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Proposal for Legislative Text

"Nanotechnology Risk Management and Public Health Protection Act"
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Proposed framework as a thought experiment for the package of nanoregulation (laws and guidelines) that can enable stakeholders, civil society, scientists entrepreneurs and lawyers to implement nanoregulations under national or international law

"Nanotechnology Risk Management and Public Health Protection Act"

Section 1. Legislative Findings

A. Nanotechnology galvanizing new commerce despite potential risks to public health

1. In the next five to ten years, trillions of dollars will be spent on research and development funding for the application of nanotechnology, touching the economy globally, across almost every industry: food processing for retail markets, cosmetics, paintings and coatings, agriculture, equipment and packaging.

2. Nanotechnology was calculated to represent about three trillion dollars of USA GDP by 2015 and is expected to be 14 trillion dollars in 2022

Heralded as a "revolution", comparable to the industrial revolution of the 19th century capable of changing daily life in a manner compared to the invention of the car, the sheer economic importance of nanotechnology will change several antiquated systems regarding industrial processes, scientific understanding and categorization of chemical informatics, and ultimately, the health care delivery systems that must use or correct the end products of these changes

3. Application of nanotechnology in industry outstrips assessment of the risks from exposure. Therefore the science of protecting the public health lags behind the science of research and development that creates new elements and new intellectual properties.

4. Risks associated with the application of such technologies are much slower to emerge, than the many new vistas of prosperity and efficiency that nanotechnology promises to humanity throughout the world.

5. The spectre of new economic frontiers with wider horizons for new products and the attendant commerce from their trade has caused many opinion leaders in science, law and health policy to herald nanotechnology as an unprecedented opportunity for human development and growth.
Yet, known dangers of many of the substances whose molecular structure are changed using nanotechnology has caused alarm among scientists and policymakers who fear that unfettered use of such new technologies can unleash a public health crisis in the event of explosion or spill of engineered or manufactured nanomaterials

6. Thus, the law and policy question arises and its answer remains unclear until new legislation is created to fill this void: *What law, if any applies to protect the general public, nanotechnology workers and their corporate social partners from both liability and preventable harms?* 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 this writing.

B. Risk Management based on Due Diligence to Promote Innovation and Protect Public Health

1. 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.

2.Therefore, Even though 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, scientists and public health officials have an obligation to the general public to institute scientific oversight employing precautionary principles that will enable products to enter commerce while
a. safeguarding the public health for consumers,
b. protecting people exposed to nanotechnology applications in their workplace
c. protecting workers children who are indirectly exposed through passive secondary exposure to nanoparticles in workplace products brought home on cars and in clothes or through direct transplacental exposure during pregnancy,

and
d. protecting the delicate balance of ecosystem of the greater planetary environment.

3. Therefore a Commission is needed to ensure the free flow of data throughout the process of risk management for the purposes of exposure assessment, risk assessment, risk mitigation through education and training, for stakeholder feedback and to ensure the ongoing flow of data in a cyclical process

4. The Commission shall be empowered with the oversight of communication, but shall not ensure the quality of data, which shall remain the responsibility of those who send the information. The Commission shall also have power and oversight for bioethical issues in the applications of nanotechnology in medicines, in the event of explosions, spills or other emergencies, and in daily consumer exposures.

C. Precedent Justifying Regulation of Nanotechnology

1. Although application of nanotechnology may be unprecedented, the concept of creating preventive policies that contain or manage risk while incubating new industries is not new-- it is the hallmark of big science in the twentieth century that fostered nuclear research, genetics, astrophysics – just to name a few, and industries that fail to accept the harness of regulation run the risk of failing; asbestos use is one example.

2. Work health and survival are inextricably linked, therefore innovation must be balanced by regulation of consumer choices and workplace exposures, in order to protect posterity. As noted by the American Society of Safety Engineers on their website, "A safe and healthy place is a fundamental right. We believe that sound SH&E practices are both socially responsible and good business"

3.The small quantities of materials involved in nanotechnology call into question the application of scientific constructs applied under law, such as threshold values and safe levels of exposure, because nanoparticles that may cause harm fall far below the baseline of existing regulatory limits .

