United States
Consumer Product Safety Commission

This document has been electronically approved and signed.

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON:

SEPTEMBER 7, 2022

TO: The Commission
Alberta E. Mills, Secretary

DATE: August 17, 2022

THROUGH: Austin C. Schlick, General Counsel
Jason K. Levine, Executive Director

FROM: Daniel R. Vice, Assistant General Counsel,
Regulatory Affairs
Hyun S. Kim, Attorney, Regulatory Affairs

SUBJECT: Final Rule: Safety Standard for Magnets

The Office of the General Counsel (OGC) is forwarding to the Commission a briefing package recommending that the Commission issue a final rule pursuant to sections 7 and 9 of the Consumer Product Safety Act, to address the risk of injury associated with ingestion of small, high-powered magnets. OGC also is providing for the Commission's consideration a draft final rule that establishes requirements for the subject magnet products with a 30-day effective date following publication of the rule in the *Federal Register*.

Please indicate your vote on the following options:

I. Approve publication of the attached document in the *Federal Register*, as drafted.

_____ _____
(Signature) (Date)

U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

II. Approve publication of the attached document in the *Federal Register*, with the specified changes.

_____

_____

_____

_____

_____ _____

(Signature) (Date)

III. Do not approve publication of the attached document in the *Federal Register*

_____ _____

(Signature) (Date)

IV. Take other action specified below.

_____

_____

_____

_____

_____ _____

(Signature) (Date)

Attachment: Draft *Federal Register* notice “Final Rule: Safety Standard for Magnets”

U.S. Consumer Product Safety Commission
4330 East–West Highway
Bethesda, MD 20814
cpsc.gov

National Product Testing & Evaluation Center
5 Research Place
Rockville, MD 20850

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1262

[Docket No. CPSC-2021-0037]

Safety Standard for Magnets

AGENCY: Consumer Product Safety Commission.

ACTION: Final Rule.

SUMMARY: The U.S. Consumer Product Safety Commission (Commission or CPSC) is issuing a rule to address the hazard associated with ingestion of one or more high-powered magnets. The CPSC has determined that unreasonable risks of injury are associated with small, powerful magnets that, when ingested, can interact internally through body tissue, which can lead to acute and long-term health consequences or death. The rule establishes requirements for consumer products that are designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contain one or more loose or separable magnets. Each loose or separable magnet in a product that is subject to the rule and that fits entirely within CPSC's small parts cylinder must have a flux index of less than 50 kG^2 mm^2. The flux index is determined by the method described in the ASTM F963 Toy Standard. The rule exempts from its requirements toys subject to the ASTM F963 Toy Standard; products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that are not also designed, marketed, or intended to be used for entertainment, jewelry, stress relief, or a combination of these purposes; and products manufactured, sold, and/or distributed solely for home use, such as hardware magnets that are not also designed, marketed, or intended to be used

for entertainment, jewelry, mental stimulation, stress relief, or a combination of these purposes. The Commission takes this action under the Consumer Product Safety Act (CPSA).[1]

DATES: *Effective Date for Magnet Rule:* This rule will become effective on **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and will apply to all subject magnet products manufactured after that date. The incorporation by reference of the publication listed in this rule is approved by the Director of the Federal Register as of **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

Effective date for Notice of Requirements: The Notice of Requirements for this rule will become effective on **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and will apply to subject magnet products that are children's products required to be tested by CPSC-accepted third party conformity assessment bodies.

FOR FURTHER INFORMATION CONTACT: Michelle Guice, Compliance Officer, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7723; e-mail: MGuice@cpsc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. CPSC's Prior Work on the Magnet Ingestion Hazard

In 2012, the Commission initiated rulemaking to address the magnet ingestion hazard for products. The rule focused on magnet sets (which are among the subject magnet products addressed in this rule) that were involved in internal interaction injuries in children and teens. 77 FR 53781 (Sep. 4, 2012) (notice of proposed rulemaking); 79 FR 59962 (Oct. 3, 2014) (2014

[1] The Commission voted __ to publish this notice in the *Federal Register*.

magnet sets rule). The rule defined "magnet sets" as "any aggregation of separable magnetic objects that is a consumer product intended, marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief." The rule required each magnet in a magnet set, and each individual magnetic object intended or marketed for use with or as a magnet set, that fit completely within CPSC's small parts cylinder, to have a flux index of 50 $kG^2 mm^2$ or less, consistent with the magnet size and strength limits specified in ASTM F963-11, which was in effect when the 2014 magnet sets rule was issued. Subsequently, ASTM F963-17 revised the definition of "hazardous magnet" to have a flux index of 50 $kG^2 mm^2$ or more. The final rule was published in October 2014, and it took effect on April 1, 2015.

On November 22, 2016, the U.S. Court of Appeals for the Tenth Circuit overturned CPSC's 2014 magnet sets rule, vacating and remanding it to the Commission. *Zen Magnets, LLC v. Consumer Prod. Safety Comm'n.*, 841 F.3d 1141 (10th Cir. 2016).[2]

On June 30, 2020, staff provided the Commission with an informational briefing package discussing the magnet ingestion hazard.[3] Staff recommended that CPSC continue to consider performance requirements for magnets, to address the ingestion hazard to children and teens.

Throughout this period, CPSC's Office of Compliance and Field Operations investigated and recalled numerous magnet products due to the magnet internal interaction hazard. From January 1, 2010, through May 25, 2022, CPSC conducted 20 recalls involving 25 firms/retailers, and totaling approximately 13,832,901 recalled units, including craft kits, desk toys, magnet sets, pencil cases, games, bicycle helmets, maps, and children's products, among others. Of these 20

[2] In accordance with the court's decision, the Commission removed the mandatory standard for magnets sets (16 CFR part 1240) from the Code of Federal Regulations on March 7, 2017. 82 FR 12716 (Mar. 7, 2017).
[3] Staff's 2020 informational briefing package is available at: Newsroom - FOIA | CPSC.gov.

recalls, five involved products that would not be subject to the rule adopted here. Specifically, four involved children's toys that are subject to the CPSC's *Safety Standard Mandating ASTM F963 for Toys*, and one involved trivets sold with cookware sets. The Commission previously incorporated by reference ASTM F963-17, as codified in 16 CFR part 1250 (referred to also as ASTM F963 Toy Standard) (82 FR 57119 (Dec. 4, 2017).

B. Notice of Proposed Rulemaking

In the *Federal Register* of January 10, 2022 (87 FR 1260), the Commission issued a notice of proposed rulemaking (NPR) under sections 7 and 9 of the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089), to address the unreasonable risk of injury and death associated with ingestion of loose or separable high-powered magnets.[4] As described in the NPR, the incident data showed that hazardous magnets continue to be ingested, in particular, by children and teens. When ingested, these powerful magnets can, among other risks, interact through body tissue with one another, or with a ferromagnetic object (*i.e.*, material attracted to magnets), leading to acute and long-term adverse health consequences or death.

The NPR proposed that each loose or separable magnet in a subject magnet product that fits entirely within CPSC's small parts cylinder, as provided in 16 CFR 1501.4, must have a flux index of less than 50 kG^2 mm^2. The NPR proposed the test procedure for determining the flux index in accordance with the test procedure in section 8.25.1 through 8.25.3 of the ASTM F963 Toy Standard.

The NPR proposed to exempt from the proposed rule, toys that are subject to the ASTM F963 Toy Standard, because that standard already includes requirements to adequately address

[4] Staff's NPR briefing package is available at: Newsroom - FOIA | CPSC.gov

the magnet ingestion hazard. Specifically, ASTM F963-17 applies to "toys," which are defined as objects "designed, manufactured, or marketed as a plaything for children under 14 years of age."

The final rule includes the toy exemption and modifies the NPR's proposal to exempt two additional categories of magnets from the new requirements of 16 CFR part 1262: (1) products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes; and (2) products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes.[5]

II. Statutory Authority

A. Rulemaking Under the Consumer Product Safety Act

The subject magnet products are "consumer products" that can be regulated by the Commission under the authority of the CPSA. 15 U.S.C. 2052(a). Under section 7 of the CPSA, the Commission is authorized to promulgate a mandatory consumer product safety standard that sets forth performance requirements for a consumer product or that sets forth requirements that a product be marked or accompanied by clear and adequate warnings or instructions. 15 U.S.C.

[5] Staff's Final Rule briefing package is available at: _____.

2056. A performance, warning, or instruction standard must be reasonably necessary to prevent or reduce an unreasonable risk or injury associated with a consumer product.

Section 9 of the CPSA specifies the procedure that the Commission must follow to issue a consumer product safety standard under section 7. In accordance with section 9, the Commission commenced this rulemaking by issuing the NPR, including the proposed rule and a preliminary regulatory analysis under section 9(c) of the CPSA. In addition, the Commission requested comments on all aspects of the NPR, including the risk of injury identified, the regulatory alternatives under consideration, and other possible alternatives for addressing the risk. 15 U.S.C. 2058(c). With this notice, the Commission issues a final rule, along with a final regulatory analysis. 15 U.S.C. 2058(f)(2).

Section 9 also requires the Commission to provide interested persons "an opportunity for the oral presentation of data, views, or arguments," in addition to an opportunity to provide written comments. *Id*. 2058(d)(2). On February 15, 2022, the hearing notice was published in the *Federal Register* (87 FR 8442). The Commission held an online public hearing on the proposed rule on March 2, 2022. The submissions forwarded to the agency by presenters before the hearing, as well as the transcript of the hearing, can be read online at: www.regulations.gov under Docket No. CPSC-2021-0037. As discussed in section VI. of this preamble, the Commission considered all the oral and written comments received in response to the proposed rule.

B. Findings Required Under the Consumer Product Safety Act

According to section 9(f)(1) of the CPSA, before promulgating a consumer product safety rule, the Commission must consider and make appropriate findings to be included in the rule on the following issues: (1) the degree and nature of the risk of injury that the rule is

designed to eliminate or reduce; (2) the approximate number of consumer products subject to the rule; (3) the public's need for the products subject to the rule, and the probable effect the rule will have on utility, cost, or availability of such products; and (4) the means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices. *Id.* 2058(f)(1).

Pursuant to section 9(f)(3) of the CPSA, to issue a final rule, the Commission must find that the rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product" and find that issuing the rule is in the public interest. *Id.* 2058(f)(3)(A)&(B). In addition, if a voluntary standard addressing the risk of injury has been adopted and implemented, the Commission must find that: (1) the voluntary standard is not likely to eliminate or adequately reduce the risk of injury, or that (2) substantial compliance with the voluntary standard is unlikely. *Id.* 2058(f)(3(D). The Commission also must find that the expected benefits of the rule bear a reasonable relationship to the costs of the rule and that the rule imposes the least burdensome requirements that would adequately reduce the risk of injury. *Id.* 2058(f)(3)(E)&(F). These findings are provided in section 1262.5 of the regulatory text, below.

III. The Product and Market

A. Description of the Product

The final rule applies to "subject magnet products," which are consumer products that are designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contain one or more loose or separable magnets.

Magnets in subject magnet products typically are small, powerful, magnetic balls, cubes, cylinders, and other shapes that can be used to create jewelry (such as necklaces, bracelets, and simulated piercings), and can be aggregated to make sculptures, or used as desk toys, and as other building sets. One common example of a subject magnet product is a magnet set intended for users 14 years and older. Magnet sets are aggregations of separable magnetic objects that are marketed or commonly used as a manipulative or construction items for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. Magnet sets often contain hundreds to thousands of loose, small, high-powered magnets. Another example of a subject magnet product is jewelry with separable magnets, such as jewelry-making sets, and faux magnetic piercings/studs. Additional examples include products commonly referred to as "executive toys," "desk toys," and "rock magnets" (rock-shaped magnets), intended for amusement of users 14 years and older.

Subject magnet products are available in a variety of shapes, sizes (*e.g.*, 2.5 mm, 3 mm, 5 mm), and number of magnets (1 to thousands). Subject magnet products often consist of numerous identical magnets, although some products include non-identical magnets, such as 2 or more different shapes. Subject magnet products commonly include magnets between 3 mm and 6 mm in size and consist of several hundred magnets.

Magnets in subject magnet products have a variety of compositions, such as alloys of neodymium, iron, boron (NIB); ferrite/hematite; aluminum, nickel, cobalt (AlNiCo); and samarium and cobalt (SmCo). NIB and SmCo magnets are often referred to as "rare earth" magnets because neodymium and samarium are "rare earth" elements found on the periodic table. NIB is typically used in smaller magnets used for magnet sets and magnetic jewelry sets, and ferrite/hematite is typically used in larger magnets, such as rock-shaped magnet toys.The

magnetized cores of subject magnet products are coated with a variety of metals and other materials to make them more attractive to consumers and to protect the brittle magnetic alloy materials from breaking, chipping, and corroding.

Staff found that 5 mm diameter NIB magnets (the most common size identified in magnet ingestion incidents) typically have strong magnetic properties, ranging between 300 and 400 $kG^2\,mm^2$; and ferrite rock magnets can measure upwards of 700 $kG^2\,mm^2$. Staff also identified products close to the limit of 50 $kG^2\,mm^2$, ranging from approximately 30 $kG^2\,mm^2$ to 70 $kG^2\,mm^2$. Some subject magnet products advertise having flux indexes lower than 50 $kG^2\,mm^2$, which is more common for smaller magnets (*e.g.*, 2.5 mm magnets).

Some subject magnet products are "children's products." A "children's product" is a consumer product that is "designed or intended primarily for children 12 years of age or younger." 15 U.S.C. 2052(a)(2). Children's products that are toys are exempt from the rule because they are already required to comply with ASTM F963-17's requirements addressing the magnet ingestion hazard. One example of a subject magnet product that is a children's product and not a toy is children's jewelry.

B. The Product Market

Magnet products intended for the purposes covered in the rule largely entered the market in 2008, with significant sales beginning in 2009. CPSC's previous efforts to address the magnet ingestion hazard have focused primarily on magnet sets, given their involvement in ingestion incidents, their popularity, uses for amusement and jewelry, and the large number of loose, small, high-powered magnets in the sets. Accordingly, much of the information CPSC has about

the market for subject magnet products focuses on magnet sets, which are the largest category of identified products involved in magnet ingestions.

From 2009 through mid-2012, most magnet set sellers were retailers with physical stores, such as bookstores, gift shops, and other outlets. In contrast, nearly all current marketers (firms or individuals) of magnet sets sell through internet sites, rather than physical stores. Some of these internet sites are operated by importers, but most operate on the sites of other internet retailer platforms.

In 2018, CPSC contracted with Industrial Economics, Incorporated (IEc), to examine the market for magnet sets. IEc found a total of 69 sellers of magnet sets on internet platforms in late 2018. IEc also identified 10 manufacturers and two retailers.[6] In 2020, CPSC reviewed the status of previously identified sellers of magnet sets on leading internet marketplaces and found evidence of the high turnover rates for these platforms. Only nine of the 69 sellers IEc identified in late 2018 were still selling magnet sets; the remainder either no longer offered magnet sets, or no longer operated on the platforms. In addition, CPSC identified 29 new sellers that had not been detected in late 2018.

In 2018, approximately 57 percent of magnet set sellers on one internet platform fulfilled orders domestically; whereas, in 2020, this number declined to 25 percent. In 2018, approximately 25 percent of magnet set sellers on another internet platform were domestic; whereas, in 2020, this number increased to 87 percent. Non-domestic sellers were located primarily in China and Hong Kong. Magnet sets purchased from foreign internet retailers can be shipped to consumers directly, or from warehouse facilities located domestically.

[6] IEc classified manufacturers as firms producing and selling their own magnet set products, and it classified retailers as firms that typically sell magnets from multiple manufacturers.

The most recent review by staff conducted in 2020 indicated that magnet sets were comprised, most commonly, of 216 magnetic spheres, with diameters of 5 mm. Retail prices per set average less than $20. IEc's review in 2018 showed similar findings.[7] Magnet sets are also available in larger sets of 512 separable magnets and 1,000 or more separable magnets. Magnet sets comprised of spheres or cubes with smaller dimensions (2.5 mm to 3 mm) are also marketed, typically at lower prices. Some of these magnet sets are advertised as having magnets with magnetic flux indices less than 50 $kG^2\ mm^2$; below the threshold for being considered hazardous magnets. CPSC staff tested samples of such smaller magnets and found that although 2.5 mm magnets typically had flux indices of less than 50 $kG^2\ mm^2$, many of the magnet sets tested failed the ASTM F963-17 requirements because at least one of the magnets in the set had a flux index of 50 $kG^2\ mm^2$ or more. Sets with 3 mm diameter magnets were found to have flux indices generally above 50 $kG^2\ mm^2$.

Children's and adult jewelry, and other types of adult magnet products intended for entertainment, mental stimulation, and stress relief, which have one or more separable/loose magnets, are also within the scope of the rule. Magnets are marketed online as jewelry-making sets, as well as fake studs/piercings. As discussed in section IV of this preamble, many magnet-ingestion cases involve the use of magnet products described as jewelry, such as bracelets and necklaces, and magnets used as jewelry (including those sold as part of a magnet set).

IV. Risk of Injury

A. Magnet Ingestion

[7] IEc found that magnet sets with 216 magnets accounted for approximately one-third of the models in their market research, with an average price of $16.67. However, sets of 216 magnets that measured 5 mm in diameter averaged $18.62.

For the NPR, CPSC's Directorate for Health Sciences (HS) assessed the magnet ingestion hazard. Specifically, HS staff found that when a subject magnet product is ingested, a magnet internal interaction hazard can occur. The magnet internal interaction hazard is described in detail in Tab A of Staff's NPR briefing package, as updated for this final rule in Tab A of the Staff's Final Rule briefing package. The risk of injury addressed by this rule is damage to intestinal tissue, caused when someone ingests more than one magnet from a subject magnet product (or one magnet and a ferromagnetic object). The magnets are attracted to each other in the digestive system, damaging the intestinal tissue that becomes trapped between the magnets. In rare cases, there can be interaction between and among magnets in the airways and digestive tract (esophagus). These injuries can be difficult to diagnose and treat because the symptoms of magnet ingestion often appear similar to entirely unrelated conditions, such as stomach viruses. Serious injury, and even death, are consequences of children ingesting magnets.

One of the health threats presented by magnet ingestion is internal magnet interaction leading to pressure necrosis injuries in the alimentary canal. Necrosis is a process of cell death, secondary to injury, which undermines cell membrane integrity and involves intricate cell-signaling responses. In the case of internal magnet interactions, the injury leading to necrosis is the pressure on the involved biological tissues that exceeds local capillary pressure and leads to ischemia.

Volvulus is another type of injury associated with the magnet internal interaction hazard. Volvulus is an obstructive twisting of the GI tract. Volvulus is often accompanied by abdominal pain, distended abdomen, vomiting, constipation, and bloody stools. If left untreated, volvulus may lead to bowel ischemia, perforation, peritonitis, and death. Volvulus following magnet ingestion has been linked to fatal outcomes. In the United States, CPSC is aware of the death of a

20-month-old child who ingested magnets from a toy construction set, which caused volvulus, and another death of a 2-year-old child who ingested multiple magnets, resulting in small intestine ischemia secondary to volvulus. In addition, CPSC is aware of one death of an 8-year-old child in Poland, due to small intestine ischemia secondary to volvulus, after the victim ingested magnets that resulted in necrosis, toxemia (blood poisoning), hypovolemic shock, and eventually cardiopulmonary failure.

Like outcomes related to volvulus, small bowel ischemia can lead to local tissue necrosis, perforation, and subsequent peritonitis. Small intestine ischemia was implicated in the death of a 19-month-old child following ingestion of multiple magnets. Bowel obstruction, often a consequence of volvulus, is associated with abdominal cramps, vomiting, constipation, and distention. With respect to the relationships among local capillary and intraluminal pressures and magnet ingestions, subsequent outcomes include possible blockage of local blood and nutrient supply; progressive pressure necrosis of the involved tissues; and local inflammation, ulceration, and tissue death, with outcomes such as perforation (hole) or fistula in the GI tract. If left untreated, or otherwise unnoticed (including diagnosis as a stomach virus as noted previously), such events can progress into infection, sepsis, and death. The obstruction from the trapped tissue can elicit vomiting, and the local mucosa irritation may stimulate diarrhea. Advancing pressure necrosis of the involved tissues can lead to necrosis and subsequent leakage of the bowel contents into the peritoneal cavity.

Another example of the potential health outcomes associated with magnet ingestion is a case in which an asymptomatic 4-year-old child sustained several fistulae in the intestines that required surgical repair after ingesting magnets. Fistulae are abnormal passages between channels in the body that are associated with increased mortality. Fistulae may enable the

leakage of gut contents into adjacent tissue structures or abdominal cavities, which can lead to infection, inflammation, perforation, sepsis, and possibly death. Fistulae may also bypass portions of the GI tract, thus undermining normal GI function.

Another potential health outcome of magnet ingestions is ulcerations. For example, one case involved a 28-month-old child who experienced stomach ulcerations after ingesting 10 magnets and received treatment with medication after the endoscopic removal and natural passage of the magnets. Untreated ulcers may require surgical intervention if they progress to perforation, and a perforated bowel may lead to leakage from the GI tract which carries risk of death as previously noted. Several magnet ingestion incident reports highlight the threat of perforation with possible outcomes like peritonitis. Peritonitis is an inflammation of the peritoneum, a membrane lining the abdominal cavity, which may be associated with leakage from the GI tract that can lead to sepsis. Sepsis is the body's response to severe infection, and it is associated with elevated rates of morbidity and mortality that can be mitigated with prompt treatment. Treatment of abdominal sepsis may require repair of a leaky GI tract.

Another potential health risk from ingested magnets is an aspiration threat. For example, in one reported case, a 3-year-old child ingested multiple magnets, two of them found attracting to each other on opposing surfaces of the pharyngoepiglottic fold in the throat, presenting an immediate aspiration threat, given the proximity to the airway. Aspiration of magnets has also been reported elsewhere in medical literature. Foreign body aspiration presents a risk of airway obstruction, ventilatory difficulty, choking, hypoxic-ischemic brain injury, pulmonary hemorrhage, and death, among other health outcomes.

Since the NPR, CPSC staff reviewed a recent multicenter cohort study that presented data on 596 cases of patients aged 0 to 21 years, from 25 children's hospitals in a 3-year period

following high-powered magnet sales re-entering the U.S. market after judicial vacatur of CPSC's 2014 magnet sets rule (2017-2019).[8] Of the 596 patients treated for high-powered magnet exposures, 562 children (96.2%) ingested magnets, 17 children (2.9%) were treated for nasal or aural magnet foreign bodies, 4 children (0.7%) were treated for magnets in their genitourinary tract, and 1 patient (0.2%) presented with magnets in their respiratory tract. Most patients required serial radiography, with 81.4 percent of children receiving more than one x-ray. Thirty-six children (6%) required a computed tomography (CT) scan. Although magnets passed spontaneously in more than half of patients (53.7%), 276 children (46.4%) required a procedure for magnet removal, or to address complications from magnet ingestion. One hundred ninety-one patients (32%) required endoscopy alone; 58 patients (9.7%) required surgery alone; and 27 patients (4.5%) required both endoscopy and surgery. Magnet exposure led to morbidity in 57 (9.6%) patients, which included perforation (6%), fistula formation (3.7%), bowel obstruction (2.7%), bleeding (0.7%), infection (0.5%), volvulus (0.2%), and/or bowel herniation (0.2%). This study identified 19 children (3.2%) who developed more than one of these listed morbidities. Approximately 55.7 percent of patients required hospitalization (332 patients) and four patients (0.7%) were admitted to the ICU. The median length of hospital stay was 3 days. This study shows that magnet ingestion frequently led to hospitalization, the need for invasive medical management, and caused morbidity in nearly 1 in 10 children who ingested magnets.

B. Incident Data - NEISS

For the NPR, CPSC's Directorate for Epidemiology, Division of Hazard Analysis analyzed reported incidents related to magnet ingestion, see Tab B of Staff's NPR briefing package. For the NPR, CPSC staff analyzed magnet ingestion incident data obtained through the

[8] This study can be found at: https://www.regulations.gov/comment/CPSC-2021-0037-0010.

National Electronic Injury Surveillance System (NEISS) and the Consumer Product Safety Risk Management System (CPSRMS). The incident data analyzed for the NPR were extracted on January 8, 2021, and they included magnet ingestion reports that occurred from January 1, 2010, through December 31, 2020. CPSC estimated that 23,700 emergency department (ED)-treated magnet ingestions occurred in that timeframe. Among other observations, CPSC noted that estimated magnet ingestions, excluding products considered to be out-of-scope of the proposed rule, fell during the period the CPSC's 2014 magnet sets rule was in effect, and the estimated ingestions rose after the 2014 magnet sets rule was vacated (79 FR 59962). Specifically, CPSC estimated for the NPR approximately 2,300 ED-treated ingestions of magnets annually from 2010 through 2013 (years prior to the announcement of the magnet sets rule), approximately 1,300 annually from 2014 through 2016 (years the rule was announced and in place), and approximately 2,300 annually from 2017 through 2020 (the years following the removal of the rule).

For the final rule, Tab B of Staff's Final Rule briefing package updated the incident data analysis, covering magnet ingestions reported to have occurred from January 1, 2010, through December 31, 2021. CPSC staff reviewed the additional data obtained since the NPR, using the same characterizations in the NPR, and staff updated the estimates for ED-treated, magnet ingestions. Staff categorized the data set to assess the involvement of specific magnet product types in magnet ingestion cases. Based on the identification and/or description of the products involved in the cases, staff organized the cases into the following magnet categories: "magnet set," "magnet toy," "jewelry," "science kit," "home/kitchen," "F963 magnet toy," and "unidentified." Staff further combined cases in those magnet categories into groupings as: "amusement/jewelry" – cases involving magnet sets, magnet toys, or jewelry; "unidentified" –

cases involving unidentified magnet products; and "exclusions" – cases involving home/kitchen products, ASTM F963 magnet toys, or science kits. In cases where magnet ingestion incident reports contained too limited information for staff to identify the type of product involved in the magnet ingestion, they were classified as "unidentified." As explained in the NPR, staff does have additional information about the incidents in the unidentified product type category; specifically, these incidents involved ingestion of one or more magnets, based on product characteristics and use patterns typically consistent with subject magnet products. 87 FR 1269-75.

To account for the lack of product identification in many magnet ingestion incidents, staff analyzed magnet ingestion incident data in several ways. For one, aggregated information for all of the in-scope, out-of-scope, and unidentified product categories indicates that magnet ingestions, in general, are an issue, and the incidents have increased in recent years. This indicates the propensity of children and teens to ingest magnets, and it demonstrates the increasing risk of injury and death as magnet ingestion cases increase.

Staff also categorized incidents into specific product groups, based on information that was available in incident reports. For incidents that provided information sufficient to enable identification of the product type, the data revealed that six categories of products were involved in magnet ingestions—magnet sets, jewelry, magnet toys, science kits, ASTM F963 magnet toys, and home/kitchen magnets. For some of the incidents in these categories, there was specific information about the product—such as brand names—that allowed staff to determine the particular product involved in the incident. For other incidents in these categories, the product was referred to as a specific type (*e.g.*, magnet sets, desk toy, science kit, kitchen magnet,

bracelet).[9] These categories provide information about the products involved in magnet ingestions, and the relative frequency of their involvement, to help determine which products the rule should address.

Staff also aggregated these categories into in-scope and out-of-scope groupings. Staff combined incidents from the magnets sets, magnet toys, and jewelry categories as "amusement/jewelry" and combined incidents from the home/kitchen, ASTM F963 magnet toys, and science kit categories as "exclusions." Grouping several product type categories together allowed staff to generate national estimates of ED-treated magnet ingestions, to provide a number of ingestions nationally, and the relative involvement of in-scope and out-of-scope products, which helps identify the magnitude of the risk and the potential benefits of the rule to reduce that risk.

In addition, staff combined the amusement/jewelry and unidentified categories to conduct more detailed analyses. Staff also included incidents in the unidentified product type category within these analyses because there are several factors that indicate that many of the incidents in the unidentified product type category likely fall within the scope of the rule. The following factors were considered.

First, the incident data discussed in this preamble support the conclusion that many of the magnet ingestion incidents in the unidentified product type category actually involved subject

[9] Staff categorized incidents based on all of the information available in the reports, including descriptions, names, and uses of the product. However, for some of the incidents in which the report provided a product type but not a specific product brand/name, it is possible that the product was actually from another category. For example, the jewelry category includes cases in which the report indicates that the magnets were described as jewelry at the time of the incident, such as magnetic earrings. It is possible that the magnets in such cases were actually from a non-jewelry product. Similarly, products categorized as magnet toys could actually be another product type; for example, a product described as an "executive desk toy," which did not meet the parameters for the magnet set category, and did not indicate marketing to children under 14 years old, was included in the magnet toy group, although it is possible that the product actually was a magnet set or other product type, and the report lacked information to indicate this. However, even if incidents in these categories were miscategorized, they likely would still fall within the scope of the rule because they meet the description of an in-scope product.

magnet products. Of the NEISS magnet ingestion incidents for which staff could identify a product category, the primary products involved were magnet sets, magnet toys, and jewelry; far fewer incidents involved ASTM F963 magnet toys, home/kitchen magnets, or science kits. The same was true for CPSRMS incidents, for which far fewer incidents were in the "unidentified" category. Given this consistency across data sets, it is reasonable to conclude that the relative involvement of magnet product types established for magnet ingestions applied to the incidents that lacked product identification as well.

Second, magnet ingestion rates before, during, and after the vacated 2014 magnet sets rule show that a significant portion of magnet ingestion cases involved magnet sets. As discussed in the NPR, CPSC's assessment of incident data, as well as other researchers' assessments of NEISS data, and national poison center data, indicate that magnet ingestion cases significantly declined during the years the magnet sets rule was announced and in effect, compared to the periods before and after the 2014 magnet sets rule. 87 FR 1273-74. Magnet sets were the only products subject to that rule. As such, the significant decline in incidents during that time the rule was in effect, and the significant increase in incidents after that rule was vacated, strongly suggest that many magnet ingestion incidents involve magnet sets. Thus, it is reasonable to conclude that many of the incidents in the unidentified product category involved magnet sets. Moreover, the definition of "magnet sets" in the vacated rule was largely equivalent to the description of amusement products in the present rule (*i.e.*, magnet sets and magnet toys), suggesting that many magnet ingestion incidents, including those with unidentified product types, involve amusement products.

Third, incident data and recalls regarding magnets in children's toys further support the conclusion that magnet ingestions categorized as relating to "unidentified" products largely

involved subject magnet products. ASTM F963 magnet toys make up only a small portion of magnet ingestion incidents where the product can be identified. It is reasonable to conclude that this holds true for unidentified products in magnet ingestions as well.

Taken together, these factors support the conclusion that most magnet ingestion incidents, including those in the "unidentified" product type category, involved products that fall within the "amusement/jewelry" (magnet sets, magnet toys, and jewelry) category, and not the "exclusions" (science kit, home/kitchen, or ASTM F963 magnet toys) category. For these reasons, staff included magnet ingestion incidents from the "unidentified" product type category in many of its analyses; to exclude such incidents likely would vastly underrepresent ingestions of subject magnet products.

For data extracted since the NPR, staff used the same categories and groupings for additional incidents. The new data extracted on January 13, 2022, included: (1) addition of 112 NEISS-reported incidents that occurred from January 1, 2021, through December 31, 2021 with an estimated 2,500 ED-treated ingestions of magnets from in-scope products which was higher than most of the preceding years, and (2) 111 additional CPSRMS-reported incidents that occurred from February 1, 2016, through December 27, 2021.[10] Staff provided the NEISS total estimates for 2010 through 2021, as follows:

- There were an estimated 26,600 (2,800 in 2021) ED-treated magnet ingestions involving magnet products of various types from 2010 through 2021.
- An estimated 5,000 of the 26,600 (20%) magnet ingestions involved magnet sets, magnet toys, or jewelry.

[10] The CPSRMS data analyzed in support of the NPR were extracted on January 13, 2022. Reporting to the CPSRMS database is ongoing, and therefore, it is common for reports to be received for incidents from prior years. This also means CPSC in the coming years may receive additional CPSRMS reports of magnet ingestions within the studied period, particularly 2021.

- An estimated 1,600 of the 26,600 (6%) magnet ingestions involved products identified as out-of-scope.
- An estimated 20,000 of the 26,600 (75.2%) magnet ingestions involved unidentified products.
- An estimated 5,000 victims (20%) were hospitalized or transferred to another hospital after treatment.
- The middle 3 years (2014 through 2016) show significantly fewer of these magnet ingestions (estimated 1,300 per year), compared with earlier and more recent years (*i.e.*, compared with 2,300 per year from 2010 through 2013, and 2,400 per year from 2017 through 2021).

Table 1 provides the number of cases for each magnet category, and Table 2 provides the estimates of ED-treated magnet ingestions identified in the NPR, since the NPR, and overall from 2010 through 2021.

Table 1. Count of Magnet Ingestion Cases Treated in NEISS Hospital Emergency Departments by Magnet Category, 2010-2021.

Individual Magnet Category	NPR	2021 (Since NPR)	2010-2021 (Combined)	Combined Magnet Category	NPR	2021 (Since NPR)	2010-2021 (Combined)
Magnet Set	58	7	65	Amusement/Jewelry	221	24	245
Jewelry*	53	1	54				
Magnet Toy	110	16	126				
Unidentified	793	81	874	Unidentified	794	81	874
Science Kit	1	0	1	Exclusions	57	7	65
F963 magnet toy	11	2	13				
Home/Kitchen	46	5	51				
Total	**1072**	**112**	**1,184**	**Total**	**1072**	**112**	**1,184**

*Includes cases of uncertain product classification for which the magnets were being used as or like jewelry.
Source: NEISS, CPSC

Table 2. Estimated Number of Magnet Ingestions Treated in Hospital Emergency Departments by Magnet Category, 2010-2021.

	NPR			Since NPR			Combined		
Magnet Category	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**
Amusement/Jewelry	4,400	0.17	221	**	**	24	5,000	0.16	245
Unidentified	18,100	0.14	793	1,900	0.26	81	20,000	0.15	874
Exclusions	1,300	0.20	58	**	**	7	1,600	0.19	65
Total	**23,700**	**0.21**	**1,072**	**2,500**	**0.22**	**105**	**26,600**	**0.14**	**1,184**

**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC. Estimates rounded to the nearest 100. Throughout this section, summations of estimates may not add to the total estimates provided in the tables, due to rounding. Estimates are derived from data in the NEISS sample. Estimates spanning periods of multiple years (such as the 12 years from 2010 to 2021) are total estimates, and *not* annual averages.

Table 3 provides the estimates for in-scope magnet categories in ED-treated ingestions in NPR, since NPR, and combined from 2010 through 2021. Combining only the "amusement/jewelry" and "unidentified" categories, and omitting "exclusions," leaves us with a total of 25,000 estimated magnet ingestions that involved or likely involved the subject magnet products, as shown in Table 3. Of the 25,000 in-scope magnet ingestions, at least an estimated 5,000 (20%) correspond to cases associated with amusement/jewelry category, and an estimated 20,000 (80%) correspond to the unidentified category. When considering the data received since the NPR, the majority of the cases involved unidentified products, similar to the NPR data. As discussed above, the record strongly supports the conclusion that many of these unidentified magnet products were likely subject magnet products.

Table 3. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Magnet Category, 2010-2021.

	NPR			Since NPR			Combined		
Magnet Category	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**
Amusement/Jewelry	4,400	0.17	221	**	**	24	5,000	0.16	245
Unidentified	18,100	0.15	793	1,900	0.26	81	20,000	0.15	874
Total	**22,500**	**0.14**	**1,014**	**2,500**	**0.22**	**105**	**25,000**	**0.14**	**1,119**

**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC. Estimates rounded to the nearest 100. Throughout this section, summations of estimates may not add to the total estimates provided in the tables, due to rounding. Estimates are derived from data in the NEISS sample. Estimates spanning periods of multiple years (such as the 12 years from 2010 to 2021) are total estimates, and *not* annual averages.

Table 4 presents the breakdown by age group.

Table 4. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Age Group, 2010-2021.

	Estimate			CV			N		
Age Group	**NPR**	**Since NPR**	**Combined**	**NPR**	**Since NPR**	**Combined**	**NPR**	**Since NPR**	**Combined**
Under 2 years	2,700	**	2,800	0.19	**	0.18	120	8	128
2 years	2,300	**	2,400	0.27	**	0.25	89	5	94
3-4 years	4,700	**	5,100	0.16	**	0.15	196	26	222
5-7 years	4,300	**	5,200	0.14	**	0.14	207	26	233
8-10 years	3,900	**	4,800	0.19	**	0.20	179	27	206
11-13 years	3,400	**	3,600	0.17	**	0.18	182	12	194
14 or More years	**	**	**	**	**	**	41	1	42
Total	**22,500**	**2,500**	**25,000**	**0.14**	**0.22**	**0.14**	**1,014**	**105**	**1,119**

**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases, and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC; estimates are rounded to nearest 100.

C. Databases Other than NEISS

CPSC staff also analyzed magnet ingestion incident data obtained through CPSRMS. Staff's review of the CPSRMS data showed that from 2010 through 2021, there were 395 reported magnet ingestions in the database. Of these, 111 were reported since the NPR, including 56 magnet ingestions that occurred in 2021. Although the CPSRMS reports are anecdotal, and therefore, cannot be used for generating nationally representative estimates, they provide a

minimum number of incidents, and they tend to include more information about the incidents and products involved, in comparison to the NEISS data. CPSRMS reports may contain photos, links to websites, detailed narratives, and medical documents; whereas NEISS reports contain brief narratives culled from medical records developed during the ED visit. At least 167 CPSRMS-reported magnet ingestions (including 43 incidents since the NPR) resulted in surgery, such as laparoscopy, laparotomy, appendectomy, cecostomy, enterotomy, colostomy, cecectomy, gastrotomy, jejunostomy, resection, and transplant, among others. At least 140 CPSRMS-reported magnet ingestions resulted in internal interaction through body tissue (including 32 incidents since the NPR). In cases that did not result in surgery, it was still common for victims to receive serial X-rays, and in many cases, endoscopies, and anesthesia.

D. Magnet Ingestions Incident Trends

As discussed in section 1.A. in the preamble, the Commission issued a magnet sets rule in 2014 that applied to magnet sets, which are a subset of the subject magnet products addressed in this rule. The 2014 magnet sets rule took effect in April 2015, and the rule remained in effect until it was vacated by the U.S. Court of Appeals for the Tenth Circuit in November 2016. As explained in the NPR, 87 FR 1274, and after further review of the incidents extracted after the NPR, staff noted a considerable change in magnet ingestion rates during the period of the Commission's later-vacated rule on magnet sets. CPSC's assessment of incident data, as well as other researchers' assessments of NEISS data and national poison center data, indicate that magnet ingestion cases significantly declined during the years in which the 2014 magnet sets rule was announced and in effect, compared to the periods before and after the rule.

Table 5 provides the annual estimates for ED-treated, magnet ingestions by year, from 2010 through 2021. Some of the year-to-year changes may be attributable to random variation in

the sample; however, statistically significant differences emerge. Overall, 2014 through 2016 (when 2014 magnets sets rule had been announced and was in effect) had the lowest number of estimated annual ED-treated magnet ingestions. The analysis of the NEISS data showed that there were insufficient cases in 2014, and only 2014, to provide an estimate. Table 5 further shows that in-scope magnet ingestions are higher for the 2017 through 2021 period, than the previous periods, with more estimated in-scope magnet ingestions in 2021 (2,500) than most of the preceding years, including 2018 through 2020.

Table 5. Estimated Number of In-Scope* Magnet Ingestions Treated in Hospital Emergency Departments by Year.

Year	Estimate	CV	N
2010	1,900a	0.18	91
2011	2,500[a,b]	0.18	101
2012	2,700[a]	0.26	115
2013	2,000	0.21	88
2014	**	**	62
2015	1,200	0.24	61
2016	1,400	0.24	77
2017	2,900[a,b]	0.25	112
2018	2,400[a,b]	0.18	120
2019	1,800	0.22	91
2020	2,200	0.21	96
2021	2,500[a,b]	0.22	105
Total	**25,000**	**0.14**	**1,119**

a Estimate is significantly greater than for the year 2015 (p-value<0.05).
b Estimate is significantly greater than for the year 2016 (p-value<0.05).
*These estimates exclude cases identifying non-subject-product-type magnets, and therefore, do not represent all magnet ingestions treated in hospital emergency departments.
**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC; estimates rounded to nearest 100. Summations of estimates may not add to the total estimates, due to rounding.

To assess these trends further, CPSC grouped years in relation to the vacated 2014 magnet sets rule, using the periods: 2010 through 2013 (prior to the announcement of the rule); 2014 through 2016 (when the final rule was announced and in effect[11]); and 2017 through 2021

[11] Staff grouped 2014, 2015, and 2016 for this analysis, because these are the years firms were likely to comply with the size and strength limits in the magnet sets rule. Because the standard took effect in April 2015, and remained in effect until November 2016, firms were required to comply with the standard for nearly all of 2015 and 2016.

(after the rule was vacated by the Court of Appeals). Table 6 shows the estimated number of magnet ingestions treated in U.S. hospital EDs during these periods, using annual estimates for each period, to account for the periods including different numbers of years. For 2010 through 2013, there were an estimated 2,300 ED-treated magnet ingestion incidents per year; for 2014 through 2016, there were an estimated 1,300 ED-treated magnet ingestion incidents per year, and for 2017 through 2021, there were an estimated 2,400 ED-treated magnet ingestion incidents per year. Thus, during the period when the 2014 magnet sets rule was announced and in effect (2014-2016), magnet injury ingestion estimates are lowest by a significant margin, compared with the earlier and more recent periods. This data is consistent with the annual yearly estimates provided in Table 5, which shows that the annual estimate for in-scope magnet ingestions is higher for the 2017 through 2021 period, than the previous periods, with more estimated in-scope magnet ingestions (2,500) than most of the preceding years, including 2018 through 2020.

Table 6. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Period.

Period	Annual Average Estimate	CV	N	Years in Period
2010 - 2013	2,300	0.16	395	4
2014 - 2016	1,300	0.20	200	3
2017 - 2021	2,400	0.15	524	5
2010 – 2021	**2,100**	**0.14**	**1,119**	**12**

Source: NEISS, CPSC; estimates rounded to nearest 100.

Although the rule was not in effect in 2014, the proposed rule was published in 2012, and the final rule was published, with essentially the same requirements, in October 2014. Once an NPR is published, firms have notice to prepare for the requirements that may be finalized; and once a final rule is published, firms often take steps to comply with the rule, even before it takes effect. Accordingly, it is reasonable to conclude that firms took steps to comply with the magnet sets standard in 2014.

Although CPSRMS data cannot be used to draw statistical conclusions, that data also suggest a similar decline in incidents for the period when the 2014 magnet sets rule was announced and in effect, as shown in Figure 1, below.

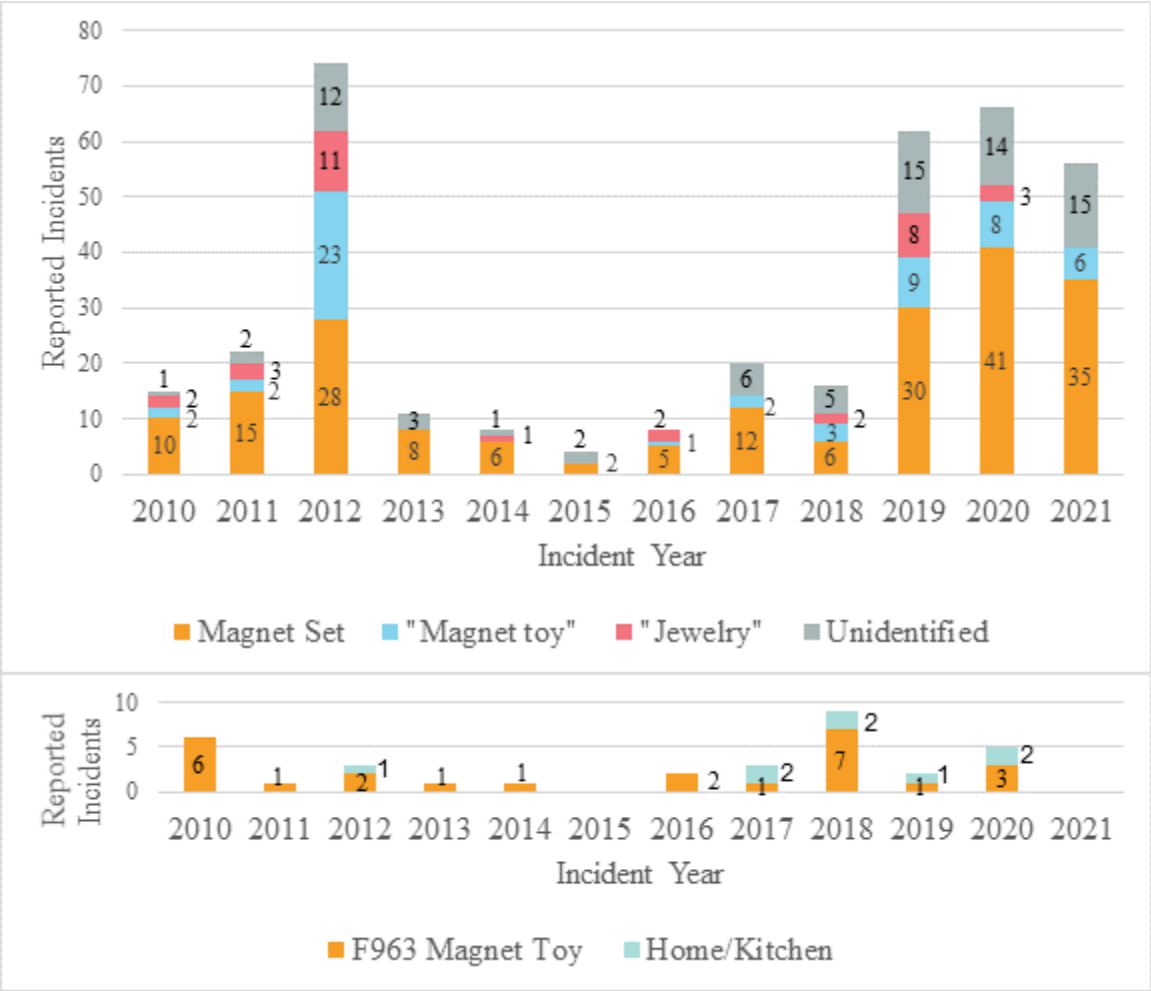

Figure 1. Annual incidents involving magnet product categories. *CPSRMS reporting for the years 2020 through 2021 is ongoing, and the counts for those years may increase as reporting continues.

Table 7 shows CPSRMS-reported magnet ingestions, by period, using incidents categorized as "amusement/jewelry" and "unidentified" product types, consistent with the NEISS analysis. Table 7 breaks down the number of reported magnet ingestions in each category, including reported incidents from the NPR, and additional reports since the NPR. Of

the 111 newly reported incidents, staff identified 64 additional incidents as involving a magnet set and 33 additional incidents as an unidentified product.

Table 7. Magnet Category and Scope for Reported Magnet-Ingestions, January 2010-December 2021.*

	Reported Incidents				Reported Incidents		
Magnet Category	**NPR**	**Since NPR**	**2010-2021 Total**	**Scope**	**NPR**	**Since NPR**	**Total**
Magnet Set	134 (47.2%)	64 (57.7%)	198 (50.1%)	Amusement/Jewelry	214 (90.5%)	72 (94.6%)	286 (91.6%)
Magnet Toy	49 (17.3%)	7 (6.3%)	56 (14.2%)				
Jewelry	31 (10.9%)	1 (0.9%)	32 (8.1%)				
Unidentified	43 (15.1%)	33 (29.7%)	76 (19.2%)	Unidentified	43 (14.8%)	33 (29.7%)	76 (19.0%)
Science Kit	0	0	0	Exclusions	27 (9.5%)	6 (5.4%)	33 (8.4%)
F963 Magnet Toy	21 (7.4%)	4 (3.6%)	25 (6.3%)				
Home/Kitchen	6 (2.1%)	2 (1.8%)	8 (2.0%)				
Total	**284 (100%)**	**111 (100%)**	**395 (100%)**	**Total**	**284 (100%)**	**111 (100%)**	**395 (100%)**

*CPSRMS reporting for the years 2020-2021 is ongoing.

Counts of reported incidents may increase, especially for 2020 and 2021, as CPSC continues to collect data. Moreover, due to the anecdotal nature of the data, the data in this analysis are to be considered a minimum of all incidents that have actually occurred.

V. Relevant Existing Standards

In the NPR, CPSC identified six existing safety standards that in some way address the magnet ingestion hazard. 87 FR 1282. The NPR described these standards in detail and provided CPSC staff's assessment of their adequacy in addressing injuries and deaths associated with magnet ingestions, focusing on provisions that are relevant to the magnet ingestion hazard. *Id.* at 1282-87. None of the standards apply to all subject magnet products, and the standards do not adequately address the hazard for the subject magnet products. Since the NPR, there were no

changes in the magnet requirements specified in these standards. The standards are summarized below.

Four of the standards are domestic standards, and all but one (ASTM F963-17) are voluntary:

- ASTM F963-17, *Standard Consumer Safety Specification for Toy Safety*;
- ASTM F2923-20, *Standard Specification for Consumer Product Safety for Children's Jewelry*;
- ASTM F2999-19, *Standard Consumer Safety Specification for Adult Jewelry*; and
- ASTM F3458-21, *Standard Specification for Marketing, Packaging, and Labeling Adult Magnet Sets Containing Small, Loose, Powerful Magnets (with a Flux Index ≥50 kG2 mm2)*.

In addition, two are international safety standards:

- EN 71-1: 2014, *Safety of Toys; Part 1: Mechanical and Physical Properties*; and
- ISO 8124-1: 2018, *Safety of Toys — Part 1: Safety Aspects Related to Mechanical and Physical Properties*.

A. ASTM F963-17

ASTM F963 was originally approved in 1986, and since then, the standard has been revised numerous times. In 2007, ASTM updated the standard to include requirements to address the magnet ingestion hazard in children's toys. In subsequent revisions, ASTM added requirements for toys containing magnets. ASTM F963 is a mandatory consumer product safety standard. ASTM approved ASTM F963-17 on May 1, 2017 and published it in August 2017.

ASTM F963-17, which is the most recent version of the standard, is incorporated by reference under 16 CFR part 1250.

1. Scope

ASTM F963-17 applies to "toys," which the standard defines as objects designed, manufactured, or marketed as playthings for children under 14 years old. As such, the standard does not apply to products that are intended for users 14 years or older, or products that would not be considered playthings. When ASTM adopted the provisions regarding magnets, it explained that the purpose of the requirements was to address magnet ingestion incidents resulting in serious injury or death, by identifying magnets and magnetic components that can be readily swallowed.[12]

2. Performance Requirements for Magnets

The standard specifies that toys may not contain a loose as-received "hazardous magnet" or a loose as-received "hazardous magnetic component." In addition, toys may not liberate a "hazardous magnet" or "hazardous magnetic component" after specified use-and-abuse testing, which consists of soaking under water, cycling attachment and detachment, drop testing, torque testing, tension testing, impact testing, and compression testing. The standard excepts from the requirements "magnetic/electrical experimental sets" intended for children 8 years and older—such products need only comply with warning requirements, discussed below.

The standard defines a "hazardous magnet" as a magnet that is a small object (*i.e.*, fits entirely within a small parts cylinder specified in the standard) and has a flux index of 50 kG^2 mm^2 or more (as measured in accordance with the method specified in the standard). Thus, a magnet must be both small and strong, according to the criteria in the standard, to be

[12] ASTM F963-17; section A9.4 (Magnets in Toys).

"hazardous." A "hazardous magnetic component" is any part of a toy that is a small object and contains an attached or imbedded magnet with a flux index of 50 kG^2 mm^2 or more.

ASTM F963-17 describes the small parts cylinder in section 4.6 and illustrates it in Figure 3; to be a small object, the magnet must fit entirely within the cylinder. The small parts cylinder depicted in ASTM F963-17 is the same as the small parts cylinder in CPSC's regulations, at 16 CFR 1501.4. Sections 8.25.1 through 8.25.3 describe the test methodology to measure the maximum absolute flux of a magnet and to calculate the flux index. A flux index is a calculated value of magnetic density and size. The flux index of a magnet is calculated by multiplying the square of the magnet's maximum surface flux density (in KGauss (kG)) by its cross-sectional area (in mm^2).

3. Warning Requirements

ASTM F963-17 does not include specific labeling requirements for toys containing loose as-received hazardous magnets or hazardous magnetic components, except for "magnetic/electrical experimental sets" intended for children 8 years and older, which are exempt from the performance requirements and need only meet labeling requirements. The standard defines a "magnetic/electrical experimental set" as a "toy containing one or more magnets intended for carrying out educational experiments that involve both magnetism and electricity." Section A12.4 (Magnets) in the standard explains that this definition is intended to cover only products that combine magnetism and electricity. The packaging and instructions for magnetic/electrical experimental sets intended for children 8 years and older must be labeled with a warning that addresses the magnet ingestion hazard.

4. Assessment of Adequacy

The size and strength requirements in ASTM F963-17 are consistent with the requirements in this rule for subject magnet products. Although the size and strength requirements are adequate to address the hazard, ASTM F963-17 only applies to products designed, manufactured, or marketed as playthings for children under 14 years old; it does not apply to products intended for older users or products that would not be considered playthings. Accordingly, the Commission does finds that compliance with the standard is not likely to adequately reduce the magnet ingestion hazard.

As the incident data indicate, children and teens commonly access and ingest magnets from products intended for older users. Both NEISS and CPSRMS data indicate that the most common products identified in magnet ingestions were magnet sets and magnet toys, which are products that are intended for users 14 years or older, or where the intended user age was unknown but there were no indications that the product was intended for users under 14 years. Despite the involvement of products intended for users 14 years and older, the vast majority of magnet ingestion incidents involved children under 14 years old. For example, among CPSRMS incidents for which the victim's age was known, the most common ages that ingested magnet sets were 2, 8, 9, and 10 years old.

The sources from which children access ingested magnets further illustrates the need to address magnets in products intended for older users. For example, according to CPSRMS data, children and teens commonly ingest magnets that belong to other family members, in the home, from friends, or loose in the environment, suggesting their access is not limited to toys intended for them.

In addition, ASTM F963-17 does not apply to products that are not intended to be playthings. Both NEISS and CPSRMS data indicate that many products involved in magnet

ingestion incidents are described as jewelry, and that children of various ages ingest magnet jewelry (*e.g.,* accidentally ingesting magnets while simulating lip, tongue, and cheek piercings). Because ASTM F963-17 only applies to playthings, it does not apply to jewelry, regardless of the intended user age.[13]

As such, ASTM F963-17 is not sufficient to address the magnet ingestion hazard, because it does not impose any requirements on products intended for users 14 years or older or non-toy jewelry, which are known to be involved in many magnet ingestion incidents.

B. ASTM F2923-20

ASTM first issued ASTM F2923 in 2011. The current version of the standard is ASTM F2923-20, which was approved on February 1, 2020, and published in March 2020.

1. Scope

ASTM F2923-20 applies to "children's jewelry," which is jewelry designed or intended primarily for use by children 12 years old or younger. The standard defines "jewelry" as a product that is primarily designed and intended as an ornament worn by a person. The standard does not apply to toy jewelry or products intended for a child when playing. The standard includes requirements that are intended to address ingestion, inhalation, and attachment hazards associated with children's jewelry that contains a hazardous magnet or hazardous magnetic component. The standard defines a "hazardous magnet" and "hazardous magnetic component"

[13] Section 1.3 of ASTM F963-17 states that the standard applies to "toys intended for use by children under 14 years of age" and section 3.1.91 defines a "toy" as "any object designed, manufactured, or marketed as a plaything for children under 14 years of age." Section 1.3.1 of ASTM F2923-20 specifies that the standard, which applies to children's jewelry, does not apply to "toy jewelry or any other products that are intended for use by a child when the child plays (that is, a necklace worn by a doll or stuffed animal; novelty jewelry with play value)" and further states that "any product which is predominately used for play value is a toy" and "toys are subject to the requirements of Consumer Safety Specification F963."

by referencing the definition in ASTM F963, except that the standard exempts chains that are longer than 6 inches from the definition of "hazardous magnetic component."

2. Performance Requirements for Magnets

ASTM F2923-20 prohibits children's jewelry from having a hazardous magnet or hazardous magnetic component. The standard excepts from this requirement children's jewelry intended for children 8 years and older consisting of earrings, brooches, necklaces, or bracelets—such products need only comply with warning requirements, discussed below. In addition, the standard prohibits children's jewelry from liberating a hazardous magnet or hazardous magnetic component after the use-and-abuse testing specified in ASTM F963.

3. Warning Requirements

ASTM F2923-20 does not include specific labeling requirements for children's jewelry containing hazardous magnets or hazardous magnetic components, except for children's jewelry intended for children 8 years and older that consists of earrings, brooches, necklaces, or bracelets. These products are exempt from the performance requirements and need to include a warning that addresses the magnet ingestion hazard. Instructions that accompany the product must also include these warnings.

4. Assessment of Adequacy

Although the size and strength requirements in the standard adequately address the magnet ingestion hazard, the standard excepts certain children's jewelry from these performance requirements, and the scope of products covered by the rule makes the standard insufficient to address magnet ingestions generally.

The first issue with the standard is that it excludes from the size and strength requirements for magnets children's jewelry that is intended for children 8 years and older that

consists of earrings, brooches, necklaces, and bracelets. Applying only warning requirements to these products is not adequate to reduce the magnet ingestion hazard. As the incident data indicate, almost half of magnet ingestion incidents involve children 8 years and older, and children and teens, particularly in this age group, commonly were using magnets as jewelry at the time of ingestion. As explained further in the discussion of ASTM F3458-21 below, caregivers and children commonly do not heed warnings, and children and teens commonly access magnets that are separated from the packaging on which warnings are provided (the magnets within the scope of the final rule are too small to have legible and complete warnings printed on them).

The second issue with the standard is that it applies only to jewelry that is designed or intended primarily for use by children 12 years old or younger. As such, it does not impose requirements on magnet sets or magnet toys intended for users 14 years and older, which are the most common product types identified in magnet ingestion incidents. The standard also does not apply to jewelry intended for users over 12 years old. Although the incident data do not indicate the intended user age of jewelry products involved in ingestions, the data indicate that children and teens of various ages ingested magnets intended for users 14 years and older when using the magnets as jewelry, making it is reasonable to conclude that jewelry intended for users over 12 years old poses an ingestion hazard for children and teens.

C. ASTM F2999-19

ASTM first issued ASTM F2999 in 2013; the current version of the standard is ASTM F2999-19, which ASTM approved on November 1, 2019, and published in November 2019.

1. Scope

ASTM F2999-19 establishes requirements and test methods for certain hazards associated with adult jewelry, including magnets. The standard defines "adult jewelry" as jewelry designed or intended primarily for use by consumers over 12 years old. It defines "jewelry" as a product primarily designed and intended as an ornament worn by a person, and provides several examples, such as bracelets, necklaces, earrings, and jewelry craft kits where the final assembled product meets the definition of "jewelry." The standard defines a "hazardous magnet" as "a magnet with a flux index >50 as measured by the method described in Consumer Safety Specification F963 and which is swallowable or a small object."

2. Performance Requirements for Magnets

ASTM F2999-19 does not include any performance requirements for adult jewelry that contains magnets; it specifies only labeling requirements, discussed below.

3. Labeling Requirements

ASTM F2999-19 states that "adult jewelry that contains hazardous magnets as received should include a warnings statement which contains the following text or substantial equivalent text which clearly conveys the same warning." Rather than the mandatory language ASTM standards typically use (*i.e.*, shall), the standard merely recommends (*i.e.*, should) that warnings regarding hazardous magnets be provided with adult jewelry. The warning statement provided in the standard warns of the internal interaction hazard if magnets are swallowed or inhaled, and the warning recommends seeking immediate medical attention.

4. Assessment of Adequacy

CPSC assesses that ASTM F2999-19 does not adequately reduce the risk of injury and death associated with magnet ingestions. The standard does not include any requirements for

adult jewelry containing magnets—rather, it suggests complying with the magnet labeling provisions. As incident data indicate, many magnet ingestion incidents involve products used as jewelry, and children and teens access products intended for older users. This demonstrates the need for a mandatory requirement for adult jewelry.

In addition, the only provisions in the standard that address magnet ingestions are warnings. As discussed further in the ASTM F3458-21 section below, warning requirements, alone, are not adequate to address the magnet ingestion hazard because caregivers and children commonly do not heed warnings, and children and teens commonly access magnets that are separated from their packaging, where warnings are provided.

The scope of the standard also makes it insufficient to address adequately the magnet ingestion hazard. Because it applies only to jewelry designed or intended primarily for use by consumers over 12 years old, the standard does not impose requirements on magnet sets or magnet toys intended for users 14 years and older, which are the most common products identified in magnet ingestion incidents. It also does not impose requirements on jewelry intended for users 12 years old and younger. Although the incident data do not indicate the intended user age of jewelry involved in magnet ingestions, because many incidents involve children 12 years old and younger, it is reasonable to conclude that jewelry intended for such users poses a magnet ingestion hazard for children and teens.

D. ASTM F3458-21

In 2019, ASTM Subcommittee F15.77 on Magnets began work to develop a standard for magnet sets intended for users 14 years and older. On February 15, 2021, ASTM approved ASTM F3458-21, and published the standard in March 2021. ASTM F3458-21 consists of

marketing, packaging, labeling, and instructional requirements for magnet sets intended for users 14 years and older.

1. Scope

ASTM F3458-21 defines a "magnet set" as "an aggregation of separable magnetic objects that are marketed or commonly used as a manipulative or construction item for puzzle working, sculpture building, mental stimulation, education, or stress relief." It also defines a "small, powerful magnet" as an "individual magnet of a magnet set that is a small object" and has a flux index of 50 kG^2 mm^2 or more. The criteria for identifying a small object and the flux index are the same as in ASTM F963-17.

2. Performance Requirements for Magnets

The standard includes performance criteria in the form of test methods to determine if a product is a "small, powerful magnet," and test methods for assessing label permanence. However, the standard does not include performance requirements preventing small, powerful magnets from being used in magnet sets. Instead, ASTM F3458-21 includes requirements for instructional literature, sales/marketing, labeling, and packaging, discussed below.

