

INTEGRATED MULTIMEDIA
CONTROL ALTERNATIVES

DRAFT Phase I Case Study

FORMALDEHYDE

Contract 68-01-6020

8 June 1981

Abt Associates Inc., Cambridge, Massachusetts

ABT ASSOCIATES INC
55 WHEELER STREET, CAMBRIDGE, MASSACHUSETTS 02138
TELEPHONE • AREA 617 492-7100
TELEX 710-320 1382

INTEGRATED MULTIMEDIA
CONTROL ALTERNATIVES
DRAFT Phase I Case Study

FORMALDEHYDE

Contract 68-01-6020

8 June 1981

Gene E. Fax, Project Director
John Reinhardt, Principal Author

Consultant:
Francis S. Wright, J.D.

Submitted for review to:

Arnold Edelman
Office of Toxics Integration
U.S. Environmental Protection
Agency
Washington, D. C. 20560

 Contract Manager	 Quality Control Reviewer	 Management Reviewer
---	---	--

TABLE OF CONTENTS

6.0	FORMALDEHYDE	1
6.1	Introduction and Findings	1
6.1.1	Introduction	1
6.1.2	Findings: Multimedia Considerations in Rulemaking	2
6.1.3	Findings: Unanticipated Effects of Regulations	3
6.1.4	Findings: Regulatory Gaps	4
6.2	REGULATORY HISTORIES	6
6.2.1	Office of Air Quality Planning and Standards (EPA/OAQPS)	6
6.2.1.1	National Ambient Air Quality Standards	6
6.2.1.2	New Source Performance Standards	6
6.2.2	Office of Mobile Source Air Pollution Control (EPA/OMSAPC)	10
6.2.2.1	Mobile Source Emission Standards	10
6.2.3	Office of Water Regulations and Standards (EPA/OWRS)	14
6.2.3.1	Designation of Hazardous Substances and Reportable Quantities	14
6.2.4	Office of Solid Waste (EPA/OSW)	15
6.2.4.1	Hazardous Waste Management System (EPA/OSW)	15
6.2.5	Office of Pesticide Programs (EPA/OPP)	19
6.2.5.1	Pesticide Tolerances	19
6.2.6	Department of Energy (DOT)	20
6.2.6.1	Residential Conservations Service Program	20

Table of Contents (continued)

6.2.7	Consumer Product Safety Commission (CPSC)	23
6.2.7.1	Hazardous Substances and Articles	23
6.2.7.2	Safety Standards for Certain Types of Home Insulation	23
6.2.8	Food and Drug Administration	32
6.2.8.1	Bureau of Foods	32
6.2.9	Occupational Safety and Health Administration (OSHA)	33
6.2.9.1	Occupational Exposure to Formaldehyde	33
6.2.10	Department of Transportation (DOT)	39
6.2.10.1	Hazardous Materials Regulations	39

APPENDIX

6.0 FORMALDEHYDE

6.1 Introduction and Findings

6.1.1 Introduction

The subject of this case study is the degree to which federal regulatory agencies have taken multimedia effects into account in their rulemaking procedures to control formaldehyde in the environment. Three major issues are the focus of attention:

1. The degree to which each agency during rulemaking, considered the presence of formaldehyde in media other than the one or ones being regulated at the time.
2. Whether regulatory actions aimed at a particular medium had unanticipated effects on releases of formaldehyde into other media.
3. Whether any gaps in regulatory coverage are apparent.

Other issues are also discussed. These include the extent to which particular regulatory efforts acknowledged similar past or ongoing efforts in other agencies; the technical basis for the standards; and the degree to which economic impacts were included in the decision-making. Findings on these subjects will be incorporated into a cross-substance analysis in a later phase of the project.

The scope of the analysis and the sources of information have been described in the introduction to the Lead case study (Section 1.1.1). Also, the general provisions of applicable toxic substance regulations (such as those under RCRA) have already been treated there.

The major reason that formaldehyde was selected for study was CPSC's action to regulate its emission from urea-formaldehyde insulation. While CPSC has played some role in the regulation of the other five substances, that role was not as prominent as was the case with formaldehyde's. Also, formaldehyde was an interesting case study because of its toxic characteristics. Formaldehyde is a well-established acute toxin that causes irritation at very low thresholds. It is a recently established carcinogen but it is not known to cause any long-term health problems otherwise. Lastly, it exists in a variety of media. For instance, while significant amounts of formaldehyde are emitted to the atmosphere in automobile exhaust, formaldehyde's solubility in water transferred it to the hydrologic system through rainfall. Formaldehyde's high volatility is the primary route of inter media transfer.

6.1.2 Findings: Multimedia Considerations in Rulemaking

Exhibit 6.1 shows the major regulatory actions regarding formaldehyde and the interrelationship among them. Two types of connections are shown: technical interactions (dotted arrows) and intermeshing of regulatory provisions (dashed arrows). It should be emphasized that the technical interactions illustrated in the exhibit are those which are evident from the agency documentation for each action: that is, the preambles to the proposed and final rules, and formal background documents such as Environmental Impact Statements, Criteria Documents, etc. Other interactions between programs-- memoranda, meetings, etc.--have not been accessed for this analysis. Therefore, it is likely that more technical interactions took place that are shown. Nevertheless, the formal documentation constitutes the public record of the technical interchange, and this is what the exhibit reflects.

The most obvious focus in Exhibit 6.1 is the proposed ban by the CPSC. This was the only regulatory action that arose directly as a result of federal panel study which established formaldehyde's carcinogenicity (see Reference 4 in Section 6.2.7.2). Most of the other regulations are based primarily on formaldehyde's acute toxicity. A recent NIOSH bulletin acknowledges the federal panel's study (see Section 6.2.9) but NIOSH does not have regulatory authority. The existing threshold limit value set by OSHA in 1971

was established well before the federal panel's report. EPA's OPP and FDA's regulations were also promulgated on the basis of formaldehyde's acute toxicity. Formaldehyde's lack of long-term effects (excluding carcinogenicity) coupled with its volatility has generally allowed agencies to disregard multimedia transfers of the substance. Consequently, Exhibit 6.1 shows relatively few regulatory or technical interactions.

Formaldehyde is not one of EPA's "Priority Pollutants" and, therefore, is not heavily regulated by the OWRS. No effluent limitations, new source performance standards, or pretreatment standards has been issued that control formaldehyde.

In air, formaldehyde is indirectly regulated as a hydrocarbon. OAQPS and OMSAPC regulate hydrocarbons to control levels of photochemical oxidants, not levels of individual hydrocarbons that themselves may be toxic. Thus, these regulatory actions do not interact with other regulations concerned specifically with formaldehyde.

The appearance of DOE on the chart is somewhat of an anomaly. DOE is not primarily concerned with health hazards presented by insulation products. However, its interim final standard for free formaldehyde content is in effect until CPSC's ban becomes effective.

6.1.3 Findings: Unanticipated Effects of Regulations

No major regulatory program has shown a broad interest in regulating formaldehyde. Most regulations deal with a specific instance of contamination. In fact, two major studies have apparently been ignored by regulators. The first was completed in August, 1976 for the Office of Toxic Substances. The report, "Investigation of Selected Potential Environmental Contaminants: Formaldehyde", was done by the Atlantic Research Corporation.* This report stated that automobile exhaust was a major source of formaldehyde and that formaldehyde was formed as a product of photo oxidation of other hydrocarbons emitted by automobiles. The document provides comprehensive coverage to formaldehyde. The following is a list of major chapter headings:

* Atlantic Research Corporation for the Environmental Protection Agency, "Investigation of Selected Potential Environmental Contaminants: Formaldehyde," August, 1976, EPA-560/2-76-009.

- Structure and Properties;
- Environmental Exposure Factors;
- Health and Environmental Effects;
- Toxicity;
- Regulations and Standards.

The only other report to reference this study was another study by the EPA analyzing exposures to formaldehyde inside residences (see Reference 2, Section 6.2.7).

Another study that was not cited in any formaldehyde-related proceedings was titled "Human Exposure to Atmospheric Concentrations of Selected Chemicals (Volumes I and II)".* This study, completed in March, 1980, was commissioned by OAQPS and estimated formaldehyde emissions, population exposure rates and dosages (see Exhibit 6.2). The report did not include auto exhaust emissions, which is a major source of environmental formaldehyde.

