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

From: Alexis Rudakewych [rudakewycha@socma.com]
Sent: Thursday, September 22, 2011 5:04 PM
To: NIOSH Docket Office (CDC)
Subject: Comments on Docket Number NIOSH-240, Carcinogen and Recommended Exposure Limit Policy Assessment
Attachments: SOCMA Comments on NIOSH Carcinogen and Recommended Exposure Limit Policy Assessment - Docket Number NIOSH-240.docx

Please ignore the last document that was sent – there was a problem with the formatting.

Attached is the correct one.

Apologies,

Alexis

From: Alexis Rudakewych
Sent: Thursday, September 22, 2011 4:51 PM
To: 'nioshdocket@cdc.gov'
Subject: Comments on Docket Number NIOSH-240, Carcinogen and Recommended Exposure Limit Policy Assessment

Dear Sir or Madam:

Please accept the attached comments of the Society of Chemical Manufacturers and Affiliates (SOCMA) on NIOSH's approach to classifying carcinogens and establishing recommended exposure limits (RELs).

Sincerely,

Alexis

Alexis Rudakewych
Manager, Government Relations
SOCMA
1850 M Street, NW, Suite 700
Washington, DC 20036
Direct: 202-721-4198
Main: 202-721-4100
Fax: 202-296-4548
www.socma.com
www.chemicalsitesecurity.com

SOCMA
Society of Chemical Manufacturers & Affiliates

September 22, 2011

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

Re: **Announcement of Carcinogen and Recommended Exposure Limit Policy Assessment -- Docket Number NIOSH–240**

Dear Sir or Madam:

The Society of Chemical Manufacturers and Affiliates (SOCMA) appreciates the opportunity to provide these comments on NIOSH's approach to classifying carcinogens and establishing recommended exposure levels (RELs).[1]

SOCMA is the only U.S.-based trade association dedicated solely to the batch, custom and specialty chemical industry. Having represented a diverse membership of small, medium and large chemical companies since 1921, SOCMA is the leading authority on this sector. SOCMA's more than 200 member companies make the products and refine the raw materials that make our standard of living possible. Over 70% of SOCMA's active members are small businesses. In fact, 71% of our members have fewer than 100 employees. Forty-six percent of our manufacturing members report sales under $10 million, and another 35% report sales between $10.1-$40 million. From pharmaceuticals to cosmetics, soaps to plastics and all manner of industrial and construction products, SOCMA members make materials that save lives, make our food supply safe and abundant, and enable the manufacture of literally thousands of other products.

ChemStewards® is SOCMA's flagship environmental, health, safety and security (EHS&S) continuous performance improvement program. It was created to meet the unique needs of the batch, custom, and specialty chemical industry, and reflects the industry's commitment to reducing the environmental footprint left by members' facilities. As a mandatory requirement for SOCMA members engaged in the manufacturing or handling of synthetic and organic chemicals, ChemStewards is helping participants reach for superior EHS&S performance.

Through their implementation of ChemStewards, as well as their compliance with workplace safety and health requirements established by the Occupational Safety and Health Administration (OSHA) and "state plan" states, SOCMA's members undertake to maintain safe and healthy workplaces for their workers. Due to the nature of their businesses, they are particularly concerned about limiting potentially unsafe workplace exposures to chemicals. Accordingly, SOCMA and its members have

[1] 76 Fed. Reg. 52664 (Aug. 23, 2011).

a deep interest in NIOSH's policies regarding classifying carcinogens and establishing RELs. The following comments are addressed to the five questions that NIOSH has asked in its notice.

(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)?

SOCMA supports NIOSH maintaining separate policies regarding the identification and classification of potential toxicants. Different toxic endpoints typically arise from different modes and mechanisms of action, are assessed by different screens and tests, and may warrant different degrees of concern depending upon regarding duration and degree of exposure and upon different susceptibility factors (e.g., age, sex, etc.). It is not clear to SOCMA what possible theoretical or practical advantage would be gained by NIOSH adopting a unitary "toxicant policy." SOCMA is also not aware of any other governmental agency adopting such a policy. At a minimum, NIOSH should be much more forthcoming to the public about its intentions and considerations before making a decision on this issue and engage stakeholders throughout the process.

(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.*)?

SOCMA agrees that NIOSH's single cancer classification ("potential occupational carcinogen") is a shortcoming in its current policy, and that a more refined policy could "allow for classification on the basis of the magnitude and sufficiency of the scientific evidence." As the science of toxicology has become more explicitly evidence-based, so agency cancer classifications have gradually been moving from a probabilistic approach (possible, probable, likely, etc.), to one that is expressed in terms of evidence. While both types of classifications require the exercise of scientific judgment to apply, the former is more inherently subjective, while the latter lends itself more readily to quantitative or structured approaches to evaluating the weight of the relevant scientific evidence. While some classification systems (e.g., EPA's) are an amalgam of probabilistic and evidentiary statements, others are now expressed fully in terms of the magnitude and sufficiency of evidence (e.g., the International Agency for Research on Cancer's). IARC's classification system also reflects the growing sophistication of the field of toxicology in understanding carcinogen mechanisms of action. Again, the IARC classification expressly recognizes mechanistic understandings. SOCMA therefore urges NIOSH to move to a classification like IARC's.[2]

SOCMA recognizes that its recommendation would create a difference between NIOSH's classification system and OSHA's current regulatory definition of "potential occupational

[2] This is not to say that SOCMA endorses all of the classification decisions that IARC has made under its policy or its practice in making those decisions, only that the IARC framework, standing alone, is a good example of an evidence-based classification system that acknowledges the relevance of mechanistic understanding.

carcinogen." SOCMA believes that OSHA's definition is outdated and less useful than it could be, and should be amended similarly. It would help that process if NIOSH were to move now to a more state-of-the art definition.

