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

From: Marc.Kolanz@materion.com
Sent: Thursday, September 22, 2011 2:40 PM
To: NIOSH Docket Office (CDC)
Subject: Materion Brush Inc. submission to NIOSH Docket No. NIOSH-240
Attachments: Materion Brush response to NIOSH RFI Docket No. NIOSH-240 9-22-2011.pdf

Attached below are the comments of Materion Brush Inc. on the Request for Information by the National Institute for Occupational Safety and Health
regarding its August 23, 2011 Federal Register Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment (Docket No. NIOSH-240)

Please reply confirming your receipt of our submission and please feel free to contact me if you have any questions regarding our comments.

Sincerely,

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Comments of Materion Brush Inc.
On the Request for Information
By the National Institute for Occupational Safety and Health
Re: Announcement of Carcinogen and Recommended Exposure Limit (REL) Policy Assessment
76 Federal Register 52664 - August 23, 2011
Docket No. NIOSH-240

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September 22, 2011

Comments of Materion Brush Inc.
On the August 23, 2011 NIOSH Request for Information
Re: Carcinogen and Recommended Exposure Limit (REL) Policy Assessment
Docket No. NIOSH-240

NIOSH Cancer Policy and REL Policy Request for Information Questions:

(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)?

ANSWER
There is no need to have a carcinogen policy or broad policies. While systems for classifying agents by organ system affected (i.e., nervous system vs. lung) or the type of disease produced (cancer vs. inflammation) are of interest, they are often misused in a variety of ways, such as judgments of social acceptability (is cancer really worse than a stroke?) and subsequent judgments about value of exposure avoidance. Substances should be evaluated on a substance-specific basis and their toxicological properties should determine the risk and the risk management measures needed to mitigate the risks. Workers will be most benefitted with informative statements regarding the nature and severity of the outcome, persons at risk and risk/exposure relationships.

In addition, there already exists multiple classification systems being used by the U.S. government and international bodies, such as the National Toxicology Program's Report on Carcinogens, U.S. Environmental Protection Agency's (USEPA) Integrated Risk Information System, Occupational Safety and Health Administration's carcinogen policy, International Agency for Research on Cancer, California's Proposition 65, and other state and international policies, programs and laws classifying substances in commerce based on their toxicological properties. NIOSH would add no new value to having its own hazard classification system.

(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.*)?

ANSWER
NIOSH should recognize that, by itself, classification with respect to being or not being a carcinogen has little risk management benefit. We recommend NIOSH evaluate each substance for causing or not causing specific types of cancer in humans using established methods for hypothesis testing and evaluating risk/exposure relationships. In addition, NIOSH needs to fully and transparently disclose where cancer risks are questionable and/or the underlying studies have likely confounders.

The assignment of nomenclature and categorizations has served a useful purpose in the past to give people an understanding of risk potential. The nomenclature/classification process, however, has become so inclusive of any type of possible risk that organizations are now generating lists of thousands of substances as posing very severe health risks. These broad classification scenarios are now commonly being used as a means to ban, restrict or require mandatory substitution of materials, including those applications where the actual risk during use can be very low or non-existent. Such classification lists often ignore the scientific evidence

and are too often being generated based on political agendas or to drive competitive advantage of one product over another in the marketplace. Also, in such scenarios, the importance tends to be placed on a highly generalized hazard classification rather than a risk assessment of the benefits versus harms of using a material in any particular application. For example, the substitution of a nickel beryllium alloy in the design of fire protection sprinkler heads resulted in sprinkler head failures and a massive recall and reinstallation of over 35 million sprinkler heads. Such use of a strict toxicity classification approach when selecting materials, without regard to societal benefits, could have resulted in the selection of a much less reliable material than the copper beryllium metal seal that was used as the final cap on the Macondo well-head in the Gulf of Mexico.

In 1976, Fairchild cautioned that *"Current regulatory practices for occupational carcinogens often appear to be based on misapplication of scientific concepts."* This caution holds true today, but likely for very different reasons. Since 1976, concepts of risk have been put into place that incorporate exposure safety factors to account for uncertainty of risk. For example, USEPA utilizes a method where the health risk exposure basis is identified and then adjusted downward, often by several levels using uncertainty factors (safety factors) that are applied based on whether or not research exists on the particular area of interest (e.g., inter-/intra-species variation, pharmacokinetics, mode of action, toxicogenomics, etc.). This is generally done using an arbitrary process utilizing the opinion of a small select panel of scientists convened for this purpose. Under this process, the greater the perceived uncertainty, the greater the applied safety factor. As an example, the USEPA drinking water standard for beryllium applied uncertainty factors of 3 for completeness of the database, 10 for inter-species extrapolation variation and 10 for intra-species extrapolation variation. This resulted in a 300-fold reduction in the measured health effect level reducing the final drinking water standard level to 4 µg/l (micrograms per liter). The application of such a methodology defies reasonable scientific logic when it is known that humans are commonly exposed to average concentrations of dissolved beryllium in groundwater and surfaces water of 13.6 µg/l and 23.8 µg/l, respectively[i]. The assigning of arbitrary uncertainty factors is simply not science and it is important to remember that the word "extrapolation" means "beyond the evidence." In fact, on September 12, 2011, a scientific peer review panel convened by the USEPA to evaluate the draft, *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies Extrapolation*, recommended that the USEPA continue its efforts to encourage risk assessors to use scientific data rather than automatic presumptions as they estimate the level of a chemical that is not likely to harm health.[ii] NIOSH should ensure that its decisions are evidence-based and transparently disclose the identified areas of uncertainty and potential confounding of the data.

