



# Mythbuster: Zapping away the Mythical Absence of Nanotechnology Law

**Ilise L Feitshans JD\***

International Law of Nanotechnology, European Scientific Institute, Archamps Technopole, France

**\*Corresponding author:** ilise L Feitshans, International Law of Nanotechnology, European Scientific Institute, Archamps Technopole, France, Email: [Ilise.feitshans@gmail.com](mailto:Ilise.feitshans@gmail.com)

## Commentary

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## Introduction

The myth that nanotechnology is easily defined For the past two decades a false sense of security has surrounded the Scientific community regarding the definition of Nanotechnology it's uses in nanomedicine and a wide variety of consumer products and Nano informatics. Traditionally the accepted definition reflecting scientific consensus involves matter of 100 nanometers or less in one or more dimensions and is often demonstrated with the example that there are one hundred thousand nanometers in the diameter of one strand of human hair.

Actually, this seemingly sharp division between clearly defined nanomaterial and the rest of the world is often haphazard in reality and can become ill-defined when forced to discuss Nano scale objects of a few hundred nanometers or the agglomeration of multiple Nano scale objects under a hundred nanometers into one clump or cluster thereby creating new nanomaterial. The definition has its limitations when trying to characterize nanomaterial in relation to their nanotoxicity, some scientists may reluctantly confess, because there is no clear relationship between known risk, attendant toxicity and shape or size.

But what about the people outside the research lab... policymakers, industrial decision-makers stakeholders in class metrical enterprises using Nano-enabled materials consumers at the end of the chain of supply and above all the people involved in recycling used nanomaterial and determining whether the laws of hazardous waste apply?

For people developing and exposed to nanomaterial outside the research lab there is a confusing juxtaposition of precision uses for nanomaterial and Nano-enabled products right alongside exciting and fascinating products

that scientists would never consider to be Nano-related at all. For example the car named nan the Swiss toy nanomania and the casino named Nano in Stockholm might have Nano-enabled components but would not be traditionally viewed as having a Nano functionality at all. Yet the name chosen for these products suggests that some inherent trait about them is by definition Nanotechnology related and therefore to the innocent consumer or end-user the notion that these items are subject to government oversight through Nano regulation may be indirectly implied. If so, what should consumers and judges in the courts of law do if there are damages caused by such products when they are unregulated remains a mirky open question. Whether the law should exclude such products or embrace them within any legal definition of Nanotechnology or nanomaterial for the purposes of Nano regulation however, is a political judgment call. Such policy decisions regarding the definitions for Nanotechnologies and commercialization of Nano related products need not be rooted in any scientific explanations. Indeed no law requires the law to have a link to scientific definitions of Nanotechnology at all.

## Zapping the Myth that there is no Law Controlling Nano-Enabled Products

Along with Scientific researcher's misplaced confidence that everyone knows the definition for Nanotechnology and nanomaterial's there comes a myth that these matters so intensely scientific are not subject to human made laws. Regardless how defined, there is a myth of exceptionalism that seems to claim Nanotechnology is so very different from all other matter that it is not subject to any previous laws. Yet this myth is very far from true. Beyond the obvious role of law that controls society by prohibiting actions that are too dangerous for achieving societal benefits and the parallel use of laws for encouraging developments that enhance the quality of life as a public good there are a host of laws

emerging that specifically address Nanotechnologies in commerce for health and daily life. As always the legality or prohibition of activity is determined by an admixture of its purpose and the context of its use. For example titanium dioxide in toothpaste may be a great teeth whitener and prevents dental caries. But titanium dioxide in toothpaste is also responsible for a new form of entry-level drug addiction that Wikipedia labeled as, “tooth pasting”. Basically tooth pasting involves spreading toothpaste on sensitive points on the human body to get high. This stimulation can then be combined with additional ingredients such as alcohol or over the counter drugs. None of the activities are illegal by themselves and certainly there is no law prohibiting the use of toothpaste designed for oral hygiene that successfully prevents dental caries. But whether there will emerge either a law limiting the sale of toothpaste by quantity or a law addressing the potential impairment of drivers, airline pilots and other responsibly positioned individuals who use the substance in an inappropriate context to perform their duties while high but escaping detection for drug abuse by using legal substances remains to be seen.

#### **Use Case: Carbon Nanotubes or Nano silver Wires for Transmitting Data**

Nano circuitry poses regulatory dilemmas that are equally tantalizing. Light weight threads made of carbon nanotubes or silver circuitry on paper made with nanowires both offer an ecologically sound alternative to the massive heavy quantities of non-reusable waste created by a wide variety of electronics and their supporting materials. Both uses are not mentioned or even contemplated by laws written fifty or seventy years before the commercialization of Nanotechnology. Yet clearly these new products employ production paradigms that were contemplated by laws governing environmental protection hazardous waste and recycling

Carbon nanotube threads to carry signal from a small patch sewn into clothing can be lifesaving for a patient high performance athlete or a rescue worker or a pilot in a high stress job. Such signals can harmlessly and unobtrusively send signals for heart rate and respiration to laptops or central data centers that monitor the other individual’s well-being so that action can be taken to prevent system failures caused by personal harm. So too the development of silver nanowires to offer complete circuitry on paper are not merely an engineering achievement. The rise of printed electronics on paper represents one great demographic success story that allows the dying paper industry in a paperless era to rise like an origami Phoenix to reach new economic goals while felling fewer trees and using less paper. Eventually such circuitry posits the capability to remove large wire circuitry from telephone and radio signal operations. Both of

these amazing advances are not exactly perfect solutions to electronic hazardous waste problems because while solving the problem of hazardous waste volume the nanotoxicity and ecotoxicity of the spent products remains unknown.

