Carbon Nanotube and Fiber Policy Analysis (draft)

The Science Advisory Board (SAB) of the Toxics Use Reduction Act (TURA) recommends that multi-walled carbon nanotubes (MWCNTs), single-walled carbon nanotubes (SWCNTs) and carbon nanofibers (CNFs) be added as three distinct categories to the TURA list of Toxic or Hazardous Substances. The SAB further recommends that MWCNT be added as a Higher Hazard Substance (HHS) with a facility-reporting threshold below that of the standard HHS 1000-pound threshold.

This policy analysis summarizes key scientific information on multi-walled and single-walled carbon nanotubes and carbon nanofibers; estimates the number of facilities that are likely to enter the program because of the proposed listing; analyzes opportunities and challenges new filers are likely to face; and discusses the implications of this policy measure for the TURA program. Based on this analysis, the Toxics Use Reduction Institute (TURI) supports the SAB's recommendation that MWCNTs, SWCNTs and CNFs be added as three distinct categories to the TURA list of Toxic or Hazardous Substances. TURI also agrees with the SAB's recommendation that MWCNTs be designated as a Higher Hazard Substance (HHS) with a lower facility reporting threshold than 1000 pounds. Drawing upon research and analysis of potential users in Massachusetts, TURI recommends a one-pound threshold for MWCNT.

OVERVIEW

In June of 2020, the Toxics Use Reduction Act (TURA) Program received a petition to list multi walled carbon nanotubes (MWCNT), single walled carbon nanotubes (SWCNT), and carbon nanofibers (CNF) from Clean Water Action (CWA) and the Public Employees for Environmental Responsibility (PEER). In addition, the petition requested that MWCNT, SWCNT, and CNF be grouped together as a single category with a reporting threshold of 100g.

Listing Recommendation

After reviewing the scientific evidence about multi walled carbon nanotubes, single walled carbon nanotubes, and carbon nanofibers, the TURA Science Advisory Board (SAB) made a recommendation to list MWCNTs, SWCNTs, and CNFs as three separate categories under TURA. The SAB further recommended that MWCNTs be added as a Higher Hazard Substance (HHS).

The SAB based their recommendation for MWCNTs on evidence that exposure may be linked with pulmonary toxicity, lung cancer, mesothelioma, and environmental persistence. Additional concerns were expressed by the SAB for genotoxicity and toxic environmental degradation products. The SAB further recommended that MWCNTs be designated as Higher Hazard Substances (HHS). The recommendation to list SWCNTs was based on evidence of pulmonary toxicity and environmental persistence. The SAB also noted additional concerns for reactive oxygen species (ROS) production and DNA damage. Lastly CNFs were recommended to be listed based on pulmonary toxicity.

Threshold Recommendation

Under TURA, regularly reportable substances have a reporting threshold of 25,000 pounds if manufactured or processed and 10,000 pounds if otherwise used. SWCNTs and CNFs would have these reporting thresholds if listed.

Substances designated as HHS under TURA have a reporting threshold of 1,000 pounds. Upon recommendation of TURI and the SAB, Section 9A of the TURA statute provides the TURA Administrative Council with the authority to lower the facility-reporting threshold on a HHS[1]. Noting their carcinogenicity and that the exposure and potential associated hazard may be similar across a range of use volumes, the SAB recommended adopting a lower threshold because many companies handling MWCNTs use less than 1,000 pounds per year.

After collecting information relevant to MWCNT applications and use in Massachusetts, TURI agrees with the SAB recommendation that MWCNTs have a lower facility-reporting threshold under TURA. Based on its analysis of possible filers, TURI recommends a facility-reporting threshold of one pound. Further details on the threshold recommendation can be found in the Use Information section.

BACKGROUND ON NANOMATERIALS

Defining Carbon Nanotubes and Carbon Nanofibers

According to the International Organization for Standardization, carbon nanotubes (CNTs) are tiny tubes formed from one or several hexagonal graphene sheets consisting of carbon atoms.[2] Carbon nanotubes can be single-walled or multi-walled and can vary significantly in physical characteristics. SWCNTs often have diameters between 1 to 3 nm, MWCNTs typically range from 10-100 nm in diameter, and CNFs are usually 40 to 200 nm in diameter. Their lengths vary more widely, from tens of micrometers (µm) to several centimeters (cm).[3] The defining feature that distinguishes CNFs from CNTs resides in graphene plane alignment. If the graphene plane and fiber axis do not align, the structure is characterized as a CNF, but when parallel, the structure is considered a CNT.[4]

SUMMARY OF SCIENTIFIC INFORMATION

Nanomaterials are increasingly used in a variety of applications due to their unique properties. However, there are potential human health hazards associated with exposure to nanomaterials, particularly regarding

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[1] Massachusetts General Laws, ch. 21I, § 9A (n.d.). Retrieved April 7, 2025, from https://malegislature.gov/Laws/GeneralLaws/PartI/TitleII/Chapter21I/Section9A

[2] ISO. (2010). ISO/TS 80004-3:2010 Nanotechnologies — Vocabulary — Part 3: Carbon nano-objects. International Organization for Standardization

[3] United States Department of Health and Human Services, Centers for Disease Control, National Institute for Occupational Safety and Health, Current Intelligence Bulletin 65: Occupational Exposure to Carbon Nanotubes and Nanofibers, April 2013.

[4] ISO/TS [2008]. Nanotechnologies: terminology and definitions for nano-object; nanoparticle, nanofibre and nanoplate. ISO/TS 27687:2008. International Organization for Standardization.

respiratory health. The summary here draws upon the literature reviewed by the SAB. A complete list of these references is provided in the annex.

Pulmonary Toxicity

Pulmonary toxicity is a major health concern for all carbon nanotubes and fibers. Extremely small, with diameters on the order of nanometers, they are easily airborne, creating the risk of human exposure through inhalation. When inhaled, they can penetrate deep into the lungs and cause damage to the respiratory system. The thin, needle-like shape of the nanotubes can cause inflammation, scarring, and even cancerous growths in the lungs. Additionally, they can cross the lung-blood barrier and travel to other organs, potentially damaging the liver, spleen, or other organs. They have a tendency to biopersist in tissues and can remain in the body for significant periods of time.

In addition to their size and shape, other properties of nanomaterials may contribute to their respiratory toxicity. For example, some studies have suggested that the surface area and surface chemistry of nanomaterials can affect their ability to cause lung damage. Some may also contain impurities or other substances that can exacerbate their toxicity.

Several studies have documented that exposure to MWCNTs may cause damage to the pulmonary region resulting in fibrosis, granuloma, mesothelioma, and lung cancer. The International Agency for Research on Cancer (IARC) classified MWCNT-7 as Class 2B Possible Carcinogen. MWCNT-7 is widely used and the most well studied MWCNT. It has been linked to mesothelioma and bronchioloalveolar carcinoma.

Animal studies have shown that inhalation of SWCNTs can lead to lung cancer in some cases. While there are limited data on the long-term effects of SWCNT exposure in humans, these materials have the potential to cause respiratory toxicity. Occupational health agencies indicate that they should be handled with caution to minimize exposure.

While limited, existing data on the pulmonary toxicity of CNFs suggests adverse health effects similar to CNTs. NIOSH recommends that all types of CNTs and CNFs should be considered a respiratory hazard.

Genotoxicity

MWCNTs and SWCNTs have been linked to genotoxicity in several in vitro studies. These studies have shown that exposure to MWCNTs and SWCNTs can cause DNA damage, oxidative stress, inflammation, and micronuclei formation. Studies have shown that prolonged exposure to MWCNTs can also cause oxidative stress and inflammation in the body, leading to various health problems such as cardiovascular disease.

Environmental

A primary environmental concern for carbon nanotubes and fibers is their persistence in biological systems, and in the environment where they do not readily break down. Several studies of MWCNT show effects on fish and other biota.

USE INFORMATION

This section summarizes a comprehensive review undertaken by TURI and OTA to identify where carbon nanomaterials are used in Massachusetts and their applications. It draws upon literature review, industry and government databases, market research, surveys and interviews.

Common Applications in Massachusetts

Due to their unique mechanical and chemical properties, carbon nanomaterials have a wide variety of applications. Some uses relevant to Massachusetts are reviewed below.

Research and Development

Given its status as a research hub, a large share of carbon nanomaterial use in Massachusetts likely occurs in research and development (R&D) settings. Under TURA, there are exemptions that often apply to companies or other entities carrying out R&D activities. A "Toxics user" only includes facilities classified in certain SIC codes (or the corresponding NAICS code). The list of such facilities does not include "Testing Labs (SIC Code 8734)" or "Commercial Physical and Biological Research (SIC Code 8731)". Also, facilities using carbon nanomaterials strictly in laboratory settings, for example in a quality control laboratory, would not be subject to reporting for that substance.

