

# Nanomaterial Product Stewardship: National Security Implications of Export-import Activities

## Fact Sheet

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## INTRODUCTION

The global economy and new technologies, such as nanotechnology, have created a number of product stewardship challenges for industrial hygienists. Industrial Hygienists (IHs) evaluate and then develop and implement programs to protect workers. Because of their technical knowledge, IHs are commonly involved in nanomaterial stewardship activities, including those ensuring compliance with U.S. and international product-safety regulations.

Businesses must fully understand the health, safety, and environmental implications of nanotechnology and how they affect business decisions. Often these responsibilities involve a certified industrial hygienist (CIH) because he or she has no potential conflict of interest, as opposed to a manager or executive whose compensation may be tied to sales and profit margins.

However, product stewardship goes beyond health, safety, and environmental requirements. It also involves ensuring products are being utilized by customers for their designated uses and other legitimate purposes. Nanotechnology regulatory compliance begins with proper product classification. That classification determines which national and international regulations apply. Nanomaterials, for example, can be used as chemicals, pesticides and antimicrobials, food, drugs, or cosmetics, or in a variety of devices.

Nanotechnology also has implications for national security. According to the Department of Commerce's Bureau of

Industry and Security (BIS), nanotechnology is targeted for theft from U.S. entities via export activities. The dangers of illicit technology transfers via export and import activities include proliferation of weapons of mass destruction, acts of terrorism, industrial espionage, and adverse impacts to the U.S. economy due to the loss of proprietary research and development information. The estimated cost is \$180 billion per year. In August 2015, the U.S. Department of Justice published the "Summary of Major U.S. Export Enforcement, Economic Espionage, Trade Secret and Embargo Related Criminal Cases," which details multiple thefts of high-tech carbon fibers from U.S. companies to sell in China and Iran, and the thefts of trade secrets related to aerospace-grade titanium, titanium dioxide production, and surface coatings.

For example, in one case, a research chemist from a U.S. chemical company accepted a position at a university department of nanotechnology in China and attempted to transfer trade-secret information from his former employer to his academic office. The report briefly reviews export security regulations that affect nanomaterials as well as recommended practices and resources related to compliance. Applicability of export regulations to nanomaterials depends on their end use.<sup>1,2,3</sup>

This product stewardship guidance will provide a brief overview of export-import regulations affecting nanomaterials, review of U.S. export regimes, and recommended practices and resources related to export-import activities. The purpose of this guidance is to give product safety specialists and industrial hygienists an

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overview of export-import requirements for nanomaterials and is not intended to be a regulatory compliance guide.

## OVERVIEW OF U.S. EXPORT AND IMPORT REGULATIONS

The following is a list of the primary federal regulatory agencies involved in export-import activities:

- U.S. Department of State: Directorate of Defense Trade Controls, International Traffic in Arms Regulations (ITAR)
- U.S. Department of the Treasury: Office of Foreign Assets Control (OFAC)
- U.S. Department of Commerce: Bureau of Industry and Security (BIS), Patent and Copyright Office, and Bureau of the Census (e.g., trade statistics)
- U.S. Department of Homeland Security: Customs and Border Protection (CBP)
- U.S. Department of Justice: Drug Enforcement Agency (DEA)
- U.S. Department of the Interior
- U.S. Department of Health and Human Services: Food and Drug Administration (FDA)
- U.S. Environmental Protection Agency, via Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

Applicability of export-import regulations to nanomaterials is dependent on their end use. In other words, nanomaterials can be regulated as foods, cosmetics, medical devices, chemicals, and antimicrobials, or as technology.<sup>4,5</sup>

Two of the abovementioned agencies, the FDA and the EPA, have prepared nanotechnology and nanomaterial fact sheets.<sup>6,7</sup> Neither agency has a unique regulatory framework for nanomaterials, and both agencies maintain import and export notification and certification requirements for regulated goods.