D. Scientific Uncertainty Regarding Unquantified Risks Is the Sole point of scientific consensus

1. Testimony from SIINN of the European Union, juridical experts and the Council of Europe consistently established that "The precautionary principle is directly applicable to emerging nanotechnologies …inadequate information, until the results from research studies can fully elucidate the characteristics of MNMs that may potentially pose a health risk (warrants) precautionary measures."

2. Scientists and governments agree that the application of nanotechnology to commerce poses important potential risks to human health and the environment, but the risks are unknown.

3. Several examples of high level respected reports that express this concern have been brought to the attention of this legislature[1]. The authors of such reports include: the Swiss Federation (Precautionary Matrix 2008) the Royal Society on Environmental Pollution (UK 2008), German Governmental science commission ("SRU"), Public testimony sought by USA National Institute for Occupational Safety and Health (NIOSH, Feb 2011) the OECD working group (since 2007),[2] the World Health Organization (WHO) the Council of Europe The Council of Europe in its report "Nanotechnology: balancing benefits and risks to public health and the environment //assembly.coe.int/ASP/NewsManager/EMB_NewsManagerView.asp?ID=8693&L=2 plus the discussions among several industrial groups, the consortium headed by the Center for International Environmental Law and various non-governmental organizations.

E. Impact of nanotechnology on constituents

1. Response to this problem requires risk communication within the context of risk management, using information that has been gathered through 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

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1 See: Swiss Federation (Precautionary Matrix 2008) the Royal Society on Environmental Pollution (UK 2008), German Governmental science commission ("SRU"), Public testimony sought by USA National Institute for Occupational Safety and Health (NIOSH, Feb 2011) the OECD working group (since 2007), the World Health Organization (WHO) the Council of Europe The Council of Europe in its report "Nanotechnology: balancing benefits and risks to public health and the environment Parliamentary Assembly of the Council of Europe (PACE) April 2013 //assembly.coe.int/ASP/NewsManager/EMB_NewsManagerView.asp?ID=8693&L=2

2 https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm see also25 Oecd.org/chemicalsafety/nanosafety publicatipns No. 91 - Guiding Principles for Measurements and Reporting for Nanomaterials: Physical Chemical Parameters (2019); No. 90 - Physical-Chemical Decision Framework to inform Decisions for Risk Assessment of Manufactured Nanomaterials (see accompanying worksheets) (2019) - Developments in Delegations on the Safety of Manufactured Nanomaterials - Tour de Table

applications is feasible and so that risks are understood by people exposed to these risks.

2.Workers, their families and dependents, consumers in the general public, and industrial purchasers of nanotechnology applications in various products have the Right to Know of these contents, their hazards and the steps for preventing harms, with special attention to the needs of vulnerable populations such as but not limited to aged persons, persons with disabilities, women who are pregnant or nursing, and children who face secondary passive exposures to these products

3. The state of the Art of nanotechnology risk assessment and risk management is undeveloped and therefore the legislature cannot draw bright lines regarding the size, function, character or end use of nanotechnology applications that would either limit or promote ongoing use

4 In the face of undefined unquantified risk, industrial purchasers and users in the general public need a regulatory framework that is dynamic in order for meaningful risk communication to be feasible and to change as new circumstances dictate

5. These issues have been successfully address in the workplace context only, by the risk mitigation techniques that form part of sound risk management that constitute the internationally accepted and widely praised GHS (Globally Harmonized System for the Classification and Labeling of Chemicals).

1. The rationale behind GHS provides consistent and predictable data from manufacturers and suppliers to downstream users. Each link in the supply chain must operationalize the right to know by providing training about materials and attaching that information to products, using Safety Data Sheets (SDS). The list of chemicals covered is impressive. It is a long list and there is widespread consensus about the dangers of these substances.

2. GHS has been viewed by many companies as a sigh of relief due to the 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. Until GHS there were so many laws governing this topic, no one set of rules applied everywhere and many rules seem to apply needlessly.

3. The success of GHS proves there can be voluntary compliance and that government can regulate in partnership with industry when global trade so dictates. Suppliers, distributers and end users need predictable laws and consistency and they need reliable quality when purchasing goods from abroad or to shipping their goods from their home country.

6. GHS has a Three pillar approach: 1 labelling, 2. safety data sheets, and 3regularly required training with risk communication about safe handling transport and possible health impacts

7.Filling the substance of these pillars meets current civil society needs for risk mitigation, risk management and risk communication about nanotechnology.