A major unanticipated impact of existing regulations is in the medium of air. Formaldehyde is regulated as a component of the hydrocarbon group. However, a reduction in hydrocarbon emissions does not necessarily produce an equivalent reduction in formaldehyde. Problems that arise from hydrocarbon emissions in general are not the same as those that arise from formaldehyde emissions. Therefore, consideration of problems that are intrinsic to formaldehyde were overlooked.

The establishment of formaldehyde's carcinogenicity by the Federal Panel's Report on Formaldehyde (see Reference 4 in Section 6.2.7.2) should generate new interest in the regulatory community.

6.1.4 Findings: Regulatory Gaps

Present regulations concerning formaldehyde are primarily based on formaldehyde's acute toxicity, not its carcinogenicity. No program has comprehensively analyzed the problem of human exposure to formaldehyde. Rather, the regulations to date have addressed specific instances of formaldehyde exposure. These instances are difficult to ignore because of formaldehyde's low irritant threshold.

* SAI International for the Environmental Protection Agency, "Human Exposure to Atmospheric Concentrations of Selected Chemicals (Volume I and II)," March, 1981.

There are no regulations that specifically concern formaldehyde levels in food or drugs. However, the FDA has set tolerances for formaldehyde content in food packaging. Therefore, it might be assumed that formaldehyde is not allowed in foods either.

All air emission regulations indirectly control formaldehyde by controlling hydrocarbons. Therefore specific sources of formaldehyde emissions, such as production facilities for urea resins and phenolic resins, are presently unregulated.

Also, effluent that contains formaldehyde is currently unregulated, except by general effluent guidelines under the Federal Water Pollution Control Act. This could be a large omission in the regulatory net because of formaldehyde's possible persistence in groundwater. However, formaldehyde's persistence in groundwater has not been verified and was only referenced once in the background document for RCRA (see Reference 1 in Section 6.2.4).

Lastly, the workplace standard for formaldehyde under OSHA is very old and does not incorporate the most recent findings on the substance's carcinogenicity.

6.2 REGULATORY HISTORIES

6.2.1 Office of Air Quality Planning and Standards (EPA/OAQPS)

6.2.1.1 National Ambient Air Quality Standards

Current Status of Action

There is no National Ambient Air Quality Standard for Formaldehyde per se. Formaldehyde is indirectly regulated by two NAAQ's, one for ozone and one for hydrocarbons. The first NAAQs allows ambient air concentrations of ozone to exceed 0.12 ppm (235 g/m^3) for not more than the equivalent of one day per year (40 CFR 50.9). One technique for complying with this standard would be to reduce emissions of volatile organic compounds, of which formaldehyde is one. The second NAAQS limits ambient air concentrations of total hydrocarbons to a maximum of 160 mg/m^3 in the 3-hour period, this limit not to be exceeded more than once per year (40 CFR 50.10). Although these standards have an indirect effect on levels of formaldehyde in the air, a review of the Federal Register and the background documentation, particularly the report "Air Quality Criteria for Ozone and Other Photochemical Oxidants" (1), makes it clear that formaldehyde was not a substance of specific concern at the time. We shall therefore not review the regulatory histories of these two standards.

6.2.1.2 New Source Performance Standards

Current Status of Action

There are no New Source Performance Standards that specifically limit formaldehyde emissions. Several stationary sources are being regulated for volatile organic compounds (VOC's), a chemical classification that includes formaldehyde. The two sources that have final standards for VOC's are the following: 1) Vessels for petroleum liquids (40 CFR Part 60 subpart K and Ka) and 2) Automobile and light-duty truck surface coating operations (40 CFR Part 60 Subpart MM). The following three sources of VOC's have proposed standards: 1) Surface Coating for Metal Furniture, 2) Bulk Gasoline Terminals and 3) Industrial Surface Coating: Appliances. The standards for the surface coating sources are expressed in terms of kg of VOC's emitted per liter of surface-coating solids applied. The limitations are as follows:

Surface Coating for Metal Furniture:	.70 kg/l
Surface Coating for Appliances:	.90 kg/l
Surface Coating for Automobiles and Light-Duty Trucks	
- prime coat:	16 kg/l
- guide coat:	1.40 kg/l
- top coat:	1.47 kg/l

The standard for bulk gasoline terminals is .35 mg per liter of gasoline loaded. The standards also include work practices, equipment design features and maintenance requirements.

Multimedia Considerations in the Regulatory History

While formaldehyde is classified as a VOC, the background documentation of the regulations for the five stationary sources above does not specifically mention formaldehyde. VOC is a classification that has replaced the term "non-methane hydrocarbons", which in turn replaced the terms "total hydrocarbons".

The first step by EPA actually to regulate the emission of formaldehyde and other hydrocarbons was the commissioning of a report by Argonne National Laboratory entitled, "Priorities for New Source Performance Standards under the Clean Air Act Amendments of 1977". This study evaluated 163 source categories with respect to their projected emissions of nine pollutant categories, of which hydrocarbons as a class was one. Ninety-three major hydrocarbon emission source categories were evaluated and prioritized. The reasons for controlling hydrocarbons, whether as oxidant precursors or for their own toxicities, were not addressed. No media other than air were considered, and the NAAQS level was assumed to represent an acceptable goal for protection of public health and welfare.

The priority list ranked stationary source categories according to a combination of the following three general criteria: 1) quantity of emissions of the nine criteria pollutants, 2) potential impact on health and welfare and 3) mobility of source category. The nine criteria pollutants include the following: hydrocarbons, nitrogen oxides, particular matter, sulfur dioxide, carbon monoxide, lead, fluorides, acid mist and hydrogen sulfide. The final list gave the synthetic organic chemical manufacturing industry (SOCMI) first priority (44 FR 49225). The EPA stated

that it would use the list to order development of future NSPS's. In another background document for the priority list, the EPA evaluated 27 representative processes of the SOCMIs.

While 600 SOCMi processes were identified, the EPA plans to develop generic standards by analysis of only the selected 27 processes. These standards will regulate most emissions from all SOCMi's. The 27 processes include vinyl acetate plants and phthalic hybriide plants, which emit significant amounts of formaldehyde (2). Consequently, formaldehyde emissions should be regulated in the future. The EPA was aware of the presence of toxic or carcinogenic pollutants in SOCMi processes (44 FR 49224). As a result, the 27 SOCMi processes are being considered for regulation under NESHAPS rather than NSPS. Again, the EPA did not indicate specific concern for formaldehyde emissions.

On 31 August 1978, EPA proposed the addition of 72 major source categories to the list of new stationary sources to be regulated. The list was developed largely on the basis of the Priorities document. The preamble to the final rule (44 FR 49222, 21 August 1979), which confirmed the proposed list, stated that the reason for controlling hydrocarbons (now interpreted to refer specifically to volatile organic compounds) was their contribution to ambient levels of photochemical oxidants. Accordingly, proposed and final standards for the various stationary sources listed above were based on the VOC emissions' contribution to the formation of atmospheric ozone (3). No discussion of individual VOCs' toxic properties was given.

While these regulations may achieve a reduction in formaldehyde emissions, the reduction is based on formaldehyde's membership in the class of VOCs. Consequently, we shall not discuss them in any more depth.

References for Section 6.2.1

1. Argonne Nation Laboratories for Environmental Protection Agency, "Priorities for New Source Performance Standards under the Clean Air Act Amendments of 1977", April 1978.
2. Environmental Protection Agency, "Source Assessment: Non Criteria Pollutant Emissions (1978 update)," July 1978.
3. Environmental Protection Agency, "Air Quality Criteria for Ozone and Other Photochemical Oxidants" (2 vols.), April 1978, EP-600/8-78-004.

6.2.2 Office of Mobile Source Air Pollution Control (EPA/OMSAPC)

6.2.2.1 Mobile Source Emission Standards

The Clean Air Act Amendments of 1977 establish statutory standards that require a minimum reduction in hydrocarbon (HC) emissions of ninety percent by the 1983 model year vehicles (under Section 202 (a)(3)(A)(ii) of the Clean Air Act). The 1969 model year is used as a base for calculating the ninety percent reduction. The emission regulations restrict HC emissions to as low as .8 gm/mile depending on whether the vehicle is diesel, gasoline-fueled, light-duty, heavy-duty, car, or truck, and on what model year the vehicle was produced.

Formaldehyde is an "oxygenated hydrocarbon" that is emitted in automobile exhaust. The regulations restricting hydrocarbon emissions from automobile exhaust therefore, restrict formaldehyde as a component of hydrocarbons.

