

EMERGING TECHNOLOGIES: Anticipating the Impact of 3D Printing on the Toy Industry



INTRODUCTION



3D printing is an evolving technology that has opened the doors to new and exciting practices within the consumer products industry. It is impacting the fields of design, engineering, manufacturing and distribution in ways that could dramatically change how new toy products are designed, produced and brought to market. The ability to create proof-of-concept samples from complex designs and the flexibility to make quick design changes make 3D printing an attractive tool for product development (e.g., prototyping) and helps explain its emergence as a highly suitable method for manufacturing real-life functional parts.

This UL white paper provides an overview of the advent of 3D printing in the toy industry. It addresses the uses, the advantages and trade-offs of 3D printing, and the potential impact on toy manufacturing. The paper briefly traces the evolution of toy safety and examines the safety and regulatory considerations facing developers of this technology for consumer utilization.



THE TERMINOLOGY

The terms "3D printing" and "additive manufacturing" (AM) collectively refer to those technologies that utilize various types and forms of materials but that operate within a fundamentally similar process. Although the two terms are often used interchangeably, AM is typically associated with industrial settings while 3D printing generally refers to the use of machines that are lower in price and/or overall capability. This paper focuses on consumer use, so the term 3D printing will be used throughout when referring to this technology.

3D PRINTING:

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⁽⁽The fabrication of objects through the deposition of a material using a print head, nozzle, or another printer technology.¹)

ADDITIVE MANUFACTURING:

⁽⁽The process of joining materials to make objects from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing methodologies, such as traditional machining.¹))

ABOUT 3D PRINTING

3D printing technology has been in existence for over 30 years, but its availability for home/consumer use has markedly increased in only the past few years. Due to its affordability and ease of use, fused deposition modeling (FDM) has become the most popular 3D printing method and the most common for printing toys, particularly in schools and homes. More than 500 manufacturers are producing FDM machines for consumers, with retail prices ranging from \$500 to \$5,000. By contrast, professional FDM printers used in commercial/industrial settings are priced from \$10,000 to \$30,000. In 2015, FDM 3D printers accounted for approximately 94 percent of the 245,000 3D printers sold. By 2019, that number is expected to soar to approximately 5.6 million units, or 97.5 percent of all 3D printers sold.² By 2025, the annual economic impact of 3D printing is expected to reach \$230 to \$550 billion, with \$100 to \$300 billion attributable to consumer products, including toys.³

Advances in 3D printing and growing consumer interest in 3D printing technology have resulted in new printers with greater flexibility, increased speed and improved resolution. The following examples of products and services currently on the market demonstrate how quickly 3D printing technology is taking hold:

- 3D printers that let children create their own toys
- 3D printing pens that use strands of food-safe and biodegradable material or that extrude gel to be cured by UV light
- Self-serve kiosks in stores and other venues that allow customers to choose and personalize toy designs
- Websites where children can design and print their own toys and dolls using 3D printing technology
- Websites that allow children to upload their photographs to create action figures that look like them





ANNUAL ECONOMIC IMPACT \$230 - \$550 BILLION

WHY 3D PRINTING?

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Early adopters in industries as diverse as automotive, aerospace, medical devices, tooling and now consumer products have embraced 3D printing due to the value it can bring to their supply chains. The benefits include the ability to efficiently and economically produce complex, low-volume parts (aerospace) and design prototypes (automotive) and to capitalize on the potential for mass customization (medical devices).

Today, home-based 3D printers not only allow consumers to create customized toys but also provide an avenue for repairing broken ones and replacing missing parts. Manufacturers can now sell 3D files of their toys rather than the physical toys themselves, allowing consumers to print toys



right at home. This could potentially reduce or eliminate the need for product packaging and product inventories, and also result in significant carbon footprint reductions by eliminating need to transport goods from manufacturer to retailer.