(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?

In his guest column "Occupational Cancer and the NIOSH Carcinogen Policy" posted on NIOSH's website, Dr. Paul Schulte recognizes that the 1 in 1,000 risk standard originated in the Supreme Court's *Benzene* decision and is thus used by OSHA to set standards.[3] It may be informative for NIOSH to seek to characterize the different levels of cancer risk that might be associated with different workplace exposure levels. However, NIOSH needs to remain cognizant of OSHA's legal authorities and the limitations that they may impose on it.

(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?

The statutory concept of "feasibility" is central to OSHA's establishment of occupational safety and health standards:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, *to the extent feasible*, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.[4]

The fundamental importance of this legal term to OSHA standard setting was demonstrated recently when OSHA proposed to redefine "feasibility" for purposes of its noise protection standard.[5]

Historically, OSHA has not relied heavily on NIOSH RELs in setting permissible exposure limits (PELs), and one reason it has not done so is because NIOSH historically has devoted inadequate attention to, or has placed differing interpretations on, the concept of "feasibility." SOCMA believes NIOSH has much to offer OSHA in OSHA's establishment of PELs, given NIOSH's scientific expertise and sophistication. In order for NIOSH's work to be useful in setting PELs, however, it is critical that NIOSH follow OSHA's interpretation of feasibility.[6]

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[3] http://www.cdc.gov/niosh/enews/enewsV8N12.html.

[4] 29 U.S.C. 655(b)(1) (emphasis added).

[5] *See* OSHA News Release No. 11-74-NAT, "US Department of Labor's OSHA withdraws proposed interpretation on occupational noise; Agency examines other approaches to prevent work-related hearing loss" (Jan. 19, 2011), available at http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=NEWS_RELEASES&p_id=19119.

[6] SOCMA does not believe it is making inconsistent recommendations by urging NIOSH to (i) adopt a different cancer

In his guest column, Dr. Schulte claims that "consideration of the extent to which NIOSH RELs should be technology-forcing" warrants a reexamination of NIOSH's interpretation of "feasibility."[7] SOCMA recognizes that NIOSH's statutory mandate includes "research, experiments, and demonstrations relating to . . . innovative methods, techniques, and approaches for dealing with occupational safety and health problems."[8] It is one thing to identify cutting-edge control technologies; it is quite another to express legal conclusions about whether those technologies are "feasible." NIOSH has an important role to play in evaluating technologies, but it remains OSHA's statutory responsibility to determine whether those technologies are "feasible." Adopting a different conclusion than OSHA about "feasibility" as means of "forcing" a technology's adoption is neither NIOSH's proper role nor likely to produce the results that NIOSH seeks.

(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?

The main uncertainties regarding the calculation of human cancer risk based on animal test data are well-known: (1) extrapolating from animal to human, (2) extrapolating from high to low doses, and (3) potential variability in sensitivity among humans. Historically, agencies have used an uncertainty factor of up to 10 for each uncertainty as a safety default. These uncertainties are not eternal, however, and toxicology has made substantial progress since the 1970s in developing mechanistic understandings that allow us to fill in these uncertainties. The most important step for NIOSH to take at this juncture is to commit to using mechanistic models and relevant data to replace standardized defaults where doing so is warranted.

There is no single solution to the challenge of assessing the risks of exposures to complex mixtures. SOCMA agrees with NIOSH that hazard banding is one potentially useful way of doing so, however, as it provides a means for making beneficial use of toxicological databases that may not be sufficient for determining RELs or PELs for individual chemicals. SOCMA urges NIOSH to continue the promising work that it has been engaged in with industry, OSHA and others to develop science-based hazard banding approaches keyed to the Globally Harmonized System (GHS) warning phrases. SOCMA cautions NIOSH, however, to recognize that hazard banding need not be linked to control banding, an approach that NIOSH itself has recognized has significant shortcomings.[9] Industry support for hazard banding will diminish dramatically if it is seen as

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classification than OSHA but (ii) follow OSHA's interpretation of "feasibility." The former is a scientific concept, and one that has evolved over time as the relevant science has advanced. The latter is at bottom a legal concept, and one that does not inherently need to change (although what standards are feasible may well change over time as technology advances or becomes cheaper).

[7] See note 3 above.

[8] 29 U.S.C. § 669(a)(1).

[9] A recent NIOSH review of the literature on control banding and efforts to validate the approach cited concerns about its effectiveness and potential to produce "potentially inappropriate workplace confidence" in it. See NIOSH,

simply a means for imposing control banding solutions.

SOCMA appreciates the opportunity to provide NIOSH with these comments. If you have any questions regarding them, please do not hesitate to contact me at 202-721-4198 or rudakewycha@socma.com.

Sincerely,

Alexis Rudakewych
Manager, Government Relations
Society of Chemical Manufacturers and Affiliates

QUALITATIVE RISK CHARACTERIZATION AND MANAGEMENT OF OCCUPATIONAL HAZARDS: CONTROL BANDING 40 (Aug. 2009), available at http://www.cdc.gov/niosh/docs/2009-152/pdfs/2009-152.pdf. NIOSH concluded that "[a]dditional development, evaluation, and discussion are required before widespread implementation of control banding in the United States can be recommended. *Id.* at vii.