risk suppliers or, alternatively, tag suspicious ones before they have left their point of export.

Other organizations include the Standards Council of Canada, the Canadian Standards Association, the Canadian General Standards Board, and the Underwriters' Laboratories of Canada. Also, Canada's Provincial governments have jurisdiction over the adoption of the National Building Code, which includes certification requirements for electrical, gas, and plumbing products.

- *Resources:* Canada’s consumer product safety agency, within Health Canada, consists of 130 employees who serve as laboratory, compliance, and policy development staff.
- *Consumer advocacy:* Consumer advocacy groups in Canada are particularly concerned with consumer safety issues related to children’s products and food products. Some advocacy groups in Canada include the Canada Toy Testing Council, the Consumers’ Association of Canada, Consumers Council of Canada, and the Public Interest Advocacy Centre.

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Regulatory  
Framework/System

- *Laws and regulations:* The Canadian government’s key legislation governing consumer product safety is the Hazardous Products Act. Part 1 of the act lists consumer products that are either restricted through regulation or outright prohibited from being advertised, sold, or imported into Canada. There are approximately 30 products and product categories that are regulated, and some 25 others that are prohibited. All imported products are subject to the D Memoranda, which incorporates legislation, regulations, policies, and procedures used by the Canada Border Services Agency. Canada’s Chemical Management Plan also has an impact on consumer product safety.
- *Definition of safe product:* Canada has no specific definition under the Hazardous Products Act. However, a new act, currently awaiting Canadian Senate approval as of June 2009, will include a definition of “danger to human health or safety,” which will support a general prohibition.
- *Standards:* Some consumer product standards are mandatory legal requirements, others are industry standards developed on a voluntary basis, and some are purely market driven as a particular technology becomes the industry standard. Approximately two-thirds of standards in Canada are voluntary. Federal and provincial legislation may impose mandatory standards for products, typically where health or safety issues are regarded as requiring regulation. Standards can also be written into the legislation itself; such is the case with certain specifications in toy regulations under the Hazardous Products Act. The Standards Council of Canada is the national coordinating body for the development of voluntary standards through the National Standards System.
- *Detection, reporting, and removal of unsafe products:* The current Canadian product safety regulatory system follows a reactive approach. When a product has been deemed to pose a risk to users—usually over a period of time, with reported injuries and/or deaths associated with the product’s use—a risk assessment is carried out. The regulatory process

involves many steps, including consultation with public, industry, and technical experts. The end result is either that the product remains available for sale in the Canadian marketplace or that Health Canada imposes a legal ban on the product under the Hazardous Product Act.

- *Business responsibility:* Currently, there is no mandatory reporting for businesses, and Health Canada relies largely on negotiating with suppliers to voluntarily recall or take other corrective measures to address a product that poses an unreasonable danger to the health or safety of consumers. The new Consumer Product Safety Act (discussed below) will give inspectors the ability to order a supplier to take corrective measures.
- *Policy enforcement and compliance:* Canadian authorities have the ability to seize products, prosecute violations through a criminal code, and impose civil money penalties. The maximum amount of a civil money penalty is \$1 million per violation, although penalties of \$25,000 are most common.

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## Future Plans

On June 12, 2009, Canada's new Consumer Product Safety Act was passed by the House of Commons and, as of the end of June 2009, is awaiting final action by the Canadian Senate. The Consumer Product Safety Act would replace Part I of the Hazardous Products Act and includes a new regulatory regime. The act focuses on three key areas:

- *Working to address problems before they happen:* The legislation introduces a general prohibition against the manufacture, importation, advertisement or sale of consumer products that pose an unreasonable danger to human health or safety. It strengthens compliance promotion and enforcement activities through increased fines up to \$5 million for some offenses and fines that are left to the discretion of the courts where the offense is committed knowingly or recklessly.
- *Targeting the highest risk:* The act provides the authority to require suppliers to conduct safety tests upon a minister's orders and to provide the results where there are indications of a problem. The legislation will also require suppliers to notify Health Canada of serious incidents or defects and to provide detailed reports about the incidents.
- *Rapid response:* The act allows the Canadian government to take more immediate responsive action to protect the public when a problem occurs. It would authorize inspectors to order mandatory recalls and other corrective measures to address unsafe consumer products and would require suppliers to maintain accurate records to enable quick product tracking. In addition, to further improve the government's ability to

respond effectively, Health Canada would double the number of product safety inspectors.