3. Instructional Literature Requirements

ASTM F3458-21 requires magnet sets intended for users 14 years and older to come with instructions that address assembly, maintenance, cleaning, storage, and use. The instructions must include warnings (as specified below), the manufacturer's suggested strategy for counting and storing magnets, a description of typical hazard patterns (*e.g.,* young children finding loose magnets), an illustration of the hazard, a description of typical symptoms associated with magnet ingestion, and statements regarding medical attention when magnets are ingested.

4. Sales/Marketing Requirements

The standard prohibits manufacturers from knowingly marketing or selling magnet sets intended for users 14 years and older to children under 14 years old and requires them to "undertake reasonable efforts" to ensure the product is not marketed or displayed as a children's toy. For online sales, manufacturers must "undertake reasonable efforts" to ensure that online sellers do not sell magnet sets intended for users 14 years and older to children under 14 years. When selling directly to consumers online, manufacturers must include warnings (as specified below) and instructional literature about the hazard pattern.

5. Labeling Requirements

ASTM F3458-21 requires magnet sets intended for users 14 years and older to bear warnings on the retail packaging and "permanent storage container," which the standard defines as a container designed to hold the magnet set when it is not in use. At a minimum, the warnings must address the hazard associated with magnet ingestions, direct users to keep the product away from children, and provide information about medical attention. The standard includes an example warning label and specifies design and style requirements for the warning label. In addition, the standard requires the label to be permanent and provides a test method for assessing label permanence.

6. Packaging Requirements

The standard requires magnet sets intended for users 14 years and older to be sold with or in a permanent storage container. The permanent storage container must include a way to verify that all the magnets have been returned to the container. In addition, the standard requires the permanent storage container to be re-closeable and include means of restricting the ability to open the container.

7. Assessment of Adequacy

CPSC assesses that ASTM F3458-21 would not adequately reduce the risk of injury and death associated with magnet ingestions. The standard only applies to magnet sets intended for users 14 years and older. As such, it imposes no requirements on other products intended for users 14 years and older, or on jewelry (both children's and adult), which are shown to be involved in magnet ingestion incidents.

In addition, ASTM F3458-21 does not include performance requirements to prevent magnet sets intended for users 14 years and older from containing small, powerful magnets, and instead, relies on requirements to inform and encourage consumers to keep magnets away from children. As incident data indicate, children and teens access magnet products, including magnet sets, that are intended for older users, making it important to address the magnet ingestion hazard for magnet sets intended for users 14 years and older. Safety messaging (*e.g.*, warnings and instructions) and packaging requirements, without performance requirements for the magnets themselves, are not likely to adequately address the hazard.

a. Safety Messaging. One factor that weighs against consumers heeding safety warnings is their perception that magnet products present a low safety risk. Magnets in products intended for amusement or jewelry are likely to appear simple, familiar, and non-threatening to children, teens, and caregivers. Incident data and consumer reviews for subject magnet products demonstrate that consumers commonly view these types of magnetic products as suitable playthings for children, which undermines the perceived credibility of warnings that state the magnets are hazardous for children. The availability of children's toys that are similar to subject magnet products intended for users 14 years and older may also affect consumers' perception of the hazard because the products appear similar, and some are marketed for children. Once familiar with a product, consumers tend to generalize across similar products, and the more

familiar consumers are with a product, the less likely they are to look for, or read, warnings and instructions. If caregivers observe their child, or their child's peers using a product or a similar product without incident, caregivers may conclude that their child can use the product safely, regardless of what the warnings state. This is also true of recommendations from others, including online reviews of products, which can influence the likelihood of consumers disregarding warnings. CPSC reviewed numerous consumer reviews of subject magnet products and found that many indicated that consumers purchased the product for a child, or that their children started playing with it, despite the product not being intended for users under 14 years old. Similarly, when a child or teen repeatedly uses the product in or around their mouth, without ingesting a magnet or experiencing consequences from ingestion, they and their caregivers are likely to conclude that the hazard is unlikely to occur or is irrelevant for them.

Another reason that safety messaging has limited effectiveness is that consumers misunderstand the hazard. For small, powerful magnets, the internal interaction hazard is a hidden hazard, so consumers are unlikely to anticipate and appreciate the risk to children, especially older children and teens who do not have a history of mouthing or ingesting inedible objects. However, of the magnet ingestion cases that identify whether the ingestions were intentional or accidental, the majority describe accidental ingestions, which is much more difficult for consumers to appreciate and prevent.

Similarly, there are developmental factors that predispose older children and teens to disregard warnings and use the small, powerful magnet products in and around their mouths and noses. Experimentation and peer influence are common determinants of behavior for this age group. Small, powerful magnets offer a seemingly safe and reversible way to try out lip, tongue,

cheek, and nose piercings; and if children and teens see their peers doing this, they may act similarly, despite being aware of the risks.

In addition, consumers misunderstand the progression of symptoms associated with magnet ingestions, which also may lead them to disregard warnings. As incident reports show, many children, teens, and caregivers assume erroneously that, when ingested, magnets will pass through the body and exit the body without causing harm.

Another factor that limits the potential effectiveness of safety messaging is how children and teens obtain magnets they ingest. As incident data show, children and teens commonly obtain magnets loose in their environments, from friends, or at school, where the product is separated from any packaging or instructions that bear warnings. Because small, powerful magnets are too small themselves to carry warnings, these children and teens, and their caregivers, may not be alerted to the hazard.

Indeed, to date, safety messaging has been ineffective at reducing the magnet ingestion hazard. CPSC staff has examined dozens of incident reports that indicate children and teens obtained and ingested small, powerful magnets, even when the product was marketed and prominently labeled with warnings about the hazard and state that the product was not appropriate for children. For example, of the CPSRMS incidents that reportedly occurred between January 1, 2010, and December 31, 2021, at least 68 incident products had magnet internal interaction warnings, at least 74 had age labels or warnings indicating the product was not for children, and at least 66 had both types of relevant safety messages. In contrast, reports for only 14 incidents (total for both data sets) mentioned that the product had neither magnet internal interaction warnings nor age labels or warnings against use by children.

Another indication of the ineffectiveness of safety messaging to address the magnet ingestion hazard is the upward trend in magnet ingestion cases in recent years, despite years of consumer awareness campaigns. For many years, CPSC has drawn attention to the magnet ingestion hazard through recalls, safety alerts, public safety bulletins, and rulemaking activity. In addition, there have been numerous public outreach efforts by health organizations and other consumer advocacy groups to warn consumers about the internal interaction hazard posed by small, powerful magnets. Despite these efforts, magnet ingestion incidents have increased in recent years.

b. Packaging. Similar to safety messaging, there are several reasons CPSC considers packaging requirements inadequate to address the magnet ingestion hazard. Incident data show that children and teens commonly access magnets loose in their environment and from friends, in which case the product is likely to be separated from its packaging, rendering CR packaging or visual cues that all magnets are in the package ineffective.

In addition, the features included in ASTM F3458-21 to make the packaging difficult for children to open would not be effective in preventing older children and teens from accessing the magnets in the packaging and ingesting them. For example, an option provided in the standard allows the packaging to meet the requirements in 16 CFR 1700.15 and 1700.20. Those provisions are intended to make packaging significantly difficult for children under 5 years old to open within a reasonable time. Thus, such packaging does not prevent all children under 5 years old from opening it, particularly if given ample time; and it is not intended to prevent any children 5 years and older from opening the packaging. As the incident data indicate, most magnet ingestion incidents involve victims 5 years and older, making this packaging ineffective

at restricting their access. Similarly, for the alternative packaging options in the standard, children and teens are likely to have cognitive and motor skills sufficient to access the products.

Even if CR packaging features did prevent children and teens from opening the packaging, the effectiveness of packaging to address the hazard would rely on consumers correctly repackaging all the magnets after and every use, which is likely unrealistic. The products often are intended for purposes that make repackaging after each use unlikely. For example, products like magnet sets are intended to assemble and display complex sculptures, and some jewelry may involve creating designs, making it unlikely consumers will disassemble their designs to repackage all the magnets after every use. In addition, consumers are not likely to perceive the products as hazardous because they are intended for amusement or jewelry and are not hazardous in appearance. Therefore, consumers would not consider it necessary to repackage all the magnets after every use. Even for products that are obviously hazardous and commonly use CR packaging, such as chemicals and pharmaceuticals, consumers may not use the packaging consistently. Consumers may also consider CR packaging a nuisance, making it unlikely for them to store magnets in the packaging after every use.

In addition, the small size and large number of magnets (particularly in some magnet sets and magnetic jewelry sets) make locating and counting the magnets after every use not feasible or realistic, leaving it difficult to impossible to ensure all the magnets in the set are returned to the package. For example, staff has identified products that were involved in magnet ingestion incidents that consisted of thousands of 2.5 mm diameter magnets. Staff has found that it is not uncommon for magnets to be flicked away from one another or dropped when consumers handle or try to separate them. These actions are foreseeable, particularly for magnets intended for fidgeting and building. In examining magnet sets, staff found that many sets are sold with extra

pieces, in part, because losing magnets is expected. In addition, many incident reports and consumer reviews of magnet sets mention lost magnets. Given the large number of magnets included in some sets, plus their small size, and the tendency for them to be separated and lost, it is unlikely that CR packaging will be used effectively by consumers. The time and effort necessary to locate, assemble, and repackage such small and numerous magnets is likely to be beyond what consumers are willing to spend.

E. EN 71-1: 2014

The European standard applies to children's toys, which are products intended for use in play by children younger than 14 years old. The requirements regarding magnets in EN 71-1: 2014 are essentially the same as in ASTM F963-17—any loose as-received magnet and magnetic component must either have a flux index less than 50 $kG^2 mm^2$, or not fit entirely in the small parts cylinder. The flux index is determined using the same method as in ASTM F963-17, and the small parts cylinder is the same as in ASTM F963-17. EN 71-1: 2014 also requires similar use-and-abuse testing as ASTM F963-17, to ensure that toys do not liberate a hazardous magnet or hazardous magnetic component. The standard includes a similar exemption to ASTM F963-17 for magnetic/electrical experimental sets intended for children 8 years of age and older, which need only bear a warning regarding the magnet ingestion hazard.

As discussed above in section V.A. of the preamble, for ASTM F963-17, CPSC assesses that these provisions do not adequately reduce the risk of injury and death associated with magnet ingestions because of the limited scope of the standard. Because the standard only applies to toys intended for children under 14 years old, it does not impose any requirements on products intended for older users, or products that would not be considered playthings. As the

incident data indicate, magnet ingestion incidents include children and teens ingesting products intended for older users, and ingesting jewelry, neither of which this standard addresses.

F. ISO 8124-1: 2018

This standard applies to toys, which are products intended for use in play by children under 14 years old. The standard requires any loose as-received magnet and magnetic component to either have a flux index less than 50 $kG^2 mm^2$ or not fit entirely within the small parts cylinder. The flux index is determined the same way as in ASTM F963-17, and the small parts cylinder is the same as in ASTM F963-17. ISO 8124-1 also requires similar use-and-abuse testing as ASTM F963-17, to ensure that a hazardous magnet or hazardous magnetic component does not liberate from a toy. Similar to ASTM F963-17, ISO 8124-1 also provides an exemption for magnetic/electrical experimental sets intended for children 8 years and older, which need only bear a warning regarding the magnet ingestion hazard.

Thus, the provisions addressing the magnet ingestion hazard in ISO 8124-1: 2018 are largely the same as in ASTM F963-17. Because the standard only applies to toys intended for children under 14 years old, it does not impose any requirements on products intended for older users, or on products that would not be considered playthings. As the incident data indicate, magnet ingestion incidents include children and teens ingesting products intended for older users and ingesting jewelry, neither of which this standard addresses.

G. Compliance with Existing Standards

CPSC has limited information about the extent to which products comply with existing standards. Based on staff's analysis, only a small number of magnet ingestion incidents for which a product type could be identified involved children's toys subject to ASTM F963-17. This provides some indication that children's toys commonly comply with the standard. Of the

magnet ingestion incidents that involved children's toys, staff identified only 7 incidents that involved internal interaction of the magnets through body tissue, again showing there may be a high level of compliance with the standard requiring flux index below 50 kG^2 mm^2. (None of the products in these seven incidents complied with the magnet requirements in ASTM F963.)

CPSC also does not have detailed information about the extent to which products comply with ASTM F2923, F2999, or F3458. Incident reports commonly do not provide enough detail to identify the specific product (*e.g.*, brand) to obtain it and assess it for compliance. In addition, for ASTM F3458, the standard was adopted recently (March 2021), making it difficult to assess the level of compliance with it. However, for the reasons discussed in this section, the Commission finds that none of the existing standards would adequately address the unreasonable risk of injury associated with subject magnet products.

H. Consideration of the Existing Standards, Collectively

For the same reasons than no existing standard is individually adequate, the standards collectively fail to adequately reduce the magnet ingestion hazard. As explained above, each standard contains critical inadequacies with regard to protecting against ingestion hazards associated with the particular products that are covered. Furthermore, there are subject magnet products, such as magnets sets, or magnet toys, or jewelry kits intended for users 14 years of age and older, and jewelry (both children and adult), that are not within the scope of the existing standards. Accordingly, even industry compliance with *all* the existing standards, were it achieved, would not adequately address the ingestion hazard.

VI. Response to Comments on the Proposed Rule

This section summarizes the issues raised by comments, both oral and written, on the proposed rule, and it provides the Commission's responses to those comments.

A. Oral Presentations

On May 2, 2022, the Commission provided the public an opportunity to present views on the proposed rule in person before the Commission. Oral comments were presented at the hearing from representatives from the American Academy of Pediatrics, North American Society for Pediatric Gastroenterology, Hepatology and Nutrition, Kids in Danger, Consumer Federation of American, and Consumer Reports. These commenters provided testimony supporting the CPSC's rulemaking for a safety standard to address the unreasonable risk of injury and death associated with ingestion of loose or separable high-powered magnets. The commenters orally testified that there is overwhelming evidence of the significant hazards associated with magnets that have a flux of 50 or greater. Commenters testified on the serious medical consequences when children ingest hazardous magnets, including gastrointestinal perforations, abdominal abscesses, fistulas in the bowel, and death. Commenters also testified testimony regarding the ineffectiveness of regulatory alternatives, including safety messaging, labeling, and packaging requirements. Commenters recommended that the Commission not rely on child-resistant containers, bittering agents, or other attempts to deter children, but rather, they asked CPSC to mandate a standard that will eliminate the hazard. Specific oral comments that covered the same issues as the written comments are addressed below in section VI.B. of the preamble.

B. Written Comments

The preamble to the NPR invited comments concerning all aspects of the proposed rule. We received written comments from more than 700 commenters in response to the NPR. The Commission reviewed and considered several late comments that were filed regarding this rule.[14]

[14] CPSC received late-filed comments in support of the proposed rule from the American Academy of Pediatrics (AAP), and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN). Retrospective Goods, LLC, also submitted a late comment. Shihan Qu also submitted a petition via: www.change.org. These comments were added to the docket on www.regulations.gov.

Many of the comments contained more than one issue, and many of the comments addressed the same or similar issues. Thus, we organized our responses by issue. All of the comments can be viewed at: www.regulations.gov, by searching under the docket number for this rulemaking, CPSC-2021-0037.

In general, most who commented in favor of the proposed rule were medical professionals and/or representatives of consumer advocacy groups and medical associations[15]; there were also some individual consumers, and a subject magnet product manufacturer, Retrospective Goods, LLC, who also generally supported the proposed rule. These commenters argued that safety messaging and safeguards are insufficient to address the magnet ingestion hazard and that the proposed rule represents a minimum standard for addressing the hazard. In contrast, most who commented in opposition to the proposed rule were individual consumers, along with several subject magnet product manufacturers and hobbyist groups.[16]

Commission Authority

(Comment 1) Commenters in favor of the proposed rule opined that it is the Commission's authority and responsibility to address the ingestion hazard posed by the subject magnet products. These commenters encouraged the Commission to promulgate the final rule expeditiously as a minimum standard to address the hazard. Some commenters opined that the rule violates consumers' constitutional rights, including the right to freedom of expression through purchasing products they desire, and that a rule that prohibits the sale of covered magnet sets is drastically out of proportion to the risks presented by the product. Many commenters requested alternative regulatory actions to address the hazard, such as limiting sales for online

[15] For example, CPSC received a joint letter in support of the proposed rule by AAP and NASPGHAN.
[16] For example, CPSC received a letter in opposition to the proposed rule, which was submitted by the Hobby Manufacturers Association , representing more than 59 manufacturers, importers, publishers, producers, and suppliers of hobby products and hobby accessories.

purchases with restrictions, such as warnings; prohibiting sales to users under specified ages; requiring identification or adult signature for purchases; restricting sales of magnets by certain manufacturers or sellers; or restricting sales to certain stores or locations.

(Response 1) Section 7 of the CPSA authorizes the Commission to promulgate consumer product safety standards as performance requirements or that require products to be marked or accompanied by clear and adequate warnings and instructions. The requirements of a standard issued under this provision must be reasonably necessary to prevent or reduce an unreasonable risk of injury associated with the product. Determining whether a product presents an unreasonable risk of injury requires the Commission to consider, among other factors, the costs and benefits of regulatory action. The regulatory analysis discusses that assessment (see section VIII. of this preamble). The Commission must balance several factors, such as the severity of injury, the likelihood of injury, and the possible harm the regulation could impose on manufacturers and consumers.

Although some consumers assert that their constitutional rights are impacted, there is no constitutional right to purchase an unreasonably dangerous product. Some commenters suggest that the way to address the hazard of children ingesting magnets from subject magnet products might be to limit the manner or places where products are sold. The CPSA authorizes the Commission to issue standards that specify performance requirements or requirements for labeling and/or instructions. *See* 15 U.S.C. § 2056. Sales restrictions do not fit within either of those categories. Furthermore, sales limitations or requirements for strong warning restrictions are unlikely to reduce ingestions significantly, because, as discussed in detail in section V.D.7 of the preamble, the Commission has determined that consumers are unlikely to heed safety warnings if they perceive the product to be low risk or they misunderstand the hazard and the

associated health consequences of ingestion. Moreover, both children and teens can access magnets of subject magnet products from many sources other than stores. As the incident data indicate, magnet ingestion incidents associated with subject magnet products include children and teens who ingested magnets from products intended for older users.

(Comment 2) A few commenters stated that there was insufficient time to consider the NPR and urged that the final rule should be delayed until more information is obtained.

(Response 2) The Commission has provided stakeholders with sufficient time to consider and comment on the proposed rule. The NPR was published in the *Federal Register* on January 10, 2022, and the public comment period ended on March 28, 2022. Although a few commenters requested that the CPSC delay the final rule until more information is obtained, CPSC has determined that the risk of injury associated with subject magnet product ingestions increases when there is no mandatory rule addressing the hazard. In particular, as already explained, during the years when the 2014 magnet sets rule was announced and in effect (2014-2016), there were appreciably fewer magnet ingestions, compared with the earlier and more recent periods. The years 2017 through 2021 saw an uptick in the number of in-scope magnet ingestions, with 2021 having more incidents than most of the preceding years. Waiting for additional data sources to become available before taking effective action would result in more magnet ingestion injuries that likely could be preventable with promulgation of the final rule.

(Comment 3) Nano Magnetics, a manufacturer of subject magnet products, asserted that CPSC has refused to communicate with manufacturers, consumers, and representative beneficiaries of the subject magnet products regarding methods to address the magnet ingestion hazard, but communicated with organizations and advocacy groups in favor of the proposed restrictions.

(*Response 3*) The CPSC provided opportunities for all stakeholders to present their views in the oral hearing, and in the NPR, we invited written comments including any opposing views, which the Commission reviewed and considered in adopting this rule.

Lack of Product Defect

(Comment 4) – Numerous commenters asserted that magnet sets pose no risk of injury when used properly, that they function as intended, and therefore, they are not defective. Other commenters argued that the Commission has no authority to issue a rule that would result in a prohibition of all subject magnet products currently on the market simply because certain consumers use magnets in a manner that is inconsistent with the purpose intended for the product. The commenters argued that the improper use of a product by a minority of consumers does not render the product defective and does not warrant promulgating a rule that would remove the product from the market.

(Response 4) - To promulgate a consumer product safety standard, the Commission must find that the rule is reasonably necessary to reduce an unreasonable risk of injury associated with the product. A product may present an unreasonable risk of injury, even if the product does not contain a fault, flaw, or irregularity that impacts the manner in which the product functions. If evidence demonstrates that foreseeable misuse of a product results in an unreasonable risk of injury, the Commission has the authority to promulgate a rule reasonably necessary to reduce or eliminate that risk. When assessing risk, CPSC considers how consumers may actually use a product, not just the manner of use intended by the manufacturer. For example, the Commission's cigarette lighter standard requires disposable and novelty lighters to meet child-resistance requirements to protect against the misuse of lighters by children. 16 CFR part 1210. Similarly, the Commission's lawn mower standard includes requirements to guard against

consumers intentionally removing a shielding safety device from the mower. 16 CFR part 1205. *See Southland Mower v. Consumer Product Safety Commission*, 619 F.2d 499, 513 (5th Cir. 1980) (reviewing the Commission's lawn mower standard, the court stated: "Congress intended for injuries resulting from foreseeable misuse of a product to be counted in assessing risk").

For this rule, CPSC has analyzed the magnet ingestion incident data and reviewed the various methods to address the hazard. CPSC determines that the subject magnet products carry the highest ingestion risk for children and teens. As detailed in section V.D.7, of the preamble, CPSC explained that consumers are likely to have a common perception of low risk pertaining to the subject magnet products and often misunderstand the magnet ingestion hazard. Safety messaging, including public awareness-raising efforts, has been insufficient to protect children and teens from the hazard. Due to factors like the inability of caregivers to provide constant supervision and manage common sources of access to hazardous magnets, consumers may be unable to avoid the hazard even if they are aware of the hazard and are actively trying to prevent it. After considering various methods by which to address the hazard, including safety messaging (*e.g.,* warnings, instructional literature, marketing, and public awareness-raising efforts) and safeguards (*e.g.,* CR packaging and aversive agents), the Commission concludes that mandating performance requirements is necessary to adequately address the hazard.

Risk and Severity of Injury

(*Comment 5*) Medical professionals, consumer advocacy groups, and medical professionals were largely supportive of the proposed rule as a minimum standard to adequately protect children from subject magnet products. Many cited the most current literature on magnet exposure in children (discussed in section IV of the preamble), and others cited firsthand professional accounts of treating high-powered magnet exposures in children and associated

medical outcomes from those injuries. AAP[17] and the NASPGHAN[18] expressed strong support for the proposed rule. In their comments, they highlighted the current medical recommendation for prompt medical intervention. The Canadian Paediatric Society's Injury Prevention Committee, Children's Safety Network (CSN) at Education Development Center (EDC), and the Pacific Institute for Research and Evaluation (PIRE) also provided comments in support of the proposed rule. Additionally, a number of medical professionals offered individual comments in favor of the proposed rule. These commenters stated that magnets, in general, present a unique health risk because some level of medical management is warranted for all magnet ingestions; magnets that have migrated past the esophagus routinely require serial imaging and surgical intervention; and children are suffering adverse health outcomes from magnet internal interaction hazards.

(*Response 5*) The Commission agrees that the magnet ingestion data and most current scientific literature related to magnet ingestion show that magnet internal interaction hazard and the associated injury mechanism continue to pose serious and long-lasting adverse health outcomes.

(Comment 6) Several individual commenters stated that the subject magnet products are rarely involved in magnet ingestion incidents. These commenters were typically individual consumers who claimed that there have been only a "few," "several," or a "handful of" injuries, based on outdated magnet ingestion data.

(Response 6) Contrary to these commenters' assertions, magnet ingestions are common and have increased in recent years. The Commission estimates that 26,600 magnet ingestions

[17] AAP represents 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults.
[18] NASPGHAN represents more than 2,500 pediatric gastroenterologists in the United States, Canada, and Mexico and is the only organization singularly dedicated to advocating for children with gastrointestinal disease.

were treated in hospital EDs from January 1, 2010, through December 31, 2021; this represents an estimated 25,000 ingestions, excluding out-of-scope products. An estimated 2,500 ED-treated ingestions of magnets from in-scope products occurred in 2021, higher than the majority of the preceding years, including 2018 through 2020. An estimated 5,000 (20% of 25,000) victims were hospitalized or transferred to another hospital due to incidents that occurred in the period from 2010 through 2021. These estimates are based on the NEISS reports, which capture only brief, medically-focused narratives from the ED visit. Therefore, the estimates do not account for the victims who were initially released and later sought medical attention for magnet-related injuries, including treatment for complications arising from medical management.

In examining CPSRMS data from this 12-year period, CPSC found that at least 167 CPSRMS-reported magnet ingestions resulted in surgery (including 43 incidents since the NPR), such as laparoscopy, laparotomy, appendectomy, cecostomy, enterotomy, colostomy, cecectomy, gastrotomy, jejunostomy, resection, and transplant, among others. Some injuries also resulted in direct hospital admissions, bypassing hospital EDs entirely. CPSC estimates the number of subject magnet product injuries treated outside of hospital EDs with CPSC's Injury Cost Model (ICM), which uses empirical relationships between the characteristics of injuries (diagnosis and body part) and victims (age and sex) initially treated in hospital EDs and the characteristics of those treated initially in other settings. Using the time period during 2017 through 2021, based on the NEISS annual estimate of about 481 magnet injuries initially treated in hospital EDs involving magnets identified as amusement/jewelry products, there were 320 injuries that were treated and released and 161 injuries that required hospitalization. Based on estimates from the ICM, 185 injuries were treated outside of hospitals annually and another 78 injuries resulted in direct hospital admission.

(Comment 7) Several commenters, including Kids in Danger and Consumer Reports, requested that CPSC continue to conduct research after the final rule to determine if the exempted products, such as magnet products intended only for educational purposes, should also be addressed.

(*Response 7*) The Commission will continue to assess any new incident data and review the adequacy of the rule in addressing magnet ingestion hazards on an ongoing basis, and CPSC staff will continue to work with the relevant standards groups on magnet ingestion hazards.

Other Approaches to Addressing the Hazard

(Comment 8) Safety Messaging - Several commenters in support of the proposed rule, including AAP and NASPGHAN, contend that the magnet internal interaction hazard cannot adequately be addressed with warnings, instructions, awareness-raising efforts, and other forms of safety messaging. The commenters explained that children, teens, and caregivers do not fully comprehend the hazard and risk of children and teens ingesting magnets.

One commenter, Independent Safety Consulting, LLC, stated that warnings will not be necessary in combination with the proposed size and strength limitations and may contribute to the growing issue of warning fatigue due to the prevalence of product warnings. Other individual commenters opposing the proposed rule argued that approaches involving safety messaging are more appropriate than strength and size limitations. These commenters stated that the CPSC should require warning labels only for certain products, require specific warnings and instructions, such as age restrictions, and limit sales and marketing of such products to specific physical stores or online.

Numerous individual commenters argued that approaches involving safety messaging and warnings are more appropriate than strength and size limitations. The majority of these

commenters stated that their personal freedoms should not be restricted because some consumers, particularly parents, are irresponsible and do not supervise their children. Several individual commenters asserted that some brands of subject magnet products already have clear warnings about the hazard and market the products only to adults, asserting that these products have been involved in few-to-no magnet ingestion injuries. Most who oppose the proposed rule requested that adult products be excluded from the scope of the rule. They compared the magnet internal interaction hazard to other common hazards, like incidents with trampolines, fireworks, scissors, knives, firearms, balloons, and toys with small parts, arguing that these other products present similar or worse hazards but they are not banned. In addition, they argued that there are other, more hazardous products on the market for adults to purchase and use (*e.g.,* guns and cigarettes).

(Response 8) CPSC's assessment of the magnet internal interaction hazard shows that it is a unique, hidden hazard, unlike common and more readily apparent hazards, like hazards from trampolines and fireworks. The hazards identified in the rule involving multi-magnet ingestions and ingestions of both a magnet and a potentially ferromagnetic object, all call for some level of medical management. It is foreseeable that consumers will not anticipate, nor appreciate, the likelihood of children and teens ingesting magnets. The majority of the incident reports for the subject magnet products involved victims above the ages typically associated with ingestion of small objects (under 3 years old) and hazardous substances (under 5 years old). CPSC finds that it is unrealistic to expect parental supervision at all times, especially for these older ages, and ingestions can be quick and difficult to notice and prevent, considering the small size and sometimes large number of magnets in the subject magnet products. Many of the reports indicated that the magnets were ingested accidentally, while children and teens were attempting

to separate the magnets with their teeth or were using the magnets to simulate oral piercings. Relatively few reports indicated the magnets were ingested intentionally.

As discussed in detail in section V.D.7. of the preamble, the Commission has determined that safety messaging has limited effectiveness for preventing the magnet ingestion hazard. In general, safety messaging relies on encouraging consumers to avoid hazards, as opposed to eliminating the hazards by design. For safety messaging to be effective, it must be seen, read, understood, and heeded. Specific to the subject magnet products, there are many obstacles to the success of safety messaging, which include, consumers commonly misperceive risk associated with the hazard; the hazard patterns and symptomology are often misunderstood; and the common sources of access to magnets (*e.g.,* children and teens sharing magnets at school) make it difficult, if not impossible, for caregivers to prevent access to the hazard and likewise, reduce the chances of children and their caregivers seeing safety messaging provided with the products. Caregivers may also forego reading warnings if they think they already know the hazard. Magnet ingestions have continued an upward trend over the past years since the CPSC's 2014 magnets sets rule was vacated, despite increased prevalence of safety messaging provided with the products, and numerous public outreach efforts by the CPSC, medical associations, consumer advocacy groups, and news sources.

(Comment 9) Packaging and Aversive Agents - Commenters who favor the proposed rule, such as Kids in Danger and Consumer Reports, opined that the magnet internal interaction hazard cannot adequately be addressed with packaging requirements. They explained that it is common for children and teens to acquire magnets without packaging, and that packaging requirements, such as child-resistant (CR) packaging, are only effective as long as the packaging is retained and used consistently to store the product. These commenters note that CR packaging

would not be effective for the majority of victims, considering the victims' ages. Several individual commenters who are against the proposed rule opined that, to the contrary, approaches involving packaging and aversive agents are more appropriate than strength and size limitations.

(Response 9) The Commission has determined that safeguards, such as special packaging and aversive agents, are ineffective at addressing the magnet internal interaction hazard. As discussed in detail in section V.D.7 of the preamble, in many cases, the magnets do not come with their original packaging, making packaging features bearing warning language immaterial (*e.g.,* when children and teens find magnets in their environment or receive them from friends). CR features, such as those specified in ASTM F3458–21, are designed to limit access to products by children under 5 years of age only, and CPSC found that the majority of magnet ingestion incidents involved victims ages 5 years and older. Furthermore, CR features would be effective for these younger ages only if the magnets are repackaged correctly and in their entirety after every use, which CPSC finds unrealistic, as explained above. Incident reports and customer reviews further demonstrate that it is common to lose magnets from the subject magnet products, particularly from products with numerous magnets (*e.g.,* magnet sets with hundreds to thousands of tiny magnets).

Similarly, deterrents, such as aversive agents (*e.g.,* foul odors or bitterants), are unlikely to be effective. Serious injury is possible when one ingests as few as two magnets, or even a single magnet in the presence of a ferromagnetic object; in addition, children may ingest multiple magnets before they detect the aversive agent. Children frequently ingest unpalatable substances, which indicates that foul odors and tastes are not sufficient to deter children from ingesting harmful substances.

Reliance on ASTM standards

(Comment 10) Numerous commenters, including Shihan Qu of Zen Magnets, LLC, and Hobby Manufacturers Association, recommended publicizing and enforcing ASTM F3458 – 21, which includes warning, instructional literature, marketing, and packaging requirements for adult magnet sets. Commenters claimed that the combination of requirements for warnings, instructions, marketing, and packaging is sufficient to address the hazard. Additionally, one commenter, Retrospective Goods, LLC, a subject magnet product manufacturer, stated that CPSC has not undertaken any meaningful safety campaigns regarding the hazard for 7 years.

(Response 10) The Commission has concluded that the requirements specified in ASTM F3458–21 are inadequate to address the magnet internal interaction hazard without size and strength requirements. Section V.D.7. of the preamble explains that warning, instructional literature, marketing, and packaging requirements for adult magnet sets do not address the hazard because the incident data indicates that children and teens commonly access and ingest magnets from products intended for older users. Clear and repeated safety messaging and marketing have been insufficient to discourage magnet ingestion, and CR packaging is unlikely to address the hazard, particularly given that most of the known magnet ingestions have involved victims ages 5 years and older.

Contrary to the assertion that CPSC has not engaged in safety campaigns, CPSC, in addition to raising awareness of the magnet ingestion hazard through publicized recalls, has drawn attention to the hazard through safety alerts and public safety bulletins. CPSC maintains a "Magnets Information Center" website,[19] which provides an informational video, a description of the hazard, what steps to take when magnets are swallowed, and links to recalls, relevant CPSC materials, applicable regulations, and informational posters. CPSC also issued a safety

[19] Available at: https://www.cpsc.gov/Safety-Education/Safety-Education-Centers/Magnets.

alert about the magnet ingestion hazard, which describes the hazard and what steps to take when magnets are swallowed. In addition to CPSC's information campaigns, health organizations and other consumer advocacy groups have made numerous public outreach efforts to warn consumers about the magnet ingestion hazard.[20] Some of the recent efforts include CPSC's annual holiday safety campaign,[21] CPSC's Twitter Chat on High-Powered Magnet Safety,[22] and numerous articles from popular news sources.[23]

Scope of the Rule

(Comment 11) Rely on Enforcement Action - Several commenters, including Magnet Safety Organization, opined that the CPSC enforcement actions, rather than rulemaking, is the appropriate approach. Other commenters, such as the Hobby Manufacturers Association, asserted that CPSC should focus enforcement activities only on manufacturers and importers that do not use clear marketing and warnings to explain the hazard and warn against use by children.

(Response 11) From January 1, 2010, through May 25, 2022, CPSC's Office of Compliance and Field Operations has investigated and recalled numerous magnet products involving the magnet internal interaction hazard. CPSC has conducted 20 recalls involving 25 firms/retailers, and totaling approximately 13,832,901 recalled units, including craft kits, desk

[20] Examples include the American Academy of Pediatrics (https://services.aap.org/en/search/?k=magnets); North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (https://www.naspghan.org/content/72/en/Foreign-Body-Ingestion); Consumer Reports (https://www.consumerreports.org/product-safety/magnets-marketed-as-toys-could-be-dangerous-to-kids/); Consumer Federation of America (https://consumerfed.org/testimonial/cfa-comments-cpscs-notice-proposed-rulemaking-safety-standard-magnet-sets/); and Kids In Danger (https://kidsindanger.org/2011/11/cpsc-warns-about-high-powered-magnets/).
[21] CPSC's Top Safety Tips for Early Holiday Shoppers Amid Reports of Expected Toy Shortage (2021): https://www.cpsc.gov/Newsroom/News-Releases/2021/Top-Safety-Tips-for-Early-Holiday-Shoppers-Amid-Reports-of-Expected-Toy-Shortage.
[22] On May 19, 2021, CPSC staff provided responses regarding magnet safety in a public Q&A.
[23] Examples of recent news articles addressing the hazard include the following, among others: https://www.washingtonpost.com/business/2021/08/17/magnet-safety-recall/, https://www.washingtonpost.com/business/2019/12/27/senator-urges-regulators-take-action-magnet-ingestions/, https://www.cnn.com/2019/04/12/health/kids-swallow-objects-study/index.html, and https://www.foxnews.com/health/parts-of-boys-colon-intestines-removed-after-swallowing-toy-magnets-mom-says.

toys, magnet sets, pencil cases, games, bicycle helmets, maps, and children's products among others. Of these 20 recalls, five involved products that would not be subject to the rule; specifically, four involved children's toys that are subject to the ASTM F963 Toy Standard. One recall involved trivets sold with cookware sets. Although these five recalls did not apply to products that are subject to the rule, they did involve serious magnet internal interaction hazards.

Despite this active enforcement to remove from the market products that present a substantial product hazard, such efforts are necessarily limited to particular entities and products. By contrast, this rulemaking establishes requirements that all non-exempt subject magnet products must meet from the effective date of the rule. The magnitude of the hazard, the similarity of the ingestion hazard across the subject magnet products, and the relevant similarities of the products themselves, make the rulemaking approach appropriate here.

(Comment 12) Mental Stimulation Should Be Removed from Definition - Several commenters, including subject magnet product manufacturers Retrospective Goods, LLC, and Nano Magnetics, requested clarifications pertaining to the NPR's proposed product scope and exemptions, particularly regarding "mental stimulation." These commenters recommended removing "mental stimulation" from the inclusion criteria for "subject magnet product." Commenters also suggested that the final rule identify more the exempted products, such as the products intended for scientific or technical research, and educational, professional, and industrial applications. Many individual commenters mentioned the artistic, educational, entertainment, social, and therapeutic benefits of small, powerful magnets in consumer products, such as magnet sets.

(Response 12) The NPR recommended exempting from the proposed rule, children's toys subject to the ASTM F963 Toy Standard. Additionally, the NPR noted: "it is reasonable to

exclude home/kitchen products from the proposed rule," and "other products that would fall outside the scope of the proposed rule include research and educational products, or those intended for commercial or industrial purposes, if they are not also intended for amusement or jewelry." 87 FR 1291-92. The NPR specifically sought comment on whether "home/kitchen magnets or education products should be addressed in the rule." *Id.* at 1312.

The Commission disagrees that "mental stimulation" should be removed from the definition of "subject magnet products." Mental stimulation is an important criterion because it is an apt descriptor for subject magnet products that appeal to children and teens, including uses like puzzle working and sculpture building. However, the Commission agrees that the term "mental stimulation" may be interpreted more broadly than intended, by capturing products not for home uses that nonetheless may be mentally stimulating, such as products manufactured, sold, and/or distributed solely for educational uses at schools and universities. Accordingly, in response to comments, the final rule codifies the exemptions to include products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes. This clarification addresses confusion between in-scope and out-of-scope products, by specifying certain products that are not subject to the final rule, even if the intended use of these products involves mental stimulation. Because these products are intended for use in school, research, professional, or commercial settings, as opposed to home settings and personal use by children, the magnet internal interaction hazard would be less likely to pose an unreasonable risk of injury to children or teens. The exemption language makes clear, however, that if any of these exempted products are also designed, marketed, or intended to be used for

entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes, such uses would cause the magnets to be subject to the requirements of the standard.

A further clarification makes explicit that products manufactured, sold, and/or distributed solely for home use, such as hardware magnets that contain one or more loose or separable magnets and that are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, are exempted from the final rule. This clarification addresses confusion between in-scope and out-of-scope products, by specifying products that are not subject to the final rule. The exemption language makes clear, however, that if any of these exempted products are *also* designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, such uses would cause the magnets to be subject to the requirements of the standard. Unlike the exemption for school, research, professional, commercial, and/or industrial purposes, these products are used in the home, and if they have subject magnet product uses, they may be appealing to children, and the magnet internal interaction hazard may pose the same unreasonable risk of injury to children or teens as identified for the subject magnet products. In particular, if these products also meet the use criteria of "mental stimulation," they would no longer be exempt from the performance requirements of the rule.

(Comment 13) Noncompliant magnets should be widely available. Some commenters, including Nano Magnetics, contend that that use of small, aggregated magnetics have resulted in great scientific and medical innovations and that the proposed rule would prevent scientific breakthroughs.

(Response 13) The Commission is not persuaded that the final rule would adversely impact innovation in scientific or medical fields. The exemptions to the rule now exclude products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes. Because these products are intended for use in school, research, professional, or commercial settings, as opposed to home settings and personal use by children, the magnet internal interaction hazard would be less likely to pose an unreasonable risk of injury to children or teens. The exemption language makes clear, however, that if any of these exempted products are also designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes, such uses would cause the magnets to be subject to the requirements of the standard.

(Comment 14) Some commenters, including individual consumers, stated that requiring magnets to be weaker or bigger would limit their beneficial uses, and the products with only one magnet should be excluded from the final rule. Other commenters asserted that magnets that are not spherical or disc-shaped should be excluded from the final rule.

(Response 14) The scope of the rule includes non-spherical and non-disc-shaped magnets because the hazard is not limited to these magnets only; for example, the Commission is aware of cases involving internal interaction of rock-shaped magnets. The product scope also includes products with only one magnet because subject magnet products may be sold per-magnet, and a single magnet can interact internally through body tissue with an unrelated magnet or ferromagnetic object.

ASTM F963 Test Method

(Comment 15) Commenters in favor of the proposed rule, including Safe Kids Worldwide, Consumers Union, AAP, and NASPHAN, generally supported incorporation of the ASTM F963 testing requirements as a minimum approach for addressing the magnet ingestion hazard. One manufacturer, Retrospective Goods, LLC, stated that the ASTM test method for measuring flux is widely used internationally and is well-understood; therefore, they assert, "there is no need to change the current ASTM test procedure for measuring a magnet's flux." As an example, the commenter provided a method from an international test lab that describes a procedure for locating the pole of a small magnet. The procedure uses a magnet's attraction to a ferromagnetic bar to orient and identify the poles, and it uses an adhesive surface to hold the magnet during testing. The commenter questioned whether the CPSC test procedure provided in Tab D of the NPR has been tested by other laboratories and stated: "changing the ASTM test procedure could lead to confusion and potentially uneven or conflicting results."

(Response 15) CPSC staff developed a test procedure consistent with ASTM F963-17 to locate the magnet pole of small diameter magnets and to secure the magnet during the flux density measurement. This test procedure is provided for informative purposes and is not specified in the performance requirement. Therefore, testing of the procedure by other laboratories is not required. CPSC staff's procedure does not change the ASTM test procedure because there is no test procedure specified in ASTM F963-17 for locating the pole surface of a magnet; nor is there a test procedure for how to secure the magnet while measuring the maximum flux density. The exemplar method cited by the commenter for locating the pole of a small diameter magnet and holding the magnet during testing is similar in concept to the test method developed by CPSC staff.

(Comment 16) One commenter, Kids in Danger, supported the wider use-and-abuse testing from ASTM F963, to ensure products do not liberate magnets. A manufacturer, Retrospective Goods, LLC, conversely stated that "no data has been presented that liberated magnets with a flux over 50 kG^2 mm^2 in adult products, which also meet the scope of the Rule, are posing a problem. Any such requirement should be supported by data."

(Response 16) CPSC's review of magnet ingestion incident data has not identified a pattern of children ingesting hazardous magnets that liberated from products not subject to ASTM F963-17. However, CPSC will continue to monitor new incident data to assess if new patterns develop that indicate use-and-abuse testing is necessary for products that are outside the scope of ASTM F963-17.

(*Comment 17)* One trade association, Magnet Safety Association, stated that the measurement of flux was created by ASTM as high-level guidance for voluntary safety measures and "was not designed to be used to determine whether magnets will present injury if ingested multiply." The commenter stated that the flux measurement in ASTM does not represent attractive force, and the ratings do not appropriately scale with the strength or shapes of magnets. Therefore, the commenter asserted that the Commission should use a measurement that is appropriately created for such usage and properly reviewed by experts.

(Response 17) The performance requirement in the final rule duplicates the ASTM F963-17 approach to addressing the magnet internal interaction hazard in children. The current ASTM test to determine flux index is a method that has been used by test laboratories to determine compliance with the toy standard and it is a method also used by other domestic and international standards for identifying hazardous magnets. The Commission has determined that the requirement effectively addresses magnet internal interaction hazard in toy products.

(Comment 18) One commenter, Joshua Pruett, suggested that a test method to measure the force applied to a membrane sandwiched between two magnets (presumably the attractive force of two magnets across body tissue) is an alternative that would be a closer analog to the hazard the agency wishes to prevent than the current method in ASTM F963-17, which measures a magnet's flux index.

(Response 18) The method proposed by the commenter is not a currently accepted test procedure, and it would not be reasonable because a specific attractive force between two magnets has not been correlated to tissue damage and severity of injury.

(Comment 19) Comments from Consumer Reports, Joshua Pruett, and Retrospective Goods, LLC, made statements regarding sampling requirements for testing magnets. Consumer Reports stated that, given the variation in flux strength across magnets due to variation in density, CPSC should require manufacturers to produce products that are consistent and uniform, adding that CPSC should require large sample sizes. Mr. Pruett suggested a representative sample consisting of 10 to 20 percent of the magnets in a set, but no less than 1 to 3 magnets per set, would provide robust test results. Retrospective Goods, LLC, stated that manufacturers should be allowed the flexibility to determine the appropriate sampling for their product and that the final rule should include an acceptable tolerance range for magnets.

(*Response 19)* The performance requirement in the final rule duplicates the ASTM F963-17 approach to addressing the magnet internal interaction hazard for children. The final rule requires all loose magnets subject to the rule to be either too large for children to swallow, or, if they are small enough to be swallowed, to have a measured flux index under 50 $kG^2 mm^2$. The performance requirement does not impose production requirements on the manufacturer; and it is the manufacturer's responsibility to have processes in place to ensure each magnet produced will

meet the proposed requirements. Manufacturers may choose sampling methods that are appropriate to their production setting and demonstrate confidence in complying with the proposed rule. Consistent with the ASTM F963-17 test method, and to prevent a hazard to children, a subject magnet product fails the proposed requirement if at least one magnet from the product has a magnetic flux index of 50 $kG^2 mm^2$ or greater.

(Comment 20) Numerous commenters opined on whether the proposed flux index limit is sufficient to address the magnet internal interaction hazard. Most supported the limit; however, several commenters, including Consumer Reports, stated that CPSC should continue to study whether magnets with flux indexes lower than 50 $kG^2 mm^2$ may also pose an unreasonable risk of injury to children, and should be brought within the scope of this rule at a later time. Additionally, Consumer Reports recommended that CPSC study whether larger magnets pose an unreasonable risk of injury.

(*Response 20*) The current ASTM test to measure flux index is the method accepted by domestic and international standards development bodies that has been used by test labs to determine compliance with ASTM F963, EN 71-1 and ISO 8124-1. CPSC's review indicates that the requirement effectively addresses the magnet internal interaction hazard in toy products. Recall information further supports this conclusion. Recalls of children's toys involving the magnet ingestion hazard have declined substantially since the ASTM F963 took effect. ASTM F963 was announced as the mandatory standard for toys in 2008, and it took effect in 2009. From 2006 through 2009, CPSC issued more than a dozen recalls of children's toys, due to the ingestion hazard associated with loose or separable, small, powerful magnets. In contrast, from January 2010 through May 2022—a period approximately three times as long—there were a total of 20 recalls related to the magnet ingestion hazard, only four involving children's toys. Of

those four recalls, only two involved confirmed violations of the magnet provisions in the ASTM F963 Toy Standard. Recalls provide some indication of the products involved in magnet ingestions, because products are recalled when they present a hazard. This marked decline in recalls of children's toys for magnet ingestion hazards indicates that children's toys largely comply with the ASTM F963 Toy Standard and are not involved in hazardous incidents. Although CPSC is currently not aware of demonstrable evidence indicating that magnets with a flux index below 50 $kG^2 mm^2$ are hazardous, CPSC staff will continue to review magnet ingestion incidents to assess whether magnets with flux indexes lower than 50 $kG^2 mm^2$ pose an unreasonable risk of injury. However, the Commission concludes that further study of whether larger magnets pose an unreasonable risk of ingestion injury is unwarranted at this time because the rule requires loose or separable magnets in the subject magnet products to have a flux index under 50 $kG^2 mm^2$ if the magnets are small enough to be ingested.

(Comment 21) Several commenters requested that, following promulgation of the final rule, the CPSC investigate whether, and to what extent, the number of magnets ingested affects the likelihood of internal interaction injuries. One manufacturer, Retrospective Goods, LLC, stated that there are no data showing that magnets in aggregate clumps increase the risk of internal interaction injury. This commenter explained that x-rays taken of ingestion incidents involving multiple magnets show that the pattern is limited to strings or rings of magnets.

(Response 21) The existing flux index method was developed to estimate the magnetic attraction force of individual conventional dipole magnets. Individual magnets stacked together with their magnetic poles aligned, or connected side-by-side, could potentially have a stronger flux index or otherwise be more difficult to separate than each individual magnet. A clump of magnets could be less powerful than an ordered aggregation, as the magnetic poles could

overlap, interact, and counteract one another. CPSC's review of NEISS and CPSRMS-reported incidents did not show evidence demonstrating that internal interaction injuries occurred because of increased strength from magnets in aggregate.

(Comment 22) One manufacturer, Retrospective Goods, LLC, asserted that the flux index is not an accurate measurement of magnetic attractive force because magnets of different size, shape, and composition can have the same flux densities but different points of contact (convex surface likes spheres and cylinder ends have a single point of contact versus flat surfaces of disks) and/or different pole surface areas. The commenter stated the result is that magnets of different size and shape can have the same flux index but different attractive forces; therefore, the commenter claimed the flux index is an arbitrary way of measuring safety risk. However, the commenter also concluded that historical health data indicate that a flux index less than 50 kG^2mm^2 is an appropriate predictor of safety for all disk magnets and spherical magnets composed of neodymium; therefore, the commenter asserted the belief that the rule should be limited to disk- and sphere-shaped neodymium magnets.

(Response 22) The commenter's analysis of attractive force does not consider the area over which the force is dispersed when two magnets attract to apply pressure (force divided by area) on the pinched tissue; attractive force, by itself, is not the only factor to consider. The commenter also did not provide evidence, and CPSC is not aware of any, that correlates tissue damage to a specific magnetic attractive force over a specific area. The Commission proposed a performance requirement that duplicates the ASTM F963-17 approach to addressing the magnet internal interaction hazard in children. The current ASTM test to determine flux index is a method that has been used by test labs to determine compliance with the toy standard, and it is a method that is also used by other domestic and international standards for identifying hazardous

magnets. CPSC's rationale for using the 50 kG^2mm^2 flux index is based on historical incident data indicating that the ASTM F963 requirement effectively addresses the magnet internal interaction hazard in toy products. In fact, the same commenter concluded that the proposed rule is effective for certain magnets, based on incident data, but the commenter did not provide an adequate rationale for excluding other magnets. Therefore, the commenter's analysis does not change our conclusion that loose or separable magnets in the subject magnet products should either be too large to fit in the small parts cylinder described in 16 CFR 1501.4, or they must have a flux index of less than 50 kG^2 mm^2, when tested in accordance with the procedures described in the ASTM F963-17.

Impacts on Businesses and Jobs

(Comment 23) Several individual commenters who are opposed to the proposed rule claim that U.S. companies will go out of business as a result of the rule.

(Response 23) In the initial regulatory flexibility analysis (IRFA), CPSC noted that a few small firms whose businesses focus on sales of magnet products that do not comply with the final rule, including some small firms selling products on their own websites, would face relatively greater losses in producer surplus (estimated to average about $5 to $10 per unit for magnet sets). 87 FR 1303. These and other small businesses could respond to the rule by undertaking measures, such as marketing or incorporating magnets that comply with the rule, or increase their marketing of products that do not have loose or separable hazardous magnets. Such measures could partially offset losses in producer surplus resulting from firms' inability to continue marketing noncomplying magnet products. A review of products currently offered by current or former sellers of products that would not meet the rule found that most of these current or former sellers also market products that either would comply with the rule or are not within the scope of

the rule. One of the leading importers of magnet sets that recalled and stopped sales of the products in March 2022, still markets a variety of magnetic products that would comply with the final rule (if the product marketing is accurate regarding the size and strength of the loose or separable magnets). These facts indicate that sellers of magnet products subject to the rule should be able to remain in business, even if the rule becomes effective.

(Comment 24) The NPR proposed that the rule take effect 30 days following its publication in the *Federal Register*. CPSC sought comments on the advantages and disadvantages of a different effective date, including extending the period before the rule becomes effective. *Id.* at 1305. Retrospective Goods, LLC, a manufacturer of subject magnet products, commented that a 30-day effective date would be workable for the firm if the rule is limited to size and strength requirements as proposed. However, the commenter asserted, if amendments change the flux index, the test method, or add additional tests or requirements, the firm, and likely other sellers, would need time to make those changes and a 90-day effective date would be more appropriate. This commenter also noted that the portion of the rule that regulates children's products requires that the Notice of Requirements (NOR) for the testing rule be amended, and the statute requires a 90-day effective date after that amendment. The commenter opined that it would make little sense, from a public safety standpoint, to have more stringent requirements for adult products than for children's products while the new rule is being fully implemented.

(Response 24) As noted in the IRFA, the alternatives to the proposed rule that the Commission considered included setting a longer period before the rule becomes effective. Although a later effective date could give firms additional time to develop complying products, or to shift marketing to nonmagnetic products, most current sellers of noncompliant subject

magnet products already market other products that either comply with the rule or do not constitute subject magnet products. Furthermore, the NPR itself alerted sellers to the potential need to adjust their marketing focus. Given the facts and the nature of the market, a 30-day effective date for the final rule should not present significant hardships to small businesses. Additionally, the 30-day effective date is consistent with the requirements in section 9(g)(1) of the CPSC, which states: "each consumer product safety rule shall specify the date such rule is to take effect," which generally "shall be set at a date at least 30 days after the date of promulgation." 15 U.S.C. 2085(g)(1),

The NPR noted that certain subject magnet products would be considered children's products if they are "designed or intended primarily for children 12 years of age or younger." For example, some jewelry items that are subject magnet products may be children's products, while others may not be. Accordingly, the NPR proposed to amend part 1112 to add a NOR to include procedures for accreditation of testing laboratories to test subject magnet products that are children's products for compliance with the new standard. Under section 14(a)(3), the testing and certificate requirements apply to any children's product manufactured more than 90 days after the Commission has established and published an NOR for accreditation of third party conformity assessment bodies to assess conformity with an applicable children's product safety rule.

Accordingly, although the effective date of the final rule for both children's and non-children's subject magnet products is 30 days after publication of the final rule, the effective date under 16 CFR part 1112 is 90 days after the publication of the final rule. All the subject magnet products must comply with the new standard, but for children's products, such as children's jewelry, that currently are not subject to the mandatory standard under ASTM F963-17, testing

laboratories also must go through the process of applying for accreditation and obtain approval to become a CPSC-accepted third party conformity assessment body. Ninety days provides sufficient time for testing laboratories to apply for, and comply with, the CPSC's procedures.

Regulatory Analysis

(Comment 25) The Magnet Safety Organization (MSO) submitted comment on the preliminary regulatory analysis. MSO asserts that CPSC's economic analysis does not account for the variety of quantities in which sets are sold. MSO's proposed regulatory alternative would set a performance standard that requires a minimum quantity of small rare earth magnets per set.

(Response 25) CPSC's review of product offerings over the years shows that magnet sets with 216 to 224 spheres have been most common (and the commenter acknowledges this) in households. If magnet products (*i.e.*, magnet sets) contain large numbers of individual magnets, or have magnets with high mass or volume that would result in costs of the rule (in the form of lost consumer surplus and producer surplus) greater than the estimated value of benefits (in the form of reduced societal costs) per set, then significant price increases for hazardous magnet products might reduce--but not eliminate--future exposure to the unreasonably dangerous products. Additionally, the Commission must assess all of the costs and benefits of the rule to address the risk of injury associated with magnet ingestion from subject magnet products. The commenter's proposed regulatory alternative that would limit sales to a minimum number of magnets per set could greatly increase prices and result in lost consumer surplus for consumers who would prefer products with smaller numbers of magnets and lower prices. Loss of that segment of the market would also decrease the producer surplus for manufacturers and importers of the products.

(Comment 26) Regarding the NPR's cost/benefit analysis, MSO stated: "According to the NPR, the range in Consumer surplus is equal to the annual magnet product sales, multiplied by the range of product price from $15 to $25. And the Producer surplus is curiously calculated with a fixed product price of $20, minus a variable cost between $10 and $15." MSO also claims that, based on the preliminary regulatory analysis's estimate of annual societal costs of $47.6 million, "above 1,904,000 units of Annual Sales is when societal benefit exceeds societal cost." Furthermore, MSO claims: " if the sales were comparable to 2009, 'the first year of significant sales, may have totaled about 2.7 million sets,' then societal benefit handily exceeds societal costs."

(Response 26) The commenter's conclusions appear to be based on several misinterpretations of the preliminary regulatory analysis. In the absence of precise data on annual sales of hazardous magnet products, CPSC presented estimates of the costs of the rule in the form of lost consumer surplus and lost producer surplus for a wide range of annual sales. When the preliminary analysis was prepared, CPSC noted that, because the assumed range of annual sales is wide and likely includes the actual sales levels, it is reasonable to conclude that the costs of the proposed rule could range from about $5 million to $8.75 million (if sales amount to about 250,000 products annually), to about $20 million to $35 million (if sales amount to about 1 million products annually). CPSC's intent was to provide estimates of costs of the rule in a range of annual sales that would capture likely costs. For the final rule, CPSC determines that it is reasonable to assume that the costs of the rule could range from about $2 million to $3.5 million (if sales amount to about 100,000 products annually), to about $20 million to $35 million (if sales amount to about 1 million products annually).

MSO is incorrect regarding CPSC's analysis of the consumer/producer surplus. The $15 to $25 figure was the assumed consumer surplus per unit, not the assumed price range. CPSC presented the example in which consumers who purchased the noncomplying subject magnet products at an average price of $20 would have been willing to spend, on average, $35 to $45 per product (*i.e.*, an additional $15 to $25 per set).

In addition, MSO speculates on sales data that, if comparable to 2009, "the first year of significant sales, may have totaled about 2.7 million sets." Contrary to MSO's assertions, the final regulatory analysis for the 2014 magnet sets rule was based on sales of about 800,000 sets annually during the 2009 to June 2012 period. MSO did not provide, and CPSC does not have, any information or basis for determining that annual sales of hazardous magnet products would approach the very high level of 2.7 million sets MSO asserts. The NPR requested commenters to provide information on sales of subject magnet products, but commenters offered no additional information. 87 FR 1312.

(Comment 27) We received comments from MSO and the Hobby Manufacturers Association, among others, asserting that if the rule is passed, it will be ineffectual because previous CPSC corrective actions have pushed domestic suppliers of subject products out of CPSC's authority, and caused "nearly all" of these products to enter the U.S. from overseas.

(Response 27) The NPR's preliminary regulatory analysis noted that an unusual aspect of the market for the subject magnets is the ability of consumers to order magnets directly, mainly from suppliers located in China. However, not all hazardous magnet products are being sold by overseas sellers. In fact, a review of sellers on two major internet platforms in 2020 and 2021 found that most sellers were domestic. The numbers of hazardous magnet products directly imported from overseas sources under the mandatory rule that are not stopped through

enforcement efforts, would likely comprise a small fraction of what total sales have been in recent years. The dramatic decline in magnet ingestion incidents during the period of the 2014 magnet sets rule supports this conclusion that the rule will be effective.

VII. Description of the Final Rule

The Commission is issuing a rule establishing a standard for subject magnet products. This section of the preamble describes the rule, including differences between the NPR's proposal and the final rule.

A. Scope, purpose, application, and exemptions - § 1262.1

Scope and purpose. This section of the rule states that the requirements of 16 CFR part 1262 are intended are intended to reduce or eliminate an unreasonable risk of death or injury to consumers who ingest one or more hazardous magnets from a subject magnet product that is designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contains one or more loose or separable magnets.

Application. Except as provided under the exemptions, all subject magnet products that are manufactured after the effective date, are subject to the requirements of this part 1262. This section makes several editorial changes to the proposed rule. The language "in the United States, or imported, on or" has been deleted to reflect the statutory language of CPSA section 9(g)(1), which provides that a safety standard subject to that section shall be applicable to consumer products "manufactured after the effective date." 15 U.S.C. 2058(g)(1). Another editorial change deletes the definition of "consumer product." Because the statutory citation is provided for the definition of "consumer product," 15 U.S.C. 2052(a)(1), a recitation of that definition is unnecessary.

Exemptions. This section of the rule also provides certain exemptions from the requirements of new 16 CFR part 1262, specifically: (i) Toys that are subject to 16 CFR part 1250, *Safety Standard Mandating ASTM F963 for Toys*; (ii) products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes; and (iii) products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes.

The NPR proposed to exempt from the standard children's toys subject to ASTM F963. The NPR also identified other products that could be excluded from the proposed rule, including home, education, research, commercial, and industrial uses. Accordingly, the NPR specifically sought comment on whether additional products should be included or excluded from the rule and whether home/kitchen magnets or education products should be addressed in the rule. 87 FR 1312. As discussed in section VI.B. of the preamble, several commenters, including magnet set manufacturers, requested clarifications pertaining to the product scope and exemptions, particularly regarding the ambiguity of the products that might meet the definition of "mental stimulation." They asserted that "mental stimulation" should be removed from the inclusion criteria for "subject magnet product" because the rule otherwise would include products primarily intended for use in scientific, technical, and professional settings, as well as educational purposes. Commenters also requested that the final rule should identify more clearly

the exempted products, such as products intended only for scientific or technical research, and educational, professional, and/or industrial applications.

In response to comments, the final rule codifies the exemptions to exclude from the rule, products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes. The exemption language excludes "mental stimulation" as a criterion for such magnets but makes clear that if any of these exempted products are *also* designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes, then such uses would make these products subject to the requirements of the standard.

The section also makes explicit that products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, are exempt from the rule's requirements. However, if any of these exempted products are *also* designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, then such uses would make these products subject to the requirements of the standard.

B. Definitions - § 1262.2

This section of the rule provides definitions for the terms "hazardous magnet" and "subject magnet product." *Hazardous magnet* is defined as "a magnet that fits entirely within the cylinder described in 16 CFR 1501.4 and that has a flux index of 50 kG^2 mm^2 or more when

tested in accordance with the method described in this part 1262." *Subject magnet product* is defined as a consumer product that is designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contains one or more loose or separable magnets.

C. Requirements - § 1262.3

Each loose or separable magnet in a *subject magnet product*, if it fits entirely within the cylinder described in 16 CFR 1501.4, must have a flux index of less than 50 kG^2 mm^2 when tested in accordance with the test procedure for determining flux index. Based on the widespread and longstanding use of the flux index limit of 50 kG^2 mm^2, its development and acceptance by multiple stakeholders, the effectiveness of standards that have used this limit to address magnet ingestion incidents, and CPSC testing showing that some magnets involved in internal interaction incidents had flux indexes close to 50 kG^2 mm^2, the final rule requires that magnets that are small enough to ingest have a flux index of less than 50 kG^2 mm.

