

POST-HEARING COMMENTS NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers Docket NO. NIOSH-161 Revised Feb 18, 2011, TESTIMONY ON BEHALF OF ISRA,¹ BEFORE NIOSH , USA

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**“LEGAL BASIS AND JUSTIFICATION:
NIOSH RECOMMENDATIONS PREVENTING RISK FROM
CARBON NANOTUBES AND NANOFIBERS”**

This document is prepared in response to the question presented by NIOSH:

« *Whether the hazard identification, risk estimation, and discussion of health effects for carbon nanotubes and nanofibers are a reasonable reflection of the current understanding of the evidence in the scientific literature* »⁴

COMMENTS IN SUPPORT OF THE NIOSH REL And Worker Protections Governing Occupational Exposure to Carbon Nanotubes and Nanofibers

The sound of freedom that resonates from civil and political rights rings hollow to a newborn who has low birth weight, because the baby's mother had no access to a clean and safe workplace, good nutrition or adequate prenatal care. And, what good are political and civil rights to a different baby, who has lost a parent due to an occupational accident, or whose parents are debilitated by an occupational disease such as lung cancer, or to the baby who may suffer personal injury due to the effects of a parent's workplace exposure to mutagens or unchecked but foreseeable harms caused by unregulated applications of nanotechnology, at home or in their parents' workplace?

¹ The International Safety Resources Association, (ISRA) headquartered in Fullerton California, with offices in Houston Texas, is a non-profit organization that develops and produces high quality affordable occupational safety and health training programs in various media, on the web and via live coaching, throughout the world. ISRA encourages supplemental safety training for small businesses, by offering online video training, 24/7. Special thanks to Dr. Michael Riediker, PD Dr.sc.nat., Institut de Santé au Travail, Lausanne, Switzerland, Member of the Board of Directors of ISRA, who provided detailed comments discussing NIOSH methodology for measuring the risk from carbon nanotubes, compared to European methods. Aurore Benhayoun, of Geneva Switzerland who studied politics and international law at the Universatd Stendahl also provided assistance. Dr Michaela Kendall, an expert in nanoparticle exposure and nanotoxicology from the European Centre of Environment and Human Health, University of Exeter, UK commented on measurement and worker protection. Special thanks to Dr. Diana Boraschi, Institute of Biomedical Technologies, ITB-CNRPisa, Italy for detailed comments, and to Dr. Vicki Stone, Heriot Watt University, for general comments regarding the oral testimony. Dr Daniel Bloch, CEA, Grenoble, France provided insightful comments for medical surveillance.

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³ Jay Feitshans, Science Policy Analyst for ISRA, BS. Albright College Reading Pa. 2010, assisted in the preparation of this document, testified and replied to questions from NIOSH regarding this position statement, on behalf of ISRA.

⁴ **Draft Document for Public Review and Comment NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers** [PDF - 804KB] Docket Number NIOSH-161-A subject to hearing for public comments, February 3, 2011 9:00am—4:00pm Millennium Hotel Cincinnati, 150 West 5th Street, Cincinnati, OH 45202

The National Institute of Occupational Safety and Health (NIOSH) was created under the Occupational Safety and Health Act of 1970 (« OSH ACT ») 29 USC 651 et seq to perform a very special job. The US Congress actually created three agencies under OSH Act:

1. OSHA, the Occupational Safety and Health Administration, with power to promulgate and enforce standards regarding safety and health in millions of USA workplaces ;
2. OSH RC the Occupational Safety and Health Review Commission, with the power to adjudicate and review OSHA enforcement decisions, and
3. NIOSH, the research arm of OSHA, which was given a very special job because the USA Congress did not trust anyone else with this job.

The job of NIOSH is: to protect workers by providing the latest, cutting edge robust scientific research to support the law. By its mission and its outstanding reputation for pathbreaking science, NIOSH defines the meaning of the terms « prevention » « risk » and « recognized hazards » among the scientific community concerned with industrial hygiene, safety engineering, occupational medicine, risk management and public health. NIOSH has been assigned the unique role by the US Congress that created it in Section 21 of the OSH Act, Section (c) “shall (1) provide for the Establishment and supervision of programs for the education and training... in the recognition, avoidance and prevention of unsafe or unhealthful working conditions”.

OSH Act Section 22 authorizes “the Institute... to : (1) develop and establish recommended occupational safety and health standards; and (2) perform all functions... under sections 20 and 21 of this Act”.

Congress understood, when it wrote the OSH Act that gave birth to NIOSH, that there were things it could not understand. The legislative history demonstrating this reality as a driver for the creation of OSH Act in general and NIOSH in particular is discussed in detail by Dr. John Howard, Director of NIOSH and several opinion leaders who were active in the legislative development of OSH Act in the video entitled "OSH 35 Still Alive", prepared for the anniversary of OSH Act and premiered at the Tenth NORA NIOSH Symposium in 2005.⁵ As the stated in the video, Congress trusted NIOSH, only NIOSH, to have an independent budget and independent thinking to engage in robust, pathbreaking science to solve problems that impact workplace safety and health. In sum, the statutory mission requires NIOSH to look ahead and forecast occupational safety and health problems--- to figure out how to prevent disasters before they happen.

A. The Statutory Obligation to Prevent "Recognized Hazards"

OSH Act requires that « Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees”⁶ The USA Congress intended an expansive view of this term⁷. In general, courts have interpreted this phrase to mean that a standard need not be published by OSHA in the Federal Register in

⁵ *OSHA 35: Still Alive!* Produced by Digital 2000 Productions Stafford Texas USA. Available from NIOSH communications office and from Digital 2000 Productions, Executive Producer Ilise Feitshans.