F. Responsible development of nanotechnology is not a spectator sport.

1.Positive Incentives For Voluntary Compliance Form A Vital Alternative Model to "punishment and deterrence" models for government regulation of organizational activity whilet preserving limited administrative resources for oversight and enforcement and also while encouraging responsible development of nanotechnology through compliance with law:

2. Positive Incentives for Voluntary compliance are offered herein:

a. To prevent organizational misconduct, especially within corporations but not limited to corporations as defined by existing laws.

b. To implement these voluntary compliance by recognizing positive achievements towards compliance using performance standards rather than bright line numbers for minimum and maximum exposures and related enforcement.

2. Every effort should be made to encourage the development of positive incentives for compliance with this law and to reduce administrative costs by granting limited waiver of fines or penalties in the event of self-reporting of violations, harms or spills discovered through routine internal audits or reported due to emergency.

G. Bioethical Concerns and Benefits of Nanomedicine and Nanotechnology Applications Must Be Addressed by a Permanent Commission

1. Based on evidence presented in expert reports and testimony from stakeholders, the legislature has therefore determined that Nanotechnology's revolution for commerce can also revolutionize public health.

2. Nanomedicine, a successful application of nanotechnology, will require society to rethink ancient notions that are the building blocks of social constructs regarding the nature of disease and its treatment, and the prejudices encountered by people who suffer from illness, forcing collective rethinking about ill-health.

3. Legal Terms such as "disabled" and "healthy" will take on a new meaning once treatments may be required or commonplace, using nanotechnology. Therefore, an unprecedented opportunity exists to benefit from both the

nanotechnology revolution and the revolutionary social change that recognizes individual human potential under international laws by preventing discrimination against people with disabilities; permanently reshaping civil society for the better. The Commission shall report on such changing paradigms and shall make recommendations for improving access to care, delivery of clear and competent instructions for informed consent, and related impacts of nanomedicine on society.

4.Key public health policy benefits of nanomedicine include:
a. Rethinking the distribution of public health care and delivery of health services
b. Rethinking the role of public health compared to private insurance

5.Bioethical Issues Associated With Nanotechnology Applications therefore are wide ranging and will change as new techniques are developed and population experience provides empirical evidence to guide the future direction of policy which are best resolved by an ongoing Permanent Advisory body in the Department of Health comprised of experts, industrial leaders, consumers, and individuals from the general public.

6The bioethical issues regarding the application of standards for protecting consumers, directly exposed workers, indirectly exposed children of consumers and workers, and the ecosystem of the planet's environment loom large in the case of possible accidents such as explosions from combustible materials the public uses every day such as aluminum and gold, and from spills of nanoparticles whose fate and transport remains poorly understood or unknown when they cross previously impermeable barriers at the protein corona between cells, across the blood brain barrier, and inside cells.

7. These developments must be monitored and controlled while encouraged and therefore must be subject to ongoing scrutiny and review of data through a multidisciplinary Commission compromised of experts, industry leaders representative of watchdog NGOs and private members of the general public from all walks of life, who shall examine the flow of , reported annually by the authority created under this Act

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H. Call for Harmonization of Nanotechnology Regulations Worldwide via collaboration and co-ordination with parallel regulatory bodies

1.A vibrant corpus of international law justifies governmental actions to address concerns about the operationalizing of the precautionary principle, in order to protect workers, consumer exposures and the public health. Accidental explosions and spills also threaten the environment and large populations.

2.Nonetheless, in the field of nanomaterials, many different institutions are working on different foca l points: standardization organizations, regulators, scientists, economic or health organizations, industries, and others. Countless nanotechnology guides and sets of best practices are available on the web and in text books. These words confuse further the question of unknown risks and what is the right course of action for a well intended employer or an instructor giving training, the inevitable solution to nano-law-proliferation is an international code with unified obligations and harmonized terms of art, especially definitions regarding the use and limits of applied nanotechnology. Quite often a given aspect of nanotechnology has more than one definition among respected references.

3.Desire to regulate nanotechnology has been clearly articulated by hundreds of draft laws and several key statutes at the national, multinational and UN level. Every nation has a statutory pbasis for its nanotechnology program, plus there are several key emerging laws at the regional and international level. Desire to regulate is clear, but too many laws exist or are emerging for any one rule of law to reign sovereign.