D. Test procedure for determining flux index - § 1262.4

This section of the rule describes how to determine the flux index of subject product magnets. Under the final rule, each loose or separable magnet in a subject magnet product that fits entirely within the small parts cylinder described in 16 CFR 1501.4 must have a flux index of less than 50 kG^2 mm^2 when tested in accordance with a prescribed method. In practice, the first step is to determine whether each loose or separable magnet in a subject magnet product fits in the small parts cylinder, and the second step is to determine what is its flux index.

The small parts cylinder is described and illustrated in 16 CFR part 1501.4. Figure 2, below, shows the illustration, including the dimensions of the cylinder provided in the regulation.

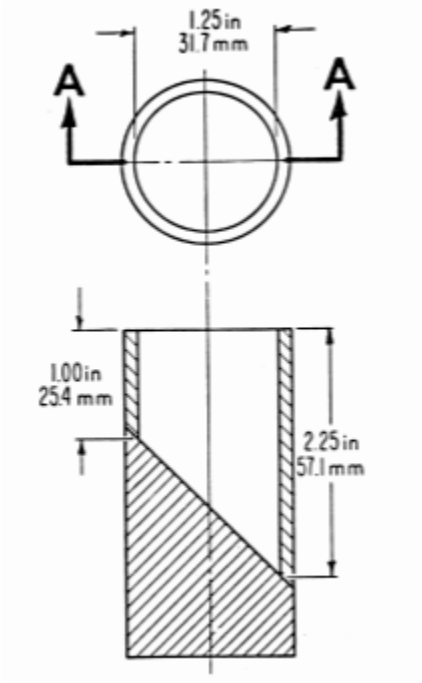

Figure 2: Small parts cylinder in 16 CFR 1501.4

If a magnet fits entirely within this cylinder, then its flux index must be less than 50 kG^2 mm^2.

To determine the flux index of a magnet, the final rule provides that at least one loose or separable magnet of each shape and size in the subject magnet product must have its flux index determined using the procedure in sections 8.25.1 through 8.25.3 of ASTM F963-17, which specify test equipment, measurements, the test method, and the calculation for determining flux index. The test requires a direct current field gauss meter with a resolution of 5 gauss (G) capable of determining the field with an accuracy of 1.5 percent or better and an axial probe with a specified active area diameter and a distance between the active area and probe tip. Using the meter, the probe tip is placed in contact with the pole surface of the magnet, the probe is kept perpendicular to the surface, and the probe is moved across the surface to find the maximum absolute flux density. The flux index, in kG^2 mm^2, is determined by multiplying the area of the

pole surface (mm^2) of the magnet by the square of the maximum flux density (kG^2). The flux density must be less than 50 kG^2 mm^2 to comply with the final rule.

As detailed in the memorandum in Tab D of Staff's NPR briefing package and in Tab D of Staff's Final Rule briefing package, CPSC staff developed a test methodology that is consistent with the test methods specified in ASTM F963-17, to assist testing laboratories in improving the accuracy and consistency in measuring the maximum flux density and calculating the maximum flux index for small diameter magnets. This test procedure is not mandatory, but it is provided as an example of how to measure flux index of small spherical magnets less than 3 mm in diameter. This example test method is available in the Appendix to Tab D of Staff's Final Rule briefing package.

E. Findings - § 1262.5

Section 9 of the CPSA requires the Commission to make certain findings when issuing a consumer product safety standard. Specifically, the Commission must consider and make findings about the degree and nature of the risk of injury; the number of consumer products subject to the rule; the need of the public for the rule and the probable effect on utility, cost, and availability of the product; and other means to achieve the objective of the rule, while minimizing the impact on competition, manufacturing, and commercial practices. The CPSA also requires the rule to be reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product; and issuing the rule must be in the public interest. 15 U.S.C. 2058(f)(3).

In addition, the Commission must find that: (1) if an applicable voluntary standard has been adopted and implemented, compliance with the voluntary standard is not likely to adequately reduce the risk of injury, or compliance with the voluntary standard is not likely to be

substantial; (2) the benefits expected from the regulation bear a reasonable relationship to the regulation's costs; and (3) the regulation imposes the least burdensome requirement that would prevent or adequately reduce the risk of injury. *Id.* These findings are stated in § 1262.5 of the rule and are based on information provided throughout this preamble and the staff's briefing packages for the proposed and final rules.

VIII. Final Regulatory Analysis

The Commission is issuing this rule under sections 7 and 9 of the CPSA. The CPSA requires that the Commission publish a final regulatory analysis with the text of the final rule. 15 U.S.C. 2058(f)(2). This section of the preamble provides the final regulatory analysis of the rule, which is discussed further in Tab F of Staff's Final Rule briefing package.

A. Societal Costs of Deaths and Injuries

The Commission's ICM provides estimates of the societal costs of injuries reported through NEISS, as well as the societal costs of other medically treated injuries. The major aggregated societal cost components provided by the ICM include medical costs, work losses, and the intangible costs associated with lost quality of life or pain and suffering.

Medical costs include three categories of expenditures: (1) medical and hospital costs associated with treating the injury victim during the initial recovery period and in the long term, including the costs associated with corrective surgery, the treatment of chronic injuries, and rehabilitation services; (2) ancillary costs, such as costs for prescriptions, medical equipment, and ambulance transport; and (3) costs of health insurance claims processing. For the ICM, CPSC derives the cost estimates for these expenditure categories from national and state databases including Medical Expenditure Panel Survey (MEPS), the Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project (HCUP-NIS), the Nationwide Emergency

Department Sample (NEDS), the National Nursing Home Survey (NNHS), MarketScan® claims data, and a variety of other federal, state, and private databases.

Work loss estimates are intended to include: (1) the forgone earnings of the victim, including lost wage work and household work; (2) the forgone earnings of parents and visitors, including lost wage work and household work; (3) imputed long-term work losses of the victim that would be associated with permanent impairment; and (4) employer productivity losses, such as the costs incurred when employers spend time juggling schedules or training replacement workers. Estimates are based on information from HCUP-NIS, NEDS, Detailed Claims Information (a workers' compensation database), the National Health Interview Survey, U.S. Bureau of Labor Statistics, and other sources. The intangible, or non-economic, costs of injury reflect the physical and emotional trauma of injury, as well as the mental anguish of victims and caregivers. Intangible costs are difficult to quantify because they do not represent products or resources traded in the marketplace. Nevertheless, they typically represent the largest component of injury cost and need to be accounted for in any benefit-cost analysis involving health outcomes. The ICM develops a monetary estimate of these intangible costs from jury awards for pain and suffering. Although these awards can vary widely on a case-by-case basis, studies have shown them to be systematically related to a number of factors, including economic losses, the type and severity of injury, and the age of the victim.[24] CPSC derived estimates for the ICM from regression analysis of jury awards in nonfatal product liability cases involving consumer products compiled by Jury Verdicts Research, Inc.

[24] W. Kip Viscusi (1988), *The determinants of the disposition of product liability cases: Systematic compensation or capricious awards?* International Review of Law and Economics, 8, 203-220; Gregory B. Rodgers (1993), *Estimating jury compensation for pain and suffering in product liability cases involving nonfatal personal injury*, Journal of Forensic Economics 6(3), 251-262; and Mark A. Cohen and Ted R. Miller (2003), *"Willingness to award" nonmonetary damages and implied value of life from jury awards*, International Journal of Law and Economics, 23, 165-184.

Table 8 below provides *annual* estimates of the injuries and societal costs associated with ingestions of magnets categorized as magnet sets, magnet toys, and jewelry. Based on NEISS estimates for 2017 through 2021, there were an estimated annual average of about 481 ED-treated injuries, comprised of 320 injuries that were treated and released and 161 injuries that required hospitalization. Additionally, based on annual estimates from the ICM, 185 injuries were treated outside of hospitals, and another 78 injuries resulted in direct hospital admission.

Based on ICM estimates, these injuries resulted in annual societal costs of $51.8 million (in 2020 dollars) during the period 2017 through 2021. The average estimated societal cost per injury was about $14,000 for injuries treated in physician's offices, clinics, and other non-hospital settings; about $24,000 for injuries that were treated and released from EDs; and about $175,000 for injuries that required admission to the hospital for treatment. Medical costs and work losses (including work losses of caregivers) accounted for about 43 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 57 percent of the estimated injury costs.

In addition to the magnet cases upon which Table 8 was based, for which identifying information was reported (*i.e.,* magnets from magnet sets, magnet toys, or jewelry), there were also 403 NEISS cases during 2017 through 2021 (representing about 1,873 ED-treated injuries annually), in which the magnet type was classified as "unidentified." These cases included narratives that mentioned that at least one magnet was ingested but presented insufficient information to classify the magnet product type. CPSC's analysis of the data, the trends in NEISS, CPSRMS, and poison center-reported[25], magnet-related incidents relative to the vacated

[25] As discussed in the NPR, annual national poison center magnet exposure calls increased by 344 percent from 281 per year (2012–2017) to 1,249 per year (2018–2019). Considering incidents dating back to 2008 (5,738 total), the incidents from 2018 and 2019, alone, accounted for 39 percent of the magnet incidents since 2008. These

2014 rule on magnet sets, support the conclusion that the "unidentified" magnet products generally involved magnets considered within scope of the rule; that is, intended for subject magnet product uses. Based on ICM estimates for all magnet products involved in ingestion injuries, including unidentified , average annual societal costs for 2017–2021 were $167.9 million. Because CPSC does not know precisely how many of these products would fall within the scope of this rule, CPSC conservatively has not included them in the primary benefit analysis summarized above. Instead, CPSC includes the benefits from unidentified magnet products in this final rule's sensitivity analysis to illustrate the theoretical upper bounds of benefits from this rule.

Table 8: Estimated average annual medically treated injuries and associated societal costs for ingestions of products categorized as magnet sets, magnet toys, and jewelry, including those for unidentified magnets for 2017 through 2021.

Injury Disposition	Estimated Number	Estimated Societal Costs ($ millions)*
Doctor/Clinic	185	$2.6
Treated and Released from Hospital ED	320	$7.5
Admitted to Hospital through ED (NEISS)	161†	$28.1
Direct Hospital Admissions, Bypassing	78	$13.6
Total Medically Attended Injuries	743	$51.8

* In 2020 dollars.
† This estimate may not be reliable because of the small number of cases on which it is based.

B. Benefits of the Rule

The benefits of the rule account for the reduction in the risk of injury from magnet ingestions and the resulting value of the societal costs of the injuries that the rule would prevent. In addition to the injuries reflected in the analysis above, staff is aware of four fatalities in the United States resulting from magnet ingestions, excluding one death involving a toy subject to

researchers drew conclusions similar to CPSC's, asserting that significant increases in magnet injuries correspond to periods in which high-powered magnet sets were allowed to be sold. 87 FR 1274.

ASTM F963.[26] Given that nearly all incidents result in injuries as opposed to deaths, CPSC focuses its benefits assessment on the mitigation of injuries. However, CPSC does include the mitigation of deaths in the benefits assessment in a sensitivity analysis in this regulatory evaluation.

The annual expected benefits of the rule, on a per-product basis, depend on the exposure to risk associated with subject magnet products, as well as the estimated societal costs described in Table 8, above. Although subject magnet products may retain their magnetism for many years, it is likely that some are discarded well before that time. Thus, the actual expected product life of subject magnet products is uncertain; this analysis presents a range of potential benefit estimates, per subject magnet product, under an assumed product life of 1.5, 2, and 3 years. Table 9 presents benefit estimates under the alternative product life assumptions (line (b)).

[26] Staff is aware of seven deaths that occurred in the period November 24, 2005, to January 5, 2021,involving ingestion of hazardous magnets. Two of these deaths occurred abroad, and one of the five U.S. ingestion cases occurred before 2010, and that case involved a children's toy subject to ASTM F963.

Table 9: Present Value of Societal Costs Per Subject Magnet Product in Use (or Gross Benefits of a Rule), for Three Expected Product Lives from 2017 through 2021.

(a) Aggregate Annual Societal Costs (millions $)	$51.8	$51.8	$51.8
(b) Expected Useful Product Life (years)	1.5	2	3
(c) Magnet Products in Use, Average Annual	515,000	626,000	818,000
(d) Annual Societal Costs per Subject Magnet Product [(a) ÷ (c)]	$101	$83	$63
(e) Present Value of Societal Costs, per Subject Magnet Product[27] (*3% Discount Rate*)	$150	$162	$180
(f) Present Value of Societal Costs, per Subject Magnet Product (*7% Discount Rate*)	$144	$154	$167

Line c presents the average annual estimated number of subject magnet products in use during the period 2017 through 2021, based on producer-reported annual magnet set sales collected by CPSC's Office of Compliance and Field Operations up through mid-2012. The estimate also includes assumptions of annual sales of all subject magnet products through 2021 (including an assumption of 500,000 units per year for 2017–2021 as explained below), an expected product life of 1.5, 2, and 3 years (line b), and the application of the CPSC's Product Population Model, a statistical model that projects the number of products in use, given estimates of annual product sales and product failure rates. In the NPR, the Commission requested comments with information on annual sales and expected product life of magnet products subject to the proposed rule. No commenter provided specific sales or product life information, however.

The annual estimated societal costs per subject magnet product in use (line d of Table 2) are presented as the quotient of the annual societal costs (line a), and the estimated average

[27] These calculations are based on estimated product survival by month after purchase, which is multiplied by monthly societal costs per unit. The streams of expected societal costs are then discounted to their present values (at 3% and 7%).

number of products in use (line c). Based on these estimates, and an assumed average product life ranging from 1.5 to 3 years, the present value of societal costs, per subject magnet product, ranges from about $150 to about $180, using a 3 percent discount rate (line e), or from about $144 to $167, using a 7 percent discount rate (line f).

Because the rule would prohibit the sale of the subject magnet products with one or more loose or separable hazardous magnets, the approximation of benefits would be equal to the present value of societal costs presented in lines (e) and (f) and would range from about $144 (with a 1.5-year product life and a 7 percent discount rate) to $180 (with a 3-year product life and a 3 percent discount rate) per product.

C. Costs Associated with the Rule

This section discusses the costs associated with the rule, which include costs to consumers and to manufacturers/importers of subject magnet products. Both consumers and producers benefit from the production and sale of consumer products. The consuming public obtains the use value or utility associated with the consumption of products; producers obtain income and profits from the production and sale of products. Consequently, the costs of requiring that subject magnet products comply with the rule would consist of: (1) the lost use value experienced by consumers who would no longer be able to purchase subject magnet products that do not meet the standard (at any price) and who cannot find an appropriate substitute; and (2) the lost income and profits to firms that could not produce, import, or sell noncomplying products in the future.

Both consumer and producer surplus depend on product sales, among other things. The unit sales of subject magnet products are not known. This analysis accordingly considers possible costs associated with several plausible estimates of sales, ranging from about 100,000 to

1 million subject magnet products per year. The lower bound of 100,000 units[28] and upper bound of 1 million units are based on information from reports by firms to CPSC's Office of Compliance and Field Operations.[29] For purposes of exposition, CPSC uses an assumption of annual sales of 500,000 units per year, in the midpoint of the range of estimates. CPSC uses a wide range, not because of the appropriate endpoints of that range are precisely determined, but instead to demonstrate that, even at the extremes of a reasonable range, the overall result of preliminary regulatory analysis is that the rule's benefits outweigh the costs.

1. Costs to Consumers

The primary cost associated with the rule is lost utility to consumers. Subject magnet products may be used for a variety of purposes, including amusement and jewelry. CPSC has received comments regarding subject magnet products, including magnet sets, citing usefulness of the magnets as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, or stress relief. Others have claimed that the magnets can have beneficial artistic, educational, social, innovative, and therapeutic values. In addition to consumer uses promoted by sellers, and uses reported in comments by consumers, use of magnets as jewelry from magnet sets is a common hazard pattern. The individual magnets might also have other uses, apart from their intended uses (*e.g.*, using magnets from a magnet set to post items on a refrigerator door). Thus, CPSC concludes that consumers derive utility from magnet sets and

[28] The lower bound estimate in the NPR was 250,000. 87 FR 1303. Since the NPR, a leading seller was subject to a recall. To account for this change, an adjustment to 100,000 was made.

[29] For the 2014 magnet sets rule CPSC assessed that 2.7 million magnet sets were sold to U.S. consumers from 2009 through mid-2012, or an average of about 800,000 annually. Since 2012, administrative actions and recalls have set the market in a state of flux and sales have likely decreased. To capture this change in lieu of industry data (of which none was subsequently provided by commenters during the NPR comment period) CPSC made an adjustment from 800,000 to 500,000 magnets sets sold on an annual basis. CPSC then added a range of -50% (250,000) and +100% (1 million) to represent the theoretical extremes. More weight was given to the upside to account for CPSC's assessment that a rebound back to 2012 sales level and beyond was likelier than the same magnitude of decline.

other subject magnet products within the scope of the rule from a wide variety of uses, even those not promoted by sellers.

CPSC cannot estimate with any precision the use value that consumers receive from these products. However, we can describe use value conceptually. In general, use value includes the amount of: (1) consumer expenditures for the product, plus (2) what is called "consumer surplus." Assuming annual sales of about 500,000 subject magnet products as explained above, and an average retail price of about $20 (based on price data for magnet sets), consumer expenditures would amount to about $10 million annually. These expenditures represent the minimum value that consumers would expect to get from these products. It is represented by the area of the rectangle OBDE in the standard supply and demand graph below (Figure 2), where B equals $20, and E equals 500,000 units.

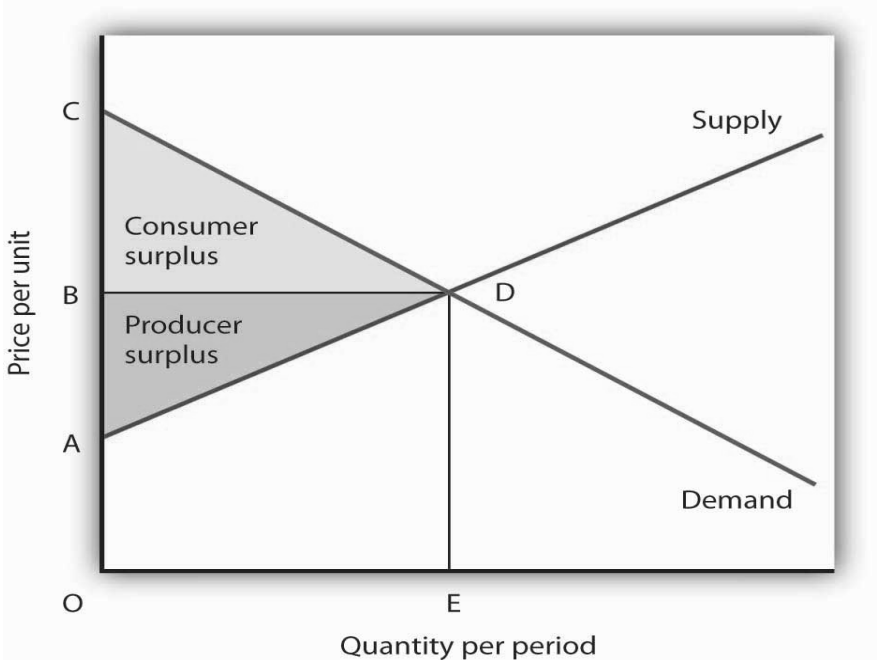

Figure 2: Supply and demand graph illustrating the concepts of consumer and producer surplus.

In Figure 2, consumer surplus is given by the area of the triangle BCD under the graph's demand function and represents the difference between the market-clearing price and the maximum amount consumers would have been willing to pay for the product. This consumer surplus will vary for individual consumers, but it represents a benefit to consumers over and above what they paid. For example, tickets to a concert might sell for $100 each, but some consumers who buy them for $100 would have been willing to pay $150 per ticket. Those consumers paid $100 and received benefits that they value at $150, thereby receiving a consumer surplus of $50.

In general, the use value of the subject magnet products obtained by consumers is represented by the area of the trapezoid OCDE in Figure 2. However, the prospective loss in use value associated with the rule would amount to, at most, the area of the triangle representing the consumer surplus. This is because consumers would no longer be able to obtain utility from the products that do not comply with the rule, but they would have the $10 million (represented by the rectangle OBDE) that they would have spent on noncomplying subject magnet products in the absence of a rule. The net loss in consumer surplus associated with the rule would be reduced by consumers' ability to purchase replacement products that comply with the rule and provide the same utility, or by their ability to purchase other products that provide use-value.

CPSC does not have, and no commenter offered, information regarding aggregate consumer surplus, or, by extension, the amount of utility that would be lost as a result of the rule. However, if, for example, consumers who purchased subject magnet products that do not comply with the rule at an average price of $20, would have been willing to spend, on average, $35 to $45 per product (*i.e.*, an additional $15 to $25 per product), then the lost utility would amount to

about $7.5 million (*i.e.*, [$35-$20] × 500,000 units annually) to $12.5 million (*i.e.*, [$45-$20] × 500,000 units annually) annually.

Finally, we note that the loss in consumer surplus just described represents the maximum loss of consumer utility from the rule. This is because consumers are likely to gain some amount of consumer surplus from products that are purchased as an alternative to those subject magnet products that would no longer be available because of the rule. If, for example, consumers purchased close substitutes (*e.g.*, products that are almost as satisfying and similarly priced) for the subject magnet products that do not meet the standard, the overall loss in consumer surplus (and, hence, the costs of the rule) would tend to be small. On the other hand, if consumers do not purchase close substitutes, the costs of the rule would be higher.

2. *Costs to Manufacturers/Importers*

The lost benefits to firms that could result from the rule are measured by a loss in what is called producer surplus. Producer surplus is a profit measure that is analogous to consumer surplus. Whereas consumer surplus is a measure of benefits received by individuals who consume products, net of the cost of purchasing the products, producer surplus is a measure of the benefits accruing to firms that produce and sell products, net of the costs of producing them. More formally, "producer surplus" is defined as the total revenue (TR) of firms selling the magnets, less the total variable costs (TVC) of production. Variable costs are costs that vary with the level of output and usually include expenditures for raw materials, wages, distribution of the product, and the like.

In Figure 2, total revenue is given by the area OBDE, which is simply the product of sales and price. The total variable costs of production are given by the area under the supply function, OADE. Consequently, producer surplus is given by the triangle ABD, which is the area

under the market clearing price and above the supply function. Note that this represents the maximum loss to producers; if suppliers produce and sell alternatives that are similar to the subject magnet products, the lost producer surplus could be less.

Following our example above, assuming sales of the subject magnet products average 500,000 units annually, with an average retail price of $20 per product total industry revenues have averaged about $10 million annually (*i.e.*, 500,000 units × $20 per product). Information provided by magnet set sellers to CPSC's Office of Compliance and Field Operations suggested that the average import cost of magnet sets to U.S. importers, a major variable cost, may amount to about $10 per set, or an average of about $5 million annually (*i.e.*, 500,000 sets × $10 import cost per set). Apart from the import costs of the magnets, the variable costs of production are probably relatively small. Because magnet sets are often packaged and shipped from China and sometimes sent directly to the importer's point of sale, U.S. labor costs may be low; and because the magnets sets are small, non-perishable, and not particularly valuable, storage costs likewise are low. For example, assuming the variable costs of production account for about half of the difference between total revenues ($10 million) and import costs ($5 million), producer surplus would amount to about $2.5 million (*i.e.*, ($10 million−$5 million) ÷ 2) annually. At most, the lost producer surplus would amount to about $5 million annually, if there were no variable costs other than the costs of importing the magnets (*i.e.*, total revenue of $10 million for 500,000 units annually, less the import costs of about $5 million). Although this information is specifically related to magnet sets, a similar relationship could apply to other subject magnet products affected by the rule.

Manufacturers and importers might be able to respond to the rule by measures such as marketing or incorporating magnets that comply with the rule or increased marketing of products

that do not have loose or separable magnets. Such measures would offset losses in producer surplus resulting from firms' inability to continue marketing noncomplying magnet products.

As noted above, actual sales levels of non-complying subject magnet products are not known with certainty. Additionally, CPSC cannot estimate precisely either consumer surplus or producer surplus; nor were any such data provided in response to the NPR's request for such information. Table 10 below provides rough estimates of the possible costs of the rule for various future hypothetical sales levels ranging from 100,000 to 1 million products annually. The cost estimates are based on the assumptions described above and are made for illustrative purposes. Nevertheless, because the range of sales is wide, and the range provide here is likely to include the actual annual sales levels, it is reasonable to assume that the costs of the rule are within the range from approximately $2 million to $3.5 million (if sales amount to about 100,000 products annually), to about $20 million to $35 million (if sales amount to about 1 million products annually). As noted above, these costs could be offset by increased marketing of products that incorporate complying magnets or by incorporating products that do not include loose or separable magnets.

Table 10. Possible Costs of the Rule, for Various Levels of Noncomplying Subject Magnet Product Sales

Magnet Product Sales (annually)	Consumer Surplus (millions $)	Producer Surplus (millions $)	Total Costs (millions $)
100,000	$1.5 to $2.5	$0.5 to $1	$2 to $3.5
500,000	$7.5 to $12.5	$2.5 to $5	$10 to $17.5
750,000	$11.25 to $18.75	$3.75 to $7.5	$15 to $26.25
1,000,000	$15 to $25	$5 to $10	$20 to $35

In addition to lost producer surplus, manufacturers and importers of subject magnet products that comply with the rule would incur some additional costs to certify that their products meet the requirements of Section 14 of the CPSA. The certification must be based on a test of each product model or a reasonable testing program. The costs of the testing might be minimal, especially for manufacturers that currently have product testing done for products subject to the requirements in ASTM F963. Importers may also rely upon testing completed by other parties, such as their foreign suppliers, if those tests provide sufficient information for the manufacturers or importers to certify that the magnets in their products comply with the rule. As noted above, for subject magnet products that are children's products, such as children's jewelry, the certification must be based on testing by an accredited third party conformity assessment body, at somewhat higher costs.

D. Sensitivity Analysis

The foregoing base-case analysis of potential costs and benefits of the rule presents estimated costs for a wide range of prospective sales in the absence of a rule, 100,000 to 1 million units. Estimated potential benefits/societal costs of injuries per unit are based on expected useful product life of 18 months, 2 years, and 3 years. The present value of expected

injury costs occurring over the lives of products are discounted at 3 percent and 7 percent. Thus, the base analysis incorporates sensitivity analysis for some important parameters and assumptions. Staff conducted additional sensitivity analysis to evaluate the impact of variations in some other important parameters. Alternative inputs for the sensitivity analysis included:

- Assuming lower and higher unit sales in recent years than the base case of 500,000 units for 2017 through 2022;
- Assuming 25 percent, 50 percent, and 100 percent of estimated injury costs involving unidentified magnet products would be addressed by the rule, and;
- Including an estimate of societal costs of fatal ingestion injuries in the potential benefits calculation.

Staff's sensitivity analysis shows that per-unit injury costs being addressed by the rule vary greatly for the wide range of assumed annual unit sales. However, for all scenarios examined, the potential benefits well exceed the estimated costs of the rule, in the form of lost consumer surplus and lost producer surplus, estimated to range generally from $20 to $35 per subject magnet product. In addition, the sensitivity analysis shows that including even a relatively small portion of NEISS cases involving unidentified magnet products to the base case, which is limited to in-scope identified products, substantially increase the estimated gross benefits of the rule.

If 100 percent of unidentified magnet injuries were within the scope of the draft final rule, average estimated annual magnet ingestion societal costs would be an additional $167.9 million. Including these societal costs with those estimated for in-scope identified subject magnet products ($51.8 million) results in average annual societal costs of magnet ingestion injuries of $219.7 million for the period 2017 through 2021, an increase of 324 percent. Including these

cases as addressable societal costs would lead to a corresponding increase the estimated gross benefits of the rule.

In estimating the benefits of the rule associated with reduced mortality, we assume that the standard will avoid two to four deaths over a 10-year period, the average annual statistical value of the rule's life-saving could be about $2.1 million to $4.2 million. Adding these potential societal costs to those associated with nonfatal magnet ingestions would increase the expected gross benefits of the proposed standard by about 4 percent to 7 percent over the base estimate.

E. Summary of the Final Regulatory Analysis Results

Estimated aggregate annual societal costs from ingestion injuries involving subject magnet products for 2017 through 2021 total $51.8 million. Assumptions about annual product sales and expected product life of 1.5, 2, and 3 years yields estimated numbers of products in use during those years ranging from 515,000 to 818,000. The estimated present value of societal costs per subject magnet product (at a 3% discount rate) ranges from $150 per unit (at a 1.5-year expected life) to $180 per unit (at a 3-year expected life). On the cost side, estimates of consumer and producer surplus were uncertain, but they might range from about $2-$3.5 million to about $20-$35 million, based on unit sales ranging from 100,000 to 1 million.

Based on annual unit sales of noncomplying subject magnet products of 500,000, expected aggregate benefits total $51.8 million annually, while costs (lost consumer and producer surplus) range from $10 million to $17.5 million annually. Thus, although both the benefits and costs of the rule are uncertain, based on a range of assumptions, our estimates suggest that the potential benefits of the rule are projected to exceed the potential costs. These estimated benefits exclude cases involving in-scope magnet products that have not been identified as amusement/jewelry products. As discussed, the sensitivity analysis shows that

including NEISS cases involving unidentified magnet products to the base case substantially increases the estimated gross benefits of the rule.

Table 11, below, shows a comparison of the estimated benefits and costs of the rule.

Table 11. Comparison of Estimated Benefits and Costs of the Rule

Annual Magnet Product Sales[1]	Benefits (millions $)		Total Costs from Lost Consumer & Producer Surplus (millions $)
	Identified as Amusement and/or Jewelry	Including 100% of Unidentified Magnet Incidents	
500,000	$51.8	$167.9	$10 to $17.5

IX. Alternatives to the Rule

CPSC considered several alternatives to reduce the risk of injuries and death associated with ingestion of subject magnet products. However, as discussed below, CPSC does not consider any of these alternatives capable of adequately reducing the risk of injury and death.

A. Rely on Voluntary Standards

One alternative to the rule is to take no regulatory action and, instead, rely on voluntary safety standards to address the magnet ingestion hazard. As discussed above, there are four ASTM standards and two international standards that address the magnet ingestion hazard, covering children's toys, jewelry, and magnet sets. Relying on these standards would eliminate the costs associated with the rule because it would not mandate compliance.

However, there are considerable limitations and unknowns associated with this alternative. The shortcomings of the standards are discussed in detail in section V. in the preamble. CPSC does not consider the existing voluntary standards capable of adequately reducing the magnet ingestion hazard, either individually or collectively, because their limited

scope fails to cover all of the subject magnet products associated with injuries and deaths, and/or the voluntary standards do not impose size and strength limits on subject magnet products with loose or separable magnets. In addition, CPSC does not know the level of compliance with ASTM F3458, ASTM F2999, or ASTM F2923; if the rate of compliance is low, these would not be an effective way to address the hazard, even if the requirements in these standards were adequate. Finally, waiting for ASTM to revise its standards to adequately address the hazard would delay the safety benefits of the final rule. For these reasons, the Commission did not select this alternative.

B. Alternative Performance Requirements

Another alternative to the rule is to adopt a mandatory standard with less stringent requirements than the rule, such as a higher flux index limit, or different requirements for certain shapes and sizes of magnets. This may reduce the costs associated with the rule, by allowing firms to market and permit consumers to use a wider variety of products than under the rule. The reduction in costs would depend on the specific requirements adopted. As discussed in section V of the preamble, no other performance requirements in the currently applicable voluntary standards, aside from flux method test requirements in ASTM F963 Toy Standard, have been shown to adequately address the ingestion hazards associated with subject magnet products. Accordingly, on the record before us, choosing alternative performance requirements would reduce the safety benefits of the rule. If the alternative performance requirements reduced costs by allowing more products to remain on the market, it would also leave more hazardous products on the market, thereby decreasing the safety benefits.

The rule mandates a performance requirement that duplicates the ASTM F963 Toy Standard's approach to addressing magnet internal interaction hazard in children, which has been

shown to be effective. The current ASTM test to determine flux index is a method that has been used by test labs to determine compliance with ASTM F963 and is a method that is also used by other domestic and international standards for identifying hazardous magnets. Importers may also rely upon testing completed by other parties, such as their foreign suppliers, if those tests provide sufficient information for the manufacturers or importers to certify that the magnets in their products comply with the rule. Firms that magnetize the products would have equipment to measure the magnetic force of their products; and many of these firms should be familiar with the test methodology or have access to testing firms that can perform the tests. The increased costs related to testing therefore should be relatively minor, especially for small manufacturers that currently have product testing done for products subject to the requirements in ASTM F963-17, which is mandated by 16 CFR part 1250. For these reasons, the Commission did not select alternative performance requirements.

C. Require Safety Messaging

Instead of performance requirements, the Commission could require safety messaging on products to address the magnet ingestion hazard, such as through labeling and instructional literature. This alternative would reduce the costs associated with the rule, because it would allow firms to continue to sell subject magnet products with loose or separable hazardous magnets and the costs of providing warnings and instructional information likely would be small.

However, CPSC does not consider this alternative effective for adequately reducing the risk of injury and death associated with magnet ingestions, as discussed in section V.D.7. of the preamble. To summarize, the effectiveness of warnings depends on convincing consumers to avoid the hazard, and there are numerous reasons consumers may disregard warnings for these products. Caregivers do not expect older children and teens to ingest inedible objects; the magnet

ingestion hazard is not readily apparent; caregivers and children underappreciate the likelihood and severity of the hazard; magnets are often ingested accidentally; and children and teens commonly access magnets without their packaging.

Warning information on labels and instructional literature, as well as public outreach efforts to inform consumers of the hazard, have been used for many years to try to address the magnet ingestion hazard. However, these efforts have not addressed the magnet ingestion hazard successfully, as evidenced by the increase in magnet ingestion incidents in recent years, including magnet ingestion incidents involving products with clear warnings. For all these reasons, the Commission did not select this alternative.

D. Require Special Packaging

Another alternative is for the Commission to require special packaging for subject magnet products that contain hazardous magnets to limit children's access to the products. Such packaging could, for example, help consumers determine if all magnets have been returned to the package and include child-resistant features. Although this alternative would create some costs associated with packaging, those costs likely would be lower than the cost of the rule because they would allow the subject magnets to remain unchanged. Staff estimates that the cost of safety packaging may amount to about $1 per magnet product, depending on the requirements and features of the packaging.

CPSC does not consider this alternative effective for adequately reducing the risk of injury and death associated with magnet ingestions. To summarize the detailed discussion in section V.D.7. of the preamble, consumers are unlikely to repackage all magnets after each use. Even if consumers return all magnets to a package after each use, safety features to prevent easy access to the contents of the package would address only a minority of the vulnerable population.

Safety packaging is generally intended to restrict children under 5 years old from accessing package contents. Older children and teens are likely to have the cognitive and motor skills necessary to access products in special packaging. This is problematic because incident data show that older children and teens make up the majority of magnet ingestion victims. In addition, many incidents involve children and teens acquiring magnets without the product packaging, such as from friends, at school, or loose in the environment. For these reasons, the Commission did not select this alternative.

E. Require Aversive Agents

Instead of the size and strength requirements in the rule, the Commission could require manufacturers to coat loose or separable hazardous magnets in subject magnet products with aversive agents, such foul odors or bitterants. Aversive agents may dissuade some children and teens from placing hazardous magnets in their mouths. This alternative would reduce the costs associated with the rule, because it would allow firms to continue to sell subject magnet products with loose or separable hazardous magnets, would allow consumers to continue to use them, and the costs of such coatings likely would be small.

CPSC does not consider this alternative effective for adequately reducing the risk of injury and death associated with magnet ingestions. To summarize the detailed discussion in section V.D.7. of the preamble, real-world investigations have not demonstrated that bitterants are effective at preventing ingestions. Bitterants do not deter initial ingestion because the user has not yet tasted the bitterant; this makes bitterants ineffective at protecting users from harms that can result from a single ingestion. Incident reports indicate that ingesting a single magnet (and ferromagnetic object), or multiple magnets at once or in quick succession, can result in serious injuries. In addition, once a magnet is in a person's mouth, they may not be able to

prevent ingestion, even if deterred by a bitterant. Bitterants would be particularly ineffective for accidental ingestions, where victims do not intentionally place magnets in their mouth; incident data indicate that some magnet ingestions involve unintentional ingestions, particularly for older victims. Moreover, children frequently ingest unpalatable substances, such as gasoline, cleaners, and ammonia, indicating that unpleasant taste or odor, alone, is not sufficient to deter children from ingesting items or substances. Finally, some portion of the population, possibly as high as 30 percent, may be insensitive to certain bitterants. For these reasons, the Commission did not select this alternative.

F. Later Effective Date

Another alternative is to provide a later effective date for a final rule. In the NPR, the Commission proposed a final rule effective 30 days after it is published. A later effective date would reduce the impact of the rule on manufacturers and importers, by providing additional time for firms to develop products that comply with the rule or modify products to comply with the rule. However, delaying the effective date would delay the safety benefits of the rule as well. Additionally, one commenter, Retrospective Goods, LLC, stated that 30 days is adequate for manufacturers and importers to come into compliance with the rule. As such, the Commission did not select this alternative.

X. Paperwork Reduction Act

This rule does not contain a "collection of information" as that term is used in the Paperwork Reduction Act (44 U.S.C. 3501-3521). Therefore, the rule need not be submitted to

the Office of Management and Budget in accordance with 44 U.S.C. 3507(d) and implementing regulations codified at 5 CFR 1320.11.[30]

XI. Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) requires that agencies review rules for their potential economic impact on small entities, including small businesses. Section 604 of the RFA calls for agencies to prepare a final regulatory flexibility analysis, describing the impact of the rule on small entities and identifying impact-reducing alternatives. Further details about the initial regulatory flexibility analysis are available in Tab F of Staff's NPR briefing package, as updated in Tab F of Staff's Final Rule briefing package. Additional information about costs associated with the rule are available in Tab E of Staff's NPR briefing package, as updated in Tab E of Staff's Final Rule briefing package.

A. The need for, and objectives of, the rule.

The rule prohibits the sale or distribution in commerce of subject magnet products that do not meet the specific requirements described in section VII of this preamble. CPSC has received information, as described in section IV of this preamble, regarding the hazards posed by, and growing numbers of injuries with, hazardous magnets in consumer products. These interactions have led to serious injuries and deaths, typically by causing intestinal twisting (volvulus injuries), fistulae, and perforations. Many of these ingestions resulted in surgical removal of magnets and surgical repair of injuries, and others required non-surgical medical interventions, such as emergency endoscopies and colonoscopies.

[30] There is an Office of Management and Budget control number, under the Paperwork Reduction Act, for collection of information regarding third party testing for children's products, addressed in 16 CFR part 1107.

The objective of the rule is to eliminate or reduce the risk of injury to consumers from the ingestion of one or more small, powerful magnets that comprise the subject magnet products, and thereby reduce the future incidence and cost to society of magnet ingestions.

B. Comments on the Initial Regulatory Flexibility Analysis

CPSC received comments from more than 700 parties in response to the NPR. The Commission's responses to comments that address issues that were mentioned in the IRFA are included in section VI.B. of the preamble. None of the comments resulted in changes to the regulatory analysis or regulatory flexibility analysis.

C. Comments from the Chief Counsel for Advocacy of the U.S. Small Business Administration

The U.S. Small Business Administration (SBA) did not file comments on the proposed rule.

D. Small Entities Subject to the Rule

The rule would affect firms or individuals who manufacture, import, and sell subject magnet products. All of the identified importers of magnet sets are small businesses under applicable SBA size standards, and we expect this is also true for manufacturers and importers of other subject magnet products, such as jewelry with loose/separable magnets.

As discussed in section III.B. of the preamble, reviews of the online market for magnet sets from 2018 to July 2021 by CPSC staff and IEc found that the leading internet marketplaces have high turnover rates for magnet set sellers and magnet set products offered on their sites. The most recent review in 2021 found that the great majority of sellers of magnet sets (in terms of distinct firms or individuals, if not unit sales) appeared to sell through their stores operated on the sites of other internet retailer platforms. The dominant business model for importers of magnet sets is expected to be direct sales to consumers using their own internet websites or other

internet shopping sites. However, the rule could also affect some third party retailers of the products, whether selling them online or physically in "brick & mortar" stores, such as bookstores, gift shops, or stores that sell novelty items.

E. Projected reporting, recordkeeping, and other compliance requirements

Section 14(a)(1) of the CPSA requires manufacturers, importers, or private labelers of a consumer product (that is not a children's product) subject to a consumer product safety rule to certify, based on a test of each product or a reasonable testing program, that the product complies with all rules, bans or standards applicable to the product. 15 U.S.C. 2063(a)(1). The rule specifies the procedure to use to determine whether a subject magnet product complies with those requirements. For products that manufacturers certify based on a test of each product or a reasonable testing program, manufacturers would issue a general certificate of conformity (GCC). Section 14(a)(2) of the CPSA, 15 U.S.C. 2063(a)(2), requires manufacturers, importers, or private labelers of any product subject to a children's product safety rule to submit sufficient samples of the children's product, or samples that are identical in all material respects to the product, to a CPSC-accepted, third party conformity body for testing. Based on passing test results from the CPSC-accepted, third party conformity body, the manufacturer, importer, or private labeler issues a Children's Product Certificate (CPC) indicating the children's product is compliant with the children's product safety rule. For example, in the case of subject magnet products that are children's products, such as children's jewelry, the CPC must be based on testing by a CPSC-accepted third party conformity assessment body. The CPC must be furnished to each distributor or retailer of the product and to the CPSC, if requested.

F. Steps taken to minimize significant impact on small entities

Small manufacturers/importers of subject magnet products would likely incur some additional costs to certify that their products meet the requirements of the rule, as required by Section 14 of the CPSA. The certification must be based on a test of each product or a reasonable testing program. CPSC is mandating a performance requirement that duplicates the ASTM F963 Toy Standard approach to addressing magnet internal interaction hazard in children. The current ASTM test to determine flux index is a method that has been used by test labs to determine compliance with the ASTM F963 and in other domestic and international standards for identifying hazardous magnets. The increased costs related to testing should be relatively minor, especially for manufacturers that currently have product testing done for products subject to the requirements in the ASTM F963. As noted above, for subject magnet products that are children's products other than toys, such as children's jewelry, the certification must be based on testing by an accredited third party conformity assessment body, at somewhat higher costs.

As discussed in section VIII of the preamble, the main impact on small businesses of a rule would be the lost income and profits to firms that could not produce, import, and sell noncomplying products in the future. The lost benefits to firms results from producer surplus is a measure of the total revenue of firms selling the magnets, less the total variable costs of production. As predominantly imported products, the variable costs for small businesses handling subject magnet products are mainly the import costs. The producer surplus for magnet sets could average about $5 to $10 per unit, based on an average retail price of $20. A similar relationship could apply to other subject magnet products affected by the rule, such as jewelry with separable magnets.

A few small firms whose businesses focus on sales of magnet products that would not comply with the rule, including some of the firms selling products on their own websites, would

face relatively greater losses in producer surplus. These and other small businesses could respond to the rule by measures such as marketing or incorporating magnets that comply with the rule or increased marketing of products that do not have loose or separable magnets. Such measures could offset losses in producer surplus resulting from firms' inability to continue marketing noncomplying magnet products.

As discussed in the analysis above, all domestic firms that are expected to manufacture or import subject magnet products are small businesses. Therefore, an exemption for small manufacturers/importers is not possible, because all manufacturers/importers that would be subject to the rule are small.

G. Alternatives to the rule

CPSC considered several other alternatives that might reduce the impact of a rule on small businesses, including promulgating an alternative set of requirements for the flux index or size of the magnets; requiring safer packaging; requiring warnings on the packaging and promotional materials; requiring aversive agents on magnets; relying on voluntary standards; delaying the effective date; and taking no action. Each of these alternatives is addressed in section IX of the preamble. All of these alternatives would reduce the expected impact of the rule on small business. However, as discussed in section IX of this preamble, these alternatives would not achieve the same injury reductions as the rule, and their adoption would not result in a rule that adequately addresses the risk of serious injury or death caused by ingestions of magnets from the subject magnet products.

XII. Incorporation by Reference

The rule incorporates by reference ASTM F963-17. The Office of the Federal Register (OFR) has regulations regarding incorporation by reference. 1 CFR part 51. Under these

regulations, in the preamble, an agency must summarize the incorporated material and discuss the ways in which the material is reasonably available to interested parties, or how the agency worked to make the materials reasonably available. 1 CFR 51.5(a). In accordance with the OFR requirements, this preamble summarizes the provisions of ASTM F963-17 that the Commission incorporates by reference in section VII of the preamble.

The standard is reasonably available to interested parties and interested parties can purchase a copy of ASTM F963-17 from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428-2959 USA; telephone: (610) 832-9585; www.astm.org. Once this rule takes effect, a read-only copy of the standard will be available for viewing at no charge on the ASTM website at: https://www.astm.org/READINGLIBRARY/. Interested parties can also schedule an appointment to inspect a copy of the standard at CPSC's Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone: (301) 504-7479; e-mail: cpsc-os@cpsc.gov.

XIII. Testing, Certification, and Notice of Requirements

Section 14(a) of the CPSA includes requirements for certifying that children's products and non-children's products comply with applicable mandatory standards. 15 U.S.C. 2063(a). Section 14(a)(1) addresses required certifications for non-children's products, and sections 14(a)(2) and (a)(3) address certification requirements specific to children's products.

A "children's product" is a consumer product that is "designed or intended primarily for children 12 years of age or younger." *Id.* 2052(a)(2). The following factors are relevant when determining whether a product is a children's product:

- manufacturer statements about the intended use of the product, including a label on the product if such statement is reasonable;

- whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger;
- whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger; and
- the Age Determination Guidelines issued by CPSC staff in September 2002, and any successor to such guidelines.

Id. "For use" by children 12 years and younger generally means that children will interact physically with the product based on reasonably foreseeable use. 16 CFR 1200.2(a)(2). Children's products may be decorated or embellished with a childish theme, be sized for children, or be marketed to appeal primarily to children. *Id*. 1200.2(d)(1).

As discussed in section III of the preamble, some subject magnet products (*e.g.*, children's jewelry) are children's products and some are not. Therefore, this rule requires subject magnet products that are not children's products to meet the certification requirements under section 14(a)(1) of the CPSA and requires subject magnet products that are children's products to meet the certification requirements under sections 14(a)(2) and (a)(3) of the CPSA. The Commission's requirements for certificates of compliance are codified in 16 CFR part 1110.

Non-Children's Products. Section 14(a)(1) of the CPSA requires every manufacturer (which includes importers[31]) of a non-children's product that is subject to a consumer product safety rule under the CPSA or a similar rule, ban, standard, or regulation under any other law enforced by the Commission to certify that the product complies with all applicable CPSC requirements. 15 U.S.C. 2063(a)(1).

[31] The CPSA defines a "manufacturer" as "any person who manufactures or imports a consumer product." 15 U.S.C. 2052(a)(11).

Children's Products. Section 14(a)(2) of the CPSA requires the manufacturer or private labeler of a children's product that is subject to a children's product safety rule to certify, based on testing by a third-party conformity assessment body (*i.e.*, testing laboratory), that the product complies with the applicable children's product safety rule. *Id.* 2063(a)(2). Section 14(a) also requires the Commission to publish an NOR for a testing laboratory to obtain accreditation to assess conformity with a children's product safety rule. *Id.* 2063(a)(3)(A). Because some subject magnet products are children's products, the rule is a children's product safety rule, as applied to those products.

The Commission published a final rule, codified at 16 CFR part 1112, entitled *Requirements Pertaining to Third Party Conformity Assessment Bodies*, which established requirements and criteria concerning testing laboratories. 78 Fed. Reg. 15836 (Mar. 12, 2013). Part 1112 includes procedures for CPSC to accept a testing laboratory's accreditation and lists the children's product safety rules for which CPSC has published NORs. When CPSC issues a new NOR, it must amend part 1112 to include that NOR. Accordingly, in this rule, the Commission amends part 1112 to add this standard for magnets to the list of children's product safety rules for which CPSC has issued an NOR.

Testing laboratories that apply for CPSC acceptance to test subject magnet products that are children's products for compliance with the new rule must meet the requirements in part 1112. When a laboratory meets the requirements of a CPSC-accepted, third party conformity assessment body, the laboratory can apply to CPSC to include 16 CFR part 1262, *Safety Standard for Magnets*, in the laboratory's scope of accreditation on the CPSC website at: www.cpsc.gov/labsearch.

XIV. Environmental Considerations

The Commission's regulations address when CPSC is required to prepare an environmental assessment (EA) or an environmental impact statement (EIS). 16 CFR 1021.5. Those regulations list CPSC actions that "normally have little or no potential for affecting the human environment," and therefore, fall within a "categorical exclusion" under the National Environmental Policy Act (42 U.S.C. 4231-4370h) and the regulations implementing it (40 CFR parts 1500-1508) and do not require an EA or EIS. 16 CFR 1021.5(c). Among those actions are rules that provide performance standards for products. *Id.* 1021.5(c)(1). Because this rule would create performance requirements for subject magnet products, the rule falls within the categorical exclusion, and thus, no EA or EIS is required.

XV. Preemption

Executive Order (EO) 12988, *Civil Justice Reform* (Feb. 5, 1996), directs agencies to specify the preemptive effect of a rule in the regulation. 61 Fed. Reg. 4729 (Feb. 7, 1996), section 3(b)(2)(A). The regulation for subject magnet products is promulgated under the authority of the CPSA. 15 U.S.C. 2051-2089. Section 26 of the CPSA provides that "whenever a consumer product safety standard under this Act is in effect and applies to a risk of injury associated with a consumer product, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a safety standard or regulation which prescribes any requirements as to the performance, composition, contents, design, finish, construction, packaging or labeling of such product which are designed to deal with the same risk of injury associated with such consumer product, unless such requirements are identical to the requirements of the Federal Standard." 15 U.S.C. 2075(a). States or political subdivisions of a state may, however, apply for an exemption from preemption regarding a

consumer product safety standard, and the Commission may issue a rule granting the exemption if it finds that the state or local standard: (1) provides a significantly higher degree of protection from the risk of injury or illness than the CPSA standard, and (2) does not unduly burden interstate commerce. *Id.* 2075(c).

Thus, absent grant of an exemption, the requirements of part 1262 preempt non-identical state or local requirements for subject magnet products designed to protect against the same risk of magnet ingestion.

XVI. Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801-808) states that before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The CRA submission must indicate whether the rule is a "major rule." The CRA states that the Office of Information and Regulatory Affairs determines whether a rule qualifies as a "major rule."

Pursuant to the CRA, this rule does not qualify as a "major rule," as defined in 5 U.S.C. 804(2). To comply with the CRA, CPSC will submit the required information to each House of Congress and the Comptroller General.

XVII. Effective Date

The CPSA requires that consumer product safety rules promulgated under sections 7 and 9 shall take effect at least 30 days after the date the rule is promulgated, but not later than 180 days after the date the rule is promulgated unless the Commission finds, for good cause shown, that an earlier or later effective date is in the public interest and, in the case of a later effective date, publishes the reasons for that finding. 15 U.S.C. 2058(g)(1). The NPR proposed a 30-day effective date after the rule is published in the Federal Register, and no comments were received

in opposition to the effective date.[32] Accordingly, the rule will go into effect **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** and will apply to all non-exempt subject magnet products manufactured after that date.

Under section 14(a)(3), 15 U.S.C. 2063(a)(3), the testing and certificate requirements apply to any children's product manufactured more than 90 days after the Commission has established and published notice of the requirements for accreditation of third-party conformity assessment bodies to assess conformity with a children's product safety rule to which such children's product is submitted. Accordingly, although the effective date of the rule for both children's and non-children's subject magnet products is 30 days after publication of the rule, the effective date for application of 16 CFR part 1112 is 90 days after the publication of the rule. Testing laboratories that meet the requirements of a CPSC-accepted third party conformity assessment body will have 90 days to become accredited to include 16 CFR part 1262, Safety Standard for Magnets, in the scope of the accreditation to test subject magnet products that are children's product for compliance with the new rule. Although all of the subject magnet products must comply with the standard, for children's products such as children's jewelry, that are not currently subject to the mandatory standard under ASTM F963-17, testing laboratories must go through the process of applying for accreditation and obtaining approval to become a CPSC-accepted third party conformity assessment body. We conclude that 90 days provides sufficient time for testing laboratories to apply for and comply with the CPSC's procedures. Accordingly,

[32] The CPSC did not propose an anti-stockpiling provision, but sought comments in the NPR on whether to include one in the rule. No commenter supported inclusion of anti-stockpiling language, and given the absence of record support as well as the relatively brief 30-day effective date period, CPSC finds it unnecessary to provide such a provision in the final rule.

the notice of requirements will go into effect [**INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

XVIII. Conclusion

For the reasons stated in this preamble, the Commission concludes that subject magnet products that do not meet the requirements specified in this rule, and are not exempt from the rule, present an unreasonable risk of injury associated with ingestion of such products. The Commission finds that the rule imposes the least burdensome requirement that prevents or adequately reduces the risk of injury associated with magnet ingestions.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third-party conformity assessment body.

16 CFR Part 1262

Consumer protection, Imports, Incorporation by reference, Safety.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

   Authority: Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008); 15 U.S.C. 2063.

2. Amend § 1112.15 by adding paragraph (b)(52) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule or test method?

* * * * *

(b) * * *

(52) 16 CFR part 1262, Safety Standard for Magnets.

* * * * *

3. Add part 1262 to read as follows:

PART 1262—SAFETY STANDARD FOR MAGNETS

Sec.

Authority: **15 U.S.C. 2056, 2058**

§ 1262.1 Scope, purpose, application, and exemptions.

(a) *Scope and purpose*. This part 1262, a consumer product safety standard, prescribes the safety requirements for a *subject magnet product*, as defined in §1262.2(b). These requirements are intended to reduce or eliminate an unreasonable risk of death or injury to consumers who ingest one or more *hazardous magnets* (as defined in §1262.2(a)) from a *subject magnet product*.

(b) *Application*. Except as provided in paragraph (c) of this section, all *subject magnet products* that are manufactured after [**[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, are subject to the requirements of this part 1262.

(c) *Exemptions.* The following consumer products are exempt from the requirements of this part 1262:

(i) Toys that are subject to 16 CFR part 1250, *Safety Standard Mandating ASTM F963 for Toys*.

(ii) Products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes; and

(iii) Products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes.

§ 1262.2 Definitions.

The following definitions apply for purposes of this part 1262:

(a) *Hazardous magnet* means a magnet that fits entirely within the cylinder described in 16 CFR 1501.4 and that has a flux index of 50 kG^2 mm^2 or more when tested in accordance with the method described in 1262.4.

(b) *Subject magnet product* means a consumer product that is designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contains one or more loose or separable magnets.

§ 1262.3 Requirements.

Each loose or separable magnet in a *subject magnet product* that fits entirely within the cylinder described in 16 CFR 1501.4 must have a flux index of less than 50 kG^2 mm^2 when tested in accordance with the method described in 1262.4.

§ 1262.4 Test procedure for determining flux index.

(a) Select at least one loose or separable magnet of each shape and size in the *subject magnet product*.

(b) Measure the flux index of each selected magnet in accordance with the procedure in section 8.25.1 through 8.25.3 of ASTM F963-17, *Standard Consumer Safety Specification for Toy Safety*, approved on May 1, 2017. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959; phone: (610) 832-9585; www.astm.org. A read-only copy of the standard is available for viewing on the ASTM website at https://www.astm.org/READINGLIBRARY/. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814, telephone (301) 504-7479, email: cpsc-os@cpsc.gov, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html.

§ 1262.5 Findings.

(a) *General*. Section 9(f) of the Consumer Product Safety Act (15 U.S.C. 2058(f)) requires the Commission to make findings concerning the following topics and to include the findings in the rule.

(b) *Degree and nature of the risk of injury.* (1) The standard is designed to reduce the risk of death and injury associated with magnet ingestions. There were an estimated 25,000 magnet ingestions that were treated in hospital EDs from January 1, 2010, through December 31, 2021. There were an estimated 5,000 magnet ingestions treated in U.S. hospital EDs between January 1, 2010, and December 31, 2021, that involved in-scope identified subject magnet products, and an additional estimated 20,000 ED-treated magnet ingestions involving unidentified magnet products, which are likely to have involved subject magnet products. There were an estimated 2,500 ED-treated ingestions of magnets from in-scope identified subject magnet products in 2021, higher than the majority of the preceding years, including 2018 through 2020. In this same period, January 1, 2010, through December 31, 2021, there were an estimated 286 CPSRMS-reported magnet ingestions involving in-scope identified subject magnet products and 76 CPSRMS-reported magnet ingestions involving unidentified subject magnet products. In addition, based on NEISS annual estimates from 2017-2021, ICM showed that there were an additional estimated 263 magnet ingestion injuries per year involving in-scope identified subject magnet products, which were treated in medical settings other than EDs (185 injuries treated outside of hospitals and 78 resulted in direct hospital admission).

(2) The potential injuries when a child or teen ingests one or more hazardous magnets are serious. Health threats posed by hazardous magnet ingestion include pressure necrosis, volvulus, bowel obstruction, bleeding, fistulae, ischemia, inflammation, perforation, peritonitis, sepsis, ileus, ulceration, aspiration, and death, among others. These conditions can result from magnets attracting to each other through internal body tissue, or a single magnet attracting to a ferromagnetic object. CPSC is aware of serious injuries and several fatal magnet ingestion incidents that occurred in the United States, resulting from internal interaction of magnets.

(c) *Number of consumer products subject to the rule.* The CPSC estimates that there are approximately 500,000 subject magnet products sold annually in the United States. However, to account for a range of sales estimates, staff provided information for sales ranging from 100,000 to 1 million units annually.

(d) *The need of the public for subject magnet products and the effects of the rule on their cost, availability, and utility.* (1) Consumers use subject magnet products for entertainment, mental stimulation, stress relief, and jewelry. The rule requires subject magnet products to meet performance requirements regarding size or strength, but it does not restrict the design of products. As such, subject magnet products that meet the standard can continue to serve the purpose of amusement or jewelry for consumers. Magnets that comply with the performance requirements of the rule, such as non-separable magnets, larger magnets, weaker magnets, or non-permanent magnets, may be useful for amusement or jewelry. However, it is possible that there may be some negative effect on the utility of subject magnet products if compliant products function differently or do not include certain desired characteristics.

(2) Retail prices of subject magnet products generally average under $20. CPSC has identified subject magnet products that comply with the rule, and the prices of compliant and non-compliant products are comparable.

(3) If the costs associated with redesigning or modifying subject magnet products to comply with the rule results in manufacturers discontinuing products, there may be some loss in availability to consumers. However, this would be mitigated to the extent that compliant products meet the same consumer needs, and there are compliant products currently available for sale to consumers.

(4) Manufacturers may sell complying products to mitigate costs. In addition to products that comply with the performance requirements, there are products that are exempt from the performance requirements. Products that are manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets are exempt from the rule, unless they are also designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes. In addition, products that are manufactured, sold, and/or distributed solely for home use, such as hardware magnets, are exempt from the rule unless they are also designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes.

(e) *Other means to achieve the objective of the rule while minimizing adverse effects on competition, manufacturing, and commercial practices.* The Commission considered other alternatives that might reduce the impact of a rule on small businesses, including promulgating an alternative set of requirements for the flux index or size of the magnets; requiring safer packaging; requiring warnings on the packaging and promotional materials; requiring aversive agents on magnets; relying on voluntary standards; delaying the effective date; and taking no action. Although each of the alternative actions would have lower costs and less impact on small business, none is likely to significantly reduce the injuries associated with ingestion of magnets from subject magnet products.

(f) *Unreasonable risk.* (1) Incident data indicate that there were an estimated 25,000 magnet ingestions treated in U.S. hospital EDs from January 1, 2010, to December 31, 2021, which involved in-scope identified subject magnet products. Of these estimated 25,000 ED-treated magnet ingestions, an estimated 5,000 involved in-scope identified subject magnet

products, and an estimated 20,000 involved "unidentified" magnet product types that, based on incident data and factors considered by the Commission, are likely to be subject magnet products. During 2017 through 2021, based on the NEISS annual estimate of about 481 magnet injuries initially treated in hospital EDs involving in-scope identified magnets, there were 320 injuries that were treated and released and 161 injuries that required hospitalization. Additionally, based on estimates from the ICM, 185 injuries were treated outside of hospitals annually and another 78 injuries resulted in direct hospital admission. These incidents indicate the frequency with which children and teens ingest magnets, and the need to address the magnet ingestion hazard.

(2) The potential injuries when a person ingests one or more magnets are serious. Health threats posed by magnet ingestion include pressure necrosis, volvulus, bowel obstruction, bleeding, fistulae, ischemia, inflammation, perforation, peritonitis, sepsis, ileus, ulceration, aspiration, and death, among others. These conditions can result from magnets attracting to each other through internal body tissue, or a single magnet attracting to a ferromagnetic object. Magnet ingestion incidents commonly result in hospitalization, particularly when subject magnet products are ingested. The Commission is aware of serious injuries as well as five fatal magnet ingestion incidents that occurred in the United States between November 24, 2005, and January 5, 2021. Four of these incidents involved children 2 years old or younger, and all five victims died from injuries resulting from internal interaction of the magnets. Four of the five incidents identified the products as magnet sets, amusement products, or described them as having characteristics that are consistent with subject magnet products.