⁶ Pub. L. No. 91-596, December 29, 1970; and as amended by Pub. L. No. 101-552, Section 3101, November 5, 1990. “Each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.” 29 U.S.C. § 651(a). 29 U.S.C. § 653(b)(4). For Detailed discussion see Feitshans, Ilise *DESIGNING AN EFFECTIVE OSHA COMPLIANCE PROGRAM* (West/Thomson Reuters) **Section 1:23.50**

⁷ Feitshans, Ilise *DESIGNING AN EFFECTIVE OSHA COMPLIANCE PRGORAM (WESTLAW)* **Section 1:23.50**

order to create a duty and responsibility for safety measures and that the courts will review in order to determine the adequacy of the employer's safety and health programs. ASARCO v. OSHRC was a case of first impression that addressed the applicability of the general duty clause to a "nonobvious hazard". In that case, the term "recognized hazard" was construed to include hazards one can "taste, hear, see or smell," as well as hazards less easily recognized by conventional testing or monitoring. Later case law expanded this responsibility so that even if an employer determines that the specified means of compliance is infeasible, it must affirmatively investigate alternative measures of preventing the hazard and implement prevention to the extent feasible.⁸

B. Assessment of the Health Risk and Recommended Exposure Limit

The issues raised by nanotechnology are new, but not as novel as they may at first seem. The notion of embracing new technology and regulating the development of that new technology by regulating in face of risk was a recurring phenomenon in the twentieth century. Then, so called "big science" confronted risks from nuclear energy development, genetics, large scale agricultural revolution, and astrophysics, in order to bring new benefits to humankind. There are lessons to be learned from these precedents: significantly, scientists, lawyers, stakeholders and policymakers can work together to incubate new industries that surround the application of new technology, and with remarkably low risk to the population. When such stakeholders form a critical mass of political will, their collective societal efforts can succeed to get it right by promoting the growth of new industries while minimizing the risk to the society at large. In this context, NIOSH plays a crucial role, defining the parameters of unquantifiable but foreseeable risk and suggesting the precautionary measure to prevent risk, which in turn make both the insurability and applicability of new technology technologically and economically feasible. NIOSH understanding of "recognized hazards" and the ability to carefully outline the contours of precautionary practices is vital to the development of new technologies such as the use of carbon nanotubes and nanofibers, in this regard.

1. NIOSH ROLE DEFINING THE SCOPE OF RECOGNIZED HAZARDS

In the four decades since the passage of the unmodified OSH Act, this statutory mandate to look out as the vanguard of protection from recognized hazards has placed NIOSH in the role of world class opinion leader in industrial hygiene, occupational medicine and occupational safety and health risk management and supporting research. In the Current Intelligence Bulletin regarding carbon nanotubes and nanomaterials,⁹ NIOSH stated : «Currently there are no studies reported in the literature of adverse health effects in workers producing or using carbon nanotubes (CNT) or carbon nanofibers (CNF). The concern about worker exposure to CNT or CNF arises from results of animal studies ».¹⁰

The question whether such hazards as have been described in the scientific literature and whether potential risks are sufficiently recognized or understood to trigger statutory protections is therefore a vital first step towards planning the research to practice phase of

⁸ Brock v. Dun-Par Engineered Form Co., 843 F.2d 1135 (8th Cir. 1988).

⁹ **Draft Document for Public Review and Comment** *NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers* [PDF - 804KB] Docket Number NIOSH-161-A subject to hearing for public comments, February 3, 2011 9:00am—4:00pm Millennium Hotel Cincinnati, 150 West 5th Street, Cincinnati, OH 45202

¹⁰ According to Dr. Diana Boraschi, Institute of Biomedical Technologies, ITB-CNRPisa, Italy « the fact that animal experimentation does not necessarily predict effects on human health. They may be however taken as indication that caution should be applied in Handling the materials »

nanotechnology applications and for preventing risks that wise people believe exist, even when those risks are not well understood.

Consistent with NIOSH concerns, according to the nanotechnology implementation strategy from the Swiss National Science Foundation, "Physically confining materials at the nanoscale alters the behaviour (sic) of electrons within them, which in turn can change the way they conduct electricity and heat, and interact with electromagnetic radiation. Moreover, materials engineered at the nanoscale can enter into places that are inaccessible to larger materials, and can therefore be used in new ways. These behaviours (sic) also have potential consequences on the abilities of synthetic nanomaterials to cause harm in novel ways."¹¹

Also consistent with NIOSH concerns, according to the Royal Commission on Environmental Pollution of the United Kingdom, (2008 Paragraph 1. 43)," the governance of emerging technologies... pose serious constraints on any regulator. First is the condition of ignorance about the possible environmental impacts in the absence of any kind of track record for the technology. Second is the condition of ubiquity – the fact that new technologies no longer develop in a context of local experimentation but emerge as globally pervasive systems – which challenges both trial-and-error learning and attempts at national regulation¹² NIOSH is therefore asking the right questions, consistent with its role by statutory mandate, in the opinion of ISRA. And when the agency, using its resources and expertise concludes that the state of the art of scientific research promoting safety and health in the workplace lags behind the implementation of new technologies in commerce, therefore raising grave concern if not alarm, NIOSH is in good company. Given the profound importance of the NIOSH mandate from the US Congress, combined with an international scientific consensus recommending precautionary approaches in a state of potential risks with great uncertainty, ISRA feels that NIOSH has been too weak in its statement of the statutory justification for its recommended practices and RELs regarding carbon nanotubes and nanomaterials, discussed here.