For example, all FDA regulated products imported into the country, including foods, drugs, medical devices, cosmetics,

tobacco products, and radiation-emitting devices, must meet the same laws and regulations as domestic goods. Several foods, cosmetics, and medical products now use nanotechnology. All imported items must have informative and truthful labeling in English. For exports, several countries require FDA export certifications for products subject to the U.S. Food, Drug, and Cosmetic Act. To the receiving country, the FDA Export Certification evidences that the product meets FDA Good Manufacturing Practices.<sup>8</sup>

Likewise, the EPA regulates the export and import of chemicals and pesticides via the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), respectively. In 2017, the EPA published a final rule under TSCA requiring a one-time reporting requirement for certain nanomaterials either manufactured or processed. Generally, in regard to whether a nanomaterial is a new or existing chemical, nanomaterials are regulated as their parent materials. In other words, nanoscale versions of existing chemicals are regulated by their chemical identities via their Chemical Abstracts Service registry numbers (CAS numbers).<sup>9,10</sup>

Nanomaterials whose CAS numbers are not listed on the TSCA Inventory are regulated as new chemicals. TSCA Section 5 requires manufacturers of new chemicals, including new nanomaterials, to submit premanufacture notifications (PMN) to the EPA for review prior to manufacture or introducing the new chemicals into commerce. The EPA may then issue a Significant New Use Rule (SNUR) to ensure that the new chemical is effectively controlled. In October 2017, for example, the EPA published a SNUR under TSCA Section 5 for certain multiwalled carbon nanotubes. Under the SNUR, manufacturers and importers who intend to manufacture, import, or process these multiwalled carbon nanotubes for a “significant new use” must file a PMN to the EPA at least 90 days prior to commencement of that activity.<sup>11</sup> Other such SNURs have been issued by the EPA over the years.

TSCA Section 12(b) requires any person who exports or intends to export a chemical substance or mixture — subject to certain TSCA regulations, the PMN and SNUR

requirements promulgated under TSCA Section 5 — to notify the EPA of the activity. In turn, EPA supplies information about the exported chemical and its related regulatory activities to the importing government. The list of chemicals subject to TSCA Section 12(b) can be found in the Code of Federal Regulations (CFR) at 40 CFR Part 707 Subpart

D.12 Nanomaterials that are the subject of SNURs, such as multiwalled carbon nanotubes, are included on this list.

TSCA Section 13 requires importers to certify that chemical imports either comply with TSCA, including the PMN and SNUR requirements promulgated under TSCA Section 5, or to certify that they are exempt from TSCA requirements (e.g., goods regulated by other U.S. regulations and agencies such as FIFRA and FDA). To provide U.S. importers with compliance assistance, in 2008 the EPA published a TSCA Section 13 Import Compliance Checklist, which is available online.

To ensure consistency in the certification process, on December 26, 2016, U.S. Customs and Border Protection (CBP) published a final rule requiring the use of the Automated Commercial Environment (ACE) when filing TSCA import certification statements electronically.<sup>13</sup> To provide assistance to exporters and importers, the EPA helped to develop a website called The Border Center, which explains the environmental aspects of international treaties and agreements.<sup>14</sup>

The EPA also regulates pesticides, including antimicrobials, under FIFRA. The first silver antimicrobial registered in the United States was a nanosilver product.<sup>15</sup> FIFRA pesticide export-import requirements are summarized below:

- Pesticides intended for use in the United States must be registered with the EPA prior to import.
- EPA-registered pesticides that are exported must bear the product label or accompany the EPA-approved product.
- Pesticides that are not EPA registered may be manufactured in the United States and then exported if their manufacture is solely for export.