The EPA regulates hydrocarbons from mobile sources to enable air quality regions to meet their National Ambient Air Quality Standards for ozone and hydrocarbons. Mobile sources of hydrocarbons were considered significant especially in urban areas (see Exhibit 6.2). Hydrocarbons were not regulated because of their direct impacts; rather, they were regulated because they were precursors of photochemical oxidants, such as ozone(1). The process of photochemical oxidation is still not completely understood because of the large number of environmental factors that enter into the process. So, while a reduction in hydrocarbons would affect a reduction in formaldehyde, the reductions would not be directly proportional. Therefore, specific amounts of reductions in formaldehyde could not be predicted from reductions in hydrocarbons.

It was clear, upon examination of the background documentation, that the regulations were not intended to control formaldehyde specifically. No multimedia considerations of formaldehyde was discussed in any of the preambles or supporting documents for mobile source standards (see all references for Section 6.2.2).

EXHIBIT 6

1974 Nationwide Estimates of Hydrocarbon
Source of Emission

(source: Reference 1, pg. 5-29)

Source category	Emissions, 10 ⁶ metric tons/yr	
	1974	1975 (preliminary)
Transportation (total)	(11.3)	(10.6)
Highway	9.8	9.1
Non-highway	1.5	1.5
Stationary fuel combustion (total)	(1.6)	(1.3)
Electric utilities	0.1	0.1
Other	1.5	1.2
Industrial processes (total)	(3.3)	(3.2)
Chemicals	1.6	1.5
Petroleum refining	0.8	0.8
Metals	0.2	0.2
Others	0.7	0.7
Solid waste (total)	(.9)	(.8)
Miscellaneous (total)	(12.7)	(12.2)
Forest wildfires	0.5	0.5
Forest managed burning	0.2	0.2
Agricultural burning	0.1	0.1
Coal refuse burning	0.1	0.1
Structural fires	0	<0.1
Organic solvents	8.1	7.5
Oil and gas production and marketing	3.7	3.8
Total	29.8	28.0

The EPA background documents for the regulations, i.e., the regulatory analysis and environmental impact studies, did not specifically discuss formaldehyde (2, 3, 4, 5). Two other background EPA studies were reviewed and found to have no discussion of formaldehyde, or its impact. The study by Charles Hare, et. al on diesel crankcase emissions merely listed findings of formaldehyde in samples that were taken from various crankcases (6). No impact analysis of these findings was included in the report. The Hare study's finding of formaldehyde was not referenced in later reports. EPA's other background document discussed mobile source emission factors (7). In this document, hydrocarbons were grouped and discussed as a class, without distinguishing formaldehyde.

References for Section 6.2.2

1. Office of Research and Development of the Environmental Protection Agency, "Air Quality Criteria for Ozone and Other Photochemical Oxidants (Vols. I and II)", April, 1978.
2. Office of Mobile Source Air Pollution Control of the Environmental Protection Agency, "Regulatory Analysis and Environmental Impact of Final Emission Regulations for 1984 and Later Model Year Heavy Duty Engines," December, 1979.
3. Office of Mobile Source Air Pollution Control of the Environmental Protection Agency, "Summary of Analysis of Comments to the NPRM: 1983 and later Model Year Heavy-Duty Engines," December, 1979.
4. Office of Mobile Source Air Pollution Control of the Environmental Protection Agency, "Regulatory Analysis and Environmental Impact of Final Emission Regulations for 1984 and Later Model Year Light-Duty Trucks," 20 May 1980.
5. Office of Mobile Source Air Pollution Control of the Environmental Protection Agency, "Summary and Analysis of Comments on the Proposed Rulemaking for Gaseous Emission Regulations for 1983 and Later Model Year Light-Duty Trucks," May, 1980.
6. Charles T. Hare, et. al for Environmental Protection Agency, "Diesel Crankcase Emissions Characterization," September, 1977, EPA/460/3-77/016.
7. Environmental Protection Agency, "Mobile Source Emission Factors," March, 1978, EPA/400/9-78/005.

6.2.3 Office of Water Regulations and Standards (EPA/OWRS)

6.2.3.1 Designation of Hazardous Substances and Reportable Quantities

Current Status of Action

Formaldehyde has been designated as a hazardous substance pursuant to Section 311(b)(2)(A) of the Clean Water Act (40 CFR Part 116.4, Table 116.4A). Under regulations in 40 CFR Part 117, reportable quantities have been established for all hazardous substances identified in 40 CFR Part 116, and any discharge into navigable waters of the United State or adjoining shorelines of a hazardous substance that is equal or in excess of its reportable quantity must be immediately brought to the attention of the Coast Guard (40 CFR 117.21), and subjects the discharger to clean up liability and civil penalties (40 CFR Part 5 117.22-23). The reportable quantity for formaldehyde is 1000 lbs (454 Kg).

Certain types of discharges are excluded from regulation under 40 CFR parts 116 and 117, including those in compliance with permits issued under the Marine Protection, Research and Sanctuaries Act; the Federal Insecticide, Fungicide and Rodenticide Act; the Resource Conservation and Recovery Act and the dredge and fill provisions and NPDES provisions of the Clean Water Act. Under certain circumstances, discharges from a point source in violation of its NPDES permit are also exempted.

Multimedia Considerations in the Regulatory History

The general history of how hazardous substances were designated has been described in the Lead case study (Section 1.2.2.4), and will not be repeated here. Formaldehyde was on the list of hazardous substances in both the proposed rule (40 FR 59960) and the Final Rule (43 FR 10474). These lists were developed based on each substance's aquatic toxicity.

6.2.4 Office of Solid Waste (EPA/OSW)

6.2.4.1 Hazardous Waste Management System (EPA/OSW)

A full discussion of the hazardous waste management system authorized by RCRA has been presented in the Lead case study (Section 1.2.50. It includes a description of the following components 1) identification and listing mechanism for hazardous wastes, 2) standards for generators, 3) standards for transporters, and 4) standards for owners and operators of treatment, storage, and disposal facilities for hazardous waste.

Hazardous wastes containing formaldehyde are subject to regulation under RCRA's Hazardous Waste Management System via three identification and listing routes. The first is through formaldehyde's listing in 40 CFR 261 (Appendix VIII) as a toxic waste constituent. Formaldehyde is also specifically listed for regulations pertaining to discarded commercial chemical products, off-specification species, containers, and spill residues thereof (40 CFR 261.33). Lastly, formaldehyde is designated in four waste streams in the regulation's list of hazardous wastes from specific sources, including the following (40 CFR Part 261.32):

- Distillation bottoms from the production of acetaldehyde from ethylene
- Distillation side cuts from the production of acetaldehyde from ethylene
- Wastewater from the washing and stripping of phorate production
- Wastewater treatment sludge from the production of phorate

Multimedia Considerations

Congress intended the hazardous waste management system under RCRA to have a very broad scope. Consequently, regulations under RCRA are process-oriented rather than pollutant-oriented because of the wide variety of hazardous waste stream constituents in existence.

Formaldehyde qualifies as a hazardous waste individually and as a constituent of certain industrial waste streams. The industrial survey background document (1) analyzed the following two industries that produce wastes containing formaldehyde:

- 1) Acetaldehyde Production
- 2) Phorate Production

The industry profiles in this RCRA background document were very general in nature. Consequently, the two profiles that mentioned formaldehyde can be discussed as if they were one. The background document did not provide production or emission figures, specifically for formaldehyde; formaldehyde discharges were grouped with other organic compounds, (see Exhibit 6.3). The report stated that formaldehyde was acutely toxic and very probably carcinogenic. In support of its description of formaldehyde's toxicity, the EPA cited the CAG's Preliminary Risk Assessment on Formaldehyde and OSHA's TWA limit of 3 ppm. The report noted that the wastes were usually disposed of in deep wells or lagoons and thus presented the potential danger of groundwater contamination. This danger would be greatly aggravated by formaldehyde's high miscibility in water. In addition, the EPA hypothesized that, due to formaldehyde's slow biodegradation, it would be persistent once present in groundwater. But the analysis did not discuss rates of groundwater migration or volatilization. It was also stated that formaldehyde oxidized into formic acid, another toxic substance.

The hazardous waste management system regulations do not mention formaldehyde specifically. However, a few issues that concern the hazardous waste management system as a whole are directly relevant to formaldehyde because it is a volatile organic waste.

