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NIOSH Docket Office  
Robert A. Taft Laboratories  
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Cincinnati, Ohio 45226

**Re: Docket Number CDC-2013-0023; NIOSH 240-A.  
NIOSH Revised Carcinogen Policy**

Founded in 1990, the California Industrial Hygiene Council (CIHC) represents the occupational and environmental health profession in California and is affiliated with the American Industrial Hygiene Association (AIHA), a 10,000 member national organization, as well as the International Occupational Hygiene Association (IOHA), which represents the global community of Occupational Hygiene organizations in over 34 countries. Go to [www.cihconline.com](http://www.cihconline.com) for further information about CIHC.

The California Industrial Hygiene Council (CIHC) is generally very pleased with NIOSH's latest version of the Carcinogen Policy.

**The CIHC believes the revised policy is positive for the following reasons:**

- **Health based RELs** - The decision to establish risk-based RELs based on health effects (vs. integrating a feasibility component at this stage) is the correct approach.
- **Use of the three existing US and international carcinogen classifications (NTP, EPA, and IARC)** -The new classification policy proposes using the assessment schemes used by the NTP, EPA and IARC to enhance harmonization and keep NIOSH from reinventing the wheel. The use of existing qualified databases is scientifically appropriate and cost effective, as is the proposed methodology for determining RELs for carcinogens that are occupationally relevant.
- **Assessment of occupational relevancy** - Assessing occupational relevancy is an important step in the draft policy. One suggestion might be to provide examples of carcinogens that are not occupationally relevant and explain why.
- **Use of a target level of increased risk at 1/1000 for the occupational population** - The use of risk-based RELs for carcinogens is a step directly into the 21<sup>st</sup> century for NIOSH. The chosen benchmark of 1 in 1000 risk at the 95<sup>th</sup> lower confidence limit for a 45 year working lifetime seems imminently appropriate and defensible. However, mention is made in the document that this risk is at least an order of magnitude higher than the cancer risk permitted in the US for the general public (1 in 100,000 or 1 in 1,000,000). It may be worth explaining the differences in risk magnitude for the two populations in the final document.

- **Mechanism for setting a recommended exposure limit (REL)**, which can be no lower than a statistically valid limit of quantification (LOQ) for the analytical method.
- **Inclusion of a pathway** for relating occupational carcinogen RELs to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
- **Clarified flow charts**
- **Decision to include “to the extent feasible”**, projecting not only a no-effect exposure, but also exposure levels at which there may be no residual risks.

**Some concerns and potential edits to the draft policy include:**

- NIOSH’s assessment of occupational relevancy could be expanded for clarity. It would be helpful for NIOSH to assess some carcinogens currently identified by existing classifications as examples of chemicals that would not be considered as occupationally relevant and explain why.
- The use of low dose non-threshold linear modeling was proposed by NIOSH to establish the REL unless data clearly were present for a nonlinear model. NIOSH should not rule out the use of low dose modeling with thresholds for carcinogens, especially for those with non-genotoxic mechanisms.
- Recommend that within the REL documentation, NIOSH provides details that document more than one mathematical model to obtain the target risk level for carcinogens and explain which was chosen and why.
- Recent statements and actions by Fed OSHA appear to place an increased relevance on recommended RELs for potential regulatory enforcement under the General Duty Clause. Suggest NIOSH include a statement in the final version that RELs for identified occupational carcinogens are recommendations alone and not intended to supercede existing compliance regulations.
- It would be helpful for NIOSH to clarify how the use of a qualitative approach and banding would be applied for the evaluation of RELs for occupational carcinogens.
- NIOSH will use quantitative risk assessment (QRA) (page 4) when data quality permits to derive the risk based REL. A concern exists regarding the default approach employed when carcinogens are evaluated for which the QRA data are marginal.
- The draft policy does not mention that, according to the Bureau of Labor Statistics (BLS), the risk for accidental death occurring during employment in a working lifetime is slightly higher than 1 in 1000 over the entire US worker population and is significantly higher for some classifications of workers (e.g., construction workers, commercial fisherman). Even with this datum, the criterion outlined by NIOSH for risk-based RELs for carcinogens seems reasonable.

**Minor edits include:**

- Section 3.0 is a helpful carcinogen classification review; however, this would be more effective as an appendix and not in the main body of the draft policy. Much of sections 5.2-5.3 would also be a good candidate for an appendix and not in the main body of the policy.

- Suggest NIOSH recommend use of 1/1000 target risk level for occupational carcinogens and not pose this as a question in the final version of the policy (page 30, line 31).
- Include the number of chemicals listed as carcinogens by IARC as was done with the other two classification systems (page 17, line 6).

This document is an important step in providing health and safety professionals, employers and worker organizations the knowledge and rationale for minimizing the risk of cancer in the workplace – an important leadership role for NIOSH.

Should you wish to discuss our comments further, please contact me, Mike Cooper, Howard Spielman, Chris Laszcz-Davis or Dr. Michael Jayjock.

Respectfully submitted,



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