The EPA participates in international treaties and agreements on pesticides including the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, the North American Free Trade Agreement Working Group on Pesticides, and the U.S.-Canada Regulatory Cooperation Council.<sup>16</sup>

## U.S. EXPORT REGIMES

Four primary U.S. agencies — the departments of State, Commerce, Treasury, and Homeland Security — regulate the export of U.S. goods and services, including technology. The term “technology” includes nanotechnology and nanomaterials. Table 1, based on information from the BIS website, summarizes related U.S. legislation, administering agencies, and corresponding regulatory citations.<sup>17,18</sup>

**TABLE 1** — U.S. legislation and regulations related to export activities

Legislation	Regulatory agency	Regulatory reference
Export Administration Act	Dept. of Commerce, Bureau of Industry and Security	Export Administration Regulations, 15 CFR 730–774
Tariff Act of 1930	Dept. of Homeland Security, Customs and Border Protection	19 CFR 1202–1683
Trading with the Enemy Act of 1917	Dept. of Treasury, Office of Foreign Assets Control	31 CFR 500 598
Arms Export Control Act (AECA)	Dept. of State, Directorate of Defense Trade Controls	International Traffic in Arms Regulations, 22 CFR 120–130

The Export Administration Act of 1979 provides legal authority to the President to control U.S. exports for reasons of national security, foreign policy, or shortage. The Department of Commerce’s BIS administers the Export Administration Regulations (EAR) with assistance from Customs and Border Protection. EAR applies to “dual-use goods and technologies” or items that have a commercial application but can also be utilized for military, terrorist,



or weapons of mass destruction uses. By contrast, defense goods and services are regulated under the International Traffic in Arms Regulations (ITAR).<sup>19,20</sup>

The definition of an export is very broad under EAR and ITAR. An export is the actual shipment or transmission of items out of the United States. This includes intellectual assets like emails, information transmitted orally, and the release of technology or source code subject to EAR to foreign nationals in the United States. The definition also covers “re-exports,” a term that refers to the actual shipment or transmission of items from one foreign country to another.

For example, if U.S. citizen in New York forwards the formulation of a corrosion inhibitor containing a nanomaterial to a Canadian co-worker in California, this may be regarded as an export to Canada. If the same American forwards the same information to a co-worker in California who either is a U.S. citizen, a permanent resident foreign national (that is, a person with a green card), a political refugee, or someone granted political asylum, the information transfer is not an export.<sup>21,22</sup>

Materials exempted from the EAR definition of export include nontechnical publications, publicly available nonencrypted software, foreign-made items with less than a de minimis percentage of a controlled U.S. content, and items regulated by other agencies such as the Nuclear Regulatory Commission.<sup>23</sup>

How export is defined can greatly affect product-safety-related communication within an international company. For example, a U.S. product-safety specialist may not be able to share the product formulation of a technology to a co-worker in Russia, China, or other countries determined by the departments of Commerce, State, or Treasury to be impermissible recipients for one reason or another. Legal counsel is essential for compliance. An industrial hygienist involved in product stewardship is part of a companywide team also comprising legal, sales, customer service, and shipping personnel to ensure export compliance.

An exporter shipping EAR-regulated goods must first

classify the products per the Commerce Control List (CCL) using Export Control Classification Numbers (ECCN) and determine its shipping destination. The ECCN system is an alphanumeric code that specifies to which of 10 categories and five product groups the product belongs. The CCL groups countries into various categories based on criteria of bilateral relations (that is, international agreements) and security. The BIS has established licensing requirements for CCL-listed items. Most commercial goods are items not specified on the CCL. These are designated “EAR99” and do not require a license.<sup>24</sup>

U.S. exports are prohibited to certain destinations. The U.S. has placed trade embargos against a list of Countries of Particular Concern, which includes countries such as North Korea, Iran, and Syria. The reason for an embargo or export restriction may not be related to global terrorism; it may be related to human rights violations (e.g., human trafficking) or drug trafficking. The Treasury Department’s Office of Foreign Assets Control (OFAC) maintains a Narcotics Sanctions Program. Embargos can also be issued for a given region. For example, on June 21, 2017, President Trump signed Administrative Order EO 13219, “Regarding the Continuation of the National Emergency with Respect to the Western Balkans,” for extremist violence (Macedonia) and acts obstructing the implementation of the Dayton Accords (Bosnia Kosovo).<sup>25–27</sup>

If the product being shipped is listed on the CCL, the exporter needs to determine the item’s reason for control and cross-reference the controls against a country chart (e.g., national security, antiterrorism, regional stability, or crime control). The stated reason for control and the destination country determine the need for an export license or authorization. License exceptions, such as an overseas shipment to a government employee, are possible.<sup>28</sup>

