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"Toxic Trailers: Have the Centers for Disease Control Failed to Protect Public Health?"

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Chairman Miller, Mr. Sensenbrenner, Members of the Subcommittee. Thank you for inviting me to testify today. In describing my background, I am a former president of the Society of Toxicology, USA, a professional organization of approximately 6,000 scientists from academia, government, and industry. I am also a former Secretary-General of the International Union of Toxicologists, an association comprised of 51 national societies of toxicology from all six continents. The goal of the International Union is to increase the knowledge base of toxicology and to extend this knowledge to other nations and societies. Academically, I am the former Associate Dean for Research and Academic Affairs at the Graduate School of Public Health at the University of Pittsburgh, in Pennsylvania. Currently, I am Professor Emerita of Environmental and Occupational Health Sciences at the University. I wish to stress that my testimony today reflects only my opinions.

As a toxicologist, I have conducted research for 34 years on mechanisms of chemically-induced lung and skin diseases. This research has been supported by the NIEHS, NIOSH, USDA, and grants from industrial corporations and professional associations. I have published more than 170 refereed scientific articles that are focused on chemical toxicity and have authored and edited several books, book chapters and monographs. Particularly relevant is a monograph (of which I was an editor) entitled, *Improving Indoor Environmental Quality for Public Health*. The monograph (1), published in the June 2007 issue of *Environmental Health Perspectives*, is comprised of six articles by international experts in indoor air quality. It contains discussion of the effects of indoor environments on human health.

I have lectured extensively, both nationally and internationally on indoor environmental quality, including meetings organized by the World Health Organization. I have taught graduate classes in environmental and occupational health, principals of toxicology, and methods in toxicology. I currently serve on the Scientific Advisory Board of the EPA, and on the National Research Council's (NRC) Committee on Toxicology. I chair the NRC Committee on Toxicologic and Radiologic Effects from Exposures to Depleted Uranium During and After Combat.

Regarding my work with formaldehyde, I have conducted research that focused on the potential allergic sensitization from skin and pulmonary exposure to formaldehyde. This research, supported by both NIEHS and NIOSH, resulted in the development of an animal model of formaldehyde sensitization, and also led to the development an immunologic assay to detect the presence in serum of antibodies directed to formaldehyde (2).

In the brief time I have available today, I would like to comment on the ATSDR's health advisory (issued February 2007) on formaldehyde levels in FEMA-provided trailers, and to specifically address one of its major recommendations, *i.e.,* that a 0.3 ppm concentration of formaldehyde be designated a "*level of concern*" for *sensitive* individuals. A *level of concern* has been defined as the level above which individuals with hypersensitivity to formaldehyde would suffer adverse health effects.

What is Formaldehyde Hypersensitivity?

Formaldehyde is normally present in low concentrations, around 3 ug/m^3 (2.5 ppb), in the outdoor air. Indoor, the concentration is usually higher and may reach 25-50 ppb depending on numerous factors that include: the construction materials used, furnishings, the age of the housing (newer homes would be expected to release formaldehyde by off-gassing from materials). Other factors that also contribute to formaldehyde concentrations within homes include the heating and ventilation systems.

Most people can detect the presence of 500 ppb (0.5 ppm) formaldehyde in the atmosphere by its characteristic odor. At this and higher concentrations, it typically causes eyes, nose and throat irritation with symptoms of eye tearing or perhaps eye, nose and throat burning, hoarseness, cough, or difficulty breathing. However, formaldehyde can be irritating, especially to the eyes when present in a concentration that is lower than this odor threshold. As I will discuss later, it is known that a considerable percentage of the population develops eye irritation when exposed to 0.24 ppm formaldehyde, a concentration considerably below its odor threshold (3) and the "level of concern".

There exist *sensitive* individuals, people who may have an adverse response when exposed to still lower concentrations of formaldehyde, *i.e.,* concentrations that are below the level that causes health effects in the majority of people. Such individuals would include those with hyperreactive "twitchy" airways, those with underlying respiratory disease, with a viral infection of the lungs, among others. Infants and the elderly would reasonably be expected to be more responsive to irritants such as formaldehyde. Their narrower airways make children more susceptible than adults to agents such as irritants that cause airway constriction.

The Formaldehyde "Level of Concern"

The ATSDR Health Consultation of February 1, 2007 offers 0.3 ppm (369µg/m^3) formaldehyde as a concentration associated with the narrowing of the lung bronchi in sensitive individuals (4). This statement implies that most individuals (*i.e.,* those without sensitivity) would not be adversely affected upon exposure to 0.3 ppm formaldehyde. Unfortunately, the Consultation statement is contrary to published reports that provide evidence that 0.3 ppm is not a protective concentration even for the general population. It certainly would not be protective for the more susceptible persons, *i.e.,* those described above.

