

Emerging Issues Survey: “What’s Up, Doc?”

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Emerging issues present assimilation challenges to safety and health professionals everywhere. These volatile issues often involve resource and time commitment for assessment and program development. The rewards for these efforts may be great, in the long run, resulting in the reduction of future litigation and claims potential.

Nanotechnology: No Small Matter

The Next Industrial Revolution

Research and commercial applications of nanotechnology are rapidly advancing. Thousands of companies all over the world are employing this new technology in research and development and production. Current applications cross a variety of industries, including electronics, cosmetics, pharmaceuticals and biomedical, photography, metals/minerals and energy.

Nanotechnology is the generic term for applications and products that contain extremely small particles, tinier than 100 nanometers. A nanometer is one-billionth of a meter. Matter this small has unique properties which are being harnessed for technological innovation.

While research and development efforts still dominate this developing field, an estimated 350 nanotechnology-based consumer products are now on the market, according to a recent survey by the Project on Emerging Nanotechnologies at Woodrow Wilson International Center for

Scholars.¹ Nanoparticles can be found in the composite materials in golf clubs, tennis racquets and bicycle frames to make them stronger and more wear-resistant. These particles also are ingredients in paints and coatings, tools, air sanitizers, self-cleaning glass, long-lasting tennis balls, stain-free coatings for clothing and mattresses, dental material, burn and wound dressings, cultured diamonds, inks, appliances and flat screen televisions. So far, the greatest use of nanotechnology mineral and metal particles is found in cosmetics, sunscreens, fabric coatings, electronics and composite materials.

Nanotechnology offers significant opportunities for nearly every industry, but it also comes bearing a host of questions. Advances in nanotechnology products and applications are outpacing research into possible adverse effects, as well as regulations that might govern the use of these products and applications. This is why it is critical that safety managers understand and keep pace with the implications of this exponentially growing field.

The very small size of nanoparticles makes them highly reactive with properties that differ from larger particles of the same substance. Their small size potentially increases health effects, risk of fire or explosion and/or environmental persistence.

Unknown Risks

Exposure to nanoparticles potentially poses a greater threat to the body than larger particles of the same substance. Experimental rat studies, for instance, have shown that nanoparticles, such as carbon nanotubes, can affect lung tissue by causing inflammation and initial lung fibrosis². Other pharmaceutical studies have found that nanoparticles are able to cross the blood-brain barrier, which safeguards the brain from chemical contamination.³ While there is concern for workers exposed to nanoparticles, the research on potential health effects is just beginning. Initial results indicate that the use of the “precautionary principle” for worker protection would be prudent at this time. Nanotechnology substance Material Safety Data Sheets often do not contain nano-specific information, reporting hazard information for larger sized particle substances. This situation may under-represent user exposure hazards as well have failure to warn implications for manufacturers.

The U.S. Bureau of Labor Statistics has no current, comprehensive data on the number of workers in businesses using nanotechnology. But tens of thousands of people work in companies engaged only in nanotechnology, indicating that many more may be exposed in firms where nanotechnology is a portion of the production process.⁴ An estimated two million workers will be employed in the nanotechnology sector over the next ten years.

All the unanswered questions in this fast-evolving world of nanotechnology make it imperative that businesses adhere to conservative safety and risk management practices. Companies need to develop their own nanotechnology safety and risk management plan to

¹ Woodrow Wilson Institute for Scholars Project on Emerging Nanotechnologies, Nanotechnology Consumer Products Inventor

² Muller, J et al, Respiratory Toxicity of Multi-Wall Carbon Nanotubes, Toxicology and Applied Pharmacology, September 15, 2005, 207(3) 221-31.

³ Koziara, J. et al, In Situ Blood-Brain Barrier Transport of Nanoparticles, Pharmaceutical Research, November, 2003, Volume 20, 1772-78

⁴ NIOSH, Publication No. 2007-123, Progress Toward Safe Nanotechnology in the Workplace

consider nanomaterials in terms of toxicity, expected applications, potential exposures and appropriate control measures. Safety managers must identify points of possible employee exposures in the production process and mitigate those exposures. Control measures will be costly, so limiting exposed employees will assist on both exposure and expense sides.

