

CLIENT ALERT

Teaching an Old Dog New Tricks – Chemical Regulation of 3D Printing

Jun.11.2018

As the 3D-printing industry evolves, many wonder about possible new regulations. In fact, certain players in the 3D-printing industry should be paying more attention to the industry's rearview mirror and the preexisting regulations that can apply to 3D printing in unexpected ways. Specifically, existing chemical regulation will shape the obligations of those using 3D printers and those providing supplies to those printers.

The Toxic Substances Control Act

The Toxic Substances Control Act (TSCA) is the U.S. government's primary chemical control law. We first explore how TSCA terms such as "manufacturer" and "processor" apply to 3D printing. Then, we examine the obligations TSCA imposes on those who 3D print and those who produce the materials for printing.

Framing the Facts in TSCA Terms

The following hypothetical scenario best illustrates how TSCA applies to the 3D-printing industry. Assume that Company A imports a filament consisting of a mixture of thermoplastic, pigment, and other additives. Company A then sells the filament to Company B, who uses it to 3D print a figurine for sale.¹

In this scenario, the filament is a mixture of chemical substances regulated under TSCA. It is not exempt from TSCA regulation as an article (a manufactured item formed to a specific shape or design during manufacture with an end-use function that depends upon this shape), because the filament loses its shape entirely during end use as a result of a phase change from a solid filament to a liquid. As a closely related analogy, EPA has explained that plastic blocks that are later processed in such a way that they lose their shape (*e.g.*, by being melted, molded, or extruded) do not qualify as articles, and neither do soldering wire and welding rods. Because the substances in the filament are not part of an exempt article, they compose a mixture, and each substance is subject to all applicable TSCA regulations.

As the importer of the filament, Company A is a TSCA "manufacturer." Under TSCA, Congress defines "manufacture" to include "import" of a substance.

Company B, who could be portrayed as the end-user of the 3D printer and the filament, is a "processor" under TSCA.² A processor is any person who prepares a chemical substance for distribution in commerce after the substance's manufacture. Thus, turning a mixture of substances in a filament into a figurine for sale qualifies as processing subject to TSCA. Many TSCA regulations do not apply to processors, but, as we discuss below, some key regulations do.

Persons Preparing Printing Materials

Companies preparing materials for use in 3D printing (e.g. filling cartridges with plastic or metal powders or preparing thermoplastic filaments) are subject to numerous TSCA requirements. These companies (henceforth called “Suppliers”) start by manufacturing, importing, or domestically acquiring chemical substances. Domestic purchases are not directly regulated under TSCA, but manufacturing and importing are regulated under the umbrella term “manufacture.” If the Supplier is a manufacturer, it must ensure that all chemicals contained in the product are on the TSCA Chemical Substance Inventory (TSCA Inventory), unless an exemption applies. For thermoplastics, Suppliers should consider whether they can rely on the polymer exemption, which encourages the manufacture of low-risk polymers. Depending on how the product will be used, it may also qualify for the research and development (R&D) exemption. The R&D exemption could apply for different types of research, including if the Supplier is testing the performance or properties of a new product or chemical component of a product or developing a new 3D printing process or product/process combination.

Once EPA has designated the commercial status of all substances on the TSCA Inventory as either active or inactive,³³ these Suppliers will need to ensure that any non-exempt substance is listed as active and, if not, must file an advance notice with EPA to redesignate the substance as active.⁴⁴

If the printing material contains nanoscale particles, the Supplier may be subject to a nanoscale material reporting obligation. Many 3D-printing powders contain nanoscale substances. If those substances are manufactured or processed at the nanoscale in order to exhibit one or more “unique or novel properties” the Supplier has a one-time reporting obligation, due August 14, 2018, for activities from August 2014 to August 2017. Going forward, if the Supplier manufactures or processes a different nanoscale form of a substance, the Supplier will have to submit a report to EPA, even if another manufacturer or processor of the same substance submitted a separate report.

The Supplier may also be subject to chemical-specific obligations. The substance may be subject to restrictions under a Significant New Use Rule (SNUR), or to obligations, such as testing or an obligation to pay for a risk evaluation. Suppliers should track EPA attempts to regulate the substances in their materials.

After obtaining the chemical components, the Supplier processes the chemicals into a useable form. This form of processing is regulated the same as processing the material into an article, as described below.

Persons Using 3D Printers

Companies using the cartridge or filament to 3D print a product for sale are TSCA “processors” subject to some of the same TSCA requirements that apply to Suppliers. These companies that use 3D printers (henceforth called “original equipment manufacturers” or OEMs) must ensure that the substances they process are on the TSCA Inventory and, once the active/inactive designations are final, confirm that the substance is listed as active, or else file an advance notice with EPA to redesignate the substance as commercially active. Like the Supplier, the OEM must comply with any applicable SNUR, though the OEM typically receives notice of the SNUR from the Supplier.

A major concern for OEMs is the nanoscale material reporting obligation, discussed above. Even though the Supplier will inform EPA of reportable nanoscale substances in 3D-printing materials, the OEM must also submit a report to EPA for past use and

when it first uses the particular nanoscale material. OEMs may be exempt for R&D use of the materials (such as printing to determine whether the supplies work for a particular purpose) or if the OEM qualifies as a small business.⁵

Other Potential Chemical Regulatory Obligations

Other chemical regulatory schemes may apply. For example, some metal powders used in 3D printing, such as aluminum powder, are Chemicals of Interest (COI) subject to Chemical Facility Anti-Terrorism Standards. Any facility that stores aluminum powder above the pertinent threshold is required to complete a Top-Screen Survey and may be required to undertake various security measures.

Furthermore, standard manufacturing requirements apply to chemicals used for 3D printing. As examples, OSHA hazard communication and safety requirements may apply, and both Suppliers and OEMs may be required to report for the Toxics Release Inventory or label their products in accordance with California's Proposition 65.

Government agencies may not have developed regulations specific to materials used in 3D printing, but existing regulations already police the chemicals used in the printing process.

¹ This article does not explore the regulation of materials used for 3D printing a medical device or other item regulated by the Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act (FFDCA), because the precursors to such products are regulated by the FDA under the FFDCA—not the Environmental Protection Agency under TSCA.

² It is possible that Company B is also a manufacturer. If any chemical reactions occur during the 3D-printing process, Company B manufactured new chemical substances as a result of its processing the filament into an article. In most situations, the new chemical substances will be exempt from regulation under TSCA.

³ EPA expects to finalize these designations in February 2019.

⁴ If the Supplier manufactured the substance between June 2006 and June 2016, it was subject to a one-time reporting requirement, the deadline for which has already passed.

⁵ EPA is evaluating potential changes to the definition of a small business.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

Michael Boucher

Partner – Washington, D.C.

Phone: +1 202.624.2787

Email: mboucher@crowell.com

Amy Symonds

Counsel – Washington, D.C.

Phone: +1 202.624.2536

Email: asymonds@crowell.com