The issue of volatile organic wastes was discussed in the preamble to the final interim regulations promulgated May 19, 1980 (45 FR 33066-33588). This discussion outlined the difficulty of developing a definition for volatile wastes as a class of wastes to be regulated separately. The EPA concluded that it would settle on reducing the amount of air emission from hazardous wastes by requiring final covers for landfills and closed waste drum specifications. In a January 12, 1981 preamble, the EPA discussed its strategy to contain volatile emissions from storage facilities (46 FR 2802-2897). The strategy is designed to prevent leakage and overflows of hazardous waste from storage facilities to avoid releases to soil, groundwater, and surface water. This containment strategy is to be followed until

Exhibit 6.3

Uncontrolled Waste Discharge Ratio (4)
(g of discharge per kg of acetaldehyde)

(Source: Reference 1,)

Component	Formula	Distillation Bottoms (Discharge Wastewater)	Distillation Side-Cut	Combined	*>
Ethylene	C ₂ H ₄	-	-	-	
Acetaldehyde	C ₂ H ₄ O	-	7.8	7.8	
Acetic Acid	C ₂ H ₄ O ₂	13.9	0.6	14.5	
Chloroacetaldehyde	C ₂ H ₃ OCl	-	5.5	5.5	
Acetyl chloride	C ₂ H ₃ OCl	4.2	5.0	9.2	
Chloral	C ₂ HOC ₁₃	2.1	3.4	5.5	
Paraldehyde	(C ₂ H ₄ O) ₃	1.6	-	1.6	
Other organics (including chloro- form, formaldehyde and methylene and methyl chloride)		4.0	2.0	6.0	
TOTAL Volatile Organics:		25.8	24.3	50.1	
Water	H ₂ O	795.6	25.5	821.1	
TOTAL STREAM:		821.4	49.8	871.2	

*>These totals are combined because combination of the two waste streams is a known method disposal. (4)

regulations directly addressing the problems of volatile organics are promulgated under phases II and III of the hazardous waste management system. In the discussion of January 12, 1981 EPA noted that the CAA is inappropriate to handle this problem because 1) the CAA is pollutant-specific and consequently too inflexible to encompass the whole problem and 2) the CAA does not regulate emissions from treatment processes and treatment process spills. EPA's containment strategy for volatile organic wastes did not address the unregulated status of air emissions from open surface impoundments, such as lagoons.

References for Section 6.2.4

1. Environmental Protection Agency, "Subtitle C - Background Document For Identification and Listing of Hazardous Wastes: 40 CFR Part 261.31 and 261.32," April, 1980.

6.2.5 Office of Pesticide Programs (EPA/OPP)

6.2.5.1 Pesticide Tolerances

Current Status of Regulatory Actions

Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. sec. 346 a(d)(2), the EPA has exempted paraformaldehyde from the requirement of an acceptable tolerance on sugar beets, when applied to the soil as an insecticide (37 FR 14229). The EPA has also exempted formaldehyde and precursors, methylene bispropionate and oxy (bixmethylene) bispropionate, from the same tolerance requirement in several animal feeds (40 FR 1042). The preambles to each of the above actions were very brief and did not reference specific studies that were considered in developing the final rules. A statement in each preamble noted that the action was sufficient to "protect public health."

6.2.6 Department of Energy (DOE)

6.2.6.1 Residential Conservations Service Program

Current Status of Actions

DOE, under the authority of the National Energy Conservation Act, has issued interim final rules limiting the formaldehyde content of resin used in urea-formaldehyde foam insulation (UFFI) (10 CFR Part 456). The interim final rules limit the free formaldehyde content of resin used in UFFI to 0.5 percent by weight. Further, fresh foam content is limited to 0.3 percent by weight of formaldehyde. These regulations also prescribe product warnings and an educational program to limit potential exposures to formaldehyde. The interim final status is intended to provide the DOE with the flexibility to incorporate changes in the regulation as more complete information becomes available.

The DOE standards for UFFI could be superceded by a ban on its use that has been proposed by CPSC (see section 6.2.7.2). However, DOE's interim final rules are effective on February 24, 1981 and CPSC's proposed ban will not go into effect until December, 1981. The CPSC ban will be in effect by December, 1981 assuming that there are no delays.

Multimedia Considerations in the Regulatory History

CPSC has worked with DOE from the beginning of the development of the DOE regulations. This began with the proposed rule on 21 December 1979. DOE issued the proposed rules controlling formaldehyde emissions from UFFI due to consumer complaints filed with the CPSC. The preamble to the proposed regulations enumerated the three following sources for the off-gassing of formaldehyde during UFFI installation:

- 1) free formaldehyde from the reaction mixture
- 2) paraformaldehyde
- 3) hydrolyzable formaldehyde.

The proposal only directly addressed formaldehyde emissions in a free form from the reaction mixture. Paraformaldehyde was not mentioned again, and hydrolyzable formaldehyde noted only as being unpredictable. The standards for free formaldehyde were reductions of the existing Canadian Standard

51-6P-24M (44 FR 75958). The precise method used to arrive at the reductions were not described. The standards were anticipated to reduce off-gassing of formaldehyde, even though the DOE admitted that the processes affecting the off-gassing were not fully understood. It was stated that off-gassing was affected by many factors such as humidity, temperature, and application technique. DOE proposed regulations also prescribed equipment criteria and manufacturer-sponsored training programs to minimize free formaldehyde exposure.

The interim final rule issued on 25 September 1980 included the same provisions for controlling free formaldehyde as the proposed rules. The preamble to the interim final rule specifically acknowledged that DOE would conform to any legal action that CPSC decided to take. The agency noted in the preamble that CPSC's action concerning UFFI was awaiting completion of the two studies, including the Federal Panel Report (see Reference 4 in Section 6.2.7.2). Consequently, even though the CPSC and EPA objected in written statements to DOE's proposed regulations, the DOE finalized them because the standards did address some of the problems of off-gassing. The DOE's strategy of minimizing exposure to formaldehyde was supported in the final regulation's preamble by a description of the study of formaldehyde's health effects by the National Academy of Sciences (NAS) (see Reference 3 in Section 6.2.7.2).

In addition, the preamble stated that CPSC, EPA and the Federal Trade Commission (FTC) among others strongly objected to DOE's standards. The CPSC's reasons for objecting were as follows:

- "Absence of knowledge regarding tolerable human reaction level to formaldehyde;
- Lack of conclusive evidence of the performance of U-F foam under varying conditions;
- Uncertainty that DOE will address off-gassing problems;
- Potential carcinogenic effects."

The EPA's reasons for objecting were as follows:

- "Potential carcinogenic effects;
- Degradation of U-F foam due to thermal and humidity cycling which cannot be controlled;
- The existence of adequate substitutes for U-F foam."

The FTC's reasons for objecting were as follows:

- "Possible health risks from U-F foam and uncertainties about insulation effectiveness;
- Inclusion of U-F foam could be mistakenly perceived as Federal assurance regarding safety and effectiveness."

DOE noted that there were other entities, such as the National Bureau of Standards, manufacturers and utility companies, that supported DOE's standards. In addition, DOE stated that "it is the responsibility of CPSC to take action to reduce or eliminate risk or injury associated with consumer products such as insulation."

Consequently, even though CPSC and EPA objected in written statements to DOE's proposed regulations, DOE finalized them because the standards did address some of the problems of off-gassing. DOE's strategy of minimizing exposure to formaldehyde was supported in the final regulation's preamble by a description of the study of formaldehyde's health effects by the National Academy of Sciences (NAS) (see Reference 3 in Section 6.2.7.2). The NAS concluded that there was no acceptable level of exposure to formaldehyde that would avoid the substances' irritant characteristics. DOE did not judge as authoritative any existing reports of formaldehyde's carcinogenicity, including the ongoing Chemical Industry Institute of Toxicology (CIIT) study. DOE also reviewed several standards that had been set in European countries; these were considered to be unenforceable because of the difficulty of reliably detecting formaldehyde at very low levels. The European standards restricted formaldehyde emissions to 0.1 ppm to 0.4 ppm. No multimedia effects, exposure estimates, or risk assessments were discussed in the regulation's preamble.

6.2.7 Consumer Product Safety Commission (CPSC)

6.2.7.1 Hazardous Substances and Articles

Current Status of Actions

The CPSC classifies formaldehyde and products containing greater than 1 percent formaldehyde as "strong sensitizers" in 16 CFR Part 1500.13. A "strong sensitizer" is defined in 16 CFR Part 1500.3 as the following: "a substance that produces an allergic sensitization in a substantial number of persons who come in contact with it." This classification is necessary for the CPSC to regulate substances under the Federal Hazardous Substances Act. The classification was recodified to accomplish a transfer of authority from the FDA to CPSC on 27 September 1973. The original classification regulations were published in the Federal Register on 29 April 1961. There is no direct regulatory mechanism triggered by this classification.

