

**Miller, Diane M. (CDC/NIOSH/EID)**

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**From:** Nancy Buermeyer <[nbuermeyer@breastcancerfund.org](mailto:nbuermeyer@breastcancerfund.org)>  
**Sent:** Saturday, December 24, 2011 11:03 AM  
**To:** NIOSH Docket Office (CDC)  
**Subject:** Docket Number NIOSH 240 - Comments  
**Attachments:** NIOSH Carcinogen Policy - Final.pdf

Please find attached the Breast Cancer Fund's Comments on NIOSH Carcinogen Policy. If there is any problem with this submission, please call my cell phone (202-213-3384).

Thank you,  
Nancy

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December 22, 2011

NIOSH Docket Office  
Robert A. Taft Laboratories  
MS-C34  
4676 Columbia Parkway  
Cincinnati, OH 45226

**RE: Request for Information: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment  
Docket Number NIOSH-240**

Dear Dr. John Howard,

The Breast Cancer Fund appreciates the opportunity to comment on the NIOSH policy assessment on carcinogens and recommended exposure limits (REL). The Breast Cancer Fund's mission is to identify—and advocate for elimination of—the environmental and other preventable causes of the disease. The organization translates the science linking breast cancer and environmental exposures into public education and advocacy campaigns that protect our health and reduce breast cancer risk. Given this mission, we are deeply concerned about occupational exposures to carcinogens and welcome the opportunity to share our thoughts on these important questions.

Below are our responses to the questions asked in the August 23 Federal Register notice.

**1) Should there explicitly be a carcinogen policy as opposed to a broader policy on toxicant identification and classification (e.g. carcinogens, reproductive hazards, neurotoxic agents)?**

Yes, the Breast Cancer Fund recommends that the explicit carcinogen policy and related outdated RELs be updated immediately. Cancer is a devastating disease and NIOSH has a responsibility to utilize the growing body of scientific evidence to establish protective recommendations as expeditiously as possible.

Once more health protective policies are in place regarding carcinogens, we strongly request that NIOSH look at the wider array of health impacts from occupational exposures to numerous other chemicals. As an organization concerned with preventing breast cancer, carcinogens are clearly a top priority for the Breast Cancer Fund. However, evolving science is increasingly supporting

the concept that traditional carcinogens are not the only environmental chemicals that affect the risk of breast cancer. For instance, a class of chemicals, called endocrine disrupting chemicals (EDCs), acts like hormones in the human body and are a growing concern for risk of breast cancer and a number of other diseases including diabetes, reproductive harm and cardiac disease. In addition, there is mounting scientific evidence linking environmental chemicals to other non-cancer endpoints such reproductive, developmental and neurological toxins. As a public health institute, it is important that NIOSH policy address not only carcinogens, but also consider the many other health impacts exposure to a range of chemicals may have on the workforce.

**2) What evidence should form the basis for determining that substances are carcinogens? How should these criteria correspond to nomenclature and categorizations (e.g., known, reasonably anticipated, etc.)?**

While human data is often considered the strongest indication of harm, it is important to make use of the relevant and strong laboratory data available. There are a number of factors that make direct human data very difficult to obtain. It is unethical and frequently not possible to conduct controlled studies on the impact of chemicals on humans; it is extremely difficult to identify and isolate exposures to particular chemicals; there is often a significant delay between exposure to a chemical and the observed health impact, requiring expensive long-term longitudinal studies to detect; humans are not exposed to a single chemical at a time, but rather to complex mixtures that are difficult to identify; and some populations may be more vulnerable than others, a concern that particularly applies to workers because exposure levels are frequently far higher and more constant than the general public. Given these constraints on human data and huge number of chemicals that need testing; animal, in vitro, rapid screening and computer modeling data provide critical information on the toxicity of a chemical, and should provide the basis for protective action.

The Breast Cancer Fund further urges NIOSH to act in a precautionary manner, not waiting for the definitive proof, but rather recommending action to protect workers when the science raises serious health concerns about a chemical substance. Definitive proof of causation is extremely rare. Continuing to allow exposure to a chemical until that extremely high bar is reached will exact an unacceptable and unethical price on human health and mortality. In fact, recent authoritative reports have called for action to reduce occupational exposure even in the absence of definitive science. The President's Cancer Panel, in its 2010 report entitled *Reducing Environmental Cancer Risk: What We Can Do Now*, recommended "precautionary, prevention-oriented approach should replace current reactionary approaches to environmental contaminants in which human harm must be proven before action is taken to reduce or eliminate exposure." Just this month, the Institute of Medicine issued a report entitled *Breast Cancer and the Environment: A Life Course Approach* where one recommendation read "limit or eliminate workplace, consumer and environmental exposure to chemicals that are plausible contributors to breast cancer risk while considering risk of substitutes." Finally, the CDC-sponsored National

Conversation on Chemical Exposures concluded: "The current lack of emphasis on primary prevention in U.S. chemicals policy creates missed opportunities to avoid harmful effects from chemical exposures....Standard scientific criteria and protocols also are needed for applying a common-sense, precautionary approach to decisions about chemicals and health that would promote the design and use of safer chemicals."

