

Report to Congressional Committees

October 2014

CONSUMER PRODUCT SAFETY COMMISSION

Challenges and Options for Responding to New and Emerging Risks



Highlights of GAO-15-17, a report to congressional committees

#### Why GAO Did This Study

CPSC is responsible for ensuring the safety of thousands of consumer products, including imports, after they enter the U.S. market. Its jurisdiction covers a range of products-from children's toys to off-road recreational vehicles. Identifying and assessing new and emerging consumer product risks can present challenges. Questions have been raised in recent congressional hearings about the length of time CPSC takes to address a safety hazard, during which injuries and fatalities can continue to occur. Section 4 of the Consolidated Appropriations Act of 2014 mandated that GAO review CPSC's ability to respond quickly to new and emerging risks.

This report discusses (1) how CPSC's authorities and other factors may affect its response time to new and emerging hazards and (2) options and their trade-offs that may be available to address CPSC's ability to respond to these hazards. GAO reviewed CPSC's laws and regulations, prior GAO reports, and other published studies. Additionally, GAO interviewed CPSC commissioners and staff, consumer safety experts, legal experts, and representatives from consumer and industry organizations.

#### What GAO Recommends

GAO makes no recommendations in this report. In prior reports GAO has made a recommendation related to CPSC's participation in voluntary standards development and suggested that Congress address restrictions on how CPSC is able to share information with its international counterparts.

View GAO-15-17. For more information, contact Alicia Puente Cackley at (202) 512-8678 or cackleya@gao.gov.

#### October 2014

### CONSUMER PRODUCT SAFETY COMMISSION

## **Challenges and Options for Responding to New and Emerging Risks**

#### What GAO Found

According to Consumer Product Safety Commission (CPSC) officials, industry representatives, consumer groups, and subject-matter experts GAO interviewed, the timeliness of CPSC's responses may be affected by several factors, including (1) compliance actions that can involve litigation, (2) reliance on voluntary standards, (3) rulemaking procedures, (4) restrictions on sharing information with the public and international agencies, and (5) limited agency resources. For example, CPSC must defer to a voluntary standard if it determines that compliance with a voluntary standard would eliminate or adequately reduce the risk of injury and there is likely to be substantial compliance with the voluntary standard. However, because the laws do not establish a time frame for finalizing a voluntary standard, conflicting industry and consumer interests can delay its development, sometimes for years. CPSC has worked with the window covering industry since 1994 to develop a voluntary standard to address strangulation hazards stemming from window blind cords, but as of September 2014, no voluntary standard that addresses the ongoing safety concerns had been finalized. Further, new and emerging product safety risks present challenges because, statutorily, CPSC was established to respond to risks after products have been introduced into market.

Various options have been suggested for improving CPSC's ability to respond to new and emerging product safety risks, including the following examples:

- Preventative regulatory approaches. Many representatives said that
  regulatory approaches designed to prevent hazardous products from
  entering the market—such as premarket approval—could reduce
  consumer injuries, but could also inhibit market innovation and impose
  burdensome costs on manufacturers and CPSC.
- Expedited rulemaking authority. Some stakeholders proposed expanding CPSC's authority to use expedited rulemaking procedures similar to those authorized in 2008 in the Consumer Product Safety Improvement Act, which streamlined the rulemaking process for durable infant products. Most believed streamlined procedures would enable CPSC to promulgate rules in a more timely manner to address risks, but opinions differed on the extent to which the authority should be expanded.
- Enhancing CPSC's authorities to address unsafe imports. CPSC has
  proposed several statutory changes to improve its ability to identify
  hazardous products at the ports of entry and prevent them from entering
  the marketplace. About half the representatives GAO talked to supported
  the proposed changes, with some exceptions where the changes would
  impose additional burdens on industry.
- Enhanced data analysis capabilities. Most representatives agreed that CPSC could respond to new and emerging hazards more quickly if it had additional funding for technology and staff with technical expertise in the areas of engineering, toxicology, and public health to analyze product hazard data and conduct risk assessments.

United States Government Accountability Office

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#### **Abbreviations**

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APA Administrative Procedure Act

BPA bisphenol A

CBP Customs and Border Protection CPSA Consumer Product Safety Act

CPSC Consumer Product Safety Commission

CPSIA Consumer Product Safety Improvement Act of 2008

EPA Environmental Protection Agency

EU European Union

FDA Food and Drug Administration
NPR notice of proposed rulemaking
RAM Risk Assessment Methodology
USDA U.S. Department of Agriculture

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October 14, 2014

The Honorable Tom Udall
Chairman
The Honorable Mike Johanns
Ranking Member
Subcommittee on Financial Services and General Government
Committee on Appropriations
United States Senate

The Honorable Ander Crenshaw
Chairman
The Honorable José Serrano
Ranking Member
Subcommittee on Financial Services and General Government
Committee on Appropriations
House of Representatives

The Consumer Product Safety Commission (CPSC), created in 1972, is charged with protecting U.S. consumers against death or injury from unsafe products, which may be manufactured in the United States or imported. CPSC has broad jurisdiction over thousands of types of consumer products, including off-road recreational vehicles and hazardous substances. It aims to identify hazards associated with a consumer product and understand whether they are known, new, or emerging. Because CPSC generally regulates consumer products after they enter the market, identifying new products and any new hazards associated with them can be challenging. In particular, the number of imported consumer products presents CPSC with challenges related to the growth of global supply chains that assemble products across a vast web of interconnected geographies as well as the difficulty of identifying product hazards among thousands of containers entering U.S. ports. CPSC reported that during calendar year 2012, more than 235,000 importers imported approximately \$706.6 billion of consumer products under CPSC's jurisdiction—an average of nearly \$2 billion per day. In addition, since 2008, four out of five product recalls in the United States involved an imported product. Although its authorities generally address product hazards post-market, CPSC reports that the continued growth in volume and diversity of consumer products has recently made strategies to prevent hazardous products from entering the marketplace a critical focus of the agency.

In 2008, Congress enacted the Consumer Product Safety Improvement Act of 2008 (CPSIA) to reform CPSC, strengthen its authority to enforce consumer product safety standards, and in some instances, enable CPSC to respond to safety hazards more quickly than it had before. For example, CPSIA required CPSC to convert voluntary standards for durable infant and toddler products, all-terrain vehicles, and children's toys to mandatory standards through a more expedited process than the rulemaking procedures set forth in the Consumer Product Safety Act (CPSA), which was enacted in 1972. Despite CPSC's expanded authorities and progress in establishing new mandatory standards, during recent congressional hearings concerns were raised about the length of time it takes for CPSC to address an identified safety hazard particularly because injuries and deaths, as well as industry uncertainty due to lack of guidance to address the risk, can continue in the interim.

In accordance with the joint explanatory statement accompanying the Consolidated Appropriations Act of 2014, GAO is conducting a study of CPSC's ability to respond quickly to emerging consumer product safety hazards using specified authorities under CPSA, the Federal Hazardous Substances Act, and the Flammable Fabrics Act.<sup>3</sup> This report discusses (1) how CPSC's authorities and other factors may affect the time it takes CPSC to respond to new and emerging hazards and (2) options that may be available to improve CPSC's ability to respond to new and emerging hazards in a timely manner and trade-offs associated with those options.

To identify and describe CPSC's authorities to respond to new and emerging risks, we reviewed relevant laws and regulations, our prior reports, timelines related to the regulation of specific consumer products,

<sup>&</sup>lt;sup>1</sup>Pub. L. No. 110-314, 122 Stat. 3016 (2008).