6.2.7.2 Safety Standards for Certain Types of Home Insulation

Current Status of Actions

CPSC does not presently regulate Urea-Formaldehyde Foam Insulation (UFFI). However, CPSC has proposed two regulations that control formaldehyde emissions from UFFI. The first, proposed 10 June 1980, requires UFFI manufacturers to warn consumers about the possible adverse health effects associated with the product's formaldehyde emissions (45 FR 39434). The second, more recently proposed, rule of 5 February 1981, is a ban on UFFI's manufacture and sale in the U.S.

Multimedia Considerations in the Regulatory History

In October of 1976, the Metropolitan Denver District Attorney Consumer Office brought CPSC's attention to the health problems associated with UFFI by filing a petition (CP77-1) requesting a safety standard under Section 7 of the Consumer Product Safety Act (15 USC Section 2065). After reviewing available information, in March, 1979 the CPSC deferred regulatory action to enable further investigation into UFFI.

In that same month Battelle completed a three-part study of the formaldehyde industry (1). The first part was a general overview of the industry as a whole. The second part focused on urea-formaldehyde production, and the third part discussed other formaldehyde-containing consumer

products. The report's estimate of formaldehyde production is shown in Exhibit 6.4, Exhibit 6.5 shows formaldehyde consumption by each intermediary product, and Exhibit 6.6 indicates the amount of formaldehyde consumed in the processes producing urea-formaldehyde resins. CPSC commissioned Battelle's study as an initial step in regulating UFFI.

The next step in the process was taken not by CPSC but by EPA, which commissioned a report from the Stanford Research Institute entitled "Population Exposures to Atmospheric Formaldehyde Inside Residences" (2). This study was one of the earliest attempts to assess the risk to formaldehyde exposure. The SRI report estimated exposures using secondary data from the U.S. Census and average inside atmospheric concentrations of formaldehyde from actual sample data. The following sources of formaldehyde were included:

- particle board
- plywood
- fiberboard
- foam insulation
- carpets
- drapery
- combustion processes, e.g., cooking and tobacco smoking

The reports' estimates are shown in Exhibit 6.7 EPA intended the results of the SRI report to be used in a study of formaldehyde being conducted by the National Academy of Science (NAS).

The NAS study utilizing the SRI exposure estimates was released in March, 1980(3). This study, primarily toxicological, reviewed formaldehyde's effects on animals and humans. It stated that formaldehyde was acutely toxic, mutagenic and possibly carcinogenic. While the NAS concluded that "there was no population threshold for the irritant effects of formaldehyde in humans," it was less definitive in assessing chronic effects. The preface strongly recommended review of a 1980 study by the Chemical Industry Institute of Toxicology (CIIT) that had preliminarily found formaldehyde to be carcinogenic in rats.

Exhibit 6.4

U.S. Formaldehyde Production and Capacity: 1960-1980
(Source: reference 6, page 7)

Year	Production ^(a)	Percent Δ	Capacity ^(a)	Capacity Utilization, percent
1960	1,872		2,450	76.4
1965	3,107	66.0	3,480	89.3
1970	4,427	42.5	5,315	83.3
1971	4,522	2.1		
1972	5,652	25.0		
1973	6,424	13.7	7,530	85.3
1974	5,765	-10.3	8,125	71.0
1975	4,558	-20.9	8,385	54.4
1976	5,521	23.3	8,705	64.6
1977	6,081	8.2	8,770	69.3
1978	6,390	5.1	9,010	70.9
1979 ^(b)	6,300	-1.4	9,010	69.9
1980 ^(b)	6,300	0	9,110	69.2

Sources: Chemical Economics Handbook, SRI International.
Chemical Products Synopsis, March, 1978.
Chemical and Engineering News, January 9, 1978.
Chemical Marketing Reporter, March 23, 1978.

(a) Aqueous solution containing 37 percent formaldehyde.

(b) Estimate

Exhibit 6.5
Formaldehyde Consumption for Important
Intermediary Products, 1978
(Source: reference 6, page 10)

Intermediate Products	Formaldehyde Consumed, millions of pounds (a)	Total, percent
Urea Formaldehyde Resins	1,600	25
Phenol-Formaldehyde Resins	1,600	25
Acetal Resins	640	10
Melamine-Formaldehyde Resins	320	5
Pentaerythritol	350	5.5
Trimethylolpropane	70	1
Urea Formaldehyde Concentrates	200	3
Chelating Agents	200	3
1,4-Butanediol	420	6.5
4,4'-Methylenediphenyl Isocyanate	160	2.5
Pyridine Chemicals	80	1.5
Hexamethylenetetramine	180	3
Nitroparaffin Derivatives	20	>0.5
N-Butyl Formcel	300	4.5
Trioxane		
Paraformaldehyde		
Formalin	150	2.5
Disinfectants		
Embalming Fluid		
Textile (100)		
Leather		
Dyes		
Various other materials	100	1.5
Totals	6,390	100.0

Source: Chemical Economics Handbook, SRI International.
Kline Guide to the Chemical Industry-1977.

(a) Aqueous solution containing 37 percent formaldehyde

Exhibit 6.6

Estimated Consumption of Formaldehyde for End-Users
of Urea-Formaldehyde Resins, 1977
(Source: reference 6, page 13)

End Use	Consumption of Formaldehyde, (a) million pounds	Share, percent
Construction Industry	1,050	65.6
Fiberboard and Particleboard		
Laminating	1	
Plywood		
Molding Compounds	80	5.0
Paper Industry	55	3.4
Textile Industry	65	4.1
Protective Coatings	50	3.1
Foam Insulation	100	6.3
Other; unaccounted for, and Export	200	12.5
Total	<u>1,600</u>	<u>100.0</u>

Source: Chemical Economics Handbook, SRI International.

Industry Contacts

Battelle Estimates

(a) Aqueous solution containing 37 percent formaldehyde

Exhibit 6.7

Estimates of Residential Installations of Urea-Formaldehyde Foam Installation

(Source: Reference 2)

<u>Measure of Exposure</u>	<u>Mobile Homes^a</u>	<u>Foam-insulated Conventional Houses</u>	<u>Nonfoam- Insulated Conventional Houses</u>
People exposed (thousands)	9,844	1,001	98,354
Exposure (10 ⁶ person-hr/yr)	56,577	5,773	566,938
Total exposures (10 ⁶ ppm/person-hr/yr)	14,930	2,021	5,700-57,000 ^b
Average inhalation exposure (g/yr/person)	1,200	1,260	36-360

^aBased on the estimation procedure that allows concentration to change with home age.

^bRange of exposures if an average concentration of 0.01 to 0.10 ppm is assumed.

On 10 June 1980, CPSC proposed rules to require manufacturers of UFFI to supply specified performance and technical information to consumers about the possible adverse health effects associated with the formaldehyde emissions that result during and after UFFI installation. CPSC issued this proposed rule because of consumer complaints and existing medical and scientific information (45 FR 39434). The latter included the NAS study of the health effects of formaldehyde, the NOISH criteria document (Reference 1 in Section 6.2.9 and several medical journal articles to illustrate formaldehyde's acute toxicity. The preamble to the June, 1980 regulations stated that formaldehyde's carcinogenicity was not established but required further investigation. The final rule has not been issued because of the overriding consequences of CPSC's next proposed regulation.

On 5 February 1981, CPSC proposed a ban on the use of UFFI in the United States. This ban was proposed pursuant to CPSC's authority under Section 8 of the Consumer Product Safety Act (15 USC section 2057). The major new factors that induced CPSC to issue the proposed ban were the following: 1) 1600 consumer complaints of health-related problems (46 FR 1118) and 2) a federal panel's report on formaldehyde (4). The November, 1980 federal panel report reviewed evidence of the substance's chronic toxicity and concluded that "formaldehyde should be presumed to pose a carcinogenic risk to humans". The panel was convened as a result of the NAS study's recommendation to review the CIIT finding that formaldehyde had induced nasal cancer in laboratory rats at 15 ppm (45 FR 34031). CPSC was not able to determine a level of exposure to formaldehyde that would prevent an unreasonable risk of injury to consumers of UFFI. Therefore, after completing a risk assessment and an economic impact analysis, the agency proposed a total ban on UFFI.

