

State of Minnesota
Department of Health
Division of Environmental Health

In the Matter of a Proposed
New Rule Relating to
Formaldehyde 7 MCAR § 1.448

Statement of Need
and Reasonableness

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Statement of Need and Reasonableness

This rule, 7 MCAR § 1.448 is being proposed pursuant to legislative direction contained in Minn. Stat. § 144.495 (1980) as amended by Laws, 1981 Chap 245. That law required that the Commissioner of Health, 1) determine whether or not the presence of formaldehyde in building materials posed a significant health problem, 2) if he determined there was a problem, that he promulgate emergency (read "temporary") rules, and 3) that he promulgate permanent rules governing the sale of building materials and housing units that contain products made with urea formaldehyde.

Formaldehyde is a colorless, flammable gas with a strong, pungent odor. It can form explosive mixtures with air and oxygen. As an important industrial chemical of major commercial use, formaldehyde is found throughout the environment. In outdoor air it can originate from many sources such as incinerators, photochemical smog, and engine exhaust. Near industrial outlets or in areas of heavy smog, atmospheric levels of formaldehyde have been reported to range from less than 0.005 parts per million (ppm) to 0.15 ppm. Cigarette smoke contains as much as 40 ppm of formaldehyde by volume. The US produced about 6.4 billion pounds of aqueous formaldehyde in 1978. The US consumption of formaldehyde will likely exceed 7.5 billion pounds by 1983.

Half of the formaldehyde produced is used to produce synthetic resins such as urea and phenol formaldehyde resins.

These resins are used primarily as adhesives when making particleboard, fiberboard and plywood. Urea formaldehyde concentrates are used in various coating processes, in paper products, and in making foams for thermal insulation. The textile industry uses formaldehyde for producing creaseproof, crushproof, flame resistant and shrinkproof fabrics. Acetal resins, made from formaldehyde, are used to mold plastic parts. Formaldehyde is used in some medicines because it modifies and reduces the toxicity of viruses, venoms and irritating pollens. The use of formaldehyde in embalming fluids is now required by all state laws. The widespread use of formaldehyde is due to its high reactivity, colorless nature, purity in commercial form and low cost.

Human Health Effects

Several studies have been conducted in an attempt to evaluate the human health effects of exposure to formaldehyde. The variety of responses which have been observed are summarized in Table 1.

Formaldehyde has a characteristic odor, and the lowest odor threshold that has been reported is 0.05 ppm (Stockinger, 1968).

At lower exposure levels the most commonly reported symptoms associated with formaldehyde are irritation of the eyes, nose, and other areas of the upper respiratory tract. Other symptoms that have been reported include headaches, lacrimation, coughing, sneezing, diarrhea, and vomiting.

Table 1

Responses of Man to Various Concentrations
of Formaldehyde Vapors

<u>Concentration</u>		<u>Exposure Time</u>	<u>Response</u>
$\mu\text{g}/\text{m}^3$	ppm		
12	.01		Eye irritation threshold
60	.05		Odor threshold
80	.07		Chronaximetric response threshold
98	.08		Cortical reflex threshold
156-540	.13-.45		Irritant threshold
300-6000	.25-5.0		Irritant threshold
600	.5		Odor threshold
1000	.8		Slight irritation
1080-1920	.9-1.6		Irritant threshold
1200	1.0		Odor threshold
2400-3600	2.0-3.0	8 hr	Tolerable; mild irritation of eyes, nose, and posterior pharynx
4800-6000	4.0-5.0	10-30 min	Intolerable to most people; mild lacrimation; very unpleasant
6000	5.0		Throat irritation threshold
12,000	10.0	few min	Profuse lacrimation
24,000	20.0	15-30 sec	Lacrimation
24,000	20.0	30 sec	Irritation of nose and throat
24,000	20.0	1-2 min	Sneezing
60,000- 120,000	50-100	5-10 min	May cause very serious damage

Taken from Patterson, et al., (1976) and Hollowell, (1978).

Although many researchers have concluded that formaldehyde causes irritation of the eyes and upper respiratory tract, the reported concentrations at which irritation begins are different. Investigations of occupational exposures at a dress shop (Bourne and Seferian, 1959), a paper processing plant (Morrill, 1966), and a funeral home (Kerfoot and Mooney, 1975) reported eye irritation occurred at 0.13 - 0.45 ppm, 0.9 - 1.6 ppm, and 0.25 - 1.39 ppm respectively. It has been reported by Roth and Swenson (1957) that for most people the irritant threshold of formaldehyde is between 0.25 ppm and 5.0 ppm with considerable individual variation.

The lowest concentration of formaldehyde that has been reported to cause eye irritation in humans is 0.01 ppm (Shuck et al, 1966). The conclusions of their controlled exposures study include the following statement;

"The linear relationship between reported eye irritation and formaldehyde concentration in simulated atmosphere experiments does not hold when the formaldehyde concentration is below 0.3 parts per million (ppm). Subjects may experience equal irritation at irritant concentrations differing by an order of magnitude. Thus most subjects experienced the same irritation intensity at 0.05 ppm formaldehyde as they did at 0.5 ppm. At irritant concentrations less than 0.3 ppm, the rate of blinking determines to an important extent the intensity of eye irritation which the subject detects. The eyes of human subjects can readily detect and react to as little as 0.01 ppm formaldehyde." (p. 575)

In another controlled exposure study, Weber-Tschopp, et al, 1977) exposed two groups of subjects to formaldehyde. In the first group, 33 subjects were continually exposed to formaldehyde for 37 minutes. The formaldehyde concentration rose from 0.03 to 3.2 ppm. The second group of subjects was subjected to five different formaldehyde concentrations for 1.5 minutes

per exposure level. The second group of subjects was allowed to recover for eight minutes in a well ventilated room. At the lowest exposure level, 0.03 ppm, the responses of subjects were similar to their responses in control air. Significant changes started to appear in the test subjects at 1.2 ppm. The authors concluded that "under our experimental conditions the average irritation threshold for pure HCHO [formaldehyde] lies in the range of 1 to 2 ppm." At the same exposure level, the subjects continually exposed to formaldehyde had greater eye irritation, while the subjects that had the discontinuous exposure had greater nose and throat irritation. "It appears as if the nose and throat are capable of a certain adaptation, whereas the eyes become more sensitive through the course of the experiment." (Weber-Tschopp, 1977)

In a study performed by Ib Andersen (1978), 16 healthy young adults were exposed to 0.25, 0.41, 0.82, and 1.64 ppm for five hours/day for four consecutive days. While no significant changes in pulmonary function were observed, a reduction in the nasal mucous flow of the upper third of the nose was found at all exposure levels except 0.82 ppm.

In addition, numerous researchers and regulatory agencies have accumulated information from persons with specific symptoms which they associated with varying airborne concentrations of formaldehyde in their residences.

During the February 5, 1980 hearing held by the U.S. Consumer Product Safety Commission (CPSC) in Minneapolis, the Wisconsin Department of Health and Social Services presented information

about their investigations of formaldehyde in residences. To date, the majority of complaints in Wisconsin have come from occupants of mobile homes. The mean formaldehyde level in 65 complaint mobile homes was 0.66 parts per million. In 65 randomly selected mobile homes (no complaints) the mean formaldehyde level was 0.24 ppm. The most common symptoms reported by occupants of the complaint mobile homes were eye irritation, burning eyes, dry or sore throat, headache, cough, difficulty sleeping, diarrhea, nausea, and breathing difficulties. "Of these symptoms in mobile home residents, the only ones that can be statistically correlated to formaldehyde on a dose response basis with any degree of significance are: eye irritation, $P = .0606$; runny nose or nasal irritation, $P = .0426$; and burning or stinging eyes, $P = .0011$. Approaching statistical significance are diarrhea, $P = .1178$ and wheezing, $P = .1313$." (Testimony of Mary Ann Woodbury, CPSC Hearing Transcript, Feb. 5, 1980).

In 1977 the Connecticut State Department of Health Services began investigating health complaints related to urea formaldehyde foam insulation (UFFI) (Sardinas et al, 1979). The formaldehyde concentrations in the 69 homes that were investigated by Connecticut ranged from 0 to 10.0 ppm. The reported symptoms included eye irritation, sore throats, coughing, nausea, stomach aches, dizziness, headaches, skin rash, and fatigue.