4.Therefore there is call for harmonization of the hundreds of existing and emerging nanotechnology laws,
a.to meet commerce's need for predictability in trade,

b. to meet the private and public need for data collection regarding risks,

c. to answer the universal need for consistent requirements regarding risk communication within industry and among industrial users and consumers of nanotechnology applications and

d. to provide risk commutation to directly impacted and secondary passive exposed populations, to protect the environment and to promote the legal viability of nanotechnology industrial users from future risk of liability from unregulated harms, while encouraging a culture of innovation for new industry.

WHEREFORE it is hereby enacted the "Nanotechnology Risk Management and Public Health Protection Act"

Section 2 Purposes:

A. To construct a regulatory framework to Anticipate, Recognize, Evaluate, Control, and Confirm the absence or presence of risks to human health and the environment in each context on a case-by-case basis, and to apply precautionary principles recognized under law to control

and manage the risks associated with the presence of nanotechnology applications in the environment impacting human health or impacting the ecosystem, in the human body and in workplaces by using the tools of risk management and risk communication when applying nanotechnology.

B. 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, their biological fate and transport in systems, including but not limited to: the ecosystem, non human species of organisms, and human beings

C. To provide ongoing contact with the directly impacted workforce, their families and dependents, and the general public regarding risk communication for primary and secondary exposures to nanotechnology applications in society;

D. To protect consumers, including industrial users as purchasers of nanotechnology applications in goods, by requiring and implementing universal risk communication that is clear, understandable by ordinary voting citizens who are not part of the scientific community.

E. To provide positive incentives for compliance with requirements for risk communication about applications of nanotechnology, mindful of the practical reality that such partnerships are needed because of the limited resources available for watchdogs and enforcement of important laws that embed precautionary principles into the daily work of public health

Section 3 Definitions

"Commission" means the "Commission for Bioethical Oversight of Nanotechnology Risk Communication in the Department of Health" established under this Act.

"Corporate criminal sanctions" refers to penalties imposed on the corporate entity itself and not individuals, as punishment for proven harms in violation of law. Such penalties include but are not limited to forbidding specific activities, suspending licences or revoking permits, or barring the corporation from engaging in specific commercial activities, such as obtaining government contracts for goods or services.

"Cyclical approach to risk management" means that compliance activities such as audits, risk mitigation programs and risk communication components of risk management are not one-shot firecracker approaches to evaluating and reducing risk. Each step in compliance must be regularly repeated on a cyclical schedule.

"Due diligence" is the fundamental concept for crafting and implementing effective in-house management systems for occupational health compliance that avoids liability. In many legal systems, the law requires that every effort has been made in advance to protect the public health and manage risk, regardless whether that risk can be quantified. The ability to prove that such efforts exist on a systematic basis throughout the employer's company, the so-called "paper trail" is dependent entirely upon proving this concept of "due diligence". Compliance programs offer concrete proof of due diligence, and thus allow an employer to enjoy a presumption of compliance in areas of the law where the limits are unknown.

"GHS" means the UN-based multinational system for Globally Harmonized System for the Classification and Labeling of Chemicals, involving hundred of nantions and hundreds of UN agencies working in collaboration with non-governmental organizations.

"Positive incentives for compliance" refers to tax credits, prizes, awards and other incentives to Good Citizen Corporations

"Risk communication" for the purposes of this Act embraces the GHS (Globally Harmonized System for the Classification and Labeling of Chemicals) three pillars: 1. labelling, 2. transfer of data sheets regarding the safe handling, transport or use of materials and their potential adverse health effects, and 3. disclosing such information to workers, consumers, end-users and the general public.

"Risk management" is a process that embraces exposure assessment, risk assessment, risk mitigation and risk communication. Risk Management is proven by documented due diligence.

«risk mitigation»; the term of art ‹risk mitigation› refers to a result-oriented process designed to prevent, detect, report and correct potentially dangerous conditions that can result in harm to human health or the global environment involving in house compliance programs.

