Review Article

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Nanotechnology Law for Commercialization of Nano-Enabled Products

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Abstract

This presentation begins with a very short overview of the emerging laws of nanotechnology and then moves forward to study the key trends in emerging nanoregulations. Now that nanomaterials are becoming part of the global codification of nanoregulations hundreds of emerging laws have begun to sprout like mushrooms in unexpected places all over the globe. Surrounding these mushrooms is a vague and treacherous swamp of new laws draft laws and pre-existing laws. Additionally there are rules emerging from powerful opinion leaders who have expertise but not regulatory authority, such as some USA federal government agencies and the World Health Organization (WHO). This overview of the emerging nanoregulations explores USA OSHA and EU REACh and NIOSH RELs (Recommended Exposure Limits) for carbon nanotubes and nanofibers, NIOSH documents such as TiO_2 guidance for nanomaterials and an entire webpage full of sound approaches to nanomaterials should remove many questions about the methods for best practices but leaves legal authority unclear because NIOSH is not an enforcement authority and the concept of RELs itself does not appear anywhere in the OSH Act that created NIOSH.

So too, WHO guidelines for workplace exposure to nanomaterials are an unprecedented well intended application of precautionary principles even though no data yet exists demonstrating a link between exposure to manufactured nanomaterials in the workplace and proven harm and WHO has no enforcement authority. This trend towards prevention in face of unquantifed risk is important. This presentation will examine what this means from the global health standpoint, regarding nanotechnology; what does this mean for global health law and governance of science and emerging technologies? This presentation concludes that the new nanomaterial rules focus on problems that haven't happened yet but that experts believe are likely to occur. This unprecedented preventive phenomenon in nanoregulations impacts risk assessment, quality assurance for compliance and inevitably the acceptaable methods for preventing corporate or professional liability. Therefore nanoregulation is a dynamic process that will influence many health laws around the world.

Basic Legal Principles Affecting Nanotechnology

Nanotechnology's revolution for commerce can revolutionize global public health: the scientific revolution that began at the dawn of the 21st century has taken hold, surpassing 3 trillion dollars in 2015. International treaties and national laws from countries where nanotechnology is a rapidly growing part of their economy abound. In the 20th century, law was about balancing diversity by maintaining cultural differences without prejudice. The 21st century has overcome many of those challenges and confronts the needs for one world with new institutions for governance and a new role for the rule of law. Nanotechnology is a key component of the social forces shaping this discourse about new approaches to governance and the regulatory state. This crossroads in science influencing policy raises new questions about how people will survive when applying nanotechnology across a gamut of medical, security, travel, housing and nutrition venues, and what will be the role of precautionary principles.

This dynamic moment in history finds society at a policy crossroads: changes wrought by technology offer the opportunity to choose which old values will be kept, and which values will be thrown away. It is not surprising therefore, that the notion that nanotechnology is a "revolution" remains successfully echoed in nanomedical literature [1]. People who use nanotechnology every day in their homes, for personal medical needs, and in cars, buses, airplanes, trains and workplaces may not realize this. But, people who ignore vital social issues raised by the implementation of nanotechnology applications in commerce, or who shy away from discourse with those with whom they disagree, risk ignoring the importance of these revolutionary developments. They will then be mystified by the results when old inequitable prejudices are accidentally embedded into the matrix for new nanotechnology laws or when old rules no longer apply. Laws written in the wake of this revolution must meet these popular needs.

Nanotechnology 's revolution for commerce and industry can bring revolutionize public heath

Case Study for Commercialization: Nanosilverwires Under USA and EU Laws

A. Research Question

Whether new advances applying nanotechnology using nanosilverwires are subject to overarching toxic substance or hazardous waste regulations in Europe or the USA.