Quantity vs. Size

From a health and safety standpoint, the past focus for worker chemical exposure in the workplace was the quantity of chemical contamination in the breathing zone or contacting the skin. An employee's chemical exposure was monitored and compared to air contaminant exposure standards and guidelines. Elevated levels posed potential injury or illness hazards.

But regarding nanotechnology material exposure, the highly reactive nature of nanoparticles makes particle size and counts potentially better exposure indicators. With this shift, companies are facing a very different way of evaluating workplace contaminants.

This means that traditional, industrial hygiene air sampling methods may not completely measure up when it comes to gauging employee exposure to nanoparticles. Instead, companies may have to use several methods to judge not just quantity, which reflects the total amount of materials, but to evaluate the size and actual number of particles. It follows, then, that monitoring methodology will have to become more complex to handle this task. Small process leaks or short term maintenance tasks which may not have been a concern with larger particle materials, may pose greater risks with nanoparticles.

Standard industrial exposure control practices apply, including enclosure, isolation and ventilation of the process with now an emphasis on HEPA filtration. Also essential are protective clothing and respirators, as well as good hygiene practices, such as clothing change areas and facilities for showering and washing hands. Employees should, as usual, be prohibited from consuming food and drink in the workplace to avoid accidental ingestion of nanoparticles. Clean-up procedure must include vacuuming with a High Efficiency Particulate Air (HEPA) filter to trap the nanoparticles instead of dispersing them via dry sweeping or manual clean up.

Additionally, companies need to follow special procedures for cleaning up spills. With potential fire risk, containment of materials and segregated storage are also important. Fire suppression and extinguishing systems must be in place, as well as explosion venting, where necessary due to combustibility.

Safety Guidelines

Based on the limited research on nanoparticles that does exist, nanotechnology applications must undergo rigorous scrutiny to incorporate the safest use of them at the present time. To aid in this effort, companies can look to the advice and leadership of NIOSH, which has established a Nanotechnology Research Center in 2004. The agency has developed a nanotechnology research strategic plan. Much of what we rely on so far for nanotechnology workplace safety comes from NIOSH in the form of best practices guidelines.⁵

⁵ NIOSH, Publication No. 2007-123, Progress Toward Safe Nanotechnology in the Workplace

NIOSH has sponsored a series of three international symposiums that promoted the sharing of nanotechnology research results and discussions on safety and health. Reports on the NIOSH Web site summarize the results of these forums.

In 2003, President Bush signed the 21st Century Nanotechnology Research and Development Act, which authorized funding for nanotechnology research and development for four years, beginning in 2005. The legislation put into law programs and activities supported by the National Nanotechnology Initiative (NNI), a multi-agency research and development priority of the Bush administration. The NNI aims to aid scientific breakthroughs and maintain U.S. competitiveness in nanoscience. Its stated goal is to ensure that nanotechnology research leads to “the responsible development of beneficial applications by giving high priority to research on societal implications, human health, and environmental issues related to nanotechnology.”⁶

Nanotechnology Poised For Exponential Growth

There’s no doubt that nanotechnology is not only here to stay but flourishing. The U.S. National Science Foundation predicts that by 2015, the global market for nanotechnology-related products will reach \$1 trillion and employ one million workers in the United States alone.⁷ The prospect of burgeoning nanotechnology applications affecting nearly every industry makes it all the more important for every safety manager to assess the need for state-of-the-art controls, because these involve advance planning and budgeting. Concerns exist that adequate safety expertise may not exist at the R & D and pilot plant phases of these emerging companies, resulting in increased employee exposures and costs to retrofit control systems.

Nanotechnology is here to stay. Rapid growth and changes coupled with the knowledge gaps that confront us on the possible human and world impact of nanoparticles, make it imperative for safety managers to get up to speed now on the potential risks, as well as exposure assessment and best practice control technology for nanotechnology.