The Department of Environmental Health of the University of Washington has been investigating complaints of formaldehyde exposures for several years (Breysse, 1981). The Department has investigated complaints in 400 mobile homes and 200 conven-

tional homes. The data from 334 mobile homes have been reviewed and the formaldehyde levels ranged from 0.03 to 1.77 ppm. Irritation of the eyes and upper respiratory system, chronic colds, headaches, coughing, drowsiness, and nausea were the most commonly reported symptoms. Residents of conventional homes with UFFI had similar symptoms, but the levels of formaldehyde in these homes were lower than the levels in mobile homes.

Table 2 summarizes a number of studies of human exposure to low levels of formaldehyde in various settings.

Animal Carcinogenicity/Mutagenicity

Evidence for the carcinogenicity of formaldehyde in animals has been reported. Preliminary data from an ongoing inhalation study of rats and mice, sponsored by the Chemical Industry Institute of Toxicology (CIIT), indicated that for exposures of 15 ppm for 6 hours/day, 5 days/week for 16 months, formaldehyde is carcinogenic in rats (Swenberg, 1980). After 24 months' exposure, rats exposed to 6 ppm and mice exposed to 15 ppm had developed nasal cancer. (CIIT, 1980).

A recent report of the New York University (NYU), Institute of Environmental Medicine supports the CIIT evidence of formaldehyde being a carcinogen in experimental animals. (Nelson, 1979)

While humans and animals may differ in their susceptibility to specific chemical compounds, any substance that produces cancer in experimental animals should be considered a cancer risk to humans. (NIOSH, 1980) Formaldehyde has also demonstrated mutagenic activity in several test systems. (Auerbach, 1977)

TABLE 2

SELECTED HUMAN EXPOSURE STUDIES:
 Ranges of low-level formaldehyde concentrations
 giving adverse effects

<u>ppm</u>	<u>Effects</u>	<u>Type of Exposure</u>	<u>Reference</u>
0.01-10	Diarrhea, eye and upper-respiratory tract irritations, headache, nausea, vomiting, stomach cramps.	Residential	CPSC 1980 Wisconsin Health Dept. 1981; Breysse 1981; Sardinas et al., 1979; Garry et al., 1980
0.09-5.6	Burning of eye and nose, sneezing, coughing, and headaches. 3 out of 7 suffered from asthma or sinus problems.	Occupational	Kerfoot and Mooney, 1975
0.3-2.7 Avg. 0.68 Median 0.4	Annoying odor, constant pricking of mucous membranes, disturbed sleep, thirst, heavy tearing.	Occupational	Shipkowitz, 1968
0.13-0.45	Burning and stinging of eyes, nose and throat; headaches.	Occupational	Bourne et al., 1959
0.83 ppm (about)	Loss of olfactory sense, increased upper respiratory disease, subatropic and hypertropic alterations in nose and throat ciliostasis of nasal mucosa, increase absorptive function of nasal mucosa.	Occupational (greater than 5 years to less than 10 years)	Yefremov, 1970
0.9-1.6	Itching eyes, dry and sore throat, disturbed sleep, unusual thirst upon awakening in the morning.	Occupational	Morrill, 1961
0.9-2.7	Tearing of eyes, irritation of nose and throat.	Occupational	Blejer et al., 1966
?	Chronic airway obstruction, respiratory tract and eye irritation, small decrease in pulmonary function during workday and workweek.	Occupational	Schoenberg and Mitchell, 1975
1.3-3.8	Menstrual disorders, pregnancy complications, low birth weight of offspring.	Occupational	Shumilina, 1975
4 or less	Inflammation, reactions of upper respiratory tract, chronic bronchitis, conjunctivitis and skin changes.	Occupational (average 7 years)	Kratochvil, 1971
0.25-1.64	Eye irritation, dryness of the nose and throat, and reduced nasal mucus flow.	Experimental	Andersen, 1979

Although a substance cannot as yet be designated a potential carcinogen based solely on the results of mutagenicity tests, positive results in mutagenicity tests should be used as supporting evidence for identifying a potential carcinogen.

Minnesota Department of Health History:

Late in 1978, the Minnesota Department of Health (MDH) began to receive many complaints from individuals regarding health effects being attributed to formaldehyde in residential environments. (cf. Garry, et al 1980) At that time the capability of private laboratories for testing for formaldehyde in air was very scarce and the test was prohibitively expensive. The MDH environmental analytical laboratory which had been analyzing formaldehyde in occupational settings began to test complainants' homes, as a diagnostic aide to physicians, in the spring of 1979.

Results of MDH Sampling:

From February, 1979 through September 30, 1981, the MDH had sampled approximately 1,000 homes. The results of this sampling effort are summarized in Table 3.

The data in Table 3 indicate that higher levels of formaldehyde are being measured in newer homes (less than 24 months old) than in older homes. This conclusion applies to both mobile and conventionally built homes. The types of symptoms which complainants reported resemble very closely those which have been reported by the State of Wisconsin (1980) and by Breysse (1981). Although symptom information was collected from occupants of homes measured for formaldehyde in Minnesota, no attempt

Table 3

Levels of Formaldehyde Measured in Minnesota Homes***

Type of Construction

	Mobile Home		Conventional Construction*			
	≤24 mos.	>24 mos.	urea formaldehyde foam insulated		Other source of formaldehyde**	
			≤24 Mos.	>24 mos.	≤24 mos.	>24 mos.
average of levels in all homes measured	0.70 ppm	0.25 ppm	0.21 ppm	0.08 ppm	0.32 ppm	0.09 ppm
range of levels measured	0-4.58 ppm	0-1.62 ppm	0-6.89 ppm	0-0.33 ppm	0-2.89 ppm	0-1.0 ppm
number of homes in sample	229	207	87	61	104	280
number of homes with the average level of formal- dehyde ≤0.4 ppm	71	169	78	61	81	276
number of homes with the average level of formal- dehyde >0.4 ppm	158	38	9	0	23	4
*includes single and multiple family residences, such as apartment buildings and townhouses **includes remodeling ***all measurements made using the NIOSH chromotropic acid method (NIOSH, 1977)						

was made to correlate symptoms with levels measured.

Regulatory Efforts in Minnesota.

A 1980 Minnesota law required the Commissioner of Health to determine if a significant health problem is presented by the use of building materials that emit formaldehyde gases. In addition, the law required that if the Commissioner determined that such a problem existed, he should promulgate rules establishing standards governing the sale of building materials and housing units that contain products made with urea formaldehyde. Minn. Stat. § 144.495 (1980). The law took effect on April 23, 1980.

Soon after passage of the 1980 law, the MDH conducted an extensive review of the relevant medical and technical literature. In addition, the MDH had been doing some field sampling of newly constructed housing units which did not contain any identifiable formaldehyde-emitting sources other than the building materials themselves. In a few newer residences the levels of formaldehyde measured exceeded the Occupational Safety and Health Administration (OSHA) level of 3.0 ppm for occupational settings. Measurements made in residences which had been insulated with urea formaldehyde foam within the preceding 24 months also produced similar results. The results of these measurements, the numbers of complaints and types of symptoms being reported by physicians, along with information gleaned from the literature review led to the conclusion that certain building materials emit considerable quantities of formaldehyde into the ambient air of residential units.

In March of 1980, the National Academy of Sciences' Committee on Toxicology issued a Report on Formaldehyde (NAS, 1980) at the request of the Consumer Product Safety Commission. The Committee reviewed studies which investigated the effects of formaldehyde on humans and animals. The Report concluded that ... "there is no evidence of a population threshold for the irritant effects of formaldehyde in humans." The Committee further stated ... "[t]he preliminary results of an ongoing carcinogenicity study in rodents, the uncertainty about the variability of responses to formaldehyde in normal populations and hypersensitive groups, and the current inadequacy of data (which leave unresolved the no-observed-effect dose in humans) all point to the advisability of maintaining formaldehyde at the lowest practical concentration to minimize adverse effects on public health." (NAS, 1980, p.17). The Report also showed that a majority of the population suffered some health effects at levels in excess of 0.5 ppm.

