



# What Compliance Really Means

As the definition of functional printing evolves, so does its regulatory landscape.

Before looking at the regulatory landscape impacting the complex, growing, and ever-changing functional printing industry sector, one must understand what it encompasses, as regulations tend to focus not only on the chemicals used but the products developed. For this piece, functional printing includes the creation of in-mold electronics or the use of direct-to-object (DTO), direct-to-shape (DTS), and 3D printers to manufacture or decorate objects that exceed the performance requirements of most advertising graphics, packaging, publications, or even the garment decoration sectors.

This is an important concept to grasp — having to consider not only the chemicals and substrates used to create the product in question, but often the print technology used as well as the functionality of the end product itself. Regulatory agencies are both investigating and seeking to develop policies and, possibly, regulations to address the use of end products that will have an immediate impact on printing companies in this sector.

It must also be recognized that different regulatory programs exist within the U.S. and internationally. And, outside of government agencies are voluntary standard organizations, such as Underwriter Laboratories (UL), American National Standards Institute (ANSI), and the American Society for Testing and Materials (ASTM). The following breaks down everything functional printers need to know to ensure they are fully compliant.

## U.S. Regulations

The majority of current regulatory activity continues to be focused on chemicals used by this print sector, and looking at the U.S. Environmental Protection Agency's

(EPA) Toxic Substance Chemical Program, as well as several state chemical programs, provides an overview of actions in this area.

The lead federal agency that has focused on products produced by functional printing is the Consumer Product Safety Commission (CPSC). This should not be too surprising as this agency addresses hazards associated with consumer products, and quite a few of the highly recognized functional products on the market today are directly related to the consumer — specifically, e-textiles.

## Chemicals

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Chemical Safety Act) was signed into law. This amended the Toxic Substance Control Act (TSCA), the nation's primary chemicals management law.

Key changes were made to TSCA, and for the first time, the EPA is required to evaluate the safety of existing chemicals in commerce, starting with those most likely to cause risks. The new law includes several other important changes to this chemical management program. Most importantly, it has increased public transparency of chemical information by limiting unwarranted claims of confidentiality and allowing for the appropriate sharing of confidential information with states and health and environmental professionals. While the average printing operation may not need to interact with this specific program, it is important to be aware of it and its similarity to California's Proposition (Prop) 65 program in limiting, and potentially deterring, the introduction and use of chemicals in the states. Due to the increased requirements of chemical manufacturers for risk assessments, there is a possibility that chemicals may no longer be

available, or prices may be higher.

While the EPA program may not have an immediate impact on the printer, state chemical programs do — most specifically Prop 65. Officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, Prop 65 was enacted as a ballot initiative, and the intent of the program is to protect the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects, or other reproductive harm. Businesses — both those operating in California, as well as selling products into the state — are required to inform Californians about exposures to such chemicals. The state maintains and updates the list of chemicals regulated by this program.

With the passage of new regulatory requirements for warning labels, increased attention has focused on the companies providing the products into the state to “certify” to the Prop 65 standards. It must be clearly stated that this regulatory program does not require businesses to certify that their products either contain or do not contain any chemical listed on the Prop 65 list. It is recommended manufacturers perform their due diligence regarding the chemicals used in production. One should check the chemicals used, found on the Safety Data Sheets, against the list of Prop 65 chemicals. If there are none of these chemicals in the products above the limit, this should be documented, but there is no need to issue a warning label.

Other states are considering adopting similar programs, and those that have focus primarily on chemicals used in children's products. Anyone producing children's products, including toys, are encouraged to look at Vermont, Washington, and Oregon's requirements. ▶



By Marci Kinter,  
VP - Government and  
Regulatory Affairs,  
PRINTING United  
Alliance



**Regulatory agencies are both investigating and seeking to develop policies and, possibly, regulations to address the use of end products that will have an immediate impact on printing companies in this sector.**

**Products**

Wearable consumer products have long been regulated by the CPSC. Recently, most of the attention has focused on the use of e-textiles, however, CPSC also includes commonly used products within the wearable technology category, such as wrist watches and earphones. With advances in electronics, software, and batteries, enhanced capabilities, which include complex data collection and wireless communication of data, are now being integrated into more products. Given the wide range of products, CPSC has started to categorize wearable technology products — often referred to as “wearables” — by product function and product type.

