Nanotechnology Regulation Implementation in Industry

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ABSTRACT

Nanotechnology is a fast growing industry with increasing applications in consumer, industrial, pharmaceutical, medical, food and personal care products. One issue facing the nanotechnology sector is that current chemical regulations focus on single chemical substances and do not consider nanomaterials produced from the same materials as unique or separate materials. As such, nanomaterials manufactured from these various substances are approved for use under current regulations. However, because nanomaterials have unique properties when compared to the non-nanomaterial substance, governments are now evaluating special regulations for nanomaterial use. Regulatory agencies have been collecting data on nanomaterial uses, exposure and potential toxicity, which will most likely increase in the coming years. New rapid screening methodologies paired with toxicity assays willallow for testing of environmentally relevant exposure pathways and doses; these data will help regulatory agencies enact policies based on the best scientific data available for developing safety measures in industry. Here, the most current nanomaterial regulations are discussed as well as how these regulations may affect current and future industrial production and processes revolving around nanomaterials.

Keywords: industry, nanomaterial, regulation, Significant New Use Rule (SNUR), TSCA

1 INTRODUCTION

Although most current regulations do not identify nanomaterials sourced from approved existing chemicals as new chemicals, the regulatory landscape for nanomaterials is changing. The regulatory agency concern over nanoscale materials exists due to their unique properties, lack of understanding of the potential for exposure and toxicity ,and other environmental concerns from the manufacture and use of nanomaterials.

A major challenge with regulating nanomaterials has been developing a harmonized defintion that encompasses all forms and uses of particles in the nano-scale range. Previously, the basic definition of a nanomaterial has been similar across various governmental agencies: 1-100 nm in size in at least one dimension [1; 2; 3]. However, updates to the definition have recently occured and may include information that the material was developed as a new material with unique or novel properties. This new definition indicates that the material is a purposefully manufactured material with size-dependent properties that differ from the properties of the material at the bulk-scale. Nanomaterials encompass a variety of materials and include single chemicals (e.g., carbon nanotubes), chemical compounds (e.g., titanium dioxide), metal-core coated particles, proteins, or DNA. All these nanomaterials can be used in a variety of products and industries including automotive, catalysis, electronics, paints, pigments, medical, pharmaceutical, agricultural, and personal care. Because nanomaterials vary in types and applications, developing one definition that satisifies the uses of nanomaterials made from multiple constituents and used in a wide variety of applications presents a challenge. Various organizations have created working groups to develop a broader definition that encompasses more variability in thye definition. For example, the American National Standards Institute (ANSI) and American Society for Testing and Materials (ASTM) International have both created groups that are responsible for developing nanotechnology standards and language [4; 5].

Historically, nanomaterial regulations have largely been left up to states or specific industries to develop. Global focus has been largely on defining the term “nanomaterial”. While initial guidelines for worker protection have been developed for worker safety via the National Institute for Occupational Safety and Health (NIOSH) NIOSH and the Occupational Safety and Health Administration (OSHA) [6], little or no regulation has been developed at the Federal level for nanomarterial production and processing. As a result, regulations governing nanomaterials will most likely be evolving over the next several years. The following provides snapshots as to how this process may develop at least in its early stages.

2 FEDERAL REGULATION

The United States Federal Government has formed a National Nanotechnology Initiative (NNI) including twenty Federal departments and agency units [7] to create a framework for nanotechnology R&D by establishing shared goals, priorities and strategies, including prioritizing environmental, safety and health research.

A recent update to nanotechnology regulation by the US EPA involves a Significant New Use Rule (SNUR) for

nanomaterials [8]. Based on the rule, persons who intend to manufacture, import, or process nanomaterials based on chemical substances already listed in the TSCA (Toxic Substances Control Act) Inventory must submit a Significant New Use Notice (SNUN) to the EPA at least 90 days prior to commencing that activity. This rule provides EPA with basic information on the nanomaterial, such as chemical identification, material characterization, physical/chemical properties, commercial uses, production volume, and exposure, fate, and toxicity data. The information allows EPA to evaluate intended uses of the nanomaterials and to take action to prohibit or limit activities that present unreasonable risks to human or environmental health.

As of October 27, 2016, EPA TSCA issued a proposed SNUR for functionalized carbon nanotubes (generic) for use as a thin film for electronic device applications [9]. Based on the review, EPA recommended additional testing including aquatic toxicity, mammalian inhalation toxicity, and surface charge testing in order to help characterize the health and environmental effects of the substance.

Additionally, NIOSH has a public comment period for feedback on occupational safety and health practices for engineered nanomaterials [10]. The purpose of the comment period is to inform NIOSH on the impact of nanotechnology on worker health. NIOSH plans to survey industries involved in the manufacturing, distribution, fabrication, formulation, and other services for nanomaterials and the types of occupational health and safety practices that have been implemented in these industries. A final report will help better guide NIOSH in the development offuture occupational health and safety practices.

3 STATE REGULATION

Regulation of nanomaterials is also being applied at the state level. In September 2016, the Minnesota Department of Health updated its list of chemicals of high concern to include multi-walled carbon nanotubes [11]. The inclusion of the nanomaterial was based upon the International Agency of Research on Cancer's (IARC) 2014 listing of single-walled and multi-walled carbon nanotubes as possibly carcinogenic to humans [12]. Other states use IARC carcinogenicity classifications as a basis for chemical regulations.

