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Governing Technology: "Nanotechnology Risk Management and Public Health Protection Act" A Harmonized Approach to Promoting Innovation While Protecting Global Health

Feitshans IL*

Director ESI Safernano & Fellow in international Law of Nanotechnology, European Scientific Institute Archamps France, and Global Health Law LLM Candidate,Georgetown University Law Center USA

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***Corresponding author:** Ilise L Feitshans, JD and ScM and DIR, Director ESI Safernano & Fellow in international Law of Nanotechnology, European Scientific Institute Archamps France, LLM Candidate, Georgetown University Law Center, O'Neill Institute for National and Global Health Law, Washington DC USA, Tel: 917 239 9960; Email: ilf@georgetown.edu

Abstract

Nanotechnology is globally in food, clothing, aviation, transport, housing construction, weaponry, medical devices, new medicines and outer space exploration. Since risks associated with the new technology emerge slowly there is time to create a rational global oversight mechanism that promotes innovation and protects public health, Because no commercial product is made entirely in the same place from start to finish without any components from other nations, nor is it marketed only in the place where it was made, innovators, must catalogue a multitude of laws and drill down into key subjects across jurisdictions[1] in order to comply with law[2] and thus soon find their compliance efforts in a swamp of legal documents, regulations and guidance without a compass to figure out which regulatory path works best or is appropriate. This plethora of laws, regardless how well intended, creates disinformation and blocking both public education and the free flow of commerce. This article proposes an international nano-risk governance framework with a bioethics commission, empowered to examine questions about nanotechnology and its commercial applications and to disseminate information to the general public. The "Nanotechnology Risk Management and Public Health Protection Act" fills a void in the nanoregulatory landscape, where information is plentiful but trustworthy sources are rare.

Keywords: Lnanotechnology law, nanoregulation, risk management, risk governmance, commercialization of nanotechnology, environmental safety and health, workplace health

1. Janeck Fordsmand, ilise feitshans et al, Bridging international approaches on environmental, health and safety aspects of nanotechnology" NATURE NANOTECHNOLOGY May 2021 DOI10.1038/s41565-021-00912-5. https://rdcu.be/clgnw
2. Ilise L Feitshans "Nanoethics for safe work; philosophical foundations of safer nanodesign protecting workplace health" 12.1 "International efforts to harness nanomaterials under law" p209-211 IN Marcel Van de Voorde and Gunjan Jeswani Eds. HANDBOOK OF NANOETHICS Walter de Gruyter GmbH Berlin/ Boston 2021 ISBN 978-3-11-066923-7. See also: US Department of Labor OSHA, 29 CFR Part 1910, Docket No. OSHA-2019-0001]RIN 1218-AC93. In June, 2021, the USA Occupational Safety and Health Administration (OSHA) revised its Hazard communication program, started in 1986, in order to align with this system, by including nanomaterials within its requirements for disclosure and training.

Introduction

Purpose of the *"Nanotechnology Risk Management and Public Health Protection Act"* Promoting Innovation, Protecting Global Health

Providing all workers and consumers accurate detailed information about Nanomaterial Exposure is a major global health Challenge[1]. Scientists and governments agree that the application of nanotechnology[2] to commerce poses potential risks to human health and the environment[3], but disagree about methods of risk management,[4] how to design compliance[5] and which risks require highest priority[6]. s[7]. The In 2011, WHO started bridging health rights regarding nanoscience from the lab to law[8]. Its Committee of Experts prepared Guidelines, finalized in 2017, offering unprecedented, visionary opportunities to operationalize precautionary principles advancing global health, before any established link between workplace exposure to nanomaterials and subsequent harm. The Guidelines training that delivers information to workers, it incorporated by reference the treaty, Global Harmonization for Chemical Safety (GHS)[9] a multiphase stepwise disclosure model for employer-based training and information dissemination Committee focussed on methods but left issues about health hazards for aother day [1].

Figure 1: Unfortunately, WHO and GHS Have Authority, but Never Developed Infrastructural Capacity to Analyze Empirical Information Disseminated to Workers Exposed to Nanomaterials.