Lastly, prior to the export, the exporter must screen all parties involved in the transition to ensure that there are no prohibited end-users nor prohibited end uses (activities) taking place. The BIS, State Department, and Treasury Department’s OFAC publish various lists that exporters are to consult to ensure a potential customer is not a prohibited

end-user. For example, BIS maintains a Denied Persons List of individuals whose authorization to export has been suspended or revoked. The State Department issues a List of Global Terrorists, which is updated via the Federal Register. A Consolidated Screening List, a compilation of 11 lists, is available at [www.export.gov](http://www.export.gov).<sup>29</sup>

Prohibited end uses include nuclear proliferation, missile technology, and chemical and biological weapons. Exporters must look for suspicious characteristics (red flags) regarding potential customers, such as:

- Is the customer paying cash for the export?
- Is the customer's name similar to a name on the BIS's Denied Persons List?
- Is the purchase not in line with the customer's reported line of business? (Example: A small business man wants to purchase a large number of sophisticated computers.)
- Is the customer vague on the use of the product? (Example: A broker from an overseas country wants one container of a nanometal powder, but he does not specify the final use of the product or state his customers' general line of business.)
- Is the customer declining typical installation, maintenance, or delivery services?

To summarize, an exporter must determine EAR license requirements by first classifying the item (i.e., determining the ECCN) and then determining its destination. The second step is to determine end users

- Export License authorization
- License Exception authorization
- No License Required (NLR) designation

The exporter then signs the Electronic Export Information form, formerly the Shipper Export Declaration, or certifies the shipment via the Automated Export System. This document includes the BIS Export License number, License Exception authorization, and ECCN (if applicable). The document is maintained for five years by the principal (exporter) or agent.<sup>30</sup>

Civil penalties for EAR and OFAC violations are \$250,000 per violation or five times the value of the goods exported/imported, whichever is greater. Additionally, the goods can be seized, and the shipper can lose export privileges. For import violations of the Tariff Act, penalties are the lesser of the goods' value or twice the duty loss. The penalty can be reduced to the interest on the duty loss, if it is voluntarily disclosed. For compliance assistance, *Customs Bulletins and Decisions* (CBP Bulletins), a weekly compilation of decisions, rulings, regulations, notices, and abstracts concerning customs, is available at the U.S. Customs and Border Protection website, [www.cbp.gov](http://www.cbp.gov).<sup>31,32</sup>

The United States also works with its allies to develop mutually agreed to export requirements. The Wassenaar Agreement on Export Controls for Conventional Arms and Dual-Use Goods and Technologies is a multilateral export control regime (MERC), with 41 participating countries including many of the former Warsaw Pact or Eastern Bloc countries. The regulation of nanotechnology can be a matter of international discussion.<sup>33</sup>

Defense goods and services are regulated by the International Traffic in Arms Regulation via the Arms Export Control Act. The Arms Export Control Act authorizes the U.S. president to control the export and import of defense articles and defense services. This authority is delegated to the Secretary of State.

ITAR outlines requirements pursuant to the act. There are four offices within the State Department involved in the implementation of ITAR, as described in Table 2 on page 7.<sup>34</sup>

Whereas the BIS maintains the CCL, the State Department maintains the U.S. Munitions List. The USML is a list of defense articles and services ranging from military vehicles to weapons. Defense articles are defined as items "specifically designed, developed, configured, adapted, or modified for a military application." They do not have predominant civil applications or civil performance equivalents.<sup>35</sup>

ITAR in its current form arose from the Cold War. Items are frequently added to the USML, but rarely taken off.