<sup>&</sup>lt;sup>2</sup>Consumer Product Safety Act, Pub. L. No. 92-573, 86 Stat. 1207 (1972). CPSIA required CPSC to convert existing voluntary standards to mandatory standards for certain categories of products. Pub. L. No. 110-314, §§ 104, 106, 232, 122 Stat. at 3028, 3033, 3071 (codified at 15 U.S.C. § 2056a (durable infant and toddler products), § 2056b (toys), and § 2089 (all-terrain vehicles)).

<sup>&</sup>lt;sup>3</sup>160 Cong. Rec. H906 (daily ed. Jan. 15, 2014)(Division E, Title V – Independent Agencies, Consumer Product Safety Commission, Salaries and Expenses). Specifically, the mandate asks us to conduct a study of the ability of the CPSC to respond quickly to emerging consumer product safety hazards using authorities under sections 7, 8, and 9 of the Consumer Product Safety Act (15 U.S.C. §§ 2056-2058); section 3 of the Federal Hazardous Substances Act (15 U.S.C. § 1262); and section 4 of the Flammable Fabrics Act (15 U.S.C. § 1193).

and other relevant studies in this area. To identify options that may be available to address CPSC's ability to respond to new and emerging risks, we reviewed our prior reports and conducted a literature review to identify published studies and reports that discussed possible options. To address both objectives, we interviewed staff at CPSC, representatives from various consumer and industry organizations, and consumer safety experts. We also interviewed former and current CPSC commissioners individually.

We conducted this performance audit from March 2014 to October 2014 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.

## Background

CPSA created CPSC to regulate consumer products and address those that pose an unreasonable risk of injury; assist consumers in evaluating the comparative safety of consumer products; and promote research and investigation into the causes and prevention of product-related deaths, injuries, and illnesses. CPSC's jurisdiction is broad, covering thousands of types of consumer products used in and around the home and in sports, recreation, and schools. Some consumer products are regulated—that is, subject to mandatory standards governing performance or labeling requirements established by CPSC through regulations. In contrast, many consumer products that are under CPSC's

<sup>&</sup>lt;sup>4</sup>See GAO, Consumer Product Safety Commission: Agency Faces Challenges in Responding to New Product Risks, GAO-13-150 (Washington, D.C.: Dec. 20, 2012); Consumer Product Safety Commission: Action Needed to Strengthen Identification of Potentially Unsafe Products, GAO-12-30 (Washington, D.C.: Oct. 12,2011); Consumer Product Safety Commission: A More Active Role in Voluntary Standards Development Should Be Considered, GAO-12-582 (Washington, D.C.: May 21, 2012); and Consumer Safety: Better Information and Planning Would Strengthen CPSC's Oversight of Imported Products, GAO-09-803 (Washington, D.C.: Aug. 14, 2009).

<sup>&</sup>lt;sup>5</sup>CPSC does not have jurisdiction over some categories of products, including automobiles and other on-road vehicles, tires, boats, alcohol, tobacco, firearms, food, drugs, cosmetics, medical devices, and pesticides. Other federal agencies—including the National Highway Traffic Safety Administration, Coast Guard, Department of Justice, Department of Agriculture, Food and Drug Administration, and Environmental Protection Agency—have jurisdiction over these products.

jurisdiction are subject to voluntary standards, which are generally determined by standard-setting organizations, with input from government representatives and industry groups. Unregulated products are those products not subject to mandatory standards and may include those covered by voluntary standards. The 1981 amendments to CPSA required CPSC to defer to a voluntary standard rather than promulgating a mandatory standard through rulemaking if CPSC determines that (1) the voluntary standard adequately addresses the hazard and (2) there is likely to be substantial compliance with the voluntary standard. To address product hazards, CPSC may attend the meetings of standard-setting organizations and contribute relevant hazard data to assist in the development of voluntary standards, but staff are not permitted to vote on the standards or hold leadership positions.

CPSC has broad authority to identify, assess, and address hazards associated with consumer products under the following laws:

- Consumer Product Safety Act (CPSA), which consolidated federal safety regulatory activity relating to consumer products within CPSC;
- Consumer Product Safety Improvement Act (CPSIA) of 2008, which amended CPSA to, among other things, expand CPSC's authorities to address consumer product safety risks and direct the agency to develop a risk assessment methodology to identify hazardous imports;
- Flammable Fabrics Act, which, among other things, authorizes
   CPSC to prescribe flammability standards for clothing, upholstery, and other fabrics:<sup>8</sup> and

<sup>&</sup>lt;sup>6</sup>Consumer Product Safety Amendments of 1981, Pub. L. No. 97-35, Tit. XII, Subtit. A, §§ 1202, 1203, 95 Stat. 703 (1981). CPSC is also required to rely on voluntary standards before issuing mandatory standards under other laws in addition to CPSA, including the Federal Hazardous Substances Act and the Flammable Fabrics Act. See 15 U.S.C. §§ 1193(h), 1262(g).

<sup>&</sup>lt;sup>7</sup>In May 2012, we recommended that CPSC staff take a more active, engaged role in developing voluntary standards. (See GAO-12-582.) As a result, in September 2013, CPSC posted a notice of proposed rulemaking that would allow Commission employees to participate as voting members and to accept leadership positions in voluntary standard-setting groups. 78 Fed. Reg. 57,818 (Sept. 20, 2013).

<sup>&</sup>lt;sup>8</sup>Act of June 30, 1953, ch. 164, 67 Stat. 111 (1953) (codified as amended at 15 U.S.C. §§ 1191 et seq.). The authority for enforcing the Flammable Fabrics Act was transferred to CPSC by CPSA in 1972. Pub. L. No. 92-573, § 30, 86 Stat. at 1231 (1972).

 Federal Hazardous Substances Act, which establishes the framework for the regulation of substances that are toxic, corrosive, combustible, or otherwise hazardous.<sup>9</sup>

Other laws provide CPSC with authorities to prescribe performance standards for specific consumer products. <sup>10</sup> In addition, CPSIA required CPSC to promulgate mandatory standards for durable infant and toddler products—such as cribs and strollers—through rulemaking in accordance with section 553 of the Administrative Procedure Act (APA), rather than the rulemaking procedures required by CPSA. <sup>11</sup> Section 553 of the APA governs "informal" or "notice and comment" rulemaking procedures for federal agencies and, according to CPSC officials, does not impose the

<sup>&</sup>lt;sup>9</sup>Pub. L. No. 86-613, 74 Stat. 372 (1960) (codified as amended at 15 U.S.C. §§ 1261 et seq.). Under the Federal Hazardous Substances Act, CPSC is authorized to declare a substance to be hazardous and to regulate the labeling of substances which are declared to be hazardous. 15 U.S.C. §§ 1261-1262. The authority for enforcing the Federal Hazardous Substances Act was transferred to CPSC by CPSA in 1972. Pub. L. No. 92-573, § 30, 86 Stat. at 1231 (1972).

