



# Graphene: Regulatory Considerations for the “Wonder Material”

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## Abstract

Graphene is the hottest area of research in nanoscience. With its incredible electrical, mechanical, and optical properties, it could be used in a variety of different products in different industries. While academic and corporate research labs around the world invest in development of graphene-based products, little attention has been devoted to the regulatory issues associated with commercialization of graphene. In this article, Matthew Kaplan and Jennifer Woloschyn review the regulation of graphene, with a focus on the Toxic Substance Control Act.

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## Graphene: What Is It?

There has been much buzz within the scientific community and popular imagination about nanoparticles and their seemingly endless uses and applications. One of the more recent wunderkinds in the world of nanotechnology is graphene, a two-dimensional allotrope composed of a single layer of carbon atoms, hexagonally arranged.<sup>1</sup> Stack several of these layers together and you have common graphite. But isolate a single layer of graphite as “graphene” and it discloses a

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<sup>1</sup> Shashi Kiran Misra and Himanshu Pandey, *Carbon Allotrope Graphene: Superstar in Nano-World*, Int'l Journal of Advances in Pharmaceutics 2 (1) 2013, available at <http://www.ijap.ssjournals.com/index.php/journal/article/view/6>.

host of unique properties.<sup>2</sup> Graphene is stronger than steel, harder than a diamond, more flexible than rubber, and more conductive than copper.<sup>3</sup> It is also extremely thin (some call it the “thinnest material on earth”), light in weight, transparent, and versatile in its applications.<sup>4</sup> While the only commercial use known to the authors is as an additive to lithium ion batteries to improve energy density, researchers are exploring dozens of other potential commercial applications, including use in transistors, television and phone screens, solar cells, DNA sequencing, and camera sensors.<sup>5</sup>

## How Is Graphene Regulated?

Given the exciting possibilities and ever expanding research into uses for graphene, it is important to consider potential regulations that may affect the manufacture or import of graphene. While it does not appear that there is any federal or state regulation that specifically identifies and addresses graphene, as a nanoscale material, graphene is likely regulated by the United States Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA). It may also be regulated under other federal laws depending on any intended future use (such as in a pesticide), but this article focuses on TSCA because it is broadly applicable to most commercial and industrial uses. California’s new Green Chemistry Initiative and Safer Consumer Products Regulations also encompass nanoscale materials, but regulation will not take effect until the California Department of Toxic Substances Control identifies specific nanomaterials in a “priority product” that it is targeting for regulation – an unlikely event for at least a couple of years given the status of the regulatory roll-out of this program.

## Regulation Under the Toxic Substances Control Act (TSCA)

TSCA governs various aspects of the use of new and existing chemical substances, including nanoscale materials. As defined by the law, a “chemical substance” is “any organic or inorganic substance of a particular molecular identity ...”<sup>6</sup> Graphene is, thus, a “chemical substance” under TSCA and subject to EPA regulation under that statute. But what does that mean?

If a chemical substance is “new” or manufactured for a “significant new use,” TSCA – in an effort to regulate both public health and environmental safety – imposes certain requirements with which

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<sup>2</sup> Jesus de La Fuente, *Graphene & Graphite – How Do They Compare?*, available at <http://www.graphenea.com/pages/graphene-graphite#>

<sup>3</sup> Mbiyimoh Ghogomu, *What’s Harder than Diamond, More Flexible than Rubber and More Conductive than Copper?*, available at <http://thehigherlearning.com/2014/01/17/graphene/>; Jiri Cervenka, *Harder than diamond, stronger than steel, super conductor ... graphene’s unreal*, available at <http://theconversation.com/harder-than-diamond-stronger-than-steel-super-conductor-graphenes-unreal-5123>.

