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

From: Dorothy Wigmore <dwigmore@worksafe.org>

Sent: Friday, December 30, 2011 2:12 PM

To: NIOSH Docket Office (CDC)

Subject: Comments about NIOSH cancer policy

Attachments: Worksafe response to NIOSH request re cancer policy final.pdf

Here are the comments from Worksafe (California) about docket number NIOSH-240. Please let me know if you have questions. I am sending a PDF version to ensure the formatting is retained. If you need a Word version, please let me know.

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December 30, 2011

NIOSH Docket Office Robert A. Taft Laboratories MS - C43, 4676 Columbia Parkway Cincinnati, Ohio USA 45226

To whom it may concern:

Response to Docket No. NIOSH-240

Request for information: Announcement of carcinogen and Recommended Exposure Limit (REL) policy assessment

Worksafe is a California-based organization dedicated to eliminating all types of workplace hazards. We advocate for protective worker health and safety laws and effective remedies for injured workers. We watchdog government agencies to ensure they enforce these laws. We engage in campaigns in coalition with unions, workers, community, environmental and legal organizations, and scientists to eliminate hazards and toxic chemicals from the workplace.

We welcome the opportunity to comment on NIOSH's request for information about its occupational carcinogen policy. We do this with a historic and international perspective on the topic, and a commitment to the public health principles of prevention, precaution, informed substitution, toxics use reduction and green chemistry. In doing so, we link environmental and occupational health, and economic, environmental and social justice.

In general, we support the responses to NIOSH's request made by organizations with a similar perspective (e.g., the Breast Cancer Fund, the Blue Green Alliance, the Lowell Center for Sustainable Production, the AFL-CIO). Our comments in response to NIOSH's specific questions follow.

 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)?

NIOSH needs a new and explicit carcinogens policy. Reasons for this include:

- There is an ignored cancer epidemic. Too many workers, their families, unions, communities, and community organizations continue to pay the price of those who work with and/or produce carcinogens. The workers pay with their health, their lives, the loss of income and their abilities to contribute to their society, for involuntary exposure to a preventable hazard. They do this, often without knowing about the hazards, to support themselves and their families, and pay the taxes governments need to protect them from hazards in all environments.
- While many people fear cancer and it continues to be the subject of public debate, too much attention and funding goes to looking for "a cure", often blaming those with cancer for their "lifestyle" choices. Too little money, time effort, and information goes to prevention. (As the Blue-Green Alliance points out, even NIOSH's parent organization -- the Centers for Disease Control -- does not mention work-related sources of carcinogens in its website statement about preventing cancer.)
- The risk assessment approach adopted by (or forced upon) NIOSH in 1995 is inconsistent with NIOSH's mandate, and its current efforts. These programs include Prevention through Design, Green Jobs and the related topic of green chemistry, Occupational Health Disparities, Total Worker Health ("which envisions workplaces that are free of recognized hazards ...") and the NORA Manufacturing Sector research (with its strategic goal to "reduce the incidence and prevalence of cancer due to exposures in the .. sector"). Furthermore, NIOSH's approach to research about cancer (as explained on its website) is filled with "risk assessment" studies that seem to be uncritical of the approach. There also are some epidemiological studies, rather than the intervention research for which the agency became well known in the construction and other sectors, and in ergonomics.
- Building on these current efforts and programs, NIOSH could provide valuable guidance about, and inspiration for, technology-forcing regulations that aim for green chemistry and toxics use reduction solutions. This includes NIOSH's role in promoting and supporting research about these kinds of solutions and informed substitution for carcinogens in specific workplace settings.
- Historical information presented on the NIOSH website to accompany this request, and elsewhere, provides helpful insights about the background for, and principles to use in, developing a re-newed policy (e.g., Edward Fairchild's 1975 comments about the absence of a "safe level" for carcinogens and that the "most important feature of the NIOSH policy for carcinogenic substances .. will be recommendation of the use-permit and the registration system"; and the 1958 paper by the grandfather of occupational cancer research, William Hueper, Prevention of occupational cancer hazards).

Work-related cancer does not play fair. Getting it, and surviving the disease, is related to social class. At the same time, many studies that identified occupational carcinogens looked at industrial and male populations. NIOSH could rectify the imbalance with a gendered approach to its policy, one that also calls attention to the wide range of lower SES jobs in which carcinogens are found, and links parental exposures to childhood cancers.