<sup>&</sup>lt;sup>10</sup>These additional laws include 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 (Pub. L. No. 91-601, 84 Stat. 1670 (1970) (codified as amended at 15 U.S.C. §§ 1471 et seq.)); the Refrigerator Safety Act of 1956, which mandates CPSC to prescribe safety standards for household refrigerators to ensure that the doors can be opened easily from the inside (Act of August 2, 1956, c. 890, 70 Stat. 953 (codified as amended at 15 U.S.C. §§ 1211 et seq.)); the Virginia Graeme Baker Pool and Spa Safety Act of 2007, 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 (Pub. L. No. 110-140, Tit. XIV, 121 Stat. 1492, 1794 (2007) (codified at 15 U.S.C. §§ 8001 et seq.)); the Children's Gasoline Burn Prevention Act of 2008, which establishes safety standards for child-resistant closures on all portable gasoline containers (Pub. L. No. 110-278, 122 Stat. 2602 (2008) (codified at 15 U.S.C. § 2056 note)); and the Child Safety Protection Act of 1994, which requires the banning or labeling of toys that pose a choking risk to small children and the reporting of certain choking incidents to CPSC (Pub. L. No. 103-267, 108 Stat. 722 (1994) (codified as amended at 15 U.S.C. §

<sup>&</sup>lt;sup>11</sup>Pub. L. No. 110-314, § 104, 122 Stat. at 3028 (codified as amended at 15 U.S.C. § 2056a(b).

cost-benefit requirements specified in the rulemaking procedures in CPSA.<sup>12</sup>

When addressing a consumer product hazard, CPSC generally assesses whether it is known, new, or emerging. New or emerging hazards may be associated with either a new or existing product. For example, a new hazard could present itself in the form of new materials used to manufacture an existing product. CPSC's Emerging Hazards Team—composed of statisticians—is responsible for reviewing incident reports to identify new and emerging product-associated hazards, performing product safety assessments, and directing new reports to appropriate Integrated Product Teams. The Emerging Hazards Team's review is one of CPSC's first steps in identifying the nature of a hazard. According to CPSC staff, the Emerging Hazards Team reviews all reports of incidents stemming from consumer products on a daily basis, including those stored in CPSC's data management system, to identify trends and patterns.

CPSC also stays informed about hazards that may be associated with new or existing products through tracking new products entering the market via the ports, retail stores, or the Internet. At the port, CPSC scrutinizes import documentation and may conduct physical screening of products. At manufacturer and retail locations, CPSC's field investigators conduct compliance monitoring, check for appropriate labeling, and may screen some products to determine whether they meet generally accepted industry voluntary standards. To monitor the extent to which products entering the market through the Internet comply with mandatory

<sup>&</sup>lt;sup>12</sup>5 U.S.C. § 553. Under APA notice and comment rulemaking, agencies publish a notice of proposed rulemaking (NPR) in the *Federal Register* and provide "interested persons" with an opportunity to comment on the proposed rule prior to the issuance of a final rule. Section 553 of the APA makes no explicit mention of an advance notice of proposed rulemaking or cost-benefit analysis. In contrast, section 8 of CPSA describes, in addition to a notice of proposed rulemaking, a detailed advance notice of proposed rulemaking (ANPR) to be issued prior to the NPR. Additionally, section 8 of CPSA requires CPSC to describe in both the NPR and final rule any reasonable alternatives along with a description of their potential benefits and costs, and a brief explanation of why they were not proposed or chosen. 15 U.S.C. § 2058.

<sup>&</sup>lt;sup>13</sup>Integrated Product Teams are composed of subject-matter experts from a number of offices within CPSC and are organized by type of hazard. The teams are responsible for a variety of risk-related activities, including reviewing incident reports, requesting investigations, recommending new activities to management as needed, and monitoring follow-up status on corrective actions and the status of projects for standard development.

standards, CPSC compliance staff conduct searches of the Internet and monitor online retailers. CPSC also monitors risks through agreements with other federal and state agencies to conduct research. For example, CPSC has a joint agreement with the Environmental Protection Agency (EPA) to research the health effects of nanotechnology in consumer products. <sup>14</sup> In addition, CPSC staff attend trade shows to identify possible products of interest and exchange information about consumer products with a number of other federal agencies, including the National Institutes of Health and the Centers for Disease Control and Prevention.

CPSIA mandated that CPSC, in tandem with Customs and Border Protection (CBP), develop a risk assessment methodology to identify products intended for import into the United States that are likely to violate consumer product safety laws enforced by CPSC. <sup>15</sup> In response, the agencies developed an import surveillance data system, known as Risk Assessment Methodology (RAM), and began to pilot it in 2011. The purpose of RAM is to evaluate products entering the United States based on criteria designed to identify imports with the highest risk to consumers. The criteria are determined through CPSC's analysis of its historical data on consumer product risks and CBP's advance shipment data. Currently, CPSC staff have access to CBP data systems and request data extracts, as necessary.

CPSC generally evaluates consumer products to determine whether products present risks to consumers and how they should be addressed, such as through a voluntary standard, a consumer product safety standard, or ban by regulation to prevent or reduce an unreasonable risk. According to CPSC, it uses a multifaceted approach to reduce the risk of injury to consumers that is intended to address both immediate and future problems stemming from the risk. CPSC's actions to address and reduce the risk of injury to consumers include the following:

<sup>&</sup>lt;sup>14</sup>Nanomaterials are defined as materials/particles that range from 1 to 100 nanometers in length. Although they may have the same name as a material currently in use, because of their small size, these new materials may demonstrate different physical and chemical properties. Some of these new nanomaterials are being used in consumer products with the stated purpose of improving the performance and durability.

<sup>&</sup>lt;sup>15</sup>Pub. L. No. 110-314, § 222, 122 Stat. at 3066 (codified at 15 U.S.C. § 2066 note).

- Compliance—CPSC conducts voluntary and mandatory recalls, enforcement of existing regulations by seeking civil and criminal penalties, and injunctive relief against prohibited acts.
- Standards and Rulemaking—As previously discussed, CPSC participates in the voluntary standards process, and develops mandatory safety standards, and product bans through rulemaking.
- Public education—CPSC notifies the public of safety hazards and educates them about safe practices.

## CPSC's Authorities and Other Factors Affect How Quickly It Responds to New and Emerging Hazards

Certain aspects of CPSC's authorities, as well as other factors, impact how quickly CPSC responds to new and emerging hazards, including (1) compliance actions involving litigation, (2) reliance on voluntary standards, (3) rulemaking procedures, and (4) information-sharing restrictions. In addition, CPSC commissioners (former and current), consumer groups, and industry representatives have stated that limited resources can prolong the time it takes CPSC to respond to new and emerging hazards.

Compliance Actions May Involve Litigation and Prolong Response to Hazardous Products

CPSC can take a number of compliance actions to address unsafe products, including conducting voluntary recalls, mandatory recalls, and mandatory bans. Generally, CPSC negotiates the terms of voluntary recalls with manufacturers of products that have been identified to be hazardous or in violation of voluntary or mandatory standards. The company submits its corrective action plan to CPSC indicating how it plans to repair, refund, or replace the product. <sup>16</sup> CPSC then reviews and, if necessary, negotiates the terms of the manufacturer's proposed corrective action plan before approving it. <sup>17</sup> According to CPSC staff and one commissioner we interviewed, because both CPSC and the manufacturer are seeking acceptable terms, the negotiations involved in the voluntary recall process could add time to CPSC's response to a new or emerging product hazard.

If CPSC and a manufacturer are unable to reach agreement on how to address a consumer product safety hazard through the voluntary recall

<sup>&</sup>lt;sup>16</sup>See 15 U.S.C § 2064(d).