In the course of its sampling program, the MDH had been finding levels in excess of 0.5 ppm with significant frequency. After having reviewed the Department's own sampling information, along with that contained in the NAS Report and particularly that Report's recommendation that formaldehyde should be kept at the lowest practical level, the Commissioner of Health concluded that the use of building materials which emit formaldehyde presents a significant health problem.

On May 22, 1980, the Commissioner of Health made that determination, and issued a statement to that effect in the form

of a press release. A copy of the press release is attached as Appendix A.

The 1980 law also authorized the Commissioner to adopt temporary rules. A temporary rule, setting a maximum permissible ambient level of 0.5 ppm of formaldehyde was formally proposed and published in the State Register, June 23, 1980 (4 S.R. 1963). According to the provisions of the Administrative Procedures Act (Minn. Stat., ch. 15 (1980)) comments were invited and received by the agency. Based on the comments received, the rule was revised and finally approved by the Attorney General. Although the rule was to take effect on December 15, 1980, the rule was never enforced because a temporary restraining order barring its enforcement was issued on December 8, 1980 in Hennepin District Court (File No. 773142).

The Department did not appeal issuance of the temporary restraining order in anticipation of the fact that the Legislature might amend the law in the 1981 session. One of the authors of the 1980 law proposed an author's amendment prescribing a maximum ambient level of 0.1 parts of formaldehyde per million parts of air (ppm). The proposed amendment was tabled in the House. The Legislature did amend the 1980 law to specifically exempt "non-cellular insulation" from inclusion within the definition of building materials. (Laws of 1981, chapter 245, section 1, subd. 1a). Since the 1980 law was not changed in terms of requiring the adoption of permanent rules governing the sale of building materials and housing units which contain materials made with urea formaldehyde, the Department has developed and

now proposes for adoption a permanent rule relating to formaldehyde. (6 SR 667, Oct. 19, 1981).

A preproposal draft of the permanent rule was sent to interested persons for comment in May, 1981. The MDH received approximately fifty comments, all of which will be entered into the permanent rule record.

Regulation of Formaldehyde Outside of Minnesota

Much attention has been paid by various governmental agencies at both the federal and state levels in the U.S. and abroad, with regard to the need to reduce human exposure to formaldehyde.

At the federal level, the U.S. Consumer Product Safety Commission (CPSC) has been interested in health effects associated with formaldehyde exposure since 1976. The Commission has taken the regulatory initiative by proposing a ban on the installation of urea formaldehyde foam insulation. (46 Fed. Reg. 11188, Feb. 5, 1981) This proposal was made after the Commission had held numerous public hearings in 1980 and had sought comments from several governmental and private organizations with expertise in environmental health. As of September 30, 1981, no further action had been taken by the Commission.

The U.S. Department of Housing and Urban Development (HUD) is responsible for setting manufactured housing standards, which include construction techniques to minimize infiltration of outside air into mobile homes. That agency has recently invited the public to comment on a number of issues associated with formaldehyde in mobile homes, including the feasibility of adopting maximum formaldehyde emission standards for materials used in

the construction of mobile homes. (46 Fed. Reg. 43466, Aug. 28, 1981).

The U.S. EPA has been reviewing the whole area of indoor air pollution for several years (Kitchens, 1976), and has worked with the U.S. Department of Energy to help set minimum ventilation standards (for energy conservation purposes) which would prevent the hazardous accumulation of indoor air pollutants. Other agencies which have demonstrated an interest in formaldehyde as it relates to human health are: Department of Health and Human Services (National Institute for Occupational Safety and Health--NIOSH), (Centers for Disease Control-- CDC), and the Department of Commerce (National Bureau of Standards).

At the state level, a variety of regulatory schemes have been undertaken. Table 4 summarizes some of the more extensive regulatory programs which have been proposed or are in effect as of September 1, 1981.

Several foreign countries have attempted to regulate levels of formaldehyde in residential environments by various means. See Table 5.

Discussion of Permanent Rule as Proposed

7 MCAR § 1.448. A. Scope. This portion of the rule describes the applicability of the rule and summarizes the significant impacts of the rule. The rule seeks to regulate the sale of housing units by setting a maximum permissible ambient level of formaldehyde in a housing unit to be sold in the state. Applicability of the rule is being restricted to newly constructed housing units because that is the type of housing in which higher

TABLE 4

State Regulatory Activities Regarding Formaldehyde
as of October 15, 1981

State	Activity	Details	Source
California	Ban in effect	State rule declares UFFI is unsafe for use as insulation. Effective September 22, 1981 the sale or installation of UFFI is prohibited. Requires warning prior to UFFI installation in those cases which are exempt from ban.	California Energy Commission Regulations for Insulating Materials, adopted December 6, 1978, as amended March 25, 1981.
16	Proposed Legislation	Bill states that the Legislature finds that UFFI "has caused significant problems to consumers in California due to the product's propensity to shrink after installation, emit odors, and induce sensitization to formaldehyde." Bill also affirms existing authority of California Energy Commission to regulate UFFI.	Assembly Bill #103, as amended by Senate, September 10, 1981.
Colorado	Ban in effect	State rule bans use of UFFI in state - licensed buildings	Rules and Regulations released by Dr. Frank Taylor, Executive Director, Colorado Dept. of Health 9/30/80; and <u>Professional Remodeling Monthly</u> , November, 1980.
	Warning in effect	Rule requires a warning statement on UFFI installation contract for all other buildings.	
Connecticut	Ban in effect	State Law bans the installation of UFFI, effective July 1, 1981.	Public Act, No. 81-250
		(table continues on next page)	

TABLE 4 (con't.)

State	Activity	Details	Source
District of Columbia	Proposed ban	Decision to ban UFFI is pending before D.C. Council.	Memo to R. Younger from L. Soffer 6/12/81.
Massachusetts	Ban in effect	Regulations adopted by the Massachusetts Dept. of Public Health ban the installation of UFFI, effective November 14, 1979, and require removal by installer if homeowner's health is impaired.	Regulations concerning Hazardous Substances 105 CMR 650.
Minnesota 17	Warning in effect Proposed Standard	State Law requires that written warning be given prior to the sale of building materials and sale or lease of housing units containing urea formaldehyde. The warning is required after January 1, 1981. Proposed rule would ban the sale of new residential units with formaldehyde levels exceeding 0.4 ppm.	Minn. Stat. §325 F. 18 (1980) Minnesota State Register, October 19, 1981.
New York	Warning in effect	State Law requires written notice to be given to purchaser of UFFI or the owner of a building in which UFFI is installed.	New York Times, May 25, 1980
Washington	Local ban in effect	Seattle Housing Authority banned use of UFFI in low-cost housing.	Seattle Post - Intelliger, February 19, 1981.
Wisconsin	Standard in effect	State rule establishes 0.4 ppm as the maximum ambient air concentration of formaldehyde in mobile homes built after Oct. 1, 1981.	Wisconsin Administrative Code March, 1981, Chapter Ind. 14.

Table 5

Recommended or Promulgated Regulations
for Formaldehyde in Foreign Countries

<u>Country</u>	<u>Regulation</u>	<u>Reference</u>
Canada	Temporary Ban of Urea Formaldehyde foam insulation	December 17, 1980 news release of Canadian Ministry of Health and Welfare
Sweden, National Board of Health and Welfare	<u>Recommend</u> : 0.1 ppm for new housing 0.4-0.7 ppm for existing housing; <0.4 no action required even if symptoms are present; 0.4-0.7 action only if symptoms present; >0.7 unacceptable, action required even if no symptoms.	"Formaldehyde Indoor Air Standards in Sweden" presented at CPSC Technical Workshop on Formaldehyde April 9-11, 1980.
Denmark, Danish Building Research Institute	Recommend 0.12 ppm	Andersen, <u>Indoor Climate</u> (1979)
Netherlands, Ministers of Housing and Health	Recommend 0.10 ppm	Ibid.
West Germany, Federal Health Office	Recommend 0.10 ppm	Ibid.
Czecho- slovakia	Recommend .08 ppm	Health Aspects related to Indoor Air Quality - Report on a WHO Working Group April 3-6, 1979

levels of formaldehyde are to be found and from which the public health needs to be protected.