(3) CPSC's trend analysis of the incident data indicates that magnet ingestions have significantly increased in recent years. In 2014, Commission issued a rule that applied to magnet

sets, which are a subset of the subject magnet products addressed in this rule. The 2014 magnet sets rule took effect in April 2015 and remained in effect until it was vacated and remanded by the U.S. Court of Appeals for the Tenth Circuit Court in November 2016. *Zen Magnets, LLC v. Consumer Prod. Safety Comm'n.*, 841 F.3d 1141 (10th Cir. 2016). ED-treated ingestions of magnets from subject magnet products continued to rise since the 2014 magnets set rule was vacated. A review of the annual estimates for ED-treated, magnet ingestions by year, from 2010 through 2021 showed that magnet ingestions are higher for the 2017 through 2021 period, than the previous periods, with more in-scope magnet ingestions in 2021 (2,500) than most of the preceding years, including 2018 through 2020. To assess these trends further, CPSC grouped the years in relation to the vacated 2014 magnet sets rule, using three separate periods. CPSC reviewed the magnet ingestions treated in U.S. hospital EDs for the periods 2010 through 2013 (years prior to the announcement of the 2014 magnet sets rule), 2014 through 2016 (years when the 2014 magnet sets rule was announced and in effect), and 2017 through 2021 (years after the magnet set rule was vacated). For 2010-2013, there were approximately 2,300 ED-treated magnet ingestion incidents per year; for 2014-2016, there were an approximately 1,300 ED-treated magnet ingestion incidents per year; for 2017-2021, there were approximately 2,400 ED-treated magnet ingestion incidents per year. Thus, during the period when the 2014 magnet sets rule was announced and in effect (2014-2016), magnet injury ingestion estimates are lowest by a significant margin, compared with the earlier and more recent periods. CPSRMS data also showed a similar decline in incidents for the period when the magnet sets rule was announced and in effect. CPSC's assessment of incident data, as well as other researchers' assessments of NEISS data, and national poison center data, all indicated that magnet ingestion cases

significantly declined during the years when the 2014 magnet sets rule was announced and in effect, compared to the periods before and after the 2014 magnet sets rule.

(4) For these reasons, the Commission finds that the rule is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with the product.

(g) *Public interest.* This rule is intended to address an unreasonable risk of injury and death posed by magnet ingestions. The Commission finds that compliance with the requirements of the rule will significantly reduce magnet ingestion deaths and injuries in the future; thus, the Commission finds that promulgation of the rule is in the public interest.

(h) *Voluntary standards.* (1) The Commission is aware of six relevant standards, four domestic and two international, that address the magnet ingestion hazard. One standard is mandatory, ASTM F963-17, *Standard Consumer Safety Specification for Toy Safety.* The other voluntary standards include: ASTM F2923-20, *Standard Specification for Consumer Product Safety for Children's Jewelry*; ASTM F2999-19, *Standard Consumer Safety Specification for Adult Jewelry*; ASTM F3458-21, *Standard Specification for Marketing, Packaging, and Labeling Adult Magnet Sets Containing Small, Loose, Powerful Magnets (with a Flux Index ≥ 50 kG^2 mm^2)*; EN-71-1: 2014, *Safety of Toys; Part 1: Mechanical and Physical Properties*; and ISO 8124-1: 2018, *Safety of Toys — Part 1: Safety Aspects Related to Mechanical and Physical Properties*.

(2) The Commission finds that compliance with existing standards is not likely to result in the elimination or adequate reduction of the risk of injury associated with ingestion of subject magnet products.

(i) *Relationship of benefits to costs.* (1) CPSC estimates that aggregate annual societal costs from ingestion injuries involving subject magnet products for 2017 through 2021 totaled $51.8 million, even when ingestion injuries involving unidentified magnet products are excluded. The expected costs of the rule include the lost value experienced by consumers who would no longer be able to purchase subject magnet products with loose or separable hazardous magnets, as well as the lost profits to firms that could not produce and sell non-complying products in the future. Estimates of consumer and producer surplus range from about $2 million – $3.5 million to about $20 million – $35 million, based on unit sales ranging from 100,000 to 1 million. If annual unit sales of non-complying subject magnet products are 500,000, expected aggregate benefits from the rule would total $51.8 million annually as noted above; costs (lost consumer and producer surplus) would range from $10 million to $17.5 million annually. Thus, the benefits of the rule would greatly exceed the costs.

(2) If unidentified magnet products involved in ingestion injuries, which are also likely to be subject magnet products, are considered as well, average annual societal costs for 2017 through 2021 would increase by $167.9 million. A sensitivity analysis shows that adding even a relatively small portion of NEISS cases involving unidentified magnet products to the base case substantially increases the estimated gross benefits of the rule. Although CPSC's analysis of the data, the trends in NEISS, CPSRMS, and poison center-reported, magnet-related incidents all support the conclusion that the unidentified magnet products generally involved magnets considered within the scope of the rule, because CPSC does not know precisely how many of these products would fall within the scope of this rule, CPSC has not included them in the primary benefit analysis. Instead, CPSC includes the benefits from unidentified magnet products in this final rule's sensitivity analysis to illustrate the theoretical upper bounds of benefits from

this rule. Theoretically, including 100 percent of these societal costs with those estimated for identified subject magnet products ($51.8 million) could yield average annual societal costs of magnet ingestion injuries of $219.7 million for the period 2017 through 2021.

(j) *Least burdensome requirement that would adequately reduce the risk of injury.* CPSC considered several less-burdensome alternatives to the proposed rule.

(1) One alternative is to take no regulatory action and, instead, rely on existing standards to address the magnet ingestion hazard. This alternative would reduce the burden associated with the rule by avoiding a mandatory standard, but it is unlikely to adequately address the magnet ingestion hazard due to the limited scope and requirements of existing standards and uncertainty regarding compliance with them.

(2) Another alternative is a mandatory standard with less stringent requirements than the proposed rule, such as a higher flux index limit, or different requirements for certain shapes and sizes of magnets. This could reduce the burden associated with a rule by allowing firms to market a wider variety of products than under the proposed rule. However, this alternative would reduce the safety benefits because allowing certain hazardous magnets in subject magnet products to remain on the market does not address the hazard such products pose.

(3) Safety messaging is another alternative to the rule. This alternative would reduce the burdens associated with the rule because it would not require modifying or discontinuing subject magnet products, and the costs of such warnings and instructional information likely would be small. However, this alternative is not likely to adequately reduce the magnet ingestion hazard. Incident data shows children commonly access ingested magnets from sources that do not include the product packaging where warnings are provided. Incident data, behavioral and developmental factors, and other information indicate that children and caregivers commonly

disregard safety messaging regarding the magnet ingestion hazard. Finally, this approach has not been effective at adequately reducing the hazard, to date.

(4) Another alternative is to require special packaging to limit children's access to subject magnet products. Although this alternative would create some packaging costs, those costs likely would be lower than the costs of the rule because this alternative would allow subject magnet products to remain unchanged. However, this alternative is not likely to adequately reduce the risk of injury and death associated with magnet ingestions. Consumers are unlikely to repackage all magnets after each use, given the small size and large number of magnets in products, the potential to lose magnets, and consumers' underappreciation of the hazard. In addition, commercially reasonable packaging requirements would only prevent young children (typically, children under 5 years old) from accessing the product, not older children, or teens, who are involved in the majority of magnet ingestion incidents.

(5) Another alternative is to require subject magnet products to be coated with aversive agents. This alternative would reduce the burden associated with the rule because it would allow firms to continue to sell subject magnet products and the costs of such coatings likely would be small. However, such requirements are not likely to adequately address the hazard because they do not address ingestions that occur when the first magnet is placed in the victim's mouth, before the aversive agent is detected, accidental ingestions, or children who are developmentally inclined to place objects in their mouths.

(6) Another alternative is to provide a later effective date for the final rule. This may reduce the burdens associated with the rule by spreading them over a longer period, but it would also delay the safety benefits of the rule.

(7) For these reasons, the Commission finds that the rule imposes the least burdensome requirement that prevents or adequately reduces the risk of injury associated with magnet ingestions.

_____

Alberta E. Mills,
Secretary,
Consumer Product Safety Commission

United States
Consumer Product Safety Commission

Staff Briefing Package

Draft Final Rule for Magnets

August 17, 2022

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This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

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Briefing Memorandum

This document has been electronically approved and signed.

TO: The Commission

Alberta E. Mills, Secretary

DATE: August 17, 2022

THROUGH: Austin C. Schlick, General Counsel

Jason Levine, Executive Director

DeWane Ray, Deputy Executive Director for Operations

FROM: Duane E. Boniface, Assistant Executive Director,
Office of Hazard Identification and Reduction

Stephen Harsanyi, Project Manager,
Division of Human Factors,
Directorate for Engineering Sciences

SUBJECT: Staff's Draft Final Rule for Magnets

Introduction

On January 10, 2022, the U.S. Consumer Product Safety Commission (CPSC, Commission) published a notice of proposed rulemaking (NPR), proposing to issue a safety standard for magnets under the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089; 87 FR 1260) and seeking public comments.[1] The draft final rule would address the unreasonable risk of serious injury associated with the ingestion of small, powerful magnets (hazardous magnets) by children and teens.[2] Ingestion of hazardous magnets has led to deaths and severe injuries from the magnets interacting internally through body tissue (internal interaction hazard) and resisting natural bodily forces to separate. Under the draft final rule, each loose or separable magnet in certain products (subject magnet products) would be required to meet the following criteria: (1) be too large to fit entirely within the small parts cylinder described in 16 CFR 1501.4[3]; or (2) have a flux index of less than 50 $kG^2\,mm^2$, as measured by the procedures for determining the magnetic attractive force described in ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, which is codified under 16 CFR part 1250.

CPSC staff's briefing package for the draft final rule provides updated analyses of magnet ingestion incident data received since the data extraction for the NPR; updated analysis of

[1] Commission NPR on magnets (2022): https://www.govinfo.gov/content/pkg/FR-2022-01-10/pdf/2021-27826.pdf.
[2] Staff identifies a magnet as hazardous consistent with ASTM F963 as a magnet that fits entirely within the cylinder described in 16 CFR 1501.4 and that has a flux index of 50 $kG^2\,mm^2$ or more when tested in accordance with the method described in the proposed part 1262.
[3] The small parts cylinder referenced in the proposed rule is specified in 16 CFR part 1501—Method for Identifying Toys and Other Articles Intended for Use by Children Under 3 Years of Age Which Present Choking, Aspiration, or Ingestion Hazards Because of Small Parts.

methods to address the hazard; summaries of public comments about the proposed rule and staff's responses to public comments; CPSC's recall activity; staff's recommendations for the final rule; and economic implications of the hazard and draft final rule. Staff provides overviews of the NPR and these updated analyses and presents the draft final rule in this document.

Discussion

Overview of NPR

The Commission's NPR on magnets proposed a rule under sections 7 and 9 of the Consumer Product Safety Act to address the internal interaction hazard associated with the ingestion of hazardous magnets by children and teens. The NPR identifies as hazardous, consistent with ASTM F963 and various international standards and prohibitions,[4] magnets that are both small enough to fit entirely within the small parts cylinder, and have a magnetic flux index of 50 kG^2 mm^2 or higher. Hazardous magnets are small enough to be ingested and strong enough to cause injury from interacting internally through body tissue. When ingested, two or more hazardous magnets, or hazardous magnet(s) and ferromagnetic object(s), pose risks of death and nonfatal acute- and long-term adverse health consequences from volvulus, fistulae, perforations, and other internal interaction injuries. Medical management of magnet ingestions also presents risks of injury, from diagnostics (*e.g.,* radiation from serial imaging) and treatments (*e.g.,* infections and other complications from surgery). To date, staff is aware of seven deaths associated with the ingestion of hazardous magnets, four that occurred in the United States and that likely involved hazardous magnets from magnet products subject to the proposed rule (see the NPR briefing package).

Based on NEISS reports of emergency department-treated ingestions of magnets that occurred from January 1, 2010, through December 31, 2020, staff estimated 23,700 emergency department-treated ingestions of magnets; 22,500 of these ingestions involved in-scope[5] magnet products. In examining magnet ingestion data from the National Electronic Injury Surveillance System (NEISS),[6] CPSC's Consumer Product Safety Risk Management System (CPSRMS),[7] and national poison control centers,[8] staff and other researchers concluded that

[4] There are other standards, including the European standard, EN 71-1:2014, *Safety of Toys; Part 1: Mechanical and Physical Properties*, and ISO 8124-1:2018, *Safety of Toys — Part 1: Safety Aspects Related to Mechanical and Physical Properties*, which align with ASTM F963 regarding the identification and prohibition of hazardous magnets. Detailed in the NPR briefing package, other countries, such as Canada, Australia, New Zealand, and member states of the European Commission have prohibitions identifying hazardous magnets consistent with these standards.

[5] Discussed further below, and in the NPR briefing package, staff uses the term "in-scope products" to refer to cases involving magnet products categorized by staff as "amusement/jewelry" or unidentified magnet products, *i.e.,* products that are likely subject to the draft final rule, based on staff's analysis of NEISS, CPSRMS, and poison center data. Staff excluded from this grouping known out-of-scope products, such as science kits, F963 magnet toys, and home/kitchen products, which would not be subject to the draft final rule.

[6] Data from NEISS are based on a nationally representative probability sample of about 100 hospitals in the United States and its territories.

[7] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS include the following: hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others.

[8] As discussed in the NPR briefing package, Middelberg et al. (2021) found that annual national poison center magnet exposure calls increased by 344 percent from 281 per year (2012–2017) to 1,249 per year (2018–2019). Considering incidents dating back to 2008 (5,738 total), the incidents from 2018 and 2019, alone, accounted for 39 percent of the magnet incidents since 2008. These researchers drew similar conclusions to CPSC staff, asserting that significant increases in magnet injuries correspond to time periods in which high-powered magnet sets were allowed to be sold.

the 2015 magnet set rule (79 FR 59962),[9,10] was effective in reducing magnet ingestion incidents. Staff estimated in the NPR 2,300 emergency department-treated ingestions of in-scope magnets *annually* from 2010 through 2013 (years prior to the announcement of the magnet set rule), 1,300 from 2014 through 2016 (years the rule was announced and in place), and 2,300 from 2017 through 2020 (the years following the removal of the rule). These trends indicate that it is likely a substantial proportion of magnet ingestions in this time period involved magnet sets, which constitute the largest portion of identified subject magnet products involved in magnet ingestion incidents. The previous rule for magnet sets had similar magnet size and strength requirements to the current proposed rule for subject magnet products.[11]

Under the proposed rule, each loose or separable magnet in the subject magnet products would be required to meet the following criteria:

> (1) be too large to fit entirely within the small parts cylinder described in 16 CFR 1501.4 (*i.e.,* too large to be swallowed by children); or
>
> (2) have a flux index of less than 50 $kG^2 mm^2$ (*i.e.,* weak enough that they are less likely to cause internal interaction injuries).

These magnet size and strength requirements were based on ASTM F963, which was developed by consensus of experts in the field for children's toys and incorporated in international standards and foreign regulations (discussed below). Staff concluded that specifying this limit of "less than 50" will likely result in manufacturers designing magnets to have a flux index below the specified limit because manufacturers may need to fabricate magnets a sufficient amount below the limit to account for manufacturing variance. The NPR identifies the subject magnet products as consumer products designed, marketed, or intended to be used by consumers for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contain one or more loose or separable magnets. Figure 1, below, provides examples of the subject magnet products. Children's toys subject to the requirements in ASTM F963 are exempt from the proposed rule because they are already required to comply with ASTM F963.[12] The NPR identifies other products that also do not meet the criteria for the subject magnet products, including home, education, research, commercial, and industrial uses (described in more detail below).

[9] The CPSC rule regarding magnet sets went into effect on April 1, 2015. See CPSC staff's briefing package: Final Rule on Safety Standard for Magnet Sets (2014): https://cpsc.gov/s3fs-public/pdfs/foia_SafetyStandardforMagnetSets-FinalRule.pdf for more information about the rule.

[10] Staff defines "magnet set" as an aggregation of separable magnetic objects that are marketed or commonly used as manipulative or construction items for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. These products often include hundreds to thousands of loose, hazardous magnets.

[11] The final rule for magnet sets included requirements limiting the size and strength of magnets, similar to the requirements in the NPR; that is, magnets in magnet sets were required to be too large to fit entirely within the small parts cylinder or required to have a flux index of 50 $kG^2 mm^2$ or less, consistent with the 2011 version of ASTM F963.

[12] ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, is codified under 16 CFR part 1250. See https://www.ecfr.gov/current/title-16/chapter-II/subchapter-B/part-1250.

Figure 1. Examples of a magnet set (left), an executive desk toy decompression magnet pen (middle-left), rock magnet toy marketed to adults (middle-right), and a magnetic jewelry set (right).

In support of the proposed rule, the NPR briefing package analyzed, among other topics: magnet ingestion incident data, product evaluations, available literature, voluntary standards, international actions, measures to address the hazard, CPSC Compliance efforts, and staff's benefit-cost analysis of the hazard and proposed rule. Staff determined that the subject magnet products carry the highest risk for children and teens ingestion-related outcomes, that alternative options to reduce risk are inadequate without performance requirements for magnets themselves, and that the benefits of the proposed rule are projected to exceed the costs. The benefits include reducing the risk of death and serious injury to children and teens, as reflected in the reduction in societal costs, which staff estimated to be about $47.6 million annually during the 4-year period since the 2014 rule was vacated (2017–2020), excluding cases involving unidentified magnet products. The expected costs of the proposed rule would consist predominantly of the lost utility to consumers because they would no longer be able to purchase and use non-complying subject magnet products, and the lost income of producers and sellers who would no longer be able to produce and sell non-complying subject magnet products. Staff estimated the costs to range from $10 million to $17.5 million. Staff estimated the average annual societal costs for cases involving unidentified magnet products could amount to $151.8 million, over and above the annual $47.6 million costs for identified subject magnet products. Based on factors, including (1) the known products involved in magnet ingestion incidents (*i.e.,* of the known products involved in magnet ingestion incidents, the subject magnet products constitute a much larger proportion of the cases than the excluded products, particularly when considering cases that resulted in surgery); (2) the success of ASTM F963 in reducing the number of children's toys involved in magnet internal interaction injuries; and (3) incidences of NEISS-, CPSRMS-, and poison center-reported magnet ingestions relative to the vacated rule on magnet sets, staff concluded that magnet ingestions involving unidentified magnet products generally involved products that would be covered by the proposed rule. Therefore, the estimated average annual societal costs associated with the subject magnet products could be substantially higher than the $47.6 million estimated above.

Updated Incident Data Analysis

In this briefing package, staff refers to the incident data analyzed for the NPR as "NPR data," and refers to the additional incident data analyzed since the NPR as "since the NPR." The data since the NPR were extracted on January 13, 2022, and include these updates analyzed for the NPR:

(1) addition of 112 NEISS-reported incidents that occurred from January 1, 2021, through December 31, 2021, and

(2) 111 additional CPSRMS-reported incidents that occurred from February 1, 2016, through December 27, 2021.[13]

Tab A is Health Sciences' analysis of the incident data since the NPR, magnet ingestion literature, and comments from medical associations and individual medical practitioners. Staff details numerous examples of magnet ingestion incidents that demonstrate the potential severity of injury, ambiguity of symptomatology, and complex medical management of magnet ingestions. Staff details how even less invasive procedures, such as endoscopies, have inherent risks, such as adverse cardiopulmonary events from sedation and anesthesia, and perforation from procedure instruments. Among other important considerations, staff explains that X-rays, which are typically one of the first diagnostic steps, cannot identify an ingested object as a magnet, and cannot show if tissue is trapped between magnets. Staff concluded that the magnet internal interaction hazard and associated injury mechanism remain unchanged since publication of the NPR, and staff affirms its previous analysis.

Tab B is the Epidemiology incident data analysis of magnet ingestions, including a comparative analysis between the NPR data and data since the NPR. Since the NPR, staff estimates 26,600 magnet ingestions were treated in hospital emergency departments from January 1, 2010, through December 31, 2021, comprising an estimated 25,000 ingestions involving in-scope products. Staff observed that the additional data affirmed staff's previous analysis, among other results, demonstrating that estimated emergency department-treated ingestions of magnets from in-scope products continued to rise since the previous rule pertaining to magnet sets was vacated. Staff estimates 2,500 emergency department-treated ingestions of magnets from in-scope products occurred in year 2021, higher than the majority of the preceding years, including 2018 through 2020. An estimated 5,000 (20% of 25,000) victims were hospitalized or transferred to another hospital from 2010 through 2021. As a comparison, for the same timeframe, injuries from all toys (combined) had a hospitalization rate of less than 5 percent.[14] For the period of 2017 through 2021, staff estimates 2,400 ED-treated magnet ingestion incidents per year; higher than the annual estimates for the abovementioned periods of 2010 through 2013 (2,300) and 2014 through 2016 (1,300). The NEISS reports capture one part of the treatment process (the emergency department visit), and they typically do not show information on treatment after the initial visit. Additionally, patients complaining of magnet ingestion initially may be sent home to monitor for natural passage. Therefore, it is possible the number of victims ultimately hospitalized or transferred in 2021 is greater than staff estimated.

In examining CPSRMS data from this 12-year period, staff identified 395 magnet ingestions. Of these, 111 were reported since the NPR, including 56 magnet ingestions that occurred in 2021. While the CPSRMS reports are anecdotal, and, therefore, cannot be used for generating nationally representative estimates, they provide a minimum number of incidents and tend to include more information about the incidents and products involved, in comparison to the NEISS data. CPSRMS reports may contain photos, links to websites, detailed narratives, and medical documents; whereas NEISS reports contain brief narratives culled from medical records developed during the emergency department visit. Staff analyzed the CPSRMS reports for information pertaining to medical management and evidence of internal interaction of ingested

[13] The CPSRMS data analyzed in support of the NPR were extracted on January 8, 2021. Reporting to the CPSRMS database is ongoing, and therefore, it is common for reports to be received pertaining to incidents from prior years. This also means CPSC in the coming years may receive additional CPSRMS reports of magnet ingestions within the studied period, particularly 2021.
[14] Source: CPSC NEISS On-Line Query System | CPSC.gov. NEISS Data Highlights - Calendar Years 2010 through 2021. https://www.cpsc.gov/cgibin/NEISSQuery/home.aspx

magnets through body tissue. Staff found that at least 167 CPSRMS-reported magnet ingestions (including 43 incidents since the NPR) resulted in surgery, such as laparoscopy, laparotomy, appendectomy, cecostomy, enterotomy, colostomy, cecectomy, gastrotomy, jejunostomy, resection, and transplant, among others. At least 140 CPSRMS-reported magnet ingestions resulted in internal interaction through body tissue (including 32 incidents since the NPR). In cases that did not result in surgery, it was still common for victims to receive serial X-rays, and in many cases, endoscopies and anesthesia. Staff observed that the additional data affirmed staff's previous analysis that estimated emergency department-treated ingestions of magnets from in-scope products continued to rise since the court vacated the previous rule on magnet sets.

Tab C is the Human Factors updated assessment of the products involved in magnet ingestion incidents, victims' ages, behavioral patterns, sources of access, use of safety messaging, and other pertinent information. Overall, staff found that the additional data affirmed staff's previous findings, which indicates that safety messaging and safeguards, absent size and strength limits, are inadequate measures to address the magnet internal interaction hazard. Ultimately, staff remains concerned that consumers are unlikely to anticipate and appreciate the nature and severity of the hazard, particularly as it often involves children and teens who do not have a history of swallowing inedible objects; and, for numerous reasons, caregivers are unable to prevent the hazard. Staff concludes that the data since the NPR are similar to the NPR data, including that magnet ingestions for which product identification was uncertain, generally involved magnets from the subject magnet products. At least 57.7 percent (64) of the CPSRMS-reported incidents since the NPR involved magnet sets, compared to 47.2 percent (134) in the NPR data. In both NEISS and CPSRMS datasets, staff again observed that products identified as out-of-scope constituted the lowest proportion of products involved in ingestions. None of the CPSRMS-reported incidents indicated that surgery or internal interaction resulted from out-of-scope ingestions, similar to the NPR data, which identified only a small number of out-of-scope products that resulted in surgery or internal interaction.

Assessment of Existing Standards

As discussed in the NPR briefing package, staff identified four domestic standards with relevant requirements for magnets in consumer products:

1. ASTM F963 – 17, *Standard Consumer Safety Specification for Toy Safety*
2. ASTM F2923 – 20, *Standard Specification for Consumer Product Safety for Children's Jewelry*
3. ASTM F2999 – 19, *Standard Consumer Safety Specification for Adult Jewelry*
4. ASTM F3458 – 21, *Standard Specification for Marketing, Packaging, and Labeling Adult Magnet Sets Containing Small, Loose, Powerful Magnets (with a Flux Index ≥50 kG^2 mm^2)*.

Tabs C and D explain that there were no changes in the magnet requirements specified in these standards since the NPR, and staff continues to find these standards inadequate to address the magnet internal interaction hazard associated with the subject magnet products. These standards and their shortcomings are explained in the NPR briefing package. Staff's main concerns are as follows:

- ASTM F963 is specific to children's toys, and therefore, it excludes the products subject to the draft final rule.
- ASTM F2923, F2999, and F3458 are specific to several subsets of the subject magnet products (*i.e.,* children's jewelry, adult jewelry, and adult magnet sets); however, they exclude other magnet products subject to the draft final rule.
- ASTM F2923 includes magnet size and strength requirements consistent with the proposed rule, but only for certain jewelry intended for children under 8 years of age.
- ASTM F2999 and F3458 address the magnet internal interaction hazard only with requirements for safety messaging and/or packaging, which are inadequate to address the hazard.

Staff's review indicates that ASTM F963 adequately addresses the magnet internal interaction hazard associated with children's toys. Staff was able to identify only a small proportion of incidents involving children's toys subject to ASTM F963 in the 2010 through 2021 incident data. The few cases that resulted in internal interaction of hazardous magnets from children's toys involved, or likely involved, recalled products. Due to ambiguities in incident data, and the recency of ASTM F3458 – 21, it is unclear to what extent manufacturers comply with ASTM F2923, F2999, and F3458.

Tab C discusses the general limitations of safety messaging and the factors specific to the subject magnet products that impede the likelihood of the safety messaging being seen, read, understood, and followed consistently. Staff explains that consumers are likely to have a common perception of low risk regarding the subject magnet products, and they often misunderstand the magnet internal interaction hazard.[15] In addition, staff notes that safety messaging, including public awareness-raising efforts, have been inadequate to protect children and teens from the hazard. Due to a number of factors, like the inability of caregivers to provide constant supervision and manage common sources of access to hazardous magnets, consumers may be unable to avoid the hazard, even if they are aware of the hazard and actively try to prevent it.[16] Similarly, there are limitations for packaging features, such as child-resistant (CR) features and visual verification of a full set of magnets. Staff explains that the majority of the magnet ingestion victims have been over the ages protected by CR features, adding that collecting and repackaging the magnets after every use is unlikely for the subject magnet products. In addition, staff notes, the incident data show magnets are often acquired without their packaging. Staff also identified limitations for aversive agents, such as bitterants, which may not be detected by children prior to ingestion, and may not deter swallowing by children who do detect the aversive agents.

Regarding ASTM F3458, following publication of ASTM F3458 – 21, the relevant subcommittee, on magnets, ASTM F15.77, resumed meetings on May 25, 2021. In the first meeting, the subcommittee decided by a vote (15 in favor, and 3 opposed) to form a task group to work on performance requirements for ASTM F3458. The task group last met in November 2021, and, to date, the standard still does not have performance requirements to prevent hazardous magnets from being used in magnet sets.

[15] Evidenced in incident reports and in public comments, many consumers misunderstand the mechanism of injury (internal interaction versus choking), the likelihood of magnet ingestion, and the progression of symptoms.
[16] For example, one report indicates that in June 2021, a 17-month-old victim swallowed magnets from a magnet set purchased for the victim's 10-year-old sibling. The magnet set had clear warnings about the hazard, instructions with warnings, and an age label for 14 years and older. The magnets were stored on a high shelf to keep them away from the victim and other young siblings. The victim's 5-year-old sibling still was able to acquire the magnets and share them with the victim, resulting in the victim swallowing the magnets. The victim underwent surgery to repair perforations caused by the magnets.

Relevant Prohibitions in Other Countries

The NPR briefing package discussed approaches taken by other countries to address the magnet internal interaction hazard. Staff explained that prohibitions and best practices in Canada, Australia, New Zealand, and member states of the European Commission align closely with the NPR, including identical size and strength requirements for magnets. However, these prohibitions vary regarding product scope beyond children's toys and magnet sets. These prohibitions have not changed since the analysis provided in the NPR. Staff received public comments, discussed below, which pertain to Canada's prohibitions. Additionally, staff continues to work with foreign regulators to understand and address the hazard. For example, members of the Consumer Affairs Agency of Japan (CAA) have expressed their concerns to CPSC staff about Japanese citizens ingesting hazardous magnets, and recently, the CAA published multiple reports on the subject.[17]

Compliance Enforcement Activities

Tab G provides an update of CPSC enforcement activities for the period January 1, 2010, through May 25, 2022. In total, CPSC conducted 20 recalls involving hazardous magnets, including two recalls, both involving magnet sets, since the analysis for the NPR. Of the 20 recalls, only five recalls did not apply to subject magnet products, four of which involved ASTM F963 toys. As discussed in the NPR briefing package, from 2006 through 2009, CPSC issued more than a dozen recalls of children's toys due to hazardous magnets not being adequately contained within children's toys, making them accessible for children to swallow.[18] There were substantially fewer recalls of children's toys for violations of the magnet requirements specified in ASTM F963 from 2010 onward, because ASTM F963 has been effective in addressing the magnet internal interaction hazard for children's toys. Additionally, Compliance has worked with third-party online platforms to promote continuous monitoring of listings and proactive voluntary removal of violative magnet set listings from platforms, such as those marketing for children magnet sets with hazardous magnets.

Public Comments on the NPR

The Commission's NPR requested comments from the public on all aspects of the proposed rule, including the scope and definitions, performance requirements, safety messaging and packaging requirements, existing standards, staff's benefit-cost analysis, and the effective date of the rule. CPSC received 713 comments on the NPR during the public comment period, which closed on March 28, 2022, and we received three additional comments after the period closed. Additionally, on March 2, 2022, CPSC held an oral hearing on the proposed rule, at which time, five comments were presented. Commenters provided statements in favor of and in opposition to the proposed rule, and some suggested changes that in their view would improve the proposed rule.

Most who commented in favor of the proposed rule were medical professionals and/or representatives of consumer advocacy groups and medical associations; and there were some consumers/individuals and a subject magnet product manufacturer who also supported the

[17] CAA articles pertaining to hazardous magnet ingestion can be found using the following URL: https://www.caa.go.jp/policies/council/csic/report/report_021/.
[18] Final decision and order, CPSC Docket No: 12-2: https://www.cpsc.gov/s3fs-public/pdfs/recall/lawsuits/abc/163--2017-10-26%20Final%20Decision%20and%20Order.pdf?Tme8u5fRF2.29_B.i4Ix7pPwb_whKng2.

proposed rule.[19] These commenters argued that safety messaging and safeguards are insufficient to address the hazard and that the proposed rule represents a minimum standard for addressing the hazard. Several of the comments referenced the Canadian prohibitions discussed in the NPR. For example, representatives of the Canadian Paediatric Society's Injury Prevention Committee, Children's Safety Network (CSN) at Education Development Center (EDC), Pacific Institute for Research and Evaluation (PIRE), American Academy of Pediatrics (AAP), and North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) provided comments explaining that Canada's prohibitions, which are similar to the proposed rule, have been effective at addressing the magnet internal interaction hazard in Canada. In contrast, most who commented in opposition to the proposed rule were consumers/individuals, as well as several subject magnet product manufacturers and hobbyist groups.[20] These comments opined that an all-ages, prohibition is not reasonable; that ASTM F3458 – 21 is an alternative; and that there are other hazards that are far more dangerous than magnets (*e.g.,* automobiles, power tools, balloons, trampolines, tobacco, firearms, and alcohol). Many also claimed that the proposed strength and size limitations are both unnecessary and costly in terms of lost product utility and harm to small businesses. Many comments understated the frequency of the incidence of the hazard, describing magnet ingestions as a "few," "several," or "handful," and these commenters claimed that specific companies had no incidents of magnet ingestion involving their subject magnet products.

These written and oral comments can be found in docket number CPSC-2021-0037 at http://www.regulations.gov/. Staff summarizes and addresses comments in the individual memoranda as follows:

- Tab A – The Directorate for Health Sciences discusses comments from medical associations and individual medical professionals regarding medical management of ingested magnets.
- Tab B – The Directorate for Epidemiology discusses comments regarding incidence of magnet ingestions.
- Tab C – The Division of Human Factors addresses comments concerning: (1) product scope and exemptions, (2) defectiveness of magnet sets; (3) safety messaging, (4) safeguards, and (5) ASTM F3458 – 21.
- Tab D – The Division of Mechanical Engineering addresses comments concerning: (1) magnet test methodology (*e.g.,* sampling, and alternative methodologies), (2) magnetic flux index limit, (3) liberation of magnets; and (4) magnets in aggregate.
- Tab F – The Directorate for Economic Analysis addresses comments concerning: (1) value/utility of the products to consumers, (2) value of the products in promoting innovation, (3) impacts on businesses and jobs, (4) effective date, and (5) alternatives to the proposed rule. Additionally, Tab E summarizes and responds to specific comments from the Magnet Safety Organization.
- Tab G – Office of Compliance and Field Operations addresses comments regarding CPSC enforcement activities.

Additional comments that are not specifically addressed in the individual memoranda and that raise legal issues about federal governance and the fundamental precepts of promulgating

[19] For example, CPSC received a joint letter in support of the proposed rule, which was submitted by the American Academy of Pediatrics (AAP), which represents 67,000 physicians and other medical specialists, and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), which represents more than 2,500 pediatric gastroenterologists.
[20] For example, CPSC received a letter in opposition to the proposed rule, which was submitted by the Hobby Manufacturers Association (HMA), representing more than 59 manufacturers, importers, publishers, producers, and suppliers of hobby products and hobby accessories.

regulations for consumer products are summarized and addressed below.

Governmental Authority

Commenters in favor of the proposed rule opined that it is the Commission's authority and responsibility to address the magnet internal interaction hazard posed by the subject magnet products. These commenters encouraged the Commission to expeditiously promulgate the final rule as a minimum standard to address the hazard.

Commenters against the proposed rule challenged the Commission's authority to promulgate the proposed rule and the legal procedures taken by the Commission. These commenters asserted that the Commission does not have authority to issue a rule prohibiting loose or separable hazardous magnets in the subject magnet products because some consumers misuse the subject magnet products. Other commenters stated that the proposed rule violates consumers' constitutional rights, including the right to freedom of expression through products they desire. Other commenters characterized the proposed rule as the government usurping responsibility for the safety of children, which they assert is a responsibility that properly resides with the children's parents or caregivers.

Staff's Response: Sections 7 and 9 of the CPSA authorize the Commission to promulgate consumer product safety standards, including performance requirements, when necessary to prevent or reduce an unreasonable risk of injury to consumers. In the NPR, the Commission made the preliminary findings that loose or separable hazardous magnets in the subject magnet products present an unreasonable risk of injury to children and teens, and that alternatives to size and strength measures are unlikely to adequately address the hazard. In assessing whether there is an unreasonable risk, the Commission must consider the costs and benefits of regulatory action. The regulatory analysis discusses that assessment (see Tab F). The Commission must balance factors such as the severity of injury, the likelihood of injury, and the possible cost the regulation could impose on manufacturers and consumers. If evidence demonstrates that misuse of a product results in an unreasonable risk of injury, the Commission has the authority to promulgate a rule reasonably necessary to reduce or eliminate that risk. Although parents and caregivers are responsible for their children's safety, the NPR demonstrated that parents and other caregivers are unlikely to appreciate the magnet internal interaction hazard and are unlikely to be able to manage common sources of access to magnets to prevent the hazard. The human factors analysis discusses that assessment (see Tab C).

Rulemaking Procedures

Commenters against the proposed rule: A few commenters stated that there was insufficient time to consider the NPR and that the final rule should be delayed until more information is obtained. One commenter, a manufacturer of subject magnet products (Nano Magnetics, CPSC-2021-0037-0716), asserted that CPSC refused to communicate with manufacturers, consumers, and representative beneficiaries of the subject magnet products regarding methods to address the magnet internal interaction hazard, but communicated with organizations and advocacy groups in favor of the proposed restrictions.

Staff's Response: The Commission has provided stakeholders with sufficient time to consider and comment on the proposed rule. The NPR was published in the *Federal Register* on January 10, 2022, and the public comment period ended on March 28, 2022. Although some commenters requested that the CPSC delay the final rule until more information is obtained, staff's evaluation shows that the available data demonstrate that there is an unreasonable risk of injury associated with subject magnet product ingestions. As discussed in Tab B, staff was conservative in grouping the majority of the NEISS cases as "unidentified." These cases

typically lacked product identifying information beyond the ingested object being described as a magnet, such as a small, round magnet. However, considering factors such as (1) the known products involved in magnet ingestion incidents, (2) the success of ASTM F963 in reducing the number of children's toys involved in magnet internal interaction injuries, and (3) incidences of NEISS-, CPSRMS-, and poison center-reported magnet ingestions relative to the vacated rule on magnet sets, staff concluded that magnet ingestions involving unidentified magnet products generally involved subject magnet products. As demonstrated by the increased number of magnet ingestion incidents following the 2016 court decision on magnet sets, waiting for additional data sources to become available before taking effective action would result in more magnet ingestion injuries that likely could be preventable with promulgation of the draft final rule.

Regarding communication with stakeholders affected by the draft final rule, the CPSC provided opportunities for all stakeholders to present their views in the oral hearing, and we invited comments from the public, including any opposing views, which the Commission reviewed and considered. Staff also notes that we received several late comments, including comments in opposition to the proposed rule, and staff still considered them in this briefing package. Additionally, staff has collaborated with a wide variety of stakeholders in related ASTM activities over the past years, such as ASTM F15.77 on magnets.

The Draft Final Rule

The draft final rule addresses the unreasonable risk of injury and death associated with the ingestion of one or more hazardous magnets, particularly to children and teens. The draft final rule seeks to address this hazard by regulating products designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, which contain one or more loose or separable magnets. Toys subject to CPSC's mandatory toy standard in 16 CFR part 1250 are exempt from the draft final rule. Each loose or separable magnet in a subject magnet product that fits entirely within the small parts cylinder described in 16 CFR 1501.4 must have a flux index of less than 50 kG^2 mm^2, as measured by the procedures for determining the magnetic attractive force described in ASTM F963. Staff recommends several revisions to the proposed rule based on the comments received from the public. Several commenters, including magnet set manufacturers, requested clarifications pertaining to the product scope and exemptions, particularly regarding "mental stimulation," and recommended that "mental stimulation" should be removed from the inclusion criteria for "subject magnet product" because the rule would include products primarily intended for use in scientific, technical, and professional settings as well as educational purposes. Commenters also requested that the final rule should more clearly identify the exempted products, which are exemplified but not codified in the proposed rule, such as products intended only for scientific or technical research, and educational, professional, and/or industrial applications.

As discussed in Tab C, the NPR specifically identified as exempt from the proposed rule children's toys subject to ASTM F963. Additionally, per the NPR, "other products that would fall outside the scope of the proposed rule include research and educational products, or those intended for commercial or industrial purposes, if they are not also intended for amusement or jewelry." CPSC staff assesses that "mental stimulation" is an important criterion for subject magnet products, as it encompasses numerous uses that appeal to children and teens, such as

puzzle working and sculpture building, which are common descriptions for subject magnet products like magnet sets. However, staff agrees that the term "mental stimulation" may be interpreted more broadly than intended, by capturing products not for home uses that may nonetheless be mentally stimulating, such as those manufactured, sold, and/or distributed solely for educative uses at schools and universities. Accordingly, in response to comments, the draft final rule codifies the exemptions to include products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes. This clarification addresses confusion between in-scope and out-of-scope products, by specifying example products that are not subject to the draft final rule if these products are also intended for mental stimulation. Because these products are intended solely for use in school, research, professional, or commercial settings, as opposed to home settings and personal use by children and teens, these products would be unlikely to pose an unreasonable risk of internal interaction injury to children and teens. The exemption language makes clear, however, that if any of these exempted products are *also* designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes, such uses would bring these products within the scope of regulated subject magnet products and subject to the requirements of the standard.

A further clarification makes explicit that products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, are exempted from the draft final rule. This clarification addresses confusion between in-scope and out-of-scope products, by specifying example products that are not subject to the draft final rule. The exemption language makes clear, however, that if any of these exempted products are *also* designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, such uses would bring these products within the scope of regulated subject magnet products and subject to the requirements of the standard. Unlike the exemption for school, research, professional, commercial, and/or industrial purposes, these products are used in the home, and if they include the subject magnet product uses, they may be appealing to children, and these products may pose the same unreasonable risk of internal interaction injury to children or teenagers as identified for the subject magnet products.

Therefore, the following products are exempt from the requirements of 16 CFR part 1262: (1) toys that are subject to 16 CFR part 1250, *Safety Standard Mandating ASTM F963 for Toys*; (2) products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes; and (3) products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes.

Testing Certification and Notice of Requirements

The NPR proposed to amend 16 CFR part 1112 to include the proposed standard for the subject magnet products to the list of children's product safety rules for which CPSC has issued a Notice of Requirements (NOR). In the draft final rule, testing laboratories that apply for CPSC acceptance to test subject magnet products that are children's products for compliance with the new rule would have to meet the requirements in part 1112. When a laboratory meets the requirements of a CPSC-accepted third-party conformity assessment body, the laboratory can apply to CPSC to include 16 CFR part 1262, *Safety Standard for Magnets*, in the laboratory's scope of accreditation of CPSC safety rules listed on the CPSC website at: www:cpsc.gov/labsearch. Accordingly, the draft final rule amends 16 CFR part 1112 to add under section 1112.15, paragraph (b)(52) 16 CFR part 1262, *Safety Standard for Magnets*.

Effective Date

The NPR proposed that the rule would become effective 30 days after publication. The public comments did not provide substantive information regarding a different implementation effective date, unless amendments to the NPR change the flux index, test method, or additional tests or requirements. The draft final rule does not incorporate changes to the flux index, test method, additional tests, or requirements. One commenter stated that for certain subject magnet products that would be considered children's products, manufacturers should have 90 days to meet the third-party testing procedures. The NPR proposed to amend part 1112 to add an NOR to include procedures for accreditation of testing laboratories to test subject magnet products that are children's products for compliance with the new standard. Under section 14(a)(3), the testing and certificate requirements apply to any children's product manufactured more than 90 days after the Commission has established and published the NOR for accreditation of third-party conformity assessment bodies to assess conformity with a children's product safety rule. Accordingly, although the effective date of the draft final rule for both children's and non-children's subject magnet products is 30 days after publication of the draft final rule, the effective date for 16 CFR part 1112 is 90 days after the publication of the draft final rule. It is important to note that all of the subject magnet products, that are not otherwise exempted, must comply with the standard including children's products such as children's jewelry. However, for such products, testing laboratories must go through the process of applying for accreditation and obtain approval to become a CPSC-accepted third-party conformity assessment body. Ninety days would provide sufficient time for testing laboratories to apply for and comply with the CPSC's procedures.

Economic Assessment of the Draft Final Rule

Final Regulatory Analysis

Tab E details staff's final regulatory analysis, describing the market for subject magnet products, including changes in the market after the NPR was published and staff's benefit-cost analysis of the draft final rule. The expected benefits of the rule are a reduction in the risk of death and serious injury to children and teens due to ingestion of hazardous magnets from the subject magnet products. Societal costs associated with magnet ingestion injuries include the following considerations, among others: medical costs, work loss, and intangible, or non-economic, costs of injury.[21] Staff estimates that aggregate annual societal costs from ingestion injuries involving

[21] Medical costs include: (1) medical and hospital costs associated with treating the injury victim during the initial recovery period and in the long run, including the costs associated with corrective surgery; the treatment of chronic injuries; and rehabilitation

subject magnet products for 2017 through 2021 totaled $51.8 million, excluding ingestion injuries involving unidentified magnet products. Because the rule would prohibit the sale of subject magnet products with loose or separable hazardous magnets, the first order estimate of benefits would be equal to the present value of societal costs and would range from about $144 per product (with a 1.5-year product life and a 7 percent discount rate) to $180 per product (with a 3-year product life and a 3 percent discount rate) per product.

The expected costs of the rule include the lost value experienced by consumers who would no longer be able to purchase subject magnet products with loose or separable hazardous magnets, as well as the lost profits to firms that could not produce and sell non-complying products in the future. Discussed in Tabs C and F, public comments by sellers and consumers cite usefulness of the subject magnet products without size and strength limitations, including amusement, art, educational, entertainment, stress relief, social, and innovative values, among others. In addition, incident data demonstrate that hazardous magnets from the subject magnet products are also commonly used for jewelry. Estimates of consumer and producer surplus[22] range from about $2 million – $3.5 million to about $20 million – $35 million, based on unit sales ranging from 100,000 to 1 million. For example, if annual unit sales of non-complying subject magnet products are 500,000, expected aggregate benefits from the rule would total $51.8 million annually; costs (lost consumer and producer surplus) would range from $10 million to $17.5 million annually. Thus, our estimates show that the potential benefits of the draft final rule would likely easily exceed the potential costs.

Furthermore, to the extent that the unidentified magnet products involved in ingestion injuries were subject magnet products, which staff assesses is likely, the potential benefits of the draft final rule would be higher. Based on estimates for unidentified magnet products involved in ingestion injuries, average annual societal costs for 2017 through 2021 totaled $167.9 million. A sensitivity analysis shows that adding even a relatively small portion of NEISS cases involving unidentified magnet products to the base case substantially increases the estimated gross benefits of the rule. Including these cases as addressable societal costs would lead to a corresponding increase in the estimated gross benefits of the rule. Table 1, below, shows a comparison of the estimated benefits and costs of the draft final rule.

Table 1. Comparison of Estimated Benefits and Costs of the Draft Final Rule

Annual Magnet Product Sales[1]	Gross Benefits (millions $)		Total Costs from Lost Consumer & Producer Surplus (millions $)
	Identified as Amusement and/or Jewelry	Including 100% of Unidentified Magnets	

services; (2) ancillary costs, such as costs for prescriptions, medical equipment, and ambulance transport; and (3) costs of health insurance claims processing. Work loss estimates include: (1) the forgone earnings of the victim, including lost wage work and household work; (2) the forgone earnings of parents and visitors, including lost wage work and household work; (3) imputed long-term work losses of the victim that would be associated with permanent impairment; and (4) employer productivity losses, such as the costs incurred when employers spend time juggling schedules or training replacement workers. Intangible, or non-economic, costs of injury include: the physical and emotional trauma of injury, as well as the mental anguish of victims and caregivers.

[22] Consumer surplus refers to the costs of the lost utility to consumers from no longer being able to purchase and use non-complying magnets. Producer surplus refers to the lost income of producers who would no longer be able to produce and sell non-complying subject magnet products.

500,000	**$51.8**	**$167.9**	**$10 to $17.5**

[1] Prospective sales in the absence of the mandatory rule.

As discussed in Tab F, staff considered various alternative options to reduce the risk of the magnet internal interaction hazard, including existing standards, and staff concluded that less stringent alternatives to the draft final rule are not likely to adequately reduce the risk of injury associated with hazardous magnet ingestions. These alternatives, as well as the potential costs and benefits associated with them, are detailed in the NPR briefing package.

Final Regulatory Flexibility Analysis

Tab F provides staff's final regulatory flexibility analysis, which examines the impact that the draft final rule would have on small entities, and it identifies efforts by the Commission to reduce those impacts. Staff assesses that the draft final rule could have a significant adverse impact on a few small importers of subject magnet products, particularly importers of magnet sets, which are believed to receive nearly all their revenues from sales of subject magnet products. Possible alternatives to the rule that would reduce the expected impact of the rule on small businesses include the adoption of alternative performance requirements, a longer effective date, relying on ASTM activities, requiring safety messaging (*e.g.,* warnings), requiring safer packaging, requiring aversive agents, or a combination of these options. However, staff concludes that these alternatives would not achieve the same injury reductions as the draft final rule. Additionally, staff explains that there are existing subject magnet products that comply with the draft final rule, which are marketed for the same purposes. To the extent that importers of subject magnet products with loose or separable hazardous magnets could instead use compliant magnets or market the products exclusively for uses exempt from the draft final rule, the burden would be lessened.

Conclusion

The draft final rule sets performance requirements to limit the likelihood of injuries associated with hazardous magnets to protect a vulnerable population of consumers from an unreasonable risk of injury. Based on staff's analysis of a number of factors, such as incident data through 2021, public comments on the NPR, product evaluations, available literature, voluntary standards, international actions, measures to address the hazard, CPSC Compliance efforts, public comments, and staff's cost-benefit analysis of the hazard and draft final rule, staff recommends promulgating the draft final rule with clarifications to the proposed rule regarding the product exemptions from the rule. Under the draft final rule, "subject magnet product," is defined as

> a consumer product that is designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contains one or more loose or separable magnets.

The requirements under the draft final rule would limit loose or separable magnets in the subject magnet products such that each magnet must either (1) be too large to fit entirely within the small parts cylinder described in 16 CFR 1501.4, or (2) have a flux index of less than 50 kG^2 mm^2, as measured by the procedures for determining the magnetic attractive force described in

ASTM F963. The draft final rule does not apply to the following magnet products with one or more loose or separable magnets:

- toys subject to CPSC's mandatory toy standard in 16 CFR part 1250;
- products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes; and
- products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes.

Staff recommends that the Commission adopt the draft final rule to be effective 30 days after the date of publication (with third-party testing requirements effective 90 days after publication). Based on staff's final regulatory analysis, staff estimates that the potential benefits of the rule would easily exceed the potential costs, and substantially more, to the extent that unidentified magnet products involved in NEISS-reported incidents were products subject to the rule, which staff assesses is likely.

Tab A: Memorandum by the Directorate for Health Sciences, Division of Pharmacology and Physiology Assessment

This document has been electronically approved and signed.

TO: Stephen Harsanyi, Project Manager,
Division of Human Factors,
Directorate for Engineering Sciences

DATE: August 17, 2022

THROUGH: Stefanie Marques, Ph.D., Supervisory Scientist
Division of Pharmacology and Physiology Assessment,
Directorate for Health Sciences

FROM: Ashley A. Johnson, Ph.D., Physiologist,
Division of Pharmacology and Physiology Assessment,
Directorate for Health Sciences

SUBJECT: Health Sciences Assessment of Hazardous Magnet Products

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Introduction

Staff from the CPSC Directorate for Health Sciences (HS), following publication of the NPR, presents an updated analysis of the magnet internal interaction hazard that may occur because of internal interactions between the subject magnet products and body tissue that are facilitated by the intrinsic magnetic properties of the subject magnet products. This memorandum discusses injuries, treatments, medical procedures, surgical interventions, and associated health outcomes and medical consequences related to the magnet internal interaction hazard and magnet ingestion, in general. Examples from the most current medical literature and select CPSC In-Depth Investigation (IDI) and Injury or Potential Injury Incident (IPII) reports from both before and following the NPR are also used to illustrate and exemplify possible health outcomes.

Discussion

Overview of NPR

Identification of Hazardous Magnets

In response to an increasing utilization of rare-earth magnets and their novel incorporation into consumer products, ASTM F963-07, *Standard Consumer Safety Specification for Toy Safety*, published in May 2007, defined a hazardous magnet that could be identified by calculating the magnetic flux index from measurements of magnetic induction, also known as magnetic flux density (in kiloGauss, kG), and the area of the magnet pole surface (in millimeters squared). The magnetic flux index is the product of magnetic induction squared and the area of the magnetic pole about which the magnetic induction is measured. Hazardous magnets and hazardous magnet components are identified by ASTM F963 by the property of a magnetic flux index greater than or equal to 50 kG^2 mm^2. The CPSC toy standard (16 CFR part 1250)

mandates compliance with ASTM F963-17. The NPR and draft final rule identify a magnet as hazardous consistent with ASTM F963.

Hazardous magnets may be made from a composite of neodymium, iron, and boron (NIB). NIB magnets impart strong attractive forces relative to their size (Croat et al., 1984, Sagawa et al., 1984, Otjen et al., 2013, Kramer et al., 2015). In addition to rare-earth magnets (*e.g.*, NIB composite, samarium cobalt composite), ferrite and hematite magnets have also been involved in the internal interaction injuries, and the same threat of injury and subsequent medical management exist with non-rare earth magnets (Otjen et al., 2013, Kramer et al., 2015). Indeed, subject magnets present a unique hazard because some level of medical management is required for all cases in which magnets or magnets and ferromagnetic objects were ingested.

Relationship Between Magnet Set Availability and Magnet Ingestions

The CPSC previously described magnet sets via a rule that became effective on April 1, 2015 (79 FR 59961), as "aggregations of separable magnetic objects that are marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief". Litigation (Zen Magnets, LLC v. Consumer Product Safety Commission, 841 F.3d 1141) led to the vacation of the rule and its removal from the Code of Federal Regulations on March 7, 2017 (82 FR 12716). The proposed rule would address the magnet internal interaction hazard similarly to the vacated rule on magnet sets, but with an expanded product scope, to account for other products involved and likely to be involved in magnet ingestion incidents, and also to be consistent with the current magnet size and strength standards specified in ASTM F963.

Magnet Internal Interaction Hazard

In the NPR briefing package, staff provided an analysis of the magnet internal interaction hazard using examples from medical literature and select IDI and IPII reports to illustrate health outcomes and medical consequences from subject magnet products. Foreign body ingestion is relatively common (Arango et al., 2011, Lee 2018) and the types of foreign bodies ingested may vary according to the age of the involved individual (Arango et al., 2011). Most ingested foreign bodies pass naturally, but hazardous magnet ingestion presents a unique health hazard, where even a single hazardous magnet ingestion requires medical management, such as x-ray imaging. Generally, medical providers do not know the magnetic flux index, composition, or, in many cases, the number of magnets or magnet type that has been swallowed. Magnets are unique among ingested foreign bodies because of their intrinsic ability to attract to one another or to ferromagnetic objects. Edwards and Edwards (2017) noted a unique characteristic of small, spherical NIB magnets of a type common in magnet sets, where spherical magnets that are initially repulsive, spontaneously reorient until they attract to each other. Such a relationship may increase the likelihood of magnet internal interaction. McCormick et al. (2002) outlined a mechanism of injury following hazardous magnet ingestion, where separate hazardous magnets in adjacent tissue walls (*e.g.*, from distinct loops of bowel) attract to each other and trap tissue in between the magnets. The mechanism of injury is the same for a single hazardous magnet and a ferromagnetic object that might interact internally, and for this reason, single magnets are within the scope of the proposed rule. For example, ingested magnets in the throat of a 3-year-old male were suddenly attracted to the optic graspers inserted to retrieve the foreign bodies (Powers et al., 2021 and IDI 210211CCC1373). In a separate incident, a 9-year-old male was evaluated at a local emergency department after ingesting more than 100 three-millimeter (3 mm) diameter magnets. Shortly thereafter, the male was transferred by helicopter to a medical

facility with more advanced medical care options. Health care providers instructed the flight crew to refrain from using metal clasps or buckles to secure the male, to avoid possible interaction with the ingested magnets (IDI 200204CCC3227).

Detailed below, the draft final rule is consistent with the proposed rule, with the addition of several clarifications to product scope. The aim of the draft final rule is to mitigate the risk of adverse health outcomes associated with subject magnet products, especially the internal interaction hazards associated with their ingestion, particularly among children and teenagers. Recent research (including the NPR) conducted by CPSC staff (see Epidemiology Tab B; Tark, 2022) and other researchers (such as Middelberg et al., 2021 and Reeves et al., 2020) indicates that the incidence of magnet ingestion injuries was greatly reduced during the period when the prior rule was in effect and has risen again substantially since the vacation of the rule. This memorandum details and discusses magnet ingestion-related risks of injury, including medical management, infections, post-surgery complications, and deaths both before and following publication of the NPR. Building on HS staff's memorandum in the NPR briefing package, HS staff analyzed the NEISS[1] and CPSRMS[2] data, including additional incident data collected since the NPR (see Tab B), along with the most current scientific literature available on magnet ingestions. For the remainder of this memorandum, the incident data analyzed for the NPR are referred to as "NPR data," and the additional incident data analyzed since the NPR are referred to as "since the NPR." However, the updated CPSRMS data include incidents from dates prior to and since publication of the NPR, because it is common for CPSRMS reports to be received in the years following incidents. For the reasons explained in the following sections, HS staff concludes that the magnet internal interaction hazard and associated injury mechanism are consistent with the description in the NPR.

Updated Incident Data Analysis

Since publication of the NPR, CPSC staff received an additional 111 CPSRMS-reported incidents of magnet ingestion.[3] Staff analyzed the CPSRMS reports, including detailed narratives and medical documentation, where available, for more information about the severity of magnet ingestions, including evidence of internal interaction of ingested magnets through body tissue and information on the diagnosis, treatment, and medical outcome of these cases. In general, the incident data reviewed since the NPR were similar to the NPR incident data. Of these additional CPSRMS-reported incidents, at least 74 patients (66.7%) required hospitalization and one case (0.9%) resulted in a fatality. Reports for 43 patients (38.7%) indicated that surgical intervention was necessary (surgical procedures are described in further detail in the following sections) and 32 cases (28.8%) had evidence of internal interaction through body tissue. In some cases, medical providers were able to avoid surgical intervention with prompt endoscopic removal. Most patients required serial x-ray radiography. These cases are characterized further in Tab B, and IDIs associated with these CPSRMS-reported incidents

[1] Data from NEISS are based on a nationally representative probability sample of about 100 hospitals in the United States and its territories. The NEISS reports capture one part of the treatment process (the emergency department visit), and typically do not show information on treatment after the initial visit.
[2] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS include hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among other sources.
[3] The NPR considered NEISS and CPSRMS data spanning January 1, 2010, through December 31, 2021, extracted on January 8, 2021. In support of the draft final rule, on January 13, 2022, staff extracted data spanning January 1, 2010, through December 31, 2022. As the CPSRMS database commonly receives reports pertaining to incidents from prior years, this additional data included CPSRMS-reported incidents that occurred from February 1, 2016, through December 27, 2021.

are used throughout this memorandum to illustrate and exemplify health risks from magnet ingestion. It is important to note that because the data almost certainly do not include every incident of magnet ingestion, the counts above very likely understate the actual rate of injury and invasive medical management. For this reason, it is important that the scope of the draft final rule addresses the hazard patterns, in addition to the specific products identified in incident reports, which are not limited to a specific magnet composition (see Human Factors Tab C; Harsanyi, 2022).

Updated Literature Review

A recent multicenter cohort study (since the NPR) presents data on 596 cases of patients aged 0 to 21 years from 25 children's hospitals in a 3-year period following high-powered magnet sales re-entering the U.S. market (2017-2019) (Middelberg et al., 2022).[4] These data represent the first robust, multicenter, retrospective study of health risks from magnet ingestion. Of the 596 patients treated for high-powered magnet exposures, 562 children (96.2%) ingested magnets, 17 children (2.9%) were treated for nasal or aural magnet foreign bodies, 4 children (0.7%) were treated for magnets in their genitourinary tract, and 1 patient (0.2%) presented with magnets in their respiratory tract. Most patients required serial radiography, with 81.4 percent of children receiving more than one x-ray. Thirty-six children (6%) required a computed tomography (CT) scan. Although magnets passed spontaneously in more than half of patients (53.7%), 276 children (46.4%) required a procedure for magnet removal or for complications from magnet ingestion. One hundred ninety-one patients (32%) required endoscopy alone, 58 patients (9.7%) required surgery alone, and 27 patients (4.5%) required both endoscopy and surgery. Magnet exposure led to morbidity in 57 (9.6%) patients, which included perforation (6%), fistula formation (3.7%), bowel obstruction (2.7%), bleeding (0.7%), infection (0.5%), volvulus (0.2%), and/or bowel herniation (0.2%). This study identified 19 children (3.2%) who developed more than one of these listed morbidities. Approximately 55.7 percent of patients required hospitalization (332 patients) and 4 patients (0.7%) were admitted to the ICU. The median length of hospital stay was 3 days. This study clearly shows that magnet ingestion frequently led to hospitalization, the need for invasive medical management, and caused morbidity in nearly 1 in 10 children who ingested magnets.

Updated Review of Health Outcomes Associated with the Subject Hazard

Medical professionals who become aware of the magnet ingestion (*e.g.,* via oral report of the ingestion or diagnosis via x-ray radiography) may be able to minimize or avoid injury by prompt removal (*e.g*., via endoscopy). IDI 210208CCC1333 (since the NPR) describes the ingestion of nine magnets by a 2-year, 11- month-old male. After the ingestion, the male reported the incident to his mother, whereupon he was immediately transported to a hospital emergency room. According to hospital medical records associated with the IDI report, x-ray radiography exams and an endoscopy procedure with anesthesia were performed promptly, and the magnets were recovered from the duodenum. The reports indicate no apparent complications, and he was discharged home. However, the presence of a firsthand account of a magnet ingestion *(e.g*., reported by the victim or reported by a sibling, parent, daycare provider, friend, or other individual) enabled timely medical care, impacting the medical outcome. Certain comorbidities may lead to more adverse health outcomes following magnet ingestions, and

[4] This study can be found on the public comment docket: CPSC-2021-0037-0010: https://www.regulations.gov/comment/CPSC-2021-0037-0010.

these include behavioral problems, developmental delays (Midgett et al., 2006, Oestreich 2009), history of pica (Oestreich 2009), autism (IDI 190412CCC1369 (NPR data), IDI 180718CFE0001 (NPR data), Midgett et al., 2006, Oestreich 2009, Otjen et al., 2013), attention deficit hyperactivity disorder (IDI 210223CCC3580 (NPR data), Midgett et al., 2006), down syndrome or trisomy 21 (Tachecí et al., 2006), intellectual disability, blindness (Henretig and Shannon 1998), learning disability (IDI 181212CBB3124, NPR data), schizophrenia (Kirrane et al., 2006, Oestreich 2009), and depression (Otjen et al., 2013), among other adverse outcomes (Oestreich 2009). Past medical history of abdominal surgery, or surgery involving the bowel, may also increase the risk of medical efforts to treat ingested magnets (IDI 181212CBB3124, NPR data), as well as comorbidities such as eosinophilic esophagitis, gastroesophageal reflux disease, GI anomalies, and neuromuscular disorders (Jaan and Mulita 2021). In the comprehensive and most recent study on high-powered magnet exposure (since the NPR) by Middelberg*,* et al., cited above, 103 children (17.3%) involved in magnet ingestion incidents had developmental delays, and 30 (5%) had a comorbid health condition including potentially noncontributory conditions, such as asthma, congenital heart disease, epilepsy, and diabetes, or more relevant conditions like gastroschisis, eosinophilic esophagitis, and eosinophilic colitis.

