Diana, Sherri A. (CDC/NIOSH/EID) (CTR)

From: Chris Trahan <CTrahan@cpwr.com>
Sent: Wednesday, December 28, 2011 9:51 AM
To: NIOSH Docket Office (CDC)
Subject: comments to NIOSH Docket Number 240
Attachments: 12-28-11 NIOSH Docket 240 comments.pdf

Dear Sir/Madam:

Please find comments from Pete Stafford, Safety and Health Director of the Building and Construction Trades Department, AFL-CIO attached.

Please do not hesitate to contact me or Pete if you have any questions.

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Building and Construction Trades Department

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December 28, 2011

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

Sent via email to nioshdocket@cdc.gov.

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

Dear Sir or Madam:

The Building and Construction Trades Department, AFL-CIO (BCTD) appreciates the opportunity to comment on the NIOSH Carcinogen REL Policy Assessment. We commend NIOSH for examining their policy, and believe the agency is in a unique position within the federal government to issue recommendations for exposure limits that are based primarily on risk of disease.

We believe that NIOSH recommended exposure limits (RELs) should be based on best available health research and knowledge. The data collected to establish the RELs should be organized in such a way that it makes research gaps more visible and can be used to establish occupational safety and health research strategic priorities. The information should also be structured to provide guidance for workers and employers until the body of all possible peer reviewed scientific information is considered adequate to support a specific mandatory numerical exposure regulation, and the formal and lengthy OSHA rulemaking process is completed.

Please find answers to some of the specific questions posed in the Federal Register Request for Information 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. We do think NIOSH needs an explicit carcinogen policy. This need is justified by the lack of thresholds for safe exposure and the irreversibility of carcinogenesis.

While a broader policy on toxicant identification and classification could be useful, NIOSH should not delay updating the carcinogen policy in order to develop it.

(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 examine the existing categorization schemes such as NTP, GHS, IARC, ACGIH, or the EU when determining the evidence to consider. Additionally, NIOSH should monitor the steps currently underway to modify the OSHA hazard communication standard, and adopt a similar approach.

We would strongly recommend that NIOSH abandon its use of the term, "potential occupational carcinogen." While the BCTD agrees evidence of a material's carcinogenicity may vary in an occupational setting, there are some materials for which occupational carcinogenicity is well documented. In such cases, the use of "potential" in categorizing the hazard can have the unintended consequence of creating doubt as to the true harmful nature of the substance in question.

We also recommend that NIOSH avoid using the term "occupational" to categorize carcinogens. Any substance determined to be a carcinogen and used in a workplace would be an occupational hazard, and NIOSH only establishes RELs when there is believed to be occupational exposure.

In addition, by adopting categories, such as those employed by the GHS or NTP, NIOSH would be able to eliminate this type of confusion and identify "clear cut" carcinogens; in other words, those with studies supporting the risk of carcinogenicity in humans. The US National Toxicology Program, for example, uses the terms "known to be a human carcinogen" and "reasonably anticipated to be a human carcinogen." These straightforward characterizations are easy to understand, and still convey the varying amount of existing evidence as to the hazard.

(3) Should one 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?

A one in 1,000 risk of occupational cancer should not be the target level for NIOSH RELs. Indeed, there is no legislative or scientific justification for such an arbitrary target for cancer risk. Instead, NIOSH should describe the best available science when they set RELs. NIOSH should perform a risk assessment on carcinogens using the best available epidemiological and experimental data. While we believe NIOSH should base RELs on a 'no effect level', we recognize this is not always possible. If it is not possible, NIOSH should be able to identify the lifetime risk of occupational cancer associated with the established effect level.

(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's role should not be confused with OSHA's. NIOSH does not have the required expertise or capacity to consider all aspects of "feasibility." Since it is not a regulatory agency, the RELs it establishes are not enforceable. It is OSHA's role, not NIOSH's, to determine feasibility through an administrative rule making process.

As noted earlier, the BCTD believes NIOSH should focus on establishing RELs based on risk. RELs are tools used by both management and workers to understand the relative risk associated with chemicals in the workplace and to identify ways to control exposure to carcinogens and other airborne hazards. As such, NIOSH should be continuously reviewing and updating its RELs to reflect incremental changes in technology and analytic methods.

Requiring NIOSH to consider "feasibility" would further impede this process, which is already too slow. For example, in 2002 NIOSH updated its health effects document on silica. Because of its interpretation of the phrase "to the extent feasible," the REL was not updated from the 1974 value because of limitations in control technologies and measurement methods at that time. Since then, much progress has been made in the study and application of technology, and lower exposure limits are achievable as a result. However, NIOSH has not updated its REL for silica to reflect these changes.

(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?

NIOSH should use all available data to develop protective RELs. If NIOSH lacks data on a substance's specific carcinogenicity in humans, and there is relevant animal or laboratory-based data to support the likelihood of carcinogenicity in humans, NIOSH should weigh the entirety of the available evidence to make risk-based decisions.

We believe there is utility in having an action level—to be a trigger when the exposure does not actually exceed the REL. NIOSH should consider 10% of the REL as an action level.

In closing, the BCTD wishes to thank NIOSH again for requesting comments on its Carcinogen and REL policy. If you have any questions related to our comments, please do not hesitate to contact me.

Sincerely,

Pete Stafford
Director of Safety and Health