(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?

ANSWER

Targets levels for risk have no scientific merit if not measurable by feasible methods. It may be reasonable to set standards for less than 1 in 1000 for diseases that are extremely unusual in the non-occupational context, such as is the case for hepatic angiosarcoma, but not in common diseases like undifferentiated lung cancer, where the lifetime risks are on the order of 100 to 200/1000 in smokers and about 13/1000 in non-smokers.

Studies with the power to reliably distinguish rates such as 100/1000 from 101/1000 or 13/1000 from 14/1000 are not likely to be feasible. Projection of risk/exposure relationships may also result in calculation of exposures which cannot be feasibly measured.

Science by definition resides in the observable range. Conjecture, including calculations, outside the observable range or either risk or exposure are by definition an extra-scientific process (ESP). ESPs are used in science for hypothesis generation, but hypotheses can only be tested through observation. ESP should not be used for setting either risk or exposure targets by scientific organizations, like NIOSH.

Of equal concern in risk target setting and exposure target setting when ESP is employed is the model used. The problem with models is that they are easily switched or modified when they do not give a result considered acceptable by the model builder or user and, hence, are very susceptible to tampering. In this respect, models should be considered no more than hypotheses, and discarded when shown to be inconsistent with data.

(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?

ANSWER

As a scientific institution NIOSH should also avoid ESP with respect to feasibility. It should look for improved language to describe risk/exposure relationships that are demonstrable with observations. Feasibility statements should be handled in the same way. Technical and economic feasibility statements should be based on observations, not on speculation. In addition, "extent feasible" should include a balanced assessment of technological feasibility in conjunction with economic feasibility.

With increasing amounts of money, almost anything can be increasingly controlled. However, an acceptable solution cannot compromise the jobs and the economic welfare of the worker or the competiveness of the U.S. economy. This is not to say that there is bright line that chooses jobs over health and safety. It is meant to illustrate that the use of safety factors and extrapolation of risks need to be quantified so that transparency is evident to those who not only establish policies but to those who could be affected by regulatory policies.

(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?

ANSWER

In the absence of data, NIOSH should not develop an REL but rather conduct the research to obtain the data necessary to develop an REL. An REL has no value if it is based on assumptions and uncertainties. In addition, since an REL is a limit, any REL recommendation by NIOSH should be based on statistical data analyses defining the 95/95 confidence level for the data set rather than the current approach which sets exposure limits based on mean or median values which fail to consider 50% of workers' exposure levels in any given assessment.

For example, because chronic beryllium disease (CBD) has been identified in persons exposed less than one year and CBD results from an immune response, beryllium is not a conventional dose/response toxin. Since CBD only occurs in a small subset of the exposed population, NIOSH should not rely on the mean and median exposure data from beryllium studies such as the 2001 study by Kelleher, the 2007 study by Madl or the 2011 study by Schuler. NIOSH should utilize analyses such as that provided by Madl who identified the 95th percentile exposure levels for workers with CBD during the highest exposed year worked. The Madl study concluded:

> *"Results showed that exposure metrics based on shorter averaging times (i.e., year versus complete work history) better identified the upper bound worker exposures which could have contributed to the development of BeS or CBD. It was observed that all beryllium sensitized and CBD workers were likely exposed to beryllium concentrations greater than 0.2 µg/m^3 (95th percentile) and 90% were exposed to concentrations greater than 0.4 µg/m^3 (95th percentile) within a given year of their work history.*

The highest year of exposure is the best metric because use of multiple years of data dilutes the actual worker high and low exposures. In addition, the use of median data tends to mask important aspects of workplace exposures relevant to exposure health risks by simply not considering the health significance of the upper half of the measured exposure values. This approach to data analysis and interpretation of upper bound exposures aligns with the recommendations found in the AIHA text, *A Strategy for Assessing and Managing Occupational Exposures*[iii], which recommends using the upper tail of the data distribution when assessing both risks and compliance. The Kelleher study specifically cautioned against the use of its central tendency data when considering an OEL for beryllium where it stated:

> *"Comparisons of our data with occupational exposure limits, however, must be made with caution because occupational exposure limits are based on the upper tail of the exposure distribution rather than on measures of central tendency."*

A similar statement is found in the 2011 NIOSH sponsored study by Schuler, et al.

> *"While these results support efforts to revise occupational exposure limits, it should be noted that our exposure estimates were based on measures of central tendency and occupational risk management strategies are often based on the upper tail of the distribution."*

As a non-regulatory agency, NIOSH should not be defining or prescribing action levels. The utility of an action level is predominantly as a tool used by OSHA to prompt required actions within the context of a regulatory standard. In addition, an action level is not an exposure limit. A "standard" action level is the result of the use of an arbitrary statistical method that has no basis in statistical process control methodologies. As is evidenced by the broad variation of how action levels have been applied in OSHA standards over the past 40 years, there is no scientific basis for a one size fits all approach in the development and use of action levels to prompt actions such as baseline inventories, hazard assessments, defining regulated areas, personal protective equipment usage, housekeeping, medical surveillance, training, etc. It is the responsibility of regulatory agencies to use the available scientific evidence to define the action level or action levels appropriate to the management of risk in the workplace.

[i] ASTDR Toxicological Profile for Beryllium 170 (Sept. 2000)
[ii] Rizzuto, P., BNA Daily Environment Report 09/13/2011
[iii] American Industrial Hygiene Association. A Strategy for Assessing and Managing Occupational Exposures. Second Edition