"Recommendations: E. Training and involvement of workers: "The GDG considers training of workers and worker involvement in health and safety issues to be best practice but cannot recommend one form of training…

This glaring lacunae jeopardizing global health requires asking: how to deliver clear and accurate training to workers using nanomaterials. Absent the "***Nanotechnology Risk Management and Public Health Protection Act"*** , workers using nanomaterials are without reliable tools to assess nanorisk-information where trustworthy experts can describe nanomaterial hazards that they face in their work environment. Although application of nanotechnology may be novel, applying a vibrant corpus of international law operationalizes the precautionary principle, to contain or manage risk while incubating new industries is not new. A plethora of nanoregulations and laws that exist without a hierarchy to prioritize these rules pose an immediate, but not insurmountable, obstacle to sound international commerce, because obeying one law does not ensure that another competing law has been obeyed. Sometimes, specific text of the laws differs across jurisdictions. For example the text of laws in the EU[12] seem to be diametrically opposed to the principles articulated in US even when implementation blurs these contrasts. Taken together, however, these laws do empirically demonstrate a global consensus that law and science must partner together to achieve global health and commercial goals.. In this context it is not surprising that there is no single regulatory space where authority has been clearly established in order to sort out complex issues of responsibility under law and the trade-offs in science policy. Nor is there any regulatory space that is authorized to organize competing laws and guidelines or prioritize their role within the legal hierarchy. The"***Nanotechnology Risk Management and Public Health Protection Act"*** Model Act fills this unmet need to advance public health protection and innovation by enabling stakeholders to have a central place for inquiry and discussion with a view to problem-solving about global health issues raised by nanotechnology.[13] The provisions establishing a Bioethical Commission in Section 5authorize a wide variety of experts and stakeholders to work together within a legal framework that will generate empirically sound information for all about legal determinants[14] of global health law in general and nanotechnologies in particular [2].

Scientific Consensus: Unquantified Risks Bring Uncertain Results

Desire to regulate nanotechnology has been clearly articulated by many draft laws and several key statutes at the national, multinational and UN level. Existing nanoregulations, environmental laws, international treaties and trade agreements, exemplify the transnational character of this jurisprudence and underscore a global need for clear

limits and permissions regarding the use of nanomaterials in commerce A bottom-up approach is advocated to hear which problems are salient and prioritize information accordingly [3]. To do so involves using information about exposure assessment, risk assessment, hazard analysis and data collection; using the tools of risk mitigation and best practices so that manufacture, use, handling, transport and safe disposal of nanotechnology applications is feasible and so that risks are understood by people exposed to risk [4].

Globally, great efforts have been devoted to developing nano-specific testing guidelines, guidance, and risk assessment or risk management frameworks, either on larger collaborative data platforms or as stand-alone data sources. [15] For example, commerce must bow to local laws about permits regarding uses and zoning of the places that engage in nanotechnology research and its applications; taxes, prohibitions against discrimination and respect for privacy. Even when they have the same goal, there can be conflicts of language or interpretation among the national laws in a world of over 195 nations; plus regional laws that bring together several nations such as the Organization of American States (OAS) the Organization for African Unity (OAU), the ASEAN group in Asia and the European Union (EU). An overwhelming majority of nations agree, [16] the Right to health is enshrined as a "fundamental" right in the WHO Constitution without ratifying additional treaties [17] These efforts[18] enhance the ability of manufacturers, regulators, end-users and the general public to incentivize the release of information that forms the underpining of safety-bydesign,[19] in an attempt to speed up innovation without overlooking very costly potential adverse health impacts to ecosystem environments on earth and in outer space, [20]and human health. [21]Consistent with with this goal, European research is rapidly developing a risk governance framework for nanomaterials covering all levels as exemplified by the Nano RIGO and RISKGONE projects [5]. [22]