UNIQUE ADVANTAGES OF 3D PRINTING	TRADE-OFFS OF 3D PRINTING
SPEED: Tooling not required, reducing development time and time to market	SPEED: Slow printing process with parts printed one layer at a time—inability to manufacture large volumes
MATERIALS: Limited material waste	MATERIALS: Limited selection of materials, potentially limiting performance expectations
COST: Savings resulting from not having to maintain inventory or to ship goods	COST: Costly equipment and materials; prices expected to decline as technology matures; potentially offset by savings in tool costs
CUSTOMIZATION: Ability for mass customization due to design flexibility	FUNCTIONALITY AND APPEARANCE: Rough surfaces, incomplete fill, and other imperfections due to layering process
OPTIMIZATION: Functional optimization of products (e.g., optimized cooling channels)	POST-PROCESSING: Labor-intensive and costly post-processing operations to enhance functionality and appearance
BATCH SIZE: Small-scale production runs appealing for niche applications	
DESIGN: Design complexity of parts not a constraint	
EFFICIENCY: Supply chain efficiency due to reduced inventories and lead time	

GENERAL SAFETY CONSIDERATIONS

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MARKET MITIGATION OF RISKS

As the market for 3D printing technology grows, the safety of 3D printing machines has become an increasingly important purchase consideration. Regulatory and standards development bodies worldwide are beginning to consider 3D printer safety, and printer manufacturers are seeking safety certification for their products. Increasingly, manufacturers want their machines to meet International Electrotechnical Commission (IEC) standards so that they can be marketed and sold globally. However, in addition to electrical safety, other risks need to be identified and better communicated.

Standardization and product certification can support this effort. UL currently certifies 3D printers in accordance with its equipment compliance guidelines. Home-assembled printers (so-called 3D printer kits) are outside the scope for this certification, so their safety for use by consumers and children requires further evaluation.

GENERAL EQUIPMENT SAFETY

As with any machine used at home or work, 3D printers expose users to a number of potential safety risks. Depending upon their intended use and market of distribution, there are regulations and requirements that address equipment safety in commercial and industrial settings. However, printing equipment marketed primarily for home use may not provide the same safeguards or be held to the same standards as equipment intended for commercial or industrial use. General equipment safety hazards that should be evaluated and addressed include:

• SHARP EDGES AND PINCH POINTS:

Mechanical parts, including motors, gears, and belts that are not properly enclosed within the printer, may present pinch points. The movable build platform can also result in injury if a user reaches under the platform as it retracts.

- THERMAL BURNS: The printing extrusion tip is typically very hot (220°C/428°F) and presents a burn risk to a user who reaches into the build area.
- FIRE: Extruded plastic melts at high temperatures. Leaving a 3D printer unattended during operation is not recommended, especially for builds that take several hours, due to the potential for overheating and fire.
- ELECTRIC SHOCK: Equipment powered by an energy source poses a risk of electric shock, if there is a means by which that energy can be transferred to a body part. Therefore, safeguards should be in place to prevent such transfer.



FILAMENT MATERIALS SAFETY

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Decisions regarding sourcing of materials are important. For example, some suppliers sell odd colors that may have been rejected from injection molding and re-melts. Consumers should source filament materials only from dealers who sell virgin materials.

Filament Material Safety Considerations

FUMES Some common primary materials, such as acrylonitrile butadiene styrene (ABS), polylactic acid (PLA), nylon thermoplastic elastomer (TPE), high-density polyethylene (HDPE), polycarbonate (PC), and polyetherimide (PEI), may emit hazardous fumes and vapors.

FLAMMABILITY AND TOXICITY

Flammable thermoplastics may contain toxic components that can cause skin irritation and sensitivity. Support materials may contain components that are hazardous if inhaled or swallowed.

HEAVY METALS Pigments may contain lead (Pb) or cadmium (Cd), both of which are commonly used to make the color of plastic more vibrant. These and other heavy metals could have adverse health effects, particularly in young children who are at risk of long-lasting or even permanent developmental and cognitive effects.⁴

ENVIRONMENT Improper disposal of non-biodegradable polymer materials could be a matter of environmental concern.



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HAZARDOUS EMISSIONS

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Most people have likely experienced the odor of burning plastic. During the 3D printing process, such an odor is produced by the heating of filament material to a melting point. Although a normal byproduct of the printing process, the odor may lead to headaches and respiratory and eye irritation in some individuals.

