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VIA email to nioshdocket@cdc.gov

NIOSH Docket Office
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RE: Comments on NIOSH's Request for Information: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment (Docket # NIOSH-240)

We applaud NIOSH for undertaking this important project. The existing carcinogen classification system and Recommended Exposure Limit (REL) policies do not adequately reflect the state of the science of occupational toxicology. Revising these policies will give employers the tools they need to better protect workers from life-changing illnesses and empower workers to demand those changes.

The comments below are organized according to the specific questions posed in the August 23, 2011 *Federal Register* notice requesting information about the proposed policy changes. For clarity, we would like to highlight three points before addressing each of NIOSH's questions.

- First, it is of paramount importance that NIOSH act quickly. The Environmental Protection Agency (EPA) has labeled thousands of chemicals as "High Production Volume" (HPV) because they are produced or imported into the US in quantities greater than 1 million pounds per year. Occupational Exposure Limits (OELs) from the Occupational Safety and Health Administration (OSHA) and NIOSH cover just a few hundred of those chemicals, and the limits are based on old science. NIOSH should quickly and efficiently assess high production volume chemicals under its new policy.

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- Second, while the process for prioritizing toxicological reviews, conducting those reviews, and publishing the results must be transparent, NIOSH should refrain from creating multiple opportunities for stakeholder involvement in the name of transparency because of the trade-off in terms of program efficiency. To achieve transparency, NIOSH should publish on its website all of its general policies for the development of carcinogenicity assessments and RELs, records concerning the development of individual chemicals' assessments/RELs, information about any stakeholders from outside NIOSH involved in the development of those documents and how they contributed, the agenda for assessing chemicals, and the agency's timeline. EPA's Integrated Risk Information System (IRIS) provides a good model for how to achieve this transparency.
- Third, risk levels should not be based on the Supreme Court's dicta in the *Benzene* decision. As explained in detail below, the Court's analysis in that case of OSHA's regulatory process is inapplicable to NIOSH's duty to set RELs that will ensure safe work environments.

NIOSH Question 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 the short term, it is in the best interest of workers, employers, and OSHA for NIOSH to focus exclusively on the carcinogenic potential of HPV chemicals. EPA has classified thousands of chemicals as HPV because they are produced or imported into the U.S. in quantities above one million pounds per year. These are the chemicals most likely to affect workers' health. Moreover, there is inadequate information about the carcinogenic potential of these chemicals. EPA has undertaken a project to develop a basic toxicological screening data set for these chemicals through its voluntary HPV Challenge Program and now through a rulemaking process, but the data gleaned from this project are not adequate for making carcinogenicity determinations. As Dr. Paul Schulte noted during NIOSH's December 12, 2011 stakeholder meeting, four to ten percent of cancer morbidity is likely attributable to occupational exposures. NIOSH is the only federal agency with a statutory mandate to research the occupational risks posed by chemical carcinogens. To meet that responsibility, NIOSH should, in the short term, focus exclusively on the chemicals' carcinogenic potential.

Ideally, the process for assessing chemicals' carcinogenic properties will be designed in a way that allows for expanded assessments focused on other health endpoints in the future. New technologies, like the EPA/NTP "Tox21" partnership, which uses high-throughput screening assays to explore potential toxicological effects of huge numbers of chemicals, could significantly enhance NIOSH's ability to assess the hazards posed by occupational exposures. The most effective approach is for NIOSH to wait to see how that program might inform an expansion of its carcinogenic assessments into a broader toxics assessment policy that covers

reproductive, neurological, or endocrine systems. At the present time, however, NIOSH should focus its efforts on developing an efficient and transparent process that focuses on carcinogenicity assessment of occupational hazards.

NIOSH Question 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 system for classifying occupational carcinogens should be updated to include categories that reflect both its assessment of a chemical's carcinogenicity and the level of confidence it has in that assessment based on the science available at the time. The current system, which has only one category for "potential occupational carcinogens," is misleading for most workers, employers, and other interested parties that are not well-versed in the history of NIOSH's policy. In its place, we recommend a five "bin" system: known occupational carcinogens, suspected occupational carcinogens, potential occupational carcinogens, chemicals with unknown carcinogenic potential, and chemicals with no existing evidence of carcinogenic potential.[1]

Chemicals should be classified into one of these five groups based on a weight of the evidence (WOE) analysis by NIOSH's staff. NIOSH should avoid using any hard-and-fast rules that would require the existence of certain types of evidence or studies that must exist before a chemical is given a particular classification. For instance, NIOSH should not require a positive case-control epidemiological study on a particular chemical before listing it as a known occupational carcinogen. The WOE analysis should take into account all available human and animal data, both *in vivo* and *in vitro*.[2] The International Agency for Research on Cancer (IARC) has policies regarding the types of information that ought to be considered in carcinogenicity assessments and criteria for evaluating the adequacy of individual studies that

[1] NIOSH should classify chemicals as "known occupational carcinogens" if metabolites of the chemical are known carcinogens or if a chemical is known to decrease cancer latency periods.