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## European Union

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### Environment for Consumer Product Safety in the EU

In 2007, in response to massive recalls of consumer products worldwide, the European Commission (EC) conducted an internal review of the European Union (EU) product safety framework.<sup>1</sup> The review concluded that the community regulatory system (discussed below), including the General Product Safety Directive, was capable of providing to European citizens a high level of protection against unsafe consumer products, as long as the rules of the system were properly applied. The review identified areas for improvement and ways of perfecting their system. The review stated that the adoption of the “Commission Decision” on magnets in toys<sup>2</sup>; the revision of the “European Directive” on the safety of toys;<sup>3</sup> and the issuance of rules called the “New Legislative Framework” for the marketing of goods; would also raise the existing level of protection.<sup>4</sup> It also identified some areas for further attention.<sup>5</sup> These findings were subsequently referred to in an official EU report on the implementation of the relevant legislation.<sup>6</sup>

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<sup>1</sup>In the EU, policy responsibilities lie with the EC— the executive arm of the EU, responsible for implementing its policies and running its programs.

<sup>2</sup>Commission Decision 2008/329/EC (OJ L 114, 26.4.2008, 90).

<sup>3</sup>COM (2008) 9.

<sup>4</sup>On July 9, 2008, a new legislative framework for the marketing of products consisting of Regulation (EC) No. 765/2008 and Decision 768/2008/EC was adopted (OJ L 218, 13.8.2008, 30, 82).

<sup>5</sup>The report suggests scope to develop the framework and further actions, outlining benefits which further coordinated market surveillance between the Member States would bring, given the increasingly global market. It also suggests that efficiency in addressing product safety issues would be increased if the Commission were enabled to act more quickly to create state-of-the-art standards for specific risky products and if a permanent ban could be imposed under the General Product Safety Directive on products or substances when a risk is generally recognized, rather than having to do this through further product specific Directives.

<sup>6</sup>*Report from the Commission to the European Parliament and to the Council on the Implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety*, Brussels, 14.1.2009, COM(2008)905 final. [http://ec.europa.eu/consumers/safety/prod\\_legis/docs/report\\_impl\\_gpsd\\_en.pdf](http://ec.europa.eu/consumers/safety/prod_legis/docs/report_impl_gpsd_en.pdf).

- *Key organizations:* The EC Directorates General for Health and Consumers (consumer product safety), Enterprise and Industry (safety of regulated products) and Taxation and Customs Union (import safety) put forth legislation aimed at further ensuring the safety of products. The Directorate General for Health and Consumers, referred to as DG SANCO, is an EU branch that is somewhat equivalent to CPSC in driving consumer product safety matters both within Europe and internationally. However, EU member states (currently 27 individual countries) are responsible for implementation and enforcement of EU legislation. Each member state has established its unique structures for handling product safety given their cultural history and industrial background. The European Commission coordinates their approaches and ensures their cooperation.
- *Resources:* Because of the very different role of the EC as compared to CPSC in product safety enforcement, EU officials had difficulties providing us with useful figures on resources and stated they risked being seriously misleading if the member states' role was not taken into consideration. They did not have conclusive data for the member states. Different commission departments also perform part of their functions related to consumer product safety, such as reviewing European legislation in certain sectors relevant for consumer safety, which would make sense to include in their "central function" resources. While the "Product and Service Safety" unit in DG SANCO is generally comparable to CPSC in terms of policy function, it does not include actual implementation and enforcement at the level of the individual member states. Many staff from the Product and Service Safety unit play a role in the "international" (versus "European") area, but also have other responsibilities. DG SANCO determines who represents the EU at the international level by the subject-matter expertise for product safety.

