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

From: Molly Jacobs <mjacobs@envhealth.net>
Sent: Friday, December 30, 2011 1:08 PM
To: NIOSH Docket Office (CDC)
Cc: david kriebel; Richard Clapp; Joel Tickner
Subject: Comments on Docket # NIOSH-240, Carcinogen Policy
Attachments: UML, Lowell Center Docket NIOSH-240 .pdf

Dear Dr. Howard,

We are pleased that NIOSH has engaged the public at this early stage of the process in revising its carcinogen policy. Attached are comments from several faculty and staff at the University of Massachusetts Lowell, Lowell Center for Sustainable Production.

Thank you for the opportunity to provide input.

Sincerely,
Molly Jacobs

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December 30, 2011

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

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Dear Dr. Howard,

Thank you for the opportunity to offer input as NIOSH revises its carcinogen and associated RELs policies to reflect new understandings of cancer and exposure science. We believe that this process also provides an opportunity for NIOSH to bring its policy in line with the most innovative thinking about science, technology, and public policy at the government and corporate levels.

Our responses follow NIOSH's five specific questions below.

(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, NIOSH should have an explicit carcinogen policy for at least two reasons. First, cancer remains a leading cause of disability and death, despite billions of dollars spent on medical research. Second, cancer continues to be a disease that is a singular focus of attention in public debate and private fears. For both these reasons, the federal government should demonstrate its commitment to reducing the human suffering from cancer with a specific policy. Reducing or eliminating exposure to a toxic chemical reduces or eliminates disease; and while this principle holds for all toxic exposures, the ability to *prevent cancer* in the workplace is a particularly powerful argument for intervening in the work environment to control chemical exposures. NIOSH's decades of experience implementing a carcinogen policy is an asset and lessons learned can be built into revising the policy so that it more effectively promotes cancer prevention.

In revising its carcinogen policy, NIOSH can build upon recent policy recommendations that have identified chemicals policy reforms as key ingredients of cancer prevention. The

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President's Cancer Panel's 2008-2009 Report stated that a "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." Similarly, 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."

We recommend that a NIOSH carcinogen policy be embedded in a broader NIOSH policy to identify, classify, prioritize, and establish prevention recommendations for all chemicals that would allow chemical users to rapidly understand whether a substance is of higher or lower concern and if substitution or some type of exposure control is needed. This is consistent with work being done by many government agencies and private companies. Such an effort may be most effectively completed in conjunction with other federal agencies. However, revisions to the carcinogen policy should not be delayed until this broader policy is established.

(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.)?

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 that 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, yet it is important that they are labeled as potentially hazardous and not simply as candidates for further study. Such an approach is consistent with efforts in some other countries and the process by which EPA evaluates new chemicals under the Toxic Substances Control Act.

We encourage NIOSH to use a simple classification system that reflects the weight of the scientific evidence available regarding the carcinogenicity of a particular substance (including bioassay data as noted above). We recommend four criteria to guide the choice of a classification system: (1) it should based on a system already used by an authoritative US agency or based on a system that has been globally harmonized; (2) it should recognize that cancer is a long-latency disease and that the evidence threshold for the category associated with potential carcinogenicity needs to be based on toxicological/structure activity evidence rather than evidence in humans; (3) it should effectively facilitate updating classifications in a *timely* manner based on new evidence; and (4) it should have no more than three or four easily understood categories to classify occupational carcinogens in order to avoid distinguishing between levels of

evidence that do not constructively and clearly communicate to workers the current state of knowledge regarding the potential for harm.

(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?

The risk of 1 cancer in 1,000 workers exposed to a specific carcinogen over a lifetime is ***not*** an acceptable level of risk. It is unethical for NIOSH to sanction cancer risks to workers that are orders of magnitude greater than what the US Environmental Protection Agency (EPA) finds acceptable for risks among the general public.

This acceptable risk level originates from the Supreme Court's Benzene Decision, where the Court gave broad discretion to OSHA to regulate risks somewhere in the range from 1 in 1,000 to 1 in 1,000,000,000. The courts never imposed a "mathematical straight-jacket" for OSHA to determine that the presence of a significant risk to workers can only be found at this upper bound. And, while NIOSH's RELs are intended to be useful to OSHA in establishing PELs, OSHA can always legally adopt lower target levels while considering economic and technological feasibility.

