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December 9, 2011

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

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

Dear Sir or Madam:

On behalf of our 1.6 million members, the American Federation of State, County and Municipal Employees (AFSCME) appreciates the opportunity to provide comments on the review and assessment of NIOSH's carcinogen and REL policies.

Below is our response to the five questions posed by NIOSH in the August 23, 2011 Federal Register notice:

(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)?*

NIOSH should continue to have a carcinogen policy, as it has for more than thirty-five years. Occupational cancers are among the most important health concerns among workers. NIOSH's views and policy are an important resource in our efforts to protect workers from exposure to harmful agents. This policy should be maintained and refined. Once the updating of its carcinogen policy is complete, the agency may want to consider developing a broader toxicant policy in the future.

(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's current system of classifying carcinogenicity--"a potential occupational carcinogen"-- is inadequate in that no substance is defined as a confirmed or known carcinogen. This single classification of potential carcinogens includes known carcinogens such as asbestos and benzene with other substances for which the evidence is not as strong. In its revised cancer policy, NIOSH should eliminate the word "potential" for known carcinogens.

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We believe that NIOSH should look at the systems used by the US EPA, the National Toxicology Program, the Globally Harmonized System (GHS) and the European Union. For example, the NTP uses two classifications –a) *known to be carcinogenic in humans* and b) *reasonably anticipated to be a human carcinogen*. This would provide a clear improvement over the current NIOSH classification of “potential”.

Determinations of carcinogenicity should rely upon broad evidence including epidemiologic studies, animal experiments, in vitro studies, structure activity-relationships and relevant case-reports.

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

NIOSH should not adopt the 1 in 1,000 working lifetime risk as the target level for RELs.

The mission of NIOSH is to generate new knowledge in the field of occupational safety and health and to transfer that knowledge into practice for the betterment of workers. To adopt 1 in 1,000 working lifetime risk as the target level for a recommended exposure limit (REL) would be contrary to NIOSH’s mission. NIOSH is a scientific organization in the U.S. Public Health Service. It does not issue binding regulations and it is not covered by Industrial Union Department, AFL-CIO v. American Petroleum Institute, et al. (1980) 448 U.S. 607. The 1 in 1,000 working lifetime risk represents an interpretation by the Solicitor of Labor’s office of a non-binding footnote to the above cited case. Following the court’s decision, OSHA has used the 1 in 1,000 risk level for establishing most of its permissible exposure limits (PELs). While OSHA PELs are influenced by this decision, NIOSH is under no such obligation to utilize this criteria.

4) In establishing RELs, how should the phrase “to the extent feasible” (defined in the 1995 NIOSH Recommended Exposure Limit Policy) be interpreted and applied?

We believe that NIOSH should publish health-based RELs without regard to the feasibility of measuring or achieving particular levels of control. Unlike OSHA, NIOSH is not constrained by the feasibility requirement and should not revise its REL policy to adopt such a restraint. However, as a research institution, NIOSH should evaluate and summarize current data on control measures that have demonstrated effectiveness for a given substance or control measures that show promise in the future.

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?

AFSCME believes that NIOSH should set RELs for substances that are possible, probable or suspected human carcinogens and not just confirmed human carcinogens. In addition, we believe that NIOSH should choose the most protective scientifically plausible assumptions when it sets RELs.

Where sufficient animal data exists but human data is lacking, NIOSH should assume that animal data is sufficient to develop a REL for the agent under consideration. NIOSH recently adopted this approach in its draft Current Intelligence Bulletin, *Occupational Exposure to Carbon Nanotubes and Nanofibers*.

The adoption of an "action level" to trigger workplace protections provides an important tool in limiting exposure and reducing risk. Typically, action levels are set at 50% of the exposure limit. Action levels recognize that there may be wide fluctuations of actual exposures in the workplace. The use of action levels are widely accepted for other substances in the workplace; i.e.: 10% of the lower flammable limit in confined spaces triggers a prohibitive condition and action must be taken. The publication of action levels stresses to employers that protective measures need to be taken before workers' exposure exceeds a certain limit, and that all persons do not react to a substance in exactly the same way.

Concerning mixtures, NIOSH could perform research to identify the most common industrial processes involving mixtures in the United States and the most common combinations of exposures in those processes. Under the proposed update to the hazard communication standard, when data on the mixture as a whole are not available, the mixture is considered to present the same health hazards as any ingredients present at a concentration of 1% or greater, or, in the case of carcinogens, concentrations of 0.1% or greater. For complex mixtures, NIOSH may also want consider ACGIH's TLV mixture formulas.

AFSCME is pleased that NIOSH is examining and revising its carcinogen and REL policies. Thank you for considering these comments, and we look forward to future participation in the process.

Sincerely,



Kerry Korpi
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Collective Bargaining Services
AFSCME
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