The agency has identified wearables as a consumer product that is worn on, applied to, or implanted or inserted into the human body, and incorporates innovative features. They can include a chemical, electronic, or mechanical function collecting or providing information to the consumer and may be directly or indirectly connected to the internet. It is recognized that wearables represent a wide range of products, and no single definition for these products exists. Consumer applications of these products include activity tracking, performance enhancement, and other methods of affecting the consumer’s senses and interactions.

Agency jurisdiction over certain wearables is not always clear. Determining which agency has jurisdiction over a product is important, because jurisdiction may dictate the regulatory requirements for a given product. For example, depending, in part, on the manufacturers’ claims and intended uses, some wearables, such

as electronic skin patches that can monitor blood glucose levels and assist insulin delivery, may be considered “medical devices” and would fall under the jurisdiction of the U.S. Food and Drug Administration (FDA). As consumer wearables add more advanced features, like glucose monitoring, it becomes more difficult to distinguish a consumer product from a medical device. Another example includes wearables intended to improve memory and cognitive function through electrical stimulation of the brain. So, depending on the marketing claims, the FDA could consider such products to be medical devices.

Adding to this confusion is the lack of specific U.S. federal consumer product safety technical regulations and few voluntary safety standards generally applicable to wearable technologies. However, CPSC can recall wearables that are under its jurisdiction, if they present a substantial product hazard.

Though there are no specific regulations, those who offer consumer products such as an e-textile, should take steps to determine whether any safety standards and regulations exist and what approaches are available for ensuring product safety. Continuing with the e-textile example, if it is a consumer product, then it must meet the requirements of 16 CFR part 1610, Standard for the Flammability of Clothing Textiles. If the wearable is a children’s toy, it must meet the requirements of 16 CFR part 1250, Safety Standard Mandating ASTM F963 for Toys.

And, yes, the use of 3D printing is also on the radar screen of federal agencies. Similar to the use of wearable technologies, the agencies are in

the beginning stages of investigating the use of this technology by both consumers and the industry. 3D printing not only involves the CPSC, but the EPA due to air emissions associated with the use of this technology.

**International Regulations**

Many should be familiar with the Restriction of Hazard Substances (RoHS) standard adopted by the European Union. RoHS impacts the entire electronics industry and many electrical products as well. Also known as Directive 2002/95/EC, RoHS originated in 2002 and restricts the use of six hazardous materials found in electrical and electronic products.

Directive 2011/65/EU was published in 2011 by the EU, and is known as RoHS-Recast or RoHS 2. RoHS 2 includes a CE-marking directive, with RoHS compliance now being required for CE marking of products. RoHS 2 also added Categories 8 and 9 and has additional compliance recordkeeping requirements. Effective as of July 22, 2019, Directive 2015/863, known as RoHS 3, requires reporting for four additional restricted substances, four different phthalates (DEHP, BBP, BBP, DIBP).

It is important to note that other countries have also adopted similar standards, including China, Korea, Japan, Taiwan, Norway, India, and Turkey. While all may have different implementation deadlines, the good news is that most follow the same restricted substance lists as the EU version. The only U.S. state that has adopted a similar program is California.

California RoHS took effect on Jan. 1, 2007. It is narrower in scope than EU RoHS in that it restricts only lead, mercury, cadmium, and hexavalent chromium and not the other six substances covered under EU RoHS 3. In addition, it only applies to “covered electronic devices” that are defined as standalone LCD, plasma, and CRT video displays with a screen greater than four inches diagonally. Displays integrated into other equipment do not apply. Other U.S. states that have enacted RoHS-like and ▶



As consumer wearables add more advanced features, like glucose monitoring, it becomes more difficult to distinguish a consumer product from a medical device.

e-waste regulations include Colorado, Illinois, Indiana, Minnesota, New Mexico, New York, Rhode Island, and Wisconsin.

### EU REACH Program

Other countries have adopted and launched initiatives similar to the EU Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) program. Due to the changes in the REACH program — most notably the launching of the Substances of Concern In articles, as such or in complex objects (Products) (SCIP) database in February 2020 as a prototype — the following focuses on this major initiative.

