Formaldehyde and Facts About Health Effects

Prepared by
Formaldehyde Epidemiology, Toxicology and Environmental Group, Inc. (FETEG)

August 2002

FORMALDEHYDE AND FACTS ABOUT HEALTH EFFECTS

The Formaldehyde Epidemiology, Toxicology and Environmental Group, Inc. (FETEG) is comprised of scientists from companies that produce formaldehyde or formaldehyde resins. Members include toxicologists, epidemiologists, industrial hygienists, engineers, and other scientists from eight companies with years of experience studying formaldehyde.

This short summary is part of FETEG's efforts to address formaldehyde science. For full details, please consult the primary source documents listed at the end of this paper.

I. WHAT IS FORMALDEHYDE, AND WHAT ARE ITS SOURCES?

A. Natural Sources of Formaldehyde in the Environment

Formaldehyde occurs naturally in our environment. It is composed of carbon, hydrogen, and oxygen.

- It does not accumulate in the environment, because it is broken down within a few hours by sunlight or by bacteria present in soil and water.[1]

- People, animals, and plants actually produce low levels of formaldehyde during normal metabolic processes.

- Formaldehyde is metabolized and excreted quickly. Thus, it does not accumulate in the body.

According to the International Programme on Chemical Safety, natural formation of formaldehyde from other molecules may contribute up to 70-90 percent of the total atmospheric formaldehyde.[2]

B. Other Sources of Formaldehyde

Formaldehyde also can be released from other sources.

- Formaldehyde is a by-product of combustion. Consequently, "mobile sources," like cars and trucks, emit the largest levels of formaldehyde after natural sources.[3] Burning wood and cigarettes also produce formaldehyde.

- Industrial facilities also contribute formaldehyde to the environment.

Industrial sources of formaldehyde are controlled within well-established safety limits:

- The Occupational Safety and Health Administration regulates workplace exposure to formaldehyde.[4] The Permissible Exposure Limit for workers averaged over an eight-hour shift is 0.75 parts per million (ppm).

- The Environmental Protection Agency limits emissions from facilities that make or use formaldehyde,[5] requires facilities to report the amount of formaldehyde they use,[6] and regulates the amount of formaldehyde in automobile exhaust.[7]

C. Uses of Formaldehyde

Formaldehyde is normally a gas, but it is usually dissolved in water for shipment and used as a colorless liquid solution. Many people may remember the liquid formaldehyde solution from high school biology lab, but formaldehyde is most often used to make resins -- glue-like substances used in a large number of products. Because of its versatility, formaldehyde is used to make household products, building materials, and other chemicals.[8]

- One of the most important uses of formaldehyde is in adhesives for wood products. Formaldehyde is used to make the resin (adhesive) used in particleboard (used in furniture, kitchen cabinets and kitchen counter underlayment), plywood (used as sheathing and flooring), and other pressed wood products. While very little formaldehyde is present in a form that can be released, small quantities of formaldehyde gas can be emitted from various wood composite products. These low level emissions will diminish over time. The Department of Housing and Urban Development (HUD) has standards that limit formaldehyde emissions from wood products.[9] There are also voluntary industry standards.

- Common consumer products containing formaldehyde include shampoos, cosmetics, household disinfectants, fabric softeners, inks, paper towels, photographic film, decorative laminates, paints, wallpapers, paper money, and textiles. Generally the formaldehyde content in these products is less than one percent.[10]

D. Levels of Formaldehyde

Advances in technology in the 1980s and 1990s have meant decreasing releases of formaldehyde from products. According to the Consumer Product Safety Commission in a 1997 paper, “Formaldehyde is normally present at low levels, usually less than 0.03 ppm (parts per million), in both outdoor and indoor air.”[11]

Research has demonstrated that indoor levels of formaldehyde are typically low:

- EPA studied a normal new home and found indoor air levels declining from 0.076 ppm initially to 0.045 ppm after 30 days.[12]

- Other authors have estimated the average indoor concentration of formaldehyde in homes is about 0.03 to 0.05 ppm.[13]

II. DOES FORMALDEHYDE CAUSE CANCER?

The risk of cancer from exposure to formaldehyde at levels normally found in the environment is virtually non-existent.

