



INTERNATIONAL CHEMICAL WORKERS UNION COUNCIL

1799 Akron-Peninsula Rd., Akron, OH 44313 / 330-926-1444 / Fax: 330-926-0816

FRANK CYPHERS, PRESIDENT
GREG VILLANOVA, SECRETARY-TREASURER

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October 13, 2011

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

RE: Request for Information: Announcement of Carcinogen and
Recommended Exposure Limit (REL) Policy Assessment

Docket Number NIOSH-240

Dear Sir/Madam:

We appreciate commenting on NIOSH's carcinogen and REL policy on occupational carcinogens. This is an important task for the health and safety of many workers including our members. Our response to NIOSH's August 23, 2011 Federal Register notice questions are:

- (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)?*

Due to the particular nature and uniqueness of carcinogens we strongly support a separate policy, a position NIOSH has held since the 1970s. Work-related cancers are an important issue for our members and we have investigated a number of cancer clusters among our facilities and have an ongoing urinary cancer screening project at one location. NIOSH's policy on carcinogens is a vital component of our work to minimize exposures and educate our members on the dangers of carcinogens.

The ICWUC believes NIOSH should focus its resources to review and revise the current carcinogen policy in a reasonable time frame rather than use resources on a broader toxicant policy at this time. In the larger context of NIOSH's policies, decisions will also have to make on the allocation of resources for policies on groups of substances such as reproductive and neurological hazards and we are not saying that these areas are more or less deserving of attention.

- (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.)?*

We believe NIOSH's carcinogen process/criteria and its categorization should be consistent with existing approaches such as those developed by NTP, IARC, the Globally Harmonized System (GHS), EPA, and the European Union. We don't believe that a single NIOSH classification for carcinogens is

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the best approach. For workers to hear "potential" may be misleading, especially for substances where there is overwhelming evidence that they are human carcinogens. Whatever the intention, "potential" will often be perceived with a good deal of uncertainty and as undocumented and be used by some people to assert that workers should not be concerned. We believe NIOSH should eliminate the term "potential" in connection with substances where we have sufficient evidence that they cause cancer in humans.

There should be at least two carcinogen classifications – one for chemicals that clearly cause cancer in humans and a second where there is substantial suspicion and evidence that the substance is likely to cause cancer in humans. This should reflect the magnitude of the evidence as pointed out in the Federal Register notice and other cancer classification systems may assist NIOSH. Many of these have more than one categorization which is reflective of the existing scientific evidence and is much more useful for workers. Other NTP and IARC designations that should be evaluated include "Known" (having sufficient evidence of carcinogenicity), "Reasonably anticipated" (limited human or animal evidence), "Reasonably anticipated", and the terms "Probably" and "Possibly" carcinogenic.

- (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?*

The risk to workers at the 1 in 1,000 risk level is far too high to be used as a target level for RELs and not appropriate for a public health agency. Rather NIOSH should evaluate the best available scientific evidence and then using that data perform working lifetime risk assessments that more adequately protect the health of workers than risks of 1 in 1,000. Given a large enough population we expect carcinogens to carry a minimal risk level but this should be for fewer workers than 1 in 1,000 at risk and be more in the neighborhood of 1 in 100,000. These risk levels can then be used by workers and employers to make informed decisions on how best to lower exposures, assist in the introduction in engineering controls and protect their workforce.

We should add that in communicating risk, we often use various levels that are commonly posed as a number of people with a disease outcome (a numerator usually of 1) in a given number of people, often a denominator of 1,000, 10,000 or 100,000. We would suggest that in order to give people the greatest opportunity to compare and understand risks, it may be preferable to set the number of people at risk as a constant number and then vary the number with a given disease. For example, for this discussion, I would suggest that we use 100,000 as the baseline population denominator. The risk levels mentioned above would then be 1 in 100,000, 10 in 100,000 or 100 in 100,000.

Regardless of the historical reasons why OSHA uses their risk level (which we do not support), they must take into account economic and technological feasibility analyses in connection with its rulemaking to set exposure limits for chemicals. NIOSH does not, nor should it, have the mandate or obligation to consider economic and technological feasibility when establishing RELs. As a public health agency under the Department of Health and Human Services, NIOSH is charged with conducting research and making recommendations to protect workers against workplace risks. It should keep that mandate in focus and not inappropriately adding other factors that will increase the risks to 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?*

It's important to state that we basically disagree with the shift in NIOSH policy stated in the 1995 policy of "an assessment of what levels can be feasibly achieved by engineering controls". Even if "no detectable exposure level" may be unrealistic as technology is capable of detecting lower levels, NIOSH should develop health-based standards without regard to feasibility considerations. Although feasibility is a very important consideration for our businesses and our workforce, this is not, nor should it be, the mandate of NIOSH nor should it be the methodology used by NIOSH to set RELs. The reality for workers is that they are often told that a level below a REL or PEL is "safe" while we believe these are not safe levels for a carcinogen. Clearly that is not the case with carcinogens and to set higher RELs because engineering controls are not currently feasible is to drive the resulting risk levels inappropriately higher.