<sup>4</sup> *Catching graphene butterflies: Dramatically changing electronic properties of world’s thinnest material*, available at <http://www.sciencedaily.com/releases/2013/05/130515131547.htm>

<sup>5</sup> Signe Brewster, *What is graphene? Here’s what you need to know about a material that could be the next silicon*, available at <http://gigaom.com/2013/07/15/what-is-graphene-heres-what-you-need-to-know-about-a-material-that-could-be-the-next-silicon/>; Nicholas Brown, *Cabot Launches First Graphene-Based Additive to Improve Energy Density of Li-ion Batteries*, available at <http://cleantechnica.com/2013/02/27/cabot-launches-first-graphene-based-additive-to-improve-energy-density-of-li-ion-batteries/>.

<sup>6</sup> 15 U.S.C. § 2602(2). “Any organic or inorganic substance of a particular molecular identity, including (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and (ii) any element or uncombined radical.”

a manufacturer or importer must comply.<sup>7</sup> Thus, when deciding whether to work with graphene, the relevant questions are: (1) is graphene a “new” chemical substance under TSCA, and (2) if not, has the EPA promulgated a “significant new use rule” for graphene that would affect manufacturing or import?

As to the first question, graphene does not appear to be a “new” chemical substance because graphite is listed on the TSCA Chemical Substance Inventory (“TSCA Inventory”). Graphite and graphene have the same molecular identity, so for purposes of TSCA’s definition of a chemical substance, graphene would not be a “new” chemical substance. An EPA guidance document published January 23, 2008 entitled “TSCA Inventory Status of Nanoscale Substances – General Approach” reinforces this conclusion as it defines graphite as “carbon atoms arranged in hexagonal sheets with each atom bonded to three other atoms in the plane of a given sheet.”<sup>8</sup>

That begs the second question: has the EPA promulgated a significant new use rule for graphite that would encompass graphene? As of right now, the answer is no.<sup>9</sup> That could change, however, if evidence is developed suggesting graphene creates a risk of harm to the public or environment.

Take carbon nanotubes (“CNTs”), for example. Scientists have been studying whether CNTs pose a potential health or environmental risk. While this research is still ongoing, researchers have expressed a variety of concerns, ranging from potential pulmonary reactions to the environmental impact of releasing CNTs into waterways.<sup>10</sup> EPA has expressed its own concern about CNTs over the years. In 2008, EPA published a report stating that it “generally considers CNTs to be chemical substances distinct from graphite or other allotropes of carbon listed on the TSCA Inventory.”<sup>11</sup> Many CNTs are thus considered “new chemicals” under TSCA Section 5, requiring manufacturers and importers to comply with TSCA’s premanufacture notice requirements.

More recently, on April 14, 2014, significant new use rules issued by EPA affecting four generic multi-walled carbon nanotubes became final. Citing concerns for “pulmonary toxicity, fibrosis, carcinogenicity, mutagenicity, and immunotoxicity” as well as potential harm from water releases, the EPA now requires any potential manufacturers or importers of these CNTs to, among other

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<sup>7</sup> 15 U.S.C. § 2604(a)(1).

<sup>8</sup> *TSCA Inventory Status of Nanoscale Substances – General Approach*, (Jan. 23, 2008), available at <http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf>

<sup>9</sup> The TSCA Inventory, which identifies “existing substances” under the law, does not include a significant new use rule for graphite. U.S. Environmental Protection Agency, *New Chemical Consent Orders and Significant New Use Rules (SNURs)*, available at <http://www.epa.gov/oppt/newchems/pubs/cnosnurs.htm>; U.S. Environmental Protection Agency, TSCA Chemical Substance Inventory, *How to Access the Inventory*, available at <http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/howto.html>

<sup>10</sup> Larry Greenemeier, *Study Says Carbon Nanotubes as Dangerous as Asbestos*, (May 20, 2008), available at <http://www.scientificamerican.com/article/carbon-nanotube-danger/>; Paulina Kociszewski, *Mesothelioma Symptoms Linked to Nanotechnology – Carbon Nanotubes*, (Feb. 12, 2013), available at <http://chemicalengineeringnews.org/mesothelioma-symptoms-linked-to-nanotechnology-carbon-nanotubes/>; Brit Liggett, *Researchers Find Carbon Nanotubes Have Harmful Effects on Waterways and Algae Health*, (Nov. 9, 2011), available at <http://inhabitat.com/researchers-find-carbon-nanotubes-have-harmful-effects-on-waterways-and-algae-health/>