As part of the EU’s ambitious Circular Economy Package, the revised Waste Framework Directive mandated the European Chemical Agency (ECHA) to establish database reporting products that contain Substances of Very High Concern (SVHC) and make the information available to waste management operators and the general public. Articles as such and complex projects (two or more components) imported or placed on the European market and that contain listed SVHC in a concentration exceeding 0.1% weight by weight fall within the database’s scope.

In 2017, ECHA released its guide for determining SVHC in articles. The document provides an

overview of the requirements for both registration and notification of substances in articles (Article 7), as well as communication of information on substances in articles (Article 33). The purpose of the SCIP database is to provide waste operators with information about the hazardous substances in the waste they process so that material streams can potentially be “cleaned” before they are recycled and reused in the production of new articles to ensure a true and safe circular economy.

Article suppliers will need to provide:

- information that allows the article to be identified (including picture and characteristics)
- the name, concentration range, and location of the SVHC in the article
- instructions on the safe use of the article

The goal of this increased transparency on the presence of hazardous substances is to help consumers make better informed choices when purchasing products and provide information on how to best use and dispose of such articles.

### Voluntary Standards

Voluntary standards are those established by a private sector body, such as UL or ASTM, and available for use by any person or organization — both private and government. There are two different

types of standards — industry standards and consensus standards. Industry standards are those that are recognized procedures and criteria as acceptable practices by peer professional, credentialing, or accrediting organizations. Consensus standards are developed through the cooperation of all parties who have an interest in participating in the development and/or use of the standards. It is not unusual to see a voluntary standard that becomes mandatory as a result of its use, reference, or adoption by a regulatory agency. The most common

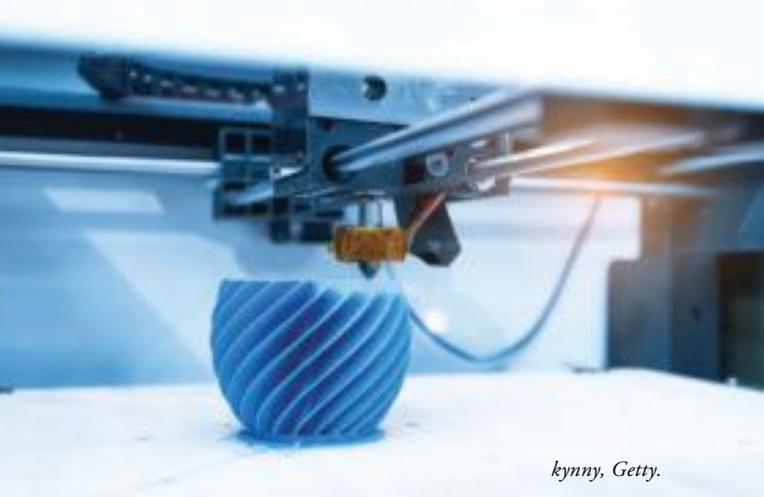
example is the Occupational Safety and Health Administration’s adoption of ANSI safety standards. Both ASTM and ANSI develop consensus standards.

Another voluntary organization that comes into play in the world of functional printing is UL. UL Standards are used to assess products; test components, materials, systems, and performance; and evaluate environmentally sustainable products, renewable energies, food and water products, recycling systems, and other innovative technologies. Both ASTM and UL are working on developing consensus/safety standards addressing the use of smart, or electronic, textiles.

Finally, IPC, the global trade association serving the printed board and electronics assembly industries, has released its E-Textiles Standard, IPC-8921, Requirements for Woven and Knitted Electronics Textiles (E-Textiles) Integrated with Conductive Fibers, Conductive Yarns and/or Wires. IPC-8921 establishes classifications and designations for e-textiles integrated with e-fibers, e-yarns, and e-wires and standardizes key characteristics, durability testing, and industry test methods.

Those engaged in the printing of functional products, or of components of these products, are experiencing an ever-changing regulatory landscape. It is critical that functional printers understand the role of both government and voluntary organizations moving forward. As these products continue to evolve, it is clear that regulations governing their development, use, and disposal are already here. ■

*Marci Kinter is the VP – government and regulatory affairs for PRINTING United Alliance. She oversees the development of management resources for the association and represents the printing industry, as well as its associated supplier base, before federal and state regulatory agencies and the U.S. Congress on environmental, safety, and other government issues directly impacting the industry.*



*kyunny, Getty.*