"in house compliance infrastructure" feature, but need not be limited to: 1. Managerial statements in writing that demonstrate the enterprise commitment to workplace safety and health and to protection of the global environment in order to reduce or stabilize the global disease burden; 2.Documentation of the use of due diligence to steer the components of the compliance infrastructure, using internal audits on a cyclical basis that can capture health disparities, isolate particular exposures that have

heightened hazards and provide documentation of the best practices that were applied in response to potential harm; 3. in house communication to staff including but not limited to interactive video training and web-based elearning regarding the safe response to problematic conditions in the workplace (regardless whether chemical or circumstantial, and embracing emergency response; 4. two way vertical communication that enables complaints about problems to be recorded with response in a timely manner, using hotlines and in -house newsletters and intranet; 5. Documented ongoing interaction with regulators, insurers, consumers, suppliers, end-users and the general public in advance of developments and in case of emergency; and any tools .. that withstand judicial or scientific scrutiny which meet and maintain lawful occupational safety and health goals."

"NSDS" refers to Nanomaterial safety data sheet, the basic tool of risk communication under this Act.

"Stakeholder" refers to any party that may be indirectly or directly harmed by the failure to disclose risk communication as required by this Act.

Section 4 Scope

A. This Act shall apply to end-use impacts of engineered or manufactured nanomaterials based upon the context in which their nanoparticles function and upon their character and fate once functionalized, without regard to size, aggregation or agglomeration with additional particles in clusters or the reason that they were used.

B. This Act shall apply to any or all materials in commerce that self-characterize as "nanomaterials", "using nanotechnology" or listing "nano" among the product features in advertisements, labelling or related publicity. For the purposes of this statute, jurisdiction requiring compliance with the provisions of this law is triggered by the use of "nano" in trade names.

C. Failure to disclose the risk communication required by this Act in order to avoid jurisdiction of this Act shall result in fine and penalties enumerated herein including but not limited to possible criminal prosecution of organizations.

D. Fines and penalties may be waived despite failure to disclose upon presentation of evidence of systemic efforts to capture the best possible data and to use due diligence in risk management of applications of nanotechnology

E. Voluntary Compliance is encouraged through Awards that will be established by the Commission created herein

F. Nothing in this Act shall create liability on the part of administrators in the Commission or enforcement authorities for the use of NSDS risk communication or manufactuer-generated data that is inaccurate, misleading or unreliable. The sender of the nanotechnology risk disclosure is solely responsible for ensuring its accuracy and for any or all liability arising from errors in the data transmitted.

Section 5 Commission Established

"Commission for Bioethical Oversight of Nanotechnology Risk Communication in the Department of Health"

A. Delegation of Authority to Propose Risk Communication for nanosafety: For the purposes of evaluating fairness, informed consent, social justice and human health parameters of nanomedicine and any applications of nanotechnology subject to the provisions of this Act, this Act hereby establishes the "Commission for Bioethical Oversight of Nanotechnology Risk Communication in the Department of Health"

B. The purpose of the Commission is to act as a conduit with oversight to confirm the 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.

C. The Commission shall hear complaints from organizations and individuals regarding the failure to disclose risk communication required by this Act

1.The Commission shall have the power to authorize remedies to correct said failures.

2.The Commission shall have the power to set penalties and fines consistent with the purposes of this Act, and to refer matters to criminal investigators if necessary.

3. The Commission shall have the power to create Positive Incentives for Voluntary Compliance

4. The Commission shall have the power to waive fines and penalties upon clear showing of due diligence in risk management leading to risk communication for workers, consumers and end-users of the nanotechnology applications involved.

D. The Commission shall review and synthesize Best Practices into a Bi-annual report: Maximizing benefits of nanotechnology, while minimizing risk.

1Report Contents:

a. The thematic scope of the report shall examine the changing social meaning of terms such as "disabled" and "healthy" will take on a new meaning once treatments may be required or commonplace, using nanotechnology. Mindful of the unprecedented opportunity exists to benefit from both the nanotechnology revolution and the revolutionary social change that recognizes individual human potential under international laws by preventing discrimination against people with disabilities;

A. The subject of the report shall examine : Key public health policy benefits of nanomedicine including:

a. Rethinking the distribution of public health care and delivery of health services

b. Rethinking the role of public health compared to private insurance

B. .Bioethical Issues Associated With Nanotechnology

Applications

C. The bioethical issues regarding the application of standards for protecting consumers, directly exposed workers, indirectly exposed children of consumers and workers, and the ecosystem

D. Emergency Planning and First Responder Protections in the case of possible accidents such as explosions

E. Long term- impact upon the global disease burdern from nanomaterials the public uses every day such as aluminum and gold, and from spills of nanoparticles whose fate and transport remains poorly understood or unknown when they cross previously impermeable barriers at the protein corona between cells, across the blood brain barrier, and inside cells

E. Commission Proceedings

1. Commission deliberations shall be open to the public

2. Commission findings and reports shall be posted on the web

3. Commission reports and materials for risk communication shall be downloadable free of charge

4. The Commission shall provide and maintain web-based Blogs with discussion of best practices, NSDS and related aspects of risk management

EXCEPTION

5.The Commission and its members shll make no warranty of the validiy of data transmitted and responsibility for the quality of blog or message content shall remain solely with the sender of the information.