BUILDING MATERIALS

With regard to the sale of building materials the rule addresses only UFFI. The retention of heat is one among many purposes for which a building is constructed. To the extent that insulation enhances the heat retention properties of a building, it is considered to be a building material. The law defines building materials to include insulation. (Laws 1981, ch. 245§1, subd. 1.a).

Because there are no generally accepted product standards for the other products containing urea formaldehyde which are commonly used in housing construction (i.e., particleboard, plywood and paneling) there is no currently implementable means of regulating the sale of these materials, short of prohibiting their sale outright. The statute did not provide for the imposition of such a blanket prohibition on sales of all building materials which contain urea formaldehyde. However, the buyer of building materials is not completely without protection since the law does provide that a warning must be given whenever any materials containing urea formaldehyde are sold in the state. In the warning which must be given, the buyer of these materials is made aware that the materials he is purchasing may pose a health problem. He has the opportunity at the time of purchase to select a different kind of material, one which does not contain formaldehyde and which might have fewer health risks associated with its use in a home.

There are two other reasons why the rule addresses only formaldehyde foam insulation (UFFI) under building materials. They are the following: the amount of formaldehyde emitted into the ambient air after the installation of UFFI can be measured. No comparable method has yet been developed for measuring the amount of formaldehyde emitted by individual products such as a length of particleboard shelving or a sheet of plywood paneling. The matter of the need for product standards will be addressed at length at p. 21. A second reason for including UFFI within the scope of the rule is the fact that whole-house installations of this insulation can result in significant and measurable levels of formaldehyde in the ambient air. The Department arrived at this conclusion after having followed up on many complaints from residents who claimed to have developed a number of health problems after foam insulation had been installed in their homes. The fact that the U.S. Consumer Product Safety Commission has proposed a ban and that several states (Table 4) and Canada have adopted a ban on UFFI supported the position that UFFI should be regulated.

MAXIMUM AMBIENT LEVEL

Once the Commissioner of Health had made the determination required by the 1980 law, the MDH had to decide how it could proceed to regulate the sale of housing units constructed of materials which contain urea formaldehyde.

Having considered all of the regulatory schemes in use elsewhere, and having eliminated those which were not considered implementable, the MDH chose to impose a maximum ambient level,

as is done in Wisconsin and in industrial settings under OSHA jurisdiction. The only decision remaining to be made had to do with selection of a level.

The rule establishes a maximum permissible ambient air level for both newly constructed housing units and for installations of UFFI. Support for adopting the ambient level is derived from a number of sources and includes levels currently in use in both the U.S. and Europe and recommendations from a number of organizations and individuals.

Numerous industry spokesmen have argued repeatedly that the ambient air level was not a reasonable means by which to regulate human exposure to formaldehyde. Instead, these commentators have urged that the State adopt product standards. The proposed State rule might have included a requirement that before a building material could be sold in Minnesota, it would have to be accompanied by a certification from some independent testing body that assures that the material does not emit more than a certain quantity of formaldehyde. Representatives of the plywood and particleboard manufacturing industries have brought to our attention a number of proposed product standards. These are still in the process of being developed and reviewed prior to their being adopted by the representative associations of these various industries. As of September 30, 1981, there are no standards governing formaldehyde emissions for materials used in the construction of housing units, which have the approval of any governmental or impartial standard setting organization in the United States.

A number of different materials such as plywood and particle-board go into the construction of a housing unit, whether it is a conventional housing unit or a mobile home. Each of these materials can give off formaldehyde at different rates and for different periods of time after construction of a housing unit. Reliance upon a standard which governs only one of those materials would not have any impact on the rate of off-gassing of the other materials and therefore would not provide sufficient protection to occupants. Therefore, the use of a standard for only one of the component building materials could not be substituted for a maximum ambient air level. Only when there is a product standard for every building material which is a significant formaldehyde emitter, could the State consider allowing such standards to be substituted for the ambient level.

The purpose of this rule is to protect the health of the public by reducing the level of formaldehyde to which they are exposed. In the absence of other available regulatory means, the proposed rule seeks to limit that exposure by focusing on the healthfulness of the air as it is inhaled by the occupant of the housing unit.

7MCAR Section 1.488 B. Definitions. Certain salient terms which are used throughout the rule have been defined for the purpose of specifying exactly what those terms mean and how they are used in the rule.

1. The term "building materials" is given the meaning prescribed in the law, which reads as follows: "... any urea formaldehyde-containing material used in the construction or

insulation of a housing unit, but does not include: (1) draperies, carpeting, furniture and furnishings not normally permanently affixed to a housing unit; and (2) non-cellular insulation." (Laws 1981, chap. 245 §1). Since the Legislature adopted this definition, it is appropriate that the rule definition be consistent with that contained in the statute.

2. The term "commissioner" is defined so as to specify the meaning of the term when used through the rule, and in order to allow the use of just a single word rather than the complete phrase "commissioner of health" every time the term appears.

3. "Newly constructed" is defined because it is one of the more significant criteria by which applicability of the rule is to be determined. The definition contained herein has been written so as to clarify what the term means and how it is intended to be used. Since this definition equates "newly constructed" with the criterion that a unit has not been previously occupied, the seller of the unit need not be concerned that the level of formaldehyde in the unit has been elevated by any occupant's life style and/or furnishings. Thus the seller is sure that whatever level of formaldehyde is measured in the unit prior to sale is that which is truly attributable to the building materials only.

The second portion of the definition which relates to completion of construction more than 30 days after the effective date of the rule was added so that building contractors or manufacturers of housing units are less likely to be caught with great numbers of housing units which are just about ready for

sale, which may not be able to meet the level prescribed in the rule. Building contractors and sellers will have, in a sense, a 30-day grace period before the ambient level applies to a unit which they are attempting to sell. Within that 30-day period they would be able to make any corrections or any retrofitting that might be necessary to bring the unit within the prescribed levels by the time of sale. Many of the comments received by the Department questioned why there was not a minimum amount of time prescribed after construction but before testing. The Department did not feel that it was necessary or even helpful to specify such a minimum amount of time. The seller could use (to his advantage) whatever interval of time he thought was necessary in order for excessive quantities of formaldehyde in the unit to be off-gassed and ventilated to the outside. The lack of further restrictions within the definition gives the seller a considerable amount of flexibility while still assuring that the ultimate buyer of the unit will be protected within the terms of the rule.

4. The term "housing unit" is not defined in the law. It was necessary to specify the scope of the rule in such a way as to carry out the intent of the law, and the definition given in the rule serves that purpose. Since the health problems associated with exposure to formaldehyde are likely to be made more severe by prolonged exposure to high levels of formaldehyde, the Department felt that it was appropriate to define the term "housing unit" to include units which are intended for long-term human habitation, but to exclude places where persons are

usually only in transit, such as hotels and recreational vehicles. The remainder of the first sentence enumerates those types of housing units which the Department felt should be included within the definition of the term, in order to provide protection to the vast majority of the population.

Persons residing in health care facilities should be covered by the provision of the rule because in many instances those persons, i.e., the old or the disabled, are confined in these facilities for the remainder of their lives. By this criterion, these long-term care facilities are equivalent to residences. To the extent that these people are ill and disabled, they in particular, require protection from exposure to health endangering environmental factors such as formaldehyde.

7 MCAR § 1.448 C. Most of the recommended or promulgated residential air quality standards for formaldehyde are in the range of 0.1 to 0.5 ppm. (cf. Table 5). Table 6 lists the levels which apply in the U.S.

Table 6

Recommended or Promulgated Levels for Formaldehyde
in Residential Environments in the U.S.

<u>Responsible Authority</u>	<u>Level (ppm)</u>	<u>Applicability</u>
State of Wisconsin	0.4 (in effect)	mobile homes
CPSC - Health Sciences	0.1 (recommended)	all residential housing
ASHRAE Ventilation standard (1980 draft)	0.1 (recommended)	all residential housing
NAS (1972)	0.1 (recommended for 90 days and 6 months)	spacecraft

In the rule being considered for adoption the MDH is proposing a maximum ambient level of 0.4 ppm. There is a considerable body of reliable information from both scientific and medical experts to warrant adoption of this level.