<sup>&</sup>lt;sup>17</sup>CPSC also has a "fast track" recall program, in which a company is eligible to participate if it reports and implements within 20 working days a corrective action that CPSC staff believe will be effective. See 62 Fed. Reg. 39,827 (July 24, 1997).

process, the agency may pursue compliance actions through administrative hearings or in district court that could result in a number of remedies, including mandatory recalls and bans, and further increase the agency's response time. 18 While mandatory recalls, once imposed, may be used to remove hazardous products from the marketplace, according to CPSC officials, litigating such an action may lead to lengthy delays. For this reason, CPSC officials said that the agency typically pursues compliance actions that involve litigation as a last resort because such actions generally require additional time and resources. For example, in 2009, CPSC staff began learning about incidents of toddlers and young children ingesting small, loose, high-powered, rare earth magnets that were marketed to consumers aged 13 and older. 19 In 2010, CPSC worked to obtain agreements with a number of retailers to voluntarily stop selling the product. After the agency continued to receive reports about ingestions and injuries, it issued a public safety alert in 2011. However, in July 2012, CPSC announced that attempts to negotiate a voluntary recall with one of the manufacturers of the high-powered magnets had failed. CPSC concluded that product warning labels and public education efforts were ineffective and could not prevent further injuries and incidents. As a result, CPSC staff filed an administrative complaint—the second in 11 years for any product, according to CPSC officials—which the commissioners approved, seeking a determination that the product constituted a substantial product hazard and that the firm stop selling the product and offer consumers a full refund. 20 The manufacturer refused to submit to the conditions, and litigation continued for almost 2 years before CPSC reached a settlement in May 2014, ordering the former owner of the company to fund a trust to refund consumers.

<sup>&</sup>lt;sup>18</sup>See, e.a., 15 U.S.C. §§ 2061, 2064.

<sup>&</sup>lt;sup>19</sup>According to CPSC officials, while ingestion hazards are not new, the product introduced "rare earth" magnetic materials that are more powerful than magnets that they were previously familiar with, and represented an emerging hazard. When two or more magnets are swallowed, they can attract to one another through the stomach and intestinal walls, resulting in serious injuries, such as holes in the stomach and intestines, intestinal blockage, blood poisoning, and possibly death. Medical professionals may not diagnose the need for immediate medical intervention in such cases, resulting in worsening of the injuries.

<sup>&</sup>lt;sup>20</sup>CPSA defines a substantial product hazard as a failure to comply with an applicable consumer product rule that creates a substantial risk of injury to the public, or a product defect, which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or other circumstances) creates substantial risk of injury to the public. 15 U.S.C. § 2064(a).

Officials with whom we spoke stated that CPSC may also address new and emerging risks through its imminent hazard authority. Specifically, if a consumer product is "imminently hazardous"—defined as a consumer product that presents an imminent and unreasonable risk of death, serious illness, or severe personal injury—CPSC may file an action in U.S. district court.<sup>21</sup> If the court declares the product to be imminently hazardous, it may grant temporary or permanent relief—such as seizure of the product, recall, or public notice of the risk—to protect the public from the hazard.<sup>22</sup> According to CPSC officials, the time needed to file the required legal actions and work through the courts using the imminent hazard authority prolongs the time CPSC takes to respond to new and emerging risks. Further, they noted that the legal standard required to prove that a product is an imminent hazard requires extensive data analysis and is difficult to prove in court.

CPSC officials said that the agency attempted to use its imminent hazard authority one time, in 1986, to address hazards related to lawn darts, but was unsuccessful. In 1970, prior to the creation of CPSC, FDA, under its authority to administer the FHSA, issued a regulation banning lawn darts other than those that were not intended for use as a toy and were marketed solely for adults.<sup>23</sup> CPSC later assumed responsibility for administering the FHSA and continued to enforce FDA's regulations regarding the ban on lawn darts as well as the exemption from that ban. After receiving several reports that lawn darts were being sold in toy stores, between 1984 and 1987, CPSC inspected nearly 200 retailers throughout the U.S. and found numerous violations of both the labeling and marketing requirements for lawn darts. In 1987, CPSC staff met with manufacturers of lawn darts and discussed several voluntary actions that could be taken to assure firms' compliance with the exemption from the ban, including making the warning label more conspicuous. Despite these efforts, continued reports of fatalities due to injuries involving lawn darts, according to CPSC, led Congress to question the adequacy of the ban. In an effort to prevent further injuries and fatalities, in 1988 CPSC issued a

<sup>&</sup>lt;sup>21</sup>15 U.S.C. § 2061(a).

<sup>&</sup>lt;sup>22</sup>15 U.S.C. § 2061(b).

<sup>&</sup>lt;sup>23</sup>35 Fed. Reg. 19,266 (Dec. 19,1970). A lawn dart manufacturer subsequently filed a petition for judicial review of this regulation banning lawn darts, and the regulation was upheld. R.B. Jarts, Inc. v. Richardson, 438 F.2d 846 (2d Cir. 1971).

ban, through its rulemaking authority, on the sale of all lawn darts.<sup>24</sup> Subsequently, CPSC received new reports of injury, and in March 2012 the agency issued a safety alert to reiterate the ban.

## Reliance on Voluntary Standards Can Prolong Response to Product Safety Hazards

As previously discussed, consumer product safety laws require CPSC to rely on voluntary standards if it determines that (1) compliance with a voluntary standard would eliminate or adequately reduce the risk of injury identified and (2) there is likely to be substantial compliance with the voluntary standard.<sup>25</sup> In addition, the agency may address the risk presented by unregulated products—that is, products not subject to mandatory standards—by recommending revisions to voluntary standards. However, if a voluntary standard does not address the particular defect or hazard that is being examined, the process of taking a corrective action to address the hazard is prolonged. In some instances, CPSC may find that a product meets a voluntary standard but still has a defect that creates a serious risk of injury or death, but the manufacturer may disagree. Because standards are voluntary, CPSC cannot legally compel a manufacturer to comply with a voluntary standard or take action against it for noncompliance. 26 According to CPSC officials and staff, the nature of voluntary standards may extend the amount of time the agency takes to properly address new and emerging risks in consumer products.

CPSC does not control the voluntary standards development process, and the laws do not establish a time frame within which standard-development organizations must finalize a voluntary standard. As a result, the voluntary standards development process can, in some instances, last for prolonged periods of time. For example, CPSC has worked with the window-covering industry since 1994 to develop voluntary standards to address strangulation hazards stemming from window blind cords, but conflicting consumer and industry goals have prolonged the process. The

<sup>&</sup>lt;sup>24</sup>53 Fed. Reg. 46,828 (Nov. 18, 1988). On November 5, 1988, shortly after the Commission voted to ban lawn darts, legislation was signed into law requiring the Commission to take action. Pub. L. No. 100-613, 102 Stat. 3183 (1988). In its final rule, CPSC stated that its rule to ban lawn darts fulfilled the congressional directive. 53 Fed. Reg. at 46.830.

<sup>&</sup>lt;sup>25</sup>See CPSA §§ 7, 9 (codified at 15 U.S.C. §§ 2056, 2058); FHSA § 3 (codified at 15 U.S.C. § 1262); Flammable Fabrics Act § 4 (codified at 15 U.S.C. § 1193).

<sup>&</sup>lt;sup>26</sup>GAO 12-582.

first voluntary standard to address this hazard was developed in 1996 and has been revised at least six times. However, some consumer groups argue that none of the revisions include designs aimed at eliminating the strangulation risk. Between 2007 and 2011, CPSC negotiated with 38 individual companies to voluntarily recall hazardous window blinds and issued multiple consumer safety alerts about hazards related to window blind cords. Consumer groups have asked standard-setting organizations to consider technologies, such as cordless window coverings, that would eliminate window cord-related hazards. Some manufacturers have said that while cordless window blinds would eliminate the hazard, a voluntary standard asking manufacturers to produce such window coverings would be too costly for some firms and could create a product that would be unaffordable for some consumers. In 2011, a coalition of consumer groups announced that they had withdrawn from the voluntary standard development process because it lacked transparency, and because resulting revisions to the standard still did not consider existing technologies that could eliminate strangulation hazards from accessible cords. In May 2013, the coalition of consumer groups petitioned CPSC to promulgate a mandatory standard because, according to the petition, the voluntary standards process had failed to develop a standard that eliminated or significantly reduced the strangulation risk. As of September 2014, CPSC continued its efforts to work with standard-setting organizations to develop a new voluntary standard. CPSC indicated in its proposed budget request for fiscal year 2015 that staff planned to include a response to the consumer groups' petition for a mandatory standard for window-coverings in a briefing package to be considered by the commission.

