Dragon, Karen E. (CDC/NIOSH/EID)

From: Bill Kojola [Bkojola@aflcio.org]
Sent: Thursday, September 22, 2011 11:01 AM
To: NIOSH Docket Office (CDC)
Subject: Docket Number NIOSH-240
Attachments: AFL-CIO Comments NIOSH Carcinogen Policy.PDF

Dear NIOSH

Attached is a copy of the AFL-CIO's comments on the NIOSH request for information regarding its carcinogen and recommended exposure limit (REL) policy assessment, docket number NIOSH-240.

Regards,

Bill Kojola

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September 22, 2011

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

Dear Sir or Madam:

The AFL-CIO appreciates the opportunity to provide comments on the review and assessment of NIOSH's carcinogen policy and REL policy regarding exposure to occupational carcinogens. This is an important undertaking concerning a significant issue affecting the health and safety of workers and we welcome NIOSH's examination of these policies.

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

(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)?

We believe NIOSH should retain an explicit policy on carcinogens. NIOSH has had a long history with an identified policy and perspective on occupational carcinogens, dating back more than 35 years. In our view, it is essential that NIOSH maintain, and update, its carcinogen policy. Work-related cancers remain one of the most critically important concerns of workers. The views and policy of NIOSH on carcinogens has been, and

will continue to be, an important component in our efforts to protect workers from exposures to carcinogenic agents in the workplace.

We do not believe, at the present time, that the carcinogen policy should be part of a broader policy on toxicant identification and classification. Such a broader NIOSH policy does not exist, so far as we know. However, a carcinogen policy has been in place for decades. Our position is that NIOSH should focus its current efforts and resources to review and revise its existing policy on carcinogens. We're confident that such a review can easily be completed in a reasonable time frame. Development of a much broader toxicant policy, on the other hand, will consume considerably more time and resources at the expense of finalizing a revised carcinogen policy and we urge NIOSH to limit its focus to carcinogens for now.

As to developing a broader toxicant policy at some point in the future, NIOSH should consider whether developing one will be beneficial in protecting workers, taking into account the effort, time, and resources that would be necessary to launch and complete the development of this policy. Should NIOSH move forward in creating a toxicant policy, it will need to determine how its cancer policy fits within a broader framework for toxicants.

(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.)?*

The AFL-CIO's overall position on these two questions is that NIOSH should harmonize its revised carcinogen determination process/criteria and its nomenclature/categorization scheme as closely as practical with existing authoritative organization determination and categorization approaches. NIOSH should look to and examine the approaches developed by NTP, IARC, the Globally Harmonized System (GHS), EPA, and the European Union for guidance in revising its carcinogen policy.

It is clear to us that the current single classification for carcinogens currently used by NIOSH – a "potential occupational carcinogen" - is a misleading and insufficiently limiting classification term for encompassing the full range of considerations that encompasses important issue. The term "potential" conveys a misleading impression that substances we know scientifically to be human carcinogens, like benzene, may be something less than known. While that is not the impression that NIOSH likely intends to convey, the use of the word "potential" cannot be easily overcome given it's connotation of uncertainty. In the revised cancer policy, NIOSH must eliminate the use of the term "potential" in connection with substances that we know with certainty cause cancer in humans.

In our view, NIOSH should establish at least two carcinogen classifications – one class indicating with certainty that the substance is capable of causing cancer in humans. The other classification would be indicative of a body of scientific evidence that, while falling short of that for a substance known to be capable of causing cancer in humans, raises substantial suspicion that the substance is likely to cause cancer in humans. Other existing classification schemes can be helpful to NIOSH in deriving its cancer classification structure. For example, NTP utilizes two classifications categories – (a) *Known to be carcinogenic in humans* and (b) *Reasonably anticipated to be a human carcinogen.* Using this NTP classification distinction is a clear improvement over the existing NIOSH single classification of "potential occupational carcinogen" in that it distinguishes between the level of scientific evidence between those substances with evidence of known human carcinogenic activity over substances where the scientific information indicates a reasonable anticipation that the chemical may cause cancer in humans. The evidence used by NTP to make the determination decisions is also distinguished – *"Known"* having sufficient evidence of carcinogenicity from human studies while *"Reasonably anticipated"* includes limited human evidence or sufficient animal evidence.

NIOSH might also want to consider subcategories for the second classification such as "*Reasonably anticipated*", as does IARC, where one subcategory includes sufficient evidence to conclude that the agent is *"probably"* carcinogenic to humans and another subcategory has evidence that the substance is *"possibly"* carcinogenic to humans. Making such a distinction allows for NIOSH to entertain an assessment of the robustness of the accumulated body of scientific evidence, recognizing that there are varying but important distinctions of the level of evidence that can and should be determined.

The evidence forming the basis for determining that a chemical is carcinogenic must include all of the data that is available to assist NIOSH with this task. That evidence would need to include epidemiological studies, relevant animal experimental data, and other appropriate information such as structure-activity relationships and genetic tests. IARC employs an evaluation criteria on the degree or strength of the evidence of carcinogenicity, including terms such as "sufficient evidence", "limited evidence", "inadequate evidence" and "evidence suggesting lack of carcinogenicity" which we think NIOSH should examine for possible adoption in its revised cancer policy as well.

All of the suggestions we've outlined above will result in a substantial enhancement of the existing NIOSH cancer policy and achieve an

improvement in the nomenclature/classification scheme and harmonization with other organization approaches.