The MDH had proposed a level of 0.5 ppm for the temporary rule which was due to take effect on Dec. 15, 1980. At that time, there was no such residential level in effect anywhere in the U.S. The Commissioner determined then that a level of 0.5 was justifiable and supportable, based on the information contained in the NAS Report (1980). When the temporary rule was proposed in June, 1980, the affected industries had only had a few months' notice (since passage of the legislation) in which to prepare themselves for any changes in manufacturing or materials' purchasing procedures. When the rule was proposed it was not known whether or not mobile home manufacturers would have difficulty in achieving that level for units sold in Minnesota.

By now, approximately 18 months have elapsed since passage of the original law. Much information has been exchanged between the Department and representatives of various industries both in writing and through meetings. The industries which would be affected by the rule have had abundant notice that a maximum level of 0.4 ppm would be proposed by the MDH.

During the CPSC formaldehyde hearings held in Minneapolis on February 5 and 6, 1980, several physicians made statements about health effects caused by formaldehyde and the level(s) at which the effects occurred.

Hugh Westgate, M.D., a physician in private practice in Minneapolis, testified that the maximum level any human should be exposed to in a home is 0.3 ppm, and that a baby should not be kept in a home with exposure levels greater than 0.1 ppm. (CPSC Hearing Transcript)

Steven Lamm, M.D., testified at both the CPSC hearing and the Wisconsin Department of Industry, Labor, and Human Relations (DILHR) hearing held later in February, 1980. At that time, Dr. Lamm was employed by Tabershaw Occupational Medicine Associates and was testifying at the request of the Formaldehyde Institute. During the CPSC hearing Dr. Lamm stated "We prepared a report for the Rapco Foam [urea formaldehyde insulation] people in which we recommend to them that they should attempt to keep exposures below 0.5 parts per million." Later during the question period Dr. Lamm was asked about the recommended level for formaldehyde exposure. Dr. Lamm replied, "This [0.5 ppm] has been our recommendation for over a year." (Transcript, CPSC Hearing, Feb. 5, 1980) Tabershaw had made the same recommendation to the Formaldehyde Institute in January, 1979. His testimony before the Wisconsin DILHR on February 18, 1980 was similar, and he ended his testimony at this hearing by concluding:

1. No significant health hazard to the general public appears to exist from residential formaldehyde exposures of less than 1 ppm.
2. An interim standard of 0.5 ppm formaldehyde is an appropriate residential indoor standard to protect the vast majority from risks of any health hazard from formaldehyde exposure.

3. Analysis of the available data on recently reported residential cases do not alter this conclusion. (Transcript, Wisconsin Department of Industry, Labor and Human Relations Hearing, Feb. 18, 1980)

The National Academy of Sciences (NAS, 1980) Report also commented on the health effects associated with exposure to various levels of formaldehyde. Table 7 is taken from the NAS Report. This table represents,

"... the Committee's best judgement as to a range of irritation responses associated with exposure to various concentrations of formaldehyde... Although the extent of irritancy has not been investigated in controlled human studies at concentrations below 0.25 ppm, the Committee expects that less than 20 percent of an exposed human population would react to such formaldehyde exposure with slight irritation of the eyes, nose, and throat and possibly a slight decrease in nasal-mucus flow. As yet there is no evidence of a population threshold for the irritant effects of formaldehyde in humans." (NAS, 1980, p. 17)

The Report summarized the Committee's best judgement as to how humans will react to various levels of formaldehyde. Below the level of 0.5 ppm, 20 percent of the population experiences slight to mild irritation. Above 0.5 ppm, the Committee believes that over 30 percent of the population would experience slight to mild irritation and 10 to 20 percent of the population would have mild to moderate irritation. The level of 0.5 ppm separates slight irritation from moderate irritation.

The American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc. (ASHRAE) has standards for natural and mechanical ventilation in buildings (ASHRAE, 1973). The purpose of the ASHRAE standards is to define "... ventilation requirements for spaces intended for human occupancy and specifies minimum and recommended ventilation air quantities for the pre-

TABLE 7**

PREDICTED IRRITATION RESPONSES OF HUMANS
EXPOSED TO AIRBORNE FORMALDEHYDE

<u>Concentration, ppm</u>	<u>% of Population Giving Indicated Response</u>	<u>Degree of Irritation*</u>
1.5-3.0	20	7-10
	>30	5-7
0.5-1.5	10-20	5-7
	>30	3-5
0.25-0.5	20	3-5
<0.25	<20	1-3

*Irritation Index (scale derived from clinical effects noted in the literature).

10 - Strong eye, nose, and throat irritation; great discomfort; strong odor.

7 - Moderate eye, nose, and throat irritation; discomfort.

5 - Mild eye, nose, and throat irritation; mild discomfort.

3 - Slight eye, nose, and throat irritation; slight discomfort.

1 - Minimal eye, nose, and throat irritation; minimal discomfort.

0 - No effects.

**This table is labelled Table 5 in the National Academy of Sciences Report, (1980).

servation of the occupants' health, safety, and well-being." According to Section 3.3 of ASHRAE's standards "Air shall be considered unacceptable for ventilation use in accordance with this standard if it contains any contaminant in a concentration greater than one-tenth the Threshold Limit Value (TLV) currently accepted by the American Conference of Governmental Industrial Hygienists" (ACGIH). The ACGIH recommended TLV was 3 ppm until early 1981 when it was reduced to 2 ppm. (ACGIH, 1981). In a recent draft revision of the ASHRAE standards, the recommended guideline for formaldehyde exposure indoors is 0.10 ppm (ASHRAE, Table 4, 1980).

As noted earlier, the only existing level for residential units in the U.S. is the 0.4 ppm level which applies to mobile homes, as approved by the Wisconsin legislature in 1981.

The only other level currently enforced is the the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA) standard for formaldehyde which requires an 8-hour time-weighted average (TWA) concentration limit of 3 ppm, a ceiling concentration of 5 ppm for one hour, and an acceptable maximum peak above the ceiling concentration of 10 ppm for no more than a total of 30 minutes during an 8-hour shift. (29 C.F.R. §1910.1000(b)) The OSHA level took effect in 1975.

In 1976, NIOSH recommended, based upon the irritant effects of formaldehyde, that employee exposure to formaldehyde in the occupational environment be controlled to a concentration no greater than 1.2 milligrams per cubic meter of air (1 ppm) for

any 30-minute sampling period. The carcinogenic potential of formaldehyde was not known at that time, and therefore was not considered in developing the recommendations. (NIOSH, 1980.)

The American Conference of Governmental Industrial Hygienists has recommended that the 8-hour time weighted average be reduced from 3 ppm to 2 ppm. (ACGIH, 1981)

When deriving from occupational standards maximum exposure levels which are intended to apply to the population at large, there is a generally accepted public health rule that the occupational level should be reduced by a significant factor. According to the Minnesota and U.S. Industrial Hygiene Field Operations Manual (revised 4-30-81) Cumulative Toxicity Standards, the equivalent permissible exposure level would be 0.71 ppm, (based on the following calculation and using the 8-hour permissible exposure level of 3.0 ppm:

$$3.0 \text{ ppm} \times \frac{40 \text{ hours (work week)}}{168 \text{ hours (total hours in 1 week)}} = 0.71$$

Using the ACGIH recommended level of 2.0 ppm, 8-hour permissible exposure level, the same calculation would yield a level of .476 ppm for continuous exposure.

Occupational standards are generally derived from epidemiological or other studies of workers who, on the average range in age from 18-65 and who are healthier than the general population. (Calabrese, 1978a, chapter 10) This "healthy worker effect" would argue strongly in favor of a level considerably lower than 1.0 ppm for a population which contains infants and a significant proportion of elderly persons. Both of these groups experi-

ence breathing difficulties at a rate greater than that of the general population and require protection from respiratory system irritants. This view is supported by a number of researchers who have recently reviewed the relevant literature. (Lippmann et al., 1979; Calabrese, 1978a, 1978b)

A glance at Table 7, taken from the 1980 NAS report, indicates that adoption of a level of 0.4 ppm would provide considerable protection from the more severe irritation effects of formaldehyde to about 80% of the population.