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Regulatory Framework in  
the EU

- *Laws and regulations:* The General Product Safety Directive sets out the basic consumer product safety requirements and defines a "consumer product," and Article 2(b) and (c) of the directive defines "safe" and "unsafe" product. A "dangerous product" is any product that does not meet the definition of a "safe" product.
- *Definition of safe product:* The directive defines a "safe product" as any product which—under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements—does not present any risk or only the minimum risks compatible with the product's use. Such a product is considered to be acceptable and consistent with a high level of protection

for the safety and health of persons taking into account the following points in particular:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, instructions for installation and maintenance;
- the effect on other products, where it is reasonably foreseeable that it will be used with other products;
- the presentation of the product, the labeling, any warnings and instructions for its use and disposal, and any other indication or information regarding the product; and
- the categories of consumers at risk when using the product, in particular children and the elderly.

In addition, the feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be “dangerous.”

In response to inconsistencies and identified weaknesses in the EU legislative framework for product safety, the EU issued additional regulations on marketing of products within the member states. Adopted in July 2008, this new framework aims to strengthen accreditation and market surveillance across member states and to remedy existing weaknesses of the legislative framework. It will apply from 2010. Guidance will be issued on its relation with the General Product Safety Directive.

- *Standards:* The EU product safety system is based on voluntary standards. However, products that are manufactured to harmonized standards developed by recognized European standardization bodies (CEN, CENELEC, and ETSI) on the basis of a mandate (formal request) by the EC and ultimately referenced on the “Official Journal” of the EU benefit from a presumption of conformity with the safety requirements of the relevant legislative framework that are covered by those standards.<sup>7</sup> The

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<sup>7</sup>The drafting of specific EU standards is handled by three European standards organizations: the European Committee for Electrotechnical Standardization (CENELEC), the European Telecommunications Standards Institute (ETSI), and the European Committee for Standardization (CEN).

EU considers their safety requirements to be the backbone of its system. The safety requirements are expressed in sectoral (industry or product-specific) directives, conformity assessment measures and, in certain sectors, the availability of European standards. The General Product Safety Directive fills in the gaps when no sectoral Directive exists. For example, the EU has specific sectoral directives on toys, and some industrial products, such as electrical products, machinery, and pressure equipment. Businesses must carry out conformity and safety assessments of their products in accordance with the General Product Safety Directive and/or specific legislation applicable to their products. Businesses are required to certify that their products are safe, as defined under the directive. For some products self-declaration is sufficient, but other products require third-party verification.

- *Detection, reporting and the removal of unsafe products:* The EU and its member states have the authorities to require mandatory recalls, and companies can negotiate voluntary recalls as necessary, similar to U.S. recalls. Under the General Product Safety Directive and applicable product-specific legislation, national authorities can ban the marketing of a dangerous product, order or organize its actual and immediate withdrawal, alert consumers to the risks it presents, order or coordinate its recall from consumers, and order or organize its destruction in suitable conditions. Businesses are required to report to the authorities if they detect that they have a dangerous product. Businesses also must remove unsafe products from markets and are under legal obligation to stop, withdraw, and/or recall their distribution. Businesses are required to repair or replace products and/or refund consumers the cost under certain criteria.
- *Policy enforcement and compliance:* DG SANCO has no inspection and no jurisdictional authority. Member-state authorities can review technical product files that all businesses are required to maintain to certify general conformity with product standards. Within the common market, the regulations apply to the importer, distributor, manufacturer, and retailer. Imported products must meet the same requirements as domestic products. Member states must have authorities to carry out appropriate sampling and safety testing of domestically manufactured or imported products and to follow-up on consumer complaints.

According to the EC report on its consumer product safety framework, the EU considers its customs controls to be reactive—no proactive obligation exists for the customs authorities to carry out controls for unsafe products at the EU borders on their own initiative. In response, the EU issued a “Council Regulation” to provide customs authorities with the legal basis

and equally applicable and comparable procedures in all member states to suspend, for no more than 72 hours, the release of products which they suspect pose a serious risk to health and safety.