B. Background: Cultivating Innovation for Nano-enabled Quality of Life Improvements

The new nano-enabled applications to old products also raise questions of how regulatory bodies use existing long standing definitions as the linchpin for unlocking regulatory keys such as: stepwise testing and data gathering requirements for obeying regulations and global harmonization of chemical safety (GHS) requirements for training and disclosure [2]. An outstanding example is found in the case study of silver nanowires. Silver nanowires offer benefits compared to older processes, promising lighter and cheaper transfer of data and enabling communication that perhaps may ultimately reduce the global load of hazardous waste, (especially highly hazardous electronic products), even though a high level of uncertainty surrounds potentially potent nanotoxicity. A discussion that was not possible a decade ago, this preliminary examination reveals many efforts at regulation but there is so much data contained in the existing legal texts that a legal survey mapping the legal landscape in detail is sorely needed, before meaningful conclusions about can be drawn about legal parameters of silver nanowires.

C. Nanotoxicity as A Legal Criterion

The World Health Organization has commented regarding nanotoxicity as a subject of regulation and controlunder law: The final report in 2017 stated that it followed precautionary principles because "while humans have long been exposed to unintentionally produced nanoparticles, such as those from combustion processes, the recent increase in MNM production demands greater investigation into the potential toxicity and adverse health effects of these materials following exposure. Since newly developed MNMs are not tested sufficiently for possible health hazards, it is generally recommended to take a precautionary approach until testing results are available. This means that MNMs should be considered as hazardous unless there is clear proof that they are not."

Trying to stop nanoparticles from continuing to migrate elsewhere once the desired job is done, or understanding their uniquely toxic characteristics compared to the bulk form challenges the fundamental precepts of existing laws. Often, the established rules of science do not apply to the same substance in the nanoscale. For example, little is known regarding the stability, dispersion or toxicity of nanoparticles in decaying plant and animal organic matter, Thus, mystery surrounds the legal responsiblity of manufacturers and endusers of nanoparticles and the subsequent impacts, (a subject examined in detail in the Safer Nano Design and Law training programs in Archamps France).

D. Definition of Silver Nanowires Under Law

Nanosilver has been the subject of extensive regulation on both sides of the Atlantic, and the subject of premarket litigation that delayed commercialization for three years in the USA. It is unclear whether the relevant laws will result in a prohibition, detailed compliance requirements or no regulation for silver nanowires based on unique features of wire structures using nanosilver compared to other wires or compared to nanosilver in other applications.

Perhaps paper with silver components, for example, may be viewed by regulators in the USA as a form of hazardous waste or solid waste, based on the required "stepwise" analysis, given the detailed regulatory history regarding hazardous waste containing silver which almost creates a presumption that silver in waste is hazardous [3]. By contrast, nanosilver in clothing and refrigerator linings may have a different fate and thus a different regulatory fate too. Absent a clear definition in the scope of jurisdiction in relevant laws, efforts at commercialization and marketing must be prepared to defend against agency claims of jurisdiction. Also, whether the existing EPA stepwise approach can use information developed for other regulations is unclear. But it is clear that any commercial application of silvernano will need, at the very least, to distinguish its use in the new context from previous uses in order to support its commercialization [4]. Furthermore, there is a massive and growing regulatory burden regarding testing and proving general safety on both sides of the Atlantic.

E. Too many mandates!

There are literally tens of thousands of pages of laws and regulations that address the questions raised by silver nanowires. The weighty regulatory burden of expensive testing whether informative or not could destroy the economic viability of nano-enabled products and this would be a loss to humanity. But, no scholars have synthesized the laws and emerging data. The laws themselves are thousand ds of pages of text. For example the European Food Safety Authority (EFSA) stepwise definition of nanomaterials to determine whether nanostructures are present in food is nearly a hundred pages but it is a subset of a much larger legislative mandate addressing nanostructures in food that is also hundreds of pages. Each of the USA federal and EU regional laws described here are also hundreds of pages, excluding legal questions about intellectual property. To better understand the exact requirements of these statutes, however requires a special closer examination featuring a mapping of the stepwise analysis in each law side by side to determine similarities differences gaps and areas of possible duplication.

Stepwise Paradigms Please step carefully! Across Several Statutory Schemes

The use of so-called stepwise analysis in statutory scheme offering adaptive regulation of new or emerging technologies where risks remain largely unknown has become common.