2. NIOSH ROLE OUTLINING THE PRECAUTIONS THAT ENABLE INDUSTRY TO PROCEED IN THE DEVELOPMENT AND APPLICATION OF NANOTECHNOLOGY

International scientific consensus points towards major risks to public health and the health and well-being of workers and the families who depend upon their wages from the unfettered application of nanotechnology, even though there is also consensus that the state of the art is such that those risks cannot be easily quantified.¹³ It is incumbent upon NIOSH to take the lead in this regard.

The NIOSH model created especially for applying nanotechnology to a wide variety of workplaces, which will likely use this recommended exposure limit for carbon nanotubes and nanofibers as precedent, must discard the burdens of treating occupational health as an "us and them" situation. NIOSH must look at the risks for professionals, for the leadership itself in the highest parts of society to which people are taught to aspire and to follow, and risk shared by workers with members of the greater community who are also stakeholders in the well-being of people who have been occupationally exposed to carbon nanotubes and nanofibers--- because there are dangers in all of our work. NIOSH must look at the impact on

¹¹ Swiss National Science Foundation, **Opportunities and Risks of Nanomaterials Implementation Plan of the National Research Programme NRP 64** Berne, 6 October 2009

¹² Royal Commission on Environmental Pollution, CHAIRMAN: SIR JOHN LAWTON CBE, FRS, **Twenty-seventh Report : Novel Materials in the Environment: The case of nanotechnology.** Presented to Parliament by Command of Her Majesty November 2008.

¹³ Swiss National Science Foundation, **Opportunities and Risks of Nanomaterials Implementation Plan of the National Research Programme NRP 64** Berne, 6 October 2009, Royal Commission

children of exposed populations, and look for the impact in the epidemiology of older workers and vulnerable populations, following Ramazzini's the 18th Century advice : Physician, ask your patient first, « What is your work?

ISRA Recommendation One :

NIOSH must assert its statutory Obligation to define and recommend measures that protect people from occupational exposure to “Recognized Hazards”, consistent with international scientific consensus regarding emerging risks from Carbon Nanotubes (CNT) and Nanofibers

NIOSH has been timid in its assertion of the justification for the use of its powers regarding nanotechnology. Instead, NIOSH must be bold in its assertion of this statutory mission once the agency has discovered that there remain logical and clear risks to human health from the implementation of a new generation of technology, and concluded that although potentially very important through its diligent research and ongoing discourse with stakeholders, private sector partners and peer organizations in Europe, the United Kingdom, and international governance around the world. NIOSH has failed to so state in its Current Intelligence Bulletin, and has left the Preface blank in the draft that was provided to ISRA¹⁴. We are prepared to work with NIOSH to draft language that can best fill that void. ISRA welcomes NIOSH to quote all or part of our discussion above that underscores the statutory justification for the NIOSH proposed Recommended Exposure Limits and proposed methods of risk management to protect workers Governing Occupational Exposure to Carbon Nanotubes and Nanofibers. Therefore, ISRA requests that NIOSH use the following language to fill this important regulatory void regarding the justification for NIOSH RELs:

« Justification for Use of NIOSH Authority to Craft Carbon Nanotube RELs and to Propose methods of risk management to protect workers facing Occupational Exposure to Carbon Nanotubes and Nanofibers:

It is NIOSH and no one else, that Congress entrusted in Section 21 of OSH Act, to take the lead in crafting methods for risk management and protection when the risks are on the horizon but the precise parameters of risk remain unquantified by science and therefore unknown at the present time. NIOSH is not a regulator or enforcer, it is the voice of reason safeguarding the live and health of everyone who works-- from the boardroom to the mailroom, from the CEO to the domestic worker using harsh chemicals to clean his house, from the diplomat to the foreign migrant, possibly undocumented who needs accurate chemical information and urgent care in the event of accidental spills that jeopardize their health ; from the Director of Coca cola to the factory worker in the bottling plant who comes into contact with food additives and new plastics that use nanotechnology, from the Nobel Laureate scientist to the lab technician at the bench using carbon nanotubes to research and develop new nanomedicines that will benefit all mankind. In essence, this research by NIOSH is essential to protecting the public health as much as it is about looking at the narrow scope of preventive measures for risk management among workers. The true value of NIOSH's mission therefore concerns preserving the work, health and survival of all civilization » End of proposed text to quote

¹⁴ **Draft Document for Public Review and Comment** NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers [PDF - 804KB] Docket Number NIOSH-161-A subject to hearing for public comments, February 3, 2011 9:00am—4:00pm Millennium Hotel Cincinnati, 150 West 5th Street, Cincinnati, OH 45202

ISRA Recommendation Number Two:

NIOSH Has the Statutory Obligation to Go Beyond Existing Data in Order to Generate New Research Protecting Public Health

Nanotechnology is already here, bombarding consumers with applications of nanotechnology in paint coatings, refrigerator linings, sun tan lotion and even a car called the "nano"¹⁵. On the day of this testimony, the chain store "migos" in Switzerland has begun an ad campaign for "nano mania"; a collectable set of toys marketed nationally in their stores.

"The protection and promotion of the health and welfare of its citizens is considered to be one of the most important functions of the modern state"¹⁶. More recently the Royal Commission on Environmental Pollution document prepared for Her Majesty the Queen of England 2008: paragraph 1.37 states: "As we have noted, history is replete with instances where such assumptions were shown to be flawed too late to avoid serious consequences. The second approach assumes that the state of the science is up to the job of detecting problems unambiguously and at an early enough stage to prevent widespread damage, which we have not found to be the case here. The third view would deny citizens and consumers the real lifestyle and health benefits that technologies based on novel materials might provide. In any case, we know that science can never definitively prove that something is safe".