- *Consumer advocacy:* A unique feature of the EU approach to consumer product safety is the funding support they provide to consumer representation groups through grants. As part of this approach, the consumer groups help define priority/future issues that require additional research and contribute to standard-making, and consumer groups can apply for grants to survey and educate consumers on these emerging issues.

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## Japan

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### Environment for Consumer Product Safety in Japan

Japan's Consumer Product Safety Law regulates the manufacture and sale of specific products to prevent harm and injury to consumers, to secure the safety of consumer products, and to promote voluntary activities of private business for the benefit of general consumers. Japan's consumer product safety policies and procedures have been developed, implemented, and enforced by a wide variety of government agencies and organizations. As with some of the other countries we reviewed, Japan recently reorganized its approach and mechanisms for consumer product safety and food safety with the creation of the new Consumer Affairs Agency, as follows:

- *Key organizations:* The Ministry of Economy, Trade, and Industry (METI) is the key government organization responsible for developing consumer product safety policy in Japan. The National Institute of Technology and Evaluation conducts on-the-spot inspections of enterprises in accordance with METI's instructions and analyzes the cause of accidents based on accident information to prevent future problems. The Consumer Policy Council, the Quality-of-Life Policy Council, and the National Consumer Affairs Center of Japan also have roles in advising and supporting the government on consumer-related issues in Japan. The Japan Cabinet Office carries out general coordination of basic consumer policies among related ministries and agencies.
- *Resources:* According to Japanese officials, 33 staff members are devoted to consumer product safety, as part of the Product Safety Division of METI. However, other staff located in other agencies, as indicated above, also work on these issues.



- *Consumer advocacy:* According to U.S. Embassy officials in Tokyo, consumer product safety issues receive considerable attention in the local press and the Japanese government, and consumers view consumer product safety as a major priority. A survey conducted by the cabinet office in 2005 found over 2,800 consumer groups active in Japan. Seven nonprofit consumer groups have been officially accredited by the Japanese government. They are
  - Consumer Organization of Japan,
  - Kansai Consumers Support Organization,
  - Japan Association of Consumer Affairs Specialists,
  - Kyoto Consumer Contract Network,
  - Consumer.net Hiroshima,
  - Hyogo Consumers Net, and
  - Saitama Organization to Abolish Damage to Consumers.

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Regulatory  
Framework/System

- *Laws and regulations:* Domestic and imported consumer products are regulated by the following laws in Japan:
  - the Consumer Product Safety Law,
  - the Household Goods Quality Labeling Law,
  - the Law for the Control of Household Goods Containing Harmful Substances,
  - the Chemical Substances Control Law, and
  - the Electrical Appliance and Material Safety Law.

Other laws relating to consumer protection include

- the Product Liability Act,
- the Consumer Contract Act,
- the Consumer Basic Act, and

- the Whistleblower Protection Act.

Under Japan's Consumer Product Safety Law, METI collects and makes public information on serious accidents involving consumer (household) products. The law requires manufacturers, marketers, and/or importers to report actual serious accidents to METI, which in turn informs the public. Manufacturers, marketers, and/or importers are also required to inform the public of the product safety issues involved. Major national consumer centers compile complaints from consumers, including product safety complaints. Depending on the product type, relevant ministries maintain regulations covering consumer products, including ensuring that products meet appropriate standards and labeling and certification requirements. Some ministries may require foreign manufacturers to register foreign manufacturing sites with the local government.