## Some CPSC Rulemaking Procedures Result in Lengthy Time Frames

CPSC's rulemaking procedures, as outlined in CPSA, often lengthen the time the agency takes to respond to new and emerging risks. According to CPSC officials, the time required for mandatory standard rulemaking varies depending on multiple factors, including the complexity of the problem to be addressed; the volume of public comments responding to a proposed rule; time constraints imposed by other federal statutes, executive orders, or other administrative obligations; agency resources; and competing agency priorities. Under CPSA, CPSC shall not promulgate a rule, including a mandatory consumer product safety standard, unless it finds that all of the following conditions exist:

- The rule is in the public interest.
- The rule is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product.

- If a voluntary standard exists, compliance with such voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or it is unlikely that there will be substantial compliance with such voluntary standard.
- The rule's expected benefits bear a reasonable relationship to its costs
- The rule imposes the least burdensome requirement that prevents or adequately reduces the risk of injury at issue.<sup>27</sup>

Additionally, any final rule must include a regulatory analysis describing (1) the potential benefits and costs of the rule; (2) any alternatives to the rule that CPSC considered, as well as the costs and benefits of the alternatives to the rule and why they were not chosen; and (3) significant issues raised by public comments submitted in response to the preliminary regulatory analysis and CPSC's assessment of the issues.<sup>28</sup> Some CPSC officials said that the required cost-benefit analysis is lengthy and resource intensive. These officials stated that requirements to explore possible alternatives to a new consumer product standard and completing the corresponding cost-benefit analysis proved to be timeconsuming elements. For example, CPSC has been considering a mandatory rule to address the risk of fire associated with ignitions of upholstered furniture since 1994. However, action has yet to be taken because, according to one commissioner, demonstrating the efficacy of the risk-reduction alternatives is difficult. The commissioner cited CPSC's efforts to address risks associated with flammable upholstered furniture. in particular, because options to address the hazard include manufacturers' use of flame retardant chemicals, which some scientific studies have indicated could cause cancer in humans.

Information-Sharing
Restrictions May Prolong
Response to New and
Emerging Product Risks

Specific sections of CPSA restrict CPSC's ability to disclose certain information about potential product hazards, which in turn may impact CPSC's ability to notify the public about new and emerging risks and prolong the time it takes for CPSC to respond to new and emerging risks. Section 6(b) of CPSA generally prohibits CPSC from publicly disclosing information that would readily identify a product manufacturer unless

<sup>&</sup>lt;sup>27</sup>15 U.S.C. § 2058(f)(3). Similar requirements exist for CPSC when issuing rules under the Flammable Fabrics Act and FHSA. See 15 U.S.C. §§ 1193(j)(2), 1262(i)(2).

<sup>&</sup>lt;sup>28</sup>15 U.S.C. §§ 1193(j)(1), 1262(i)(1), 2058(f)(2).

CPSC first takes reasonable steps to ensure that the information is accurate, and that the disclosure is fair in the circumstances, and reasonably related to carrying out CPSC's purposes under its jurisdiction. <sup>29</sup> Before publicly disclosing information, CPSC is required to provide the manufacturer advance notice and opportunity to comment on the accuracy of the information. If CPSC decides to disclose information that the manufacturer claims to be inaccurate, it generally must provide 5 days advance notice of the disclosure, and the manufacturer may bring suit to prevent the disclosure. Some consumer representatives and CPSC officials we interviewed said that these confidentiality requirements in CPSA may prolong the time it takes to get hazardous products out of consumers' homes because CPSC is prohibited from releasing the name of the product or manufacturer until it has followed the 6(b) procedures or until the manufacturer has waived any objections to the information's release.

Additional information-sharing restrictions within CPSA may also increase CPSC's response time to new and emerging hazards. Section 29(e) of CPSA permits CPSC to disclose accident or investigation reports to officials of other federal, state, and local agencies engaged in health. safety, or consumer protection activities, but only if confidential business information is removed and the recipient agency agrees to maintain certain confidentiality restrictions. 30 Section 29(f) authorizes CPSC to disclose certain information to federal, state, local, and foreign government agencies if the recipient agency certifies in writing in advance that the information will be kept confidential and used only for specified law enforcement or consumer protection purposes and if certain other conditions are met.<sup>31</sup> CPSC may terminate an information-sharing agreement if it determines that an agency has failed to abide by its confidentiality requirements. Section 29(f) further provides that CPSC generally is not required to disclose, under the Freedom of Information Act or other law, confidential information that it has received from a foreign agency. However, this provision does not authorize the withholding of information from Congress or from a court in an action commenced by the United States or the Commission. In 2012, we

<sup>&</sup>lt;sup>29</sup>15 U.S.C. § 2055(b).

<sup>&</sup>lt;sup>30</sup>15 U.S.C. § 2078(e).

<sup>&</sup>lt;sup>31</sup>15 U.S.C. § 2078(f). Among other things, the agency must provide a bona fide legal basis for its authority to maintain the confidentiality of the information.

concluded that CPSC has been unable to complete certain informationsharing agreements with foreign counterparts because it cannot offer them reciprocal terms on disclosure of nonpublic information.<sup>32</sup> We further reported that CPSC's inability to establish information-sharing agreements with its foreign counterparts may hinder the agency's ability to respond to a potential hazard in a timely manner because of the delay that might occur between when a foreign counterpart decides to take action in response to a product hazard and when that action becomes public. In that report, we also concluded that to better enable CPSC to target unsafe consumer products, Congress may wish to amend section 29(f) of CPSA to allow CPSC greater ability to enter into informationsharing agreements with its foreign counterparts that permit reciprocal terms on disclosure of nonpublic information. Our report concluded that this restriction on sharing information may hinder CPSC's ability to identify risks from new products in a timely manner, possibly leading to injury and death if unsafe products enter the U.S. market. As of September 2014, there have been no changes to section 29(f) of CPSA.

## Limited Resources Could Hinder the Timeliness of CPSC's Response

In addition to factors previously discussed, CPSC's ability to respond to new and emerging risks in a timely manner depends on the resources required to understand the nature of and address the specific product hazard. For example, the simplest risk assessments, such as lead testing, may require few resources to complete. However, assessing complex products, such as those involving phthalates, may require additional time, staff, and laboratory resources because the agency may need to develop new standards or consult outside scientific expertise in areas such as toxicology and epidemiology. 33 CPSC data indicate that the dollar value of U.S. imports under the agency's jurisdiction increased by ten percent in two years—from about \$637 billion in calendar year 2010 to \$706.6 billion in calendar year 2012. In addition, CPSC's full-time-equivalent staff generally decreased between fiscal years 2000 and 2008—from 492 to 396—until fiscal year 2009, when CPSC saw an increase in staff, to 435. As of September 2014, CPSC has 528 full-time equivalent staff, which is 41 percent less than the 890 full-time equivalent staff the agency had in

<sup>&</sup>lt;sup>32</sup>See GAO-13-150.

<sup>&</sup>lt;sup>33</sup>Phthalates are chemical plasticizers that are often used in the production of many types of plastics. Phthalates most often, but not always, are used to make plastics softer and/or more pliable.

1975. Further, many of the CPSC commissioners, consumer groups, and industry representatives we spoke with stated that CPSC currently lacks the staff, laboratory resources, and related funding to conduct risk assessments more efficiently than it currently does. According to these sources, CPSC's lack of sufficient staff with scientific expertise could also prolong the time the agency takes to assess product hazards and ultimately address new and emerging risks.