The CPSC-created federal panel of experts issued a report on formaldehyde's chronic toxicity in November 1980 (4). This report reviewed and analyzed data from previous experiments. The Panel's analysis used the multistage prediction model used by the EPA's Carcinogen Assessment Group, and its findings supported the CIIT's experimental findings that formaldehyde was a carcinogen. The panel calculated risk factors on an individual basis, but lacked sufficient exposure data to conduct a complete risk assessment.

CPSC's November, 1980 risk assessment built upon the Federal Panel's risk factors and dose-response curves (5). The agency noted that the animal studies used to derive human risk factors had exposed the animals to doses of formaldehyde similar to those levels of formaldehyde present inside residences. The risk assessment estimated that a maximum of 150 cases of cancer may develop among the 1.75 million persons currently exposed in UFFI houses. This estimate was very speculative and was only used in weighing the benefits and costs of the proposed ban. The risk assessment was specifically focused on UFFI formaldehyde exposures, so that no other sources of formaldehyde were included in the calculations. Also, no considerations of insulation workers' exposure was given.

Also in November of 1980, the CPSC published an economic assessment (6) of the proposed ban. Again, the study was centered on the UFFI industry. The economic assessment discussed costs of the ban in the following areas:

- o UFFI contractors
- o Foregone Energy Savings
- o Availability of Other Insulating Materials
- o Real Estate Values of UFFI - Houses
- o Ensueing Litigation and Remedial Measures

Costs were discounted to present value at a discount rate of ten percent. The magnitude of the problem was estimated through calculation of the number of UFFI installations (see Exhibit 6.8). The only benefit that was compared against the costs was the avoidance of 23 cases of cancer (this figure was derived from CPSC's risk assessment, reference 5). Other benefits of the ban were discussed, but not included in the cost-benefit analysis because of the lack of information. These other benefits included reduction in adverse acute health effects and the avoidance of medical and social costs of the treatment of cancer.

CPSC also documented the environmental impacts of the proposed ban (7). The foregone energy caused by the ban was calculated to cause insignificant environmental impacts. The brief document noted an improvement in indoor ambient air quality. Otherwise, no environmental impacts were expected and consequently CPSC stated that a full environmental impact statement was unnecessary.

Exhibit 6.8

Estimates of Residential Installation of UF Foam Insulation *

(Source: Reference 5, page 2)

	1975	1976	1977	1978	1979	1980	total
Battelle estimates	-	60,000	170,000	125,000	150,000	-	
Tim and Smith estimates	30,000	52,000	221,000	103,000	-	-	
HICP estimates based on NAUFIM board feet data							
low	-	41,000	145,000	68,000	69,000	-	
high	-	52,000	181,000	85,000	86,000	-	
HICP estimates based on installations of a major company	-	-	-	-	60,000 to 70,000	60,000 to 80,000	
Range of estimates	30,000	41,000 to 60,000	145,000 to 221,000	68,000 to 125,000	60,000 to 150,000	60,000 to 80,000	404,000 to 666,000
Mean of estimates	30,000	51,000	179,000	95,000	87,000	70,000	512,000
"Best" estimates	30,000	48,000	170,000	80,000	71,000	75,000	474,000

* Source: CPSC, Division of Economic Program Analysis, November, 1980

References for Section 6.2.7

1. Battelle for Consumer Product Safety Commission, "Product/Industry Profile and Related Analysis for Formaldehyde and Formaldehyde-Containing Consumer Products: Parts I and II," 5 February, 1979.
2. SRI International For Environmental Protection Agency, "Population Exposures to Atmospheric Formaldehyde Inside Residences - Final Report," January, 1980.
3. National Academy of Science for Consumer Product Safety Commission, "Formaldehyde - An Assessment of Its Health Effects," March, 1980.
4. R.A. Griesemo, A.G. Ulsamer, et al., "Report of the Federal Panel on Formaldehyde," November, 1980.
5. Murray S. Cohn of Consumer Product Safety Commission, "Risk Assessment For Formaldehyde Released From Urea-Formaldehyde Foam," 18 November, 1980.
6. Charles Smith of Economic Analysis Division of Consumer Product Safety Commission, "Urea Formaldehyde Foam Insulation: Preliminary Economic Assessment of a Ban on Sales," November, 1980.
7. Charles Smith of Economic Analysis Division of Consumer Product Safety Commission, "Revised Environmental Assessment of a Ban of Sales of UF Foam Insulation," January, 1981.

6.2.8 Food and Drug Administration

6.2.8.1 Bureau of Foods

Current Status of Actions

The FDA prescribes procedures for the safe usage of formaldehyde in certain animal feeds (21 CFR Part 573.460) pursuant to the Federal, Food, Drug & Cosmetic Act, 21 U.S.C. sec. 348(b)(5). In addition, the FDA restricts the addition of formaldehyde in the production of food for human consumption. Specifically, the FDA regulates the use of formaldehyde in the following categories of indirect food additives:

1. Adhesive coatings and components
2. paper and paperboard
3. polymers
4. adjuvants, production aids and sanitizers

These regulations do not designate specific numerical tolerances; rather, they prescribe procedures to minimize contamination of food for human consumption.

Multimedia Considerations in the Regulatory History

All the regulations, except for the procedures pertaining to animal feeds, were promulgated prior to 1970. The preamble to the proposed rule referenced an environment impact analysis that concluded that the regulations would have no significant environmental impact (40 FR 58485). The final rule's brief preamble made no reference to environmental or health impacts (41 FR 9543).

Interviews with persons at FDA indicated that they were not very concerned with the hazards presented by formaldehyde because inhalation was considered to be the major route of exposure to cause cancer. These people felt that their concern would increase if future evidence showed formaldehyde to be carcinogenic through percutaneous absorption.

The FDA stated that they were aware of CPCC's regulatory actions and were giving them close scrutiny.

6.2.9 Occupational Safety and Health Administration (OSHA)

6.2.9.1 Occupational Exposure to Formaldehyde

Current Status of Actions

OSHA limits the concentration of formaldehyde in workplace air to an eight-hour time-weighted average concentration of 3 ppm and a ceiling concentration of 5 ppm. Excursions above 5 ppm may not total more than 30 minutes in length per day, and may never exceed 10 ppm. (Table Z-2, 29 CFR 1910.1000). This limit was derived from the Threshold Limit Values specified by the American National Standards Institute (ANSI) in 1967. No independent rule-making has been initiated by OSHA.

Multimedia Considerations in the Regulatory History

The Occupational Safety and Health Act, which became effective on 28 April 1971, required the Secretary of Labor to adopt as mandatory any national consensus standard or any established Federal standard relating to employee health and safety (Section 6(a)). Within a month, OSHA had adopted the Threshold Limit Values for airborne contaminants which ANSI, a private standard-setting organization, had published in 1967 (36 FR 10466). TLVs were specified for formaldehyde as described above. The TLV was based on formaldehyde's properties as a skin and respiratory irritant.

In 1976, the National Institute of Occupational Safety and Health (NIOSH) issued a Criteria Document for occupational exposure to formaldehyde (1). The recommended standard limited workplace concentrations to a maximum of 1 ppm (1.2 mg/m³). This recommendation was also based on protection of workers (except for sensitized workers) from the irritating effects of formaldehyde, of which many examples were cited from the literature. No estimate of numbers of exposed employees was provided, and no multimedia issues were mentioned.

In November of 1980, OSHA received a report from the Federal Panel on Formaldehyde (2), which had been convened to consider the implications of experimental evidence showing formaldehyde to cause cancer in animals. Of the many studies referenced in the report, only one was judged to

CPSC's November, 1980 risk assessment built upon the Federal Panel's risk factors and dose-response curves (5). The agency noted that the animal studies used to derive human risk factors had exposed the animals to doses of formaldehyde similar to those levels of formaldehyde present inside residences. The risk assessment estimated that a maximum of 150 cases of cancer may develop among the 1.75 million persons currently exposed in UFFI houses. This estimate was very speculative and was only used in weighing the benefits and costs of the proposed ban. The risk assessment was specifically focused on UFFI formaldehyde exposures, so that no other sources of formaldehyde were included in the calculations. Also, no considerations of insulation workers' exposure was given.