The basis for establishment of the 0.3 ppm level of concern is a 2001 ATSDR document (5) that lists OSHA permissible exposure limit (PEL) of 0.75 ppm

formaldehyde (averaged over an 8-hour workshift) as a guideline for an acceptable exposure level. However, it must be emphasized that the PEL is an occupational standard, established for healthy adults, individuals expected to have only an 8 hour (workday) exposure. In order to use this guideline to set indoor environmental exposures that are safe for the general population, one must consider applying safety factors that would lower the permissible concentration of formaldehyde to make it appropriate for a population that is diverse with regard to age, underlying health status, concurrent environmental exposures, and may be exposed for 24 hr/day.

October 2007 Revision of the Feb 2007 ATSDR Health Consultation

The October 2007 revision sought to address, among other items, the deficiency in the Feb 2007 report regarding the insufficient discussion of the health implications resulting from formaldehyde exposure. It addressed the question, "Are air formaldehyde levels in closed, unventilated trailers high enough to be associated with health effects in humans?"

When corrected, the air samples taken in closed trailers yielded an average value of 1.04 ppm formaldehyde (with some values extending to 3.5 ppm). Concentrations in air-conditioned trailers averaged 0.39 ppm, whereas concentrations in trailers with open windows were 0.09 ppm. The advisory correctly concluded that the levels in the air-conditioned trailers exceeded federal exposure guidelines. OSHA warns that "Airborne concentrations of formaldehyde above 0.1 ppm can cause irritation of the respiratory tract" (6).

Guidelines for safe formaldehyde exposure

What are the known effects of formaldehyde on humans? Which are the susceptible populations? What guidelines are appropriate to protect the health of human subpopulations?

Irritation

Formaldehyde is known to cause irritation of the eyes, nose, throat and respiratory tract. During the past 60 years, the Occupational Exposure Guideline for formaldehyde (to prevent irritation reactions in workers) has been revised downward from 10 ppm in 1947 to 0.3 ppm (as a ceiling value) in 1992. In 1997, a panel of experts critically reviewed 150 scientific articles related to formaldehyde to derive an occupational exposure limit that would prevent irritation (3). The panel found that eye irritation occurred at concentrations lower than those that caused nose/throat irritation and concluded that it was the most sensitive irritative effect. They found reports of eye irritation at 0.24 ppm (19% of 16 subjects) clearly indicating the variation that exists among humans with regard to this endpoint. The panel concluded that maintaining a formaldehyde concentration below 0.1 ppm in the indoor environment where exposures might occur 24 hour/day might avoid irritation in virtually all persons. In agreement, the current OSHA guideline states that between 0.1-0.5 ppm, irritation may occur in some individuals.

Chronic airway disease

Formaldehyde does not appear to pose a hazard for pulmonary emphysema or chronic obstructive pulmonary disease (COPD).

Allergic sensitivity

Formaldehyde has been associated with allergic skin sensitivity in humans and animals (2). It remains uncertain whether inhaled formaldehyde will or will not induce lung sensitization in humans (7) although controlled animal studies have failed to detect this response (2).

Cancer

Based on the reported concentration-dependent carcinogenic effect of formaldehyde in rats and mice, and on inadequate epidemiologic data on the cancer risk in humans, ACGIH (1989) recommended that workplace formaldehyde exposures be reduced to the “lowest possible level”. ACGIH has adopted the 0.3 ppm TLV-CV

(ceiling value) for formaldehyde and lists it as an A2 suspected human carcinogen.

There is considerable controversy regarding the conclusion that formaldehyde causes cancer in humans. In 2004, the International Agency for Research on Cancer (IARC) reclassified formaldehyde as a Group 1 carcinogen based largely on the results of the National Cancer Institute (NCI) study on nasopharyngeal cancer (NPC). However, the NPC findings in the NCI study were driven by a large excess in one plant (6 or 10 cases from that one plant). Nine other plants collectively had no NPC excess, nor was an NPC excess observed in two other cohort studies, one by NIOSH and one in the UK.

The NCI nasal pharyngeal excess driven by one plant was the subject of several papers by the Marsh group. In a recent update (8), the investigators found that the large NPC excess in this plant appears to be due to prior employment in the metal working industries of the local area, where exposures to many agents known or suspected to cause upper respiratory cancers (e.g., sulfuric acid mists, mineral acid, metal dusts and heat) have occurred.

The causal association of formaldehyde with leukemia has also been questioned. A reanalysis (9) of the data provided little evidence to support a causal association between formaldehyde exposure and mortality from leukemia.

Summary and Recommendations

The literature regarding the adverse effects from formaldehyde indicates the potential for both acute and chronic health effects. Guidelines for safe exposure to formaldehyde to protect against these effects have been established for the workplace. To protect residents against adverse effects from formaldehyde inside their trailers, guidelines must take into consideration the diversity of the exposed population (including age and underlying health conditions) as well the diversity of the indoor environment (including the temperature, ventilation, furnishings, other airborne chemicals). The suggestion that 0.3 ppm be designated a "*level of concern"* for formaldehyde would not

protect sensitive or non*sensitive* individuals from irritation reactions. The level of concern should be lowered and not exceed 0.1 ppm. Uncertainty remains regarding the likelihood of chronic adverse health effects resulting from continued formaldehyde exposure in trailer residences.

References

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