We reported in 2012 that CPSC has taken steps to improve its responsiveness through better technologies for identifying risks, more targeted surveillance of imported products, and a program for manufacturers to streamline the process for conducting recalls.34 According to CPSC, in fiscal year 2013, the pilot RAM helped port investigators to identify and prevent more than 12.5 million units of violative imports from entering the U.S. stream of commerce. In addition, since our December 2012 report on CPSC's risk assessment activities, CPSC has stationed an additional full-time investigator at another port, for a total of 21 investigators at 16 of the 327 ports of entry. 35 However, CPSC has reported that increased resources would help to expand these efforts. For example, according to CPSC, the pilot RAM import surveillance program is focused on import surveillance and compliance. but the fully developed program would emphasize prevention and programs that provide incentives for importers to implement preventive actions to improve product safety and better ensure legal and regulatory compliance. CPSC requested additional funding in its 2015 congressional budget request to expand the RAM and reports that additional funding would increase its capacity for laboratory sample testing and software acquisition for the RAM.

<sup>&</sup>lt;sup>34</sup>GAO-13-150.

<sup>&</sup>lt;sup>35</sup>U.S. Consumer Product Safety Commission, *Fiscal Year 2013 Annual Performance Report*. (Bethesda, MD; March 2014).

Proposed Options for Improving CPSC's Timeliness in Responding to New and Emerging Hazards Involve Trade-offs

Over the years, stakeholders and observers have proposed various options to shorten the time CPSC takes to respond to new and emerging hazards. Some options, such as expanding CPSC's use of regulatory approaches to prevent product safety hazards, may pose more challenges to implementation than others, such as enhancing CPSC's resources to address product hazards, which could be achieved within the existing regulatory framework. We asked a range of consumer and industry representatives about the viability of these regulatory options as well as others that could be used to improve CPSC's timeliness. Some options have the potential to prevent hazardous products from entering the market; and some could reduce the number of deaths and injuries from these products. But each also involves trade-offs that should be considered. These options and their trade-offs are summarized in figure 1.

Figure 1: Options to Improve CPSC's Timeliness in Responding to New and **Emerging Risks and Their Trade-offs** 

#### **Options** Enhancing Improve Expedited CPSC's CPSC's capabilities to Preventive mandatory import regulatory rulemaking surveillance analyze authority approaches authorities scientific data Could prevent some hazardous products from entering the markets Could reduce some injuries and deaths from hazardous products Could help obtain some data on new and emerging risks Could be achieved within the existing regulatory framework Could inhibit some market innovation Could impose some additional costs on CPSC Could prolong the time for some products to come to market Could impose some additional costs on manufacturers Not discussed as a benefit or challenge **Benefits** Challenges

Source: GAO. | GAO-15-17

**Expanding Preventive** Approaches to Regulating **Consumer Products** 

According to CPSC, preventing hazards from entering the marketplace is one of the most effective ways the agency can protect consumers. CPSC reports that many consumer product hazards and safety defects arise in the very early stages of the supply chain, including product design and the selection and use of raw materials. As discussed earlier, CPSC addresses product hazards after the product has entered the market and after a specific product hazard has been identified. According to CPSC,

given the large volume and diversity of products under CPSC's jurisdiction, recalls and bans alone may not prevent product hazards from occurring. CPSIA mandated a preventive approach to the development and marketing of certain juvenile products by requiring that manufacturers of such products, prior to importing or distributing them for sale, submit samples of their product for third-party testing and certify that, based on such testing, their product complies with applicable safety standards.

The precautionary principle approach is a preventive framework for guiding decision making that is used in some policy areas in the United States, such as the regulation of environmental policy and drugs, and more broadly in other countries, such as the European Union. The precautionary principle approach to regulation generally specifies that when a product, technology, or activity presents the possibility of severe or irreversible risk to human health or the environment, precautionary measures should be taken to reduce or eliminate the risk, even if the cause and effect are not fully understood. For example, Sweden has taken an approach to reducing the occurrence of pharmaceuticals in drinking water that is based on the precautionary principle. 36 Sweden has taken steps, such as encouraging that prescriptions be written in smaller amounts to limit the amount of unused pharmaceuticals patients dispose of, even though there is no scientific evidence that the occurrence of pharmaceuticals in the environment is affecting human health. According to the precautionary principle, action should be taken preventively because definitive knowledge about causation might take decades of further research. In the United States, a consumer product is generally allowed on the market unless sufficient evidence can be presented to demonstrate that that product is unsafe. Under a precautionary principle approach, a product would generally not be allowed on the market unless sufficient evidence could be presented to demonstrate that it is safe. Further, the precautionary principle approach generally places the burden of proving the safety of a new product, technology, or activity on its proponents—such as manufacturers and distributors—rather than on the regulator.

Premarket approval is an application of the precautionary principle in which certain products must be tested and approved before they can be

<sup>&</sup>lt;sup>36</sup>For a full discussion of the example as referenced, see GAO, *Environmental Health: Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water*, GAO-11-346 (Washington, D.C.: Aug. 8, 2011).

marketed to consumers. In the United States, regulatory agencies such as FDA and EPA require that some products undergo an approval process. As part of the premarket approval process, regulators establish specific safety standards that products must meet before being approved for marketing to consumers. As in the precautionary principle approach, manufacturers generally bear the burden of demonstrating—with reasonable certainty and through sufficient scientific data and other requirements—that the product will not harm consumers. Regulators, then, must evaluate the data as part of the product approval process.

A few consumer representatives we interviewed said a broad application of the precautionary principle approach to regulating consumer goods could decrease the number of products that come to market with unknown safety hazards and that as a result, injuries and deaths from hazardous products could decrease. However, the majority of the industry and consumer representatives we spoke with did not believe it was wise for CPSC to fully implement a precautionary principle approach. Representatives discussed various challenges the approach could present. For example, one representative said the approach would require manufacturers to incorporate into a product's design a means of addressing all of the ways that consumers could potentially be harmed by using the product; in practice, the representative noted, manufacturers improve upon a product's safety by learning how consumers actually use it. In addition, an industry representative noted that manufacturers could face significant additional costs from requirements to design and conduct an unknown number of new safety tests applicable to each new product. Several representatives said that, given the vast number of products under CPSC's jurisdiction, the agency would need a significant increase in staff and budget to facilitate the ability to evaluate risk assessment data for all new consumer products. A commissioner and an industry representative also expressed concern about underlying assumptions that the approach would result in improvements over the current regulatory scheme. For example, both noted that because CPSC's actions are already driven by data, a precautionary principle approach may not necessarily result in better outcomes.

In addition, CPSC officials said that it would be unrealistic for the agency to implement a premarket approval process for all consumer goods given the vast number of products under CPSC's jurisdiction. However, officials noted that a focused application of premarket approval on a specific product line, such as for cribs, could be an acceptable approach. An industry representative, a consumer representative, and a commissioner commented that certain children's products regulated by CPSC are

already subject to a process similar to premarket approval because of CPSIA's requirement that such products meet third-party testing for compliance with applicable safety standards before they can be marketed to consumers. 37 Two consumer representatives and a consumer safety expert we interviewed said that implementing a premarket approval process for all consumer products could, in theory, prevent hazardous products from entering the market and potentially reduce related injuries and deaths. However, most representatives we interviewed agreed that implementing premarket approval for all consumer products would not enable CPSC to respond to new and emerging hazards faster than it currently does. Some representatives said that such an approach could, among other things, increase (1) the time CPSC takes to respond to product risks, (2) the agency's costs, and (3) the time for new products to come to market. In addition, one commissioner said that CPSC lacks the laboratory testing capacity to effectively implement a full premarket approval process. An industry representative also noted that a full premarket approval process would require CPSC to develop standards for testing all products, which would not be consistent with the current regulatory framework requiring CPSC to rely upon voluntary standards.