Additionally, most FDM printers are not designed to trap or contain the ultra-fine particles (UFPs) emitted as part of the printing process. These easily-inhaled UFPs can migrate to various tissues and organs. Organs that filter toxic substances in the human body such as the liver and spleen are particularly vulnerable to damage from UFPs, which can be irreversible in some cases.⁵

ABS filament materials also release volatile organic compounds (VOCs), such as styrene, ethylbenzene and acrylonitrile, during heating. PLA is the preferred material for simple prototyping because it is considered safer and emits less offensive fumes than those emitted by ABS. Studies confirm that particle and VOC emissions are higher from printers using ABS filaments than from those using PLA filaments.⁶ A study conducted by filament manufacturer Eastman Chemical Company purports to refute the notion that emissions from 3D printers are a matter of concern. Their results show that an open-air VOC emission concentration is several orders of magnitude below regulatory agency concern level for an office environment. However, combined traces of VOCs and UFPs may exceed the threshold limits, particularly for ABS.⁷

Recognizing the importance of safety from harmful emissions, UL has partnered with Georgia Tech and Emory University to perform research on the impact of emissions from 3D printers on indoor air quality.⁸ The objective of this research is to develop methodologies that will produce accurate comparisons of the emissions from different machines and the environments in which they are placed. Phase I of the research seeks to characterize and assess the particle and chemical emissions from 3D printing technologies, and Phase II to assess potential health hazards from emissions exposure. Although the study's initial focus is FDM machines, other printing technologies will be addressed once a standard method for evaluating emissions is established.

Preliminary results from Phase I have identified key factors that control particle emissions from FDM machines, specifically, filament material, filament brand, printer brand and nozzle temperature. Filament color has been shown to have a less significant impact.



TOY SAFETY CONSIDERATIONS

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THE EVOLUTION OF TOY SAFETY

Toy safety standards establish product requirements that are intended to mitigate potential risks to children who interact with toys. In the U.S., formalized toy safety standards have been in existence since 1976. Over time, broader and more detailed standards have been developed to better reflect the increased knowledge of toy safety issues and to address safety requirements of the global toy marketplace. The most well-known and widely applied toy safety standards include ASTM F963, Consumer Safety Specification for Toy Safety (U.S.),9 EN 71, Safety of Toys (European Union)¹⁰ and ISO 8124, Safety of Toys (international).¹¹

To supplement these safety standards, a robust assessment of toy safety might also include a human factors evaluation

which considers play patterns and interactions of children at specific ages. Such evaluations go beyond regulatory requirements and provide insight into anticipated hazards based upon physical, cognitive and developmental abilities. Specific aspects of a human factors evaluation involve age analysis of both intended and unintended users, as well as anthropometric data, foreseeable use and misuse, design evaluation and injury analysis. The results of a human factors evaluation can help toy designers incorporate modifications to accommodate variations in human behavior and to minimize the potential for injury.

TOY DESIGN SAFETY

Toy design plays a significant role in the overall safety of 3D-printed toys. A poorly designed toy can lead to injury or even death. In an industrial-commercial setting, a professional designer has the requisite knowledge and skills to design a safe toy. In contrast, users of consumer-grade 3D printers may have limited knowledge of safety-related issues and may not be aware how their specific toy design has the potential to cause harm. In fact, hazards related to poor toy design could have greater safety impact than those related to the use of 3D printers and their materials. Some examples of safety issues associated with 3D-printed toy design include:

- Printed shapes tend to have rough, porous surfaces that are difficult to clean, leading to bacteria growth;
- Lead-containing brass printer components can contaminate both raw materials and the finished toy;
- Printed components launched from projectile toys could cause injuries if such features have not been evaluated for safety; and
- A circular-shaped hole in a printed toy could potentially create a finger entrapment hazard.



