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Attached are the comments of the International Union, UAW

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Comments on NIOSH Carcinogen Policy Docket Number NIOSH-240

Submitted by Darius D. Sivin, PhD

On behalf of
International Union, United Automobile, Aerospace and Agricultural Implement Workers
of America (UAW)

The International Union, United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), representing approximately one million active and retired members, is pleased to have the opportunity to comment on NIOSH's Carcinogen Policy.

- (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)?*

In our opinion, NIOSH should continue to have a carcinogen policy, as it has for more than thirty-five years. Occupational cancers are among the most important chronic health concerns of workers. NIOSH's policy plays a key role in protecting of workers from carcinogens. This policy should be maintained and refined. After revising and updating of its carcinogen policy, the agency should develop policies for other major health endpoints. Ultimately, it is a desirable goal to unify the approach to dose-response assessment for cancer and other health endpoints as recommended by the authors of *Science and Decisions: Advancing Risk Assessment* (National Research Council, 2009). However, that process should start only after NIOSH has completed a revision of its carcinogen policy.

- (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 is inadequate in that no substance is defined as a confirmed or known carcinogen. The single classification of potential carcinogens includes known carcinogens such as asbestos and Benzene and other substances for which the evidence is less strong. This is not as useful as it could be.

The UAW believes that it would be quite helpful if NIOSH were to choose a classification scheme compatible with, but not necessarily identical to, the one used for

ACGIH TLVs because many practicing occupational health and safety professionals are already familiar with it. We believe that NIOSH should refer to the detailed discussion about the evaluation of evidence from human and animal data contained in the *Preamble to the IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* when developing guidelines for determining the carcinogenicity of substances. In addition NIOSH should look at the systems used by the USEPA, the National Toxicology Program and the German MAK commission. Types of evidence to be used in making determinations of carcinogenicity should include epidemiologic studies, animal experiments, in vitro studies, structure activity-relationships and relevant case-reports.

NIOSH should make its own judgments about which agents belong in which categories rather than relying on those of other organizations. NIOSH should publish detailed justifications for all its categorizations and it should be especially detailed in any cases in which its judgments differ with those of other organizations. In classifying agents, NIOSH should be extremely cautious about finding that an agent is carcinogenic by means not relevant to humans. Too often, the absolute and binary conclusion that a mechanism is "not relevant to people" (e.g. peroxisome proliferation associated rodent liver tumors, kidney tumors in male rats, urinary bladder tumors associated with calculi) stops risk assessment at the hazard identification stage and forecloses exposure response assessment (Mirer, 2002, 2003). We urge NIOSH to be cautious in the use of this approach.

(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 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. Moreover the 1 in 1,000 working lifetime risk represents an interpretation by the Solicitor of Labor's (SOL) office of a non-binding footnote to the above cited case. While OSHA must respond to the SOL, NIOSH is under no such obligation. 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.

Scientifically, it is not necessary to have a particular target risk level. Due to the uncertainties described in *Science and Decisions: Advancing Risk Assessment*, any target risk level chosen may be associated with a wide range of exposure levels. NIOSH criteria documents for carcinogens should be explicit about the uncertainties and the variability involved in any estimate of risk and should provide details as to the uncertainties and variability involved in estimating the risk associated with a particular substance.

More robust data sets have less uncertainty and, for any given data set, the further away one extrapolates from the range of observed data, the more uncertainty there is. This means that it might be the case that for one substance there is adequate evidence to estimate an exposure level associated with a 10^{-4} risk while for another substance the evidence supports an estimate of a 10^{-5} risk. For each substance, it might be the case that uncertainties are such that meaningful estimates of exposure levels associated with lower risks are not possible. This would be an adequate reason to publish RELs associated with different risk levels as long as NIOSH clearly articulates the uncertainties involved and the reasons for its choices in its criteria documents. For this reason the UAW does not believe that NIOSH necessarily has to choose a target risk level.

If NIOSH determines that it is necessary to establish a target risk level, the UAW would encourage NIOSH to use EPA's *de minimis* risk level of 10^{-6} . This is because in principle, workers have the same human rights to protection from carcinogenic exposures as other members of our society. If NIOSH were to find it necessary, for some reason, to choose a target risk level higher than 10^{-6} , the UAW would strongly encourage NIOSH to provide detailed reasons for which the choice is necessary and to issue a statement that NIOSH nevertheless believes that, in principle, workers have the same human rights to protection from carcinogenic exposures as other members of our society.

(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 should published health-based RELs without regard to the feasibility of measuring or achieving particular levels of control. In addition, it should research the feasibility of substitution, engineering controls and other forms of control for particular agents.

(5) In the absence of data, what uncertainties or assumptions are appropriate for use in the development of RELs?

The UAW 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. *Deviations from the most protective assumptions should be permitted only in cases in which it can be demonstrated that such assumptions are not scientifically defensible.*

In the work cited above, the National Research Council recommended that risk assessments provide descriptions of uncertainty and variability consistent with available

data and that, to maximize understanding of and participation in risk-related decision-making, uncertainty should be explained with sufficient clarity to be understood by the public. We support these recommendations.

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?

The concept of an action level exists because of exposures vary and measurement has a cost. If the cost of measurement were negligible, every worker could be monitored every day. Monitoring could be used to eliminate exposures in excess of established limits. However, since that is not the case, we are faced with the problem of using a small number of samples (often just one) to keep exposures below limits. Traditionally, action levels have been chosen to be such that a small number of measurements below the action level is expected to provide a reasonable degree of confidence that exposure rarely exceeds the established limit, which is presumably health based. In our experience, only those employers with the greatest resources make use of action levels, except where an action level is written into an enforceable standard.

We would suggest that NIOSH consider an alternate method. Suppose NIOSH plans to set a REL to meet a specified risk target and the evidence indicates that a certain average exposure is associated with the target level of risk. Instead of setting the REL at the average level of exposure associated with the target risk, we recommend that NIOSH set the REL such that, given one sample below the REL, the probability is less than 5% that workers average exposure exceeds the average exposure associated with the risk. In that way, the action level would be built into the REL instead of requiring employers to understand and act on the reasons for which a sample below the REL does not necessarily mean that a worker's exposure is below the REL.

How should NIOSH address worker exposure to complex mixtures?

For mixtures all of whose components have adequate toxicity data and similar health affects, the approach should be similar to the TLV mixture formula. For mixtures of substances with similar health effects for which fewer data are available, the approach should be similar to ACGIH's reciprocal calculation method for refined hydrocarbon solvent vapors or to EPA's relative potency factor or toxic equivalency factor approaches. Regardless of the approach used, NIOSH should describe the effect of key assumptions (e.g. toxicologic independence or toxicologic similarity) on final risk estimates and delineate the uncertainties involved.

Heterogeneous mixtures pose a more difficult challenge. One service that NIOSH could perform would be to do research to identify the most common industrial processes in the United States and the most common combinations of exposures in those processes.

References

International Agency for Research on Cancer (IARC 2006). *Preamble to IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*. Lyon: IARC.

Mirer FE (2003). Distortions of the "Mis-Read" Book: Adding Procedural Botox to Paralysis by Analysis. *Human and Ecological Risk Assessment: An International Journal* 9(5): 1129-1143.

Mirer FE (2002). Does the Emperor Have Any Clothes: Using Mechanistic Information or Doing Houdini Risk Assessments? *Human and Ecological Risk Assessment: An International Journal* Volume 8, Issue 6, pp. 1229-1242.

National Research Council (2009). *Science and Decisions : Advancing Risk Assessment*. Washington DC: National Academies Press.