CPSC officials said that the nature of CPSC's work already incorporates some preventive measures because the agency relies upon an array of data and scientific analyses to determine the best way to reduce or prevent consumer safety risks. One industry representative noted that CPSC used a preventative approach to address risks stemming from the use of phthalates, as required by statute, much like the precautionary principle prescribes. Specifically, in 1998, CPSC asked manufacturers to remove specific types of phthalates from certain juvenile products, such as soft rattles and teething rings, after its study identified areas of scientific uncertainty about negative effects of the chemical on human health. In 2008, Congress passed a ban on certain phthalates in children's toys until CPSC could convene an independent advisory panel to study the chemicals' effects. The study, published in July 2014, concluded that additional phthalates should also be permanently banned and others should be subject to further risk assessment.

<sup>&</sup>lt;sup>37</sup>See 15 U.S.C. § 2063(a)(2).

## Expedited Mandatory Standard Rulemaking Authority

As previously discussed, CPSIA mandated that CPSC promulgate mandatory standards for durable infant and toddler products using rulemaking procedures in the Administrative Procedure Act (APA) which, according to CPSC staff, lack the cost-benefit analysis requirements specified in the rulemaking procedures in CPSA. CPSC staff said that APA rulemaking procedures enabled them to promulgate the mandated standards more easily and quickly than if they had been required to use CPSA's procedures. Officials expressed interest in expanding CPSC's authority to promulgate rules for other types of products with existing voluntary standards using APA rulemaking procedures. Several consumer representatives and a commissioner supported this idea and said if CPSC had such authority, its response to new and emerging hazards could be timelier. However, CPSC officials noted that expanding its use of this authority could inhibit the industry's access to CPSC and due process as provided by section 9 of CPSA. Opinions vary among current and former commissioners about the extent to which expedited rulemaking authority should be used. At least two commissioners have said that the APA procedures provided CPSC with more flexibility to quickly issue the mandatory standards as required by CPSIA and one said that they could expedite its consideration of others, such as a standard to address the flammability of upholstered fabric. Conversely, one commissioner has said that CPSA's cost-benefit analysis requirements make agencies, like CPSC, take the costs and benefits of their regulations more seriously before finalizing them; and another commissioner commented that CPSA's cost benefit analysis is an important part of rulemaking because it requires agencies to identify a rational justification for proposing a rule.

## Enhancing CPSC's Authorities to Address Unsafe Imports

In September 2011, CPSC staff submitted a report to Congress that recommended several statutory changes designed to improve CPSC's ability to identify hazardous products at the ports of entry and prevent them from entering the marketplace.<sup>38</sup> For example, CPSC staff proposed that CPSC be granted authority to detain products at the ports like other federal agencies, such as Customs and Border Protection. Given the agency's relatively small staff size, another proposal suggested giving CPSC authority to commission employees of other federal agencies to

<sup>&</sup>lt;sup>38</sup>See CPSC, Staff Report to Congress Pursuant to Section 222 of the Consumer Product Safety Improvement Act of 2008 Risk Assessment Methodology, Sept. 2011.

assist in the agency's investigations and inspections to allow for greater enforcement efficiency. In August 2014, CPSC officials confirmed that they continue to support all of the statutory changes recommended in the 2011 report.

Almost half of the 23 consumer and industry representatives and commissioners we interviewed expressed an opinion about whether the proposed statutory changes would enable CPSC to respond more quickly to new and emerging risks. Of these, about half generally supported efforts to improve CPSC's import surveillance authorities. For example, a consumer safety expert said that improvements to CPSC's import surveillance authorities could improve opportunities to stop hazardous products from entering the markets.

However, a commissioner and a consumer safety expert we interviewed did not support the proposed statutory changes and said that they would not help CPSC address new and emerging risks. The commissioner said that new and emerging product risks are rarely identified at the ports. The consumer safety expert expressed concern that some of the statutory changes would add an undue cost burden particularly to the juvenile products industry. According to this representative, one of the statutory changes could result in manufacturers of certain children's products incurring costs to have containers marked "refused for entry" in addition to the costs of compliance with CPSIA's requirement that juvenile products be tested by third-party facilities to ensure compliance with applicable safety standards.<sup>39</sup> Specifically, CPSC's September 2011 report included a proposal to add a new statutory provision to both CPSA and the Federal Hazardous Substances Act designed to prevent the re-entry of all products that have been refused entry into U.S. ports by authorizing CPSC to require visible markings on all containers transporting refused consumer products. Refused products are currently prohibited from being sold or re-exported to other ports unless revised to address the safety violations. In some cases, manufacturers must destroy products that are refused for entry. Some importers attempt to circumvent the requirements by presenting the same violative product at a different port. According to CPSC, the "refused for entry" marking would enhance CPSC's ability to identify such products.

<sup>&</sup>lt;sup>39</sup>Pub. L. No. 110-314, § 102(a)(2), 122 Stat. at 3022 (2008) (codified at 15 U.S.C. § 2063(a)(2)).

# Improving CPSC's Capabilities to Analyze Data

In 2012, we reported that CPSC faced challenges in collecting and analyzing large quantities of data to identify potential product risks. Some sources it uses to identify injuries or death are dated—for instance, death certificates can be 2 or more years old—or contain limited information about the product involved in the incident. 40 According to one CPSC official, additional resources could enable CPSC to purchase death certificates from a more direct source than it currently does, shortening the time it takes to analyze incidents and identify trends. According to CPSC, the agency has upgraded its data management system to enhance CPSC's efficiency and effectiveness, enable a more rapid dissemination of information, and allow public access to its searchable database on consumer product safety information. As previously discussed, CPSC also recently requested additional funding in its fiscal year 2015 congressional budget request to expand the RAM. 41 The majority of consumer and industry representatives and commissioners we interviewed agreed that additional funding and staff would better enable CPSC to identify and address consumer safety hazards, and more than half had suggestions to improve CPSC's efforts. Specifically, because the agency relies heavily upon analyses of scientific and technical data to assess potential hazards from a growing number of consumer products. these representatives said that additional resources to hire staff with expertise in technical areas, such as toxicology, public health, epidemiology, and engineering, could improve the timeliness of CPSC's response to new or emerging product risks.

## Other Options

Several consumer groups and a commissioner we interviewed discussed two other options to improve CPSC's ability to respond more quickly to new and emerging risks than it currently does, both of which would involve changes to CPSA.

Amend Section 6(b) of CPSA. As previously discussed, the
confidentiality requirements in section 6(b) of CPSA may prolong the
time it takes to notify the public about potentially hazardous products,
which could increase the time that hazardous products remain in
consumers' homes. Specifically, two consumer groups, a consumer

<sup>&</sup>lt;sup>40</sup>GAO-13-150.

<sup>&</sup>lt;sup>41</sup>Consumer Product Safety Commission, Fiscal Year 2015 Performance Budget Request, to Congress (Bethesda, MD: March 2014).

safety expert, and two commissioners we interviewed commented that changes to section 6(b) of CPSA could improve CPSC's ability to notify consumers about new and emerging safety hazards. A consumer safety expert we interviewed said that both consumers and manufacturers would benefit from knowing about potential product safety hazards as soon as they are identified. According to a consumer representative, consumers would be able to make informed purchases and manufacturers would learn about potential design defects that may be applicable to their own products. CPSC officials, however, said that releasing information to consumers before manufacturers have had an opportunity to review the details for accuracy could potentially unfairly harm manufacturers and inhibit their right to due process.