Achievability

The level of 0.4 is achievable in newly constructed housing and with some installations of urea formaldehyde foam insulation. These assertions are based on a variety of sources. With regard to mobile homes, one Wisconsin manufacturer which produces at least 25% of the units sold in Minnesota has assured us that the units sold by their company can comply with the proposed level. (personal communication, from Wick Systems, Inc., 1980) With regard to builders of conventional housing units, little information has been made available to this department as to whether or not they could meet the 0.4 ppm level with ease. Certain builders have argued that their units posed no problem. The number of complaints received from owners of new conventional housing units is considerably smaller than the number from mobile home owners. This would tend to support the builders' assertions. If conventional home builders cannot manufacture units which emit less than .4 ppm, then they will have the choice of 1) ventilating a unit until the level is less than 0.4 ppm, 2)

sealing the exposed surfaces of the high-emitting materials or replacing them altogether, or 3) constructing the unit from materials which are known to be low formaldehyde emitters. (Hardwood Plywood Manufacturers Association, 1979). As for installations of UFFI, those industry spokesmen who have commented on our earlier proposal have informed us that such installations do not pose a problem when the components are properly mixed.

The 0.4 ppm maximum ambient level being proposed by the MDH is a reasonable level because it provides a necessary degree of health protection to the vast majority of the public, it is achievable through use of currently available technology and it is within the reliable range of measurement by the NIOSH chromotropic acid method which is one of the more commonly used methods for analysis for formaldehyde.

Based on all of the foregoing information, the maximum ambient indoor concentration of 0.4 ppm which the MDH is proposing is a reasonable level to be imposed at this time.

7MCAR Section 1.488.D. Test Method. The test method which is prescribed in the rule is taken from the National Institute for Occupational Safety and Health Manual of Analytical Methods, because this method is one which is widely used both in the occupational setting where tests for ambient formaldehyde are routinely made, and in research settings where scientists are looking at the effects of formaldehyde or are actually experimenting with development of new methods. The method has been available for several years and because numerous researchers and analytical chemists are familiar with it, the method has

gained wide acceptability in terms of reliability and accuracy. Other analytical methods were reviewed but none of them seem to have the same degree of acceptability as the NIOSH method does. In paragraph D.2., the rule provides for the opportunity to use a different test method. The Department recognized that if and when an alternate method should come into general use, one which, as prescribed in the rule, has the same precision, reliability and accuracy as the NIOSH method, that a seller should be permitted to rely on results obtained with the use of the alternate method. Since the Department is not concerned with the method per se but rather with the results which are obtainable with that method, we are willing to accept the fact that there may be other methods being developed which could have advantages over the NIOSH method and which should therefore be allowed.

Some have argued that outdoor levels of formaldehyde can cause an artificial elevation of the indoor levels if they are measured according to the procedure contained in the proposed rule. The U.S. EPA did some monitoring for total aldehydes at various locations in and around the City of St. Paul, Minnesota in 1975. The highest 24-hour average reading for the months of January through June, for each of four different sampling sites was .017 ppm, .014 ppm, .024 ppm and .014 ppm. Even assuming that the levels measured were composed entirely of formaldehyde (which they are not), the MDH does not believe, based on these monitoring results, that outdoor levels would contribute measurement variation which is significantly beyond that which is inherent in the method itself.

7MCAR Section 1.488. E. Testing Conditions. This part and the following part F of the rule prescribe the conditions under which a test for formaldehyde is to be carried out. The reader will note that the rule states "Whenever the level of formaldehyde is to be measured ...". The rule does not require that a measurement be made prior to the sale of a housing unit. The rule merely prescribes the conditions to be met if and when a test is to be done. The lack of an absolute requirement that every unit be measured prior to sale allows the builder or manufacturer to develop and rely upon a quality assurance program which could eliminate the need to test every unit.

It is necessary to standardize those conditions under which a test must be done in order to assure that results of tests which are made to assure compliance with the rule are comparable. There are several variables which can affect the level which is to be measured. Therefore it is necessary to specify how those variables are to be controlled in order to assure that the level which is reported can be compared to measurements made in other units and has the same meaning to each person who attempts to interpret it. Because the rate at which formaldehyde off-gasses is so dependent upon temperature, rate of ventilation, and humidity conditions within an enclosed space, it is appropriate that the conditions prescribed for the test be roughly comparable to those conditions under which a human occupant will be exposed.

Temperature and Humidity. The rule specifies that the testing has to be done within an indoor temperature range which

is generally comfortable for humans. The temperature range prescribed in the rule is on the higher end of the scale of temperatures currently used in Minnesota. The range was purposely chosen to allow for the taking of samples under summer conditions when the temperature is higher and formaldehyde off-gassing is enhanced. Since formaldehyde off-gasses at a much slower rate at lower temperatures, it is conceivable that measurements made when the temperature is only 50° would show the level to be much lower; however, since most people don't tend to keep their housing units at a temperature of 50°, it is important to have the measurement made somewhere in the range of normally accepted comfortable temperatures. The temperature range is also one which can be readily achieved at the manufacturing site. This is of particular concern to manufacturers of mobile homes where these units are constructed in enclosed buildings when the indoor working temperature may be as low as 70° in the winter time. On the other end of the scale there may be a few days during the summer when the working temperature might exceed 85° but it is likely that those days would be very few in number. The rule provides for the measurement to be made at ambient relative humidity conditions because achieving a specific level of humidity might be difficult during the very cold and dry winter months, when the humidity level would have to be artificially increased before the test is made. The conversion formula prescribed in the rule has been used reliably by a number of industry laboratories. It has also been prescribed for use in the Wisconsin rule.

Ventilation. In subpart E.2. the rule prescribes requirements for ventilation of the unit, the rate at which such ventilation shall take place and the amount of time during which the unit must be ventilated before the test air sample can be taken. As noted above, the rate of ventilation (measured in number of air changes per hour) within the housing unit can affect the measured amount of formaldehyde in a living unit. For this reason it is necessary to standardize the ventilation conditions under which a test air sample is to be collected. Construction techniques in current use result in the production of housing units which have rates of ventilation (exchange of indoor and outdoor air) which are many times lower than were achievable a few years ago. It is now not uncommon for a housing unit which is constructed for purposes of heat conservation, to have a ventilation rate which is in the range of 0.5 to 1.5 air exchanges per hour. Indeed there is a U.S. HUD standard for mobile home construction which says that a unit must be ..."constructed to limit air infiltration to the living area of home.... The goal of the infiltration control criteria is to reduce heat loss/heat gain due to infiltration as much as possible without impinging on health and comfort and within the limits of reasonable economics." (24 CFR 3280.505) Since the proposed rule addresses newly constructed housing units, the rule must also take into account the ventilation rates at which these units are intended to be occupied. Therefore the rule specifies a ventilation rate for test purposes which is within the range of the rates currently achievable for housing

units. Since the purpose of the test is to approximate living conditions to which occupants would be exposed over the long term, it is appropriate to prescribe that a ventilation rate within the range of rates possible during occupancy is the one under which the test sample will be taken. The rule requires that prior to testing, the unit be ventilated at a specified rate for a two-hour period, during which all interior doors, cabinets, closets and doors are open. This allows for maximum air exchange between surfaces which may be off-gassing formaldehyde and the ambient air. Then the rule requires that the same rate be maintained during a period when all exterior doors and windows are closed. This allows for equilibration of the off-gassing of formaldehyde with the air in the unit. At the end of the two-hour equilibration period, the test air sample(s) can be collected. The amount measured in those samples should be representative of the amount of formaldehyde present in the unit when it is maintained at that ventilation rate. Some will argue that all of the windows should be open, others argue that all of the windows should be closed. To the extent that the test is intended to measure a level of formaldehyde which might be present under normal habitable conditions, it is necessary to prescribe what we view as being those normal habitable conditions. The windows and doors are not normally open except on hot summer days. These amount to no more than three months of the year. That means that for the remaining nine months the windows and doors are probably closed except when people are entering or leaving the unit. Therefore it is appropriate

to make the measurement under conditions which are comparable to the way the unit is maintained during that nine-month period. This portion of the rule requires that all non-vented gas appliances be shut off and that smoking not be allowed. Both of these activities are known to generate measurable quantities of formaldehyde which could accumulate in the unit during the two-hour period. This accumulation would result in the measurement of a falsely high level which is composed of formaldehyde from two sources: building materials and smoking or the burning of gas. The prohibitions imposed in this portion of the rule help to assure that that level of formaldehyde which is measured is truly attributable to the building materials.