This sharpens the edge of the dilemma that NIOSH must courageously examine on the cutting edge of science. As noted by the Royal Commission on Environmental Pollution of the United Kingdom (2008, Paragraph 1.39) « ... in the early stages of a technology we don't know enough to establish the most appropriate controls for managing it. But by the time problems emerge, the technology is too entrenched to be changed without major disruptions... (paragraph 1.40) "The solution to this dilemma is not simply to impose a moratorium that stops development, but to be vigilant with regard to inflexible technologies that are harder to abandon or modify than more flexible ones... To this list we might add irreversibility, in the form of widespread and uncontrolled release of substances into the environment."¹⁷

In the context of such uniquely foreseeable uncertainty of risk, risk management requires erring on the side of caution rather than rushing to mistakenly claim that an absence of evidence of risk means that nanotechnology is "risk free".

It is not possible to understate the importance of medical surveillance in this context. Basic sound occupational medicine and industrial hygiene practices such as but not limited to: screening and sound, on-going and accessible medical care services for workers who face a variety of unquantified risks from novel nanotechnology exposures take on greater importance in light of uncertainty. Although it may be premature for NIOSH to recommend specific

¹⁵ Mark Hoover, presentation : « **Safe Nanotechnology in the Workplace** », **NanoImpactNet Training School**, Lausanne, Switzerland, March 9, 2010, slide 5 « **Nano-enabled consumer products, are on the market now** : Eddie Bauer ; Ruston Fit Nano-Care khakis ; Wilson Double Core tennis balls; Mercedes CLS-class; 3M Adper Single Bond Plus ; Wyeth Rapamune immuno-suppressant dental adhesive ; Smith & Nephew Acticoat 7 ; Laufen Gallery washbasin antimicrobial wound dressing ; Samsung NanoSilverSeal Refrigerator ; Kodak EasyShare LS633 camera with Wondergliss ; GM Hummer H2 ; NanoOpto subwavelength polarizing beam splitter/combiner

¹⁶ George Rosen A History of Public Health MD Monographs on Medical History New York 1958 p17

¹⁷ Royal Commission on Environmental Pollution, CHAIRMAN: SIR JOHN LAWTON CBE, FRS, **Twenty-seventh Report** : Novel Materials in the Environment: The case of nanotechnology. Presented to Parliament by Command of Her Majesty November 2008. See also : UK Department for Environment, Food, and Rural Affairs. 2010. Research into the likelihood and possible pathways of human exposure via inhalation arising throughout the life cycle of a selection of commercially available articles containing carbon nanotubes – CB0423. <http://www.defra.gov.uk/>

procedures for occupational exposure, in reality that baseline data must be collected and that infrastructure for such precautions must be encouraged to develop along side the research and development of industrial and pharmaceutical applications of nanotechnology.

To emphasize this statement, ISRA wishes to note that defining internationally accepted components of basic occupational health services for medical surveillance and future epidemiological studies typically should be considered as one of the top priorities for precautionary programs. In addition to any existing programs for worker health as may be created by the employer in compliance with existing occupational health and safety laws, it is recommended that people who have an occupational exposure to carbon nanotubes and nanofibers have regular screenings at least once a year, using the most recent accepted best practices to confirm the status of lung function after exposure to nanomaterials. Dr. Michaela Kendall, an expert in nanoparticle exposure and nanotoxicology from the European Centre of Environment and Human Health (University of Exeter, UK) recommends: "All secondary exposures of children (via worker exposures leading to offspring exposure or potentially intergenerational effects) should be identified and monitored. The epigenetics of environmental contaminants are currently of scientific interest and this area may expand to include effects in those exposed to CNTs/CNFs and other nanomaterials."

ISRA Recommendation Number Three:
**Synthesizing Precautionary Concerns with New Data Requires a Flexible Framework,
In Partnership with Industry, Multinational Corporations, Foreign Governments,
Research Institutions and Stakeholders from Novel Branches of Civil Society.**

ISRA endorses the approach suggested by Murashov and Howard,¹⁸ which offers an admixture of an array of ways to manage risk. Their six-prong approach to the management of occupational health risks in emerging technologies combines: qualitative risk assessment; the ability to adapt strategies and refine requirements; an appropriate level of precaution; global applicability; the ability to elicit voluntary cooperation by companies; and stakeholder involvement. This array can only be offered by NIOSH, because it is a research-driven agency, without enforcement power but with the financial and statutory backing of the federal government. It must be underscored that voluntary programs must be used with guarded optimism for their success, because of their inherent conflict of interest. Nonetheless, there is ample precedent for such voluntary co-operation, such as but not limited to the OSHA experience of Voluntary Protection Programs (VPP)¹⁹ and the US Environmental Protection Agency (EPA) Review of Nanomaterials in the Pre Manufacture Notice ("PMN") process as a part of its broader Nanoscale Materials Stewardship Program²⁰. This means creating new

¹⁸ Vladimir Murashov and John Howard, Essential features for proactive risk management IN : nature nanotechnology| VolL 4, www.nature.com/naturenanotechnology Aug 2009 Macmillan Publishers. Noting: « There is a significant time lag between the emergence of any new technology and the generation of sufficient risk assessment information to be able to conduct a thorough quantitative risk assessment and to write a traditional regulatory occupational risk management standard.... In the case of nanotechnology, the remarkable variability of nanomaterial compositions, the new properties of these nanomaterials and the introduction of new manufacturing processes bring extra challenges to the process of adopting either mandatory or voluntary risk management approaches »

¹⁹ Feitshans, Ilise Compliance on the Cheap: The USA's Voluntary Protection Programs" Safety and Health Practitioner, Paramount Publishing, Hertfordshire, UK, June 1998 and Feitshans Ilise, « More Than Just A Pretty Program: OSHA Voluntary Protection Programs Confront Workplace Hazards Head On" CORPORATE CONDUCT QUARTERLY Sept 1997 Reprinted in : Bringing Health to Work, Emalyn Press 1997.