TURI and OTA's research suggests that a significant number of facilities using carbon nanomaterials in Massachusetts likely fall under these exemptions. Inventories carried out in Cambridge, MA and Berkeley, CA identified many facilities using nanomaterials in conditions potentially consistent with TURA's R&D exemptions[5]. A nationwide review carried out in 2007 by The Woodrow Wilson Institute's Project on Emerging Nanotechnology found many users in Massachusetts to be universities, government organizations, hospitals and analytical laboratories, all of which typically do not have associated SIC codes covered by TURA[6].

The benefits of TURA often extend to businesses that are exempt. Many companies seek the services of the TURA Program to adopt safer alternatives to toxic substances despite not being required to report. Furthermore, the R&D stage is widely recognized as an efficient and effective entry point for applying the principles of Toxics Use Reduction, as making process changes is typically more difficult once manufacturing begins.

Nanocomposite Materials

Lightweight and exceptionally strong, carbon fiber composite materials have been used for many years in sectors such as aerospace and sporting equipment (e.g. tennis rackets, bikes, golf clubs, and hockey sticks). Composite materials are created by dispersing the carbon nanofibers into a polymer matrix. Demand for these composites is increasing, for example for use in clean energy devices (wind turbines, fly wheels) and in automobile components. Composites reinforced with CNTs are seen by some as the next generation high-performing carbonaceous materials[7]. Carbon nanotubes may also be incorporated into polymers used for food packaging. Their presence can improve the antimicrobial properties of the packaging, or act as sensors that detect spoilage[8].

[5] Bosso, Christopher and McAllister, Caitlin, Local Government and Conditions of Uncertainty: Cambridge and the Regulation of Nanomaterials (June 18, 2010). Available at SSRN: https://ssrn.com/abstract=2443105 or http://dx.doi.org/10.2139/ssrn.2443105
[6] Project on Emerging Nanotechnologies. (n.d.). US NanoMetro Map. Retrieved from Internet Archive website: https://web.archive.org/web/20200327160519/http://www.nanotechproject.org/inventories/map/ on April 4, 2025
[7] Peijs, T., Kirschbaum, R., & Lemstra, P. J. (2022). A critical review of carbon fiber and related products from an industrial perspective. *Advanced Industrial and Engineering Polymer Research, 5*(2), 90-106. https://doi.org/10.1016/j.aiepr.2022.03.008
[8] Ashfaq, A., Khursheed, N., Fatima, S., Anjum, Z., & Younis, K. (2022). Application of nanotechnology in food packaging: Pros and cons. Journal of Agriculture and Food Research, 7, 100270. https://doi.org/10.1016/j.jafr.2022.100270

Pharmaceutical and Biomedical

Particularly relevant to Massachusetts is the application of carbon nanomaterials in the pharmaceutical and biomedical fields. Their unique properties make them promising for medical applications such as drug delivery, biosensing and tissue engineering. The high surface area of CNTs and their ability to penetrate cell walls naturally lends itself to drug delivery, but their toxicity is of serious concern. CNF synthesis methods allow for easier functionalization, leading to increased interest in their use as biosensors and for tissue engineering[9].

Electronics, computing and batteries

The electrical and directional thermal conductivity of CNTs make them attractive for a range of applications in electronic devices. They have been implemented and studied in electrochemical energy storage systems, for example, as electrodes for lithium-ion batteries or fuel cells[10]. CNTs have also emerged as a potential alternative to silicon as a transistor material in next generation integrated circuits[11]. CNT chemical solutions are already being used in MA within components of high performing memory devices[12]. Finally, CNTs are attractive for use as chemical sensors which can be helpful for environmental and health monitoring[13].

Carbon Nanomaterial Users in Massachusetts - Results

TURI was able to produce a broad, non-comprehensive list of approximately 300 facilities that appear to manufacture or use nanomaterials (including materials that are not CNTs and CNFs) within Massachusetts. The research leading to this list was based upon publicly available information and databases along with preliminary work from the Office of Technical Assistance (OTA).

Once the list of facilities likely using nanomaterials within Massachusetts was compiled, the website of each company was visited to identify its category of industry, the specific nanomaterial(s) it is likely to be using, as well as the specific products it makes or distributes. In addition, a database search using EBSCO[14] information services was conducted to identify common uses of nanomaterials within each industry. This allowed for the creation of a list of possible nanomaterials used, and possible uses for the list of identified companies. An appendix to this policy analysis outlines in more detail the methodology used to identify potential companies in Massachusetts that use CNFs and CNTs.

After removing facilities that use nanomaterials that are not carbon based or are not in TURA SIC codes (e.g. R&D), eight companies in Massachusetts were identified as likely using CNTs and CNFs in Massachusetts. An additional 36 companies were identified as possibly using CNTs and CNFs in Massachusetts. Table 1 summarizes the information gathered on companies that are either likely or possibly using CNTs and CNFs in Massachusetts, and what they may be using them for.

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[9] Gaur, M., Misra, C., Yadav, A. B., Swaroop, S., Maolmhuaidh, F. Ó., Bechelany, M., & Barhoum, A. (2021). Biomedical Applications of Carbon Nanomaterials: Fullerenes, Quantum Dots, Nanotubes, Nanofibers, and Graphene. Materials (Basel, Switzerland), 14(20), 5978. https://doi.org/10.3390/ma14205978

[10] Shoukat, R., Khan, M.I. Carbon nanotubes: a review on properties, synthesis methods and applications in micro and nanotechnology. Microsyst Technol 27, 4183–4192 (2021). https://doi.org/10.1007/s00542-021-05211-6

[11] Sandalow, B. (2022, November). Looking to the future of carbon nanotube transistors. Northwestern Engineering News. https://www.mccormick.northwestern.edu/news/articles/2022/11/looking-to-the-future-of-carbon-nanotube-transistors/ (Accessed April 9, 2025).

[12] Nantero Carbon NanoTechnology. https://www.nantero.com/technology/. (Accessed May 21, 2024)

[13] Vera Schroeder, Suchol Savagatrup, Maggie He, Sibo Lin, and Timothy M. SwagerChemical Reviews 2019 119 (1), 599-663 DOI: 10.1021/acs.chemrev.8b00340

[14] EBSCO. (n.d.). Research databases. EBSCO. https://www.ebsco.com/products/research-databases. (Accessed April 9, 2025)

Table 1: Identified Likely and Possible Users of CNT and CNF in MA

Industry	***# of companies with likely use***/*# of companies with possible use*	***Nanomaterial***	***Uses*** ***(*Definitive application in MA)***	***Estimated Use Volume (per facility)***
Electronics and Computing	**4**/3	CNT, CNF	**Electronics** (semiconductors, *Memory RAMS, *Optical Devices) **Computers** (*Semiconductors, computer chips, *quantum computers, display panels)	**1-100 lb**
Advanced Materials	**1**/3	CNF	**Carbon Fiber Flywheel: Storage of Kinetic Energy** (composite rim core) **Protective Equipment** **Aerospace** (*Thrusters) **Specialty Paper Manufacturing** (Activated Carbon and Filter paper)	**500-5,000 lb**
Batteries	**0**/8	CNT, CNF	**Lithium-Ion Batteries** (Anode materials)	
Food Packaging/ Plastics	**0**/9	CNT	**Structural Pieces** (incorporated into synthetic polymer matrix to provide strength and antimicrobial properties), **Sensors** (Spoilage detection) ***Plastics**	
Sensor Manufacturers	**1**/8	SWCNT	**Gas Sensors** (*Sensing element), **Temperature Sensors** (sensing element), **Pressure Sensors** (sensing element), **Humidity Sensors** (sensing element), **Electrochemical Biosensors** (sensing element)	**0.25-2 lbs**
Sports Equipment Manufacturers	**0**/1	CNT	**Sports Surfaces/Tracks/Courts** (synthetic rubber)	
Biopharmaceutical	**0**/4	CNT	**Chromatography Columns** , **Spectroscopy** (1 dimensional systems), **Pharmaceuticals** (sustained - release drugs)	
Nanomaterial Manufacturing	**2/0**	SWCNT, MWCNT	***Fullerenes** ***Fullerene Derivatives** ***Carbon Nanotubes**	**1,000-5,000 lbs**
Total	**8/36**			

Carbon Nanomaterial Users in Massachusetts - Discussion

Of the eight companies identified as "likely users" in Table 1, two are manufacturers of carbon nanomaterials and six use carbon nanomaterials to manufacture other products, such as sensors, semi-conductor components, and advanced composite materials.

Potential users, for example in food packaging, lithium-ion batteries, biopharmaceuticals and sports equipment, may be subject to TURA filing and planning as well. Furthermore, due to MA's status as a carbon nanomaterial research hub, some users of carbon nanomaterials may not fall under the SIC codes indicated in the TURA statute.

Carbon Nanomaterial Users in Massachusetts – Threshold Discussion

The TURA statute, upon the recommendation of TURI and the SAB, provides the TURA Administrative Council with the authority to lower the facility-reporting thresholds for a Higher Hazard Substance. The SAB recommended a lowered reporting threshold for MWCNT.

