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

From: Diana Zuckerman <dz@center4research.org>
Sent: Friday, December 30, 2011 2:16 PM
To: NIOSH Docket Office (CDC)
Cc: 'Diana Zuckerman'; 'Dana Casciotti'
Subject: Docket 240
Attachments: NIOSH_Response to Docket Number 240 Dec 29.pdf

Thank you for the opportunity to comment.

Sincerely,

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December 30, 2011

NIOSH Docket Office
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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. John Howard,

Thank you for the opportunity to provide comments as NIOSH revises its carcinogen and associated RELs policies. This letter responds to five questions posed by NIOSH in its request for information.

(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. Cancer is a leading cause of disability and death, and the public is particularly fearful of the disease. Preventing cancer in the workplace is of particularly concern to the American public. NIOSH's decades of experience implementing a carcinogen policy is an important strength and it is essential that the agency build on that experience to more effectively prevent cancer in the years ahead.

(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 is rightly re-evaluating its cancer policy. The current terminology, "potential occupational carcinogen," results in a singular category of carcinogenic substances. Lives could be saved if the classification system is expanded to include substances for which there is not yet sufficient scientific evidence to classify them as "potential occupational carcinogen," but which are nonetheless likely to increase the risk of cancer.

NIOSH and OSHA support the use of a Globally Harmonized System of Classification and Labeling of Chemicals (GHS). The GHS justifiably places greater weight on evidence of carcinogenicity in humans, but also allows evidence based on animal exposure and resulting effects. The GHS is a good place to start

in terms of carcinogen classification, but it only contains two categories and it depends on a level of evidence that is difficult to obtain and not timely.

NIOSH should use all potential sources of data when evaluating the carcinogenicity of a substance, including data from epidemiological studies, toxicological studies, rapid screening assays, and structure activity studies. For example, chemicals which test positive in rapid screening assays and meet other key criteria should be identified and included in a new category defined as potentially hazardous, rather than as candidates for further study.

We encourage NIOSH to use a simple classification system (3 or 4 categories) that reflects the weight of the scientific evidence available regarding the carcinogenicity of a particular substance (including bioassay data as noted above).

The new classification system should be based on a system already used by an authoritative U.S. agency or based on a system that has been globally harmonized. It should be a system that makes it easy to reclassify substances from one category to another on the basis of new evidence. And, obviously, since the latency for cancer is often 15-20 years in humans, the evidence threshold needs to be based on toxicological and structure activity evidence, not just evidence in humans.

It can take years for epidemiological data to prove a substance causes cancer, and extensive, irreparable harm can occur during that time. The new classification system should incorporate substances that have a range of evidence of carcinogenicity, from a preliminary to a more established evidence base.

NIOSH should reword the definition of Category 2: "Suspected Carcinogen," which is currently defined as "limited evidence of human or animal carcinogenicity." The term "suspected carcinogen" implies a potentially harmful substance, but the term "limited evidence" is more likely to encourage complacency when it comes to the protection of people in the workforce. "Limited evidence" may be scientifically accurate, but it is also potentially misleading. This definition should be reworded as "modest evidence of carcinogenicity in human or animal studies."

A third category should be added, "Suspected Carcinogen Based on Non-animal Research," which is based on evidence from toxicological and structure activity evidence.

(3) Should 1 in 1000 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?

A 1 in 1000 working lifetime risk is too high; the target level for a REL for carcinogens should be lower. It is unethical for NIOSH to accept cancer risks for workers that are so much greater than what the U.S. Environmental Protection Agency considers acceptable risks for the general public.

This lifetime risk estimate is based on the Supreme Court's 1980 benzene decision where the court stated:

> Some risks are plainly acceptable and others are plainly unacceptable. If for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (I.U.D. v. A.P.I., 448 U.S. 607, 655).

Clearly, in this decision the Court pointed out that a 1 in 1,000 risk level can be considered unacceptable, and that statistic represented a high risk in the continuum between 1 in 1,000 and 1 in a billion that the court presented as examples. The Court did not discuss risk levels in between those two, and there is no reason to assume that all risks higher than 1 in 1,000 would have been considered acceptable by the court. NIOSH's mission is to promote workplace safety and prevent work-related illness, thus it is necessary to strive for a lower REL for workers.

The Supreme Court was not making a definitive scientific judgment, and even if it had tried to do so that judgment would not necessarily be relevant more than 30 years later. A lower REL for carcinogens is especially important given the likelihood of multiple and mixed exposures in the workplace. In its December 2004 report, the National Occupational Research Agenda (NORA)'s Mixed Exposures Team stated: "In fact, all exposures are mixed exposures in the sense that none occur in isolation from exposures to other simultaneous or sequential stressors inside or outside the workplace."

Additive and synergistic effects of multiple exposures are extremely hard to study and to quantify. However, these effects are almost certain to occur and to threaten workers' health. Lowering RELs for a given substance, whether a confirmed or suspected carcinogen, has the potential for dramatically lowering risks associated with additive and synergistic effects resulting from multiple exposures.

NIOSH should use the best scientific evidence available to determine safer working conditions, but for known carcinogens employers and workers should be notified that there is no safe level of exposure. A comparable example is the EPA's Safe Drinking Water Act, where the maximum contaminant level goal for known carcinogens is zero. The goal of preventing cancer among workers should be the same as for the general public.

Rather than focusing NIOSH research and resources primarily on risk assessments to develop a REL, NIOSH should also focus on providing information and tools to evaluate safer alternatives. For example, the European Union's 2004 carcinogen policy requires that employers replace carcinogens with less dangerous substitutes wherever feasible.

RELs are needed to protect workers and consider strategies for reducing exposures, before alternatives have been identified. But, it is essential that NIOSH devote its resources to identifying and evaluating alternatives as well as RELs.

(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?

NIOSH should encourage a zero exposure level for all carcinogens, regardless of currently available technologies to control exposure. The goal of a zero exposure level will encourage technological advancement in finding safer alternatives and new control measures to reduce and ultimately eliminate exposures. The RELs should serve as guidelines as to which exposures warrant the most attention and require the most urgent action.

(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?

There are many uncertainties in studying exposures and disease outcomes. The latency period of most cancers requires earlier action to prevent potentially dangerous disease outcomes, even in the absence of definitive scientific evidence. In situations where substances are likely to be carcinogenic, risk management actions should be initiated to reduce all exposure levels, with a goal of zero exposure.

As previously mentioned, the risk of multiple exposures, or exposure to complex mixtures, is difficult to quantify but poses an enormous threat to workers. While new statistical methods that may help measure the risk of exposure to multiple toxic substances should be utilized, NIOSH should stress that the goal is zero exposure.

Sincerely,

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