The National Toxicology Program (NTP), housed at the National Institute for Environmental Health Sciences, has a list of carcinogens and uses the nomenclature of "Known To Be Human Carcinogen" or "Reasonable Anticipated To Be Human Carcinogen." While there are other lists available, for instance the International Agency for Research on Cancer (IARC) list, the NTP list seems an adequate and logical choice for NIOSH.

**3) Should 1 in 1,000 working lifetime risk (for person occupationally exposed) be the target level for a recommended exposure lime (REL) for carcinogens or should lower targets be considered?**

No. One 1 in 1,000 life time risk is FAR too high and poses an unacceptable risk for workers. As a public health agency, NIOSH should be exclusively focused on providing information on exposure levels that are truly safe for workers. The Breast Cancer Fund would support a return to the previous hazard based standard of "no detectable exposure level to proven carcinogenic substances" and a precautionary approach to suspected or probable carcinogens. While other factors, such as economics and feasibility, may be considered in setting permissible levels of exposure, NIOSH's charge is to provide information about how to fully protect workers. While NIOSH's policy provides for a "residual risk" analysis, 1 in 1000 is not "residual" and is not sufficient or appropriate for protecting workers. NIOSH should use the same standards to protect workers as are used to protect community members. Finally, workers have a right to know their risk and should be given a voice in how carcinogens are used in the workplace and strategies that can be employed to reduce exposure.

**4) In establishing NIOSH RELs, how should the phrase "to the extent feasible" (defined in the 1995 NIOSH Recommended Exposure Limit Policy) be interpreted?**

The Breast Cancer Fund urges NIOSH to return to the pre-1995 standard of "no detectable exposure levels to proven carcinogenic substances." Science does not always provide a clear-cut picture of a "safe level" for carcinogens. Cumulative exposure to a particular chemical, both in and outside the workplace, as well as the impact of adding exposures to other carcinogens, is not well understood and raises serious concern. In addition, scientists and health professionals are still struggling to understand how carcinogens interact with numerous other factors, including chemical mixtures, genetics, epigenetics, hours of work and exposure to chemicals outside the workplace. With this uncertainty, preventing exposure to known carcinogens is the safest and most responsible option.

In considering the current policy, “to the extent feasible” is not a concept that should be used in accurately identifying a level at which workers are protected, and as a public health agency, should not be a consideration in how NIOSH establishes RELs. Setting RELs at a level that adequately protects workers, even where current technologies make that level of exposure difficult to meet, provides workers an understanding of their true risk and will potentially drive research and innovation into better technologies. Those new technologies may better protect workers from exposure to harmful substances or find less hazardous alternatives through the application of green chemistry and informed substitution. NIOSH’s Prevention through Design program should be used to find less hazardous chemicals and processes to minimize toxic exposures.

Ultimately, NIOSH, as a public health organization, should remain focused on recommending policies to fully protect workers, based on the best available science, and leave policy decisions about acceptable levels of risk to workers, industry and regulatory agencies.

**5) In the absence of data, what uncertainties or assumptions are appropriate for use in the development of RELs? What is the utility of a standard “action level” (i.e., an exposure limit set below REL typically used to trigger risk management actions) and how should it be set? How should NIOSH address worker exposure to complex mixtures?**

Unfortunately, far too many chemicals that workers are exposed to have little or inadequate safety data. Our national chemical management policy, particularly the Toxic Substances Control Act, has failed to give EPA the authority to require the basic testing necessary to determine health risks of tens of thousands of chemicals currently in commerce. As mentioned above, human data is extremely difficult and often unethical to obtain. Where they exist, laboratory data give us the best indication of the toxicity of a substance and should be used in the development of REL’s. The Breast Cancer Fund urges NIOSH to incorporate a precautionary approach in setting REL’s for known, probable and possible carcinogens.

Many scientists and health professionals believe that there is no safe threshold for carcinogens, which is why the Breast Cancer Fund urges NIOSH to set the goal of “no exposure to known or probable carcinogens.” Action levels can provide an important tool for anticipating and avoiding harmful exposures, particularly accounting for the variability of exposure within a workforce, and as a transition measure to reaching zero exposure. Waiting to take action until the REL for a chemical is met or exceeded can result in unsafe and unnecessary exposures. The current practice of setting action levels at 50% of the REL may be appropriate for some exposures, but NIOSH should consider developing lower action levels via a tiered approach as industry works to meet the goal of zero exposure to carcinogens.

Assessing the impact of mixtures of chemicals is a difficult task. The body of scientific evidence on this issue is limited, but has found that chemicals have additive and sometimes synergistic effects (greater than the sum of the impact of the individual chemicals). Workers and the general

population are not exposed a single chemical, making it very difficult to truly understand the impact of a particular exposure. As a result, using adequate factors of uncertainty and continuing to develop new and more relevant ways to identify risk is critically important. We urge NIOSH to monitor the developing science to assure it is using the best available science on exposure levels and hazard, and that this science be used to take precautionary action.

Thank you for the opportunity to address the important issues surrounding RELs for carcinogens. The Breast Cancer urges NIOSH to move forward expeditiously to update this important but outdated public health policy and to expand protections to other toxic substances. We stand ready to assist you in these efforts.

Sincerely,

Jeanne Rizzo, R.N.  
President and CEO  
Breast Cancer Fund