Also in November of 1980, the CPSC published an economic assessment (6) of the proposed ban. Again, the study was centered on the UFFI industry. The economic assessment discussed costs of the ban in the following areas:

- UFFI contractors
- Foregone Energy Savings
- Availability of Other Insulating Materials
- Real Estate Values of UFFI - Houses
- Ensueing Litigation and Remedial Measures

Costs were discounted to present value at a discount rate of ten percent. The magnitude of the problem was estimated through calculation of the number of UFFI installations (see Exhibit 6.8). The only benefit that was compared against the costs was the avoidance of 23 cases of cancer (this figure was derived from CPSC's risk assessment, reference 5). Other benefits of the ban were discussed, but not included in the cost-benefit analysis because of the lack of information. These other benefits included reduction in adverse acute health effects and the avoidance of medical and social costs of the treatment of cancer.

CPSC also documented the environmental impacts of the proposed ban (7). The foregone energy caused by the ban was calculated to cause insignificant environmental impacts. The brief document noted an improvement in indoor ambient air quality. Otherwise, no environmental impacts were expected and consequently CPSC stated that a full environmental impact statement was unnecessary.

demonstrate formaldehyde's carcinogenicity unequivocally. Swenberg, et al.*, in a study sponsored by the Chemical Industry Institute of Toxicology, found a 20% incidence rate of a rare form of nasal cancer in rats killed after 18 months exposure to 15 ppm of formaldehyde vapors. Other studies, inconclusive in themselves, were cited in support of these findings, and to indicate that the chemical may be linked to cancers in other species and at other sites as well. The panel concluded that formaldehyde should be considered to pose a carcinogenic risk to humans. Laboratory evidence for teratogenicity and mutagenicity was reviewed by the panel, but was found to be inadequate to support conclusions on human risk. Epidemiological studies revealed many formaldehyde-related illnesses, mostly irritative in nature but also including menstrual and reproductive disorders, sexual dysfunction, and possibly cancer. But the general lack of appropriate controls or environmental measurements in these studies made it difficult to pinpoint formaldehyde as the causative agent. The questions of formaldehyde's presence in the environment and the degree of human exposure were not addressed; but CPSC's concern over urea formaldehyde foam insulation was acknowledged.

The conclusions of the federal panel were reiterated by NIOSH in a Current Intelligence Bulletin issued in December of 1980 (3). The purpose of the bulletin was to make employers aware of formaldehyde's carcinogenicity and to encourage them to adopt voluntarily work practices and ventilation procedures which would minimize workers' exposures. In addition to a recapitulation of the panel report's findings, the bulletin provided information on formaldehyde concentrations in selected industries (Exhibit 6.9). No other media were mentioned.

To date, OSHA has not announced any plans for revising the workplace standard for formaldehyde. It is possible that the agency may decide to regulate the substance under its current rule governing occupational

*Swenberg, J. A., Karns, W.D., Mitchell, R. J., Gralla, E.J., and Pavkov, K. L. 1980. "Induction of squamous cell carcinoma of the rat nasal cavity by inhalation exposure to formaldehyde vapor." Cancer Res. 40 3398-3402.

carcinogens (29 CFR 1990). Formaldehyde was not included in OSHA's first list of candidate substances (45 FR 53672), which was issued before the federal panel's report was completed.

Exhibit 6.9

Formaldehyde Concentrations by
Reported NIOSH Industrial Hygiene Surveys

(Source: Reference 3)

<u>Industry</u>	<u>Formaldehyde Level</u>			
Fertilizer Production	0.2	-	1.9	ppm
Dyestuffs	<0.1	-	5.9	ppm
Textile Manufacture	<0.1	-	1.4	ppm
Resins (Non-foundry)	<0.1	-	5.5	ppm
Bronze Foundry	0.12	-	8.0	ppm
Iron Foundry	<0.02	-	18.3	ppm
Treated paper	0.14	-	0.99	ppm
Hospital Autopsy Room	2.2	-	7.9	ppm
Plywood Industry	1.0	-	2.5	ppm

References for Section 6.2.9

1. National Institute for Occupational Safety and Health," Criteria for a Recommended Standard: Occupational Exposure to Formaldehyde, 77-126, December, 1976.
2. "Report of the Federal Panel on Formaldehyde, November, 1980.
3. National Institute for Occupational Safety and Health, "Formaldehyde: Evidence of Carcinogenicity", Current Intelligence Bulletin #34, 23 December, 1980.

6.2.10 Department of Transportation (DOT)

6.2.9.10 Hazardous Materials Regulations

Current Status of Actions

Pursuant to the Hazardous Materials Transportation Act, the Department of Transportation has promulgated rules governing the transportation of hazardous materials. The rules require that shippers and transportation of hazardous materials (as defined in 49 CFR 172.101) adhere to standards for containing, packaging and labeling such materials and for maintaining manifests and documentation (49 CFR 171-177). Amendments to the rules were promulgated on 22 May 1980 (45 CFR 34560) which add to the hazardous materials table the hazardous substances and hazardous wastes regulated by EPA (40 CFR 116 and 262 respectively). Further provisions were added requiring transporters to notify the appropriate Federal Agency of any discharges of hazardous wastes and hazardous substances (49 CFR 171.16, 117.17). The revised Hazardous Materials Table, published as 49 CFR 172.101, includes formaldehyde.

Multimedial Considerations in the Regulatory History

The revised Hazardous Material Transportation regulations were issued concurrently with EPA's issuance of Standards for Transporters of Hazardous Wastes under Subtitle C of RCRA. EPA's rules have the effect of supplementing the DOT reporting requirements for hazardous waste spills with a stipulation that the transporter responsible must clean up the discharged wastes. No background documentation was issued in support of DOT's amended rules, and there is no evidence that multimedia factors were considered in their promulgation.

APPENDIX

Federal Register Notices Reviewed for Formaldehyde Case Study

CHEMICAL: Formaldehyde

AGENCY: EPA

STATUTE: Clean Air Act, 42 USC s7401 et. seq.

PROGRAM: Mobile Source Emission Standards; 42 USC s.7521;
40 CFR Part 86 ;

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
41 FR 21292 5/24/76	40 CFR s.86.079 10 + 11	Proposed Rule	Proposed Hydrocarbon (HC) emission stan- dards for 1979 diesel and gasoline heavy duty engines
42 FR 32906 6/28/77	40 CFR Part 86	Final Rule (no proposed rule)	Republication of 1977-79 model year motor vehicle certifi- cation regulations, including emission standards for HC (40 CFR ss.86.077-8 through 86.077-11; 86.078-8 through 86.078-11; 86.079-9)
42 FR 40697 8/11/77	40 CFR s.86.028-8	Final Rule (no proposed rule)	As required by the Clean Air Act Amend- ments of 1977, HC emission standard for 1978 light-duty vehi- cles set at 1.5 grams per vehicle mile (gvm)
42 FR 45132 9/8/77	40 CFR s.86.079- 10 + 11	Final Rule	Final HC emission standards for 1979 diesel and gasoline heavy duty engines (1.5 grams per brake horsepower hour [gbhh])
43 FR 43299 9/25/78	40 CFR ss.86.079-8 and 86.080-8	Final Rule (no proposed rule)	As required by the Clean Air Act Amendments of 1977, HC emission stan- dards for 1979 and 1980 light duty vehicles set at 1.5 gvm and .41 gvm, respectively

CHEMICAL: Formaldehyde

AGENCY: EPA

STATUTE: Clean Air Act, 42 USC s7401 et. seq.

PROGRAM: Mobile Source Emission Standards; 42 USC s.7521;
40 CFR Part 86 (continued)

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
44 FR 9464 2/13/79	40 CFR ss.86.083-10 and 11	Proposed Rule	Proposed HC emission standards for 1983 gasoline and diesel heavy duty engines (not more than 10% of emissions from 1969 heavy duty engines)
44 FR 40784 7/12/79	40 CFR s.86.083-9	Proposed Rule	Proposed HC emission standard for 1983 light duty trucks (not more than 0.8 gvm)
45 FR 4136 1/21/80	40 CFR ss.86.084-10 and 11	Final Rule	Final HC emission standards for 1984 gasoline and diesel heavy duty engines (1.3 gbhh)
45 FR 5988 1/24/80	40 CFR Part 86	Notice	Control of Air Pollution from new motor vehicles and new motor vehicle engines; proposed new high altitude emission standards for 1982 & 1983 model year light duty motor vehicles
45 FR 20402 3/27/80	40 CFR Part 86	Final Rule	Control of Air Pollution from new motor vehicle engines; high altitude emission standards voluntary compliance program for 1981 model year LDV
45 FR 63734 9/25/80	40 CFR Part 86	Final Rule	Control of Air Pollution from motor vehicles and motor vehicle engines; gaseous emission regulation for 1984 and later model year light-duty trucks

CHEMICAL: Formaldehyde

AGENCY: EPA

STATUTE: Water Pollution Control Act, 33 USC s1251 et. seq.