Based on its extensive research of MWCNT use, TURI agrees with the SAB recommendation to lower the reporting threshold, and suggests a one-pound threshold. Otherwise, it is likely that the TURA reporting and planning requirements would not apply to most, if not all, MWCNT users in Massachusetts. TURI's research on quantities of MWCNT use included reviews of global nanomaterial inventories and regulatory databases, market research and interviews with government officials. When data was available, it often suggested that facilities were using MWCNT in quantities far below the 1000-pound HHS threshold. As shown in Table 1, when CNTs are being used in Massachusetts, there is limited public information about whether these CNTs are MWCNTs or SWCNTs. In addition, there is often no information on the quantity being used.

There is precedence for adopting lower reporting thresholds for CNTs and CNFs. An EPA rule requires lower reporting thresholds under EPCRA section 313 for Persistent, Bioaccumulative and Toxic (PBT) substances[15]. The research reviewed by the SAB included evidence of persistence, biopersistence, and toxicity of CNTs and CNFs. The French National Registry for Nanomaterials[16] and an inventory conducted by the Belgian government both required entities to report their use of nanomaterials in quantities greater than 100 grams/year[17]. Under these inventories several entities have reported CNT use in the 100-gram range.

A one-pound threshold would capture a reasonable portion of MWCNT users in Massachusetts resulting in improved public access to valuable information. As mentioned above, it is prohibitively difficult to find detailed information on MWCNT use and release. TURA has demonstrated that access to this type of information empowers communities, companies and governments to strengthen protection of worker and public health. Additional knowledge on where MWCNTs are used would be particularly valuable to municipal emergency responders and planners so that they can respond safely when issues arise.

A lower threshold would connect more MA companies with TURA program services such as free performance testing, confidential on-site visits and the TURI grant program. Businesses reporting MWCNT use would become subject to toxics use reduction (TUR) planning requirements. The TUR planning process has shown to

[15] U.S. Environmental Protection Agency. (1999). EPA final rule: TRI reporting for persistent bioaccumulative toxic (PBT) chemicals (EPA 745-F-99-002). https://www.epa.gov/sites/default/files/documents/pbtrule-fs.pdf. (Accessed April 7, 2025)

[16] R-Nano. (n.d.). The French national registry for nanomaterials. https://www.r-nano.fr/?locale=en. (Accessed April 7, 2025.)

[17] Belgian Federal Public Service Health, Food Chain Safety and Environment. (n.d.). Register of nanomaterials. https://www.health.belgium.be/en/environment/chemical-substances/nanomaterials/register. (Accessed April 7, 2025.)

reveal opportunities for innovation which save money while reducing the use of toxics. On-site technical assistance, which would become available for TURA filers using MWCNTs, has also proven to help companies identify and implement TUR opportunities that protect workers and promote efficient use of resources.

TOXICS USE REDUCTION (TUR) FOR CARBON NANOMATERIALS

The Toxics Use Reduction (TUR) Approach

Toxics Use Reduction is a best practice for advancing innovations to fulfill societal needs, while reducing negative impacts on human health and the environment. The pyramid in Figure 1 illustrates a pollution prevention hierarchy with TUR efforts prioritizing elimination and substitution followed by engineering controls. Minimizing the use of toxic substances upstream is often the most efficient approach to reducing harmful pollution.

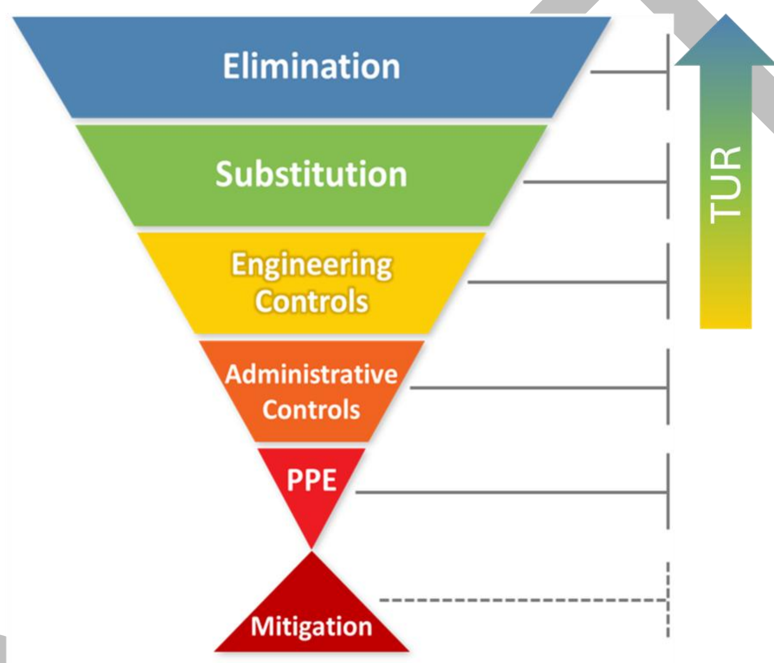

Figure 1: The Occupational Safety and Health Administration's Hierarchy of Controls[18]

Advancing Safer Alternatives under TURA

Due to their groundbreaking applications, TUR opportunities for carbon nanomaterials are unique with many relevant technologies still in early research stages. It is important to recognize that the availability of alternatives is not a pre-requisite for addition to the TURA list of toxic substances. Nonetheless, there are opportunities for continued research and development of alternatives, and safer by design strategies to reduce negative impacts of CNTs and CNFs without sacrificing their properties and societal benefits.

Adding substances to the TURA list has proven to support the development and implementation of TUR innovations. In 2022, the Certain PFAS Not Otherwise Listed category was added to the TURA list of Toxic Substances. Research conducted by TURA program agencies on TUR opportunities, and the establishment of relationships between companies using PFAS have helped to advance safer solutions. A collaboration between

[18] Occupational Safety and Health Administration. (2023). Identifying hazard control options: The hierarchy of controls. U.S. Department of Labor. https://www.osha.gov/sites/default/files/Hierarchy_of_Controls_02.01.23_form_508_2.pdf (Accessed April 8, 2025)

TURI and the microelectronics company Transene resulted in the elimination of PFAS from a key product formulation[19]. As with PFAS, listing carbon nanomaterials would result in access to valuable reporting data and the development of TUR plans. TURA program services such as research grants, access to laboratory infrastructure and free confidential on-site assistance would also be prioritized to MA businesses using these substances.

The experience of TURA is not isolated. Research shows that stricter laws on the use of toxic substances often trigger the invention, development and adoption of safer alternatives. A landscape analysis of patents for alternatives to toxic substances shows a clear correlation between the invention of alternatives to toxic substances and the development of European legislation for toxic chemicals. The study demonstrates the potential of stronger laws to spark the invention and disclosure of alternatives, to pull safer alternatives into the market, and thus to drive innovation[20]. As has been demonstrated with many other toxic substances, listing carbon nanomaterials under TURA has the potential to further accelerate innovation in Massachusetts.

Opportunities for TUR

This section provides an overview of key TUR options related to the use of carbon nanomaterials. It aims to strike a balance between maintaining the societal benefits which these materials can provide, while ensuring they do not harm human health and the environment.

Considering the need

A helpful first step when identifying TUR opportunities for carbon nanomaterials is to assess whether their use is truly necessary. The use of CNTs and CNFs in certain applications that have exposure risks and in which the main benefit is questionable, could be deemed unnecessary[21] and avoided by users.

An in-depth alternatives assessment comparing performance, cost and safety may reveal benefits associated with switching away from carbon nanomaterials. Flywheels are an important energy storage device, and sometimes contain components that incorporate CNTs or CNFs to leverage their unique mechanical properties. One line of research is exploring the use of laminated steel for cheaper and more compact flywheels[22].

Alternatives to Carbon Nanomaterials

Given their evolving applications and unique properties, there are relatively few potential alternatives to carbon nanomaterials. However, there are some lines of research looking for alternative materials which retain performance while possibly reducing toxicity. Similar nanostructures based on bio feedstocks have been

[19] Transene Company Eliminates its Use of PFAS and Saves Money (2023). TURI Case Study. https://www.turi.org/transene-company-eliminates-its-use-of-pfas-and-saves-money-case-study-2023/ (Accessed April 7, 2025)
[20] Tuncak, Baskut. "Driving Innovation: How Stronger Laws Pull Safer Chemicals into the Market." Sustainable Development Law & Policy 14, no. 3 (2014): 4-11, 44-46. https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?params=/context/sdlp/article/1549/&path_info=tuncak.pdf (Accessed April 6, 2025)
[21] Bilal, M., & Iqbal, H. M. N. (2020). New Insights on Unique Features and Role of Nanostructured Materials in Cosmetics. Cosmetics, 7(2), 24. https://doi.org/10.3390/cosmetics7020024
[22] Olabi, A. G., Wilberforce, T., Abdelkareem, M. A., & Ramadan, M. (2021). Critical Review of Flywheel Energy Storage System. Energies, 14(8), 2159. https://doi.org/10.3390/en14082159

explored for use in reinforcing concrete[23], in sporting equipment[24], and in load-bearing automotive components[25].