²⁰ U.S. EPA. 2008a. TSCA Inventory Status of Nanoscale Substances --General Approach. See <http://www.epa.gov/oppt/nano/nmsp-inventorypaper2008.pdf>. and U.S. EPA. 73 Federal Register 64946. October 31, 2008 ; U.S. EPA Information on the Premanufacture Notice Submission Process. See <http://www.epa.gov/oppt/newchems/> and U.S. EPA Nanoscale Materials Stewardship Program.

methods for risk communication; new paradigms for the awareness of risk; new concepts of the right to know and the implications for all society from exposure to workplace toxins-- for all people regardless of business size.²¹ ISRA expresses concern that these efforts must be long-term and on-going, once the scientific consensus regarding the best possible parameters has been established. This is a process, of learning about risks and therefore cannot be a one-shot firecracker approach that looks at a situation, arguably finds few or no problems, and then ceases to monitor the situation for evaluation of long term effect. Many of these concepts are well-established cornerstones of a sound occupational safety and health compliance program²², noting that a flexible research agenda must be reviewed periodically to refresh the program. NIOSH must encourage detailed gaps analysis, daring to brave the difficult questions by asking, What is the question that we are not asking ourselves, and when we ask it, are we confronting it properly?

Summary of Recommendations

ISRA Recommendation One :

NIOSH must assert its statutory Obligation to define and recommend measures that protect people from occupational exposure to “Recognized Hazards”, consistent with international scientific consensus regarding emerging risks from Carbon Nanotubes (CNT) and Nanofibers

ISRA Recommendation Number Two:

NIOSH Has the Statutory Obligation to Go Beyond Existing Data in Order to Generate New Research Protecting Public Health

ISRA Recommendation Number Three:

Synthesizing Precautionary Concerns with New Data Requires a Flexible Framework, In Partnership with Industry, Multinational Corporations, Foreign Governments, Research Institutions and Stakeholders from Novel Branches of Civil Society.

Appendix I. Specific comments regarding proposed language from NIOSH

ISRA hereby offers Specific comments regarding proposed language from NIOSH

1.1 Medical screening and surveillance

The evidence summarized in this document leads to the conclusion that workers occupationally exposed to CNT and CNF may be at risk of adverse respiratory effects . These

<http://www.epa.gov/opptintro/nano/nmspfr.htm> and <http://www.epa.gov/oppt/nano/nmsp-interim-report.final.pdf>.

²¹ John Howard, MD, MPH JD LLM, Director of the National Institute for Occupational Safety and Health (NIOSH) US DHHS CDC speaking at the International Labour Office “Nanotechnology the Newest Slice of Economic Daily Life” First Lecture Sponsored by the Fifth Edition ILO Encyclopaedia of Occupational Safety and Health, November 26 2008, Dr Howard presented an overview of the emerging industrial applications of nanotechnology and the societal implications of this new technology from an occupational health and safety perspective. Dr. Howard provided an overview of the development of national and international standards in the area of nanotechnology, with reference to the moratorium called for by some nongovernmental organizations, due to the unknown risks and attendant uncertainties of nanotech factories. In his conclusions, Dr Howard drew the analogy to a commuter running after a train that has just left the station, urging his audience that the occupational safety and health community has much work to catch the train and get on board with long term issues confronting society as civilization embarks upon the new era of nanotechnologies.

²² Ilise Feitshans DESIGNING AN EFFECTIVE OSHA COMPLIANCE PROGRAM, Westlaw (online) hard copy Thomson Reuters updated annually. Chapter One « Necessity of A Program » and Bringing HEalth to Work, « The Nuts and Bolts of Compliance » (Emalyn Press.

workers may benefit from inclusion in a medical screening program recommended as a prudent means to help protect their health"

Comment: This is a platitude, not law. Any worker benefits once they have been included in a screening program!

ISRA proposes the following language:

In addition to any existing programs for worker health as may be created by the employer in compliance with existing occupational health and safety laws, it is recommended that people who have an occupational exposure to carbon nanotubes and nanofibers have regular screenings at least once a year, using the most recent accepted best practices to confirm the status of lung function after exposure to nanomaterials.

NOTE: Dr Michaela Kendall, an expert in nanoparticle exposure and nanotoxicology from the European Centre of Environment and Human Health (University of Exeter, UK) recommends: "All secondary exposures of children (via worker exposures leading to offspring exposure or potentially intergenerational effects) should be identified and monitored. The epigenetics of environmental contaminants are currently of scientific interest and this area may expand to include effects in those exposed to CNTs/CNFs and other nanomaterials."

1.1.1 Worker participation

should refer to the role of workers in identifying hazards and implementing programs for risk management and prevention of adverse health effects

The correct term to be used in a header that would actually describe the text as it presently appears is

ISRA proposes the following language as a Header:

« Scope of Protected Population of Workers »

1.1.2 Program oversight

Oversight of the medical surveillance program should be assigned to a qualified health care professional who is informed and knowledgeable about potential workplace exposures, routes of exposure, and potential health effects related to CNT and CNF.