Ambiguous symptomatology following hazardous magnet ingestion that results in an internal interaction injury may complicate the timely delivery of medical care (Hodges *et al*., 2017). In many cases, victims do not experience serious symptomatology. In IDI 210325CCC2518 (since the NPR), a 2-year-old female who ingested three 5 mm magnets eventually required a laparotomy under general anesthesia after a failed endoscopy, and she also required closure of an intestinal perforation. Over the course of 3 days, the female experienced only one episode of vomiting and intermittent abdominal pain. Symptoms related to hazardous magnet ingestion may be characterized as flu-like and include vomiting, fever, and abdominal pain, among others (Hodges et al., 2017, see IDI 051213CCC3192, NPR data). For example, symptomatology following magnet ingestion has been mistaken for a stomach virus (IDI 140115CAA2304, NPR data), ear infection, bronchitis (see IDI 110311HCC3475, NPR data), and COVID-19 (IDI 210827CCC1856, since the NPR). IDI 211117CAA1363 (since the NPR) describes a 6-year-old male who ingested eight 5 mm magnets. After complaints of abdominal pain and vomiting, the male was seen the same day by a primary care physician who diagnosed the symptoms as pertaining to a stomach virus. Four days later, symptoms worsened, and the male was taken to the emergency room where an X-ray radiography exam revealed he had ingested eight magnets. Surgery was performed to remove the magnets, including a bowel resection and repair of intestinal perforations, and the male was discharged home 4 days later. The next day, the male was seen in the emergency room for constipation. Two days later, he was admitted for bowel obstruction and required a follow-up surgery to correct the issue. The male was hospitalized for 6 days and discharged home. IDI 210827CCC1856 (since the NPR) involved the death of a 14-month-old female who ingested (unwitnessed) seven magnets. The female had not been eating or drinking and was vomiting 2-3 days leading up to death, but the symptoms were thought to be COVID-19-related because the victim's father had COVID-19, and entire family had been quarantining. The female was transported to the hospital when she became unresponsive. CPR was performed, but the female was pronounced deceased upon arrival at hospital. The cause of death was bowel perforation.

When medical care is delayed, health threats posed by hazardous magnet ingestions include volvulus, bowel obstruction, bleeding, pressure necrosis, fistulae, ischemia, inflammation,

perforation, peritonitis, sepsis, and death (Inkster 2012, Inkster 2020), which are discussed in detail below.

Volvulus is an obstructive twisting of the gastrointestinal tract and is often accompanied by abdominal pain, distended abdomen, vomiting, constipation, and bloody stools. Volvulus may lead to bowel ischemia, perforation, peritonitis, and death, if left untreated (Le et al., 2021). Bowel obstruction, often a consequence of volvulus, is associated with abdominal cramps, vomiting, constipation, and distention (Kulaylat and Doerr 2001). A 20-month-old male died following ingestion of magnets from a toy construction set; the ingestion caused volvulus (IDI 051213CCC3192, NPR data). Outside the U.S., an 8-year-old male died in Warsaw, Poland, due to small intestine ischemia secondary to volvulus after ingesting magnets that resulted in necrosis, toxemia (blood poisoning), hypovolemic shock, and eventually cardiopulmonary failure (Olczak and Skrzypek 2015). A 2-year-old male died at home from small intestine ischemia secondary to volvulus following multiple magnet ingestion (IDI 181206CCC2102, NPR data). Small intestine ischemia was implicated in the death of a 19-month-old female following ingestion of multiple magnets (IDI 140115CAA2304, NPR data). Like outcomes related to volvulus, small bowel ischemia can lead to local tissue necrosis, perforation, fistulae, and subsequent peritonitis (Diamond et al., 2019, Umphrey et al., 2008).

Necrosis is a process of cell death secondary to injury that undermines cell membrane integrity (Guyton and Hall 2006) and involves intricate cell signaling responses (Vanlangenakker et al., 2008). When hazardous magnets attract internally through the intestinal wall, the injury leading to necrosis is a pressure on the involved biological tissues that exceeds local capillary pressure and causes ischemia (Agrawal and Chauhan 2012). Hazardous magnets that attract to each other through tissues in the body may do so with increasing force (and pressure) until they overcome the intrinsic physiological pressures that contribute to the shape and form of the intestinal tissue and join together (Lambe et al., 2014). Progressive pressure necrosis of the involved tissues can result in local inflammation, ulceration, and tissue death (with putative outcomes such as perforation or fistula in the GI tract). HS staff previously discussed the relationships among local capillary and intraluminal pressures and magnet set ingestions (Inkster 2008).

Perforations and fistulas are both disruptions of the GI wall; however, a fistula is an abnormal connection or passageway between organs or vessels that normally do not connect, while a perforation is an abnormal opening in an organ or tissue, such as a rupture or leak (Goenka and Goenka, 2015). Fistulae and intestinal perforations may enable the leakage of gut contents into adjacent tissue structures or abdominal cavities (Falconi and Pederzoli 2001) that can lead to infection, inflammation, perforation, sepsis, and possibly death (Farooqi and Tuma 2021). Both morbidities are associated with increased mortality (Falconi and Pederzoli 2001) and require surgical intervention. If left untreated or otherwise unnoticed, such events can progress into infection, sepsis, and death (Inkster 2008).

Updated Review of Other Magnet Health Outcomes and Injuries

Ingested magnets that are not attracting to each other through tissue walls may still cause harm, such as irritation of the GI mucosa (IDI 200707CCC3656, NPR data) in the form of erythematous (mucosal redden; see IDI 190412CCC1369, NPR data), mucosal inflammation (IDI 191015CCC1039, NPR data), and minor tears (IDI 91114CFE0001, NPR data). Foreign body irritation of the GI tract may also prompt local mucosal irritation that can stimulate diarrhea

(McCormick et al., 2002). Ingested magnets that do not perforate the bowel but embed in the bowel can lead to multiple days of hospitalization (IDI 190716CFE0001, NPR data). IDIs 210309CCC1552 (since the NPR) and 210726CCC1448 (since the NPR) describe magnets that lodge in the appendix, leading to surgical appendectomies.

The simulation of ear, nose, mouth, and genital piercings with hazardous magnets present external magnet interaction risks that are unique, but similar to, magnet internal interaction injuries (McCormick et al., 2002). A 10-year-old male with attention deficit hyperactivity disorder (ADHD) experienced erosion of the nasal septum (a hole) after simulation of nose piercings and after failing to report the hazardous magnet interaction inside his nose for several weeks. Shortly after discovery of the hazardous magnets (two NIB magnets that were 2.5 mm in diameter and spherical in shape) via an unrelated orthodontic x-ray radiography exam, the magnets were removed with forceps in the presence of general anesthesia, and a hole in the nasal septum was expected to heal on its own. Notably, the initial application of suction to retrieve the magnets failed. Prior to removal, the male experienced headache and several nose bleeds (IDI 210223CCC3580, NPR data). McCormick et al. (2002) also reported that the removal of magnets from body parts, such as the nose and genitalia, caused extensive pain and required sedation or general anesthesia to enable retrieval in some instances.

Consumer magnets also may interfere with medical devices. Toy magnets were shown to disrupt the normal function of a programmable Codman valve used to reduce the subdural pooling of cerebrospinal fluid following surgery to treat hydrocephalus (fluid buildup in the brain) in a 2-year-old male (Anderson et al., 2004). It is possible for magnets, including those containing neodymium (Wolber et al., 2007), to interfere with the normal operation of cardiac pacemakers (Jongnaragnsin et al., 2009, Ryf et al., 2018) and implantable cardioverter-defibrillators (see Jongnaragnsin et al., 2009). Pääkkönen and Korpinen (2018) presented data indicating that the distance between a magnetic object and an implanted medical device is an important factor driving interference, such that the closer a magnetic object is to the implanted medical device, the more likely the potential for interference.

Updated Review of Medical Care of Subject Hazard Health Outcomes

The use of medical procedures and surgery to treat magnet ingestions and/or associated injuries suggests that the intrinsic risk of surgery or other medical procedures is less than the risk of no medical intervention (see Chand et al., 2007), and thus indicates the seriousness of the magnet hazard. The American Society for Gastrointestinal Endoscopy (ASGE) recommends removal of all ingested magnets that are accessible via endoscopy (Ikenberry et al., 2011). Similarly, guidance from the ASGE recommends emergent removal when two or more rare-earth neodymium magnets have been ingested in the pediatric patient (Lightdale et al., 2014), although the ASGE further notes that the complexities unique to distinct clinical cases will ultimately direct the course of care (Ikenberry et al., 2011, Lightdale et al., 2014). The presence or absence of a firsthand account or ability to self-report magnet ingestion may impact the delivery of timely medical care (Hodges et al., 2017), however.

Medical Imaging

Without an oral history specifically identifying magnet ingestion, it may be difficult to conclude from medical imaging alone that the foreign bodies are magnets (Otjen et al., 2013). It may also be difficult to utilize medical imaging to determine if magnets are interacting internally through tissue structures (Otjen et al., 2013). For example, x-ray radiography reports early in the

treatment course for a foreign body ingestion in a 10-year-old female described a “foreign body likely representing swallowed jewelry” in the bowel. Several magnets were later removed from the alimentary canal via two endoscopic procedures (IDI 181212CBB3124, NPR data). X-ray radiography may be the most common medical imaging procedure used to monitor ingested magnets. Serial x-ray radiography is useful for monitoring the progress of a magnet or magnets through the GI tract. In some cases, if the magnets have progressed to the large bowel, the magnet(s) may be monitored to see if they pass naturally. If the passage of the magnets through the GI tract is arrested or if symptoms manifest, then endoscopic or surgical intervention (depending on the location of the magnets) may be indicated. Otjen et al. (2013) describe a case in which a 10-year-old female swallowed two small spherical magnets that were first considered for endoscopic retrieval. Instead, the coupled magnets were monitored via x-ray radiography and passed naturally in the absence of symptomatology. Fluoroscopy is frequently used intraoperatively to augment efforts to retrieve ingested magnets, but it can also be used along with x-ray radiography for monitoring the position of ingested magnets (see Otjen et al., 2013). Computed tomography (CT) scans may also be used to monitor ingested magnets (see İlçe et al., 2007). For example, CT scans of a 7-year-old male identified the location of an ingested magnet that could not be fully defined via x-ray radiography (Otjen et al., 2013). Kim et al. (2017) suggest that CT scans may be particularly useful if perforation is suspected. CT scans may also be useful in the management of bowel obstruction (Kulaylat and Doerr 2001). However, according to the U.S. Food and Drug Administration (FDA 2020), the ionizing radiation associated with x-ray radiography has the potential to damage DNA and perhaps drive the development of cancer later in life. The risks from CT scans are similar, while prolonged fluoroscopy, often used during surgery or medical procedures such as endoscopy, may contribute to the development of cataracts, skin reddening, and/or hair loss. Magnetic resonance imaging (MRI) must be avoided if overt magnet ingestion is suspected because of the powerful magnetic fields used for MRI that could interact with ingested magnets (Otjen et al., 2013). Avoiding the use of MRI for the treatment of ingested magnets has also been noted by others (IDI 181212CBB3124, NPR data), Taher et al. 2019).

Bowel Cleanout

Bowel cleanout, or bowel preparation, are procedures that use laxatives, such as polyethylene glycol, which may be used to try to flush ingested magnets out of the GI tract (IDI 200707CCC3655, NPR data; IDI 200707CCC3656, NPR data) and/or to prepare patients for endoscopy or other medical procedures (Dabaja et al., 2021). Bowel cleanout is not often associated with risk in the pediatric population, but dehydration is the most common adverse event that occurs (Pall et al., 2014). In certain instances, bowel cleanout laxatives may be delivered via nasogastric tube (IDI 200707CCC3655, NPR data; IDI 200707CCC3656, NPR data).

Endoscopy

Endoscopy may be used to retrieve ingested magnets from the stomach (IPII I1440063A, NPR data; IPII H1540133A, NPR data), duodenum (IPII I17C0176A, NPR data), esophagus, pylorus (IDI 180823CCC2979, NPR data), and cecum (*via* colonoscopy, IDI 191114CFE0001, NPR data) among other portions of the alimentary canal. Endoscopy may also be used to treat bowel obstruction (Kulaylat and Doerr 2001) secondary to magnet ingestion. Endoscopy is associated with a risk of bleeding from mucosal shearing or tearing that is elevated in the presence of anemia. There is also risk of adverse cardiopulmonary events (*e.g.*, oxygen desaturation,

aspiration, respiratory arrest, shock, myocardial infarction) as a result of sedation and anesthesia; perforation from procedure instruments; infection from contaminated equipment or from a perturbed endogenous source; and procedural risks largely associated with instances of comorbidities, such as obesity, cardiac disease, and diabetes, among others (Lightdale et al., 2019). The most important comorbidities that might complicate endoscopy are cardiopulmonary disorders, blood disorders, allergies, sepsis, and immunocompromise. Associated adverse events that require cessation of procedures include hypotension, hypertension, dysrhythmia, cardiac arrest, hypoxia, bronchospasm, and infection, among others (Cotton et al., 2010). Colonoscopy is a common endoscopic procedure performed *via* the anus, and accordingly, it shares many of the same risks as endoscopy in general (Kothari et al., 2019). Laryngoscopy is a medical procedure to evaluate the upper aerodigestive tract. Laryngoscopy was used to investigate suspected magnets lodged in the throat of a 3-year-old male (IDI 210211CCC1373, NPR data, and Powers et al., 2021). Associated risks of laryngoscopy include esophageal perforation, airway compromise, bleeding, dysphagia, and fever, among others (Hendrix et al., 1994). Nasal endoscopy may be useful to treat magnets embedded in the nose (IDI 210223CCC3580, NPR data). Nasal endoscopy is associated with risks of mucosal irritation, minor hemorrhage, and overt hemorrhage (Mori et al., 2008).

Surgery

Surgical interventions may be used to treat magnet ingestions when less invasive procedures, such as endoscopy or bowel cleanout, prove clinically inappropriate or unsuccessful. Accordingly, medical procedures may be converted into surgical procedures to improve medical treatment outcomes.

IDI 210329CCC3802 (since the NPR) describes a case in which an endoscopy failed to retrieve all ingested magnets. A 2-year-old female ingested five 3 mm magnets. The female was first taken to an urgent care where an x-ray radiography exam was done, and the magnets were detected. According to associated medical records, the female was referred to the ER where she presented with appetite change, abdominal pain, and constipation. A second x-ray radiography exam showed the magnets had not significantly changed position compared to the prior study. From the operative report, the female underwent a diagnostic laparoscopy, exploratory laparotomy, and an endoscopy procedure under general anesthesia. Due to the position of the magnets and presence of duodenal perforation and duodenal-colonic fistula, this was converted to a laparotomy to close the perforations, repair the fistula, and remove the magnets. After a 5-day hospital stay, the female was released.

IDI 210527CEP9062 (since the NPR) describes a 20-month-old male victim who ingested 17 5 mm magnets that belonged to an older 6-year-old sibling. According to medical records, he presented with generalized abdominal pain and one episode of vomiting. He was initially admitted and held for a 24-hour observation period after an x-ray radiography exam indicated the magnets were in the left side of the large bowel, and it was thought they would pass after a bowel cleanout and laxative treatment. A series of x-rays radiographs showed lack of movement of the magnets and concern for intestinal perforation. Exploratory and diagnostic laparoscopy were performed under general anesthesia and were converted to a laparotomy for removal of the magnets and a jejunal perforation repair. After a 5-day hospital stay, the male was released.

Laparotomy may be accompanied by incisions of the stomach (gastrotomy; see IDI 200204CCC3277, NPR data) or intestines (enterotomy; see IDI 120321CWE2021, NPR data) to

retrieve ingested magnets. Abdominal surgeries, such as laparotomy (abdominal incision) and laparoscopy (fiber-optic visualization of the viscera via abdominal incision), which involve abdominal incisions and manipulation of abdominal organs, are associated with the risk of adhesions that can cause pain, bowel obstructions that may require additional surgical intervention, female infertility, and bowel injury (Okabayashi et al., 2014). Six months after enterotomy and gastrostomy to remove 26 rare-earth magnets from the jejunum and stomach, a 2-year-old female developed bowel adhesions that caused obstructions and required treatment with surgical adhesiolysis (Mandhan et al., 2014) to cut the adhesions (Nahirniak and Tuma 2021). IDI 210325CCC2518 (since the NPR) describes a 2-year-old female who ingested three 5 mm magnets. The victim postoperatively developed complications, including a small bowel obstruction as a result of the first surgery and required a second surgery 4 months later to correct these issues.

In general, laparoscopy procedures may be associated with reduced incidents of wound infection, pneumonia, decreased procedure time, and decreased length of hospital stay compared to more invasive laparotomy procedures (Hajibandeh et al., 2016). But laparotomy alone is associated with complications, such as pain, fever, nausea, infection of the surgical site, wound dehiscence (rupture), respiratory tract infection, complications involving the heart, kidney, and GI tract, and septicemia. In addition, emergency laparotomies may be more prone to complications than elective laparotomies (Ravishankar et al., 2020). Possible complications associated with laparotomy include pneumonia, cardiac complications, surgical site infection, urinary tract infection, venous thromboembolism, kidney failure, and death (Burgess et al., 2017). Indeed, a 6-year-old female underwent a 20-day hospital stay to treat surgical wound infections following exploratory laparotomy with small bowel resection and appendectomy to retrieve 20 ingested magnets (IPII I18B0438A, NPR data).

Surgical resection of the bowel may be performed to remove necrotic portions of the bowel secondary to magnet ingestion (IPII H19A0102A, IPII I1990335A, IPII I18B0438A (NPR data)). Small bowel resection is associated with risks of infection, fistulae, peritonitis, abscess, sepsis, and wound dehiscence secondary to leaky anastomoses. There is also the possibility of impairment to the intrinsic nutrient absorption functions of the bowel, depending on the resection location (Clatterbuck and Moore 2020). End-to-end surgical anastomoses used to restore bowel continuity following resection are associated with the risk of leakage, intra-abdominal abscess, and mortality (Goulder 2012). Patients who required a surgical procedure to treat magnet ingestion, such as a laparotomy, now carry a 4.6 percent lifetime risk of adhesive bowel obstruction (Barmparas et al., 2010).

Complications associated with surgery to treat magnet ingestion have also included pancreatitis and additional hospitalization (IDI 120713CAA3752, NPR data), additional surgery to treat incisional hernia (IDI 140115CAA1287, NPR data), and the need for a lifelong feeding tube (IDI 200211CFE0002, NPR data), among others (IDI 120419CBB3615, NPR data). Endotracheal general anesthesia may be required for surgical treatments of magnet ingestion (IDI 210223CCC3580, NPR data). Possible complications associated with general anesthesia include nausea, vomiting, sore throat, dental damage, myocardial ischemia or infarction, heart failure, cardiac arrest, arrhythmia, atelectasis (lung collapse), aspiration, bronchospasm, neurological effects, and renal effects among others (Harris and Chung 2013).

Public Comments on the NPR pertaining to Health Sciences

CPSC staff received 716 public comments regarding the proposed rule. On March 2, 2022, CPSC held a hearing on the proposed rule, where five oral comments were presented. Written and oral comments can be found in docket number CPSC-2021-0037 at: http://www.regulations.gov/. Public comments on the NPR from medical professionals, consumer advocacy groups, and medical associations were largely supportive of the proposed rule as a minimum standard to adequately protect children from hazardous magnet products ("hazardous magnet products" refers to subject magnet products containing one or more loose or separable hazardous magnets). Many cite the most current literature on magnet exposure in children (see Updated Literature Search section), and others cite firsthand professional accounts of treating high-powered magnet exposures in children and associated medical outcomes from those injuries. The American Academy of Pediatrics (AAP)[5] and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN)[6] commented publicly on the NPR to express strong support for the proposed rule. In their comments, they highlighted the current medical recommendation for prompt medical intervention. It is well understood that children are undergoing medical procedures that carry inherent risk (as discussed above in this tab) due to the ingestion of hazardous magnets. Indeed, NASPGHAN indicated previously in published literature that it is mandatory to remove foreign bodies located in the esophagus and that most of these esophageal foreign bodies require removal within 2 hours of presentation (Kramer et al., 2015). The Canadian Paediatric Society's Injury Prevention Committee, Children's Safety Network (CSN) at Education Development Center (EDC), and the Pacific Institute for Research and Evaluation (PIRE) also provided comments in support of the proposed rule. Additionally, a number of medical providers presented individual comments in favor of the proposed rule and stated that magnets, in general, present a unique health risk because some level of medical management is warranted for all magnet ingestions; magnets that have migrated past the esophagus routinely require serial imaging and surgical intervention; and children are suffering adverse health outcomes from magnet internal interaction hazards.

Conclusion and Recommendations

Health Sciences staff examined magnet ingestion data received after the data extraction for the NPR and reviewed public comments and the most current scientific literature related to magnet ingestion. Staff's assessment of the magnet internal interaction hazard and associated injury mechanism remains unchanged since the publication of the NPR. HS staff recognizes the health threats associated with hazardous magnets, especially when the magnets are ingested and attracted to each other or to ferromagnetic objects through internal tissue structures. The possibility also exists for ingested hazardous magnets to pass naturally through the GI tract without medical intervention, especially if only one hazardous magnet is ingested alone, or if hazardous magnets are coupled together prior to ingestion. Prompt recognition of hazardous magnet ingestion and the associated internal interaction hazard enable swift medical treatment that can mitigate adverse health outcomes, such as injury or death. Delays between recognition of the hazardous magnet ingestion and receipt of appropriate medical treatment may occur due to the absence of firsthand reports, from ambiguous symptomatology, or both.

[5] AAP represents 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety and well-being of infants, children, adolescents, and young adults.
[6] NASPGHAN represents more than 2,500 pediatric gastroenterologists in the United States, Canada, and Mexico and is the only organization singularly dedicated to advocating for children with gastrointestinal disease.

Contemporaneous physiological states and/or medical conditions may influence exposure to the magnet internal interaction hazard (*e.g.*, learning disabilities) and physiological responses to treatment or injuries (*e.g.*, GI disease). According to the available information, the ingestion of magnets is associated with medical treatments such as serial x-ray radiography, bowel cleanout, endoscopy, exploratory laparotomy, fluoroscopy, and GI surgery, among others. As described previously in this memorandum, certain medical procedures, such as laparotomy and surgical resection of the bowel, may be associated with health risks, such as bleeding, infection, tissue injury, or adverse cardiopulmonary events, among others. Related health outcomes, possible with hazardous magnet ingestion, include mucosal inflammation, volvulus, bowel obstruction, pressure necrosis, fistulae, tissue ischemia, inflammation, perforation, peritonitis, sepsis, ulceration, and death, among others.

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Tab B: Memorandum by the Directorate for Epidemiology, Division of Hazard Analysis

This document has been electronically approved and signed.

TO: Stephen Harsanyi, Project Manager,
Division of Human Factors,
Directorate for Engineering Sciences

DATE: August 17, 2022

THROUGH: Risana Chowdhury, Division Director,
Division of Hazard Analysis,
Directorate for Epidemiology

FROM: James Tark, Mathematical Statistician,
Division of Hazard Analysis,
Directorate for Epidemiology

SUBJECT: Epidemiological Analysis of Reported Incidents Related to Ingestion of Magnets

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Introduction

In the notice of proposed rulemaking (NPR) for magnets, staff from the Hazard Analysis division in the Epidemiology Directorate provided a memorandum analyzing magnet ingestion incident data obtained through the National Electronic Injury Surveillance System (NEISS) and the Consumer Product Safety Risk Management System (CPSRMS) database.[1] The incident data analyzed for the NPR were extracted on January 8, 2021, and they included magnet ingestion reports that occurred from January 1, 2010, through December 31, 2020. Staff estimated that 23,700 emergency department-treated ingestions of magnets occurred in that timeframe. Among other observations, staff noted that estimates for magnet ingestions, excluding products considered to be out-of-scope of the proposed rule, fell during the period the CPSC magnet set rule was in effect, and they rose after the rule was subsequently vacated (79 FR 59962).[2] That is, staff estimated for the NPR 2,300 emergency department-treated ingestions of magnets from 2010 through 2013 (years prior to the announcement of the magnet set rule), 1,300 from 2014 through 2016 (years the rule was announced and in place), and 2,300 from 2017 through 2020 (the years following the removal of the rule).

As detailed in the NPR briefing package, the proposed rule addresses the magnet internal interaction hazard using magnet size and strength requirements for products with one or more magnets that are loose or separable, and designed, marketed, or intended to be used by consumers for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes (collectively referred to as "subject magnet products"). The subject magnet products do not include "children's toys," subject to the requirements

[1] CPSC staff's *Notice of Proposed Rulemaking Briefing Package* (2022): https://www.govinfo.gov/content/pkg/FR-2022-01-10/pdf/2021-27826.pdf. U.S. Consumer Product Safety Commission.
[2] CPSC staff's briefing package: Final Rule on Safety Standard for Magnet Sets (2014): https://cpsc.gov/s3fs-public/pdfs/foia_SafetyStandardforMagnetSets-FinalRule.pdf. The final rule for magnet sets included requirements limiting the size and strength of magnets, similar to the requirements in the NPR; that is, magnets in magnet sets were required to be too large to fit entirely within the small parts cylinder or have a flux index of 50 $kG^2 mm^2$ or less, consistent with the 2011 version of ASTM F963.

specified in ASTM F963 (16 CFR part 1250). Other products considered out-of-scope of the proposed rule include home and kitchen products, education and research products, and commercial and industrial products, contingent on these products not meeting the criteria for the subject magnet products. The draft final rule is described in the briefing memorandum. It is similar to the proposed rule, except for adding clarification regarding products not subject to the rule.

This memorandum provides an updated incident data analysis, covering magnet ingestions reported to have occurred from January 1, 2010, through December 31, 2021. The data were extracted on January 13, 2022, and they include the following updates to the data analyzed for the NPR: (1) addition of NEISS-reported ingestions that occurred from January 1, 2021, through December 31, 2021, and (2) additional CPSRMS-reported ingestions that occurred from February 1, 2016, through December 27, 2021. For the remainder of this memorandum, the incident data analyzed for the NPR are referred to as "NPR data," and the additional incident data analyzed since the NPR are referred to as "since the NPR"; however, the updated CPSRMS data include incidents from dates prior to and since the publication of the NPR because it is common for CPSRMS reports to be received in years following the incidents.[3] In this memorandum, staff reviews the additional data obtained since the NPR using the same characterizations in the NPR; updates the estimates for emergency department-treated, magnet ingestions; provides comparative analysis between the NPR data and data obtained since the NPR; and the memo responds to public comments on the NPR.

Updated NEISS Estimates 2010-2021 Summary:

- There were an estimated 26,600 (2,800 in 2021) emergency department-treated magnet ingestions involving magnet products of various types from 2010 through 2021.
- An estimated 5,000 of the 26,600 (20%) magnet ingestions involved magnet sets, magnet toys, or jewelry.
- An estimated 20,000 of the 26,600 (75.2%) magnet ingestions involved unidentified products.
- An estimated 1,600 of the 26,600 (6%) magnet ingestions involved products identified as out-of-scope.
- An estimated 5,000 victims (20%) were hospitalized or transferred to another hospital after treatment.
- The middle 3 years (2014 through 2016) show significantly fewer of these magnet ingestions (estimated 1,300 per year) compared with earlier and more recent years (*i.e.*, compared with 2,300 per year from 2010 through 2013 and 2,400 per year from 2017 through 2021).

Updated CPSRMS-Reported Incident Data Since NPR:

- Staff received 111 reports of magnet ingestions since the NPR, including 56 magnet ingestions that occurred in 2021.
- One (0.9%) magnet ingestion resulted in a death, and at least 74 (66.7%) resulted in hospitalizations.
- Reports for 72 (64.8%) magnet ingestions indicated the magnets came from magnet sets, magnet toys, or jewelry.
- Reports for 33 (29.7%) magnet ingestions indicated the magnets came from unidentified products.

[3] Staff considers the later years' of CPSRMS data to be incomplete and ongoing as the reports come from various sources, including consumer complaints, news clips, state/local authorities, medical examiners, manufacturers and retailers, among others.

- Reports for 6 (5.4%) magnet ingestions indicated the magnets came from products identified as out-of-scope.
- At least 43 (38.7%) incidents resulted in surgery.
- At least 32 (28.9%) incidents resulted in internal interaction through body tissue.

Discussion

NEISS Estimates Analysis

Staff considered all magnet ingestion cases in the NEISS database with treatment dates from January 1, 2010, through December 31, 2021, before removing cases determined irrelevant or too uncertain (using the criteria below). Data from NEISS are based on a nationally representative probability sample of about 100 hospitals in the United States and its territories. To gather all possible data related to the magnets of interest, staff implemented a keyword search and considered any case that mentioned "magnet" or other keywords[4] in the narrative field. This was completed across all products. Unless otherwise noted, all estimates span the 2010 through 2021 timeframe. From this master set, cases were excluded from the analysis, if any of the following applied:

- Any case that could not be determined to be magnet related, for example, "5YOF, acc swallowed dog toy vs magnet . . .";
- Any case with no ingestion, or with uncertainty as to whether any ingestion actually occurred;
- Any case with ambiguity about whether what was ingested included at least one magnet.

Consequently, cases describing "possible ingestion," or "may have ingested," are excluded, unless a final diagnosis confirming ingestion was explicit. Staff also excluded a few cases involving a magnet and a diagnosed ingestion, when staff was unable to discern whether the magnet was the object ingested. Collectively, the above criteria may have excluded some ingestions of in-scope magnets.[5]

CPSC staff categorized the resulting data set to assess the involvement of specific magnet product types in magnet ingestion cases. Based on the identification and/or description of the products involved in the cases, staff organized the cases into the following magnet categories, consistent with the NPR: "magnet set," "magnet toy," "jewelry," "science kit," "home/kitchen," "F963 magnet toy," and "unidentified," as described below.

- Magnet Set: Magnets from sets of loose-as-received ingestible magnets that are marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. These items met at least one of the following criteria: referred to as a magnet set or identified as a magnet set through product name. This excludes building sets with plastic and/or ferromagnetic components, unless otherwise identified as a magnet set. This also

[4] Other keywords searched include "science kit," "experiment," and some specific brand product names of known subject magnet products. Staff searched for cases referring to "science kit" and "experiment" to determine potential involvement in ingestion incidents of out-of-scope products subject to ASTM F963; ASTM F963 currently exempts from performance requirements products identified in the standard as "magnetic/electrical experimental sets," which are sometimes referred to as "science kits."
[5] Discussed further, below, staff uses the term "in-scope products" to refer to cases involving magnet products categorized by staff as "amusement/jewelry" or unidentified magnet products; *i.e.,* products that are likely subject to the draft final rule based on staff's analysis of NEISS, CPSRMS, and poison center data relative to the vacated magnet sets rule, among other considerations (see NPR briefing package). Staff excluded from this grouping known out-of-scope products, such as science kits, F963 magnet toys, and home/kitchen products, which would not be subject to the draft final rule.

excludes products reasonably identified as belonging to the other product types described below (*e.g.*, a magnetic clasp from a necklace).

- Magnet Toy: Magnets from products referred to as toys or games, but not also identified as a magnet set. This count includes products for which the manufacturer-intended user of the toy was an adult or unknown, and it excludes cases that positively identified toys subject to ASTM F963 (*i.e.*, excludes products confirmed to have been designed, manufactured, or marketed as playthings for children under 14 years of age).
- Jewelry: Magnets described as jewelry and not identified as a magnet set. Most of these cases involve magnets described as a bracelet, necklace, or piercing jewelry.
- Science Kit: Magnets from products identified as a science kit or magnetic/electrical experimental set.
- Home/Kitchen: Magnets from products such as non-toy magnet decorations, shower curtains, hardware, and kitchen products. Many of these cases specifically refer to the magnets as "kitchen magnets."
- F963 Magnet Toy: Magnets from toys subject to ASTM F963 (*i.e.,* products designed, manufactured, or marketed as playthings for children under 14 years of age). Reports for these cases included brand names or other information sufficient for staff to identify the involved products as toys subject to ASTM F963. The majority of these cases involved the magnetic tip of a children's magnetic stylus toy.
- Unidentified: Magnets from unidentified products, although product characteristics and use patterns typically shared commonalities with subject magnet products.

Shown in Tables 1 and 2 below, CPSC staff combined cases in the above magnet categories into groupings, as follows:

- "Amusement/Jewelry" – Cases involving "magnet sets," "magnet toys," or "jewelry";
- "Unidentified" – Cases involving "unidentified" magnet products;
- "Exclusions" – Cases involving "home/kitchen" products, "F963 magnet toys," or "science kits."[6]

Cases grouped as "amusement/jewelry" involved products identified or described consistent with the subject magnet products, such as magnetic desk toys and faux piercings/studs. Staff considered the use of the product in determining the most appropriate grouping. For example, magnets described as piercing jewelry, but with no other information, were considered "jewelry"; although some portion of these cases may have involved a magnet set or other magnet product.

Cases grouped as "unidentified" had insufficient information to identify the magnet product category, although product characteristics and use patterns may share commonalities with subject magnet products. Staff was conservative in grouping the majority of the NEISS cases as "unidentified." These cases typically lacked product identifying information beyond the ingested object being a magnet, such as a small, round magnet. However, as staff concluded in the NPR briefing package, considering distributions among these and other categories, as well as NEISS, CPSRMS, and poison center[7] magnet ingestion data relative to the vacated rule on

[6] The excluded product types are consistent with the NPR.
[7] As discussed in the NPR briefing package, Middelberg et al. (2021) found that annual national poison center magnet exposure calls increased by 344 percent from 281 per year (2012–2017) to 1,249 per year (2018–2019). Considering incidents dating back to 2008 (5,738 total), the incidents from 2018 and 2019, alone, accounted for 39 percent of the magnet incidents since 2008. These researchers drew similar conclusions to CPSC staff, asserting that significant increases in magnet injuries correspond to time periods in which high-powered magnet sets were allowed to be sold.

magnet sets, among other considerations, it is likely that the unidentified magnet products were subject magnet products (see the NPR briefing package for more information).

Cases grouped as "exclusions" involved products identified or described to be for purposes other than for amusement or jewelry, or that are already subject to ASTM F963, and therefore, are excluded from the draft final rule. For example, many of the "home/kitchen" products were shower curtains with a single magnet that was liberated and swallowed. "Home/kitchen" products and "F963 magnet toys" were rarely involved in internal interaction incidents or the common hazard pattern of use as jewelry, such as magnets used around the tongue, lip, and cheek to mimic piercings. There was a single case involving a product referred to as a "science kit," and staff finds it plausible that the product was intended for education and research, and it may have been a children's toy subject to ASTM F963.[8]

Table 1 provides the number of cases for each individual magnet category, and **Error! Reference source not found.** provides the estimates of emergency department-treated magnet ingestions in NPR, since NPR, and overall combined from 2010 through 2021.

Table 1. Count of Magnet Ingestion Cases Treated in NEISS Hospital Emergency Departments by Magnet Category, 2010-2021.

Individual Magnet Category	NPR	2021 (Since NPR)	2010-2021 (Combined)	Combined Magnet Category	NPR	2021 (Since NPR)	2010-2021 (Combined)
Magnet Set	58	7	65	Amusement/Jewelry	221	24	245
Jewelry*	53	1	54				
Magnet Toy	110	16	126				
Unidentified	793	81	874	Unidentified	794	81	874
Science Kit	1	0	1	Exclusions	57	7	65
F963 magnet toy	11	2	13				
Home/Kitchen	46	5	51				
Total	**1072**	**112**	**1,184**	**Total**	**1072**	**112**	**1,184**

*Includes cases of uncertain product classification for which the magnets were being used as or like jewelry.
Source: NEISS, CPSC

Table 2. Estimated Number of Magnet Ingestions Treated in Hospital Emergency Departments by Magnet Category, 2010-2021.

	NPR			Since NPR			Combined		
Magnet Category	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**
Amusement/Jewelry	4,400	0.17	221	**	**	24	5,000	0.16	245
Unidentified	18,100	0.14	793	1,900	0.26	81	20,000	0.15	874
Exclusions	1,300	0.20	58	**	**	7	1,600	0.19	65
Total	**23,700**	**0.21**	**1,072**	**2,500**	**0.22**	**105**	**26,600**	**0.14**	**1,184**

[8] Detailed in Tab C of this Briefing Package, staff reviewed the incident reports for the involvement of products subject to the performance requirements exemption in ASTM F963 for magnetic/electrical experimental sets, which therefore, would be considered out-of-scope of the draft final rule. These children's toys, which combine magnetism and electricity, such as electrical motors and doorbells, are sometimes referred to as "science kits." Staff identified in the data one case that referred to the involved product as a "science kit."

**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC. Estimates rounded to the nearest 100. Throughout this section, summations of estimates may not add to the total estimates provided in the tables, due to rounding. Estimates are derived from data in the NEISS sample. Estimates spanning periods of multiple years (such as the 12 years from 2010 to 2021) are total estimates, and *not* annual averages.

Table 3 provides the estimates for in-scope magnet categories in emergency department-treated ingestions in NPR, since NPR, and combined from 2010 through 2021. Combining only the Amusement/Jewelry and Unidentified categories, and omitting Exclusions, leaves us with a total of 25,000 estimated magnet ingestions that involved or likely involved the subject magnet products, as shown in Table 3. Of the 25,000 in-scope magnet ingestions, at least an estimated 5,000 (20%) correspond to cases associated with Amusement/Jewelry, and an estimated 20,000 (80%) correspond to the Unidentified categories. When considering the data received since the NPR, the majority of the cases involved unidentified products, similar to the NPR data. As mentioned above, staff assesses it is likely that many of these unidentified magnet products were subject magnet products.

Table 3. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Magnet Category, 2010-2021.

	NPR			Since NPR			Combined		
Magnet Category	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**	**Estimate**	**CV**	**N**
Amusement/Jewelry	4,400	0.17	221	**	**	24	5,000	0.16	245
Unidentified	18,100	0.15	793	1,900	0.26	81	20,000	0.15	874
Total	**22,500**	**0.14**	**1,014**	**2,500**	**0.22**	**105**	**25,000**	**0.14**	**1,119**

**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC. Estimates rounded to the nearest 100. Throughout this section, summations of estimates may not add to the total estimates provided in the tables, due to rounding. Estimates are derived from data in the NEISS sample. Estimates spanning periods of multiple years (such as the 12 years from 2010 to 2021) are total estimates, and *not* annual averages.

Table 4 provides the annual estimates for emergency department-treated, magnet ingestions by year from 2010 through 2021. Some of the year-to-year changes may be attributable to random variation in the sample; however, some differences are statistically significant. Overall, 2014 through 2016 still had the lowest number of estimated annual ED-treated magnet ingestions. The analysis of the NEISS data showed that there were insufficient cases in 2014, and only 2014, to provide an estimate. For 2015, estimated magnet ingestions were significantly lower than for any of the years 2010, 2011, 2012, 2017, 2018, and 2021. Similarly, estimated magnet ingestions in 2016 were significantly lower than for any of the years 2011, 2017, 2018, and 2021. Considering data received since the NPR, there were more estimated magnet ingestions in 2021 than the preceding years, with the exception of 2011, 2012, and 2017.

Table 4. Estimated Number of In-Scope* Magnet Ingestions Treated in Hospital Emergency Departments by Year.

Year	Estimate	CV	N
2010	1,900[a]	0.18	91
2011	2,500[a,b]	0.18	101
2012	2,700[a]	0.26	115
2013	2,000	0.21	88

2014	**	**	62
2015	1,200	0.24	61
2016	1,400	0.24	77
2017	2,900[a,b]	0.25	112
2018	2,400[a,b]	0.18	120
2019	1,800	0.22	91
2020	2,200	0.21	96
2021	2,500[a,b]	0.22	105
Total	**25,000**	**0.14**	**1,119**

a Estimate is significantly greater than that for the year 2015 (p-value<0.05).
b Estimate is significantly greater than that for the year 2016 (p-value<0.05).
*These estimates exclude cases identifying non-subject-product-type magnets, and therefore, do not represent all magnet ingestions treated in hospital emergency departments.
**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC; estimates rounded to nearest 100. Summations of estimates may not add to the total estimates, due to rounding.

The magnet injury ingestion estimates are lowest by a significant margin during the middle 3 years (2014-2016). Table 5 compares these middle 3 years against the earlier 4-year and most recent 5-year periods (2010-2013 and 2017-2021, respectively). Given these periods are not all of equivalent duration, annual averages are estimated to support fair comparisons. The data since the NPR affirms staff's previous analysis, demonstrating that magnet ingestions continued to rise since the magnet set rule was vacated.

Table 5. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Period.

Period	Annual Average Estimate	CV	N	Years in Period
2010 - 2013	2,300	0.16	395	4
2014 - 2016	1,300	0.20	200	3
2017 - 2021	2,400	0.15	524	5
2010 – 2021	**2,100**	**0.14**	**1,119**	**12**

Source: NEISS, CPSC; estimates rounded to nearest 100.

In the following tables, estimates are shown for NPR, since NPR, and entire 12-year timeframe 2010-2021. Table 6 presents the breakdown by age group.

Table 6. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Age Group, 2010-2021.

	Estimate			CV			N		
Age Group	NPR	Since NPR	Combined	NPR	Since NPR	Combined	NPR	Since NPR	Combined
Under 2 years	2,700	**	2,800	0.19	**	0.18	120	8	128
2 years	2,300	**	2,400	0.27	**	0.25	89	5	94
3-4 years	4,700	**	5,100	0.16	**	0.15	196	26	222
5-7 years	4,300	**	5,200	0.14	**	0.14	207	26	233
8-10 years	3,900	**	4,800	0.19	**	0.20	179	27	206

11-13 years	3,400	**	3,600	0.17	**	0.18	182	12	194
14 or More years	**	**	**	**	**	**	41	1	42
Total	**22,500**	**2,500**	**25,000**	**0.14**	**0.22**	**0.14**	**1,014**	**105**	**1,119**

**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases, and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC; estimates are rounded to nearest 100.

The estimated number of emergency department-treated magnet ingestions by sex, is provided in Table 7.

Table 7. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Sex, 2010-2021.

Sex	Estimate			CV			N		
	NPR	Since NPR	Combined	NPR	Since NPR	Combined	NPR	Since NPR	Combined
Female	9,100	1,300	10,400	0.15	0.24	0.15	421	47	468
Male	13,300	1,300	14,600	0.14	0.27	0.14	593	58	651
Total	**22,500**	**2,500**	**25,000**	**0.14**	**0.22**	**0.14**	**1,014**	**105**	**1,119**

Source: NEISS, CPSC; estimates are rounded to nearest 100.

Table 8 cross-tabulates sex against whether the victim is under the age of 8 or older. Victims' ages are split between younger than 8 years and over 8 years (see Tab C for more information pertaining to these age groupings). The 2021 estimates by sex and the two age groups are not presented as they do not meet NEISS reporting criteria.

Table 8. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Sex and Age Group, 2010-2021.

Sex	Under 8 Years			8 or More Years			Total		
	NPR	Since NPR	Combined	NPR	Since NPR	Combined	NPR	Since NPR	Combined
Female	5,600	**	6,200	3,500	**	4,100	9,100	**	**10,400**
Male	8,400	**	9,200	4,900	**	5,400	13,300	**	**14,600**
Total	**14,000**	****	**15,500**	**8,500**	****	**9,500**	**22,500**	****	**25,000**

NEISS, CPSC; estimates are rounded to nearest 100. Estimates do not always add to Total due to rounding.

An estimated 5,000 (20% of 25,000) victims were hospitalized or transferred to another hospital, and an estimated 19,600 (79%) victims were treated and released from 2010 through 2021, as shown in Table 9. Some portion of cases resulting in victims "treated and released" may have resulted in further hospitalization, because victims complaining of magnet ingestions are often sent home initially to monitor for natural passage, and the NEISS data typically capture only one part of the treatment process (the emergency department visit), and do not show information on treatment after the initial visit.

Table 9. Estimated Number of In-Scope Magnet Ingestions Treated in Hospital Emergency Departments by Disposition, 2010-2021.

	Estimate			CV			N		
Disposition	**NPR**	**Since NPR**	**Comb-ined**	**NPR**	**Since NPR**	**Comb-ined**	**NPR**	**Since NPR**	**Comb-ined**
Hospitalized/ Transferred	4,200	**	5,000	0.19	**	0.21	264	33	297
Treated and Released	18,000	1,700	19,600	0.14	0.21	0.13	735	68	803
Other *	**	**	**	**	**	**	15	4	19
Total	**22,500**	**2,500**	**25,000**	**0.14**	**0.22**	**0.14**	**1,014**	**105**	**1,119**

*Dispositions observed among the "other" category in the sample cases include "Held for observation (includes admitted for observation)" and "Left without being seen/Left against medical advice."
**This estimate does not meet NEISS reporting criteria. For a NEISS estimate to satisfy all reporting criteria, the coefficient of variation (CV) cannot exceed 0.33, there must be at least 20 sample cases (N), and there must be at least 1,200 estimated injuries.
Source: NEISS, CPSC; estimates are rounded to nearest 100.

CPSRMS-Reported Incident Analysis Results

This section provides a summary of the additional CPSRMS-reported magnet ingestions since the NPR. CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries.[9] Examples of documents in CPSRMS include hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others. As stated above, these additional magnet ingestions occurred from February 1, 2016, through December 27, 2021, but were reported to CPSC staff from January 14, 2021 (data extraction date for NPR) through January 8, 2022. Additionally, the total numbers of CPSRMS-reported incidents for both the NPR data and data since the NPR, spanning January 1, 2010, through December 31, 2021, are provided. Since publication of the NPR, the Commission has received reports of 111 additional incidents involving the ingestion of magnets, including one report of a fatality associated with the ingestion of small spherical magnets. The same methodology as used in the NPR analysis was used to identify and classify incidents in this analysis. The categories and their criteria are provided below:

- Magnet Set: Magnets from sets of loose-as-received ingestible magnets that are marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. These items met at least one of the following criteria: referred to as a magnet set, identified as a magnet set through product name, included photos identifying the product, or other available information providing staff reasonable certainty that the involved product was a magnet set (*e.g.*, products described identically to known magnet sets, such as desk toys consisting of 216 loose, magnetic balls). Brand was indicated for most of these

[9] CPSC staff considers CSPRMS reports to be anecdotal, because, unlike NEISS data, they cannot be used to identify statistical estimates or year-to-year trend analysis, and because incident reports CPSC receives in CPSRMS can range in hazard severity, including incidents with only the potential to cause injury. Although these anecdotal data do not provide for statistical analyses, they often provide rich data with important information to identify hazard patterns, as well as provide a minimum count of certain injuries and deaths.

incidents. Incidents were excluded from this grouping if a medical professional identified the product as a magnet set, but the investigator and victim indicated that they were unable to identify the product as a magnet set.

- Magnet Toy: Magnets from products referred to as toys or games, but not also identified as a magnet set. This count includes products for which the manufacturer-intended user of the toy was an adult or unknown, and it excludes cases that positively identified toys subject to ASTM F963 (*i.e.,* excludes products confirmed to have been designed, manufactured, or marketed as playthings for children under 14 years of age).
- Jewelry: Magnets described as jewelry and not definitively identified as a magnet set. Most of these cases involve magnets described as a bracelet, necklace, or piercing jewelry.
- Science Kit: Magnets from products identified as a science kit or magnetic/electrical experimental set.
- Home/Kitchen: Magnets from products such as non-toy magnet decorations, shower curtains, hardware, and kitchen products.
- F963 Magnet Toy: Magnets from toys subject to ASTM F963 (*i.e.,* products designed, manufactured, or marketed as playthings for children under 14 years of age). Reports for these incidents included brand names or other information sufficient for staff to identify the products involved as toys subject to ASTM F963. The majority of these cases involved magnetic building sets with magnets encased in plastic.
- Unidentified: Magnets from unidentified products, although product characteristics and use patterns typically shared commonalities with subject magnet products.

Consistent with the NEISS data analysis, staff further sorted incidents, as follows:

- "Amusement/Jewelry" – Incidents involving "magnet sets," "magnet toys," or "jewelry";
- "Unidentified" – Incidents involving "unidentified" magnet products;
- "Exclusions" – Incidents involving "home/kitchen" products, "F963 magnet toys," or "science kits."

As with the NEISS-reported data, many of the cases in these groupings include a degree of uncertainty in product identification (such as a "magnet toy" actually involving a "magnet set"), and staff finds it likely that magnet ingestion incidents in which there was insufficient information to identify the product, involved subject magnet products.

Regarding the "exclusions," none of the incident reports identified or described science kits or other magnet products used for education and research only.

Table 10 breaks down the number of reported magnet ingestions in each category as presented in the NPR briefing package and incidents reported since the NPR. Of the 111 newly reported incidents, staff identified 64 incidents as involving a *Magnet Set* and 33 incidents as an *Unidentified* product.

Table 10. Magnet Category and Scope for Reported Magnet-Ingestions, January 2010-December 2021.*

	Reported Incidents				Reported Incidents		
Magnet Category	**NPR**	**Since NPR**	**2010-2021 Total**	**Scope**	**NPR**	**Since NPR**	**Total**
Magnet Set	134 (47.2%)	64 (57.7%)	198 (50.1%)	Amusement/ Jewelry	214 (90.5%)	72 (94.6%)	286 (91.6%)

Magnet toy	49 (17.3%)	7 (6.3%)	56 (14.2%)				
Jewelry	31 (10.9%)	1 (0.9%)	32 (8.1%)				
Unidentified	43 (15.1%)	33 (29.7%)	76 (19.2%)	Unidentified	43 (14.8%)	33 (29.7%)	76 (19.0%)
Science Kit	0	0	0	Exclusions	27 (9.5%)	6 (5.4%)	33 (8.4%)
F963 Magnet Toy	21 (7.4%)	4 (3.6%)	25 (6.3%)				
Home/Kitchen	6 (2.1%)	2 (1.8%)	8 (2.0%)				
Total	**284 (100%)**	**111 (100%)**	**395 (100%)**	**Total**	**284 (100%)**	**111 (100%)**	**395 (100%)**

*CPSRMS reporting for the years 2020-2021 is ongoing.

Figure 1 shows the year of incident by magnet category. Because data reporting is ongoing, staff received 3, 5, 10, 13, 24, and 56 additional incident reports which occurred in 2016, 2017, 2018, 2019, 2020, and 2021, respectively, since the completion of the analysis for the NPR. Counts for reported incidents, especially in 2020 and 2021, may increase as CPSC continues to collect data. Moreover, due to the anecdotal nature of the data, the data in this analysis are to be considered a minimum of all incidents that have actually occurred.

Histogram by Incident Year and Magnet Category for Reported Magnet-Ingestions, January 2010-December 2021*

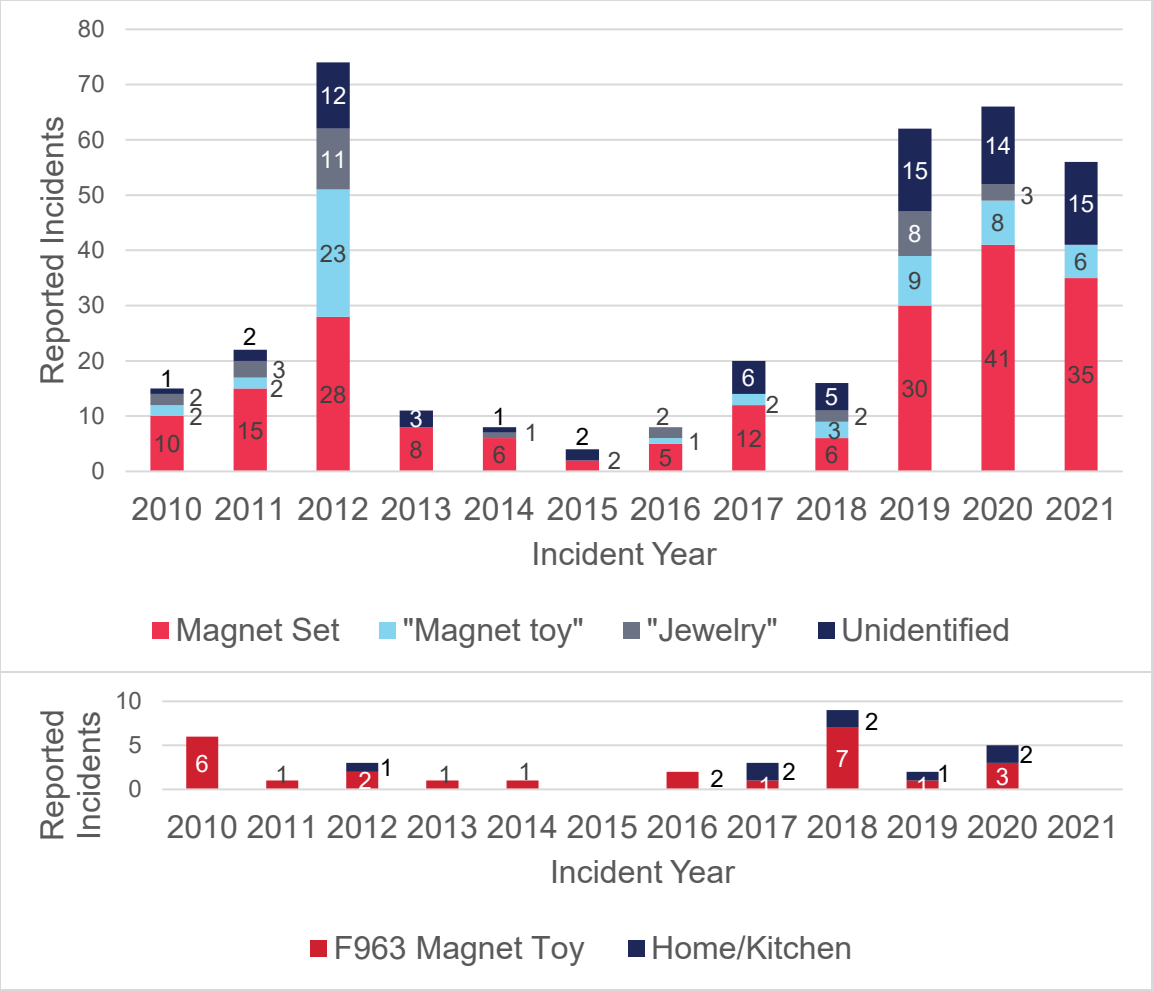

Figure 1. Annual incidents involving magnet product categories. *CPSRMS reporting for the years 2020-2021 is ongoing, and the counts for those years may increase as reporting continues.

Table 11 provides the number of reported incidents by disposition of the incident (e.g., severity of outcome) and magnet category. Of the 111 reported ingestions since NPR, 74 (66.7% compared to 65.8% in NPR) resulted in a hospitalization and 1 (0.9% compared to 1.1% in NPR) resulted in a death.

Table 11. Disposition by Magnet Category for Reported Magnet-Ingestions, January 2010-December 2021.*

Magnet Category	Disposition											
	Death			Hospitalization			Other			Total		
	2010-2020 (NPR)	2017-2021 Since NPR	Comb-ined	NPR	Since NPR	Comb-ined	NPR	Since NPR	Comb-ined	NPR	Since NPR	Comb-ined
Magnet Set	0	1	1	88	48	136	46	15	61	134	64	198
Magnet toy	1	0	1	35	5	40	13	2	15	49	7	56
Jewelry	0	0	0	20	0	20	11	1	12	31	1	32
Unidentified	2	0	2	28	18	46	13	15	28	43	33	76
F963 toy	0	0	0	11	2	13	10	2	12	21	4	25
Home/ Kitchen	0	0	0	5	1	6	1	1	2	6	2	8
Total	**3**	**1**	**4**	**187**	**74**	**261**	**94**	**36**	**130**	**284**	**111**	**395**

*CPSRMS reporting for the years 2020-2021 is ongoing. "Other" includes all remaining incidents reported *without indicating* hospitalization or death.

Public Comments Pertaining to Epidemiology

Discussed in the Briefing Memorandum, CPSC received 716 comments regarding the proposed rule. Additionally, on March 2, 2022, CPSC held an oral hearing pertaining to the proposed rule, at which time five comments were presented. Commenters provided statements in favor and in opposition to the proposed rule, and some suggested ways to improve the proposed rule in their view. These written and oral comments can be found in docket number CPSC-2021-0037 at: http://www.regulations.gov/. Below, staff addresses the comments regarding the incidence of magnet ingestions.

Commenters in favor of the proposed rule claimed that magnet ingestions are prevalent, providing medical treatment anecdotes and referring to NEISS, CPSRMS, and poison center data regarding magnet ingestions (see Tab A). These commenters were typically medical associations and individual medical professionals.

Commenters against the proposed rule generally opined that the subject magnet products are rarely involved in magnet ingestion incidents. These commenters were typically individual consumers, many of whom claimed that there have been only a "few," "several," or "handful of" injuries. Commenters commonly cited outdated magnet ingestion data relative to sales, such as from staff's 2012 NPR briefing package regarding magnet sets (NEISS incident data spanning 2009 through 2011).[10]

Staff's Response: Detailed in this memorandum and Tab C, magnet ingestions are common and have increased in recent years. Staff estimates 26,600 magnet ingestions were treated in hospital emergency departments from January 1, 2010 through December 31, 2021; an estimated 25,000 ingestions excluding out-of-scope products. Staff estimates 2,500 emergency department-treated ingestions of magnets from in-scope products occurred in year 2021, higher than the majority of the preceding years, including 2018 through 2020. An estimated 5,000 (20% of 25,000) victims were hospitalized or transferred to another hospital from 2010 through 2021. These estimates are based on the NEISS reports, which capture only brief narratives from the emergency department visit; therefore, they do not account for the victims who were initially released and later sought medical attention for magnet-related injuries, including from

[10] See "Safety Standard for Magnet Sets; Notice of Proposed Rulemaking": https://www.cpsc.gov/s3fs-public/pdfs/foia_magnetstd.pdf.

complications due to the medical management (see Tab A). In examining CPSRMS data from this 12-year period, staff found that at least 167 CPSRMS-reported magnet ingestions resulted in surgery (including 43 incidents since the NPR), such as laparoscopy, laparotomy, appendectomy, cecostomy, enterotomy, colostomy, cecectomy, gastrotomy, jejunostomy, resection, and transplant, among others.

Conclusion

This memorandum provides an updated incident data analysis, covering NEISS- and CPSRMS-reported magnet ingestions that occurred from January 1, 2010, through December 31, 2021. In addition to the data analyzed for the NPR, staff reviewed 112 NEISS-reported magnet ingestions and an additional 111 CPSRMS-reported magnet ingestions since the NPR. For the full studied period of January 1, 2010, through December 31, 2021, staff estimates 25,000 emergency department-treated ingestions of magnets from "in-scope" products. Staff observed that the additional data affirmed staff's previous analysis, including that estimated emergency department-treated ingestions of magnets from "in-scope" products continued to rise since the previous rule pertaining to magnet sets was vacated. Staff estimates 2,500 emergency department-treated ingestions of magnets from "in-scope" products occurred in year 2021, which is higher than the majority of the preceding years, including 2018 through 2020.

Tab C: Memorandum by the Directorate for Engineering Sciences, Division of Human Factors

This document has been electronically approved and signed.

TO: The Magnets Rulemaking Project File **DATE:** August 17, 2022

THROUGH: Rana Balci-Sinha, Division Director,
Division of Human Factors,
Directorate for Engineering Sciences

FROM: Stephen Harsanyi, Engineering Psychologist,
Division of Human Factors,
Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of the Magnet Internal Interaction Hazard

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Introduction

This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), updates ESHF staff's analysis of the magnet internal interaction hazard provided in the NPR briefing package.[1] In the following sections, staff reviews the hazard, provides a comparative analysis of the incident data for and since the NPR, discusses staff's current assessment of existing standards and alternative measures for addressing the hazard, summarizes and responds to public comments on the NPR, and provides recommendations regarding the draft final rule.

Discussion

Background of NPR

The briefing memorandum (Harsanyi, 2022; Tab A) discusses the Commission's 2022 NPR on magnets[2] and summarizes the NPR briefing package. The NPR addresses the magnet internal interaction hazard associated with children and teens ingesting small, powerful magnets ("hazardous magnets"). The magnet internal interaction hazard is described in the NPR as internal injuries from ingested hazardous magnets, or an ingested hazardous magnet and an ingested ferromagnetic object, interacting internally through body tissue and resisting natural bodily forces to separate. In 16 CFR 1262.2, the proposed rule identifies a magnet as hazardous consistent with ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, which is codified under 16 CFR part 1250, as a magnet that fits entirely within the cylinder described in 16 CFR 1501.4 and that has a flux index of 50 kG^2 mm^2 or more when tested in accordance with the method described in 16 CFR part 1262. The proposed rule addresses this hazard by requiring that subject magnet products may not contain one or more loose or

[1] CPSC staff briefing package, *Draft Notice of Proposed Rulemaking for Hazardous Magnet Products* (2021), https://www.cpsc.gov/s3fs-public/Proposed-Rule-Safety-Standard-for-Magnets.pdf?VersionId=2Xizl5izY1OvQRVazWpkqdJHXg5vzRY_.
[2] Commission NPR on magnets (2022): https://www.govinfo.gov/content/pkg/FR-2022-01-10/pdf/2021-27826.pdf.

separable hazardous magnets (§ 1262.3). "Subject magnet product" is defined as a consumer product that is designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contains one or more loose or separable magnets (§ 1262.2). Toys subject to ASTM F963 are exempted from the proposed rule. The NPR provides examples of other products not subject to the rule, such as products intended for home, education, research, and/or commercial purposes, which are not also intended for subject magnet product uses.

In the NPR briefing package, staff provides an analysis of the following, among others: magnet ingestion incident data, product samples, available literature, voluntary standards, international actions, CPSC recall activity, methods to address the hazard, and economic factors pertaining to the proposed rule and related injuries. Staff determined that the subject magnet products carry the highest risk for children and teens in terms of ingestion-related outcomes, and staff concluded that products involved in incidents for which identification was uncertain generally involved subject magnet products (see Tab A). After considering various methods by which to address the hazard, including safety messaging (*e.g.,* warnings, instructional literature, marketing, and public awareness raising efforts) and safeguards (*e.g.,* CR packaging and aversive agents), staff concluded that the proposed performance requirements were necessary to adequately address the hazard. Discussed below, the draft final rule is consistent with the proposed rule, except for several clarifications to the product scope.