Along with potential for improved biocompatibility, polypeptide nanotubes sourced from food proteins have exhibited certain advantages over their purely carbonaceous counterparts[26,27]. Boron Nitride nanotubes are of interest due to their superior thermo-mechanical stability[28]. While many of these alternatives are attractive for their potential for reduced cost and sustainable feedstock sources, they have not been thoroughly evaluated from a human health and safety perspective. Such an evaluation is a pre-requisite before determining if they are viable alternatives.

Safer by Design Carbon Nanomaterials

TUR actions can be taken which reduce the hazards of nanomaterials, without compromising their properties. This section will introduce lines of research related to modifying the toxicity and exposure potential of CNTs and CNFs along their lifecycle. It is important to note that at present a key obstacle for many of these safer by design approaches is their scalability and how they impact functionality.

Biodegradability

Due to their rigid and strong structure, CNTs are particularly persistent in both the human body and the environment. The biodegradability of carbon nanomaterials is therefore particularly relevant to the biomedical field, a key sector in MA[29]. Approaches are being studied to ensure carbon nanomaterials can biodegrade in a timely and safe manner, thus reducing their potential to accumulate in the human body and environment.

Functionalization of the CNTs can accelerate their elimination from the human body and the environment, for example, studies have observed certain coatings can invoke positive immune responses towards the elimination of the CNTs from the body. SWCNTs treated with hydrogen peroxide biodegrade more rapidly than the non-treated material[30]. Grafting carbon nanotubes onto small organic molecules may also reduce the

[23] El-Feky, M. S., El-Tair, A. M., Kohail, M., & Serag, M. I. (2019). Nano-fibrillated cellulose as a green alternative to carbon nanotubes in nano-reinforced cement composites. International Journal of Innovative Technology and Exploring Engineering, 8(12), 484-491. https://doi.org/10.35940/ijitee.L3377.1081219

[24] Wu, Y., Gao, X., Nguyen, T. T., Wu, J., Guo, M., Liu, W., & Du, C. (2022). Green and Low-Cost Natural Lignocellulosic Biomass-Based Carbon Fibers—Processing, Properties, and Applications in Sports Equipment: A Review. Polymers, 14(13), 2591. https://doi.org/10.3390/polym14132591

[25] Anwer, A. H., Ahtesham, A., Shoeb, M., Mashkoor, F., Ansari, M. Z., Zhu, S., & Jeong, C. (2023). State-of-the-art advances in nanocomposite and bio-nanocomposite polymeric materials: A comprehensive review. Advances in Colloid and Interface Science, 318, 102955. https://doi.org/10.1016/j.cis.2023.102955

[26] Katouzian, I., & Jafari, S. M. (2019). Protein nanotubes as state-of-the-art nanocarriers: Synthesis methods, simulation, and applications. Journal of Controlled Release, 303, 302-318. https://doi.org/10.1016/j.jconrel.2019.04.026

[27] Praveena, G., Kolandaivel, P., Santhanamoorthi, N., Renugopalakrishnan, V., & Ramakrishna, S. (2007). Looking beyond carbon nanotubes: polypeptide nanotubes as alternatives?. Journal of nanoscience and nanotechnology, 7(7), 2253–2259. https://doi.org/10.1166/jnn.2007.649

[28] Kim, J.H., Pham, T.V., Hwang, J.H. et al. Boron nitride nanotubes: synthesis and applications. Nano Convergence 5, 17 (2018). https://doi.org/10.1186/s40580-018-0149-y

[29] Chen, M., Qin, X., & Zeng, G. (2017). Biodegradation of carbon nanotubes, graphene, and their derivatives. Trends in Biotechnology, 35(9), 836-846. https://doi.org/10.1016/j.tibtech.2016.12.001

[30] Bianco, A., Kostarelos, K., & Prato, M. (2011). Making carbon nanotubes biocompatible and biodegradable. Chemical Communications, 47(37), 10182-10188. https://doi.org/10.1039/C1CC13011K

persistence of CNTs in cells[31]. As the functionalization will also likely modify the CNTs' hazard profile, it is important to evaluate this prior to assuming it (and its degradation products) will be a safer alternative.

Morphology

Countless structures of CNTs and CNFs exist and continue to be invented. While this is of concern for tracking their fate and toxicological properties, modifications to the shape or structure of carbon nanomaterials can sometimes reduce their hazards. For example, studies have shown that longer MWCNTs provoked greater inflammatory responses in the lungs[32]. In general, nanoparticles with a diameter less than 20 nm can permeate skin[33]. However, larger diameters do not exclude possible exposures, as the carbon nanofibers can split into smaller fragments[34]. Using more flexible CNTs has also been recommended as a measure to reduce the risk of mesothelioma[35].

The structure of the nanomaterial itself can also be considered when looking to improve human health outcomes. For example, CNFs have been found to exhibit stronger cytotoxicity than SWCNTs[36]. Different morphologies may also reduce potential for worker exposures during processing. As is the case with carbon nanoribbons (a monolayer of graphite patterned into a narrow strip) which, unlike nanotubes, can be inserted into electronic components using lithography rather than manual placement[37]. A life-cycle assessment is thus important when considering alternative structures in product design, or for manufacturing.

Treatment and Processing

Carbon nanomaterials can undergo treatments, during or after processing, which may serve to reduce their toxicity or other concerning properties. For example, certain CNT coatings may inhibit their tendency to cause lung fibrosis[38] or CNFs oxidized in air at 800°C exhibited lower genotoxicity[39]. Grafting the nanomaterials onto biocompatible films or small organic materials have also been reported to neutralize certain toxic properties

[31] Reijnders, L. (2020). Chapter 10 - Safer-by-design for nanomaterials. In S. Rajendran, A. Mukherjee, T. A. Nguyen, C. Godugu, & R. K. Shukla (Eds.), Nanotoxicity (pp. 215-237). Elsevier. https://doi.org/10.1016/B978-0-12-819943-5.00010-5

[32] Oberdörster, G., Castranova, V., Asgharian, B., & Sayre, P. (2015). Inhalation Exposure to Carbon Nanotubes (CNT) and Carbon Nanofibers (CNF): Methodology and Dosimetry. Journal of Toxicology and Environmental Health, Part B, 18(3–4), 121–212. https://doi.org/10.1080/10937404.2015.1051611

[33] Larese Filon, F., Mauro, M., Adami, G., Bovenzi, M., & Crosera, M. (2015). Nanoparticles skin absorption: New aspects for a safety profile evaluation. Regulatory Toxicology and Pharmacology, 72(2), 310-322. https://doi.org/10.1016/j.yrtph.2015.05.005

[34] Wang, J., Schlagenhauf, L. & Setyan, A. Transformation of the released asbestos, carbon fibers and carbon nanotubes from composite materials and the changes of their potential health impacts. J Nanobiotechnol 15, 15 (2017). https://doi.org/10.1186/s12951-017-0248-7

[35] Bhattacharya, K., Mukherjee, S. P., Gallud, A., Burkert, S. C., Bistarelli, S., Bellucci, S., Bottini, M., Star, A., & Fadeel, B. (2016). Biological interactions of carbon-based nanomaterials: From coronation to degradation. Nanomedicine: Nanotechnology, Biology and Medicine, 12(2), 333–351. https://doi.org/10.1016/j.nano.2015.11.011

[36] Kisin, E. R., Murray, A. R., Sargent, L., Lowry, D., Chirila, M., Siegrist, K. J., Schwegler-Berry, D., Leonard, S., Castranova, V., Fadeel, B., Kagan, V. E., & Shvedova, A. A. (2011). Genotoxicity of carbon nanofibers: Are they potentially more or less dangerous than carbon nanotubes or asbestos? Toxicology and Applied Pharmacology, 252(1), 1-10. https://doi.org/10.1016/j.taap.2011.02.001

[37] B. Obradovic et al., "Carbon Nanoribbons: An Alternative to Carbon Nanotubes," 2006 International Conference on Simulation of Semiconductor Processes and Devices, Monterey, CA, USA, 2006, pp. 27-30, doi: 10.1109/SISPAD.2006.282830.

[38] Reijnders, L. (2020). Chapter 10 - Safer-by-design for nanomaterials. In S. Rajendran, A. Mukherjee, T. A. Nguyen, C. Godugu, & R. K. Shukla (Eds.), Nanotoxicity (pp. 215-237). Elsevier. https://doi.org/10.1016/B978-0-12-819943-5.00010-5

[39] Yadav, D., Amini, F., & Ehrmann, A. (2020). Recent advances in carbon nanofibers and their applications – A review. European Polymer Journal, 138, 109963. https://doi.org/10.1016/j.eurpolymj.2020.109963

of CNTs[40]. A review of CNT functionalization approaches to reduce their toxicity are explained in Vardharajula, 2012[41].