• Establish Timeframes for CPSC Rulemaking Activities. As noted earlier, existing laws do not provide a time frame for standard-setting organizations to complete the development of voluntary standards, which often prolongs the time CPSC takes to promulgate a rule to address a product safety hazard. One commissioner we spoke with suggested giving CPSC authority to set a time limit after which it would promulgate a final rule if industry has not developed a voluntary rule. When asked about the viability of this option, CPSC officials said that it takes time to sort through the complex issues associated with some safety hazards, and that it would be difficult to establish a meaningful time frame for the process.

## Concluding Observations

Expansion of international trade, increasingly global supply chains, and technological advances have increased the spectrum of consumer products available to U.S. consumers. These changes have increased the challenges of overseeing and regulating thousands of product types and the potential for new and emerging hazards in the marketplace. Certain aspects of CPSC's authorities, and other factors such as litigation and limited resources, prolong the time it takes CPSC to respond, potentially increasing the risk that consumers will be harmed by hazardous products. A number of options have been proposed that, individually or in combination, could improve CPSC's ability to respond to new and emerging risks in a more timely manner. However, these options require making trade-offs, such as balancing sometimes competing consumer and industry interests. For example, changes to expand CPSC's use of preventive approaches to consumer product safety could give the agency greater ability to respond to risks by preventing hazardous products from entering the market, but also could inhibit market innovation and impose costs on manufacturers. Statutory changes, such as enhanced authority

to address unsafe imports, could allow CPSC to address existing hazards in a more timely manner and prevent hazardous products from entering the market, but also could create disadvantages for manufacturers by imposing costs and prolonging the time for some products to come to market. In addition, improving CPSC's ability to analyze scientific and other data could also help the agency to respond to risks more quickly but may require enhanced resources in a constrained fiscal environment.

## **Agency Comments**

We provided a draft of this report to CPSC for review and comment. In written comments, CPSC expressed appreciation for the report, but took no position since we made no new recommendations. These comments are reprinted in appendix II. In addition, CPSC provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to appropriate congressional committees and the Chairman and Commissioners of CPSC. The report also will be available at no charge on the GAO website at <a href="http://www.gao.gov">http://www.gao.gov</a>.

If you or your staff have any questions about this report, please contact me at (202)512-8678 or <a href="mailto:cackleya@gao.gov">cackleya@gao.gov</a>. 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 II.

Alicia Puente Cackley Director, Financial Markets

and Community Investment

Davia Rente Cackley

# Appendix I: Objectives, Scope, and Methodology

In accordance with section 4 of the Consolidated Appropriations Act of 2014, GAO conducted a study of the ability of the Consumer Product Safety Commission (CPSC) to respond quickly to emerging consumer product safety hazards using authorities under the Consumer Product Safety Act (15 U.S.C. §§ 2056-2058), the Federal Hazardous Substances Act (15 U.S.C. § 1262), and the Flammable Fabrics Act (15 U.S.C. § 1193); and report to congressional appropriations committees on an assessment of CPSC's ability to respond quickly to new and emerging risks. This report discusses (1) how CPSC's authorities and other factors may affect the time it takes CPSC to respond to new and emerging risks and (2) proposed options that may be available to improve CPSC's ability to respond to new and emerging risks in a timely manner and trade-offs associated with those options.

To address both objectives, we reviewed our prior work on CPSC's authorities, CPSC standard operating procedures, performance and accountability reports, and agency budget documentation in order to obtain information on the resources currently available to CPSC and how those resources may impact the agency's ability to respond to new and emerging consumer product safety hazards. In addition to our document review, we interviewed cognizant CPSC officials, knowledgeable staff, and three current and three former CPSC commissioners, including CPSC's acting Chairman, regarding CPSC's ability and authority to identify, assess, and address new and emerging risks in a timely manner.<sup>2</sup> To gather perspectives on the sufficiency of CPSC's current statutory authority and specific factors affecting its ability to respond to emerging risks and to seek opinions on potential options that may be available to CPSC to address these risks in a more timely manner, we interviewed representatives from four consumer advocate groups and representatives from seven industry organizations that represented manufacturers for various consumer products, including juvenile products, clothing and home goods, chemical production, and general consumer goods. We also interviewed six consumer safety experts, three of which were legal experts in the consumer product safety field regarding CPSC's existing statutory and regulatory authorities for addressing new and emerging risks and other potential options available to CPSC.

<sup>&</sup>lt;sup>1</sup>Consolidated Appropriations Act of 2014, Pub. L. No. 113-76, § 4, 128 Stat. 5, 7 (2014); 140 Cong. Rec. H475. (Jan. 15, 2014).

<sup>&</sup>lt;sup>2</sup>A new Chairman and commissioner were appointed after we conducted our interviews.

To address objective one, we reviewed and analyzed relevant federal laws that authorize CPSC to both promulgate and enforce consumer product safety standards, as well as those that authorize the agency to take corrective action necessary to remove a potentially hazardous product from the consumer market. We then examined CPSC rulemaking procedures as stipulated in relevant sections of the Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Flammable Fabrics Act. We identified additional administrative and statutory requirements that may impede CPSC's implementation of corrective action, and we reviewed CPSC's ability to issue mandatory standards and enforce voluntary standards designed to address new and emerging consumer product safety hazards.

To address objective two, we conducted a literature review of scholarly articles using Proguest, Nexis.com, and law review databases. Some of the search terms we used to identify articles on options available to respond to new and emerging risks were "consumer safety," "new and emerging risks," "precautionary principle," "premarket model," and the "Consumer Product Safety Commission" either in combination or alone with geographic delimiters such as "European Union," or "United States," and a date boundary of "after 2007". After removing duplicate articles, we selected 96 scholarly articles and legal reviews from the thousands that were identified based on the extent to which they discussed (1) advantages and disadvantages of the precautionary principle approach or premarket approval or (2) the regulation of relevant policy areas such as consumer product safety, public health, or the environment. Two team members independently reviewed these articles for relevance and found that 18 were relevant for our study. We reviewed these articles more closely for background information on CPSC's authorities and factors that affect timeliness of responding to new and emerging risks and also to identify trade-offs for any options the article discussed. Similarly, we also searched for additional material on the Internet using search terms such as "United States," "precautionary principle," and "premarket approval" and identified an additional 4 articles that we used for contextual purposes.

We conducted this performance audit from March 2014 to October 2014 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.

# Appendix II: Comments from Consumer Product Safety Commission



U.S. CONSUMER PRODUCT SAFETY COMMISSION 4330 EAST WEST HIGHWAY BETHESDA, MD 20814

October 2, 2014

Ms. Alicia Puente Cackley Director, Financial Markets and Community Investment U.S. Government Accountability Office 411 G Street, NW Washington, DC 20548

Dear Ms. Cackley:

The U.S. Consumer Product Safety Commission (CPSC) appreciates the opportunity to review and provide comments on the draft U.S. Government Accountability Office (GAO) report "Consumer Product Safety Commission: Challenges and Options for Responding to New and Emerging Risks." The Commission greatly appreciates GAO's work, but takes no position on the report because it makes no specific recommendations for action.

Thank you again for providing us with the opportunity to comment on the draft report.

Sincerely,

Elliot F. Kaye Chairman

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# Appendix III: GAO Staff Contact and Acknowledgments

### **GAO Contact**

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

## Staff Acknowledgments

In addition to the contact named above, Debra Johnson (Assistant Director), Tiffani Humble (Analyst in Charge), Thomas Beall, Tarik Carter, Marc Molino, Patricia Moye, Rhonda Rose, Jennifer Schwartz, and Carrie Watkins made key contributions to this report.

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