[2] NIOSH should also avoid a Mode of Action (MOA)-based framework for assessing carcinogenicity because of the difficulty of making this assessment based on the state of scientific information that is readily available. While the MOA is relevant to making carcinogenicity determinations, it should not be the starting point of the assessment until the scientific information regarding MOA is better developed. The adoption of a MOA-based framework for the purpose of NIOSH assessments of the carcinogenic potential of HPV chemicals would be a departure from conservative practices that provide workers with the greatest protection. Congress did not intend that workers should have to wait for a complete understanding of the carcinogenic potential of chemicals in order for NIOSH to issue appropriate information about such chemicals based on what is known as the current time.

should serve as a model for NIOSH's new policy in order to expedite the development of a system of analysis.[3]

NIOSH's analysis should be clearly documented in a report that is available on the agency's website. All studies that were assessed by NIOSH staff should be linked from the report so that the public has access to at least the abstract free of charge. The profiles that have been most recently added to EPA's IRIS database provide a good example of how this might work. The bibliography in these profiles contains links to copies of the study available in EPA's HERO (Health and Environmental Research Online) database.

At the Dec. 12, 2011 stakeholder meeting, participants discussed whether and how NIOSH might utilize carcinogen classifications made by other organizations like IARC, the National Toxicology Program (NTP), and EPA's IRIS program. We believe NIOSH should selectively adopt certain categorizations developed by other groups working in other contexts, while using others as tools for to prioritizing NIOSH's own reviews. For instance, NIOSH could adopt "known carcinogen" classifications of chemicals that have been classified as such by another organization if the cancer was caused by inhalation; but if a chemical has been classified as a "known carcinogen" by another organization because of a route of exposure not relevant to workers (*e.g.*, oral exposure), NIOSH should not adopt the classification outright, but should place the chemical high on its list of priorities for further assessment. In addition, NIOSH should prioritize for review any chemical that another influential organization has classified as a presumed, suspected, possible, probable, or potential carcinogen. Prioritizing in this way would allow NIOSH to tackle new assessments most effectively because the agency can build on existing work by other organizations, but focus its efforts on exposure scenarios most relevant to workers.

NIOSH Question 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 adopt a lower target for its RELs than the 10^{-3} working lifetime risk. The 10^{-3} target is one thousand times less protective than the 10^{-6} target that EPA uses to set regulations for the air workers breathe during non-working hours. NIOSH should adopt a more conservative target for three other reasons: first, because the law expects NIOSH to set protective levels and there is no reason to believe that a 10^{-3} target meets these protective goals; second because the synergistic effects of multiple chemical exposures are not well understood; and third, because

[3] *See* WORLD HEALTH ORG. INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble* (2006), *available at* http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf (accessed Dec. 22, 2011).

RELs that are based on carcinogenic potential do not adequately address other hazards posed by the chemicals (e.g., COPD or neurological effects).

The 10^{-3} target is derived from language in the Supreme Court's *Benzene* decision.[4] The *Benzene* case focused on the findings OSHA must make in order to have authority to regulate a chemical hazard. The Supreme Court reasoned that since Congress gave OSHA the power to regulate chemical hazards through "occupational safety and health standards" and defined by those standards to be those which are "reasonably necessary or appropriate to provide safe or healthful employment and places of employment," it must have intended that OSHA make a threshold determination that a chemical is *unsafe*. The Court then imagined that Congress defined a chemical as "unsafe" when it presents a "significant risk" of harm, a requirement that is nowhere to be found in the language of the statute. After announcing this new procedural step for OSHA, the Supreme Court neglected to define what it meant by "significant risk," but provided some guidance by way of rhetorical example:

> Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take appropriate steps to decrease or eliminate it.[5]

Taken at face value, this passage suggests that there is a wide range of risks – somewhere between 10^{-3} and 10^{-9} – that could be considered significant enough to warrant OSHA regulation.

NIOSH should not regard 10^{-3} as the target level for a REL. OSHA's duty to protect workers is not limited to reducing a risk to 10^{-3} when it regulates a chemical. While OSHA must find that a chemical presents a significant risk in order to regulate the substance, OSH Act §6(b)(5) requires it to reduce the level of exposure to the point where no worker will suffer a material impairment of his or her health during a working lifetime of exposure to the substance, a duty which may well require a lower exposure level lower than 10^{-3}. NIOSH has a similar duty. OSH Act § 20(a)(3) requires NIOSH to develop "exposure levels that are safe for various periods of employment, including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."[6] Like OSHA, NIOSH is required to minimize the risk to workers, which also may require a REL that is lower than 10^{-3}. In order to accomplish the precautionary intention of Congress, NIOSH should at least adopt the 10^{-6} target that EPA has adopted to protect the public under its air toxics rules.