Ensuring the composition and purity of carbon nanomaterial products is also key to minimizing concerns for human health and the environment. The presence of transition metal contaminants which originate from the catalyst is suspected to increase their genotoxicity. Therefore, post-processing purification techniques, or replacing the metal catalysts with safer alternatives could eliminate these metal contaminants[42].

Safer Manufacturing and Product Design

As a persistent substance, it is important to understand exposures and TUR opportunities associated with each stage of the carbon nanomaterial life cycle. For example, unintended releases of carbon nanomaterials, as in the case of tire wear and the use of crumb rubber in synthetic turf[43], may occur during use. Batteries and nanocomposite materials, the sectors responsible for the majority of CNT use in industry[44]., present end-of-life concerns despite low potential for exposure during the use phase[45]. At end-of-life these materials are often landfilled, incinerated or exported to developing countries with reduced waste management capacity, sometimes becoming an environmental justice issue.

Innovations and product and process design have proven to reduce releases of nanomaterials along their life cycle with many showing potential for TUR. This section provides an overview of these lines of research and provides examples of innovations which may align with established TUR techniques.

Product Design

Product design offers opportunities to reduce use while improving safety during product use, manufacturing and at end-of-life. When using polymer-nanomaterial composites, measures can be taken to inhibit the release of the nanomaterial from the matrix[46]. The retro Diels-Alder reaction has been used on nanocomposites to enhance their durability and integrity[47]. Designing products, especially electronic devices, for easier disassembly and safer end-of-life management can allow for TUR through integrated recycling systems[48].

[40] Reijnders, L. (2020). Chapter 10 - Safer-by-design for nanomaterials. In S. Rajendran, A. Mukherjee, T. A. Nguyen, C. Godugu, & R. K. Shukla (Eds.), Nanotoxicity (pp. 215-237). Elsevier. https://doi.org/10.1016/B978-0-12-819943-5.00010-5

[41] Vardharajula, S., Ali, S. Z., Tiwari, P. M., Eroğlu, E., Vig, K., Dennis, V. A., & Singh, S. R. (2012). Functionalized carbon nanotubes: biomedical applications. International journal of nanomedicine, 7, 5361–5374. https://doi.org/10.2147/IJN.S35832

[42] Reijnders, L. (2020). Chapter 10 - Safer-by-design for nanomaterials. In S. Rajendran, A. Mukherjee, T. A. Nguyen, C. Godugu, & R. K. Shukla (Eds.), Nanotoxicity (pp. 215-237). Elsevier. https://doi.org/10.1016/B978-0-12-819943-5.00010-5

[43] Watterson, A. (2017). Artificial Turf: Contested Terrains for Precautionary Public Health with Particular Reference to Europe? International Journal of Environmental Research and Public Health, 14(9), 1050. https://doi.org/10.3390/ijerph14091050

[44] Kim, M., Goerzen, D., Jena, P.V. et al. Human and environmental safety of carbon nanotubes across their life cycle. Nat Rev Mater 9, 63–81 (2024). https://doi.org/10.1038/s41578-023-00611-8

[45] Ibid.

[46] Reijnders, L. (2008). Hazard reduction in nanotechnology. Journal of Industrial Ecology, 12(3), 297-306. https://doi.org/10.1111/j.1530-9290.2008.00049.x

[47] Li, Q. T., Jiang, M. J., Wu, G., Chen, L., Chen, S. C., Cao, Y. X., & Wang, Y. Z. (2017). Photothermal Conversion Triggered Precisely Targeted Healing of Epoxy Resin Based on Thermoreversible Diels-Alder Network and Amino-Functionalized Carbon Nanotubes. ACS applied materials & interfaces, 9(24), 20797–20807. https://doi.org/10.1021/acsami.7b01954
nanotubes, Appl. Mater. (2017) 2079720807.

[48] Bigum, M., Brogaard, L., & Christensen, T. H. (2012). Metal recovery from high-grade WEEE: a life cycle assessment. Journal of hazardous materials, 207-208, 8–14. https://doi.org/10.1016/j.jhazmat.2011.10.001

Process Design

Process innovations have been implemented which reduce use of nanomaterials during manufacturing and the associated risk for workers. Engineering controls, such as in-situ synthesis of nanomaterials on their substrates[49], can promote efficient use while reducing opportunities for exposure.

Under the European NANoREG and Prosafe projects, a safer-by-design approach was developed for nanomaterials. It was implemented to create six industrial case studies, many containing examples of TUR-relevant techniques. An electronic coatings company participating in the project used wet synthesis, recycling and automated packaging to reduce exposure and byproduct generation of a carbon nanomaterial. Another company that manufactures materials for automobile parts tested three different CNFs and chose the material with the least toxicity. They also switched to a fully automated dispersion system, a technique that may be considered improved operations and maintenance under TURA[50].

REGULATORY CONTEXT

Carbon Nanotubes Regulations (CNT) and Guidance Review

Due to the evolving understanding of carbon nanomaterial applications, and their effects on human and environmental health, a number of regulatory and non-regulatory frameworks are in place or under development. This review includes broader regulations on manufactured nanomaterials, as well as those which specifically cover CNTs and CNFs. Regulations are evolving, as research continues to uncover potential risks and applications.

International Organizations

The Organization for Economic Cooperation and Development (OECD)

The OECD is carrying out a strategic program on the safety evaluation and risk assessment of manufactured nanomaterials to assist countries in the implementation of national policies. The program focuses on generating appropriate methods and strategies to ensure potential safety issues through the following:[51]

- Establishing an OECD database on manufactured nanomaterials to inform and analyze research activities and strategies on environmental, human health and safety issues;
- Testing specific nanomaterials for their human health and safety evaluation, while ensuring appropriate testing methods (in vivo & in vitro);
- Promoting co-operation on voluntary schemes and regulatory programs;
- Facilitating international co-operation on risk assessment strategies;
- Developing guidance on exposure measurement and exposure mitigation (workplace; consumers; and the environment); and

[49] Reijnders, L. (2020). Chapter 10 - Safer-by-design for nanomaterials. In S. Rajendran, A. Mukherjee, T. A. Nguyen, C. Godugu, & R. K. Shukla (Eds.), Nanotoxicity (pp. 215-237). Elsevier. https://doi.org/10.1016/B978-0-12-819943-5.00010-5
[50] Sánchez Jiménez, A., Puelles, R., Pérez-Fernández, M., et al. (2020). Safe(r) by design implementation in the nanotechnology industry. NanoImpact, 20, 100267. https://doi.org/10.1016/j.impact.2020.100267
[51] Organisation for Economic Co-operation and Development. (n.d.). Nanomaterials and advanced materials. OECD. https://www.oecd.org/en/topics/nanomaterials-and-advanced-materials.html. (Accessed April 9, 2025)

- Promoting the environmentally sustainable use of nanotechnology through enhancing the knowledge base about life cycle aspects of manufactured nanomaterials. This should be done at their different stages of development and applications regarding the impacts on human health and environmental safety.

The OECD series on the safety of manufactured nanomaterials includes reports on both SWCNT and MWCNT. They contain information on physical and chemical properties, exposure, hazards and toxicology[52,53].

Strategic Approach to International Chemicals Management (SAICM) / Global Chemicals Framework

"Nanotechnology and manufactured nanomaterials" was designated an emerging policy issue at the second session of the International Conference on Chemicals Management (ICCM) in 2009. Stakeholders stressed the need to close knowledge gaps; to understand, avoid, reduce and manage risks; and to review the methods used for testing and assessing safety[54]. Subsequently, the topics were included under the SAICM Global Plan of Action.

Under the Global Framework on Chemicals, of which SAICM is a predecessor, The International Conference on Chemicals may adopt issues of concern, such as nanomaterials. Among other actions, the adoption of issues of concern will result in the formation of an ad-hoc working group which can recommend courses of action to address these issues[55].

World Health Organization (WHO)

A report titled "*Guidelines on protecting workers from potential risks of manufactured nanomaterials*" was published by WHO in February 2017. The guidelines are aimed at policymakers and professionals in the field of occupational health and safety with recommendations on how best to protect workers from the potential risks of manufactured nanomaterials[56].

In collaboration with the Food and Agriculture Organization, WHO published a technical paper in 2013 titled "State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors" [57]

US Federal

TSCA (Recordkeeping)

As of May 2017, the EPA has reporting and recordkeeping requirements for certain chemical substances when they are manufactured or processed at the nanoscale (forms with particle sizes of 1-100 nm). This does not

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[52] OECD (2016), Single Walled Carbon Nanotubes (SWCNTs): Summary of the Dossier, OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, OECD Publishing, Paris, https://doi.org/10.1787/cd95c45f en.

[53] OECD (2016), Multiwalled Carbon Nanotubes (MWCNT): Summary of the Dossier, OECD Series on the Safety of Manufactured Nanomaterials and other Advanced Materials, OECD Publishing, Paris, https://doi.org/10.1787/98807ee1-en.