Stepwise analysis is a lock and key approach to regulation, with specified testing serving as the linchpin in the lock. A new test appears at each step. If the test unlocks certain types of information, the substance being examined is deemed safe or otherwise not relevant for further examination or additional testing may be required. Results that reflect outcomes listed in a second set of criteria at the same step then lead to the next step of analytical testing. For example, Resource Conservation and Recovery Act (RCRA) stepwise analysis first asks if a substance is solid waste or hazardous waste. Solid waste is then subject to comparatively less exhaustive scrutiny. If an enduser following the required stepwise testing determines that their process creates hazardous waste, several more steps are required and then the enduser must examine the so called "toxicity characteristics" of the hazardous waste. And, transport of hazardous

waste is regulated by the US Department of Transportation and therefore is also subject to parallel rules that dovetail the EPA rules, making sure that another agency continues to monitor the hazardous waste when the laws governing production and storage.

In USA also, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the newly revised Toxic substances Control Act (TSCA) each require a stepwise approach to determining compliance with their statute. Each of these laws employs a stepwis analysis that places the burden of submitting to the regulations on the producer or user of hazardous waste; failure to comply with the law holds criminal as well as civil penalties if hazardous waste is determined to be present without a compliance program.

This stepwise approach also appears in the EU European Food Safety Authoirty guidelines concerning nanostructures in food, (including contact transmission that could embrace nanowires depending on use and context). For example the EU EFSA published in 2011 a "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain" (EFSA Scientific Committee, 2011) which was refined in May 2018. The 95 page document offers on page 79 an important stepwise analysis for "NanoDefine decision flow scheme" with multitiered testing. Although the stated goal is to provide a practical approach for assessing potential risks arising from applications of nanoscience and nanotechnologies in food additives, enzymes, flavourings, food contact materials, novel foods, feed additives and pesticides including nanopesticides (including pesticides that use nanosilver) the scope of this jurisdiction is so broad that it brings in many additional processes and end products than plain meaning for these terms suggests.

Unfortunately, the theory that this lock and key approach is useful is the only point they share from the standpoint of implementation. The stepwise approach has flexibility that lies in the ability to require the endusers themselves to engage in such testing. Self-examination with candor is the heart of stepwise analysis, because enforcement penalties are typically quite high if the analysis is wrong. In theory too, one false or incorrect evaluation can ruin all the subsequent analysis. Under this theory, regulated entities have a strong incentive to test accurately without disclosing their ingredients or processes to authorities and without wasting public administrative resources on needless inspection. Self-enforcing provisions based on the validity of working assumptions at each stage of testing is the hallmark of stepwise regulation—step carefully!.

Specific Statutes in USA and EU That May Regulate Nano-enabled Developments

There are different stepwise questions and different expensive tests to be performed in each of the key acts of legislation that may touch upon silvernanowires. In both EU and USA, laws that have claimed jurisdiction over these nanostructures or nanomaterials are each quite complicated requiring specialized testing and agency review of the test results. Unfortunately too, these laws are not necessarily consistent with each other from the standpoint of their requirements for testing prior to marketing. In fact there is a credible argument to be made that the USA and EU laws governing these same nano-enabled processes have contradictory if not simply different purposes and regulatory goals. If so, there is a conflict of laws question that must somehow be resolved before providing complete legal analysis by examining the differences and similarities in required testing across major laws.

A. USA: Does FDA law apply to silver nanowires?

Regulatory authority for the US FDA (Food and Drug Administration) ranges from cosmetics to chemotherapy agents to food packaging and cosmetics skin creams and food additives. FDA's approach treats products differently depending upon their purpose. For example, Food additives are considered safe when there is a reasonable certainty of no harm from their intended use [1]. But, drugs are evaluated based on risk profile compared to predicted benefit. Therefore different contexts lead to different regulatory outcomes for the same product. Yet, FDA policy supports innovation and the safe use of nanotechnology according to FDA's nanotechnology regulatory science research plan), designed to ensure transparent and predictable regulations grounded in its so-called product-focused, science-based regulatory policy [5].