III GHS: Successful Precedent Protecting Global Health and Advancing Commerce

History shows that innovation can thrive when there is a superstructure that consistently operationalizes precautionary principles across jurisdictions, because enterprises and economic actors, (including governments in their employment capacity) cannot be held liable when obeying the law[23]. On the contrary, legal principles that support obeying the law create an "affirmative defense": when a defendant has obeyed the law with the result that harm arises from acts that are legally in compliance with the relevant law, then the fault lies in weak laws, not bad acts. The linchpin of an affirmative defense, however, is that the defendant accused of creating liability has obeyed the relevant law, not merely any old law that they choose. A flexible framework can laser focus its terms on a particularly problematic aspect of nano-enabled applications to the greater society, using the priorities that stakeholders want and those legislative drafters believe will work best [6]. Many well-intended and widely accepted nongovernmental sources of nanotechnology standards, guidelines and consensus documents, so-called "soft law" have been generated to address nanotechnologies. Soft laws may be more attuned to the needs of users or more aligned with the needs of a particular interest group, but lack power; soft laws cannot provide the protection that compliance with laws provides against liability in the event of harm. The resulting admixture of guidance and government- empowered regulations, with new laws springing up like mushrooms[24].

One outstanding model for coherent and efficient harmonization of laws is the Global Harmonization of Chemical Safety, (GHS) [25] which is respected worldwide and followed by hundreds of nations. Even in the case of the USA, which does not typically ratify the major global treaties, the government has seen fit to create an end-run around the typical treaty ratification process, by creating an interagency entity with oversight to monitor compliance with GHS under the auspices of over 100 agencies ranging from US Department of State, Food and Drug Administration (FDA) Occupational Safety and Health Administration (OSHA) and Homeland Security. Under GHS suppliers, distributers and end users meet their globally shared need predictable laws and consistency. Requirements to pass forward the information about toxicity nanotoxicity, adverse health effects and possible hazards in the context of other materials are embodied in the Safety Data Sheets (SDS) that travel the world and often can be found on the web. Furthermore the goals of information transmittal are operationalized by requirements for labelling under a new universal code of pictograms and requirements for training in the use of SDS, the use of materials, safe handling methods and detailed explanations for clean-up in the event of spills or unplanned exposures. All sectors and across all job descriptions, employer entities, including government entities acting in their capacity as employers, are required to offer this information free of charge and update it annually in training. Many nations including the USA have incorporated these requirements by reference into their existing laws about occupational health and safety and therefore fulfilling these requirements is a subject of national enforcement, subject to inspection, fines, abatement requirements or penalties such as closing down the facilities involved. These precepts are also included in unexpected places such as university experimental facilities and government labs around the world. As a result, GHS provides pre-emptory protection for the health of the general public and buffers participants against liability. GHS is inherently transparent because any participant in the process, including end-users (whether

consumers or an enterprise incorporating final products into their new product) is entitled to trace back along the supply chain to obtain detailed information [7-11].

Suppliers, distributers and end users need predictable laws and consistency and they need reliable information when purchasing goods from abroad or shipping their goods from their home country. Therefore GHS has been viewed by many companies as a sigh of relief, ending previous confusion regarding labeling and the right of companies to know the accurate information from their suppliers, regarding chemicals that are shipped around the world and used in thousands of different applications in international trade. Providing consistent and predictable data from manufacturers and suppliers to downstream users is central to the GHS rationale. Each link in the supply chain must operationalize the right to know by providing training about materials and attaching that information to products, by using a unified template called Safety Data Sheet (SDS). Plugging-in data they used and then passing that information along to the next link in the chain of commerce enables each participant in the chain of commerce to enjoy the right to know about relevant health hazard information.

Therefore, GHS has been viewed by many companies as a sigh of relief, ending previous confusion regarding labelling and the right of companies to know the accurate information from their suppliers, regarding chemicals that are shipped around the world and used in thousands of different applications in international trade. Under GHS suppliers, distributers and end users have the opportunity to enjoy predictable laws and consistency and they need reliable information when purchasing goods from abroad or shipping their goods from their home country. Providing consistent and predictable data from manufacturers and suppliers to downstream users is central to the GHS rationale. Each link in the supply chain must operationalize the right to know by providing training about materials and attaching that information to products, by using a unified template called Safety Data Sheet (SDS). Plugging-in data they used and then passing that information along to the next link in the chain of commerce enables each participant in the chain of commerce to enjoy the right to know about relevant health hazard information. GHS process is inherently transparent because any participant in the process, including end-users (whether consumers or an enterprise incorporating final products into their new product) is entitled to trace back along the supply chain to obtain detailed information about products that are in use, whether already in the workplace or the subject of possible purchase [12-14].