[54] SAICM. (n.d.). Nanotechnology. SAICM Knowledge. https://saicmknowledge.org/epi/nanotechnology (Accessed April 7, 2025)

[55] Global Framework on Chemicals – For a Planet Free of Harm from Chemicals and Waste (2023). https://www.unep.org/resources/global-framework-chemicals-planet-free-harm-chemicals-and-waste. (Accessed March 17, 2025)

[56] WHO guidelines on protecting workers from potential risks of manufactured nanomaterials (2017). World Health Organization. https://www.who.int/publications/i/item/9789241550048. (Accessed May 31, 2024.)

[57] FAO/WHO [Food and Agriculture Organization of the United Nations/World Health Organization]. 2013. FAO/WHO Paper: State of the art on the initiatives and activities relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors. Geneva. 56 pp. https://openknowledge.fao.org/server/api/core/bitstreams/1955340e-f512-4f75-ae3e-e4258b2e401e/content. (Accessed April 7th, 2025)

apply to, for example, pesticides, foods, food additives, drugs or cosmetics. The rule requires one-time reporting of certain information including specific chemical identity, production volume, methods of manufacture and processing, use, exposure and release information and available health and safety information.

This rule applies to chemical substances, as defined in section 3 of TSCA, that are solids at 25 °C and standard atmospheric pressure; that are manufactured or processed in a form where any particles, including aggregates and agglomerates, are in the size range of 1-100 nanometers (nm) in at least one dimension; and that are manufactured or processed to exhibit one or more unique and novel properties. Manufacturers and processors of multiple nanoscale forms of the same chemical substance will, in some cases, need to report separately for each discrete form of the reportable chemical substance.[58]

TSCA (Regulatory Approach)

TSCA requires manufacturers of new chemical substances to provide specific information prior to manufacturing chemicals or introducing them into commerce. Many new chemical notices have been reviewed under TSCA for nanoscale materials, including CNTs. The EPA has permitted manufacturing of CNTs using consent orders or significant new use rules (SNURs). The document *Nanoscale Substances on the TSCA Inventory* provides guidance on how EPA determines whether a nanoscale substance is new for the purposes of the TSCA inventory[59].

This is an example of how EPA can regulate MWCNTs under TSCA. In December of 2023, the EPA issued SNURs for four MWCNTs which had been the subject of premanufacturing notices (PMNs). The SNURs include the following four closed MWCNTs:

- 4.4-12.8 nanometer (nm) diameter; bundle length 10.6-211.1 micrometer (µm); Grade: Jenotube 6 (PMN P-20-62);
- 5.1-11.6 nm diameter; bundle length 1.9-552.0 µm; Grade: Jenotube 8 (PMN P-20-63);
- 7.9-14.2 nm diameter; bundle length 9.4-106.4 µm; Grade: Jenotube 10 (PMN P-20-64); and
- 17.0-34.7 nm diameter; globular shape; Grade: Jenotube 20 (PMN P-20-65)

Significant new uses include manufacturing the substance with a maximum weight of cobalt oxide impurity and processing or using the substances other than as an electrically conductive material, an additive in batteries, energy storage and others. Any persons who intend to manufacture, import or process any of these MWCNTs for an activity designated as a significant new use under these SNURs must notify EPA at least 90 days ahead of doing so[60].

[58] U.S. Environmental Protection Agency. (2017, January 12). TSCA reporting and recordkeeping requirements. Federal Register, 82(8). https://www.regulations.gov/document/EPA-HQ-OPPT-2010-0572-0137
[59] U.S. Environmental Protection Agency. (n.d.). Nanoscale substances in the TSCA Inventory. https://www.epa.gov/tsca-inventory/nanoscale-substances-tsca-inventory (Accessed April 7, 2025)
[60] Bergeson & Campbell, P.C. (2023, December 18). EPA issues final SNURs for four multi-walled carbon nanotubes. Bergeson & Campbell, P.C. https://www.lawbc.com/epa-issues-final-snurs-for-four-multi-walled-carbon-nanotubes/ (Accessed April 7, 2025)

Europe

EU Classification, Labeling and Packaging Regulation

Classification and labelling data has been provided by industry to the European Chemicals Agency (ECHA) for MWCNTs and SWCNTs. At this time, labels must indicate that MWCNTs "cause damage to organs through prolonged or repeated exposure". The substance is classified as hazardous to lungs via inhalation[61]. Labelling for SWCNTs must indicate the substance as an eye irritant and as toxic to aquatic life with long lasting effects[62].

EU REACH

Companies who manufacture and market CNTs and CNFs in the EU have certain obligations regarding the identification of hazards and management of the corresponding risks. They must demonstrate to ECHA how the substance can be safely used, and they must communicate risk management measures to users. If the risks cannot be safely managed, authorities can restrict the use of the substance. These basic registration requirements are triggered once use surpasses the 1 metric tonne threshold (2,204.6 lbs.) [63].

CNTs are considered a nanomaterial under REACH (Nanomaterials are defined as chemical substances or materials with particle sizes between 1 to 100 nanometers in at least one dimension). This means that companies must provide additional information on these materials. Registration dossiers for nanomaterials must characterize the various "nanoforms" of nanomaterial substances and fulfill information requirements for each [64]. For example, the dossier must include information on the dustiness and the acute toxicity for each nanoform[65].

Multi-Walled Carbon Nanotubes (MWCNT) and Single Walled Carbon Nanotubes (SWCNT) are registered under REACH[66]. As of March 2025, there are 13 active registrations for MWCNTs and 2 for SWCNTs. Compliance checks of the dossiers are ongoing.

A substance evaluation report for MWCNTs was carried out on behalf of the ECHA to clarify concerns about[67]:

- Widespread use
- Consumer use
- Discrepancy in self-classification between different registrants of the joint submission(s)

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[61] European Chemicals Agency. (n.d.). Multi Walled Carbon Nanotubes (MWCNT) ECHA Substance Info Card. https://echa.europa.eu/substance-information/-/substanceinfo/100.217.898. (Accessed March 18, 2025).
[62] European Chemicals Agency. (n.d.). Single Wall Carbon Nanotubes (SWCNT) ECHA Substance Info Card. https://echa.europa.eu/substance-information/-/substanceinfo/100.242.364. (Accessed March 18, 2025).
[63] European Chemicals Agency. (n.d.). Understanding REACH. https://echa.europa.eu/regulations/reach/understanding-reach. (Accessed April 11, 2025)
[64] European Chemicals Agency. Appendix for nanoforms applicable to the Guidance on Registration and Substance Identification (2022). https://echa.europa.eu/documents/10162/13655/how_to_register_nano_en.pdf/f8c046ec-f60b-4349-492b-e915fd9e3ca0.
[65] European Chemicals Agency. Guidance on information requirements and chemical safety assessment Appendix R7-1 for nanomaterials applicable to Chapter R7a Endpoint specific guidance (2022). https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.
[66] European Chemicals Agency. (n.d.). Single Wall Carbon Nanotube ECHA Overview. https://chem.echa.europa.eu/100.242.364/overview?searchText=carbon%20nanotube.(Accessed March 18, 2025).
[67] European Chemicals Agency. Substance Evaluation Conclusion and Evaluation Report as required by REACH Article 48 for Multi-Walled Carbon Nanotubes (MWCNTs) (2020). https://echa.europa.eu/documents/10162/801e9ee1-1347-0072-44a5-b044510e79b5. (Accessed March 17, 2025).

- Differences in physico-chemical properties that affect toxicity, i.e. number of different registered nanoforms and the choice of representative test material(s)
- Suspected STOT RE (differing NOAEL/Cs in several animal studies using different forms of the same test material)
- Suspected carcinogen
- Effects on environmental organisms
- Suspected environmental exposure
- Cumulative exposure
- Suspected persistency

The evaluation concluded that it was not possible to fully resolve these concerns and urged companies to provide further information. It also stated that the dossiers had not made it transparent which data is appropriate for which nanoforms. A decision on further action is awaiting completion of the compliance check of the dossiers.

National legislation in EU

A 2012 decree in France established a registry for any manufacturing, import or use of over 100 grams of nanomaterials. Similar registries are now in place in Belgium, Denmark, Norway and under consideration in Sweden and Italy. Much of the reporting under these registries falls below the REACH threshold[68]

Additional EU Legislation

In addition to REACH, nanomaterials are also referenced in other EU regulatory frameworks. The table below is adapted from a review of nanotechnology standardization and regulation by Soltani and Pouypouy of the Tehran Technology Studies Institute[69].