B. EPA laws that might Apply to silver nanowires

In the USA the Environmental Protection Agency,(EPA) is responsible for regulating pesticides under FIFRA and Clean Air, Clean Water, Pesticide, Hazardous Waste disposal, Brownfield cleanup and Toxic substances Control. EPA defines solid waste as garbage, refuse, sludge, or other discarded material (including solids, semisolids, liquids, and contained gaseous materials). Some but not all solid waste may be considered hazardous waste.

Since silver is already subject to extensive regulation by EPA it is unlikely that a credible argument will be made that silver nanowires are harmless or exempt from existing regulations. Instead, a scientist should be partnered with lawyers to chart the stepwise analysis under law. If silver nanowires do not meet the stepwise criteria for resource recovery, it will be necessary to defend the efforts that were made under the stepwise framework if they analysis was challenged.

a. RCRA

Resource Conservation and Recovery Act Solid Waste Regulations and Hazardous Waste Regulations offer a stepwise analysis, which considers bulk silver as hazardous waste. Even if silver nanowires are harmless there would be a burden on the users to demonstrate that their waste products are sufficiently different from other uses of silver so that regulation is not needed, based on toxic characteristics, the unique properties of nanomaterials, how they behave during manufacturing, product use, and end of life disposal in context; quantity is not relevant.

b. TSCA Compared to REACH

According to the EPA official determination, many nanoscale materials are regarded as "chemical substances" under the Toxic Substances Control Act (TSCA). As part of the Agency's effort to ensure a more comprehensive understanding of nanoscale materials in commerce, EPA issued a final regulation requiring one-time reporting and recordkeeping of existing exposure and health and safety information on nanoscale chemical substances in commerce pursuant to its authority under TSCA stating specific chemical identity; production volume; methods of manufacture; processing, use, exposure and release information; and health and safety data. Persons who manufacture or process a reportable chemical substance must report to EPA so that EPA can take action to ensure that chemicals that may or will pose an unreasonable risk to human health or the environment are effectively controlled, but the substances are not required to meet the rigorous criteria of being proven to be safe before use. Nanosilver use was litigated in the USA for 3 years in NRDC v EPA; thus new uses of nanosilver may face stronger

scrutiny. In stark contrast to the Regulation (EC) No 1907/2006 called Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (European Parliament and Council, 2006) designed to protect human health and the environment from the risks that can be posed by chemicals and applies horizontally to all chemical substances in the European Union, TSCA does not require proof that materials are safe. REACH addresses chemicals in whatever size, shape or physical form. Nanomaterials that are applied as food contact materials (e.g. SAS, TiO_2, nano- silver etc.) or in industrial sectors (e.g. TiO_2in paints), are not exempted from registration under REACH. and therefore its provisions also apply to NMs.

C. EU: A Plethora of Directives that Have Concurrent Laws in EU Nations

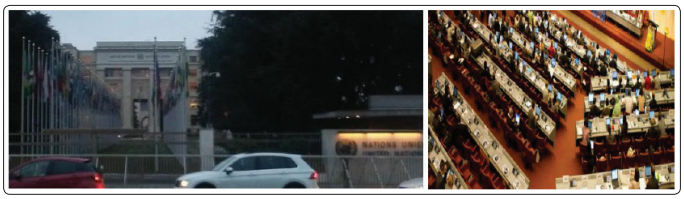
The emerging federal framework across EU member nations means that there is a desire and operationalization of goals for unity, but nation states who are EU members retain their own right to create or modify the overarching EU laws. In a manner that is consistent with principles n the USA, EU enables Member states to regulate. It is not considered duplicative or conflict of laws if both the superstructure and the state regulate a substance at the same time. Precedents in this aspect of the law, however, are inconsistent and therefore confusing. Revised "Plastic Food Contact Materials" Regulation (EU) 10/2011 states that substances in nanoform shall only be used if the nanoform is explicitly authorised and mentioned in the specifications, such as Titanium nitride for use as additive or polymer production aid. In addition, carbon black and amorphous silicon dioxide are listed without being specifically named as "nanoparticle.