GHS is Self-Enforcing Rather than Subject to Inspections

GHS is widely accepted and subject to detailed training and certification in schools of public health, programs for industrial hygiene or occupational hygiene and its international scope includes training by UNITAR, (United Nations Institute for Training and Research). Its impact has clearly become a pre-emptory strike against long negotiations about whether a product is safe or how to characterize its risks when starting negotiations for purchase or sale, thus saving money time and staffing resources from the outset of any commercial negotiation regardless whom is the purchaser or the supplier.

GHS operationalizes a legal theory called “Stepwise analysis”. The stepwise approach is a lock and key theory, wherein each step unlocks a series of questions, and those questions determine whether the next step of analysis is required[26]. False information and missteps can be easily discovered by the next partners in the supply chain, and any resulting harm caused by inaccurate disclosure can result in liability. The notion that the next entity in the supply chain will accept responsibility and possible liability for adverse health impacts following use or exposure to toxic and hazardous substances is an important underpinning of the stepwise analysis triggered by accepting materials that have an SDS, and therefore the next user in the supply chain will always need reliable information when purchasing goods from abroad or shipping their goods from their home country [15].

Each recipient of information has a burden to confirm the information disclosed to them is correct, in order to avoid potential liability when passing forward the same data. This does not require specific standards or arbitrary language to ensure the quality of data, which remains the responsibility of those who send the information, because of the so-called “garbage in, garbage out” risk of stepping incorrectly. Implementing GHS therefore favors candid selfevaluation before disclosure. Missteps produce mistakes; inaccurate disclosure causing harm is traceable, so that the source of the error becomes accountable for consequences. Stepwise, but step carefully, with due diligence supporting decisions about unquantifiable risks! [16].

Precedents for Harmonization of Laws Across the Globe

Harmonization across jurisdictions is not a new challenge; but acceptance of a harmonized regime for nanotechnology requires that governments forsake a piece of their sovereign power in order to bend to the will of other governments so that a nanoregulatory process can emerge with one unified law [17].

Therefore harmonization of the existing and emerging

nanotechnology laws requires a hierarchical superstructure set forth in the framework proposed here to meet civil society's need for predictability in trade, to meet the private and public need for data collection regarding risks, to answer the universal need for consistent requirements regarding risk communication within industry and among industrial users and consumers of nanotechnology applications and to provide risk communication to directly impacted and secondary passive exposed populations. Tools for benchmarking, data collection, archiving data and synthesizing data from several sources with a view to protecting health is toooften misunderstood as a needless restraint on industry and not the invaluable resource for establishing commerce and industry that regulation has proven to be. A threshold need for clear mechanisms to encourage harmonization of conflicting nanotechnology laws swiftly takes centre stage in order to reconcile conflicts of law. Without a framework to guide application of diverse standards and guidelines, global nanoregulation can be a jungle hampering future development and use of nanotechnology in commerce regardless how logical, popular or well-intended these nanoregulations and parallel commercial or public health laws may be. This process is unlikely to be completed quickly, but inevitably some laws will take center stage and others will stay in the periphery as societal needs change. In order to facilitate trade and protect global health, governments relinquish sovereignty, thereby bowing to international law. If realized however, this structure could meet civil society's need for predictability in trade, the private and public need for data collection regarding risks, answer the universal need for consistent requirements regarding risk communication, including a clear transfer path for risk communication [18].

Key Points: "Nanotechnology Risk Management and Public Health Protection Act"

The goal of our overarching superstructure is to design a package for the tools that already exist in law and the science of risk management, A strong and clear framework can organize the relationship between existing laws, existing guidelines and standards and indicate the gaps where new laws may be required. This also helps to harmonize the already large and unwieldy body of nanoregulations by bringing clarity to priorities [19].