Comment: This is a platitude, not law.

Any worker benefits once they have been included in a screening program

Furthermore, there is nothing new added to the discourse to note that a qualified professional is aware of basic precepts of occupational medicine,

NIOSH should suggest something precise regarding carbon black or MWCNTs or SWCNTS and recommend experts with expertise in this area.

ISRA proposes the following language:

1. Staff in charge of the medical surveillance program should be qualified in occupational medicine, or a certified public health specialist, who has dedicated at least thirty (30) hours per year of professional time to becoming conversant in the emerging risks to workers from nanotechnology and any or all attendant adverse health effects.
2. Defining internationally accepted components of basic occupational health services for medical surveillance and future epidemiological studies typically should be considered as one of the top

priorities for precautionary programs. In addition to any existing programs for worker health as may be created by the employer in compliance with existing occupational health and safety laws, it is recommended that people who have an occupational exposure to carbon nanotubes and nanofibers have regular screenings at least once a year, using the most recent accepted best practices to confirm the status of lung function after exposure to nanomaterials.

3. All secondary exposures of children (via worker exposures leading to offspring exposure or potentially intergenerational effects) should be identified and monitored. The epigenetics of environmental contaminants are currently of scientific interest and this area may expand to include effects in those exposed to CNTs/CNFs and other nanomaterials.

Rationale

In addition to the fact that staff must have very precisely specialized training in order to design and implement effective programs, the requirement of at least thirty hours per year for such development will provide an incentive that fosters new training programs that will integrate research into fieldwork.

Program Elements

The existing text makes sense when collecting baseline data but in the case of nanotechnology has no specific relevance:

a chest X-ray (All chest X-ray images should be interpreted by a NIOSH-certified B Reader using the standard International Classification of Radiographs of Pneumoconiosis [ILO 2000 or the most recent equivalent].)

ISRA proposes the following language:

Until such time as NIOSH announces the approval or certification of nano-specific instruments that are reliable and replicable tests to measure the impact of CNTs on the individual worker, the medical surveillance program should make good faith efforts to capture accepted baseline data including but not limited to NIOSH-certified B Reader using the standard International Classification of Radiographs of Pneumoconiosis [ILO 2000 or the most recent equivalent],

Rationale

Without baseline data, it will not be possible to understand the long term impact of occupational exposure to carbon nanotubes. Such data cannot, however, serve to replace more refined instruments once they will have been developed and approved or certified by NIOSH. Furthermore, lung function may prove to be less important than recent evidence about spleen and liver accumulation of nanomaterials and the pseudo-allergic response of mammals to nanomaterials is emerging as a potentially important facet of nano-exposures. Liver function measurements, spleen accumulation measurements and appropriate biomarkers of exposure may be conducted (e.g. serum levels thereof), according to Dr Michaela Kendall, University of Exeter, cited above.

1.1.4 Worker training

This section erroneously omits Description of worker rights under OSH act and international law

This section also neglects the needs of vulnerable populations, such as but not limited to workers of reproductive age and capability who may be sensitive to teratogenic or cytogenetic aspects of nanofibers, older workers who be sensitized due to cumulative or synergistic effects of exposure to nanomaterials across their lifetime, and subpopulations not discovered thusfar, who may develop particular sensitization to some but not all types of nanofibers and nanomaterials.

ISRA proposes the following language:

Worker training programs must comply with existing law. Therefore, in addition to discussion of the best practices for the safe handling of carbon nanotubes, nanofibers and nanomaterials containing CNTs and CNFs, and a description of the possible long-term and acute health effects, each session of worker training, in order to be considered adequate, must include a review of the key elements of worker rights to information and to follow-up those rights under the OSHA Hazard Communication Standard (29 CFR 1900.1200), relevant USA statutes such as but not limited to the EPA Nanoscale Materials Stewardship Program and international treaties and agreements such as but not limited to Globally Harmonized System of Classification and Labelling of Chemicals (GHS)²³.

1.1.5 Periodic evaluation of data and screening program

NIOSH wrote:

“Confidentiality of worker’s medical records should be enforced in accordance with all applicable regulations and guidelines”

ISRA Comment:

Unfortunately this is a gross understatement of the employer obligations under a host of existing laws beyond the scope of OSH Act, but relevant in USA workplaces all the same. Even though NIOSH is not the enforcer, it behooves NIOSH to remind employers that there exist a host of fines and penalties under parallel USA law protecting individuals regarding their confidential medical information, even when such information is generated by the employer. Two such statutes leap to mind: The Americans With Disabilities Act and the Health Insurance Portability and Accountability Act. Both laws have very severe penalties for any breach of patient confidentiality, even if such information is generated by an employer at the employer’s own worksite.

ISRA proposes the following language:

Confidentiality of Medical Information is governed by a wide variety of laws, including but not limited to: the Americans With Disabilities Act (ADA) and the Health Insurance Portability and Accountability Act (HIPAA). Each of these laws carry major penalties for violation of confidentiality, and therefore a prudent employer should consult with counsel before designing and implementing a medical program that plans to release information to third parties including release of information to staff within the employer’s enterprise.