PHYSICAL AND MECHANICAL SAFETY

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Traditional design and manufacturing processes, which includes verification of compliance with toy safety standards, are the best ways to mitigate many toy-related physical and mechanical hazards, including those listed in the following table:

HAZARD	DESCRIPTION	SOURCE
Choking and Aspiration	Object lodged in a child's throat or aspirated into the lungs and/or ingested, obstructing the airway or causing internal complications	Small parts, particles or granules
Puncture and Laceration	A hole or cut on the skin made by an object	Hard, pointed, or sharp components
Finger Entrapment, Pinching or Crushing	Retention of finger in an opening or clearance area such that the user is unable to freely extricate it without causing injury, or entrapment or compression of the flesh usually resulting in a contusion or laceration	Holes circular in shape with some depth and moving parts or hinges
Eye Injury	Puncture, contusion, abrasion, or laceration to the eye and/or various soft tissues surrounding the eye	Hard and sharp components and launching projectiles
Suffocation	Object that 'cups' the face, creating a vacuum suction seal that impedes airflow to the mouth/nose, airway, and lungs, obstructing breathing	Cup-shaped objects or components
Impalement	Injury from a fall onto an offending object resulting in penetration, such as anal or vaginal, and causing serious internal complications	Post-like designs that are stable and protrude upwards while on the ground
Ear Impaction	Object lodged in the ear that poses risk of infection, puncture or rupture of the eardrum resulting in severe pain, as well as permanent or partial hearing loss	Long, rigid, and thin objects or components

To prevent these and other injuries, reputable commercial manufacturers design and produce toys to comply with mandatory or voluntary safety standards, and integrate formal safety assessments throughout their product development cycle. However, in home-based 3D printing, the consumer assumes the roles of designer, manufacturer, quality assurance manager and distributor. Unfortunately, because the average consumer usually lacks the expertise to reliably evaluate a toy for safety, these critical safety assessments are generally not performed in home-based 3D printing.



The following table compares the steps commonly used by professionals in commercial toy manufacturing with those typically used by consumers in home-based 3D printing:

	COMMERCIAL TOY DESIGN AND MANUFACTURING	HOME-BASED 3D PRINTING OF TOYS
1. Toy is designed by experienced design professional	\checkmark	No
2. Toy is reviewed by experienced safety professional	\checkmark	No
3. Robust, consistent, and repeatable production takes place at quality-controlled facility staffed with experienced personnel	\checkmark	No
4. Post-production design review and testing to universally accepted international toy safety standards is conducted	\checkmark	No
5. Product is distributed to market	\checkmark	No
6. Feedback (customers and agencies) based on real-world use is received and continuous improvements are implemented	\checkmark	No

To help address this safety gap, manufacturers of 3D printers should consider the following measures:

- Take steps to ensure that consumer 3D-printed toys meet current toy safety standards
- Oversee and monitor suppliers of raw materials, since inconsistencies can affect the robustness of the design build and result in product hazards under normal use conditions
- Provide thorough instructions for users of 3D printing devices
- To the extent possible, evaluate unforeseen design hazards created by this new technology
- Raise awareness about potential safety issues by providing consumers with comprehensive guidance on the safe use of the technology
- While taking the above measures is not likely to address every potential design-related safety gap, it can go a long way toward improving the overall safety of home-based 3D printing of toys





CHEMICAL SAFETY AND 3D PRINTING

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Although physical harm resulting from chemical hazards may not be as immediately apparent as harm related to mechanical hazards such as small parts or sharp points, potential hazards from filament materials should be evaluated. Short-term chemical exposure can lead to skin irritation, while long-term exposure can result in more serious conditions such as lead poisoning, cancer and harm to reproductive organs.

In most markets throughout the world, toys and their raw materials, including filaments used in 3D printing, are required to meet specified chemical safety requirements prior to being sold or distributed. While the requirements vary from country to country, the intent is the same, that is, to prevent harm or illness related to a toy's use.

With respect to toys, heavy metal content (e.g., lead and cadmium) is closely regulated, as evidenced by strict limits imposed by ASTM F963, EN 71, and ISO 8124. Phthalates, which are plasticizers used to make plastics softer and more pliable, represent another strictly regulated class of chemicals. Phthalates are considered to be reproductive toxicants,¹² and many jurisdictions limit the amount of phthalates that can be used in toys and children's products, especially those intended for mouthing and sucking by children under three years of age.