Compliance with Existing Global Systems:

[27]Embedding the existing body of well-respected established GHS law into a new legislative framework enables the new law to have benchmarks from the time of its effective date, even if those benchmarks are modified at a later time. A central feature of our proposed structure is a commission or governance council with (a) power of oversight for bioethical issues in the applications of nanotechnology (b) procedures for investigation and (c) redress to consumers and the general public in the event of explosions, spills or emergencies. A proposed structure embedded within the Model Act embraces data generation, risk evaluation and related management by creating compliance oversight structure across the life cycle of products that contain nanomaterials or self-styled "nano" products in order to enable products sale and distribution to flow across the chain of commerce throughout each product life cycle while safeguarding the environment and without sacrificing health. These provisions are enforceable because Section 9 enables individual citizens to trigger enforcement by petition with clear and convincing evidence to the Commission. The last sections address penalties, a legislative "Saving Clause" in case part of the law is repealed or deemed unenforceable and Effective Date [20].

New Model for Risk Communication to the Public

Nanotechnology information for all is a fundamental tenet of this proposed legal initiative[28]. This notion of Nanotechnology information for all is inspired by the practical reality that nano-enabled products are ubiquitous in society: nanotechnology has become a foundational methodology for several new disciplines including AI (artificial intelligence) big data collection and use, genetic manipulations (such as CRSPR mRNA vaccines) and a host of products for packaging, transport, food, drugs, cosmetics, housing construction materials, instant clothing, communication by telephone and internet, and novel consumer objects that everyone encounters every day.[29] Innovation in nanotechnology is a catalyst for prosperity that can both innovate to bring economic benefits and overcome environmental challenges, if managed correctly[30]. Response to the multifaceted problems of informing workers and their families about risks associated with nanomaterials in the workplace requires a new paradigm for risk communication within the context of risk management[31]. Countless nanotechnology guides and sets of best practices are available [21].

There is global health precedent for this approach, but it is not found in hard law. The World Health Organization (WHO) without regulatory authority has nonetheless issued a well-respected set of guidelines about workplace exposure to nanomaterials after several years of careful expert consultations. Similarly, the USA National Institute of Occupational Safety and Health (NIOSH), also well respected worldwide without regulatory authority to inspect workplaces or enforce occupational health standards, has generated accessible information and guidelines about the use of nanomaterials such as titanium dioxide and also general guidelines.[32] Many of the same experts worked on these guidelines so it is not surprising that their texts dovetail nicely, but these words are not enforceable under

law and are not accountable to the public under principles of transparency or delegation of authority[33].

Section 1 of the Model Act Framework for Nano Risk Governance

This section sets forth the importance of advancing a culture of innovation while protecting environment and health safety across the lifecycle of nano-enabled commercial products [21].

The background description of the economic and public health problems addressed in the proposed Model Act embraces steps from data generation to the actual risk evaluation and related management, positive incentives for inhouse compliance programs and an oversight commission. Finding that use of a flexible framework enables targeting broader societal and environmental concerns, the Model Act allows for a mechanism to generate responsible nanotechnology research and use consistently, across cultures and jurisdictions. The findings that justify the framework recognize the interdisciplinary character of nanotechnology research and applications, which generates the need for stakeholders to be heard, while reflecting perspectives from the general public and the media, legal theory and good science by Zooming in on nanoregulation decisionmaking: the center of the interface between public health, emerging technologies and international laws [22].

Purposes in Section 2 Target Broader Societal and Environmental Concerns

This includes to construct a regulatory framework:

To Anticipate, Recognize, Evaluate, Control, and Confirm risks to human health and the environment on a case-by-case basis, that applies precautionary principles to control and manage risks and communicate those risks when applying nanotechnology [23].

To require and develop ongoing regulatory mechanisms for oversight and monitoring of communication about risk, safe handling and projected long term health effects of nanotechnology products and, their biological fate the ecosystem and human beings [24].

To provide positive incentives for compliance with requirements for risk communication

Section 3 Definitions include: "Corporate Criminal Sanctions" For Violations, "Due Diligence"; "Risk Management", "Risk Mitigation", and "Inhouse Compliance"

Definitions found in the Model Act explain to whom the legislature has granted authority, limit the scope of jurisdiction and clarify the roles of key players in the implementation of the new law. Clearly written definitions therefore enable consistent interpretations. For example, "Due diligence" is the fundamental concept for crafting and implementing effective in-house management systems. Our proposed Act therefore offers details about how t construct compliance programs, which in turn offer concrete proof of due diligence, ultimately allowing an entity to enjoy a presumption that activities are reasonable although the limits for preventing harm are unknown. The scope of the Model Act in **Section 4** applies to end-use impacts of engineered or manufactured nanomaterials without regard to size, including materials in commerce that self-characterize as "nanomaterials", "using nanotechnology" or listing "nano" among product features in labelling, publicity or using "nano" in trade names [25].