**TABLE 2** — State Department offices involved in the implementation of ITAR

Office name	ITAR activities
Office of Defense Controls Management	Responsibilities related to the management of defense trade controls operations (i.e., processes, activities, and tools for the export licensing regime)
Office of Defense Controls Licensing	Responsibilities related to licensing or other authorization of defense trade
Office of Defense Controls Compliance	Responsibilities related to violations of ITAR
Office of Defense Controls Policy	Responsibilities related to general policies of defense trade, including negotiating defense cooperation treaties

Revision of the USML requires agreement between the President and Congress. Over time, technology, such as satellites, have moved from the military sector to the commercial (telecommunications) sector, but the USML has not kept pace with these technological advancements. In response, the Obama administration implemented export-import reforms to streamline export and import processes for U.S. businesses, including ITAR. The reforms included the evaluation and improvement of ITAR related processes including updating the USML.<sup>36,37</sup>

The transfer of an ITAR-controlled commodity or information to a “foreign national,” even if the person is in the United States, is regarded as an export and requires a license. Unlike EAR, there is no de minimis exception. Furthermore, ITAR is applicable regardless of location. In other words, ITAR controlled items remain regulated in foreign countries, which can also affect defense shipments to U.S. allies. Additionally, if a piece of equipment contains one ITAR-controlled part, the equipment is considered ITAR regulated.<sup>38</sup>

Lastly, an ITAR empowered official (a “U.S. person”) from a company that manufactures defense articles or

provides defense services must sign license applications and registrations to export or manufacture such items or services, verify the legality of such transactions, and oversee ITAR compliance. The licensing process may exceed a year. Repeat shipments to the same recipient require a license for each shipment.<sup>39,40</sup>

Penalties for ITAR are quite severe. Civil penalties are \$500,000 per violation. Criminal penalties are

\$1,000,000 and up to one year in prison per violation. United Technologies was fined \$55 million in 2012 for ITAR violations. In 2013, Aeroflex and Raytheon were each fined \$8 million for ITAR violations.<sup>41</sup>

## RECOMMENDED PRACTICES FOR EMPLOYERS

To avoid loss of export privileges and costly fines, companies must develop and implement compliance policies. The key component of a successful compliance program is management commitment.

Management must devote adequate resources to its export programs. Written policies must define the responsibilities of people involved in export activities. This includes appointing program champions who stay current on applicable regulations and train others.

Due to the technical nature of nanomaterials, ethical or conflict-of-interest reasons, and complexity of applicable regulations, one of the export champions will likely be a certified IH. Nanomaterials can be regulated as “technology” under U.S. export regimes. Therefore, it is imperative to stay abreast of pertinent regulatory changes.<sup>42</sup>

The easiest way to develop export compliance procedures is to first assemble a multidisciplinary team to map out existing product ordering and shipping processes in flowcharts, listing associated documentation. The team should include applicable stakeholders such as legal, product safety, sales and customer service, purchasing, and shipping personnel. Screening of employees, customers, visitors, contractors,



transactions, and products is an important control measure. Screening software programs expedite this process and also track updates to the various BIS, OFAC, and State Department lists. Self-audits are important to ensure compliance. Lastly, there must be internal procedures in place to report possible export violations and implement corrective actions.<sup>43</sup>

An important aspect of EAR and ITAR compliance is related to the screening of foreign nationals. Company security policies should describe how visitors, including foreign employees, are screened against the Consolidated Screening List prior to site visits. A written visitors log documenting a visitor's name, citizenship, address, visit date, and purpose of the visit should be maintained for recordkeeping purposes. Company policy may require that foreign nationals sign a nondisclosure agreement and restrict them from taking photos to protect

both national security and intellectual property.<sup>44</sup>

Other requirements pertain to temporary employees who are foreign nationals and who will be exposed to controlled technology or technical data in the course of their work. Part 6 of Form I-129, Petition for a Nonimmigrant Worker, must be completed and submitted to Citizenship and Immigration Services (Department of Homeland Security) for approval.<sup>45</sup>

### AVAILABLE GOVERNMENT RESOURCES

The U.S. government offers a number of free or low-cost resources to American businesses wishing to export or import goods, including nanomaterials. Table 3 provides a brief description of government agencies offering compliance assistance or training. Table 4 describes publications,