<sup>11</sup> U.S. Environmental Protection Agency Notice, *Toxic Substances Control Act Inventory Status of Carbon Nanotubes*, 73 Fed. Reg. 212 (Oct. 31, 2008), available at <http://www.epa.gov/fedrgstr/EPA-TOX/2008/October/Day-31/t26026.htm>

things, use certain personal protective equipment and to avoid use of the substances in a manner that will result in surface water releases.<sup>12</sup>

These significant new use rules do not – and should not – affect the manufacture or import of graphene. While graphene is a component of a CNT and has a similar carbon structure, graphene itself is not a CNT because it has a completely different shape.<sup>13</sup> Where graphene is a flat allotrope of carbon, CNTs are allotropes of carbon with a cylindrical nanostructure.<sup>14</sup> Essentially, if you slice the cylinder vertically and lay it flat, you have a sheet of graphene.<sup>15</sup> Because it is flat, graphene has certain advantages over CNTs, including better interfacing with polymer materials and more effective crack deflection processes.<sup>16</sup>

## Future Regulation of Graphene?

Given EPA's specific regulations regarding CNTs, there is reason to believe that EPA will regulate other nanomaterials – including graphene – in a similar fashion if scientific studies suggest that there are potential health and environmental risks for a substance. In fact, EPA is currently pursuing a comprehensive regulatory approach under TSCA for nanoscale materials in an effort to protect against "unreasonable risks to health and the environment."<sup>17</sup> Now that studies are surfacing that suggest that graphene may interfere with normal cell function and may negatively impact the environment, a future with graphene-specific regulations may not be too far off.<sup>18</sup> As such, it is imperative that any potential manufacturer or importer of graphene be well aware of the TSCA's evolving nanomaterial regulations before beginning any such manufacture or import.

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<sup>12</sup> Significant New Use Rules on Certain Chemical Substances, available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2013-0739-0001>

<sup>13</sup> UnderstandingNano.com, *What is Graphene?* (excerpted from *Nanotechnology For Dummies, 2nd edition*), available at <http://www.understandingnano.com/what-is-graphene.html>

<sup>14</sup> Science Daily, *Carbon nanotube*, available at [http://www.sciencedaily.com/articles/c/carbon\\_nanotube.htm](http://www.sciencedaily.com/articles/c/carbon_nanotube.htm)

<sup>15</sup> Northwestern University Mesoscopic Physics Group, Department of Physics and Astronomy, *Carbon Nanotubes and Graphene*, available at <http://meso.phys.northwestern.edu/research/carbon-nanotubes-and-graphene>

<sup>16</sup> Rensselaer Polytechnic Institute, School of Engineering, Troy, NY, *Graphene Outperforms Carbon Nanotubes for Creating Stronger, More Crack-Resistant Materials*, available at <http://www.mse.rpi.edu/node/53>; Earl Boysen and Nancy C. Muir, *Graphene: Sheets of Carbon-based Nanoparticles*, (excerpted from *Nanotechnology For Dummies, 2nd Edition*), available at <http://www.dummies.com/how-to/content/graphene-sheets-of-carbonbased-nanoparticles.html>

<sup>17</sup> U.S. Environmental Protection Agency, *Control of Nanoscale Materials under the Toxic Substances Control Act*, available at <http://www.epa.gov/oppt/nano/>

<sup>18</sup> R. Colin Johnson, *Graphene Said to Pose Health Hazard*, (July 18, 2013), available at [http://www.eetimes.com/document.asp?doc\\_id=1318965](http://www.eetimes.com/document.asp?doc_id=1318965); George Dvorsky, *Graphene 'miracle material' could be toxic to humans*, (July 15, 2013) available at <http://io9.com/graphene-miracle-material-could-be-toxic-to-humans-786847545>; Signe Brewster, *Graphene, that magical material, might actually be bad for the environment, and you*, (April 29, 2013), available at <https://gigaom.com/2014/04/29/graphene-that-magical-material-might-actually-be-bad-for-the-environment-and-you/>