In subpart E.2.d., the rule also allows for a heat exchange device to be operated when the unit is being equilibrated prior to taking the test sample, because such a device would probably be operated under normal living conditions in the unit. Since for test purposes we are attempting to duplicate the conditions under which the unit is normally maintained, it is appropriate that this device be in operation when the test sample is taken.

Sampling. Subpart E.3 prescribes the location in a room where the sample will be taken. The first sentence specifies the minimum locations from which air test samples must be taken. If the contractor or seller has a reliable quality assurance program, it ought not be necessary to measure every single unit and the rule does not require that he do so. The rule does require that if a unit is to be measured, air in both the kitchen and one bedroom must be measured. This provision specifying

rooms to be sampled was added because many sellers asked where the sample should be taken. Experience has shown that the highest concentration of formaldehyde can be found inside closed kitchen cabinets. This might favor a requirement that the test sample be taken inside the cabinets. However, the person who spends the most amount of time in the kitchen does not spend that time inside the closed cabinet but probably spends more of the time somewhat closer to the middle of the room, or is exposed to conditions which more closely resemble those which would be present in the middle of the room. Therefore it is appropriate that the sample should be taken at a point which is representative of the conditions the occupant will usually encounter. Again the purpose of prescribing this condition is to assure that results of tests taken in different rooms can be compared with each other. The test sample is to be taken at a height of 3.5 to 4 feet above the floor to assure that the sample is being collected at that height at which many of the occupants in the house would be exposed. A test sample taken up near the ceiling or down close to the floor where very few of the occupants are inhaling would not be representative of the conditions most of the occupants would be experiencing.

7MCAR, Section 1.488.F. This part of the rule prescribes testing conditions which must be used when measurements are being made in association with the installation of UFFI. Since the rule provides that the level of .4 parts per million cannot be exceeded, both pre-and post-installation tests must be made. The requirement that the level of .4 parts per million not be

exceeded suggests that: 1) the installer has to be reasonably confident that his method of installation will not cause the ambient level of formaldehyde in the housing unit to exceed .4 parts per million, 2) and further, that there may be housing units in which the existing level of formaldehyde is close enough to .4 parts per million that UFFI should not be installed.

Industry spokesmen insist that the only installations of UFFI which cause health problems (and/or levels of formaldehyde well in excess of .4 parts per million) are those which have been made improperly, or where the materials were not properly mixed. In view of this assertions and the fact that the level of formaldehyde being off-gassed is largely within the control of the installer, it should be possible to continue to install urea formaldehyde foam insulation in housing units in Minnesota.

Under subpart 1, the rule requires that a pre-installation measurement be made no more than two weeks prior to installation and that post-installation measurement be made within 30 days after installation. These time limits are imposed to assure that the climatic conditions (temperature, humidity) will be roughly comparable before and after installation so that the measurements will represent the actual amount of formaldehyde present without any influence from altered climatic conditions. The rule must prescribe a time limit after installation within which the post-installation measurement must be made. Without such a time limit it would be possible for the installer to postpone making the measurement until some date long after installation when much of the formaldehyde would have off-gassed.

Because this rule is concerned with minimizing exposure to high levels of formaldehyde, we feel that the 30-day limit is a reasonable accommodation which: 1) allows for an initial off-gassing, and 2) allows for a minimum exposure interval for the occupants of the household. It also allows for the installer to be able to select a date for retesting at the convenience of the consumer, and one on which the climatic conditions are as similar as possible to those which existed when the pre-installation test was made.

Since the rule limits itself to urea formaldehyde emitted by building materials, the Department thought that it was reasonable to require that other urea formaldehyde containing materials, which are not building materials, should be removed from the housing unit before a test sample is taken. The items which must be removed are listed in the rule and include those which have been brought to our attention as being significant formaldehyde emitters when they are relatively new.

Under subpart 3, the rule provides that air samples should be taken in those rooms which are closest to the walls or ceiling where the urea formaldehyde insulation has been installed. The levels of ambient formaldehyde in the rooms closest to those portions of the housing unit where the insulation is installed will be higher than the levels of formaldehyde in rooms which are farther removed from the insulated portions. Since the purpose of the rule is to minimize exposure to formaldehyde, it is proper that the measurements be made in those rooms which are closest to the installation where we know that the levels

will be highest. Again for the purpose of making results comparable, the rule requires that the post-installation measurements be made in the same rooms as those which were tested prior to installation.

7MCAR Section 1.488.G. This portion of the rule sets an effective date which is 30 days after the date which would be dictated by the State Administrative Procedures Act. The Department felt that it was appropriate to postpone the effective date for at least this amount of time in order to allow the housing construction industry to become cognizant of the fact that the rule is now in effect. This one-month delay will also allow the industry some time in which to change its construction practices, and set up testing facilities or make arrangements for testing through private testing laboratories. It is the Department's position that a postponement of the effective date, such as is being proposed here, would be reasonable for the purposes explained above. Another reason why this time interval is appropriate is that it allows a person who is contemplating buying a new housing unit to be able to defer his or her decision for a relatively short time after which he can purchase a housing unit which he knows has to be in compliance with the rule.

Each of the provisions in the proposed rule has been discussed in terms of its need. Either it is based on statutory requirements or it is necessary in order to provide consistency within the rule itself. The rule is reasonable in that it is the product of considerable deliberation as to the merits and

implementability of a variety of means for satisfying the legislative purpose.

Oct. 26, 1981.

References

American Conference of Governmental Industrial Hygienist, (1981) Threshold Limit Values for Chemical Substances and Physical Agents in the Workroom Environment With Intended Changes for 1981, ACGIH, Cincinnati, Ohio.

American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., (1973) ASHRAE Standard 62-73, Standards for Natural and Mechanical Ventilation, New York.

American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., (1980) Ventilation for Acceptable Indoor Air Quality, Draft Revision, Nov. 15, 1980.

Andersen, I., (1979) Formaldehyde in Indoor Environment -Health Implications and the Setting of Standards, in Indoor Climate - Proc. First Int. Indoor climate Symp., Copenhagen, Denmark: Danish Building Research Institute.

Auerbach, C., M. Mautschen - Damen, and J. Mautschen, (1977) Genetic and Cytogenetical Effects of Formaldehyde and Related Compounds, Mutat. Res., 39:317-361

Blejer, H.P., and B.H. Miller, (1966) Occupational Health Report of Formaldehyde Concentrations and Effects on Workers at the Bayly Manufacturing Company, Visalia, California Department of Public Health Study Report No. S-1806, April 5, 1966.

Bourne and Seferian (1959) Formaldehyde in Wrinkle-Proof Apparel Produces Tears for Milady. Ind. Med. Surg. 28:232-33.

Breysse, P.A. (1981) The Health Cost of 'Tight' Homes, Journal of the American Medical Assoc., 245 No. 3:267-268.

Calabrese, E.J., (1978a) Methodological Approaches to Deriving Environmental and Occupational Health Standards, J. Wiley, New York.

Calabrese, E.J., (1978b) Pollutants and High-Risk Groups, J. Wiley, New York.

Chemical Industry Institute of Toxicology 1980 Annual Report and Scientific Review, CIIT, Research Triangle Park, North Carolina.

Community Air Quality Committee of the American Industrial Hygiene Association, (1968) Community Air Quality Guide -Aldehydes, American Industrial Hygiene Association Journal 29:505-512.