Section 5 Creating A "Commission for Bioethical Oversight of Nanotechnology Risk Communication in the Department of Health" is the Heart of the Model Act

This central structure provides a reasonable alternative to the present chaos created by inconsistent laws with varying degrees of efficiency and conflicting jurisdiction. These components of the proposed framework will enable predictable oversight that will enable products to flow across the chain of commerce throughout the product life-cycle while safeguarding the environment and without sacrificing health. Oversight for risk communication embraces fairness, informed consent, and human health parameters of any applications of nanotechnology. The Commission can act as a conduit for monitoring and oversight, confirming ongoing free flow of information from the manufacturers, industrial consumers and product distributors of applications of nanotechnology to workers, consumers, the general public and end-users. It has power to: hear complaints from organizations and individuals regarding the failure to disclose required risk communication, authorize remedies to correct failures; set (or waive) penalties or fines; and create an accessible bi-annual report about best practices for maximizing benefits of nanotechnology, while minimizing risk [26].

Section 6, "Rewards For Proven Due Diligence In Risk Management" Enables The Commission To Offer "Positive Incentives" For Compliance

With Requirements For: Disclosure; Risk Management; Risk Communication And Risk Mitigation.

The Key Components For Operationalizing These Tasks Are Detailed In **Section7, "Risk Management To Promote Responsible Development Of Nanotechnology" Setting**

forth: components of risk management systems; data to Hazard analysis, quality-controlled, remotely accessible, searchable archives of comparable characterization, toxicological exposure information, methods for exposure assessment, and risk communication, with ongoing discourse between the Commission, regulated entities and stakeholders. Due diligence is required for auditing and periodic reviews about compliance; the Commission could require an entity to rewrite their risk management plan in the event of system failure leading to harm. Section 8, GHS applies an ancient legislative drafting technique called incorporation by reference Embedding the existing body of well-respected established GHS law into a new legislative framework enables the new law to have benchmarks from the time of its effective date, even if those benchmarks are modified at a later time. Section 9 enables individual citizens to trigger enforcement by petition with clear and convincing evidence to the Commission. The final sections address penalties, "Saving Clause" and Date for taking effect [27].

Can Law Govern EHS Issues for Applied

Nanotechnology to Prevent Liability and Harm?

Harmonization across jurisdictions is not a new challenge, but acceptance of a harmonized regime for nanotechnology law must be bottomed on more than consensus-- achieving harmonization requires that governments forsake a piece of their sovereign power in order to bend to the will of other governments so that a nanoregulatory process can emerge with one unified law. Therefore harmonization of the existing and emerging nanotechnology laws, requires a hierarchical superstructure set forth in the framework proposed here to meet civil society's need for predictability in trade, to meet the private and public need for data collection regarding risks, to answer the universal need for consistent requirements regarding risk communication within industry and among industrial users and consumers of nanotechnology applications and to provide risk communication to directly impacted and secondary passive exposed populations. This process is unlikely to be completed quickly, if at all. Inevitably some laws will take center stage and others will stay in the periphery once there is a framework with clear priorities. It is not to expect that governments will relinquish sovereignty or that any administration responsible for public and environmental health would give up its power, thereby bowing to international law [28].

While plenty of global efforts for harmonisation exist, there is no clear indication which harmonized body of nanoregulations will become the most important. Simultaneously, well intended researchers in academia and governments and private industry are nonetheless filling the regulatory void with scientific guidance and guideline development aiming for a risk testing framework In sum, the rapidly changing nanoregulatory situation cries out for harmonization, transparency and consistency across hundreds of possible jurisdictions that are home to legitimate and enforceable laws. Regarding the substantive steps to be followed, risk management, employing best practices and exposure assessment and tools for risk communication provides the best answer to the problem of avoiding liability and forseeable harms, and for anticipating problems that cannot be predicted at the time of its writing. Therefore a base is needed to ensure the flow of data throughout the process of nanotechnology commercialization ensuring sound and replicable risk management: exposure assessment, risk assessment[34], followed by education and training that will ensure the ongoing flow of data for stakeholder feedback in a cyclical process [29].