- *Definition of safe product:* Article 1 of the Consumer Product Safety Law defines products as unsafe if they cause threat to consumers' life or health. In addition, Article 2, Section 2, of the Product Liability Act provides that a defective product is to be considered as unsafe, taking into account the nature of the product, the ordinarily foreseeable use of the product, the time when the manufacturer delivered the product, and other circumstances.
- *Standards:* Product requirements in Japan fall into two categories: technical regulations (or mandatory standards) and nonmandatory voluntary standards. Compliance with regulations and standards is also governed by a certification system in which inspection results determine whether or not approval (certification/quality mark) is granted. To affix a mandatory quality mark or a voluntary quality mark requires prior product type approval and possibly factory inspections for quality control assessment. Certain regulated products must bear the appropriate mandatory mark when shipped to Japan in order to clear Japanese Customs. Safety standards are specific to types of products and fall under the jurisdiction of the relevant ministry.
- *Policy enforcement and compliance:* Generally, the importer of record is responsible for ensuring the quality and safety of imported consumer products in Japan. If a product is deemed harmful or defective, the importer is responsible for working with local authorities and consumer outlets to take necessary measures. The government may take action against the importer, such as conducting on-site inspection of business offices, plants, stores, and/or warehouses; ordering mandatory product recalls; suspending business operations for a certain period of time; or imposing penalties including fines and/or imprisonment.

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## Future Plans

On May 29, 2009, the Japanese Diet approved bills establishing the Consumer Affairs Agency, which will administer consumer protection issues in Japan. The agency will begin operating in the fall with about 200 staff from the Cabinet Office; the Fair Trade Commission; the Ministry of Economy, Trade and Industry; the Ministry of Agriculture, Forestry and Fisheries; and the Ministry of Health, Labor and Welfare. In addition, 60 temporary staff will be appointed from attorneys, consumer affairs consultants, and academics. The Consumer Affairs Agency will be placed under the Cabinet Office, and Consumer Affairs Centers nationwide will be established to provide information about product-related accidents and complaints. In addition, the Consumer Affairs Committee will be established at the same time to monitor the Consumer Affairs Agency. The committee—an independent body— will have authority to request information and reports from ministries and make recommendations for crisis management, through the Prime Minister, in the event of consumer incidents.

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## China

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### Environment for Consumer Product Safety in China

China imports relatively few manufactured products compared with its exports. Consumer products that are imported tend to come from more developed and more regulated markets in Europe, Japan, and the United States. Therefore, China faces proportionally fewer challenges with regard to import products. Further, the costs of testing products and certifying them for sale, as well as the costs of shipping and tariffs, make it difficult for imported products to compete with Chinese domestic products in similar product categories.

Recent high-profile cases in China involving food and product safety have affected China's export reputation. These cases appear to have prompted the government to raise the priority of food and product safety.

- *Laws and regulations:* China's fundamental law on product safety is The Law of the People's Republic of China on Product Quality, which was written in 1993 and revised in 2000. This law preceded the establishment of China's leading quality and safety agency, the General Administration for Quality Supervision, Inspection, and Quarantine (AQSIQ). The law sets a very low standard for corporate liability by defining the amount of damages and fines that can be collected through lawsuits. It also applies some penalties to entities that can claim ignorance of the law. The law makes no reference to foreign manufactures or domestic goods.

China's main regulatory code pertaining to imported consumer goods is found in AQSIQ's Regulations for Compulsory Product Certification. Issued in 2001, this regulation created a uniform standard for imported and domestically manufactured goods, as well as a certification mark known as China Compulsory Certification (CCC) or 3C. The regulation applies to a catalogue of products that must be approved by AQSIQ prior to general sale in China. The standards for individual products are defined separately by national and industry standards. CCC testing is conducted mostly by enterprises owned in whole or in part by AQSIQ; foreign testing companies have not been approved to conduct CCC tests, but neither have they been explicitly excluded.

The Law of the People's Republic of China on Import and Export Commodity Inspection is the main law pertaining to import and export inspections. The law dates to 1989 and provides for fee-based inspections at port, as well as preshipment inspections that may be conducted in a foreign country. The law empowers the provincial-level organizations of AQSIQ—known as Customs, Inspection and Quarantine (CIQ)—to conduct inspections. The law also provides for an appeal process in case the importer or exporter disagrees with the result of an inspection. The law sets penalties for evading the inspection process, trading in counterfeit goods, and corrupt practices. However, recent problems with food and product safety demonstrate that the local inspection offices responsible for both food and product testing may lack robust technical abilities and the capacity to deal with the current volume of trade.