- Garry, V.F., L. Oatman, R. Pleus, and D. Gray, (1980) Formaldehyde in the Home Some Environmental Disease Perspectives, Minnesota Medicine, 63:107-111.
- Hardwood Plywood Manufacturers Association, (HPMA) (1979) Reduction of Low Concentrations of Formaldehyde in Mobile Homes, Draft, September 4, 1979.
- Hollowell C.D., (1978) Formaldehyde in the Indoor Environment, Lawrence Berkeley Laboratory, Berkeley, California, September 25, 1978.
- Kerfoot, E.J., Mooney T.F., (1975) Formaldehyde and Paraformaldehyde Study in Funeral Homes, Am. Ind. Hyg. Assoc. J. 36, 533-537.
- Kratochvil, I. (1971). The effect of formaldehyde on the health of workers employed in the production of crease resistant ready made dresses. Pr. Lck. 23:376-75.
- Kitchens, J.F., R.E. Casner, G.S. Edwards, W.E. Harward and B.J. Macri, 1976. Investigation of Selected Potential Environmental Contaminants: Formaldehyde, U.S. Environmental Protection Agency, Pub. -EPA-560/2-76-009. Washington, D.C., U.S. Government Printing Office.
- Lippmann, M., and R.B. Schlesinger, (1979) Chemical Contamination in the Human Environment, Oxford University Press, New York.
- Minnesota Department of Labor and Industry Occupational Safety and Health Division, (1980) Industrial Hygiene Field Operations Manual, revised April 30, 1981, page XIII-3.
- Morrill, E.E., (1961) Formaldehyde Exposure from Paper Process Solved by Air Sampling and Current Studies, Air Cond. Heat. Vent. 53:94-95.
- National Academy of Sciences, National Research Council Committee on Toxicology, (March, 1980) Formaldehyde -An Assessment of Its Health Effects.
- National Academy of Sciences, (1972) Atmospheric Contaminants in Spacecraft, Report of the Panel on Air Quality in Manned Spacecraft, Committee on Toxicology, Table 1, June, 1972.
- National Institute for Occupational Safety and Health (NIOSH), (1980) Formaldehyde: Evidence of Carcinogenicity, Current Intelligence Bulletin 34, December 23, 1980, Dept. of Health and Human Services, DHHS (NIOSH), Publication #81-111, NIOSH, Cincinnati, Ohio.
- National Institute for Occupational Safety and Health (NIOSH), (1977) Formaldehyde in Air - Analytical Method, NIOSH Manual of Analytical Methods 2nd Edition, 1 125-1 - 125-9.

National Institute for Occupational Safety and Health (NIOSH), (1976) Criteria for a Recommended Standard, Occupational Exposure to Formaldehyde, DHEW (NIOSH) Publication No. 77-126, U.S. Government Printing Office, Washington, D.C.

Nelson, N., (1979) Written Communication to National Institute for Occupational Safety and Health, Rockville, Maryland, October 19, 1979.

Patterson, R.M., M.I. Bornstein, and E. Garshick, (1976) Assessment of Formaldehyde As A Potential Air Pollution Problem, Volume VIII, Prepared under contract to U.S. Environmental Protection Agency, January, 1976.

Roth and Swenson, Physiological Studies of Irritant Aspects of Atmospheric Pollution, Report to Los Angeles County Air Pollution Control District, Los Angeles, Calif., (Dec., 1957), as reported in Community Air Quality Committee of the American Industrial Hygiene Association, (1968).

Sardinas, A.V., R.S. Most, M.A. Giulietti, and P. Honchar, (1979) Health Effects Associated with Urea Formaldehyde Foam Insulation in Connecticut, Journal of Environmental Health, 41, No. 5:270-272. (the levels reported should read "mg/li" and not "ug/li" - personal communication).

Schoenberg, J.B. and Mitchell, C.A. (1975). Airway disease caused by phenolic (phenol-formaldehyde) resin exposure. Arch. Environ. Health 30: 574-77.

Schuck, E.A., Stevens, E.R., and Middleton, J.R., (1966) Eye Irritation Response at Low Concentrations of Irritants Arch. Env. Health 31: 570-575.

Shipkovitz, H.D. (1968) Formaldehyde Vapor Emissions in the Permanent-Press Fabrics Industry, U.S. Dept. of Health, Education, and Welfare, Public Health Service, September, 1968.

Shumilina, A.V. (1975). Menstrual and childbearing functions of female workers exposed to the effects of formaldehyde. Gig. Tr. Prof. Zabol. 12: 18-21.

Stockinger, H.E., and D.L. Coffin; (1968) in Stern, A.C., Air Pollution, 2nd Revised Ed., V.1. pp. 484, Academic Press, N.Y.

Swenberg, J.A., W.D. Kerns, R.I. Mitchell, E.J. Gralla, and K.L. Pavkov, 1980, Induction of Squamous Cell Carcinomas of the Rat Nasal Cavity by Inhalation Exposure to Formaldehyde Vapor, Cancer Research, 40:3398-3402.

U.S. Consumer Product Safety Commission (1980) Memorandum to the Commission from Richard A. Gross, Executive Director, November 18, 1980.

Weber - Tschopp, A., T. Fischer, and E. Grandjean (1977)
Irritating Effects of Formaldehyde (HCHO) on Humans. Int.
Arch. Occup. Environ. Health 39:207-218. (translation courtesy
of Manufactured Housing Institute).

Wisconsin Department of Health and Social Services, (1981)
Irritant Symptomatology, Clinical Observations and Formal-
dehyde Exposure Among Wisconsin Mobile Home Residents,
International Symposium on Indoor Air Pollution, Health
and Energy Conservation (extended summary) Amherst,
Massachusetts, October 13-16, 1981.

Yefremov, G.G. (1970). The state of the upper respiratory
tract in formaldehyde production employees. Zh. Ushn.
Nos. Gorl Bolazn. 30:11-15.

**YOUR
HEALTH**



Appendix A

NEWS RELEASE FROM THE MINNESOTA DEPARTMENT OF HEALTH

May 22, 1980
FOR IMMEDIATE RELEASE

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State Health Commissioner George R. Petterson, M.D., has declared that the use of building materials which give off formaldehyde vapor can be a "significant health problem" under certain circumstances.

In accordance with Minnesota Laws of 1980, Chapter 594, a bill on formaldehyde passed during the last session of the state legislature, Dr. Petterson issued the following statement:

"Persons in newly constructed or remodelled residential environments may be exposed to the formaldehyde gas released from such materials as particle board, plywood, and recently installed foam insulation. We have determined that a significant health problem is presented by the use of building materials that emit formaldehyde gases. This determination is consistent with the recent findings of the committee on Toxicology of the National Academy of Sciences that:

- a. The first level of response to low airborne concentrations of formaldehyde appears to be irritational effects;
- b. Possible revised assessments of health implications need to await the results of ongoing and planned toxicologic studies; and
- c. At present, with all the uncertainties and variabilities of response of humans to low

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airborne concentrations of formaldehyde which are attributable to building materials in residential environments, the formaldehyde should be maintained 'at the lowest practical concentration.'

Resins manufactured with formaldehyde have been used to make building materials for several years, Dr. Pettersen said. Large amounts of the resins are used in products like plywood, particle board, insulation cloth and adhesives, and formaldehyde gases given off by these materials have been blamed for a variety of health problems.

Government officials nationwide report that they have received many complaints about the problem, Dr. Pettersen said. The reported symptoms range from eye and skin irritation to breathing difficulties, nosebleed and nausea.

Dr. Pettersen said that the Minnesota Department of Health investigated complaints about possible formaldehyde exposure in 486 homes during a 15 month period ending April 30. The air inside those homes was found to contain formaldehyde vapor in amounts ranging from undetectable to 3.29 parts per million. After conducting a similar investigation, Wisconsin proposed regulations which would limit levels of formaldehyde vapor inside new mobile homes.

Dr. Pettersen also noted that the Massachusetts Department of Health completely banned the sale of urea formaldehyde foam insulation in that state after holding public hearings on health problems allegedly caused by the insulating materials. The U.S. Consumer Products Safety Commission held a series of public hearings on the possible health effects of formaldehyde after receiving over 1600 complaints about products containing urea formaldehyde. Last December the U.S. Department of Energy proposed standards for making and installing urea formaldehyde foam insulation.

Dr. Pettersen said that, as soon as possible, he plans to issue temporary rules limiting the permissible amount of formaldehyde vapor inside newly constructed dwelling units. These rules will establish a maximum limit of 0.5 parts per million for the air inside these dwelling units.

Permanent rules will be adopted only after the state health department holds public hearings on the formaldehyde issue, sometime later this year. Dr. Pettersen said evidence presented at the hearing may justify provisions in the permanent rules which would gradually lower the permissible level of formaldehyde.