Concern about whether formaldehyde might cause cancer in humans arose in the late 1970s and early 1980s, when it was discovered that high levels of formaldehyde (6-15 ppm) caused nasal cancer in laboratory rats. Low levels (at or below 2 ppm) did not cause cancer in the animals, and scientists set about trying to learn why this was the case.

After more than two decades of research -- making formaldehyde one of the most widely examined chemicals in history -- there is widespread scientific recognition that the effects observed in laboratory animals at levels of 6 to 15 ppm will not occur in people exposed to much lower levels (such as typical levels of hundredths of a ppm). This is because scientists now have a good understanding of *how* formaldehyde causes cancer in animals at high levels. Unless levels get high enough to kill cells, cancer is not expected to occur. Thus, at the levels to which people are exposed, there is essentially no risk of cancer.

Here are some of the recent scientific findings.

A. The CIIT Assessment

In 1999, the CIIT Centers for Health Research, a scientifically independent, not-for-profit research organization, completed a thorough evaluation of potential cancer risk from formaldehyde.[14] (CIIT conducted the original cancer study on formaldehyde in the 1970s, and has been a leader in conducting related research since then.) CIIT also received input from the U.S. Environmental Protection Agency, Health Canada, and peer reviewers. Pulling together years of research, the report concluded:

- "[A]t concentrations to which humans are typically exposed, formaldehyde is not likely to be carcinogenic."[15]

- "[O]ne would expect extremely high and sustained exposure levels would be needed for formaldehyde to pose a potential carcinogenic risk to humans."[16]

CIIT developed a state-of-the-art mathematical model that took into account doses to the nasal passages and respiratory tract of rats and humans, and all of the detailed research about *how* formaldehyde leads to cancer in the rats at high levels. The CIIT model predicts that cancer risk does not even begin to increase until continuous lifetime exposures reach 0.6 to 1.0 ppm, and becomes significant at levels above that. As noted above, environmental exposures are well below this level.[17]

Using this model, the CIIT scientists provided quantitative estimates of human cancer risk.

- For example, CIIT determined that a non-smoker with 80 years of *continuous* 24-hour exposure to 0.1 ppm formaldehyde (which is higher than most exposures to formaldehyde in outdoor or indoor air) would have less than a three in *one hundred million* chance of developing cancer from formaldehyde exposure.[18] At levels closer to the levels commonly found in the environment, there is even less cancer risk.

Thus, the cancer risk to humans is negligible.

B. Other Authoritative Groups

Governmental authorities have recently reached similar conclusions about formaldehyde cancer risk, many of them relying on the CIIT work:

- **U.S. EPA** has expressed a strong commitment to using the new mechanistic information on formaldehyde to update its current risk assessment information for formaldehyde.[19] (EPA's current risk estimate is 15 years old and relies on even older data.) EPA has stated that it plans to have its Science Advisory Board consider this updated information in early 2003.[20]

- **U.S. Consumer Product Safety Commission** concluded that "any risk of causing cancer is believed to be small at the level at which humans are exposed."[21]

- The **Organisation for Economic Cooperation and Development (OECD)**, a group representing regulators from thirty developed countries, has reviewed formaldehyde under its Existing Chemicals program and found that "[t]aking into account the extensive information on its mode of action, formaldehyde is not likely to be a potent carcinogen to humans under low exposure conditions."[22]

- The **World Health Organization (WHO)**, as part of its International Programme on Chemical Safety, issued a Concise International Chemical Assessment Document for formaldehyde that concluded formaldehyde exposure poses a cancer hazard only under conditions that both induce toxicity and cause sustained regenerative proliferation.[23] (These conditions do not occur at environmental levels.)

- The **German MAK Commission**, which sets occupational exposure values, relied on the CIIT work to conclude: "In the low dose range, which does not lead to an increase in cell proliferation, the Commission therefore considers that the genotoxicity of formaldehyde plays no or at most a minor part in its carcinogenic potential so that no significant contribution to human cancer risk is expected."[24]

- **Health Canada** stated that it considered the CIIT dose-response model "to provide the most defensible estimates of cancer risk, on the basis that it encompasses more of the available biological data, thereby offering considerable improvement over default."[25]

In sum, two decades of research has shown that the cancer observed at high levels in laboratory animals does not indicate a risk to people at low (environmental) levels.

