

CLIENT ALERT

NIOSH Issues Revised Chemical Carcinogen Policy

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On December 27, 2016, the National Institute for Occupational Safety and Health (NIOSH) published a revised Chemical Carcinogen Policy (Current Intelligence Bulletin 68). It is the first such revision in over 10 years and embodies a significant change in policy from earlier versions.

NIOSH first developed cancer guidelines in 1975, and its authority to issue “recommended exposure limits” (RELs) to reduce the purported risk of occupational cancer and other health effects from hazards in the workplace derives from the Occupational Safety and Health Act of 1970 (“OSH Act”) and the Federal Mine Safety and Health Act of 1977 (“MSH Act”). Since its last policy revision, issued in 1995, NIOSH RELs have been based on (1) quantitative assessments of hypothesized health risks at various exposure concentrations and (2) assessments of the feasibility of accurately measuring and controlling exposures to the hazard in the workplace.

Since 1995, NIOSH has most frequently recommended exposure limits for various chemicals at concentrations corresponding to a presumed excess risk of 1 in 1,000 workers exposed to the substance consistently over a 45-year working lifetime. For example, NIOSH’s coal mine dust risk assessment discussed one in 1,000 as a risk level for chronic and serious respiratory health effects that did not involve cancer and recommended an exposure limit of one mg/m³.

Change is now afoot. In Bulletin 68, NIOSH announces that its updated policy reflects “advances in science . . . with the intent of providing transparent guidance on how NIOSH assesses and addresses cancer risks.” It advances the regulatory public health policy presumption “that there is no *known* safe level of exposure to a carcinogen” (emphasis added). (The NIOSH announcement accompanying the Bulletin states that NIOSH found that there is “no safe level” of exposure to any carcinogenic substance, rather than “no known safe level” of exposure, a significant distinction.) And it now keys on the risk level of 1 in 10,000 workers, instead of 1 in 1,000, as its point of reference.

Furthermore, the Bulletin finds that “reduction of worker exposure to chemical carcinogens as much as possible through elimination or substitution and engineering controls is the primary way to prevent occupational cancer.” Accordingly, NIOSH will no longer use the term “REL” and will instead adopt a “Risk Management Limit for a Carcinogen” (RML-CA) as “an initial starting point for control.”

Under the new policy, NIOSH will issue authoritative documents evaluating existing cancer hazard assessments conducted by the U.S. National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), and the International Agency for Research on Cancer (IARC). NIOSH emphasizes the importance of employing “a systematic methodology for critically assessing and interpreting a body of scientific information” and deems the NTP, EPA, and IARC compliant with NIOSH criteria. Bulletin 68 provides extensive detail on the carcinogen classifications and related methodologies utilized by each organization.

Bulletin 68 reflects NIOSH updates to three distinct policies, collectively called the NIOSH Carcinogen Policy: (1) the *NIOSH Occupational Chemical Carcinogen Classification Policy*, (2) the *Carcinogen Risk Management Limit Policy*, and (3) the *Analytical*

Feasibility and Engineering Achievability Policy. NIOSH seeks to simplify the process of assessing purported cancer risks, enhance the utility of its published documents, and be more consistent with other agencies that assess cancer risks. Bulletin 68 explains the key revisions to each of these distinct policies:

NIOSH Occupational Chemical Carcinogen Classification Policy

NIOSH will determine whether a chemical is an occupational carcinogen by using one of three methods:

1. Evaluation of chemical carcinogen hazard assessments developed by NTP, EPA, or IARC.
2. Nomination by NIOSH for classification by NTP.
3. Classification by NIOSH.

Evaluation of NTP, EPA, and IARC Carcinogen Classification Hazard Assessments

NIOSH will determine the occupational relevance of a chemical carcinogen by using certain, enumerated designations utilized by each of the assessing entities. Notably, in determining the occupational relevance of a particular chemical, “NIOSH will presume that a chemical classified as a carcinogen is occupationally relevant unless NIOSH finds convincing evidence that the chemical carcinogen is not relevant for the occupational exposure situation.” In making such a determination, NIOSH will consider data relating to industrial usage of the chemical in question. Among other sources, NIOSH “will assume that inhalation and dermal studies are occupationally relevant because these are the typical exposures that workers encounter.” NIOSH will also review information and scientific studies relied upon by NTP, EPA, or IARC in developing its hazard assessments to determine (1) if the assessment is not relevant to occupational exposure or (2) if new information casts doubt on the scientific credibility of the assessment, under which circumstances NIOSH will seek a new classification of the chemical to account for, among other things, new information that may have become available about the chemical in question since the original assessments were conducted.

NIOSH will determine whether the chemical is occupationally relevant and classify it as a NIOSH occupational carcinogen when there is a potential for worker exposure and the hazard assessments and scientific studies are applicable to occupational exposures. When NIOSH adopts a hazard assessment, it will periodically review its determinations and update them as necessary.

Nomination by NIOSH for Classification by NTP

NIOSH may nominate a chemical for review by NTP when NIOSH has determined that the chemical has the potential for worker exposure and (1) there is no prior NTP, EPA, or IARC carcinogen classification or (2) information in the occupational relevance evaluation indicates the need for reconsideration of the evidence.