The 1995 NIOSH statement is especially troubling in its acceptance of residual risk linked to the feasibility of controls. As instrumentation improves and detection levels drop, we will be able to measure lower exposure levels. The level of risk must be evaluated but should not be linked the lack of feasible controls at these lower levels to justify higher RELs. NIOSH would do better to use its resources to determine the risk to workers without regard to the feasibility of existing control measures.

Further, Director Rosenstock's statement includes the assertion that "this policy applies equally to chemical carcinogens and other health or safety hazards". Although uniform policies are a laudable goal, treating carcinogens and non carcinogens equally is not. There are fundamental toxicological distinctions between the two groups of substances and to believe they act the same is to lead to erroneous policies. Since many carcinogens likely operate without a threshold, retaining a common policy for RELs for both groups is not appropriate.

Recommended Exposure Limits for carcinogens that are based on health risks can be used by workers and employers in at least two ways. One, they will help everyone understand what the potential risk is at each job given that job's exposure level. Two, they will then assist employers, workers and professionals to take steps to reduce exposures based on the REL risk assessment. NIOSH can then evaluate and summarize current control measures, their effectiveness and explore other approaches including technological innovations.

- (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?*

In the investigation of possible carcinogens, there is a wide range of scientific data. In the continuum of the strength of scientific evidence, there may be enough data for a substance to be considered a "possible", "suspected", or "reasonably anticipated" human carcinogen or there may only be clear animal evidence. For each group of substances NIOSH should have a procedure for setting a REL that reflects the evidence to date. Basically when there is a reasonable likelihood that the substance could cause cancer, employers and workers need that information to take the appropriate protective steps.

When there is little or no human evidence but there is animal studies, NIOSH should use the animal data to develop an REL since it is likely it will cause cancer in workers. This was the rationale NIOSH recently used in their Current Intelligence Bulletin on Nanotubes and Nanofibers. This is an important issue for us given that we represent workers at 4 facilities that manufacture carbon black, a nano material. Although not as small as nanotubes and nanofibers, NIOSH's recommended REL assists us in educating our members, better understanding the health risks and controlling exposures.

Action levels (historically usually set at half of the exposure limit) have been a very important step to initiate control steps well before a dangerous exposure level is reached. Although all measures may not be taken at an action level, it is a valuable tool that increases concern, assists in mobilizing resources, can help to reducing exposures. Given that measured exposure levels are only the best estimate of actual exposure and the wide variations that are found in almost all jobs, the action level helps to ensure that appropriate steps are taken well before the REL is reached.

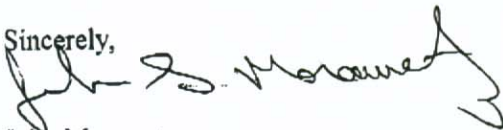
Since there will always be residual risk for carcinogens at the REL and even at the action level, NIOSH should evaluate a tiered approach for action levels. Some control measures could be recommended at various levels below the REL and even below 50% of the REL. There is no magic line to always use 50% of the REL to determine an action level. Dividing a threshold level by 3 or 10 is often used in risk assessment and these and other options should be investigated by NIOSH for carcinogens.

Although we are not sure which "complex mixtures" NIOSH is considering here, one possibility is that this refers to a mixture that contains more than one carcinogen. In general mixtures are a difficult question to address in risk assessment but is one that is commonly asked by our members. The reality at most jobs is that people are exposed to a number of substances at any given day, task or department. An evaluation of risk is further complicated given mobility between departments, transfers within a workplace or from one facility to another.

Regardless of the scientific difficulties in evaluating these exposures NIOSH should begin to address this issue and have an overall policy that combines the risk of exposure to multiple carcinogens. The risk of a mixture should never be less than the arithmetic addition of the risks of each component regardless of different types of cancer found in either animal or human studies. Further, consideration should be given to the multiplicative effect of combined exposures as is well known from exposure to asbestos and cigarette smoke.

These are difficult questions and we welcome the opportunity to contribute to the discussion on NIOSH's carcinogen and REL policy. We look forward to continuing this process and please contact us if you have any questions.

Sincerely,



John Morawetz
International Chemical Workers Union Council/UFCW

cc: Frank Cyphers
Greg Villanova
Darrell Hornback
Bill Kojola
Eric Frumin