Flavorings; Food For Thought

Identification of Respiratory Disease

Food flavoring manufacturing and usage emerged as a worker respiratory health issue in the early 1990’s. What began as a hazard identified at microwave popcorn plants, has expanded to include flavoring and snack food manufacturing facilities. Federal and California OSHA have been petitioned by food unions to promulgate an Emergency Temporary Standard for diacetyl and CA OSHA is working on a standard. U. S. NIOSH visited the “sentinel” microwave popcorn plant and several others, making a determination that ranging stages of respiratory disease was observed even at fairly low air concentrations among some of the employees in mixing and quality control areas.⁸

⁶ National Nanotechnology Initiative Strategic Plan, December 2004

⁷ Roco, M. C., National Science Foundation, Government Nanotechnology Funding: An International Outlook, June 30, 2003

⁸ NIOSH, Publication No. 2004-110: Preventing Lung Disease in Workers Who Use or Make Flavorings

The severity of the full blown disease, bronchiolitis obliterans, propelled the notoriety of this issue. These cases require lung transplant and have limited life expectancy. Worker exposure time periods ranged from less than a year to more than 10 years and continuous and intermittent exposure were both identified as problematic. While the litigation points towards diacetyl as the culprit, groups like NIOSH and the Flavoring and Extract Manufacturers Association, are taking a broader view and have taken a precautionary approach, identifying a number of priority compounds that the flavoring and food processing industries should assess and address by limiting worker exposure.⁹

Food flavorings are classified by the U.S. Food and Drug Administration as Generally Recognized As Safe (GRAS). Of the more than 1,000 GRAS flavorings in use, less than 50 have OSHA Permissible Exposure Limits. Acute and chronic occupational exposures to certain flavorings may potentially cause occupational illness. U. S. NIOSH identified lung restriction, lung obstruction and skin effects from exposure to diacetyl containing flavorings in addition to bronchiolitis obliterans.

Litigation

There are currently over 150 lawsuits against flavoring manufacturers alleging bodily injury from exposure to flavorings and “failure to warn”. Awards have averaged \$5,000,000 in these product liability suits. The plaintiffs in the majority of these suits are microwave popcorn plant workers, but a small number of plaintiffs worked for flavoring, snack food and candy companies. Concern exists for employees handling flavorings at food and beverage processing locations until further studies are conducted as they employ workers who measure, pour and mix flavorings intermittently.

Assessment and Controls

The flavoring employee exposure assessment process begins with the identification of diacetyl and diacetyl containing raw materials and finished products. Material Safety Data Sheets often do not list specific diacetyl hazards and controls as recommended by NIOSH and FEMA. The extra step of querying the manufacturer must occur in those cases and response time varies widely. The concentration of diacetyl in the material should be acquired and the quantity, frequency and duration, handling steps and number of exposed employees should be assessed to determine exposure. Diacetyl content in flavorings normally ranges from .0001% to 7%. Diacetyl content in microwave popcorn flavoring typically ranges from 1 – 2 % prior to being mixed with soybean oil. It is difficult from an industrial hygiene exposure monitoring standpoint to measure short bursts of exposure from addition or opening of vat lids, yet NIOSH has indicated these tasks may be problematic. Respiratory protection is advisable for these types of exposures.

Regulatory

Many U. S. microwave popcorn and California flavoring facilities have been visited by OSHA or NIOSH resulting in joint actions to limit worker exposure. Remaining concern exists for potential food processing industry exposures. NIOSH is conducting a limited public health records surveillance to look for links between past cases of bronchiolitis obliterans and flavoring use.

⁹ Flavor and Extract Manufacturers Association, Respiratory Health and Safety in the Flavor Manufacturing Workplace, August, 2004

Best Practice Controls

Satisfactory controls over worker exposure to flavorings require a variety of “best practices”. Substitution of toxic flavorings would be a preferred control, but most flavoring users claim that substitutes to date are unsatisfactory from a flavor standpoint. Engineering controls such as closed systems and local exhaust ventilation are recommended by both NIOSH and FEMA for flavoring exposure areas, but may not address short exposure bursts possibly requiring additional respiratory protection. Worker training and Standard Operating Procedures (SOPs) are considered key to achieve worker compliance. Baseline and annual spirometry provide an inexpensive way to identify pre-existing or developing lung disease. Bronchiolitis obliterans is irreversible. Prevention and early detection are key. Hopefully more substitution options will become available.