At the same time, current and emerging knowledge tells us that some work-related hazards that lead to cancer also have other chronic and acute effects of concern. The carcinogens policy should make this clear. As policies about other health effects are prepared, they should also make this link to carcinogens, as appropriate.

The policy also should be placed in the context of public health principles, starting with prevention. In doing so, NIOSH should take the lead from three sources. The first is the President's Cancer Panel 2008 - 2009 report. Its authors' first recommendation is:

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. Though not applicable in every instance, this approach should be the cornerstone of a new national cancer prevention strategy that emphasizes primary prevention, redirects accordingly both research and policy agendas, and sets tangible goals for reducing or eliminating toxic environmental exposures implicated in cancer causation. ... Optimally, it should shift the burden of proving safety to manufacturers prior to new chemical approval, in mandatory post-market studies for new and existing agents, and in renewal applications for chemical approval.

The second suggestion for a source of inspiration for NIOSH is the *Asturias Declaration: A call to action*, and recommendations from the WHO's 2011 First International Conference on Environmental and Occupational Determinants of Cancer: Interventions for Primary Prevention. Pointing to primary prevention as the single-most effective prevention method, recommendations talk about:

- Shifting the paradigm to primary prevention in cancer control as a fundamental principle at global, national and regional level; ..
- The use of easy-to-understand messages (such as reminding the general public that primary prevention is not the same as secondary prevention, or that individual behaviour is also related to the environment) and to educate populations about environmental and occupational causes of cancer and preventive strategies; ... (and)
- The creation of a multi-sectoral approach for primary prevention of environmental and occupational causes of cancer and to identify new ways of collaboration...

NIOSH also should look north to the work being done in two Canadian locations. The first is the CAREX (CARcinogen Exposure) hazard surveillance project at the

University of British Columbia (<a href="http://www.carexcanada.ca">http://www.carexcanada.ca</a>). Borrowed from Finland (<a href="http://www.ttl.fi/en/chemical\_safety/carex/Pages/default.aspx">http://www.ttl.fi/en/chemical\_safety/carex/Pages/default.aspx</a>), the project has developed innovative data collection methods and tools (e.g., mapping) that are proving popular and useful to researchers and others alike. The second is the Ontario Cancer Research Centre (OCRC), a unique organization based on a partnership amongst research, healthcare, workplace health and safety, labour and industry groups (<a href="http://occupationalcancer.ca/">http://occupationalcancer.ca/</a>). Its guiding principles include use of the precautionary principle.

Finally, the NIOSH carcinogens policy needs to explain how to develop and implement "just transition" programs to support workplaces, workers and/or communities that face job losses because a carcinogen is no longer produced or used. We are happy to provide sample policies about and examples of this important concept that is key to "total worker health".

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 sources, inside and outside the United States, to compile lists of carcinogens. Epidemiological studies may offer the "best" evidence if the agency wants to ignore the precautionary principle. If it does not, studies should include animal data, rapid screening assays and structure activity to identify possible or likely carcinogens. The EPA's *Distributed structure-searchable toxicity database network* and its Tox 21 inventory offer great possibilities

In terms of using what we know, and the urgency to do so, a good example to consult is an analysis by California's Office of Environmental Health Hazard Assessment (OEHHA), part of the state's Environmental Protection Agency. The 2007 report, Occupational health hazard risk assessment project for California: Identification of chemicals of concern, possible risk assessment methods, and examples of health protective occupational air concentrations (http://www.cdph.ca.gov/programs/hesis/Documents/riskreport.pdf) paints a stark and disturbing picture of the inadequate regulation of occupational carcinogens in California -- which is even worse federally. For example, 44 workplace chemicals on the state's Proposition 65 list lack a Cal/OSHA permissible exposure limit (PEL), although they are named as carcinogens. Another 62 workplace chemicals listed as carcinogens under Proposition 65 have state PELs, but only for non-carcinogenic effects. OEHHA estimated that workplace exposure to one Prop 65 chemical leads to 730 - 940 excess cases of cancer per 1,000 workers at the current PEL.

For further information about what we know, besides the lists compiled by others, NIOSH also should look, and advocate, for hazard surveillance approaches (e.g., the CAREX Canada work).