Other regulated classes of chemicals include organic solvents, azo dyes and, more recently, endocrine disruptors such as bisphenol A (BPA). While some chemicals are used during the manufacturing process, they may not be present in the finished product, or they may be present only as a contaminant. For these reasons, regulatory compliance is typically verified by the testing of the finished product by an independent, accredited testing organization.

Manufacturers of 3D printers are strongly encouraged to take the necessary steps to help ensure that their products do not present any chemical hazards to users. The scope of this evaluation should include the printing device and the raw materials used to print 3D products, as well as the printed products themselves.



REGULATORY CONSIDERATIONS FOR CONSUMER 3D PRINTERS

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The regulatory landscape for 3D printers and the toys and components they print is still emerging. Although there are thousands of laws and regulations that apply globally to consumer products, consumer 3D printers and the products that they produce remain largely unregulated.

IN THE U.S., 3D PRINTING DEVICES AND PRINTING MATERIALS WOULD TYPICALLY BE SUBJECT TO RULES AND REGULATIONS UNDER THE U.S. CONSUMER PRODUCT SAFETY ACT (CPSA), WHICH ARE ENFORCED BY THE U.S. CONSUMER PRODUCT SAFETY COMMISSION (CPSC).¹³

In the European Union (EU), such products may fall under the scope of the EU's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulations,¹⁴ as well as the EU's Restriction of Hazardous Substances (RoHS)¹⁵ and Toy Safety¹⁶ directives. However, the direct applicability and regulatory reach of these rules and requirements is likely to depend on answers to the following questions:

- Is the 3D printer classified as office equipment (intended for use by adults) or as a toy (intended for children)?
- Will applicable regulatory bodies regulate the printer, the printed toy, or both the printer and the printed toy?
- Who is considered the manufacturer of the printed toy? Is it the printer



manufacturer, the designer of the model file or the printer operator who printed the toy?

- Is the operator of the printer under any regulatory obligations?
- Is the printed toy subject to the same regulatory scheme and standards as commercially-manufactured consumer products?

In May 2016, the U.S. Food and Drug Administration (FDA) distributed a draft guidance document for public comment entitled "Technical Considerations for Additive Manufactured Medical Devices."¹⁷ This document addresses the output of the 3D-printed object rather than the printer itself, and recommends testing, labeling and other technical considerations to meet quality system requirements applicable to these devices. This draft guidance could serve as a model for a similar guidance from the CPSC on the safety of 3D-printed toys. The potential safety issues pertaining to 3D printing have also gained the more direct attention of the CPSC.

DURING TESTIMONY TO A HOUSE APPROPRIATIONS SUB-COMMITTEE IN FEBRUARY 2016, CPSC CHAIRMAN ELLIOT KAYE STATED THAT IT IS NECESSARY TO "STAY ON TOP" OF EMERGING TECHNOLOGIES, INCLUDING 3D PRINTING.¹⁸

Additionally, in the Chairman's Challenge document issued in August 2015, Kaye identified two primary issues regarding 3D printing being pursued by the CPSC, the first related to the design of appropriate systems for household air quality control and ventilation to reduce exposure to 3D printing fumes, and the second related to (i) the development of standards and systems to limit the presence of harmful chemicals in homemade or recycled 3D printer feed stock plastics and (ii) the development of a method for consumers to identify plastics that are not safe for recycling in a 3D printer.¹⁹

SUMMARY AND CONCLUSION

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3D printing is an emerging and evolving technology that has seemingly endless possibilities, especially in the production of toys. However, the technology, the materials and the printed toy each need to address the potential safety risks posed to both the operator of the printer and the consumer who ultimately uses the toys it produces. As global regulations related to 3D printing emerge, manufacturers and distributors of 3D printing equipment and supplies should closely track the development of new regulations and standards to help ensure that their products are compliant. Further, manufacturers are well advised to consider conducting a thorough risk assessment of their products to identify potential hazards and to reduce the risk to consumers.



To learn more, please contact **TOYTEAM@UL.COM** or **ADDITIVEMANUFACTURING@UL.COM** or visit **WWW.UL.COM/TOYS** or **WWW.UL.COM/AM**.