NIOSH should use the best science available to determine safer exposure levels to hazards, but should not be dependent on developing RELs for known carcinogens where it is clear that the "best" exposure limit is no exposure. In these circumstances, NIOSH should be clear to employers and to workers that there is no safe level of exposure to a carcinogen, which is contrary to establishing a numeric REL of anything other than a goal of zero. This is analogous to health goals set by EPA under the Safe Drinking Water Act where the Maximum Contaminant Level Goal for known carcinogens is set at zero. The goal of preventing cancer among workers should be the same as for the general public.

For known and suspected occupational carcinogens, NIOSH should redirect its research and technical assistance capacity away from risk assessments focused on developing a REL and towards research that provides information and tools to evaluate alternatives, including comparison of hazards, costs and performance. Such an approach is consistent with NIOSH's Prevention through Design framework and with principles of cancer prevention found in OSHA's generic carcinogen standard and more recently in the European Union's 2004 carcinogen policy, which requires that employers replace the use of carcinogens with less dangerous substitutes wherever feasible. A determination that a substance is a known or suspect carcinogen should lead to an automatic recommendation to reduce exposure to as close to zero as possible while alternatives are being evaluated and implemented. While NIOSH moved away from such a policy in 1995 in favor of a risk-management approach, we strongly urge NIOSH to reconsider this decision.

Preventive actions to reduce exposures and protect workers should not be delayed during the time it takes NIOSH to evaluate alternatives and issue final recommendations, or when alternatives assessments demonstrate no available safer alternative. In these circumstances, it may be necessary to continue to use an occupational carcinogen, and RELs are instructive

regarding the level of stringent exposure control needed to protect workers. The use of an exposure limit in such a circumstance is consistent with the policy strategy of using Maximum Contaminant Levels for carcinogens under the Safe Drinking Water Act to help advance towards the Maximum Contaminant Level Goal of zero. Any resulting REL for carcinogens should ensure both protection of workers at increased susceptibility, cumulative effects of multiple exposures (chemical and physical) both in the workplace and community, and source reduction. This is consistent with the control banding approach.

(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?

First and foremost, NIOSH should focus on occupational cancer prevention by encouraging the necessary technological innovation to fully control or eliminate the exposure, regardless of the current feasibility of engineering and other exposure control measures. NIOSH should always be clear that the goal is zero exposure for carcinogens, while helping industries find alternatives and control strategies which reduce exposures during the transition to complete elimination. There is substantial literature indicating that strong policies (regulatory, market, or non-regulatory signals) can help spur technology innovation. Further, a large hurdle to the implementation of more sustainable technologies is often the technical capacity of firms. NIOSH can help firms overcome barriers to change by working with other agencies to ensure research and technical support. Thus, RELs are seen as guidance on the urgency with which the chemical should be completely controlled, and indicators of acceptable practice in the transition phase. RELs for occupational carcinogens are not "safe" levels and the policy can make this clear in the way that they are set and described. To set higher RELs because engineering controls are not currently feasible is to drive the resulting risk levels inappropriately higher.

(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?

Where there are uncertainties about evidence of carcinogenicity, it is important to assume that there is a reasonable likelihood that a substance is carcinogenic to humans and should be treated as such to prevent cancer among workers. 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. It is prudent to assume there is no safe level of a carcinogen and therefore to initiate prevention strategies, especially a search for a substitute chemical, whenever a carcinogen is in use. Under such a scheme, a specific Action Level would not be appropriate.

With regard to complex mixtures, workers are routinely exposed to a range of substances (carcinogens, reproductive toxicants, neurotoxicants, etc.) on the job and in their general environment. New high throughput screening assays and statistical methods are beginning to provide some guidance for evaluating combined risks from exposures to multiple toxicants operating via a common mechanism (for example in EPA's Food Quality Protection Act). But where the goal is zero exposure, the challenges of combining risks from complex mixtures need

not delay action. Finally, for those substances where there are no safer feasible alternatives, we recommend that NIOSH follow the recommendations of the National Research Council's report Science and Decisions: Advancing Risk Assessment regarding evaluation of cumulative effects of multiple exposures.

We look forward to continuing this process and please contact us if you have any questions.

Sincerely,

David Kriebel, *Professor and Chair, Department of Work Environment, University of Massachusetts Lowell*
Joel Tickner, *Associate Professor, Department of Community Health & Sustainability, University of Massachusetts Lowell*
Richard Clapp, *Adjunct Professor, Department of Work Environment, University of Massachusetts Lowell & Professor Emeritus of Environmental Health, Boston University School of Public Health*
Molly Jacobs, *Program Manager, Lowell Center for Sustainable Production, University of Massachusetts Lowell*