Welding Rods and Equipment; It’s a Fume Thing

Welding Operations

Welding operations have been conducted for over 100 years. Welding operations are commonly encountered in most industrial workplaces. Production welding consists primarily of arc welding methods. There are more than 12 various types and applications of welding, many of which use welding rod or wire filling material or consumable electrodes. The filler material contains various metal compositions, examples including toxic metals like cadmium, chromium, lead and manganese. During welding operations the filler material and base metal may volatilize, forming welding fume which contains some toxic metal constituents.¹⁰ Metal fume may also be created by operations similar to welding including oxy-fuel cutting, brazing, thermal spraying, soldering and thermal cutting.¹¹

Litigation

While welders may be potentially exposed to a variety of toxic metals, welding rod litigation has focused on the manganese portion of welding rods. Plaintiffs allege that exposure to manganese in welding rods caused their Parkinson’s Disease or early onset. There are over 40,000 such suits at the current time. The suits allege bodily injury and “failure to warn”. The majority of suits completed to date have won defense verdicts. Scientific evidence to date has not proven a link between welding and Parkinson’s Disease.¹²

Regulatory

OSHA attempted to lower the 1910.1000 Z-1 manganese standard to 1 mg/m³ from 5 mg/m³, but the standard was vacated, except for a few states, in 1989. The American Conference of Governmental Industrial Hygienists has published an updated manganese air contaminant standard of .2 mg/m³.

¹⁰ Apostoli, P, Multiple exposure to metals in eight types of welding, *Giomale Italiano di Medicina*, 1997 Apr-Jun;19(2):8-14

¹¹ OSHA, Safety and Health Topics; Welding, Cutting and Brazing,

¹² Robinson, Richard, IS WELDING A RISK FACTOR FOR PARKINSON'S DISEASE? *Neurology Reviews.com*, Vol. 12, Number 8, August 2004

OSHA recently changed their hexavalent chromium Permissible Exposure Limit, which has spurred air monitoring activities for this potential air contaminant when welding is conducted on stainless steel and nonferrous chromium alloys. The standard was changed due to carcinogenic properties. While welding fume analysis will incorporate trivalent chromium, separate samples must be taken to analyze for hexavalent chromium.¹³

OSHA provides welding and cutting mechanical ventilation criteria which assists in the initial determination of need for additional local exhaust based on room size and ceiling height. The standard also stipulates minimal face velocity of 100 feet per minute in the welding zone.¹⁴ Local exhaust ventilation can take the form of a downdraft hood, a moveable duct and hood, or welding fume extraction nozzle on welding equipment. Supplied air and powered air purifying welding helmets, with built in eye protection, are available to protect employees from toxic metals exposures.

Exposure Assessment Strategy

Traditionally worker respiratory hazard assessment is conducted for production welding and cutting operations. This assessment includes an analysis of potential air contaminants based on welding method, base metal, filler material and any coatings. Exposure frequency and duration are compiled as well as details on the work environment. Presence of local exhaust ventilation and actual usage are reviewed. Because welders often move around the piece they are working on, they oftentimes do not continually adjust flexible exhaust opening placement, thus negating effect. Any respiratory protection use should be checked for satisfactory selection, fit and program components. Full shift air monitoring is accomplished with OSHA acknowledgement of best exposure representation by filter placement inside the mask at the breathing zone.¹⁵ Workplace crowding of welders or group welding may significantly increase air contaminant exposures.

Proper air sampling and materials use review are key for validation of an adequate welding air contaminant safety program. Satisfactory controls can be assessed by comparison to OSHA standards and review of air sampling results. The simple presence of local exhaust ventilation does not confirm usage.