III. ARE THERE OTHER HEALTH EFFECTS FROM FORMALDEHYDE?

A. Irritation

Formaldehyde can be irritating to the eyes, nose, and throat, but for most people, irritation is temporary and reversible.[26] It is difficult to measure levels at which irritation begins due to the subjective nature of comparison.[27]

The eyes are most sensitive to formaldehyde exposure:

- The lowest level at which many people can begin to smell formaldehyde is about 0.3 ppm.

- In controlled chamber studies, individuals begin to sense eye irritation at about 0.5 ppm; 5 to 20 percent report eye irritation at 0.5 to 1 ppm; and greater certainty for sensory irritation occurred at 1 ppm and above.[28] (In these controlled studies, persons not exposed to formaldehyde often reported a 20-30% response rate for eye, nose and throat irritation. Thus, the background rate of response was often higher than the rate in people reporting subjective signs of irritation at low levels of formaldehyde exposure.)

- An expert panel review of over 150 published studies found that eye irritation does not become significant until around 1 ppm, and moderate to severe eye, nose, and throat irritation occurs at 2 to 3 ppm.[29]

- While some agencies have used a level as low as 0.1 ppm as a threshold for irritation, the expert panel found that a level of 0.3 ppm would protect against nearly all irritation. In fact, the expert panel found that a level of 1.0 ppm would avoid eye irritation -- the most sensitive endpoint -- in 75-95% of all people exposed.[30]

In any event, normal environmental exposures are below these levels. As noted above, EPA's study found a new home measured 0.076 ppm when brand new and 0.045 ppm after 30 days.

B. Asthma

Formaldehyde exposure has not been demonstrated to cause bronchial asthma. The Agency for Toxic Substances and Disease Registry states that investigations into this possibility have provided very limited evidence of an association.[31] A report by the National Academy of Sciences Institute of Medicine similarly found inadequate evidence of any association between formaldehyde exposure and asthma induction.[32] Several clinical investigations of asthma cases suspected to be due to formaldehyde failed to confirm even a single case based on inhalation challenge tests.[33]

There are also studies indicating that asthmatic individuals are not more sensitive to the irritant effects of formaldehyde than healthy people.[34]

C. Reproductive or Developmental Effects

Formaldehyde is not considered to have reproductive or developmental effects on humans. A comprehensive review of the scientific literature concluded: "Given formaldehyde's rapid metabolism and reactivity, reproductive and developmental effects appear unlikely from low inhalation and dermal exposure."[35]

* * *

FETEG is devoted to addressing scientific issues regarding formaldehyde. FETEG members include:

BASF	DuPont
Borden Chemical, Inc.	Dynea
Celanese Ltd.	Georgia-Pacific Corporation
Cytec Industries Inc.	Solutia, Inc.

As scientific information is constantly emerging, we encourage formaldehyde users to review both the underlying data described here and any new information. This summary is not intended to substitute for a thorough review and independent evaluation. Please follow the manufacturer's instructions when handling formaldehyde, and contact your supplier with any questions.

[1] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Formaldehyde* (hereafter ATSDR), at 269, 285, 298 (1999).

[2] World Health Organization, International Programme on Chemical Safety, *Concise International Chemical Assessment Document: Formaldehyde* (hereafter "WHO CICAD"), at 9 (2002).

[3] EPA Office of Air Quality, *National-Scale Air Toxics Assessment*, SAB Review Draft, Table 4-8, at 66 (Jan. 2001), available at http://www.epa.gov/ttn/atw/sab/natareport.pdf.

[4] 29 Code of Federal Regulations (C.F.R.) § 1910.1048.

[5] *See* 40 C.F.R. various sections.

[6] 42 U.S.C. § 11023.

[7] *See* 40 C.F.R. various sections.

[8] U.S. Consumer Product Safety Commission, *An Update on Formaldehyde: 1997 Revision* (hereafter CPSC), at 2 (1997), available at http://www.cpsc.gov/CPSCPUB/PUBS/725.pdf, at 2.

[9] 24 C.F.R. § 3280.308.

[10] ATSDR, *supra*, at 276, 285.

[11] CPSC, *supra*.

[12] Daniel A. Hare *et al*., Evaluating the Contribution of UF-Bonded Building Materials to Indoor Formaldehyde Levels in a Newly Constructed House, at 19 (1996) (presented at *30th Annual Particle Board/ Composite Materials Symposium* in Pullman, Washington; full report available from Composite Panel Association). See also M. Koontz *et al., Residential Indoor Air Formaldehyde Testing Program: Pilot Study* (prepared for U.S. EPA, Office of Pollution Prevention and Toxics) (1996).