Nanoparticle authorization is a case-by-case process.Substances released from active food contact materials (e.g. nano-silver as antimicrobial) into food matrix are considered intentionally added to food and therefore an authorisation as food additive may be required. European legislative acts for food contact materials (e.g. Directive 84/500/EEC on ceramic articles) currently do not contain provisions for nanomaterials. Minerals or vitamins are regulated by Directive 2002/46/EC on food supplements (European Parliament and Council, 2002a).

Nanoforms of minerals or vitamins (e.g. encapsulations) require a safety evaluation under the Novel Food Regulation, due to the differences in production, potential differences in nutritional value and bioavailability when compared to macro-scale counterparts.

Global Response

"The protection and promotion of the health and welfare of its citizens is considered to be one of the most important functions of the modern state".George Rosen [6]. A vast and vibrant corpus of laws protects health. This concept of government obligation to protect its citizens is as old as the Great Wall of China, which was built thousands of years ago to keep out invaders and preserve the integrity of an empire. And this concept of government responsibility is met by actions of thousands of diplomats and civil servants who meet to plan and implement health policy and protect rights. International laws reflect, and do not ignore, the societal need for a legislative response to hazards that exist in daily life. Legal tools exist for promoting the implementation of precautionary principles without civil society seeking to reinvent them. Strong international norms demonstrate a universal desire to protect consumers, protect the environment throughout the life cycle of product use, and enhance occupational health protections for all societies. Protecting public safety, defense, and national security and controlling toxic or hazardous substances are reflected among national laws and intergovernmental agreements designed to promote those goals.



Left Main entrance, Palais des Nations of the United Nations, Geneva, Switzerland, home of expert meetings about precautionary principles and the law of health. Photo by Dr. Ilise L. Feitshans. Right Governments and stakeholders deliberate the UNEP agenda, Geneva, Switzerland. Photo source: United Nations Environment Programme.

A. The World Health Organization Constitution: Codifying Precautionary Principles

The movement to codify health norms as legal principles had a defining moment at the end of World War II, when the entire world cared about attempting to set written legal limits upon behavior by governments and individuals. UN activity brought codification of international norms regarding the right to health into the positivist, plain language of several key international human rights instruments, with a spirit of hope for all humanity's survival.

Logo from the WHO website. This logo, as used here, is only to assist readers to identify WHO and does not constitute or imply any endorsement of content.

Although merely an administrative agency, many view WHO as the paragon of rights- based health programming and respected references for health research and health policy. The most widely accepted definition of "health" in the world is written in the preamble to the WHO Constitution [14] : ***Health is a state of complete physical, mental and social well-being and not merely the absence of disease and infirmit*** [7].

The drafters of the WHO Constitution envisioned scientific breakthroughs and therefore offers an elastic framework that can be expanded to include new developments and reduced when a problem has successfully been diminished, as in the case of eradication of smallpox. This text has been quoted around the globe in constitutions, international treaties, and public health practical guides. This remarkably broad but flexible definition of health makes virtually any human endeavor a matter of health jurisdiction-- few endeavors have no impact on human health. Drafters of the WHO Constitution also understood the notion of latent disease, because long-term exposures that may appear to be harmless at the outset

may, after many years, take their toll due to a cumulative effect, also is important for warning about presently unknown disease caused by exposure to nanomaterials.

B. WHO Guidelines for "Protecting Workers from Potential Risks of Manufactured Nanomaterials"

Purpose: "These guidelines aim to facilitate improvements in occupational health and safety of workers potentially exposed to nanomaterials in a broad range of manufacturing and social environments. The guidelines will incorporate elements of risk assessment and risk management and contextual issues. They will provide recommendations to improve occupational safety and protect the health of workers using nanomaterials in all countries and especially in low and medium-income countries" [8]. This ultimate precautionary principle was applied even though no nanomaterial exposure has been linked to causing a specific diagnosis,when WHO created nanomaterial exposure guidelines.

C. WHO guidelines: a flexible definition of nanomaterials

"Nanomaterials' refers to materials that have at least one dimension that is smaller than 100 nm (10^{-7} m)," but also take into account that manufactured nanomaterials (MNMs) may glom together into substances of much larger sizes [9]. The ability to include the larger group of MNMs without reaching into standards for a bulk form of the same substance is a conceptual breakthrough, showing that nanomaterials are now viewed in context.