Avian Flu; Not Just For the Birds

Global Financial and Health Effects

H5N1 subtype Avian Flu outbreaks severely impact poultry farms and product processors because of the requirement to cull flocks of chickens, geese and turkeys, as well as destroy eggs. Millions of animals have been culled to date. It has been estimated that a global epidemic would potentially deficit the world economy by hundreds of billions of dollars. Economic losses have already topped 10 billion dollars. ¹⁶H5N1 is a highly virulent and contagious strain of Avian Flu which poses health risks to poultry workers as well as disease transmission between animals and

¹³ OSHA, Safety and Health Topics; Hexavalent Chromium

¹⁴ OSHA, Safety and Health Topics; Welding, Cutting and Brazing

¹⁵ OSHA Interpretation Letter, February 3, 1999

¹⁶ World Health Organization. Avian Influenza

birds. Widespread human transmission could significantly disrupt business operations contributing to economic losses.

Pandemic Speculation

There's been great speculation as to when Avian Flu will arrive in the U. S. Various non H5N1 strains are already here and have been here for some time. Different strains of Avian Flu have broken out in various parts of the U. S. over many years demonstrating the difficulty of disease eradication. Pandemics arise when new diseases surface for which the population has little immunity, as is the case with H5N1.

There have been at least 5 flu pandemics in the past 100 years. The H5N1 is a new virus and all or most people will be susceptible. If it becomes a pandemic, it would be a highly pathogenic virus that could cause devastating mortality across the globe. Pandemics can have second and third waves and could last 6 to 12 months. With air travel, a new pandemic could move much faster than the Spanish flu of 1918, which killed 40 million people worldwide.¹⁷

H5N1 is a type A influenza virus that is usually only found in birds but can cause death in humans. The first recorded case of H5N1 bird flu in humans occurred in Hong Kong in 1997. The current outbreak of the H5N1 virus in birds began in South Asia in mid 2003 and is considered the most severe on record by the World Health Organization.¹⁸ Avian or bird flu is an infection caused by an influenza virus that occurs naturally in wild birds. H5N1, is spread easily among birds and can sicken and kill wild and domesticated birds such as chickens, ducks, turkeys and migratory birds. Infected birds shed influenza virus in their saliva, nasal secretions, and feces. Domesticated birds may become infected with avian influenza virus through direct contact with infected waterfowl or poultry, surfaces, water or feed.

Infection with avian influenza viruses in domestic poultry causes two main forms of disease that are distinguished by low and high extremes of virulence. The "low pathogenic" form may go undetected and usually causes only mild symptoms (such as ruffled feathers or drop in egg production). However, the highly pathogenic form spreads more rapidly through flocks of poultry. This form has a mortality rate that can reach 90-100% often within 48 hours.

Most human cases have resulted from contact with infected poultry (e.g., domesticated chicken, ducks, and turkeys) or surfaces contaminated with secretion/excretions from infected birds. The spread of avian influenza viruses from one ill person to another has been reported very rarely, and transmission has not yet been observed to continue beyond one person.

The world is currently at Phase 3 of the World Health Organization's 6 Phase Pandemic Alert which indicates a pandemic alert with no or very limited human to human transmission. The next phase would indicate the increase of human to human transmission and thus the world is closer now to a new pandemic than it has been in a long time.¹⁹

There currently is no commercially available vaccine to protect humans against H5N1 virus, but vaccines are being manufactured for animals. Vaccines are virus specific and the widespread

¹⁷ CDC, Key Facts About Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus

¹⁸ World Health Organization. Avian Influenza

¹⁹ World Health Organization. Avian Influenza

human to human pandemic strain has not yet developed. Pandemic vaccines cannot be produced until the specific virus has been identified, involving a 2- month time lag. Vaccine development efforts are underway, however. Influenza viruses can become resistant to these drugs, so these medications may not always work. Resistance to common anti-viral drugs has already been seen and new resistance to Tamiflu and animal vaccines have been observed.