Updated Incident Data Analysis

Detailed in the Epidemiology memorandum (Tab B; Tark, 2022), staff extracted for this updated analysis National Electronic Injury Surveillance System (NEISS)[3] and Consumer Product Safety Risk Management System (CPSRMS)[4] magnet ingestion incident data reported to have occurred from January 1, 2010, through December 31, 2021. The data were extracted on January 13, 2022, and they include the following updates to the data analyzed for the NPR: (1) addition of NEISS-reported incidents that occurred from January 1, 2021, through December 31, 2021, and (2) additional CPSRMS-reported incidents that occurred from February 1, 2016, through December 27, 2021.[5] For the remainder of this memorandum, the incident data analyzed for the NPR are referred to as "NPR data," and the additional incident data analyzed since the NPR are referred to as "since the NPR"; however, the updated CPSRMS data include incidents from dates prior to and since the publication of the NPR.

Staff analyzed the updated data to assess the incidence and severity, products involved, victims' ages, behavioral patterns, sources of access, use of safety messaging, and other pertinent information. In the following sections, staff provides a comparative analysis of the NPR data and data since the NPR, and staff concludes that the data since the NPR affirm staff's previous analysis.

[3] Data from NEISS are based on a nationally representative probability sample of about 100 hospitals in the United States and its territories.
[4] CPSRMS is the epidemiological database that houses all anecdotal reports of incidents received by CPSC, "external cause"-based death certificates purchased by CPSC, all in-depth investigations of these anecdotal reports, as well as investigations of select NEISS injuries. Examples of documents in CPSRMS include the following: hotline reports, Internet reports, news reports, medical examiner's reports, death certificates, retailer/manufacturer reports, and documents sent by state/local authorities, among others.
[5] The CPSRMS data analyzed in support of the NPR were extracted on January 8, 2021. Reporting to the CPSRMS database is ongoing, and therefore, it is common for reports to be received pertaining to incidents from prior years.

Incidence and Severity

Tab B provides staff's epidemiological assessment of NEISS and CPSRMS reported magnet ingestion data, such as staff's estimates for magnet ingestions treated in hospital emergency departments. Staff found that the 2021 NEISS data supported staff's previous analysis, including staff's analysis that cases continued to rise since the previous rule on magnet sets (79 FR 59962) was vacated,[6] adding support to staff's conclusion that the similar magnet set rule was effective for addressing the largest proportion of subject magnet products with loose or separable hazardous magnets, and that unidentified magnet products involved in ingestion incidents generally involved subject magnet products.

In examining CPSRMS data from this 12-year period, staff identified 395 magnet ingestions. Of these 395 magnet ingestions, 111 magnet ingestions were reported since the NPR, including 56 magnet ingestions that occurred in 2021. The CPSRMS reports tended to include more information about the incidents and involved more product-specific information than the NEISS reports, often containing photos, websites, detailed narratives, and medical documents. In contrast, the NEISS reports contained brief narratives culled from medical records developed during the emergency department visit. Staff analyzed the CPSRMS reports for information pertaining to medical management and evidence of internal interaction of ingested magnets through body tissue. Staff found that at least 167 CPSRMS-reported magnet ingestions resulted in surgery (including 43 incidents since the NPR), such as laparoscopy, laparotomy, appendectomy, cecostomy, enterotomy, colostomy, cecectomy, gastrotomy, jejunostomy, resection, and transplant, among others. At least 140 CPSRMS-reported magnet ingestions resulted in internal interaction through body tissue (including 32 incidents since the NPR). In cases that did not result in surgery, it was still common for victims to receive serial X-rays, and, in many cases, endoscopies and anesthesia.

The Health Sciences memorandum (Tab A; Johnson, 2022), summarizes magnet ingestion literature and findings from medical associations and individual medical practitioners. Staff discusses numerous examples of magnet ingestion incidents that demonstrate the potential severity of injury, ambiguity of symptomatology, and complex medical management of magnet ingestions. Among other important considerations, staff explains that X-rays, which are typically one of the first diagnostic steps, are unable to identify an ingested object as a magnet, whether it is a hazardous magnet, and cannot show if tissue is trapped between magnets.

Magnet Categories

Based on the identification and/or description of the products involved in the incidents, staff organized the incidents into the following magnet product categories: "magnet set," "magnet toy," "jewelry," "science kit," "home/kitchen," "F963 magnet toy," and "unidentified." These magnet categories are consistent between the NPR data and data since the NPR. Tables 1 and 2, below, provide the counts and percentages of incidents involving these magnet categories and the criteria staff used to categorize incidents into them. The descriptions vary slightly between these tables because the CPSRMS reports typically contain more product-specific information than the NEISS reports. The tables show a comparison of magnet ingestions analyzed for the NPR and since the NPR.

[6] Staff defines magnet set as an aggregation of separable magnetic objects that are marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. Magnet sets typically contain hundreds to thousands of loose magnets, and constitute the largest and most concerning portion of identified subject magnet products involved in ingestion incidents.

Table 1. Magnet categories in the 1,184 NEISS-reported magnet ingestion incidents. The percentages in this table are rounded to the nearest tenth. There were 112 cases reported since the NPR, all of which occurred in year 2021.

Magnet Category	NPR		Since NPR		Total		Description
	#	%	#	%	#	%	
Magnet Set	58	5.4%	7	6.3%	65	5.5%	Magnets from sets of loose-as-received ingestible magnets that are marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. Referred to as a magnet set or identified as a magnet set through product name. Excludes: • Building sets with plastic and/or ferromagnetic components. • Products reasonably identified as belonging to the other product types.
Magnet Toy	110	10.3%	16	14.3%	126	10.6%	Magnets from products referred to as toys or games, but not also identified as a magnet set. This count includes products for which the manufacturer-intended user of the toy was an adult or unknown age, and it excludes cases that positively identified toys subject to ASTM F963 (*i.e.,* excludes products confirmed to have been designed, manufactured, or marketed as playthings for children under 14 years of age).
Jewelry	53	4.9%	1	0.9%	54	4.6%	Magnets described as jewelry and not identified as a magnet set. Most of these cases involve magnets described as a bracelet, necklace, or piercing jewelry.
Science Kit	1	0.1%	0	0	1	0	Magnets from products identified as a science kit or magnetic/electrical experimental set.
Home/Kitchen	46	4.3%	5	4.5%	51	4.3%	Magnets from products such as non-toy magnet decorations, shower curtains, hardware, and kitchen products. Many of these cases specifically refer to the magnets as "kitchen magnets."
F963 Magnet Toy	11	1%	2	1.8%	13	1.1%	Magnets from toys subject to ASTM F963. Reports for these cases included brand names or other information sufficient for staff to identify the involved products as toys subject to ASTM F963. The majority of these cases involved the magnetic tip of a children's magnetic stylus toy.
Unidentified	793	74%	81	72.3%	874	73.8%	Magnets from unidentified products, although product characteristics and use patterns typically shared commonalities with subject magnet products.
Total	**1,072**		**112**		**1,184**		

Table 2. Magnet categories in the 395 CPSRMS-reported magnet ingestion incidents. The percentages in this table are rounded to the nearest tenth. There were 111 cases reported since the NPR, which occurred in years 2016 through 2021.

Magnet Category	NPR		Since NPR		Total		Description
	#	%	#	%	#	%	
Magnet Set	134	47.2%	64	57.7%	198	50.1%	Magnets from sets of loose-as-received ingestible magnets that are marketed or commonly used as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief. These items met at least one of the following criteria: • referred to as a magnet set, • identified as a magnet set through product name, • included photos identifying the product, or • other information provided to claim with reasonable certainty that the involved product was a magnet set (*e.g.,* products described identically to known magnet sets, such as desk toys consisting of 216 loose, magnetic balls). Brand was indicated for most of these incidents. Incidents were excluded from this grouping if a medical professional identified the product as a magnet set, but the investigator and victim indicated that they were unable to identify the product as a magnet set.
Magnet Toy	49	17.3%	7	6.3%	56	14.2%	Magnets from products referred to as toys or games, but not also identified as a magnet set. This count includes products for which the manufacturer-intended user of the toy was an adult or unknown, and it excludes incidents that positively identified toys subject to ASTM F963 (*i.e.,* excludes products confirmed to have been designed, manufactured, or marketed as playthings for children under 14 years of age).
Jewelry	31	10.9%	1	0.9%	32	8.1%	Magnets described as jewelry and not definitively identified as a magnet set. Most of these incidents involve magnets described as a bracelet, necklace, or piercing jewelry.
Science Kit	0	0%	0	0%	0	0%	Magnets from products identified as a science kit or magnetic/electrical experimental set.
Home/Kitchen	6	2.1%	2	1.8%	8	2%	Magnets from products such as non-toy magnet decorations, shower curtains, hardware, and kitchen products.
F963 Magnet Toy	21	7.4%	4	3.6%	25	6.3%	Magnets from toys subject to ASTM F963. Reports for these incidents included brand names or other information sufficient for staff to identify the involved products as toys subject to ASTM F963. The majority of these incidents involved magnetic building sets with magnets encased in plastic.
Unidentified	43	15.1%	33	29.7%	76	19.2%	Magnets from unidentified products, although product characteristics and use patterns typically shared commonalities with subject magnet products.
Total	**284**		**111**		**395**		

Staff combined these magnet categories as follows (counts provided for incidents reviewed since the NPR):

- "Amusement/Jewelry" – ingestions of magnets from "magnet sets," "magnet toys," and "jewelry" (24 NEISS incidents and 72 CPSRMS incidents);
- "Unidentified" – ingestions of magnets from "unidentified" magnet products (81 NEISS incidents and 33 CPSRMS incidents); and
- "Exclusions" – ingestions of magnets from "science kits," "home/kitchen" products, and "F963 magnet toys" (7 NEISS incidents and 6 CPSRMS incidents).

Staff did not identify any cases involving products intended only for school, research, professional, commercial, or industrial purposes, consistent with staff's analysis for the NPR. None of the data since the NPR indicated a science kit was involved.

In general, the incident data reviewed since the NPR were similar to the NPR incident data. Product identification was uncertain in most cases, particularly the NEISS reports. For example, many of the "jewelry" incidents involved magnets from products described as bracelets, necklaces, and faux piercings/studs, but some portion of these incidents may have involved magnet sets or other products. Similarly, products were categorized as "magnet toys," based on brand/model name and/or description as "toys," "games," or similar. Staff attempted to separate from this "magnet toys" category products identified as children's toys subject to ASTM F963 (out-of-scope of the draft final rule) or magnet sets. As a consequence of uncertainties, some portion of the "magnet toy" incidents may have involved other products. Products categorized as "amusement/jewelry" were substantially more prevalent in the incident data than "exclusions," and they were more likely to have involved surgery and internal interaction through tissue. None of the incident reports indicated that surgery or internal interaction resulted from the exclusions, similarly to the NPR data, which identified only a small number of out-of-scope products that resulted in surgery or internal interaction.

Based on factors, including (1) the known products involved in magnet ingestion incidents (*i.e.,* of the known products involved in magnet ingestion incidents, the subject magnet products constitute a much larger proportion of the cases than the excluded products, particularly when considering cases that resulted in surgery); (2) the success of ASTM F963 in reducing the number of children's toys involved in magnet internal interaction injuries; and (3) incidences of NEISS-, CPSRMS-, and poison center-reported[7] magnet ingestions relative to the vacated rule on magnet sets, staff concluded that magnet ingestions involving unidentified magnet products generally involved products that would be covered by the proposed rule (see the NPR briefing package for more information). In the sections that follow, unless otherwise specified, the counts and percentages exclude the incidents categorized by staff as exclusions.

Victims' Ages

Tab B provides NEISS estimates for ages involved in magnet ingestion incidents. Staff found that the victims' ages in the data since the NPR were similar to the NPR data. Table 3, below, shows a comparison of the ages of victims in magnet ingestion incidents in the NPR data and since the NPR.

Table 3. Age distribution of NEISS- and CPSRMS-reported magnet ingestion victims. These counts and percentages exclude the incidents categorized as exclusions. The percentages in this table are rounded to the nearest tenth.

Victim Age	NEISS						CPSRMS					
	NPR		Since NPR		Total		NPR		Since NPR		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
< 2 yrs	120	11.8%	8	7.6%	128	11.4%	21	8.2%	9	8.6%	30	8.3%

[7] As discussed in the NPR briefing package, Middelberg et al. (2021) found that annual national poison center magnet exposure calls increased by 344 percent from 281 per year (2012–2017) to 1,249 per year (2018–2019). Considering incidents dating back to 2008 (5,738 total), the incidents from 2018 and 2019, alone, accounted for 39 percent of the magnet incidents since 2008. These researchers drew similar conclusions to CPSC staff, asserting that significant increases in magnet injuries correspond to time periods in which high-powered magnet sets were allowed to be sold.

2 yrs	89	8.8%	5	4.8%	94	8.4%	32	12.5%	15	14.3%	47	13.0%
3 yrs thru 4 yrs	196	19.3%	26	24.8%	222	19.8%	31	12.1%	17	16.2%	48	13.3%
5 yrs thru 7 yrs	207	20.4%	26	24.8%	233	20.8%	28	10.9%	19	18.1%	47	13.0%
8 yrs thru 10 yrs	179	17.7%	27	25.7%	206	18.4%	66	25.7%	23	21.9%	89	24.6%
11 yrs thru 13 yrs	182	18%	12	11.4%	194	17.3%	37	14.4%	15	14.3%	52	14.4%
14 yrs thru 16 yrs	30	3%	1	1.0%	31	2.8%	12	4.7%	1	1.0%	13	3.6%
> 16 yrs	11	1.1%	0	0.0%	11	1.0%	1	0.4%	0	0.0%	1	0.3%
Unknown	0	0%	0	0.0%	0	0.0%	29	11.3%	6	5.7%	35	9.7%
Totals:	**1,014**		**105**		**1,119**		**257**		**105**		**362**	

Staff highlights the following observations for the data collected since the NPR (percentages are approximated):

- the youngest victim in NEISS-reported incidents was 8 months old (age 6 months in NPR data), and age 14 months (age 11 months in NPR data) in CPSRMS-reported incidents;
- the oldest victim in NEISS-reported incidents was 15 years old (age 54 years in NPR data) and age 16 years (age 43 years in NPR data) in CPSRMS-reported incidents;
- 12.4 percent (19.8% NPR data) of the NEISS-reported incidents and 22.9 percent (21.3% NPR data) of the CPSRMS-reported incidents involved victims under 3 years of age;
- 37.2 percent (39.7% NPR data) of the NEISS-reported incidents and 39.1 percent (34.5% NPR data) of the CPSRMS-reported incidents identified victims under 5 years of age;
- 62 percent (60.5% NPR data) of the NEISS-reported incidents and 57.2 percent (47.5% NPR data) of the CPSRMS-reported incidents identified victims under 8 years of age; and
- 38.1 percent (39.5% NPR data) of NEISS-reported incidents and 42.9 percent (42.8% NPR data) of CPSRMS-reported incidents identified victims 8 years of age or older.[8]

Victims' ages were similar between the NPR data and data collected since the NPR, although the NPR data included several adult victims. Detailed in the NPR briefing package, the age groups bulleted above are important to consider for understanding and addressing the hazard. Explanations and implications of these observations are summarized, below:

- victim age is a very important consideration for the magnet internal interaction hazard, both in terms of hazard patterns and measures by which to address the hazard;
- the subject magnet products, or at least the loose or separable magnets from these products, have appeal to children and teens, including magnet sets known to be intended for consumers 14 years and older, and therefore not subject to the requirements specified in ASTM F963;

[8] Note: approximately 5.7 percent (9.7% NPR data) of CPSRMS-reported incidents involved children of unspecified ages.

- foreign body ingestions of all kinds are common among children, typically peaking from 6 months to 3 years of age (Green, 2015), and children ages 2 years and older are likely to be mobile and unlikely to be under direct supervision at all times;
- infants and toddlers are unlikely to comprehend warnings and may be unable to communicate that they ingested magnets;
- child-resistant (CR) packaging consistent with the Poison Prevention Packaging Act (PPPA)[9] is designed or constructed to be significantly difficult for children under 5 years of age to open within a reasonable amount of time, and the majority of the victims were above this age; and
- various standards bodies consider children ages 8 years and older to be capable of understanding and following warnings pertaining to hazardous magnets, yet a large proportion of victims were ages 8 years and older.

Behavioral Patterns

Staff categorized the behaviors at the time of ingestion as follows:

- "Playing" – ingestions of magnets while playing, fidgeting, orally exploring the magnets (examples include testing the attraction through teeth or on braces), or a combination of these actions. If playing involved use of the product as jewelry, the incident was identified as "jewelry." Excludes incidents involving intentional ingestion.
- "Jewelry" – ingestions involving magnets used as jewelry at the time of the incident, such as bracelets, necklaces, and simulated piercings (examples include magnets used around the tongue, lip, and cheek to look like real piercings).
- "Intentionally ate" – ingestions in which victims reportedly swallowed magnets on purpose (examples include curiosity and mistaking the magnets as edible).
- "Other" – ingestions involving identified actions that do not fit the above use categories (examples include transporting magnets orally, magnets thrown into a victim's mouth when not playing, and magnets placed into a victim's drink).
- "Unknown" – ingestions in which it is unclear what led to the ingestion of magnets.

Staff found that the use patterns and responses to magnet ingestions specified in incident data since the NPR were similar to the NPR data. Table 4, below, shows a comparison of the counts and percentages of magnet ingestions that occurred during specified use patterns in the NPR data and since the NPR.

Table 4. Use patterns identified in NEISS- and CPSRMS-reported magnet ingestions. These counts and percentages exclude the incidents categorized as exclusions. The percentages in this table are rounded to the nearest tenth.

Use Category	NEISS						CPSRMS					
	NPR		Since NPR		Total		NPR		Since NPR		Total	
	#	%	#	%	#	%	#	%	#	%	#	%
Playing	143	14.1%	13	12.4%	156	13.9%	61	23.7%	42	40.0%	103	28.5%
Jewelry	31	3.1%	4	3.8%	35	3.1%	43	16.7%	7	6.7%	50	13.8%
Intentionally Ate	19	1.9%	0	0.0%	19	1.7%	21	8.2%	8	7.6%	29	8.0%
Other	10	1%	0	0.0%	10	0.9%	4	1.6%	0	0.0%	4	1.1%
Unknown	811	80%	88	83.8%	899	80.3%	128	49.8%	48	45.7%	176	48.6%
Totals:	**1014**		**105**		**1119**		**257**		**105**		**362**	

[9] 16 CFR parts 1700, 1701, 1702. For more information, see the CPSC webpage on "Poison Prevention Packaging Act": https://www.cpsc.gov/Regulations-Laws--Standards/Statutes/Poison-Prevention-Packaging-Act/.

Figures 1 and 2, below, show the use patterns by age in NEISS- and CPSRMS-reported incidents since the NPR (excluding incidents categorized as exclusions and incidents for which age was not specified).

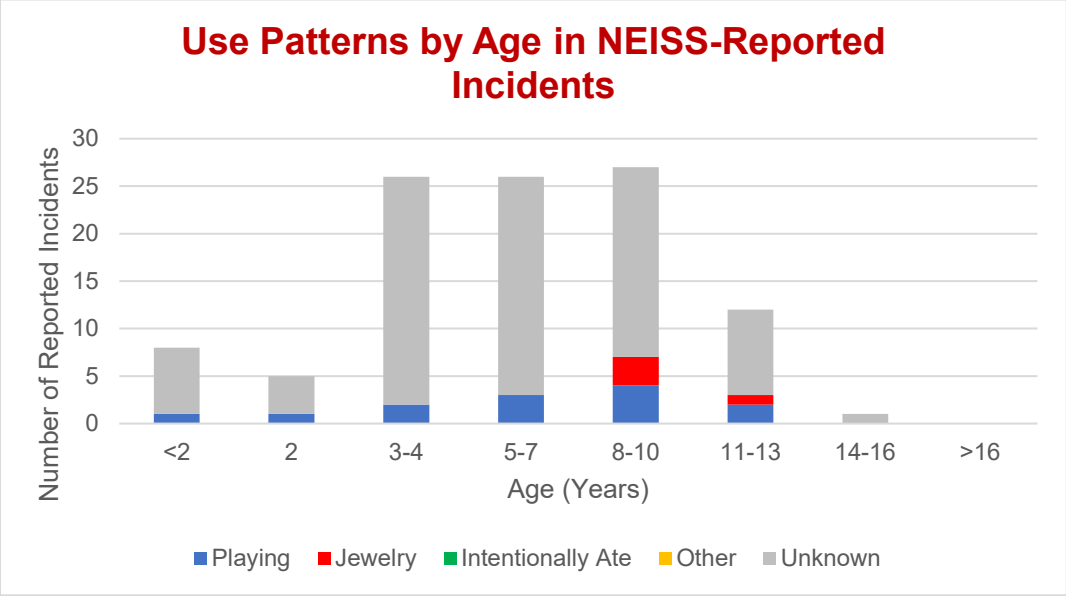

Figure 1. Use patterns by age in NEISS-reported magnet ingestions since the NPR, excluding incidents categorized as exclusions and incidents for which age was not specified.

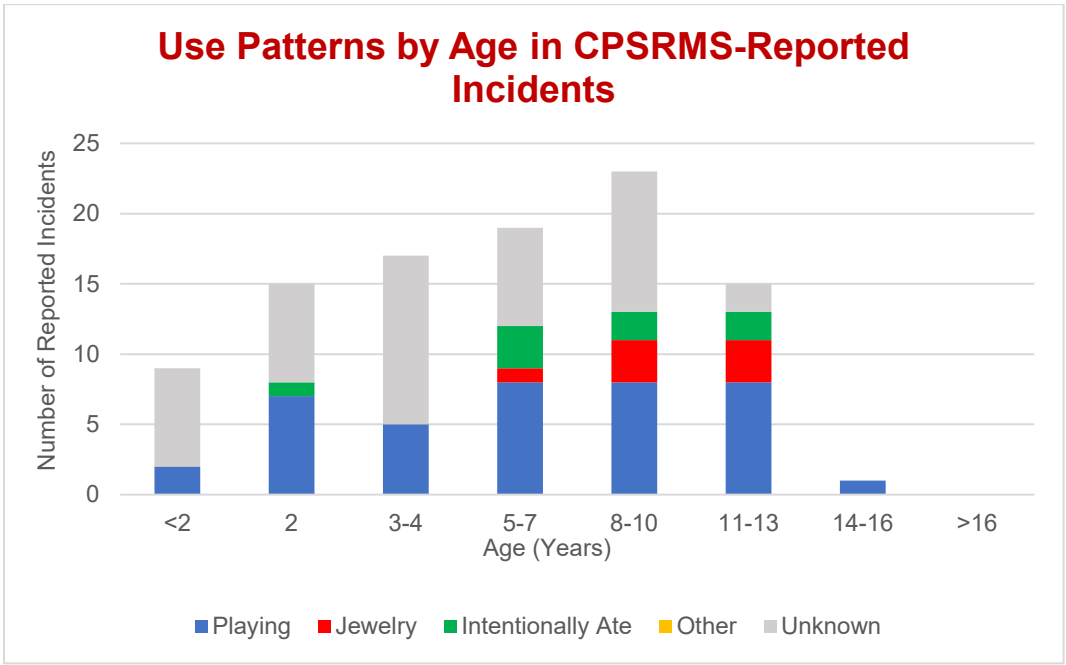

Figure 2. Use patterns by age in CPSRMS-reported magnet ingestions since the NPR, excluding incidents categorized as exclusions and incidents for which age was not specified.

Staff highlights the following observations for the data collected since the NPR (percentages are approximated):

- as a percentage of the known use patterns:
  - 76.5 percent (70.4% NPR data) of the NEISS-reported incidents and 73.7 percent (47.3% NPR data) of the CPSRMS-reported incidents involved playing at the time of ingestion, where use is known;
  - 23.5 percent (15.3% NPR data) of the NEISS-reported incidents and 12.3 percent (33.3% NPR data) of the CPSRMS-reported incidents involved use of the magnets as jewelry at the time of ingestion, where use is known; and
  - none (9.4% NPR data) of the NEISS-reported incidents and 14 percent (16.3% NPR data) of the CPSRMS-reported incidents indicated the magnets were ingested intentionally;
- out-of-scope products were not associated with use as jewelry at the time of ingestion (versus 1 case in NPR data involving "fridge magnets");
- victims ages 8 years and older were more likely than younger ages to swallow magnets while simulating piercings;
- reports for accidental ingestions tended to describe children using the magnets in or around their mouths, such as to separate magnets with their teeth, when the magnets unexpectedly rolled to the backs of their throats and were unintentionally swallowed;
- at least 24 (72 NPR data) CPSRMS-reported incidents involved a delay of one day or greater between ingestion and correct treatment, with some delays spanning months;[10] and
- children ages 8 years and older were more likely than younger ages to ingest magnets while using the magnets as jewelry, such as simulating piercings.

As in the NPR, playing was the most common reported behavior at the time of ingestion, followed by use as jewelry, and a smaller percentage of cases involved intentional ingestion in the data collected since the NPR. Delays between ingestion and treatment were also common in both datasets. In general, CPSRMS reports from recent years often mentioned that the caregivers contacted Poison Control for advice if they were made aware that their children ingested magnets, and they were typically instructed to seek medical attention if more than one magnet was ingested or suspected of being ingested. These observations are explained in the NPR briefing package and summarized, below:

- exploration, fidgeting, and other forms of entertainment are normal aspects of child development and children, and teens are likely to be drawn to magnets;

[10] For example, one report indicates that in May 2020, a 9-year-old victim was given a magnet set by her parents, despite warnings and marketing about the hazard and to keep the product away from children. The parents stated in the report that they assumed the victim could use the magnets safely. The victim ended up swallowing three of the magnets and having stomach pains. Her parents were not aware of the ingestion and misdiagnosed her stomach pains as the result of food poisoning. Eventually, her symptoms graduated to the point that her parents assumed she had appendicitis, and she was taken to an emergency room. X-rays were performed and three "dots" were identified. At that time, the victim admitted to ingesting magnets, and surgeons consequently found perforations in her bowels. In another case, which occurred in April 2021, a 2-year-old victim consumed magnets that belonged to an 11-year-old sibling (the sibling received the magnets from a friend at school). The victims' parents estimate that weeks went by between ingestion and correct treatment, because the ingestion was unknown to the parents, and the victim's pediatrician misattributed the victim's symptoms a stomach bug. Eventually, the symptoms worsened, and an x-ray revealed ingested, metallic objects (the magnets). Surgeons had to remove 3 feet of damaged intestines, and the victim almost died from internal injuries, including bowel leakage. The victim had numerous post-surgery complications, including small bowel syndrome and infection. At the time of the report, the victim still had a nasogastric tube for nutritional supplements.

- use of magnets as jewelry in or around the mouth is foreseeable, particularly for ages 8 years and older, for whom experimentation and peer influence are common determinants of behavior (Tomé, et al. 2012; Knoll et al., 2017), and because the subject magnet products offer a seemingly safe and reversible way to try out lip, tongue, cheek, and nose piercings;
- older children and early adolescents are at a developmental stage in which they test limits and bend rules (Brown & Beran, 2008; Vredenburgh & Zackowitz, 2006), meaning it is common for them to have increased risk-taking behaviors;
- accidental ingestion has serious implications for the perceived credibility of safety messaging, particularly safety messaging intended to protect children above the ages typically associated with the ingestion of inedible objects;
- common causes of delays between ingestion and correct treatment included the following, among others: (1) caregivers were unaware of the ingestion event, resulting in delayed hospital visits and subsequent misdiagnoses; (2) caregivers misunderstood the hazard, such as expecting the magnets to pass naturally, which may not be the case; and (3) symptoms following magnet ingestion were misattributed to common illnesses (*e.g.,* food poisoning); and
- victims and caregivers often sought treatment only after the victim experienced significant discomfort, at which point substantial internal damage occurred.

Sources of Access

Staff categorized the sources of access to magnets at the time of ingestion as follows:

- "Family Owned" – Magnets belonged to the victim's family. Includes incidents of siblings finding magnets and bringing them home.
- "Friend/Classmate/School/Neighbor" – Magnets belonged to friends, classmates, or neighbors, or found by the victim at daycares or schools.
- "Purchased for Victim" – Magnet(s) was/were purchased for, or otherwise gifted to, the victim.
- "Purchased by Victim" – Magnet(s) was/were purchased by the victim.
- "Found Outside" – Victim found the magnets outside, such as on a playground. Excludes if sibling found outside and brought home.
- "Unknown" – Unclear where the magnet(s) was/were acquired, by whom, or for whom; includes incidents of magnets found in home but product owner unknown.

The sources of access in incident data since the NPR were similar to the NPR data. The majority of the NEISS-reported incidents did not include sufficient detail to identify the sources of access; however, the majority of the reports for the CPSRMS data did provide this information, as shown in Table 5, below.

Table 5. Sources of access identified in CPSRMS-reported magnet ingestion incidents. These counts and percentages exclude the incidents categorized as exclusions. The percentages in this table are rounded to the nearest tenth.

Source of Access	CPSRMS					
	NPR		Since NPR		Total	
	#	%	#	%	#	%
Family Owned	59	23%	37	35.2%	96	26.5%
Friend/classmate/School/neighbor	41	16%	9	8.6%	50	13.8%

Purchased for Victim	26	10.10%	23	21.9%	49	13.5%
Purchased by Victim	5	1.90%	2	1.9%	7	1.9%
Found Outside/Rental Home	4	1.60%	3	2.9%	7	1.9%
Unknown	122	47.50%	31	29.5%	153	42.3%
Totals:	**257**		**105**		**362**	

Figure 3, below, shows the sources of access by age in CPSRMS-reported incidents since the NPR (excluding incidents categorized as exclusions and incidents for which age was not specified).

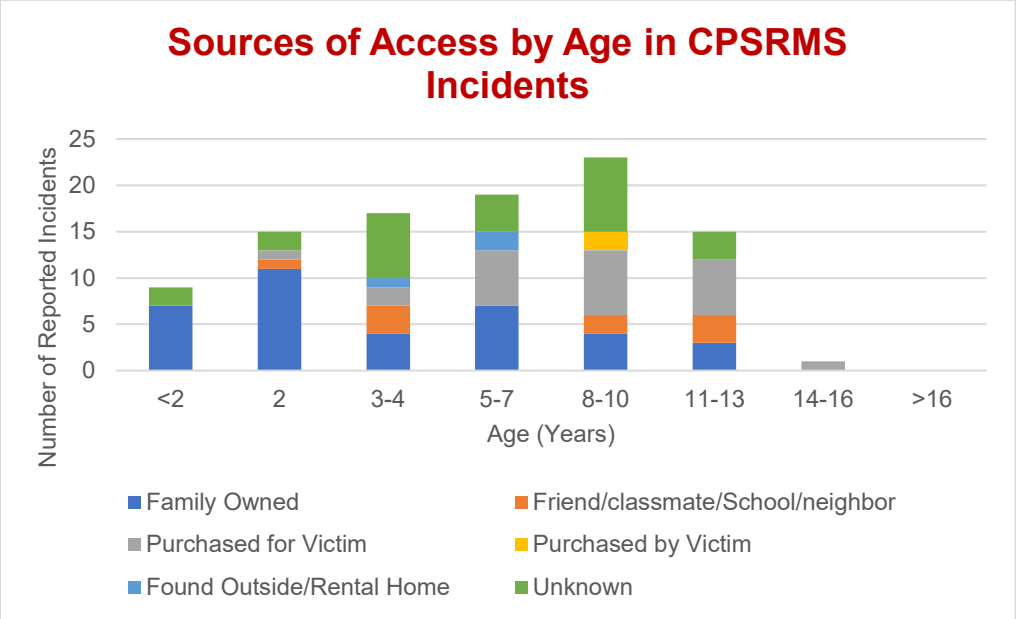

Figure 3. Sources of access by age in CPSRMS-reported magnet ingestions since the NPR, excluding incidents categorized as exclusions and incidents for which age was not specified.

Staff highlights the following observations for the data collected since the NPR (percentages are approximated):

- as a percentage of the known sources of access:
  - 50 percent (44% NPR data) of the CPSRMS-reported incidents involved magnets that belonged to family members;
  - 31.1 percent (19% NPR data) of the CPSRMS-reported incidents involved magnets that were purchased for the victim;
  - 12.2 percent (30% NPR data) of the CPSRMS-reported incidents involved magnets that were acquired from friends, classmates, neighbors, or at school;
  - 4.1 percent (3% NPR data) of the CPSRMS-reported incidents involved magnets found by the victim outside or in a rental home; and
  - 2.7 percent (4% NPR data) of the CPSRMS-reported incidents involved magnets purchased by the victim;
- victims under 8 years old typically gained access to magnets that belonged to family members, such as siblings, parents, and relatives;

- magnets from family members were usually found on floors, in or on furniture, in bags, and affixed to surfaces (*e.g.,* refrigerators and wallboards), or provided to the victims by family members;
- victims ages 8 years and older often obtained magnets from friends, classmates, or schools, or the magnets were purchased for them; and
- children and teens typically acquired loose magnets, as opposed to accessing the full set or product at the time of ingestion.

Where source of access was specified, the majority of the incidents involved magnets that belonged to family members. The next two most common sources were magnets purchased for the victim and magnets acquired from friends, classmates, neighbors, and at school; however, in the data since the NPR, a higher percentage of magnets were purchased for the victims than acquired from friends, classmates, neighbors, and at school. These observations are explained in the NPR briefing package and summarized, below:

- it is common for children to find magnets in their homes, even when their family members try to keep the magnets away;[11]
- children and teens often acquire magnets from outside the home, making it difficult for caregivers to control access;
- magnets acquired loose will not have safety messaging; and
- caregivers find the products appropriate for children (*e.g.,* they see similar products marketed to children, they are aware of other children using the products without incident, and they think their child is mature enough to not swallow magnets).

Safety Messaging in Incident Data

The majority of the NEISS- and CPSRMS-reported incidents did not include sufficient detail to determine if safety messaging was provided with the involved products; however, a portion of the CPSRMS-reported incidents did indicate if safety messaging was provided with the product. Similar to the analysis for the NPR, staff identified numerous CPSRMS-reported incidents in the data since the NPR that involved products with magnet internal interaction warnings, age labels/warnings not for children, or both. Table 6, below, shows a comparison of safety messaging between these data sets for the cases that specified whether there was relevant safety messaging (*i.e.,* excluding cases that did not indicate if the involved product had safety messaging).

[11] For example, one report indicates that in April 2016, a 2-year-old victim acquired magnets from a magnet set belonging to a 9-year-old sibling. The parents and sibling tried to keep the magnets away from the victim and other siblings; however, the victim moved a chair to a cabinet in which the magnets were stored, climbed the chair, retrieved the magnets, and ingested the magnets. In a similar case, which occurred in June 2021, a 17-month-old victim swallowed magnets from a magnet set purchased for the victim's 10-year-old sibling. The magnet set had clear warnings about the hazard, instructions with warnings, and an age label for 14 years and older. The magnets were stored on a high shelf to keep them away from the victim and other young siblings. The victim's 5-year-old sibling managed to acquire the magnets and shared them with the victim, resulting in the victim swallowing the magnets. The victim underwent surgery to repair perforations caused by the magnets.

Table 6. Safety messaging identified in CPSRMS-reported magnet ingestion incidents. These counts and percentages exclude the incidents categorized as exclusions and incidents that did not indicate if safety messaging was provided with the product. The percentages in this table are rounded to the nearest tenth.

Safety Messaging	CPSRMS					
	NPR		Since NPR		Total	
	#	%	#	%	#	%
Magnet Warning	45	72.6%	23	74.2%	68	73.1%
No Magnet Warning	12	19.4%	5	16.1%	17	18.3%
Age Label/Warning	49	79.0%	25	80.6%	74	79.6%
No Age Label/Warning	11	17.7%	6	19.4%	17	18.3%
Both Magnet Warning and Age Label/Warning	44	71.0%	22	71.0%	66	71.0%
Neither Magnet Warning Nor Age Label/Warning	9	14.5%	5	16.1%	14	15.1%

Staff highlights the following observations for the data collected since the NPR (the counts below represent minimums, as approximately 70.5 percent (~75.9% NPR data) of the CPSRMS reports did not indicate if safety messaging was present):

- 23 (45 NPR data) CPSRMS-reported incidents involved products with magnet internal interaction warnings, whereas 5 (12 NPR data) involved products without magnet internal interaction warnings;
- 25 (49 NPR data) CPSRMS-reported incidents involved products with an age label or warning indicating the product was not for children, whereas 6 (11 NPR data) indicated there was no such label or warning; and
- 22 (44 NPR data) CPSRMS-reported incidents involved products with both a magnet internal interaction warning and an age label or warning indicating that the product was not for children, whereas 5 (9 NPR data) had neither a magnet internal interaction warning nor an age label or warning indicating the product was not for children.

Both the NPR data and data since the NPR involved dozens of products with magnet internal interaction warnings, age labels or warnings indicating the product was not for children, or both. For the full period 2010 through 2021, at least 68 incident products had magnet internal interaction warnings, at least 74 had age labels or warnings indicating the product was not for children, and at least 66 had both types of relevant safety messages.[12] In contrast, reports for only 14 incidents (total for both data sets) mentioned that the product had neither magnet internal interaction warnings nor age labels or warnings against use by children. These observations are explained in the NPR briefing package and summarized, below:

[12] For example, one report indicates that in March 2021, a 3-year-old ingested magnets that belonged to a 10-year-old sibling. The magnets were part of a magnet set, which had warnings about the hazard and an age label of "14+." Despite the safety messaging, the magnet set was purchased for the sibling to treat his ADHD and anxiety. The victim had entered the sibling's room and played with the magnets at the time of ingestion. The ingestion was unwitnessed and unknown to the caregivers for five days, resulting in perforations and a fistula. Many similar cases are exemplified in Tab C of the NPR briefing package.

- hazardous magnets acquired absent packaging are too small to have legible and complete on-product warnings;
- magnet ingestions have occurred despite magnet internal interaction warnings and age labels or warnings indicating the products were not for children; and
- there are numerous limitations to the effectiveness of magnet internal interaction warnings and age labels/warnings.

Detailed in the following sections, staff assesses consistent with the NPR that safety messaging without magnet size and strength requirements is an inadequate measure to address the magnet internal interaction hazard associated with the subject magnet products.

Assessment of Existing Standards and Prohibitions Associated with Hazardous Magnets

Domestic Standards Regarding Hazardous Magnets

Staff identified four domestic standards with relevant requirements for magnets in consumer products in the U.S.:

1. ASTM F963 – 17, *Standard Consumer Safety Specification for Toy Safety*
2. ASTM F2923 – 20, *Standard Specification for Consumer Product Safety for Children's Jewelry*
3. ASTM F2999 – 19, *Standard Consumer Safety Specification for Adult Jewelry*
4. ASTM F3458 – 21, *Standard Specification for Marketing, Packaging, and Labeling Adult Magnet Sets Containing Small, Loose, Powerful Magnets (with a Flux Index* $\geq 50\ kG^2\ mm^2$*)*

There were no changes in the magnet requirements specified in these standards since the NPR, and staff continues to find these standards inadequate to address the magnet internal interaction hazard associated with the subject magnet products. These standards and their shortcomings are explained in the NPR briefing package and summarized in staff's Mechanical Engineering memorandum (Tab D; Paul, 2022). Among other concerns, staff notes the following:

- ASTM F963 is specific to children's toys, and, therefore, it excludes the products subject to the draft final rule.
- ASTM F2923, F2999, and F3458 are specific to several subsets of the subject magnet products (*i.e.,* children's jewelry, adult jewelry, and adult magnet sets); however, they exclude other products intended for adult entertainment.
- ASTM F2923 includes magnet size and strength requirements consistent with the proposed rule, but only for certain jewelry intended for children under 8 years of age.
- ASTM F2999 and F3458 address the magnet internal interaction hazard only with requirements for safety messaging and/or packaging, which are inadequate to address the hazard.

Staff's review indicates that ASTM F963 adequately addresses the magnet internal interaction hazard associated with children's toys. Staff was only able to identify in the 2010 through 2021 incident data a small proportion of incidents involving internal interaction of magnets from children's toys subject to ASTM F963. Due to ambiguities in incident data, and the recency of

ASTM F3458, it is unclear to what extent manufacturers comply with ASTM F2923, F2999, and F3458.

Regarding ASTM F3458, following the publication of ASTM F3458 – 21, the relevant subcommittee, ASTM F15.77 on magnets, resumed meetings on May 25, 2021. In the first meeting, the subcommittee decided through a vote (15 in favor and 3 opposed) to form a task group to work on performance requirements for ASTM F3458. The task group last met in November 2021 and to date, the standard still does not have performance requirements to prevent hazardous magnets from being used in magnet sets.

Prohibitions of Hazardous Magnets in Other Countries

The NPR briefing package discusses approaches taken by other countries to address the magnet internal interaction hazard. Staff explained that prohibitions and best practices in Canada, Australia, New Zealand, and member states of the European Commission align closely with the NPR, including identical size and strength requirements for magnets; however, they vary regarding product scope beyond children's toys and magnet sets. These prohibitions have not changed since the analysis provided in the NPR. As discussed in Tab A, staff received numerous public comments opining that Canada's prohibitions have been effective. Additionally, staff has continued to work with foreign regulators to understand and address the hazard. For example, members of the Consumer Affairs Agency of Japan (CAA) have expressed to CPSC staff concerns about Japanese citizens ingesting hazardous magnets, and recently published multiple reports on the subject.[13]

Evaluation of Safety Messaging and Safeguards

Consistent with staff's analysis in the NPR briefing package, staff assesses that safety messaging (*e.g.,* warnings, marketing, instructional literature, and public awareness raising efforts) and safeguards (*e.g.,* packaging requirements and aversive agents), in lieu of effective performance requirements, are not adequate methods by which to address the internal interaction hazard posed by the ingestion of hazardous magnets from the subject magnet products.

Tab C in the NPR briefing package details the general limitations of safety messaging, and the factors specific to the subject magnet products, which impede the likelihood of the safety messaging being seen, read, understood, and followed consistently. Among other concerns, staff explained that consumers are likely to have a common perception of low risk pertaining to the subject magnet products and often misunderstand the magnet internal interaction hazard, and that safety messaging, including public awareness raising efforts, has been insufficient to protect children and teens from the hazard. Due to a number of factors, such as the inability of caregivers to provide constant supervision and manage common sources of access to hazardous magnets, consumers may be unable to avoid the hazard even if they are aware of the hazard and actively trying to prevent it.

Similarly, Tab C of the NPR briefing package details limitations of packaging features, such as CR features and visual verification of a full set. Among other concerns, staff explained that the majority of the magnet ingestion victims have been over the ages protected by CR features, that collecting and repackaging the magnets after every use is unlikely for some products, and that the incident data show magnets are often acquired without their packaging. Staff also identified

[13] CAA articles pertaining to magnet ingestion can be found using the following URL: https://www.caa.go.jp/policies/council/csic/report/report_021/.

limitations for aversive agents, such as bitterants, explaining that aversive agents may not be detected by children prior to ingestion, and may not deter swallowing for children who do detect the aversive agents.[14]

Public Comments Pertaining to Human Factors

Discussed in Tab A, CPSC received 716 comments regarding the NPR. Additionally, on March 2, 2022, CPSC held an oral hearing pertaining to the NPR, at which time five comments were presented. Commenters provided statements in favor and in opposition to the proposed rule, and some opined on ways to improve the proposed rule from their perspective. Most who commented in favor of the proposed rule were medical professionals and/or representatives of consumer advocacy groups and medical associations; and there were some consumers/individuals and a manufacturer who also supported the proposed rule.[15] In contrast, most who commented in opposition to the proposed rule were consumers/individuals, as well as several manufacturers and hobbyist groups.[16] These written and oral comments can be found in docket number CPSC-2021-0037 at http://www.regulations.gov/. Below, staff addresses the comments relevant to the human factors analysis, which included opinions regarding the product scope, the defectiveness of magnet sets, and the adequacy of safety messaging and safeguards for addressing the magnet internal interaction hazard.

Comments Pertaining to the Product Scope and Exemptions

Commenters in favor of the proposed rule generally supported the proposed product scope as a minimum approach for addressing the hazard. Some commenters requested continued research after the final rule to determine if the exempted products, such as magnet products intended only for educational purposes, should also be addressed by the final rule.

Commenters against the proposed rule varied in their reasons for opposing the product scope specified in the proposed rule. The majority of those in opposition requested that adult products be excluded from the proposed rule. They typically argued that there are other, more hazardous products on the market available for adult purchase and use (*e.g.,* guns and cigarettes). They mentioned artistic, educational, entertainment, social, and therapeutic benefits of small, powerful magnets (magnets staff considers to be hazardous) in consumer products, such as magnet sets, and opined that products intended for these uses should be excluded from the final rule. Some commenters stated that requiring magnets to be weaker or bigger would limit these uses. Several commenters opined that non-spherical magnets should be excluded from the final rule, as well as products with only one magnet. One commenter recommended reducing the product scope to only magnet sets, similar to ASTM F3458. Additionally, several commenters, including subject magnet product manufacturers (*e.g.,* Retrospective Goods, CPSC-2021-0037-0701; and Nano Magnetics, CPSC-2021-0037-0716), requested clarifications pertaining to the product scope and exemptions, particularly regarding

[14] CPSC found there lacked sufficient evidence to support the use of bitterants to prevent ingestion of hazardous substances (CPSC, 1992). Fifteen percent to 30 percent of adults do not detect the taste of bitter compounds (CPSC, 1992; NIDCD, 2010; NIDCD, 2019). Recent epidemiology studies in several U.S. states have also demonstrated that adding bitterants to antifreeze did not prevent pediatric ingestions or suicidal ingestions of antifreeze (White et al., 2008, 2009; PLOS One, 2015).
[15] For example, CPSC received a joint letter in support of the proposed rule, which was submitted by the American Academy of Pediatrics (AAP), which represents 67,000 physicians and other medical specialists, and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), which represents more than 2,500 pediatric gastroenterologists.
[16] For example, CPSC received a letter in opposition to the proposed rule, which was submitted by the Hobby Manufacturers Association (HMA), representing more than 59 manufacturers, importers, publishers, producers, and suppliers of hobby products and hobby accessories.

"mental stimulation," and recommended that "mental stimulation" should be removed from the inclusion criteria for "subject magnet product." Commenters also requested that the final rule should more clearly identify the exempted products, which are exemplified but not codified in the proposed rule, such as products intended for scientific or technical research, and educational, professional, and industrial applications.

Staff's Response:

As detailed in this memorandum and the NPR briefing package, the product scope of the draft final rule is based on staff's analysis of the following factors, among others: magnet ingestion incident data, behavioral patterns, product samples, product marketing, available literature, voluntary standards, international actions, CPSC recall activity, and economic factors regarding the draft final rule and related injuries. Staff determined that the subject magnet products carry the highest risk for children and teens in terms of ingestion-related outcomes. The product scope includes non-spherical magnets because the hazard is not limited only to spherical magnets; for example, the NPR briefing package discusses cases involving internal interaction of rock-shaped magnets. The product scope includes products with only one magnet for reasons including the following: subject magnet products may be sold per-magnet, and a single magnet can interact internally through body tissue with an unrelated magnet or ferromagnetic object. Tab A discusses additional concerns regarding single magnets attracting through tissue to ferromagnetic objects.

While staff appreciates the concerns regarding loss of benefits associated with requiring magnets in the subject magnet products to be bigger or weaker, staff continues to find it necessary to require the proposed magnet size and strength limitations for the subject magnet products. Magnet incident data have demonstrated that products marketed to adults, particularly magnet sets, are commonly involved in magnet ingestion incidents, both in the U.S. and abroad, which is why CPSC previously promulgated a rule limiting the size and strength of magnets in magnet sets, and why numerous other countries still have prohibitions for magnet sets and other magnet products. Discussed in staff's Economic Analysis memoranda (Tabs E and F; Smith, 2022), the societal costs from magnet ingestion warrant the proposed size and strength limitations for the subject magnet products, including products intended for adults.

The NPR specifically identified as exempt from the proposed rule children's toys subject to ASTM F963. Additionally, per the NPR, "other products that would fall outside the scope of the proposed rule include research and educational products, or those intended for commercial or industrial purposes, if they are not also intended for amusement or jewelry." These additional exemptions were exemplified but not codified in the proposed rule set out in the NPR. Staff assesses that "mental stimulation" is an important criterion for subject magnet products, as it encompasses numerous uses that appeal to children and teens, such as puzzle working and sculpture building, which are common descriptions for subject magnet products like magnet sets. However, staff agrees that the term "mental stimulation" may be interpreted more broadly than intended by capturing products not for home uses that may nonetheless be mentally stimulating, such as those manufactured, sold, and/or distributed solely for educative uses at schools and universities. Accordingly, in response to comments, the draft final rule codifies the exemptions to include products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes. This

clarification addresses confusion between in-scope and out-of-scope products by specifying example products that are not subject to the draft final rule if these products are also intended for mental stimulation. Because these products are intended for use in school, research, professional, or commercial settings, as opposed to home settings and personal use by children, the magnet internal interaction hazard would be unlikely to pose an unreasonable risk of injury to children or teens. The exemption language makes clear, however, that if any of these exempted products are also designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes, such uses would cause the magnets to be within the scope of regulated subject magnet products and subject to the requirements of the standard.

A further clarification makes explicit that products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, are exempted from the draft final rule. This clarification addresses confusion between in-scope and out-of-scope products by specifying example products that are not subject to the draft final rule. The exemption language makes clear, however, that if any of these exempted products are *also* designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, such uses would bring these products within the scope of regulated subject magnet products and subject to the requirements of the standard. Unlike the exemption for school, research, professional, commercial, and/or industrial purposes, these products are used in the home and if they have subject magnet product uses, they may be appealing to children and the magnet internal interaction hazard may pose the same unreasonable risk of injury to children or teens as identified for the subject magnet products.

Additionally, staff acknowledges the concerns from commenters that products excluded from the final rule should be monitored in the future to determine if they should be subject to the proposed requirements.

Comments Pertaining to Defectiveness of Magnet Sets

Commenters in favor of the proposed rule generally supported the proposed product scope as a minimum approach for addressing the hazard. They opined that hazardous magnets in the subject magnet products present an unreasonable risk of injury to children and teens, as injuries are widespread and foreseeable, and safety precautions that do not limit the size and strength of magnets are not sufficient to prevent the hazard.

Commenters against the proposed rule generally opined that the subject magnet products, particularly magnet sets, are not defective because they do not pose the magnet internal interaction hazard when they are used responsibly and consistent with their marketing and safety messaging. That is, the subject hazard results only from hazardous magnets being given to children and ingested contrary to the intended uses and warnings.

Staff's Response: To promulgate a consumer product safety standard, the Commission must find that the rule is reasonably necessary to reduce an unreasonable risk of injury associated with the product. When assessing risk, CPSC considers how consumers may use a product, not just the manner of use intended by the manufacturer. Detailed in the NPR briefing package, the magnet internal interaction hazard associated with magnet sets and other subject magnet

products is a hidden and reasonably foreseeable hazard. The incident data, including the data since the NPR, demonstrate the hazard is widespread and has been increasing in prevalence, and that it involves a wide range of ages, the majority of whom are above the ages typically associated with ingestion of small objects and hazardous substances. Consumers are unlikely to anticipate and appreciate the hazard, particularly regarding older children and teens, and caregivers are unlikely to be able to manage common sources of access to the magnets. Of the subject magnet products, magnet sets remain the most concerning to staff, considering their involvement in magnet ingestion injuries, and because they typically contain hundreds to thousands of loose, hazardous magnets.

Comments Pertaining to Safety Messaging:

Commenters in favor of the proposed rule opined that the magnet internal interaction hazard cannot adequately be addressed with warnings, instructions, awareness-raising efforts, and other forms safety messaging. They explained that children, teens, and caregivers do not fully comprehend the hazard and risk of children and teens ingesting magnets. Their points include the following:

- warnings, instructions, and public education campaigns about the hazard have historically been ineffective, as evidenced by the return to a higher level of ingestion incidents after judicial vacatur of the previous CPSC rule;
- it is common for children and teens to use magnet products marketed to adults;
- ingestion of magnets by children is foreseeable due to developmentally appropriate exploratory behaviors and the hidden nature of the hazard posed by products intended for the subject magnet product uses;
- when caregivers believe they know the risk (often mistaking it for a choking hazard), they are less likely to read the warnings;
- caregivers are unable to provide constant supervision to prevent magnet ingestion; and
- warnings cannot be placed on the magnets, so the warnings are lost if the packaging and instructions are discarded.

Additionally, one commenter (Independent Safety Consulting, CPSC-2021-0037-0525) stated that warnings will not be necessary in combination with the proposed size and strength limitations and may contribute to the growing issue of warning fatigue (consumers foregoing reading warning labels due to the prevalence of product warnings).

Commenters against the proposed rule typically argued that approaches involving safety messaging are more appropriate than strength and size limitations. The majority of these commenters stated that their personal freedoms should not be restricted because some consumers, particularly parents, are irresponsible and not supervising their children. They often compared the magnet internal interaction hazard to other common hazards, such as involving trampolines, fireworks, scissors, knives, firearms, balloons, and toys with small parts, arguing that these other products present similar or worse hazards and are not banned. Commenters indicated that some brands of subject magnet products already have clear warnings about the hazard and market the products only to adults, and they asserted these products have been involved in little-to-no magnet ingestion injuries. Several commenters claimed that the proposed rule will result in a cessation of public awareness activities regarding the hazard; meaning that existing owners of subject magnet products with loose or separable hazardous magnets and future owners of these products will not be informed about the hazard.

Commenters made requests of CPSC, such as follows:

- educate the public about the hazard;
- require warning labels on the packaging and point-of-sale;
- require warning labels for products that meet the proposed size and strength limits;
- require instructional literature;
- require marketing only to adults;
- require that the products may not be marketed as toys; and
- require age labels for 5+, 8+, 14+, or 18+.

Many of these commenters recommended publicizing and enforcing ASTM F3458 – 21, which includes warning, instructional literature, and marketing requirements for adult magnet sets. Additionally, one commenter, a subject magnet product manufacturer, (Retrospective Goods, CPSC-2021-0037-0701) stated that CPSC has not undertaken any meaningful safety campaigns regarding the hazard for seven years.

Staff's Response:

Detailed at length in the NPR briefing package, safety messaging has limited effectiveness for preventing the magnet internal interaction hazard. In general, safety messaging is inherently fallible because it relies on encouraging consumers to avoid hazards, as opposed to eliminating the hazards by design. For safety messaging to be effective, it must be seen, read, understood, and heeded. Specific to the subject magnet products, there are many obstacles to the success of safety messaging, which include among others: consumers commonly have a misperception of low risk of the hazard, the hazard patterns and symptomology are often misunderstood, and the common sources of access to magnets (*e.g.,* children and teens sharing magnets at school) make it difficult, if not impossible, for caregivers to prevent access to the hazard, and reduce the chances of children and their caregivers seeing safety messaging provided with the products. Caregivers may also forego reading warnings if they think they already know the hazard; for example, commenters and incident reports indicate some consumers continue to think the magnet internal interaction hazard is just a choking hazard, no different from other small objects.

Staff understands there are claims that some brands/models of the subject magnet products have not been involved in magnet ingestion incidents because of the safety messaging used for these products. However, the majority of incident reports do not identify the brand/model of the involved magnet products, and the common design of subject magnet products (often including similar size, weight, shape, and magnetism) makes branding differences generally irrelevant to the hazard. Historically, both in the U.S. and abroad, safety messaging in numerous forms has been inadequate to address the magnet internal interaction hazard. Clear and repeated warnings about the hazard and to keep the product away from children have been used on product packaging and in instructional literature for over a decade, and magnet ingestions continued to occur despite this information (see above and the NPR briefing package for examples). Magnet ingestions have continued an upward trend over the past years since the CPSC's prior rule was struck down by a court, despite increased prevalence of safety messaging provided with the products, and numerous public outreach efforts by the CPSC, medical associations, consumer advocacy groups, and news sources (see the NPR briefing

package). Some of the recent efforts include CPSC's annual holiday safety campaign,[17] CPSC's Twitter Chat on High-Powered Magnet Safety,[18] CPSC's magnet information center website,[19] and numerous articles from popular news sources.[20]

Staff disagrees that magnet ingestions occur simply because caregivers are negligent or the children lack common sense; rather, staff assesses that the magnet internal interaction hazard is a unique, hidden hazard, unlike common and more readily apparent hazards, such as involving trampolines and fireworks, and all multi-magnet ingestions and ingestions involving a magnet and a potentially ferromagnetic object, call for some level of medical management. It is foreseeable and justifiable for consumers to neither anticipate nor appreciate the likelihood of children and teens ingesting magnets absent a history of swallowing inedible objects. Nonetheless, the majority of the incident reports involved victims above the ages typically associated with ingestion of small objects (under 3 years old) and hazardous substances (under 5 years old). Many of the reports indicated the magnets were ingested accidentally, such as while children and teens were attempting to separate the magnets with their teeth or use the magnets to simulate oral piercings, and relatively few reports indicated the magnets were ingested intentionally. It is unrealistic to expect parental supervision at all times, especially for these older ages, and ingestions can be quick and difficult to notice and prevent, considering the small size and sometimes large number of magnets in the subject magnet products.

Staff therefore concludes that safety messaging may still have an important role to play in supplementing size and strength limitations, such as through voluntary standards, as the draft final rule represents a minimum standard for addressing the hazard, and it remains uncertain to what extent magnets within the specified limit, and in aggregate, may present risks of internal injury.

Comments Pertaining to Alternative Safeguards

Commenters in favor of the proposed rule opined that the magnet internal interaction hazard cannot adequately be addressed with packaging requirements and aversive agents. They explained that it is common for children and teens to acquire magnets without packaging, and that packaging requirements, such as CR packaging, are only effective as long as the packaging is retained and used consistently, and CR packaging would not be effective for the majority of victims, considering the victims' ages.

Commenters against the proposed rule opined that approaches involving packaging and aversive agents are more appropriate than strength and size limitations. Specifically, commenters requested the following:

- require child-resistant packaging or other lockable containers;
- require packaging that enables better accounting of lost magnets; and

[17] CPSC's Top Safety Tips for Early Holiday Shoppers Amid Reports of Expected Toy Shortage (2021): https://www.cpsc.gov/Newsroom/News-Releases/2021/Top-Safety-Tips-for-Early-Holiday-Shoppers-Amid-Reports-of-Expected-Toy-Shortage.
[18] On May 19, 2021, CPSC staff provided responses regarding magnet safety in a public Q&A.
[19] CPSC staff continually updates its Safety Education Center on magnets with information pertaining to the hazard and staff's activities, including the recent briefing packages pertaining to magnets and notices of magnet violations. See https://www.cpsc.gov/Safety-Education/Safety-Education-Centers/Magnets for more information.
[20] Examples of recent news articles addressing the hazard include the following, among others: https://www.washingtonpost.com/business/2021/08/17/magnet-safety-recall/, https://www.washingtonpost.com/business/2019/12/27/senator-urges-regulators-take-action-magnet-ingestions/, https://www.cnn.com/2019/04/12/health/kids-swallow-objects-study/index.html, and https://www.foxnews.com/health/parts-of-boys-colon-intestines-removed-after-swallowing-toy-magnets-mom-says.

- require bitterants or other aversive agents to deter putting magnets in mouths.

Many of these commenters recommended publicizing and enforcing ASTM F3458-21, which includes packaging requirements for adult magnet sets.

Staff's Response:

Consistent with the NPR briefing package, staff concludes that safeguards, such as special packaging and aversive agents, are ineffective for addressing the magnet internal interaction hazard. In many cases, such as when children and teens find magnets in their environment or receive them from friends, the magnets are acquired absent packaging, making packaging features immaterial. CR features, such as those specified in ASTM F3458 – 21, are designed to limit access to products only by children under 5 years of age, and staff found that the majority of magnet ingestion incidents involved victims ages 5 years and older. Furthermore, CR features would only be effective for these younger ages if the magnets are repackaged correctly and in their entirety after every use, which staff finds unrealistic for the following reasons, among others: the products are not threatening in appearance or intended use (*e.g.,* entertainment and jewelry), CR or other lockable features may be perceived as a nuisance, and some of the products include uses that preclude consistent repackaging (*e.g.,* sculpture building). The number and size of magnets may also have a negative impact on the effectiveness of packaging features. Incident reports and customer reviews demonstrate that it is common to lose magnets from the subject magnet products, particularly from products with numerous magnets (*e.g.,* magnet sets with hundreds to thousands of tiny magnets). Additionally, consumers may lack the time, capability, or both, to locate and repackage all the magnets after every use.

Deterrents, such as aversive agents (*e.g.,* foul odors or bitterants), are unlikely to be effective. CPSC has found that aversive agents do not adequately deter or prevent ingestions. Serious injury is possible when one ingests as few as two magnets, or even a single magnet in the presence of a ferromagnetic object, and children may ingest multiple magnets before they detect the aversive agent. Children frequently ingest unpalatable substances, indicating that foul odors and tastes are not sufficient to deter children from ingesting harmful substances.

Comments Pertaining to Combination of Requirements in ASTM F3458 – 21

CPSC received comments opining that staff did not assess the adequacy of the requirements in ASTM F3458 – 21 used in combination, as opposed to individually. Commenters claimed that the combination of requirements for warnings, instructions, marketing, and packaging is sufficient to address the hazard. Additionally, one commenter (a consumer/individual, CPSC-2021-0037-0039) asserted that CPSC should postpone rulemaking until more current and relevant data are made available than the pre-2021 data, in order to better assess the effectiveness of ASTM F3458 – 21.

Staff's Response:

Based on staff's analysis, staff concludes that the requirements specified in ASTM F3458 – 21, even in combination, are inadequate to address the magnet internal interaction hazard without size and strength requirements. Discussed in the preceding sections, clear and repeated safety messaging and marketing have been insufficient to discourage magnet ingestion, and there are a multitude of reasons that would inhibit the success of CR packaging to address the hazard, particularly the fact that most of the known magnet ingestions have involved victims ages 5 years and older. This draft final rule briefing package assesses incident data received through

2021, and staff found that the data are consistent with staff's analysis for the NPR. Staff does not recommend postponing promulgation of the draft final rule until more incident data are analyzed, as doing so will likely result in more preventable injuries and societal costs with little if any gain in scientific understanding of the hazard.

ESHF Staff's Recommendations Regarding the Draft Final Rule

Under the draft final rule, and consistent with the NPR, each loose or separable magnet in the subject magnet products must either be too large to fit entirely within the small parts cylinder described in 16 CFR 1501.4, or have a flux index of less than 50 $kG^2\,mm^2$, as measured by the procedures for determining the magnetic attractive force described in ASTM F963. The draft final rule identifies subject magnet products as consumer products that are designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, and that contain one or more loose or separable magnets. The rule would codify as an exemption toys subject to ASTM F963, as proposed in the NPR.