PROGRAM: Designation of Hazardous Substances and Reportable Quantities
s311(b)(2)(A), 33 USC s1321(b)(2)(A); 40 CFR Parts 116,117

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
40 FR 59960 12/30/75	40 CFR Part 116	Proposed Rule	Proposed list of hazardous substances, including formaldehyde
43 FR 10474 3/13/78	40 CFR Part 116	Final Rule	List of hazardous substances including formaldehyde
44 FR 10270 2/16/79	40 CFR Part 117	Proposed Rule	Reportable quantities for hazardous substance discharges proposed, including RQ of 1,000 lbs for formaldehyde
44 FR 50766 8/29/79	40 CFR Part 117	Final Rule	Reportable quantities for hazardous substance discharges, including RQ of 1,000 lbs for formaldehyde

A/4 FORM/

CHEMICAL: Formaldehyde

AGENCY: EPA

STATUTE: Resource Conservation and Recovery Act, 42 USC s.6901 et. seq.

PROGRAM: Hazardous Waste Management System, Sections 1006, 2002 (a),
3001-7, 3010, 7004; 42 USC ss.6905, 6912(a), 6924-25;
40 CFR Parts 260-65

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
45 FR 33119 5/19/80	40 CFR Part 261	Interim Final Rule	Listing of hazardous wastes; formaldehyde listed as a toxic waste (40 CFR s.261.33[f]) and as a hazardous constituent (40 CFR, Part 261, App. VIII) and as the basis for listing certain specific sources as hazardous (40 CFR Part 261, App. VII)
45 FR 74884 11/21/80	40 CFR Part 261	Final Rule	Final listing of hazardous constituents (40 CFR Part 261, Apps. VII and VIII)
45 FR 78532 11/25/80	40 CFR Part 261	Final Rule	Final listing of toxic wastes (40 CFR ss.261.33 [f])

A/5 FORM/

CHEMICAL: Formaldehyde

AGENCY: EPA

STATUTE: Federal Food, Drug and Cosmetic Act, 21 USC s.301 et. seq.

PROGRAM: Pesticide Tolerances; 21 USC s.346a;
40 CFR Part 180

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
37 FR 14229 7/18/72	40 CFR s.180.1024	Final Rule	Exemption from tolerance requirement for paraformaldehyde when used as an insecticide in the production of sugar beets
39 FR 22453 6/24/74		Notice	Temporary tolerance of 2,000 ppm established for residues of formaldehyde within USRD as a fungicide on corn grain intended for animal feed use (Expires 6/19/75)
40 FR 1042 1/6/75	40 CFR s.180.1032	Final Rule	Exemption from tolerance requirement for formaldehyde when used as a fungicide on agricultural products intended for animal use

A/6 FORM/

CHEMICAL: Formaldehyde

AGENCY: DOE

STATUTE: National Energy Conservation Policy Act (Title II, Part 1),
42 USC s.7101 et. seq.

PROGRAM: Residential Conservation Service Program,
10 CFR Part 456

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
44 FR 75956 12/21/79	10 CFR Part 456	Proposed Rule	Proposed material and installation standards for area - formaldehyde foam insulation
45 FR 63786 9/25/80	10 CFR Part 456	Interim Final Rule	Interim final material and installation stan- dards for area - formal- dehyde foam insulation

CHEMICAL: Formaldehyde

AGENCY: CPSC

STATUTE: Consumer Product Safety Act, 15 USC s.2051 et. seq.
Section 27(e) of CPSA, 15 USC s. 2076(e);
16 CFR Part 1405

PROGRAM: Safety Standards for Certain Types of Home Insulation

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
44 FR 69578 12/3/79		Notice	Notice of public hearings concerning safety of area formaldehyde (UF) foam insulation
45 FR 34031 5/21/80		Notice	Notice of formation of panel to evaluate the health units of formaldehyde
45 FR 39434 6/10/80	16 CFR Part 1405	Proposed Rule	Proposed requirement manufacturers of UF foam insulation to provide purchasers with performance and technical information
46 FR 11188 2/5/81	16 CFR Part 1306	Proposed Rule	Ban of Urea-formaldehyde Foam Insulation

A/8 FORM/

CHEMICAL: Formaldehyde

AGENCY: CPSC

STATUTE: Federal Hazardous Substances Act, 15 USC s.1261 et. seq.

PROGRAM: Hazardous Substances and Articles (originally 16 CFR Part 191, now
16 CFR Part 1500)

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
26 FR 3705 4/29/61	16 CFR Part 191	Proposed Rule	Formaldehyde defined as a "strong sensitizer"
26 FR 7333 8/12/61	16 CFR Part 191	Final Rule	Formaldehyde defined as a "strong sensitizer"
38 FR 27012 9/27/73	16 CFR Part 1500.13	Final Rule	Above rule repromul- gated at 16 CFR s.1500.13

A/9 FORM/

CHEMICAL: Formaldehyde

AGENCY: FDA

STATUTE: Federal Food, Drug and Cosmetic Act, 21 USC s.301 et. seq.

PROGRAM:

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
40 FR 58484 12/17/75	21 CFR Part 573.460	Notice	Notice of receipt of petition requesting issuance of regulation providing for use of formaldehyde in the manufacture of animal feeds
41 FR 9543 3/5/76	21 CFR s.121.329	Final Rule	Regulating use of formaldehyde in the manufacture of animal feeds

A/11 FORM/

CHEMICAL: Formaldehyde

AGENCY: DOT

STATUTE: Hazardous Material Transportation Act, 49 USC 1801 et. seq.

PROGRAM: Materials Transportation Bureau

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
45 FR 34560 5/22/80	49 CFR Part 172	Final Rule	Regulations for the packaging, labelling and shipping of hazardous materials, including formaldehyde at CFR 172.101, table of hazardous materials, and at 49 CFR 172.102, optional hazardous materials table

CHEMICAL: Formaldehyde

AGENCY: OSHA

STATUTE: Occupational Safety and Health Act of 1970, 29 USC ss651-78

PROGRAM: Limitations for Toxic and Hazardous Substances in Workplace Air;
s6(a) and (b), 29 USC s655(a) and (b)(5); 29 CFR Part 1910

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
36 FR 10466 5/29/71	20 CFR 1910.93 Table G-2	Final Rule	Promulgation of national concensors standards for workplace exposure to air containinants, in- cluding 3 ppm PEL for formaldehyde
40 FR 23072 5/28/75	29 CFR 1910.1000 Table Z-2		Above standards recodified at 29 CFR 1910.1000, Table Z-2

A/12 FORM/

CHEMICAL: Formaldehyde

AGENCY: EPA

STATUTE: Clean Air Act, 42 USC s.7401, et. seq.

PROGRAM: New Stationary Source Performance Standards (NSPS);
s111, 42 USC s7411; 40 CFR Part 60

<u>FR/DATE</u>	<u>CFR</u>	<u>ACTION</u>	<u>DESCRIPTION</u>
43 FR 21616 5/18/78	40 CFR Part 60 subpart K and Ka	Proposed Rule	Standards for storage vessels for petroleum liquids
43 FR 38872 8/31/78	40 CFR Part 60	Proposed Rule	List of major source categories
44 FR 49222 8/21/79	40 CFR Part 60	Final Rule	Prioritized major source categories
44 FR 10/5/79	40 CFR subpart MM	Proposed Rule	Standards for automobile and light duty truck surface coating opera- tions
45 FR 23374 4/4/80	40 CFR Part 60 subpart K and Ka	Final Rule	Standards for storage vessels for petroleum liquids
45 FR 79390 11/28/80	40 CFR Part 60 subpart EE	Proposed Rule	Standards for surface coating of metal furniture
45 FR 83126 12/17/80	40 CFR Part 60.500	Proposed Rule	Standards of performance for new stationary sources; bulk gasoline terminals
45 FR 85085 12/24/80	40 CFR subpart SS	Proposed Rule	Standards for industrial surface coating: appliances
45 FR 85410 12/24/80	40 CFR subpart MM	Final Rule	Standards for automobile and light duty truck surface coating operations