4 INTERNATIONAL COMMUNICATIONS AND REGULATION

The Organisation for Economic Co-operation and Development (OECD) is also active in the field of nanotechnology. Efforts at the OECD include a Working Party on Nanotechnology (WPN), a testing program for manufactured nanomaterials, and a database for publications on the safety of manufactured nanomaterials [13; 1; 14].

During the period of 2011-2014, a Nanotechnology Work Plan was developed between the United States and Canada to develop consistent policies on the regulatory oversight of nanotechnology. A final report was released in 2014 with one of the objectives being an assessment of useful information for nanomaterial risk assessments [15].

In Europe, nanomaterials are regulated by the European Chemicals Agency (ECHA) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Classification, Labelling and Packaging (CLP) regulations, and the Biocidal Products Regulation (BPR). REACH and CLP do not regulate the nanoform of a material separately from the non-nano form, but must evaluate the safe use of the nanoforms. In contrast, the BPR states that the approval of the active substance does not cover the nanoform of the active substance except where explicitly mentioned. ECHA has formed a nanomaterials working group and also is researching nanomaterials already registered.

In Sweden, the Swedish Chemicals Agency (KEMI) is dicsussing with stakeholders a new regulation that would require industries to report information regarding nanomaterials used in chemical products, with informatuion being added to the Swedish products register starting February 28, 2019 [16; 17]. Certain industries, such as tattoo ink and cosmestics, pharmaceuticals, food and animal feed, and waste are exempt from reporting nanomaterials in their products.

The United States and the European Union held their 5th annual nano environmental health and safety scrimmage in 2016 [18]. The purpose of the meeting is to publicize progress on research, future plans, and best practices in nanomaterials. Additionally, the meeting is held to develop a response strategy to nanomaterial release into the environment. Stakeholder concerns are also addressed as part of the meeting.

5 PREPARATION FOR NEW REGULATIONS AT THE INDUSTRIAL SCALE

In order to proactively manage the changing regulatory landscape, the nano-based industry needs to be aware of emerging policies and regulations and assess the impact on current and future products. Commercialization of nano-products must consider the following: knowledge of the supply chain and life cycle of the products, identification of unique properties, and assessment of the potential for human and ecological exposure and toxicity. Companies should be engaged in assisting regulatory authorities and international agencies in developing policies and regulations.

5.1 Increased Documentation

Current chemical regulations already require detailed information to be provided for the non-nano scale versions of products and compounds. Internationally, regulatory authorities are moving toward increased requirements requiring more detailed information for nanomaterials. Using the same internal systems already in place for generating data, companies can often transition the same paperwork and resources to developing standard operating procedures for nanomaterials reporting.

Increased documentation and reporting to regulatory agencies will assist the agencies in understanding the variety of nanoscale materials in commerce, the application of those nanoscale materials, and the potential exposure to humans and the environment. Futher regulations can be expected once the agencies understand the nanomaterial landscape.

Companies should be vocal and engaged during stakeholder feedback periods concerning draft regulations. Requesting that the government streamline internal processes for reporting data will save time and energy by avoiding implementing entirely new processes for reporting.

5.2 Potential for Increased Costs for Chemical Identification and Hazards Assessments

Under current regulations, companies are already required to submit information on chemicals used in products. Information on the chemical characterization, physical-chemical properties, human health effects and environmental fate and toxicity are assessed for new chemcials and depend on the regulatory authority overseeing new uses of chemicals. With an already proactive approach required on behalf of the companies for other chemicals, companies will have to use resources and potentially new types of test strategies to stay proactive with nanomaterials.

Additionally, non-governmental agencies such as IARC are reviewing the available information on nanoscale materials in terms of carcinogenicity and making classifications based on available literature. Classification by IARC as a carcinogenic can affect the viability of a nanoscale matererial globally.

From a product stewardship perspective, it is critical that companies understand their products, evaluate the potential for exposure and toxicity throughout product lifecycles, and assess the product risk to humans and the environment. This proactive approach will ensure that companies will be ready for upcoming regulations.

5.3 Communication with Federal Regulatory Agencies

Numerous organizations are already active with defining nanomaterials, assessing nanomaterial toxicity, and developing policies and regulations. At the Federal level, organizations such as ASTM, ANSI, NIOSH, and OSHA have developed standards and guidelines for the use and measurement of nanomaterials. Moving forward, nanomaterial industries must engage and help organizations to further develop policies and regulations that are scientifically defensible and actionable. Preemptive measures which can be taken by industry to openly communicate with fFederal regulatory bodies before and during the drafting and implementation of regulations are opportunities to increase the success of these measures. Additonally, at the international level, the OECD and events such as the US-EU nano EHS scrimmage also play a role in molding future international policies.

6 FUTURE DIRECTION OF NANOTECHNOLOGY AND REGULATION

The global nanotechnology market is anticipated to grow to nearly $175 billion by 2025 [19]. Even within the home, consumers are likely to handle products on a daily basis that contain nanomaterials. Currently, popular consumer products containing nanomaterials include cleaning products, clothing, cosmetics, personal care products, sporting equipment, and paints [20].

More regulation on nanomaterials made from various materials or in specific shapes, will continue to be promulgated both within the United States and globally. Furthermore, with producers, processors, manufacturers and industries developing markets throughout the world, companies will need to be better informed on regulations related to importing and exporting nanomaterials and specific requirements for material information required by other countries. As standardized nomenclature and testing emerge, the future regulations of nanomaterials is sure to follow.

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