Conclusion

Harmonization is Key and a Commission is Needed to Traffic the Process

Historically, law and science have successfully partnered together throughout the 20th century to take on "Big science" projects that were fraught with risk, and succeeded in harnessing atomic energy and decoding the human genome without blowing up the world or unleashing mutant monsters. Each of those endeavors undertook innovative projects that were fraught with risk, promoted new industries and ameliorated the quality of life for humanity. And, each of those projects had strong overarching legal frameworks to guide their discovery and provide oversight for their compliance with law. Therefore, a vast field of long and often inconsistent text governing commercialization of nanoenabled processes already exists. 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. But, when scientists develop various regulatory minded nano-risk framework they often are not aware of that such a framework will operate under various laws in different jurisdictions, laws covering many different related issues. Thus, the plethora of nanoregulations and laws that exist without a hierarchy to prioritize them becomes an immediate obstacle to sound international commerce because obeying one law does not ensure than another, competing law has also been obeyed. The complex area of jurisprudence concerning the questions about which law applies involves resolving conflicts of law. A threshold need for clear mechanisms to encourage harmonization of conflicting nanotechnology laws swiftly takes center stage in order to reconcile conflicts of law. Without any proposed framework to guide application of diverse standards and guidelines, global nanoregulation becomes a jungle

hampering future development and use of nanotechnology in commerce regardless how logical, popular or well-intended these nanoregulations and environmental, commercial or public health laws may be. Legal analysis of these rules within the larger superstructure can also yield important policy benefits by indicating gaps where new laws may be required, but also can demonstrate where duplicative or useless provisions can be removed [30].

The world needs nanotechnology and therefore, it is not surprising that its application across all industrial sectors and throughout commerce has become ubiquitous, as its proponnents in the previous century envisioned. The resulting plethora of nanoregulations, an admixture of statutory laws, treaties, private contracts and soft law, leaves many gaps and many overlapping areas of conflicting jurisdiction.

While plenty of global efforts for harmonisation exist, there is no clear indication which harmonized body of nanoregulations will become the most important. Simultaneously, well intended researchers in academia and governments and private industry are nonetheless filling the regulatory void with scientific guidance and guideline development aiming for a risk testing framework In sum, the rapidly changing nanoregulatory situation cries out for harmonization, transparency and consistency across hundreds of possible jurisdictions that are home to legitimate and enforceable laws. Regarding the substantive steps to be followed, risk management, employing best practices and exposure assessment and tools for risk communication provides the best answer to the problem of avoiding liability and forseeable harms, and for anticipating problems that cannot be predicted at the time of its writing. Therefore a base is needed to ensure the flow of data throughout the process of nanotechnology commercialization ensuring sound and replicable risk management: exposure assessment, risk assessment, risk mitigation through education and training, and to ensure the ongoing flow of data for stakeholder feedback in a cyclical process.

Oversight by a Commission comprised of an admixture of experts and novices gives a wide range of relevant perspectives for open discussion of technical points so that regulators have clarity regarding swiftly changing benchmarks, such as the Integrated Approaches to Testing and Assessment (IATA). Ultimately the result of these long discussions will enable manufacturers, employers including government entities, and consumers to know where they stand in relation to information about risk management when making choices about products that deploy nanotechnologies or nano-enabled offshoots of baseline nanotechnology [31].

The proposed ***Nanotechnology Risk Management and Public Health Protection Act*** does not override or repeal any of those laws or rewrite guides for best practices. Instead it offers an overarching superstructure to prioritize rules, to sort out the useful wheat from the chaff of duplicative, politically biased or otherwise flawed risk management analysis, and to clarify the roadmap for implementing nanotechnology information for all so that every stakeholder can become aware of and enable sound practices that foster innovation and protect global health across the legal landscape. Consequently, a commission created under a "Nanotechnology Risk Management and Public Health Protection Act" offering oversight of communication; following the blueprint of the GHS treaty; and incorporating by reference its terms as a start-up source for benchmarks can provide accountability for self-enforcing responsibility among those who send the information to protect the work health and survival of civil society and posterity [32-36].

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Endnotes

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