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APPENDIX – 3D PRINTING PROCESSES AND STAGES THE PROCESS CATEGORIES

- Vat polymerization: A process in which a liquid photopolymer in a vat (tub) is selectively cured by light-activated polymerization, e.g., stereolithography (SLA) and digital light processing (DLP)
- Material extrusion: A process that uses material in the form of a filament that is melted and extruded through a heated nozzle to create parts, layer upon layer; also known as fused deposition modeling (FDM) or fused filament modeling (FFM)
- Material jetting: A process in which droplets of building material are selectively deposited and form the structure of the part, e.g., polyjet
- Binder jetting: A process in which a liquid bonding agent is selectively deposited to join powder materials
- Sheet lamination: A process in which sheets of material are bonded together to form an object, e.g., laminated object manufacturing (LOM) and ultrasonic consolidation (UC)
- Powder bed fusion: A process in which thermal energy, usually created by a laser/electron beam, selectively fuses regions of a powder bed, e.g., selective laser sintering (SLS), selective laser melting (SLM) and electron beam melting (EBM)
- Directed energy deposition: A process that uses focused thermal energy to fuse materials by melting as they are being deposited, e.g., LENS[®] and electron beam melting (EBM)

Two commercial variations of the above process categories can be found in the following:

- Continuous liquid interface production (CLIP): A derivative of vat polymerization, with a processing speed of 25 to 100 times that of vat polymerization
- Multi-jet fusion: A process that uses binding ink and heat energy to fuse layers of polymer

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saving model files in compatible .STL, .AMF and .3MF formats:

- A. Use of a commercially available 3D modeling software, such as SOLIDWORKS™ and CATIA; and
- **B.** Use of a 3D scanner to convert the object's physical profile into a digital solid state.

Software is used to fix the 3D model file for errors and to slice the solid model into 2D layered information. Slicing is done because a 3D printer cannot process 3D information. "Sliced" 2D information is transferred to the printer, and the parts are printed layer-bylayer until a complete part is made.

Parts produced by the 3D printer that are not yet suitable for use in their final application(s) may require additional finishing or enhancements, such as milling, grinding, polishing, or heat treatment.

END NOTES

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- ⁴ CPSC Staff Report on Lead and Cadmium in Children's Polyvinyl Chloride (PVC) Products, 21 November 1997, http://www.cpsc.gov/pagefiles/95613/pbcdtoys.pdf
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- ⁸ Underwriters Laboratories Inc. Convenes 3D printing Safety Stakeholder Round Table, December 1, 2015
- ⁹ ASTM F963-11 Standard Consumer Safety Specification for Toy Safety, https://www.astm.org/Standards/F963.htm
- ¹⁰ BS EN 71-1: 2014, http://shop.bsigroup.com/ProductDetail/?pid=00000000030301842
- ¹¹ ISO 8124-1:2014 Safety of Toys -- Part 1: Safety aspects related to mechanical and physical properties, http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=66626
- ¹² Centers for Disease Control and Prevention. National Biomonitoring Program.
- ¹³ Consumer Product Safety Act, (Codified at 15 U.S.C. §§ 2051–2089) (Public Law 92-573; 86 Stat. 1207,Oct. 27, 1972), August 12, 2011 Version
- ¹⁴ European Chemicals Agency (ECHA) REACH Regulation
- ¹⁵ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment Text with EEA relevance
- ¹⁶ Directive 2009/48/EC Of The European Parliament And Of The Council of 18 June 2009 on the Safety of Toys
- ¹⁷ Technical Considerations for Additive Manufactured Devices—Draft Guidance for Industry and Food and Drug Administration Staff. May 10, 2016
- ¹⁸ Statement of U.S. Consumer Product Safety Commission Chairman Elliot F. Kaye. Financial Services and General Government Subcommittee of the U.S. House of Representatives Committee on Appropriations. February 25, 2016
- ¹⁹ U.S. Consumer Product Safety Commission Chairman Elliot Kaye's Chairman's Challenge. August 2015. Page 11