Area	**Description**
Nanomaterials in novel foods	• Foods consisting of engineered nanomaterials should be considered a novel food • Food consisting of engineered nanomaterials should be assessed using most up-to-date test methods to assess safety
Nanomaterials in food contact materials	• Substances in nanoform shall only be used if explicitly authorized • Authorization of conventional substance does not cover the same substance in nanoform

[68] R-Nano. (n.d.). The French national registry for nanomaterials. https://www.r-nano.fr/?locale=en. (Accessed April 11, 2025)
[69] Soltani, A. M., & Pouypouy, H. (2019). Standardization and regulations of nanotechnology and recent government policies across the world on nanomaterials. In M. Ghorbanpour & S. H. Wani (Eds.), Advances in phytonanotechnology (pp. 419–446). Academic Press. https://doi.org/10.1016/B978-0-12-815322-2.00020-1

Area	Description
Nanomaterials in Cosmetic Products	• Definition of nanomaterial: insoluble or biopersistent and intentionally manufactured materials with one or more external dimensions from 1 to 100 nm • Labeling obligation of nanomaterial. • Nanomaterials used as colorants, preservatives and UV-filters must be explicitly authorized.
Biocidal Products Legislation[70]	• A separate dossier with all data requirements must usually be prepared for nanoforms of active substances.

State/Local

California

In 2006, Berkeley, California, adopted the first local regulation specifically for nanomaterials, requiring all facilities manufacturing or using manufactured nanomaterials to disclose current toxicology information. In 2010 and 2011, the California Department of Toxic Substances Control (CA DTSC) issued formal request letters to the manufacturers of certain CNTs, nanometal oxides, nanometals and quantum dots requesting information related to their use, their chemical and physical properties, and risk management measures.[71]

Cambridge

In 2007, the city council of Cambridge in MA requested an examination of the Berkeley nanotechnology ordinance (see above) and to recommend an appropriate ordinance for Cambridge. A committee was convened to develop recommendations. Some of the recommendations identified included (i) the establishment of an inventory of facilities which use nanomaterials; (ii) Offer technical assistance to help nanomaterial users evaluate health and safety plans for limiting risks to workers; (iii) Offer up-to-date health information to residents on products containing nanomaterials[72].

Occupational Regulations and Guidance

US NIOSH

The Occupational Safety and Health Act of 1970 (Public Law 91-596) charges the National Institute for Occupational Safety and Health (NIOSH) with recommending occupational safety and health standards and describing exposures that are safe for various periods of employment, including (but not limited to) the exposures at which no worker will suffer diminished health, functional capacity, or life expectancy because of his or her work experience.

NIOSH reviewed 54 animal laboratory studies on CNT and CNF exposure as part of their current intelligence bulletin 65. Many of these studies indicated that CNT/CNF exposure could cause adverse pulmonary effects including inflammation (44 of 54 studies), granulomas (27 of 54 studies), and pulmonary fibrosis (25 of 54

[70] European Chemicals Agency. (n.d.). Nanomaterials under Biocidal Products Regulation. https://echa.europa.eu/regulations/nanomaterials-under-bpr. (Accessed March 18, 2025).
[71] Environmental Protection Agency. Fact Sheet: Nanoscale Materials (2024). EPA. https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/fact-sheet-nanoscale-materials. (Accessed April 11, 2025)
[72] Lipson, S (2008). Recommendations for a Municipal Health & Safety Policy for Nanomaterials. Cambridge Nanomaterials Advisory Committee https://www.loe.org/images/content/080801/NanoRecommendations.pdf

studies).Based on these results the bulletin recommends that exposures to CNT and CNF be kept below a recommended exposure limit (REL) of 1.0 µg/m3 of respirable elemental carbon as an 8-hr TWA.[73]

NIOSH also hosts a Nanotechnology Research Center (NTRC). The center maintains a carbon nanotube registry and a roster of U.S. workers employed in relevant industries. The registry helps researchers understand exposures and track potential chronic health impacts. NIOSH is currently recruiting companies that handle or produce CNTs to participate in the registry[74].

US OSHA

There is no Permissible Exposure Limit (PEL) for CNTs or CNFs. However, there are PELs for similar substances for which CNT exposure may fall under. For example, Respirable Carbon Black's PEL of 3.5 mg/m^3 and Graphite's PEL of 15 mg/m^3 [75].

In the absence of a specific PEL, OSHA recommends that worker exposure to respirable carbon nanotubes and carbon nanofibers not exceed 1.0 micrograms per cubic meter (µg/m3) as an 8-hour time-weighted average, based on the National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limit (REL).[76]

Standards

International Organization for Standardization

Through its nanotechnology technical committee, The International Organization for Standardization (ISO) has developed a series of standards for the characterization and measurement of carbon nanotubes. These standards help ensure consistency in the characterization of CNTs across different laboratories and facilitate comparisons between studies[77].

IMPLICATIONS FOR THE TURA PROGRAM

Implications of Category Designation

Chemical categories are used in certain cases when listing substances under TURA. The TURA program's approach to categories has generally been based on the approach used under the U.S. Emergency Planning and Community Right-to-Know Act (EPCRA). Defining a chemical category is appropriate in a number of circumstances, and can provide several advantages compared with listing chemicals individually. Advantages to the use of chemical categories include avoiding adverse substitutions; and addressing a set of chemicals with similar health or environmental effects together. It is also appropriate when members of the category are often present as mixtures in commercial products.

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[73] Occupational Exposure to Carbon Nanotubes and Nanofibers (2013). Center for Disease Control – National Institute for Occupational Safety and Health. https://www.cdc.gov/niosh/docs/2013-145/pdfs/2013-145.pdf?id=10.26616/NIOSHPUB2013145

[74] Kelly-Reif, K., & Dahm, M. (2024, May 2). The Nanotechnology Research Center Carbon Nanotube Registry. NIOSH Science Blog. https://blogs.cdc.gov/niosh-science-blog/2024/05/02/nano-20-registry/. (Accessed April 8, 2025).

[75] Occupational Safety and Health Administration (2024). Occupational Chemical Database. Carbon Black. https://www.osha.gov/chemicaldata/236. (Accessed March 18, 2025).

[76] Occupational Safety and Health Administration (2013). Working Safely with Nanomaterials Factsheet. https://www.osha.gov/sites/default/files/publications/OSHA_FS-3634.pdf. (Accessed April 11, 2025)

[77] International Organization for Standardization. (n.d.). ISO/TC 229 - Nanotechnologies. https://www.iso.org/committee/381983.html (Accessed April 8, 2025)

- **Adverse substitutions:** One important reason to list a chemical category is to address concerns related to adverse, or "regrettable," substitutions. If structurally similar substances within a large group of chemicals may potentially be used as substitutes for one another, listing substances one at a time can create unintended consequences, in which the listed substance(s) may be replaced by an equally hazardous, unlisted substances. Creating a category provides clear guidance to chemical users, and helps to avoid such adverse substitutions.
- **Similar hazards across a group:** Listing a chemical category is also useful when a number of structurally similar chemicals have, or are reasonably anticipated to have, similar human health and/or environmental impacts. This makes it possible to address these hazards proactively by addressing the group of chemicals together. A category is also helpful when members within a group of chemicals are manufactured or used as mixtures.

The proposed multi-walled carbon nanotubes, single-walled carbon nanotubes, and carbon nanofibers categories are appropriate, as a number of the nanotubes and fibers may be reasonably anticipated to be used as substitutes for one another, they are commonly in mixtures, are structurally similar and specific health and environmental impacts (e.g., pulmonary toxicity and persistence) appear frequently.

By defining and listing multi-walled carbon nanotubes, single-walled carbon nanotubes, and carbon nanofibers categories, the TURA program can efficiently address these groups of chemicals. The TURA program can provide clear, proactive guidance to businesses to assist them in addressing all chemicals in the categories.

TURA Program Services

Both the Office of Technical Assistance (OTA) and TURI are available as a resource for new filers entering the program, as well as other users of CNTs and CNFs.

If a specific application of the use of chemicals presents an ongoing challenge for companies with respect to shifting to safer alternatives, OTA and TURI could support R&D to find feasible solutions. OTA provides free, confidential, onsite technical assistance to Massachusetts manufacturers, businesses, and institutions. TURI's research capacity and capabilities can help businesses identify and adopt safer alternatives to toxic chemicals for specific applications. When specific industry needs are identified, ideally with companies willing to share performance criteria, materials and/or other forms of expertise, TURI can identify researchers interested in focusing their R&D efforts to develop safer solutions. TURI can also provide limited financial support to businesses and academic experts to advance research, development and deployment of safer alternatives.

TURI and OTA collaborate to provide targeted information to MA businesses on opportunities to reduce toxics. The TURA program draws on knowledge from the Commonwealth and beyond to help businesses adopt safer solutions. TURI's incentive grants support businesses as they test and implement innovative safer technologies. TURI's demonstration events and case studies help businesses showcase their innovations to other businesses in related sectors, amplifying the positive impact of success stories in Toxics Use Reduction. In addition to the TURA program's ongoing trainings for businesses, Toxics Use Reduction planners are regularly trained, certified and educated by implementing agencies through bi-annual continuing education conferences, courses and workshops.