**TABLE 3** — Compliance resources for export and import activities

U.S. agency	Website	Available services
U.S. Commercial Service	<a href="http://www.export.gov">www.export.gov</a>	First stop for export assistance from the federal government; informs shippers of all government export programs. Has district offices throughout the U.S.
U.S. Commercial Service China	<a href="http://www.export.gov/china">www.export.gov/china</a>	Comprehensive source of information on China
National Centers for Manufacturing Sciences (a Compliance Assistance Center, developed with support of the EPA Office of Enforcement and Compliance)	<a href="http://www.bordercenter.org">www.bordercenter.org</a>	Provides assistance with regard to environmental regulations impacting imports and exports
U.S. Customs and Border Protection	<a href="http://www.cbp.gov/trade/rulings/bulletin-decision">www.cbp.gov/trade/rulings/bulletin-decision</a>	Weekly compilation of decisions, rulings, regulations, notices, and abstracts concerning customs and related matters
Small Business Administration	<a href="http://www.sba.gov">www.sba.gov</a>	Tools and resources for small businesses that wish to export. Has district offices throughout the U.S.
Department of Commerce, Bureau of Industry and Security	<a href="http://www.bis.doc.gov">www.bis.doc.gov</a>	Offers compliance training and counseling on export controls and regulations
Department of Commerce, Office of Trade Agreements Negotiations and Compliance	<a href="http://www.tcc.export.gov">www.tcc.export.gov</a>	Assists shippers with compliance regarding international trade agreements
Department of Agriculture, Office of Outreach and Exporter Assistance	<a href="http://www.fas.usda.gov">www.fas.usda.gov</a>	First point of contact for exporters of U.S. food, farm, and forest products
Department of Commerce, Office of Textiles and Apparel	<a href="http://www.otexa.ita.doc.gov">www.otexa.ita.doc.gov</a>	Database provides information on applicable export rules and regulations
Department of Justice	<a href="http://www.usdoj.gov/criminal/fraud/fcpa">www.usdoj.gov/criminal/fraud/fcpa</a>	Report issues related to the U.S. Foreign Corrupt Practices Act
Department of Commerce (with European Commission)	<a href="http://www.export.gov/safeharbor">www.export.gov/safeharbor</a>	Provides U.S. companies with a streamlined process to comply with EU requirements



TABLE 4 — Business, finance, and marketing resources related to exports and imports

Resource	Website	Available service/information
The CIA World Fact Book	<a href="https://www.cia.gov/library/publications/resources/the-world-factbook/index.html">https://www.cia.gov/library/publications/resources/the-world-factbook/index.html</a>	Annual free online publication that provides country to country data on demographics, economy, communications, and defense
Trade Finance Guide: A Quick Reference for U.S. Exporters	<a href="http://www.export.gov/tradefinanceguide">www.export.gov/tradefinanceguide</a>	Dept. of Commerce publication covers methods of payment in international trade and foreign trade risk
U.S. Census Bureau	<a href="http://www.census.gov/foreign-trade">www.census.gov/foreign-trade</a>	Publishes statistics for product exports to various countries
Department of Commerce, Office of Trade and Industry	<a href="http://www.tse.export.gov">www.tse.export.gov</a>	Comprehensive resource on export and import data (both historical and current)
Department of State, Business Information Database System	<a href="http://www.bids.state.gov">www.bids.state.gov</a>	Online trade lead program that collects business opportunities across the U.S. embassy system
Department of Commerce, Market Research Library	<a href="http://www.export.gov/mrktresearch">www.export.gov/mrktresearch</a>	Contains more than 100,000 industry- and country-specific market reports
Export-Import Bank of the U.S.	<a href="http://www.exim.gov">www.exim.gov</a>	Provides export credit insurance, loan guarantees to lenders, direct loans to exporters, and loans to foreign buyers

databases, and other services for U.S. companies wishing to explore international business opportunities.<sup>46</sup>

Nanotechnology is a rapidly changing field with significant health, safety, environmental, and product stewardship considerations. The export of nanomaterials presents additional global product stewardship challenges. These challenges require the cooperation of several departments within a business organization. For their part, IHs contribute technical, ethical, and critical-thinking skills to global business teams.

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