(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?*

No, NIOSH must absolutely not adopt a 1 in 1,000 risk level as the target level for establishing an REL. It is an arbitrary target with a risk level that is far too high, in our view, for workers exposed to occupational carcinogens. This risk level originates with OSHA's regulatory efforts to set a permissible exposure level (PEL) for benzene - and its subsequent challenge in the US Supreme Court (the so-called "benzene decision"). Following the court's decision, this risk level (1 in 1,000) has now essentially been adopted by OSHA (improperly, in our view) as the target level for establishing most all of its PELs. Importantly, however, OSHA's PELs are not exclusively health-based but instead are also subject to the agency's legal requirement to conduct and take into account economic and technological feasibility analyses in connection with its rulemaking to set exposure limits for chemicals.

On the other hand, NIOSH is under no such restriction or obligation to consider economic and technological feasibility in connection with its efforts to establish RELs or to adhere to what amounts to a target risk level established by a regulatory agency such as OSHA. As a public health entity, NIOSH is charged with the responsibility to conduct research and make recommendations for protecting workers against workplace risks. It is, unlike OSHA, free of the constraints that a regulatory body like OSHA must address when setting legally required workplace exposure limits. Risk level recommendations at 1 in 1,000 for workers exposed to workplace carcinogens are not appropriate for a public health agency to put forward. Rather, when developing an REL for a carcinogen, NIOSH should evaluate the best available scientific evidence in making a determination regarding its carcinogen classification. Then, using that scientific data, NIOSH should perform working lifetime risk assessments that more adequately protect the health of workers than risks of 1 in 1,000, including a no effect or de minimus risk level and other risk levels that may leave some, but substantially less than 1 in 1,000, residual risk. These more protective risk levels can then be used by workers and employers as a means and impetus to initiate efforts to lower exposures to risk levels that will more fully protect the health of workers.

(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?

We believe that NIOSH needs to develop health-based RELs that are based on risk and not on feasibility considerations. Unlike regulatory agencies, NIOSH is not constrained by a feasibility requirement – and it must not revise an REL policy that adopts this constraint. OSHA is a regulatory agency that promulgates legally permissible exposure limits requirements that are subject to feasibility considerations. NIOSH is not a regulatory agency nor are its RELs legally binding upon employers. NIOSH should address its attention to determining risk to workers irrespective of the feasibility of existing engineering and other control measures or on analytical methods for determining worker exposure.

The value of establishing health-based RELs for workplace carcinogens is that they can be used by workers and employers to (a) understand the risk that may be present in a given workplace and (b) undertake efforts to reduce worker exposures, based on the understanding of risk that the RELs would inform. While we don't believe NIOSH should be limited by feasibility issues, we do think that when establishing RELs for carcinogens, we recommend that NIOSH evaluate and summarize the current scientific understanding of control measures that have been demonstrated to be effective for the given substance (or similar agent) and other control approaches that show promise with further research. We also see establishing health-based RELs as providing momentum for and an environment conducive to enhancing technology forcing efforts for reducing and controlling worker exposures 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?

We believe that NIOSH should set RELs for all the carcinogen classification categories it establishes in its new policy. That would include not only agents "known" to be human carcinogens but also for those agents that are "reasonably anticipated" or "suspected" of being a human carcinogen. It's obvious why NIOSH should set RELs for known human carcinogens – there are no uncertainties or assumptions necessary for developing an REL. However, it is important to assume that for those agents that do not (yet?) achieve the classification of a "known" human carcinogen but are instead "suspected", there is a reasonable likelihood assumption that they are carcinogenic to humans and that they should be

treated as such for the purpose of protecting workers and developing an REL for the agent, including agents shown to be carcinogenic in animal studies.

For example, there may be insufficient or no data that an agent is carcinogenic in humans. However, sufficient animal data may exist demonstrating that the agent is carcinogenic. In these circumstances, NIOSH should assume that the animal data is enough to cause it to develop an REL for the agent because of the likelihood that the agent is carcinogenic in humans. NIOSH has recently adopted this approach in its draft Current Intelligence Bulletin, *Occupational Exposure to Carbon Nanotubes and Nanofibers* by conducting a risk assessment and developing an REL where there is no human evidence of harm but sufficient evidence of harm in animal studies does exist. We believe NIOSH should make this type of assumption when developing RELs for carcinogens where sufficient animal data exists but human data is lacking.

There is important utility in the adoption of an "action level" for initiating various workplace measures that protect workers at exposure levels less than that of the recommended exposure limit. While the action level doesn't trigger the full comprehensive response that are put in place in circumstances where the REL is exceeded, the triggering of some protective measures, like worker training, can assist in reducing exposures and lowering the risk of developing an adverse health consequence among exposed workers. Typically, the action level is set at 50% of the exposure limit. This action level is established in recognition that there may be wide fluctuations in the exposures that workers are actually experiencing in the workplace. The action level also recognizes that there are residual risk levels that remain at the exposure limit as well as the action level and that measures that reduce that residual risk are important for workers. Given that most carcinogens are thought to operate in a linear, no-threshold dose-response manner, all action level actions that have the effect of lowering exposures will have an impact on lowering the risks experienced by workers. Because there appears to be no-threshold of effect for carcinogens, we think NIOSH should explore the development of tiered actions levels – for example, one at 10% of the REL and another at 50% of the REL – so that an increasing implementation of protective measures are instituted as the REL is more closely approached. This may be a useful approach for addressing issues of residual risk.

It's not clear to us exactly what NIOSH means by "complex mixtures"? Is this a mixture of several chemicals and one of which is a carcinogen? Or is it a mixture that contains more than one carcinogen (one which may be a known carcinogen and another a suspected carcinogen)?

We're pleased that NIOSH is examining and revising its carcinogen and REL policy. We look forward to our continued participation in the process that NIOSH is instituting to accomplish this objective. Please contact us if you have any questions about our comments.

Sincerely,

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