D. WHO Guidelines Main message: disclose possible risks using GHS

WHO developed its guidelines for the target audience of workers, policy makers, and professionals making decisions about protection against the potential risks at the local, national, or international level .The guidelines project aims to avoid the catastrophic effects of uncontrolled exposure such as the asbestos industry experienced because "Recourse to precaution should be used to reduce or prevent exposure as far as possible. This was seen as an important underlying approach in the interest of protecting workers' health, especially given previous experience with asbestos".

The big news for people who apply the final guidelines is one message: Use the GHS methods of classification and labeling of chemicals, and using the authorized safety data sheets (SDS), disclose potential harm from workplace exposure to nanomaterials. "updating safety data sheets with MNM-specific hazard information or indicating which toxicological end-points did not have adequate testing available including respirable fibres and granular biopersistent particles' groups" . To operationalize these goals, the WHO guidelines recommend using the GHS for all manufactured nanomaterials, which requires worker training and disclosure of potential hazards in paperwork that trvels across the supply chain.

E GHS Globally Harmonized System of Classification and Labeling of Chemicals

Precautionary principles and government responsibilities protecting health operationalized in national state and local laws, major international legislation that adhere to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). GHS is best known for the Safety Data Sheets (SDS) that follow each substance as it travels through global commerce. The SDS lists the composition of the product and its potential health hazards and the best practices for handling transport storage and clean up. Significantly GHS is self-enforcing because a manufacturer producer or seller of toxic or hazardous materials discloses information voluntarily. Enforcement s triggered by corporate culture: as each recipient of the goods gets their incoming shipment they have the right to obtain the SDS that travels with the goods, to question the quality of its information and to confirm that the SDS is correct before sending it along the next stop along the supply chain. Best practices for use and cleanup are also part of training that is required under GHS using a global unified system of symbols for dangers such as fire explosion or corrosion.

Data Source

A. USA NIOSH Guidelines about Nanomaterials

"***Sound occupational health programs that implement best strategies are the grease for the machinery of powerful economic engines." Ilise L Feitshans***

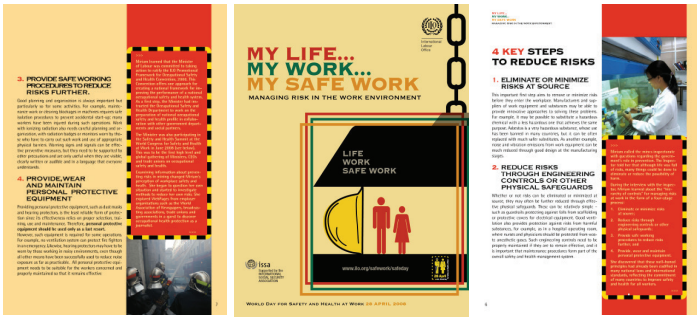
The USA Occupational Safety and Health Act (OSH Act) does not specifically mention nanotechnology carbon nanotubes or nanomaterials but the law does charge employers with the obligation to "provide employment and places of employment that are free of recognized hazards" in the General Duty Clause [10] The term "recognized hazards" is however subject to interpretation by experts in the scientific community. The National Institute for Occupational Safety an Health (NIOSH) in the Centers for Disease Control and Prevention (CDC) created under Sections 21 and 22 of OSH Act are internationally respected as leadrrs of the scientific community and capable of offering scientific definitions of "recognized hazards". Their public hearings regarding nanomaterials explored « Whether the hazard identification, risk estimation, and discussion of health effects for carbon nanotubes and nanofibers are a reasonable reflection of the current understanding of the evidence in the scientific literature » [11] . The justification under OSH Act for the Recommended Exposure Levels (RELs) for nanomaterials implicit in implementing the General Duty Clause have resulted in the creation of a series of NIOSH guidelines for workplace exposure to titanium dioxide carbon nanotubes and a variety of other nanomaterials including nanosilver. Although not law and therefore not enforceable as standards, the information offered for free by NIOSH is an important resource filling the void regarding risk assessment of nanomaterials, risk management and the best practices to prevent harm.