TURA implementing agencies are funded via fees paid by facilities which file under TURA. The fee structure has not been updated since the adoption of the legislation in 1989. This has led to diminished capacity of TURA implementing agencies to provide the services described in this section, even with the potential additional funds which would accompany the inclusion of CNTs and CNFs on the TURA list of Toxic Substances.

Fees and Planning-Related Costs

There would be some additional cost to companies that would begin reporting the multi-walled carbon nanotubes, single-walled carbon nanotubes and/or carbon nanofibers categories, including preparing annual toxics use reports and biennial toxics use reduction plans, and paying toxics use fees.

If there are new filers that only need to report the multi-walled carbon nanotubes, single-walled carbon nanotubes or carbon nanofibers categories, the cost of hiring a consulting planner will likely be in the range of $1,000 - $3,500. Companies that want to have their own in-house TUR planner can qualify either by relying on past work experience in toxics use reduction or by having a staff member take the TUR Planners certification course. Those facilities with experienced staff can become certified by MassDEP for as little as $100. For those that want staff to take a course, the cost will be between $630 - $2000, depending on whether the employee will be planning only for the company or will be able to do planning for other companies as well. Companies with in-house toxics use reduction planners are likely to reap ancillary benefits from having an employee on staff who is knowledgeable about methods for reducing the costs and liabilities of toxics use. Additionally, through the process of planning and reducing or eliminating use of chemicals in the category, facilities may be able to expand their markets, better comply with other chemical restrictions or regulations and reduce their overall regulatory burden.

The total additional cost in fees to filers (and revenue to the program) can be calculated using the fee structure outlined in the table below.

TURA Program Fee Structure			
Full Time Employees	**Base Fee**	**Per Chemical Fee**	**Maximum Fee**
≥10 and <50	$1,850	$1,100	$5,550
≥50 and <100	$2,775	$1,100	$7,400
≥100 and <500	$4,625	$1,100	$14,800
≥500	$9,250	$1,100	$31,450

TURI estimates between five and thirty-six filers of MWCNT, SWCNT and CNF combined, with the lower end most likely. The majority of filers for these materials are expected to be small companies (10-50 employees) and new to the program (so they would incur a base fee as well as the per chemical fee). Thus, the program estimates an increase in revenue of $14,750 (5 small filers, all new to the program) to 106,200 (36 small filers, all new to the program).

APPENDIX A: SCIENCE REVIEWED BY THE SAB

Multi-Walled Carbon Nanotubes

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APPENDIX B: USERS IN MA - METHODOLOGY

- Several entities that manufacture, handle, or process nanoscale materials were identified through the Cambridge Public Health Department Nanomaterials Survey in 2007. The Cambridge Public Health Department also provided prior research done through the Woodrow Wilson Institute.
- A survey initiated by the Massachusetts Office of Technical Assistance launched in 2017 was able to identify several industries within the state that likely manufacture, handle, or process nanomaterials. These industries include manufacturing (specifically coatings and semiconductors), healthcare (specifically pharmaceuticals, biomedical research and development), academic and higher education institutions, chemicals research and development, biological research, and military defense.
- Section 8a of the Toxic Substances Control Act of 2017 required reporting by companies across the U.S to provide certain information on chemical substances (as defined in section 3 of TSCA) which are manufactured or processed at the nanoscale. No responses from Massachusetts were reported.
- A database search using the S+P Capital IQ database available at Baker Library at Harvard Business School was conducted. This database allows users to search within business and industry descriptions. A keyword search for "Nano" was conducted identifying additional industries within the state that nanomaterials are likely manufactured, handled, or processed. These industries include technology, materials, and consumer discretionaries. This database search also identified forty companies in Massachusetts that manufacture, handle, or process nanomaterials. Through this database search, several nanomaterials used in Massachusetts were identified including carbon nanotubes. Further work was done using Dun and Bradstreet Hoovers database to identify industry codes, sales, and companies using 'nano' in the description of their products.
- A database search using the Nanowerk database was conducted under carbon nanotube usage.
- Several companies located in Massachusetts or that are associated with work in Massachusetts were identified by being members of MIT's Nano Corporate Research Consortium.
- EPCRA Tier II requires reporting of any chemical with a Safety Data Sheet if it is stored at 10,000 pounds or more at a facility (or at 500 pounds or more if the chemical is designated as an Extremely Hazardous Substance). A query of the EPCRA Tier II data was carried out for carbon nanotubes and carbon fibers. Two additional companies using carbon fibers were identified. They were added as potential users, due to lack of data regarding the size of the carbon fibers being used.
- A search of the Nano Science and Technology Institute's Nanotech Company Directory was performed for Massachusetts.

APPENDIX C: ADDITIONAL REGULATIONS RELEVANT TO CARBON NANOMATERIAL

Strategic Approach to International Chemicals Management (SAICM) / Global Chemicals Framework

"Nanotechnology and manufactured nanomaterials" was designated an emerging policy issue at the second session of the International Conference on Chemicals Management (ICCM) in 2009. Stakeholders stressed the need to close knowledge gaps; to understand, avoid, reduce and manage risks; and to review the methods used for testing and assessing safety.

ChemSec

In 2019, CNTs became the first nanomaterial to be added to the SIN (Substitute it Now) list by the Swedish non-profit, ChemSec (https://chemsec.org/sin-list/). The reason for inclusion on the SIN list is stated as *"Suspected of causing cancer, damaging fertility or the unborn child and shows limited degradation in the environment. It is therefore considered to be of an "equivalent level of concern*[78]". The SIN List is a comprehensive database of chemicals that ChemSec believe should be restricted or banned in the EU. Criteria for the SIN list are the same as the REACH criteria for substances of very high concern. Inclusion on the SIN list has often been a precursor for future regulation and restrictions by companies and governments.[79]

France and other individual EU members

A 2012 decree in France established a registry for any manufacturing, import or use of over 100 grams of nanomaterials. Similar registries are now in place in Belgium, Denmark, Norway and under consideration in Sweden and Italy. Much of the reporting under these registries falls below the REACH threshold[80]

Iran

In October 2017, Iran approved a second ten-year national nanotechnology plan. The new plan will continue to develop standards and guidelines for health and safety issues of nanotechnology and provided advice on corresponding legislation. The previous plan developed three guidelines on occupational safety for handling, storage and transportation of nanomaterials. Guidelines were also developed to assess and approve of nanotechnology products in food, cosmetics, pharmaceuticals and more[81].

Australia

Australia's work health and safety legislation aims to protect the health and safety of researchers and other workers developing, manufacturing or using carbon nanotubes.

The WHS Regulations for workplace chemicals include but are not limited to the following:

- The manufacturer or importer must determine whether the substance is a hazardous chemical. If it is, they must prepare a safety data sheet (SDS) and correct label. Carbon nanotubes should be considered to be hazardous unless data indicate otherwise and therefore an appropriate SDS and label should be

[78] https://sinsearch.chemsec.org/chemical/308068-56-6
[79] https://www.nature.com/articles/s41565-019-0613-9
[80] https://www.r-nano.fr/?locale=en
[81] Standardization and Regulations of Nanotechnology and Recent Government Policies Across the World on Nanomaterials

provided. The supplier of a product containing carbon nanotubes must ensure a current safety data sheet is provided to workplaces receiving the product.

- A person conducting a business or undertaking must ensure hazards in relation to using, handling or storing carbon nanotubes or products containing carbon nanotubes at the workplace are identified. The associated risks must be eliminated or minimized so far as is reasonably practicable.[82]

Germany

The Federal Institute for Occupational Safety and Health of Germany, through the [CarboSafe project,](CarboSafe project) developed principles for workplace measurement and workplace exposure levels of carbon nanotubes.

United Kingdom (UK)

The UK Health and Safety Executive has published guidance on nanotechnology and has established a nanosafety group to study and improve nanomaterial health and safety systems. The publication "Using Nanomaterials at Work" describes how to control occupational exposure to nanomaterials in the workplace, with specific guidance on carbon nanotubes.

Canada

Canada developed a report titled "Engineered nanoparticles: Health and safety considerations" This Guideline is intended to help health and safety professionals, employers, and employees to evaluate exposures to engineered nanoparticles in workplaces governed by federal jurisdiction and to apply control measures. Specific guidance on CNTs and MWCNTs is included.

FDA

The FDA developed guidance intended for manufacturers, suppliers, importers, and other stakeholders on the overarching framework for the agency's approach to the regulation of nanotechnology products. The guidance document does not establish legally enforceable responsibilities but describes the FDA's current thinking on determining whether FDA-regulated products involve the application of nanotechnology[83].

FIFRA/FFDCA[84]

NMs that are used as pesticides are subject to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA section 2(u) and 3(a)). If their use as a pesticide will result in residues in food or animal feed, a tolerance (maximum residue level) must be established under the Federal Food, Drug and Cosmetic Act (FFDCA).

[82] https://www.safeworkaustralia.gov.au/system/files/documents/1702/safe_handling_of_nanotubes_info_sheet.pdf
[83] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considering-whether-fda-regulated-product-involves-application-nanotechnology#intro
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