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[4] *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980).
[5] *Id., at* 655.
[6] 29 U.S.C. § 669(a)(3).

It is also worth noting that the Supreme Court's range of potentially significant risks lacks the scientific rigor and mathematical accuracy that should undergird NIOSH policy. Consider this analysis from McGarity and Shapiro's *Workers at Risk: The Failed Promise of the Occupational Safety and Health Administration*:

> Drinking chlorinate water is an activity engaged in by practically everyone in American society. If 250 million Americans drink 4 glasses of water a day and are exposed to a 1 in 1 billion risk each time, then an average of 1 cancer per day will result. This amounts to about 365 cancers per year, a number that reasonable people might find significant. Justice Stevens's example of a significant risk is harder to address from a public health perspective, because he neglected to provide two important pieces of information: the length of exposure that would result in a cancer and the number of persons who regularly breathe gasoline vapors. If we assume that exposure for a year presents the 1 in 1,000 risk and that 2 employees in each of the approximately 200,000 service stations in America are regularly exposed to benzene (an estimate that is, by the way, on the high side), then a 1 in 1,000 risk would yield 400 cancers per year, a number that is not meaningfully different from the 365 cancers per year that Justice Stevens found to be clearly insignificant.[7]

In sum, basing RELs on a cancer risk of 10^{-3} is not good public health policy. NIOSH should adopt a new policy that aligns the goals of reducing potential risks from occupational carcinogens with the goals of reducing potential risks from carcinogens in the ambient air, which Congress has set at 10^{-6}.[8]

NIOSH Question 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?

NIOSH should abandon the practice of assessing what exposure levels can feasibly be achieved by engineering controls when it sets RELs. The OSH Act gives NIOSH the discretion to set RELs at "exposure levels…including but not limited to the exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience."[9] NIOSH has used this discretion to develop RELs that take into account technological feasibility of engineering controls, but we believe the better policy is to set RELs based on risk alone, thereby establishing technology-forcing benchmarks for employers.

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[7] Thomas McGarity and Sidney Shapiro, WORKERS AT RISK: THE FAILED PROMISE OF THE OCCUPATIONAL SAFETY AND HEALTH ACT 56-57 (Praeger, 1993).
[8] 42 U.S.C. § 7412(f).
[9] 29 U.S.C. § 669(a)(3).

NIOSH Question 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?

Data-poor assessments: NIOSH should use default assumptions to bridge data gaps. The National Academies' National Research Council has provided guidance to EPA on the best methods for developing and using default assumptions in three influential publications: *Risk Assessment in the Federal Government: Managing the Process*, *Science and Judgment in Risk Assessment*, and *Science and Decisions: Advancing Risk Assessment*. Those publications should guide NIOSH's development of policies regarding the use of default assumptions. The most important issues for NIOSH to consider in developing a policy on defaults are: (1) all default assumptions should be explicitly stated in a transparent manner; (2) there must be clear criteria for the both type of evidence and quality of evidence needed to justify departure from default assumptions; and (3) all decisions regarding the use of alternative assumptions should be carefully documented in reports accessible online.

Action levels: Action levels are an important public health tool that NIOSH should continue to use. A standardized action level at some fraction of the REL is an appropriate tool for protecting workers' health. It should be set at a level where there is high confidence (*e.g.*, 95 percent) that no worker is exposed above the REL will suffer impairments.

Complex mixtures: The problem of cumulative and synergistic effects of multiple-chemical exposure is an important issue for NIOSH to consider. It is a primary driver behind the previous recommendation that NIOSH develop RELs targeted at lower risks than the current policy—if multiple chemicals in a worksite are controlled to keep risks below a 10^{-6} threshold (determined by conservative risk analysis), then the workers' overall risk will hopefully remain low. NIOSH could greatly advance the science of toxicology regarding complex mixtures by engaging in field sampling to characterize common multiple-chemical expose scenarios. That work should be prioritized according to NAICS sectors that are already high-hazard based on individual chemical exposures and sectors that employ workers who are covered by the Department of Health and Human Services' environmental justice strategy.[10]

[10] U.S. DEPT. OF HEALTH AND HUMAN SERVICES, *Draft 2012 HHS Environmental Justice Strategy*, *available at* http://www.hhs.gov/environmentaljustice/draft_2012_envirojust_strategy.pdf.pdf (accessed Dec. 22, 2011).

Conclusion

Thank you for the opportunity to provide comments on this important policy change. The Center for Progressive Reform is a network of scholars who work with the organization's staff to protect health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in occupational and environmental policy serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations.

Sincerely,

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