There is no scientific evidence that the virus can be spread through properly cooked poultry or eggs. H5N1 resides in poultry meat, not just in the gut and respiratory system of the poultry making uncooked contaminated products an infection threat. Poultry smuggling is second only to drug smuggling and millions of pounds of illegal poultry from quarantined regions in China have been seized by officials in the U. S. and Europe.²⁰

Workplace Impact

Local authorities will issue quarantine mandates in the event of outbreaks to restrict disease spread. People will be told to stay home unless there is a medical emergency. Employee absenteeism during a pandemic is estimated to range from 10-40%. Companies have a business imperative to develop a pandemic response plans.²¹ A Pandemic Planning Committee with cross organization membership supports plan comprehensiveness and action validation. Companies must plan ahead by identifying vital employees and making arrangements for them to work at home, rigorously following up on IT requirements. Outsourcing to non quarantined regions may be considered. Temporary help may not be available and cross training where possible is a good practice. Pandemicflu.gov displays useful plan development checklists for a wide variety of occupancies.

Employee relations will experience unique challenges during a pandemic. Policies on sick employees coming to work will have to be established. Employees having sick family members at home may need additional time off as caregivers. Business travel may result in extended return delays in the event of an outbreak or critical needs for medical attention. Travel bans will affect employees that have to travel internationally or domestically. It is possible that employees may be detained on a flight with infected passengers and need to be educated on self protection. Even normal business contact may pose contact issues as employees or customers may be hesitant to meet face to face or shake hands. Sick/absent workers will require follow up. Companies must make individual decisions as to how far they will go to address these issues.

Supply chain management issues exist. There may be utility service interruptions which affect on site production. Service companies, such as utilities, must be highly diligent with their response plans due to the dependency of others. Problems may arise with raw material providers and shipping. “Just in time” manufacturing may experience down time due to supply delays. Import and export restrictions may apply to specific products. Sourcing agreements with vendors, maintenance of building inventories and alternate source identification will assist in addressing these issues. Companies with multiple locations may be able to divert business to other offices.

²⁰ Handwerk, Brian, Smugglers Spreading Bird Flu Experts Warn, National Geographic News, May 9, 2006

²¹ Pandemicflu.gov

Workplace and home hygiene issues will come under close scrutiny in an effort to restrict disease spread. Most human influenza infections are spread by virus-laden respiratory droplets that are expelled during coughing and sneezing. Disinfection and personal hygiene are important to reduce human to human contact spread of disease. Additional facility sanitization is being considered by many companies during outbreaks between periods of quarantine. Surgical masks and N95 respiratory protection are best utilized during proximity to infected people.

Biosecurity

Poultry producers are strengthening their biosecurity prevention practices to protect their flocks.²² These steps include keeping poultry flocks from coming into contact with wild or migratory birds by keeping them inside houses during migratory travel time periods and keeping poultry away from any source of water that may have been contaminated by wild birds. These facilities permit only essential workers and vehicles to enter the farm. Special visitor procedures emphasize use of hygienic clothing and practices.

Workers must be provided with clean clothing and disinfection facilities. Equipment and vehicles should be thoroughly cleaned and disinfected entering and leaving the farm. Borrowing or loaning of farm equipment should be avoided, as should visitation between farms. Birds from slaughter channels, and especially live-bird markets, should not be brought back to the farm.

Workers should be trained on the signs of illness in domestic poultry. A program for testing poultry prior to slaughter should be developed with appropriate follow up. Procedures and additional protective clothing for quarantine, eradication and animal culling (respirators, coveralls, gloves, goggles etc.) should be in place and rehearsed.

Contingency plans should be reviewed with local authorities, because an outbreak of H5N1 presents a serious situation. Each farm should have an established Pandemic Planning Committee. Poultry facilities and workers are clearly at greatest risk during the current spread of H5N1.

Conclusion

Safety Managers are well advised to maintain current knowledge on cutting edge Emerging Issues which have to potential to affect their business and lives. The issues and their potential impact are in a continual state of flux and applicability could change over time. Attendance at Safety Conferences, subscriptions to issue update newsletters and periodic review of regulatory body web sites are all highly useful and economical ways to maintain this knowledge. The likely rewards for this high level of endeavor will be worker health and litigation avoidance.

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