(**Left**) Laborer cutting wood in Switzerland (2015) Photos: Charoy family. (**Right**) the ILO's main headquarters building Geneva, Switzerland. Photos by Dr. Ilise L. Feitshans.

B. The International Labor Organization C 155

The Preamble to the ILO Constitution of 1919 states, "Universal and lasting peace can be established only if it is based upon social justice" ILO Convention No. 155 (Convention on Occupational Safety and Health; C155) provides a framework for governance

infrastructures that can ensure the implementation of a coherent national policy to generate robust data for training and updated information about injuries, illness, statistics, risk assessment data and best practices [12]. The heart of ILO C155 about national occupational safety and health laws concerns the creation of effective national, regional, and workplace mechanisms for implementation and periodic evaluation of occupational safety and health standards among member states of the ILO. For example, Article 4.1 states ILO C155's goal of fostering the development of a "coherent national policy" concerning occupational safety and health protections through research, statistical monitoring of hazardous exposures (such as medical surveillance measures, not unlike technical standards in member states), and worker education and training. ILO C155 uses broad terminology to provide a regulatory framework.



Role of due diligence for crafting worker protections

Due diligence is the coherent strand that pulls the entire nanomaterials safety mechanism together [13]. Due diligence is achieved in the process of following the WHO and NIOSH guidelines: First, noting the embryonic state of the art of understanding nanotoxicity and the responses for nanosafety, employers, workers, and policy makers who apply these guidelines have nonetheless shown a keen concern about preventing potential hazards.

Second, the process itself allows employers and policy makers to write compliance programs with a blank check regarding specific methods of assessment and precautionary measures to be implemented. Scientists and governments agree there are unknown risks and therefore, have begun drafting laws despite the absence of clear and compelling information. Therefore there is consensus that nanotechnology poses risks of significant harm to presently exposed populations, the greater ecological environment and to the public health. But qualitative data to protect exposed people and the greater ecological system that surrounds the human environment lags behind industrial use, research and application of nanotechnology to consumer products.

Left Dignitary addressing the United Nations General Assembly, New York. Source: US government. Right Swiss representative to the United Nations Human Rights Council prepares to address a public session in the Palais des Nations Geneva, Switzerland. Photo by Dr. Ilise Feitshans.

The ubiquitous character of nano-enabled products may be a weakness as well as its strength. The very attractive feature of small nanoparticles that can traverse previously impermeable barriers also means that little is known about how to stop them from migrating, how to predict where they will go on their own despite human calculations, or which substances can interact as a trigger to make the nanoparticles cluster together or adhere to other substances with unpredictable results. It is not possible to precisely estimate risk, because so little is known about the emerging field of nanotoxicity. Conequently, questions about so called "fate" of nanoparticles loom important about controlling risk at the nanoscale under law. Demonstrating concern for the reasonable actions to prevent harm makes Due Diligence your best friend.

Conclusions

Nanotechnology is exciting because the state of the art of manipulating matter at the nanoscale is in its infancy, and the possibilities to be explored are wide and uncharted. At the same time that newness brings untold and unforseen risks, which law as a general principle does not handle very well. For example, 3D printing may make intellectual property regulation irrelevant or even a liability, as the embedded codes to protect patents will be easily reproduced along with the possibly faulty copy. Lawyers can contribute information to this discourse. Good legal training can inform every phase of this process. Creativity, however, is not random; cultivating innovations that save money and reduce duplication of efforts requires much forethought as well as new ideas. This means that policy documents and their regulatory content must be filled with more than compromise; it requires training outside one's own professional career path and then applying the lessons learned from that training.

The cumulative effect of exposure to a variety of nanomaterials will also be subject to scrutiny using new legal tools to allocate responsibility, because exposures will be in combinations that cannot be quantified in places where exposure cannot be controlled and the source of potential harms may remain unknown. In conclusion, silver nanowires provide one example of an exciting new development that creates great promise but unknown risks due to gaps in information about nanotoxicity which in turn, makes it difficult to determine whether the material is subject to existing laws.

Stay tuned! The next nanotechnology decisionmaker may be you!

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