[13] Dennis Paustenbach *et al.*, A Recommended Occupational Exposure Limit for Formaldehyde Based on Irritation, *J. Toxicology and Envtl. Health* 50:217, 220 (1997).

[14] CIIT Centers for Health Research, *Formaldehyde: Hazard characterization and dose-response assessment for carcinogenicity by the route of inhalation* (revised ed. 1999) (full report available from CIIT or EPA IRIS docket; Executive Summary available at http://www.ciit.org/newsrs/formaldehydesummary). CIIT receives funding from the chemical industry generally, but FETEG did not provide any funding for the risk assessment project.

[15] *Id.* at 4-27.

[16] *Id.* at 5-1.

[17] CPSC, *supra*, at 4; M. Koontz *et al.*, *supra*.

[18] CPSC, *supra*, at xxxv.

[19] Letter from Paul Gilman, Ph.D., Asst. Administrator EPA Office of Research and Development, to Dr. James P. Mieure, President, FETEG, July 3, 2002; U.S. EPA, *Review of Mode-of-Action Model Assessments for Vinyl Acetate and Formaldehyde*, previously available at http://www.epa.gov/sab/proj0120.htm (2001 project list); and 2003 project list at http://www.epa.gov/sab/pdf/projcomm2003ec71602.pdf.

[20] *Id.*

[21] CPSC, *supra*, at 3.

[22] Organisation for Economic Cooperation and Development (OECD), SIDS Initial Assessment Profile (hereafter "OECD SIAP"), at 2 (Apr. 2002).

[23] WHO CICAD, *supra*, at 38.

[24] German MAK Commission, *Formaldehyde*, Official English Translation, at 193 (2001).

[25] Environment Canada and Health Canada, *Priority Substances List Assessment Report: Formaldehyde*, at 65-66 (2001), available at http://www.ec.gc.ca/substances/ese/eng/psap/final/reports/formaldehyde.pdf .

[26] Paustenbach *et al.*, *supra*, at 248-252.

[27] Joel Bender, The Use of Noncancer Endpoints as a Basis for Establishing a Reference Concentration for Formaldehyde, *Reg. Toxicology and Pharmacology* 35:23, 30 (Feb. 2002).

[28] *Id.* at 29.

[29] OECD SIAP, *supra*, at 1; Paustenbach *et al.*, *supra*, at 252.

[30] Paustenbach *et al.*, *supra*, at 252.

[31] ATSDR, *supra*, at 71.

[32] National Academy of Sciences, Institute of Medicine, *Clearing the Air: Asthma and Indoor Air Exposures*, at 246 (2000), available at http://www.nap.edu/books/0309064961/html.

[33] See, e.g., Evangelo Frigas *et al.*, Bronchial Challenge with Formaldehyde Gas: Lack of Bronchoconstriction in 13 Patients Suspected of Having Formaldehyde-Induced Asthma, *Mayo Clinic Proceedings* 59:295 (1984); L. C. Grammer *et al.*, Evaluation of a Worker with Possible Formaldehyde-Induced Asthma, *J. Allergy Clin. Immunol.* 92 (1 Pt. 1): 29-33 (1993); Krakowiak *et al.*, Airway Response to Formaldehyde Inhalation in Asthmatic Subjects with Suspected Respiratory Formaldehyde Sensitization, *A. J. Ind. Med.* 33:274-281 (1998).

[34] See, e.g., Bender, *supra*, at 30; Paustenbach *et al.*, *supra*, at 248-249; D.J. Green *et al.*, Acute response to 3 ppm formaldehyde in exercising healthy nonsmoker and asthmatics, *Am. Rev. Respir. Dis.* 135:1261 (1987); Witek *et al.*, An evaluation of respiratory effects following exposure to 2 ppm formaldehyde in asthmatics: lung function, symptoms, and airway reactivity, *Arch. Environ. Health* 42:230 (1987).

[35] James J. Collins et al., A Review of Adverse Pregnancy Outcomes and Formaldehyde Exposure in Human and Animal Studies, *Reg. Toxicology and Pharmacology* 34 :17, 31 (2001); OECD SIAP, *supra*, at 2.

August 2002