2. Recommendations for workers •

NIOSH wrote this entire section in the second person. There is no grammatical reason for this shift in tense, there is nothing to suggest that only workers should participate in this section or

²³ Implementation of the WHO’s International Programme for Chemical Safety (IPCS) is one component of the very complex endeavor involving over twenty five United Nations Agencies and regional groups such as the EU, governments and individual trade organizations. This effort, called the Globally Harmonized System for the Classification and Labelling of Chemicals (GHS) has participation by WHO under IPCS. IPCS has an established and internationally recognized leadership role in the preparation of risk assessments on specific chemicals and for developing and harmonizing hazard and risk assessment methods. These products include Concise International Chemical Risk Assessment Documents, International Chemical Safety Cards, Pesticide Data Sheets, and Poisons Information Monographs These products are of particular benefit to countries that may lack high levels of toxicological expertise. IPCS promotes consistency among hazard and risk assessment products with the global system for classification of hazards, with a view to enable national governments to use these products across border by implementing the GHS at the national level.

that workers are not affected by other sections. NIOSH should write the entire list of recommendations in the same tense.

Regarding substantive rights of workers under law that cannot be changed by NIOSH, see the discussion of worker rights and obligations that are settled law under OSH Act and several additional USA and international regulatory regimes, in DESIGNING AN EFFECTIVE OSHA COMPLIANCE PROGRAM (Westlaw).

ISRA proposes the following language:

A. Workers have rights and duties

The right to be provided information about the hazards, safe handling and use of dangerous materials and have access to working safety equipment free of charge. Dr Kendall of ISRA an expert in nanoparticle exposure and nanotoxicology from the European Centre of Environment and Human Health (University of Exeter, UK) recommends the following approach: Vulnerable groups such as pregnant women, the elderly and others identified in the literature should be informed of the potential hazard. The right to be involved in the management and supervision of OSH measures at the workplace includes the right to be organized in a representative group that can select delegates to OSH committees; the right to regularly scheduled updates concerning information and training on hazards/risks associated to their work and the measures to prevent them; The right to be offered protection against retaliation or untoward consequences when they take action to implement those measures; The right to refuse hazardous work in case of imminent serious danger to their health and life, without retaliation; l

B. Rights bring responsibilities!

Workers must:

- Follow safety and health rules when using protective equipment; Participate in safety and health training and awareness-raising activities; Cooperate with their employer to implement safety and health measures ; Inform to their direct supervisor if they withdraw from an imminent and serious danger to their health and life, and the reasons for it.

3. Evidence for Potential Adverse Health Effects

It is expected that NIOSH will offer a flexible framework that can be revisited periodically, as recommended by Hoover and Cox²⁴ that provides a « foundation for the development and application of methods and their associated instrumentation to accomplish any mission »

4. Current exposure measurement methods and challenges in measuring workplace exposures to carbon nanotubes and nanofibers;

NIOSH wrote: ²⁵ "Given the low density and small diameters of individual CNT and CNF structures, a mass-based sampling method may not be sufficiently sensitive to detect all

²⁴ Mark Hoover and Morgan Cox, « A Life-Cycle Approach to Development and Application of Air Sampling Methods and Instrumentation » Figure 4.1, Radioactive Air Sampling Methods Edited by Mark L. Maiello and Mark D. Hoover, « the cycle begins with evaluation of a mission or performance requirement, (real or emerging) ; proceeds through research and development, prototype testing, production control testing, training, and acceptance of a method and the associated instrumentation to accomplish the mission ; continues with initial calibration, functional checks, and accumulation and review of operational experience to conduct the mission in a scientifically defensible manner, proceeds through maintenance and recalibration and through periodic performance testing to ensure the method is still working ; and eventually ends with either the ultimate completion of the mission or with the replacement of the method by more effective methods.

²⁵ **Draft Document for Public Review and Comment** NIOSH Current Intelligence Bulletin: Occupational Exposure to Carbon Nanotubes and Nanofibers [PDF - 804KB] Docket Number NIOSH-161-A subject

CNT and CNF structures in the air at low mass concentrations. Thus, research is needed to determine the most sensitive dose metrics for estimating various health risks of exposures to CNT and CNF and to develop sampling and analytical methods corresponding to those metrics. CNT are widely accepted to be durable due to the process they undergo during synthesis in which contaminating catalytic metals are frequently removed either by high temperature vaporization or acid treatment. Neither treatment is found to significantly alter the physical structure of CNT. "

Dr Michaela Kendall an expert in nanoparticle exposure and nanotoxicology from the European Centre of Environment and Human Health (University of Exeter, UK) recommends the following approach: Workplace exposure measurement, by either stationary or personal measurement techniques, is a crucial part of worker protection and critical in the case of CNTs/CNFs. Mass based measurements will not suffice for nanomaterials and this is explained variously in the literature. In the absence of a viable real-time worksite-based detection/measurement technique capable of such measurement (clearly a scientific challenge today), we recommend NIOSH identify and publish a detailed viable CNT/CNF detection and quantification method for workplaces, whereby a workplace must install/implement such a method on worksites with potential CNT/CNF exposures within 60 days of the NIOSH notice.

Dr. Kendall recommends a long-term, possibly low volume gaseous collection method which deposits CNT/CNFs onto a substrate which may be followed by a microscopic counting procedure (preferably TEM [transmission electron microscopy] or AFM [atomic force microscopy]), with parallels to the asbestos fiber identification method. If such a method cannot be identified or the scientific community do not reach consensus on an accepted method, a desk-based risk and hazard assessment of each CNT/CNF should be conducted which in particular focuses on the length of the CNT/CNF and propensity of the particular CNT/CNF of interest to occur as single fibers or small agglomerates that are capable of lung penetration. Workers/workplaces must be monitored where long CNT/CNFs with propensity to disperse as single fibers are prevalent. Worker protection from CNT/CNF exposure must be carefully considered and this may include respirators, gloves, clothing, emergency clean-up facilities, etc, depending on the classification of the CNT/CNF type.