- *Key organizations:* AQSIQ is China's leading quality and safety agency. Standards are issued by the Standards Administration of China, a division of AQSIQ, which also represents China in international standards organizations. The Certification and Accreditation Administration of the People's Republic of China (CNCA), which is also technically part of AQSIQ, is responsible for certifying and accrediting functions related to CCC tests. Numerous testing companies, almost all partially owned by AQSIQ, carry out testing for the CCC system. A catalogue of China's specific products required to obtain CCC approval can be found on CNCA's Web site.<sup>8</sup> In 2009, CNCA revoked a provision to allow the limited importation of any product not certified with a CCC mark. Unlike similar approvals for the United States, foreign manufacturers applying for CCC

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<sup>8</sup>CNCA's English-language Web site is <http://219.238.178.8/20040420/column/227.htm> (accessed 7/6/09). It lists the types of products that require CCC tests.

approval must pay all costs, including travel and lodging expenses of Chinese inspectors traveling to the foreign country for factory inspections.

Routine inspections, factory checks, recalls, and other regulatory actions are carried out mostly by AQSIQ's provincial representative offices, CIQ. China also has a product recall entity known as the Defective Product Administrative Center, a part of AQSIQ, which is responsible for the oversight of product recalls. The center is technically responsible for consumer products, but its primary focus is on automobile safety. The local CIQ offices are responsible for overseeing recalls at the local level. The national system for product recalls is still undeveloped.

- *Standards:* China has a comprehensive body of regulatory standards that fall into four categories: National Standards, Industry Standards, Local Standards, and Enterprise Standards. Each category includes aspects of product safety. The governing law for these categories dates to 1988 and applies to a range of industries and fields, not just consumer products. Some of these regulatory standards are more clearly spelled out in product-specific codes published on the CNCA Web site.

Under China's system, there are both mandatory and voluntary standards. Mandatory standards are those intended to safeguard human health, personal property, and safety and those enforced by laws and administrative regulations. All others are voluntary standards. Similarly, under the CCC product certification system, some products are not subject to compulsory certification but can be certified on a voluntary basis. The voluntary process is known as the China Quality Certification Center's Voluntary Product Certification System. It applies to products that are not included in an itemized catalogue of products subject to mandatory certification. The system is also an AQSIQ function, and this certification is limited to Chinese companies only.

- *Policy enforcement and compliance:* CIQ offices are responsible for local enforcement actions. Local CIQ offices have responsibility for inspecting and certifying factories, issuing and revoking manufacturing licenses, issuing or revoking export permits, conducting preshipment export inspections, and clearing or refusing goods for importation into China. Local CIQ offices have their own laboratory facilities but often call upon AQSIQ headquarters for policy guidance and technical support. Local CIQ offices also have the authority to initiate a mandatory recall, although China's recall system is still developing. As of July 2009, China's recall provisions emphasized the cessation of manufacturing and sale of dangerous goods and included no methodical system for the physical

collection of goods already sold. According to U.S. Embassy officials in Beijing, draft regulations in China on product recalls represent a positive step for improved product safety.

- *Authority to inspect foreign manufacturing plants:* China unambiguously holds and maintains the authority to inspect foreign-owned plants operating in China, and such inspections are conducted by AQSIQ and the Ministry of Health. However, for any plant operating only for the purpose of export manufacturing (i.e., no sales in China), AQSIQ takes a less rigorous approach to regulation. Such plants are not required to undergo the same assessments as plants manufacturing for local consumption.

U.S. Embassy officials in Beijing stated that they are unaware of any memorandum of understanding that AQSIQ may have to facilitate foreign inspections. However, the CCC system requires factory inspection to be conducted by a certification body that has been accredited by CNCA. Only one non-Chinese certification and testing body, Underwriters Laboratories, has been accredited to conduct follow-up factory inspections in the United States for CCC approval. CNCA has similar arrangements with other countries.

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# Appendix V: GAO Contact and Staff Acknowledgments

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## GAO Contact

Alicia Puente Cackley, (202) 512-8678, or [cackleya@gao.gov](mailto:cackleya@gao.gov)

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## Staff Acknowledgments

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## GAO's Mission

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