#### **The Litany of Legal Issues in Nanotechnology Uses**

Several key legal questions are raised by both examples of transmitting potentially lifesaving data with less electronic waste as raised by the use case above.

#### **Privacy Concerns**

Is the data that travels across these circuits protected under the European GDPR or Sim lar laws in Africa or Asia?

#### **Law Governing ownership of Nanotechnology Research and the Fruits of Nano enabled Discoveries**

#Research scientists frequently express concerns about intellectual property rights governing patent and copyright regimes in the relevant jurisdictions for their discoveries. These regimes are expensive in the short term because of the large expense for patent research filing fees and choice of law questions in competing national and international patent regimes. These legal questions become insignificant in the long term however as more and more research is the product of multiteam multidisciplinary collaborative work. No single research or research team can easily lay claim to original work especially in the context of borrowed research facilities shared under the terms of a treaty such as for example the European synatron in France. Furthermore the ease of copying matter using Nano-enabled technologies makes enforcement of intellectual property protections illusory in the long term.

#### **Regulations for Nanotechnology use in Commerce**

\$\$ Once any protected intellectual property is approved for protection, the next step is to obtain approvals under medical regulations or relevant Communication regulations in a variety of countries where the signal will be transferred and ultimately received. In addition to national laws there is the regime of the ITU (international telecommunications union) in Geneva Switzerland

Intellectual property protections and regulatory approvals are merely the beginning, a foundational floor, and not an end in itself.

#### **Nano regulations Protecting Public Health**

> Occupational health regimes exist under law and in guideline formats, regarding workplace exposure to nanomaterial

> Ecotoxicity is addressed by specifically mentioning nanomaterial's. For example in the USA FIFRA (federal insecticide fungicide and rodenticide act) there are specific provisions pertaining to the use storage transport and disposal of Nano pesticides. Additionally EFSA (the European food safety authority) has issued guidelines about nanostructures in food. "From field to fork". Nano pesticides and contact transmission of migrating nanoparticles are discussed within the scope of these rules.

> Nanotoxicity is the subject of toxic substance control in Europe such as REACH (registration evaluation assessment of chemicals) and by function under the recently revised by USA TSCA (toxic substances control act) Collective impact on social values and cumulative effect of retrospective exposures are yet to be explored and therefore are likely to create new rules.

> Good news! Nanotechnology can transform definitions of disability as people who are blind and deaf can drive autonomous cars but also expanding the population considered disabled as we explore presymptomatic testing

> New legal questions if individual patients are recommended or required to obtain treatment for presymptomatic problems discovered using Nano-enabled technologies. Are they covered by insurance excused time from employment pay for lost?

> Work and most of all protections against discrimination under disability

## Who Needs Law? Differences between Guidelines and Law

### Guidelines are not Regulations but Who Cares?

Text box: List of guidelines about nanotechnology safety health and

- > Potential risks to be managed
- > OECD
- > WHO
- > NIOSH (USA National Institute of Occupational Safety and Health)
- > EFSA
- > Misc tools

Versus Regulations

- > Nanoreg template
- > EFSA use of word nanostructure
- > USA Nano silver FIFRA
- > Nano silver possible
- > TSCA circa FDA

End of textbox

### Guidelines Fill the Necessary Void in the Law

Spinning the underlying thread in the seamless web called law and legal systems leaves little chance that there could be validity to the myth that there are no laws governing Nanotechnology at all. Whether guidelines or hard laws, there are now many rules to follow in order to demonstrate a method of compliance with a respected standard of care. There are nonetheless a few key legal principles to bear in mind when deciding whether to follow guidelines or established law. Guidelines are nice because they are soft and friendly. A trap for the unwary they are soft and fuzzy. Soft law not enforceable by the enforcement authorities but they nonetheless fill the void in legal regimes that cannot possibly discuss every possible permeation of substances and uses. Nor would civil society want to have so much law in the interacts of action.

### Who cares? Who needs law?

Guidelines are not law but time after time scientific researchers cite their adherence to guidelines when writing protocols and creating infrastructure supposedly defensible under law. In their efforts to show their work is not merely creative and innovative but also essential and paradigmatically defining... Presenter after presenter consistently confused law and legislative tools such as regulation with guidelines when discussing their amazing life transforming work at scientific meetings. Any law student knows laws written by duly elected people with legitimate legislative power are not guidelines. Laws are enforceable and typically hold penalties for enforcement regardless where the law draws the lines whether scientific criteria or the price of tolls for Bridges and tunnels.