F. Commission Composition

1.The Commission shall be comprised of no less than 27 members and not to exceed 99, with an odd number divisible by 3 for its voting membership

2. The Commission shall provide an opportunity for a democratic voice for stakeholders in the process and for the monitoring and follow up of nanotechnology applications in commerce and related risk mitigation and risk management activities.

3.A There shall be established a panel of Commissioners representing a balanced cross section of civil society, with duly authorized representatives of stakeholders from:

1.Leading corporations

2.Governments: national, local and municipal

3.Non profit organizations and international non governmental organizations

4.Scientific academies

5.International organizations

6.Consumer groups

7.Public health research institutes

8. professional associations

9. Private individuals

3.B Members may represent also a collaborative or collective group of organizations

E.Voting

1. Voting strength shall be equal among all members

2.At least two thirds of the members shall be present to create a quorum for voting

3. Sessions shall be transparent and open to the public, except for voting, where ballots shall be secret

4.AVoting Commission members shall each provide no less than four (4) sessions of focus groups regarding the understandability of labels, NSDS and training for risk communication per year.

4.B. Each Voting Commission member shall report the results of focus groups to the Commission as a whole, to determine whether the methods used are readable, clear, and when necessary, alert the recipients to scientific uncertainty that requires further research.

Section 6 .Rewards for Proven Due Diligence in Risk Management

A. Positive Incentives for Compliance with Risk Disclosure provisions, risk management to enhance the quality of risk communication and risk mitigation technioques to reduce avoidable exposures

1.Within the first six (6) months of its establishment, the Commission shall seek stakeholder comments and vote on a list of innovative Positive Incentives for Compliance with the provisions of this Act.

2. Positive Incentives for Compliance shall include but not be limited to competitive prizes, awards for the broad-reaching and high level of risk communicating achieved through interactive programming with vulnerable populations or high-risk groups, and recognition of achievements in research and development of safer products.

Section7 Risk Management to Promote Responsible Development of Nanotechnology

A. Components of risk management systems

1. Data to Hazard analysis

The degree of acceptable risk, the methods of risk assessment and the measures of effectiveness for the same or similar hazards shall be determined by the context in which they arise, and therefore may differ depending upon circumstances.

2. Databases

To achieve the purposes of this Act, acceptable types of databases include but are not limited to :

Quality-controlled inventory of products incorporating nanomaterials or resulting

a. from nanoscience- and/or nanotechnology-based food or feed processes based on

b. substantiated, statistically tested claims and random samples of new products likely to

c. stem from nanoscience or the nanotechnologies.

3. Quality-controlled, remotely accessible, searchable archives of comparable characterization, toxicological, and

exposure information.

4. Quality-controlled, remotely accessible, searchable archives of risk assessment and test methods.

5. Quality-controlled, remotely accessible, searchable archives of safety equipment and equipment characteristics.

6. Exposure assessment

Analytical methods and instruments required to assess the (external) exposure of populations and the (internal) exposure of organs in the body – favouring noninvasive approaches.

Analytical methods and instruments required to characterize, detect and trace inorganic and organic nanomaterials in food and feed matrices, preferably in a high throughput mode; pathways for exposure assessment, risk assessment risk mitigation and risk managemen.t

B. The components listed here must be refined into risk communication.

7. Flow if data is multidimensional, but must include views of stakeholders

1. Inside the entity this requires soliciting the views and experiences of staff

2. For persons entitled to this information outside the entitiy, focus groups shall be convened to determine readability and comprehension of written materials such as but not limited to labels, NSDS (Nanomaterial safety data sheet, "NSDS") and materials generated for risk communication training and coursework.

3. Risk communication requires ongoing discourse between the Commission, regulated entities under this Act and stakeholders, in order to confirm that risk management activities are undertaken, that those activities are visible and open to the Commission's oversight and that the disclosures made through risk communication are understandable to stakeholders.