Staff's updated analysis affirms staff's technical opinion that the proposed magnet size and strength requirements are appropriate for addressing the magnet internal interaction hazard. However, with consideration to the additional data since the NPR and public comments pertaining to the NPR, the draft final rule incorporates clarifications to the NPR regarding products subject to and exempt from the rule. As discussed in staff's comment-response section, above, the draft final rule incorporates the following changes to the NPR:

1. Codify that products manufactured, sold, and/or distributed solely for school, research, professional, commercial, and/or industrial purposes that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), stress relief, or a combination of these purposes, are exempted from the draft final rule. This clarification addresses concerns regarding potential confusion between in-scope and out-of-scope products by specifically identifying products that are not subject to the draft final rule.
2. Codify that products manufactured, sold, and/or distributed solely for home use, such as hardware magnets, that contain one or more loose or separable magnets and are not designed, marketed, or intended to be used for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes, are exempted from the draft final rule. This clarification further addresses possible confusion between in-scope and out-of-scope products by describing products that are not subject to the draft final rule.

Conclusion

The incident data received since the data extraction for the NPR further supports staff's previous analysis for the NPR. Staff continues to find that safety messaging and safeguards, absent size and strength limits, are inadequate measures to address the magnet internal interaction hazard. Ultimately, consumers are unlikely to anticipate and appreciate the nature and severity of the hazard, particularly as it often involves children and teens absent a history of swallowing inedible objects, and, for numerous reasons, caregivers are unable to prevent the hazard. Staff recommends promulgating the draft final rule, which incorporates several clarifications pertaining to the product scope specified in the proposed rule.

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Tab D: Memorandum by the Directorate for Engineering Sciences, Division of Mechanical and Combustion Engineering

TO: Stephen Harsanyi, Project Manager,
Division of Human Factors,
Directorate for Engineering Sciences

DATE: August 17, 2022

THROUGH: Mark Kumagai, Associate Executive Director,
Directorate for Engineering Sciences

FROM: Caroleene Paul, Division Director,
Division of Mechanical and Combustion Engineering,
Directorate for Engineering Sciences

SUBJECT: Recommended Performance Requirements for Magnets

Introduction

In January 2022, the U.S. Consumer Product Safety Commission (CPSC) published a notice of proposed rulemaking (NPR) that would establish a performance standard to address the unreasonable risk of injury and death of children associated with ingestion of loose or separable high-powered magnets (87 FR 1260). The proposed rule would require, for products subject to the rule, that all loose or separable magnets must either 1) be too large to fit in CPSC's small parts cylinder, or 2) have a flux index less than 50 $kG^2\,mm^2$, when tested in accordance with the procedures in the Magnet Test Methods specified in ASTM F963, *Standard Consumer Safety Specification for Toy Safety*. CPSC staff provided a test procedure for measuring the flux density of small spherical magnets to improve accuracy and consistency in calculating the flux index for small diameter spherical magnets.

This memorandum provides Engineering staff's responses to comments on the NPR, assessment of voluntary standards, and recommendation for the draft final rule.

Discussion

Notice of Proposed Rule (NPR)

The Commission issued the notice of proposed rulemaking (NPR) for magnet safety under sections 7 and 9 of the Consumer Product Safety Act.[1]

In Tab D of the NPR briefing package, CPSC staff recommended a performance requirement for loose, separable magnets that are subject to the proposed rule to 1) be too large to fit in CPSC's small parts cylinder, or 2) have a flux index less than 50 $kG^2\,mm^2$, as measured by the Magnet Test Methods specified in ASTM F963, *Standard Consumer Safety Specification for Toy Safety*.

[1] Commission NPR on magnets (2022): https://www.govinfo.gov/content/pkg/FR-2022-01-10/pdf/2021-27826.pdf.

CPSC technical staff also provided a test methodology, consistent with the test methods specified in ASTM F963, for determining the flux index of small spherical magnets less than 3 mm in diameter. Staff developed this test procedure to improve the accuracy and consistency in measuring the maximum flux density and calculating the maximum flux index for small diameter magnets.

Comments on NPR

On March 2, 2022, the Commission provided the public an opportunity to present views on the proposed rule in person before the Commission. Five presenters provided oral comments in support of the proposed rule. In addition to their support of the NPR, two commenters suggested further study was needed of magnets with flux index below 50 $kG^2 mm^2$ and whether they may pose a hazard. A third commenter urged further study of whether individual magnets with flux index under 50 $kG^2 mm^2$ will have a combined flux that is greater when two or more of those magnets aggregated into a clump. CPSC also received 716 written comments. Below, staff summarizes and responds to comments related to the proposed test methodology and strength limit.

Comment: One manufacturer, Retrospective Goods, LLC (CPSC-2021-0037-0701), stated that the ASTM test method for measuring flux is widely used internationally and well-understood; therefore, "there is no need to change the current ASTM test procedure for measuring a magnet's flux." As an example, the commenter provided a method from an international test lab that describes a procedure for locating the pole of a small magnet. The procedure uses a magnet's attraction to a ferromagnetic bar to orient and identify the poles and uses an adhesive surface to hold the magnet during testing. The commenter questioned whether the CPSC test procedure provided in Tab D of the NPR has been tested by other laboratories and stated that "changing the ASTM test procedure could lead to confusion and potentially uneven or conflicting results."

Response: CPSC staff developed a test procedure consistent with ASTM F963 to locate the magnet pole of small diameter magnets and to secure the magnet during the flux density measurement. This test procedure is provided for informative purposes and is not specified in the performance requirement; therefore, testing by other laboratories is not warranted. Staff did not and does not recommend changing the ASTM test procedure for measuring a magnet's flux, which consists of measuring the maximum flux density perpendicular to the magnet's pole surface. CPSC staff's procedure does not "[change] the ASTM test procedure" because there is no test procedure specified in ASTM F963 for locating the pole surface of a magnet or test procedure for how to secure the magnet while measuring the maximum flux density. The exemplar method used by an international test lab for locating the pole of a small diameter magnet and holding the magnet during testing is similar in concept to the test method developed by CPSC staff.

Comment: In response to the NPR solicitation for comment on whether to include Use and Abuse testing from ASTM F963 to ensure products do not liberate magnets, one manufacturer, Retrospective Goods, LLC (CPSC-2021-0037-0701), stated "no data has been presented that liberated magnets with a flux over 50 kG^2mm^2 in adult products, which also meet the scope of the Rule, are posing a problem. Any such requirement should be supported by data."

Response: CPSC staff requested comment on whether the rule should include Use and Abuse testing that is similar to that specified in ASTM F963, which determines if a hazardous magnet may separate from any part of a toy. The commenter responded that there are no data indicating that magnets are separating from products outside the scope of ASTM F963 and being swallowed by young children. CPSC staff's review of magnet ingestion incident data has not identified a pattern of children ingesting hazardous magnets that liberated from products not subject to ASTM F963.

Comment: One trade association, Magnet Safety Association (CPSC-2021-0037-0716), stated that the measurement of flux was created by ASTM as a high-level guidance for voluntary safety measures and "was not designed to be used to determine whether magnets will present injury if ingested multiply." The commenter stated that the flux measurement in ASTM does not represent attractive force, and the ratings do not appropriately scale with the strength or shapes of magnets. Therefore, the Commission should use a measurement that is appropriately created for such usage and properly reviewed by experts.

Response: CPSC staff proposed a performance requirement that duplicates the ASTM F963 Toy Standard approach to addressing magnet internal interaction hazard in children. The current ASTM test to determine flux index is a method that has been used by test labs to determine compliance with the toy standard and is a method that is also used by other domestic and international standards for identifying hazardous magnets. The requirement effectively addresses magnet internal interaction hazard in toy products. CPSC staff is not aware of another adequate method to measure the flux or strength of magnets, and the commenter did not offer one.

Comment: One consumer, Joshua Pruett (CPSC-2021-0037-0690), suggested that a test method to measure the force applied to a membrane sandwiched between two magnets (presumably the attractive force of two magnets across body tissue) is an alternative that would be a closer analog to the hazard the agency wishes to prevent than the current method in ASTM F963 Toy Standard, which measures a magnet's flux index.

Response: CPSC staff proposed a performance requirement that duplicates the ASTM F963 Toy Standard approach to addressing magnet internal interaction hazard in children. The current ASTM test to measure flux density has been used by test labs and by CPSC staff to determine compliance with the toy standard, and the requirement effectively addresses magnet internal interaction hazard in toy products. The method proposed by the commenter is not a currently accepted test procedure, and it would not be adequate because a specific attractive force between two magnets has not been correlated to tissue damage and severity of injury.

Comment: Comments from a consumer advocacy group (Consumer Reports), an individual consumer (Joshua Pruett), and a manufacturer (Retrospective Goods, LLC) made statements regarding sampling requirements for testing magnets. Consumer Reports (CPSC-2021-0037-0634) stated that given the variation in flux strength across magnets due to variation in density, the CPSC should require manufacturers to produce products that are consistent and uniform, and the CPSC should require large sample sizes. Mr. Pruett (CPSC-2021-0037-0690) suggested a representative sample consisting of 10 to 20 percent of the magnets in a set, but no less than 1 to 3 magnets per set, would provide robust test results. Retrospective Goods,

LLC (CPSC-2021-0037-0701) stated that manufacturers should be allowed the flexibility to determine the appropriate sampling for their product. This commenter requested that the final rule include an acceptable tolerance range for magnets.

Response: CPSC staff proposed a performance requirement that duplicates the ASTM F963 Toy Standard approach to addressing magnet internal interaction hazard in children. The proposed rule requires all loose magnets subject to the rule to either be too large for children to swallow or, if they are small enough to be swallowed, to have a measured flux index under 50 $kG^2\,mm^2$. The performance requirement does not impose design or production requirements on the manufacturer; and it is the manufacturer's responsibility to have processes in place to ensure each magnet produced will meet the proposed requirements. Manufacturers may choose sampling methods that are appropriate to their production setting and confidence in compliance to the proposed rule. Consistent with ASTM F963, and to prevent a hazard to children, staff considers a magnet product to fail the proposed requirement if at least one magnet from the product has a magnetic flux index of 50 $kG^2\,mm^2$ or greater.

*Commen*t: Numerous commenters opined on whether the proposed flux index limit is sufficient to address the magnet internal interaction hazard. Most supported the limit; however, several commenters stated that the CPSC should continue to study whether magnets with flux indexes lower than 50 $kG^2\,mm^2$ may also pose an unreasonable risk of injury to children and therefore should be brought within the scope of this rule at a later time. Additionally, one consumer advocacy group, Consumer Reports (CPSC-2021-0037-0634), recommended CPSC study whether larger magnets may also pose an unreasonable risk of injury.

Response: The current ASTM test to measure flux index is an accepted method by domestic and international standards development bodies and has been used by test labs to determine compliance with ASTM F963, EN 71-1, and ISO 8124-1. Staff's review indicates that the requirement effectively addresses magnet internal interaction hazard in toy products. Although staff is currently not aware of demonstrable evidence indicating that magnets with flux index below 50 $kG^2\,mm^2$ are hazardous, staff will continue to review magnet ingestion incidents to assess whether magnets with flux indexes lower than 50 $kG^2\,mm^2$ pose an unreasonable risk of injury. Based on the higher flux indexes associated with larger magnets, staff concludes that study of whether larger magnets pose an unreasonable risk of injury is unnecessary because the recommended rule would prohibit magnets that are small enough to pose a choking hazard with flux indexes lower than 50 $kG^2\,mm^2$.

Comment: Several commenters requested that, following promulgation of the final rule, the CPSC investigate whether and to what extent the number of magnets ingested affects the likelihood of internal interaction injuries. One manufacturer, Retrospective Goods, LLC (CPSC-2021-0037-0701), stated that there are no data showing that magnets in aggregate clumps increase the risk of internal interaction injury. This commenter explained that x-rays taken of ingestion incidents involving multiple magnets show that the pattern is limited to strings or rings of magnets.

Response: The existing flux index method was developed to estimate the magnetic attraction force of individual conventional dipole magnets. Individual magnets stacked together with their magnetic poles aligned, or connected side-by-side, could potentially have a stronger flux index

or otherwise be more difficult to separate than each individual magnet. A clump of magnets could be less powerful than an ordered aggregation, as the magnetic poles could overlap, interact, and counteract one another. CPSC staff's review of NEISS and CPSRMS-reported incidents did not show evidence demonstrating that internal interaction injuries occurred because of increased strength from magnets in aggregate.

Comment: One manufacturer, Retrospective Goods, LLC, provided a late comment (CPSC-2021-0037-0720) stating that the flux index is not an accurate measurement of magnetic attractive force because magnets of different size, shape, and composition can have the same flux densities but different points of contact (convex surface likes spheres and cylinder ends have a single point of contact versus flat surfaces of disks) and/or different pole surface areas. The commenter states the result is magnets of different size and shape can have the same flux index but different attractive forces; therefore, the commenter claims the flux index is an arbitrary way of measuring safety risk. However, the commenter also concludes that historical health data indicates that a flux index less than 50 kG^2mm^2 is an appropriate predictor of safety for all disk magnets and spherical magnets composed of neodymium; therefore, the commenter believes the rule should be limited to disk- and sphere-shaped neodymium magnets.

Response: The commenter's analysis of attractive force does not take into account the area over which the force is applied when two magnets attract to apply pressure (force divided by area) on the pinched tissue; therefore, attractive force by itself is not the only factor to consider. The commenter did not provide evidence, and staff is not aware of any, that correlates tissue damage to a specific magnetic attractive force over a specific area. CPSC staff proposed a performance requirement that duplicates the ASTM F963 Toy Standard approach to addressing the magnet internal interaction hazard in children. The current ASTM test to determine flux index is a method that has been used by test labs to determine compliance with the toy standard and is a method that is also used by other domestic and international standards for identifying hazardous magnets. Staff's rationale for using the 50 kG^2mm^2 flux index is based on historical incident data indicating the ASTM F963 requirement effectively addresses magnet internal interaction hazard in toy products. In fact, the commenter also concludes that the proposed rule is effective for certain magnets based on incident data, but the commenter does not provide an adequate rationale for excluding other magnets. Therefore, CPSC staff finds that the commenter's analysis does not change staff's conclusion that loose or separable magnets in the subject magnet products should either be too large to fit in the small parts cylinder described in 16 CFR 1501.4 or have a flux index of less than 50 $kG^2\,mm^2$, when tested in accordance with the procedures described in the ASTM F963 toy standard.

Assessment of Voluntary Standards

In Tab D of the NPR package, CPSC staff identified several voluntary and international standards that address the magnet internal interaction hazard. These standards include:

- ASTM F963-17, *Standard Consumer Safety Specification for Toy Safety*
- ASTM F3458-21, *Standard Specification for Marketing, Packaging, and Labeling Adult Magnet Sets Containing Small, Loose, Powerful Magnets (with a Flux index ≥50 kG2 mm2)*
- ASTM F2923-20, *Standard Consumer Safety Specification for Children's Jewelry*
- ASTM F2999-19, *Standard Consumer Safety Specification for Adult Jewelry*

- EN 71-1:2014, *Safety of Toys – Part 1: Mechanical and Physical Properties*
- ISO 8124-1:2018, *Safety of Toys – Part 1: Safety Aspects Related to Mechanical and Physical Properties*

Staff's technical assessment of the voluntary standards has not changed since the NPR.

ASTM F963-17

In the NPR, CPSC staff assessed the adequacy of the requirements in ASTM F963-17 *Standard Consumer Safety Specification for Toy Safety* in addressing magnet internal interaction hazard. Staff determined that ASTM F963-17 addresses the magnet internal interaction hazard with a two-part requirement:

1) Each magnet must be too large to fit entirely within the small parts cylinder (described in 16 CFR 1501.4), or
2) Each magnet must have a flux index (a calculated value of magnetic strength) less than 50 $kG^2\,mm^2$.

ASTM F963 avoids ingestion hazards by requiring that the size of magnets be too large for a child to swallow according to the test method for identifying parts which present a choking or ingestion hazard, codified in 16 CFR Part 1501. When that is not satisfied, ASTM F963 requires the magnetic attractive force of the magnet to be below a threshold that was developed by the ASTM working group to address internal interaction injuries involving strong magnets that separated from toys. The Code of Federal Regulations, 16 CFR part 1250, currently requires toys to comply with ASTM F963-17.

Assessment:

Based on the safety engineering approach used in ASTM F963 to address magnet internal interaction hazard, and the incident data since the ASTM magnet requirements for toys have been in effect (and became mandatory through regulation), CPSC staff concludes that the magnet requirements in ASTM F963 adequately address ingestion hazards associated with loose hazardous magnets in children's toys.

However, ASTM F963 does not apply to magnet products intended for entertainment, mental stimulation, and stress relief of consumers 14 years and older, and it excludes adult jewelry and children's non-toy jewelry. As the incident data in this briefing package indicate, these additional products that are not subject to ASTM F963 are involved in magnet ingestion incidents. Therefore, staff concludes that while ASTM F963 has effective performance requirements regarding hazardous magnets; the standard does not adequately address the hazard associated with ingestion of hazardous magnets by children and teens because the scope of the safety standard excludes the subject magnet products.

CPSC staff recommends the magnet size and strength performance requirements established by ASTM F963 for toy magnet products be used to address the same identified hazards in the subject magnet products.

ASTM F3458-21

In March 2021, ASTM published ASTM F3458, *Standard Specification for Marketing, Packaging, and Labeling Adult Magnet Sets Containing Small, Loose, Powerful Magnets (with a Flux Index ≥50 $kG^2\,mm^2$)*. In the NPR, CPSC staff assessed that ASTM F3458 includes test

methods consistent with ASTM F963-17 to determine if a magnet is a hazardous magnet; however, the standard does not require that each loose or separable magnet in magnet sets must either be too large to fit entirely within the small parts cylinder (described in 16 CFR 1501.4) or have a flux index of less than 50 $kG^2 mm^2$. In addition, the standard applies only to adult magnet sets, and does not address other products in the scope of the draft final rule, such as jewelry and other products intended for adult entertainment, mental stimulation, and stress relief. (As separately discussed, these products are not adequately addressed by any other voluntary standard.) Therefore, staff concludes ASTM F3458 does not adequately address the hazard associated with the ingestion of hazardous magnets by children and teens. In May 2021, the ASTM F15.77 subcommittee formed a task group to consider development of performance requirements for adult magnet sets. The task group last met in November 2021 and to date, the standard still does not have performance requirements to prevent hazardous magnets from being used in magnet sets.

Assessment:

Despite ongoing work by the voluntary standards task groups since publication of the NPR, ASTM F3458 still does not include performance requirements to address magnet ingestion by children. Therefore, staff concludes the standard does not adequately address the hazard associated with ingestion of hazardous magnets (defined as small enough to fit within the small parts cylinder and with flux index of 50 or greater) by children and teens. See Human Factors Tab C for more information regarding ASTM F3458.

ASTM F2923-20, ASTM F2999-19, EN 71-1:2014, ISO 8124-1:2018

ASTM F2923-20, *Standard Consumer Safety Specification for Children's Jewelry,* establishes requirements and test methods for certain mechanical hazards in children's jewelry, including ingestion, inhalation, and attachment hazards associated with hazardous magnets in children's jewelry. This voluntary standard applies to jewelry that is designed or intended primarily for use by children 12 years old or younger and includes criteria for identifying children's jewelry. In the NPR, staff concluded ASTM F2923-20 does not adequately address the hazard associated with ingestion of hazardous magnets by children and teens because (1) the voluntary standard allows for loose as-received hazardous magnets and loose as-received hazardous magnetic components in jewelry products intended for children 8 years of age or older,[2] and (2) the scope of the standard does not include other products included in the scope of the draft final rule.

ASTM F2999-19, *Standard Consumer Safety Specification for Adult Jewelry,* establishes requirements and test methods for certain mechanical hazards in adult jewelry, which is jewelry designed or intended primarily for users over 12 years old. The voluntary standard requires jewelry that contains magnets with flux index greater than 50 to provide warning statements regarding the ingestion hazard. In the NPR, staff concluded ASTM F2999-19 does not adequately address the hazard associated with ingestion of hazardous magnets by children and teens because the voluntary standard allows the use of hazardous magnets in jewelry and relies on recommended warning statements to address the ingestion hazard. In addition, the scope of

[2] ASTM F2923-20 requires children's jewelry intended for children 8 years of age or older consisting of earrings, brooches, necklaces, or bracelets, which contain loose as-received hazardous magnets or loose as-received hazardous magnet components to include specified warning statements in lieu of magnet size and strength limitations and use and abuse testing.

the voluntary standard does not include other products included in the scope of the draft final rule.

European standard EN 71-1:2014, *Safety of Toys – Part 1: Mechanical and Physical Properties,* applies to toys for children with toys being any product or material designed or intended, whether or not exclusively, for use in play by children of less than 14 years. International standard ISO 8124-1:2018, *Safety of Toys – Part 1: Safety Aspects Related to Mechanical and Physical Properties,* applies to all toys, meaning any product or material designed or clearly intended for use in play by children under 14 years of age. EN 71-1:2014, ISO 8124-1:2018, and ASTM F963 intentionally revised their requirements for magnets to align with one another in terms of definition of hazardous magnet, method to measure and calculate flux index, use and abuse tests, and definition and exemption for "magnetic/electrical experimental sets." Both standards prohibit hazardous magnets as defined by the ASTM F963 Toy Standard and use the same test method described in ASTM F963 to determine a magnet's flux index. In the NPR, staff concluded that these standards that align with ASTM F963 adequately address the ingestion hazard associated with loose magnets in children's toys; however, the standards on their own are inadequate because they exclude magnet products intended for entertainment, mental stimulation, and stress relief of consumers 14 years and older, and they exclude children's non-toy jewelry and adult jewelry.

CPSC staff notes that no changes have been made to ASTM F2923-20, ASTM F2999-19, EN 71-1:2014, and ISO 8124-1:2018 since the NPR. Based on staff's continued analysis of the hazard, staff's assessment regarding these standards has not changed since the NPR.

Conclusion and Recommendation

CPSC staff recommends performance requirements for products that contain one or more loose or separable magnets that were proposed in the NPR without revisions. Under the draft final rule, each loose or separable magnet in the subject magnet products must either:

1) be too large to fit entirely within the small parts cylinder described in 16 CFR 1501.4 (*e.g.*, a ball-shaped magnet with a diameter greater than 1.25 inches or 31.7 mm); or
2) have a flux index of less than 50 $kG^2\,mm^2$, when tested in accordance with the procedures for determining the magnetic attractive force of magnets described in ASTM F963 toy standard.

To ensure accuracy and consistency in measuring the flux index for small diameter magnets, staff recommends a test procedure that follows the concepts provided in *Example Test Method for Measuring Flux Index of Small Spherical Magnets* in Tab D of the NPR (see Appendix).

Appendix

Example Test Method for Measuring Flux Index of Small Spherical Magnets

To measure the flux index for small spherical magnets that are 2 to 3 mm in diameter, staff developed the following test methodology with the objective of reducing variability in test results due to difficulties in handling small objects and in determining the location of the poles.

This test method can be used for any size spherical magnet.

1) Acceptance limits and requirements. Magnets that fit completely within the small parts cylinder (described in 16 CFR 1501.4) must have a flux index less than 50 $kG^2\,mm^2$.

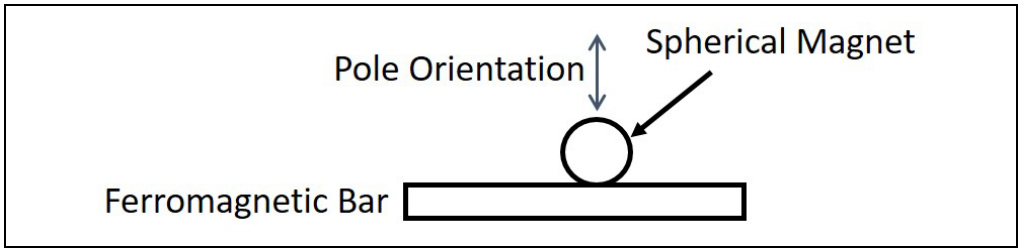
2) Test Equipment.

   a. Direct current field gaussmeter with a resolution of 5 gauss (G) and an axial type probe, capable of determining the field with an accuracy of 1.5 percent or better.
   b. Flat ferromagnetic bar nominally large enough to attract and hold test magnet sample(s).
   c. Adhesive such as clay/putty of sufficient density to hold magnet sample.
   d. Flat board or countertop that is not magnetic.

e. Calipers or similar device with resolution of 0.1 mm.

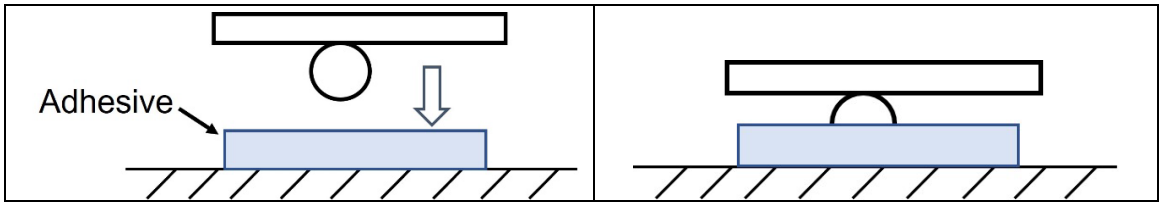
3) Test Method.

a. Measure the diameter of the magnet sample with the calipers.
b. Affix the test magnet to the ferromagnetic bar through its attraction to the bar. This establishes the pole orientation of the magnet. This can also work with ferrous calipers.

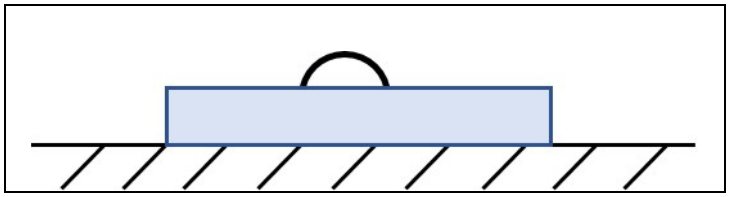


c. Prepare flat surface with adhesive to secure sample magnet.

d. Holding the bar with the sample magnet parallel and facing towards the table surface, lower the bar and press the magnet into the adhesive. Maintain the orientation of the spherical magnet when transferring to the adhesive surface.



e. Once magnet is stabilized in adhesive, remove flat bar. Spherical magnet is now held with magnetic pole perpendicular to the table surface.



4) Test Procedure

a. Position gaussmeter probe tip in contact with the pole surface of the magnet.
b. Keep gaussmeter probe perpendicular to pole surface.
c. Move the probe across the surface to locate the maximum absolute flux density.
d. Record the maximum absolute flux density.
e. Calculate the cross-sectional area of the spherical magnet.

$$A = \pi r^2$$

r = radius (mm)
= ½ diameter (mm)

f. Calculate the flux index ($kG^2\,mm^2$) by multiplying the area of the pole surface (mm^2) of the magnet by the square of the maximum flux density (kG^2).

5) Performance requirement.

a. The flux index shall be less than 50 $kG^2\,mm^2$.

Tab E: Final Regulatory Analysis Memorandum by the Directorate for Economic Analysis

This document has been electronically approved and signed.

TO: Stephen Harsanyi, Project Manager,
Division of Human Factors,
Directorate for Engineering Sciences

DATE: August 17, 2022

THROUGH: Alexander P. Moscoso, Associate Executive Director,
Directorate for Economic Analysis

Jose E. Tejeda, Senior Staff Coordinator,
Directorate for Economic Analysis

FROM: Charles L. Smith, Economist,
Directorate for Economic Analysis

SUBJECT: Final Regulatory Analysis of a Rule that Would Establish a Standard for Magnets

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Introduction

On January 10, 2022, the U.S. Consumer Product Safety Commission (CPSC; Commission) published a notice of proposed rulemaking (NPR), proposing to issue a safety standard for magnets under the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089; 87 FR 1260) and seeking public comments.[1] The proposed standard for magnets would require loose or separable magnets in subject magnet products, which fit within the CPSC's small parts cylinder, to have an attraction force of less than 50 kG^2 mm^2, as measured by their flux index. Staff recommends that the Commission issue a final rule with the same requirements as proposed to address the internal interaction hazard associated with the ingestion of small, powerful magnets ("hazardous magnets")[2] by children and teens; however, as discussed in the briefing memorandum, staff recommends listing the exempted products under 16 CFR § 1262.1 to make them explicit in the regulation. This memorandum provides a regulatory analysis of the recommended final rule, including assessment of its expected benefits and costs, alternatives to the rule, and consideration of comments received on the NPR that address those issues.

Discussion

Final Regulatory Analysis

Section 9 of the Consumer Product Safety Act (CPSA) requires that the Commission publish a "final regulatory analysis" in the *Federal Register* containing:

[1] Commission NPR on magnets (2021): https://www.govinfo.gov/content/pkg/FR-2022-01-10/pdf/2021-27826.pdf.
[2] Staff identifies a magnet as hazardous consistent with ASTM F963, *Standard Consumer Safety Specification for Toy Safety*, as a magnet that fits entirely within the cylinder described in 16 CFR 1501.4 and that has a flux index of 50 kG^2 mm^2 or more when tested in accordance with the method described in the proposed part 1262.

(1) A description of the potential benefits and potential costs of the rule, including costs and benefits that cannot be quantified in monetary terms, and the identification of those likely to receive the benefits and bear the costs.
(2) A description of any alternatives to the final rule which were considered by the Commission, together with a summary description of their potential benefits and costs and a brief explanation of the reasons why these alternatives were not chosen.
(3) A summary of any significant issues raised by the comments submitted during the public comment period in response to the preliminary regulatory analysis, and a summary of the assessment by the Commission of such issues.

Description of the Product and Market

The subject magnet products are products with one or more magnets, which are loose or separable, and designed, marketed, or intended to be used by consumers for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes. The subject magnet products do not include children's toys subject to the requirements in ASTM F963 (codified in 16 CFR part 1250) because they are already required to comply with ASTM F963. The NPR briefing package explains that, of the subject magnet products, magnet sets are the most concerning to staff.[3] Magnet sets are aggregations of separable magnetic objects that are marketed or commonly used as manipulative or construction items for entertainment, such as puzzle working, sculpture building, mental stimulation, or stress relief.

The Directorate for Economic Analysis (EC) has investigated magnet sets in previous CPSC staff packages, including the 2014 rule on magnet sets,[4] the 2020 informational briefing package regarding magnet sets,[5] and the 2021 NPR briefing package on hazardous magnet products ("hazardous magnet products" refers to subject magnet products containing one or more loose or separable hazardous magnets). The most recent market reviews found that nearly all of the marketers (firms or individuals) of magnet sets sell these products through Internet sites, rather than through "brick-and-mortar" retailers (such as bookstores, gift shops, and other outlets, which commonly sold magnet sets during 2009 through mid-2012). Some of these Internet sites have been operated by the importers of magnet sets.

Magnet sets currently offered for sale are typically comprised of hazardous magnets in the shapes of spheres or cubes in a range of dimensions and number of individual magnets. Magnet sets seen in our review of the market were, most commonly, comprised of 216 magnetic spheres, with diameters of 5 mm.[6] Retail prices average under $20 per set. A market review by Industrial Economics, Incorporated (IEc) in late 2018 had similar findings.[7] Magnet sets are also available in larger sets of 512 magnets and 1,000 or more.

[3] CPSC staff briefing package, *Draft Notice of Proposed Rulemaking for Hazardous Magnet Products* (2021), https://www.cpsc.gov/s3fs-public/Proposed-Rule-Safety-Standard-for-Magnets.pdf?VersionId=2Xizl5izY1OvQRVazWpkqdJHXg5vzRY_.
[4] CPSC staff's briefing package: Final Rule on Safety Standard for Magnet Sets (2014): https://cpsc.gov/s3fs-public/pdfs/foia_SafetyStandardforMagnetSets-FinalRule.pdf.
[5] CPSC staff's informational briefing package, "Staff Briefing Package In Response to Petition CP 17-1, Requesting Rulemaking Regarding Magnet Sets," dated June 3, 2020: https://cpsc.gov/s3fs-public/Informational Briefing Package Regarding Magnet Sets.pdf?FKVcZpHmPKWCZNb7JEl6Ir0a31WV72PI.
[6] Our 2018 review of the market found high-powered magnet sets for sale ranging from 20 or fewer spheres up to 1,728 spheres.
[7] IEc found that magnet sets with 216 magnets accounted for approximately one-third of the models in their market research, with an average price of $16.67 (IEc, 2019, p. 7). However, sets of 216 magnets that measured 5 mm in diameter averaged $18.62.

Magnet sets comprised of spheres or cubes with smaller dimensions (2.5 mm to 3 mm) are also marketed, typically at lower prices. Some of these magnet sets are advertised as having magnets with magnetic flux indices less than 50 $kG^2\,mm^2$; below the threshold for being considered hazardous magnets. Testing of samples of such smaller magnets by staff of the Directorate for Laboratory Sciences (as reported in the NPR memorandum from the Directorate for Engineering Sciences, Division of Mechanical and Combustion Engineering) found that while 2.5 mm magnets typically had flux indices of less than 50 $kG^2\,mm^2$, many of the magnet sets tested failed the ASTM F963 requirements because at least one of the magnets in the set had a flux index of 50 $kG^2\,mm^2$ or over. Sets with 3 mm diameter magnets were found to have flux indices generally above 50 $kG^2\,mm$ (Paul, 2021).

Children's and adult jewelry, and other types of adult magnet products intended for entertainment, mental stimulation, and stress relief, which have one or more separable/loose magnets are within the scope of the draft final rule; however, EC has not found information on unit sales of these products.[8,9] CPSC staff is aware of magnets marketed online as jewelry making sets, as well as fake studs/piercings; although it is unclear how many of these products contain hazardous magnets. It is clear from the incident data that many magnet ingestion cases involve the use of magnet products described as jewelry, such as bracelets and necklaces, and magnets used as jewelry (including those sold as part of a magnet set), such as to simulate mouth, cheek, and tongue piercings, at the time of the incidents.

Final Regulatory Analysis – Potential Benefits and Costs Assessment

The draft final rule is conducted from a societal perspective and considers all the significant costs and health outcomes (Gold et al., 1996; Haddix, Teutsch, Corso & Phaedra, 2003; Neumann et al, 2016). Benefits and costs may be calculated on a per-product in-use basis, an approach that has been found useful at the CPSC (Rodgers & Rubin, 1989; Tohamy, 2006; Smith, 2016; Rodgers & Garland, 2016).

The expected benefits of the draft final rule are the reduction in the risk of serious injury or death from hazardous magnet ingestion and the resulting elimination of the societal costs associated with the injuries and deaths involving the subject magnet products that do not comply with the requirements. The costs are the lost utility to consumers from no longer being able to purchase and use non-complying magnets (referred to as lost consumer surplus), and the lost income of producers who would no longer be able to produce and sell the subject magnet products (lost producer surplus). It is possible, however, that these costs to consumers and producers could be offset by the availability of highly similar products that do comply with the draft final rule.

Reduction in Risk of Serious Injury or Death and Societal Costs

We begin by discussing the characteristics and societal costs of the injuries that involved identified subject magnet product categories—namely, magnet sets, magnet toys (not subject to ASTM F963), and jewelry. Preventing these injuries would represent benefits of the draft final rule. National estimates of injuries treated in emergency departments (ED) were derived from

[8] No information on these markets was provided by individuals submitting comments in response to the NPR.
[9] Detailed below, certain products marketed for mental stimulation are exempt from the draft final rule.

the CPSC's National Electronic Injury Surveillance System (NEISS), a stratified national probability sample of U.S. hospital EDs consisting of about 100 U.S. hospitals that have at least six beds and provide 24-hour emergency service (Schroeder & Ault, 2001).

In addition to injuries initially treated in hospital EDs, many product-related injuries are treated in other medical settings, such as, physicians' offices, clinics, and ambulatory surgery centers. Some injuries also result in direct hospital admission, bypassing the hospital ED entirely. The number of subject magnet product injuries treated outside of hospital EDs is estimated with the CPSC's Injury Cost Model (ICM), which uses empirical relationships between the characteristics of injuries (diagnosis and body part) and victims (age and sex) initially treated in hospital EDs and the characteristics of those initially treated in other settings. A detailed discussion of the ICM and these methods is given in Miller et al. (2000); Bhattachara, Lawrence, Miller, Zaloshnja & Jones (2012); and Lawrence (2013).

The ICM estimate of injuries treated outside of hospitals or hospital EDs (*e.g.*, in doctors' offices, clinics, etc.) is based on data from the Medical Expenditure Panel Survey (MEPS). The MEPS is a nationally representative survey of the civilian, non-institutionalized population that quantifies individuals' use of health services and corresponding medical expenditures. It combines data from a panel of participants interviewed quarterly over a two-year time period with data from the respondents' medical providers. The MEPS is administered by the Agency for Healthcare Research and Quality (AHRQ). The ICM uses the MEPS data, in combination with a classification tree analysis technique, to project the number and characteristics of injuries treated outside of hospitals.

To project the number of direct hospital admissions which bypass hospital EDs, the ICM uses data from the Nationwide Inpatient Sample of the Healthcare Cost and Utilization Project (HCUP-NIS), which was also analyzed using a classification tree analysis technique (described below). HCUP is a family of healthcare databases and related software tools and products developed through a federal-state-industry partnership and sponsored by AHRQ. The HCUP-NIS provides information annually on approximately 3 to 4 million in-patient stays from about 1,000 hospitals.

The classification tree analysis technique (also called decision tree) is a statistical tool that divides and sorts data into smaller and smaller groups for estimating the ED share of injuries until no further gains in predictive power can be obtained. This technique allows for more precise estimates of injuries treated in doctor visits or injuries admitted directly to the hospital than other regression techniques. For example, where data permit, the age and sex of the victim can have an influence on the estimates of the number of injuries treated outside the ED. When we combine the national estimates of the NEISS with the non-ED estimates from the ICM using classification tree techniques, we obtain total estimated medically-treated injuries.

Based on the NEISS annual estimate of about 481 magnet injuries initially treated in hospital EDs during 2017 through 2021 involving magnets identified as entertainment or jewelry products. The 481 injuries are comprised of 320 injuries that were treated and released and 161 injuries that required hospitalization. Additionally, based on estimates from the ICM, 185 injuries were treated outside of hospitals annually and another 78 injuries resulted in direct hospital admission..

The ICM is fully integrated with NEISS and provides estimates of the societal costs of injuries reported through NEISS, as well as the societal costs of other medically treated injuries estimated by the ICM. The major aggregated societal cost components provided by the ICM include medical costs, work losses, and the intangible costs associated with lost quality of life or pain and suffering.[10]

Medical costs include three categories of expenditures: (1) medical and hospital costs associated with treating the injury victim during the initial recovery period and in the long run, including the costs associated with corrective surgery, the treatment of chronic injuries, and rehabilitation services; (2) ancillary costs, such as costs for prescriptions, medical equipment, and ambulance transport; and (3) costs of health insurance claims processing. Cost estimates for these expenditure categories were derived from a number of national and state databases, including the Medical Expenditure Panel Survey, the Nationwide Inpatient Sample of the HCUP-NIS, the Nationwide Emergency Department Sample (NEDS), the National Nursing Home Survey (NNHS), MarketScan® claims data, and a variety of other federal, state, and private databases.

Work loss estimates are intended to include: (1) the forgone earnings of the victim, including lost wage work and household work, (2) the forgone earnings of parents and visitors, including lost wage work and household work, (3) imputed long term work losses of the victim that would be associated with permanent impairment, and (4) employer productivity losses, such as the costs incurred when employers spend time juggling schedules or training replacement workers. Estimates are based on information from the Nationwide Inpatient Sample of the HCUP-NIS, NEDS, Detailed Claims Information (a workers' compensation database), the National Health Interview Survey, U.S. Bureau of Labor Statistics, and other sources.

The intangible, or non-economic, costs of injury reflect the physical and emotional trauma of injury as well as the mental anguish of victims and caregivers. Intangible costs are difficult to quantify because they do not represent products or resources traded in the marketplace. Nevertheless, they typically represent the largest component of injury cost and need to be accounted for in any benefit-cost analysis involving health outcomes (Rice et al., 1989; Haddix, Teutsch and Corso, 2003; Cohen and Miller, 2003; Neumann et al, 2016). The ICM develops a monetary estimate of these intangible costs from jury awards for pain and suffering. While these awards can vary widely on a case-by-case basis, studies have shown them to be systematically related to a number of factors, including economic losses, the type and severity of injury, and the age of the victim (Viscusi, 1988; Rodgers, 1993; Cohen and Miller, 2003). Estimates for the ICM were derived from regression analysis of jury awards in nonfatal product liability cases involving consumer products compiled by Jury Verdicts Research, Inc.

Based on ICM estimates, these injuries resulted in annual societal costs of about $51.8 million (in 2020 dollars) during the 2017 through 2021 time period.[11] The average estimated

[10]A detailed description of the cost components, the general methodology and data sources used to develop the CPSC's Injury Cost Model, and Injury Cost Model Updates, can be found in Miller et al. (2000); Lawrence (2008, 2013, 2014, 2015a, 2015b, 2015c); Lawrence et al. (2018); and Bhattachara, et al. (2012).
[11] The preliminary regulatory analysis considered injuries occurring during 2017 through 2020, and found annual societal costs of about $47.6 million (in 2018 dollars).

societal cost per injury was about $14,000 for injuries treated in physician's offices, clinics, and other non-hospital settings; about $24,000 for injuries that were treated and released from EDs; and about $175,000 for injuries that required admission to the hospital for treatment. Medical costs and work losses (including work losses of caregivers) accounted for about 43 percent of these injury cost estimates, and the less tangible costs of injury associated with pain and suffering accounted for about 57 percent of the estimated injury costs.

Table 1 provides *annual* estimates of the injuries and the societal costs associated with ingestions of subject magnet products identified as "magnet sets," "magnet toys," or "jewelry." See the hazard data analysis by EPHA staff for details on these categories (Tark, 2022; Tab B).

Table 1. Estimated average annual medically treated injuries and associated societal costs for magnet ingestions that were identified as involving subject magnet products, 2017 – 2021.

Injury Disposition	Estimated Number	Estimated Societal Costs ($ millions)*
Doctor / Clinic (ICM)	185	$2.6
Treated and Released from Hospital Emergency Department (NEISS)	320	$7.5
Admitted to Hospital Through the ED (NEISS)	161†	$28.1
Direct Hospital Admissions, bypassing the ED (ICM)	78	$13.6
Total Medically Attended Injuries	743	$51.8

* In 2020 dollars.
† According to the Directorate for Epidemiology, the NEISS-estimated number of hospital-admitted, emergency department-treated injuries represents a highly uncertain estimate because of the small number of cases upon which the estimate was based (NEISS reportability criteria requires that the estimated number of injuries needs to be 1,200 or higher, the sample size be 20 or larger, and the coefficient of variation be less than 33 percent).

Uncertainty Regarding the Injury Data. In addition to the magnet cases upon which Table 1 was based, for which identifying information was reported (*i.e.*, magnets from magnet sets, magnet toys, or jewelry), there were also 403 NEISS cases during 2017 through 2021 (representing about 1,873 ED-treated injuries annually), in which the magnet type was classified as "unidentified." These cases included narratives that mentioned that at least one magnet was ingested but presented insufficient information to classify the magnet product type. Based on analysis of the data, and the trends in NEISS, CPSRMS, and poison center[12] reported magnet-

related incidents relative to the vacated rule on magnet sets, staff finds it reasonable to conclude that the "unidentified" magnet products generally involved magnets considered within scope of the draft final rule; that is, intended for subject magnet product uses (Harsanyi, 2022, Tab C). Based on ICM estimates for unidentified magnet products involved in ingestion injuries, average annual societal costs for 2017 – 2021 totaled $167.9 million. Consequently, to the extent that the unidentified in-scope magnet products were products that would be covered by the draft final rule, which staff assesses is likely, the Table 1 results understate the societal costs associated with the magnet products subject to the draft final rule.

Estimated Benefits

As noted above, the benefits of the draft final rule would be the reduction in the risk of serious injury or death from magnet ingestion and the resulting value of the societal costs of the injuries that would be prevented. Because subject magnet products would be required to meet the requirements of the draft final rule, injuries that would have occurred in the absence of a rule will be prevented. As detailed in the health sciences memorandum (Johnson, 2022; Tab A), ingestion of hazardous magnets from the subject magnet products and related medical management may result in life-threatening injuries. Staff is aware of four deaths involving the ingestion of hazardous magnets likely from subject magnet products, which occurred in the United States from 2010 through 2021 (see the NPR briefing package).[13] Given that nearly all incidents result in injuries, rather than deaths, CPSC focuses its benefits assessment on the mitigation of injuries. However, CPSC includes the mitigation of deaths in the benefits assessment in a sensitivity analysis in this regulatory evaluation.

The annual expected benefits of the rule, on a per-product basis, depend upon the ability of the draft final rule to reduce incidents due to reduced exposure to the risks associated with the subject magnet products, as presented in Table 1. Although many of the subject magnet products retain much of their magnetism for many years, it is likely that many are discarded well before that time. The final regulatory analysis uses the estimate for expected product life of the subject magnet products from the initial regulatory analysis in the NPR: one-and-one-half, two, and three years. Table 2 presents benefit estimates under the alternative product life assumptions (line (b)). Line (a) shows average annual aggregate societal injury costs from Table 1.

[13] Detailed in the NPR briefing package, staff is aware of seven deaths involving ingestion of hazardous magnets between November 24, 2005, and January 5, 2021. Two of these occurred abroad and one of the five U.S. ingestion cases occurred before 2010 and involved a children's toy subject to ASTM F963.

Table 2. Present Value of Societal Costs per Subject Magnet Product in Use (or Gross Benefits of a Rule), for Various Expected Product Lives during the 2017 through 2021 period.

(a) Aggregate Annual Societal Costs (millions $)	$51.8	$51.8	$51.8
(b) Expected Useful Product Life (years)	1.5	2	3
(c) Magnet Products in Use, Average Annual	515,000	626,000	818,000
(d) Annual Societal Costs per Subject Magnet Product [(a) ÷ (c)]	$101	$83	$63
(e) Present Value of Societal Costs, per Subject Magnet Product[1] (*3% Discount Rate*)	$150	$162	$180
(f) Present Value of Societal Costs, per Subject Magnet Product[1] (*7% Discount Rate*)	$144	$154	$167

[1] These calculations are based on estimated product survival by month after purchase, which is multiplied by monthly societal costs per unit. The streams of expected societal costs are then discounted to their present values (at 3% and 7%).

Line c presents the average annual estimated number of subject magnet products in use during the 2017 through 2021 time period, based on producer-reported annual magnet set sales collected by the Office of Compliance and Field Operations up through mid-2012, and assumptions of annual sales of all subject magnet products through 2021 (including an assumption of 500,000 units per year for 2018 – 2021), an expected product life of one and a half, two, and three years (line b), and the application of the CPSC's Product Population Model, a computer algorithm that projects the number of products in use given estimates of annual product sales and product failure rates (Lahr and Gordon,1980). In the NPR, staff requested comments with information on annual sales and expected product life of magnet products subject to the proposed rule. No specific sales and product life information was provided to CPSC. Implications of potential lower and higher unit sales are addressed in the sensitivity analysis below.

The annual estimated societal costs per subject magnet product in use (line d of Table 2) are presented as the quotient of the annual societal costs (line a), and the estimated average number of products in use (line c).

Based on these estimates, and an assumed average product life ranging from 1.5 to 3 years, the present value of societal costs, per subject magnet product, range from about $150 to about $180 using a 3 percent discount rate (line e), or from about $144 to $167 using a 7 percent discount rate (line f).

Because the rule would prohibit the sale of the subject magnet products with one or more loose or separable hazardous magnets, the first order estimate of benefits would be equal to the present value of societal costs, presented in lines (e) and (f) and would range from about

$144 (with a 1.5-year product life and a 7 percent discount rate) to $180 (with a 3-year product life and a 3 percent discount rate) per product.

Estimated Costs of the Draft Final Rule

Both consumers and producers benefit from the production and sale of consumer products. The consuming public obtains the use value or utility associated with the consumption of products; producers obtain income and profits from the production and sale of products. Consequently, the costs of requiring that subject magnet products comply with the draft final rule would consist of: (1) the lost use value experienced by consumers who would no longer be able to purchase subject magnet products that do not meet the standard (at any price); and (2) the lost income and profits to firms that could not produce, import, or sell non-complying products in the future.

Both consumer and producer surplus depend upon, among other things, product sales. However, we are unable to estimate the precise number of unit sales of subject magnet products, nor were any such data provided in response to the NPR's request for such information. Therefore, we will consider possible costs associated with several reasonable estimates of sales, ranging from about 100,000 to 1 million subject magnet products per year. The lower bound of 100,000 units[14] and upper bound of 1 million units was based on information reviewed on reports by firms to the Office of Compliance and Field Operations. For purposes of exposition, Table 2, above, and the immediate discussion below assume annual sales of 500,000 per year.

Lost Utility to Consumers. First, consider the lost utility to consumers. In the case of magnet sets, which likely comprise the vast majority of subject magnet products on the market, public comments by sellers and consumers cite usefulness of the magnets as a manipulative or construction item for entertainment, such as puzzle working, sculpture building, or stress relief. Others have claimed that the magnets can have beneficial artistic, educational, social, innovative, and therapeutic values. In addition to consumer uses promoted by sellers, and reported in comments by consumers, Directorate for Engineering Sciences, Division of Human Factors (ESHF) staff notes that use of magnets from magnet sets as jewelry is a common hazard pattern (Tab C). The individual magnets might also have additional uses, apart from those for which they are intended (e.g., using magnets from a magnet set on a refrigerator). Thus, we may conclude that consumers derive utility from magnet sets and other subject magnet products within the scope of the rule from a wide variety of uses, even those not promoted by sellers.

We cannot estimate in any precise way the use value that consumers receive from these products, but we can describe use value conceptually. In general, use value includes the amount of: (1) consumer expenditures for the product, plus (2) what is called "consumer surplus." Assuming annual sales of about 500,000 subject magnet products annually, and an average retail price of about $20 (based on price data for magnet sets), consumer expenditures would amount to about $10 million annually. These expenditures represent the minimum value that consumers would expect to get from these products. It is represented by the area of the

[14] The lower bound estimate was 250,000 in the NPR. Since the NPR, a leading seller was subject to a recall. To account for this change, staff made a notional adjustment to 100,000.

rectangle OBDE in the standard supply and demand graph below (Figure 1), where B equals $20, and E equals 500,000 units.

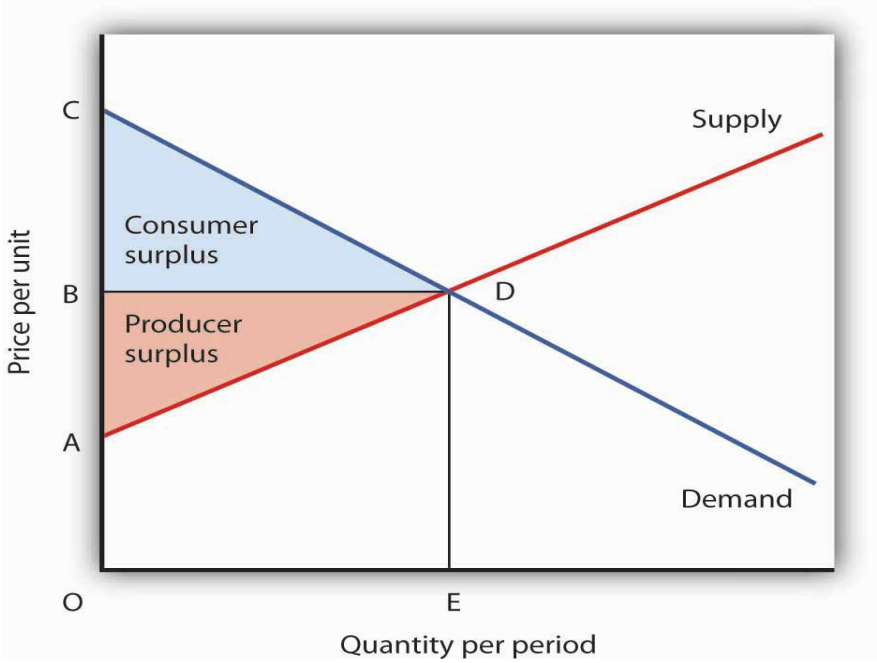

Figure 1. Supply and demand graph illustrating the concepts of consumer and producer surplus.

Consumer surplus is given by the area of the triangle BCD under the graph's demand function and represents the difference between the market-clearing price and the maximum amount consumers would have been willing to pay for the product. This consumer surplus will vary for individual consumers, but it represents a benefit to consumers over and above what they had to pay (McCloskey, 1982).[15] For example, although tickets to a concert or football game might sell for $100 each, some consumers who buy them for $100 would have been willing to pay $150 per ticket. In other words, they paid $100 and received benefits that they value at $150. Hence, each of these consumers would receive a *consumer surplus* of $50.[16]

In general, the use value of the subject magnet products obtained by consumers is represented by the area of the trapezoid OCDE. However, the prospective *loss* in use value associated with the draft final rule, which will require that products comply with the rule, would amount to, at most, the area of the triangle representing the consumer surplus. This is because consumers would no longer be able to obtain utility from the prohibited product, but they would, nevertheless, still have the $10 million (represented by the rectangle OBDE) that they would have spent on non-complying subject magnet products in the absence of a rule. Although consumers will no longer be able to purchase subject magnet products that do not comply with the draft final rule, which would have been their preferred choice, they can use this money to

[15] The concept of consumer surplus is discussed in OMB's Circular A-4 (OMB, 2003) and has been applied in a number of staff analyses, including Tohamy (2006); Smith (2016); and Zamula, Rodgers & Bailey (2016).
[16] If the above graph represents the market for tickets, the demand curve describes the quantity of tickets demanded at each price (*i.e.*, the quantity of tickets consumers are willing and able to purchase at each price). In this example, the $150 that the consumer would have been willing to pay for the ticket is represented on the demand curve at a point to the left of point D. The consumer surplus is given by the relevant point on the demand curve (*i.e.*, where price = $150), minus the market clearing price of $100.

buy other products providing use-value. This ability to purchase alternative complying products and obtain consumer surplus from them could reduce the net loss in consumer surplus resulting from the rule.

We have no information regarding aggregate consumer surplus, nor were any such data provided in response to the NPR's request for such information; and hence, the amount of utility that would be lost as a result of the draft final rule. However, as an illustration, if consumers who purchased the non-complying subject magnet products at an average price of $20 would have been willing to spend, on average, $35 to $45 per product (*i.e.*, an additional $15 to $25 per set), the lost utility might amount to about $7.5 million (*i.e*., [$35-$20] × 500,000 units annually) to $12.5 million (*i.e*., [$45-$20] × 500,000 units annually) on an annual basis.

Finally, we note that the loss in consumer surplus just described represents the maximum loss of consumer utility from the draft final rule. This is because consumers are likely to gain some amount of consumer surplus from products that are purchased as an alternative to those subject magnet products that would no longer be available because of the rule. If, for example, there were close substitutes (*e.g*., products that are almost as satisfying and similarly priced) for the subject magnet products that do not meet the standard, the overall loss in consumer surplus (and, hence, the costs of the draft final rule) would probably tend to be small. On the other hand, if there are no close substitutes, the costs of the rule would tend to be higher.

Staff is aware of magnet sets advertised as having magnets with a magnetic flux index less than 50 $kG^2\,mm^2$ (and thus would be compliant with the draft final rule), which are marketed for the same purposes as the more common hazardous magnet sets. As noted above, CPSC staff has found through recent testing of 2.5 mm diameter magnets from magnet sets that many of the magnets measured less than 50 $kG^2\,mm^2$, although many of the magnet sets failed the ASTM F963 requirements (and draft final rule) because at least one of the magnets in the set exceeded that flux index. Regarding magnet sets and other toys subject to the draft final rule, there are alternative products with similar functions for amusement and stress relief, such as magnetic desk sculptures which use a magnetic base (not a "small part") and ferromagnetic pieces, sets of large magnetic balls, and a wide variety of "fidget toys."

Manufacturers of magnetic jewelry with loose or separable magnets have options for complying with the rule, including using magnets that are not hazardous, or close substitutes that are nonmagnetic. If jewelry manufacturers wish to offer separable pieces on necklaces or bracelets, they might offer nonmagnetic pieces that attach to a bracelet or necklace incorporating attached magnets. Additionally, magnetic stud earrings and faux piercing jewelry have clip-on alternatives and pierced jewelry as substitutes.

Regardless of the availability of product alternatives for the many uses consumers find for magnet sets and other subject magnet products, the draft final rule will result in some level of lost utility. Consumer purchases of subject magnet products that exceed the size or strength requirements in the draft final rule suggests that some consumers may prefer these products over compliant versions of the products (*e.g.,* they prefer higher strength or smaller magnets); for such consumers, compliant versions may provide less utility.

Lost Benefits to Producers. The lost benefits to firms that could result from the draft final rule are measured by a loss in what is called *producer surplus*. Producer surplus is a profit measure that is somewhat analogous to consumer surplus. Whereas consumer surplus is a measure of benefits received by individuals who consume products, net of the cost of purchasing the products, producer surplus is a measure of the benefits accruing to firms that produce and sell products, net of the costs of producing them. More formally, "producer surplus" is defined as the total revenue (TR) of firms selling the magnets, less the total variable costs (TVC) of production. Variable costs are costs that vary with the level of output and usually include expenditures for raw materials, wages, distribution of the product, and the like.

In Figure 1, total revenue is given by the area OBDE, which is simply the product of sales and price. The total variable costs of production are given by the area under the supply function, OADE. Consequently, producer surplus is given by the triangle ABD, which is the area under the market clearing price and above the supply function. Note that this represents the maximum loss to producers; if there were product alternatives that were similar to the subject magnet products that suppliers could produce and sell, the lost producer surplus could be less.

Following our example above, if sales of the subject magnet products average 500,000 units annually, with an average retail price of $20 per product total industry revenues have averaged about $10 million annually (*i.e.,* 500,000 units × $20 per product). Information provided by magnet set sellers to the Office of Compliance and Field Operations suggested that the average import cost of magnet sets to U.S. importers, a major variable cost, may amount to about $10 per set, or an average of about $5 million annually (*i.e.,* 500,000 sets × $10 import cost per set). Apart from the import costs of the magnets the variable costs of production are probably relatively small. Because magnet sets are often packaged and shipped from China and sometimes sent directly to the importer's point of sale, U.S. labor costs may be low; and because the magnets sets are small, storage costs are probably low. If, for example, the variable costs of production account for about half of the difference between total revenues ($10 million) and import costs ($5 million), producer surplus would amount to about $2.5 million (*i.e*., ($10 million − $5 million) ÷ 2) annually. At most, the lost producer surplus would amount to about $5 million annually, if there were no variable costs other than the costs of importing the magnets (*i.e.*, total revenue of $10 million for 500,000 units annually less the import costs of about $5 million). While this information is specifically related to magnet sets, a similar relationship could apply to other subject magnet products affected by the draft final rule. We note that manufacturers and importers might be able to respond to the rule by measures such as marketing or incorporating magnets that comply with the rule or increased marketing of products that do not have loose or separable magnets. Such measures could partially offset losses in producer surplus resulting from firms' inability to continue marketing noncomplying magnet products.

As noted above, actual sales levels of non-complying subject magnet products are not known with certainty. Additionally, we have no precise estimates of either consumer surplus or producer surplus, nor were any such data provided in response to the NPR's request for such information. Table 3 below provides rough estimates of the possible costs of the rule, for various future hypothetical sales levels ranging from 100,000 to 1 million products annually. The cost estimates are based on a number of assumptions described above and are made for illustrative purposes. Nevertheless, because the range of sales is wide, and is likely to include actual sales

levels on an annual basis, it is reasonable to assume that the costs of the draft final rule could range from $2 to $3.5 million (if sales amount to about 100,000 products annually), to about $20 to $35 million (if sales amount to about 1 million products annually). As noted above, these costs could be partially offset by increased marketing of products that incorporate complying magnets, or products that do not include loose or separable magnets.

Table 3. Possible Costs of the Draft Final Rule, for Various Levels of Non-Complying Subject Magnet Product Sales

Magnet Product Sales (annually)	Consumer Surplus (millions $)	Producer Surplus (millions $)	Total Costs (millions $)
100,000	$1.5 to $2.5	$0.5 to $1	$2 to $3.5
500,000	$7.5 to $12.5	$2.5 to $5	$10 to $17.5
750,000	$11.25 to $18.75	$3.75 to $7.5	$15 to $26.25
1,000,000	$15 to $25	$5 to $10	$20 to $35

In addition to lost producer surplus, manufacturers/importers of subject magnet products that comply with the rule would likely incur some additional costs to certify that their products meet the requirements as required by Section 14 of the CPSA. The certification must be based on a test of each product model or a reasonable testing program. The costs of the testing might be minimal, especially for manufacturers that currently have product testing done for products subject to the requirements in ASTM F963. Importers may also rely upon testing completed by other parties, such as their foreign suppliers, if those tests provide sufficient information for the manufacturers or importers to certify that the magnets in their products comply with the draft final rule. As noted above, for subject magnet products that could be considered to be children's products, such as children's jewelry, the certification must be based on testing by an accredited third-party conformity assessment body, at somewhat higher costs.