Regulations are the detailed rules created under laws by the administrative agency that has been delegated the authority by a duly elected legislature to create the fine-tuning of achieving the goals and mission of the law. It is enforce required and not subject to dispute Therefore regulations and the statutes that create the permission to write them are called hard law yet, regulations may become blurry because they are the product of compromise as is the case of any legitimate political document under law. But inconsistencies produced by political compromise and poor quality of legislative drafting does not, convert regulations into soft law. Regulations written by a duly authorized regulatory agency with an underlying statutory mission are indeed hard law. This remains true regardless how weak or soft their requirements may appear to be.

Guidelines that are clear and direct however can be followed by millions of people in contracts and research protocols but will not ripen into hard law unless one of two

remarkably unusual events occurs. First the guidelines can be used so often with so much trust in the private sector that they might. But not definitively...ripen into customary law. For example the International standards organization (ISO) in Geneva Switzerland self-styled consensus standards are an excellent example of customary global standardization. Text in contracts that require signatory parties to follow ISO standards make the I to law for the purposes of the agreement when they are used and applied by mutual agreement. The ISO has no regulatory power. It is a confederation of trade associations and it is not an International organization in the traditional sense of the legal term of art. ISO has offices around the world and its members come from Different Nations. But no it is not a treaty body created by the plenipotentiary powers of diplomats from legitimately elected governments of Nations such as OECD (Organization for Economic Cooperation and Development, twenty nations) WHO (World Health Organization) WIPO (World Intellectual Property Office) WTO (World Trade Organization) and the UN (United Nations). No matter how many contracts discuss and apply ISO so called standards they remain soft not hard law.

Second soft law can be given the same imprimatur of the state when soft law guidelines are adopted by regulatory authorities in a given jurisdiction whether state local regional or International treaty body. A well-known example is the so-called start-up standards at the time of the writing that created the USA occupational safety and health act of 1970 under USA law. Faced with a crisis of mounting unexplained incidence prevalence and occupationally related deaths from cancer occupational exposure to a wide variety of known toxins the USA congress authorized the occupational safety and health administration (OSHA) to set up business by codifying the American national standards institute(ANSI ) guidelines until new rules could be written by the new regulatory agency. But that was true only for a limited time (called a sunset clause in the statute) and more importantly the statute itself authorized this incorporation y reference under law.

### Who Cares?

Besides these superficial differences between soft and attractive guidelines in contrast to the looming enforcement with penalties of regulations under law there really is a major key difference between these types of governance that is too often overlooked by people who mistakenly have been led to believe they are better off without law. Sure guidelines are a stake in the ground offering an anchor for programs that demonstrates due diligence for concerns about public health. This is particularly invaluable for those situations when guidelines fill the void in underdeveloped or emerging laws both by codifying the state if the art of scientific beliefs

and by offering a nice consensus blueprint for hard laws. But the one thing guidelines can never provide is assurance that one has done the best under law. In times of catastrophe guidelines can be attacked as inadequate because in reality such rules have not been created by legitimate government. Guidelines are basically nothing more than idea if what many people want to do.

By contrast, Laws provide certainty and stability. If someone goes through a red light in any nation when they should have stopped. Well no one would debate that they made a calculus of risk and must accept the consequences under law. But turn that idea around and consider the vehicle that proceeded when the light was green and was hit or even destroyed by an oncoming illegal vehicle. If at the time of collision the traffic light was green for the damaged vehicle that fact is a valid defense against claims of damages for having caused harm. With very limited exceptions such as the rights of emergency vehicles or pedestrians proving that the traffic light was green is a valid defense that prevents a defendant from being held accountable for liability. This is the insurance provided to law abiding citizens under the social contract that governs civil society Guidelines are soft and warm and fuzzy but they therefore cannot provide a blanket protection against liability. Why? Because only a government can make the political determination what is too little too much or just enough preventive activity in society. That is the role of law and line drawing is where the rule of law lives. If the traffic light was green too long that > may be a weakness in the law but the law-abiding citizen is not liable for acting in compliance with the law. Scientific researchers should therefore spend more time and resources offering input to regulatory agencies and participating in legislative efforts that create statutes governing emerging technologies such as nanotechnologies and nano-enabled commercialization under law rather than touting their implementation of guidelines that are not law.

### Conclusions

In sum, guidelines are useful to go where there is no law--- but only law can provide the assurance to scientific researchers and commercialization by industries that in conducting their activities they have done the right thing. And there is no law shortage, on the contrary there is a plethora of existing nanotechnology law Laws concerning Nanotechnologies are sprouting like so many mushrooms along the legal landscape. And so too are written rules for preemptory efforts at precaution and risk management. These rules serve to amplify well established regulations that apply to projecting the public health in face of Nanotechnologies, regardless whether the terms are defined within those laws or not. The notion that there are no laws of Nanotechnology however is an antiquated and misguided

myth at best. There are laws governing Nanotechnology and implementing those laws effectively reasonably and pro-

actively is in every stakeholder's best interest.