The final list and related classification system should be easy to use and reflect the weight of evidence available. The Lowell Center's four criteria for a classification system integrate recommendations from others into a sensible framework.

Whatever the categories of evidence, NIOSH should recommend action in a precautionary framework that uses the information collected, and what we "know" now. It also should recommend information for workplaces that let employers and workers know if a chemical, mixture or set of specific hazards has not been tested for carcinogenicity, particularly for chemicals, mixtures or hazard combinations that are related to anything on the list.

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?

Worksafe joins many other organizations in an adamant "NO". It is unethical for NIOSH to sanction worker exposure to carcinogens at levels that are orders of magnitude greater than what the US EPA says is "acceptable" for workers when they are part of the "general public".

NIOSH could do the world a favor by repudiating this inaccurate interpretation of the "Benzene decision", and explaining why it is inaccurate and inappropriate to protect the health of workers and their families. (See the comments by the American Association of Justice, the Lowell Center, contemporary papers analyzing the decision, and the original decision itself.)

On a related front, NIOSH needs to be clear that it is not constrained in the same way that OSHA is, when it comes to a carcinogens policy. As its website says, the agency is supposed to be about *providing national and world leadership to prevent workplace illnesses and injuries*. The statute providing its authority has an impressive public health focus, mandating NIOSH to conduct research, investigate workplace illnesses and injuries, educate workers and management, and support development of science-based regulations.

NIOSH should use this independence to develop an innovative and truly preventive carcinogens policy that avoids recommendations for exposure limits, while emphasizing the need for informed substitution, precaution and technological innovation. It can provide examples of successful efforts to do this, as the Lowell Center did in its publication, *Lessons learned: Solutions for workplace safety and health* (with appropriate attention to the role of workers, employers, researchers, engineers, etc.) The examples can come from outside the United States too, especially if the workplaces concerned have US counterparts.

This is not a new idea. In his 1976 report to the Ford Foundation, *Crisis in the workplace: Occupational disease and injury*, Nicholas Ashford suggested that an "alternative and more sensible approach (to trying to obtain information about

"safe levels" for carcinogens and other toxic materials) may be to redesign our industrial processes, to automate where necessary, and to reduce unnecessary proliferation of new chemicals" (p. 124).

It is time for NIOSH to follow Ashford's advice, and his later work about technology-forcing activities. It is time for NIOSH to catch up with the innovative work of other agencies and organizations (e.g., the Lowell Center, the Berkeley Center for Green Chemistry, Clean Production Action) that try to protect workers' health and the environment, and with ground-breaking companies such as Interface.

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?

Feasibility is not part of a preventive and precautionary carcinogens policy. NIOSH should be clear (like the laws in some other jurisdictions) that workers should NOT be exposed to carcinogens. It should encourage, research and support replacement of carcinogens with less toxic or non-toxic processes or substances.

As interim measures, RELs can play a role during transitions to informed substitution of chemicals and/or processes. They could provide guidance about how important it is to eliminate exposure to specific carcinogens, and how well this is happening. NIOSH must be clear that RELs are not "safe levels", and that they are interim guidelines en route to preventing occupational-related cancer.

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?

Action levels are not appropriate either, unless the REL is re-named that and defined as interim, non-"safe" levels.

Complex mixtures are "real life" for most workers, especially on the job. Most products are these types of mixtures, and are not tested for their combined effects (whether additive or synergistic). The products themselves interact with other workplace hazards (e.g., hours of work, sunlight, noise) and other products and chemicals, again in often-unknown and untested ways. This reality is one limit to epidemiological and toxicological studies.

Since science cannot help on this front, it requires policy that aims for no exposure for carcinogens (and other chemicals with serious and/or long-term and intergenerational effects), informed substitution and toxic use reduction. The policy

also needs to explain why these types of mixtures cannot be studied easily, and how they can affect workers' health. Furthermore, it needs to be clear about the information workers and employers should get about carcinogens and complex mixtures, the hazard and health surveillance required and the training needed for healthy and safe work practices to go with efforts to control (not prevent) worker exposure.

We are happy to respond to any questions you have, and look forward to being included in on-going conversations, meetings, and activities about this topic that is so important to workers in California and elsewhere.

Sincerely

Amanda Hawes Chair, Worksafe Board