4. The Commission has discretion to require an entity governed by this Act to rewrite their risk management plan in the event of system failure leading to emergency incidents that threaten the public health with harm.

C Apply the data using the hierarchy of controls within the context of an in-house compliance system that has been documented and tested by the governed entity using :

1the components of the 4 key steps to reduce risks include but are not limited to :

a.Eliminate or minimize risks at their source;

b.Reduce risks through engineering controls or other physical safeguards;

c.Provide safe working procedures to reduce risks further, and

d.Provide, wear and maintain personal protective equipment.

D. Due diligence in auditing and periodic reviews shall be required to be demonstrated as proof of compliance with the requirements of this Act in the event of violations, in the determination of fines and penalties and in order to determine the rewards for positive incentives for compliance

E. Nanomaterial safety data sheet, "NSDS"

1. For the purposes of this Act, governed entities must produce, develop research to support and transmit Nanomaterial safety data sheet, "NSDS" to the next user in the chain of distribution.
2. NSDS shall follow the basic form of safety data sheets generated in compliance with GHS, with the exception, however, that NSDS will pay particular attention to the know and unquantified risks of exposure to the nanoparticles or nanomaterials involved.

F. Cyclical approach to risk management

1. Each entity is required, in order to warrant the validity of information transmitted in the NSDS, that it has followed the key steps of risk management:

Anticipate, Recognize, Evaluate, Control, and Confirm the absence or presence of risks to human health and the environment in each context on a case-by-case basis, and to apply precautionary principles recognized under law to control and manage the risks associated with the presence of nanotechnology applications in the environment impacting human health or impacting the ecosystem, in the human body and in workplaces.

2.Each governed entity must repeat the Anticipate, Recognize, Evaluate, Control, and Confirm cycle annually or as new processes so dictate, but in no case less often than once a year.

3. Stakeholder views to be incorporated in procedures and measures of effectiveness, with focus groups of stakeholders for labels, S and risk communiciation seminars ("train the trainer")

Section 8 Integration with GHS

A. GHS- The Globally Harmonized System for the Classification and Labeling of Chemicals, is hereby incorporated by reference to the extent that it may apply to applications of nanotechnology in the workplace and to workplace exposure to nanomaterials.

1. Adoption and Incorporation by Reference of the Justification and Modes of Practice in the GHS Model GHS Globally Harmonized System for the Classification and Labeling of Chemicals means that the three pillars of GHS are also the fundamental three prongs of enforcement for this Act

Labelling

2. NSDS

3. Risk Communication through training and education regarding the safe handling, transport and potential health and safety hazards of the materials

4. a.To the extent that GHS data conflicts with data transmitted under the terms of this Act, the Commission shall review both sets of data and make a determination regarding which rule is most respectful of scientific precautionary principles in the context.

b. In such cases, entities using products involved shall have the right to apply for and be granted a temporary waiver of

the requirements of this Act, provided that

1. The entity is not already subject to fines and penalties under this Act and

2. The entity demonstrates due diligence in the development and implementation of its in-house risk management programs for compliance with this Act.

Section 9 Enforcement Provisions

A Individual citizens.can trigger enforcement by petitioning, with clear and convincing evidence to the Commission created under this Act.

B The procedures for petitions shall be set forth by the Commission on or before the second session of its meetings, consistent with administrative procedures and constitutional requirements of the jurisdiction in which the Commission shall reside.

Section 10 Penalties

Failure to disclose risk communications for labels, NSDS or training and education by a commercial or government entity that is involved in the manufacture or direct purchase and use of nanomaterials in order to avoid risk management and risk communication required in compliance with this Act shall result in fine and penalties enumerated herein including, possible criminal prosecution of organizations.

Section 11: Saving Clause

In the event that any of the terms or provisions of this act are declared invalid or unenforceable by any court of competent jurisdiction or any federal or state government agency having jurisdiction over the subject matter of this act, the remaining terms and provisions that are not effected thereby shall remain in full force and effect.

Section 12: Effective Date

1. This act shall take effect 30 days after passage.
2. Start-up grace period:
   a. This act shall take effect 30 days after passage with a 6-month start-up period for the preparation of risk communication materials for implementation and dissemination.
   b. No fines or penalties shall be assessed during the 6-month start-up period.