Classification by NIOSH

If a chemical is of particular concern to NIOSH, it may develop its own hazard assessment to determine whether it should be classified as an occupational carcinogen when NIOSH has determined that the chemical has potential for worker exposure and (1) there is no prior NTP, EPA, or IARC carcinogen classification or (2) information in the occupational relevance evaluation indicates the need for reconsideration of the evidence underlying a published chemical carcinogen assessment. Bulletin 68 sets

forth the standards that NIOSH will use in developing its own chemical carcinogen classification, with reference to several international and domestic standards relating to the classification and labeling of hazardous chemicals.

Chemical Carcinogen Risk Management Limit Policy

NIOSH will (1) determine a range of estimates from 1 excess cancer case in 100 workers to 1 excess cancer case in 1 million workers over a 45-year working lifetime when the data permit, and (2) set a risk management limit. Of note, NIOSH specifically reiterates that “[b]ecause there is no known safe level of exposure to occupational carcinogens, NIOSH will continue to recommend reduction of exposure to an occupational carcinogen as much as possible through substitution or engineering controls and administrative controls before use of personal protective equipment (PPE).” Bulletin 68 summarizes key elements of the NIOSH approach to quantitative risk assessments (QRAs), indicating that further guidance on its approach to risk assessment is forthcoming.

NIOSH will then determine a range of risk estimates and set an RML-CA, reflecting that “advances in exposure assessment, sensor and control technologies, containment, ventilation, risk management, and safety and health management systems have made it possible in many cases to control chemical carcinogens to a lower exposure level.” NIOSH will set RML-CAs for occupational carcinogens “at the concentration corresponding to the 95% lower confidence limit of the 1 in 10,000 risk estimate, but only when occupational measurement of the carcinogen at the RML-CA is analytically feasible.” In the foreword to Bulletin 68, NIOSH notes that, “[k]eeping exposures within the risk level of 1 in 10,000 is the minimum level of protection and striving for lower levels of exposure is recommended.”

NIOSH emphasizes its recommended hierarchy of controls, again underscoring the “elimination or substitution of other chemicals that are known to be less hazardous, and engineering controls,” followed by “[a]dministrative controls, such as work practice controls” and “[p]ersonal protective equipment,” which NIOSH called “the last line of defense, used when other methods do not adequately reduce exposures.”

Analytical Feasibility and Engineering Achievability Policy

NIOSH recognizes that a sampling or analytical method that can accurately measure exposure concentration is necessary to ensuring occupational exposures below the RML-CA, and indicates that where such a method does not exist, NIOSH will consider initiating research to develop such a method. Notably, NIOSH recognizes that OSHA is required to consider feasibility when setting occupational safety and health standards, but determines nonetheless that, “given the fast pace of rapidly changing engineering controls, NIOSH will not utilize the capability of controlling exposures (that is, engineering achievability) in setting RML-CAs” and “will continue to recommend using a hierarchy of controls to reduce exposures to workers.”

THE ROAD AHEAD

The revised policy has no current binding effect under either the OSH Act or the MSH Act. Under both of those statutes, NIOSH is mandated to:

“...develop criteria dealing with toxic materials and harmful physical agents and substances which will describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of

his work experience.” [29 United States Code (USC) 669 (a)(3) and for mining, 30 USC 811 (a)(1) and 30 USC 811 (a)(6)(B)].

Since 1970, NIOSH has reviewed evidence on chemical carcinogenicity to support its RELs. But agencies charged with the implementation of health and safety standards are subject to their own rulemaking requirements. Whether and how NIOSH recommendations and forthcoming guidance might affect regulated industries remains an open question, but there are several potential opportunities for predicting the road ahead.

The Past: Similar Shifts in Cancer Risk Assessment Policy

NIOSH’s revised policy and its emphasis on the regulatory presumption that there is “no known safe level of exposure to a carcinogen” is not the first such shift in cancer risk assessment methodology, and appears to track EPA’s endorsement of the “linear, no-threshold dose” (LNT) response model for determining the risk of cancer associated with a particular chemical. LNT presumes that a hypothesized risk is proportional to the dose received. In other words, it extrapolates the risk of cancer from actual test results at high exposure levels straight down to zero, presuming there is some measurable level of risk for any exposure above zero. This policy represents a significant departure from the classic dose-response curve which exists for virtually every substance.

The Future: Opportunities for Public Comment

NIOSH reports an extensive engagement with stakeholders since it first announced its effort to revise its Chemical Carcinogen Policy, summarized on its Bulletin 68 summary page. For example, two public meetings, one in December 2011 and one in December 2013 featured public commenters from across the stakeholder spectrum, including the National Center for Environmental Health (NCEH), United Steelworkers Union, the American Federation of Labor and Congress of Industrial Organizations (AFL/CIO), the American Chemistry Council, the National Research Center for Women and Families, and the New York State Laborers’ Health and Safety Trust Fund.

In similar fashion, NIOSH has committed to continuing its policy of seeking peer review and public comment in connection with determinations regarding (1) chemical hazard assessment and occupational relevance reviews; (2) QRA for each occupational carcinogen, including but not limited to selection of data and mathematical models; (3) analytical methods for measuring the RML-CA; and (4) information regarding engineering controls. Moreover, NIOSH will publish a notice in the Federal Register regarding whether a chemical has been determined by NIOSH to be an occupational carcinogen, the reasons for the NIOSH classification, the RML-CA, and the range of presumed risk estimates.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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