Based on the expert opinion of ISRA Member, Dr Michael Riediker of the University of Lausanne Institut de Santé au Travail, ISRA believes that the NIOSH approach proposes a mass-based limit for CNTs.

Specifically, NIOSH proposes a method that is commonly used to quantify carbon black (Elemental Carbon and Organic Carbon). Thus, this method will quantify not only CNTs but also other types of carbonaceous particles. The proposed NIOSH REL is very low (lower than carbonaceous levels that are frequent in ambient air). To reach such low levels, a company usually has to remove all types of airborne particles e.g. through an air filtration system. So, one might argue that working conditions will be characterized by very clean air. However, if for some reason long stiff individual CNTs and CNFs are the only carbon source, then workers still might be faced with too high (in the sense of possibly dangerous) levels of fiber counts, as discussed by NIOSH.

By contrast, the Swiss government-based insurance agency, Suva defined in the 2011-OEL edition guidance values for carbon nano-tubes and -fibres that correspond to those for asbestos (definition of fibre dimensions concerned and also concentration). I.e. it does not

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provide a mass-limit for all CNT (NIOSH), but a number limit for those believed to be the most hazardous.²⁶ The SUVA approach assumes that CNTs and CNFs that have the same dimensions as hazardous asbestos fibers pose a similar risk as asbestos. Shorter CNTs and CNFs are not treated differently than normal particles. The mechanistic idea of CNTs and CNFs being similar to asbestos is supported by animal experiments. The problem is that for the animal studies, the fibres were prepared to be "nicely individualized". However, in real world situations, CNTs are very often big bundles consisting of dozens to hundreds of fibres with a diameter of a few micrometers.

This poses a problem on how to count them. Research only started about how to correctly count fibers contained in these bundles and how easily fibers can be released from these bundles in-vivo over many years. The NIOSH publication has the strength that it proposes an overall strategy for an initial guidance towards healthy working conditions until fully validated sampling and analytical methods are developed (*page 8 NIOSH doc*). The recommendations provide a comprehensive guidance to employers and workers. However, it does not address the question of dimension of CNTs and CNFs. This might be considered as a weakness because in worst-case situations (as outlined above), workers' health might be at risk even though all recommendations were followed.

In conclusion, the NIOSH and the Suva approaches each raise methodological questions. The challenge that might reduce the applicability of the NIOSH approach is that one REL would applied to all CNTs, i.e. both, relatively short ones and long ones with similar dimensions as asbestos. By contrast, the challenge of the SUVA approach is that there is no validated sampling method for CNTs and CNFs and that the risk of short CNT/CNFs are not at all addressed by their guidance values. ISRA therefore recommends that NIOSH include the CNT and CNF dimensions into the recommendations. One possible approach could be to ask for regular visualization and documentation of airborne particle samples in situations where CNTs and CNFs of critical dimensions are being handled, and to propose increased vigilance if they are found to become airborne independent of whether this is in the form of individual fibers or as bundles.

Workplace exposures, measurement, and controls

According to Dr. Diana Boraschi, Institute of Biomedical Technologies, ITB-CNR Pisa, Italy « the fact that animal experimentation does not necessarily predict effects on human health. They may be however taken as indication that caution should be applied in Handling the materials ». As presently written by NIOSH, this section provides a succinct checklist, but is premature to take the form of a road map that one can critique in detail. ISRA accepts this as a placeholder until such time as NIOSH can further develop the state of the art of the understanding regarding the emerging risks of Nanotechnology in general, and the potential adverse health effects on the skin, lungs and reproductive health of workers from occupational exposure to carbon nanotubes and nanofibers in particular.

²⁶ <https://www.epp1.suva.ch/webshop/4D/4D212E53C9BB06F0E10080000A630358.pdf> Aufgrund der aktuellen Datenlage können folgende Richtwerte formuliert werden: „Kohlenstoffnanoröhrchen und -fasern (Länge über 5 µm, Durchmesser weniger als 3 µm, Länge - zu Durchmesser - Verhältnis von über 3:1): 0.01 Fasern/ml; dieser Wert entspricht dem Grenzwert für lungengängige Asbestfasern.“

5. Areas for future collaborative efforts (e.g., research, communication, development of exposure measurement and control strategies).

ISRA expresses concern that these efforts must be sustained for the long-term and maintained by refreshing data and training under the auspices of on-going flexible compliance programs for occupational safety and health protections for workers exposed to carbon nanotubes and nanofibers. This task will be simplified, but not finished, once the scientific consensus regarding the best possible parameters has been established.

This is a process, one that requires diligently learning about risks. Such programs and their overarching description of safety and health precautions to be implemented in the workplace therefore cannot employ a one-shot firecracker approach that looks at a situation, arguably finds few or no problems, and then ceases to monitor the situation for evaluation of long term effect. ISRA agrees with all the measures suggested by NIOSH in this section. Many of these concepts are well-established cornerstones of a sound occupational safety and health compliance program²⁷

In conclusion, ISRA endorses the approach offered by NIOSH, noting that a flexible research agenda must be reviewed periodically to refresh the program.

²⁷ Ilise Feitshans DESIGNING AN EFFECTIVE OSHA COMPLIANCE PROGRAM, Westlaw (online) hard copy Thomson Reuters updated annually. Chapter One « Necessity of A Program » and Bringing Health to Work, « The Nuts and Bolts of Compliance » (Emalyn Press.