

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

From: Alexandra Gorman Scranton <alexs@womensvoices.org>
Sent: Thursday, December 29, 2011 4:27 PM
To: NIOSH Docket Office (CDC)
Cc: Jamie Silberberger
Subject: Comments re: Docket Number NIOSH-240 from WVE

December 29, 2011

John Howard, Director
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
NIOSH Docket Office
Robert A. Taft Laboratories
4676 Columbia Parkway, MS-C34
Cincinnati, Ohio 45226
Submitted by e-mail to: nioshdocket@cdc.gov.

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

Dear Dr. Howard:

Thank you for the opportunity to provide comments on the NIOSH carcinogen and REL Policy Assessment. I am writing on behalf of Women's Voices for the Earth, a national environmental public health advocacy organization, based in Missoula, MT. Our mission is to eliminate toxic chemicals that impact women's health by changing consumer behaviors, corporate practices and government policies. We believe NIOSH must play an important role in protecting public health particularly women's occupational health, which has received less attention in the past than it deserves. We hope our contributions to this effort can help improve NIOSH's policies in this arena.

- (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, there is certainly a role for NIOSH to have an explicit carcinogen policy. Cancer poses a significant burden on public health, and occupationally-caused cancers compose a significant portion of this burden which can be prevented. Reducing or eliminating exposure to carcinogens in the workplace can reduce or eliminate disease. NIOSH should be at the forefront promoting efforts to prevent cancer in the workplace through reducing exposures to occupational carcinogens.

While cancer concerns are certainly important, we are also concerned about reproductive hazards in the workplace which have long been ignored or at the least glossed over in their significance. Even small exposures of toxic chemicals to women of childbearing age (whether pregnant at the time, or merely intending to become pregnant) can lead to significant effects on fertility, as well as lifelong conditions experienced by their children. Again these exposures can and should be prevented to avoid these outcomes. These hazards deserve the development of their own NIOSH policy to ensure a safe workplace for women regardless of their reproductive status.

- (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.)?

We support a change in the way carcinogens are currently classified by NIOSH to allow for distinctions between known carcinogens and potential carcinogens. This allows for both greater authority in preventing highly likely cancers from occurring, as well as flexibility to allow a precautionary approach to reducing exposure to suspected carcinogens. A harmonization with other classification systems (IARC, NTP etc) seems a logical choice, allowing for NIOSH to utilize the wisdom of others, while applying additional experience and knowledge of occupational exposures to protect American workers.

We also support new methods of determining the carcinogenicity of a substance in order to allow for a faster updating of the carcinogen classifications as new science is developed. Too many workers have suffered from outdated carcinogen policies based on science that is too old, and no longer relevant.

Specifically, NIOSH should use all available data when evaluating the carcinogenicity of a substance, including data from epidemiologic and toxicological studies as well as data from rapid screening assays and structure activity studies. Perhaps the most important change the NIOSH should make in a new carcinogen policy is to enable substances to be identified as carcinogens on the basis of in vitro screening methods. A policy which uses only animal and human evidence cannot address the enormous problem of new and emerging hazards, let alone the backlog of thousands of untested chemicals already in commerce. Chemicals which test positive in rapid screening assays and which meet other relevant criteria (such as sharing structural features with known carcinogens) should be identified for early preventive action in the workplace. A new category of weight of evidence of carcinogenicity may need to be set for these chemicals but it is important that they are labeled as potentially hazardous and not simply as candidates for further study.

To the extent possible, sex-based research should also be considered as cancer risks can differ between men and women both based on differing exposures as well as on biological differences.

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

No. We do not believe a 1 in 1,000 working lifetime risk is an acceptable risk for American workers. We believe it is immoral for a government agency tasked with protecting public health to officially endorse a policy allowing workers to suffer greater risks than the rest of the population. The goals of the carcinogen policy should be to eliminate occupational cancer risks, not merely to reduce them to levels orders of magnitude higher than the rest of the population. In fact keeping workers healthy (even healthier than the rest of the population) would be the better (and smarter, and less expensive) way to go for our country. At the minimum, a 1 in 1,000,000 lifetime risk may be considered where absolutely necessary, but it should also be strongly considered that many RELs for known carcinogens should simply be zero.

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

A recommended exposure limit – should be health-based, not technology-based. The goal of an REL is to establish limits which protect health – and in the current discussion – prevent cancers from occurring. Allowing for technical feasibility is one thing where specific control measures are being regulated. In the case of recommended health levels however, it is inappropriate to allow for the assumed technical infeasibility, as this simply removes any incentive for improvement and

innovation. It is the responsibility of industry to create and provide an inherently safe workplace for their employees, and NIOSH should be encouraging this with every tool it has.

(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 the REL typically used to trigger risk management actions) and how should it be set? How should NIOSH address worker exposure to complex mixtures?

As part of its harmonization with authoritative bodies, NIOSH should develop RELs for all workplace exposures to known, reasonably anticipated, probable, possible, presumed or suspected human carcinogens. This is consistent with the President's Cancer Panel's conclusions, which urged adopting an environmental (and occupational) health paradigm for long-latency diseases to enable action based on compelling animal and in vitro evidence before cause and effect in humans has been proven. Yes there is always a possibility that taking a precautionary approach, we will get something wrong – leading to the restriction of a substance that turns out not to be an occupational carcinogen after further research. However, suspected carcinogens are suspect for a reason – even if they are not proven in the end to be occupational carcinogens it is highly unlikely these substances are entirely innocent. These substances may well have genotoxic effects, for example, leading to reproductive impacts like birth defects. Being overly precautionary on suspected carcinogens (even in error) is likely to have a positive effect on worker health regardless.

Complex mixtures, sensitive populations, the lack of a threshold, and aggregate exposures should all factor in to setting of action levels at zero or at levels that are substantially lower than RELs. Complex mixtures are especially important in occupational settings where the exposures (and mixtures) can vary tremendously from exposures in everyday life. While the statistical methods needed to assess the infinite variety of possible mixtures is overwhelming to say the least, it is significantly simplified when the goal for exposure to harmful chemicals is zero.

NIOSH should also employ its research capabilities to further examine the impacts of factors such as complex mixtures, sensitive populations, and other uncertainties through pilot projects and research grants.

Again, we appreciate the opportunity to comment and contribute to this important process.

Sincerely,

Alexandra Scranton
Director of Science and Research
Women's Voices for the Earth

P.O. Box 8743
Missoula, MT 59807
alex@womensvoices.org
(406) 543-3747