Sensitivity Analysis

The base-case analysis of potential costs and benefits of the draft final rule presents estimated costs for a wide range of prospective sales in the absence of a rule, 100,000 to 1 million units. Estimated potential benefits/societal costs of injuries per unit are based on expected useful product life of 18 months, 2 years, and 3 years. The present value of expected injury costs occurring over the lives of products are discounted at 3 percent and 7 percent. Thus, the base analysis incorporates sensitivity analysis for some important parameters and assumptions. In this section, we present additional sensitivity analysis to evaluate the impact of variations in some other important parameters. Alternative inputs for the sensitivity analysis include:

1. Assuming lower and higher unit sales in recent years than the base case of 500,000 units for 2017 through 2022;
2. Assuming 25 percent, 50 percent, and 100 percent of estimated injury costs involving unidentified magnet products would be addressed by the rule, and;

3. Including an estimate of societal costs of fatal ingestion injuries in the potential benefits calculation.

Recent Historical Sales

Recent annual unit sales of subject hazardous magnet products are uncertain, and no information was provided in response to requests in the NPR for information on sales. The estimated costs and benefits of the draft final rule were based on unit sales ranging from 100,000 to 1 million annually for hazardous magnet products within the scope of the rule. The base analysis of societal costs per hazardous magnet product assumes annual sales of 500,000 units for 2017 through 2021. In the following analysis we examine the sensitivity of estimated potential benefits/societal costs per subject magnet product to lower and higher recent unit sales.

a. **Lower Recent Annual Sales**

The lower sales scenario assumes annual unit sales of hazardous magnet products from 2017 through 2021 have been 100,000 units. Lower sales result in estimated average numbers of hazardous magnet products in use during 2017 through 2021 ranging from about 296,000 to 512,000 for 1.5 to 3 year expected product lives.

Table 2a. Present Value of Societal Costs per Subject Magnet Product in Use (or Gross Benefits of a Rule), for Various Expected Product Lives during the 2017 through 2021 period, and Lower (100,0000) Recent Annual Unit Sales.

(a) Aggregate Annual Societal Costs (millions $)	$51.8	$51.8	$51.8
(b) Expected Useful Product Life (years)	1.5	2	3
(c) Magnet Products in Use, Average Annual	296,000	368,000	512,000
(d) Annual Societal Costs per Subject Magnet Product [(a) ÷ (c)]	$175	$141	$101
(e) Present Value of Societal Costs, per Subject Magnet Product (*3% Discount Rate*)	$261	$276	$288
(f) Present Value of Societal Costs, per Subject Magnet Product (*7% Discount Rate*)	$251	$262	$267

The estimated present value of societal costs of subject magnet product ingestion injuries under this assumption of lower recent unit sales ranges from $251 per subject magnet product (1.5 year expected life, 7% discount rate) to $288 (3-year expected product life, 3% discount rate). The estimated per unit societal costs are over $100 greater than the base analysis which assumes recent annual unit sales of 500,000.

b. Higher Recent Annual Sales

The higher sales scenario assumes annual unit sales of hazardous magnet products from 2017 through 2021 have been 1,000,000 units. Higher sales result in estimated average numbers of hazardous magnet products in use during 2017 through 2021 ranging from about 1.1 million to 1.6 million for 1.5 to 3 year expected product lives.

Table 2b. Present Value of Societal Costs per Subject Magnet Product in Use (or Gross Benefits of a Rule), for Various Expected Product Lives during the 2017 through 2021 period, and Higher (1,000,0000) Recent Annual Unit Sales.

(a) Aggregate Annual Societal Costs (millions $)	$51.8	$51.8	$51.8
(b) Expected Useful Product Life (years)	1.5	2	3
(c) Magnet Products in Use, Average Annual	1,066,000	1,292,000	1,643,000
(d) Annual Societal Costs per Subject Magnet Product [(a) ÷ (c)]	$49	$40	$32
(e) Present Value of Societal Costs, per Subject Magnet Product (*3% Discount Rate*)	$73	$79	$90
(f) Present Value of Societal Costs, per Subject Magnet Product (*7% Discount Rate*)	$70	$74	$83

The estimated present value of societal costs of subject magnet product ingestion injuries under this assumption of higher recent unit sales ranges from $70 per subject magnet product (1.5 year expected life, 7% discount rate) to $90 (3-year expected product life, 3% discount rate). The estimated per unit societal costs are about half of those estimated for the base analysis which assumes recent annual unit sales of 500,000.

Summary

The sensitivity analysis shows that per unit injury costs being addressed by the draft final rule vary greatly for the wide range of assumed annual unit sales. However, for all scenarios examined, the potential benefits well exceed the estimated costs of the rule in the form of lost consumer surplus and lost producer surplus, estimated to generally range from $20 to $35 per subject magnet product.

Consideration of Benefits from Unidentified Magnet Products

Table 1 shows estimated average annual medically treated injuries and associated societal costs for magnet ingestions that were identified as involving subject magnet products during 2017 through 2021. These estimates are based on cases for which identifying information was reported (*i.e.*, magnets from magnet sets, magnet toys, or jewelry). In addition to these NEISS cases there were also 403 NEISS cases during 2017 through 2021 (representing about 1,873 ED-treated injuries annually), in which the magnet type was classified as “unidentified.” *i.e.*, narratives mentioned that at least one magnet was ingested, but

presented insufficient information to classify the magnet product type. Staff analysis of the data finds it reasonable to conclude that the "unidentified" magnet products generally involved magnets considered within scope of the draft final rule; that is, intended for amusement and/or jewelry (TAB C). Based on ICM estimates for unidentified magnet products involved in ingestion injuries, average annual societal costs for 2017 – 2021 totaled $167.9 million. Including some of these magnet ingestion injuries on total estimated societal costs and potential gross benefits is considered below.

a. Assume 25 Percent of Unidentified Magnet Product Injuries were In-Scope

If we assume that 25 percent of unidentified magnet injuries were within the scope of the draft final rule, average estimated annual magnet ingestion societal costs would be an additional $42.0 million. Including these societal costs with those estimated for identified subject magnet products ($51.8 million) results in average annual societal costs of magnet ingestion injuries of $93.8 million for the period 2017 through 2021, an increase of 81 percent. Including these cases as addressable societal costs would lead to a corresponding increase the estimated gross benefits of the rule.

b. Assume 50 Percent of Unidentified Magnet Product Injuries were In-Scope

If 50 percent of unidentified magnet injuries were within the scope of the draft final rule, average estimated annual magnet ingestion societal costs would be an additional $83.9 million. Including these societal costs with those estimated for identified subject magnet products ($51.8 million) results in average annual societal costs of magnet ingestion injuries of $135.8 million for the period 2017 through 2021, an increase of 162 percent. Including these cases as addressable societal costs would lead to a corresponding increase the estimated gross benefits of the rule.

c. Assume 100 Percent of Unidentified Magnet Product Injuries were In-Scope

If 100 percent of unidentified magnet injuries were within the scope of the draft final rule, average estimated annual magnet ingestion societal costs would be an additional $167.9 million. Including these societal costs with those estimated for identified subject magnet products ($51.8 million) results in average annual societal costs of magnet ingestion injuries of $219.7 million for the period 2017 through 2021, an increase of 324 percent. Including these cases as addressable societal costs would lead to a corresponding increase the estimated gross benefits of the rule.

Summary

The sensitivity analysis shows that including even a relatively small portion of NEISS cases involving unidentified magnet products to the base case, which is limited to identified products, substantially increases the estimated gross benefits of the rule.

Considering Possible Benefits from Avoided Fatal Magnet Ingestions

Estimated societal injury costs from subject magnet products, and potential gross benefits of the draft final rule, are based on non-fatal injuries reported on NEISS. As noted above, staff is aware of four deaths in the U.S. that have occurred from ingesting magnets of interest. Prospective deaths from magnet ingestions might also be avoided by the draft final rule. In estimating the benefits associated with reduced mortality of the rule, we apply an estimate of the value of a statistical life (VSL) of $10.5 million (2020 dollars) per premature death potentially averted. This estimate is based on estimates of the VSL developed by the EPA. We note that the VSL does not place a value on individual lives, but rather, it represents an extrapolated estimate based on the rate at which individuals trade money for small changes in mortality risk (OMB, 2003). If we assume that the standard will avoid two to four deaths over a 10-year period, the average annual statistical value of the rule's life-saving could be about $2.1 million to $4.2 million. Adding these potential societal costs to those associated with non-fatal magnet ingestions would increase the expected gross benefits of the proposed standard by about 4 percent to 7 percent over the base estimate.

Summary

Including estimates of the statistical value of potential deaths averted increases the estimated benefits of the rule

Summary of the Final Regulatory Analysis Results

(1) a description of the potential benefits and costs of the draft final rule,

Estimated aggregate annual societal costs from ingestion injuries involving subject magnet products for 2017 through 2021 totaled $51.8 million. Assumptions about annual product sales and expected product life of one-and-one-half, two, and three years yields estimated numbers of products in use during those years ranging from 515,000 to 818,000. The estimated present value of societal costs per subject magnet product (at a 3% discount rate) ranges from $150 per unit (at a 1.5-year expected life) to $180 per unit (at a 3-year expected life). On the cost side, estimates of consumer and producer surplus were uncertain, but might range from about $2-$3.5 million to about $20-$35 million, based on unit sales ranging from 100,000 to 1 million.

For illustrative purposes, if we consider annual unit sales of non-complying subject magnet products of 500,000, expected aggregate benefits could total $51.8 million annually; costs (lost consumer and producer surplus) could range from $10 million to $17.5 million annually. Thus, although both the benefits and costs of the draft final rule are uncertain, based on a range of assumptions, our estimates suggest that the potential benefits of the draft final rule are projected to exceed the potential costs. These estimated benefits exclude cases involving in-scope magnet products which have not been identified as amusement/jewelry products. A sensitivity analysis shows that including even a relatively small portion of NEISS cases involving unidentified magnet products to the base case substantially increases the estimated gross benefits of the rule.

A description of any alternatives to the final rule which were considered by the Commission, together with a summary description of their potential benefits and costs and a brief explanation of the reasons why these alternatives were not chosen.

CPSC staff considered several alternatives to reduce the risk of injuries and death associated with ingestion of hazardous magnets from subject magnet products. However, as discussed below, CPSC staff does not consider any of these alternatives capable of adequately reducing the risk of injury and death.

No Mandatory Standard

One alternative to the final rule is to take no regulatory action and, instead, rely on existing domestic standards to address the magnet internal interaction hazard. There are four ASTM standards, ASTM F963, F2923, F2999, and F3458, that address the magnet internal interaction hazard in consumer products, covering children's toys, children's jewelry, adult jewelry, and magnet sets, respectively. Relying on these standards would eliminate the costs associated with the final rule because it would not mandate compliance.

However, as detailed in the NPR briefing package, these standards have considerable limitations and do not have adequate requirements to address the hazard. Staff's main concerns are as follows:

- ASTM F963 is specific to children's toys, and, therefore, it excludes the products subject to the draft final rule.
- ASTM F2923, F2999, and F3458 are specific to several subsets of the subject magnet products (*i.e.,* children's jewelry, adult jewelry, and adult magnet sets); however, they exclude other magnet products subject to the draft final rule.
- ASTM F2923 includes magnet size and strength requirements consistent with the proposed rule, but only for jewelry intended for children under 8 years of age.
- ASTM F2999 and F3458 address the magnet internal interaction hazard only with requirements for safety messaging and/or packaging, which are inadequate to address the hazard.

Finally, waiting for ASTM to revise its standards to adequately address the hazard would delay the safety benefits of the rule. For these reasons, the Commission did not select this alternative for the NPR and staff recommends promulgating the draft final rule.

Alternative Performance Requirements

Another alternative to the final rule is to adopt less stringent requirements, such as a higher flux index limit, or different requirements for certain shapes and sizes of magnets. This may reduce the costs associated with the rule by allowing firms to market and consumers to use a wider variety of products than under the final rule. The reduction in costs would depend on the specific requirements adopted.

However, this option would reduce the safety benefits of the rule. If the alternative performance requirements reduced costs by allowing more products to remain on the market, it would also leave more hazardous products on the market, thereby decreasing the safety benefits. Therefore, the Commission did not select this alternative for the NPR and staff recommends promulgating the draft final rule.

Safety Messaging

Instead of performance requirements, the Commission could rely on safety messaging, such as through additional public awareness raising efforts and/or requirements for warnings and instructional literature for subject magnet products containing one or more loose or separable hazardous magnets. This alternative would reduce the costs associated with the final rule because it would allow firms to continue to sell subject magnet products with loose or separable hazardous magnets and the costs of warnings and instructional information likely would be small.

However, CPSC staff does not consider this alternative adequately effective for reducing the risk of injury and death associated with ingestion of hazardous magnets from the subject magnet products. Warnings are the least effective strategy for addressing a hazard, relative to designing out the hazard. The effectiveness of warnings depends on convincing consumers to avoid the hazard, and there are numerous reasons consumers may disregard warnings for these products. Caregivers do not expect older children and teens to ingest inedible objects; the magnet internal interaction hazard is not readily apparent; caregivers and children underappreciate the likelihood and severity of the hazard; hazardous magnets are too small to have warnings; magnets are often ingested accidentally; and children and teens commonly access magnets loose without their packaging, such as from friends or at school. Warning information on labels and instructional literature, as well as public outreach efforts to inform consumers of the hazard, have been used to try to address the magnet internal interaction hazard for many years. However, these efforts have been unsuccessful at reducing the magnet internal interaction hazard, as evidenced by the increase in magnet ingestion incidents in recent years and magnet ingestion incidents involving products with clear warnings. For these reasons, the Commission did not select this alternative for the NPR and staff recommends promulgating the draft final rule.

Packaging Requirements

Another alternative is for the Commission to require special packaging for subject magnet products that contain hazardous magnets to limit children's access to the products. Such packaging could, for example, help consumers determine if all magnets have been returned to the packaging and include child-resistant features. Although this alternative would create some costs associated with packaging, those costs likely would be lower than the final rule because they would allow subject magnet products to remain unchanged. Staff estimates that the cost of safety packaging may amount to about $1 per magnet product, depending on the requirements and features of the packaging.

However, CPSC staff does not consider this alternative adequately effective for reducing the risk of injury and death associated with ingestion of hazardous magnets from the subject magnet products. For packaging requirements to be effective at preventing the magnet internal interaction hazard, users would have to repackage all magnets after each use, and the packaging would have to prevent children and teens from accessing the magnets. Neither of these are likely to occur to a sufficient extent to address the hazard. For one, consumers are unlikely to repackage all magnets after each use. After assembling structures or jewelry, or using the magnets for other purposes, consumers would be unlikely to disassemble their creations to return them to the package. In addition, subject magnet products may contain numerous loose magnets, such as magnet sets with hundreds or thousands of magnets, making it time consuming and difficult to ensure all the magnets are returned to the package. Moreover,

small magnets become loose in the environment and are hard to locate to return to the package. In addition, consumers often do not perceive subject magnet products as hazardous, making it less likely that they would repackage all the magnets. Even for products that are obviously hazardous and commonly use CR packaging, such as chemicals and pharmaceuticals, consumers use the packaging inconsistently. Consumers may also consider safety packaging a nuisance, making them unlikely to store magnets in the packaging after every use. Even if consumers return all magnets to a package after each use, safety features to prevent easy access to the contents of the package would only address a minority of the vulnerable population. Safety packaging is generally intended to restrict children under 5 years old from accessing package contents. Older children and teens are likely to have the cognitive and motor skills necessary to access products in special packaging. This is problematic because incident data show that older children and teens make up the majority of magnet ingestion victims. In addition, many incidents involve children and teens acquiring magnets without the product packaging, such as from friends, at school, or loose in the environment. For these reasons, the Commission did not select this alternative for the NPR and staff recommends promulgating the draft final rule.

Aversive Agents

Instead of the size and strength requirements in the final rule, the Commission could require manufacturers to coat loose or separable hazardous magnets in subject magnet products with aversive agents, such as foul odors or bitterants. Aversive agents may dissuade some children and teens from placing hazardous magnets in their mouths. This alternative would reduce the costs associated with the final rule because it would allow firms to continue to sell subject magnet products with loose or separable hazardous magnets, would allow consumers to continue to use them, and the costs of such coatings likely would be small.

However, real-world investigations have not demonstrated that bitterants are effective at preventing ingestions (CPSC, 1992). Bitterants do not deter initial ingestion because the user has not yet tasted the bitterant; this makes them ineffective at protecting users from harms that can result from a single ingestion. Incident reports indicate that ingesting a single magnet (and ferromagnetic object), or multiple magnets at once or in quick succession, can result in serious injuries. Thus, the ineffectiveness of bitterants to prevent an initial ingestion makes them ineffective for addressing the magnet internal interaction hazard. Similarly, once a hazardous magnet is in a person's mouth, they may not be able to prevent ingestion even if deterred by a bitterant. The power of the magnetic forces can cause magnets to move erratically as pieces repel or attract, and movement of magnets toward the back of the throat can trigger the reflex to swallow the magnets before the person can remove them. Bitterants would be particularly ineffective for accidental ingestions, where victims did not intentionally place magnets in their mouths; incident data indicate that magnet ingestions commonly involve unintentional ingestions, particularly for older victims. Moreover, incidents involving ingestion of other hazardous substances by children demonstrates the ineffectiveness of aversive agents to prevent ingestions (White et al., 2008, 2009; PLOS One, 2015). In addition, some portion of the population, possibly as high as 30 percent, may be insensitive to certain bitterants (CPSC, 1992; NIDCD, 2010; NIDCD, 2019). For these reasons, the Commission did not select this alternative for the NPR and staff recommends promulgating the draft final rule.

Longer Effective Date

Another alternative is to provide a longer effective date for the final rule. The Commission proposes to make the final rule effective 30 days after the final rule is published. A longer effective date would reduce the impact of the rule on manufacturers and importers by extending the time firms have to develop products that comply with the rule or modify products to comply with the rule. However, delaying the effective date would delay the safety benefits of the rule as well. As such, the Commission did not select this alternative. Additionally, CPSC did not receive comments from the public with substantive information regarding a different implementation effective date.

A summary of any significant issues raised by the comments submitted during the public comment period in response to the preliminary regulatory analysis, and a summary of the assessment by the Commission of such issues

The CPSC received over 700 comments regarding the NPR for magnets at www.regulations.gov, filed under the docket number CPSC-2012-0037. Some of these comments described possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, hazard costs associated with the product, and alternative actions that the Commission could take. None of the comments, however, resulted in changes to the regulatory analysis. These comments and staff's responses are addressed in detail in the Appendix of the Final Regulatory Flexibility Analysis for the draft final rule (Smith, 2022, Tab F).

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Tab F: Final Regulatory Flexibility Analysis Memorandum by the Directorate for Economic Analysis

This document has been electronically approved and signed.

TO: Stephen Harsanyi, Project Manager,
Division of Human Factors,
Directorate for Engineering Sciences

DATE: August 17, 2022

THROUGH: Alexander P. Moscoso, Associate Executive Director,
Directorate for Economic Analysis

Jose E. Tejeda, Senior Staff Coordinator,
Directorate for Economic Analysis

FROM: Charles L. Smith, Economist,
Directorate for Economic Analysis

SUBJECT: Final Regulatory Flexibility Analysis of a Rule that Would Establish a Standard for Magnets

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Introduction

On January 10, 2022, the Commission published a notice of proposed rulemaking (NPR), proposing to issue a safety standard for magnets under the Consumer Product Safety Act (CPSA; 15 U.S.C. 2051-2089; 87 FR 1260) and seeking public comments.[1]

Before a final rule is issued, Section 604 of the Regulatory Flexibility Act requires the Commission to prepare a Final Regulatory Flexibility Analysis (FRFA), describing the impact of the rule on small entities and identifying efforts by the Commission to reduce those impacts.

The FRFA is to contain:

(1) a statement of the need for, and objectives of, the rule;

(2) a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;

(3) the response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments; [Not applicable for this FRFA, because no comments were filed by the SBA.]

[1] Commission NPR on magnets (2021): https://www.govinfo.gov/content/pkg/FR-2022-01-10/pdf/2021-27826.pdf.

(4) a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available;

(5) a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record; and

(6) a description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

Discussion

(1) A statement of the need for, and objectives of, the rule.

The draft final rule would establish mandatory performance requirements for products with one or more magnets, which are loose or separable, and designed, marketed, or intended, to be used by consumers for entertainment, jewelry (including children's jewelry), mental stimulation, stress relief, or a combination of these purposes ("subject magnet products"). Exemptions to the draft final rule are detailed below, including two clarifications to the proposed rule.

The CPSC has collected information regarding growing numbers of injuries with, and hazards posed by, hazardous magnets in consumer products. Many of these ingestions resulted in surgical removal of magnets and surgical repair of injuries,[2] and others required non-surgical medical interventions, such as emergency endoscopies and colonoscopies. Detailed in the Directorate for Health Sciences (HS) memorandum, this interaction has led to serious injuries and deaths, typically by causing intestinal twisting (volvulus injuries), fistulae, and perforations (Johnson, 2022, TAB A). Detailed in the NPR briefing package, in total, staff is aware of seven deaths involving the ingestion of hazardous magnets between November 24, 2005, and January 5, 2021, five of which occurred in the U.S. and two abroad.[3] Regarding the deaths in the U.S., one death involved a children's toy magnet building set subject to ASTM F963 and four deaths likely involved subject magnet products.

The purpose of the draft final rule is to reduce the risks of death and serious injury from ingestion of hazardous magnets. As noted above, if ingested, hazardous magnets, as a consequence of their properties, are powerful enough to interact internally with one another or with other ferromagnetic objects through body tissue and resist natural bodily forces to separate

[2] ESHF reports: "At least 167 CPSRMS-reported magnet ingestions resulted in surgery (including 43 incidents since the NPR), such as laparoscopy, laparotomy, appendectomy, cecostomy, enterotomy, colostomy, cecectomy, gastrotomy, jejunostomy, resection, and transplant, among others." (Harsanyi, 2022, TAB C).
[3] Two of the seven deaths occurred abroad (one in Australia in 2011 and one in Poland in 2014). Each of these deaths involved magnets from unknown products; however, the magnets were similar, if not identical, to magnets typically found in magnet sets.

the magnets. Detailed in Tab A, this interaction has led to deaths and serious injuries, typically by causing intestinal twisting (volvulus injuries), fistulae, and perforations.

(2) A statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments.

CPSC received comments on the costs and benefits calculations presented in the preliminary regulatory analysis and IRFA, scope and effective date of the proposed rule, and possible economic impacts of the rule, including economic impacts on firms, the utility of the product for consumers, hazard costs associated with the product, and alternative actions that the Commission could take. None of the comments, however, resulted in changes to the regulatory analysis. Relevant comments and staff's responses are presented in an Appendix to this analysis.

(3) The response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.

No comments on the proposed rule were filed by the Chief Counsel for Advocacy of the SBA.

(4) A description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.

The draft final rule would affect firms or individuals that manufacture, import, and sell subject magnet products. All of the identified importers of magnet sets are small businesses under applicable SBA size standards, and we expect this is also true for manufacturers and importers of other subject magnet products, such as jewelry with loose/separable magnets. Of the various magnet products covered in the draft final rule, magnet sets have been particularly concerning to CPSC staff, given their popularity among children and teens, their typical inclusion of numerous, loose hazardous magnets, and their well-documented involvement in internal interaction injuries. EC has investigated magnet sets in previous CPSC staff packages, including regarding the 2014 rule on magnet sets,[4] the 2020 informational briefing package regarding magnet sets,[5] and the 2021 NPR briefing package regarding hazardous magnet products ("hazardous magnet products" refers to subject magnet products containing one or more loose or separable hazardous magnets).[6] The latter market reviews found that nearly all of the marketers (firms or individuals) of magnet sets sold through Internet sites, rather than through "brick-and-mortar" retailers such as bookstores, gift shops, and other outlets (which commonly sold magnet sets during 2009 through mid-2012). Some of these Internet sites have been operated by the importers.

[4] CPSC staff's briefing package: Final Rule on Safety Standard for Magnet Sets (2014): https://cpsc.gov/s3fs-public/pdfs/foia_SafetyStandardforMagnetSets-FinalRule.pdf.
[5] CPSC staff's informational briefing package regarding magnet sets, "Staff Briefing Package in Response to Petition CP 17-1, Requesting Rulemaking Regarding Magnet Sets," dated June 3, 2020: https://cpsc.gov/s3fs-public/Informational Briefing Package Regarding Magnet Sets.pdf?FKVcZpHmPKWCZNb7JEl6Ir0a31WV72PI.
[6] CPSC staff briefing package, *Draft Notice of Proposed Rulemaking for Hazardous Magnet Products* (2021), https://www.cpsc.gov/s3fs-public/Proposed-Rule-Safety-Standard-for-Magnets.pdf?VersionId=2XizI5izY1OvQRVazWpkqdJHXg5vzRY_.

As detailed in the NPR preliminary regulatory analysis (Smith, 2021), reviews of the online market for magnet sets by CPSC staff and Industrial Economics, Incorporated (IEc) from 2018 to July 2021 found that sellers of magnet sets on two major Internet retailing platforms fluctuated greatly from one review to the next. EC staff identified at least 121 sellers of magnet sets on the two Internet retailing platforms early in 2018. A few months later, IEc found that the great majority of sellers recorded by CPSC on one of the sites were no longer selling relevant magnet set models. Further, more than half of the sellers on the other site no longer sold relevant magnet set models. IEc's review showed that the leading Internet marketplaces have high turnover rates for magnet set products offered on their sites (Israel, J. & Baxter, J. (IEc), 2019, p. 8). In 2020, staff reviewed the status of previously identified sellers of magnet sets on the leading Internet retailing platforms and found further evidence of the high turnover rates: most of the sellers identified in late 2018 had either ceased selling magnet sets or had abandoned their stores. We found that only 9 of 69 sellers were still selling magnet sets. The remaining sellers either no longer offer magnet sets or no longer operate on the platforms. However, we did identify 29 new sellers that were not identified by IEc as being active in the market late in 2018. This review provided further evidence of the high turnover rate among sellers of magnet sets on the leading Internet platforms. Further review in 2021 found the great majority of sellers of magnet sets (in terms of distinct firms or individuals, if not unit sales) appeared to sell through their stores operated on the sites of other Internet retailer platforms.

EC expects the dominant business model for importers of magnet sets will be direct sales to consumers using their own Internet websites or other Internet shopping sites; however, the draft final rule could also affect some third-party retailers of the products, whether selling them online or physically in "brick & mortar" stores, such as bookstores, gift shops, or stores that sell novelty items.

(5) Projected reporting, recordkeeping, and other compliance requirements of the draft final rule.

Section 14(a)(1) of the CPSA requires manufacturers, importers, or private labelers of a consumer product (that is not a children's product) subject to a consumer product safety rule to certify, based on a test of each product or a reasonable testing program, that the product complies with all rules, bans or standards applicable to the product. The draft final rule specifies the procedure to use to determine whether a subject magnet product complies with those requirements. For those products that manufacturers certify based on a test of each product or a reasonable testing program, manufacturers would issue a general certificate of conformity (GCC). Section 14(a)(2) of the CPSA requires manufacturers, importers, or private labelers of any product subject to a children's product safety rule to submit sufficient samples of the children's product, or samples that are identical in all material respects to the product to a CPSC-accepted third-party conformity body for testing. Based on passing test results from the CPSC-accepted third-party conformity body, the manufacturer, importer, or private labeler issues a Children's Product Certificate (CPC) indicating the children's product is compliant with the children's product safety rule. For example, in the case of subject magnet products that could be considered to be children's products, such as children's jewelry, the CPC must be based on testing by a CPSC accepted third-party conformity assessment body.

Both GCCs and CPCs are required to meet certain requirements for certificates. Among the other requirements, each certificate must identify the manufacturer or private labeler issuing the certificate and any third-party conformity assessment body on whose testing the certificate depends, the date and place of manufacture, the date and place where the product was tested, each party's name, full mailing address, telephone number, and contact information for the individual responsible for maintaining records of test results. The certificates must be in English. The certificates must be furnished to each distributor or retailer of the product and to the CPSC, if requested.

(6) A description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.

Small manufacturers/importers of subject magnet products would likely incur some additional costs to certify that their products meet the requirements of the draft final rule as required by Section 14 of the CPSA. The certification must be based on a test of each product or a reasonable testing program. CPSC staff proposed a performance requirement that duplicates the ASTM F963 Toy Standard approach to addressing magnet internal interaction hazard in children. The current ASTM test to determine flux index is a method that has been used by test labs to determine compliance with the toy standard and is a method that is also used by other domestic and international standards for identifying hazardous magnets. Importers may also rely upon testing completed by other parties, such as their foreign suppliers, if those tests provide sufficient information for the manufacturers or importers to certify that the magnets in their products comply with the draft final rule. Firms that magnetize the products would have equipment to measure the magnetic force of their products, and many of these firms should be familiar with the test methodology or have access to testing firms that can perform the tests. The increased costs related to testing should be relatively minor, especially for small manufacturers that currently have product testing done for products subject to the requirements in ASTM F963, *Standard Consumer Safety Specification for Toy Safety,* which is mandated by 16 CFR part 1250. As noted above, for subject magnet products that could be considered to be children's products, such as children's jewelry, the certification must be based on testing by an accredited third-party conformity assessment body, at somewhat higher costs.

As discussed in the preliminary regulatory analysis for the NPR (Smith, 2021), the main impact on small businesses of a rule would be the lost income and profits to firms that could not produce, import, and sell non-complying products in the future. The lost benefits to firms resulting from a rule are measured by a loss in what is called *producer surplus*. Producer surplus is a measure of the total revenue of firms selling the magnets, less the total variable costs of production. As predominantly imported products, the variable costs for small businesses handling subject magnet products are mainly the import costs. The producer surplus for magnet sets could average about $5 to $10 per unit, based on an average retail price of $20. A similar relationship could apply to other subject magnet products affected by the rule, such as jewelry with separable magnets (Smith, 2021).

A few small firms whose businesses focus on sales of magnet products that would not comply with the draft final rule, including some of the firms selling products on their own websites, would face relatively greater losses in producer surplus. These and other small businesses could respond to the rule by measures such as marketing or incorporating magnets that comply with the rule or increased marketing products that do not have loose or separable magnets. Such measures could partially offset losses in producer surplus resulting from firms' inability to continue marketing noncomplying magnet products.

As discussed in the analysis above, all domestic firms that are expected to manufacture or import subject magnet products are small businesses. Therefore, an exemption for small manufacturers/importers is not possible because all manufacturers/importers that would be subject to the rule are small. CPSC considered several other alternatives that reduce the impact of a rule on small businesses. These alternatives are discussed below.

a) Adoption of Alternative Performance Requirements

As an alternative to the draft final rule, the Commission considered promulgating an alternative set of requirements that are less stringent than the draft final rule. For example, some alternatives might include: setting a different flux index for loose or separable magnets in the subject magnet products; requiring different specifications for shapes and sizes of magnets within the scope of the standard; or setting forth some other criteria that have not yet been developed.

Such alternatives could reduce the burden on small entities because they would allow the firms to market a wider variety of products than allowed under the draft final rule. The same alternatives could benefit consumers to the extent that a wider variety of products would be available for their use. However, these options would also reduce the expected benefits of a rule, because hazardous magnets would still be available in certain products that staff has determined children and teenagers may access and use consistent with known hazard patterns that have caused serious injury or death.

The staff's evaluation of the data finds that the unreasonable risk of injury would not be adequately addressed by alternative, less stringent requirements.

b) Different (Longer) Effective Date

The NPR specifies that the standard will take effect 30 days after a final rule is published in the *Federal Register*. A possible alternative considered to reduce the impact of the rule on small manufacturers/importers was extending the period before the rule becomes effective. This could give firms additional time to develop complying products, or to shift marketing to nonmagnetic products. Staff sought comments on the advantages and disadvantages of a longer effective date for the rule, and none of the comments specified a different effective date beyond using the same effective date for both children's products and general use products affected by the final rule (see Appendix).

c) Requiring Safer Packaging

The Commission considered requiring subject magnet products with hazardous magnets to be sold with special storage containers that, if effective, could help limit access to the magnets by younger children. For example, special packaging could incorporate child-resistant

(CR) features, help consumers determine if all magnets have been collected, or both. The costs of this alternative would depend upon the packaging requirements, but the burden on small businesses would be substantially less costly than the draft final rule because it would allow small businesses to continue to sell the subject magnet products with loose/separable hazardous magnets. It seems unlikely that the costs of the safer packaging would amount to more than a dollar or so per magnet product, though these costs might be somewhat higher if child resistant packaging was required.

ESHF staff (Harsanyi, 2022, Tab C) provides an assessment of these measures after addressing relevant public comments on the NPR, and concludes that packaging requirements, without magnet size and strength requirements, are inadequate methods by which to address effectively the internal interaction hazard associated with these products. Among other factors detailed, CR features would not prevent access to hazardous magnets by most children in age groups involved in magnet ingestion incidents, and both CR features and features that afford visual verification of all magnets from the product depend on an unrealistic expectation that the small magnets will be located and repackaged in their entirety, and correctly, after every use (Harsanyi, 2022).

d) Requiring Warnings

The Commission considered requiring strong safety messaging pertaining to the hazard and intended users, such as in warning labels and instructional literature. For example, there is a relatively new standard on adult magnet sets, ASTM F3458 – 21, *Standard Specification for Marketing, Packaging, and Labeling Adult Magnet Sets Containing Small, Loose, Powerful Magnets (with a Flux Index ≥50 kG^2 mm^2),* which includes safety messaging requirements pertaining to hazardous magnets in magnet sets intended for ages 14 and older. This alternative could reduce the burden on small firms because it would allow them to continue to sell the subject magnet products with loose/separable hazardous magnets and the costs of such warnings would most likely be small.

In Tab C, staff provides an assessment of safety messaging for the subject magnet products after addressing relevant public comments on the NPR, and staff concludes that safety messaging without magnet strength and size requirements is inadequate to address the internal interaction hazard associated with these products (Harsanyi, 2022). Among other factors detailed, strong and repeated warnings in labels, instructions, and public outreach efforts, which explain the internal interaction hazard and to keep the magnets away from children, have been unable to adequately prevent magnet ingestion. The effectiveness of warnings depends on convincing consumers to avoid the hazard, and there are numerous reasons consumers may disregard warnings for these products. They are particularly unlikely to anticipate and appreciate the risk of magnet ingestion by children and teens, which is largely accidental due to unique uses of the magnets, and distinct from the normal risk of ingestion of non-edible objects young children.

e) Requiring Aversive Agents

The Commission considered requiring manufacturers to coat loose or separable hazardous magnets in the subject magnet products with aversive agents, such as foul odors or bitterants. The desired effect of these approaches is to make the hazardous magnets less appealing for children and teens to put in their mouths. This alternative could reduce the burden

on small firms because it would allow them to continue to sell the subject magnet products with loose/separable hazardous magnets and the costs of such coatings would likely be small.

In Tab C, staff provides an assessment of aversive agents for the subject magnet products and relevant public comments on the NPR (Harsanyi, 2022). Staff explains that aversive agents, such as foul odors or bitterants, may dissuade some children and teens from placing hazardous magnets into their mouths; however, ultimately, such features would not be effective, and CPSC has found that aversive agents do not adequately deter or prevent ingestions. Although the use of aversive agents might discourage some children from placing additional magnets in their mouths, incident reports indicate that serious injury is possible when one ingests as few as two hazardous magnets, or one hazardous magnet and a ferromagnetic object, and children might ingest multiple hazardous magnets before they detect the aversive agent.

f) Relying on ASTM Activities

Rather than proceeding with rulemaking, the Commission considered relying on ongoing ASTM activities pertaining to hazardous magnets in consumer products. Detailed in Tabs C and D, staff assessed existing domestic and international standards pertaining to hazardous magnets in consumer products (Harsanyi, 2022; Paul, 2022), and found that the existing standards do not adequately address the hazard. Staff explains that there appears to be interest in the ASTM F15.77 subcommittee on magnets to devise performance requirements for adult magnet sets, including limitations in size and strength. Such requirements might address the internal interaction hazard for the most concerning type of subject magnet product (magnet sets); however, there are considerable risks for delaying staff's draft final rule on that account, including the following: (1) it is unknown if and when the ASTM standard will incorporate adequate performance requirements, (2) the rate of compliance with the possible ASTM standard is unknown, and (3) the product scope is limited to magnet sets, and may be further limited for performance requirements (such as specific shapes of magnets), and therefore may not adequately address the hazard. (While magnet sets are a particular concern, the majority of incidents involve uncertain magnet products, including magnets described as jewelry.)

Conclusion

The results of this final regulatory flexibility analysis suggest that the draft final rule could have a significant adverse impact on small importers of magnet sets or other subject magnet products which receive much of their revenues from sales of affected products. Possible alternatives to the draft final rule have been considered by the Commission. All of these alternatives could reduce the expected impact of the rule on small businesses. However, the staff's assessment of them finds that their adoption would not result in a rule that adequately addresses the risk of serious injury or death caused by ingestions of magnets from the subject magnet products.

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Appendix

Comments on Economic Issues Received in Response to the NPR & Staff Responses

The CPSC received over 700 comments regarding the proposed rule. These comments may be found in docket number CPSC-2021-0037 at http://www.regulations.gov/.
Comments related to issues that have a bearing on the economic impacts of the proposed rule include:

Value/Utility of the Products to Consumers

Comments: Many consumers who commented in opposition to the proposed rule describe numerous uses of the subject magnet products, and they commended the products' artistic value. Several refer to online communities for sharing complex magnetic sculptures and other creations. Commenters also often mentioned the various educational benefits to consumers, including children and teens, from manipulating the subject magnets and learning about math, science, and chemistry. Other common uses specified by these commenters include decorative, amusement, and therapeutic uses.

Response: Consumers receive value from the products as a medium for artistic expression, fun, and creativity; as items with perceived therapeutic properties; and as educational tools. These qualities drive consumer demand for the products. Staff has considered the value of the products to consumers in the form of lost consumer surplus. In the case of most reported uses which provide utility, alternative products are available, including separable magnetic products that could comply with the draft final rule. Alternative products are also widely available for modeling geometric and molecular structures. Further, certain educational sales of magnet products with one or more loose or separable hazardous magnets are not within the scope of the rule, and availability of small powerful magnets for use in schools and universities is not prohibited by the rule (see Tab A for exemptions added to proposed rule).

Value of the Products in Promoting Innovation

Comment: One commenter, ASTM Workgroup Chair for subcommittee ASTM F3458-21 and Chairman of a firm (Nano Magnetics) that markets magnet products, claims that use of small, aggregated magnetics have resulted in "millions of dollars of real, material, and calculable innovations." The commenter further stated his belief that "small aggregate magnetic products hold billions of dollars' worth of future innovation in the hands of responsible consumers, unlocking breakthroughs, even in medical areas like gastroenterology. A simple query on nih.gov (https://pubmed.ncbi.nlm.nih.gov/?linkname=pubmed_pubmed&from_uid=31839874) shows that such innovations are already happening."

Response: Staff considers certain scientific and industrial uses of magnet products with one or more loose or separable hazardous magnets to be outside the scope of the draft final rule (see Tab A for exemptions added to proposed rule). Furthermore, staff notes that review of the use of magnets in medical literature cited in the commenter's NIH.gov query did not show uses of hazardous magnet products of typical sizes and shapes that would be affected by the rule. The draft final rule should not appreciably retard innovation in scientific or medical fields.

Impacts on Businesses and Jobs

Comment: Some commenters opposed to the proposed rule claim that U.S. companies will go out of business as a result of the rule.

Response: In the IRFA, staff noted that a few small firms whose businesses focus on sales of magnet products that would not comply with the draft final rule, including some of those selling products on their own websites, would face relatively greater losses in producer surplus (estimated to average about $5 to $10 per unit for magnet sets). These and other small businesses could respond to the rule by measures such as marketing or incorporating magnets that comply with the rule or increased marketing of products that do not have loose or separable hazardous magnets. Such measures could partially offset losses in producer surplus resulting from firms' inability to continue marketing noncomplying magnet products. A review of products currently offered by current or former sellers of products that would not meet the rule found that most also market products that either would comply with the rule or are not within the scope of the rule. One of the leading importers of magnet sets that recalled and stopped sales of the products this March still markets a variety of magnetic products that would comply with the draft final rule if the product marketing is accurate regarding the size and strength of the loose or separable magnets. These facts indicate that sellers of magnet products that are subject to the rule should be able to remain in business even if the rule becomes effective.

Effective Date

The NPR, as amended by the Commission, proposed that the rule take effect 30 days following its publication in the *Federal Register*. The CPSC sought comments on the advantages and disadvantages to a different effective date, including extending the period before the rule becomes effective.

Comments: Retrospective Goods, LLC, a manufacturer of subject magnet products, which according to the firm's marketing would comply with the size and strength requirements in the proposed rule, commented that a 30-day effective date would be workable for the firm if the rule is limited to size and strength requirements as is now written; however, if amendments change the flux index, the test method or add additional tests or requirements, the firm and likely other sellers would need time to make those changes and a 90-day effective date is appropriate. The commenter also noted that the portion of the rule that regulates children's products requires that the Notice of Requirements portion of the testing rule be amended, and the statute requires a 90-day effective date after that amendment. A consistent approach is recommended since it makes little sense, from a public safety standpoint, to have more stringent requirements for adult products than those for children's products.

Response: As noted in the IRFA, a longer period before a rule becomes effective could give firms additional time to develop complying products, or to shift marketing to nonmagnetic products. Although this issue may not be critical for the commenter, it could be helpful for other small businesses that currently market products that do not comply with the draft final rule. However, most current sellers of non-compliant subject magnet products already market other products that would either comply with the rule or are not subject magnet products. The notice of proposed rulemaking also has alerted sellers to the probable need to adjust their marketing focus. Given the nature of the market, a 30-day effective date for the rule should not present significant hardships to small businesses. Additionally, the 30-day effective date comports with Section 9(g)(1) of the Consumer Product Safety Act, which states that "each consumer product safety rule shall specify the date such rule is to take effect," which generally "shall be set at a date at least 30 days after the date of promulgation" but "not exceeding 180 days from the date

promulgated…". The NPR noted, however, that certain subject magnet products would be considered children's products if they are "designed on intended primarily for children 12 years of age or younger." For example, some jewelry that are subject magnet products may be children's products and others may not be. Accordingly, the NPR proposed to amend part 1112 to add a notice of requirements (NOR) to include procedures for accreditation of testing laboratories to test subject magnet products that are children's products for compliance with the new standard. Under section 14(a)(3), the testing and certificate requirements apply to any children's product manufactured more than 90 days after the Commission has established and published notice of the requirements for accreditation of third-party conformity assessment bodies to assess conformity with a children's product safety rule to which such children's product is submitted. Accordingly, although the effective date of the draft final rule for both children's and non-children's subject magnet products is 30 days after publication of the draft final rule, the effective date for 16 CFR part 1112 is 90 days after the publication of the draft final rule.

Alternatives to the Proposed Rule

Comment: Many commenters requested alternative regulatory actions to address the hazard, such as limiting sales to online purchases, prohibiting sales to users under specified ages, requiring identification or adult signature for purchases, requiring waivers, restricting sales of magnets by certain manufacturers or sellers, or restricting sales to certain stores or locations. It was also common for commenters to recommend safety messaging, packaging, or deterrents instead of strength and size requirements.

Response: Staff evaluated the potential effectiveness of alternative regulatory actions to address the hazard and concluded that alternatives to strength and size requirements would not achieve the same level of protection as a mandatory standard. See Tab E for staff's updated assessment of the benefits and costs associated with the subject magnet products and magnet ingestion. See Tab C for staff's response to comments pertaining to safety messaging, packaging, and deterrents as alternatives to the proposed rule.

Comments by The Magnet Safety Organization

Several specific comments on the preliminary regulatory analysis were submitted by The Magnet Safety Organization, whose director is the founder of Zen Magnets. These comments, and staff's responses, are discussed below.

Comment: "The Economic Analysis in the 2022 Magnet Set Ban NPR does not account for the variety of quantities that sets are sold in. Instead of taking a deeper look into how the variable quantity of magnets in a set relates to both hazard and utility, the entire NPR does not go deeper than considering that the unit of product sets sold is proportional to risk... [This] misses important variables that affect both societal cost and benefit; therefore, invalidating the conclusions drawn from both the cost and benefit side of the Preliminary Regulatory Analysis."

Response: Societal costs are related both to the number of households with hazardous magnet products and the number of individual magnets present in a household. In the case of magnet sets, our review of product offerings over the years showed that sets with 216 to 224 spheres have been most common (and the commenter acknowledges this). The commenter cites the case of "Zen Magnets [which] sold approximately 40% of all individual magnets in sets of 1,728 magnets." Staff notes that even for that firm, for which large sets comprised a much greater

portion of its sales than other sellers, its large sets likely accounted for under 10 percent of all magnet set sales.

The commenter presents a discussion of "The Law of Demand" and marginal utility intended to argue for a regulatory alternative which would require magnet products (specifically magnet sets) to have large numbers of individual magnets or high mass or volume that would result in costs of the rule (in the form of lost consumer surplus and producer surplus) greater than the estimated value of benefits (in the form of reduced societal costs) per set. Although significant price increases for hazardous magnet products would reduce future exposure to the products, the Commission must meet the statutory requirements for promulgating consumer product safety standards to address product hazards, and the Commission must assess all of the costs and benefits of the rule under the Consumer Product Safety Act. Staff also notes that the commenter's proposed regulatory alternative that would limit sales to products with large numbers of individual magnets at greatly increased prices would still result in lost consumer surplus for consumers who would only purchase products with smaller numbers of magnets and lower prices. Loss of that segment of the market would also decrease the producer surplus for manufacturers and importers of the products.

Comment: "The Economic Analysis in the 2022 Magnet Set Ban NPR shows that societal benefit should exceed societal cost [lost consumer surplus and lost producer surplus], and precisely does not support the conclusion of a market elimination of high-powered recreational magnets from the market."

Response: The commenter's conclusions are apparently based on several errors in interpreting the preliminary regulatory analysis. In the absence of precise data on annual sales of hazardous magnet products, staff presents estimates of the costs of the rule in the form of lost consumer surplus and lost producer surplus for a wide range of annual sales, which the commenter characterizes as arbitrary. When the preliminary analysis was prepared, staff noted that, because the range of sales is wide, and is likely to include actual sales levels on an annual basis, it is reasonable to assume that the costs of the proposed rule could range from $5 to $8.75 million (if sales amount to about 250,000 products annually), to about $20 to $35 million (if sales amount to about 1 million products annually). Staff's intent was to provide estimates of costs of the proposed rule in a range of annual sales that would capture likely costs, given the uncertainty presented.

The commenter stated that "According to the NPR, the range in Consumer surplus is equal to the annual magnet product sales, multiplied by the range of product price from $15 to $25. And the Producer surplus is curiously calculated with a fixed product price of $20, minus a variable cost between $10 and $15." The commenter was incorrect; $15 to $25 was the assumed consumer surplus per unit, not the assumed price range. Staff presented the example in which consumers who purchased the non-complying subject magnet products at an average price of $20 would have been willing to spend, on average, $35 to $45 per product (*i.e.*, an additional $15 to $25 per set).

The commenter claims to estimate "At what sales volume societal costs < societal benefits." Based on the preliminary regulatory analysis estimate of annual societal costs of $47.6 million, the commenter estimates that "above 1,904,000 units of Annual Sales is when societal benefit exceeds societal cost." Further, the commenter claims that "…if the sales were comparable to 2009, 'the first year of significant sales, may have totaled about 2.7 million sets' (federalregister.gov/d/2012-21608/p-42) as stated in the 2014 Magnet Ban NPR, then Societal benefit handily exceeds Societal costs according to the calculations of the Preliminary

Regulatory Analysis. Notably, the CPSC does not have any data to show that recent annual sales did not significantly exceed the 2.7 million set per year in 2009." Staff's response to this analysis is that the commenter badly excerpted the quote from the preliminary regulatory analysis. The full quote reads: "Based on information reviewed on product sales, including reports by firms to the Office of Compliance and Field Operations, the number of such magnet sets that have been sold to U.S. consumers since 2009, the first year of significant sales, may have totaled about 2.7 million sets…." These sales were through mid-2012, when CPSC Compliance activities led to a dramatic reduction in sales. The 2014 final regulatory analysis was based on "sales of about 800,000 sets annually during the 2009 to June 2012 time period." Staff does not have any information indicating that annual sales of hazardous magnet products approach the very high level estimated by the commenter for a calculation of costs of the standard exceeding benefits.

Comment: "The Economic Analysis in the 2022 Magnet Set Ban NPR is meaningless; as CPSC admits it has no data on quantity of magnets for its cost-benefit, and has instead substituted a range of entirely arbitrary guesses."

Response: As explained above, the range of annual unit sales considered by the staff, although wide, provided an analysis of costs that likely includes actual sales. The analysis of societal costs of hazardous magnet products has also considered a wide range of historical sales. For assumptions of higher historical sales, which lead to lower societal costs per unit in use, the value of projected benefits still exceeds the highest reasonable estimate of costs of the rule. Staff notes that information on sales of subject magnet products was requested by the NPR; no information was offered by commenters.

Comment: "The rule, if passed, would be especially ineffectual as CPSC's own actions have pushed the market supply of subject products out of CPSC's control. The fact that the majority of suppliers of the subject products are now out of CPSC reach brings into question the enforcement efficacy of the 2022 Magnet Ban Rule. As noted prior, the supply for the subject product has dropped from being "perhaps over 98%" domestic to 'Nearly all' overseas."

Another commenter, representing a manufacturer of magnet sets that reportedly comply with the proposed rule, also expressed concern that the rule would drive consumers to foreign sellers who can easily advertise their products on internet sites and ship them from foreign countries directly to consumers. The commenter states that the rule does not address this issue and calls into question the effectiveness of a rule that does not impact a major portion of sellers. A similar comment was submitted by the Hobby Manufactures Association.

Response: Staff notes that the supply of neodymium magnets, including packaged products, has always been mainly from China. The preliminary regulatory analysis does report that "[a]n unusual aspect of the market for the subject magnets is the ability of consumers to order magnets directly, mainly from suppliers located in China." Staff did not assert that "nearly all" hazardous magnet products were being sold by overseas sellers. In fact, a review of sellers on two major Internet platforms in 2020 and 2021 found that most sellers were domestic. The numbers of hazardous magnet products directly imported from overseas sources under the mandatory rule would likely comprise a small fraction of what total sales have been in recent years.

Tab G: Memorandum by the Office of Compliance and Field Operations, Division of Enforcement and Litigation

This document has been electronically approved and signed.

TO: Stephen Harsanyi, Project Manager,
Division of Human Factors,
Directorate for Engineering Sciences

DATE: August 17, 2022

THROUGH: Carolyn T. Manley, Assistant Division Director,
Children's & Flammability Team,
Office of Compliance and Field Operations

FROM: Michelle Guice, Compliance Officer,
Children's Product Team,
Office of Compliance and Field Operations

SUBJECT: Summary of Recalls Involving Small, Powerful Magnets
January 1, 2010, through May 25, 2022

Introduction

This memorandum from CPSC's Office of Compliance updates staff's summary provided in support of the Commission's NPR, which detailed Compliance activity between January 1, 2010, and August 17, 2021.[1] The Office of Compliance has investigated and recalled numerous magnet products involving the magnet internal interaction hazard. Listed in Table I, below, from January 1, 2010, as updated through May 25, 2022, CPSC conducted 20 recalls (including 2 since the analysis for the NPR), involving 25 firms/retailers, and totaling approximately 13,832,901 recalled units, including craft kits, desk toys, magnet sets, pencil cases, games, bicycle helmets, maps, and children's products among others. Of these 20 recalls, 5 involved products that would not be subject to the proposed rule; specifically, 4 involved children's toys that are subject to the mandatory toy standard (ASTM F963, codified in 16 CFR part 1250), and 1 involved trivets sold with cookware sets. Although these 5 recalls did not apply to products that would be subject to the rule, they also illustrate the magnet internal interaction hazard.

Discussion

Summary of Recalls Involving Small, Powerful Magnets

TABLE 1 includes all of the recalls that were identified in the NPR briefing package. The two additional recalls since the NPR are identified by the last two entries (March 17, 2022, and March 24, 2022).

[1] Commission NPR on magnets (2021): https://www.govinfo.gov/content/pkg/FR-2022-01-10/pdf/2021-27826.pdf.

TABLE 1 – Summary of Recalls Involving Small, Powerful ("Hazardous") Magnets.

Recall Date	Firm	Hazard	Number of Recalled Units	Number of Incidents Reported (Injuries Reported)	Press Release Number
May 27, 2010	Maxfield and Oberton LLC	Aspiration and Intestinal Perforations or Blockages	About 175,000 Buckyballs® High Powered Magnets Sets	Two Reports of Children Swallowing One or More Magnets/ No Injuries Reported	10-251 [2]
November 21, 2012	Jo-Ann Fabric and Craft Stores	Magnets Can Become Loose - Ingestion Hazard for Children	About 1,800 Foam Pumpkin Turkey Craft Kit	No Incidents/Injuries Reported	13-046[3]
December 10, 2012	Reiss Innovations	Aspiration and Intestinal Perforations or Blockages	About 500 High-Powered Magnet Desk Toy; DynoCube	No Incidents/Injuries Reported	13-062 [4]
January 31, 2013	SCS Direct	Intestinal Obstructions, Perforations, Sepsis and Death	About 106,000 Magnet Balls® Manipulative Magnet Sets	No Incidents/Injuries Reported	13-112 [5]
January 31, 2013	Kringles Toys and Gifts	Intestinal Obstructions, Perforations, Sepsis and Death. Internal injuries.	About 4,200 Nanospheres Magnetic Desk Toys	Firm Received No Reports of Incidents or Injury	13-111[6]

[2] https://cpsc.gov/Recalls/2010/Buckyballs-High-Powered-Magnets-Sets-Recalled-by-Maxfield-and-Oberton-Due-to-Violation-of-Federal-Toy-Standard

[3] https://cpsc.gov/Recalls/2013/Jo-Ann-Fabric-and-Craft-Recalls-Foam-Pumpkin-Turkey-Craft-Kit-Due-to-Risk-of-Magnet-Ingestion-Hazard

[4] https://cpsc.gov/Recalls/2013/High-Powered-Magnet-Sets-Recalled-by-Reiss-Innovations-Due-to-Ingestion-Hazard-Sold-Exclusively-on-Amazoncom

[5] https://cpsc.gov/Recalls/2013/High-Powered-Magnet-Balls

[6] https://cpsc.gov/Recalls/2013/Kringles-Toys-and-Gifts-Recalls-High-Powered-Magnets

April 12, 2013	Six Retailers: Barnes & Noble, Bed Bath & Beyond, Brookstone, Participating Hallmark Retailers, Marbles the Brain Store and, ThinkGeek	These Products Contain Defects in the Design, Warnings and Instructions, which Pose a Substantial Risk of Injury and Death to Children and Teenagers	About 3,000,000 sets of Buckyballs and Buckycubes	CPSC received 54 Reports of Children and Teens Ingesting This Product, with 53 of These Requiring Medical Interventions	13-168 [7]
April 15, 2013	Overstock.com	Intestinal Obstructions, Perforations, Sepsis and Death	539 Buckyballs High-Powered Magnet Sets	No Injuries Reported	13-731 [8]
April 15, 2013	Toys R Us	Intestinal Obstructions, Perforations, Sepsis and Death	About 60 Buckyballs High-Powered Magnet Sets	No Injuries Reported	13-732 [9]
June 7, 2013	Adobe	Intestinal Obstructions, Perforations, Sepsis and Death	About 500 High-Powered Magnets distributed with Adobe Connect™ "Effective Collaboration is Magnetic" Promotional Materials Package	No Incidents/Injuries Reported	13-736 [10]
March 6, 2014	Design Ideas	Intestinal Obstructions, Perforations, Sepsis and Death	About 21,700 Rubber Ducky Magnets, 3,200 Blowfish Magnets and 2,000 Splat Magnets	No Incidents/Injuries Reported	14-126 [11]

[7] https://cpsc.gov/Recalls/2013/Six-Retailers-Announce-Recall-of-Buckyballs-and-Buckycubes-High-Powered-Magnet-Sets

[8] https://cpsc.gov/Recalls/2013/Overstock-Recalls-High-Powered-Magnet-Sets
[9] https://cpsc.gov/Recalls/2013/Toys-R-Us-Recalls-High-Powered-Magnet-Sets

[10] https://cpsc.gov/Recalls/2013/Adobe-Recalls-High-Powered-Magnets-Distributed-with-Promotional-Materials-Package

[11] https://cpsc.gov/Recalls/2014/Design-Ideas-Recalls-Magnets

August 5, 2015	Disney Store	The Magnets Can Detach, Posing an Ingestion Hazard. These Magnets can Link Together if Swallowed & Result in Serious Internal Injuries	About 300 Gadget Pencil Cases	No Incidents/Injuries Reported	15-745[12]
September 10, 2015	Juratoys U.S.	The small Magnet Inside the Worm can Liberate. Swallowing Multiple Magnets Can Result in Serious Internal Injury.	About 14,00 (About 200 in Canada) Sardines Fishing Game & Starfish Fishing Game	417 Reports of the Plastic Worm at the end of the Fishing Pole Line Separating and Releasing Small Parts, Including Four Reports of Children Ingesting a Small Part/ No injury reported.	15-241[13]
May 17, 2016	Pacific Cycle	Magnetic Buckle on helmet's chin strap contains small plastic covers & magnets that can come loose; posing a risk of choking and magnet ingestion to young children.	About 129,000 Infant Bicycle Helmets with Magnetic No-Pinch Buckle Chin Strap	Pacific Cycle Received Three Reports of the Plastic Cover Coming Loose. No Injuries Reported.	16-162[14]
August 4, 2016	Cinmar, LLC	Intestinal Obstructions, Perforations, Sepsis and Death	About 4,500 Magnetic travel maps	No Incidents/Injuries Reported	16-766[15]
March 29, 2017	Target	Intestinal Obstructions, Perforations, Sepsis and Death	About 19,000 Magnetic tic tac toe games	Target Received One Report of the Magnets Falling Off the Game Piece /No Injuries	17-119[16]

[12] https://cpsc.gov/Recalls/2015/Disney-Store-Recalls-Pencil-Cases

[13] https://cpsc.gov/Recalls/2015/Juratoys-Recalls-Fishing-Games
[14] https://cpsc.gov/Recalls/2016/Pacific-Cycle-Recalls-Infant-Bicycle-Helmets
[15] https://cpsc.gov/Recalls/2016/Cinmar-Recalls-World-Magnetic-Travel-Maps
[16] https://cpsc.gov/Recalls/2017/Target-Recalls-Magnetic-Tic-Tac-Toe-Games

July 30, 2019	Tristar Products	Intestinal Obstructions, Perforations, Sepsis and Death	About 350,000 Magnetic Trivets	One report of Magnets Detaching from a Trivet and Swallowed by a Child. The Child Suffered Intestinal Perforations and Blockage, Requiring Surgery	19-765 [17]
June 27, 2019	Sobeauty Inc.	Intestinal Obstructions, Perforations, Sepsis and Death	About 600 "Mag Cube" Magnetic Ball Sets	No Incidents/Injuries Reported	20-741 [18]
August 17, 2021	Zen Magnets LLC	Perforations, twisting and/or blockage of the intestines, infection, blood poisoning, and death.	About 10 million Zen Magnets and Neoballs Magnets, sold individually and in magnet sets beginning in January 2009	Two children ingested Zen Magnets and required surgery to remove the magnets and parts of their intestines and bowels. CPSC is aware of other reports of children and teenagers ingesting high-powered magnets and requiring surgery. A 19-month-girl died after ingesting similar high-powered magnets.	21-179[19]
March 17, 2022	HD Premier Inc.	Perforations, twisting and/or blockage of the intestines, infection, blood poisoning, and death.	About 119,620 DigitDots 3mm and 5mm Magnetic Balls	HD Premier is aware of four children who have ingested DigitDots and required surgery to remove the magnets.	22-101[20]

[17] https://cpsc.gov/Recalls/2019/Tristar-Products-Recalls-Magnetic-Trivets-Due-to-Magnet-Ingestion-Hazard-Recall-Alert
[18] https://cpsc.gov/Recalls/2020/Sobeauty-Recalls-Mag-Cube-Magnetic-Ball-Sets-Due-to-Risk-of-Ingestion-by-Children-That-Could-Cause-Serious-and-Permanent-Intestinal-Injuries-or-Death-Recall-Alert
[19] https://cpsc.gov/Recalls/2021/Zen-Magnets-and-Neoballs-Magnets-Recalled-Due-to-Ingestion-Hazard
[20] https://cpsc.gov/Recalls/2022/HD-Premier-Recalls-DigitDots-Magnetic-Balls-Due-to-Ingestion-Hazard

March 24, 2022	Boxine US Inc.	Perforations, twisting and/or blockage of the intestines, infection, blood poisoning, and death.	About 4,200 tonies® Blocks	tonies has received one report of the magnet detaching from the product. No injuries have been reported.	22-736[21]

Public Comments Pertaining to CPSC Enforcement Activities

Discussed in the Briefing Memorandum, CPSC received 716 comments regarding the NPR. Additionally, on March 2, 2022, CPSC held an oral hearing pertaining to the NPR, at which time five comments were presented. Commenters provided statements in favor and in opposition to the proposed rule, and some opined on ways to improve the proposed rule. These written and oral comments can be found in docket number CPSC-2021-0037 at http://www.regulations.gov/. Below, staff addresses the comments regarding CPSC's enforcement activities.

Commenters against the proposed rule claimed that magnet ingestion injury trends correspond to insufficient CPSC enforcement of ASTM F963 and ASTM F3458. Many argue that CPSC should focus only on manufacturers and importers that do not use clear marketing and warnings to explain the hazard and warn against use by children.

Staff's Response:

Magnet sets marketed as children's toys must meet mandatory magnet toy requirements under ASTM F963. Compliance enforces the requirements of ASTM F963, issues Notices of Violation (NOVs), and works with U.S. Customs & Border Protection (CBP) to order seizure and forfeiture of magnets that do not comply with ASTM F963. In addition, Compliance investigates magnet sets marketed to ages 14 and over for potential violations of Section 15 of the CPSA addressing substantial product hazards and related reporting requirements. As discussed in the ESHF memorandum in Tab C, clear marketing and warnings about the magnet internal interaction hazard and to keep the products away from children have failed to address the hazard. As a result, Compliance investigates magnet ingestion hazards posed by such products, even if they include such marketing and warnings. Compliance also has worked with third-party online platforms to promote continuous monitoring of listings and proactive voluntary removal of magnet set listings from platforms. However, these actions only focus on products after they enter the market, creating an ingestion hazard. Toy standard enforcement activities do not address the hazard presented by magnet sets that are marketed to users 14 years old and older; incident data indicate that many ingestions involve children accessing products that are marketed to consumers over age 14 or are not marketed as toys and therefore do not fall under the toy standard.

[21] https://cpsc.gov/Recalls/2022/Boxine-U-S-Recalls-tonies-Blocks-Due-to-Magnet-Ingestion-Hazard-Sold-Exclusively-at-tonies-com-Recall-Alert